

Single-Incision Surgery Today



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News and expert opinion
on the single-incision laparoscopic technique

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Guest editorial



Dr Thomas Carus, MD

Director, Department of General, Visceral and Vascular Surgery, Centre of Minimally Invasive Surgery, Academic Teaching Hospital, University of Hanover and Hospital Cuxhaven, Germany

Dr Carus has been using the single-incision laparoscopic technique since 2008. He has performed approximately 90 procedures using this approach, including cholecystectomies and colonic resections, as well as more specialist operations, such as left-side pancreatic resections and liver resections.

It is clear that interest in minimally invasive surgical techniques is growing, given their potential to reduce trauma for the patient in comparison with conventional laparoscopic or open surgical options. However, currently used for less than 20% of cholecystectomies, the single-incision laparoscopic technique is not being used widely enough to realise its full potential. One reason perhaps is that, by adopting the technique, experienced surgeons are faced with a new learning curve (as is the case with the adoption of any new surgical technique). If we can better equip surgeons to undertake the initial learning curve rapidly and increase the uptake of the technique to around 80% for general procedures, focusing especially on areas such as cholecystectomy, colonic surgery and adhesiolysis for adhesions, where single-incision laparoscopy may be of particular interest, we can begin to realise the potential benefits of single-incision laparoscopy more fully and in a much greater number of patients. In doing so, we can also accelerate our progress toward minimally invasive surgery.

Taking the benefits to patients

Several factors will be key in this endeavour, all of which are discussed in detail in this issue. If uptake is to increase, more robust clinical data must be available to support the potential benefits afforded by the single-incision laparoscopic technique (page 3). Furthermore, the availability of a central

registry to enhance access to these data will be invaluable in highlighting the associated benefits and resolving potential issues (page 4). In terms of minimising the initial learning curve, the greater provision of training will help surgeons to adapt to the technique quickly and effectively (see page 5), as will the widespread availability of tailored instruments, specially designed for use in the abdominal cavity with single-incision laparoscopy.

The future of the single-incision technique

At the moment, we are still in the early days of the single-incision laparoscopic technique. Experienced surgeons are using the technique innovatively to realise benefits in areas such as pancreatic, bariatric, urological and gynaecological surgery. There is also anticipation for the potential benefits of this approach in colonic surgery; a single-incision laparoscopic approach would provide the surgeon with much greater flexibility for a left-side colonic resection procedure, for example, which would typically require an incision of 20–30 cm using a traditional open surgical approach.

It will be interesting to see how these experiences unfold over the coming years as we strive to further reduce trauma for patients and move closer to a future in which minimally invasive surgery is the norm.

Robust clinical data essential for advancements in minimally invasive surgery



A forthcoming meta-analysis paper comparing results for natural-orifice transluminal endoscopic surgery (NOTES) and single-incision laparoscopic surgery with conventional laparoscopy will hopefully shed light on the status of currently available safety and efficacy data for the new techniques. We spoke to one author of the paper, Mr Irfan Ahmed, Consultant Hepatico-Pancreatico-Biliary Surgeon, Aberdeen Royal Infirmary, UK, to learn more about the need for a greater, more robust evidence base for minimally invasive surgery and how this might benefit future surgical advancement.

Q. What is the status of available evidence for NOTES and single-incision laparoscopic surgery?

A. Current clinical evidence is minimal, featuring only personal experience in single centres. These techniques are still too young to be supported by robust data; however, there are several randomised controlled trials ongoing, which will mature in the coming years and produce more meaningful results.

Q. What impact is the shortage of robust data having?

A. It is limiting the uptake of these new minimally invasive techniques. Once a solid clinical evidence base is available, surgeons, institutions and health authorities will be able to make informed judgements about the safety, efficacy and cost-effectiveness of these techniques.

Q. How do available NOTES and single-incision laparoscopy data compare with each other?

A. NOTES offers the ultimate dream of surgeons – the potential for totally scarless surgery – but it involves the opening of an otherwise healthy organ. Currently, there is no clinical evidence available to support the safe closure of these organs during such procedures (except for the vagina). While large randomised clinical trials have yet to report, existing data for single-incision laparoscopic surgery, which offers the potential for virtually scarless surgery through only one hidden umbilical scar, suggest that it is as safe as conventional laparoscopy,¹⁻⁶ which has been widely used since the early 1990s.⁷ Taking available results into account, I don't think we're ready yet for NOTES – we need more research, better instruments and proven ways of closing natural orifices – but we are ready

for single-incision laparoscopic surgery, for which there is increasing positive evidence and specially designed instrumentation. Single-incision laparoscopic surgery seems to be the logical step towards scarless surgery in the future.

Q. How would you like to see the data for single-incision laparoscopic surgery evolve?

A. The ability to access, isolate and compare robust data is important to drive progress with any new technique. I'm in favour of a centralised registry, with open access to data at local, national and international levels. Through a broad database, we can record and collate results, make direct comparisons with the established data for conventional laparoscopy and track evidence for important endpoints, such as complications, pain score, time to recovery and cosmesis. We can also use it to identify any issues for resolution, for example, if a particular complication is highlighted.

Q. How is the single-incision technique helping on the journey to even less-invasive surgery?

A. As the single-incision laparoscopic technique is maturing, industry continues to work with us, drawing on our insights to develop tailored instrumentation (as was the case with the uptake of conventional laparoscopy). A similar, partnered approach would be vital to even less-invasive surgery, once there are enough robust data to support its introduction. In the meantime, widespread uptake and mastering of the single-incision laparoscopic technique will be a crucial step to preparing for future surgical technologies and techniques.

References: 1. Ahmed K, et al. *Surg Endosc* 2010 [Epub ahead of print]; 2. Chow A, et al. *Surg Endosc* 2010;24(10):2567-74; 3. Hodgett SE, et al. *J Gastrointest Surg* 2009;13(2):188-92; 4. Raman JD, et al. *Eur Urol* 2009;55(5):1198-204; 5. Teixeira J, et al. *Surg Obes Relat Dis* 2010;6(1):41-5; 6. Vestweber B, et al. *Surg Endosc* 2010 [Epub ahead of print]; 7. Himal HS. *Surg Endosc* 2002;16(12):1647-52



European registry to generate invaluable outcomes data for single-incision laparoscopic surgery

Work is underway to create a European registry to collate data on single-incision laparoscopic procedures across the region. Stemming from existing industry- and surgeon-led databases, the registry, which is due to be piloted in 2010, will provide a means to track single-incision laparoscopic procedures throughout Europe, generating an invaluable source of outcomes data on this innovative surgical technique.

Gathering data in this way will allow leading surgeons to assess the outcomes of single-incision laparoscopic surgery *versus* conventional laparoscopic surgery, and begin to consider some key issues that will help to further establish the technique in Europe:

- Which procedures are particularly suited to single-incision laparoscopic surgery
- What is needed in terms of training
- Whether there are any emerging complications and how these can be reduced.

Dr Walter Brunner, General and Visceral Surgeon, St John of God (SJOG) Hospital, Salzburg, Austria, who instigated one of the original registries on which the European registry is based, commented on the value of such a database: *'Registries provide invaluable data on surgical outcomes and will provide a way of establishing quality control for this new technique, moving forward. It will play an important part in further establishing this new minimally invasive surgical technique.'*

Patient case study^a

'I am ecstatic with the results. There was no pain after the surgery and I was able to leave hospital the same day. Furthermore, I was able to return to work two weeks after the surgery, something which was very important to me. When people ask about the surgery I tell them it was absolutely fantastic.' – **Noelene**

On the advice of her surgeon, Noelene, a Senior Sister in Anaesthetics, underwent a single-incision laparoscopic cholecystectomy in February 2009. The procedure was successfully performed under a general anaesthetic in less than three hours. Crucially, Noelene did not suffer from any post-operative pain and was allowed to leave hospital three hours after the surgery. She was able to return to work after two weeks; she believes that she could have gone back within a week if her job wasn't so physically demanding. The ability to return to normal day-to-day activities so quickly after the surgery was of vital importance to her. Now, more than a year after the surgery, she is delighted to have had no post-operative complications and to have no visible scar. Apart from a slightly distorted belly button, there is no evidence that she has undergone surgery.

^aThese results are not typical and cannot be expected in every case. The procedure described was not performed using the Covidien SILS™ Port, which was not commercially available until April 2009.

Guidance on the route to the adoption of the single-incision laparoscopic technique



Single-incision laparoscopic surgery gives surgeons a new option to offer to patients – one that has the potential to provide numerous benefits and has been used for more

than three years across a variety of surgical areas.¹⁻⁵ We spoke to single-incision laparoscopic surgery mentor Mr Paraskevas Paraskeva, Reader in Surgery and Consultant Surgeon, Imperial College London and Imperial College Healthcare NHS Trust, UK, about the route through which surgeons can adopt this latest development in minimally invasive surgery to allow their patients to benefit from the technique.

Q. Is single-incision laparoscopy difficult to adopt?

A. Single-incision laparoscopy is something that almost all surgeons competent in conventional laparoscopy can do. It is still laparoscopic surgery; a modification of something that most surgeons are proficient in. The important thing is that surgeons adopt it through a proper and safe route.

Q. How can surgeons get started?

A. Appropriate training is vital. Hands-on workshops using simulators, such as those run by Covidien under the company's Masterclass programme, provide an invaluable introduction to the technique as part of a broader programme that offers a complete training pathway for surgeons at all stages of adoption. These classes reduce the initial difficulties and frustrations inherent in adopting a new technique, as well as allowing surgeons to benefit from the experience of practised surgeons. The lessons learnt can be immediately extrapolated to the clinical environment; I recommend that surgeons perform their first single-incision laparoscopic operation within weeks, if not days, of their training.

Q. Is there continued support available?

A. Training courses such as the Covidien programme offer a 'Clinical Immersion' class, whereby surgeons learning single-incision laparoscopic surgery visit experts in their own institutions. In some institutions, surgeons may be able to assist. There are also 'Mentorship programmes', under which experienced surgeons visit trainees. Surgeons have found these very beneficial.

Q. Is there a learning curve associated with the adoption of this new technique?

A. Yes, but this can be minimised with appropriate training. For an experienced surgeon, the learning curve is typically about 20 procedures for simpler operations, such as appendectomy; for more complex operations, this may increase to 25 procedures for surgeons to feel comfortable and 50 for complete confidence.

Q. What factors should surgeons consider before performing single-incision laparoscopy?

A. It is important that the technique is accommodated in surgeons' work practices, as well as their theatre lists; time must be allowed for mastering and refining the technique. The correct equipment must be available. Operating teams should also be familiar with the benefits of the technique, the potential for increased operating times and any new instrumentation. It may be valuable for at least one other team member to attend a 'Clinical Immersion' session with their surgeon.

Q. How could this advice help surgeons to provide patients with a better experience?

A. Single-incision laparoscopic surgery is another option for patients. Appropriate preparation and training will allow surgeons to advocate the technique from a position of knowledge and gain the skills needed to perform it safely. Training courses, such as those provided by Covidien, provide a route for competent surgeons to offer this important technique and its associated benefits to their patients.

References: 1. Podolsky ER, et al. *Surg Endosc* 2010;24(7):1557-61; 2. Fader AN, Escobar PF. *Gynecol Oncol* 2009;114(2):157-61; 3. Kaouk JH, Goel RK. *Eur Urol* 2009;55(5):1163-9; 4. Chambers W, et al. *Colorectal Dis* 2009 [Epub ahead of print]; 5. Saber AA, El-Ghazaly TH. *Int J Surg* 2009;7(5):456-9



Expert consensus to guide future adoption of single-incision laparoscopic surgery



Expert panel (left to right): Dr Salvador Morales-Conde, University Hospital Virgen del Rocío, Spain; Professor Oliver Mann, Universitätsklinikum Hamburg-Eppendorf, Germany; Dr Boris Vestweber, Klinikum Leverkusen, Germany; Dr Anna Dupree (guest); Dr Fabio Ciancio, Centre Hospitalier de Mont-de-Marsan, France; Professor Lars N Jorgensen, Bispebjerg Hospital, Denmark; Mr Paraskevas Paraskeva, Imperial College London, UK; Mr Irfan Ahmed (Chair), Aberdeen Royal Infirmary, UK.

On 2 June 2010, leading experts from the field of single-incision laparoscopic surgery met to reach consensus on the current status of, and future expectations for, this innovative technique.^a The experts, who have collectively performed over 1800 single-incision laparoscopic surgeries, discussed key issues, including potential patient benefits, the need for more clinical data, best practice for completing the surgery and the optimal route for surgeon training. As a result, the panel agreed a number of statements and recommendations that will not only help guide surgeons who are new to the technique, but may also contribute to achieving a broader consensus in the surgical community.

The expert panel discussed their own experiences of the single-incision laparoscopic technique, with a view to reaching consensus on key issues. One of the main objectives of the meeting was to discuss and agree on methods that could help support surgeons wishing to offer single-incision laparoscopic surgery to patients.



'There is a great need for guidance ... my hope is that the expert recommendations will guide surgeons on how to implement the technique in their practices in a safe and proper way.' – Professor Lars N Jorgensen, Professor, Department of Surgery K, Bispebjerg Hospital, Denmark

Potential patient benefits and the need for clinical data

The experts agreed that single-incision laparoscopic surgery may offer a number of benefits to patients (when compared with open and conventional laparoscopic surgery), but that further published clinical data are necessary to verify these attributes – this will be particularly important for surgeons looking to make an informed choice in terms of adopting the technique. Recommendations were made at the meeting on the nature of the trials required, the need for a universal clinical registry to gather surgical data and the dissemination of results to remove a barrier to the further adoption of single-incision laparoscopic surgery.

Best practice and surgical training

A number of recommendations were agreed for accomplishing single-incision laparoscopic surgery efficiently. These included proposals for appropriate instrumentation and the criteria to implement when selecting patients. The panel also agreed on the ideal prerequisite skills for single-incision laparoscopic surgery and the training route for surgeons who are adapting to the technique – this was recommended to include an introductory training programme, clinical immersion (training surgeons observing/assisting experts at leading institutions) and expert mentorship, with the option of additional animal work and/or dry and wet simulators. A procedure-focused pathway for adopting the technique was also proposed.

Valuable recommendations to be published shortly

The single-incision laparoscopic technique is the latest evolution in laparoscopic surgery; therefore, there is a need in the surgical community for clarity on its value, as well as guidance on its safe and efficient implementation. The recommendations resulting from the meeting, which are to be the subject of a forthcoming publication, will not only provide this guidance, but will also help drive innovation in the field – for example, new clinical studies or instrumentation. As such, the consensus meeting was an important step in defining the role and importance of single-incision laparoscopic surgery in today's surgical field and in bringing this innovative surgical option to more patients around the world.



Mr Irfan Ahmed, Consultant
Hepatico-Pancreatico-Biliary
Surgeon, Aberdeen Royal
Infirmary, UK

'The single-incision laparoscopic technique has been independently adopted and modified by surgeons in different corners of the world. This meeting brought many of these experts together to review their experience and the lessons learnt, so that surgeons adopting the technique today do not have to go through the same learning curve.'

'This kind of consensus is important for maturing the technique, so that when we take it forward there is unanimous opinion on all aspects, including identifying the patients who will benefit from this surgery, maintaining a robust and international database and identifying the different techniques used. There are lots of articles expressing individuals' opinions on these issues; as a result of this meeting, we are aiming to reach a consensus on the value of the technique and how it should be implemented.'



Professor Helmut Weiss, Head of
Surgical Department, St John
of God (SJOG) Hospital,
Salzburg, Austria

'The use of single-incision laparoscopic surgery is not widespread within the surgical community; therefore, the expert recommendations help to highlight this technique and the possibility that it may offer a better outcome to patients.'

'Although we know that the potential for improved cosmesis is one of the big advantages of single-incision laparoscopic surgery, there is a lack of clinical evidence regarding other potential benefits for patients, such as reduced pain and shorter recovery time. Since there are no definitive answers, the consensus meeting allows experts to recommend strategies and guide surgeons. Recommendations from experts who have extensive experience in their respective fields can support colleagues when they are adopting the technique, for example, by giving 'tips and tricks' and highlighting those patients who are most suitable for the procedure, when the surgeon is at the start of the learning curve.'

Due to the continuous evolution of the technique, another expert meeting is envisaged once more clinical data are available.

^aThe meeting was sponsored by Covidien through an unrestricted educational grant.

New Covidien SILS™ instruments available

In a continued commitment to surgeons and to innovation, Covidien has launched a range of new SILS™ instruments to complement the portfolio of devices and instrumentation already available to support the single-incision laparoscopic technique. Developed in close collaboration with surgeons and their surgical teams, the instruments address the emerging needs of surgeons undertaking these innovative procedures.

SILS™ hand instruments

The SILS™ hand instruments are designed to enhance flexibility and visualisation in single-incision laparoscopic procedures, offering improved precision and manoeuvrability in a limited operating space.

Features

- Infinite positions over 85°
- Articulation lock lever to fix shaft in a chosen position
- Increased shaft strength
- 360° tip rotation
- Available in two lengths (to increase versatility and help reduce handle clashing).

SILS™ Dissector

Electrocautery connection



SILS™ Hook

'Cut' and 'coagulate' modes



SILS™ Shears

Electrocautery connection



SILS™ Clinch

Push on/off ratchet lock, allowing jaws to be locked onto tissue



SILS™ Ports

The newly launched SILS™ Port 15 mm incorporates novel features that address customer needs in advanced single-incision laparoscopic bariatric, colorectal, gynaecological and urological procedures. The port retains the flexible blue port of the established SILS™ Port 5 mm and SILS™ Port 12 mm, while incorporating two important new features:

- 10–15 mm obturator/cannula
- Separate 5 mm smoke-evacuation cannula to remove smoke/moisture generated during procedures requiring use of cautery.



This document contains information about the single-incision laparoscopic technique and its potential benefits. Neither the information presented nor the benefits described can be related to the Covidien SILS™ Port. Clinical studies are underway to establish if the benefits of the single-incision laparoscopic technique can be expected from the SILS™ Port. This document was produced by Alpharmaxim Healthcare Communications. The content does not necessarily represent the views of Alpharmaxim Healthcare Communications.

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