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TABLE OF CONTENTS

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Review Article

Coming to Terms With the Fact That the Evidence for Laparoscopic Entry Is as Good as It Gets

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ABSTRACT Entry to the peritoneal cavity for laparoscopic surgery is associated with defined morbidity, with all entry techniques associated with substantial complications. Debate over the safest entry technique has raged over the last 2 decades, and yet, we are no closer to arriving at a scientifically valid conclusion regarding technique superiority. With hundreds of thousands of patients required to perform adequately powered studies, it is unlikely that appropriately powered comparative studies could be undertaken. This review examines the risk of complications related to laparoscopic entry, current statements from examining bodies around the world, and the medicolegal ramifications of laparoscopic entry complications. Because of the numbers required for any complications study, with regard to arriving at an evidence-based decision for laparoscopic entry, we ask: is the current literature perhaps as good as it gets? Journal of Minimally Invasive Gynecology (2015) 22, 332–341 Crown Copyright © 2015 Published by Elsevier Inc. on behalf of AAGL. All rights reserved.

Keywords: Abdominal entry; Closed entry; Complications; Gynecology; Hasson entry; Laparoscopy; Open entry; Veress needle

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Laparoscopic surgery has numerous benefits for patients, including improved cosmesis, reduced risk of adhesion formation, and quicker hospitalization recovery times [1,2]. For healthcare providers, better public health and economic outcomes from shorter hospital stays are advantageous [1]. However, the entry complications of laparoscopic surgery constitute the "Achilles heel" of this procedure, particularly because unrecognized complications at the time of the injury often result in greater morbidity or even mortality than surgery by laparotomy [2–5].

Surgical complications associated with laparoscopic techniques include those typical for all surgical modalities, including anesthetic issues, thromboembolic problems, hemorrhages, and infections. Procedural complications include hemorrhage [6–11], vascular injury [7,8,10–13], bowel injury [7,8,10–12,14–16], and urinary tract injury [7–13,17–19]. Laparoscopic techniques also involve complications associated with abdominal entry and a restricted field of view, including visceral injury [5,14,16,20,21], major and anterior wall vessel injury [5,8,22–25], urological injury (including bladder and ureter) [4,8], herniation through trocar sites [26,27], extraperitoneal insufflation [4,5,23,28], and failure to gain entry into the abdomen [5,29]. Complications associated with gynecological laparoscopy are uncommon, with an overall complication rate of 3 to 8 per 1000 patients [1,30], which has remained largely unchanged over the past decade [12,20].

We provide a brief overview of entry techniques, followed by a description of the complications of abdominal entry at laparoscopy, their subsequent medicolegal ramifications, and a discussion of statements from colleges and advisory boards worldwide.

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Methods

We undertook 3 searches using published data between 1953 and June 2014 using the electronic databases Medline, Embase, PubMed, and the Cochrane Library. First, information pertaining to laparoscopic surgery and entry complications was retrieved using the keywords "laparoscopic entry," "Veress entry," "Hasson entry," and "direct entry," as well as the search terms "laparoscopy" and "artificial pneumoperitoneum," with a focus on the subheadings of "adverse effects," "instrumentation," "mortality," and "complications." A similar search was conducted for medicolegal issues, using the previous search terms in combination with "malpractice" and "medical legislation." Finally, variations of previous searches were combined with the term "practice guidelines" to retrieve literature on recommendations for laparoscopic entry, and various governing bodies' websites were also individually assessed to search for statements and recommendations. The bibliographies of selected references were hand-searched to identify additional articles.

Entry Techniques

Veress Needle

The Veress needle technique is a closed approach that involves the insertion and retraction of a 2-mm, sharp-tipped outer needle, which is followed by a hollow blunt-tipped needle sliding forward and delivering gas. Insufflation to varied pressure, time, or volume parameters then occurs before insertion of the primary trocar. The Veress method is the most common entry modality used by gynecologists worldwide [31–35], and is reported to be associated with increased risks of minor complications, including preperitoneal and omental injuries, and entry failure [36–39]. The 2 most widely recommended sites for abdominal entry using this technique are at the umbilicus, or in the left upper quadrant (the Palmer point) [40–43].

Direct Entry

An alternative closed entry option is direct insertion of the primary trocar, followed by laparoscopic inspection and gas insufflation. Closed techniques have a potentially greater risk of bowel and vessel damage [44], but these techniques have shorter operation times and near exclusion of entry failure [39,45].

Hasson Open Entry

Hasson entry [46] commences with a cut down of the peritoneum and the insertion of a blunt trocar under direct visualization, thereby preventing the blind entry of sharp instruments into the abdomen [47]. This is followed by insufflation and insertion of the laparoscope. Theoretically, this technique may avoid injury to the retroperitoneal vessels; however, there is still a risk of bowel damage [46].

Vision-Guided Direct Entry

This group of techniques involves the insertion of trocars with optical guidance through the layers of the abdominal wall and into the peritoneal cavity, using a downward pressure or a screwing motion [48]. These techniques theoretically reduce the risk of vessel injury [49–51], particularly in higher risk patients, such as those with previous abdominal surgery or who are obese [50]; however, there are similar risks of bowel damage with the open technique [49–51].

Radially Expanding Entry

Radially expanding systems use a sleeve over a Veress needle and progressively expand the entry point with minimal trauma [52–54].

Complications Related to Laparoscopic Entry

Surgical complications associated with entry to the peritoneal cavity at the time of laparoscopic surgery may include:

1. Damage to the anterior abdominal wall and major retroperitoneal vessels;
2. Damage to the bowel (when damaged in its normal anatomical position, this is considered a type I injury; when the bowel adherent to the abdominal wall is damaged, this is a type II injury);
3. Extraperitoneal insufflation;
4. Herniation through port sites; and
5. Failure to achieve access to the peritoneal cavity.

A substantial number of complications that occur at laparoscopy also occur at entry to the abdominal wall [13,16,44,55–64], and the overall injury rate at the time of entry is estimated to be 1.1 per 1000 cases in 1 meta-analysis [65]. In particular, the rate of abdominal vessel and abdominal wall vessel perforation is reported to be 0.9 per 1000 cases, and bowel perforation is reported to be 1.8 per 1000 cases [2,66], whereas pooled overall risks, according to some meta-analyses, have revealed vascular injury to be 0.2 per 1000 cases and bowel injuries to be 0.4 per 1000 cases [11,17,32,62,67–70]. Table 1 shows the rate of complications during laparoscopic entry, regardless of the technique used [7–13,19,26,28,29,49,67,71–75].

Vascular Injuries

Vascular injuries at entry have an incidence of up to 0.5%. They require immediate resuscitation and repair; mortality following laparoscopic vascular injuries is cited to be up to 17% [4,5,22,24,41,76–82]. Vascular injuries may occur during entry to the peritoneum with insertion of the Veress needle, the subsequent insertion of any of the trocars, or at open entry [4,5,81]. The proximity of the aorta and right common iliac vessels to the umbilicus on initial entry places them at the highest risk [4], whereas injuries to the inferior epigastric vessels and their tributaries are more common with secondary port placement [5,31,76,78]. Injury of these smaller vessels may also result in patient death. A recent

Table 1

Rates of complications during laparoscopy

Author and year	Number of patients	Study type	Entry technique	Overall complication rate (%)	Vascular injury (%)	Visceral injury (%)	Urological injury (%)
Dunne 2011 [71]	3126	Prospective	Veress vs open	0.13	0	0.13	0
Liu 2009 [29]	17 350	Prospective	Open vs Veress	0.10	NS	NS	NS
Perunovic 2009 [28]	4940	Retrospective	Direct and Veress	0.0	0.0	0.0	0.0
Kyung 2008 [8]	2668	Retrospective	Closed entry	1.24	0.22	0.11	0.78
Johnston 2007 [12]	1265	Prospective	Direct and Veress	0.6	0.0	0.3	0.3
Kaloo 2006 [7]	796	Prospective	Closed entry	0.87	0.13	0.50	0.25
Agresta 2004 [72]	598	Prospective	Direct vs Veress	1.3	0	0.6	0
Miranda 2003 [10]	2140	Retrospective	Closed entry	0.79	0.09	0.14	0.18
Jacobson 2002 [26]	1385	Retrospective	Open vs direct vs Veress	0.21	0	0.21	0
Meraney 2002 [73]	404	Retrospective	Closed entry	1.98	1.73	0.25	0
Catarci 2001 [67]	12 919	Retrospective	Open vs vision vs direct	0.18	0.12	0.06	0
String 2001 [49]	650	Prospective	Vision vs Veress	0.3	0	0.3	0
Wang 2001 [11]	6451	Retrospective	Closed entry	0.65	0.04	0.17	0.43
Wu 2001 [74]	1507	Retrospective	Closed entry	1.59	0.07	0.33	0.66
Leng 2000 [9]	1769	Retrospective	Direct and Veress	1.92	0.39	NS	NS
MacCordick 1999 [13]	743	Prospective	Veress entry	2.96	0.13	0.4	0.4
Tamussino 1998 [19]	790	Retrospective	Closed entry	NS	0	0	0.38
Querleu 1993 [75]	17 521	Retrospective/ prospective	Direct vs Veress	0.63	0.09	0.15	0.03

NS = not stated.

meta-analysis reported that blunt trocars were associated with less risk, with regard to abdominal wall vascular injury than the bladed trocars. This analysis concluded that the determination of other types of complications, including injuries to major vessels and viscal injuries, required larger numbers to study [83].

Gastrointestinal Injuries

Entry injury may occur to any hollow viscus, including the esophagus [4] and stomach [11], and such injuries most commonly affect the small bowel and colon [5,21,84]. The overall incidence of bowel injury at laparoscopy was found to be 0.13% in both a review of 329 935 patients [16], and a 6-year prospective study of 3126 participants that also reported previous surgery as a significant risk factor [71]. Visceral injuries occur with closed insertion of both primary and secondary trocars, and with open entry techniques. Although type I bowel injuries rarely occur with open or closed entry techniques when the appropriate surgical technique is used, type II injuries are difficult to avoid when the bowel is adherent no matter what technique is used. Studies have reported that the insertion of a primary trocar or Veress needle results in approximately 50% of all laparoscopic intestinal injuries [14,23,85], which is similar to that of open techniques, with an overall rate of 0.048% to 0.1% [23,86,87]. A possible confounding issue with these data are the denominators—how many of each technique is undertaken with regard to injury risk and reporting bias.

Extraperitoneal Insufflation

Extraperitoneal insufflation is uncommon, occurring at 0.001% to 0.59% of all laparoscopic cases [88–90]. It can cause difficult or failed entry, and rarely, subcutaneous emphysema, pneumothorax, pneumopericardium [4], and most seriously, carbon dioxide embolism [88–90] which although quite rare, has a mortality rate of up to 28.5% [89]. Flow rates for carbon dioxide with various entry techniques may affect the risk of complications depending on the physical properties of the Veress needle or cannulas [91]. The risk may be less likely in direct and open techniques compared with Veress entry [39]; however, because of the rarity of this problem and the sequelae arising from it, the impact on choice of entry technique is small. Underreporting of this complication when there are few clinical consequences is likely.

Comparative data support a reduced risk of extraperitoneal insufflation and failed entry using a direct technique compared with Veress needle entry [20,65,92–94]. However, there are no reported changes in the risk of major complications when the techniques are compared [20,65,92–96]. The question is about the importance of preventing extraperitoneal insufflation when balanced against perceived or actual increased vascular injury risk, which is, at this time, a purely academic discussion.

Herniation at Port Sites

Herniation of the bowel through a port site (the Richter hernia) is uncommon [97], but when it does occur, it is related to port size [98] and occurs more commonly laterally than centrally [98]. It is much less common than hernias associated with laparotomy [5]. Herniation has been found to occur rarely in 5- [4,99] and 7-mm ports [47] and more commonly in ports >10 mm, with a 3.1% increased risk with 12-mm ports [4,100]. Richter hernia may be fatal if unrecognized [101,102].

Recommendations for Entry Techniques

There are statements from various governing bodies around the world with regard to entry techniques.

United States and Canada

The Society of Obstetrician and Gynecologists of Canada (SOGC) guidelines state that Veress entry, open entry, and direct entry are all suitable methodologies, and the SOGC provides extensive details on the variations and safe execution of these 3 techniques [41]. However, the majority of Canadian practitioners prefer Veress entry [41], and a Canadian survey of 407 obstetricians and gynecologists revealed that 96.3% of respondents established pneumoperitoneum before inserting the primary trocar [31]. Similar to the SOGC guidelines, the standardized curriculum established by the American Congress of Obstetricians and Gynecologists [103–105] states that residents and fellows can, and should be, proficient in any of the 3 previously mentioned techniques, which is a position that is also endorsed by the U.S. Food and Drug Administration [35].

United Kingdom and France

The Royal College of Obstetricians and Gynecologists (RCOG) guidelines report continuing controversy over the safest procedure, with United Kingdom gynecologists favoring the Veress technique [40,106]. The RCOG acknowledges that the Royal College of Surgeons of England recommends the Hasson approach for all laparoscopic surgeries [107]; however, the position of the RCOG is based on current evidence that indicates no advantage to any entry technique. The French College of Gynecologists and Obstetricians (CNGOF) similarly acknowledges that Veress, direct, and open entries may all be considered first-line procedures, again due to a lack of evidence showing that one technique is superior to another. Radially expanding and vision-guided entry are discouraged by the CNGOF because their efficacy has not yet been adequately evaluated [108,109].

Australasia

A systematic review culminating in a 2010 guideline by the Royal Australasian College of Surgeons (RACS) found no definitive difference in the safety and efficacy of open versus direct versus needle access techniques, noting that there was difficulty in arriving at statistically significant recommendations. The RACS continues to advocate for studies with clinically significant numbers, but the society also recognizes that the size of such a study may be unfeasible [110,111]. The Royal Australian and New Zealand College of Obstetrics and Gynecology (RANZCOG) and Australian Gynecological Endoscopy and Surgery Society combined guideline of 2008 [33] recommends that RANZCOG fellows use the entry technique that they have been trained in and are familiar with. Supported techniques include umbilical, suprapubic, and the Palmer point Veress needle entry, Hasson open entry, and direct entry.

There are many surgical and gynecological bodies globally that have produced documents detailing safe laparoscopic technique. The majority of these come to the same conclusion, based on current evidence, that there is no major advantage in any one technique over another. Table 2 summarizes these bodies' findings [33,35,40,41,71,103–105,108,112,113].

Medicolegal Ramifications of Laparoscopic Entry Injury

There is a public perception that laparoscopic surgery is a safer procedure in comparison to laparotomy based on

Table 2

Recommendations for laparoscopic entry technique by governing surgical and gynecological bodies

Body	Date	Recommendation on techniques
American Congress of Obstetricians and Gynecologists [103–105]	2014	Surgeon preference
Society of American Gastrointestinal and Endoscopic Surgeons [113]	2014	Surgeon preference
U. S. Food and Drug Administration [35]	2014	Surgeon preference
French College of Gynecologists and Obstetricians [108]	2011	Surgeon preference
Royal College of Surgeons of England [71]	2011	Open entry
Royal College of Obstetricians and Gynecologists [40]	2008	Surgeon preference
Royal Australian and New Zealand College of Obstetricians and Gynecologists/Australasian Gynecological Endoscopy and Surgery Society [33]	2008	Surgeon Preference
Canadian Society for Obstetrics and Gynecology [41]	2007	Surgeon preference
European Association for Endoscopic Surgery [112]	2002	Surgeon preference

Table 3

Studies comparing entry techniques

Author and year	Technique studied	Number of patients	Principal outcomes	Comments
RCTs				
Angioli 2013 [39]	Open, Veress, direct	595	Extraperitoneal insufflation, site infection/bleeding, omental injury, failed entry, time of entry	Lower risk of complications in direct and open entry compared with Veress. Direct is faster than open and Veress entry.
Shayani-Nasab 2013 [126]	Direct, Veress, open	453	Vascular injury, visceral injury, extraperitoneal insufflation	Reduced major complications in open compared with Veress and direct entry
Tinelli 2010 [51]	Vision, Veress	194	Vascular and visceral injury	Nil significant difference
Tansatit 2006 [130]	Direct, Veress	100	Nil reported	Nil significant difference
Gunenc 2005 [125]	Direct, Veress	578	Vascular injury, extraperitoneal insufflation, failed entry	Nil significant difference
Bemelman 2000 [123]	Open, Veress, direct	62	Establishment of pneumoperitoneum, number of motions to complete entry	Nil significant difference. No power calculation. Underpowered for this outcome
Bhoyrul 2000 [52]	Expanding, direct	244	Vascular injury, visceral injury, trocar site bleeding, incisional hernia	Nil significant difference
Feste 2000 [53]	Expanding, direct	87	Vascular injury, visceral injury	Nil significant difference
Mettler 2000 [54]	Expanding, direct	100	Vascular injury, visceral injury, failed entry, incisional hernia	Nil significant difference
Cogliandolo 1998 [124]	Open, Veress	150	Vascular injury, visceral injury, extraperitoneal insufflation	Nil significant difference demonstrated.
Ostrzenski 1998 [127]	Direct, Veress	100	Vascular injury, visceral injury, extraperitoneal insufflation	Nil significant difference.
Byron 1993 [128]	Direct, Veress	386	Extraperitoneal insufflation, failed entry	Reduced failure of entry and extraperitoneal insufflation in direct compared with Veress.
Borgatta 1990 [129]	Direct, Veress	212	Visceral injury, extraperitoneal insufflation	Nil significant difference.
Prospective				
Dunne 2011 [71]	Open, Veress	3126	Visceral injury	Nil significant difference.
Liu 2009 [29]	Open, Veress	17 350	Successful entry on first attempt, puncture complications	Nil significant difference.
Agresta 2004 [72]	Direct, Veress	598	Failed entry, extraperitoneal insufflation, visceral injury, vascular injury, mortality	Nil significant difference.
String 2001 [49]	Vision, Veress	650	Visceral injury	Nil significant difference.
Retrospective				
Jacobson 2002 [26]	Open, direct, Veress	1385	Visceral injury, vascular injury	Nil significant difference.
Catarci 2001 [67]	Open, Veress, vision	12 919	Vascular injury, visceral injury	Nil significant difference.

RCT = randomized clinical trial.

decreased recovery time and improved cosmesis [114]. A survey that examined the expectations for surgical treatment and the preferences between laparoscopy, single incision laparoscopic surgery, and natural orifice transluminal endoscopic surgery [115] reported that cure was of primary importance to patients, with safety also being a high concern. Interestingly, this population also favored the perception of scarless surgery even with an increased procedural risk.

It is this assumed safety that may lead to medical and legal ramifications following a complicated laparoscopic procedure [116–119]. In a review of malpractice allegations following laparoscopic entry injuries, major vessel injuries during biliary-gastrointestinal surgery were

the most common injury, leading to legal action [120]. Of these injuries, 185 (83%) were related to trocar injuries, with 39 (17%) Veress needle injuries. Visceral injuries remain the most common laparoscopic complication that leads to litigation, with a mean settlement of US$250 000 for all injuries, and US$437 500 for bowel injuries [121].

In a retrospective review of laparoscopic bowel injuries leading to litigation in Canada between 1990 and 1998, 55% of injuries occurred during peritoneal entry, with the majority being caused by the primary trocar [117]. Legally, the outcome favored the physician in 75% of cases; however, with delayed recognition of complications (noted in 45% of cases), the outcome favored the claimant.

A Dutch study reported that 18% of all of their laparoscopic complications leading to claims were related to entry [119]. Total laparoscopic claims proportionately made up only 2% of all claims filed in this study, which examined a 5-year period. Of the 41 laparoscopic entry-related claims, 20 were related to general surgery, and 21 were related to gynecological routine elective procedures. Claims were settled in 57% of cases, with 2/3 related to bowel injury and 1/3 related to vascular injury.

A legal precedent exists in the United Kingdom, for the case of Palmer vs. Cardiff and Vale NHS Trust [122], in which it was stated that the likelihood of a bowel injury was improbable in an uncomplicated laparoscopic gynecology case when the surgeon follows safe technique and there are no patient-related risk factors. As such, any injury implies negligence. This is supported by literature that states that the majority of laparoscopic vascular injuries are due to surgeon error [35]. Such rulings have considerable impact on the performance of gynecological surgery in general, and this must be considered when making final decisions regarding route of surgery and patient counseling.

Discussion

Although there have been many reviews of laparoscopic entry, the continued debate as to superiority of any technique in preventing major complications remains intense. A 2012 Cochrane review of laparoscopic entry techniques that included 28 randomized clinical trials (RCTs) of 4860 patients concluded that there is no advantage of any technique in preventing the major complications of mortality, bowel or urinary injury, vascular injury, gas embolism, or other organ injury [37]. Table 3 outlines the evidence available for entry techniques and their associated complications [26,29,39,49,51–54,67,71,72,123–130]. The issue is about appropriately powered studies, and therefore, the inherent limitations that a Cochrane review will have. It has been calculated that the number of patients required to show a significant reduction in bowel injury (from 0.3% to 0.2%) would be 828 204 [1,36,65]. What ensues is that proponents, without a solid scientific basis, influence individual techniques [36]. Because major complications and death are reported after all techniques, it is difficult to be dogmatic about any particular approach because of the currently inconclusive evidence.

In an unprecedented situation in Australia, the medical director (a general surgeon) at a major metropolitan hospital banned the use of the Veress needle following injuries in 2 gynecological patients [131]. The result was that emergency gynecological procedures were transferred to nearby hospitals because gynecologists would not operate without the Veress needle being available (personal communication, Doctor Greg Jenkins, Director of Training, Westmead Hospital, June 12, 2013.). This situation has now been reversed. Although both the Australasian Colleges of Surgery and Obstetrics and Gynecology continue to support the use of the Veress needle in their statements, this localized impasse between general surgeons and gynecologists reflects the strong feelings regarding issues of safety. However, single cases do not constitute evidence, and science must prevail over passion. Furthermore, a laparoscopic vascular injury and the subsequent death of a young woman in Australia in 2011 has also raised questions on the safety of entry techniques and the subsequent management of sustained injuries [132]. These issues highlight the importance of collectively endorsing scientifically valid approaches to surgical techniques and recognizing and reviewing serious injuries in a calm and nonjudgmental manner to assess whether we may learn from such incidents.

RCTs have failed to reveal a difference in major complication rates [123,124] between open and Veress needle entry; however, it is important that an open technique that causes injury allows for earlier detection [133], thus preventing the poorer clinical outcomes associated with undetected injuries [69,134]. The results from medicolegal cases around the world certainly support early detection of injuries to avoid litigation. Therefore, techniques that examine the abdominal contents in a systematic and regimented manner are encouraged. For any complication that is demonstrated, an active approach to its repair—and by any approach, including laparotomy—is likely to produce a substantially better clinical outcome for the patient and avoid medicolegal ramifications [20,53,54,62,65,72,96,123,125,135].

In 1999, a group of leaders in laparoscopy met in the United Kingdom for the Middlesbrough Consensus Meeting on laparoscopic entry. There was no agreement on the superiority of any individual entry technique, other than to say that the technique most familiar to the surgeon was the one that was most appropriate. For Veress needle entry, it was concluded that an infraumbilical incision with a sharp Veress needle and the patient in a horizontal position were valuable safety considerations, as was observation of gas pressure, not volume or time, with insufflation [134,136–139]. More than 14 years on, the consensus is the same; statements from Colleges and regulatory bodies all state that any entry technique is appropriate while emphasizing the impact and influence of training. As is the case in most other features of surgery, technical aspects of entry may provide additional

safeguards. Tissue handling is an inherent aspect of our craft and should be endorsed.

Therefore, it follows that it is not just the approach to entry that has attracted champions. Variants to entry techniques also influence the likelihood of complications, such as the site of insertion of Veress needles (e.g., transumbilical or infraumbilical), various tests to ensure correct placement of Veress needles, patient positioning, and lifting the abdominal wall before needle insertion [33,140–144]. Unfortunately, studies that compare these technical variations all share the same constraints regarding inadequate power as do current studies that investigate the initial choice of entry method. Subdividing individual entry methods will only exacerbate the problem of poorly powered evidence. What seems most pertinent to note from the existing literature is that appropriate supervision, meticulous surgical approach, and the diligent repetition of a technique are likely to give an individual operator the best outcomes for their patients [35].

Perhaps most relevant to this discussion is the implication of proscribing certain entry techniques, and therefore, requiring senior, established surgeons to change their practice and teach these techniques to trainees. It is clear that the learning curve is greatest in the initial stages of any new procedure [145], and the literature indicates that examiner experience has the greatest influence on the likelihood of laparoscopic complications [146]. In the United States, where the number of annual gynecological laparoscopic procedures exceeds 702 322 [35], if half of all surgeons were made to change their entry technique to reduce an already small risk, then the resulting complications (and even rarer ones) may be counter-productive [8,139,147,148].

Conclusion

Without a scientific basis on the surgical superiority of various laparoscopic entry techniques, should surgeon opinion based on preference and skill set prevail? Because the necessary studies to determine safety parameters for individual techniques require hundreds of thousands of patients, the costs, time, and methodological restrictions are prohibitive [1,36,37,65]. The current recommendations of governing bodies regarding laparoscopic entry techniques reflect these facts and deem that a suitably trained surgeon operating on a suitably selected patient is regarded as appropriate medical care. Women who are obese, have had previous abdominal surgery, or are underweight are all at increased risk of entry-related injury and should be considered an at-risk group, and should be counseled preoperatively with careful consideration of appropriate laparoscopic entry or alternate procedures [149–152].

Despite both the increasing complexity and higher volume of laparoscopic surgical procedures, the rate of complication remains low, and when injuries do occur, they are being managed successfully laparoscopically. Complications are an unfortunate but almost inevitable component of any surgical procedure, and the combination of sound surgical training and supervision, surgical experience, continuous vigilance during a procedure, and careful selection of patients remains the foundation of the prevention of harm during laparoscopic surgery. Ultimately, in the case of laparoscopic entry, we may have to accept that the present evidence base is as good as it gets.

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Australasian Gynaecological Endoscopy & Surgery Society Limited

The Royal Australian and New Zealand College of Obstetricians and Gynaecologists

AGES/RANZCOG Statement on Tissue Extraction at Minimally Invasive Procedures

This statement has been developed by the AGES Society and ratified by the AGES Board in May 2014. This statement was reviewed by the Women's Health Committee and approved by the RANZCOG Board and Council.

A list of the AGES Society Board and Contributors can be found in Appendix A.

A list of Women's Health Committee Members can be found in Appendix B.

Disclosure statements have been received from all members of this committee.

Disclaimer This information is intended to provide general advice to practitioners. This information should not be relied on as a substitute for proper assessment with respect to the particular circumstances of each case and the needs of any patient. This document reflects emerging clinical and scientific advances as of the date issued and is subject to change. The document has been prepared having regard to general circumstances.

First endorsed by RANZCOG: June 2014
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Objectives: To provide advice on the use of mechanical morcellators for removal of tissues.

Target audience: Health professionals who use mechanical morcellators, and patients undergoing procedures that use mechanical morcellators.

Values: The evidence was reviewed, and applied to local factors relating to Australia and New Zealand.

Background: This statement was first developed by the AGES Society in May 2014.

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Table of contents

1. Patient summary

At times, organs or tissues that are to be taken out during surgery need to be broken up in order to allow removal through small incisions or the birth canal. This statement provides guidance for specialists to reduce the risk of injury to patients or the spread of unrecognised abnormalities.

2. Introduction

Minimally invasive surgery, including endoscopic and vaginal procedures, offer patients the benefits of improved recovery, less postoperative pain, lower risk of postoperative complications (reduction of inherent risks of laparotomy). Furthermore, less invasive procedures, such as myomectomies, have also allowed for uterine preservation in settings that traditionally would have resulted in a hysterectomy and loss of fertility.

By their nature, these minimally invasive procedures may at times require the morcellation, drainage or deflation of abdominal or pelvic masses to permit extraction through the vagina or other access points. Morcellation may be defined as the division of a large specimen into smaller fragments to permit removal from the peritoneal cavity. Morcellation may be performed manually with the use of a scalpel in techniques such as bivalving or coring, or electromechanically, utilising devices specifically designed for this purpose, such as a morcellator.

As such, gynaecologists recognise that tissue extraction by morcellation may be associated with a number of risks:

1. Patient injury: other tissue, such as bowel, may be inadvertently injured during the morcellation process. The efficiency of electromechanical morcellation poses a specific hazard in this setting.
2. Dissemination: fragments of tissue generated by the morcellation process may disseminate throughout the peritoneal cavity. This has been reported for both benign disease (fibroids, endometriosis) and malignancy where this may have a detrimental effect on prognosis and/or increase the need for adjuvant treatment. Concerns have been expressed that electromechanical morcellators may increase the risk of dissemination by creating a larger volume of smaller fragments.
3. Pathology: the size of the fragments and, at times, the loss of anatomical relationships, may complicate the diagnosis by the pathologist. Concerns have been expressed that electromechanical morcellation may yield a large volume of small and dissociated fragments, which may further complicate analysis.

3. Discussion and recommendations

3.1 Risks of Tissue Extraction

This AGES/RANZCOG statement addresses each of the defined risks of tissue extraction as follows:

3.1.1 Patient Injury

Manual morcellation is a core gynaecological technique that is acquired during membership and fellowship training. However, electromechanical morcellation is an advanced surgical technique. Local credentialing bodies need to be satisfied that specialists using such devices have received appropriate training and education in the use of such devices. In general, the use of such devices is restricted to practitioners at AGES/RANZCOG Level 5 and above.

3.1.2 Dissemination

AGES and RANZCOG recognise that the dissemination of both benign and malignant disease cannot be completely prevented if a decision is made to morcellate a specimen. However, appropriate steps may be taken to minimise this risk:

3.1.2.1 Case Selection

Patients requiring a hysterectomy or removal of an abdominopelvic mass represent a heterogeneous group, each with inherent risk factors. As such, it is not possible to distil the assessment of any patient to a simple decision matrix. This assessment is inherent to the core knowledge of a specialist in obstetrics and gynaecology.

3.1.2.2 Preoperative Assessment

Patients should have an appropriate history and examination performed, specifically to assess the risk of malignancy. Routine preoperative investigations should include a Pap smear and an ultrasound. Further investigations must be targeted to the type of pathology and may include blood tests, such as tumour markers, endometrial sampling and/or extended imaging.

3.1.2.3 Consent

Patients must be engaged in the discussion of the risks and benefits of the route of any proposed surgical procedure, including the mechanism of tissue extraction. This discussion should include the risks, benefits and likely outcomes of alternative management options.

3.1.2.4 Intraoperative Assessment

Clinical intraoperative assessment of a pelvic mass is difficult and inaccurate. If gynaecologists unexpectedly encounter suspicious pathology, it may be appropriate to abandon the procedure, seek the advice of a gynaecological oncologist intraoperatively or avoid techniques that may increase the risk of dissemination, such as morcellation.

3.2 Pathological assessment

The postoperative histopathological diagnosis of a morcellated specimen may be compromised. It is recommended that members seek the opinion of a gynaecological oncologist and specialised pathologist in the diagnosis of any gynaecological malignancy, whether expected or unexpected.

3.3 Specific Consideration: Leiomyosarcoma

In April 2014, the United States Food and Drug Administration (FDA) issued an FDA Safety Communication regarding power morcellation in hysterectomy and myomectomy, followed shortly by a Safety Alert on laparoscopic power morcellators from the Australian Therapeutic Goods Administration (TGA). These alerts reacted to reports of adverse patient outcomes in patients with fibroids related to the potential for the devices to spread malignant cells in patients with previously undetected malignancy.

AGES and RANZCOG recognise the specific problem posed by the diagnosis of uterine sarcoma, as there are no reliable preoperative diagnostic tools to differentiate malignant mesenchymal tumours of the uterus from their benign counterparts.

Local gynaecological units are encouraged to develop their own guidelines, based on the availability of local resources and expertise.

The incidence of leiomyosarcoma (LMS) has been variably quoted at between 0.02 to 0.3%, depending on the study population. The difficulty in attaining an exact incidence relates to both case capture and the determination of an appropriate denominator.

Reported demographic risk factors for LMS include:

- Age (mean age of diagnosis: 60)
- Menopausal status
- African American ethnic background
- Current or prior tamoxifen exposure
- History of pelvic Irradiation
- Hereditary Leiomyomatosis and Renal Cell Carcinoma (HLRCC) syndrome
- Survivors of childhood retinoblastoma

In the clinical assessment, practitioners should be alert to the possibility of malignancy, if:

- Rapidly expanding mass
- Abnormal uterine bleeding, including postmenopausal bleeding
- Ascites
- Lymphadenopathy
- Evidence of secondary spread

A Pap smear should be taken and endometrial assessment be performed by imaging and / or endometrial sampling prior to engaging in any invasive procedure if there is a history of abnormal uterine bleeding.

Patients should have preoperative imaging by ultrasound or MRI, depending local guidelines. Risk factors for LMS include:

- Large size or large interval growth
- Tissue signal heterogeneity
- Central necrosis

- Ill-defined margins
- Ascites
- Metastases

With the exception of the last two elements, it is recognised that these features have a significant overlap with degenerating fibroids. There are no established tumour markers for LMS, though there may be an elevation in LDH, related to an increased cell turnover.

Recommendation 1	Grade
Following evaluation, it is recommended that myomectomy only be performed in women who wish to retain the uterus after an appropriate discussion of the risks and benefits of uterine preservation. Furthermore, morcellation of a fibroid or uterus should only be performed in the absence of a suspicion of malignancy.	Consensus-based recommendation
Recommendation 2	**Grade**
Patients must be engaged in the discussion of the risks and benefits of procedure, the route of any proposed procedure, and the mechanism of tissue extraction. This discussion should include the risks and benefits of alternative management options.	Consensus-based recommendation
Recommendation 3	**Grade**
Recommendations for the use of an electromechanical morcellator include: 1. Practitioner credentialed for the use of an electromechanical morcellator by the local credentialing committee 2. No suspicion of malignancy on preoperative or intraoperative assessment 3. Maintain the tip of the instrument in view at all times 4. Maintain control of the specimen at all times 5. Feed the specimen into the morcellator in a controlled manner 6. Minimise spillage of specimen fragments wherever possible 7. Post-morcellation retrieval of all microscopic fragments.	Consensus-based recommendation

4. Conclusion

It is recognised that these measures will not completely preclude the occurrence of an unsuspected malignancy at myomectomy or hysterectomy. If the diagnosis is made postoperatively, early consultation with a gynaecological oncologist is mandatory.

5. Other suggested reading

1. American College of Obstetricans and Gynecologists. Power Morcellation and Occult Malignancy in Gynecologic Surgery. May 2014.

2. AAGL Advancing Minimally Invasive Gynecology Worldwide. AAGL Tissue Extraction Task Force Report. May 2014.

Appendices

Appendix A AGES Society Board and Contributors

Name	Position on Committee
Associate Professor Anusch Yazdani	Primary author, Vice President
Dr Jim Tsaltas	President
Dr Stuart Salfinger	Member
Associate Professor Harry Merkur	Member
Associate Professor Jason Abbott	Member
Dr Stephen Lyons	Member
Dr Keith Harrison	Member
Dr Haider Najjar	Member
Prof Ajay Rane	Member
Dr Martin Ritossa	Member
Professor Andreas Obermair	Consultant

Appendix B Women's Health Committee Membership

Name	Position on Committee
Associate Professor Stephen Robson	Chair
Professor Susan Walker	Deputy Chair - Obstetrics
Dr Gino Pecoraro	Deputy Chair - Gynaecology
Professor Yee Leung	Member
Associate Professor Anuschirawan Yazdani	Member
Dr Simon Craig	Member
Associate Professor Paul Duggan	Member
Dr Vijay Roach	Member
Dr Stephen Lyons	Member
Dr Ian Page	Member
Dr Donald Clark	Member
Dr Amber Moore	Member
Dr Martin Ritossa	Member
Dr Benjamin Bopp	Member
Dr James Harvey	Member
Dr John Tait	Member
Dr Anthony Frumar	Member
Associate Professor Kirsten Black	Member
Dr Jacqueline Boyle	Chair of IWHC
Dr Louise Sterling	GPOAC representative
Ms Catherine Whitby	Council Consumer representative
Ms Susan Hughes	Consumer representative
Ms Sherryn Elworthy	Midwifery representative
Dr Scott White	Trainee representative
Dr Agnes Wilson	RANZCOG Guideline developer

Appendix C Overview of the development and review process for this statement

i. Steps in developing and updating this statement

This statement was originally developed in June 2014 by AGES. The following steps were carried out in developing this statement:

- Declarations of interest were sought from all authors prior to developing this statement.
- Declarations of interest were sought from all Women's Health Committee members prior to developing this statement.
- An updated literature search to answer the clinical questions was undertaken.
- A draft was developed by AGES in May 2014 and ratified by the AGES Board.
- At the June 2014 Women's Health Committee teleconference, the draft was reviewed and subsequently circulated to RANZCOG Board for out of session approval. The statement was subsequently reviewed by RANZCOG throughout July 2014 and approved by RANZCOG Board in July 2014.

ii. Declaration of interest process and management

Declaring interests is essential in order to prevent any potential conflict between the private interests of members, and their duties as part of the Women's Health Committee.

A declaration of interest form specific to guidelines and statements was developed by RANZCOG and approved by the RANZCOG Board in September 2012. The Women's Health Committee members were required to declare their relevant interests in writing on this form prior to participating in the review of this statement.

Members were required to update their information as soon as they become aware of any changes to their interests and there was also a standing agenda item at each meeting where declarations of interest were called for and recorded as part of the meeting minutes.

There were no significant real or perceived conflicts of interest that required management during the process of development of this statement.

iii. Grading of recommendations

Each recommendation in this College statement is given an overall grade as per the table below, based on the National Health and Medical Research Council (NHMRC) Levels of Evidence and Grades of Recommendations for Developers of Guidelines. Where no robust evidence was available but there was sufficient consensus amongst the AGES writing group, consensus-based recommendations were developed and are identifiable as such. Consensus-based recommendations were agreed to by the entire AGES writing group. Good Practice Notes are highlighted throughout and provide practical guidance to facilitate implementation. These were also developed through consensus of the entire AGES writing group.

Recommendation category		Description
Evidence-based	A	Body of evidence can be trusted to guide practice
	B	Body of evidence can be trusted to guide practice in most situations
	C	Body of evidence provides some support for recommendation(s) but care should be taken in its application
	D	The body of evidence is weak and the recommendation must be applied with caution
Consensus-based		Recommendation based on clinical opinion and expertise as insufficient evidence available
Good Practice Note		Practical advice and information based on clinical opinion and expertise

Appendix D Full Disclaimer

This information is intended to provide general advice to practitioners, and should not be relied on as a substitute for proper assessment with respect to the particular circumstances of each case and the needs of any patient.

This information has been prepared having regard to general circumstances. It is the responsibility of each practitioner to have regard to the particular circumstances of each case. Clinical management should be responsive to the needs of the individual patient and the particular circumstances of each case.

This information has been prepared having regard to the information available at the time of its preparation, and each practitioner should have regard to relevant information, research or material which may have been published or become available subsequently.

Whilst the College endeavours to ensure that information is accurate and current at the time of preparation, it takes no responsibility for matters arising from changed circumstances or information or material that may have become subsequently available.

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JMIG The Journal of Minimally Invasive Gynecology

Special Article

Comparative Studies of Energy Sources in Gynecologic Laparoscopy

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ABSTRACT Energy sources incorporating "vessel sealing" capabilities are being increasingly used in gynecologic laparoscopic surgery although conventional monopolar and bipolar electrosurgery remain popular. The preference for one device over another is based on a combination of factors, including the surgeon's subjective experience, availability, and cost. Although comparative clinical studies and meta-analyses of laparoscopic energy sources have reported small but statistically significant differences in volumes of blood loss, the clinical significance of such small volumes is questionable. The overall usefulness of the various energy sources available will depend on a number of factors including vessel burst pressure and seal time, lateral thermal spread, and smoke production. Animal studies and laboratory-based trials are useful in providing a controlled environment to investigate such parameters. At present, there is insufficient evidence to support the use of one energy source over another. Journal of Minimally Invasive Gynecology (2013) 20, 308–318 © 2013 AAGL. All rights reserved.

Keywords: Comparative trials; Energy sources; Gynecologic laparoscopy

DISCUSS You can discuss this article with its authors and with other AAGL members at **http://www.AAGL.org/jmig-20-3-12-00582**

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The use of new-generation energy sources in gynecologic laparoscopy is steadily increasing. In addition to conventional monopolar and bipolar electrosurgery, many surgeons use advanced bipolar "vessel sealers" that incorporate tissue feedback monitoring or devices that use ultrasonic technology to both seal vessels and transect tissue. The tissue effects of these instruments are summarized in Table 1. The choice of instrumentation may vary according to the nature of the surgical task being performed and additionally may be influenced by various factors including previous training or experience, the availability and cost of instrumentation, relative tissue transection/hemostatic properties of the instrument, the degree of anticipated pathology in the tissues, and industry marketing. Ideally, the decision to use a particular energy source should be based on the results of well-designed randomized controlled clinical trials. However, there are only a limited number of such clinical studies in general surgery, and even fewer such studies for gynecologic laparoscopic surgery. Comparative laboratory-based and animal studies are also useful in providing a controlled environment to investigate various properties of energy sources available for laparoscopic surgery. This article reviews the comparative literature on laparoscopic energy sources with an emphasis on their usefulness in gynecologic surgery.

Methods

Although there are many comparative clinical studies and 3 meta-analyses of the performance of laparoscopic energy sources in colectomy [1], cholecystectomy [2], and general surgery [3] published in the medical literature, we are unaware of similar systematic reviews in gynecologic laparoscopy. We searched the National Library of Medicine's Medline and the Cochrane Library databases (1946 to October 1, 2012) for comparative clinical trials of energy sources in gynecologic patients. We used the following

The authors declare that they have no conflict of interest.

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Table 1

The main classes of laparoscopic energy sources and their tissue effects [37]

Energy Source	Tissue Effects
Monopolar electrosurgery	Vaporization (tissue transection), fulguration, desiccation, coaptation*
Conventional bipolar electrosurgery	Desiccation, coaptation
Advanced bipolar technology†	Desiccation, coaptation, tissue transection‡
Ultrasonic technology	Desiccation, coaptation, mechanical tissue transection

* Vessel sealing achieved with coagulation and compression.
† Activation time limited by tissue-response feedback.
‡ Transection with incorporated blade or bipolar energy.

search strategy: randomized controlled trial/ or "randomized" or "randomized" or prospective studies/ or "prospective" AND "monopolar" or "bipolar electrosealing device" or "bipolar electrosurgery" or "bipolar vessel sealing system" or "tripolar" or "EBVS" or "electrothermal bipolar coagulation" or "electrothermal bipolar vessel sealer" or "electrothermal bipolar vessel sealing system" or "electrothermal vessel sealing" or "energized vessel sealing" or "energy-based vessel ligation" or "vessel sealer" or "vessel sealing" or "LSVS" or "LigaSure" or "EnSeal" or "(Gyrus and bipolar)" or "Harmonic Scalpel" or "Harmonic shears" or "Harmonic ACE" or "SonoSurg" or "ultrasonic vessel sealer" or "ultrasonic sealer" or "ultrasonic coagulating shears" or "Thunderbeat" or "AutoSonix" AND gynecology/ or "gynecology" or "gynaecology" or "hysterectomy" or "myomectomy" or "endometriosis" or "ovarian cystectomy" or "oophorectomy" AND laparoscopy/.

This search identified 22 abstracts, which were screened independently by the 2 authors. Animals studies (n = 3), hysteroscopic studies (n = 2), and studies that did not compare 2 or more energy sources (n = 9) were excluded. Eight comparative clinical trials in energy sources relating to laparoscopic gynecologic surgery were identified. Table 2 summarizes the relevant key findings of these studies. These data were analyzed and compared with data from meta-analyses on laparoscopic colectomy [1], cholecystectomy [2], and general surgery [3].

Of the 8 studies, 2 were randomized controlled trials, 2 were nonrandomized trials, and 4 were retrospective comparative studies (Table 2). Seven studies related to benign gynecologic conditions [4–10], and 1 study was undertaken in women with cervical cancer [11]. With the exception of 1 study comparing 2 vessel sealing devices (Harmonic Scalpel [Ethicon Endo-Surgery, Cincinnati, OH] vs LigaSure [Covidien, Mainsfield, MA]) [6], the remaining 7 studies compared vessel sealing devices with conventional electrosurgery [4,5,7–11].

Results and Discussion

Clinical Comparative Studies

This is the first review in the literature looking at comparative clinical trials of energy sources in laparoscopic gynecologic surgery. A Cochrane review has been published on energy source instruments for laparoscopic colectomy [1], and meta-analyses on the performance of laparoscopic energy sources in cholecystectomy [2] and general surgery [3] have also been published. However, given the lack of randomized studies in gynecologic surgery, a meta-analysis of the few studies relating to gynecologic procedures would not yield useful information. Moreover, although such meta-analyses can offer a comparison of different broad categories of vessel sealers, they cannot be used to show significant differences between specific instruments. Six randomized controlled trials (N = 446) were included in the Cochrane review on various energy sources for laparoscopic colectomy, but a major limitation of this meta-analysis is the heterogeneity of the studies [1]. Furthermore, the authors considered LigaSure, Gyrus PlasmaKinetic (PK; Gyrus ACMI, Maple Grove, MN), and EnSeal (Ethicon Endo-Surgery, Cincinnati, OH) collectively as "electrothermal bipolar vessel sealers" although laboratory-based trials (see later) and clinical experience indicate that each of these devices has a different profile of efficacy for the range of evaluated parameters.

A systematic review has previously reported on LigaSure versus other energy sources and included gynecologic and nongynecologic studies [3]. Results from nongynecologic studies may not always be generalizable to gynecologic procedures. For example, fewer vessels need to be sealed during a hysterectomy compared with a left colectomy. Accordingly, the total time saved by using vessel sealing devices in laparoscopic gynecologic surgery may not be as significant as in colorectal surgery. A review of the clinical data on blood loss, operating time, postoperative pain, and complications from comparative clinical studies of laparoscopic energy sources follows.

Blood Loss

One of the purported advantages of the modern vessel sealers is the reduction of intraoperative blood loss. Seven of the 8 comparative studies in gynecologic laparoscopy reported data on blood loss [4–9,11]. Because of the heterogeneity of the surgical procedure among the studies, and the differing energy sources used in the studies, it is not possible to pool data from these studies (Table 2). Of the 2 randomized controlled trials in gynecologic surgery, one showed no significant difference in intraoperative blood loss (234.1 vs 273.1 mL, p = .46) [4], whereas the other showed a statistically significant difference of 47.6 mL (135.2 ± 89.1 vs 182.8 ± 116.8 mL, p = .004) [5]. The study that showed no significant difference in blood loss was for total laparoscopic hysterectomy (TLH) using LigaSure versus conventional bipolar forceps [4]. The study showing

Table 2

Comparative trials on energy sources in gynecologic laparoscopy

Authors	Study design	Sample size	Procedure	Study groups	Relevant key findings
Janssen et al., 2011 [4]	Randomized controlled trial	140	Laparoscopic hysterectomy	LS vs CB	Operating time from skin incision to detachment of uterus: 97.6 vs 91.8 minutes ($p = .39$) Total operating time: 148.1 vs 142.1 minutes ($p = .46$) Intraoperative blood loss: 234.1 vs 273.1 mL ($p = .46$)
Litta et al., 2010 [5]	Randomized controlled trial	160	Laparoscopic myomectomy	HS vs EV	Post-operative pain: at 24 hours (VAS 0 to 10): 4.4 ± 1.1 vs 5.6 ± 0.8 ($p < .001$) (at 48 hours: no significant difference) Operation time: 71.8 ± 26.7 vs 88.8 ± 35.5 minutes ($p < .0001$) Intraoperative blood loss: 135.2 ± 89.1 vs 182.8 ± 116.8 mL ($p = .004$) Blood transfusion rate: no transfusions in either group Myoma recurrence rate: no recurrence in any patient (6-month follow-up)
Demirturk et al., 2007 [6]	Retrospective comparative study	40	TLH + BSO	LS vs HS	Operation time: 59.57 ± 3.71 vs 90.95 ± 5.73 minutes ($p < .001$) Blood loss: 87.76 ± 25.48 vs 152.63 ± 60.90 mL ($p < .001$)
Lee et al., 2007 [11]	Retrospective case-control study	76	Laparoscopic radical hysterectomy with pelvic lymphadenectomy	PK vs CB	Blood loss: 397 vs 564 mL Blood transfusion rate: no significant difference Operation time: 172 vs 229 minutes ($p < .001$) Postoperative complications: less for PK
Wang et al., 2005 [7]	Prospective, nonrandomized trial	62	LAVH	PK vs CB	Operation time, blood loss, transfusion rate, length of hospital stay: no significant difference
Ou et al., 2004 [8]	Retrospective comparative study	50 PM 73 CB	TLH	PM vs CB	Blood loss: less for PM cost per case: $70 more per case for PM
Ou et al., 2002 [9]	Retrospective cohort study	168	Laparoscopic myomectomy	Uterine incision using HS vs CM	Blood loss: 243 vs 378 mL ($p < .01$)
Holub et al., 2002 [10]	Nonrandomized controlled trial	60	TLH		C-reactive protein, interleukin-6, creatine kinase, white blood cell count: no significant difference

CB = conventional bipolar; CM = conventional monopolar; EV = electrosurgery with vasoconstrictive solution (epinephrine); HS = Harmonic Scalpel; LAVH = laparoscopically assisted vaginal hysterectomy; LS = LigaSure; PK = PlasmaKinetic pulsed bipolar system; PM = PlasmaKinetic multifunction cutting forceps and monopolar spatula electrode; TLH = total laparoscopic hysterectomy.

a difference in blood loss was in laparoscopic myomectomy using the Harmonic Scalpel compared with conventional electrosurgery [5].

For laparoscopic colectomy, a Cochrane review has reported that advanced bipolar technologies and ultrasonic shears are associated with better hemostatic control. However, even though the blood loss with the ultrasonic energy source was less than the blood loss with monopolar scissors, the difference was only 42 mL [1]. An industry-sponsored meta-analysis of 29 prospective randomized trials in general surgery comparing LigaSure (n = 1107) with either clamping with suture ligation/monopolar electrosurgery (n = 1079), or ultrasonic energy also reported that LigaSure was associated with 43 mL less blood loss (95% confidence interval [CI], 14–73 mL; p = .0021) [3].

Such small volumes, even though statistically significant, are unlikely to make clinically significant differences to patient outcomes. A statistically significant difference in transfusion rates would be more clinically relevant. Three gynecologic comparative studies reported on transfusion rates, and none showed any significant difference in transfusion rates [5,7,11].

In contrast, a retrospective comparative study of open radical hysterectomy and pelvic lymphadenectomy reported a significantly lower transfusion rate of 5.6% (1/18) in the LigaSure group compared with 40.3% (27/67) in the traditional clamping and suture ligation group [12]. The fact that this was a study of open surgery, and the retrospective nature of this study, limit the relevance of this finding to gynecologic laparoscopy.

Operating Time

The other purported advantage of modern laparoscopic energy sources is a decreased operating time. This may be attributable to the reduction in instrument traffic (for instruments with an integrated cutting function) as well as a shorter vessel seal time. However, the reliability of the vessel sealing is more important as a time saver because it usually takes substantially longer to identify and control hemostasis after a blood vessel has started to bleed (with or without vessel retraction into the tissues). In the Cochrane review of laparoscopic colectomy, the operating time was 40 minutes shorter with advanced bipolar technologies than with monopolar scissors [1]. Similarly, the meta-analysis of laparoscopic cholecystectomy (N = 695) showed that, compared with monopolar electrosurgery, the operating time with ultrasonic energy sources is significantly shorter in elective surgical cases (weighted mean difference [WMD] = −8.19; 95% CI, −10.36 to −6.02; p < .0001), acute cholecystitis cases (WMD = −17; 95% CI, −28.68 to −5.32; p = .004), and complicated cases (WMD = −15, 95% CI, −28.15 to −1.85; p = .03) and if surgery was performed by trainee surgeons who had performed <10 procedures (p = .043) [2]. In the general surgical meta-analysis, LigaSure was associated with a shorter operating time (normalized mean reduction in operative time of 28%, p < .0001) compared with suture ligation/monopolar electrosurgery [3]. Such time savings are not only statistically significant but may also result in real cost savings in operating room time. Much larger studies would be required to evaluate whether shorter operating times would result in improved clinical outcomes.

Despite these findings from general surgical studies, similar time savings have not been consistently reported in gynecologic studies. For laparoscopic radical hysterectomy with pelvic lymphadenectomy, Gyrus PK was reported to be associated with a time saving of 57 minutes compared with conventional bipolar electrosurgery (229 vs 172 minutes, p < .001) [11]. However, another study of laparoscopically assisted vaginal hysterectomy using the same instruments did not show any significant difference in operation time [7]. The randomized controlled trial for TLH also reported that there was no significant difference in the total operating time between LigaSure (148.1 minutes) and conventional bipolar electrosurgery (142.1 minutes, p = .46) [4]. One plausible explanation for this discrepancy is that the time-sparing effect of using vessel sealing devices is proportional to the complexity of the surgery. In an uncomplicated TLH, there are only 2 major vessels to be sealed (uterine arteries), whereas more vessels or vascular pedicles need to be sealed when performing a colectomy or a radical hysterectomy.

Postoperative Pain

For general surgery, the meta-analysis showed that postoperative pain was 2.8 units less on a 0 to 10 visual analog scale (95% CI, 1.5–4.1; p < .0001) for LigaSure compared with suture ligation/monopolar electrosurgery [3]. In cholecystectomy, postoperative abdominal pain scores at 1, 4, and 24 hours were also significantly lower with ultrasonic dissection compared with monopolar electrosurgery [2].

There are limited data on postoperative pain from randomized gynecologic laparoscopy trials, but a similar reduction in postoperative pain was reported for laparoscopic myomectomy. Visual analog scale pain scores for postoperative pain after myomectomy were significantly less at 24 hours with the Harmonic Scalpel compared with conventional electrosurgery (5.6 ± 0.8 vs 4.4 ± 1.1, p = .0001), but there was no significant difference at 48 hours (2.5 ± 0.8 vs 2.4 ± 1.1, p = .2) [5].

Complications

In the general surgery meta-analysis, LigaSure was associated with fewer complications compared with suture ligation/monopolar electrosurgery, ranging in severity from minor (e.g., pruritus) to severe (e.g., pelvic abscess) [3]. In gynecologic surgery, 7 of the 8 comparative studies reported on complications (Table 2) [4–9,11]. A retrospective case-control study (N = 76) of radical hysterectomy and bilateral pelvic lymphadenectomy reported 1 intraoperative complication (rectal perforation during the right uterosacral ligament dissection) and postoperative complications in 4 women (2 cases of intestinal obstruction, 2 cases of acute

Table 3

Comparative laboratory-based and animal studies comparing 2 or more vessel sealing devices

Authors	Study design	Devices compared*	Vessel type	Significant findings
Milsom et al., 2012 [17]	Ex vivo study	Thunderbeat, Harmonic ACE, LigaSure V, EnSeal	Small (2–3 mm), medium (4–5 mm), large (6–7 mm) porcine vessels	Burst pressure: no significant difference between devices Lateral thermal spread: similar for Thunderbeat and Harmonic ACE ($p = .4167$), EnSeal ($p = .6817$), and LigaSure ($p = .8254$)
Noble et al., 2011 [18]	Ex vivo study	LOTUS, Harmonic ACE, LigaSure	Human mesenteric vessels ($n = 93$)	Burst pressure: no difference between instruments ($p = .058$) Lateral thermal spread: greater with LigaSure (3.37 mm) than Lotus (2.18 mm, $p < .001$), Harmonic ACE (1.95 mm, $p < .001$)
Katsuno et al., 2010 [38]	Ex vivo study	LSAt, LSAFt, Endoclip II	Inferior mesenteric, splenic, hepatic, renal, iliac, femoral arteries	Sealing time: shorter with LSAFt (3.5 seconds) than LSAt (7.6 seconds) Burst pressure: higher with LSAFt (1375 mm Hg) than LSAt (961 mm Hg); no Significant difference between LSAt and Endoclip Lateral thermal spread: less with LSAFt (1.0 mm) than LSAt (2.1 mm)
Newcomb et al., 2009 [13]	Ex vivo study	GC, GP, Harmonic Scalpel, EnSeal, LS, LSFt, LC	2- to 3-mm, 4- to 5-mm, 6- to 7-mm vessels	Burst pressure: 2–3 mm or 6–7 mm vessels: no significant difference 4–5 mm vessels: LS had the highest mean burst pressure (1261 mm Hg), statistically higher than other devices except EnSeal (928 mm Hg)
Person et al., 2008 [20]	In vivo study: vessels are sealed, then harvested for testing (burst pressure, histology)	Harmonic ACE, 5-mm LigaSure V, 10-mm LigaSure Atlas, EnSeal	3.3- to 4.1-mm bovine vessels	Burst pressure: higher with EnSeal (678 mm Hg) than LigaSure V (380 mm Hg), Harmonic ACE (435 mm Hg), and LigaSure Atlas (489 mm Hg) Sealing time: shorter with Harmonic ACE (3.3 seconds) than EnSeal (4.1 seconds), LigaSure Atlas (7.9 seconds), LigaSure V (5.2 seconds)
Phillips et al., 2008 [21]	Ex vivo study	Harmonic ACE, LigaSure V	<5-mm porcine arteries and veins	Burst pressure: ≤3 mm vessels: elevated with supraphysiologic for both Harmonic ACE and LigaSure V 3.1–5 mm arteries: no significant difference
Lamberton et al., 2008 [14]	Ex vivo study: harvested vessels were sealed in a simulated laparoscopic environment created using a neonatal incubator	LigaSure V, Gyrus PK, Harmonic ACE, EnSeal	5-mm arteries	Sealing time: shorter for LigaSure (10.0 seconds) and Gyrus (11.1 seconds) than EnSeal (19.2 seconds) and Harmonic ACE (14.3 seconds) Lateral thermal spread: less with Harmonic ACE (49.9°C) with Gyrus (64.5°C) but similar to LigaSure (55.5°C) and EnSeal (58.9°C) Smoke production: less with Harmonic ACE (mean 2.88 ppm) than Gyrus PK (74.1 ppm, $p < .0001$) and EnSeal (21.6 ppm, $p < .0001$), no difference with LigaSure (12.5 ppm, $p = .11$) 12.5; blinded) Blinded reviewers rated the Harmonic ACE the best visibility score

Hruby et al., 2007 [19]	In vivo study	LigaSure V, Harmonic ACE, Harmonic LCS-C5, Trissector	Porcine arteries and veins	Burst pressure: arteries: LigaSure V 536 mm Hg, Harmonic ACE 436 mm Hg, LCS-C5 363 mm Hg, Trissector 328 mm Hg Veins: LigaSure V 386 mm Hg, Harmonic ACE 160 mm Hg, LCS-C5 215 mm Hg, Trissector 237 mm Hg Lateral thermal spread (for sealing arteries): LigaSure V 4.5 mm, Harmonic ACE 0.6 mm, LCS-C5 0.3 mm, Trissector 8.0 mm ($p < .0001$) Lateral thermal spread (for sealing veins): LigaSure V 6.3 mm, Harmonic ACE 1.5 mm, LCS-C5 1.3 mm, Trissector 8.5 mm ($p = .003$)
Richter et al., 2006 [39]	Ex vivo study	LigaSure, BiClamp	Splenic, renal, salpingo-ovarian, mesenteric	Initial seal failure: no significant difference (Biclamp: 2.78%; LigaSure 8.57%)
Carbonell et al., 2003 [40]	Ex vivo study, with histologic examination for lateral thermal damage	Gyrus PK, LigaSure	2- to 3-mm, 4- to 5-mm, 6- to 7-mm bovine vessels	Burst pressure: Burst pressure (4–5 mm vessels): 2–3 mm vessels: no significant difference 4–5 mm vessels: lower with Gyrus PK (389 mm Hg) than LigaSure (573 mm Hg) 6–7 mm vessels: lower with Gyrus PK (317 mm Hg) than LigaSure (585 mm Hg) Lateral thermal spread (2–3 mm, 4–5 mm and 6–7 mm vessels): no difference between LigaSure (1.2, 2.4, 2.5 mm) and Gyrus PK (1.5, 2.4, 3.2 mm)
Landman et al., 2003 [15]	In vivo study: vessels harvested for histologic examination	LigaSure, LC, Endo-GIA, Klepinger and Trimax bipolar forceps, Harmonic Scalpel	Porcine arteries up to 6 mm, veins up to 12 mm	Lateral thermal spread: LigaSure 1–3 mm, conventional bipolar 1–6 mm, Harmonic Scalpel 0–1 mm
Harold et al., 2003 [16]	Ex vivo study	LCS, EBVS, LC, PC	2- to 3-mm, 4- to 5-mm, 6- to 7-mm porcine arteries	Mean burst pressure: 2–3 mm arteries: EBVS vs LCS no significant difference 4–5 mm arteries: EBVS (601 mm Hg) vs LCS (205 mm Hg) ($p < .0001$) 6–7 mm arteries: EBVS (442 mm Hg) vs LCS (175 mm Hg) ($p < .0001$) Lateral thermal spread: EBVS vs LCS no significant difference (EBVS mean = 2.57 mm vs LCS mean = 2.18 mm)
Goldstein et al., 2002 [41]	Ex vivo study	LCS, LigaSure	Bovine ureters	Lateral thermal spread: no significant difference (LigaSure: 2.11 mm, LCS: 1.92 mm)
Matthews et al., 2001 [42]	After cholecystectomy, cystic ducts were resealed ex vivo In vivo common bile duct in 6 pigs	LCS, LigaSure, LigaClip	Human cystic duct	Burst pressure: more for LigaClip and LigaSure than LCS Lateral thermal spread: less for LCS (3.5 mm) than LigaSure (13.4 mm)

EBVS = electrothermal bipolar vessel sealer; GC = Gyrus PK cutting forceps; GP = Gyrus Plasma Trissector; LC = titanium laparoscopic clips; LCS = LaparoSonic coagulating shears; LOTUS = Laparoscopic Operation by Torsional Ultrasound; LS = LigaSure V with LigaSure vessel sealing generator; LSAt = 10-mm LigaSure Atlas with LigaSure vessel sealing generator; LSAFt = 10-mm LigaSure Atlas with ForceTriad Generator; LSFt = LigaSure V with ForceTriad Generator; PC = plastic laparoscopic clips.

* Five-millimeter laparoscopic instruments unless otherwise specified.

renal failure, and 1 case of vesicovaginal fistula) in the conventional bipolar group, whereas there were no complications reported for the Gyrus PK group (p = .02) [11]. In the other comparative trials of energy sources in laparoscopic gynecology, no significant difference in complication rates was reported [4–9]. All of these other trials related to laparoscopy for benign gynecologic conditions, and because complication rates are generally low for these procedures, studies with much larger sample sizes would be required to detect any statistically significant difference in complication rates.

Laboratory and Animal Studies

Laboratory-based studies and (to a lesser extent) animal studies offer a controlled environment in which various properties of laparoscopic energy sources can be tested and compared. In such studies, confounding factors inherent in the clinical situation can be controlled for; nonetheless, care must be taken when drawing conclusions based on laboratory studies that may not be reproducible in the clinical setting. Moreover, results from different studies cannot be readily compared because the observed result in each study can depend greatly on the study design (e.g., the duration of device activation, environmental control including temperature and humidity, and method of histologic staining of tissue samples). For these reasons, when comparing one laparoscopic energy source with another using data derived from laboratory-based research, studies that investigate 2 or more instruments in the same controlled environment are the most valuable (Table 3). There is no study that compares all properties of the various energy sources available to gynecologic surgeons. Despite this, the available studies are somewhat useful for clinicians to compare the properties of different energy sources (Table 4). Four important parameters of laparoscopic energy sources have been assessed in laboratory-based and animal studies: mean burst pressure, vessel seal time, lateral thermal spread, and smoke/plume.

Table 4

Summary of comparative studies of energy sources for gynecologic laparoscopy

	Energy source			
	Monopolar electrosurgery	Conventional bipolar electrosurgery	Advanced bipolar electrosurgery	Ultrasonic
Configuration(s)	Scissors Hook Forceps	Forceps Forceps + blade	Forceps with tissue response feedback ± cutting mechanism†	Shears hook
Overall dissection rating (1 [worse]–4 [best])	4	1	2	3
Tissue effect				
Transection	Vaporization Fulguration Sharp*	Sharp (blade, e.g., "Tripolar")	Sharp (blade, e.g., LigaSure, EnSeal) Bipolar "cut" mode (e.g., Gyrus PK)	Thermal (cavitation) and mechanical tissue disruption
Hemostasis	Fulgaration Desiccation Coaptation	Desiccation Coaptation	Desiccation Coaptation	Desiccation Coaptation
Vessel seal diameter	<2 mm	7 mm	7 mm	5 mm
Burst pressure	NA	NA	Largest	Smallest
Seal time	NA	NA	Faster	Slower
Intraoperative blood loss	More than advanced bipolar or ultrasonics	More than advanced bipolar or ultrasonics	Less than conventional electrosurgery	Less than conventional electrosurgery
Blood transfusion rate	NSD	NSD	NSD	NSD
Operation time	Longer than advanced bipolar or ultrasonics	Longer than advanced bipolar or ultrasonics	Shorter than conventional electrosurgery	Shorter than conventional electrosurgery
Complications	NSD	NSD	NSD	NSD
Lateral thermal spread	Significant	Significant	Significant	Significant
Instrument tip temperature	Above "cell kill" range	Above "cell kill" range	Above "cell kill" range	Above "cell kill" range
Smoke/vapor rating (1–4, worst-best)	4	3	3–4	4
Availability	High	High	Intermediate/High	Intermediate/High
Cost	Low	Low	Intermediate/High	Intermediate/High

NA = not applicable; NSD = no significant difference.
* Blade or bipolar energy.
† Scissors.

Vessel Burst Pressure

United States Food and Drug Administration approval has been granted for ultrasonic devices to seal vessels up to 5 mm in diameter and for advanced bipolar devices (i.e., LigaSure, EnSeal, and Gyrus PK) to seal vessels up to 7 mm in diameter [13]. These "sealed" vessels can theoretically withstand up to 3 times the normal systolic blood pressure [14]. The fact that these burst pressures are lower than that achieved with traditional laparoscopic stapling devices and clips [15,16] may not be clinically relevant; as long as the burst pressure is in the supraphysiologic range (with a reasonable buffer), the vessel seal should remain stable despite usual fluctuations in postoperative blood pressure.

However, seal failures still occur despite supraphysiologic burst pressures. For example, in 1 study, the Plasma Trissector (Gyrus ACMI, Maple Grove, MN) had a mean burst pressure of 322.7 mm Hg for sealing 6- to 7-mm vessels, but the failure rate (defined in this study as the number of seal failures divided by the total number of attempted seals required to obtain 13 seals for burst pressure testing) was 92% [13]. Such a high failure rate is unacceptable in clinical practice, and surgeons should be aware of this when using such devices for sealing 6- to 7-mm vessels.

A number of studies have reported no significant difference in burst pressures between advanced bipolar and ultrasonic devices, with both groups of devices achieving results in the supraphysiologic range [17–19]. In contrast, a statistically significant difference in burst pressure was reported for LigaSure (385 $\pm$ 76 mm Hg) versus the Harmonic ACE (Ethicon Endo-Surgery, Cincinnati, OH) (204 $\pm$ 59 mm Hg) in a simulated laparoscopic environment using harvested 5-mm bovine vessels [14]. Despite LigaSure having a higher mean burst pressure than the Harmonic ACE, Gyrus PK (290 $\pm$ 110 mm Hg), and EnSeal (255 $\pm$ 80 mm Hg), the burst pressures for all these devices were in the supraphysiologic range [14]. In a study performed in live pigs sponsored by the manufacturers of EnSeal, this device was found to yield significantly higher burst pressures than other vessel sealing devices [20]. This difference in findings may be explained partly by the difference in study methodology, namely ex vivo and in vivo. One of the disadvantages of ex vivo studies is that the absence of blood and clotting factors may spuriously affect the sealing abilities of a device. In support of this notion, another laboratory-based study has shown that increasing hematocrit in harvested blood vessels is associated with increasing burst pressures [21].

Vessel Seal Time

Seal time is defined as the duration of time between device activation and when the device emits a signal that the vessel is sealed or when there is gross visual evidence of seal division. In the previously mentioned study [14], which also included cutting of the vessel in the seal time, the time to seal for the Harmonic Scalpel, LigaSure, Gyrus PK, and EnSeal were 14.3, 10.0, 11.1, and 19.2 seconds, respectively. The LigaSure and Gyrus PK had the shortest vessel sealing times compared with the group ($p < .0001$). However, upon transection, the "sealed vessel" was found to be completely open in 30% of the vessels sealed with the Gyrus PK. Hence, although this device had a statistically shorter seal time, the overall operating time may be extended when using this device if extra time is needed to identify and control bleeding vessels in the event of initial seal failure.

Lateral Thermal Spread

Tissue damage may be caused at temperatures above 42°C [22,23], especially with prolonged exposure, and this has been shown histologically in a rat model [24]. Such tissue damage can occur some distance from the point of application of the laparoscopic energy source in a phenomenon referred to as "lateral thermal spread." Lateral thermal spread occurs with all laparoscopic energy sources, to a lesser or greater extent, whether the delivered tissue effect is electrosurgical vaporization, fulguration, desiccation, or coaptation, or ultrasonic tissue transection or vessel sealing. Apart from histologic assessment, lateral thermal spread may also be quantified using real-time thermal imaging or temperature probes.

Tissue healing could be impaired by lateral thermal spread, but evidence for this is limited; it would require large studies with long follow-up to show any significant difference in outcomes for different energy sources. In a study comparing the use of the Harmonic Scalpel (at a power setting of 3), CO_2 laser, monopolar scissors, and bipolar forceps at oral surgery in guinea pigs, use of the Harmonic Scalpel was associated with the fastest tissue re-epithelialization and greater tensile strength, similar to the steel scalpel [25].

Many variables may affect the degree of lateral thermal spread apart from the individual laparoscopic energy source in use. Such variables include the power settings, the current waveform (continuous or interrupted for monopolar electrosurgery), contact or noncontact application (for monopolar electrosurgery), the duration of device activation, and the tissues to which the device is applied. Just as it is important to control for these variables, study methodology is also very important. For example, in a porcine study ($N = 8$) using the 5-mm LigaSure, lateral thermal spread was reported to be 4.4 mm by real-time thermal imaging, but when examined histologically, the lateral thermal spread was <1 mm [26]. For these reasons, it is also difficult to compare results from one study to another.

Laboratory-based studies that control for these variables and compare several devices in the same study are the most useful. An ex vivo study using the Harmonic Scalpel, LigaSure, conventional bipolar forceps, and monopolar hook on porcine muscle reported that tissues at or beyond 1 cm from the instruments are generally safe from lateral thermal spread [23]. Even so, surgeons must be alert of the fact that important structures (e.g., ureters) may be within 1 cm of a vessel being sealed (e.g., uterine arteries). Moreover, exceptions to the 1-cm "safety margin" for

lateral thermal spread have been identified with the monopolar hook, which when activated for greater than 15 seconds with a power setting of 30 W, or for greater than 10 seconds with a power setting of 40 W, a temperature rise to over 42°C may be measured at tissue 1 cm away from the instrument tip [23]. Caution is necessary in extrapolating these data to the clinical situation because extended activation of any energy source to a fixed tissue site is not recommended.

Another histologic study has shown that monopolar electrosurgery is associated with greater lateral thermal spread compared with bipolar electrosurgery, the Harmonic Scalpel, and a CO_2 laser [27]. The Harmonic ACE has also been reported to cause less lateral thermal spread compared with LigaSure (for sealing arteries: 0.6 vs 4.5 mm, $p < .0001$; for sealing veins 1.5 vs 6.3 mm, $p = .003$) [19]. This is in contrast to a comparative study that reported that the laparoscopic coagulating (ultrasonic) shears were associated with more than double the lateral thermal spread compared with monopolar electrosurgery during transection of the uteri and bowel of sheep [28].

Lateral thermal spread sustained at the time of colpotomy during conventional or robotic total laparoscopic hysterectomy has been implicated in vaginal cuff dehiscence [29]. A study using a porcine model for performing colpotomy using the bipolar PKS Plasma J-Hook (Gyrus ACMI, Southborough, MA), bipolar PKS Lyons forceps (Gyrus ACMI, Southborough, MA), monopolar scissors (continuous waveform at 50-W power), or the Harmonic Scalpel (at a power setting of 5) showed histologically that the lateral thermal spread at the vaginal cuff was 3.7, 2.5, 2.0, and 0.78 mm, respectively [29]. There are no data available to causally link the extent of vaginal cuff lateral thermal spread with an increased rate of vault dehiscence.

In clinical practice, surgeons may reduce lateral thermal spread by avoiding prolonged device activation using the lowest energy settings to achieve the desired tissue effects as well as applying irrigation fluid after device activation. In a urologic study of 20 robotic radical prostatectomies using EnSeal, it was reported that the application of cold (<4°C) saline to the device after activation reduced the lateral thermal spread from 0.98 to 0.31 mm ($p < .0002$) [30].

One of the purported advantages of ultrasonic technology is that of lower operating temperatures and, therefore, less lateral thermal spread [31]. This notion is supported by a study using a needle thermistor to record temperature at 2 mm from the cut edge of vessels, which reported that the Harmonic Scalpel had a significantly lower mean maximum temperature compared with the Gyrus PK (49.9 ± 1.8°C vs 64.5 ± 2.7°C, $p < .001$) [14]. Analogous results might not be replicated in studies of vessel sealing because the tissue effects with ultrasonic and advanced bipolar devices is the same in this instance (desiccation, coagulation, and coaptation).

If the instrument tip is used for tissue handling when it is still hot after activation, thermal conductivity may cause injury to tissues [22]. The temperature at the tip of a monopolar hook reaches 100.1°C after 15 seconds of activation of the continuous waveform at a power setting of 40 W, and it takes another 55 seconds for it to cool to 42°C [23]. Similarly, the device head of the 5-mm LigaSure was reported to have a temperature of 97°C during activation, and, even after activation ceased, it remained hot enough to cause injury (>45°C) for 14 seconds [26].

An ex vivo thermographic study has shown that the monopolar hook, LigaSure, and Harmonic ACE can cause a temperature rise of over 20°C by thermal conductivity at 2.5 seconds after activation [22]. Even at 20 seconds after activation at a power setting of 5, the Harmonic ACE can increase tissue temperature by 24°C [22]. An ischemic bowel lesion (undetected at the time of surgery) has been reported after contact of the bowel with the active blade of the Harmonic ACE after instrument activation ceased [32]. Therefore, surgeons must remember to allow adequate time for the instrument tips to cool and to avoid tissue handling with the instruments before this time.

Smoke Plume

The activation of all laparoscopic energy sources results in the production of a smoke or vapor plume. This cloud not only hinders surgical vision but also may be a hazard to staff in the operating room, with potential cytotoxic, genotoxic, and mutagenic properties [33,34].

An objective comparison of the degree of smoke produced by various energy sources is difficult, and there are limited comparative trials in this area. By applying light-scattering theories to the measured particle size of the smoke/plume/vapor produced, a study has reported that in a controlled environment (relative visibility = 1.0) bipolar forceps (relative visibility = 0.887) offers similar visibility to the Harmonic Scalpel (relative visibility = 0.801), and both offer better visibility compared with monopolar scissors (relative visibility = 0.026) [35]. Another study using an aerosol density meter reported that the Harmonic Scalpel (2.88 ppm) produced less smoke than the Gyrus PK (74.1 ppm, $p < .0001$) and EnSeal (21.6 ppm, $p < .0001$), but there was no statistically significant difference with LigaSure (12.5 ppm, $p = 0.11$) [14]. Reviewers who were blinded to the energy source also subjectively rated visibility with the Harmonic Scalpel better than with LigaSure or EnSeal, with the worst subjective visibility reported for the Gyrus PK [14]. Of the ultrasonic devices, a study using digital image analysis software has shown that Sonicision (Covidien, Mansfield, MA; 8.76% of image filled by plume; range, 4.32%–17.41%) and SonoSurg (Olympus USA, Center Valley, PA; 9.46%; range, 5.68%–22.12%) produce less smoke than the Harmonic ACE (18.04%; range, 9.07%–55.12%; $p = .026$) [36].

Conclusions

This review highlights the lack of adequately powered comparative clinical trials of laparoscopic energy sources,

especially for gynecologic laparoscopy. Furthermore, although comparative laboratory-based trials are useful in defining functional properties of energy sources in a controlled environment, it is clear that perceived benefits in the laboratory may not translate to clinically significant advantages. In addition, clinical and laboratory-based trials often compare only 2 categories of the available laparoscopic energy sources, and extrapolation between different studies to indirectly compare and contrast the pros and cons of energy sources is fraught with confounding factors.

A number of these studies are industry sponsored; this is an important consideration given the fact that negative findings from such trials are often not published. However, from the data presented the following conclusions may be drawn: (1) advanced bipolar devices may be associated with less intraoperative blood loss than monopolar, conventional bipolar, and ultrasonic devices, and the latter 2 are more effective in vessel sealing than monopolar devices; (2) laboratory data consistently show advanced bipolar devices can seal larger vessels than ultrasonic devices; (3) seal burst pressures are also generally higher with advanced bipolar devices; (4) despite the previously mentioned conclusions, none of the available data translate to a significant benefit in perioperative blood transfusion rates for any device category; (5) an anticipated decreased operating time with ultrasonic and advanced bipolar devices over conventional electrosurgical devices may only be valid with more complicated laparoscopic procedures; (6) postoperative pain is lower in the early postoperative period with ultrasonic and advanced bipolar devices, but there are limited data for gynecologic laparoscopy; (7) the complication rate in gynecologic laparoscopic surgery is small, and there is no significant difference in complication rates between the different energy sources; (8) lateral thermal spread occurs with all laparoscopic energy sources, to a lesser or greater extent, whether the delivered tissue effect is vaporization, fulguration, desiccation, or coaptation; (9) a temperature rise above the "cell kill" threshold occurs in the tips of all laparoscopic energy sources and inadvertent tissue contact may result in patient morbidity and mortality; and (10) all laparoscopic energy sources give rise to smoke or vapor plumes, with visibility most affected with monopolar electrosurgery and least affected with ultrasonic devices.

Many laparoscopic surgeons will use several energy sources for a particular procedure. For example, advanced bipolar electrosurgery might be the most appropriate technology for sealing larger vessels and vascular pedicles, and ultrasonic technology may be used for the transection of adhesions and pericolic adipose tissue, with monopolar electrosurgery retaining its general utility in simple tasks such as peritoneal transection and in more difficult cases requiring maximal dissection capability in which tissue planes are distorted by pathology. It is clear that adequately powered clinical trials with direct head-to-head comparisons of the various energy sources are required in order to guide surgeons in choosing the most appropriate energy source for laparoscopic surgery.

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Special Article

Laparoscopic Vessel Sealing Technologies

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ABSTRACT Laparoscopic vessel sealing devices have revolutionized modern laparoscopy. These devices fall into 2 major categories: advanced bipolar and ultrasonic instruments. The range of tissue effects available with these technologies is more limited than with conventional monopolar electrosurgery; however, both advanced bipolar and ultrasonic devices efficiently seal vessels ($\leq$7-mm and $\leq$5-mm diameter, respectively), and most also have built-in tissue transection capabilities. These technologies have been the subject of a range of comparative studies on their relative advantages and disadvantages, and, to date, neither advanced bipolar or ultrasonic devices has been proven to be superior. Journal of Minimally Invasive Gynecology (2013) 20, 301–307 Crown Copyright © 2013 Published by Elsevier Inc. All rights reserved.

Keywords: Bipolar electrosurgery; Electrosurgical generator; Monopolar electrosurgery; Return/Dispersive electrode

Conventional monopolar electrosurgery remains a popular laparoscopic modality because of its low cost, general availability, and diverse range of available tissue effects. However, potential shortcomings of monopolar electrosurgery, including the need for a dispersive electrode, the relatively high power settings, the possibility of stray current injuries, and the inability to seal vessels larger than 1–2 mm diameter, led to the development of conventional bipolar electrosurgery to address these issues. More recently, ultrasonic energy sources were developed to limit the risks associated with electrosurgery, at the same time providing more efficient vessel sealing and tissue transection. Advanced bipolar technologies were subsequently introduced with optimized vessel compression and the delivery of electrical energy to provide even better vessel sealing capabilities. These new vessel sealing technologies are so successful that they have largely made the need for laparoscopic suturing of vascular pedicles redundant.

All electrosurgical devices achieve their tissue effects via the passage of electrical current through the target tissue, with the sequential conversion of electrical energy to mechanical energy to thermal energy. Ultrasonic devices also sequentially convert electrical energy to mechanical energy to thermal energy to facilitate vessel sealing but without the passage of electrical current through the tissue.

The tissue effects possible with monopolar electrosurgery include tissue vaporization and transection, fulguration, desiccation, and small vessel coaptation (Table 1) [1,2]. The tissue effects possible with advanced bipolar and ultrasonic technologies encompass a smaller subset of these tissue effects (Table 2). However, these new vessel sealing technologies have a significant advantage over monopolar electrosurgery in their ability to seal larger vessels (i.e, 5–7 mm diameter); with this, they have revolutionized modern laparoscopy. Furthermore, this vessel sealing capability is achieved without some of the risks inherent in monopolar electrosurgery. However, both advanced bipolar and ultrasonic technologies exert their surgical effects via the

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Table 1

Monopolar electrosurgery tissue effects

Tissue effect	Current waveform	Mode
Vaporization (tissue destruction and/or transection)	Continuous	Noncontact
Fulguration (tissue destruction and small vessel hemostasis [≤1-mm diameter])	Interrupted	Noncontact
Desiccation (tissue dehydration)	Continuous or interrupted	Contact
Coagulation (protein denaturation and coagulum formation)	Continuous or interrupted	Contact
Coaptation (small vessel hemostasis [≤2-mm diameter])	Continuous or interrupted	Contact (vessel compression)

production of heat, and their use is not free of the risk of lateral thermal spread injury. This review focuses on the advanced bipolar and ultrasonic devices that seal vessels via analogous thermal processes, resulting in tissue desiccation, protein coagulation, and vessel coaptation.

Advanced Bipolar Devices

In reality, all electrosurgery is "bipolar" inasmuch as there needs to be 1 electrode from which the electrical current enters tissues and another electrode through which the current leaves the patient and returns to the electrosurgical unit (ESU) [1,3]. By convention, monopolar electrosurgery refers to the arrangement of a single small electrode contained within the surgical instrument that delivers focused alternating electrical current to the target tissue to impart the desired surgical effect. The second electrode is placed on the patient at a site remote from the surgical site to complete the electrical circuit; it is relatively large in size and is designed to disperse current (and prevent tissue heating) as it leaves the patient on its way back to the ESU. The tissue effects available with monopolar electrosurgery are achieved using either contact ("closed circuit") or noncontact ("open circuit") modes, with either continuous (ESU "cut" setting) or interrupted (ESU "coag" setting) current waveforms (Table 1).

In bipolar electrosurgery, both electrodes are contained within the surgical device, with current passing from 1 electrode to another. Current passes through tissue grasped between the electrodes to achieve the desired surgical effect. There are significant advantages to this arrangement over monopolar electrosurgery, mostly relating to the fact that the electrical current in bipolar electrosurgery does not have to take pathways through the patient to complete the circuit with the ESU. For example, power settings are typically lower, there is no need for a remote return electrode attached to the patient (eliminating the risk of return electrode injury), and there is no generation of capacitance-coupling current (eliminating the risk of capacitive coupling injury) [1,3]. Bipolar electrosurgery uses alternating current so the orientation of the "active" and "return" electrodes also rapidly alternates, resulting in an even distribution of thermal effects on the tissue grasped between the electrodes. In addition, because a continuous current waveform is used, the voltage is less for a given power setting and the tissue temperature rise to achieve the desired surgical effect is less. With prolonged activation, an interrupted current waveform may result in tissue temperatures exceeding 200°C with resultant carbon deposition and the adherence of tissue to the instrument jaws [2,3].

Bipolar electrosurgery is a modality in which there is minimal ability to vary the operational parameters; the electrical current is only delivered in a "closed circuit" (both electrodes are in contact with the target tissue), a continuous current waveform is standard, and both electrodes are the same size (for a given instrument) and have a relatively large surface area to maximize contact with the tissues. In contrast, monopolar electrosurgery offers more flexibility in that many of the operational parameters can be varied, which accounts for the range of available tissue effects (Table 1) [2]. It should be noted that when a monopolar forceps is activated whilst grasping tissue between the jaws (or, analogously, if a nonactive forceps holding tissue is intentionally

Table 2

A comparison of the tissue effects with monopolar electrosurgery, bipolar electrosurgery, and ultrasonic devices

Energy source	Tissue vaporization	Tissue transection	Fulguration	Desiccation	Coagulation and coaptation
Monopolar	Yes	Yes	Yes	Yes	Yes (≤2-mm diameter)
Bipolar	No	Yes*	No	Yes	Yes (≤7-mm diameter)
Ultrasonic	No	Yes	No	Yes	Yes (≤5-mm diameter)†

* With cutting mechanism incorporated into instrument tip.
† 7-mm diameter vessel sealing possible with advanced bipolar (less with conventional bipolar).

contacted by a monopolar electrosurgical instrument), the electrosurgical tissue effect is essentially the same as that obtained with bipolar forceps (desiccation, coagulation, and coaptation; Table 2). However, in this case, the electrical current must still pass back through the patient to a remote return electrode.

Both monopolar and bipolar electrosurgery achieve the respective range of tissue effects by the conversion of radiofrequency electrical energy into mechanical energy and thence into thermal energy [1]. With noncontact mode monopolar electrosurgery, tissue temperatures greater than 100°C and 200°C result from continuous and interrupted waveforms, respectively, yielding vaporization and fulguration tissue effects (Table 1) [2]. As mentioned previously, the tissue effects available with contact mode monopolar electrosurgery and bipolar electrosurgery are essentially the same (Table 2), and the tissue temperatures are lower, typically in the range of 60° to 100°C. At these temperatures, cell membrane integrity is lost, and the loss of cytoplasm results in desiccation of the tissues. In addition, synchronous protein denaturation results as stabilizing hydrogen bonds are broken. As the tissue temperature subsequently decreases, hydrogen bonds reform but in a different configuration. This so-called "coagulum" is the "biological glue" that enables vessel walls to adhere to one another [3]. An essential requirement in achieving these tissue effects is the ability of the electrosurgical instrument to apply even contact to the tissue and with adequate compressive force. Compression of the vessel ensures that blood flow is interrupted and the potential heat sink effect of the moving liquid is removed. Furthermore, compression of the vessel brings the coagulum of the opposing vessel walls into close proximity so that hydrogen bonds can reform with resultant vessel sealing.

An awareness of the risk of lateral spread is essential, irrespective of the energy source used during laparoscopy, with the amount of lateral thermal spread proportional to the duration of instrument activation. Hence, lateral thermal spread will be detected at increasing distances from the primary surgical site for as long as the energy source is activated. Therefore, the specter of lateral thermal spread during conventional bipolar electrosurgery has been a quandary for the surgeon who must use personal experience and visual cues to estimate the time of device activation necessary for vessel sealing whilst being mindful of the risk of collateral tissue damage.

The delivery of electrical energy by advanced bipolar ESUs is highly pulsatile, allowing for tissue cooling during activation in an attempt to minimize lateral thermal spread. These proprietary ESUs also use computer-controlled tissue feedback response systems that monitor tissue impedance and/or temperature in order to continuously adjust the current and voltage generated by the unit. Hence, with graspers designed to enhance mechanical pressure delivery and electrosurgical energy optimized to improve the tissue effects at the lowest possible power settings, advanced bipolar technology combines optimal thermal and mechanical properties

Fig. 1

The LigaSure advanced bipolar device is the "blunt-tip" model of this range (c.f., the LigaSure V "dolphin-tip" instrument) with a cutting blade incorporated into the tip.

to seal vessels [4,5]. The advanced bipolar ESUs also either automatically switch off or alert the surgeon via an audio signal when the desired tissue effect has been achieved, thereby avoiding prolonged activation, increased tissue temperatures, excessive charring, and adherence of tissue to the instrument jaws and minimizing lateral thermal spread. However, despite promising laboratory and animal studies, it has yet to be shown in clinical trials that these safeguards actually result in a reduction in electrosurgical injury due to lateral thermal spread [6]. Nevertheless, the optimized mechanical force and electrical energy delivered to the tissues by advanced bipolar devices has been rewarded by the US Food and Drug Administration with approval to seal vessels up to 7 mm in diameter [7].

Currently available advanced bipolar technologies include LigaSure (Covidien, Mansfield, MD; Fig. 1), EnSeal (Ethicon Endo-Surgery, Cincinnati, OH; Fig. 2), and PlasmaKinetic System (PKS; Gyrus ACMI, Southborough, MA; Fig. 3). Each of these technologies is different although all are approved to seal vessels up to 7 mm in diameter. Each system also offers a range of devices that vary in aspects of their design. LigaSure, the first commercially available vessel sealing system (1998), has recently been improved with the introduction of the ForceTriad generator, which performs 4000 measurements of tissue impedance per second compared with 200 measurements per second for the conventional LigaSure to provide real-time adjustment control of the energy output with significantly improved mean burst pressures and shorter sealing times [8]. The electrical output between the EnSeal instrument jaws is autoregulated using a proprietary electrode that contains millions of nanometer-sized conductive particles embedded in a temperature-sensitive material, which

Fig. 2

The EnSeal G2 advanced bipolar device. This is the curved-tip model of this range (c.f., the straight-tip instrument). Note the retracted copper-colored transection blade at the jaw hinge.

Fig. 3

The PKS Lyons dissecting forceps is a nonbladed model of this range of advanced bipolar devices. It has good tissue grasping and dissection capability.

maintains the sealing temperature at around 100°C. PKS delivers a pulsed energy with continuous feedback control. In theory, the pulsatile delivery of energy allows tissues to cool between energy bursts, reducing tissue drying at the contact point and therefore resulting in less electrode sticking; the effectiveness of this strategy is yet to be proven in clinical trials.

Apart from rapid and efficient vessel sealing, most advanced bipolar devices are capable of tissue transection with an incorporated cutting mechanism. The cutting device is most commonly a retractable blade built into the jaws of the instrument. PKS Omni (Gyrus ACMI) has an accessory electrode incorporated into the instrument jaws to provide a specialized bipolar tissue-transection function [3]. The advantage of incorporating a cutting device into the vessel sealer is a reduction in "instrument traffic" during laparoscopy, which may translate to shorter operative times and a reduction in hospital costs [9]. However, a downside is that the instrument tips of these "hybrid devices" may be bulkier than conventional bipolar devices because of the additional cutting mechanism, potentially compromising their dissection capabilities. Modifications of these instruments have been produced with curved and/or pointed tips to assist with tissue dissection. Concerns that the smaller surface area of the electrodes could potentially affect the quality of vessel sealing are yet to be proven. Despite attempts to improve the design of the instrument tips of advanced bipolar devices, many surgeons may also continue to use traditional curved monopolar scissors or conventional bipolar graspers for their superior dissecting capabilities.

Ultrasonic Devices

Not dissimilar in appearance to new-generation bipolar electrosurgical devices, ultrasonic laparoscopic energy sources are also able to seal vessels and transect tissues. Indeed, most of the tissue effects produced by ultrasonic devices are the same as those for bipolar devices (Table 2). However, these tissue effects are produced without the passage of electrical current through the patient or target tissue. Ultrasonic devices instead convert electrical energy to both mechanical and thermal energy via ultrasonic vibrations to achieve tissue transection and vessel sealing. Combining these 2 modalities into a single device helps to decrease "instrument traffic" (as for advanced bipolar devices), with potential economic advantages [9].

Ultrasonic devices produce tissue effects by generating mechanical vibrations at over 20,000 cycles per second (i.e., above the audible range). The ultrasonic generator delivers alternating electrical current to the handpiece transducer where excitation in piezoelectrodes interspersed between metal cylinders converts electrical energy into mechanical energy by vibrating the cylinders at frequencies ranging from 23 to 55 kHz [10]. The shaft of the instrument, the active component of the device, is in contact with the cylinders and oscillates linearly at the same frequency. The tip of the shaft forms the nonarticulating jaw of the ultrasonic shears. The articulating jaw of the instrument provides a mechanism for grasping and holding tissue against the active nonarticulating jaw so that the desired tissue effect can be achieved.

The ultrasonic generator varies the amount of mechanical energy applied to the tissue to achieve a particular effect. There are 2 generator settings available: "Max" and "Min." The mechanical energy delivered to the tissue is greatest on the "Max" setting with larger oscillations of the shaft tip (fixed at 100 μm) and is suitable for rapid tissue transection; lateral thermal spread is less with this mode, but the hemostatic potential is poor. The oscillation distance of the ultrasonic shaft tip is smaller on the "Min" setting (adjustable down to 50 μm); the lower level of mechanical energy is ideal for vessel sealing, but there is an increased risk of lateral thermal spread with this mode.

Ultrasonic tissue transection occurs as a result of mechanical friction between the oscillating device shaft and the tissue. The surgeon has some control over this process, which is significantly shorter than for vessel sealing. For example, tissue transection will be more rapid (and less hemostatic) as the pressure applied by the articulating jaw is increased, due to greater resultant frictional and shearing forces. The application of pressure perpendicular to the tissue plane with the oscillating tip (e.g., lifting the pedicle) will similarly facilitate tissue transection. In addition to mechanical friction, cavitation may also facilitate tissue transection [11]. Cavitation is a phenomenon that occurs during tissue vaporization, which is the same process that is observed in electrosurgery when cells explosively rupture as the cytoplasm boils. Cavitation occurs when steam released from vaporized cells expands preexisting tissue planes, thereby assisting dissection. Because of the local environment created by the oscillating tip, cavitation may occur at lower temperatures with ultrasonic devices than in electrosurgery [11].

As with advanced bipolar devices, ultrasonic vessel sealing results from desiccation, coagulation, and coaptation

Fig. 4

The Harmonic ACE ultrasonic vessel sealer and tissue transector. The tip of the device is comprised of the oscillating nonarticulating jaw and the compressing articulating jaw.

(Table 2). However, the mechanism by which these effects are obtained is very different. With electrosurgery, the alternating current oscillates intracellular molecules as the polarity of the cell changes. Consequently, electrical energy is sequentially converted to mechanical energy to thermal energy via intracellular frictional effects to yield the desired tissue effects. With ultrasonic energy, electrical energy is likewise converted to mechanical energy to thermal energy as the frictional force exerted on the tissues by the oscillating shaft tip results in sequential extracellular heating followed by intracellular heating. So, for both bipolar and ultrasonic devices, thermal energy is responsible for the tissue desiccation, coagulation, and coaptation effects. The lateral thermal spread with ultrasonic devices is greatest during vessel sealing mode (i.e., desiccation and coagulation) and least with tissue transection mode (i.e., mechanical cutting and cavitation).

The laparoscopic "ultrasonic scalpel" was first described in 1993 by Amaral [12] with an ability to provide both vessel sealing and tissue transection. The Ultracision Harmonic Scalpel (Ethicon Endo-Surgery) was developed for commercial use and approved to seal vessels up to 3 mm in diameter [13]. The Harmonic ACE (Ethicon Endo-Surgery; Fig. 4) was subsequently developed; its "active" jaw oscillates at a frequency of 55,000 cycles per second, and it gained Food and Drug Administration approval to seal vessels up to 5 mm in diameter [7]. Other examples of currently available laparoscopic ultrasonic devices include the AutoSonix (Covidien), Sonocision (Covidien; Fig. 5), and SonoSurg (Olympus America, Center Valley, PA). These devices operate at similar frequencies to the Harmonic ACE and seal vessels up to 5 mm in diameter with similar mean burst pressures [14]. The AutoSonix, Harmonic ACE, and Sonocision are single-use disposable instruments, whereas SonoSurg is reusable and autoclavable. Sonocision is a newly released cordless ultrasonic device.

Fig. 5

The Sonocision vessel sealer and tissue transector is the first cordless ultrasonic laparoscopic device on the market.

Purported advantages of ultrasonic vessel sealers included less tissue necrosis and charring, reduced lateral thermal spread, and less smoke generation compared with electrosurgery [15,16]. Because the tissue temperature resulting from ultrasonic vessel sealing (desiccation, coagulation, and coaptation) is less than 100°C, tissue charring will be much less than with the higher temperatures generated by noncontact continuous waveform (vaporization) or noncontact interrupted waveform (fulguration) monopolar electrosurgery (Tables 1 and 2). However, the tissue charring resulting from contact monopolar electrosurgery, conventional bipolar electrosurgery, and advanced bipolar electrosurgery (all producing desiccation, coagulation, and coaptation) is much less; the resultant tissue temperatures are similar to those for ultrasonic technologies [17]. In addition, the activation time for vessel sealing with ultrasonic devices is subjective (as for monopolar and conventional bipolar electrosurgery) because there is no tissue impedance/temperature cutoff or audio signal (available with advanced bipolar devices) to inform the surgeon when vessel sealing is complete. Hence, although the risk of lateral thermal spread may be low with ultrasonic devices, higher tissue temperatures (proportional to the increased time of activation) mean that lateral thermal spread injury remains a risk. Interestingly, the Harmonic ACE is associated with greater increases in tissue temperature compared with the Ultracision Harmonic Scalpel [13]. The newly available Harmonic ACE+ (Ethicon Endo-Surgery; Fig. 6) uses "adaptive tissue technology" to regulate energy delivery according to tissue conditions and provides the surgeon with an audio signal of energy output; it is yet to be proven that lateral thermal spread is decreased with this device compared to the Harmonic ACE. The smoke plume generated by ultrasonic vessel sealers is less than with other laparoscopic energy

Fig. 6

The Harmonic ACE+ ultrasonic vessel sealer and tissue transector uses "adaptive tissue technology" to regulate energy delivery. The oscillating and compressing jaws are shown in close-up.

Table 3

A comparison of the advanced bipolar and ultrasonic laparoscopic vessel sealers [1,3,6,11,19–22]

	Energy source	
Parameter	Advanced bipolar	Ultrasonic
Vessel sealing: maximum vessel diameter	Superior (7 mm)	Inferior (5 mm)
Vessel sealing: time to seal	Equal	Equal
Lateral thermal spread*	Inferior	Superior
Residual instrument tip temperature	Superior	Inferior
Smoke/vapor plume	Inferior	Superior

* The time of activation for ultrasonic vessel sealing is operator-dependent so the degree of lateral thermal spread may vary.

sources [11] although the smoke plume from these devices may still significantly obscure the surgeon's view [18]. The tips of the Harmonic ACE are more effective for dissection than the Harmonic Scalpel but overall may have more limited dissection capability when compared with monopolar scissors and conventional bipolar forceps [13].

Comparison of Advanced Bipolar and Ultrasonic Vessel Sealing Technologies

The reasons for a surgeon's preference for a particular laparoscopic energy source may be many and varied. A common reason for choosing a particular instrument is the surgeon's own experience with that instrument that may have been preordained by a mentor during surgical training. Unfamiliar technologies often are not trialed. Surgeons are also subjected to marketing strategies and even inducements. Indeed, device manufacturers sponsor many of the studies on energy sources published in the medical literature. To complicate matters further, it is generally not possible to compare vessel sealing data from different studies because study conditions may vary widely. Hence, it is difficult for surgeons to make an objective, informed decision about the relative merits of different laparoscopic energy sources.

The relative merits of advanced bipolar and ultrasonic devices are summarized in Table 3. These data are from recent studies that compared at least 1 of the advanced bipolar devices with an ultrasonic vessel sealer. Both bipolar and ultrasonic devices are effective at sealing vessels up to 5 mm in diameter, but only bipolar devices are approved to seal vessels 6–7 mm in diameter [7,16,19–21]. There are conflicting data on the "time to seal." No firm conclusion can be drawn as to which class of device is the faster vessel sealer [16,19]. For all laparoscopic energy sources (monopolar [contact mode], bipolar [conventional and advanced], and ultrasonic [vessel sealing mode]), the amount of lateral thermal spread and the risk of collateral tissue damage are proportional to the length of time of activation of the instrument. In general, lateral thermal

Fig. 7

The LigaSure Advance device incorporates advanced bipolar vessel sealing and a blade for tissue transection, as well as a monopolar electrode (visible at the distal end of the blue jaw) for extra dissection capability.

spread generally seems to be less with ultrasonic devices [20,21] although the time of activation with this technology, and the resultant amount of lateral spread, are operator dependent. Interestingly, the residual temperature of the instrument tip after activation is less with bipolar devices [22]. As a general principle, tissue should not be grasped with any energy source immediately after activation. Particulate formation is less with ultrasonic devices although all laparoscopic energy sources produce a plume of smoke or steam [16]. In summary, there is insufficient evidence for one vessel sealing technology to be considered superior to the other. A detailed critical evaluation of comparative clinical, laboratory, and animal studies of all classes of laparoscopic energy sources is available elsewhere [6].

Devices have recently been developed that combine bipolar vessel sealing and bipolar tissue transection (PKS Omni, Gyrus ACMI), monopolar and bipolar electrosurgery (LigaSure Advance, Covidien; Fig. 7), and ultrasonic and bipolar technologies (Thunderbeat, Olympus America; Fig. 8) into a single instrument. Although it is desirable to incorporate multiple functionalities into 1 handpiece so that "instrument traffic" can be minimized, it is important not to compromise the functionality of individual technologies for the sake of efficiency. A single laparoscopic energy source that can produce all the tissue effects available with individual energy sources may become a reality for the future laparoscopic surgeon. Along with ultrasonic and electrosurgical modalities, the "ideal laparoscopic energy source" would also possess the capabilities of

Fig. 8

The Thunderbeat device incorporates both ultrasonic capability for tissue transection (nonarticulating jaw) and advanced bipolar technology for vessel sealing (articulating jaw).

fine tissue grasping and sharp tissue dissection. The dissecting abilities of various laparoscopic forceps have been reported previously [23], but the dissecting abilities of the newer-generation bipolar forceps and the ultrasonic shears have yet to be evaluated.

Conclusions

The development of laparoscopic vessel sealing devices has revolutionized modern laparoscopy. Despite these advances, the reliance on monopolar electrosurgery persists because of its wider range of tissue effects and dissection capabilities. At present, there is no clear evidence to support the use of either advanced bipolar or ultrasonic devices in preference to the other, although each technology has well-characterized advantages and disadvantages. It is likely that the surgeon will rely on 2 or more laparoscopic energy sources (or hybrid instruments incorporating multiple technologies) depending on the cost and availability of the devices (and their proprietary generator boxes), personal preference and experience, the surgical procedure to be performed, and the presence or absence of significant pathology in the surgical field.

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Special Article

Electrosurgical Generators and Monopolar and Bipolar Electrosurgery

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ABSTRACT Electrosurgery is the most commonly used and misunderstood technology by all surgical and medical disciplines. A lack of basic knowledge or ignorance of principles of electrosurgery and equipment among obstetricians and gynecologists is reported. As a result, thermal injuries during laparoscopic electrosurgery occur, which frequently lead to significant morbidity and mortality and medicolegal actions. Surveys indicate that up to 90% of general surgeons and gynecologists use monopolar radiofrequency (RF) during laparoscopy, 18% have experienced visceral burns, and 13% admitted 1 or more ongoing cases of litigations associated with such burns. This article describes the basics of electrosurgery beginning with the generation of electrons and their physical characteristics and governing laws before their arrival in the operating room where they are fed to an electrosurgical unit (ESU) to boost their frequency with step-up transformers from 60 Hz to >500 000 Hz. This RF creates heat, resulting in dissection, desiccation, coagulation, and fulguration of tissues without neuromuscular stimulation, pain, or burn to the patient. The ESU delivers power (wattage = volts × amps) in monopolar or bipolar (1 vs 2 high-density electrodes) configuration. Because of RF, monopolar electrosurgery compared with other energy sources is associated with unique characteristics, inherent risks, and complications caused by the requirement of a return/dispersive electrode, inadvertent direct and/or capacitive coupling, or insulation failure of instruments. These dangers become particularly important with the popular and frequent use of monopolar electrodes (hook, needle, and scissors) during cholecystectomy; robot-assisted surgeries; and the re-emergence of single-port laparoscopy, which requires close proximity and crossing of multiple intraabdominal instruments outside the surgeon's field of view. Presently, we identify all these potential risks and complications associated with the use of electrosurgery and provide suggestions and solutions to mitigate/minimize these risks based on good clinical practice and sound biophysical principles. Journal of Minimally Invasive Gynecology (2013) 20, 279–287 © 2013 AAGL. All rights reserved.

Keywords: Bipolar electrosurgery; Electrosurgical generator; Electrosurgical unit; Monopolar electrosurgery; Return/Dispersive electrode

The application of electrical energy provided by the newly designed Bovie generator as an aid to the removal of intracranial tumors was popularized by Harvey Cushing at Johns Hopkins at the beginning of the last century [1]. Since then, it has been well entrenched as an integral part among all health care providers to treat disease by heating, cutting, coagulating, or ablating tissue. Although it is the most commonly used energy in clinics and operating rooms, it is the least understood by the majority of users because of a lack of basic knowledge or ignorance of principles of electrosurgery and equipment [2,3].

The intent of this article was to allow the reader to travel together with the generated electrons from the nearest power plant and follow them all the way into the operating room, where their mode of delivery is reshaped by electrosurgical units (ESUs); then, they are transferred by a cable to patients

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where they achieve their intended effect, and, finally, they return back to the ESU via another cable. Along the journey, the characteristics, properties, and governing physical laws of these electrons are discussed as well as some of their inherent yet mostly predictable and preventable risks and complications. Finally, we provide suggestions and simple solutions to mitigate/minimize the aforementioned potential risks based on cumulative knowledge, experience, research, and basic biophysical scientific principles. The overall intent is to make the electrons more user friendly and electrosurgery an uneventful, safer, and satisfactory experience for both patients and health care providers.

Generation of Electrical Energy

The source of electrical energy in the operating room originates from surrounding power generation facilities and is delivered to the operating room through many kilometers of wire. It is then modulated by the ESU or generator in order to imbue current with appropriate and specific characteristics to produce the desired effects on tissues without the stimulation of muscles or nerves.

With the exception of solar energy, which takes advantage of the photoelectric effect that was described by Heinrich Hertz in 1887, electricity is generated through the conversion of kinetic energy in the form of a rotating turbine to electrical potential energy. Be it geothermal, tidal, wind, nuclear, coal, or hydroelectric, the prime directive is the mechanical rotation of a magnet, referred to as an alternator, surrounded by multiple coils of wire. The wires are made of atomic particles consisting of a nucleus and a specific number of electrons orbiting the nucleus in several specific orbits. When electrons are pushed or forced to jump from their corresponding atom to their nearest neighbor in 1 direction, a parade or flow of electrons is initiated, which is referred to as electrical current.

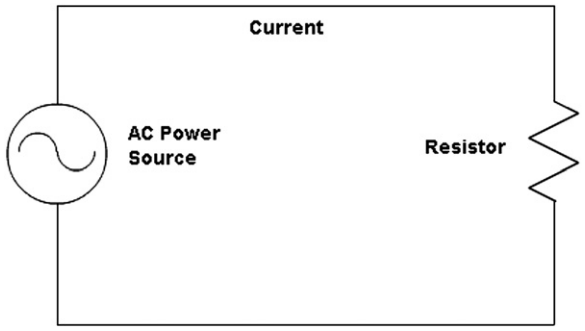
In 1831, Michael Faraday experimented with hanging wires over stationary magnets and noted that the wires were moving in circles over the magnets. This "electromagnetic engine," which was later formulated as electromagnetic induction to move electric trains, trams, cars, and so on, stems from Faraday's findings that any conductor in motion relative to a magnetic field will generate within it movement of electrons or electric current. As the kinetic energy generated by steam, wind, or water imparts movement of a large magnet within a shell of tightly wound wire with high conductivity (e.g., copper, silver, and so on), the rotation of the magnet causes the movement of electrons within the wire and produces the current used in our daily lives. This is then carried to our homes, commercial centers, industry, and hospitals through several kilometers of wire.

Voltage, Current, and Resistance

The concept of voltage, current, and resistance and their relationship are described in the first article in this special series.

Fig. 1

A simplified representation of an ESU circuit.



Frequency and Direct and Alternating Currents

Unlike the flow of water, which is driven by gravity only in 1 direction [4], current can be direct (DC) or alternating (AC). In the former, the anode and cathode are fixed, and there is unidirectional travel of electrons (e.g., car battery). In the latter, the anode and cathode are continually interchanged by a mechanically rotating magnet arbitrarily 60 times per second, hence the frequency of 60 Hz. Frequency then refers to the number of cycles or exchanges of polarity between the anode and cathode in a fixed period of time and is measured in hertz (Hz). Essentially, DC can be thought of as AC with a frequency of 0.

Electrosurgical Generators

The generator-active electrode–patient–return electrode relationship can be shown by a simple circuit involving a power source (i.e., the ESU), a body of resistance (the patient), and to and from connecting wires between the 2 (Fig. 1). The ESU modulates the input current from the outlet into that suitable for use on living tissue.

For safe application to the human body, a key characteristic that must be altered is the frequency of the AC. This is based on an important observation on the effects of current on animal muscle noted in 1786 by Luigi Galvani when he showed muscle spasms in frog legs secondary to electrical potentials evoked through galvanization in the metal hooks in his suspension apparatus [5]. If this phenomenon occurs while attempting to electrocoagulate a blood vessel perforating a muscle, it could prove to be very challenging and potentially traumatic to the patient. Furthermore, the standard frequency of 60 Hz also stimulates muscles and nerves, causing unwelcome muscle spasms, contractions, and movement of body parts during surgery. However, the most adverse effect of the 60-Hz frequency is interference with conductivity of heart muscle, resulting in cardiac arrest and death by electrocution, a method used in the past to execute criminals in the so-called electric chair.

Radiofrequency and Radiofrequency Currents

The adverse effects of muscle and nerve stimulation were overcome by the use of high-frequency AC. Based on Morton's observations in 1881 that oscillating current at a frequency of 100 000 Hz could pass through the human body without inducing pain, spasm, or burn, Parisian Jacques d'Arsonval showed in 1891 that AC with a frequency of greater than 10 000 Hz also could elevate tissue temperature without causing burn, muscle contraction, or pain [6]. Subsequently, it was also noted that temperature elevation was proportional to the square of the current density.

Modern-day ESUs use frequency ranges of 200 000 Hz to 5 000 000 Hz because this allows for desired thermal effects without muscle fasciculation or nerve stimulation [7]. Because this frequency is in the range of AM radio waves, the energy used in electrosurgery is also referred to as radiofrequency (RF) or RF currents.

Occasionally, muscle spasm or nerve stimulation is noticed with the application of an active electrode, indicating that the frequency of the current is altered through interaction with surrounding tissues, moisture, gas, and so on. This is referred to as harmonic demodulation of high frequencies to lower frequencies (<100 000 Hz) and possibly the generation of DCs. Currents with frequency <100 000 Hz that stimulate muscle and nerves are referred to as galvanic. Although occasional inconvenience may be unavoidable, the use of this RF range has greatly improved the efficacy of electrosurgery while minimizing traumatic morbidity.

Modifying the frequency of AC is complex; however, generating AC with a desired frequency from a DC source is far simpler. Thus, the ESU converts the input of 60 Hz AC into DC and then back to AC with a new higher frequency. This is made possible by a subunit within the generator known as an oscillator. High-frequency AC can now be channeled through the active electrode to heat tissues with little or no neuromuscular stimulation. Tissue effects are a result of the change in temperature at and around the electrode.

Power, Energy, and Power Density

All generators are programmed to deliver power in watts, frequently called "wattage," and it is defined as the rate at which energy is used and commercially billed to the users. One watt is the product of 1 volt and 1 ampere ($W = V \times I$). However, the effect of the active electrode on tissue is also dependent on the time the electrode is applied to the tissue. Therefore, the product of wattage and time (in seconds) required to affect tissue is referred to as joule energy ($J = W \times t$). When time and electrode size are kept equal, the effect on tissue is primarily dependent on the ratio of voltage and current (V/I). Power density is the relationship between the size of the active electrode in contact with tissue and the effect on tissue at a given power setting ($PD = V \times I$/contact surface area).

Capacitors, Capacitance, and Capacitive Coupling

A capacitor is defined as 2 conductors separated by an insulator. Capacitance is the number of electrons (amount of energy) stored in a capacitor, and capacitive coupling is a condition that occurs when electrical current is transferred from 1 conductor, through intact insulation, into adjacent conductive materials.

Effects of Electrosurgery on Tissues

Electrosurgery uses the conversion of electrical potential energy into thermal energy to cause tissue cutting, coagulation, desiccation, or fulguration. Coagulation (*L. coagulatio*, to curdle) is the clotting of blood or agglutination of tissue (the formation of coagulum) with no cutting effect by desiccation or fulguration. Desiccation (*L. desiccatus*, to dry up completely) is the electrosurgical effect of tissue dehydration and protein denaturation caused by direct contact between the active electrode and tissue. Fulguration (*L. fulguratio*, to flash, to lighten) is the process of arcing, sparking, or jumping of electrons from the active electrode across air or liquid to the target tissue causing superficial coagulation and carbonization.

Spark Gap Electrosurgical Generators

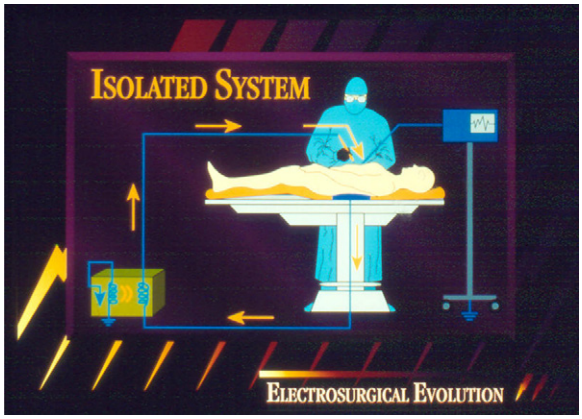
Lightning and Fulguration

In addition to varying the delivery of current by the ESU, further tissue effects can be achieved by the manner in which the electrode is manipulated. Fulguration was the first technique of electrocoagulation identified and applied by Simon Pozzi and refined by Doyen at the beginning of the 20th century [5]. When the electrode is elevated and activated over tissues targeted for coagulation, the electrical potential causes ionization of air/gas in the gap between electrode and tissue, and a spark ensues similar to spark plugs in our cars. Fulguration then can be represented initially by a capacitor wherein the electrode and underlying tissues are conductors, and the 1- to 2-mm air/gas gap acts as an insulator. Subsequently, the air/gas (oxygen/CO_2) is ionized by the high voltage of the interrupted ("coag") mode, resulting in insulation/dielectric failure of the circuit. At this stage, 30 000 to 40 000 sparks are delivered per second, and the target tissue is superficially desiccated and coagulated by carbonization.

This scenario is not dissimilar to the relationship between a storm cloud, the surface of the Earth, and the interposed atmosphere. Upon reaching maximum capacitance (charge), a spark is discharged across the gap to tissues beneath much like lightning. The voltage associated with lightning is in the range of 100 000 000 V, whereas the voltage of the ESU discharge spikes can be up to 10 000 V peak to peak (p-p) [8,9]. These discharges, arcs, or sparks have been identified to reach temperatures of 700° to 1000°C

Fig. 2

An isolated ESU in which the therapeutic and power currents are independent of each other and do not cross pathways.



[10], and these generators are referred to as spark gap generators.

The Hyfrecator Electrosurgical Generator

The hyfrecator ESU is frequently used in conscious patients in an office setting. It uses high voltage, but very low current to produce low power, very high RF (1–5 MHz) discharges. The patient becomes a capacitor to Earth ground and a sink of electrons similar to the cloud-lightning-Earth capacity scenario described previously. A ground or return/dispersive electrode is not required. However, the instruction for use suggests mentioning to the patient if he/she feels any pain or burning other than the surgical site to let the surgeon know. The patients unbeknown to the surgeon may have a current concentration to the ground point on the table or chair on which they are positioned. Tissue temperatures exceed 200°C, and the target tissue is destroyed by the process of fulguration and carbonization.

The "Bovie" Electrosurgical Generator

A further application of electrosurgery was described in 1914 by William Clark. He coined tissue desiccation as a means of tissue destruction not by carbonization, as described in the former technique of fulguration, but rather tissue dehydration [5,6].

William T. Bovie, a botanist and plant physiologist at Harvard, was the first to develop an ESU providing both continuous and interrupted waveforms to cut or desiccate tissue (Fig. 2). He also added a pistol grip activation handle with interchangeable electrodes [5]. This was a feature of the original Bovie unit in 1926, facilitating cellular dehydration through a relatively slow elevation of temperature to greater than 90°C. At these temperatures, intracellular water is vaporized and cells explode causing dissection of tissue (cut) or cells are dehydrated and protein is denatured (50°–80°C) resulting in a coagulum and hemostasis [11]. The use of Joule heating to provide coagulation is the most commonly practiced technique in electrosurgery today. Reportedly, Bovie never financially profited from his invention although his generators were popularized and adopted by many surgeons including the father of modern neurosurgery Harvey Cushing.

The Ground Pad

To complete the circuit from the ESU to the patient and back to the ESU, the Bovie generators required a return or pad plate electrode, which was referenced to the ground. Because this was truly a ground electrode, all return electrodes used today are frequently, but erroneously, referred to as ground pads, ground electrodes, or simply grounds. Furthermore, all modern generators are frequently referred to as "Bovies," and the process of electrocoagulation of vessels has been verbalized to "bovieing."

Modern Electrosurgical Generators

Isolated Electrosurgical Units

In 1968, the use of isolated systems was introduced in which the therapeutic current is isolated from the power current by a transformer (Fig. 2). Under this configuration, the therapeutic current must return to the ESU itself to complete the circuit. The therapeutic current does not cross pathways with the power current, and it does not recognize the ground because it is not referenced to it. These isolated systems virtually eliminate current division/diversion and alternate site ground point burns. However, under high-voltage conditions, stray currents may be generated by capacitive coupling, which seek the ground, just like lightning, and cause burns to intermediate tissues as will be discussed later. Thus, by removing the ground as a reference for the current, the isolated ESUs virtually eliminated all the hazards inherent in the grounded systems, such as current diversion and alternate site burns.

Adaptive Electrosurgical Generators

To minimize capacitive coupling, advanced feedback systems, also referred to as instant response technology that automatically adjusts the computer-controlled output, are now available on many ESUs [12]. These devices measure tissue impedance/resistance at the active electrode–target tissue contact site and provide instant response to changes producing a consistent tissue effect. In addition, they control maximum output voltage, thereby reducing capacitive coupling and video interference and minimizing sparking. However, the ability to reduce capacitive coupling is dependent on some variables outside the control of the ESU. One such important variable may be insulation deficiency of the active electrode, which is not recognized by the ESU, resulting in

stray currents and serious burn to patients as discussed elsewhere in this series.

Return or Dispersive Electrodes

Split Return or Dispersive Electrodes

As stated earlier, current starts flowing from the ESU to the patient through the so-called active electrode disperses through the patient tissue around the neighborhood where surgery is performed, and it must be collected and return back to the ESU through a second attachment to the patient to complete the circuit.

Capacitively Coupled Return Electrodes

Capacitive-coupled return electrodes are large reusable gel pads on which the patient lies. As there is no direct contact with the inner conductive material these electrodes transfer current similarly to the cloud-lightning-Earth concept described earlier. They are designed to be large enough to maximize contact with the body and thus minimize current density.

Dispersive Electrodes and Implanted Electronic Devices

Implanted electronic devices (IEDs) are battery-powered units implanted within a patient's body to treat a physiologic deficiency or replace a sensory function. Common examples include cardiac pacemakers, ventricular assist devices, and neurologic stimulators such as vagal nerve and spinal cord stimulators. Because of RF used in electrosurgery, electromagnetic interference may interrupt, obstruct, or degrade the effective performance of an IED. Therefore, in the presence of an IED, an effort should be made to consult the IED manufacturer to determine if the device will be affected by the use of electrosurgery and, if so, what the recommendations are. They may also suggest this IED is checked postoperatively to be sure that it is functioning as initially intended.

Alternatively, surgeons should avoid the use of monopolar electrosurgery and use alternatives such as bipolar electrosurgery, ultrasonic energy, or laser energy. If monopolar energy is necessary, the dispersive electrode should be applied as far as possible from the IED and avoid the use of capacitively coupled return electrodes [13].

Electrosurgery and Body Piercing

Body piercings are commonplace in our society and have been a part of human culture for thousands of years. The general recommendation is that piercings be removed before surgery regardless of the use of electrosurgery. This is to prevent the potential morbidity of skin damage or piercing loss when patients are transported or positioned intraoperatively, aspiration and tissue trauma during endotracheal intubation, and infection and hindrances to the operator when within the surgical field (i.e., the umbilicus or labia) [14–16].

It has also been a longstanding belief that if metal body piercings are left in place during electrosurgery this may result in alternate site burns. This complication may have been more prevalent with the use of ground-referenced ESUs (the predecessors to modern-day isolated generators). Unlike the latter, ground-referenced generators transmitted current through the active electrode to the Earth via the site of interest and the patient. This was much more hazardous with respect to alternate site burns because any conductor in contact with ground (i.e., the operating table touching the operating room floor drain) and in proximity to the patient could cause inadvertent concentration of current in an unexpected area of the body and result in a burn [17]. With modern-day ESUs, this phenomenon has been abolished.

Because metal is a far superior conductor than tissue, it is possible that current density can be increased around metal body piercings if located between the active and dispersive electrodes. Alternate site burns can occur as well if insulation failure, in proximity to metal body piercings, results in arcing. Furthermore, if a metal piercing were sufficiently close to but not communicating with an active monopolar electrode, then capacitive coupling may result.

No case reports involving body piercings–related alternate site burns have been published to date. Because metal body piercings can only concentrate energy if en route from an active to a dispersive electrode, an elegant means of eliminating this risk when piercings cannot be removed is to reduce the distance between these electrodes or use bipolar electrosurgery.

Tissue Effects from Electrosurgery

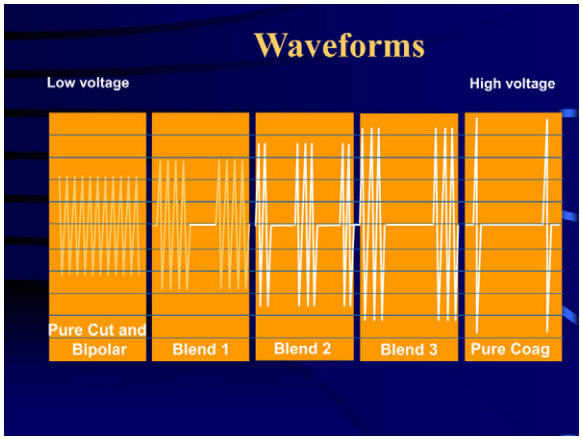
As stated earlier, all modern ESUs are programmed to deliver power in watts in the so-called monopolar or bipolar configuration. To deliver the requested wattage, the ESU must adjust the voltage and current in a given time. By adjusting the voltage and active time of the electrode that energy is applied to target tissues, effects vary. In the monopolar configuration, the adjustment of these electrosurgical waveforms provides various settings on the ESU (Fig. 3).

In the "pure cut" mode, current is continuously delivered 100% of the time. Because current is plentiful, the requirement for voltage is low in accordance with $W = V \times I$. Therefore, this mode is better referred to as the high-current/low-voltage waveform rather than the cut mode.

This continuous, low-voltage, high-current output rapidly elevates the temperature of tissues and can exceed 100°C [11]. This causes explosive vaporization of intracellular fluid and then ionization of the gas/moisture released. The superheated ionized gas forms plasma surrounding the electrode and further conducts current to nearby tissues to propagate this effect as the electrode is carried through target tissues. This produces a clean incision with minimal hemostasis and a collateral thermal damage zone of 100 to 400 microns

Fig. 3

Conventional waveforms of a typical ESU. In the continuous (pure cut) and interrupted (coag) modes, at 50 W of power, the corresponding peak to peak (Vp-p) voltage is 1000 Vp-p and 5000 Vp-p, respectively.



[18]. This mode produces the least charring tissue destruction and collateral thermal injury [9].

In the interrupted mode, current is delivered only 6% of the activated time. Therefore, the generator must compensate by increasing the voltage to deliver the preset wattage in accordance with $W = V \times I$. Coag current then is better described as an interrupted or low-current/high-voltage waveform because it uses current at a significantly higher voltage (4000–10 000 V p-p) [19]. This is necessary to generate the heat required to render tissues hemostatic. However, because current is delivered in a pulsatile (interrupted) manner, in this mode a greater voltage is necessary to achieve tissue destruction [11]. Because of the lower current density, the rate of temperature change is significantly less. This results in the denaturation of proteins and the formation of a coagulum as well as greater thermal spread. In the bipolar mode, current is also continuously delivered 100% of the activated time. Therefore, the bipolar configuration waveform is also of low voltage/high current to accomplish the desired clinical effect (<1000 V p-p).

As current flows through the tissues, air, or vapor that surrounds the active electrode, the resistance of these media causes the generation of heat through the process of Joule heating (i.e., the rate of temperature change is directly proportional to the resistivity of the substance and the square of the concentration of electrical current or current density). This relationship of heat factor was described by Pearce [20] as proportional to the square of the current delivered times the duration of the current applied. This relationship is approximated by the following: heat factor $= I^2 \times t$.

As stated earlier, in addition to these 2 extreme modalities, the pulsatile release of current can be varied between 6% and 100%, interrupted and continuous, respectively, to produce the "mix" or "blend" settings found on many modern-day ESUs (Fig. 3). The blended currents in between are arbitrarily chosen, and one could construct an unlimited number of such combinations. By convention, in blend 1, 2, and 3 modes, current is delivered 80%, 60%, and 50% of the time, respectively. This middle ground setting provides good dissection with varying degrees of coagulation. The active time of current delivery or duty cycle is manufacturer specific. The ratio of "on" to "off" duration is referred to as the duty cycle.

ESU Settings

The requirements of power settings of the ESU may vary in accordance with the needs and experience of the surgeon as well as tissue characteristics. For example, a monopolar hook may provide an adequate effect at 80 to 90 W of continuous current for peritoneal incisions, dissecting gallbladder, or cutting bowel wall. On the other hand, 50 W of interrupted current may be all that is required to control small bleeders or cutting through fat. For resectoscopic surgery, a power setting of 100 W (±20 W) in both interrupted and continuous waveforms provides an adequate effect in ablating or resecting tissue.

Monopolar Electrosurgery

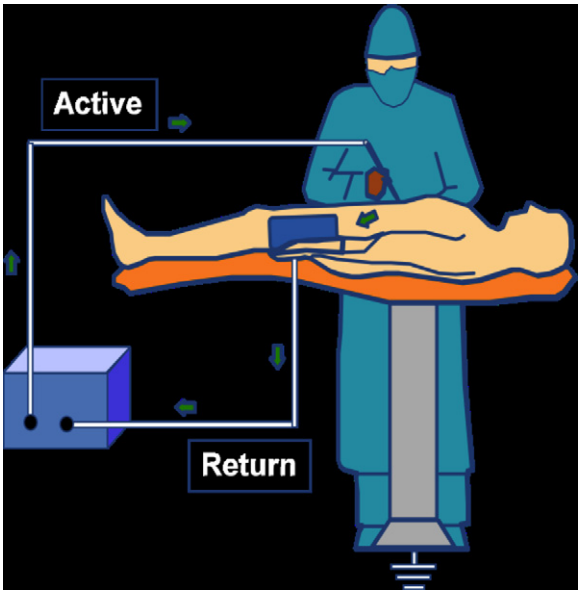
There is no such a thing as monopolar electrosurgery. However, all modern ESUs are designed to provide power in the so-called "monopolar" and bipolar configuration. The nomenclature regarding monopolar and bipolar configuration of the electrosurgical circuit, although misleading, stems from our forefathers' logical notion that monopolar had "one" site where the therapeutic effect was desirable and bipolar had "two." Monopolar implies that there is only a single pole or electrode in the ESU-electrode-patient circuit when in fact there must always be 2: 1 high-power density pole (i.e., the active electrode) and a second low-power density pole (i.e., the dispersive ["return"] electrode at a remote site). A more appropriate rationale to support the designation "monopolar" is that the active electrode in monopolar electrosurgery contains only 1 of the poles in the circuit. In this construct, the patient is the other electrode. An example of this is the hyfrecator described earlier.

In the bipolar configuration, both electrodes are high-density power and are situated across from each other. In the monopolar configuration, electrons travel from the generator through a wire to the tip of the active electrode where the current density it greatest and thus where maximal Joule heating can occur. From the point of contact between the active electrode and the patient's tissue, electrons disperse throughout the patient's body. The pattern of dispersion is not uniform and is a function of electrostatic repulsion between electrons and varying tissue resistivities [18]. Finally, the electrons must return to the ESU through the dispersive electrode to close the circuit for the desired clinical effect (Fig. 4).

Because body compositions vary across individuals, a generalized model to predict the flow of current would

Fig. 4

A monopolar configuration of the circuit.



be inaccurate. The displaced charge must travel to a location relatively deplete of electrons to achieve a net neutral charge and a state of lowest entropy. Electrons will always take the path of least resistance to achieve this goal. Because temperature change is a function of the square of current density and this is significantly reduced as electrons disperse, the change in tissue temperatures elsewhere are miniscule. Furthermore, because of the high-frequency nature of the AC used, there is no excitation of nervous or muscle tissues en route. Ideally, electrons will return to the ESU by means of the return/dispersive electrode pad. However, if there is a source of ground (a conductor with sufficient contact with the Earth) in contact with the patient, electrons may preferentially travel to this site, and if current density is sufficiently elevated at any point along this alternate path, a burn may occur. This issue has been addressed in modern ESUs through circuitry that does not reference ground and actively monitor the condition of the return electrode circuit as described earlier.

Advantages of Monopolar Electrosurgery

Advantages to this configuration include the ability to use continuous and "mix/blend" current to dissect with ease while providing some hemostasis, fulguration in the interrupted mode can produce adequate hemostasis by carbonizing tissues with high capillary or small vessel density, and coaptive coagulation of grasped tissue can be achieved where desiccation occurs and proteins denature resulting in a "collagen weld" [21,22].

Disadvantages of Monopolar Electrosurgery

Monopolar electrosurgery requires considerable knowledge, understanding, and vigilance of the operator to avoid the hazards of unintentional thermal injury by means of accidental visceral contact with active or heated electrodes; direct or capacitive coupling; insulation defects in instruments or connecting wires; damaged, faulty, or improper placement of the return electrode; and combustion of volatile substances [23,24].

Clinical Implications of Monopolar Electrosurgery

Laparoscopic Tubal Electrocoagulation

A review of monopolar sterilization of 3500 patients yielded 10 cases of electrical bowel injury. The incidence of approximately 3 per 1000 was deemed to result from direct coupling. In these cases, it is believed that current traveled to the nearby bowel by way of either grasping forceps (direct contact with bowel visualized by the surgeon in 5 cases) or via the fallopian tube [25]. It is important to recognize that tissues targeted for dissection or coagulation can act as secondary conductors and convey energy to unintended termini. However, because the majority of these cases were performed through a single port using an operative laparoscope, the mechanism of capacitive coupling as a cause of the bowel burns appears more plausible.

Laparoscopic Cholecystectomy

In March 2010, a newsletter from the Canadian Medical Protective Association reported on 131 litigated and concluded cholecystectomy cases from 2003 to 2007. Among these, there were 22 laparoscopic cholecystectomies associated with intestinal complications, 20 of which were caused by direct trauma (10 duodenal [3 died], 9 jejunoileal [3 died], and 1 transverse colon). The exact mechanism of injury was often difficult to determine because there was frequently a significant inflammatory response by the time the site of the intestinal damage was visually examined. Surgical experts were critical of the technique, the use of cautery, and the delay in diagnosis. Of the intestinal injuries, 52% were settled in favor of the patients. This percentage is higher than the overall Canadian Medical Protective Association experience with legal action [26]. From the location of bowel injuries (duodenum, jejunoileal, transverse colon) and the delay in diagnosis, it is more than likely that some of the bowel injuries were caused by capacitive coupling and/or insulation failure associated with monopolar electrosurgery and the hook electrode used frequently during laparoscopic cholecystectomy.

Single-Port Endoscopy

The inherent dangers of monopolar electrosurgery may become particularly important with the reemergence of single-port laparoscopy, which requires close proximity and

crossing of multiple intraabdominal instruments. Indeed, simulation in a dry laboratory using livers from pigs and sheep and the bowels and livers of anesthetized animals (1 dog and 1 sheep) during single-port laparoscopy and the use of monopolar RF indicated that the proximity and crossing of multiple instruments generated sufficient capacitive and/or direct coupled currents, which caused visceral burns [10].

Robotic Assisted Laparoscopic Electrosurgery:

The risk of bowel burns may be particularly amplified with the use of some of the new popular technologies such as robotics (da Vinci; Intuitive Surgical, Sunnyvale, CA). As a rule, the da Vinci robot uses both monopolar and bipolar energy to affect tissue. Indeed, we have witnessed arcing of energy with burns to bladder and kidney in our own operating room during robotic urologic procedures. Furthermore, we analyzed all incidents from the Manufacturer and User Facility Device Experience database, which is administered by the US Food and Drug Administration, in the context of robotic surgery between January 2001 and June 2011 to identify those related to the use of electrosurgery.

Of the 605 cases identified, 24 (3.9%) were related to potential or actual electrosurgical injury, 9 of which (37.5%) required additional surgical intervention. There were 6 bowel injuries, of which only 1 was recognized and managed intraoperatively. The remainder required laparotomy between 5 and 8 days after the initial robotic procedure. Additionally, there were 3 skin burns [27].

Furthermore, the da Vinci instruments are reusable with a limited number of uses. One study reported on 81 robotic and 299 laparoscopic instruments visually inspected and electrically tested. Insulation failures were detected in 72.8% and 35.1% of robotic and laparoscopic instruments, respectively. Most of the robotic insulation failures were located in the intraabdominal portion of the instrument, whereas the laparoscopic insulation failures were extraperitoneal [28].

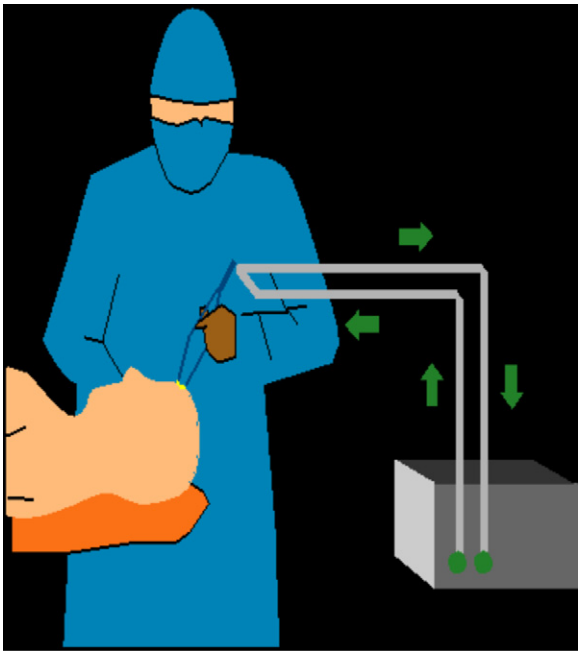
Our group previously conducted an in vitro study that provided both a qualitative and quantitative assessment of stray current in laparoscopic instruments used for robotic surgery [29]. By using an electrosurgical generator at pure cut and coagulation waveforms, a total of 37 robotic instruments at the end of their programmed life were assessed. The magnitude of stray currents was measured by an electrosurgical analyzer. This showed energy leakage from all tested instruments. The magnitude was noted to be higher during coagulation (i.e., high-voltage) waveforms.

Bipolar Electrosurgery

Bipolar electrosurgery was devised and applied in gynecologic surgery in 1973 by Canadian gynecologist Dr. Jacques-Emile Rioux. In fact, he constructed the first laparoscopic bipolar forceps using a coat hanger and broom handle. A nylon version of the prototype was used to perform the first laparoscopic bipolar sterilization on March 12, 1973, and histologically showed significantly less collateral thermal damage when compared with the monopolar technique [30]. Many variations of Rioux's design have been used for bipolar electrosurgery, of which the most popular was coengineered by Dr. Richard Kleppinger [31].

Fig. 5

A configuration of the electrosurgical circuit during bipolar electrosurgery.



Forceps and clamp configurations are the 2 principle bipolar devices. In both cases, the circuit is as such that electrons travel from the ESU to the distal aspect of 1 tine (or active electrode), through grasped tissues, to the sister tine (or return electrode), and back to the generator. In bipolar electrosurgery, electrons do not dissipate throughout the patient's body because the active and return electrode are in close proximity to each other and only those tissues that are interposed are included in the circuit. Thus, only said tissues and those immediately surrounding are affected by the heat generated (Fig. 5).

As shown in Figure 3 and stated earlier, in the bipolar configuration, current is delivered 100% of the time just as in the continuous mode of the monopolar configuration. Therefore, the bipolar setting is also a high-current/low-voltage waveform. The principle of Joule heating applies equally to this modality; the simple difference is the location of the return electrode. Because these devices have similarly sized electrodes, the current density is approximately equivalent at both the active and return electrodes. This produces similar Joule heating and temperature changes at each tine of the instrument and, thus, desiccates target tissues from both sides, simultaneously allowing for lower power settings on

the generator. Desiccation is superior to their monopolar counterparts and yields less collateral thermal damage [21].

Advantages of Bipolar Electrosurgery

In addition to superior desiccation and the lower voltage requirement, the close configuration of the active and return electrode in bipolar instruments virtually eliminates the threats of alternate site burns as well as direct and capacitive coupling [21]. Because the corona discharge travels in opposite directions along the 2 cables, it cancels itself out, and capacitive coupling does not occur. Furthermore, a return/dispersive electrode is not required, and the risk of dispersive electrode burns is also eliminated. In addition, during resectoscopic surgery, the use of bipolar technology requires a conductive irrigant solution such as saline, thus eliminating the potential risk of hyponatremia. However, a common pitfall among users who rely on the safety of bipolar devices is prolonged activation of the electrode. This may generate significant heat, which is absorbed by the metal electrode head and can cause injury to other tissues upon contact.

Disadvantages of Bipolar Electrosurgery

Bipolar electrodes cannot cut tissue. Although a continuous ("cut") waveform is applied to bipolar instruments, cutting is inefficient because the amount of tissue involved is minimal, and vaporization is inefficient and cumbersome [21]. In lieu of this shortcoming, advanced bipolar devices incorporate a mechanical cutting blade at the electrode site allowing for virtually bloodless dissection after excellent tissue desiccation.

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SOGC CLINICAL PRACTICE GUIDELINE

No. 193, May 2007

Laparoscopic Entry: A Review of Techniques, Technologies, and Complications

This guideline has been reviewed and approved by the Executive and Council of the Society of Obstetricians and Gynaecologists of Canada.

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Abstract

Objective: To provide clinical direction, based on the best evidence available, on laparoscopic entry techniques and technologies and their associated complications.

Options: The laparoscopic entry techniques and technologies reviewed in formulating this guideline include the classic pneumoperitoneum (Veress/trocar), the open (Hasson), the direct trocar insertion, the use of disposable shielded trocars, radially expanding trocars, and visual entry systems.

Outcomes: Implementation of this guideline should optimize the decision-making process in choosing a particular technique to enter the abdomen during laparoscopy.

Evidence: English-language articles from Medline, PubMed, and the Cochrane Database published before the end of September 2005 were searched, using the key words laparoscopic entry, laparoscopy access, pneumoperitoneum, Veress needle, open (Hasson), direct trocar, visual entry, shielded trocars, radially expanded trocars, and laparoscopic complications.

Values: The quality of evidence was rated using the criteria described in the Report of the Canadian Task Force on the Periodic Health Examination.

Key Words: Laparoscopy, entry, pneumoperitoneun, Veress needle, Hasson technique, visual entry system

Recommendations and Summary Statement

1. Left upper quadrant (LUQ, Palmer's) laparoscopic entry should be considered in patients with suspected or known periumbilical adhesions or history or presence of umbilical hernia, or after three failed insufflation attempts at the umbilicus. (II-2 A) Other sites of insertion, such as transuterine Veress CO_2 insufflation, may be considered if the umbilical and LUQ insertions have failed or have been considered and are not an option. (I-A)
2. The various Veress needle safety tests or checks provide very little useful information on the placement of the Veress needle. It is therefore not necessary to perform various safety checks on inserting the Veress needle; however, waggling of the Veress needle from side to side must be avoided, as this can enlarge a 1.6 mm puncture injury to an injury of up to 1 cm in viscera or blood vessels. (II-1 A)
3. The Veress intraperitoneal (VIP-pressure $\leq$ 10 mm Hg) is a reliable indicator of correct intraperitoneal placement of the Veress needle; therefore, it is appropriate to attach the CO_2 source to the Veress needle on entry. (II-1 A)
4. Elevation of the anterior abdominal wall at the time of Veress or primary trocar insertion is not routinely recommended, as it does not avoid visceral or vessel injury. (II-2 B)
5. The angle of the Veress needle insertion should vary according to the BMI of the patient, from 45° in non-obese women to 90° in obese women. (II-2 B)
6. The volume of CO_2 inserted with the Veress needle should depend on the intra-abdominal pressure. Adequate pneumoperitoneum should be determined by a pressure of 20 to 30 mm Hg and not by predetermined CO_2 volume. (II-1 A)
7. In the Veress needle method of entry, the abdominal pressure may be increased immediately prior to insertion of the first trocar. The high intraperitoneal (HIP-pressure) laparoscopic entry technique does not adversely affect cardiopulmonary function in healthy women. (II-1 A)
8. The open entry technique may be utilized as an alternative to the Veress needle technique, although the majority of gynaecologists

prefer the Veress entry. There is no evidence that the open entry technique is superior to or inferior to the other entry techniques currently available. (II-2 C)

9. Direct insertion of the trocar without prior pneumoperitoneum may be considered as a safe alternative to Veress needle technique. (II-2)
10. Direct insertion of the trocar is associated with less insufflation-related complications such as gas embolism, and it is a faster technique than the Veress needle technique. (I)
11. Shielded trocars may be used in an effort to decrease entry injuries. There is no evidence that they result in fewer visceral and vascular injuries during laparoscopic access. (II-B)
12. Radially expanding trocars are not recommended as being superior to the traditional trocars. They do have blunt tips that may provide some protection from injuries, but the force required for entry is significantly greater than with disposable trocars. (I-A)
13. The visual entry cannula system may represent an advantage over traditional trocars, as it allows a clear optical entry, but this advantage has not been fully explored. The visual entry cannula trocars have the advantage of minimizing the size of the entry wound and reducing the force necessary for insertion. Visual entry trocars are non-superior to other trocars since they do not avoid visceral and vascular injury. (2 B)

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INTRODUCTION

Laparoscopy (Gr: *Laparo*-abdomen, *scopein*-to examine) is the art of examining the abdominal cavity and its contents. It requires insertion of a cannula through the abdominal wall, distention of the abdominal cavity with gas or air (pneumoperitoneum), and visualization and examination of the abdomen's contents with an illuminated telescope. With the advent of videocameras and other ancillary instruments, laparoscopy rapidly advanced from a being a diagnostic procedure to one used in fallopian tubal occlusion for sterilization and eventually in the performance of numerous surgical procedures in all surgical disciplines for a variety of indications.

A minimally invasive procedure has many advantages for patients, health care systems, and society at large. A meta-analysis of 27 randomized controlled trials (RCTs) compared laparoscopy and laparotomy for benign gynaecological procedures.[1] The authors concluded that the risk of minor complications after gynaecological surgery is 40% lower with laparoscopy than with laparotomy, although the risks of major complications are similar. The overall risk for any complication is 8.9% with laparoscopy, compared with 15.2% with laparotomy (relative risk [RR] 0.6; 95% confidence interval [CI] 0.5–0.7). There is no difference between laparoscopy and laparotomy in the risk of major complications (1.4% in each group, RR 1.0; 95% CI 0.6–1.7), but minor complications were significantly less frequent with laparoscopy (7.5% vs. 13.8%, RR 0.6; 95% CI 0.5–0.7).[1]

A Cochrane review of trials involving 324 patients concluded that laparoscopic surgery for benign ovarian tumours is associated with reduced risk of any adverse effect of surgery, reduced pain, and fewer days in hospital compared with laparotomy. There was no difference between the procedures with regard postoperative infections and tumour recurrence.[2]

Access into the abdomen is the one challenge of laparoscopy that is particular to the insertion of surgical instruments through small incisions. Access is therefore associated with injuries to the gastrointestinal tract and major blood vessels, and at least 50% of these major complications occur prior to commencement of the intended surgery.[3–8] This complication rate has remained the same during the last 25 years.[8] The majority of injuries are due to the insertion of the primary umbilical trocar.[9] Increased morbidity and mortality result when laparoscopists or patients do not recognize injuries early or do not address them quickly.[9]

To minimize entry-related injuries, several techniques, instruments, and approaches have been introduced during the last century. These include the Veress-pneumoperitoneum-trocar, "classic" or closed entry,[10] the open (Hasson) technique,[11] direct trocar insertion without prior pneumoperitoneum,[12] use of shielded disposable trocars,[13–15] optical Veress needle,[16,17] optical trocars,[18,19] radially expanding trocars,[20,21] and a trocarless reusable, visual access cannula.[22,23] Each of these methods of entry enjoys a certain degree of popularity according to the surgeon's training, experience, and bias, and according to regional and interdisciplinary variability.

This guideline examines the available evidence on each of the existing laparoscopic entry techniques and provides recommendations according to the Canadian Task Force on the Periodic Preventive Health Examination Care (Table 1).[24]

CLOSED ENTRY (CLASSIC) LAPAROSCOPY

Historical

The classic, or closed entry, laparoscopic technique requires cutting of the abdominal skin with a scalpel, insufflation of air or gas into the abdomen (establishment of pneumoperitoneum), and insertion of a sharp trocar/cannula system into the abdomen. Following removal of the sharp trocar, the abdominal cavity is examined by an illuminated telescope through the cannula.

The first laparoscopy in a human was performed by Jacobeus of Sweden in 1910.[25] In Canada, laparoscopy was introduced by Dr Victor Gomel, University of British Columbia, Dr Jacques Rioux, Laval University, Quebec, and Dr Albert Yuzpe, University of Western Ontario, in 1970.[26]

Key to evidence statements and grading of recommendations, using the ranking of the Canadian Task Force on Preventive Health Care

Quality of Evidence Assessment*	Classification of Recommendations†
I: Evidence obtained from at least one properly randomized controlled trial	A. There is good evidence to recommend the clinical preventive action
II-1: Evidence from well-designed controlled trials without randomization	B. There is fair evidence to recommend the clinical preventive action
II-2: Evidence from well-designed cohort (prospective or retrospective) or case-control studies, preferably from more than one centre or research group	C. The existing evidence is conflicting and does not allow to make a recommendation for or against use of the clinical preventive action; however, other factors may influence decision-making
II-3: Evidence obtained from comparisons between times or places with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of treatment with penicillin in the 1940s) could also be included in this category	D. There is fair evidence to recommend against the clinical preventive action
III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees	E. There is good evidence to recommend against the clinical preventive action
	I. There is insufficient evidence (in quantity or quality) to make a recommendation; however, other factors may influence decision-making

*The quality of evidence reported in these guidelines has been adapted from the Evaluation of Evidence criteria described in the Canadian Task Force on Preventive Health Care.[24]
†Recommendations included in these guidelines have been adapted from the Classification of Recommendations criteria described in the Canadian Task Force on Preventive Health Care.[24]

ESTABLISHMENT OF PNEUMOPERITONEUM: THE VERESS NEEDLE

In 1947, Raoul Palmer of France popularized the use of the Veress needle using CO_2 to induce pneumoperitoneum for laparoscopy, and he subsequently published on its safety in the first 250 patients.[10] Palmer emphasized that the creation of pneumoperitoneum remains a vital first step, and it is one still associated with recognized complications.

Several surveys indicate that most gynaecologists practising laparoscopy worldwide use the Veress needle-pneumoperitoneum-primary trocar technique to access the abdomen.[8,27–33] In a Canadian survey of 407 (51% responding) obstetricians and gynaecologists, 96.3% reported always inducing pneumoperitoneum prior to insertion of the primary trocar, 1.2% sometimes, and 2% never (0.5% made no response).[27] Furthermore, 26.4% of respondents had experienced vessel or organ injury attributable to the Veress needle, and 25.6% and 15.0% experienced vessel or organ injury from the primary and secondary trocars, respectively.[27]

Veress Needle Insertion Sites

Under usual circumstances, the Veress needle is inserted in the umbilical area, in the midsagittal plane, with or without stabilizing or lifting the anterior abdominal wall. In patients known or suspected to have periumbilical adhesions, or after failure to establish pneumoperitoneum after three attempts, alternative sites for Veress needle insertion may be sought.[34–37]

Left upper quadrant (LUQ, Palmer's point) CO_2 insufflation

In patients with previous laparotomy, Palmer advocated insertion of the Veress needle 3 cm below the left subcostal border in the midclavicular line.[10] This technique should be considered in the obese as well as the very thin patient. In very thin patients, especially those with a prominent sacral promontory and android pelvis, the great vessels lie 1 cm to 2 cm underneath the umbilicus,[38,39] and in obese women, the umbilicus is shifted caudally to the aortic bifurcation.[40]

LUQ insufflation requires emptying of the stomach by nasogastric suction and introduction of the Veress needle perpendicularly to the skin. Patients with previous splenic or gastric surgery, significant hepatosplenomegaly, portal hypertension, or gastropancreatic masses should be excluded.[41] There is significantly more subcutaneous fat at the umbilical area than at the LUQ insertion site. Tulikangas et al. found a positive correlation between body mass index (BMI) and the distance between various intra-abdominal organs and the insertion site.[41] After establishment of the pneumoperitoneum, trocars of various diameters and shapes may be introduced at the same site as the Veress, followed by additional trocar/cannula systems inserted under direct vision, as required.[42–50]

Transuterine Veress CO_2 insufflation

Using a long Veress needle, pneumoperitoneum has been established through the fundus of the uterus transvaginally.[51–56] This technique has been especially helpful in obese women.[53,55,56] In one study of 138 women weighing 250 lbs to 400 lbs, failure to establish pneumoperitoneum occurred in 13.8% (5/36) through the umbilicus, in 3.6% (3/83) through the uterus, in 8.3% (1/12) subcostally, and in 28.6% (2/7) through the open (Hasson) technique.[55] A prospective randomized study compared the conventional infraumbilical route with a transuterine route in 100 overweight and obese women (BMI ≥ 25 kg/m^2) in establishing pneumoperitoneum.[56] In the infraumbilical group, pneumoperitoneum was achieved at a ratio (punctures/pneumoperitoneum) of 56/49 (1.14) with one failure, but in the transuterine group the ratio was 53/51 (1.04).[56]

Trans cul-de-sac CO_2 insufflation

The posterior vaginal fornix has been reported as another site through which to establish pneumoperitoneum,[57] especially in obese women.[58]

Ninth or tenth intercostal space CO_2 insufflation

Since the parietal peritoneum is adhered to the undersurface of the ribs at the costal margin, some gynaecologists insert the Veress needle through the ninth or tenth intercostal space.[48,50,59] The inclusion and exclusion criteria are the same as per LUQ insertion. The Veress needle is inserted directly through the intercostal space at the anterior axillary line along the superior surface of the lower rib to avoid injury to the underlying neurovascular bundle.

Following pneumoperitoneum, established at 20 to 25 mm Hg pressure, 5 mm laparoscopes are introduced at Palmer's point for inspection, followed by additional trocars, inserted under direct vision, to facilitate the required surgery and/or perform adhesiolysis when indicated.

A retrospective review of 918 insufflations through the ninth intercostal space found one entry into the stomach and one into the pleural space (causing a pneumothorax) by the Veress needle.[50]

Challenges

Anterior abdominal wall adhesions

Adhesions at the umbilical area are found in approximately 10% of all laparoscopies.[47] One series of 4532 laparoscopies reported an incidence of only 0.2 per 1000.[60] In women with no previous abdominal surgery, umbilical adhesions are found in 0% to 0.68% of laparoscopies. Rates of umbilical adhesions range from 0% to 15% in women with prior laparoscopic surgery, from 20% to 28% in those who have had previous laparotomy with horizontal suprapubic incision, and from 50% to 60% in those who have had previous laparotomy with longitudinal incision.[47,50,61,62] Patients with midline incisions performed for gynaecologic indications had significantly more adhesions (109/259, 42%) than those with all types of incisions performed for obstetric indications (12/55, 22%).[62]

In some research protocols, preoperative ultrasonography to detect anterior wall adhesions has been found to be useful, but it needs further evaluation, and there is insufficient evidence to recommend routine preoperative ultrasound.[63,64] In 58 of 69 subjects, laparoscopic or laparotomy findings confirmed the ultrasound findings of "restricted visceral slide" in the presence of visceral adhesions.[63]

Angle of Veress needle insertion

Hurd et al. reported on computerized axial tomography (CT) scans of 38 unanaesthetized women of reproductive age. The position of the umbilicus was found, on average, 0.4 cm, 2.4 cm, and 2.9 cm caudally to the aortic bifurcation in normal weight (BMI < 25 kg/m^2), overweight (BMI 25–30 kg/m^2), and obese (BMI > 30 kg/m^2) women, respectively. In all cases, the umbilicus was cephalad to where the left common iliac vein crossed the midline at the sacral promontory.[38] Therefore, the angle of the Veress needle insertion should vary accordingly from 45° in non-obese women to 90° in very obese women.[40]

Veress needle safety tests or checks

Several studies have described tests and techniques for determining the correct placement of the Veress needle. These include the double click sound of the Veress needle, the aspiration test, the hanging drop of saline test,[65] the "hiss" sound test,[66] and the syringe test.[34,37,67,68] Although all these tests and techniques may be helpful in accessing the peritoneal cavity, the fact that visceral and vascular injuries occur shows that they are not foolproof. In fact, a recent prospective study reported that the double click, aspiration, and hanging drop tests provided very little useful information on the placement of the Veress needle.[69] In view of recent evidence, failure to perform these tests should no longer be considered as substandard care or negligence.[69]

Some surgeons waggle the Veress needle from side to side, believing that this shakes an attached organ from the tip of the needle and confirms correct intra-abdominal placement. However, this manoeuvre can enlarge a 1.6 mm puncture injury to an injury of up to 1 cm in viscera or blood vessels.[70]

Elevation of the anterior abdominal wall

Many surgeons advocate elevating the lower anterior abdominal wall by hand or using towel clips at the time of Veress or primary trocar insertion.[14,71] One study used a suprapubic port to compare the efficacy of manual

elevation below the umbilicus and of towel clips placed within and 2 cm from the umbilicus.[71] They reported that only towel clips provided significant elevation of peritoneum (mean 6.8 cm above the viscera) that was maintained during the force of the primary trocar insertion.[71] Using this technique, however, one surgeon caused aortic injury to two patients in one month.[72]

Hill and Maher reported 26 (4.8%) omental perforations as the omentum was elevated (lifted by hand), together with the anterior wall, during 542 direct trocar insertions for laparoscopic access.[73]

Number of Veress needle insertions attempts

Studies have reported placing the Veress needle into the peritoneal cavity on the first attempt at frequencies of 85.5% to 86.9%[69,74]; two attempts were required in 8.5% to 11.6% of procedures, three attempts in 2.6% to 3.0%, and more than three attempts in 0.3% to 1.6%.[69,74]

Complication rates were as follows: at one attempt, 0.8% to 16.3%; at two attempts, 16.31% to 37.5%; at three attempts, 44.4% to 64%; and at more than three attempts, 84.6% to 100%. Complications were extraperitoneal insufflation, omental and bowel injuries, and failed laparoscopy.[69,74]

Extraperitoneal insufflation

Extraperitoneal insufflation is one of the most common complications of laparoscopy, frequently leading to abandonment of the procedure because further attempts to achieve pneumoperitoneum are usually unsuccessful.[12,75,76] In one study, preperitoneal insufflation occurred in 2.7%, 15%, 44.4%, and 100% of cases at one, two, three, and more than three attempts, respectively.[69]

Kabukoba and Skillern described a technique to deal with extraperitoneal insufflation that requires the laparoscope to be left in the preperitoneal space and the gas not evacuated. The Veress needle is then reintroduced into the preperitoneal space in front of the telescope and visually guided into the peritoneal cavity.[77]

Veress Needle Modifications

Pressure-sensor-equipped Veress needle

A modified pressure-sensor-equipped Veress needle to provide the surgeon immediate feedback the moment the tip enters the peritoneal cavity has been described.[78]

Optical Veress needle (minilaparoscopy)

The Veress needle has been modified to a 2.1 mm diameter and cannula 10.5 cm long to allow insertion of a thin (≤ 1.2 mm diameter), zero degree, semirigid fiberoptic minilaparoscope. This system may be inserted in the umbilicus or the left upper quadrant, and subsequent ancillary ports are inserted under direct vision.[16,17]

During insertion of the assembled unit (Veress cannula and telescope) the surgeon observes a cascade of monitor colour sequences that represent different abdominal wall layers: subcutaneous fat appears yellow, fascia white, anterior rectus muscle red, and peritoneum translucent or shiny bright.[79,80] When the Veress needle enters the peritoneum, CO_2 gas can be seen bubbling forwards, and the intra-abdominal structures soon come into view. Alternatively, some surgeons insert the optical Veress needle first, secure insufflation, and then introduce the minilaparoscope.[17,47,49]

In patients with longitudinal abdominal wall incisions, utilization of the optical Veress system through the LUQ and insertion of the ancillary ports under direct vision may present a safer alternative. However, in a prospective study of 184 cases, two bowel perforations occurred.[81] Therefore, the relative predictive risks of the optical Veress needle remain uncertain in the absence of randomized studies.[47,82]

Veress intraperitoneal pressure (VIP pressure)

Several investigators have reported initial intraperitoneal insufflation pressures ≤ 10 mm Hg indicating correct Veress needle placement.[69,74,83–87] Prospective studies have concluded that initial intra-abdominal pressures of 10 mm Hg or below indicate correct placement of the Veress needle, regardless of the women's body habitus, parity, and age.[86,87] In fact, another study concluded that the initial gas pressure (≤ 9 mm Hg) is the only accurate measure of correct intraperitoneal Veress needle placement.[69] Finally, a recent study has confirmed that the initial intraperitoneal insufflation pressure (≤ 10 mm Hg) correlates positively with the patient's weight and BMI and negatively with parity.[87]

Adequate Pneumoperitoneum

Controversy exists as to what defines an "adequate," "appropriate," or "sufficient" pneumoperitoneum prior to insertion of the primary trocar. Traditionally, it has been defined by an arbitrary volume of 1 L to 4 L of CO_2[74] or an arbitrary intraperitoneal pressure of 10 to 15 mm Hg.[74] Richardson and Sutton undertook a prospective study of 836 patients undergoing laparoscopy to determine the complications associated with the first entry, using the volume technique (n = 291) and the pressure technique (n = 335, median pressure 14 mm Hg) as the end points.[74] The average volume of CO_2 used in the pressure technique group was significantly greater than that used with the volume technique group (4.3 vs. 2.8 L; $P > 0.01$), and the complication rate in the pressure technique group was significantly lower than that in the volume technique group (4.1% vs. 8.2%; $\chi^2 = 5.22$, $df = 1, 0.5 > P > 0.02$), at all levels of operator experience. The authors suggested that the pressure technique should be universally adopted.[74]

High Pressure Entry (The HIP Entry)

The pressure technique has been adopted by many surgeons worldwide, but the appropriate volume to establish an appropriate intra-abdominal pressure remains controversial. Final pressures up to 10 mm Hg,[88] 15 mm Hg,[84,89,90] 14 to 18 mm Hg,[91] 20 mm Hg,[50,69] and even 25[48,83,86,92,93] to 30 mm Hg[93–95] have been advocated.

The rationale for the higher pressure entry technique is that it produces greater splinting of the anterior abdominal wall and a deeper intra-abdominal CO_2 bubble than the traditional volume-limited pneumoperitoneum of 2 L to 4 L. One study determined that 3 L and 4 L of insufflated CO_2 volume established intraperitoneal pressures of 10 and 15 mm Hg, respectively.[92] The same study demonstrated that when a downward force of 3 kg was applied to an umbilical trocar, the intra-abdominal CO_2 bubble was reduced to zero at 15 mm Hg, and the tip of the trocar touched abdominal contents; when the same force was applied at 25 mm Hg pressure, a CO_2 gas bubble at least 4 cm deep was maintained in all cases, and the tip of the trocar never touched abdominal contents.[92] It has been determined that trocar insertion requires 4 to 6 kg of force, and shielded disposable trocars require half the force of reusable trocars.[96,97]

The combined results of three series involving 8997 laparoscopies using entry pressures of 25 to 30 mm Hg included reports of four (0.04%) bowel injuries[29,92,95] and one (0.01%) major vessel injury.[29] In all cases of bowel injuries, the bowel was adhered at the entry site of the anterior abdominal wall, and the vascular injury occurred because of inadvertent loss of pneumoperitoneum during trocar insertion.

Although the high-pressure entry technique is easier for the surgeon and safer for the patient, surgeons may be reluctant to accept it for fear of compromising the patient's cardiopulmonary function. It has been demonstrated that the use of transient high-pressure pneumoperitoneum causes minor hemodynamic alterations of no clinical significance.[92,95] However, although there is a significant decrease in pulmonary compliance (approximately 20%) from 15 to 30 mm Hg, the maximum respiratory effects at 25 to 30 mm Hg have not been shown to differ from the effect of Trendelenburg position with intra-abdominal pressure at 15 mm Hg.[92,95]

Recommendations

1. Left upper quadrant (LUQ, Palmer's) laparoscopic entry should be considered in patients with suspected or known periumbilical adhesions or history or presence of umbilical hernia, or after three failed insufflation attempts at the umbilicus. (II-2 A) Other sites of insertion, such as transuterine Veress CO_2 insufflation, may be considered if the umbilical and LUQ insertions have failed or have been considered and are not an option. (I-A)
2. The various Veress needle safety tests or checks provide very little useful information on the placement of the Veress needle. It is therefore not necessary to perform various safety checks on inserting the Veress needle; however, waggling of the Veress needle from side to side must be avoided, as this can enlarge a 1.6 mm puncture injury to an injury of up to 1 cm in viscera or blood vessels. (II-1 A)
3. The Veress intraperitoneal (VIP-pressure ≤ 10 mm Hg) is a reliable indicator of correct intraperitoneal placement of the Veress needle; therefore, it is appropriate to attach the CO_2 source to the Veress needle on entry. (II-1 A)
4. Elevation of the anterior abdominal wall at the time of Veress or primary trocar insertion is not routinely recommended, as it does not avoid visceral or vessel injury. (II-2 B)
5. The angle of the Veress needle insertion should vary according to the BMI of the patient from 45° in non-obese women to 90° in obese women. (II-2 B)
6. The volume of CO_2 inserted with the Veress needle should depend on the intra-abdominal pressure. Adequate pneumoperitoneum should be determined by a pressure of 20 to 30 mm Hg and not by predetermined CO_2 volume. (II-1 A)
7. In the Veress needle method of entry, the abdominal pressure may be increased immediately prior to insertion of the first trocar. The high intraperitoneal (HIP-pressure) laparoscopic entry technique does not adversely affect cardiopulmonary function in healthy women. (II-1 A)

OPEN LAPAROSCOPIC ENTRY OR HASSON TECHNIQUE

Hasson first described the open entry technique in 1971.[11] The suggested benefits are prevention of gas embolism, of preperitoneal insufflation, and possibly of visceral and major vascular injury.

The technique involves using a cannula fitted with a cone-shaped sleeve, a blunt obturator, and possibly a second sleeve to which stay sutures can be attached. The entry is essentially a mini-laparotomy. A small incision is made transversely or longitudinally at the umbilicus. This incision is long enough to be able to dissect down to the fascia, incise it, and enter the peritoneal cavity under direct vision.[11] The cannula is inserted into the peritoneal cavity with the blunt obturator in place. Sutures are placed on either side of the cannula in the fascia and attached to the cannula or purse-stringed around the cannula to seal the abdominal wall incision to the cone-shaped sleeve. The laparoscope is then introduced and insufflation is

commenced. At the end of the procedure the fascial defect is closed and the skin is re-approximated. The open technique is favoured by general surgeons and considered by some to be indicated in patients with previous abdominal surgery, especially those with longitudinal abdominal wall incisions.

Several studies on the benefits and complications of the various laparoscopic entry techniques have been published. Hasson reviewed 17 publications of open laparoscopy by general surgeons (9 publications, 7205 laparoscopies) and gynaecologists (8 publications, 13 486 laparoscopies) and compared them with closed laparoscopy performed by general surgeons (7 publications, 90 152 patients) and gynaecologists (12 publications, 579 510 patients).[76] Hasson reported that for open laparoscopy the rate of umbilical infection was 0.4%, bowel injury 0.1%, and vascular injury 0%. The corresponding rates for closed laparoscopy were 1%, 0.2%, and 0.2%. Hasson advocated the open technique as the preferred method of access for laparoscopic surgery.[76]

Further analysis of Hasson's review suggests that the prospective studies and surveys indicate that general surgeons experience higher complication rates than gynaecologists with the closed technique, but experience similar complication rates with the open technique. Using the closed technique, the visceral and vascular complication rates were 0.22% and 0.04% for general surgeons and 0.10% and 0.03% for gynaecologists. In a published record of his own 29-year experience with laparoscopy in 5284 patients, Hasson reports only one bowel injury within the first 50 cases.[98]

Bonjer et al. published their experience in general surgery and reviewed publications up to 1996 on closed (6 series, n = 489 335 patients) and open (6 series, n = 12 444 patients) laparoscopy. The rates of visceral and vascular injury were respectively 0.08% and 0.07% after closed laparoscopy, and 0.05% and 0% after open laparoscopy (P = 0.002). Mortality rates after closed and open laparoscopy were respectively 0.003% and 0% (NS).[99]

The Swiss Association for Laparoscopic and Thoracoscopic Surgery (SALTS) prospectively collected data on 90.3% of low-risk patients undergoing various laparoscopic procedures between 1995 and 1997 (14 243 patients, M/F ratio 0.7).[100] The insertion of umbilical trocars caused eight visceral injuries: six after blind insertion and two after Hasson entry. The authors stated that in contrast to findings in general surgery publications by Sigman et al.,[28] Bonjer et al.,[99] and Zaraca et al.,[101] the open access method used in the current series failed to show any superiority over the closed establishment of pneumoperitoneum.[100]

Garry reviewed six reports (n = 357 257) of closed laparoscopy and six reports and one survey (n = 20 410) of open laparoscopy performed by gynaecologists. With the closed entry technique, the rates of bowel and major vessel injury were 0.04% and 0.02%, respectively; with the open entry, they were 0.5% and 0%, respectively. When the survey report (n = 8000) was excluded, the rate of bowel injury with the open technique was 0.06%. Garry concluded that open laparoscopy is an acceptable alternative method that has been shown to avoid the risk of injury almost completely in normally situated intra-abdominal structures.[29]

In its clinical practice guideline on the pneumoperitoneum for laparoscopic surgery, the European Association for Endoscopic Surgery states:

> Insertion of the first trocar with the open technique is faster as compared to the Veress needle (grade A).
>
> The randomised controlled trials comparing closed (Veress plus trocar) versus open approach have inadequate sample size to find a difference in serious complications. In large outcomes studies there were less complications in the closed group (grade B). Although RCTs found the open approach faster and associated with a lower incidence of minor complications (grade A), the panel cannot favour the use of either access technique. However, the use of either techniques may have advantages in specific patient subgroups (grade B).[90]

A 2002 meta-analysis of English language studies from both the gynaecological and general surgical literature addresses only major complications defined as bowel or vascular injury.[36]

The studies reporting complication rates for open laparoscopic entry show that 23 bowel injuries occurred in the course of 21 547 procedures (0.1%) and that one vascular injury occurred in the course of 21 292 procedures (0.005%). The majority of the studies provide only level III evidence as they are primarily mail-in surveys or chart reviews. The findings of this meta-analysis showed that vascular injuries are prevented almost entirely by the open technique (4.7/100 000).[36] However, several case reports of vascular injuries with the open technique have been published.[30,102,103]

Molloy et al.[36] also reported a statistically significant difference in bowel complication rates: 0.4/1000 (gynaecologists) versus 1.5/1000 (general surgeons) (P = 0.001). When all open laparoscopies were excluded from the analysis, the incidence of bowel injuries was 0.3/1000 in gynaecological procedures and 1.3/1000 in general surgical procedures (P = 0.001). The authors speculated that the difference may be due to a variety of confounding variables, including

heterogeneous data, retrospective data, underreporting of adverse events, differences in clinical practices between centres, and patient selection bias. In addition, they pointed out that gynaecologists may have more experience than general surgeons with laparoscopic surgery.[36]

Bowel injuries are reported more frequently with open laparoscopy than with other techniques (0.11%: 0.04% Veress needle entry, 0.05% direct entry). This may be influenced by patient selection bias, as open procedures may be more likely to be chosen for patients who have had previous abdominal surgery. Another potential bias is that the number of practitioners involved in the reports on open entry is likely much smaller than the number reporting on the Veress needle (open: 21 547 patients, Veress: 134 917 patients). Consequently, practitioner experience is not accounted for.[36] The authors conclude that the optimal form of laparoscopic entry in the low-risk patient remains unclear.

Chapron et al. reported on a non-randomized comparison of open versus closed laparoscopic entry practised by university affiliated hospital teams. The bowel and major vessel injury rates were 0.04% and 0.01% in the closed technique (n = 8324) and 0.19% and 0% in the open technique (n = 1562), respectively. They concluded that open laparoscopy does not reduce the risk of major complications during laparoscopic access.[104]

Merlin et al.[33] reported on a systematic review of the various methods used by general surgeons and gynaecologists to establish access for laparoscopic surgery. They noted that retrospective studies compared a high-risk with a low-risk patient population, and prospective studies investigated an unselected patient population. The result was a clear trend towards a reduced risk of major complications in unselected patients undergoing open access procedures.[33] The authors also noted that the most common of the major complications associated with access were bowel injuries. The risk of bowel injury in non-randomized studies was higher with the open technique than with closed technique, although bias introduced through patient selection may have been a factor. Meta-analysis of prospective, non-randomized studies of open versus closed (needle/trocar) access indicated a trend during open access towards a reduced risk of major complications (pooled relative risk [RR_p] 0.30; 95% CI 0.09–1.03). Open access was also associated with a trend towards a reduced risk of access-site herniation (RR_p 0.21; 95% CI 0.04–1.03) and in non-obese patients, a 57% reduced risk of minor complications (RR_p 0.43; 95% CI 0.02–0.92) and a trend for fewer conversions to laparotomy (RR_p 0.21; 95% CI 0.04–1.17). The authors concluded that the evidence on the comparative safety and effectiveness of the different access methods was not definitive, but trends in the data merit further exploration.[33]

A multicentre questionnaire survey of general surgeons (57% responding) reported a relatively high incidence of major injuries; the highest with optical trocars (0.27%), the second highest with the closed technique (0.18%, used 82% of the time), and the lowest with the open technique (0.09%).[105]

In clinical trials that compared closed and open entry techniques, the complication rates were 0.07% and 0.17% for the closed and open techniques, respectively.[8] The authors concluded that, in contrast to the findings of Catarci and colleagues,[105] the number of entry-related complications with the open entry technique was significantly higher than with the closed entry technique. Hasson et al. conclude "There is no evidence to support abandoning the closed entry technique in laparoscopy; however, the selection of patients for an open or alternative procedure is still recommended."[8]

Finally, Chandler et al.[30] reported a study of 594 structures or organs injured during laparoscopic access in 566 patients. They found that bowel injuries were no less common with the open technique and could still be obscure. Eighteen Hasson-type entries were associated with primary entry injuries of the small bowel in four patients, two with delayed recognition and death, and with retroperitoneal vessels in another four patients, one of which resulted in the patient's death. In the remaining 10 patients, there were four instances of colon injuries, three of abdominal wall vessel laceration, and one each of liver, urinary bladder, or mesenteric vessel injury.[30]

Studies have suggested that 30% to 50% of bowel injuries and 13% to 50% of vascular injuries are undiagnosed at the time of surgery.[7,30] Because bowel injury is more common than vascular injury, it is more likely to produce serious sequelae because of the delay in diagnosis. The mortality rate from bowel injury is 2.5% to 5%.[7] Bonjer et al. reported six bowel injuries in 12 444 open laparoscopies, two of which (33%) were not recognized during laparoscopy.[99] Marret et al. reported delayed recognition of 25/52 (48%) of bowel injuries following optical trocar insertions.[67]

The rate of carbon dioxide embolism was 0.001% in a review of 489 335 closed laparoscopies.[99] Several case reports have detailed fatal or near-fatal coronary, cerebral, or other gas embolism.[76,90] Such a complication has not been reported at open laparoscopy.

At this time, there is not convincing evidence that the open entry technique is superior to or inferior to the other entry techniques currently available. The open entry technique does have a lower incidence of vascular injuries, but this is

balanced by a potentially higher incidence of bowel injury, although this can be mitigated if alternative entry sites are chosen in high-risk patients. Instead of dissecting down at the umbilicus on suspected bowel adhesions, an alternative site of entry may be more appropriate, such as the left upper quadrant or the ninth/tenth intercostal spaces. This could possibly decrease the rate of bowel injury, as these sites are rarely affected by adhesions and have been shown to be safe in small studies when hepatosplenomegaly and stomach distension have been excluded.

Recommendation

8. The open entry technique may be utilized as an alternative to the Veress needle technique, although the majority of gynaecologists prefer the Veress entry. There is no evidence that the open entry technique is superior to or inferior to the other entry techniques currently available. (II-2 C)

DIRECT TROCAR ENTRY

Dingfelder was the first to publish (in 1978) on direct entry into the abdomen with a trocar.[12] The suggested advantages of this method of entry are the avoidance of complications related to the use of the Veress needle: failed pneumoperitoneum, preperitoneal insufflation, intestinal insufflation, or the more serious CO_2 embolism.[105] Laparoscopic entry is initiated with only one blind step (trocar) instead of three (Veress needle, insufflation, trocar). The direct entry method is faster than any other method of entry[106,107]; however, it is the least performed laparoscopic technique in clinical practice today.[36]

The technique begins with an infra-umbilical skin incision wide enough to accommodate the diameter of a sharp trocar/cannual system. The anterior abdominal wall must be adequately elevated by hand, and the trocar is inserted directly into the cavity, aiming towards the pelvic hollow. Alternatively, the abdominal wall is elevated by pulling on two towel clips placed 3 cm on either side of the umbilicus, and the trocar is inserted at a 90° angle.[107] On removal of the sharp trocar, the laparoscope is inserted to confirm the presence of omentum or bowel in the visual field.[37]

There are several retrospective studies published on the safety of this method of entry.[60,73,108–112] Although a few studies were prospective, only three (n = 664 patients) were randomized.[14,106,107]

The methodology of the three RCTs is sound, and two reported on insertion time as well as morbidity and mortality.[105,106] Nezhat et al. excluded past abdominal surgery but took into account BMI; they showed fewer minor complications with direct trocar entry than with the Veress needle. No major complications occurred in either group (n = 200 patients).[14] Fewer complications were found with direct trocar insertion, but there was no difference with respect to frequency of multiple attempts or ease of insertion.[14]

Byron et al. used the direct entry technique on an unselected group of 937 women. The authors reported more than three attempts to enter the abdomen in 2.7% of cases, failed technique in 1.4%, and a total complication rate of 4.2% (39/937) with a significant increased risk of minor complications ($P < 0.001$). A history of abdominal surgery was not associated with an increased risk of complications.[13] Subsequently, Byron et al. randomized 252 women into Veress needle (n = 141) and direct trocar insertion (n = 111) for laparoscopy.[106] The authors reported a four-fold increase of minor complications with the Veress needle over the direct entry method (11.3% vs. 2.7%, $P < 0.05$) and a significantly longer insertion time (5.9 vs. 2.2 min, $P < 0.01$). Similarly, Borgatta et al. included women with previous surgery and demonstrated a two-fold increase in omental injury with the Veress needle over the direct trocar insertion and a longer insertion time of 2 minutes and 10 seconds with the Veress needle.[107]

Copeland et al. reported on 2000 unselected women with whom direct trocar insertion was utilized. Eight cases (0.4%) required conversion to insufflation with Veress needle, and one of these resulted in bowel injury. Two additional bowel injuries were encountered with the direct trocar entry (0.1%).[109]

Hill and Maher perforated the omentum with the direct trocar in 26 of 542 patients (4.8%), as it was elevated with peritoneum.[73]

Molloy et al. reported on a review of 51 publications including 134 917 Veress/trocar, 21 547 open, and 16 739 direct entries.[36] Entry-related bowel injury rates were 0.04% (Veress/trocar), 0.11% (open), and 0.05% (direct entry); corresponding vascular injury rates were 0.04%, 0.01%, and 0%, respectively.[36] Case reports of major vessel injury with direct entry have been reported.[31,103] Five deaths were reported among the studies of case reports, all occurring in the Veress/trocar group. Two deaths were attributable to delayed diagnosis of bowel perforation and three were attributable to gas embolism during insufflation.[113] The calculated overall mortality associated with laparoscopic entry was 1 per 100 000 procedures.[36] Bowel injury is reported more frequently in general surgical patients than in gynaecological patients 0.15% versus 0.04% ($P = 0.0001$). Vascular injuries during open and direct entry technique have an identical incidence of 0.0%.[36] The authors concluded that "there is no clear evidence as to the optimal form of laparoscopic entry in the low-risk patient. However, direct entry may be an under-utilized and safe alternative to the Veress needle and open entry technique."[36]

Sharp trocars are recommended for a direct insertion technique. Reusable trocars are not subject to a standardized frequency of sharpening[14,27]; this and the strength required to adequately elevate the abdominal wall and to make a controlled forward thrust with the trocar may be limiting factors to the use of this technique. Yuzpe reported that a higher proportion of women than men experienced difficulty inserting both the primary and secondary trocars.[27] In addition, injuries appeared to occur twice as often amongst those gynaecologists who experienced difficulty with trocar insertion ($P = 0.04$). When difficulty was associated with the primary trocar, the correlation was even more striking ($P = 0.02$).[27]

Recommendation

9. Direct insertion of the trocar without prior pneumoperitoneum may be considered as a safe alternative to Veress needle technique. (II-2)

Summary Statement

10. Direct insertion of the trocar is associated with less insufflation-related complications such as gas embolism, and it is a faster technique than the Veress needle technique. (I)

DISPOSABLE SHIELDED TROCARS

Disposable shielded "safety" trocars were introduced in 1984.[9] These trocars are designed with a shield that partially retracts and exposes the sharp tip as it encounters resistance through the abdominal wall. As the shield enters the abdominal cavity, it springs forward and covers the sharp tip of the trocar.

These trocars were intended to prevent the sharp tip from injuring intra-abdominal contents. However, it must be pointed out that even when a shielded trocar functions properly and is used according to the specifications, there is a brief moment when the sharp trocar tip is exposed and unprotected as it enters the abdominal cavity.[114,115]

In the presence of pneumoperitoneum, disposable shielded trocars have been shown to require half the force needed for a reusable trocar. The force required to enter the abdomen with various disposable trocars in the pig model was 4 to 6 kg.[96,116] Increased entry force frequently results in loss of operator control and overthrusting of the trocar, which is a potential cause of serious vascular and visceral injuries.[116]

In a randomized study of 100 direct laparoscopic entries, no complications occurred with the disposable trocars (n = 50), and three (6%) minor complications occurred with the conventional trocars ($P > 0.05$, χ^2 1.375). Ten cases in each group required two insertions, and failed insertion occurred in 8% and 4% of cases ($P > 0.05$, $\chi^2 = 0.177$) in the conventional and disposable trocar groups, respectively.[14]

A randomized experimental study in rabbits concluded that initial insufflation was safer than direct trocar insertion; the use of disposable trocars did not improve the safety of the procedure.[15]

Champault et al. reported on 103 852 operations involving the use of 386 784 trocars. They found that 10 out of 36 (28%) serious injuries and two out of seven (29%) deaths involved shielded trocars.[117] Saville and Woods reported four major retroperitoneal vessel injuries in 3 591 laparoscopies, all of which involved shielded trocars.[118]

Marret et al. reported 47 complications due to trocar insertions between 1994 and 1997. Half of the trocars used were disposable and this type of so-called safety trocar was responsible for half of the large blood vessel injuries.[67]

Bhoyrul et al. analyzed 629 trocar injuries reported to the FDA database from 1993 to 1996. There were 408 injuries to major vessels, 182 injuries to other viscera (mainly bowel), and 30 abdominal wall hematomas. Of the 32 deaths, 26 (81%) resulted from visceral injuries, and 6 (19%) resulted from vascular injuries. Eighty-seven percent of deaths from vascular injuries involved the use of disposable trocars with safety shields, and 9% involved disposable optical trocars. Ninety-one percent of bowel injuries involved trocars with safety shields, and 7% involved optical trocars. The diagnosis of bowel injury was delayed in 10% of cases, and the mortality rate in this group was 21%. The authors concluded that safety shields and direct-view trocars cannot prevent serious injuries during laparoscopic access.[91] Furthermore, the data would not support a contention that safety-shield malfunction was a common factor. There were few reports in which a safety-shield malfunction was alleged to have contributed and even fewer in which malfunction was actually found.[91]

Corson et al. reviewed 135 entry-related litigated cases in the United States. There were no injuries from reusable trocars, but there were 12 (9%) injuries with shielded trocars. The authors point out that the lack of reusable trocar injuries reflects the popularity of disposable devices in the United States.[31]

Finally, the FDA in a letter to the manufacturers of laparoscopic trocars, dated August 23, 1996, requested that, in the absence of clinical data showing reduced incidence of injuries, manufacturers and distributors voluntarily eliminate safety claims from the labelling of shielded trocars and needles.[119]

In 1998 and 2000, the Emergency Care Research Institute (ECRI) concluded that although shielded trocars do not totally protect against injuries, they are preferable to unshielded trocars.[114,115] A trocar use survey of 62 health care facilities reported that shielded trocars were used for

primary trocar entry by 37% of surgeons for 100% of procedure, by 59% for at least 90% of procedures, and by 79% for at least 80% of procedures.[120]

Recommendation

11. Shielded trocars may be used in an effort to decrease entry injuries. There is no evidence that they result in fewer visceral and vascular injuries during laparoscopic access. (II-B)

RADIALLY EXPANDING ACCESS SYSTEM

The radially expanding access system (Step, InnerDyne, Sunnyvale, CA) was introduced in 1994. It consists of a 1.9 mm Veress surrounded by an expanding polymeric sleeve. The abdomen may first be insufflated using the Veress needle. The needle is removed, and the sleeve acts as a tract through the abdominal wall that can be dilated up to 12 mm by inserting a blunt obturator with a twisting motion.[21,121,122] The force required to push this trocar through the abdomen in pigs is 14.2 kg compared with forces of 4 to 6 kg needed for disposable trocars.[116]

Several case series and randomized studies have reported no injury to major vessels and no deaths.[21] Abdominal wall bleeding and Veress injury to mesentery have been encountered.[21] In addition, RCTs have demonstrated less postoperative pain and more patient satisfaction with the radially expanding device than with the conventional trocar entry techniques.[123–126]

Advantages of this system include elimination of sharp trocars, application of radial force, stabilization of the cannula's position (cannula does not slide in and out), avoidance of injury to abdominal wall vessels, and elimination of the need for suturing of fascial defects.

Recommendation

12. Radially expanding trocars are not recommended as being superior to the traditional trocars. They do have blunt tips that may provide some protection from injuries, but the force required for entry is significantly greater than with disposable trocars. (I-A)

VISUAL ENTRY SYSTEMS

Disposable Optical Trocars

Optical/access trocars were introduced in 1994[9] and are popular among urologists. Two disposable visual entry systems are available that retain the conventional trocar and cannula push-through design: the Endopath Optiview optical trocar (Ethicon Endo-Surgery, Inc., Cincinnati, OH) and The Visiport optical trocar, (Tyco-United States Surgical, Norwalk, CT). These single-use visual trocars trade blind sharp trocars for a hollow trocar, in which a zero degree laparoscope is loaded for the distal crystal tip to transmit real-time monitor images while transecting abdominal wall tissue layers. Their application recruits significant axial thrust through the surgeon's dominant upper body muscles to transect abdominal myofascial layers.

Endopath Optiview optical trocar

The Endopath Optiview optical trocar comprises a hollowed trocar and a cannula. When insufflation is complete, the Veress needle is withdrawn, and the subcutaneous fatty tissue is dissected off, using peanut sponges, to expose the white anterior rectus fascia. A 5 mm incision is then made with a scalpel to accommodate the visual trocar's pointed tip.

When the Endopath optical trocar is used directly, without pre-insufflation, two anterior rectus fascia stay sutures are placed at 3 and 9 o'clock and held with snaps. The fascia is then divided between the stay sutures over a length of approximately 5 mm. During insertion, the stay sutures are pulled to lift the abdominal wall against the advancing trajectory and facilitate proper port site closure at the end of the operation. Alternatively, the assistant may grasp the abdominal wall with towel clips, while the surgeon negotiates the visual trocar.[127]

Twisting the handle advances the hydrophobic and winged trocar tip to dissect successive tissue layers on its way towards the abdomen. The cascade of generated entry images displayed on the monitor demonstrates level of penetration.

Some surgeons advocate use of visual trocars during gasless laparoscopy, in which abdominal wall lifting devices are used to tent the abdominal wall before the primary visual trocar is inserted under visual control. Experience with such methods is limited, and large-scale studies are lacking.[128]

The retention of the push-through trocar design necessitates considerable axial force to propel the trajectory, with no mechanism to offset overshoot. Given the winged trocar tip, the generated axial force dents tissue layers, and compression renders layer recognition more difficult.[127]

Visiport optical trocars

The Visiport optical trocar is a disposable visual entry instrument that comprises a hollow trocar and a cannula. Every trigger squeeze advances the sharp cutting knife 1 mm to transect tissue in contact with the crystal tip and swiftly retract back into the crystal hemisphere. It is advised that, as with other visual trocars, the Visiport optical trocar is to be applied only after CO_2 insufflation.[129]

When insufflation is complete, the Veress needle is withdrawn, and subcutaneous fatty tissue is dissected off the white anterior rectus fascia using peanut sponges. The Visiport optical trocar is palmed by the surgeon's dominant hand and held perpendicular to the supine patient's CO_2

distended abdomen. Once the exact anatomical position of the trocar tip is verified on the monitor, downward axial pressure is applied while activating the trigger. Then downward pressure is relieved, the trigger released, and the trocar tip position verified on the monitor again. This entry sequence is repeated until the peritoneal cavity is entered. The trigger is not fired until the exact anatomical position of the trocar tip is known.

The push-through entry design requires significant perpendicular force to drive a trajectory across tissue planes with no means of avoiding trocar overshoot. Sometimes, the anterior abdominal wall may be grasped with the non-dominant hand of the surgeon and lifted to offer counter pressure against the advancing trocar. The Visiport optical trocar comes in only one diameter and accommodates only a 10 mm laparoscope.

EndoTIP visual cannula

The endoscopic threaded imaging port, EndoTIP (Karl STORZ Endoscopy, Tuttlingen, Germany), is a reusable visual cannula system that allows real-time interactive port creation, when port-dynamics are archived, for recall and analysis. The principal differentiating aspects of EndoTIP include reduction of push-force, visually controlled entry, elimination of overshoot, and lack of sharp trocar.

Conventional primary trocar insertion requires application of considerable axial push-force (2–14 kg)[96,97] to the trocar and cannula where the anterior abdominal wall dents towards the viscera; entry is blind. The EndoTIP consists of a stainless steel cannula with a proximal valve segment and distal hollow threaded cannula section. The conventional valve sector houses a standard CO_2 stopcock, and the cannula's outer surface is wrapped with a single thread, winding diagonally to end in a distal blunt notched tip. The cannula is available in different lengths and diameters for different surgical applications. A retaining ring keeps the mounted laparoscope from sliding out of focus during insertion.[130]

The EndoTIP visual cannula system requires no trocar and has no crystal tip compressing and distorting monitor images at tissue–cannula interface. Interpretations of observed monitor images are identified, layered-entry, and real-time interactive.

A generous umbilical skin incision is made using a surgical blade to avoid skin dystonia. Ribbon retractors and peanut sponges are used to expose the white anterior rectus fascia. As when using the optical trocar, insertion starts at the fascial level. A 7 mm rectus fascial incision is then made under direct vision, and the Veress needle is inserted through the fascial incision with the CO_2 stopcock in the open position.

When insufflation is complete, the surgeon holds the laparoscope with mounted cannula perpendicular to patient's supine abdomen, using the non-dominant hand. The unit, (laparoscope and mounted cannula) with the CO_2 stopcock in the closed position is then lowered into the umbilical wound. The surgeon uses the muscles of the dominant wrist to rotate the cannula clockwise, while keeping the forearm horizontal to the patient's abdomen. Downward axial pressure during rotation is kept to a minimum.

The blunt cannula's notched tip engages the anterior rectus fascial window and stretches it radially. Rotation applies Archimedes' principle to lift the anterior abdominal wall and transpose successive tissue layers onto the cannula's outer thread. The white anterior rectus fascia, red rectus muscle, pearly white posterior rectus fascia, yellowish preperitoneal space, and transparent greyish peritoneal membrane are all observed sequentially on the monitor.

As the cannula has no cutting or sharp end, tissue layers are not transected; instead, they are taken up along the outer pitch. The parted tissue layers preserve port competence and result in a smaller fascial entry wound area with less muscle damage than with pyramidal trocar wounds.[131]

Further clockwise rotation parts the peritoneal membrane radially to advance the cannula incrementally into the peritoneal cavity under direct visual control, while avoiding cannula overshoot.

Recommendation

13. The visual entry cannula system may represent an advantage over traditional trocars, as it allows a clear optical entry, but this advantage has not been fully explored. The visual entry cannula trocars have the advantage of minimizing the size of the entry wound and reducing the force necessary for insertion. Visual entry trocars are non-superior to other trocars since they do not avoid visceral and vascular injury. (2 B)

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Total Laparoscopic Hysterectomy with a Transvaginal Tube

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Abstract ***(J Am Assoc Gynecol Laparosc 2004, 11(1):79–82)***

Several techniques of laparoscopic hysterectomies have been described, but loss of carbon dioxide (CO_2) pneumoperitoneum is still a problem when the vagina is incised and the specimen has been removed. Our technique allows maintenance of CO_2 pneumoperitoneum by inserting a silicone tube into the vagina. The McCartney tube is open at its vaginal (proximal) end and a cap covers the outer distal end. The total hysterectomy specimen, adnexa, and, if necessary, lymph nodes can be easily removed through the tube.

The rate of hysterectomy currently is 5.6/1000 women in the United States.[1] The abdominal approach is still the most common, but laparoscopic approaches accounted for 9.9% of cases by 1997.[1] Prospective, randomized surgical trials showed many known advantages of laparoscopic-assisted vaginal hysterectomy over total abdominal hysterectomy (TAH).[2,3] However, in morbidly obese and nulliparous patients, the vaginal phase may be difficult to perform.

In our center, total laparoscopic hysterectomy (TLH) allows completion of the entire operation laparoscopically. The technique was first described in 1995,[4] and its morbidity was reported.[5] It has been improved, in our experience, since 1996 by use of bipolar diathermy rather than laparoscopic stapling devices.

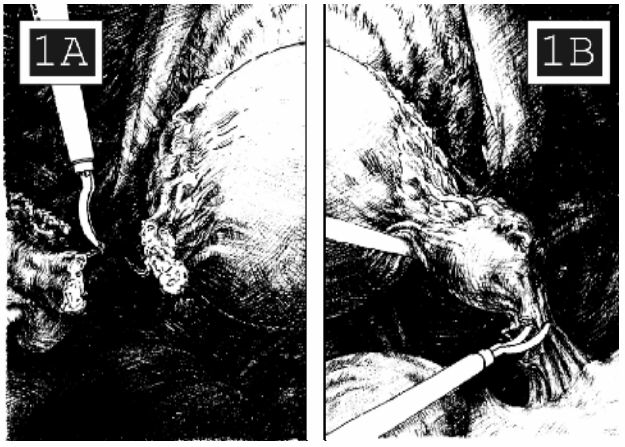

FIGURE 1. Either (A) the ovarian ligament (ovaries are preserved) or (B) the infundibulopelvic ligament is secured with bipolar diathermy.

Operative Technique

The patient is placed in lower Trendelenburg position with legs resting in Allan stirrups. We use one 12-mm subumbilical port, which carries the telescope, plus two 5-mm ports in the left and the right lower abdomen medial to inferior epigastric vessels, and one 5-mm port in the right midabdomen. Surgical instruments are hinged bipolar diathermy forceps, monopolar scissors, various graspers, laparoscopic needle holder, and suction-irrigation system.

The first step of TLH is to divide the round ligament in order to enter retroperitoneum. Either the ovarian ligament (ovaries are preserved) or the infundibulopelvic ligament is secured with bipolar diathermy and divided with monopolar scissors (Figure 1). The peritoneum of the broad ligament and both anterior and posterior leaves are divided with unipolar scissors. The incision is carried anteriorly, and bladder peritoneum is incised below the cervicovesical fold.

The McCartney tube (Tyco Healthcare, Inc., Sydney, Australia), which is a disposable silicone tube with a diameter of 45 mm or 35 mm, is inserted transvaginally. Its vaginal (proximal) end is open and the outer, distal end is covered by a cap containing 5- and 10-mm valves. The tube stretches the cervicovaginal junction, which facilitates completion of reflection of the bladder from the cervix and upper vagina. The tube also allows identification and exposure of vaginal fornices (Figure 2). Bladder pillars

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Dr. McCartney is a director of Gynetech Pty. Ltd., which manufactures the McCartney transvaginal tube. The tube is marketed in Australia and Europe by Tyco Healthcare, Inc., Sydney, Australia.

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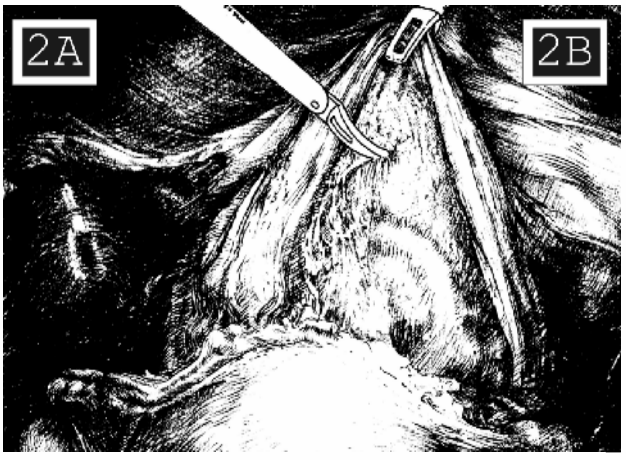

FIGURE 2. (A) Insertion of the McCartney tube allows reflection of bladder peritoneum. (B) Bladder pillars are lateralized.

are reflected laterally over the edge of the tube. Uterine vessels are prominently displayed when bladder pillars are lateralized and peritoneum on the posterior leaf of the broad ligament is divided. In this case, uterine vessels are seen as they cross the lateral margins of the tube in vaginal fornices.

Uterine vessels are secured with bipolar diathermy at the margin of the tube and medially toward the cervix (Figure 3) and then divided with monopolar scissors (Figure 4). It is essential not to coagulate lateral to the margin of the tube in order to avoid ureteric injury. Finally, the vagina is circumcised with monopolar diathermy over the end margin of the vaginal tube (Figure 5). Since silicone is nonconducting material, no injury to the patient would be expected and no effects on the tube have been observed so far.

The tube prevents loss of carbon dioxide (CO_2) pneumoperitoneum when the vagina is opened. A vaginal cuff of variable length can be resected when indicated. The total specimen is removed through the tube by applying suction or inserting a toothed grasper through the valve end (Figures 6 and 7). Removal of the tube is associated with loss of pneumoperitoneum. After hysterectomy is completed, the tube can be reinserted, and the pneumoperitoneum reestablished. Pelvic lymph node dissection may be performed, with the tube used as a conduit to remove nodes from the abdominal cavity.

Finally, a needle suture is placed into the tube and the tube is reinserted into the vaginal vault (Figure 8). Continuous laparoscopic suture of the vault across and back from right to left is carried out while CO_2 pneumoperitoneum is maintained (Figure 9). The needle end of the suture is delivered into the vagina with a dolphin-nose forceps, the tube is removed, and the suture is tied transvaginally (Figure 10).

Experience

To date more than 1500 TLHs have been performed at our center, including 226 for management of endometrial

FIGURE 3. Uterine vessels are secured with bipolar diathermy at the margin of the tube.

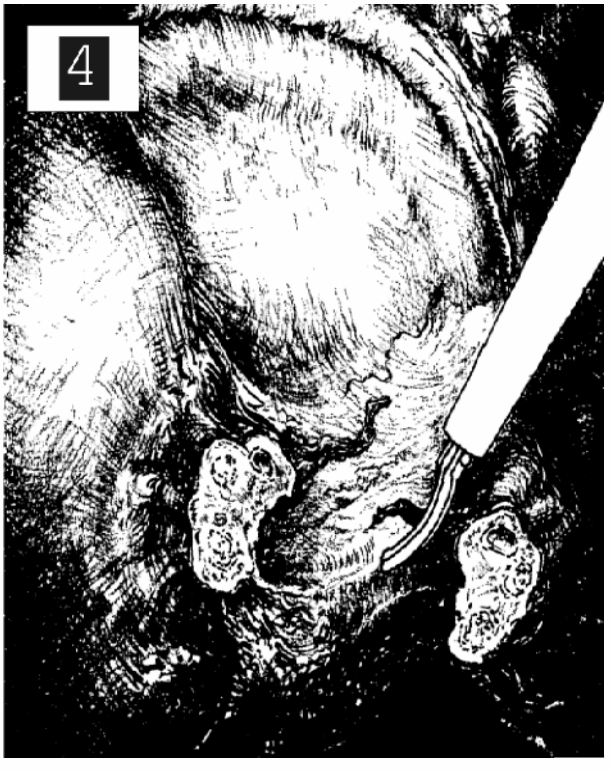

FIGURE 4. Uterine vessels are divided with monopolar diathermy.

FIGURE 5. Circumcision of vagina.

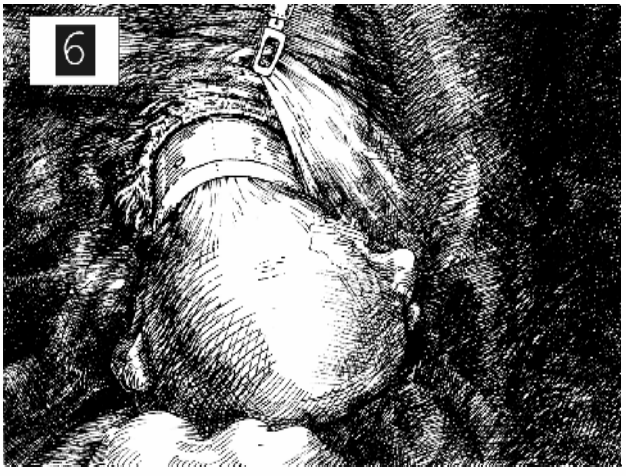

FIGURE 6. Introduction of specimen into the tube.

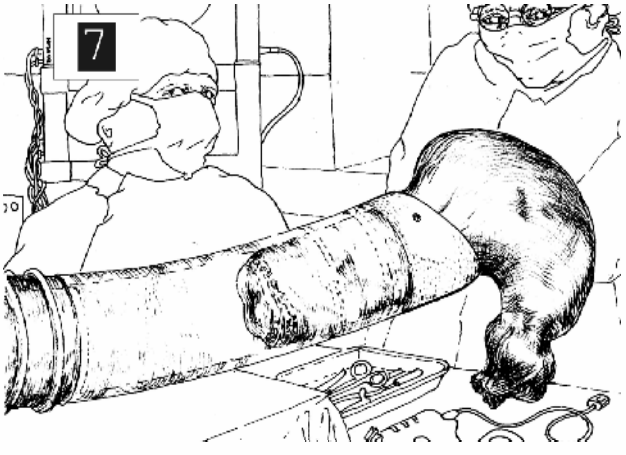

FIGURE 7. The tube prevents loss of CO_2 pneumoperitoneum when the vagina is opened. The specimen may be removed through the vaginal tube.

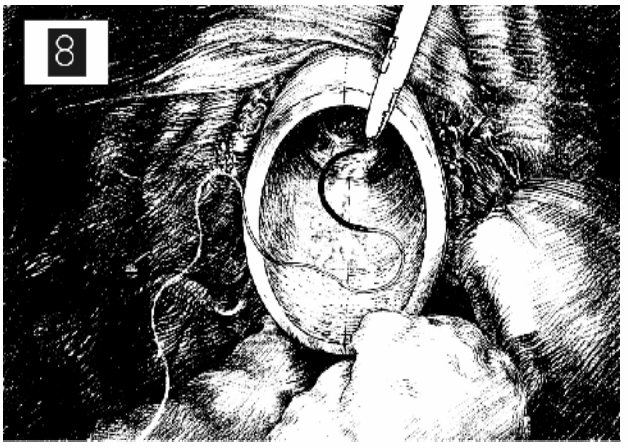

FIGURE 8. A needle suture is inserted.

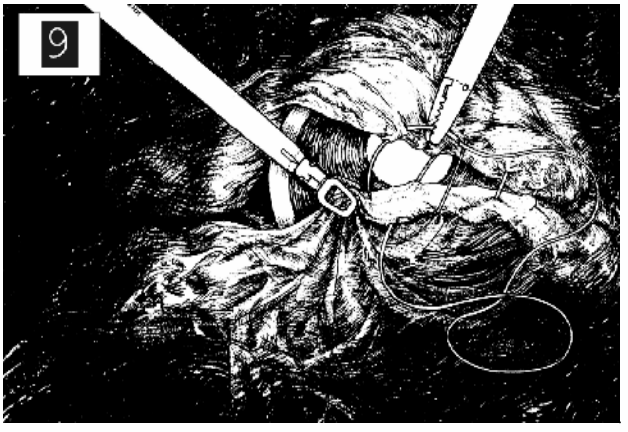

FIGURE 9. Continuous suture of the vault from right to left and back is carried out laparoscopically.

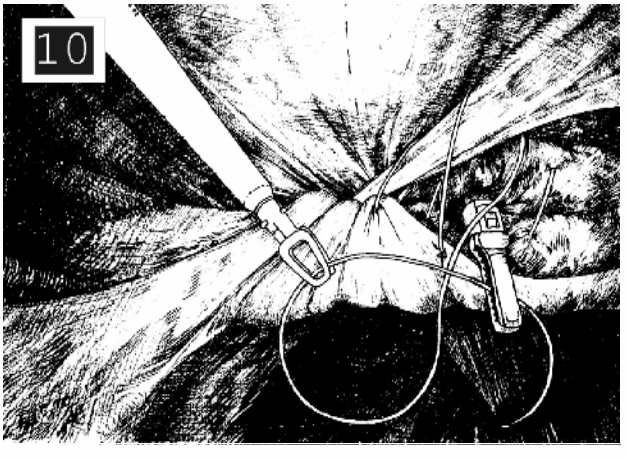

FIGURE 10. A dolphin-nose forceps retrieves the needle end of the suture through the vagina and the suture is tied transvaginally.

cancer.[6] The laparoscopic procedure was converted to laparotomy in 11 (4.8%) of 226 patients due to failed access associated with severe adhesions (6 women, 2.6%) and to control significant hemorrhage (5, 2.2%).

Compared with abdominal hysterectomy, TLH was associated with shorter postoperative hospital stay and decreased blood loss. Overall, the rate of any treatment-related morbidity was 17% in the TLH group compared with 43% in the TAH group.[5] We also performed the operation for benign uterine disease (endometriosis-adenomyosis, myomas) and benign ovarian tumors. We currently limit TLH for endometrial cancer to women with a uterine size that can be delivered comfortably through the vagina. In women with a large myomatous uterus, the uterus may be reduced by morcellation and delivered through the tube. By preventing wound morbidity, the operation is particularly effective in obese patients (Obermair A et al, unpublished data).

Discussion

Several techniques of laparoscopic hysterectomy have been described. Some limit the laparoscopic approach to securing the ovarian pedicles, and others even secure uterine pedicles laparoscopically. These techniques complete the operation by adding a vaginal surgical phase to the laparoscopic phase.[7] Inserting a tube into the vagina allows completion of the entire procedure laparoscopically by preventing loss of pneumoperitoneum, even after the vagina is opened and the specimen removed. This allows suturing of the vaginal vault under direct laparoscopic vision.

The major disadvantage of the procedure is the need for specialized surgical training. We recommend that at least 20 cases as an assistant and 20 additional supervised cases as the surgeon be performed before accreditation.

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A consensus document concerning laparoscopic entry techniques: Middlesbrough, March 19–20 1999

1. INTRODUCTION

This is a consensus document, prepared by an international group of gynaecologists and general surgeons with a special interest in laparoscopic surgery, whose names appear below. This group met in Middlesbrough, UK on March 19–20 1999. In reaching the consensus, the group critically evaluated the available published evidence on entry techniques. Areas worthy of further research were identified, and also questions which could not be answered because of the extremely large sample sizes required. The group recommends that with ongoing data collection and research, this consensus statement should be reviewed no later than March 2001.

2. THE BENEFITS OF LAPAROSCOPY

2.1 There is clear evidence that laparoscopic surgery provides significant benefits compared with laparotomy, for patients, providers and surgeons.

2.2 The benefits for patients include reduced mortality, less visible scarring, less operative pain and quicker recovery from surgery.

2.3 The benefits for healthcare providers include shorter hospital stay and quicker recovery times with consequent reduced inpatient and social costs.

2.3 The benefits for surgeons include an almost 'closed and no-touch' operative approach with reduced risk of infection, better display of anatomy and pathology, more precise removal of diseased tissue and more accurate tissue repair.

3. COMPLICATIONS

3.1 As with any surgical technique, the laparoscopic approach is associated with complications which must be offset against the expected clinical benefits. There are a number of complications of the laparoscopic approach which do not occur or occur much less frequently with conventional surgical approaches. It is these laparoscopy-specific complications which are the subject of this consensus statement.

3.2 Most laparoscopy-specific complications are related to the laparoscopic methods of entry into the abdominal cavity, and particularly the need to insert sharp instruments into the abdomen in a blind manner. The most important adverse outcomes are damage to the gastrointestinal tract and the major blood vessels, as these may be associated with life-threatening consequences. Such very severe complications can occur during diagnostic or very minor surgical procedures.

3.3 It is therefore vital that the incidence, nature and causes of these complications are fully understood. It is also essential to identify optimal methodology and equipment to ensure that the rate of these major complications is reduced to the unavoidable minimum. It is also important to determine the best ways to identify as rapidly as possible those complications which do occur, in order to minimize the consequences.

3.4 The complications specific to laparoscopy are rare. The available evidence from the largest studies suggests that the incidence of bowel injury is of the order of 0.4 per 1000 cases. Whilst this low rate is obviously reassuring, it still implies that about 50 women in the UK will suffer laparoscopic entry-related bowel damage each year. This low rate was obtained from over 350 000 laparoscopies reported in a number of large, multicentre studies. It is a rate which must nevertheless be quoted with caution, for in two recent prospective studies from single hospitals, which would be expected to provide more complete data, the risk of bowel damage was reported to be much higher, at around 3 per 1000. The incidence of injury to major blood vessels appears to be about half that of damage to the bowel. The infrequent occurrence of severe complications also makes it very difficult to produce statistically significant evidence-based statements about factors affecting these complications. To demonstrate a 33% reduction in incidence of bowel injury with 80% power and 95% confidence limits would require a sample size in excess of 800 000 cases. This paper seeks to make recommendations only as far as the relatively inadequate information permits.

3.5 Any method of entry into the abdominal cavity may result in bowel damage. There is evidence to suggest that the incidence of such injury is no greater following laparoscopy than following laparotomy or vaginal surgery.

4. CLASSIFICATION OF LAPAROSCOPIC INJURIES

4.1 We suggest that it is helpful to classify laparoscopic entry-related injuries into two groups:

Type 1 injuries Damage by Veress needle or trocar to major blood vessels and normally located bowel.

Type 2 injuries Damage by Veress needle or trocar to bowel adherent to the abdominal wall.

It is recognised that when the bowel is firmly adherent to the abdominal wall at the point of entry into the cavity then bowel damage may occur *whether the mode of access is by laparotomy or laparoscopy*. With our current state of knowledge, some type 2 lesions may be inevitable whatever method of access is selected.

5. CLOSED LAPAROSCOPY

5.1 There is no current evidence that closed laparoscopic entry is more or less dangerous than existing alternative methods.

5.2 Attempts should be made to identify adherence of bowel to the anterior abdominal wall prior to insertion of trocars. A history of prior laparotomy, particularly with a midline scar, or previous peritonitis and inflammatory bowel diseases are associated with a significant increase in the risk of bowel damage.

5.3 If such adhesions are suspected, an alternative entry site should be selected. Palmer's point in the left upper quadrant is preferred, but care must be taken to exclude splenomegaly and previous surgery in the area first. It has been shown that insertion of a microlaparoscope in the left upper quadrant with the subsequent insertion of the umbilical trocar under direct vision reduces the risk of type 2 bowel damage.

5.4 In most circumstances the primary incision should be made in the base of the umbilicus after ensuring that the bladder is emptied. Care should be taken to ensure that the scalpel is used in such a way as to incise the skin but not enter the cavity.

5.5 The Veress needle should be sharp with a good spring action. A narrow diameter is preferred and disposable devices may have advantages.

5.6 The abdomen should be checked for masses and the position of the aorta palpated prior to entry. Many feel that all entry phases of laparoscopy should be performed with the patient lying level with no Trendelenberg tilt.

5.7 The umbilicus should be elevated or stabilized in such a way that the Veress needle can be inserted at right angles to the skin. It should be pushed inwards until it has just penetrated the fascia and peritoneum. The 'give' of the tissues should be sensed and the insertion should be stopped as soon as the cavity is entered. This is often detected by hearing and sensing a double 'click' sound.

5.8 The correct positioning of the needle should be checked. A number of tests such as Palmer's aspiration test and/or observation of gas flow-pressure rates may be utilized for this. Excessive movement of the needle should be avoided, for vigorous rocking movement will convert a small needlepoint injury into a large complex tear if the needle comes to lie in bowel or a major vessel.

5.9 The CO_2 should be insufflated until an appropriate degree of abdominal distension is achieved. It has been shown that high intra-abdominal pressures of up to 25 mmHg at the time of insertion of the trocars are associated with an increased depth of the 'gas bubble' and an increased splinting effect on the abdominal wall. This has been shown to be associated with a lower risk of type 1 injury, but the safety of this approach in those with poor cardiorespiratory function has not yet been established. If such high pressure is used, it should be maintained *only* until the trocars are inserted; the pressure should then be reduced to the normal working pressure of 12–15 mmHg.

5.10 In most cases the primary trocar should also be inserted through the thinnest part of the abdominal wall in the base of the umbilicus. Insertion should be stopped immediately the trocar is inside the cavity.

5.11 Once the laparoscope has been introduced down the primary trocar it should be rotated through 360° to check visually for adherent and potentially damaged bowel and for evidence of haemorrhage and/or retroperitoneal haematoma.

5.12 Attempts to replace the blind element of the entry process with visually aided techniques, using either optical Veress needles or optical trocars, are receiving attention. Such approaches may result in the reduction and/or early diagnosis of bowel lesions. The effectiveness of such approaches is as yet unknown and a few complications have been described. Large-scale evaluation is required before these approaches can be recommended.

5.13 Attempts to replace the use of sharp-tipped primary trocars with blunt-ended devices are attracting considerable interest. Devices such as the reusable EndoTip System (Karl Storz, Tuttlingen, Germany) and the single-use Step Radial Expanding System (InnerDyne, Salt Lake City, Utah, USA) should prevent most type 1 injuries. They may also sometimes displace rather than penetrate tissue when bowel is adherent to the entry site, and thereby also reduce the incidence of type 2 injuries. The US Food and Drug Administration

has already been satisfied that the Step Radial Expanding system has been shown the to reduce the risks of laparoscopic entry. Each of these techniques is used effectively by some members of the group. The rest recognise that these approaches merit further detailed evaluation but that their efficacy is not yet defined. All agree that large-scale trials of such approaches are required.

5.14 At the end of the procedure the primary trocar should be removed under direct vision to exclude any previously unnoticed bowel lesion.

6. OPEN LAPAROSCOPY

6.1 Open laparoscopy is an appropriate alternative to closed laparoscopy. This approach avoids the use of sharp instruments after the initial skin incision with a scalpel. A blunt-ended trocar is inserted under direct vision.

6.2 Open laparoscopy effectively avoids type 1 lesions including almost all vascular injuries.

6.3 Open laparoscopy does not eliminate type 2 bowel lesions.

6.4 To minimize the risks of damage using this procedure, it is important to ensure that following the placement of a skin incision at the lower border of the umbilicus, the deep fascia is elevated with suitable clamps to separate the abdominal wall from its contents.

6.5 A small incision should then be made in the raised fascia and enlarged with a blunt-ended haemostat; this usually effects piecemeal entry. If it does not, the abdomen is lifted and the peritoneum is carefully incised to avoid injury to the underlying bowel.

6.6 The fascial edges are tagged with an adequate suture.

6.7 Entry must be confirmed by visualizing bowel or omentum before inserting the blunt-tipped cannula into the abdomen.

6.8 The trocar insertion should be guided between thin retractors to prevent displacement of the cannula.

6.9 The fascial sutures should be pulled firmly into the suture holders on the cannula to produce an airtight seal with the cone of the cannula. This should be done while applying steady downward pressure on the cannula.

6.10 Gas is insufflated directly through the cannula to produce the pneumoperitoneum. The blunt trocar is withdrawn only after the abdomen is partially distended.

6.11 At the end of the procedure, the fascial defect should be closed using the tag sutures, to minimize the risk of herniation.

7. SECONDARY TROCARS

7.1 Trocars inserted in the lower abdomen should always be introduced under direct laparoscopic guidance, in order to precisely control the depth and direction of the trocar insertion. The superficial vessels should be located by transillumination and the deep epigastric vessels by direct laparoscopic inspection. Lateral trocars should be inserted with both transillumination and direct laparoscopic guidance.

8. COUNSELLING

8.1 As in all surgery, the avoidance of some complications may depend upon correct case selection, the use of good quality, well maintained instruments and careful attention to the minutiae of the technique. Nevertheless not all complications can be avoided and patients should be made aware of this.

8.2 All patients should be told about the following risks:

(i) The possibility of injury to bowel, blood vessels and bladder. On present evidence the risk of all three may be in the region of 1–4 per 1000 cases.

(ii) The possibility that conversion to laparotomy may be required and that on very rare occasions a temporary colostomy may be required.

8.3 Patients and their doctors should expect a progressive and maintained improvement after laparoscopic surgery. Increasing pain or vomiting is not usual after this type of procedure, and either occurrence should alert the patient and doctor to the real risk of complications. Increasing pain should be assumed to be a consequence of bowel damage until proven otherwise. It is essential that all concerned maintain a very high index of suspicion about these rare but potentially very serious complications.

8.14 The patient and her family should leave hospital with written information about recognition of complications and the action to be taken in the event of these developing.

9. IDENTIFICATION OF PATIENTS WITH RISK FACTORS

9.1 Having assessed the available evidence, the group identified risk factors that might be associated with difficulties with entry. These included previous abdominal surgery, particularly with midline incisions, and obesity or thinness of the patient.

10. CONCLUSION

10.1 The group believes that in many circumstances the laparoscopic approach to surgery is associated with significant advantages over laparotomy, with a lower overall morbidity rate. Its appropriate use appears to be of benefit to the vast majority of patients. This demands that the surgeon does all in his power to prevent the rare but serious complications potentially associated with this approach. The patients must also be fully informed of the nature and extent of these risks. Prior to surgery, patients must be made clearly aware that any laparoscopic procedure may result in the need for an associated laparotomy, with the risk of extensive bowel or blood vessel surgery. In some circumstances the conversion to laparotomy to complete the procedure must be considered good practice. The patient should give appropriate written acknowledgement that the nature of the risk has been explained.

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Instruments & Methods

The 4-S modification of the Roeder knot: How to tie it

Howard T. Sharp, MD, and James H. Dorsey, MD

Background: **The 4-S modification of the Roeder knot may be tied laparoscopically as a single-throw knot.**

Technique: **It is tied by adding a fourth wrap around the suture loop and securing the loop in place with a square knot rather than a single half-hitch.**

Experience: **We have used this knot in laparoscopic surgeries for more than 2 years and have not observed knot slippage.**

Conclusion: **This modification results in a knot comparable in strength to the strongest laparoscopic multiple-throw square knots. (Obstet Gynecol 1997;90:1004–6. © 1997 by The American College of Obstetricians and Gynecologists.)**

We recently compared the strength of six different laparoscopic slip knots with multiple-throw square knots.[1] Two slip knots were comparable in strength to multiple-throw square knots: the Duncan knot[2] and a new modification of the Roeder knot known as the 4-S modification. The 4-S modification was devised because the Roeder knot was observed to slip during surgery. We first modified the Roeder knot by adding another wrap to the existing three wraps around the suture loop and adding a second half-hitch to secure the loop.[3] This resulted in a stronger slip knot, but the two half-hitches used to secure the loop resulted in a granny knot. It made theoretical sense that the granny knot should be changed to a square knot for greater knot strength. Subsequent laboratory testing verified this assumption, yielding a knot that was comparable in strength to the strongest laparoscopic square knots.[1] The term "4-S knot," or "four-square knot," stands for four wraps around the suture loop and one square knot to secure the loop. However, we call this knot the 4-S modification of the Roeder knot to give credit to the German physician who pioneered the original knot.[4] Although this knot was mentioned in an earlier publication,[1] inquiries by physicians asking for greater detail about how the knot is tied has prompted us to describe this knot in greater detail.

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Funding was provided by the Institute of Conservative and Minimally Invasive Surgery, the Greater Baltimore Medical Center, Baltimore, Maryland.

Technique

To tie the 4-S modification of the Roeder knot, a single flat throw is followed by wrapping the free end of the suture around the suture loop four times (Figures 1–3). The free end of the suture is passed over the loop, rather than under, and passed from anterior to posterior around the proximal leg of the loop to form a half-hitch (Figure 4). The free end of the suture is then passed posterior to anterior to form a square knot to secure the four suture wraps (Figure 5). Lastly, the free end of the suture is pulled toward the surgeon to flatten out the knot (Figure 6).

Experience

The mean knot strength for the 4-S modification of the Roeder knot was 28.01 ± 11.45 N,[1] which compares favorably to laparoscopic sliding square knots with multiple throws. We have used this knot predominantly for colposuspension and soft tissue pedicle ligation during oophorectomy and hysterectomy for more than 2 years. We have found it easy to tie and have not seen the slippage we have experienced with the Roeder knot.

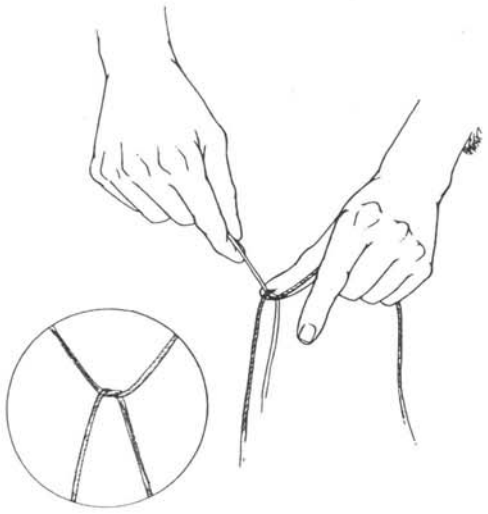

Figure 1. In step one, a single throw of the suture. (Reprinted with permission from Sharp HT, Dorsey JH, Chovan JD, Holtz PM. A simple modification to add strength to the Roeder knot. J Am Assoc Gynecol Laparosc 1996;3:305–7.)

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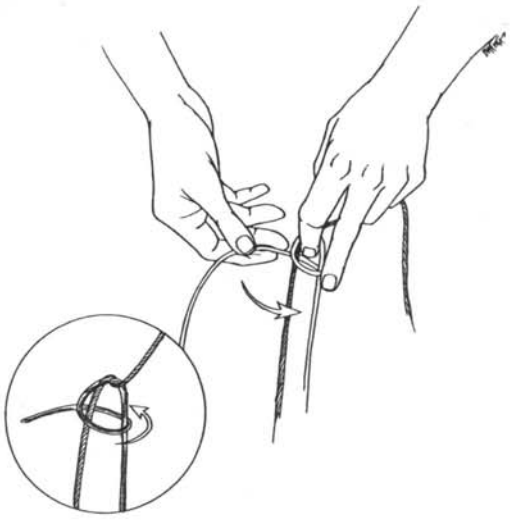

Figure 2. In step two, the free end of the suture is wrapped over the top of the suture loop. (Reprinted with permission from Sharp HT, Dorsey JH, Chovan JD, Holtz PM. A simple modification to add strength to the Roeder knot. J Am Assoc Gynecol Laparosc 1996;3:305–7.)

Comment

We recommend using the strongest laparoscopic knots when performing any procedure that requires continued tension on tissues. Multiple-throw knots such as the intracorporeal flat square and the extracorporeal sliding square knots are comparable to conventional square knots in terms of knot strength.[5] Slip knots are unique in that they can be tied extracorporeally and be

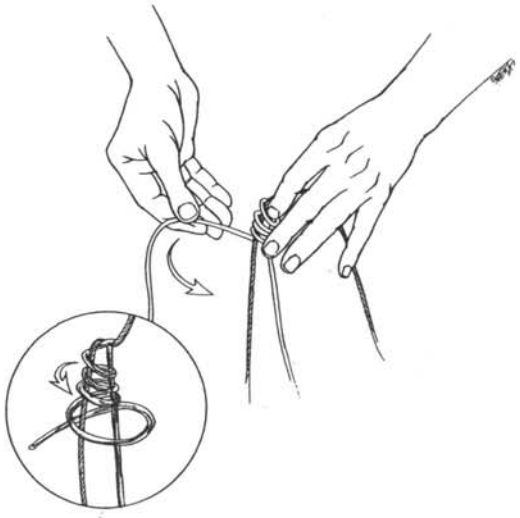

Figure 3. In step three, the free end of suture is wrapped an additional three times around the suture loop (to make a total of four loops). (Reprinted with permission from Sharp HT, Dorsey JH, Chovan JD, Holtz PM. A simple modification to add strength to the Roeder knot. J Am Assoc Gynecol Laparosc 1996;3:305–7.)

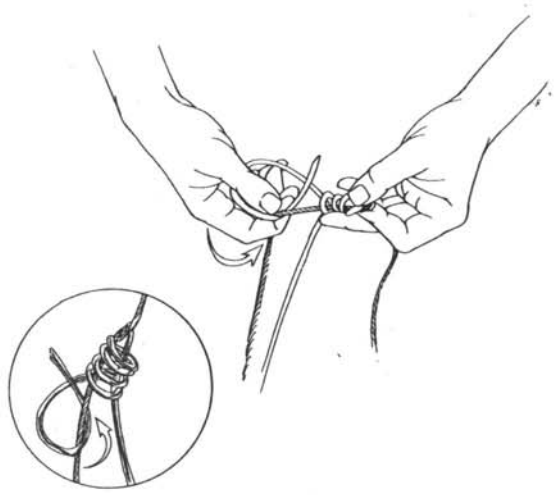

Figure 4. In step four, the free end of suture is passed from anterior to posterior around the proximal leg of the suture loop to form a half-hitch. (Reprinted with permission from Sharp HT, Dorsey JH, Chovan JD, Holtz PM. A simple modification to add strength to the Roeder knot. J Am Assoc Gynecol Laparosc 1996;3:305–7.)

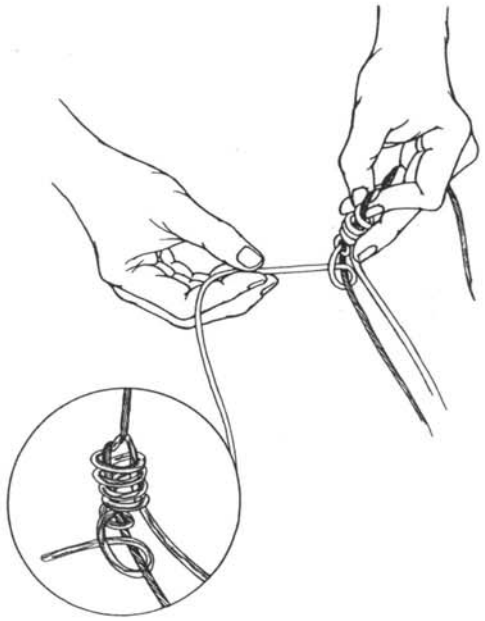

Figure 5. In step five, the free end of suture is passed from posterior to anterior around the proximal leg of the suture loop to complete a square knot.

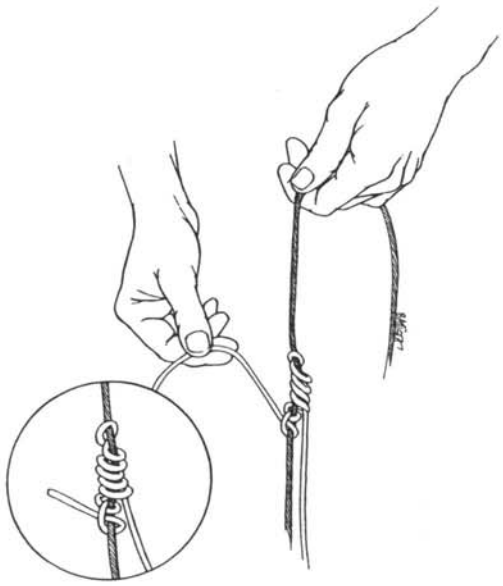

Figure 6. In step six, the free end and the anchored end of the suture are pulled toward the surgeon to flatten out the knot before sliding it down with a knot pusher.

passed to the target tissue with a single pass of a knot pusher. However, because of the inferior geometry of most slip knots, the convenience of a single pass through a laparoscopic port often is offset by decreased knot strength. The 4-S modification of the Roeder knot is a convenient single-throw knot with strength comparable to multiple-throw square knots.

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SURGICAL TECHNIQUE

A SIMPLIFIED TECHNIQUE FOR LAPAROSCOPIC INSTRUMENT TIES

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A technique is described which simplifies intracorporeal knot-tying during laparoscopic surgery. The technique is applicable to both novice and experienced laparoscopic surgeons, and has ergonomic, cost and safety advantages over previously reported methods.

Key words: laparoscopy, suture-techniques.

INTRODUCTION

The evolution of laparoscopic surgery has relatively rapidly reached the stage where complicated abdominal operations are being attempted. In an attempt to change only the mode of access, the dictum of performing the same operation laparoscopically as at laparotomy has become established. Unfortunately, as surgeons confront the difficulty of intracorporeal knot-tying, this feature of traditional operations is frequently forsaken in favour of novel and untested methods of tissue approximation that are quicker and simpler to perform. The technique described herein simplifies the tying of intracorporeal knots, eliminating the inefficiencies and frustrations of previous methods. With limited practice on an endotrainer, the present authors have witnessed novice laparoscopic surgeons become proficient in this technique within a short period of time.

SURGICAL TECHNIQUE

The suture is loaded into the port by grasping it just behind the needle, with the needle pointing in the direction it will be passed through the tissue. If the suture is grasped too far back from the swage on the needle, time is wasted attempting to correctly orientate the needle in the needle-holder. Either straight, ski or curved needles can be used. Twenty-six millimetre curved needles will pass down a 10/11 mm Ethicon port without requiring back-loading into a sleeve (Fig. 1).

The needle is passed through the tissue to be approximated and is immediately brought out of the same port. The thread is then carefully pulled by hand until a short tail of only 1–1.5 cm is left as the working end (Fig. 2). This prevents the tail being tangled into the knot as it is locked down. The suture itself is then grasped by the

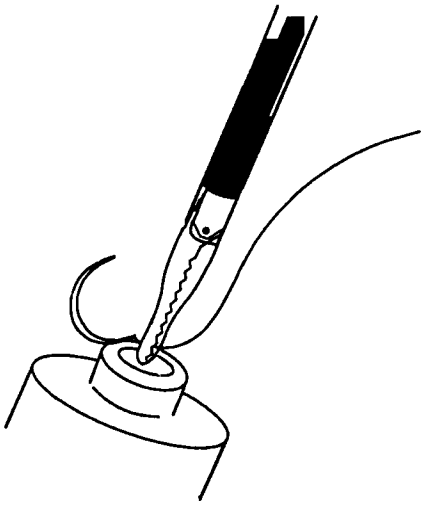

Fig. 1. The suture is loaded directly into the port.

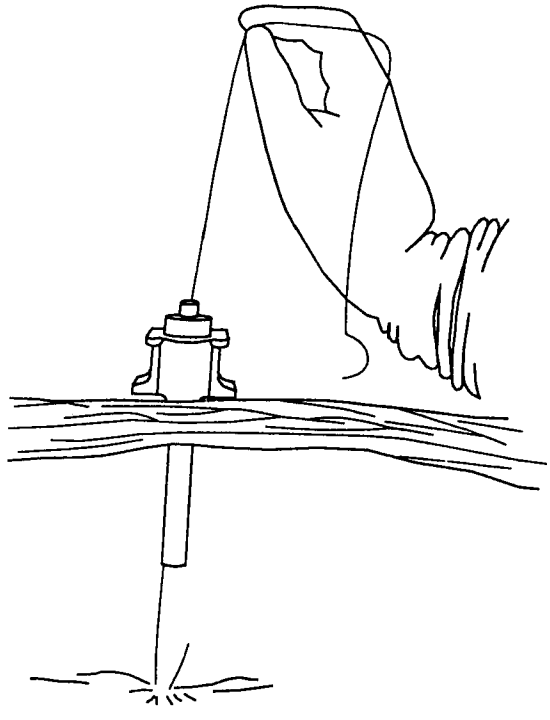

Fig. 2. The needle is brought back out of the entry port.

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needle holder which is geographically on the same (right hand) side as the tail (Fig. 3). By keeping the suture close to the tail as pictured, ergonomically wasteful movements are avoided, and the whole procedure can be kept within the field of vision of a stationary laparoscope. Note that the suture material enters the medial aspect of the needle-holder, facilitating the formation of a 'C-loop'. The suture is then wound twice around the left hand side graspers, the jaws of which are held open to prevent the throws slipping off (Fig. 4).

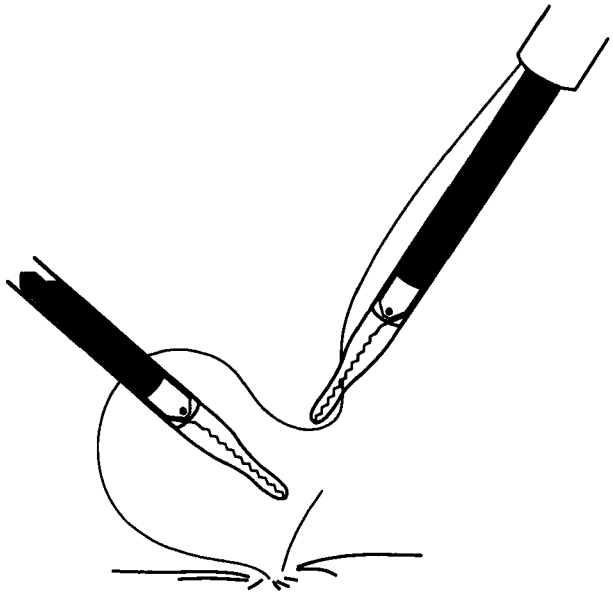

Fig. 3. The suture enters the medial aspect of the needle-holder forming a C-loop.

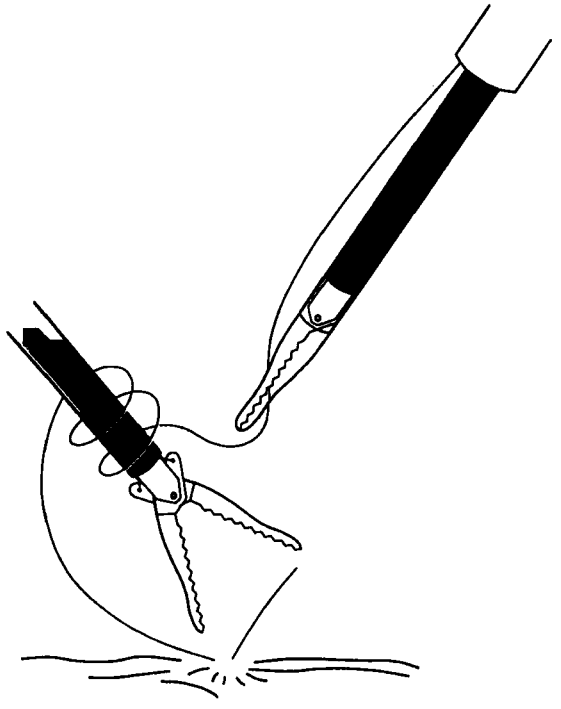

Fig. 4. The suture is wound twice around a stationary needle-holder.

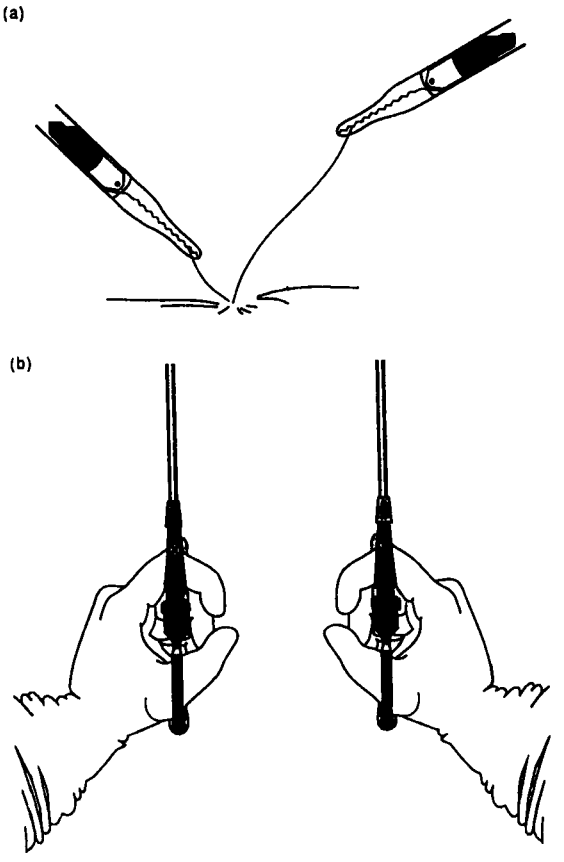

Fig. 5. When the knot is (**a**) pulled tight, (**b**) the surgeon's palms face inward.

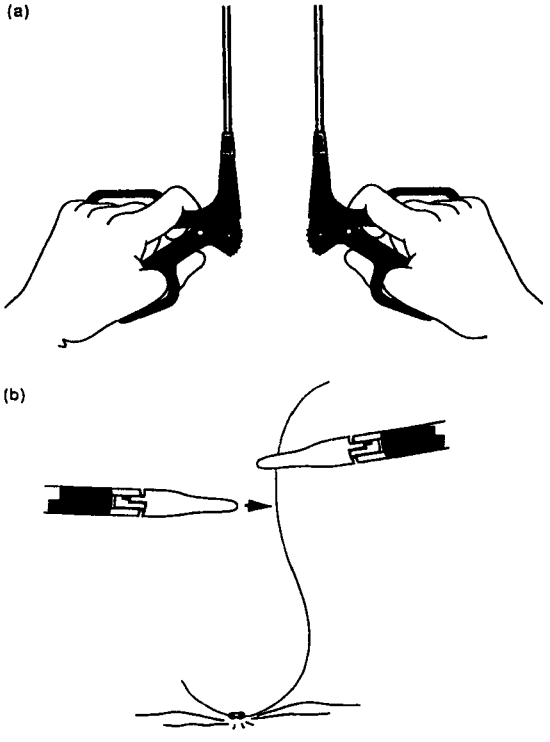

Fig. 6. (**a**) The 'palms down' action facilitates (**b**) passing the suture from one needle-holder to the other in the correct orientation.

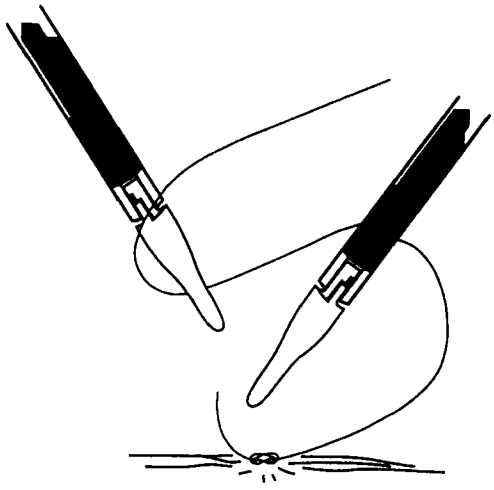

Fig. 7. As the palms are again brought to face inward, the suture falls naturally into another C-loop for the second throw.

The tail is then grasped, and the throw secured by pulling the threads in opposite directions. At this stage the surgeon's palms are usually facing inward towards each other (Fig. 5). The tail should be released, and the crucial 'palms down' action (Fig. 6) enables the suture to be passed from one needle-holder to the other so that it is correctly positioned over the tail, entering the medial aspect of the needle holder on that side, and naturally falling into a C-loop to facilitate the winding on of the second throw (Fig. 7). Sometimes it is necessary to pull down a greater length of suture if the C-loop is too small and difficulty is experienced achieving the second throw. These steps are repeated for the desired number of throws, each of which is in opposite directions in order to achieve a square knot.

DISCUSSION

The technique described works best with sutures that retain 'memory', particularly monofilament sutures such as Prolene or PDS (Ethicon Inc., North Ryde, NSW). If sutures with more pliable handling properties are employed such as Vicryl (Ethicon) or silk, the technique should be modified whereby a short (15 cm) thread is placed completely within the abdomen, so that the needle is not withdrawn out of the port. The C-loop is then formed on the working end by holding the needle rather than the thread emerging from the port.

The described technique has several advantages over previously reported methods.[1-4] It is ergonomically more economical because all movements occur within the field of vision of a stationary laparoscope thereby minimizing frustration and operator fatigue. There is no need to twist the needle-holder on its long axis to wind throws on, as the thread falls naturally into position. This technique provides cost-savings because a single thread can be reused for multiple sutures, and standard sutures can be used rather than more expensive specifically laparoscopic sutures. Because the needle is withdrawn outside the abdomen this technique also has superior safety, eliminating the possibility that an intracorporeal needle might pass out of the visual range risking unwitnessed damage to adjacent organs.

In conclusion, the application of this technique simplifies the hitherto tedious task of laparoscopic instrument ties, dispensing with the possibility of compromise to the techniques of well-established operations by introducing novel untested methods of tissue approximation.

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Instruments & Methods

A NEW CLINCH KNOT

Peter V. Weston, MD

A new slip knot is introduced. It can be used as the beginning knot of a running suture and for ligation of pedicles where accessibility is limited. When used at the beginning of a running suture to close abdominal-wall fascia, the knot can be safely used with monofilament material such as polydioxanone. It locks readily, it takes less time to tie than numerous square knots, and it is not as bulky as other knots. The clinch knot has been found to be especially useful for securing pedicles in relatively inaccessible places such as the infundibulopelvic ligament when performing oophorectomy at the time of vaginal hysterectomy. During endoscopic surgery, the knot has been used as an alternative to the Endoloop and as the preferred knot to secure the Endo-knot. ***(Obstet Gynecol 78:144, 1991)***

Knot tying is often taken for granted. The square knot and the surgeon's knot are the only knots usually taught to residents. Gynecologic and surgical textbooks devote little or no space to alternate knots. The square knot is ideal for tying pedicles and for tying two sutures together, but it is not the perfect knot for tying the initial knot of a continuous suture. Continuous traction on one end of the knot, especially when using monofilament suture, tends to convert the knot into a series of half hitches. This can cause the knot to slip and loosen, even if the initial throw is a double twist as in a surgeon's knot. Because of slippage, Knight and Griffen[1] have recommended using six throws of the knot when using a continuous monofilament suture to close abdominal incisions. Gallup et al[2] also recommended the addition of a small hemoclip to prevent unraveling. Archie and Feldtman[3] advocated at least eight knots. This article introduces a knot that overcomes this difficulty.

Oophorectomy is not routinely performed at vaginal hysterectomy, even in patients in whom it would be undertaken if the hysterectomy were performed abdominally. The reason for this is that the infundibulopelvic ligament is often too far from the introitus to be tied safely. In most instances, this problem can be overcome by using the clinch knot and securing it in place with the forked knot pusher.

Description of the New Clinch Knot and an Instrument for Tightening the Knot

Before describing the knot, certain knot-tying terms will be defined (Figure 1). "Standing part" is the long strand of the material or the part to which the needle is attached. "Bight" is the loop around which the knot is made. "End" is used to fashion the knot. "Hitch" is described as a turn with the end under the standing part.

The legend to Figure 2 describes how to tie the new clinch knot using knot-tying terms. The figure illustrates the stages in the development of the knot and the final appearance. Figure 3 is a series of sketches demonstrating a practical way of tying the knot. Surgeons should become familiar with tying the various parts with either hand. If the end is on the left side of the surgeon, the right hand should be used to make the first loop, and vice versa. The demonstration shows the first part being tied with the right hand. When the knot is completed, traction applied to the standing part slides the knot into position.

An alternate method of tightening the knot consists of using an inverted spoon-like instrument with a V-shaped groove through which the standing part is passed (Figure 4). The standing part is held firmly while the instrument is pushed against the part of the knot labeled "C" in Figure 2, thereby closing the loop and securing the tissues.

Discussion

The clinch knot is a true slip knot but differs from other slip knots because the direction of the standing part is

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The author is grateful to Mr. John Martini for the artwork.

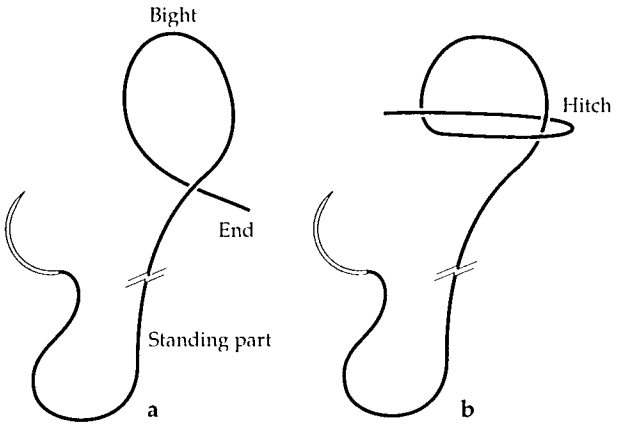

Figure 1. a) Knot-tying terms. b) A simple hitch.

distorted in four places, as shown in Figure 2d. Other slip knots such as the fisherman's knot, the Brooks knot,[4] and the Roeder loop[5] are not as efficient. The fisherman's knot and the Brooks knot distort the direction of the standing part in only one place. The Roeder loop, which is the knot used in the Ethiloop, distorts the direction of the standing part in two places. Slippage of the Roeder loop has been documented by Hay et al.[6] Thus, when the new clinch knot is compared with the other surgical slip knots, it is more efficient and less likely to slip.

After the new clinch knot has been tied, traction of the "end" securely locks the knot by placing a bight in the standing part, thereby giving the appearance of a bowline knot. However, if traction is applied to the end before the loop has been tightly closed, the knot will lock prematurely; the suture will have to be removed and new suture applied. Surgeons must resist the temptation to pull on the end before the knot is securely in position.

Many authors have recommended closure of the fascia of abdominal-wall incisions with running sutures of monofilament material.[1–4] The new clinch knot has a smaller knot volume than multiple throws of square knots and the Brooks knot. Trimbos et al[7] recommended that large-volume knots not be used. The greater the knot volume, the greater the tissue reaction.[8] My method of abdominal-wall closure is to use two running sutures of monofilament material such as polydioxanone. Each starts with the new clinch knot at opposite ends of the incision. The two sutures are tied together at the middle of the incision using a surgeon's knot with six throws. The knots are all buried to reduce the likelihood of postoperative discomfort. This method can be used with transverse and vertical incisions. The knot can also be used at the beginning of any running suture.

Tying knots deep in the pelvis or at the apex of the vagina requires surgical dexterity. It is imperative that the surgeon keep one or both of the index fingers at the level of or below the knot to prevent the suture from being pulled off of the pedicle. Figure 5 demonstrates that deep pedicles can be safely ligated with the forked knot pusher. Oophorectomy at the time of vaginal hysterectomy is a procedure in which the clinch knot together with the forked knot pusher can be extremely useful. The knot has been used to place sutures in the tonsillar bed, where accessibility is limited.

The greater the variety of surgical procedures performed endoscopically, the greater will be the need to suture tissue and to tie knots. Instrument knot tying is time-consuming and difficult. Semm[9] described a technique using the Ethi-endo suture. His method is to suture the tissues, remove the needle, make a Roeder knot, and push it into position under direct vision. The new clinch knot can be used to replace the Roeder loop. Laparoscopic procedures that require ligation include oophorectomy, partial or complete salpingectomy, appendectomy, myomectomy, ligation of arterial bleeders and vascular pedicles, closure of uterine lacerations, etc. These surgical procedures have been well documented by Semm.[5]

A videotape demonstrating tying of the knot and surgical applications is available from the author. Al-

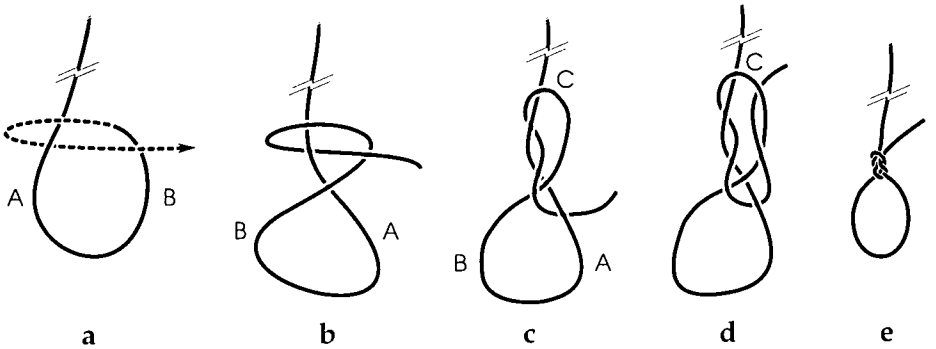

Figure 2. The clinch knot. a) After making a bight, a right-hand hitch is made around the standing part. b) The strand of the bight (B) is twisted over the strand (A). c) The end is passed over (B) and under (A). d) The end is passed under (C) to end up adjacent but running in the opposite direction to the standing part. e) The completed knot is tightened.

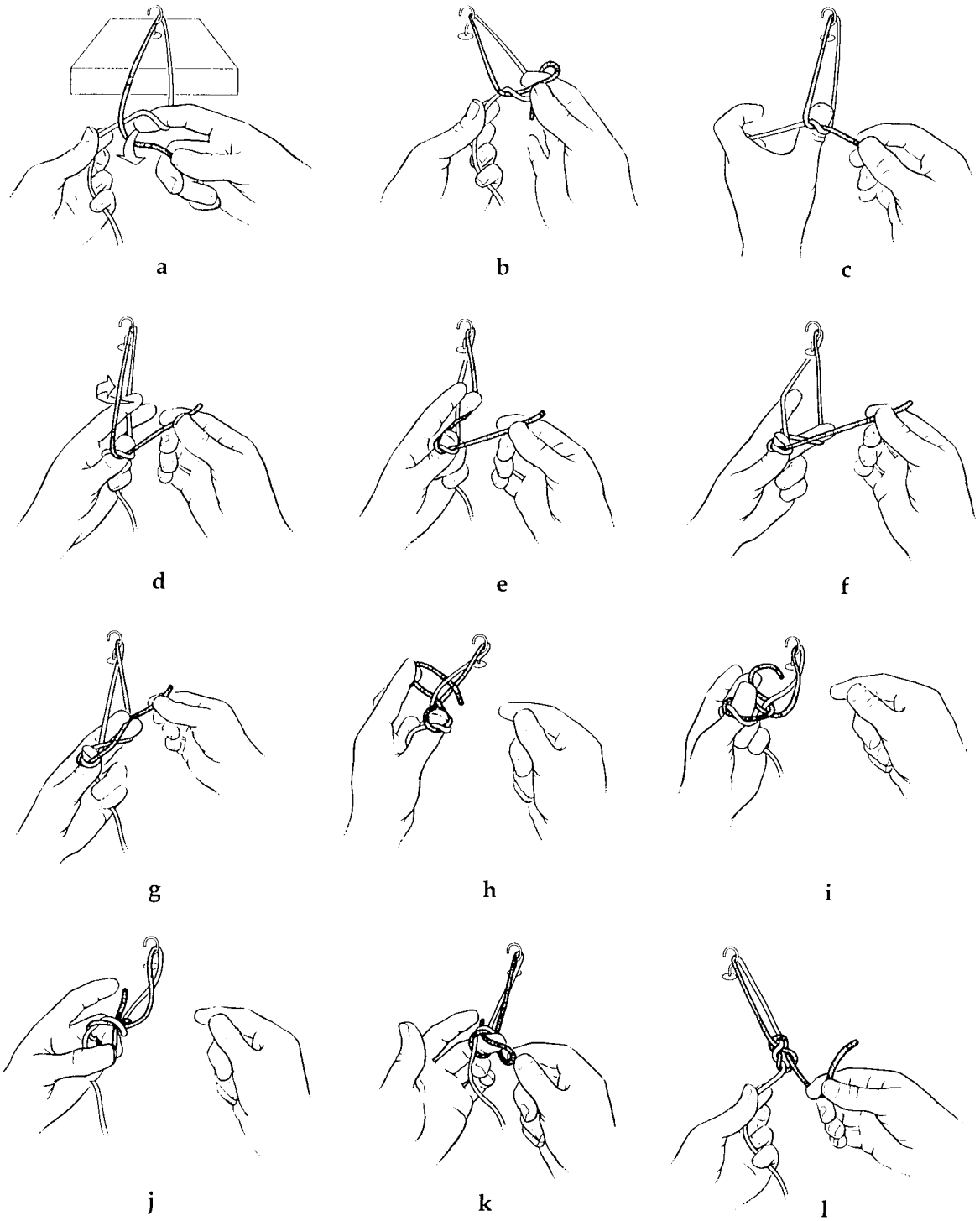

Figure 3. Steps in tying the clinch knot. a) The end is hatched. A knot-practicing block is shown. Hold the standing part between the thumb and index fingers of the left hand and with the acutely flexed fifth finger against the palm of the hand. The end is held with the thumb and third finger of the right hand. The end must lie above the standing part. Place the right index finger over the standing part. b) Make the first loop of a square knot with the right hand by placing the right index finger within the bight and using it to pull the end through the bight. Continue to hold the end with the right hand. c) Place the left thumb inside the loop while still holding the standing part with the fifth finger. d) Pass the second and third fingers under the end and grasp the standing part of the bight. e) Bring the standing part to the left with the third finger between the two strands. f) Place the left second finger next to the third finger between the two strands; separate the fingers. g) Use the second and third fingers of the left hand to grasp the end. h) Pull the end between the two strands. i) Grasp the end with the left thumb and third fingers. j) Extract the thumb together with the end through the loop. k) Grasp the end with the right hand. l) The finished knot.

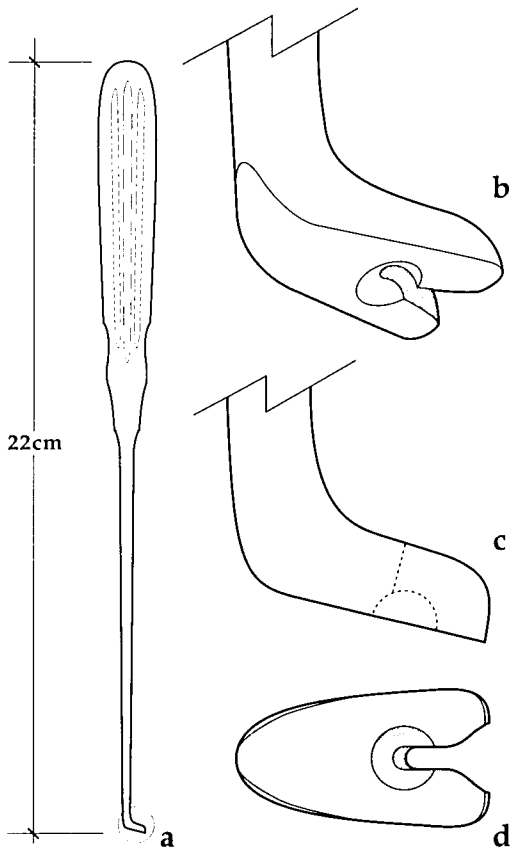

Figure 4. a) The forked knot pusher. b) Angled view of the base showing the V-shaped groove and countersunk area. c) Side views with the broken lines showing the countersunk area and the V-shaped groove. d) View of undersurface of the base.

though the forked knot pusher is not yet marketed commercially, samples are currently available from the author in limited numbers.

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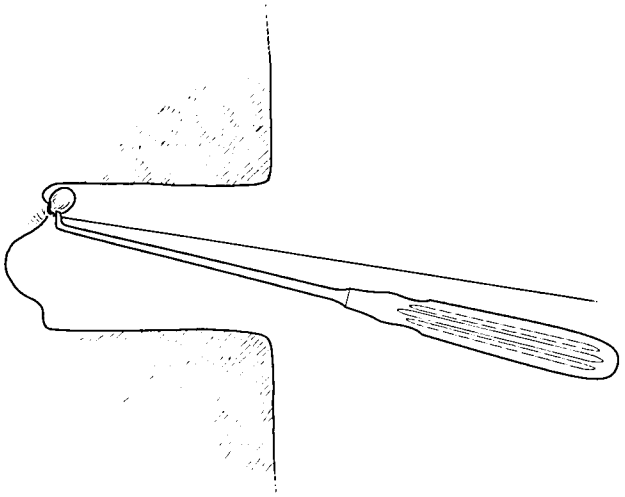

Figure 5. Securing an inaccessible pedicle with the forked knot pusher.

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MODIFICATIONS OF THE CLOSED TECHNIQUE

How much gas is required for initial insufflation at laparoscopy?

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Keywords

insufflation, laparoscopy, Veress needle.

ABSTRACT

Objective To determine how much gas is required for initial insufflation of the abdomen at laparoscopy.
Design A prospective observational study.
Setting Specialized minimal access gynaecological operating theatre in a district general hospital.
Subjects 43 female patients undergoing laparoscopy.
Interventions In 30 patients, changes in the vertical depth of the pneumoperitoneum at the umbilicus were measured when the volume and pressure of the insufflated CO_2 was changed. The depth was also measured in response to changes in the downward force applied to the umbilicus with insertion of the primary cannula. Non-invasive monitoring of respiratory and circulatory parameters was carried out on a further 13 patients during these procedures and with variation in head-down tilt.
Main outcome measures The vertical depth of the pneumoperitoneum, and cardiovascular and respiratory parameters.
Results When a downward force of 3 kg force is applied at the umbilicus, the mean vertical depth of the pneumoperitoneum is only 0.6 cm (the range includes zero) when the intra-abdominal pressure is 10 mmHg (approximately equivalent to insufflation of 3 l CO_2). This increases to 5.6 cm (range 4–8) when the intra-abdominal pressure is raised to 25 mmHg. The mean volume of CO_2 required to achieve a pressure of 25 mmHg is 5.58 l (range 3.7–11.1). The maximum respiratory effects of the 25-mmHg intra-abdominal pressure (with the patient flat) are no greater than the effect of the Trendelenburg position with an intra-abdominal pressure of 15 mmHg. No adverse circulatory effects are demonstrated.
Conclusions This 25-mmHg pressure-limited method produces a greater splinting of the abdominal wall and a deeper gas bubble than the traditional volume-limited pneumoperitoneum of 2–3 l, which should lead to a reduced risk of injury.

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INTRODUCTION

Standard textbooks of surgery do not agree on the volume of gas that is required for initial insufflation with the Veress needle, as can be seen from Table 1.[1–9] As with most surgical procedures, the techniques used for laparoscopic entry represent a distillate of the various approaches that an individual surgeon has been taught. There are no adequate randomized controlled trials. assessing the relative safety of the various techniques.[10–13] Very large numbers of patients would be required. For example, to compare two laparoscopic

Table 1 Recommended amounts of gas for initial insufflation with a Veress needle

Monaghan[1]	2–4 l
Sutton[2]	'about 3 l'
Gordon[3]	1–2 l
Soderstrom[4]	'pressure' (not specified)
Deprest & Brosens[5]	'preset pressure' (not specified)
Bruhat[6]	Not specified
Hulka & Reich[7]	20–25 mmHg
Thompson & Rock[8]	'should not exceed 10 mmHg'
Tulandi[9]	2–3 l ('usually')

entry procedures which have a complication rate of 1 per 1000, and to detect a 50% difference in incidence of complications with 80% power, 102 000 patients would be required in each arm of the trial.[14] This is unlikely to be achieved.

This study attempts to look at the technique and purpose of the initial pneumoperitoneum. A system has been developed by one of the authors (G.P.) for assessing the depth of the pneumoperitoneum whilst the primary trocar is being introduced. This allows an objective assessment of the effectiveness of the initial pneumoperitoneum in creating a 'safety zone' into which the first trocar is inserted. In essence it is a gas bubble that must have a significant vertical depth, even when the trocar is being forced in. This study assesses the anterior-to-posterior depth of the pneumoperitoneum while the trocar is being inserted, and this is correlated with the gas volume and pressures used. Circulatory and respiratory parameters were also assessed during the procedure.

SUBJECTS AND METHODS

Permission to conduct this study was obtained from the Hospital Research Ethics Committee, and all patients gave written consent to participation in the study.

A total of 43 patients undergoing routine operative or diagnostic laparoscopies were included in the study. All were ASA I and II. All patients received premedication with temazepam 20 mg orally 1 hour before surgery, and a standard anaesthetic was administered using analgesia (fentanyl), induction agent (propofol), and muscle relaxant (atracurium). The anaesthetic was delivered and monitored using a sophisticated computerized anaesthetic machine (Drager Cato, Drager Medizintechnik, Lubeck, Germany). The cardiopulmonary effects of the pneumoperitoneum were assessed in 13 of these patients.

Tidal volume (600 ml/breath), respiratory rate (12/min), and hence the minute volume (7.2 l/min) were kept constant during the procedure to minimize any changes due to ventilation. Peak ventilator pressure, mean ventilatory pressure, plateau pressure, positive end-expiratory pressure (PEEP), lung compliance, and end-tidal CO_2 were noted during insufflation. Recordings were made with intra-abdominal pressures of 0, 5, 10, 15, 20, and 25 mmHg with the patient in the supine position, together with additional measurements at a pressure of 15 mmHg supine, and 15 mmHg at maximum head-down tilt (approximately 30°), zero mmHg head-down (i.e. abdomen fully deflated), and finally 15 mmHg head-down. Haemodynamic parameters, i.e. systolic, diastolic, and mean blood pressures, heart rate and haemoglobin saturation were recorded simultaneously.

A standard laparoscopic entry technique was used, with the legs in stirrups, the hips abducted to 30° and flexed no more than 10° from the horizontal. The bladder was drained. Bupivicaine 0.5% was injected into the umbilicus in order to provide postoperative analgesia. A small skin incision (sufficient to allow a 10-mm port to fit snugly) was made at the base of the umbilicus and the Veress needle was passed into the peritoneal cavity with the patient flat. The abdomen was insufflated to a preset pressure of 25 mmHg. The Veress was then removed. A short (8–10 cm length) trocar and cannula, held in the palm of the hand, with the index finger placed 1–2 cm behind the tip of the trocar as a depth stop, was pushed vertically through the intra-umbilical incision (i.e. the thinnest part of the abdominal wall, rarely more than 2 cm thick even in the largest patients). The intra-abdominal pressure was then reduced to the conventional pressure of 15 mmHg. A secondary 5-mm port was then placed suprapubically under direct laparoscopic vision. The patient was then tipped into a steep Trendelenburg position. The 25 mmHg pressure was maintained for no more than a few minutes.

Patients were studied as follows: a few drops of fluid were left in the umbilicus with the Veress needle in position and all gas tubing connections checked to ensure that the system was gas-tight. During insufflation, corresponding pressure–volume readings were obtained at 5-mmHg pressure intervals. In order to measure the vertical depth of the pneumoperitoneum at the level of the umbilicus, the intraumbilical laparoscope was removed and a 5-mm laparoscope inserted via the suprapubic incision. A depth gauge was inserted at the intraumbilical port, allowing depth measurements

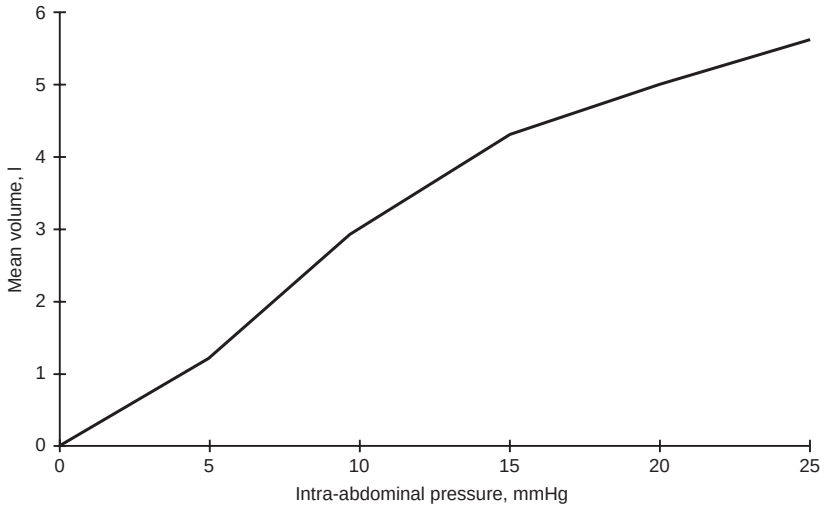

Figure 1 Volume–pressure relationship during insufflation.

to be made at the level of the umbilicus (to an accuracy of ± 5 mm). A specially designed device was used to exert known downward pressures of 1, 2, 3, 4 and 5 kg force on the intraumbilical port.

The intra-abdominal gas was then evacuated, and insufflation started over again. The depth from the underside of the umbilicus to whatever was immediately below (bowel or omentum in most cases) was measured at 5-mmHg pressure steps up to 25 mmHg, with 0, 1, 2, 3, 4 or 5 kgf downward force exerted on the umbilical port at each pressure setting. After these measurements had been made, the pressure was reduced to 15 mmHg, the patient tipped head-down, and the operative procedure then continued. These forces were used because a previous study[15] had reported that the mean peak pressure required for insertion of one particular make of disposable trocar and cannula was 3.2 kgf (7.14 pounds-force, standard deviation 5.35 pounds force).

RESULTS

The 30 patients had a mean age of 33.8 years (range

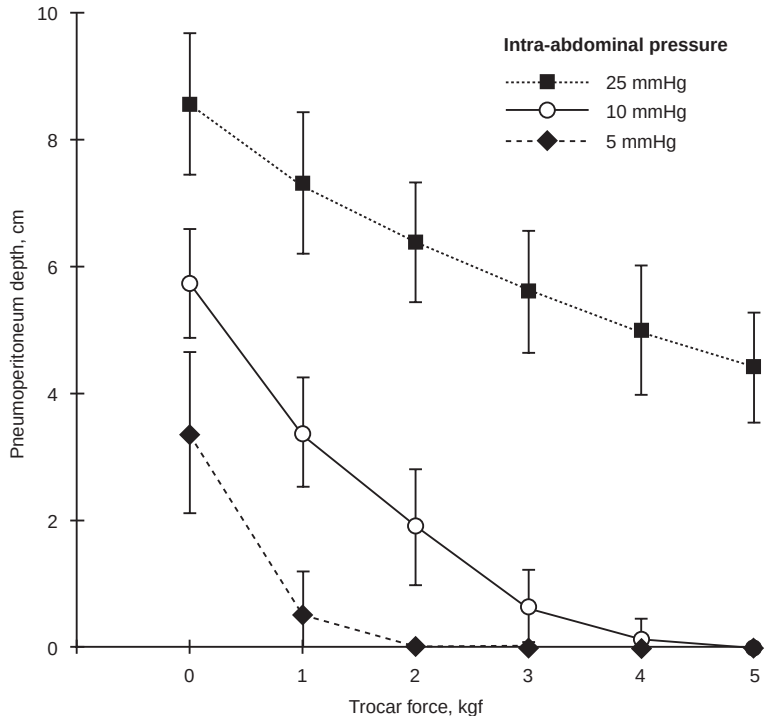

Figure 2 Effect of trocar force and intra-abdominal pressure on the pneumoperitoneum depth.

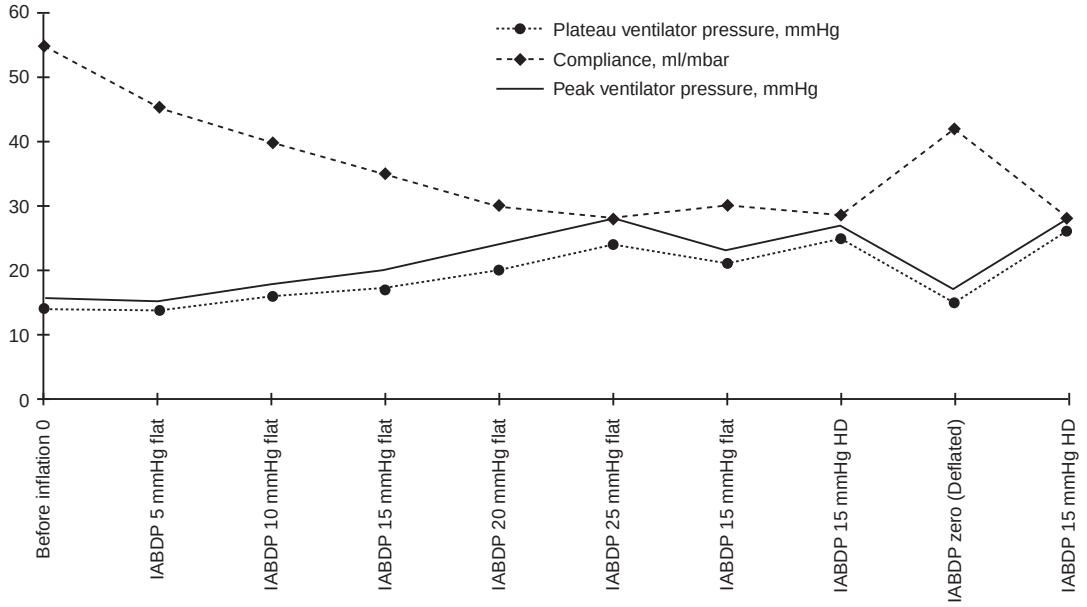

Figure 3 Relationship between intra-abdominal pressure, ventilator pressure and compliance. Mean peak ventilator pressure, mean plateau ventilator pressure, lung compliance with change in intra-abdominal pressure (IABDP) and patient tilt (head-down HD).

19–49), height 1.61 m (range 1.50–1.78) and weight 64.1 kg (range 44.5–85.9), a parity range of 0–3 (mode 2) and six patients had undergone at least one previous laparotomy.

The relationship between volume and pressure is illustrated in Fig. 1. The mean pressure produced by a 3-l pneumoperitoneum was 10.3 mmHg. In order to produce a pressure of 25 mmHg, a mean of 5.58 l gas was required (minimum 3.7 l and maximum 11.1 l). The patient who required 11.1 l was was 9 weeks postpartum and not particularly large (height 67 inches, weight 136 pounds, with no previous surgery, and only mild striae gravidarum) and yet she required 2.9 l more gas than anyone else. There were no other postpartum patients in this series.

The mean depth of the pneumoperitoneum at 10 mmHg was 5.75 cm when no downward pressure was applied to the umbilical port. However, this reduced to 0.65 cm when 3 kgforce was applied—a reduction of over 5 cm. At 4 kgforce and over there was no gap (i.e. depth 0 cm) between the underside of the abdominal wall and the underlying structures in any of the patients, at 10 mmHg pressure. The abdominal wall is therefore very flaccid at this pressure and with poorly performing trocars 3 kgforce will be exceeded almost every time. However at 25 mmHg, although the depth of the pneumoperitoneum increased by 50% to 8.58 cm when there was no downward force on the umbilicus, the depth when 3 kgforce was applied was still 5.63 cm (range 4–8) an increase of 766% (almost 5 cm) compared with the 10-mmHg pneumoperitoneum. (see Fig. 2). The most important result was that the minimum depth of 4 cm at 25 mmHg with 3 kgforce was always maintained, indicating that this

Table 2 Circulatory parameters with different intra-abdominal pressures and patient tilt

	Patient tilt, and intra-abdominal pressure, mmHg									
	Flat							Head-down		
Circulatory parameters	0	5	10	15	20	25	15	15	0	15
Haemoglobin saturation, %	98	98	98	98	98	99	98	98	99	98
Heart rate, per minute	85	86	84	85	80	81	82	85	86	85
Systolic blood pressure, mmHg	125	126	123	134	124	123	132	122	120	125
Diastolic blood pressure, mmHg	76	78	75	89	81	83	89	80	68	70
Mean blood pressure, mmHg	85	85	84	90	95	95	95	92	89	89

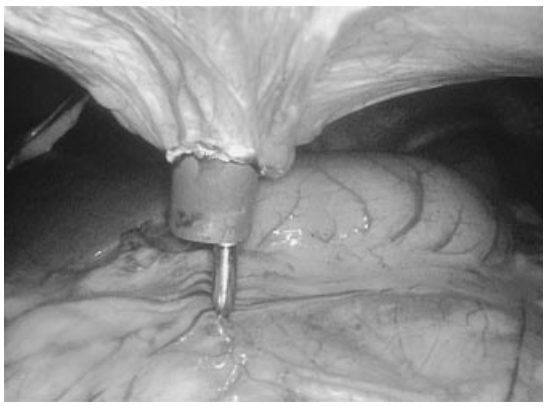

Figure 4 Laparoscopic photograph of a trocar inserted at the umbilicus with 3 kgforce and with an intra-abdominal pressure of 15 mmHg (approximately equivalent to 4 l of gas insufflation).

pressure always gave a satisfactory depth to the pneumoperitoneum. It should also be noted from Fig. 2 that there is no overlap between any of the curves clearly illustrating the massive benefit of the higher pressure.

The mean peak ventilator pressure and mean plateau ventilator pressure increased in line with the initially increasing intra-abdominal pressure, and as might be expected this was mirrored by the falling lung compliance (Fig. 3). Maximum mean compliance occurred prior to insufflation with the patient flat (55 ml/mbar). Once the abdomen was deflated, compliance increased and ventilator pressures dropped even with the patient in the head-down position. It would appear then that the maximum adverse effect of this technique (patient flat, intra-abdominal pressure 25 mmHg) on lung compliance is no worse than that which is obtained using the more conventional lower pressure (15 mmHg) technique with the patient head-down. Change in the intra-abdominal pressure or in the patient's position caused no significant changes in mean systolic or diastolic blood pressures, mean heart rate or mean haemoglobin saturation (Table 2).

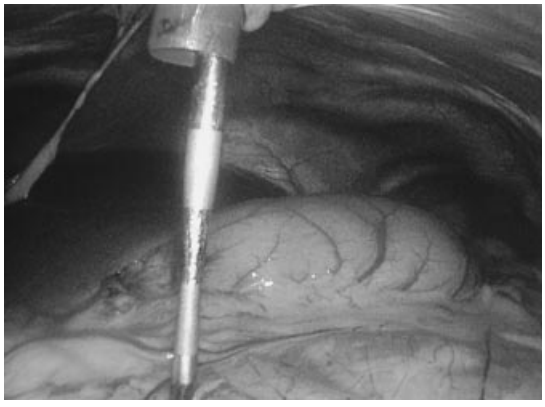

Figure 5 Laparoscopic photograph of a trocar inserted at the umbilicus with 3 kgforce and with an intra-abdominal pressure of 25 mmHg.

DISCUSSION

The entry technique which has been used in our departments for many years involves inflating the peritoneal cavity to a preset pressure limit of 25 mmHg (with the patient flat) using whatever volume is required, via an intraumbilical Veress needle. Certainly one reason for using a set pressure end-point rather than a volume-limited insufflation is that, if there are any leaks in the system, the volume recorded on the gas insufflator is utterly meaningless. Figures 4 and 5 illustrate the importance of an adequate pressure within the peritoneal cavity. If the surgeon uses a technique which requires a pneumoperitoneum, then a volume limit simply does not give a reliable safety zone.

Our results clearly show that the depth of the pneumoperitoneum during trocar insertion is determined by the pressure rather than by the volume of gas insufflated. As can be seen from the large variation in volume required to achieve any particular gas pressure, it would be exceedingly unwise to assume that one particular volume of gas can be used for all patients. For instance 4 l of gas in a patient who requires 11 l to reach an intra-abdominal pressure of 25 mmHg (e.g. the postpartum patient described), will simply not prevent the trocar tip from touching underlying bowel.

It must be emphasised that Fig. 2 shows the mean plus range (not standard deviations), and that at 25 mmHg the minimum depth of the pneumoperitoneum is over 4 cm, even with 5 kgforce of downward force from the trocar. Intuitively, this should represent an increased margin of safety. The most reserved conclusion is that insufflation should be pressure- and not volume-limited. There is as yet no published large series on this high pressure technique, although our clinical experience suggests that it has an excellent safety record.

In summary the technique described here involves four essential steps.

1 Use an intraumbilical incision: the base of the umbilicus is the thinnest part of the abdominal wall and the peritoneum is adherent. It is also better cosmetically.
2 Insufflate to 25 mmHg with the patient flat.
3 Use a short trocar and cannula (8–10 cm), inserted vertically initially.

4 Use the index finger placed 1–2 cm behind the tip as a depth stop, so that the trocar only reaches the gas bubble.

This study demonstrates that there are no untoward circulatory or ventilatory effects from creating a 25-mmHg pneumoperitoneum when the patient is in the supine position. It also demonstrates the dramatic increase in the margin of safety (as measured by the depth of the pneumoperitoneum) for insertion of the primary trocar when the 25-mmHg pressure limit is used, and illustrates that the volume of the pneumoperitoneum is meaningless and irrelevant.

ACKNOWLEDGEMENTS

Dr Robert Royal helped develop the equipment used for these measurements, with the Department of Medical Physics at the South Cleveland Hospital.

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The Royal Australian and New Zealand College of Obstetricians and Gynaecologists

College Statement
C-Gyn 7
1st Endorsed: April 1990
Current: March 2012
Review: March 2015

C-Gyn 7

Use of the Veres needle to obtain pneumoperitoneum prior to laparoscopy

Consensus statement of the Royal Australian & New Zealand College of Obstetricians & Gynaecologists (RANZCOG) and the Australasian Gynaecological Endoscopy and Surgery Society (AGES).

Laparoscopy using the Veres needle has been performed by gynaecologists since 1970. Members in gynaecological training and Fellows of the RANZCOG have been trained in insertion of the Veres needle with the same skill and care as when taught peritoneal entry at laparotomy by consultants.

Teachers adopt specific techniques and guidelines when instructing junior doctors in the application of the Veres needle. These include amongst others: intra-umbilical incision, direction away from major vessels, modification of the technique or consideration of alternative sites following previous surgery and consideration under some circumstances of the use of micro-laparotomy technology when underlying adhesions are suspected.

In gynaecological practice, laparoscopy is a procedure which may need to be repeated several times over a patient's lifetime (eg for infertility, endometriosis, and/or pelvic pain).

Adhesion formation is rare as a result of a repeated use of closed laparoscopy whereas adhesion formation is more likely with Hasson technique.

Complication rates from the Veres needle insertion are reported to be in the order of 1:1000-1500. The method used to obtain pneumoperitoneum should remain at the discretion of the surgeon, depending on skill, individual case judgement and previous training.

AGES Entry Guidelines

Intraumbilical Veres Needle Entry

This technique of inserting the Veres needle has been developed as a guideline by the Australasian Gynaecological Endoscopy and Surgery Society.

Preparation
Patient cleaned, draped and bladder emptied. No tilt. Palpation of the aorta and sacral promontory if possible.

Instrumentation
Minimal equipment standards. Veres needle: assess sharpness and spring mechanism prior to insertion. Gynaecologists should ask for a disposable Veres if not happy with the state of the reusable entry Veres that is handed to them.

Insufflator and tubing - assess correct connections and free flow of CO_2 with Veres attached. Assess baseline pressures in system.

Light lead, camera and laparoscope - produces adequate lighting, resolution and white balance system.

Trocars - appropriately functioning trocars.

Scalpel blade - size 15 or size 11 preferable.

Incision
Intra-umbilical incision of dermis. Preferable technique of the blade cutting up and out from centre of umbilicus.

Insertion of Veres
- Tap open
- Insertion perpendicular to skin, aiming for centre of the pelvis (with/without abdominal wall elevation dependant on patient habitus)
- Constant gentle pressure
- A single or two 'pops' may be felt (fascia and peritoneum)
- Cease insertion as soon as peritoneal entry achieved

Test placement
Gas pressure- observe patient pressure and flow. These should be adequate assessments of whether the Veres needle is in the intra-abdominal space (in the correct position). Some gynaecologists may chose to also perform an aspiration test or a syringe test. These extra tests are not mandatory. The 'swinging needle' test, where the tip of the Veres is manipulated, should be avoided as it may compound any injury.

If placement of the Veres needle fails after 3 attempts consider abandoning the procedure or look at alternative entry methods or ask for senior assistance.

Insufflation
Commence insufflation at 1 litre per minute. Initial pressure in the non obese patient should be less than 8mm Hg. Sometimes it can be 10mm Hg if the patient is significantly overweight or if insufflating at Palmer's point (left mid clavicular line below the last rib). Volume insufflated should be sufficient to allow splinting of the abdominal wall for initial port entry without any anaesthetic complications. Some gynaecologists may choose to hyperdistend the abdominal cavity to an insufflation pressure of 25mm Hg before inserting the ports. Once the ports have been inserted this insufflation pressure should be reduced to maximum 15mm Hg.

Insertion of trocar
Perpendicular to skin, then aiming for the centre of the pelvis. Finger down trocar to act as guard. Constant pressure and/or twisting motion. Cease trocar insertion as soon as tip of trocar is in the peritoneal cavity. Insert laparoscope to confirm cannula is in the peritoneal cavity. Inspection should then occur with the laparoscope to 360 degrees. This is to check underlying bowel and vascular structures for possible injury.

Alternative Entry Techniques

- Insertion of Veres needle at Palmer's point
- Hasson open laparoscopy technique
- Direct entry technique
- Suprapubic entry of Veres needle

Other suggested reading

A consensus document concerning laparoscopic entry techniques: Middlesbrough, March 19-20 1999.

Laparoscopic Entry: A Review of Techniques,Technologies and Complications. SOGC Clinical practice guideline. May 2007.

Australasian Gynaecological Endoscopy and Surgery Society
http://www.ages.com.au

DIRECT ENTRY

PREPARATION

- Pt cleaned, draped and bladder emptied.
- No tilt.
- Palpation of the aorta and sacral promontory if possible.

INSTRUMENTATION

Minimum equipment standards:

- Insufflator & tubing – assess correct connections and free flow of CO2.
- Light lead, camera and laparoscope – Produces adequate lighting, resolution and white balanced.
- Trocars – Correctly fitting with sharp or muscle splitting tips.
- Scalpel – Size 15 blade preferably.
  If number 11 blade cut from deep to superficial with Abdominal wall elevation

INCISION

- Adequate intrai-umbilical incision with abdominal wall elevation.

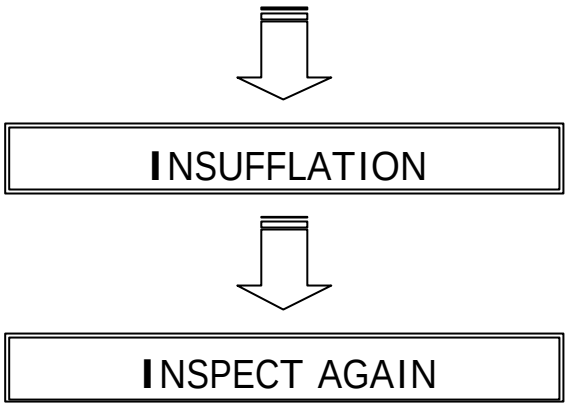
INSERTION OF TROCAR

- Elevation of the abdominal wall
- Perpendicular to skin, then aiming for the centre of the pelvis, once through skin.
- Constant pressure and 'twisting' motion.

If fails after 3 attempts consider abandoning procedure/ alternative entry method/senior assistance.

INSPECTION

- Insert laparoscope to confirm in peritoneal cavity.



- Inspect 360 degrees underlying bowel and vascular structures for injury.

Additional points

The horizontal positioning of the subject allows easier reference to the underlying anatomy. Because of this, tilting or a Trendelenburg position is generally considered less safe.

Palpation of the aorta is especially important in the very thin subject because anatomical variants do occur with the aortic bifurcation occurring below the umbilicus.

The important factors to be remembered at time of trocar entry are entry perpendicular to the skin but at 45^{o} to the pelvis and to remain in the midline at all times. The motion of gentlely twisting the trocar whilst exerting constant moderate pressure allows for a controlled entry.

INTRAUMBILICAL VERESS NEEDLE ENTRY

PREPARATION

- Patient cleaned, draped and bladder emptied.
- No tilt.
- Palpation of the aorta and sacral promontory if possible.

INSTRUMENTATION

Minimum equipment standards

- Veress needle -Assess sharpness and spring mechanism prior to insertion. Disposable may be preferable.
- Insufflator & tubing – assess correct connections and free flow of CO2 with Veress attached. Assess baseline pressures in system.
- Light lead, camera and laparoscope – Produces adequate lighting, resolution and white balanced.
- Trocars – Correctly fitting with sharp tips.
- Scalpel – Size 15 blade preferable.

INCISION

- Intra-umbilical incision of dermis
- If No 11 blade cut up and out from centre of umbilicus.

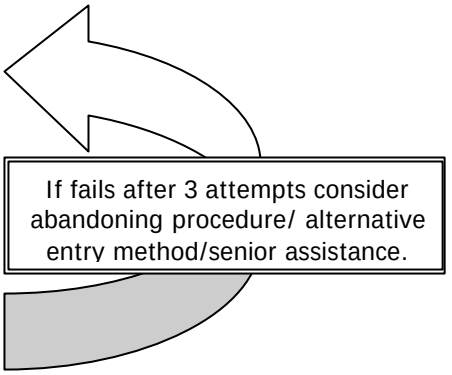
INSERTION OF VERESS

- Tap open
- Insertion perpendicular to skin, aimed to centre of the pelvis (With/without abdominal wall elevation dependent on patient habitus)
- Constant gentle pressure.
- 2 ‘pops’ may be felt(Fascia and peritoneum).
- If inserted through directly through the base of the umbilicus only 1 pop felt
- Cease insertion as soon as peritoneal entry achieved

TEST PLACEMENT

- Gas pressure – Flow resistance should be <8mmHg
- Perform any one of:

Aspiration test.
Syringe test.
Swinging needle test



INSUFFLATION

- Commence at 1l/min, check loss of liver dullness (400mls insufflated).
- Initial Pressure> 8mmHg suggests incorrect positioning.
- Volume insufflated sufficient to allow splinting of abdominal wall for initial port entry, without anaesthetic complications.

INSERTION OF TROCAR

- Perpendicular to skin, then aiming for the centre of the pelvis.
- Finger down trocar to act as guard
- Constant pressure and/or 'twisting' motion.
- Cease trocar insertion as soon as tip of trocar is in peritoneal cavity
- Insert laparoscope to confirm in peritoneal cavity.

INSPECTION

- Inspect through 360 degrees underlying bowel and vascular structures for injury.

OPEN ENTRY

PREPARATION

- Pt cleaned, draped and bladder emptied.
- No tilt.
- Palpation of the aorta and sacral promontory if possible.

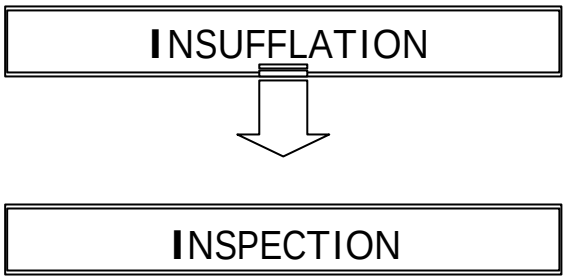
INSTRUMENTATION

Minimum equipment standards

- Insufflator & tubing – assess correct connections and free flow of CO_2.
- Light lead, camera and laparoscope – Produces adequate lighting, resolution and white balanced.
- Trocars – Correctly fitting
- Scalpel – Size 15 preferable.
  -Size 11 if used with abdominal wall elevation and cut from deep to superficial

INCISION

- Periumbilical incision and dissection of fascia and opening of peritoneum with abdominal wall elevation.
- Confirmation of peritoneal entry(Omentum/bowel visualised).
- Trocar sleeve/open laparoscopy cannula inserted.



- Insert laparoscope.
- Inspect 360 degrees underlying bowel and vascular structures for injury.

Additional notes

The horizontal positioning of the subject allows easier reference to the underlying anatomy. Because of this, tilting or a Trendelenburg position is generally considered less safe.

Palpation of the aorta is especially important in the very thin subject because anatomical variants do occur with the aortic bifurcation occurring below the umbilicus.

Prevention of intra-operative gas escape can be prevented by inserting a purse–string suture at time of entry to be tied around the trocar sleeve or the use of a Hasson cannula.

VERESS NEEDLE AND DIRECT VISION TROCHAR ENTRY

INTRAUMBILICAL VERESS ENTRY AS PER GUIDELINES

INCISION

- Make appropriate skin incision.

INSERTION OF TROCAR

- Use direct vision, laparoscope controlled entry trochar, with layer by layer entry.
- Remove trochar.
- Insert laparoscope to confirm in peritoneal cavity.

INSPECTION

- Inspect 360 degrees underlying bowel and vascular structures for injury.

Laparoscopic Instrument Insulation Failure: The Hidden Hazard

Anusch Yazdani[a] *and Hannah Krause*[b]

Mater Misericordiae Hospital, Brisbane, Australia[a]; Greenslopes Private Hospital, Brisbane, Australia[b]

Primary Objective: To determine the prevalence of insulation failure in gynaecological laparoscopic instruments
Secondary Objective: To assess the impact of systematic insulation failure testing
Design: Cross sectional Study
Setting: Public tertiary teaching hospitals
Intervention: Systematic insulation failure testing
Main Outcome Measure: Dichotomous assessment of instrument insulation failure. Characterisation of insulation defects.
Results: One hundred and eleven instruments were tested. The overall prevalence of insulation failure was 27% with a rate of 39% in dedicated monopolar instruments. The sensitivity of visual inspection to predict a damaged instrument was 10%. Even when the site of the failure was identified, the defect was only detectable in 35% of instruments without magnification. The mean site of insulation failure was at 71mm from the tip of the instrument, placing the majority of insulation defects within the abdominopelvic cavity during surgery. Following the introduction of routine electrosurgical instrument testing, the prevalence of insulation failure dropped to 5.9% and was completely eliminated in monopolar instruments.
Conclusion: There is an unacceptably high prevalence of instrument insulation failure in gynaecological laparoscopic instruments. Visual inspection is not an appropriate screening mechanism for insulation failure but biomedical testing can eliminate insulation failure in monopolar instruments.

Keywords: Electrosurgery/adverse effects/instrumentation; Equipment Safety; Insulation Failure; Laparoscopy/methods; Surgical Procedures, Minimally Invasive/adverse effects

Since its introduction in the 1960s, monopolar diathermy has been the favoured energy source of gynaecological laparoscopic surgeons on the basis of efficacy, availability and cost effectiveness [1, 2]. While alternative energy modalities, such as ultrasonic shears, have made significant inroads, electrosurgery remains the preferred modality. Yet the practical application of electrosurgery requires a fundamental understanding of electrophysics which is often poorly developed and has only relatively recently been added to gynaecological surgical curricula. Furthermore, electrosurgery requires significant adaptation to minimally invasive surgery due to altered gas dynamics, altered visuospatial skills, restrictions in surgical space and the limitations of the laparoscopic visual field.

Electrosurgical injuries may arise in a number of ways, of which insulation failure is but one [3]. The shaft of an electrosurgical instruments is insulated by a coating that is susceptible to damage through sterilisation, misuse, or general wear and tear. As the insulation is compromised, current may flow through such defects if they come in contact with other structures, such as bowel. As any given insulation defect is likely to be small, the consequent power density over the defect is large with a high potential for injury.

Unfortunately, the precise incidence of laparoscopic electrosurgical injuries is difficult to ascertain. Thermal bowel injury related to laparoscopic procedures has been variably estimated at between 1 to 5 incidents per 1000 procedures [4-6]. These reports are limited by significant methodologic deficiencies. Insurance data and self reported surveys are subject to significant biases that preclude extrapolation: for example, up to 18% of surgeons report an electrosurgical burn incident during laparoscopic procedures when responding to a survey [1]. Similarly, up to 95% of surgeons have been either involved in or heard of a monopolar electrosurgical injury in their practice.

Furthermore, electrosurgical injuries often present later and non-specifically, making it difficult to determine the aetiology [6]. A histological diagnosis may not be possible at the time of intervention as the primary injury may be obscured by secondary changes (such as inflammation), particularly if the histopathologist has not been notified of the suspected aetiology [7]. As with all complications, there are significant medicolegal barriers to appropriate data collection and disclosure.

Additionally, electrosurgical injuries are often missed if they occur outside the surgeon's view. Depending on the type of surgery, only a small percentage of the total length of the instrument may be in the

laparoscopic field of view (zone1 of the active electrode)[2]. A much larger percentage may be within the abdomen, outside of the laparoscopic field of view. An insulation failure in this zone (zone 2) may escape attention and remain unrecognised.

While a number of recommendations have been made to reduce injury from insulation failure, there are no published data on the prevalence of insulation failure and the effect of monitoring. This study assesses the prevalence of electrosurgical injury in two tertiary institutions and the effect of a formal monitoring system.

Materials and Methods

Approval for this study was granted by the Operational Management Committee of the institutions involved.

Phase 1 established the prevalence of insulation failure in non-disposable electrosurgical instruments. All gynaecological laparoscopic instruments in two tertiary public institutions were removed and tested independently in April 2002. All testing was performed by the authors, HK and AY.

Each instrument was removed from sterile packaging and assembled as per standard operational practice. The instrument was classified (monopolar or bipolar) and visually inspected for defects. Any potential defect was marked.

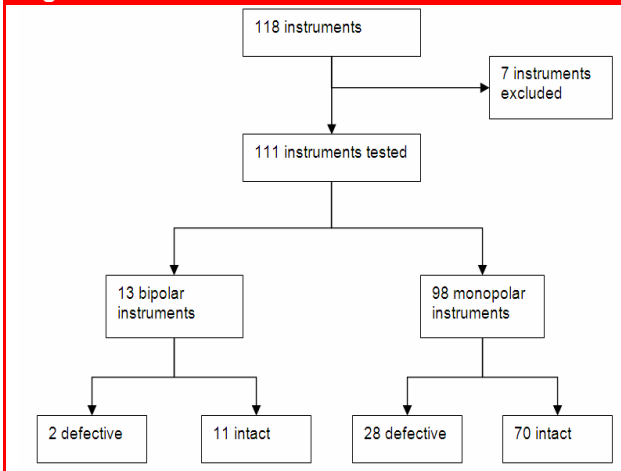
Subsequently, each instrument was tested in accordance with biomedical engineering guidelines [8] using the PCWI Porosity Detector (PCWI International Pty Ltd, Cardiff, Australia). Each instrument was categorised as intact (pass) or defective (fail).

Defective instruments were inspected without magnification to ascertain whether the defect would be detectable to the naked eye. Defects were then classified as predictable (defined as a visually detectable breech in the insulation identified at the initial inspection) or detectable (defined as a visually detectable breech in the insulation not identified at the initial inspection). The distance of the defect from the tip of the instrument was recorded. The defective instrument was removed from circulation.

Following phase 1, insulation testing was introduced in the clean-sterile cycle after the use of each of instrument. Staff of the Central Sterilising Unit were required to attend a workshop to be accredited for the testing of instruments. Approximately twenty staff attended a two hour workshop conducted by PCWI, covering issues such as the principles of electrosurgery, complications and testing practicalities. Routine checking of each instrument was instituted after each use. The testing was performed within the unit after cleaning and prior to sterilisation by trained in-house staff. Failed instruments were sent for repair or disposed.

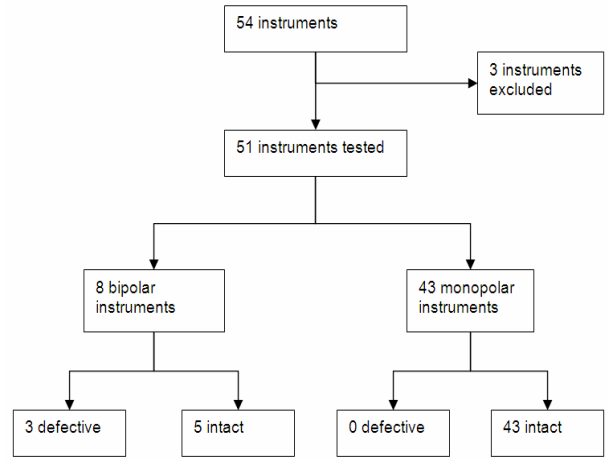
Phase 2 sought to establish the prevalence of insulation defects in one institution following the introduction of routine testing. All gynaecological laparoscopic instruments of this tertiary institution

Figure 1



Instruments in Phase 1 of the Analysis.

Figure 2



Instruments in Phase 2 of the Analysis.

were removed and tested in single session independently in December 2005.

Each instrument was classified and tested in accordance with the methodology for phase 1. All testing was performed by one author, AY.

Statistical Analysis

Contingency table analysis was performed by Fischer's exact test. Analysis was performed by the Centre for Clinical Studies, Mater Misericordiae Hospital, Brisbane.

Results

Table 1 summarizes the results of this study. One hundred and eighteen (118) instruments were eligible for testing. Seven (7) instruments were unable to be tested because of the need to maintain emergency instruments over the testing phase. A total of 111 instruments were tested.

Twenty seven (27) percent of the instruments were classified as defective in this phase of the study. If bipolar instruments were excluded from the analysis, 28.6% of monopolar instruments were found to have a breech in insulation. The prevalence of insulation failure was highest in dedicated electrosurgical instruments, such as hooks and scissors, where the overall failure rate was 39%.

Thirty-four (34) defects were detected in the 30 instruments that failed. The mean number of defects per instrument was 1.1 (range:1 – 3).

There were 12 (35%) visually detectable defects, but only 3 (9%) were predictable. The sensitivity of visual inspection to predict a damaged instrument was therefore 10%.

Figure 3 summarizes the distribution of the defects along the shaft of a prototypical instrument. The mean site of insulation failure was 126mm from the tip of the instrument. If insulation failures at the junction of the shaft and handle were excluded, the mean site of insulation failure was at 71mm from the tip of the instrument.

All sheath insulation failures occurred in sheaths with a metal core and an insulating coating. There were no failures in non-metallic sheathes.

In phase 2, 54 instruments were eligible for testing. Three (3) instruments were unable to be tested because of the need to maintain emergency instruments over the testing phase. A total of 51 instruments were tested.

No insulation failure was detected in monopolar instruments. Insulation failure was detected in 3 out of 8 (37.5%) of bipolar instruments.

Discussion

This study has established an unacceptably high prevalence of insulation failure in institutions with an ad hoc policy of instrument testing. While the overall prevalence was 27%, the prevalence in dedicated monopolar instruments was considerably higher at 39%. Up to three defects were documented in affected instruments in phase 1 of this study (mean: 1.1).

The majority of defects in this study were not predictable consistent with other reports that most electrosurgical insulation failures are microscopic [2]. The sensitivity of visual inspection to predict a damaged instrument was only 10%. Even when the site of failure was identified, it was only detectable in 35% of instruments without magnification. Therefore, visual inspection is not an appropriate screening mechanism for insulation failure.

The mean site of insulation failure was at 71mm from the tip of the instrument. This would place the majority of insulation defects within the abdominopelvic cavity during surgery, but not necessarily within the visual filed of the surgeon. Consequently, stray current may cause thermal damage that may escape intraoperative detection.

Following the introduction of routine electrosurgical instrument testing, the prevalence of insulation failure dropped to 5.9% and was completely eliminated in monopolar instruments, a clinically and statistically significant change. In the subcategory analysis of monopolar instruments, we were unable to show a significant difference in some of the categories. This is a function of the small number of instruments in each category.

All bipolar defects occurred in the jaws of one type of instrument, a versatile but delicate bipolar forceps. As fractures develop in the ceramic insulation within the jaws of the forceps, the instrument will fail. This can be difficult to detect and usually does not affect patient safety though it may lead to reduced efficacy and heating of the instrument. No shaft failures were detected in this instrument.

In our study, the institutions involved had a policy of testing on an ad hoc basis when problems were flagged by staff (one institution) or on a scheduled basis, involving sterilisation, transport to offsite biomedical engineering, return and re-sterilisation (one institution). The cost of each sterilisation, testing in offsite biomedical engineering and re-sterilising

Table 1

Instrument	Type	Phase 1		Phase 2		Fisher's Exact Probability
		Total	Defective (%)	Total	Defective (%)	
Monopolar						
	Hook	30	10 (33.3%)	4	0 (0.0%)	0.296
	Scissors	11	6 (54.5%)	5	0 (0.0%)	0.093
	Forceps	9	5 (55.6%)	16	0 (0.0%)	0.002
	Sheath	48	7 (14.6%)	18	0 (0.0%)	0.176
	Total	98	28 (28.6%)	43	0 (0.0%)	< 0.001
Bipolar						
	Forceps	13	2 (15.4%)	8	3 (37.5%)	0.325
Total		**111**	**30 (27.0%)**	**51**	**3 (5.9%)**	**0.001**

cycle was estimated at AUD65 per instrument per instance (charged cost to the cost centre). After the institution of in-house testing, the continued cost of checking was estimated at less than AUD1 per instrument per instance following the initial cost of training and purchase of equipment.

Defects in the insulation sheath of an instrument may arise during manufacture, during the clean-sterilisation cycle, as a result of operative wear and tear or with inappropriate use.

A number of strategies have been advocated to minimise the risk of thermal injury resulting from insulation failure [7, 9, 10]. Most importantly, staff utilising electrosurgical modalities should be appropriately trained in fundamental electrophysics [11, 12]. Emphasis must be placed on appropriate energy modalities in applicable surgical procedures with the appropriate electrosurgical unit settings [10].

Secondly, if non-disposable electrosurgical instruments are to be used in an institution, a protocol of instrument checking must be operational. There is no consensus on how often, where or by whom the testing should be performed. The current Australian standard for sterilization and electrosurgical checking [13] simply recommends that insulated instruments be tested, preferably by a biomedical engineer, to ensure the integrity of the insulation material. The previous standard (AS3551:1996) stipulated a maximum testing interval of 12 months. However, testing is most appropriately performed following the use of each instrument in the clean-sterile cycle by trained on-site staff [14]. Alternatively, testing has been advocated prior to the use of each instrument in the operating room (InsulScan, Mobile Instrument, Bellefontaine, United States).

While disposable (single use) instruments are checked at the time of manufacture, the insulation of these instruments is generally thinner than that of non-disposable instruments [15]. It is therefore possible to damage the insulation of most disposable instruments with inappropriate use and electrosurgical unit (ESU) settings. Settings that may damage the insulation of disposable instruments can be selected on the majority of ESU and therefore the risk of insulation failure is not eliminated [16].

While testing procedures have the potential to reduce insulation failure prior to the use of the instrument, these processes do not eliminate injuries from breeches that arise during a surgical procedure. To this extent, Active Electrode Monitoring (AEM Encision Inc) addresses the two prime causes of stray electrosurgical burns, insulation failure and capacitive coupling [9]. The ESU continously monitors energy and deactivates the electrosurgical generator before injury can occur. More recently the Director General of NSW Health recommended that AEM be introduced in all NSW public hospitals in response to a Coroners report (June 25, 2003). Despite a decade of such recommendations, those of professional bodies [17] or the lay press [18], there has been limited acceptance of this system.

Finally, alternative energy sources, ultrasonic and LASER instruments do not suffer from insulation failure. However, each of these modalities experience other limitations and have specific failures inherent to their energy modalities.

Despite such a high insulation failure rate, the reported incidence of injuries is disproportionately small. Both of these institutions perform over one thousand operative laparoscopic procedures per year. The scope of this study was limited to the prevalence of insulation failure and did not include correlation with clinical injuries. We are unable to comment on the incidence of injuries in the institutions involved, but neither had flagged electrosurgical injuries as a particular problem. This apparent disparity may be explained in a number of ways. Firstly, the practices of laparoscopic surgeons are generally safe, minimising potential situations where injuries could occur. Secondly, injuries that occur are often minor or non-

Figure 3

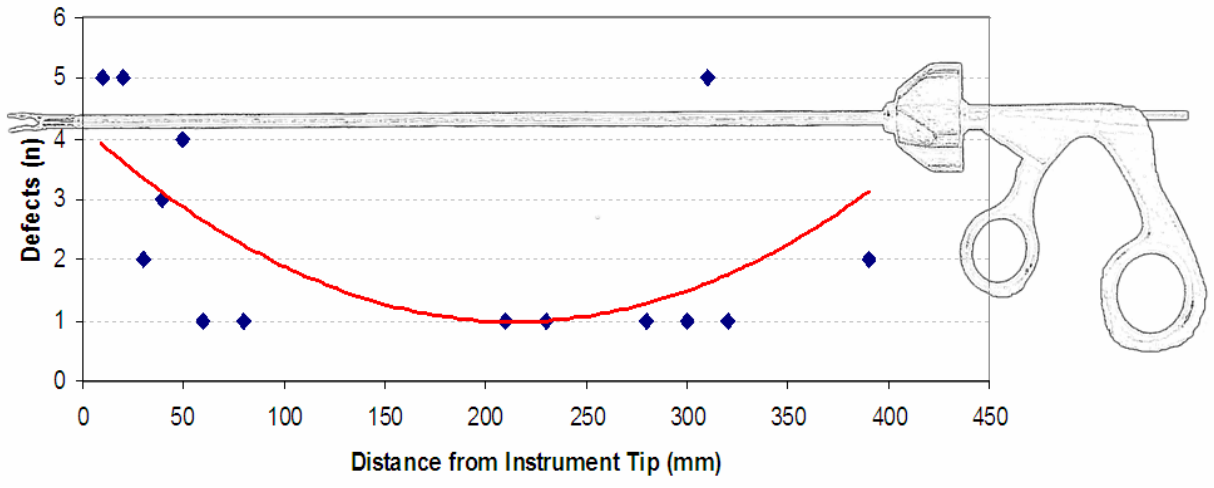
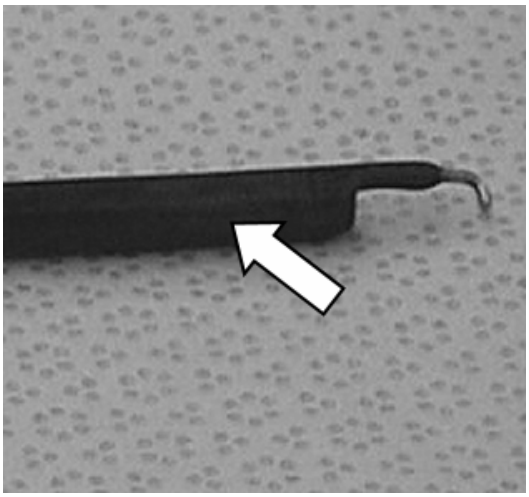


Figure 4



Microscopic insulation defect on a hook (arrow).

critical (such as burns to the uterus) and the affected instrument is either repaired or disposed. As previously discussed, major injuries may not be reported or the aetiology of the injury may not be apparent at the time of intervention. Finally, the incidence of significant injuries is so low that even unsafe practices do not result in significant increases in complications when assessed from an individual institutional point of view. It is likely that without systematic reporting and no-fault assessment of claims, the true incidence of such injuries will never be known.

Similarly, on the basis of the current analysis, it is unlikely that further studies would be justified.

Conclusion

This study provides the first systematic analysis of the prevalence of insulation failure and the effect of methodical testing. The data confirm that in the unmonitored or limited monitored environment, there is a high insulation failure rate in non-disposable instruments. This failure rate is highest in dedicated electrosurgical instruments. Furthermore, this study has demonstrated that it is possible to eliminate monopolar instrument insulation failure through a process of surveillance.

Acknowledgements

We wish to thank Dr Alan Chan for the statistical analysis, Dr Clare Boothroyd for review of the manuscript and the staff of Sterilizing and Biomedical Engineering Units of the Mater and Royal Brisbane and Women's Hospitals, Brisbane.

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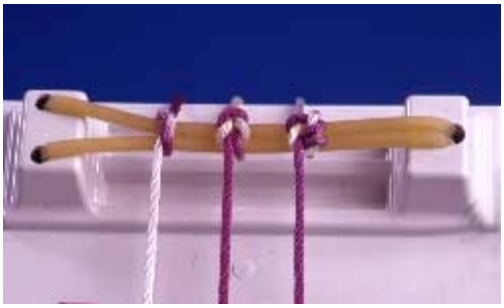
Basic Knots

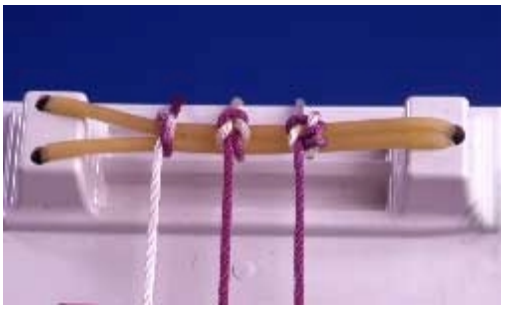
The knots demonstrated on the following pages are those most frequently used, and are applicable to all types of operative procedures. The camera was placed behind the demonstrator so that each step of the knot is shown as seen by the operator. For clarity, one-half of the strand is purple and the other white. *The purple working strand is initially held in the right hand.* The left-handed person may choose to study the photographs in a mirror.



1. **Simple knot:** incomplete basic unit
2. **Square knot:** completed knot
3. **Surgeon's or Friction knot:** completed tension knot

Knot Security

The knots demonstrated on the following pages are those most frequently used, and are applicable to all types of operative procedures. The camera was placed behind the demonstrator so that each step of the knot is shown as seen by the operator. For clarity, one-half of the strand is purple and the other white. *The purple working strand is initially held in the right hand.* The left-handed person may choose to study the photographs in a mirror.



1. **Simple knot:** incomplete basic unit
2. **Square knot:** completed knot
3. **Surgeon's or Friction knot:** completed tension knot

Knot Security

The construction of ETHICON* sutures has been carefully designed to produce the optimum combination of strength, uniformity, and hand for each material. The term *hand* is the most subtle of all suture quality aspects. It relates to the feel of the suture in the surgeon's hands, the smoothness with which it passes through tissue and ties down, the way in which knots can be set and snugged down, and most of all, to the firmness or body of the suture. *Extensibility* relates to the way in which the suture will stretch slightly during knot tying and then recover. The stretching characteristics provide the signal that alerts the surgeon to the precise moment when the suture knot is snug.

Multifilament sutures are generally easier to handle and to tie than monofilament sutures, however, all the synthetic materials require a specific knotting technique. With multifilament sutures, the nature of the material and the braided or twisted construction provide a high coefficient of friction and the knots remain as they are laid down. In monofilament sutures, on the other hand, the coefficient of friction is relatively low, resulting in a greater tendency for the knot to loosen after it has been tied. In addition, monofilament synthetic polymeric materials possess the property of memory. *Memory* is the tendency not to lie flat, but to return to a given shape set by the material's extrusion process or the suture's packaging. The RELAY* suture delivery system delivers sutures with minimal package memory due to its unique package design.

Suture knots must be properly placed to be secure. Speed in tying knots may result in less than perfect placement of the strands. In addition to variables inherent in the suture materials, considerable variation can be found between knots tied by different surgeons and even between knots tied by the same individual on different occasions.

General Principles of Knot Tying

Certain general principles govern the tying of all knots and apply to all suture materials.

1. The completed knot must be firm, and so tied that slipping is virtually impossible. The simplest knot for the material is the most desirable.

2. The knot must be as small as possible to prevent an excessive amount of tissue reaction when absorbable sutures are used, or to minimize foreign body reaction to nonabsorbable sutures. Ends should be cut as short as possible.

3. In tying any knot, friction between strands ("sawing") must be avoided as this can weaken the integrity of the suture.

4. Care should be taken to avoid damage to the suture material when handling. Avoid the crushing or crimping application of surgical instruments, such as needleholders and forceps, to the strand except when grasping the free end of the suture during an instrument tie.

5. Excessive tension applied by the surgeon will cause breaking of the suture and may cut tissue. Practice in avoiding excessive tension leads to successful use of finer gauge materials.

6. Sutures used for approximation should not be tied too tightly, because this may contribute to tissue strangulation.

7. After the first loop is tied, it is necessary to maintain traction on one end of the strand to avoid loosening of the throw if being tied under any tension.

8. Final tension on final throw should be as nearly horizontal as possible.

9. The surgeon should not hesitate to change stance or position in relation to the patient in order to place a knot securely and flat.

10. Extra ties do not add to the strength of a properly tied knot. They only contribute to its bulk. With some synthetic materials, knot security requires the standard surgical technique of flat and square ties with additional throws if indicated by surgical circumstance and the experience of the surgeon.

An important part of good suturing technique is correct method in knot tying. A seesaw motion, or the sawing of one strand down over another until the knot is formed, may materially weaken sutures to the point that they may break when the second throw is made or, even worse, in the postoperative period when the suture is further weakened by increased tension or motion.

If the two ends of the suture are pulled in opposite directions with uniform rate and tension, the knot may be tied more securely. This point is well-illustrated in the knot tying techniques shown in the next section of this manual.

Square Knot

Square Knot Pictures

Two-Hand Technique

One-Hand Technique

Two Hand Technique

Square Knot **Two-Hand Technique**

The two-hand square knot is the easiest and most reliable for tying most suture materials. It may be used to tie surgical gut, virgin silk, surgical cotton, and surgical stainless steel.

Standard technique of flat and square ties with additional throws if indicated by the surgical circumstance and the experience of the operator should be used to tie PANACRYL* braided synthetic absorbable suture, MONOCRYL* (poliglecaprone 25) suture, Coated VICRYL* (polyglactin 910) suture, Coated VICRYL *RAPIDE** (polyglactin 910) suture, PDS* II (polydioxanone) suture, ETHILON* nylon suture, ETHIBOND* *EXCEL* polyester suture, PERMA-HAND* silk suture, PRONOVA* poly (hexafluoropropylene-VDF) suture, and PROLENE* polypropylene suture.

1 White strand placed over extended index finger of left hand acting as bridge, and held in palm of left hand. Purple strand held in right hand.

Purple strand held in right hand brought between left thumb and index finger. 2

3

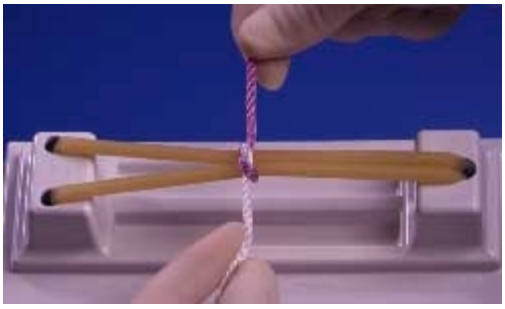
Left hand turned inward by pronation, and thumb swung under white strand to form the first loop.

Purple strand crossed over white and held between thumb and index finger of left hand.

4

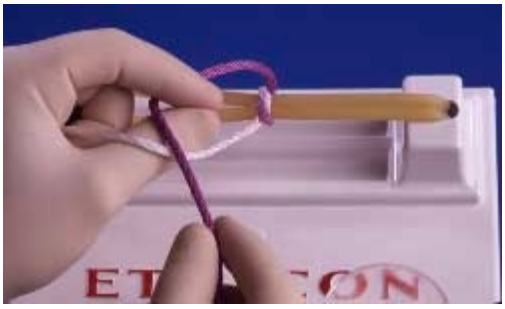
Square Knot **Two-Hand Technique**

5 Right hand releases purple strand. Then left hand supinated, with thumb and index finger still grasping purple strand, to bring purple strand through the white loop. Regrasp purple strand with right hand.



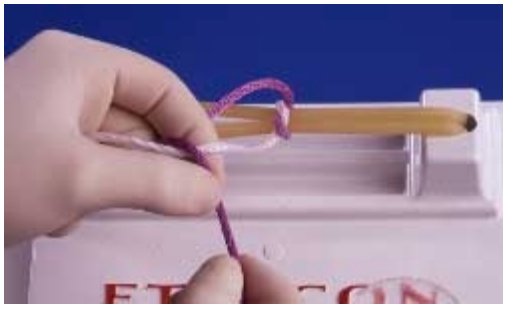
Purple strand released by left hand and grasped by right. Horizontal tension is applied with left hand toward and right hand away from operator. This completes first half hitch. 6

7 Left index finger released from white strand and left hand again supinated to loop white strand over left thumb. Purple strand held in right hand is angled slightly to the left.



Purple strand brought toward the operator with the right hand and placed between left thumb and index finger. Purple strand crosses over white strand. 8

Square Knot **Two-Hand Technique**



9

By further supinating left hand, white strand slides onto left index finger to form a loop as purple strand is grasped between left index finger and thumb.

10

Left hand rotated inward by pronation with thumb carrying purple strand through loop of white strand. Purple strand is grasped between right thumb and index finger.

11

Horizontal tension applied with left hand away from and right hand toward the operator. This completes the second half hitch.

12

The final tension on the final throw should be as nearly horizontal as possible.

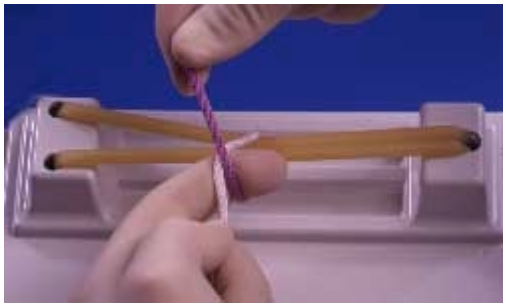
One-Handed Technique

Square Knot **One-Hand Technique**

Wherever possible, the square knot is tied using the two-hand technique. On some occasions it will be necessary to use one hand, either the left or the right, to tie a square knot. These illustrations employ the left-handed technique.

The sequence of throws illustrated is most commonly used for tying single suture strands. The sequence may be reversed should the surgeon be holding a reel of suture material in the right hand and placing a series of ligatures. In either case, it cannot be too strongly emphasized that the directions the hands travel must be reversed proceeding from one throw to the next to ensure that the knot formed lands flat and square. Half hitches result if this precaution is not taken.

1 White strand held between thumb and index finger of left hand with loop over extended index finger. Purple strand held between thumb and index finger of right hand.



Purple strand brought over white strand on left index finger by moving right hand away from operator. 2

3	With purple strand supported in right hand, the distal phalanx of left index finger passes under the white strand to place it over tip of left index finger. Then the white strand is pulled through loop in preparation for applying tension.	The first half hitch is completed by advancing tension in the horizontal plane with the left hand drawn toward and right hand away from the operator.

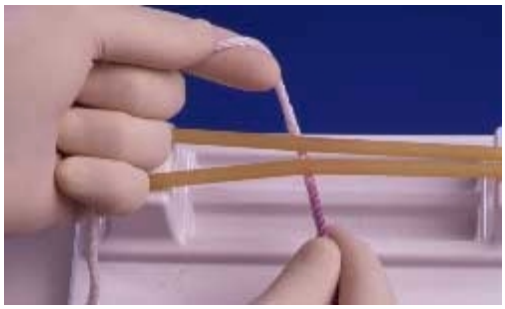
Surgeon’s or Friction Knot

Surgeon's or Friction Knot

The surgeon's or friction knot is recommended for tying PANACRYL* braided synthetic absorbable suture, Coated VICRYL* (polyglactin 910) suture, ETHIBOND* *EXCEL* polyester suture, ETHILON* nylon suture, MERSILENE* polyester fiber suture, NUROLON* nylon suture,

PRONOVA* poly (hexafluoropropylene-VDF) suture, and PROLENE* polypropylene suture.

The surgeon's knot also may be performed using a one-hand technique in a manner analogous to that illustrated for the square knot one-hand technique.



1 White strand placed over extended index finger of left hand and held in palm of left hand. Purple strand held between thumb and index finger of right hand.

Purple strand crossed over white strand by moving right hand away from operator at an angle to the left. Thumb and index finger of left hand pinched to form loop in the white strand over index finger. 2

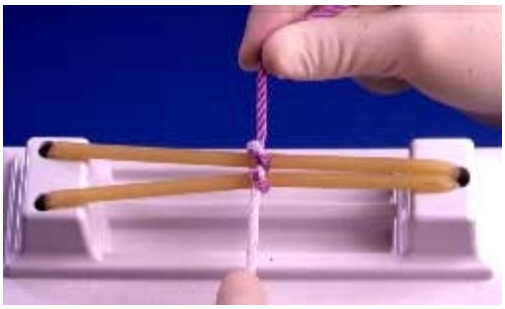
3	Left hand turned inward by pronation, and loop of white strand slipped onto left thumb. Purple strand grasped between thumb and index finger of left hand. Release right hand.	Left hand rotated by supination extending left index finger to pass purple strand through loop. Regrasp purple strand with right hand.

Surgeon's or Friction Knot

5 The loop is slid onto the thumb of the left hand by pronating the pinched thumb and index finger of left hand beneath the loop.

Purple strand drawn left with right hand and again grasped between thumb and index finger of left hand. 6

7 Left hand rotated by supination extending left index finger to again pass purple strand through forming a double loop.



Horizontal tension is applied with left hand toward and right hand away from the operator. This double loop must be placed in precise position for the final knot. 8

Surgeon's or Friction Knot

9 With thumb swung under white strand, purple strand is grasped between thumb and index finger of left hand and held over white strand with right hand.

Purple strand released. Left hand supinates to regrasp purple strand with index finger beneath the loop of the white strand. 10

11 Purple strand rotated beneath the white strand by supinating pinched thumb and index finger of left hand to draw purple strand through the loop. Right hand regrasps purple strand to complete

Hands continue to apply horizontal tension with left hand away from and right hand toward the operator. Final tension on final throw should be as nearly horizontal as possible.

the second throw square.

Deep Tie

Deep Tie
Page 1 of 2

Tying deep in a body cavity can be difficult. The square knot must be firmly snugged down as in all situations.

However the operator must avoid upward tension which may tear or avulse the tissue.

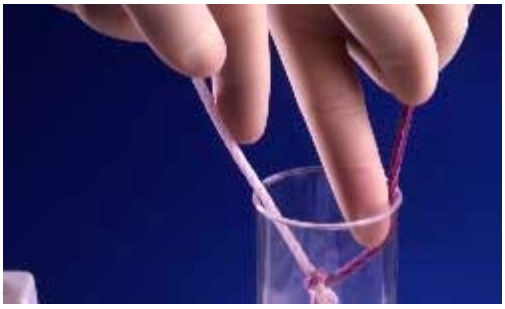
1 Strand looped around hook in plastic cup on Practice Board with index finger of right hand which holds purple strand in palm of hand. White strand held in left hand.

Purple strand held in right hand brought between left thumb and index finger. Left hand turned inward by pronation, and thumb swung under white strand to form the first loop. 2

3	By placing index finger of left hand on white strand, advance the loop into the cavity.	Horizontal tension applied by pushing down on white strand with left index finger while maintaining counter-tension with index finger of right hand on purple strand.	4

5 Purple strand looped over and under white strand with right hand.

6 Purple strand looped around white strand to form second loop. This throw is advanced into the depths of the cavity.



7 Horizontal tension applied by pushing down on purple strand with right index finger while maintaining counter-tension on white strand with left index finger. Final tension should be as nearly horizontal as possible.

Ligation Around Hemostatic Clamp

Ligation Around Memostatic Clamp -More Common of Two Methods

Frequently it is necessary to ligate a blood vessel or tissue grasped in a hemostatic clamp to achieve hemostasis in the operative field.

1 When sufficient tissue has been cleared away to permit easy passage of the suture ligature, the white strand held in the right hand is passed behind the clamp.

Left hand grasps free end of the strand and gently advances it behind clamp until both ends are of equal length. 2

3 To prepare for placing the knot

As the first throw of the knot is completed, the 4

square, the white strand is transferred to the right hand and the purple strand to the left hand, thus crossing the white strand over the purple.	assistant removes the clamp. This maneuver permits any tissue that may have been bunched in the clamp to be securely crushed by the first throw. The second throw of the square knot is then completed with either a two-hand or one-hand technique as previously illustrated.

Ligation Around Hemostatic Clamp -Alternate Technique

Some surgeons prefer this technique because the operator never loses contact with the suture ligature as in the preceding technique.

1 Center of the strand placed in front of the tip of hemostatic clamp with purple strand held in right hand and white strand in left hand.

Purple strand swung behind clamp and grasped with index finger of left hand. Purple strand will be transferred to left hand and released by right. 2

3 Purple strand crossed under white strand with left index finger and regrasped

First throw is completed in usual manner. Tension is placed on both strands 4

with right hand.	below the tip of the clamp as the first throw of the knot is tied. The assistant then removes the clamp. The square knot is completed with either a two-hand or one-hand technique as previously illustrated.

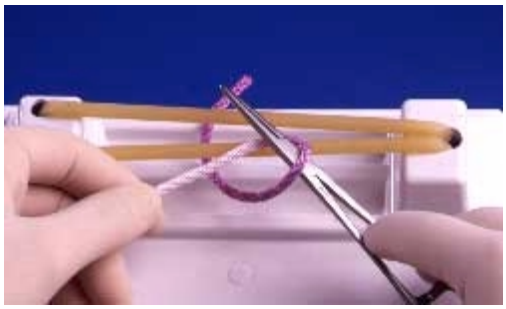
Instrument Tie

Instrument Tie

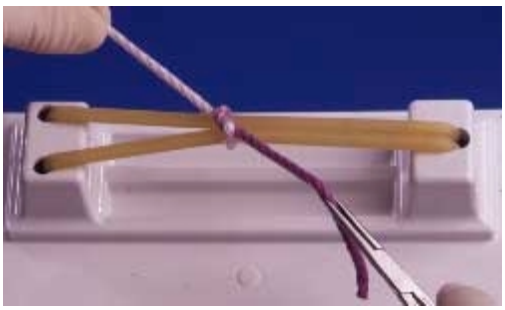
The instrument tie is useful when one or both ends of the suture material are short. For best results, exercise caution when using a needleholder with PANACRYL* braided synthetic

absorbable suture or any monofilament suture, as repeated bending may cause these sutures to break.

1 Short purple strand lies freely. Long white end of strand held between thumb and index finger of left hand. Loop formed by placing needleholder on side of strand away from the operator.

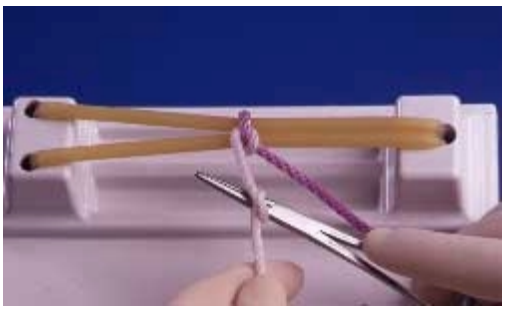


Needleholder in right hand grasps short purple end of strand. 2



3

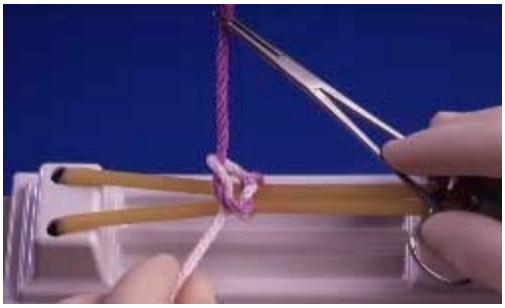
First half hitch completed by pulling needleholder toward operator with right hand and drawing white strand away from operator. Needleholder is released from purple strand.



4

White strand is drawn toward operator with left hand and looped around needleholder held in right hand. Loop is formed by placing needleholder on side of strand toward the operator.

Instrument Tie



5

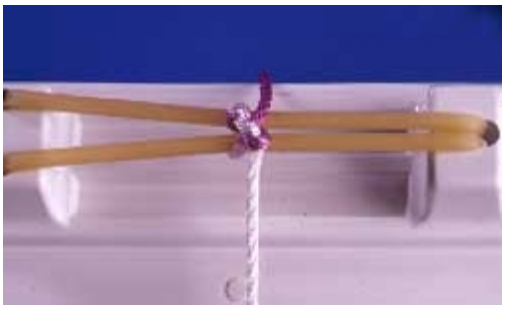
With end of the strand grasped by the needleholder, purple strand is drawn through loop in the white strand away from the operator.

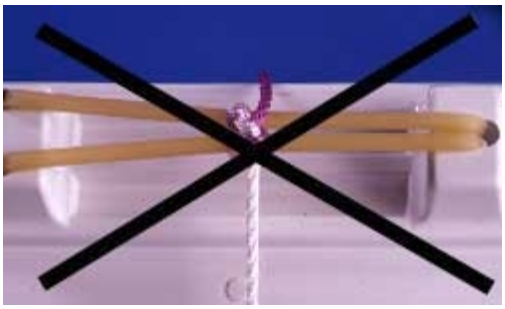
6

Square knot completed by horizontal tension applied with left hand holding white strand toward operator and purple strand in needleholder away from operator. Final tension should be as nearly horizontal as possible.

Granny Knot

A granny knot is not recommended. However, it may be inadvertently tied by incorrectly crossing the strands of a square knot. It is shown only to warn against its use. It has the tendency to slip when subjected to increasing pressure.





Suture Materials

The requirement for wound support varies in different tissues from a few days for muscle, subcutaneous tissue, and skin; weeks or months for fascia and tendon; to long-term stability, as for a vascular prosthesis. The surgeon must be aware of these differences in the healing rates of various tissues and organs. In addition, factors present in the individual patient, such as infection, debility, respiratory problems, obesity, etc., can influence the postoperative course and the rate of healing.

Suture selection should be based on the knowledge of the physical and biologic characteristics of the material in relationship to the healing process. The surgeon wants to ensure that a suture will retain its strength until the tissue regains enough strength to keep the wound edges together on its own. In some tissue that might never regain preoperative strength, the surgeon will want suture material that retains strength for a long time. If a suture is going to be placed in tissue that heals rapidly, the surgeon may prefer to select a suture that will lose its tensile strength at about the same rate as the tissue gains strength and that will be absorbed by the tissue so that no foreign material remains in the wound once the tissue has healed. With all sutures, acceptable surgical practice must be followed with respect to drainage and closure of infected wounds. The amount of tissue reaction caused by the suture encourages or retards the healing process.

When all these factors are taken into account, the surgeon has several choices of suture materials available. Selection can then be made on the basis of familiarity with the material, its ease of handling, and other subjective preferences.

Sutures can conveniently be divided into two broad groups: absorbable and nonabsorbable. Regardless of its composition, suture material is a *foreign body* to the human tissues in which it is implanted and to a greater or lesser degree will elicit a foreign body reaction.

Two major mechanisms of absorption result in the degradation of absorbable sutures. Sutures of biological origin such as surgical gut are gradually digested by tissue enzymes. Sutures manufactured from synthetic polymers are principally broken down by hydrolysis in tissue fluids.

Nonabsorbable sutures made from a variety of nonbio-degradable materials are ultimately encapsulated or walled off by the body?s fibroblasts. Nonabsorbable sutures ordinarilv remain where thev

are buried within the tissues. When used for skin closure, they must be removed postoperatively.

A further subdivision of suture materials is useful: monofilament and multifilament. A *monofilament* suture is made of a single strand. It resists harboring microorganisms, and it ties down smoothly. A *multifilament* suture consists of several filaments twisted or braided together. This gives good handling and tying qualities. However, variability in knot strength among multifilament sutures might arise from the technical aspects of the braiding or twisting process.

The sizes and tensile strengths for all suture materials are standardized by U.S.P. regulations. Size denotes the diameter of the material. Stated numerically, the more zeroes (0's) in the number, the smaller the size of the strand. As the number of 0's decreases, the size of the strand increases. The 0's are designated as 5-0, for example, meaning 00000 which is smaller than a size 4-0. The smaller the size, the less tensile strength the strand will have. Tensile strength of a suture is the measured pounds of tension that the strand will withstand before it breaks when knotted. **(Refer to Absorbable Sutures & Nonabsorbable Sutures section)**

Principles of Suture Selection

The surgeon has a choice of suture materials from which to select for use in body tissues. Adequate strength of the suture material will prevent suture breakage. Secure knots will prevent knot slippage. But the surgeon must understand the nature of the suture material, the biologic forces in the healing wound, and the interaction of the suture and the tissues. The following principles should guide the surgeon in suture selection.

1. When a wound has reached maximal strength, sutures are no longer needed. Therefore:

a. Tissues that ordinarily heal slowly such as skin, fascia, and tendons should usually be closed with nonabsorbable sutures. An absorbable suture with extended (up to 6 months) wound support may also be used.

b. Tissues that heal rapidly such as stomach,colon, and bladder may be closed with absorbable sutures.

2. Foreign bodies in potentially contaminated tissues may convert contamination to infection. Therefore:

a. Avoid multifilament sutures which may convert a contaminated wound into an infected one.

b. Use monofilament or absorbable sutures in potentially contaminated tissues.

3. Where cosmetic results are important, close and prolonged apposition of wounds and avoidance of irritants will produce the best result. Therefore:

a. Use the smallest inert monofilament suture materials such as nylon or polypropylene.

b. Avoid skin sutures and close subcuticularly, whenever possible.

c. Under certain circumstances, to secure close apposition of skin edges, a topical skin adhesive or skin closure tape may be used.

4. Foreign bodies in the presence of fluids containing high concentrations of crystalloids may act as a nidus for precipitation and stone formation. Therefore:

a. In the urinary and biliary tract, use rapidly absorbed

sutures.

5. Regarding suture size:

a. Use the finest size, commensurate with the natural strength of the tissue.

b. If the postoperative course of the patient may produce sudden strains on the suture line, reinforce it with retention sutures. Remove them as soon as the patient?s condition is stabilized.

Metric Measures and U.S.P Suture Diameter Equivalents

U.S.P. Size	11-0	10-0	9-0	8-0	7-0	6-0	5-0	4-0	3-0	2-0	0	1	2	3	4	5	6
Natural Collagen	-	0.2	0.3	0.5	0.7	1.0	1.5	2.0	3.0	3.5	4.0	5.0	6.0	7.0	8.0	-	-
Synthetic Absorbables	-	0.2	0.3	0.4	0.5	0.7	1.0	1.5	2.0	3.0	3.5	4.0	5.0	6.0	6.0	7.0	-
Nonabsorbable Materials	0.1	0.2	0.3	0.4	0.5	0.7	1.0	1.5	2.0	3.0	3.5	4.0	5.0	6.0	6.0	7.0	8.0

Absorbable Sutures

Absorbable Sutures

Page 1

The United States Pharmacopeia (U.S.P.) defines an absorbable surgical suture as a "sterile strand prepared from collagen derived from healthy mammals or a synthetic polymer. It is capable of being absorbed by living mammalian tissue, but may be treated to modify its resistance to absorption. It may be impregnated or coated with a suitable antimicrobial agent. It may be colored by a color additive approved by the Federal Food and Drug Administration (F.D.A.)."

The United States Pharmacopeia, Twentieth Revision, Official from July 1, 1980.

Absorbable Suture Materials Most Commonly Used

SUTURE	TYPES	COLOR OF MATERIAL	RAW MATERIAL	TENSILE STRENGTH RETENTION *in vivo*	ABSORPTION RATE
Surgical Gut Suture	Plain	Yellowish-tan Blue Dyed	Collagen derived from healthy beef and sheep.	Individual patient characteristics can affect rate of tensile strength loss.	Absorbed by proteolytic enzymatic digestive process.
Surgical Gut Suture	Chromic	Brown Blue Dyed	Collagen derived from healthy beef and sheep.	Individual patient characteristics can affect rate of tensile strength loss.	Absorbed by proteolytic enzymatic digestive process.
Coated VICRYL (polyglactin 910) Suture	Braided Monofilament	Violet Undyed (Natural)	Copolymer of lactide and glycolide coated with polyglactin 370 and calcium stearate.	Approximately 75% remains at two weeks. Approximately 50% remains at three weeks.	Essentially complete between 56-70 days. Absorbed by hydrolysis.
Coated	Braided	Undyed	Copolymer of lactide	Approximately	Essentially

VICRYL *RAPIDE* (polyglactin 910) Suture		(Natural)	and glycolide coated with polyglactin 370 and calcium stearate.	50% remains at 5 days. All tensile strength is lost at approximately 14 days.	complete by 42 days. Absorbed by hydrolysis.
MONOCRYL (poliglecaprone 25) Suture	Monofilament	Undyed (Natural) Violet	Copolymer of glycolide and epsilon-caprolactone.	Approximately 50-60% (violet: 60-70%) remains at one week. Approximately 20-30% (violet: 30-40%) remains at two weeks. Lost within three weeks (violet: four weeks).	Complete at 91-119 days. Absorbed by hydrolysis.
PDS II (polydioxanone) Suture	Monofilament	Violet Blue Clear	Polyester polymer.	Approximately 70% remains at two weeks. Approximately 50% remains at four weeks. Approximately 25% remains at six weeks.	Minimal until about 90th day. Essentially complete within six months. Absorbed by slow hydrolysis.
PANACRYL Braided Synthetic Absorbable Suture	Braided	Undyed (White)	Copolymer of lactide and glycolide coated with caprolactone/glycolide.	Approximately 80% remains at 3 months. Approximately 60% remains at 6 months. Approximately 20% remains at 12 months.	Essentially complete between 18 and 30 months. Absorbed by slow hydrolysis.

Absorbable Sutures

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The United States Pharmacopeia, Twentieth Revision, Official from July 1, 1980.

SUTURE	CONTRAINDICATIONS	FREQUENT USES	HOW SUPPLIED	COLOR CODE OF PACKETS
Moderate reaction	Being absorbable, should not be used where extended approximation of tissues under stress is required. Should not be used in patients with known sensitivities or allergies to collagen or chromium.	General soft tissue approximation and/or ligation, including use in ophthalmic procedures. Not for use in cardiovascular and neurological tissues.	7-0 thru 3 with and without needles, and on LIGAPAK dispensing reels 0 thru 1 with CONTROL RELEASE needles	Yellow
Moderate reaction	Being absorbable, should not be used where extended approximation of tissues under stress is required. Should not be used in patients with known sensitivities or allergies to collagen or chromium.	General soft tissue approximation and/or ligation, including use in ophthalmic procedures. Not for use in	7-0 thru 3 with and without needles, and on LIGAPAK dispensing reels 0 thru 1	Beige

		cardiovascular and neurological tissues.	with CONTROL RELEASE needles	
Minimal acute inflammatory reaction	Being absorbable, should not be used where extended approximation of tissue is required.	General soft tissue approximation and/or ligation, including use in ophthalmic procedures. Not for use in cardiovascular and neurological tissues.	8-0 thru 3 with and without needles, and on LIGAPAK dispensing reels 4-0 thru 2 with CONTROL RELEASE needles 8-0 with attached beads for ophthalmic use	Violet
Minimal to moderate acute inflammatory reaction	Should not be used where extended approximation of tissue under stress is required or where wound support beyond 7 days is required.Superficial soft tissue approximation of skin and mucosa only. Not for use in ligation, ophthalmic, cardiovascular or neurological procedures. 5-0 thru 1 with needles.	Superficial soft tissue approximation of skin and mucosa only. Not for use in ligation, ophthalmic, cardiovascular or neurological procedures.	.5-0 thru 1 with needles.	Violet and Red
Minimal acute inflammatory	Being absorbable, should not be used where extended approximation of tissue under stress is required. Undyed not indicated for use in fascia.	General soft tissue approximation and/or ligation. Not for use in cardiovascular	6-0 thru 2 with and without needles 3-0 thru 1 with	Coral

		or neurological tissues, microsurgery, or ophthalmic surgery.	CONTROL RELEASE needles.	
Slight reaction	Being absorbable, should not be used where prolonged approximation of tissues under stress is required. Should not be used with prosthetic devices, such as heart valves or synthetic grafts.	All types of soft tissue approximation, including pediatric cardiovascular and ophthalmic procedures. Not for use in adult cardiovascular tissue, microsurgery, and neural tissue.	9-0 thru 2 with needles 4-0 thru 1 with CONTROL RELEASE needles 9-0 thru 7-0 with needles 7-0 thru 1 with needles	Silver
Minimal acute inflammatory reaction	Being absorbable, should not be used where extended approximation of tissue beyond six months is required.	General soft tissue approximation and/or ligation, and orthopaedic uses including tendon and ligament repairs and reattachment to bone. Particularly useful where extended wound support (up to 6 months) is desirable. Not for use in ophthalmic, cardiovascular,	2-0 through 2 with needles 2-0 through 1 with CONTROL RELEASE needles	Purple

		or neurological tissue.		

Nonabsorbable Sutures

Nonabsorbable Sutures

Page 1

By U.S.P. definition, "nonabsorbable sutures are strands of material that are suitably resistant to the action of living mammalian tissue. A suture may be composed of a single or multiple filaments of metal or organic fibers rendered into a strand by spinning, twisting, or braiding. Each strand is substantially uniform in diameter throughout its length within U.S.P. limitations for each size. The material may be uncolored, naturally colored, or dyed with an F.D.A. approved dyestuff. It may be coated or uncoated; treated or untreated for capillarity."

Nonabsorbable Suture Materials Most Commonly Used

SUTURE	TYPES	COLOR OF MATERIAL	RAW MATERIAL	TENSILE STRENGTH RETENTION *in vivo*	ABSORPTION RATE
PERMA-HAND Silk Suture	Braided	Violet White	Organic protein called fibroin.	Progressive degradation of fiber may result in gradual loss of tensile strength over time.	Gradual encapsulation by fibrous connective tissue.
Surgical Stainless Steel Suture	Monofilament Multifilament	Silver metallic	316L stainless steel.	Indefinite.	Nonabsorbable.
ETHILON Nylon Suture	Monofilament	Violet Green Undyed (Clear)	Long-chain aliphatic polymers Nylon 6 or Nylon 6,6.	Progressive hydrolysis may result in gradual loss of tensile strength over time.	Gradual encapsulation by fibrous connective tissue.

NUROLON Nylon Suture	Braided	Violet Green Undyed (Clear)	Long-chain aliphatic polymers Nylon 6 or Nylon 6,6.	Progressive hydrolysis may result in gradual loss of tensile strength over time.	Gradual encapsulation by fibrous connective tissue.
MERSILENE Polyester Fiber Suture	Braided Monofilament	Green Undyed (White)	Poly (ethylene terephthalate).	No significant change known to occur *in vivo.*	Gradual encapsulation by fibrous connective tissue.
ETHIBOND *EXCEL* Polyester Fiber Suture	Braided	Green Undyed (White)	Poly (ethylene terephthalate) coated with polybutilate.	No significant change knownto occur *in vivo.*	Gradual encapsulation by fibrous connective tissue.
PROLENE Polypropylene Suture	Monofilament	Clear Blue	Isotactic crystalline stereoisomer of polypropylene.	Not subject to degradation or weakening by action of tissue enzymes.	Nonabsorbable.
PRONOVA* Poly (hexafluoropropylene-VDF) Suture	Monofilament	Blue	Polymer blend of poly (vinylidene fluoride) and poly (vinylidene fluoride-co-hexafluoropropylene).	Not subject to degradation or weakening by action of tissue enzymes.	Nonabsorbable.

Nonabsorbable Sutures

By U.S.P. definition, "nonabsorbable sutures are strands of material that are suitably resistant to the action of living mammalian tissue. A suture may be composed of a single or multiple filaments of metal or organic fibers rendered into a strand by spinning, twisting, or braiding. Each strand is substantially uniform in diameter throughout its length within U.S.P. limitations for each size. The material may be uncolored, naturally colored, or dyed with an F.D.A. approved dyestuff. It may be coated or uncoated; treated or untreated for capillarity."

TISSUE REACTION	CONTRAINDICATIONS	FREQUENT USES	HOW SUPPLIED	COLOR CODE OF PACKETS
Acute inflammatory reaction	Should not be used in patients with known sensitivities or allergies to silk	General soft tissue approximation and/or ligation, including cardiovascular, opthalmic and neaurological procedures.	9-0 thru 5 with and without needles, and on LIGAPAK dispensing reels 4-0 thru 1 with CONTROL RELEASE needles	Light Blue
Minimal acute inflammatory reaction	Should not be used in patients with known sensitivities or allergies to 316L stainless steel, or constituent metals such as chromium and nickel.	Abdominal wound closure, hernia repair, sternal closure and orthopaedic procedures including cerclage and tendon repair.	10-0 thru 7 with and without needles	Yellow-Ochre

Minimal acute inflammatory reaction	Should not be used where permanent retention of tensile strength is required.	General soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.	11-0 thru 2 with and without needles	Mint Green
Minimal acute inflammatory reaction	Should not be used where permanent retention of tensile strength is required.	General soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.	6-0 thru 1 with and without needles 4-0 thru 1 with CONTROL RELEASE needles	Mint Green
Minimal acute inflammatory reaction	None known.	General soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.	6-0 thru 5 with and without needles 10-0 and 11-0 for opthalmic (green monofilament) 0 with CONTROL RELEASE needles	Turquoise
Minimal acute inflammatory reaction	None known.	General soft tissue approximation and/or ligation, including use	7-0 thru 5 with and without needles 4-0 thru 1	Orange

		including use in cardiovascular, ophthalmic and neurological procedures.	with CONTROL RELEASE needles various sizes attached to TFE polymer pledgets	
Minimal acute inflammatory reaction	None known.	General soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.	6-0 thru 2 (clear) with and without needles 10-0 thru 8-0 and 6-0 thru 2 (blue) with and without needles 0 thru 2 wuth CONTROL RELEASE needles various sizes attached to TFE polymer pledgets	Deep Blue
Minimal acute inflammatory reaction	None known.	General soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.	6-0 through 5-0 with TAPERCUT* surgical needle 8-0 through 5-0 with taper point needle.	Royal Blue

Trademarks

The following are trademarks of ETHICON, INC.:

ATRALOC surgical needle
Coated VICRYL (polyglactin 910) suture
Coated VICRYL *RAPIDE* (polyglactin 910) suture
CONTROL RELEASE needle/needle suture
CS ULTIMA ophthalmic needle
ETHALLOY needle alloy
ETHIBOND *EXCEL* polyester suture capitalized
ETHICON sutures or products
ETHILON nylon suture
LIGAPAK dispensing reel
MERSILENE polyester fiber suture
MICRO-POINT surgical needle
MONOCRYL (poliglecaprone 25) suture
NUROLON nylon suture
PANACRYL braided synthetic absorbable suture
P PRIME needle
PC PRIME needle
PS PRIME needle
PDS II (polydioxanone) suture
PERMA-HAND silk suture
PROLENE polypropylene suture
PRONOVA poly (hexafluoropropylene-VDF) suture
RELAY suture delivery system
SABRELOC spatula needle
TAPERCUT surgical needle
VICRYL (polyglactin 910) suture
VISI-BLACK surgical needle

Surgical Needles

Necessary for the placement of sutures in tissue, surgical needles must be designed to carry suture material through tissue with minimal trauma. They must be sharp enough to penetrate tissue with minimal resistance. They should be rigid enough to resist bending, yet flexible enough to bend before breaking. They must be sterile and corrosion-resistant to prevent introduction of microorganisms or foreign bodies into the wound.

To meet these requirements, the best surgical needles are made of high quality stainless steel, a noncorrosive material. Surgical needles made of carbon steel may corrode, leaving pits that can harbor microorganisms. All ETHICON* stainless steel needles are heat-treated to give them the maximum possible strength and ductility to perform satisfactorily in the body tissues for which they are designed. ETHALLOY* needle alloy, a noncorrosive material, was developed for unsurpassed strength and ductility in precision needles used in cardiovascular, ophthalmic, plastic, and microsurgical procedures.

Ductility is the ability of the needle to bend to a given angle under a given amount of pressure, called load, without breaking. If too great a force is applied to a needle it may break, but a ductile needle will bend before breaking. If a surgeon feels a needle bending, this is a signal that excessive force is being applied. The *strength* of a needle is determined in the laboratory by bending the needle 900; the required force is a measurement of the strength of the needle. If a needle is weak, it will bend too easily and can compromise the surgeon?s control and damage surrounding tissue during the procedure.

Regardless of ultimate intended use, all surgical needles have three basic components: the attachment end, the body, and the point.

The majority of sutures used today have appropriate needles attached by the manufacturer. *Swaged* sutures join the needle and suture together as a continuous unit that is convenient to use and minimizes tissue trauma. ATRALOC* surgical needles, which are permanently swaged to the suture strand, are supplied in a variety

of sizes, shapes, and strengths. Some incorporate the CONTROL RELEASE* needle suture principle which facilitates fast separation of the needle from the suture when desired by the surgeon. Even though the suture is securely fastened to the needle, a slight, straight tug on the needleholder will release it. This feature allows rapid placement of many sutures, as in interrupted suture techniques.

The *body*, or shaft, of a needle is the portion which is grasped by the needleholder during the surgical procedure. The body should be as close as possible to the diameter of the suture material. The curvature of the body may be straight, half-curved, curved, or compound curved. The cross-sectional configuration of the body may be round, oval, side-flattened rectangular, triangular, or trapezoidal. The oval, side-flattened rectangular, and triangular shapes may be fabricated with longitudinal ribs on the inside or outside surfaces. This feature provides greater stability of the needle in the needleholder.

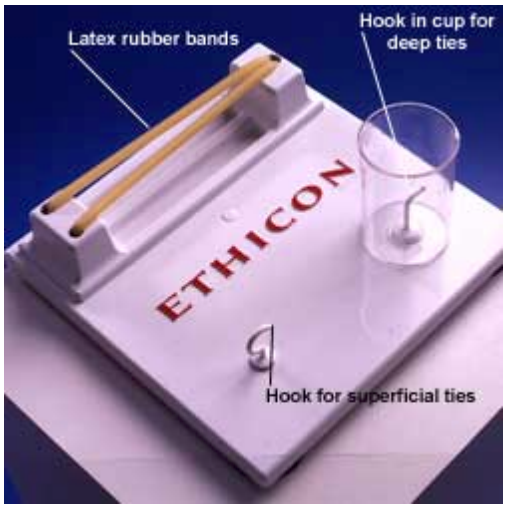
The *point* extends from the extreme tip of the needle to the maximum cross-section of the body. The basic needle points are cutting, tapered, or blunt. Each needle point is designed and produced to the required degree of sharpness to smoothly penetrate the types of tissue to be sutured.

Surgical needles vary in size and wire gauge. The diameter is the gauge or thickness of the needle wire. This varies from 30 microns (.001 inch) to 56 mil (.045 inch, 1.4 mm). Very small needles of fine gauge wire are needed for micro-surgery. Large, heavy gauge needles are used to penetrate the sternum and to place retention sutures in the abdominal wall. A broad spectrum of sizes are available between these two extremes.

Of the many types available, the specific needle selected for use is determined by the type of tissue to be sutured, the location and accessibility, size of the suture material, and the surgeon's preference.

Practice Board

Practice Board*



The KNOT TYING MANUAL and practice board are available from ETHICON, INC., without charge for all learners of suturing and knot tying techniques.

*Contributing Designer-Bashir Zikria, MD, FACS

Selected Terms

Absorption Rate	Measures how quickly a suture is absorbed, or broken down by the body. Refers only to the presence or absence of suture material and not to the amount of strength remaining in the suture.
Breaking Strength Retention (BSR)	Measures *tensile strength* (see below) retained by a suture *in vivo* over time. For example, a suture with an initial tensile strength of 20 lbs. and 50% of its BSR at 1 week has 10 lbs. of tensile strength *in vivo* at 1 week.
Extensibility	The characteristic of suture stretch during knot tying and recovery thereafter. Familiarity with a suture's extensibility will help the surgeon know when the suture knot is snug.
Memory	Refers to a suture's tendency to retain kinks or bends (set by the material's extrusion process or packaging) instead of lying flat.
Monofilament	Describes a suture made of a single strand or filament.
Multifilament	Describes a suture made of several braided or twisted strands or filaments.
Tensile Strength	The measured pounds of tension that a knotted suture strand can withstand before breaking.
United States Pharmacopeia (U.S.P.)	An organization that promotes the public health by establishing and disseminating officially recognized standards of quality and authoritative information for the use of medicines and other health care technologies by health professionals, patients, and consumers.