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No specialty alone: the Wilder Penfield strategy

To gather knowledge and to find out new knowledge is the noblest occupation of the physician. To apply that knowledge with understanding and sympathy to the relief of human suffering is the loveliest occupation; and to do both with unassuming faithfulness sets the seal on the whole. — Edward Archibald, 1934.

CJS has posted to its website (www.canjsurg.ca) a “work-in-progress” commentary as part of the CJS consensus protocol. The authors’ goal is to develop a statement regarding gastrointestinal endoscopy training for general surgery residents. The setting for their review is a growing discord between the specialties of gastroenterology and general surgery over endoscopy. In parts of Canada, one specialty has refused to teach trainees of the other. In other jurisdictions, qualifications required to participate in provincially sponsored screening programs have been written to favour one specialty over the other. These events may be aberrations as the historical partnership between these specialties continues to be driven by the demands of patient care.

Edward Archibald’s gentle challenge was contained in his address at the opening of the Montreal Neurological Institute in 1934. Almost 40 years later when the University Hospital in London, Ontario, was being built, the design was selected with this challenge in mind. In-hospital and out-patient care areas were clustered by specialty and colocated with research laboratories and doctors’ offices. There was no place for a distinction between physicians and surgeons. In 1972, the founders chose Wilder Penfield to give the opening address. The purpose of this choice was to leave us a message. Prior to his arrival in Canada, Penfield was aware that the restrictive practices of surgeons and physicians of related specialties had put a great limitation on the development of the science of medicine. His personal response was to become an expert in neurology and neuropathology while he learned neurosurgery. Later he became a pioneering neuroradiologist. Once in Montréal, he ceaselessly campaigned for an institute where physicians, surgeons and scientists would collaborate in research and patient care.

The divide between physicians and surgeons is as old as the science of medicine itself. While Hippocrates made physicians promise to leave cutting for stone to surgeons who were practised in the art, it was not until physicians and surgeons collaborated in the 17th century that the mysteries of circulation were discovered and the development of scientific medicine was begun. Penfield thought at first that all knowledge of a specialty could reside within one person. However neuroscience expanded so rapidly, due in no small part to the success of his own collaborative strategy, that Penfield was forced to recognize the need subspecialize. Canada’s Royal College was founded in 1929 by physicians and surgeons, who were colleagues of Penfield, as a place for all specialties. The Royal College’s recently launched “Competence by Design” initiative will transform education within specialties. It may also break down the barriers that confine each specialty. The needs of patients will become the principle determinant of the boundaries of specialties. It is clear today that Canadian patients need the competent care of gastroenterologists and general surgeons, just as they need the collaborative care of other sister medical and surgical specialties.

Vivian C. McAlister, MB
Coeditor, Canadian Journal of Surgery

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Aucune spécialité n’est une île : la stratégie de Wilder Penfield

Acquérir des connaissances et en découvrir de nouvelles est la plus noble occupation du médecin. Appliquer ces connaissances en faisant preuve de compréhension et d’empathie pour le soulagement de la souffrance humaine est la plus belle profession; et faire les deux avec une fidélité sans prétention est le couronnement de la profession. — Edward Archibald, 1934.

Le fossé entre les médecins et les chirurgiens est aussi vieux que la science de la médecine. Hippocrate a fait promettre aux médecins de laisser les opérations aux chirurgiens qualifiés, mais il aurait fallu attendre une collaboration entre les médecins et les chirurgiens au 17e siècle pour découvrir les mystères de la circulation et permettre l’avènement de la médecine scientifique. Au départ, le D’ Penfield pensait qu’une seule personne pouvait posséder toutes les connaissances d’une spécialité. La neurosciences a toutefois connu une expansion si rapide, en grande partie en raison de la réussite de sa propre stratégie de collaboration, que le D’ Penfield a dû reconnaître la nécessité de la surspécialisation. Le Collège royal des médecins et chirurgiens du Canada a été fondé en 1929 par des médecins et des chirurgiens, qui étaient des collègues du D’ Penfield, comme un lieu de rassemblement de toutes les spécialités. L’initiative « La compétence par conception », que le Collège royal a récemment lancée, transformera la formation au sein des spécialités. Elle pourrait en outre faire tomber les barrières qui délimitent chaque spécialité. Les besoins des patients deviendront le principal déterminant des limites des spécialités. Il est évident aujourd’hui que les patients ont besoin des soins compétents des gastro-entérologues et des chirurgiens généraux, tout autant qu’ils ont besoin des soins en collaboration d’autres spécialités médicales et chirurgicales.

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Références

Enhancing medical students’ education and careers in global surgery

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SUMMARY

With surgical conditions being significant contributors to the global burden of disease, efforts aimed at increasing future practitioners’ understanding, interest and participation in global surgery must be expanded. Unfortunately, despite the increasing popularity of global health among medical students, possibilities for exposure and involvement during medical school remain limited. By evaluating student participation in the 2011 Bethune Round Table, we explored the role that global surgery conferences can play in enhancing this neglected component of undergraduate medical education. Study results indicate high rates of student dissatisfaction with current global health teaching and opportunities, along with high indices of conference satisfaction and knowledge gain, suggesting that global health conferences can serve as important adjuncts to undergraduate medical education.

Despite the substantial contribution of surgical conditions to the global burden of disease, the field of global surgery remains severely under-resourced, especially when compared with the well-staffed and well-funded campaigns combatting communicable and other nonsurgical diseases. One important avenue toward meeting surgical workforce needs involves exposing, educating and motivating future surgeons to participate in global surgery initiatives. Over the past decade, global surgery has become increasingly popular among medical students, many of whom hope to translate their interest into active participation.1

Despite these developments, current opportunities for medical student exposure and involvement in global surgery remain limited. In the absence of uniform guidelines regarding global health teaching, experiences vary significantly, and dissatisfaction rates remain high, with 41% of graduating American medical students finding their global health curriculum inadequate.1,2 There are also important limitations to global health electives as currently offered; these range from prohibitive cost to lack of organizational support from medical faculties.1

In this context, it becomes important to seek complementary opportunities for student exposure to global health and surgery. Based on our experience with student participation in the 2011 Bethune Round Table, we suggest that global surgery conferences can serve as key adjuncts to undergraduate medical education, helping to inform, motivate and integrate students into the global surgery community.

The Bethune Round Table is an international conference dedicated to the surgical issues facing low- and middle-income countries. Organized by the Canadian Network for International Surgery (CNIS) and held annually in Canada, the conference features important participation of global surgery leaders from resource-limited settings in Africa, Eastern Europe and Asia; leaders from these settings accounted for more than half of the speakers at the 2011 conference.1 The conference, which was hosted in Montréal, Canada on June 3–5, featured an unprecedented level of student
Involvement, with 35 first-year medical students from McGill University attending the proceedings, their registration having been waived in exchange for volunteering to help run the event.

We took advantage of this opportunity by constructing a 56-item questionnaire meant to gauge student experiences and attitudes toward global health and surgery as well as to assess the outcomes and educational value of such conferences. Administered electronically to all 173 first-year medical students from McGill University, the survey was completed by 102 students, including 31 of the 35 conference participants.

Survey results highlight substantial interest in the discipline among medical students, with 42% of the 102 respondents reporting involvement in global health research, volunteering or student initiatives and 55% intending to incorporate global health into their future careers. Concurrently, dissatisfaction with global health teaching as currently offered was reported by 55%, with 68% of these respondents desiring an expansion of its place in the curriculum, suggesting greater discontentment among this cohort than among American medical students, as stated previously. Although no similar information is available for medical students across Canada, these results should be of concern, given that McGill University stands slightly above the Canadian average in terms of global health training offered.1 This unmet student demand illustrates the importance of supplementing available opportunities for global health exposure.

In terms of conference participation outcomes, major self-perceived general surgery knowledge gain was reported by 71% of the 31 attendees who completed the survey, while substantial increase in global health interest and in intentions to participate in global health activities was reported by 87% and 77%, respectively. Although student participants were self-selected by their pre-existing interests, 9 of the 31 respondents (31%) had no prior global health experience, as measured by past participation in global health conferences, research, volunteering or other initiatives. This diversity among attendees did not translate into differences in perceived outcomes, which remained highly positive regardless of previous exposure. Similarly, the Bethune Round Table attracted both surgically minded (15 of 31) and medically minded (16 of 31) students, appealing equally to both disciplines and leading 8 participants into newly considering surgical careers. These results indicate that events like the Bethune Round Table can be as beneficial to newcomers than among American medical students, as stated previously. Although no similar information is available for medical students across Canada, these results should be of concern, given that McGill University stands slightly above the Canadian average in terms of global health training offered.1 This unmet student demand illustrates the importance of supplementing available opportunities for global health exposure.

In terms of conference participation outcomes, major self-perceived general surgery knowledge gain was reported by 71% of the 31 attendees who completed the survey, while substantial increase in global health interest and in intentions to participate in global health activities was reported by 87% and 77%, respectively. Although student participants were self-selected by their pre-existing interests, 9 of the 31 respondents (31%) had no prior global health experience, as measured by past participation in global health conferences, research, volunteering or other initiatives. This diversity among attendees did not translate into differences in perceived outcomes, which remained highly positive regardless of previous exposure. Similarly, the Bethune Round Table attracted both surgically minded (15 of 31) and medically minded (16 of 31) students, appealing equally to both disciplines and leading 8 participants into newly considering surgical careers. These results indicate that events like the Bethune Round Table can be as beneficial to newcomers that they are to more experienced participants and that they are equally appreciated by both groups. This versatility suggests that global surgery conferences can be valuable and easily accessible complements to the limited options currently available to medical students, functioning both as entry points into the discipline and as opportunities to reinforce existing interest and participation.

Interestingly, despite high rates of involvement among medical students, only 12 of 102 respondents felt like legitimate members of the global health community. Considering the link established between students’ sense of belonging to an academic community and the retention rate within that particular discipline, this finding has important implications.4 As previous studies on higher education have shown, academic conferences can be ideal forums for informal discussions between students and experienced practitioners, contributing to the enculturation process of the former.1 In this context, it is encouraging that, on average, 40% of medical students’ interactions during the conference were with practising surgeons and that 55% of respondents reported an increased sense of community following the event. The fact that a now annual student-organized global surgery conference was held at McGill University less than 12 months after the 2011 Bethune Round Table, with more than 120 guests in attendance, serves to further illustrate this point. We would therefore argue that such conferences favour the continuation and intensification of student involvement in global health and surgery, helping to transform what is initially an interest among others into an issue seen as intrinsic to the practice of medicine.

If the rising interest in global health and surgery among future doctors is to be cultivated, we must become better at offering diverse and easily accessible opportunities for student exposure. This will require enhancing the global health curriculum and increasing faculty support for international electives as well as facilitating student participation in global surgery conferences like the Bethune Round Table. By stimulating global health involvement early on in medical education, such steps will help ensure that the current surge in interest translates into more students striving to become tomorrow’s global health leaders.

Competing interests: G. Ntakiyiruta and P. Kyamanywa have received travel support from McGill University Health Centre. T. Razek is a board member (unpaid) for the Canadian Network for International Surgery. No other competing interests declared.

References
The validity of surgical simulation

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Simulation is an increasingly important role in training surgeons. As hours between registrar and consultant grades have decreased, trainees are required to train smarter. While the majority of simulation is limited, advances in computing and design are enabling ever more realistic, varied simulation.

SUMMARY

Simulation is an important tool in the training of juniors, but work is required to expand this training to a wider variety of surgical techniques, not only laparoscopic ones. The very first surgical simulators were leaf and clay models used in India in 600 BC to simulate a forehead nasal flap reconstruction. Since then, simulation has become a highly refined training format that is used in number of high-risk industries. It has become a key tool in the education of clinicians at all levels in a wide selection of specialties and is an important component in recent drives to improve patient safety.

A large proportion of the methodological and technological development in simulation has been in the aviation industry, where pilots have long been trained to fly before stepping into an aircraft. In the United Kingdom, the combination of many registrar grades into the single grade of “Specialist Registrar” (known as Calmanisation) and the European Working Time Directive have reduced the period available for training. As such, the working hours between becoming a senior house officer and a consultant have estimated to have reduced by a factor of 5. Simulation has evolved as an effective training technique alongside this changing environment for the training of surgeons — namely the reduction in hours available for training.

This drastic change in training time and practices necessitated a paradigm shift in the model of surgical education. There has been a move away from the apprenticeship model in which expertise was acquired through experience, to a more standardized, objective and competency-based approach that requires a more proactive attitude to training. Simulation has become a key part of providing this objective training and assessment, allowing mistakes to be made in a safe environment and to develop further attributes, such as understanding human factors, that exist outside the realm of pure technical ability.

Much work has been carried out looking into the use of laparoscopic simulators. Seymour and colleagues randomized 16 surgical trainees to either a laparoscopic simulator (MIST-VR; Virtalis) training group or a control group trained traditionally. Participants then performed a cholecystectomy in an operating theatre, and the procedures were recorded for assessment. Participants in the simulator group dissected the gallbladder 29% faster and were 5 times less likely to make errors than those in the control group. These findings were supported in a similar investigation undertaken by Grantcharov and colleagues involving laparoscopic novices. The MIST-VR group performed significantly faster than the control group, with better economy of movement and error scores. A recent
systematic review of laparoscopic surgery simulation encompassing 219 studies and 7138 trainees concluded that “simulation-based laparoscopic training of health professionals [has] large benefits when compared with no intervention and is moderately more effective than nonsimulation instruction.”

Work by Kneebone and colleagues has taken the concept of simulation a step further: “simulated patients” force trainees to interact with real people while performing procedures. This technique has been extended to laparoscopic surgery, where tactile feedback allows trainees to undertake the operation with a number of anatomic variants and get used to the feeling of handling different tissues. Alongside these technically useful features, authenticity is enhanced by giving the model patient head and feet, artificial skin and a theatre team, including all those normally present for such an operation. The quality of simulator used may impact the outcomes for patients — simulators without haptics can lead to distortions of pulling and pushing forces required. Much work still remains to be done on transferring teamwork and leadership skills as well as human factors from the simulation suite to the operating room.

Growing evidence suggests that skills gained within simulated environments transition well into the real clinical setting. A recent review found good skill transfer in pediatric emergency situations, tracheal intubation and central venous catheter insertion, with reported decreases in complications and infections. Zendejas and colleagues investigated laparoscopic inguinal hernia repair in a randomized controlled trial and subsequently found decreased procedure duration and complications. Stefanidis and colleagues found that 71% of novices trained to proficiency on a simulator retained their skills in the operating theatre.

The vast majority of work pertaining to skills translation has been undertaken in laparoscopic surgical techniques. Future research should examine the wider aspects of surgery. Simulation should be part of the learning experience but cannot replace the requisite clinical hard “graft” and experience a trainee surgeon needs on the “shop floor,” supported by good trainers and mentors.

Competing interests: None declared.

References

Balancing surgical innovation with cost and efficiency

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See the related research paper by Wang and colleagues on p. 263.

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SUMMARY

The standard approach to neoplasia of the pancreatic head is pancreaticoduodenectomy, otherwise known as the Whipple procedure. Traditionally, this operation is performed through an open laparotomy incision. In high-volume centres, and when performed by appropriately qualified surgeons, the Whipple procedure is safe and effective management for diseases of the pancreatic head. Still, this operation remains one of the most complex abdominal procedures. With the proliferation of minimally invasive surgery, more complex operations are being performed using laparoscopy and other minimal access techniques. A group from McGill University and the Montreal Jewish General Hospital have prospectively evaluated their experience with minimally invasive pancreaticoduodenectomy and have compared this experience to the open approach. This is the first comparative series of its kind from Canada.

The world’s first minimally invasive pancreaticoduodenectomy was reported by Canadian surgeons in 1994. Since then, several smaller reports have followed that suggest that many of the traditional advantages of minimally invasive surgery may be possible in select patients undergoing surgery for neoplasms of the pancreatic head. In this edition of the Canadian Journal of Surgery (CJS), Wang and colleagues report Canada’s first comparative series between minimally invasive pancreaticoduodenectomy using a hybrid approach and open pancreaticoduodenectomy. In their series, they demonstrate a shorter length of stay in hospital for the minimally invasive group, with similar perioperative outcomes and complication rates between the minimally invasive and open surgery groups. They also report a trend toward lengthier operations in the minimally invasive group.

This experience highlights one of the conflicts we face in our health care system. As health care budgets shrink, there are increased fiscal pressures on hospitals and, by extension, operating room resources. Likewise, a key metric for quality in Canadian surgery is waiting times. These realities may challenge the technical progress suggested by Wang and colleagues.

If advanced approaches are more broadly applied and if the observation of increased duration of surgery and the possibility of greater resource utilization persist, widespread uptake of this novel approach may have to be limited. On the other hand, if it can be demonstrated that improved perioperative outcomes are reproducible with minimally invasive pancreaticoduodenectomy and that once a suitable learning curve is overcome good outcomes can be provided to patients in a timely and efficient manner, then more widespread, systematic uptake may be possible. Likewise, new technology may permit greater efficiency in such complex minimally invasive procedures, facilitating an improvement in important perioperative parameters and thereby decreasing costs.

As mentioned in a previous CJS editorial, surgeons need to find solutions to the fiscal and societal restraints currently in place for our health care system. With new technology and novel approaches to surgical diseases, we are
challenged to balance our desire to improve patient outcomes and incorporate new approaches while maintaining a fiscally sound and efficient system. If more surgeons embrace minimally invasive pancreaticoduodenectomy in Canada, it will be important to better understand whether the potentially increased costs of this approach are justified by superior outcomes, new efficiencies and improved quality of life for patients.

Competing interests: None declared.

References

#Nomoretextbooks? The impact of rapid communications technologies on medical education

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SUMMARY

This paper was selected as the 2013 student essay winner by the Canadian Undergraduate Surgical Education Committee. The essay was in response to the question “How does rapid communications technology affect learning?”. Tomorrow, I start my vascular surgery rotation. Before bed tonight, I will watch a YouTube video of a femoral-popliteal bypass surgery, review the surgical anatomy from Zollinger’s Atlas of Surgical Operations on my iPad while waiting for my car tires to be changed, listen to a podcast on peripheral vascular disease while riding my exercise bike and perhaps tweet about my new rotation. My day is typical of a medical student in the context of increasing use of rapid communications technology: 91% of health professions students between the ages of 18 and 25 use Facebook.1 Rapid communications technology is defined broadly in this essay as any technology that enables access to information through an electronic device and/or permits that information to be shared in a public, social way. This includes mobile phones, laptops, tablets, online textbooks and social media. In this essay, I’ll discuss the impact of these technologies on medical education.

Rapid communications technology has made access to information instantaneous and ubiquitous. Students no longer need to wait until they have access to their textbooks or handbooks to recall information — they can pull out their mobile phones and look it up instantly. There are a number of medical apps that allow users to look up drug dosing and approaches to common conditions and recall surgical anatomy.2 The ubiquity of access to information helps students to maximize their time and learning opportunities. In addition, this rapid access to information can help to reinforce learning in a contextual manner.3 Ho and colleagues4 found that having a personal digital assistant case log versus a paper case log enhanced student learning and reflection.

Beyond access to information, rapid communications technology potentially offers exciting new ways of learning. For example, users of anatomy.tv are able to view 3-dimensional (3D) reconstructions of anatomy as opposed to the 2-dimensional images available in print textbooks. In addition, users can toggle between an abdominal computed tomography scan and the virtual 3D anatomy representation and correlate the two.5 Medical students now also regularly use podcasts and vodcasts to supplement their learning in novel ways, all while driving to clinic or exercising.6

Social media provides a means for learners to engage with their teachers and each other. Twitter, for example, could be used to involve students by creating a dialogue on the subject matter by retweeting key points and messages from lecture material.7 Through Twitter, students can continue a discussion long after the lecture is over and tie information to current events by using hashtags.7 Social media platforms provide a powerful way to integrate
medical education in a global setting. The New England Journal of Medicine Facebook group, for example, has more than 500 000 “likes” from users around the world. Each week a new “Image Challenge” is posted, and Facebook users can comment and give their diagnosis.8 A recent systematic review found that social media can improve collaborative learning and engagement.9

However, many authors have pointed out the challenges these new technologies present to medical education.2,10 As long as mobile phones are on, students are bombarded by text messages, emails and phone calls, constantly interrupting the day.2 There is the potential for “distracted doctoring” – mobile technology interfering with the focus on the patient.9 These technologies also have the potential to make students more superficial learners without a deeper grasp of the material.2 Instead of reading the whole chapter on a topic, learners look up bits and pieces and end up with chunks of knowledge that aren’t integrated. In addition, the overwhelming amount of online information can be difficult for students to sift through and decipher.6 Concerns over patient confidentiality and student professionalism have spurred professional associations, such as the Canadian Medical Association and Canadian Federation of Medical Students, to release guidelines regarding social media.11,12 Other challenges include blurring of professional/personal boundaries, cost and technical issues.3

It is difficult to assess the impact of rapid communications technology on medical education, largely because it is such a rapidly changing and diverse area.13 The technology continues to change and progress — what was once “hip” is now passé. The challenge for educators is to keep up with the speed of innovation while limiting the problematic impacts of these new technologies.14 From a personal perspective, it is important that medical educators remember the limitations of technology. Medical students need to learn an approach to chest pain, the branches of the aorta and the dosing of morphine; rapid communications technologies provide new ways of learning that are not integrated. In addition, the overwhelming amount of knowledge can be difficult for students to sift through and decipher.6

References

How to assess communication, professionalism, collaboration and the other intrinsic CanMEDS roles in orthopedic residents: use of an objective structured clinical examination (OSCE)

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** Contexte : Évaluer la compréhension et l’application des 6 rôles intrinsèques CanMEDS (communicateur, professionnel, gestionnaire, collaborateur, promoteur de la santé, érudit) chez les résidents pose un défi pour les responsables de la formation médicale postdoctorale. Nous avons émis l’hypothèse selon laquelle un examen clinique objectif structuré (ECOS) conçu pour évaluer plusieurs rôles CanMEDS intrinsèques serait suffisamment fiable et valide.

†† Méthodes : L’ECOS comportait 6 stations de 10 minutes, permettant chacune d’évaluer 2 rôles intrinsèques à l’aide de scénarios basés sur des cas (avec ou sans recours à des patients standardisés). Les résidents ont été notés au moyen d’échelles en 5 points et d’une évaluation globale de leur rendement à chacune des stations. La validité convergente a été vérifiée par corrélation avec les rapports d’évaluation en cours de formation (ITERs) des 12 mois précédents et un classement chiffré créé par les directeurs du programme (PDs).

‡‡ Résultats : Vingt-cinq résidents des années 0, 3 et 5 y ont participé. La fiabilité interstation pour les scores totaux aux tests (en pourcentage) a été de 0,87, tandis que la fiabilité pour chacun des 6 rôles de communicateur, collaborateur, gestionnaire et professionnel, a été supérieure à 0,8. Les scores totaux aux tests, les scores aux stations individuelles et les scores pour les rôles CanMEDS individuels ont tous fait état d’un effet significatif selon le niveau des résidents. L’analyse des classements établis par les PD quant aux rôles intrinsèques a révélé une forte corrélation avec les scores au test ECOS pour les rôles. On a observé une corrélation entre les REF et l’ECOS pour le rôle de communicateur, tandis que les REF pour le rôle d’expert médical et les scores totaux ont été en forte corrélation avec les scores de l’ECOS pour les rôles de communicateur, de gestionnaire et de professionnel.

‡§ Conclusion : Un ECOS conçu pour évaluer les rôles CanMEDS intrinsèques s’est révélé suffisamment valide et fiable pour un usage régulier dans un programme de résidence en orthopédie.

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The 7 CanMEDS competencies (medical expert, communicator, collaborator, manager, health advocate, scholar and professional) have been clearly outlined in the CanMEDS 2005 Physician Competency Framework, by the Royal College of Physicians and Surgeons of Canada. A similar framework has been described by the Accreditation Council for Graduate Medical Education (ACGME), defining 6 core competencies. Each of these frameworks describe the principal generic abilities of physicians in health care, and are an integral component of postgraduate education. However, despite the widespread popularity of CanMEDS and other competency frameworks and the mandate to both teach and assess these competencies, the best methods of teaching them remain unknown.

Assessment options for the intrinsic roles (those other than the medical expert role) include in-training evaluation reports (ITERs), structured oral examinations, 360° assessments and objective structured clinical examinations (OSCE). A survey of a wide variety of medical and surgical program directors in Canada identified that the ITER is the most commonly used method to evaluate the CanMEDS roles, despite its acknowledged subjective nature. Respondents reported dissatisfaction with current methods of evaluating the intrinsic roles, especially the manager and health advocate roles.

The “OSCE” is a term used to describe a variety of multistation examinations and is a format currently favoured at orthopedic certification examinations in Canada and other countries. Studies using OSCEs to assess the role of medical expert have demonstrated reliability and validity in postgraduate physician training, with some literature demonstrating the ability of the OSCE to assess communication skills. In fact, there is evidence that improved interpersonal skills are linked to better overall OSCE performance.

There is also some evidence that an OSCE can be used to assess other CanMEDS roles, including the scholar role (application of evidence-base medicine or demonstration of teaching skills) and the professional role (cultural awareness and the application of ethical principles). An OSCE has also been used to assess multiple CanMEDS competencies in other fields of postgraduate training, such as radiology and neonatology.

To our knowledge, no research exists regarding methods of assessing the intrinsic roles in orthopedic postgraduate training. We hypothesized that an OSCE designed to assess multiple intrinsic CanMEDS roles would have sufficient reliability and validity to distinguish between different years of postgraduate training in orthopedic residents.

METHODS

Exam development

The orthopaedic residency program at the University of Toronto, in collaboration with the Postgraduate Medical Education Department, designed an orthopedic OSCE to test the 6 intrinsic CanMEDS roles. A focus group of academic orthopedic specialists was assembled with the goal of creating clinical scenarios evaluating selected CanMEDS principles for each of the roles. The focus group relied on the source document from The Royal College of Physician and Surgeons of Canada, in which each of the roles, and their key competencies, is clearly defined.

The OSCE was 1 hour long and comprised 6 10-minute stations. The roles of communicator, collaborator, professional, manager, health advocate and scholar were assessed; a deliberate attempt was made to avoid testing the medical expert role. Most of the 6 case-based scenarios were designed to assess a primary and secondary role. Stations 2–4 used standardized patients (SPs; station 2: relative concern regarding delay in surgery; station 3: grandmother of child with suspected nonaccidental injury; station 4: teenager being informed of osteosarcoma diagnosis), whereas station 5 used a standardized health professional (SHP; operating room manager). Two stations did not have an SP or SHP (station 1: ethical approach to needlestick injuries; station 6: evidence-based medicine in spinal surgery). Table 1 lists the roles and associated key competencies tested in each station.

The CanMEDS OSCE development was facilitated by an exam blueprint and case development guides. A member of the focus group was assigned as the lead to design each station, which was then reviewed by the entire focus group. Any discrepancies or ambiguities were addressed or removed. A number of 5-point performance rating scales were developed for each of the intrinsic roles. The ratings were anchored by descriptions of performance to be demonstrated by the residents for each role. An overall 5-point global rating was also assigned for each resident at the end of the station. The SPs and SHPs were selected from an established standardized patient bank at the University of Toronto. For the OSCE, 2 SPs/SHPs were trained for each of the stations by an experienced SP trainer; each received a minimum of 3 hours’ training for each role. No SP or SHP assessment of performance was used.

Study design

Convenience sampling was used to recruit residents from specific postgraduate years (PGY) of training: PGY0 (incoming residents who had not yet begun training), PGY3 residents and PGY5 residents (volunteers who asked to sit the OSCE). The PGY5 residents had all recently passed their orthopedic certification examinations, and were included as the “gold standard.” Members of the orthopedic faculty at each station evaluated residents independently. It was not possible to blind examiners from the year of training of the residents, as many of the residents were familiar to the staff surgeons. However, examiners were asked to disregard the year of training when making assessments. The OSCE was
conducted in 4 1-hour sessions over the course of a single day. Each candidate signed a consent form permitting the use of exam results for research purposes. On completion of the exam, residents were invited to provide feedback using a 5-point Likert scale. Summative and formative feedback was given to each resident at the end of the OSCE.

Concurrent validity was sought in 2 ways. First, we obtained the ITERs from the preceding 12 months for the PGY3 and PGY5 residents, and the results on the 6 intrinsic roles correlated with the OSCE total score and role scores. Second, the 2 program directors (PDs) formed an ordinal ranking of the residents in PGY3 and PGY5 and rated each resident’s ability in each of the CanMEDS roles using a 5-point scale (1 = needs significant improvement; 2 = below expectations; 3 = solid, competent performance; 4 = exceeds expectations; 5 = superb). The overall ranking and the rating for each role were also correlated to the total OSCE score and role scores.

Approval for this study was obtained from the Research Ethics Board, University of Toronto. Each resident signed a consent form to permit the use of the OSCE results and ITER results for research purposes.

Statistical analysis

All data were deidentified, and residents were assigned a study-specific number. Raw scores from the individual station scores and role scores were entered into a spreadsheet and analyzed using SPSS version 19. All scores were converted into a percentage, with results reported as mean ± standard deviation. Reliability was established using the interstation \( \alpha \) coefficient of reliability (Cronbach \( \alpha \)) for each of the rating tools. We evaluated scores from the different rating scales using regression analysis. The effect of PGY on total test scores (%), overall ratings of performance, individual station scores and role scores were evaluated using 1-way analysis of variance (ANOVA). We considered results to be significant at \( p < 0.05 \). We used the Scheffe test for post hoc analysis to understand differences in scores between each possible pair of years of training. We determined the correlation between total OSCE scores and role scores with ITER role scores and PD rankings using Pearson correlation and Spearman Rho \( (R^2) \), and the Student \( t \) test was used to compare the PD ratings of resident performance between PGY levels.

RESULTS

Twenty-five residents from PGY0, 3 and 5 took part in the OSCE (Table 2). The roles of communicator, manager and professional were assessed in multiple stations; collaborator, health advocate and scholar were assessed in 1 station each. The total test scores (converted to a percentage) and the mean overall rating of performance are shown in Table 3; ANOVA testing demonstrated a significant
difference of the effect of PGY on both scores ($p < 0.001$). We found a significant difference between PGY0 and PGY3 ($p = 0.039$), PGY3 and PGY5 ($p = 0.001$), and PGY0 and PGY5 ($p < 0.001$).

The interstation reliability (percent) was 0.87 for total test scores and 0.83 for overall ratings of performance. The internal consistency for 4 of the 6 role scores is shown in Table 4; the consistency for each of these 4 roles was very high ($> 0.80$). We were not able to compute internal consistency coefficients for the scholar and advocate roles, as only 1 rating scale was used for each of these roles.

The total test scores for the individual stations by PGY are displayed in Figure 1. The effect of PGY on the individual station scores was significant (stations 1, 5 and 6, all $p < 0.01$; stations 2 and 4, both $p < 0.05$) with the exception of station 3 ($p = 0.07$). Post hoc analysis demonstrated a significant difference in station scores between the PGY5 and PGY0 groups and between the PGY5 and PGY3 groups for all stations except station 3. No significant difference in scores was seen between the PGY0 and PGY3 groups, but there was a trend for increased scores in the PGY3 group.

The total test scores for each of the intrinsic roles by PGY are shown in Figure 2. The ANOVA testing for the effect of PGY on each of the role scores was significant (communicator, collaborator, manager and professional roles, all $p < 0.001$; health advocate and scholar roles, both $p < 0.05$). For each of the role scores, the PGY0 and PGY3 groups differed significantly from the PGY5 group, but not from each other.

Analysis of the PD ratings of intrinsic roles demonstrated a good correlation between these and the corresponding OSCE role scores (Table 5). The ITERs from 12 months before the OSCE were available for the PGY3 and PGY5 residents. There was no correlation between ITERs and OSCE scores within any role except for communicator ($0.64$); however, the ITER overall scores correlated with the communicator ($0.58$), manager ($0.51$) and professional ($0.56$) OSCE role scores.

There was a 64% (16 of 25) response rate to the resident survey. Overall, 87.6% of respondents agreed or strongly agreed that the scenarios reflected encounters that an orthopedic surgeon would have to deal with in general practice, and 81.3% agreed or strongly agreed that participating in the OSCE would help prepare them for their final Royal College examination. However, only 56.3% agreed or strongly agreed that the OSCE was an effective way to assess their understanding of each of the CanMEDS roles.

### Table 4. Internal consistency for the 4 role scores with more than 1 rating scale

<table>
<thead>
<tr>
<th>Role</th>
<th>$\alpha$ Coefficient</th>
<th>Item numbers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Communicator</td>
<td>0.91</td>
<td>17 items in 5 of 6 stations</td>
</tr>
<tr>
<td>Collaborator</td>
<td>0.96</td>
<td>3 items in 1 of 6 stations</td>
</tr>
<tr>
<td>Manager</td>
<td>0.83</td>
<td>5 items in 3 of 6 stations</td>
</tr>
<tr>
<td>Professional</td>
<td>0.84</td>
<td>3 items in 2 of 6 stations</td>
</tr>
</tbody>
</table>
**DISCUSSION**

This orthopedic OSCE, designed to test the 6 intrinsic CanMEDS roles, has shown excellent overall reliability, as well as excellent reliability for the communicator, collaborator, professional and manager roles. Furthermore, using role-specific global ratings, we demonstrated an ability to distinguish between orthopedic residents at different levels of training. To our knowledge, this is the first time formal assessment of intrinsic roles has been studied in the field of postgraduate orthopedic surgical training.

With regards to total test scores, each of the stations were able to demonstrate a statistically significant difference by year of training, with the exception of station 3. Station 3 was a case-based scenario using a standardized patient — a grandmother who has brought in a child thought to have sustained a nonaccidental injury. Residents were asked to take a focused history regarding the home situation and explain to the grandmother the need to alert the appropriate authorities and admit the child. Despite the fact that the PGY effect on station 3 scores was not statistically significant \( (p = 0.07) \), the scores demonstrate the same general trend as all other stations: PGY5 (mean 90.5%) > PGY3 (mean 74.3%) > PGY1 (mean 69.5%). It may be that this station did not achieve significance because the PGY0 and PGY3 residents performed well, suggesting that these competencies may have been covered in undergraduate medical programs.

Careful blueprinting was used in this CanMEDS OSCE to avoid redundancy. Roles were spread among stations, and the stations that assessed the same roles focused on different competencies within that role, as outlined in the CanMEDS 2005 Framework.\(^3\) For example, in this OSCE, 2 stations (needlestick and trauma list) both examined the roles of communicator and manager, with the needlestick station additionally examining resident understanding of the professional role (bioethical principles and informed consent). However, the trauma list station focused on the competencies of priority setting and time management within the manager role, while the needlestick station sought to examine the competency of managing practice and career effectively.

The OSCE has been previously been shown to be a valid and reliable tool for the assessment of the medical expert role, with some evidence for its use in assessing the communicator role.\(^{12–14}\) Improved communication skills have previously been linked to both advanced year of training\(^18\) and to increased clinical competence.\(^19\) The OSCE has also been adapted to assess competencies within the roles of professional\(^3,24,26\) and scholar,\(^21,22\) with varying amounts of success. For example, Singer and colleagues,\(^4\) in an OSCE designed to assess clinical ethics, found a low reliability with only 4 stations; it was felt that increasing the number of stations would be required to obtain acceptable reliability.

Jeffries and colleagues\(^6\) recently demonstrated that the OSCE may be a valid and reliable method of simultaneously assessing multiple competencies in neonatal/perinatal medicine. Subspecialty trainees were assessed using a combination of binary checklists, 5-point CanMEDS ratings, as well as SPs’ and SHPs’ assessments of interpersonal and communication skills. Interstation reliability was acceptable to excellent for 6 of the 7 roles, with the scholar role being the exception. Only the teaching component of the scholar role was assessed; the authors recommended creating a single station to assess the competencies inherent to the scholar role, including the ability to understand and evaluate research. We applied this technique with success; our scholar station, designed to assess application of evidence-based medicine, was able to distinguish between residents with different levels of training.

Jeffries and colleagues\(^7\) also studied the use of the structured oral examination in assessing the 7 CanMEDS roles, including the medical expert role. Interstation reliability was acceptable for the roles of medical expert, scholar and professional (0.6–0.8), but not for the roles of communicator, collaborator or health advocate (0.4–0.6) or for the role of manager (0.19). In comparison to their previous OSCE study, interstation reliability was lower for all roles except scholar. However, costs were reduced significantly by not using standardized patients. Although we felt that SPs were an important component of our OSCE, the costs (in the region of $3000) were not insignificant, equating to a cost of $250 per resident. It may be possible to substitute orthopedic fellows or staff in place of SPs in future iterations. However, given the importance of establishing competence in these areas by both the Royal College and the ACGME, this could be seen as a reasonable cost for training programs to bear on an annual basis.

The Royal College has a published handbook detailing assessment methods for the CanMEDS competencies.\(^27\) It states that oral examinations and OSCEs are not well suited to evaluate the roles of manager and scholar. Other documents attest to the perceived difficulty with assessing the intrinsic roles, especially the role of health advocate.\(^5,28,29\) However, the reliability of the manager role in our study was high enough to be used in a high-stakes examination. While we cannot attest to the reliability of the health advocate and scholar roles owing to insufficient items, ANOVA testing demonstrated a significant ability to distinguish between residents of different PGY levels for both of these roles. We believe that the OSCE is a very appropriate means of assessment, as clinical scenarios that mimic real life encounters can be used.

An advantage of this type of OSCE is that both teaching (formative evaluation) and assessment (summative evaluation) can be incorporated. As noted by Zuckerman and colleagues,\(^4\) assessment motivates residents to learn important skills and is therefore a form of learning in itself. We believe that by exposing very junior residents (PGY0) to
scenarios they will likely soon encounter (complaints of delayed surgery, difficult interaction with operating room staff), learning opportunities can be created in an environment suitable for feedback and coaching. Furthermore, by retesting mid-rank residents (PGY3), an assessment of their skills in each of the CanMEDS roles can be re-evaluated, and appropriate feedback can be provided. At our institution, a bank of multiple CanMEDS scenarios has been created; we believe that all residents will benefit from exposure to a CanMEDS OSCE twice in their training, once as a junior and once as a senior resident.

We are not aware of any OSCE designed to test only the intrinsic CanMEDS roles. While it is difficult to remove the medical expert role from such an examination, every effort was made to minimize scenarios dependent on orthopedic knowledge. For example, in the station focusing on the role of manager, residents were asked to manage an overbooked trauma list; some degree of orthopedic knowledge was required to know the urgency of each case, but residents were graded on their reasoning and on their ability to handle a phone call from a disgruntled relative. In the scholar station, residents were expected to know levels of evidence and how to perform database searches; in the needlestick case (professional role) residents were expected to know the immediate and delayed management of such an occurrence as well as the ethical principles involved regarding patient consent and notification of the appropriate monitoring bodies. For this reason, we do not believe that there were any major qualitative differences regarding the degree of core knowledge assessed in each station.

We were interested in obtaining concurrent validity; for example how could the station creator be certain that communicators, and adherent to role descriptions provided by the appropriate monitoring bodies. For this reason, we do not believe that there were any major qualitative differences regarding the degree of core knowledge assessed in each station.

We were interested in obtaining concurrent validity; for example how could the station creator be certain that communication stations were truly assessing the communicator role. All case scenarios were based on real-life clinical situations, and adherent to role descriptions provided by the Royal College of Physicians and Surgeons Canada. Interestingly, no correlation was seen between the ITER role score and the OSCE role scores, but a good correlation was seen with program director ratings of the roles. This suggests that ITERs are not a particularly effective form of assessment for the intrinsic roles.

**Limitations**

Limitations included our inability to comment on the reliability of the roles of scholar and health advocate, as only a single global rating was used for each of these roles — this will be remedied in the future. However, each of these roles was useful in distinguishing between different years of training. Objectivity may have been increased by the use of SPs or SHPs to provide global ratings of the residents, a method that has been used to good effect in the medical education literature, with evidence of good correlation between ratings completed by SPs and faculty physicians. Importantly, the examiners will have known some residents and their PGY of training, raising the potential for bias. Examiners were asked to disregard the PGY level of the resident; however, it may be that the use of SPs’ ratings will help to offset this risk. In this OSCE, neither station nor role weighting was used, as it was felt that each of the CanMEDS roles was equally important. Finally, it is not possible to know how this CanMEDS OSCE compares to a more traditional OSCE with incorporated assessment of CanMEDS roles within those stations; however, we have demonstrated a high degree of reliability or internal consistency, a measure that indicates an exam is performing well. It may be that the high degree of reliability seen in this CanMEDS OSCE may be a result of its narrow focus.

**Conclusion**

An OSCE designed to assess the intrinsic CanMEDS roles proved to be sufficiently valid and reliable for regular use in an orthopedic residency program.

**Competing interests:** None declared.

**Contributors:** T. Dwyer, P Ferguson, M.L. Murnaghan, B. Hodges and D. Ogilvie-Harris designed the study. T. Dwyer, D. Wasserstein, M. Nousainen, P. Ferguson, V. Wedley, T. Leroux and D. Ogilvie-Harris acquired the data, which T. Dwyer, S. Glover-Takahashi, M. Hynes, J. Herold, J.L. Semple, B. Hodges and D. Ogilvie-Harris analyzed. T. Dwyer, S. Glover-Takahashi, M. Hynes, J. Herold, B. Hodges and D. Ogilvie-Harris wrote the article, which all authors reviewed and approved for publication.

**References**


Parathyroid hormone levels 1 hour after thyroidectomy: an early predictor of postoperative hypocalcemia

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Background: Parathyroid dysfunction leading to symptomatic hypocalcemia is not uncommon following a total or completion thyroidectomy and is often associated with significant patient morbidity and a prolonged hospital stay. A simple, reliable indicator to identify patients at risk would permit earlier pharmacologic prophylaxis to avoid these adverse outcomes. We examined the role of intact parathormone (PTH) levels 1 hour after surgery as a predictor of post-thyroidectomy hypocalcemia.

Methods: We prospectively reviewed the cases of consecutive patients undergoing total or completion thyroidectomy. Ionized calcium (Ca\(^{2+}\)) and intact PTH levels were measured preoperatively and at 1-, 6- and 24-hour intervals postoperatively. The specificity, sensitivity, negative and positive predictive values of the 1-hour PTH serum levels (PTH-1) in predicting 24-hour post-thyroidectomy hypocalcemia and eucalcaemia were determined.

Results: We reviewed the cases of 149 patients. Biochemical hypocalcaemia (Ca\(^{2+}\) < 1.1 mmol/L) developed in 38 of 149 (25.7%) patients 24 hours after thyroidectomy. The sensitivity, specificity, positive and negative predictive values of a low PTH-1 were 89%, 100%, 97% and 100%, respectively.

Conclusion: We found that PTH-1 levels were predictive of symptomatic hypocalcemia 24 hours after thyroidectomy. Routine use of this assay should be considered, as it could prompt the early administration of calcitriol in patients at risk of hypocalcemia and allow for the safe and timely discharge of patients expected to remain eucalcaemic.

Contexte : Il n’est pas rare qu’un dysfonctionnement des glandes parathyroïdes entraîne une hypocalcémie symptomatique s’observe après une thyroidectomie totale ou de complétion et il est souvent associé à une importante morbidité chez les patients et à un séjour hospitalier prolongé. Un indicateur simple et fiable permettant de reconnaître les patients à risque pourrait favoriser une prophylaxie pharmacologique précoce afin d’éviter ces complications. Nous avons examiné le rôle des taux de parathormone (PTH) intacte une heure après la chirurgie comme prédicteurs de l’hypocalcémie post-thyroidectomie.

Méthodes : Nous avons passé en revue de manière prospective des cas consécutifs de patients soumis à une thyroidectomie totale ou de complétion. Les taux de calcium ionisé (Ca\(^{2+}\)) et de PTH intacte ont été mesurés avant l’intervention, puis 1 heure, 6 heures et 24 heures après. Il a ainsi été possible de déterminer la spécificité, la sensibilité, la valeur prédictive négative et positive des taux sériques de PTH 1 heure après l’intervention (PTH-1) pour ce qui est de prédire l’hypocalcémie et l’eucalcaémie 24 heures après la thyroidectomie.

Résultats : Nous avons analysé 149 cas. L’hypocalcémie biochimique (Ca\(^{2+}\) < 1,1 mmol/L) a été observée chez 38 patients sur 149 (25,7 %) 24 heures après la thyroidectomie. La sensibilité, la spécificité, la valeur prédictive positive et négative d’un taux de PTH-1 faible ont été respectivement de 89 %, 100 %, 97 % et 100 %.

Conclusion : Nous avons noté que les taux de PTH-1 étaient prédictifs d’une hypocalcémie symptomatique 24 heures après la thyroidectomie. L’utilisation d’emblée de ce test est à envisager puisqu’elle permettrait l’administration précoce de calcitriol chez les patients exposés à un risque d’hypocalcémie et un congé sécuritaire et rapide chez les patients dont on s’attend à ce qu’ils demeurent eucalcaémiques.
Panhypoparathyroidism is associated with hypocalcemia that may be either transient or permanent. The hyposecretion of parathyroid hormone (PTH) can result from various causes, including surgical injury, remote ischemia, or primary parathyroid disease. The clinical presentation of hypocalcemia includes paresthesias, numbness, muscular weakness, and tetany. However, laboratory confirmation is necessary to establish the diagnosis of hypocalcemia.

**Methods**

We retrospectively reviewed the cases of consecutive patients undergoing total or completion thyroidectomy at a single institution (Montreal General Hospital) between July 2009 and February 2011. No patients with coexisting parathyroid or renal pathology were included. All patients were recorded for age, sex, indication for surgery (benign v. malignant lesion) and type of surgery (completion v. total thyroidectomy). Preoperative serum ionized calcium (Ca\(^{2+}\)) levels and preoperative PTH (PTH-P) levels were measured; we also recorded PTH levels determined 1, 6 and 24 hours postoperatively (PTH-1, PTH-6 and PTH-24, respectively). Ionized calcium was measured on a blood gas machine, the ABL800 Flex (Radiometer). Normal Ca\(^{2+}\) ranged from 1.10–1.32 mmol/L. Serum intact PTH was measured using the Roche Elecsys 2010 System electrochemiluminescence immunoassay (Roche Diagnostics). The normal PTH level in our laboratory ranges from 1.5–6.9 pmol/L. Hypocalcaemia was defined as at least 1 ionized serum calcium measurement below 1.10 mmol/L (normal range: 1.1–1.32 mmol/L). Oral calcium supplementation with or without calcitriol was given to patients in whom symptomatic hypocalcemia developed or when the serum calcium level was less than 1.0 mmol/L. Patients with acral numbness, paresthesias, a positive Chvostek or Trousseau sign, cardiac arrhythmias or muscular spasms with or without stridor were considered symptomatic. Severe hypocalcemia was defined as Ca\(^{2+}\) of 0.9 mmol/L or less. An intravenous calcium gluconate (10%) infusion was reserved for patients with severe, symptomatic hypocalcemia.

**Results**

We reviewed the cases of 149 patients (14 [9.4%] men and 135 [90.6%] women). The mean age of the entire cohort was 57.8 years and the median age was 58 years. Of the entire cohort, 136 (91.3%) patients underwent total thyroidectomy and 13 (8.7%) underwent completion thyroidectomy for malignancy. On final histologic review, 140 (94%) patients had diagnoses of primary thyroid cancer, whereas the 9 (6%) remaining patients had benign lesions.

A significant number of patients had hypoparathyroidism (as defined by a PTH < 1.5 pmol/L (normal range: 1.5–6.9 pmol/L). The incidence at 1, 6 and 24 hours postoperative was 34 (22.8%), 36 (24.2%) and 38 (25.5%), respectively (Table 1). The incidence of hypoparathyroidism at 1, 6 and

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**Table 1. Incidence of hypoparathyroidism and hypocalcemia after total or completion thyroidectomy, \(n = 149\)**

<table>
<thead>
<tr>
<th>Post-thyroidectomy</th>
<th>PTH &lt; 1.5 pmol/L</th>
<th>Ca(^{2+}) &lt; 1.1 mmol/L</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 h</td>
<td>22.8</td>
<td>2</td>
</tr>
<tr>
<td>6 h</td>
<td>24.2</td>
<td>5</td>
</tr>
<tr>
<td>24 h</td>
<td>25.5</td>
<td>25.5</td>
</tr>
</tbody>
</table>

Ca\(^{2+}\) = Ionized calcium; PTH = parathormone.
Hypocalcemia, as defined by Ca\(^2+\) less than 1.1 mmol/L (normal range: 1.1–1.32 mmol/L) at 1, 6 and 24 hours postoperative was documented in 3 (3.5%), 8 (5.4%) and 38 (25.5%) patients, respectively (Table 1). To assess the ability of Ca\(^2+\)-1 measurements to predict hypocalcemia 24 hours postoperative, we performed sensitivity and specificity analyses. Of 149 patients, only 3 (3.5%) had Ca\(^2+\)-1; Ca\(^2+\)-24 was low in 38 (25.5%) patients. Thus, the sensitivity of a low Ca\(^2+\)-1 in predicting a low Ca\(^2+\)-24 was only 11%. The specificity, however, was 100%. The negative (NPV) and positive predictive values (PPV) were 76% and 80%, respectively. Thus, Ca\(^2+\)-1 is of limited use in predicting hypocalcemia 24 hours post-thyroidectomy. This is reflected in the Pearson r coefficients comparing Ca\(^2+\)-1 and Ca\(^2+\)-6 with Ca\(^2+\)-24 of only 0.33 and 0.41, respectively. Unless they are low, Ca\(^2+\)-1 levels are a poor predictor of hypocalcemia at 24 hours postoperative.

Of the 38 patients in whom hypocalcemia developed 24 hours post-thyroidectomy, PTH-1 levels less than 1.15 pmol/L (normal range: 1.5–6.9 pmol/L) in 34. Thus, the sensitivity of the PTH-1 in predicting the incidence of hypocalcemia at 24 hours postoperative is 89%. The specificity of PTH-1 less than 1.5 pmol/L in predicting hypocalcemia at 24 hours postoperative is 100%. The NPV and PPV were 97% and 100%, respectively (Table 2). Thus, PTH-1 is highly reliable in predicting which patients are at risk of hypocalcemia and which will remain eucalcemic the day after surgery.

Of our entire cohort, 30 patients were discharged on oral medication consisting of combinations calcium, calcitriol and magnesium.

**Table 2. Sensitivity and specificity analysis of PTH-1 measurement comparing Ca\(^2+\)-24 and hypocalcemia**

<table>
<thead>
<tr>
<th>Factor</th>
<th>Ca(^2+) &lt; 1.1 mmol/L</th>
<th>Ca(^2+) ≥ 1.1 mmol/L</th>
</tr>
</thead>
<tbody>
<tr>
<td>PTH-1 &gt; 1.5 pmol/L, no.</td>
<td>4</td>
<td>111</td>
</tr>
<tr>
<td>PTH-1 ≤ 1.5 pmol/L, no.</td>
<td>34</td>
<td>0</td>
</tr>
<tr>
<td>Total no.</td>
<td>38</td>
<td>111</td>
</tr>
<tr>
<td>Sensitivity</td>
<td>89%</td>
<td></td>
</tr>
<tr>
<td>Specificity</td>
<td>100%</td>
<td></td>
</tr>
<tr>
<td>NPV</td>
<td>97%</td>
<td></td>
</tr>
<tr>
<td>PPV</td>
<td>100%</td>
<td></td>
</tr>
</tbody>
</table>

Ca\(^2+\) = Ionized calcium; NPV = negative predictive value; PPV = positive predictive value; PTH = parathormone.
values were obtained. Lombardi and colleagues found greater precision with measurements taken at 4 and 6 hours, with an overall accuracy of 98%. Lam and Kerr reported that all patients with a PTH level less than 8 pg/mL measured 1 hour after the surgery became hypocalcemic, and all patients with a PTH level greater than 9 pg/mL did not. Higgins and colleagues demonstrated that 64% of those patients who subsequently required calcium supplementation had a decrease in PTH levels greater than 75% from baseline 20 minutes after surgery, and 74% of those who did not need calcium supplementation demonstrated a decrease of less than 75% from baseline. The Australian Endocrine Guidelines, published in 2007, adopted the recommendations of Lombardi and colleagues to standardize obtaining a PTH level 4 hours after a thyroidectomy. The wide variability of the predictors for the development of hypocalcemia across centres suggests that the measurement of PTH at any time in the postoperative period may be a reliable predictor of hypocalcemia. We believe that obtaining a PTH level 1 hour after an operation is the optimal time to predict the need for calcium and/or calcitriol supplementation after discharge from the hospital.

The present study demonstrates that PTH-1, PTH-6, and PTH-24 assays are good predictors of hypocalcemia 24 hours post-thyroidectomy. A PTH-1 assay alone is predictive of the development of postoperative hypocalcemia at 24 hours, with a sensitivity of 89% and an NPV of 97%. Practically, we found no significant advantage in determining PTH-6 and PTH-24 in asymptomatic patients with a PTH-1 greater than 1.5 pmol/L.

Should PTH-1 be greater than 1.5 pmol/L, asymptomatic patients can be discharged without the need for further routine calcium monitoring. Should PTH-1 be less than 1.5 pmol/L, patients can be administered a “loading dose” of calcitriol early in the recovery room. This is of practical importance given a lag of 24–48 hours before calcitriol exhibits its clinical effects.

The purpose of the present study was to identify a simple predictor of early postoperative hypocalcemia, which may either be transient (lasting weeks–months) or may persist. Factors other than PTH-1, such as extent of dissection, number of parathyroids visualized intraoperatively, number of parathyroids identified in the pathologic specimen, and vitamin D levels, should be taken into account to predict chronic hypoparathyroidism and the need for calcitriol and calcium for longer than 6 months after surgery.

CONCLUSION

Our results suggest that PTH-1 is an excellent predictor of patients who are at risk for hypocalcemia 24 hours postoperatively. Should PTH-1 be less than 1.5 pmol/L, prophylactic pharmacotherapy with calcitriol should be started to avoid the development of symptomatic hypocalcemia.

Competing interests: None declared.

Contributors: A. Alqahtani and R.J. Tabah participated in all manuscript preparation activities. A. Parsyan and R. Payne designed the study and reviewed and approved the final version for publication.

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Functional outcome of supracondylar elbow fractures in children: a 3- to 5-year follow-up

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Background: Long-term functional outcomes of supracondylar elbow fractures (SCEF) have not been well documented in the literature. We retrospectively evaluated functional outcomes of pediatric SCEF using the Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire.

Methods: We retrospectively reviewed the outcomes of patients who presented to our tertiary care pediatric emergency department with SCEF between January 2005 and December 2009. We reviewed their charts to assess several clinical parameters, including age, sex, Gartland classification of SCEF, weight, comorbidities, treatment intervention, physiotherapy and the extremity involved. The DASH questionnaire was administered in 2012. We performed a multiple linear regression analysis to determine the significance of these clinical parameters as they related to the DASH score for functional outcome.

Results: We included 94 patients with SCEF in our review. Pediatric SCEF had good functional outcomes based on the DASH questionnaire (mean score 0.77 ± 2.10). We obtained the following DASH scores: 0.45 ± 2.20 for type I, 1.09 ± 1.70 for type II and 1.43 ± 2.40 for type III fractures. There was no statistical difference in functional outcome, regardless of sex ($p = 0.07$), age at injury ($p = 0.96$), fracture type ($p = 0.14$), weight ($p = 0.59$), right/left extremity ($p = 0.26$) or surgery ($p = 0.52$).

Conclusion: Our results demonstrate that good functional outcomes can be expected with pediatric SCEF based on the DASH questionnaire, regardless of age at injury, sex, weight, right/left extremity or surgical/nonsurgical intervention, provided satisfactory reduction is achieved and maintained.


Résultats : Nous avons inclus 94 patients ayant subi une FCSC dans notre analyse. La FCSC pédiatrique évolue bien au plan fonctionnel selon le questionnaire DASH (score moyen 0.77 ± 2.10). Nous avons obtenu les scores DASH suivants : 0.45 ± 2.20 pour les fractures de type I, 1.09 ± 1.70 pour les fractures de type II et 1.43 ± 2.40 pour les fractures de type III. On n’a noté aucune différence statistique quant aux résultats fonctionnels, indépendamment du sexe ($p = 0.07$), de l’âge au moment de la fracture ($p = 0.96$), du type de fracture ($p = 0.14$), du poids ($p = 0.59$), de la latéralité ($p = 0.26$) ou de la chirurgie ($p = 0.52$).

Conclusion : Nos observations démontrent qu’on peut s’attendre à de bons résultats fonctionnels dans les cas de FCSC en se fondant sur le questionnaire DASH, indépendamment de l’âge au moment de la fracture, du sexe, du poids, de la latéralité ou de l’intervention chirurgicale ou non chirurgicale, à la condition d’obtenir et de maintenir une réduction satisfaisante.
Pediatric supracondylar elbow fractures (SCEF) are a common occurrence in children. These fractures are commonly extra-articular, unlike adult SCEF. Return of elbow motion after treatment of supracondylar humeral fracture in children has been well documented in the literature. However, the return of elbow range of motion and function is usually measured as an objective parameter, such as a return of normal range of arc motion in the sagittal plane (flexion and extension). Long-term functional outcome using standardized tools has not been well documented in the literature. One study analyzed the correlation between the values of a modified Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire and change of elbow function after SCEF of the humerus. However, the study addressed only flexion SCEF, which represents a small percentage of pediatric SCEF. The authors concluded that the value of a modified DASH questionnaire correlates with objective indicators of elbow function after flexion SCEF in children. A standardized functional outcome tool, such as the well-validated DASH questionnaire, has been instrumental in measuring functional disability.

Bot and colleagues evaluated the clinimetric quality of 16 self-administered shoulder disability questionnaires, including DASH, the Shoulder Pain and Disability Index and the American Shoulder and Elbow Surgeons Standardised Shoulder Assessment Form. For clinimetric purposes, the DASH questionnaire received the best ratings. Thus, we chose the DASH questionnaire, as it is a region-specific standardized functional outcome tool that is well validated and has been important in measuring functional disability.

The purpose of the present study was to provide a retrospective, longitudinal evaluation of functional outcome in a large population of children treated for pediatric SCEF, using the DASH for standardized measure of outcome. A secondary goal was to determine whether factors such as age at injury, sex, weight, right or left extremity, Gartland fracture type and surgical versus nonsurgical intervention could predict long-term functional outcomes.

**Methods**

We retrospectively reviewed the cases of children with SCEF who presented to our tertiary care pediatric emergency department between January 2005 and December 2009. We reviewed their charts for several parameters, including age, sex, classification of fracture severity, weight, comorbidities, operative or nonoperative treatment intervention, postoperative physiotherapy and associated nerve injury. A DASH questionnaire was administered in 2012 by the parents of the patients with the child present; if they were old enough, the patients completed the questionnaire themselves under a parent’s supervision. We chose to remove the sex-related question to make the questionnaire more age appropriate. The optional work module was not used, but the optional sports/performing arts module was.

The DASH score is scaled between 0 and 100. Higher scores indicate worse function, and lower scores indicate better function relating to upper-extremity disability.

Our inclusion criteria for joining the study were isolated extension SCEF in patients younger than 13 years at the time of injury, closed injury and consent to join the study (obtained from parents). The exclusion criteria were poly-trauma, flexion type SCEF, ipsilateral injury requiring surgery, iatrogenic neurologic injury, reinjury to the same elbow within the study period, metabolic bone disease, condyle, epicondyle fractures and transphyseal fractures that had been reported as SCEF. We chose to exclude the flexion type SCEF owing to the small number (1.2%) of patients with this condition.

Three fellowship-trained pediatric orthopedic surgeons independently reviewed the radiographs and grouped the patients according to the Gartland classification, which is widely used in the literature. In the Gartland classification system, type I fractures are essentially nondisplaced. Type II fractures are displaced with a variable amount of angulation, but more importantly, the posterior cortex of the humerus is intact. Type III fractures are completely displaced, with no cortical continuity (Fig. 1). A value for interobserver agreement was then calculated.

The pediatric orthopedic surgeons in our tertiary care centre treated patients either operatively or nonoperatively based on the degree of angulation and displacement (displacement of the anterior humeral line [Fig. 2] and alteration of the Baumann angle [Fig. 3]).

The anterior humeral line should intersect the middle third of the capitellum on lateral radiographs. A Baumann angle within 5° of the uninjured side was considered acceptable. This was the radiographic measure of coronal plane deformity. The normal physiologic tilt of the capitellum on the humerus is about 30° anteriorly; reduction was not required if this physiologic angulation was 20° or more and if the anterior humeral line intersected the middle third of the capitellum on lateral radiographs in extension type SCEF. Type I fractures were treated nonoperatively. Type II fractures were treated operatively or nonoperatively depending on the amount of angulation and displacement. Type II fractures that failed closed reduction based on the radiographic parameters mentioned previously were treated operatively. All type III fractures were treated operatively. Patients who were managed operatively underwent closed reduction and percutaneous pinning using Kirschner wires under fluoroscopy. If reduction could not be obtained with closed reduction, open reduction and percutaneous pinning was performed.

Patients were seen by the pediatric orthopedic surgeons for scheduled follow-up visits. They were seen...
10–14 days postoperatively for a cast change, wound check and radiographs to ensure displacement had not occurred. Displacement was measured using the anterior humeral line and the relationship with the capitellum. Alignment was considered acceptable if the anterior humeral line intersected the middle third of the capitellum on lateral radiographs. Patients were seen for pin removal and cast change at 4 weeks postoperative and again for final cast removal, radiographs and range of motion check at 6 weeks postoperative. At the 3-month follow-up, patients were seen to assess the need for physiotherapy and to check range of motion.

The patients who received closed reduction or who sustained a nondisplaced or minimally displaced SCEF not requiring closed reduction were casted and seen in clinic at 2 weeks postinjury for a cast check and radiographs and at 4 weeks for cast removal, radiographs and range of motion check.

Three fellowship-trained pediatric orthopedic surgeons followed all patients to ensure fracture healing, as seen radiographically. One of us (A.L.) independently reviewed all the radiographs to ensure that reductions were maintained and that fractures had healed.

Statistical analysis

Mean DASH scores were then calculated based on sex, right or left extremity, weight, intervention (operative v.
nonoperative) and age at time of injury. A multiple linear regression analysis was then performed, and we considered results to be significant at $p < 0.05$.

**Results**

A total of 158 patients with 161 SCEF were eligible to participate in our study. Ten patients were excluded, as they did not meet the inclusion criteria. Fifty-four patients did not respond because they had moved away or changed phone numbers without providing an update in the medical record system, and 1 patient declined participation, leaving 94 patients for analysis (Fig. 4). Patients who did not reply or declined participation had a similar distribution in terms of type of SCEF compared with our study group (Table 1).

Of the 94 patients included in the study (Table 2), 54 (57%) were male and 40 (43%) were female. We subdivided patients by fracture type: 53 (56.4%) had type I, 26 (27.7%) had type II and 15 (15.9%) had type III fractures; 2 (2.1%) had flexion type SCEF. Patients were further subdivided by sex, right or left extremity, weight, intervention (operative vs. nonoperative) and age at time of injury (Table 2). There was a higher incidence of SCEF in boys (57%) than in girls, and the left elbow was more commonly injured than the right elbow (61.7%). The mean age of patients with type I SCEF was 70 months, type II was 74 months, type III was 83 months and Flexion type SCEF was 73.5 months (Table 2).

A multiple linear regression analysis was performed to determine the significance of the clinical parameters as they related to the DASH score for functional outcome. There was no statistical difference in functional outcome using the DASH score regardless of sex ($p = 0.07$), age at injury ($p =$.
Using the optional module (sports/performing arts), there was no statistical difference in functional outcome regardless of sex \( (p = 0.33) \), age at injury \( (p = 0.90) \), type of fracture \( (p = 0.62) \), weight \( (p = 0.99) \), or right or left extremity \( (p = 0.28) \); Tables 3 and 4).

Our interobserver agreement to indicate the reproducibility of the classification was calculated using weighted Fleiss \( \kappa \), with \( \kappa \) representing the proportion of agreement among the orthopedic surgeons beyond that expected by chance. A value of 0 indicates what would be expected by chance and a value of 1 indicates perfect agreement. A value less than 0 is an indication that agreement is less than what is expected by chance.\(^5\) Our calculated \( \kappa \) score was 0.76, which represents good interobserver reliability (Table 6).

**DISCUSSION**

Supracondylar elbow fractures are common in children. The Gartland classification has been widely used for classification of pediatric SCEF. Ideally, a fracture classification system should be both prognostic and provide a guide to clinical management. Our study demonstrated no statistical difference in functional outcomes across all pediatric SCEF despite Gartland classification. There were no significant differences between other parameters, such as sex, right or left extremity, weight, intervention (operative v. nonoperative) and age at time of injury and their correlation with functional outcomes. These types of fractures, regardless of several parameters, tend to have good functional outcomes based on the DASH score, provided that satisfactory reduction is maintained by either surgical or nonsurgical (cast) means and that the technique of reduction and subsequent treatment course is uncomplicated.

The pediatric orthopedic surgeons at our institution still use the Gartland classification; however, for clinical decision making, degree of displacement is used. For example, not all Gartland type II SCEF were treated operatively; based on degree of displacement/intersection of the anterior humeral line and capitellum (Fig. 3) and the Baumann angle (Fig. 4) as well as on failure of closed reduction, patients were treated operatively or nonoperatively. There was no significant difference in DASH scores \( (p = 0.52) \) between patients treated operatively and those treated nonoperatively. This does not mean that surgery is not important in the management of pediatric SCEF; adequate reduction is important to the functional outcome. Inadequate reduction can lead to potential functional long-term problems.\(^6\) Garland type II SCEF is not an indication for surgery. The degree of displacement should guide management, as SCEF tend to do well if adequate reduction is obtained and maintained and if it follows an uncomplicated course. A study by Heal and colleagues\(^7\) further supports this, as they also conclude that pediatric SCEF should be treated based on the degree of displacement rather than the Gartland classification.

In the same study, based on a calculated \( \kappa \) score of 0.54, Heal and colleagues\(^7\) concluded that there was a moderate interobserver agreement with the Gartland classification, with poor agreement over type I extension SCEF, fair to moderate agreement with type II and good to very good agreement with type III using \( \kappa \) scores. Our interobserver agreement to indicate the reproducibility of the classification was calculated using weighted Fleiss \( \kappa \), which represents the proportion of agreement among the orthopedic surgeons beyond that expected by chance. In contrast to Heal and colleagues,\(^7\) our calculated score was 0.76, which indicates substantial or good agreement among the orthopedic surgeons, bearing in mind that the calculated \( \kappa \) scores could also be due to chance.

Our study showed no statistical difference in the functional outcome based on the Gartland classification. Pediatric SCEF, if treated appropriately based on degree of displacement and adequacy/maintenance of closed reduction tend to do well despite the classification of fracture with little to no functional limitation of day-
to-day activities or associated pain. In the sports/performing arts module, there was also no statistical difference in mean DASH score among the groups (Table 4), regardless of age, weight, right or left extremity, sex, intervention (operative vs. nonoperative) or Gartland classification of severity. These patients also tend to function well with no significant limitation in sports or performing arts (Table 5).

Spencer and colleagues demonstrated the effect of age and severity of fracture (determined by those requiring operative intervention) on the recovery of elbow motion, with patients older than 5 years demonstrating a 3%–9% lower relative arc of motion at the follow-up points than younger patients and a slower recovery in motion in those who had more severe fractures requiring surgical intervention. We studied whether there were any functional differences between these groups using the DASH questionnaire and found that despite the findings of Spencer and colleagues, there was no statistical difference in functional outcome regardless of age or operative or nonoperative intervention ($p = 0.52$) based on multiple linear regression analysis.

**Limitations**

The limitations of our study include the fact that it was retrospective and, in some cases, the parents filled out the DASH questionnaire based on their perceptions of their children’s functioning. Another limitation is the validity of this questionnaire in this age group. Although the DASH questionnaire has not yet been formally validated in this age group, multiple studies have used the DASH questionnaire in pediatric populations. There is also a possibility for skewed data given that 54 patients did not respond and 1 declined participation. Thus, given our small sample size, there is a chance that we missed the difference in DASH scores among the groups. We did not perform a subgroup analysis on the fractures treated with open reduction, as the numbers would be small and we would have therefore been unable to make firm statistical conclusions; however, this was not the primary focus of our study and represents a potential future area of research. Despite the small number at follow-up, we reviewed the charts of all 149 patients who were eligible for participation in the study to identify any adverse outcomes or the need for further therapy or intervention. There were none identified from our chart review. We also reviewed the surgeon’s notes at subsequent follow-ups.

To our knowledge, our study is the first to attempt to identify risk factors for poor functional outcomes using a standardized measure of outcome in a large group of children with all types of extension SCEF. Our study further provides a longitudinal evaluation of functional outcome in a large population of children treated for pediatric SCEF fracture using the DASH for standardized measure of outcome.

**Conclusion**

Return of range of motion after an isolated pediatric SCEF has been well documented in the literature. We found that overall, most parents and patients reported no functional interference with normal social activities, sports or performing arts, activities of daily living (including self-care), and no functionally limiting symptoms, regardless of age at injury, sex, weight, right or left extremity, operative or nonoperative intervention or Gartland classification, provided that satisfactory reduction is maintained by either surgical or nonsurgical (cast) means and that the means of reduction and treatment course are not complicated. Perhaps adequate reduction is more important than simply treatment of fracture type.

**Acknowledgments:** We thank Minnie Parsons for her help in the assembling of patient data, ensuring we had the necessary documentation to meet the ethics board requirements and printing and distributing the DASH questionnaire.

**Competing interests:** None declared.

**Contributors:** All authors designed the study. A.D. Isa acquired the data, which all authors analyzed. A.D. Isa and A. Furey wrote the article, which all authors reviewed and approved for publication.

**References**


Comparison of cast materials for the treatment of congenital idiopathic clubfoot using the Ponseti method: a prospective randomized controlled trial

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Background: The Ponseti method of congenital idiopathic clubfoot correction has traditionally specified plaster of Paris (POP) as the cast material of choice; however, there are negative aspects to using POP. We sought to determine the influence of cast material (POP v. semirigid fibreglass [SRF]) on clubfoot correction using the Ponseti method.

Methods: Patients were randomized to POP or SRF before undergoing the Ponseti method. The primary outcome measure was the number of casts required for clubfoot correction. Secondary outcome measures included the number of casts by severity, ease of cast removal, need for Achilles tenotomy, brace compliance, deformity relapse, need for repeat casting and need for ancillary surgical procedures.

Results: We enrolled 30 patients: 12 randomized to POP and 18 to SRF. There was no difference in the number of casts required for clubfoot correction between the groups (p = 0.13). According to parents, removal of POP was more difficult (p < 0.001), more time consuming (p < 0.001) and required more than 1 method (p < 0.001). At a final follow-up of 30.8 months, the mean times to deformity relapse requiring repeat casting, surgery or both were 18.7 and 16.4 months for the SRF and POP groups, respectively.

Conclusion: There was no significant difference in the number of casts required for correction of clubfoot between the 2 materials, but SRF resulted in a more favourable parental experience, which cannot be ignored as it may have a positive impact on psychological well-being despite the increased cost associated.

Contexte : La méthode de Ponseti pour la correction du pied bot congénital idiopathique a de tout temps spécifié l’utilisation du plâtre de Paris comme matériau de choix; il y a toutefois certains inconvénients associés au plâtre de Paris. Nous avons voulu déterminer l’influence du matériau utilisé (plâtre de Paris c. fibre de verre semi-rigide) sur la correction du pied bot selon la méthode de Ponseti.

Méthodes : Les patients ont été assignés aléatoirement soit au plâtre de Paris soit à la fibre de verre semi-rigide en vue de l’intervention de Ponseti. Le principal paramètre mesuré était le nombre de plâtres requis pour corriger le pied bot. Les paramètres secondaires incluaient le nombre de plâtres en fonction de la gravité, la facilité de retrait du plâtre, la nécessité de sectionner le tendon d’Achille, le port assidu de l’attelle, le retour de la difformité, la nécessité d’autres plâtres et interventions chirurgicales auxiliaires.

Résultats : Nous avons inscrit 30 patients : 12 ont été assignés au plâtre de Paris et 18 à la fibre de verre. On n’a noté aucune différence entre les groupes quant au nombre de plâtres requis pour la correction du pied bot (p = 0,13). Selon les parents, le retrait du plâtre de Paris était plus difficile (p < 0,001), prenait plus de temps (p < 0,001) et nécessitait le recours à plus d’une méthode (p < 0,001). Au moment du dernier suivi à 30,8 mois, les intervalles moyens avant un retour de la difformité nécessitant la pose d’un autre plâtre et/ou une chirurgie ont été de 18,7 et 16,4 mois dans les groupes traités au moyen de la fibre de verre semi-rigide et du plâtre de Paris, respectivement.

Conclusion : On n’a noté aucune différence significative entre les 2 matériaux quant au nombre de plâtres requis pour corriger le pied bot, mais la fibre de verre a donné lieu à une expérience plus agréable pour les parents, ce qui ne peut être ignoré en raison de l’impact potentiellement positif sur le bien-être psychologique, et ce, malgré un coût plus élevé.
Congenital idiopathic clubfoot is a 3-dimensional deformity that includes cavus and adductus of the midfoot, combined with hindfoot varus and equinus. The goal of treatment is to correct all components of the deformity, such that a pain-free, plantigrade foot with good mobility is achieved for the long term. Initiation of timely and appropriate treatment is paramount to achieve these successful long-term outcomes. Though nonoperative management of clubfoot had been the standard for centuries, modern treatment of clubfoot has, until recently, been primarily surgical. The resurgence of the Ponseti method in recent years has been punctuated by less than favourable long-term outcomes for surgically treated feet. The Ponseti method consists of weekly serial manipulations and above-knee plaster casting. With more recent studies confirming its long-term success, it is the current gold standard of treatment.

The 2 most common casting materials currently used in the treatment of idiopathic clubfoot are plaster of Paris (POP) and semirigid fibreglass (SRF). The Ponseti method of clubfoot correction has traditionally specified POP as the cast material of choice. It is a cheaper and stiffer material than SRF and is easily mouldable. Some negative aspects associated with its use, however, may include a small risk of injury associated with the exothermic reaction that occurs during curing, more difficult cast removal and the potential for cast saw accidents (Fig. 1).

Fibreglass casting materials were introduced in the 1970s and have the advantages of radiolucency, lighter weight, improved durability, faster curing time, lower risk of thermal burn, cleaner application and potentially easier removal. Semirigid fibreglass materials have been previously used for clubfoot correction and the treatment of resistant metatarsus adductus with some success. Scotchcast Soft Cast Casting Tape (3M) is a popular fibreglass casting material that was originally developed for extremity injuries not requiring rigid immobilization. This material is semirigid when dry and has the benefit of not tightly adhering to itself, thus allowing easy removal by unwrapping. Many centres ask parents to remove their children’s Ponseti casts just before their clinic visits to avoid injury during removal with a cast knife or saw, which may give SRF an advantage over POP. In a related study investigating parental satisfaction and clubfoot casting, SRF was preferred to POP owing to improved durability, performance, ease of removal, ulcer prevention, weight, appearance, ease of cleaning and water resistance. Despite these advantages, a recent study by Zmuko and colleagues demonstrated that SRF costs about 7 times more than POP and is biomechanically inferior to both POP and traditional rigid fibreglass material. They suggested the need for a prospective trial to evaluate these materials for clinical significance.

Our goal was to determine whether the choice of cast material influenced the number of casts required for correction of clubfoot deformity using the Ponseti method. We also assessed the parents’ experience with the cast material, particularly with respect to ease of removal.

Methods

Study design and patient selection

We conducted a prospective randomized controlled trial, completed in a tertiary-level children’s hospital. We enrolled consecutive patients with congenital idiopathic clubfoot presenting to the regional tertiary-level children’s hospital between July 2007 and December 2008. Patient referrals were screened through a central intake within the orthopedic clinic and were distributed equally and sequentially among the 7 pediatric orthopedic surgeons participating in the study. Following ethics approval from our institutional review board, we obtained written informed consent from the parents of all patients included in our study.

Clubfoot casting was initiated at the first clinical visit and subsequently at weekly intervals using serial manipulation and above-knee casting according to the Ponseti method. Clubfoot etiology was determined by a thorough history and physical examination (and additional tests as necessary) performed by the treating surgeon. Once the diagnosis of congenital idiopathic clubfoot was made, the patient was randomly assigned to receive either POP or SRF casts. Patients were excluded from this study if the cause of clubfoot was nonidiopathic (e.g., arthrogryposis), or if they had been previously treated for clubfoot. Patients with positional clubfoot deformities were also excluded.

Fig. 1. Infant with substantial skin injury following removal of a Ponseti plaster cast with oscillating saw. This incident caused substantial parental anxiety, such that subsequent casts were removed using prolonged soaking in warm water and unwrapping of the plaster roll.
**Ponseti method and Pirani classification**

Each of the participating pediatric orthopedic surgeons had considerable previous experience and specialized training in the Ponseti method. To ensure that the indications for cessation of cast treatment were reasonably uniform, each surgeon was required to attend a refresher training session in the Ponseti method and the Pirani classification system. The Pirani classification was used to measure initial clubfoot severity and allowed for surveillance during treatment. This 6-grade ordinal system is scored based on the status of the midfoot and hindfoot during correction and has been shown to have excellent intra- and interobserver reliability. A Pirani score of 6 is the most severe grading, and a score of 0 represents a fully corrected foot (Fig. 2). A poster outlining the Pirani classification and the indications for cessation of casting and/or tenotomy was displayed for reference in the clubfoot casting room for the duration of the study.

**Assessment and outcomes**

Photographs were taken before initiation of casting and at the end of casting during foot-abduction orthosis fitting. At each visit, a Pirani grade was given and tabulated using standardized data collection forms. The parents were told to remove the cast at home before each clinic visit. A clinic nurse provided instructions for cast removal specific to each material. After the first cast and fourth casts were removed, the parents were asked to complete a questionnaire (see the Appendix, available at canjsurg.ca) relating to their experience with the selected casting material. The questions were primarily related to the ease of cast removal, the time needed for removal and the number of methods required.

The primary outcome variable in this study was the number of casts required for correction of the clubfoot deformity to the point where the foot was ready for a percutaneous teno-Achilles tenotomy, if necessary, or when dorsiflexion of the ankle greater than or equal to 15° was achieved. A percutaneous teno-Achilles tenotomy was performed when there was sufficient abduction of the foot, verified by palpation of the anterior process of the calcaneus as it externally rotates from beneath the talus; foot abduction of approximately 60° in relation to the frontal plane of the tibia; and neutral or slight valgus of the calcaneus. According to the Ponseti method, the foot should be casted in 15° of dorsiflexion and abducted to 70° for 3 weeks after tenotomy. This cast was not included in the analysis, as each foot was fully corrected at the time of its application.

Secondary outcome variables included the need for percutaneous teno-Achilles tenotomy, total time in casts (weeks), ease of cast removal, duration of cast removal (minutes), method(s) of cast removal, complications relating to the casting material, compliance with postcorrection foot-abduction orthosis (FAO), deformity relapse, the need for repeat Ponseti casting and the need for ancillary surgical procedures.

**Sample size and randomization**

Based on the results of a pilot study of SRF and POP materials performed at our institution involving 10 patients with idiopathic clubfoot, we determined that a sample size of 30 was required. Our calculation was based on a desired assessment of the primary outcome variable with a clinically significant difference of 2 casts and an equal standard deviation of 1.88 (from pilot data) for a power of 80% based on a 2 sample t-test at a significance level of α = 0.05.

---

**Fig. 2.** Pirani scoring system for clubfeet. (A) Hindfoot score (HS); (B) midfoot score (MS). Total score = (HS + MS) ÷ 6. Reproduced with permission from Global HELP organization.10
Randomization of patients was performed using concealed number tracked envelopes according to a computer-generated randomization list. The envelope remained sealed and was opened by the surgeon just before the initiation of cast treatment. Only 1 type of cast material was used for each patient to prevent crossover (i.e., randomization was by patient, not by foot). Block randomization was not applied.

**Statistical analysis**

Collected data are reported as descriptive statistics (mean ± standard deviation) for continuous variables and percentages for categorical variables. We generated box plots for the primary variable. Confidence intervals (CIs) were determined where appropriate. We used a Student *t* test at a 5% significance level to determine if there was a significant difference between the means of the number of casts needed per material. Other tests for analysis of secondary outcomes were $\chi^2$ or Fisher exact test (as appropriate) for categorical variables. A PhD statistician (A.N.-A.) performed the data analysis.

**RESULTS**

Forty-five patients with clubfoot were initially assessed for eligibility in the study; 15 were excluded for various reasons (Fig. 3). Of the 30 patients identified for inclusion, 18 (60%) were randomized to SRF and 12 (40%) to POP. No patients were lost to follow-up during the casting phase of this study. The mean ages at first visit for the SRF and POP groups were 2.0 (range 1–11.7) and 2.3 (range 0.7–5.7) weeks, respectively. In the SRF group, a unilateral clubfoot was present in 10 of 18 patients (56%), and bilateral clubfeet were present in the remaining 8 patients, for a total of 26 clubfeet. In the POP group, a unilateral clubfoot was present in 6 of 12 patients (50%), and bilateral clubfeet were present in the remaining 6 patients, for a total of 18 clubfeet. Whenever bilateral clubfeet were present, the primary outcome (number of casts) was taken from the more severe foot (i.e., higher Pirani score at initial assessment). The mean initial Pirani score was 5.3 (range 2–6) and 4.9 (range 3–6) in the SRF and POP groups, respectively. In addition, patients were grouped according to clubfoot severity, with more severe deformities having Pirani scores of 5 or more and less severe deformities having Pirani scores less than 5. Assigning levels of severity using the Pirani score has been suggested previously by other authors. The number of more severe clubfeet was 22 of 26 feet (85%) in the SRF group and 12 of 18 feet (67%) in the POP group. For bilateral cases, the most severe clubfoot was analyzed for consistency. A tendo-Achilles tenotomy was performed for 15 of 26 clubfeet (58%) in the SRF group and 14 of 18 clubfeet (78%) in the POP group.

There was no significant difference in the mean number of casts required for clubfoot correction between the groups (SRF: 5.7 ± 2.8 casts; POP: 4.4 ± 1.6 casts, $p = 0.13$). The distributions for the groups are displayed as box plots in Figure 4. The 95% CI for the difference in the mean number of casts ($\mu_{SRF} - \mu_{POP}$) was (–0.41 to 3.0). When
analyzed by clubfoot severity, the mean number of casts for both materials in the less severe group was 3. In the more severe group, the mean number of casts was 6.4 in the SRF group and 4.7 in the POP group.

Twenty-four of 30 (80%) parental questionnaires were completed after the first visit and subsequently analyzed. The response rate for the fourth cast questionnaire was too low to provide useful results and thus they were not included in the analysis. According to parents, POP removal was rated as “manageable” or “difficult” by 8 of 12 (67%) parents compared with 1 of 12 (8%) parents in the SRF group ($p < 0.001$). The remaining parents in each group rated cast removal as “easy” or “very easy.” The 95% CI for the difference in the proportion of “easy/very easy” removals between groups ($\rho_{\text{SRF}} - \rho_{\text{POP}}$) was (0.317–0.916). Plaster of Paris took longer than 30 minutes for removal in 8 of 12 (67%) patients compared with 1 of 12 (8%) patients in the SRF group ($p < 0.001$). The remaining patients in each group had removal durations of 0–29 minutes. The 95% CI for the difference in the proportion of “0–29 minutes” removals between groups ($\rho_{\text{SRF}} - \rho_{\text{POP}}$) was (0.317–0.916). Plaster of Paris casts required more than 1 method for removal in 9 of 12 (75%) patients compared with 2 of 12 (17%) patients in the SRF group ($p < 0.001$). The 95% CI for the difference in the proportion of removals that needed 1 method ($\rho_{\text{SRF}} - \rho_{\text{POP}}$) was (0.341–0.926).

Data for secondary outcome measures, including compliance with FAO, deformity relapse, need for repeat Ponseti casting and need for ancillary surgical procedures following successful initial clubfoot correction by the Ponseti method, were collected at a mean final follow-up of 30.8 ± 14.2 months. A summary of these results is provided in Table 1. The mean final follow-up for the SRF and POP groups was 35.8 ± 11.3 months and 23.7 ± 14.4 months, respectively. Two of 30 patients (1 in each treatment group) were lost to final follow-up. The mean times to deformity relapse requiring repeat Ponseti casting, surgery or both were 18.7 ± 15.0 and 16.4 ± 21.1 months for the SRF and POP groups, respectively. Surgical interventions were varied, but included posterior release, posteromedial release, tibialis anterior tendon transfer and tibialis posterior recession.

**Discussion**

The Ponseti method of clubfoot management has revolutionized the treatment of this common condition through the reduction in extensive surgical procedures and improved long-term outcomes. Despite this, there are important emotional and psychological impacts associated with the execution of this treatment regimen that may have an impact on parental compliance with the Ponseti protocol. As such, measures that serve to shorten treatment duration and improve parental satisfaction while still achieving clinical success should be sought. The present study was designed to determine whether the choice of cast material influenced the number of casts required for correction of clubfoot deformity using the Ponseti method. Parental experience with the cast material, particularly with respect to ease of removal, was also investigated to determine if there was a preference for one material over the other.

Successful treatment of idiopathic clubfoot through serial manipulation and casting by the Ponseti method requires strict adherence to the ordered reduction of the components of the deformity, followed by subsequent immobilization in the corrected position for a defined time.

![Fig. 4. Number of casts necessary for clubfoot correction, by material. POP = plaster of Paris; SRF = semirigid fibreglass.](image)

<table>
<thead>
<tr>
<th>Table 1. Deformity relapse and need for repeat Ponseti casting and/or late surgical intervention according to cast material and at final follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Group; no. (%)</strong></td>
</tr>
<tr>
<td><strong>Semirigid fibreglass</strong></td>
</tr>
<tr>
<td><strong>Plaster of Paris</strong></td>
</tr>
<tr>
<td><strong>Total</strong></td>
</tr>
</tbody>
</table>

FAO = foot abduction orthosis.
period. This method has been purported to allow for gradi
tual ligamentous and muscular lengthening through creep
and stress relaxation in keeping with the viscoelastic prop-
erties of the tissues involved.21 Theoretically, a more rigid
casting material (e.g., POP) would allow for a more rapid
correction, given the increased stretch imposed on the tar-
get tissues. In our study this theory appeared to have some
merit, given the indication of a reduction in casts required
for more severe clubfeet (Pirani ≥ 5) when POP was used
than when SRF was used. For clubfeet with a Pirani score
less than 5, SRF seemed to perform as well as POP, sug-
gesting that the stiffness of this material was sufficient for
less severe cases. Although it seems that POP provided a
more rapid correction for severe clubfeet, our study was not
designed to have the power to statistically test this result.
To verify whether the superior material properties of POP
would be advantageous for the treatment of more severe
clubfeet would require a larger sample size.

Several technical points concerning casting during club-
foot correction have been emphasized by Ponseti.25 Given
that the talonavicular joint is the fulcrum about which mid-
foot and hindfoot correction is achieved, cast moulding
over the lateral aspect of the talar head is one of the tenets
of this procedure. Stabilization of the talar head seems to
be more effectively achieved with POP, given the stiffness
of the material and the reported difficulties with moulding
SRF casts.19,22 In addition, Ponseti also suggested providing
adequate posterior moulding superior to the calcaneus to
help prevent cast slippage; this is more difficult to perform
with SRF than with POP. Despite these theoretical advan-
tages, POP was not shown to be superior to SRF for cor-
crection of idiopathic clubfoot (p = 0.13), and cast slippage
was not a significant problem in the present study.

Since the commencement of the present study, Pittner
and colleagues30 have reported the results of the first ran-
domized trial comparing POP to SRF. As in the present
study, there was no significant difference in the mean num-
ber of casts required for Ponseti correction between the
2 groups (6.1 in the SRF group v. 5.2 in the POP group,
p = 0.20). They did, however, note a statistically significant
difference in the final severity scores (according to the
Dimeglio system) post-Ponseti casting, with the SRF and
POP groups each having residual scores of 6.4 (moderate)
and 4.1 (benign), respectively.30 This suggests incomplete
clubfoot correction on average (at least for the SRF group).
As such, it is unclear whether further casting would have
reduced the deformity to a more benign Dimeglio score, in
turn increasing the number of casts to final correction even
further. In the present study, the indications for cessation of
clubfoot casting and/or tentomy were clearly defined and,
as such, we were satisfied that the number of casts reported
for each treatment group was accurate.

A previous study investigating cast treatment for club-
foot and metatarsus adductus reported that 94% of parents
had a definite preference for SRF-type casting over POP.22
This preference was supported by our study, in which a
higher proportion of parents whose children had SRF
reported positive outcomes with respect to ease and time of
removal of casts. Semirigid fibreglass can be quickly
removed by simply unwrapping the cast tape, whereas pro-
longed soaking in warm water and/or other agents (e.g.,
vinegar) was required to soften POP to facilitate its
removal. In the present study, the poor response rate for
the parental questionnaire after the fourth cast may indi-
cate a decreasing learning curve with successive cast
removals, which might diminish the importance of
material choice overall. One could surmise, however, that
the emotional stress associated with having a child born
with clubfoot might be compounded by the need for more
onerous parental involvement with POP — especially for
the initial few casts. A recent study showed that the
psychological well-being and coping strategies for mothers
of children with clubfoot are negatively impacted.31 This
situation might be further exacerbated by difficulties with
cast handling and removal. Interestingly, in the study by
Pittner and colleagues,10 there was no difference in paren-
tal satisfaction between the 2 casting groups. Further study
using validated questionnaires is required to definitively
answer the question relating psychological well-being to
ease of cast removal and the relative importance of a
parental preference in clubfoot casting material.

Despite some clear disadvantages with respect to paren-
tal satisfaction, POP has been shown to be more economi-
tical than SRF, although this was not investigated in the
present study. Zmurko and colleagues21 showed that the
cost of SRF was purported to be up to 7 times that of
PO. The question remains whether the advantages in
parental experience warrant the increased cost of SRF
given the lack of improvement in clinical outcomes com-
pared with the substantially cheaper POP.

In the present study, more patients in the SRF than the
PO group had a deformity relapse, requiring repeat
Ponseti casting, surgical intervention or both. There may be
several reasons for this unrelated to the choice of cast
material used for initial clubfoot correction. The mean
duration of final follow-up for the SRF group was signifi-
cantly longer than for the POP group (35.8 v. 23.7 months,
respectively), allowing more time for the deformity to
relapse. Despite this, the mean times to deformity relapse
and initiation of further treatment were similar for the SRF
and POP groups (18.7 v. 16.4 mo, respectively). More
importantly, FAO compliance post-Ponseti casting was
markedly reduced in the SRF group compared with the
PO group (70.6% v. 91.7%, respectively). Noncompliance
with the standard Ponseti bracing protocol (FAO worn
3 months full-time, then at night and naptime for 3 years)
has been shown to be the factor most related to the risk of
relapse in several previous studies and may be the most
likely reason why the SRF group in the present study had an
increased prevalence of repeat casting and surgery.29,32
The strength of this study lies in its design. It is a prospective, randomized controlled trial, with sample size and power calculations determined from the results of a pilot study conducted before the commencement of data collection. Applying block randomization techniques would have resulted in a more even distribution of patients between the treatment groups but would not likely have had an effect on the results obtained with respect to number of casts. Our sample size was determined based on pilot data with a standard deviation of 1.88 casts and a power of 0.8. Prestudy calculations using a standard deviation of 1 cast called for 7 patients in each group. As such, the current treatment group numbers were adequate for the desired study power. The Ponseti technique and Pirani classification was reviewed before commencing the study with all participating surgeons, to control the casting technique. Despite this, the sample size was not large enough for subgroup analysis according to clubfoot severity or deformity relapse. The main weakness of the study was the use of a nonvalidated questionnaire to evaluate parental experience.

CONCLUSION

There was no significant difference in the number of casts required for correction of clubfoot between the 2 materials, SRF and POP. There may be an advantage in using POP both economically and in the correction of more severe clubfeet (Pirani score ≥ 5), but our study was not powered or designed to determine these aspects. In addition, the significant improvement in parental experience with SRF determined in this study cannot be ignored, as it may have a positive impact on psychological well-being despite the increased cost associated.

Competing interests: None declared.

Contributors: C. Hui, A. Nettel-Aguirre and J.J. Howard designed the study. C. Hui, V. Joughin, S. Goldstein, G. Kiefer, D. Parsons, C. Brauer and J.J. Howard acquired the data, which C. Hui, V. Joughin, A. Nettel-Aguirre and J.J. Howard analyzed. C. Hui and J.J. Howard wrote the article, which all authors reviewed and approved for publication.

References

Computed tomography features associated with operative management for nonstrangulating small bowel obstruction

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Background: The management of nonstrangulating small bowel obstruction (SBO) may require surgery, but the need for and timing of surgical intervention isn’t always apparent. We sought to determine whether specific features on computed tomography (CT) can predict the necessity for operative management.

Methods: Two radiologists independently reviewed CT scans from all patients admitted to hospital with SBO between 2004 and 2006. We examined the association between radiographic features and operative management by univariate analysis using the $\chi^2$ or Fisher exact test. Significant factors with high concordance between radiologists were entered into a multivariable stepwise logistic regression model.

Results: There were 228 patients with SBO, 63 of whom met our inclusion criteria and had CT scans available for review. Three CT features were frequently associated with operative management and had good concordance between radiologists: complete bowel obstruction, small bowel dilation greater than 4 cm and transition point. Transition point was the only significant factor predictive of operative management for SBO on multivariable logistic regression analysis (OR 19, 95% confidence interval 1.8–201, $p = 0.014$).

Conclusion: In patients with nonstrangulating SBO, the presence of a transition point on CT scan should alert the surgeon to the increased likelihood that operative management may be required.
The management of nonstrangulating small bowel obstruction (SBO) may require surgical intervention. The goal of operative management is to avoid the increased morbidity and mortality associated with intestinal strangulation while recognizing the potential for surgical morbidity and mortality. Unfortunately, both the requirement for surgery and the timing of surgical intervention may not always be readily apparent, which continues to challenge surgeons.

Various imaging modalities help the surgeon diagnose SBO. Most radiographic methods are currently unable to predict which patients will benefit from early surgery; rather, they may illustrate strangulation once this has occurred. One exception is the administration of oral gastrograffin, as its appearance in the colon 24 hours after administration has been shown to successfully predict the nonoperative resolution of SBO.

The role of computed tomography (CT) in predicting the need for surgical intervention in patients with nonstrangulating SBO is currently under active investigation. Two studies have shown the small bowel feces sign to be predictive of nonoperative resolution of SBO. However, there are conflicting reports on the association between other radiographic features, such as the presence of a transition point or ascites, and the need for surgical intervention. Furthermore, it is currently unknown whether the aforementioned CT findings are reliably interpreted by independent radiologists in the setting of nonstrangulating SBO. Ideally, radiographic features with both good interobserver correlation and a strong association with operative management will enable the surgeon to monitor selected patients who warrant careful observation for the increased likelihood of surgical intervention without progressing to intestinal strangulation. The purpose of this study was to determine whether specific features on CT scans exhibiting good interobserver correlation can predict the necessity for operative management in patients with nonstrangulating SBO.

### METHODS

#### Patients

We identified patients discharged with a diagnosis of SBO between June 2004 and March 2006 from 3 tertiary care hospitals with joint academic affiliation. We included those who had a CT scan performed within 48 hours of admission. Exclusion criteria were history of intra-abdominal cancer, inflammatory bowel disease, abdominal surgery within 30 days, previous abdominopelvic radiation, comorbidities precluding surgical intervention, immediate surgical intervention based on clinical evaluation and transfer from outside hospitals. From the hospital’s electronic database and written patient records, we collected information on patient demographics, clinical and laboratory data, operative findings and pathological specimens when a resection was performed. Recurrence of SBO within 2 years was documented.

We acquired CT data from the level of the diaphragm to the lesser trochanters. Oral contrast consisted of 20 mL of ioiodixanol mixed in 1000 mL of water and was administered 1 hour before the study. Rectal contrast, when given, consisted of 3 mL of ioiodixanol in 150 mL of water, 10 mL of iohexol-300 in 250 mL of water or 15 mL of ioxanol in 500 mL of water at hospitals 1, 2 and 3, respectively. Intravenous contrast was iodixanol, administered as 2 mL/kg to a maximum of 150 mL at a rate of 3 mL/second, and the data were acquired in the portal venous phase with a 60- to 70-second delay. Data were obtained on multidetector CT scanners: a single- or 16-slice scanner at hospital 2, and a 4- or 16-slice scanner at hospital 3. Based on a review of the literature for commonly described CT radiographic features in patients with SBO and at the recommendation of a body radiologist, we evaluated 9 CT features: ascites, beak sign, complete bowel obstruction, internal hernia, diameter at point of maximal small bowel dilation (in centimetres), small bowel feces sign, target sign, transition point and whirl sign. Definitions of these features are provided in Table 1, with selected illustrations in Figure 1. Two radiologists (P.V. and T.F.) reviewed the CT scans and scored each radiographic finding. Agreement between these two observers was high for all features, as calculated by means of Cohen’s kappa statistics.

### Table 1. Definitions of CT features seen in patients with small bowel obstruction

<table>
<thead>
<tr>
<th>CT feature</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ascites</td>
<td>Presence of excess peritoneal fluid</td>
</tr>
<tr>
<td>Beak sign</td>
<td>Tapering of the dilated bowel to form what resembles a bird’s beak at the point of obstruction</td>
</tr>
<tr>
<td>Complete bowel obstruction</td>
<td>Lack of oral contrast distal to the point of obstruction</td>
</tr>
<tr>
<td>Internal hernia</td>
<td>Presence of a mesenteric defect through which intestinal loops traverse</td>
</tr>
<tr>
<td>Maximal small bowel dilation</td>
<td>Measurement of the largest small bowel diameter from 1 outer wall to the opposite outer wall</td>
</tr>
<tr>
<td>Small bowel feces sign</td>
<td>Intraluminal particulate matter containing gas bubbles identified in the dilated small bowel segment</td>
</tr>
<tr>
<td>Target sign</td>
<td>Thickened enhancing bowel wall with submucosal edema giving the appearance of 3 concentric rings, with inner and outer rings displaying high attenuation and a middle ring displaying low attenuation</td>
</tr>
<tr>
<td>Transition point</td>
<td>A discrete, focal change in calibre from dilated bowel proximally to collapsed bowel distally</td>
</tr>
<tr>
<td>Whirl sign</td>
<td>Stretched mesenteric vessels converging to a point of intestinal torsion</td>
</tr>
</tbody>
</table>

CT = computed tomography.
J.K.), blinded to both clinical outcome and prior CT reports, independently analyzed the CT scans. Consensus was achieved through joint consultation. The local research ethics board approved our study protocol.

**Statistical analysis**

The primary outcome was operative management for SBO. The secondary outcome was recurrence of SBO within 2 years of discharge from hospital.

Baseline characteristics between patients undergoing operative management and those managed nonoperatively were compared using the \( \chi^2 \) test or Student t test as appropriate. We tested associations between each of the radiographic features and the primary outcome of surgical intervention using either the \( \chi^2 \) test or Fisher exact test for sample sizes of fewer than 6 patients. Concordance was calculated between the 2 independent radiologists using \( \kappa \) for those features with a significance of \( p < 0.05 \) on univariate analysis. Features with both \( p < 0.05 \) and \( \kappa > 0.5 \) on univariate analysis were entered stepwise into a multivariable logistic regression model to obtain adjusted odds ratios (OR) with 95% confidence intervals (CI). Finally, we compared recurrence of SBO in the surgical and nonsurgical groups using the \( \chi^2 \) test. We considered results to be significant at \( p < 0.05 \).

**RESULTS**

There were 228 patients with a diagnosis of SBO during the specified time interval. Of these, 104 patients were excluded: history of intra-abdominal cancer (\( n = 43 \)), inflammatory bowel disease (\( n = 20 \)), abdominal surgery within 30 days (\( n = 17 \)), abdominal or pelvic radiation (\( n = 3 \)), comorbidities precluding surgical intervention (\( n = 4 \)), clinical parameters to mandate immediate surgical intervention (\( n = 8 \)), and transfer from other hospitals (\( n = 9 \)). Of the remaining 124 patients, 63 had CT images available for review. Of these 63 patients, 27 (43%) underwent operative management and 36 (57%) were managed nonoperatively (Fig. 2).
All patients undergoing operative management were confirmed to have SBO at surgery. The etiologies for obstruction included adhesions \((n = 21)\), incisional hernias \((n = 3)\), mesenteric mass \((n = 1)\), appendicitis \((n = 1)\) and peristomal hernia \((n = 1)\). In 6 patients with adhesions, there were concomitant diagnoses of internal hernia \((n = 5)\) and small bowel volvulus \((n = 1)\). Seven patients \((26\%)\) required small bowel resection; small bowel ischemia was confirmed pathologically in 6 of these patients.

There was no significant difference in baseline demographic characteristics between the operative and nonoperative groups (Table 2). The presence of abdominal tenderness on examination and white blood cell count on admission were similar between the groups. Patients with a history of multiple abdominal procedures were more likely to require surgical intervention \((OR 2.8, 95\% CI 0.90–8.8, p = 0.08)\), although this was not significant.

Of the 9 radiographic features studied, 5 were significantly associated with surgical intervention: beak sign \((OR 10, 95\% CI 3.1–32, p < 0.001)\), complete bowel obstruction \((OR 8.5, 95\% CI 2.6–28, p < 0.001)\), maximal small bowel dilation greater than 4 cm \((OR 5.1, 95\% CI 1.5–7.9, p = 0.010)\), small bowel feces sign \((OR 3.6, 95\% CI 1.1–12, p = 0.039)\) and transition point \((OR 32, 95\% CI 4.0–270, p < 0.001)\). Those features not achieving statistical significance were the presence of ascites \((p = 0.14)\) and target sign \((p = 0.71)\). Internal hernia and whirl sign were found in 6 \((22\%)\) and 5 \((19\%)\) patients, respectively, and all 11 patients were submitted to operative management. The type of CT contrast used was not significant between the operative and nonoperative groups (Table 3).

**Table 2. Demographic and clinical characteristics of patients with small bowel obstruction managed operatively and nonoperatively**

<table>
<thead>
<tr>
<th>Clinical factor</th>
<th>Surgery, (n = 27)</th>
<th>No surgery, (n = 36)</th>
<th>(p) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td>0.82</td>
</tr>
<tr>
<td>Female</td>
<td>15 (56)</td>
<td>21 (58)</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>12 (44)</td>
<td>15 (42)</td>
<td></td>
</tr>
<tr>
<td>Mean age, yr</td>
<td>64 (27)</td>
<td>63 (26)</td>
<td>0.87</td>
</tr>
<tr>
<td>No. of previous surgeries</td>
<td>0.08</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt; 1</td>
<td>19 (70)</td>
<td>18 (50)</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>6 (22)</td>
<td>16 (44)</td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>2 (7)</td>
<td>2 (6)</td>
<td></td>
</tr>
<tr>
<td>Abdominal tenderness</td>
<td>0.17</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>22 (82)</td>
<td>34 (94)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>3 (11)</td>
<td>2 (6)</td>
<td></td>
</tr>
<tr>
<td>Unknown</td>
<td>2 (7)</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td>Mean WBC x (10^3) mm(^{-1})</td>
<td>13 (12)</td>
<td>12 (0.36)</td>
<td></td>
</tr>
</tbody>
</table>

WBC = white blood cell count.

*Unless otherwise indicated.

**Table 3. Univariate analysis of CT features in operative and nonoperative patients, and \(\kappa\) values for features with \(p < 0.05\)**

<table>
<thead>
<tr>
<th>CT feature</th>
<th>Group; no. (%)</th>
<th>(OR (95% CI))</th>
<th>(p) value</th>
<th>(\kappa)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ascites</td>
<td></td>
<td>2.2 (0.77–6.0)</td>
<td>0.14</td>
<td></td>
</tr>
<tr>
<td>Beak sign</td>
<td></td>
<td>10 (3.1–32)</td>
<td>&lt; 0.001</td>
<td>0.43</td>
</tr>
<tr>
<td>Complete bowel obstruction</td>
<td></td>
<td>8.5 (2.6–28)</td>
<td>&lt; 0.001</td>
<td>0.52</td>
</tr>
<tr>
<td>Internal hernia</td>
<td></td>
<td>5.1 (1.5–7.9)</td>
<td>0.010</td>
<td>0.63</td>
</tr>
<tr>
<td>SB dilation &gt; 4 cm</td>
<td></td>
<td>3.6 (1.1–12)</td>
<td>0.039</td>
<td>0.30</td>
</tr>
<tr>
<td>SB feces sign</td>
<td></td>
<td>1.4 (0.26–7.4)</td>
<td>0.71</td>
<td></td>
</tr>
<tr>
<td>Target sign</td>
<td></td>
<td>32 (4.0, 266)</td>
<td>&lt; 0.001</td>
<td>0.66</td>
</tr>
<tr>
<td>Transition point</td>
<td></td>
<td>1.43 (0.40–5.0)</td>
<td>0.58</td>
<td></td>
</tr>
<tr>
<td>Intravenous contrast</td>
<td></td>
<td>0.56 (0.13–2.28)</td>
<td>0.41</td>
<td></td>
</tr>
<tr>
<td>Oral contrast</td>
<td></td>
<td>0.73 (0.13–3.9)</td>
<td>0.71</td>
<td></td>
</tr>
<tr>
<td>Rectal contrast</td>
<td></td>
<td>1.43 (0.40–5.0)</td>
<td>0.58</td>
<td></td>
</tr>
</tbody>
</table>

CI = confidence interval; CT = computed tomography; OR = odds ratio; SB = small bowel.

**Table 4. Multivariable model of CT features associated with operative management for small bowel obstruction**

<table>
<thead>
<tr>
<th>CT feature</th>
<th>(OR (95% CI))</th>
<th>(p) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete bowel obstruction</td>
<td>3.2 (0.15, 13)</td>
<td>0.09</td>
</tr>
<tr>
<td>SB dilation &gt; 4 cm</td>
<td>0.87 (0.15, 4.9)</td>
<td>0.88</td>
</tr>
<tr>
<td>Transition point</td>
<td>19 (1.8, &gt; 200)</td>
<td>0.014</td>
</tr>
</tbody>
</table>

CI = confidence interval; CT = computed tomography; OR = odds ratio; SB = small bowel.
Of the 5 radiographic features achieving statistical significance, 3 showed good correlation between radiologists with κ values greater than 0.5: complete bowel obstruction (κ = 0.52), maximal small bowel dilation greater than 4 cm (κ = 0.63) and transition point (κ = 0.66; Table 3). These 3 features were entered into a multivariable stepwise logistic regression model. Transition point retained statistical significance (OR 19, 95% CI 1.8–201, \( p = 0.014 \)), while complete bowel obstruction (\( p = 0.09 \)) and maximal small bowel dilation greater than 4 cm (\( p = 0.88 \)) did not; including complete bowel obstruction and small bowel dilation did not significantly improve the fit of the model (Table 4). A transition point was identified in all 7 patients requiring a small bowel resection.

Recurrence of SBO did not differ significantly (\( p = 0.75 \)) between the groups, occurring in 3 (12%) patients managed operatively and 5 (14%) patients managed nonoperatively.

**Discussion**

The current role of CT in the management of SBO lies in its ability to diagnose obstruction, to define the etiology and probable location of the obstruction, and to differentiate nonstrangulating from strangulating obstruction. Computed tomography assessment is effective, with a sensitivity of 83%–100% and specificity of 61%–93%. In patients with nonstrangulating SBO, there are limited data on whether CT may help predict which patients will require surgical intervention. While a surgeon’s decision to operate ultimately depends on the patient’s clinical condition, CT features predictive for operative management of patients with nonstrangulating SBO may facilitate care. Such CT findings could target a subset of these patients for heightened vigilance in an effort to minimize operative delay, thereby reducing the increased morbidity and mortality from intestinal ischemia and associated complications.

The cohort of patients in this study with nonstrangulating, adhesive SBO is representative of analogous populations in comparable studies. The proportion of patients having had multiple, 1 or no prior abdominal surgeries is corroborated by previous studies, and the operative rate of 43% lies within the widely reported range of 27%–66%. The rates of small bowel resection and small bowel ischemia are comparable to those reported in another recent study. Furthermore, the similar recurrence rates of SBO in operative and nonoperative patients are also supported by current literature.

Other studies have shown that clinical findings and laboratory measurements at initial presentation are inadequate to predict the need for surgical intervention. Consistent with previous reports, the presence of abdominal tenderness or leukocytosis at admission in the present study had no predictive value for requiring surgical intervention. There was, however, a trend toward operative management in patients having undergone more than 1 previous abdominal surgery; this finding may be explained by the development of extensive adhesions often anticipated in patients with multiple prior surgeries.

In comparison with other studies to date that have explored the association between CT radiographic features and the need for subsequent surgical intervention in patients with SBO, the present study consists of a strictly defined cohort. The study population was selected to consist only of patients with suspected adhesive nonstrangulating SBO through predefined exclusion criteria. Patients were excluded for clinical suspicion of strangulation that would require immediate operative management. Patients were also excluded if there was the potential for favouring nonoperative management owing to other medical circumstances, such as in patients with incurable intra-abdominal malignancy, inflammatory bowel disease, recent abdominal surgery, prior abdominal or pelvic radiation, or severe comorbid illnesses. By using 2 expert radiologists blinded to each other’s interpretations and to patient outcomes, only CT findings with good interobserver correlation were included in the multivariable logistic regression model. Our study was specifically designed to achieve results that may be more readily extrapolated to the surgical management of patients with nonstrangulating SBO at other centres.

An identifiable transition point on CT was most significantly associated with the need for operation in patients with nonstrangulating SBO, both on univariate and multivariate analyses. A transition point was also the only consistent CT finding in all patients who required a small bowel resection. The association is plausible, given the discrete and localized change in intestinal calibre seen in a transition point. Our results suggest that a transition point represents a fixed rather than a transient point of intestinal obstruction unlikely to resolve without operative intervention. Four studies to date have evaluated the clinical relevance of a transition point; however, only the study by Hwang and colleagues supports the finding of an increased likelihood of operative management. All 4 of these studies were subject to less stringent inclusion/exclusion criteria and may not represent the population of patients targeted in the present study. Furthermore, CT interpretation in these studies may have been subject to observer bias, as analysis was performed by either a single radiologist or without blinding, or was based on findings extracted from the original CT reports.

In the present study, complete bowel obstruction was significantly associated with surgical intervention on univariate analysis, clearly a sound and probably anticipated clinical decision. Although not significant on
multivariate analysis and perhaps a function of the small number of patients involved, there was a clear association with operative management in patients with this CT finding on univariate analysis (OR 8.5, 95% CI 2.6–28). Other studies have reported a similar association on univariate analysis.8,10 The absence of orally administered contrast beyond a fixed point of obstruction (i.e., complete bowel obstruction) may be a sufficient indication for surgical intervention.

The positive correlation between small bowel feces sign and operative management found in the present study is discordant with the findings of 2 recent studies.5,6 That said, the small bowel feces sign was previously reported to occur more frequently in patients with moderate and high-grade SBO.11 While further prospective studies are required to clarify this discrepancy, modest interobserver agreement among reporting radiologists, as demonstrated in this study, may limit the usefulness of the small bowel feces sign in guiding clinical decision making.

Additional CT features, which have not been extensively reported in the literature, were evaluated in the present study. Identification of an internal hernia and whirl sign, although infrequent, was found only in the group of surgically managed patients. In the setting of SBO, an internal hernia may be similar in clinical behaviour to an incarcerated external hernia. Entrapped small bowel is unlikely to reduce spontaneously, prompting operative intervention. The whirl sign suggests stretching of the mesenteric vessels toward a point of intestinal torsion; such tension on the small bowel mesentery may signify an irreversible consequence of intestinal obstruction that requires surgical correction. Although it was not possible to calculate an OR for these 2 CT features, internal hernia and whirl sign appear to represent findings with a physiologic basis and clinical rationale for surgical intervention.

CONCLUSION

The management of patients with nonstrangulating SBO remains a clinical challenge. While the timing and need for surgery ultimately depends on the surgeon’s assessment of the patient’s condition and course in hospital, the presence of a transition point on early CT scan should alert the surgeon to an increased likelihood that operative management will be required to resolve the SBO. Heightened awareness driven by CT findings should prompt close patient monitoring to minimize delay in surgical intervention and thereby reduce the potential risk for intestinal ischemia and its consequences in this population.

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Competing interests: None declared.

Contributors: All authors designed the study, acquired and analyzed the data, wrote and reviewed the article and approved the final version for publication.

References

The historic predictive value of Canadian orthopedic surgery residents’ orthopedic in-training examination scores on their success on the RCPSC certification examination

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Background: Positive correlation between the orthopedic in-training examination (OITE) and success in the American Board of Orthopaedic Surgery examination has been reported. Canadian training programs in internal medicine, anesthesiology and urology have found a positive correlation between in-training examination scores and performance on the Royal College of Physicians and Surgeons of Canada (RCPSC) certification examination. We sought to determine the potential predictive value of the OITE scores of Canadian orthopedic surgery residents on their success on their RCPSC examinations.

Methods: A total of 118 Canadian orthopedic surgery residents had their annual OITE scores during their 5 years of training matched to the RCPSC examination oral and multiple-choice questions and to overall examination pass/fail scores. We calculated Pearson correlations between the in-training examination for each postgraduate year and the certification oral and multiple-choice questions and pass/fail marks.

Results: There was a predictive association between the OITE and success on the RCPSC examination. The association was strongest between the OITE and the written multiple-choice examination and weakest between the OITE and the overall examination pass/fail marks.

Conclusion: Overall, the OITE was able to provide useful feedback to Canadian orthopedic surgery residents and their training programs in preparing them for their RCPSC examinations. However, when these data were collected, truly normative data based on a Canadian sample were not available. Further study is warranted based on a more refined analysis of the OITE, which is now being produced and includes normative percentile data based on Canadian residents.

Contexte : On a signalé une corrélation positive entre l’examen intermédiaire en orthopédie (EIO) et la réussite aux examens de l’American Board of Orthopaedic Surgery. Les programmes canadiens de formation en médecine interne, en anesthésiologie et en urologie ont constaté une corrélation positive entre les notes aux EIO et les résultats aux examens du Collège royal des médecins et chirurgiens du Canada (CRMCC). Nous avons cherché à déterminer la valeur prédictive potentielle des notes des résidents en chirurgie orthopédique à l’EIO pour ce qui est de leur réussite aux examens du CRMCC.


Résultats : Il y avait un rapport prédictif entre le résultat à l’EIO et la réussite de l’examen du CRMCC. Le rapport était le plus étroit entre les résultats à l’EIO et les résultats à l’examen écrit à choix multiples, et il était le plus faible entre les résultats à l’EIO et les notes globales de passage ou d’échec.

Conclusion : Dans l’ensemble, l’EIO a produit une rétroaction utile pour les résidents en chirurgie orthopédique et leurs programmes de formation pour les préparer aux examens du CRMCC. Toutefois, lorsque ces données ont été recueillies, de véritables données normatives fondées sur un échantillon canadien n’étaient pas disponibles. Une étude plus poussée s’impose à partir d’une analyse plus approfondie de l’EIO; cette analyse est en voie de réalisation et comprend des données normatives percentiles sur les résidents canadiens.
Canadian orthopedic surgery residency training programs require residents to write the orthopedic in-training examination (OITE) annually. This is a multiple-choice examination overseen by the Committee on Examinations and Evaluation of the American Academy of Orthopaedic Surgeons (AAOS), administered continuously since 1963. It covers all aspects of orthopedic surgery with questions designed to test recall, comprehension, application, problem solving, evaluation and synthesis (taxonomy levels 1 through 6, respectively).

Correlation between the OITE and success in the American Board of Orthopaedic Surgery (ABOS) examination has been studied. One study reported a high risk of failure (63%; 5 of 8 failed) on the ABOS Part-I examination when a resident scored below the 29th percentile for postgraduate year (PGY)-3 and below the 20th percentile for PGY5. No failures occurred (50 passed) when either the PGY3 score was above the 32nd percentile or the PGY4 score was above the 27th percentile.2 Another study reported that those who averaged in the 27th percentile or lower on the OITE had a 57% chance of failing the ABOS Part-I examination.3 Crawford and colleagues4 reported that PGY3 OITE percentile scores predicted ABOS Part-I and Part-II passage, with residents who scored in the lower quartile having a 5.2 times greater risk of failure on ABOS Part-I. Herndon and colleagues5 reported that the OITE percentile score in the final year in training was a predictor of success on the ABOS Part-I and Part-II examinations.

Canadian training programs in internal medicine, anesthesiology and urology make use of examinations similar to the OITE and have studied the correlation between resident performance on these examinations and their subsequent success on their Royal College of Physicians and Surgeons of Canada (RCPSC) certification examinations.6–8 All 3 specialties have found a positive correlation between in-training examination scores and performance on the RCPSC certification examination. Specifically, in internal medicine, it has been reported that there is a high correlation between the results of the in-training examination and the written component of the RCPSC certification examination. In-training examination scores above the 50th percentile were predictive of a low failure rate (< 1.5%), and scores below the 10th percentile were associated with a high failure rate (24%) on the written component of the RCPSC examination6. In anesthesiology, in-training scores above the 50th percentile were highly predictive of success on the written component of the RCPSC examination, and scores above the 60th percentile were highly predictive of success on the oral component of the examination. In-training scores below the 20th percentile were predictive of failure on both the written and oral components.7 This provides useful feedback to the residents and their training programs in preparing them for RCPSC certification examinations. To our knowledge, no similar investigation has been done for orthopedic surgery.

The purpose of this study was to determine the potential predictive value of OITE scores of Canadian orthopedic surgery residents for their success on their RCPSC certification examinations. The RCPSC certification in orthopedic surgery is based on a compensatory examination combining oral and written components to yield an overall mark that determines whether the candidates pass or fail.

**METHODS**

Thirteen English-speaking residency training programs elected to participate in this study. The study cohort consisted of 118 Canadian orthopedic surgery residents (38 in 2000–2001, 44 in 2001–2002, 36 in 2002–2003). The annual OITE scores obtained by each resident during their 5 years of training were collected by their program directors and matched to their corresponding residents’ RCPSC ID numbers in a nonidentifying blinded fashion on a data sheet. Similarly, a staff member of the Educational Research Unit of the RCPSC Office of Education entered the residents’ RCPSC certification examination scores on a data sheet matched to their corresponding residents’ RCPSC ID numbers, with no reference to resident names. The data sheets were sent to another individual at the RCPSC to match the certification oral and multiple-choice examinations and overall pass/fail examination marks using the nonidentifying resident RCPSC ID numbers. No resident names were attached to any of the data, and their confidentiality was preserved.

**Statistical analysis**

The Pearson correlations between the OITE raw and percentile scores for each of the candidates’ final PGY and the certification scores on the oral and written multiple-choice examinations and on the overall pass/fail marks were calculated.

**RESULTS**

The correlation between the OITE percentile and RCPSC oral and written multiple-choice examination marks was significant at the 0.01 level in each of the 3 final academic years. The correlation between the OITE raw score and the RCPSC pass/fail marks was significant at the 0.01 level in 2 of the 3 years; the calculation in the third year was not possible because all the candidates passed. There was a stronger association between the RCPSC oral and written multiple-choice examinations and overall pass/fail marks and the OITE raw score than with the OITE percentile in 2 of the 3 years. The strongest OITE association was with the RCPSC multiple-choice examination, and the weakest association was with the overall pass/fail mark (Table 1).

**DISCUSSION**

The RCPSC certification examination in orthopedic surgery was a compensatory examination combining oral and written
components. The OITE was a multiple-choice examination representing the spectrum of clinical orthopedics. It is not surprising that the strongest correlation was with the RCPSC multiple-choice examination, which is a similar assessment measure. There was also a significant correlation with the RCPSC oral examination marks, indicating that the OITE was a useful tool for preparing residents for this component as well. There was a significant correlation between the OITE raw scores and the RCPSC overall pass/fail marks in 2 of the 3 years; the calculation in the third year was not possible because all the candidates were successful. These results indicate that the OITE was able to provide useful feedback to the residents and their training programs concerning their acquisition of appropriate knowledge in preparation for RCPSC certification.

There was a stronger association between the RCPSC oral and written multiple-choice examinations and the overall examination pass/fail marks with the OITE raw scores than with the OITE percentiles. The percentile scores provided were not an accurate reflection of the competence of the Canadian residents. The percentile is an individual’s raw score compared with their peers in the same year in training (YIT) with a resident in YIT-1 defined as having completed 6 months of orthopedic training. In Canada, individual training programs vary in terms of the amount of time spent in orthopedics during the first 2 years of core surgery training, thus resulting in the possibility of different YIT assignment for the OITE between programs of residents in the same PGY. We believe that this inconsistent association between PGY and YIT in different programs is one reason that we could not find an OITE threshold percentile for those passing or failing the RCPSC multiple-choice and oral examinations and the overall examination. A second reason that the percentile scores were inaccurate is that they were based on the entire sample of residents taking the OITE, most of whom were American candidates.

CONCLUSION

This study has demonstrated that the OITE had the potential to predict the success of Canadian residents in the years 2000 through 2003 on the RCPSC certification examination. Since 2009, substantial improvements have been made to the OITE reports. Prior to 2009 there was no standardization of scores on the OITE and no breakdown of norms into different groups. The OITE reports now contain Canadian norms (i.e., percentiles) as well as reports for the different content domains in orthopedics. This presents the possibility that greater prediction may be possible not only based on the overall percentile scores, but also based on a regression analysis representing the content domains. In addition, an objective structured clinical examination format has been added to the oral component of the RCPSC certification examination. Overall, further study into the current association between the OITE and the RCPSC certification examination is warranted.

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Competing interests: None declared.

Contributors: D. Yen and G. Athwal designed the study. D. Yen and G. Cole acquired the data, which G. Cole analyzed. D. Yen wrote the article, which G. Athwal and G. Cole reviewed. All authors approved the paper for publication.

References

Bridging the gap between open and minimally invasive pancreaticoduodenectomy: the hybrid approach

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See the related commentary by Jayaraman on p. 228.

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Background: Minimally invasive pancreatic surgery has evolved rapidly, but total laparoscopic pancreaticoduodenectomy has not been widely adopted owing to its technical complexity. Hybrid laparoscopy-assisted pancreaticoduodenectomy (HLAPD) combines the relative ease of open surgery with the benefits of a minimally invasive approach. This study evaluates the safety and effectiveness of the hybrid approach compared with open surgery.

Methods: We retrospectively analyzed data of consecutive patients undergoing either hybrid or open pancreaticoduodenectomy (OPD) at our institution between September 2009 and December 2013. Demographic, operative and oncologic data were collected to compare outcomes between HLAPD and OPD.

Results: Our analysis included 33 patients (HLAPD: n = 13; OPD: n = 20). There were no differences in patient demographics, comorbidities or surgical indications. The HLAPD group had significantly lower intraoperative blood loss (450 mL v. 1000 mL, \( p = 0.023 \)) and shorter length of hospital stay (8 v. 12 d, \( p = 0.025 \)) than the OPD group. Duration of surgery did not differ significantly between the groups. There were no differences in postoperative analgesic requirements, Clavien grade I/II or grade III/IV complications or 90-day mortality. Oncologic outcomes showed no significant differences in tumour size, R1 resection rate or number of lymph nodes harvested.

Conclusion: In select patients, HLAPD is a safe and effective procedure with comparable outcomes to conventional open surgery. Wider adoption of the hybrid approach will allow a greater number of patients to benefit from a less invasive procedure while facilitating the transition toward purely minimally invasive pancreaticoduodenectomy.
Recent advances in laparoscopic techniques have led to an increased interest in minimally invasive pancreatic surgery. Compared with conventional open surgery, minimally invasive procedures allow for decreased postoperative pain, shorter hospital stay and improved cosmesis.\(^1\)\(^-\)\(^3\) Despite these benefits, the adoption of total laparoscopic pancreaticoduodenectomy (TLPD) has been hindered by concerns regarding the technical complexity of laparoscopic reconstruction. Since the first report by Gagner and Pomp in 1994,\(^4\) only a few centres worldwide have published large TLPD patient series.\(^4\)\(^-\)\(^6\) A direct transition from open surgery to TLPD may constitute a hazardous and imprudent leap for surgeons without extensive prior laparoscopic experience. In light of the steep learning curve, the transition toward TLPD may be more safely and effectively achieved as a multistep progression using a spectrum of minimally invasive techniques. In this report, we describe hybrid laparoscopy-assisted pancreaticoduodenectomy (HLAPD): a hybrid laparoscopic–open approach in which pancreaticoduodenal resection is performed laparoscopically, while reconstruction is completed via a small upper midline minilaparotomy.\(^7\) The hybrid method combines the relative ease of conventional open surgery with the benefits of a minimally invasive approach. Potentially, HLAPD may serve as a valuable stepping stone to facilitate the transition from open to purely minimally invasive pancreaticoduodenectomy without incurring additional risk to the patient. Although the feasibility of HLAPD has been described, the current literature mainly comprises small patient series lacking comparison groups.\(^7\)\(^-\)\(^1\)\(^2\)\(^-\)\(^1\)\(^2\) To our knowledge, only 3 reports have compared the outcomes of patients undergoing HLAPD versus open pancreaticoduodenectomy (OPD).\(^5\)\(^-\)\(^7\)\(^-\)\(^9\) In the studies by Cho and colleagues\(^1\)\(^3\)\(^-\) and Lee and colleagues,\(^1\)\(^4\) patients with preoperatively diagnosed periampullary carcinoma automatically underwent OPD; patients who underwent HLAPD displayed only benign or low-grade lesions. To our knowledge, we report the first Canadian study evaluating the safety, feasibility and operative outcomes of HLAPD compared with OPD.

**Methods**

With institutional review board approval, we performed a retrospective chart review on all patients undergoing HLAPD or OPD at a single institution between September 2009 and December 2013. Demographic, operative and outcome data were collected from a prospectively maintained database. All surgeries were performed by a single experienced pancreatic surgeon (T.V.), with another attending surgeon (S.B.) as first assistant.

**Patient selection**

Preoperatively, all patients underwent appropriate imaging studies to assess tumour resectability. The selection criteria for HLAPD were tumours of any size without preoperative evidence of major vascular involvement. Patients whose lesions were at high risk of a positive margin or of abutment of major vessels were excluded from the HLAPD group and underwent OPD. Patients were not excluded on the basis of demographic factors, such as age, body mass index (BMI), Charlson Index and American Society of Anesthesiologists (ASA) grade. Prior to surgery, all patients were informed of the potential advantages and complications of both techniques, and they provided written informed consent.

In our initial institutional experience, we imposed a low threshold to convert to an open procedure. To accurately interpret the benefits and shortcomings of the hybrid approach, we conducted a non-intent-to-treat analysis, defining procedures as HLAPD only when all 3 resections (antrectomy, choledochojulectomy and pancreatectomy) had been performed laparoscopically. Patients whose cases began laparoscopically but were converted to open surgery before completion of the resections were included in the OPD group.

**Operative technique**

The patient is placed in the supine position on a split-leg table, and CO\(_2\) pneumoperitoneum is established via a 12 mm infraumbilical trocar inserted using an open Hasson technique. A 30° camera is used to assess for any evidence of metastatic disease. If no contraindications to resection are found, 6 additional trocars are inserted along a semicircle centred on the head of the pancreas (Fig. 1). The operation is begun by dividing the gastrocolic ligament with a LigaSure (Valleylab). With the stomach and left lateral segment of the liver retracted against the anterior abdominal wall using a miniretractor (Mediflex), the gastroepiploic omentum is separated off the transverse mesocolon. The right gastroepiploic vein is followed to its junction with the infrapancreatic superior mesenteric vein (SMV) and divided. The right colon is mobilized, and a laparoscopic Kocher manoeuvre is performed to the level of the ligament of Treitz. The gastric antrum is transected using serial purple loads of the EndoGIA stapler (US Surgical Corp.). The common hepatic node is identified and resected. The gastrohepatic ligament is opened to expose the common hepatic artery, from which the gastroduodenal artery can be traced down. Flow within the common hepatic artery is verified using a laparoscopic ultrasound probe before transecting the gastroduodenal artery using the white load of the EndoGIA stapler. A retropancreatic tunnel is created by dissecting between the posterior surface of the pancreas and the anterior plane of the SMV in a cephalad direction. The tunnelled pancreas is then encircled using a Penrose tape. A complete hilar lymphadenectomy is undertaken to harvest periportal and peri-pancreatic lymph nodes. A retrograde choledochojulectomy is performed, leaving the gallbladder attached to the common bile duct for traction. The hepatoduodenal ligament is dissected to isolate the underlying portal vein. The
common bile duct is encircled with an umbilical tape and transected above the junction with the cystic duct using the white load of the EndoGIA stapler. The proximal jejunum is brought back to the right side of the abdomen and transected 10 cm distal to the ligament of Treitz using the white load of the EndoGIA stapler. The pancreas parenchyma is then divided across the neck using the LigaSure starting inferiorly and moving toward the superior border anterior to the portal vein and mesenteric vessels, making sure to immediately identify the pancreatic duct after transection. The uncinate process dissection is performed by dividing the SMV and jejunal branches along the adventitial layers of the superior mesenteric vessels to ensure adequate clearance of the uncinate margin.

The reconstruction is begun by creating a 5–6 cm vertical upper midline minilaparotomy incision through which the en bloc resected specimen is retrieved in an endobag. The transected end of the proximal jejunum is brought up to the right upper quadrant through a defect in the transverse mesocolon. A 2-layer duct-to-mucosa pancreaticojejunostomy is constructed in Blumgart fashion using 5–0 polydioxanone sutures (PDS) and through-and-through 3–0 silk stitches. Next, an end-to-side hepaticojejunostomy is performed using interrupted 5–0 PDS, and a side-to-side retrogastric antecolic loop gastrojejunostomy is completed using the blue load of the EndoGIA stapler. Two Jackson–Pratt drains (Allegiance Healthcare Corporation) are placed near the biliary and pancreatic anastomoses at the end of the procedure.

Outcomes

The preoperative variables we examined included age, sex, BMI, Charlson Index and ASA grade. Operative data included duration of surgery, intraoperative blood loss and blood transfusions. We also examined oncologic outcomes, such as tumour size and histopathology, margin status and number of lymph nodes harvested. The R1 resection rate reflects the number of patients who had a positive margin out of the total number of patients with a malignant pathology. Seven-day analgesic use consisted of the total amount of narcotics administered over the first 7 postoperative days. Analgesic requirement data were collected from the medical administration record, which documents daily scheduled medications and those administered when necessary (PRN) for each patient. Each medication that is actually taken by the patient is subsequently signed off by the nursing staff. We calculated daily epidural and patient-controlled analgesia rates from specific documentation sheets. All routes of opioid administration (i.e., epidural, oral, intravenous, intramuscular, transdermal) were tabulated and subsequently converted into intravenous (IV) morphine equivalents. Nonopioid analgesics, such as acetaminophen and ibuprofen, were not included in the analysis.

Postoperatively, we analyzed length of hospital stay, and morbidity and mortality were recorded up to 90 days after surgery. We classified complications according to the Clavien system, which grades severity according to the invasiveness of the required treatment. For patients with multiple complications, only the most severe one was registered. Pancreatic fistula was defined, according to International Study Group of Pancreatic Fistula (ISGPF) criteria, as any measurable drain output on or after postoperative day 3, with an amylase content greater than 3 times the normal serum level. Cases were divided into 4 categories: no fistula; biochemical fistula without clinical sequelae (grade A), fistula requiring any therapeutic intervention (grade B) and fistula with severe clinical sequelae (grade C).

Statistical analysis

Continuous variables were expressed as medians with ranges and compared using the Mann–Whitney U test. Categorical variables were compared using the chi-squared test or Fisher exact test. We considered results to be significant at $p < 0.05$, 2-tailed. We performed all statistical analyses using SPSS version 17.0.
RESULTS

Between September 2009 and December 2013, we performed HLAPD and OPD on 13 and 20 patients, respectively. Of the 22 cases begun laparoscopically, 9 were converted to open surgery before completion of the resections (5 patients had extensive abdominal adhesions, 4 had tumours showing vascular abutment or involvement); they were included in the OPD group. There were no significant differences in age, sex, BMI, ASA grade or Charlson Index between the groups (Table 1).

The HLAPD group had a significantly lower estimated intraoperative blood loss (450 mL v. 1000 mL, \( p = 0.023 \)) and a shorter length of hospital stay (8 v. 12 d, \( p = 0.025 \)) than the OPD group. There were no significant differences in duration of surgery or intraoperative blood transfusion rates between the groups. There were no intraoperative deaths. Twelve (92%) patients in the HLAPD group used an epidural for postoperative pain control compared with 19 (95%) patients in the OPD group. Mean 7-day analgesic requirements were lower in patients who underwent HLAPD than those who underwent OPD (174 mg v. 288 mg), but this trend did not achieve significance (\( p = 0.08 \); Fig. 2). Ninety-day mortality was similar between the HLAPD and OPD groups (8% v. 20%).

Pathology findings are summarized in Table 2. Malignant lesions were found in 10 (77%) patients in the HLAPD group compared with 15 (75%) patients in the OPD group. Median tumour size, R1 resection rate and lymph node harvest did not differ significantly between the groups.

Within 90 days postoperative, major complications (Clavien grade III/IV) occurred in 2 (15%) patients in the HLAPD group compared with 8 (40%) patients in the OPD group. Six (46%) patients in the HLAPD group experienced minor complications (Clavien grade I/II) compared with 9 (45%) patients in the OPD group (Table 3). One patient in the HLAPD group died due to refractory sepsis following a leak at a gastric staple site, which required surgical repair and drainage. In the OPD group, 4 deaths occurred within 90 days. One patient had acute hepatic and renal failure after 2 subsequent surgeries for portal vein thrombosis; 1 had an acute myocardial infarction; 1 had hemorrhagic shock due to bleeding from the portal vein, which required surgical intervention; and 1 succumbed to abdominal sepsis following operative repair of hepaticojejunostomy and gastrojejunostomy leaks.

DISCUSSION

The advent of minimally invasive surgery has resulted in increased use of laparoscopic techniques to pancreatic surgery. The benefits of a minimally invasive approach include reduced incisional pain, decreased postoperative complications, shortened hospital stay and improved cosmesis. Although some surgeons have advocated a direct transition from an open to a purely laparoscopic approach, such a shift requires extensive prior laparoscopic experience and has been successfully accomplished in only a few centres. Concerns regarding the complexity of laparoscopic reconstruction and the adequacy of oncologic resection have hindered the adoption of TLPD. This report describes the value of HLAPD as a pragmatic stepping stone in the transition from open to purely minimally invasive pancreaticoduodenectomy at our institution. The hybrid method combines the safety and familiarity of conventional open surgery with the benefits of a minimally invasive approach. Given its favourable learning curve, it may be more realistically and widely adopted by hepatobiliary surgeons, even those without extensive laparoscopic experience. The adoption of a multistep

**Table 1. Demographic and outcome data**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Group; median (range)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of patients</td>
<td>HLAPD: 13</td>
</tr>
<tr>
<td>Age, yr</td>
<td>69 (49–88)</td>
</tr>
<tr>
<td>Sex, male:female, %</td>
<td>85%:15%</td>
</tr>
<tr>
<td>BMI</td>
<td>24.2 (20.6–32.0)</td>
</tr>
<tr>
<td>Charlson Comorbidity Index</td>
<td>1 (0–4)</td>
</tr>
<tr>
<td>ASA score</td>
<td>2 (2–3)</td>
</tr>
<tr>
<td>Operative time, min</td>
<td>594 (407–779)</td>
</tr>
<tr>
<td>Estimated blood loss, mL</td>
<td>450 (100–4000)</td>
</tr>
<tr>
<td>Intraoperative blood transfusion, no. (%)</td>
<td>5 (38%)</td>
</tr>
<tr>
<td>Total 7-day analgesic use, mg IV, mean ± SD</td>
<td>174 ± 117</td>
</tr>
<tr>
<td>Length of stay, d</td>
<td>8 (6–14)</td>
</tr>
<tr>
<td>90-day mortality, no. (%)</td>
<td>1 (8%)</td>
</tr>
</tbody>
</table>

ASA = American Society of Anesthesiologists; BMI = body mass index; HLAPD = hybrid laparoscopy-assisted pancreaticoduodenectomy; IV = Intravenous; OPD = open pancreaticoduodenectomy; SD = standard deviation.

*Unless otherwise indicated.
approach using a spectrum of minimal access procedures may allow more institutions to successfully implement minimally invasive pancreatic surgery programs.

The main concerns regarding HLAPD are whether smaller incisions are achieved at the expense of the quality of oncologic resection and whether any tangible patient benefit is achieved. For pancreaticoduodenectomy, positive margin rates of 20%-40% have been reported in the literature. Recently, a systematic review of 707 patients undergoing laparoscopic pancreaticoduodenectomy reported an R1 resection rate of 42.5%. Our oncological outcomes with HLAPD compare favourably to these standards (R1 resection rate 30%) and confirm the oncologic soundness of the hybrid method. In our study, lymph node retrieval and R1 resection rates did not differ between the OPD and HLAPD groups, further corroborating the adequacy of laparoscopic resection.

Certain groups who perform minimally invasive pancreaticoduodenectomy only for benign or low malignant potential disease have reported much lower R1 resection rates. However, these rates are not comparable to those found in our study, in which 77% of HLAPD procedures were performed for malignant indications. Although certain patients with complex tumours were inherently selected to the open group (including conversions), we nonetheless achieved acceptable oncologic outcomes in HLAPD patients with malignant disease, as compared with values reported in the literature. Our results demonstrate that oncologic principles are not compromised by the use of the hybrid approach, provided careful patient selection.

Long learning curves and increased duration of surgery are often invoked as drawbacks of minimally invasive pancreaticoduodenectomy. An advantage of our study is that all operations were performed by the same surgeons, allowing for a more accurate assessment of progression along the learning curve. In our cumulative experience, duration of surgery did not differ significantly between the HLAPD and OPD groups (594 v. 553 min., \( p = 0.6 \)). Figure 3 depicts the duration of surgery of HLAPD and OPD in chronological order. Initially, we observed significantly longer surgery with HLAPD, as expected during the initial learning phase. An analysis conducted after 2 years of institutional experience, including 7 HLAPD and 12 OPD procedures, revealed significantly longer surgeries in the HLAPD group than in the OPD group (703 v. 572 min.; \( p = 0.035 \)). However, the duration of HLAPD decreased from a median 703 minutes in the first 7 patients to 582 minutes in the last 6 patients (\( p = 0.003 \)), whereas the duration of OPD remained relatively stable. Our results project the continued convergence of the 2 trendlines with increasing operative experience. Importantly, the learning curve appears to affect the duration of the procedure, but is not associated with increased morbidity or compromise of oncologic outcomes. Tseng and colleagues reported that surgeons typically achieved significantly decreased estimated blood loss, duration of surgery, length of stay and R1 resection rates after performing approximately 60 OPD procedures. In light of the important learning curve, preference should be given to a hybrid approach before transitioning to total laparoscopic pancreaticoduodenectomy to acquire sufficient experience and ensure patient safety.

Despite technical advancements and increased surgeon experience, pancreaticoduodenectomy remains associated with high morbidity. We stratified adverse events by severity of the clinical treatment required. Our 90-day Clavien III/IV complication rates for the HLAPD and OPD groups were 15% and 40%, respectively, which compare acceptably to the 40% morbidity reported in Figure 2. Seven-day analgesic use. HLAPD = hybrid laparoscopy-assisted pancreaticoduodenectomy; OPD = open pancreaticoduodenectomy.

![Fig. 2. Seven-day analgesic use. HLAPD = hybrid laparoscopy-assisted pancreaticoduodenectomy; OPD = open pancreaticoduodenectomy.](image-url)

### Table 2. Pathology and oncologic outcomes

<table>
<thead>
<tr>
<th>Group; no. (%)*</th>
<th>HLAPD, ( n = 13 )</th>
<th>OPD, ( n = 20 )</th>
<th>( p ) value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Factor</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tumour size, cm</td>
<td>3.5 (1.8–4.2)</td>
<td>3.5 (1.5–6.5)</td>
<td>0.71</td>
</tr>
<tr>
<td>R1 resection margin</td>
<td>3/10 (30)</td>
<td>7/15 (47)</td>
<td>0.68</td>
</tr>
<tr>
<td>Lymph node harvest</td>
<td>22 (14–56)</td>
<td>20 (17–45)</td>
<td>0.09</td>
</tr>
<tr>
<td>Positive lymph nodes</td>
<td>9 (69)</td>
<td>9 (53)</td>
<td>0.47</td>
</tr>
<tr>
<td><strong>Pathology</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Malignant</td>
<td>10 (77)</td>
<td>15 (75)</td>
<td>—</td>
</tr>
<tr>
<td>Pancreatic adenocarcinoma</td>
<td>9</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>Ampullary adenocarcinoma</td>
<td>1</td>
<td>3</td>
<td>—</td>
</tr>
<tr>
<td>Neuroendocrine tumour</td>
<td>0</td>
<td>1</td>
<td>—</td>
</tr>
<tr>
<td>Benign</td>
<td>3 (23)</td>
<td>5 (25)</td>
<td>—</td>
</tr>
<tr>
<td>Intraductal papillary mucinous neoplasm</td>
<td>1</td>
<td>3</td>
<td>—</td>
</tr>
<tr>
<td>Duodenal polyp</td>
<td>1</td>
<td>1</td>
<td>—</td>
</tr>
<tr>
<td>Autoimmune pancreatitis</td>
<td>1</td>
<td>0</td>
<td>—</td>
</tr>
<tr>
<td>Perforated gastric ulcer</td>
<td>0</td>
<td>1</td>
<td>—</td>
</tr>
</tbody>
</table>

HLAPD = hybrid laparoscopy-assisted pancreaticoduodenectomy; OPD = open pancreaticoduodenectomy

*Unless otherwise indicated.
previously published studies.\textsuperscript{8,27} Pancreatic fistula remains the most important morbidity after pancreaticoduodenectomy. In our study, pancreatic fistula rates in the HLAPD and OPD groups were similar: 31\% and 30\%, respectively. Although the pancreatic fistula rate was not reduced with the hybrid approach, our data suggest that, even within the initial learning curve, complication rates with HLAPD are acceptable and consistent with those reported in large open and TLPD series.\textsuperscript{6,28} Ninety-day mortality was comparable between the HLAPD and OPD cohorts. Importantly, a very large proportion of patients in both study groups had malignant pathology, which may explain the higher mortality in our study than other studies focusing on benign disease. In addition, our sample size was small, and any calculated rates should be taken in the context of these limited patient numbers.

Patients who underwent HLAPD had a significantly shorter length of hospital stay than those who underwent OPD. Larger series with longer patient follow-up will be required to assess for any tangible benefits, such as quicker return to baseline function. Total analgesic use during the first 7 postoperative days was consistently lower and tapered off faster in the HLAPD group than in the OPD group, but this trend did not achieve statistical significance (Fig. 2). The decreased analgesic requirements following a minilaparotomy versus a standard subcostal incision likely reflect the correlation between postoperative pain and incision length. Furthermore, while TLPD constitutes the least invasive procedure, it classically requires a 5 cm Pfannenstiel incision for specimen extraction. The difference in morbidity from a Pfannenstiel versus a minilaparotomy incision may be of limited clinical importance, thus attenuating some benefits of directly transitioning to a purely minimally invasive approach.

Our study’s small sample size does not allow for definitive conclusions to be drawn regarding the comparative effectiveness of either technique. However, our objective was not to define the better procedure, but rather to assess whether the hybrid procedure is feasible and effective without incurring additional risk to the patient. Our study is limited methodologically by its nonrandomized and retrospective design. Selection bias is inherent, given that patients with major vascular involvement, which poses additional technical challenges, were excluded from the HLAPD group. We had an important conversion rate in our study, as 9 of 22 (41\%) cases begun laparoscopically were converted to laparotomy. It is important to highlight that these conversions largely occurred early during the procedure: 4 cases were converted before any resection, 4 after gastrectomy only and 1 after choledochectomy only. As such, the surgery performed in these converted cases is more comparable to an open than to a hybrid procedure, and the associated outcomes are more representative when included in the OPD group. A subanalysis of strictly open versus converted patients was undertaken to compare patient outcomes (Table 4). Oncologic outcomes, such as R1 resection rate and lymph node harvest, were similar between the open and converted groups. The duration of surgery in the converted group was also longer. Although this difference did not achieve statistical significance in our study, the duration of surgery is undoubtedly affected by the process of converting from laparoscopic to open surgery. Patients in the converted group had significantly higher estimated

<table>
<thead>
<tr>
<th>Table 3. Ninety-day complications</th>
<th>Group, no.</th>
<th>HLAPD, (n=13)</th>
<th>OPD, (n=20)</th>
<th>(p) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complication</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clavien I/II*</td>
<td>6</td>
<td>9</td>
<td>&gt; 0.99</td>
<td></td>
</tr>
<tr>
<td>Wound infection</td>
<td>1</td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypotension</td>
<td>1</td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intra-abdominal abscess</td>
<td>1</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Delayed gastric emptying</td>
<td>1</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thrombocytopenia</td>
<td>1</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urinary retention</td>
<td>1</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anemia</td>
<td>0</td>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pneumonia</td>
<td>0</td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clavien III/IV†</td>
<td>2</td>
<td>8</td>
<td>0.25</td>
<td></td>
</tr>
<tr>
<td>Intra-abdominal abscess</td>
<td>1</td>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anastomotic breakdown</td>
<td>1</td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Portal vein thrombosis</td>
<td>0</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Postoperative hemorrhage</td>
<td>0</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute myocardial infarction</td>
<td>0</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pancreatic fistula</td>
<td>4</td>
<td>6</td>
<td>&gt; 0.99</td>
<td></td>
</tr>
<tr>
<td>Grade A</td>
<td>3</td>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grade B</td>
<td>1</td>
<td>3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

HLAPD = hybrid laparoscopy-assisted pancreaticoduodenectomy; OPD = open pancreaticoduodenectomy.

*Not necessitating radiological, endoscopic or operative intervention and not causing organ failure.
†Necessitating radiological, endoscopic or operative intervention and/or causing organ failure.

Fig. 3. Operative times in chronological order. HLAPD = hybrid laparoscopy-assisted pancreaticoduodenectomy; OPD = open pancreaticoduodenectomy.
blood loss (1650 mL v. 700 mL; p = 0.020) than those who began with open surgery. Importantly, however, since no case was converted due to excessive bleeding, this difference in blood loss likely reflects inherently difficult pathology and surgical complexity rather than complications of laparoscopic resection or the act of conversion. As such, these outcomes may have remained largely unchanged even if they had initially been begun by laparotomy. Because similar conversion rates have been reported in the literature, further studies evaluating the validity of more rigorous selection criteria are warranted to reduce conversion rates going forward.19

Robotic-assisted pancreaticoduodenectomy (RAPD) has gained increasing acceptance because it offers 3-dimensional visualization, superior ergonomics and enhanced suturing capabilities.29 Since 2011, our centre has progressed from an open to a robotic reconstruction with favourable results, and the laparoscopic experience initially acquired with HLAPD has been valuable in this transition. All patients eligible for a minimally invasive procedure now undergo RAPD, provided robot availability. We reserve HLAPD for those patients for whom the robotic platform is unavailable for logistic reasons.

CONCLUSION

Hybrid laparoscopy-assisted pancreaticoduodenectomy is a safe, feasible and effective procedure with comparable outcomes to OPD in select patients. The favourable learning curve makes HLAPD a pragmatic procedure that may allow a greater number of patients to benefit from a minimally invasive approach. The transition from open to purely minimally invasive pancreaticoduodenectomy may be more effectively achieved as a multistep process using the hybrid approach as a valuable stepping stone.

**Table 4. Comparison of cases begun open versus converted cases**

<table>
<thead>
<tr>
<th>Factor</th>
<th>Open</th>
<th>Converted</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of patients</td>
<td>11</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>Age, yr</td>
<td>62 (33–76)</td>
<td>72 (47–78)</td>
<td>0.06</td>
</tr>
<tr>
<td>Sex, male/female</td>
<td>55%/45%</td>
<td>78%/22%</td>
<td>0.37</td>
</tr>
<tr>
<td>BMI</td>
<td>26.2 (18.5–33.3)</td>
<td>23.5 (16.4–31.6)</td>
<td>0.53</td>
</tr>
<tr>
<td>ASA score</td>
<td>2 (2–3)</td>
<td>3 (2–3)</td>
<td>0.36</td>
</tr>
<tr>
<td>Operative time, min.</td>
<td>518 (303–665)</td>
<td>613 (470–892)</td>
<td>0.07</td>
</tr>
<tr>
<td>Estimated blood loss, mL</td>
<td>700 (300–4900)</td>
<td>1650 (800–5050)</td>
<td>0.020</td>
</tr>
<tr>
<td>Tumour size, cm</td>
<td>3.1 (1.8–4.5)</td>
<td>3.7 (2.8–6.5)</td>
<td>0.27</td>
</tr>
<tr>
<td>R0 resection margin, no. (%)</td>
<td>3/8 (38%)</td>
<td>4/7 (67%)</td>
<td>0.62</td>
</tr>
<tr>
<td>Lymph node harvest</td>
<td>20 (7–30)</td>
<td>19 (15–45)</td>
<td>0.56</td>
</tr>
<tr>
<td>Length of stay, d</td>
<td>11 (6–23)</td>
<td>15.5 (7–26)</td>
<td>0.31</td>
</tr>
<tr>
<td>Clavien III, no. (%)</td>
<td>5 (45%)</td>
<td>4 (44%)</td>
<td>&gt; 0.99</td>
</tr>
<tr>
<td>Clavien IV, no. (%)</td>
<td>4 (36%)</td>
<td>4 (44%)</td>
<td>&gt; 0.99</td>
</tr>
<tr>
<td>90-day mortality, no. (%)</td>
<td>1 (10%)</td>
<td>3 (33%)</td>
<td>0.30</td>
</tr>
</tbody>
</table>

ASA = American Society of Anesthesiologists; BMI = body mass index.

**Funding:** This work was supported by a medical student research bursary from the McGill University Faculty of Medicine.

**Competing interests:** None declared.

**Contributors:** Y. Wang, S. Bergman and T. Vanounou designed the study. Y. Wang acquired the data, which all authors analyzed. All authors wrote and reviewed the article and approved it for publication.

**References**


**Correction**

Trauma Association of Canada abstracts

DOI: 10.1503/cjs.005714

The Trauma Association of Canada (TAC) 2014 Annual Scientific Meeting abstract supplement published in May 2014 contained an error in the abstract on page S48, entitled “Chest drain insertion in the emergency department: compliance with guidelines in a university hospital emergency department.” The author list should read K.T.D. Yeung, J. Ollerton. We apologize for this error.
The accuracy of the Alvarado score in predicting acute appendicitis in the black South African population needs to be validated

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Colleen Aldous, PhD*  
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DOI: 10.1503/cjs.023013

**Background:** The Alvarado score is the most widely used clinical prediction tool to facilitate decision-making in patients with acute appendicitis, but it has not been validated in the black South African population, which has much wider differential diagnosis than developed world populations. We investigated the applicability of this score to our local population and sought to introduce a checklist for rural doctors to facilitate early referral.

**Methods:** We analyzed patients with proven appendicitis for the period January 2008 to December 2012. Alvarado scores were retrospectively assigned based on patients’ admission charts. We generated a clinical probability score (1–4 = low, 5–6 = intermediate, 7–10 = high).

**Results:** We studied 1000 patients (54% male, median age 21 yr). Forty percent had inflamed, nonperforated appendices and 60% had perforated appendices. Alvarado scores were 1–4 in 20.9%, 5–6 in 35.7% and 7–10 in 43.4%, indicating low, intermediate and high clinical probability, respectively. In our subgroup analysis of 510 patients without generalized peritonitis, Alvarado scores were 1–4 in 5.5%, 5–6 in 18.1% and 7–10 in 76.4%, indicating low, intermediate and high clinical probability, respectively.

**Conclusion:** The widespread use of the Alvarado score has its merits, but its applicability in the black South African population is unclear, with a significant proportion of patients with the disease being potentially missed. Further prospective validation of the Alvarado score and possible modification is needed to increase its relevance in our setting.

**Contexte** : Le score d’Alvarado est l’outil de prédiction clinique le plus couramment utilisé pour faciliter la prise de décision chez les patients présentant une appendicite aiguë, mais il n’a pas été validé dans la population noire sud-africaine chez qui le diagnostic différentiel est beaucoup plus vaste que dans les populations des pays industrialisés. Nous avons exploré l’applicabilité de ce score à notre population locale et tenté de présenter une liste de vérification aux médecins ruraux pour accélérer les demandes de consultation.

**Méthodes** : Nous avons analysé les dossiers de patients atteints d’une appendicite avérée pendant la période allant de janvier 2008 à décembre 2012. Les scores d’Alvarado ont été assignés rétrospectivement selon les dossiers d’admission des patients. Nous avons généré un score de probabilité clinique (1–4 = faible, 5–6 = intermédiaire, 7–10 = élevé).

**Résultats** : Nous avons ainsi étudié 1000 patients (54 % de sexe masculin, âge médian 21 ans). Quarante pour cent présentaient des appendices enflammés non perforés et 60 % des appendices perforés. Les scores d’Alvarado se situaient à 1–4 chez 20,9 %, à 5–6 chez 35,7 % et à 7–10 chez 43,4 %, correspondant à une probabilité clinique faible, intermédiaire et élevée, respectivement. Dans notre analyse de sous-groupes sur 510 patients indemnes de péritonite généralisée, les scores d’Alvarado se situaient à 1–4 chez 5,5 %, à 5–6 chez 18,1 % et à 7–10 chez 76,4 %, correspondant à une probabilité clinique faible, intermédiaire et élevée, respectivement.

**Conclusion** : L’utilisation répandue du score d’Alvarado a ses mérites, mais son applicabilité dans la population noire d’Afrique du Sud est indéterminée, la maladie risquant de passer inaperçue chez une proportion significative de patients. Il faudra procéder à une validation prospective plus approfondie du score d’Alvarado et le modifier peut-être si l’on veut en accroître la pertinence dans notre contexte.
It is increasingly accepted that the omission of surgical care from the Millennium Development Goals was a serious oversight, and over the last decade there has been an increased awareness of the important role that surgery plays in global health. Disparities in access to surgical care result in major discrepancies in the outcomes of patients with common surgical conditions, and our group has studied the outcomes of acute appendicitis in our setting. We have demonstrated that acute appendicitis in rural South Africa has a very different disease profile to that seen in the developed world. It is associated with prolonged delays to definitive surgical care and significant morbidity due to intra-abdominal sepsis. We proceeded to investigate the reasons behind these lengthy delays in presentation and identified rural origin as an independent risk factor for poor outcome from this disease. It would appear that rural patients in South Africa experience delays before presenting to district hospitals, and once they have presented to these district facilities they experience further delays owing to failure of staff to diagnose the condition and refer them through to regional centres with surgical capacity. There is a causal relationship between delay to definitive surgery and poor outcome in the management of acute appendicitis, and strategies to reduce these delays are urgently required.

One of the suggested strategies aimed at facilitating the diagnosis of acute appendicitis is the introduction of tick-box-style clerking sheets to facilitate clinical decision-making among junior doctors working in relatively unsupervised, resource-constrained environments. A number of authors have advocated the use of clinical prediction rules (CPRs) to assist with clinical decision-making in cases of acute appendicitis. These CPRs attempt to quantify the possibility of a disease being present based on key symptoms, signs and the results of special investigations and to generate a score that predicts the probability of the disease being present. We sought to generate a tick-box-style sheet with a CPR that would allow junior staff working in relatively unsupervised district hospitals to triage patients with abdominal pain into those who require urgent referral and those who can be discharged home.

The Alvarado score is the most widely used CPR for acute appendicitis and sums up 3 symptoms and 3 signs as well as the results of standard blood tests to give an overall score out of 10 (Box 1). On the basis of this score, 3 groups of patients are identified. Patients with a score of 1–4 can be discharged home, those with a score 5–6 should be admitted and those with a score of 7–10 should be considered candidates for surgery. A recent review of the published data on the Alvarado score reported that it is most useful in predicting the absence of appendicitis, and an Alvarado score below 5 has a sensitivity of 94%–99% for appendicitis not being present. The authors concluded that a score of 5 or less rules out appendicitis. When it comes to positively establishing the presence of acute appendicitis, the score is less reliable; the same review stated that “the pooled diagnostic accuracy in terms of ‘ruling in’ appendicitis at a cut-point of 7 points is not sufficiently specific in any patient group to proceed directly to surgery.” The score is well calibrated in men, but tends to overpredict the presence of acute appendicitis in women.

In children, the score has also been shown to be inaccurate. The applicability of the Alvarado score in South Africa is unclear, and there is evidence to suggest that the clinical presentation of acute appendicitis is different to that in the developed world. Furthermore, the differential diagnosis of abdominal pain in South Africa is much broader than in the developed world. There is a high incidence of childhood diarrheal illness; HIV; and tropical diseases, such as amoebiasis, abdominal tuberculosis and typhoid, which may all present with acute abdominal symptoms.

Prior to designing a possible tick-box-style sheet for abdominal pain to be used in our rural hospitals, we set out to establish the validity of the Alvarado score at our institution.

**Methods**

We obtained ethics approval to audit acute appendicitis from the Umgungundlovu Health Ethics review board and from the Biomedical Research Committee of the University of KwaZulu-Natal. This study was conducted at Edendale Hospital, a large regional hospital in Pietermaritzburg, the capital city of KwaZulu-Natal, South Africa. Edendale Hospital drains a predominantly black African population from the urban areas around Pietermaritzburg and from the deep rural areas of Sisonke Health District (SHD), a rural area in southwestern KwaZulu-Natal with a population of half a million people and 4 district hospitals. This study was conducted from January 2008 to December 2012. For the period from January 2008 to December 2009, we retrospectively reviewed the records of all patients with acute appendicitis and entered the data into an Excel database. From January 2010 onwards, data from all patients with acute appendicitis were entered prospectively into the same database. Individual Alvarado scores were generated for all patients using data from their charts, and a score was
assigned to each patient. On the basis of each individual score a clinical probability score was generated, as previously described.9

**Statistical analysis**

We entered all data into an Excel spreadsheet for processing. All statistical analysis was performed using SPSS version 19 (IBM Corp).

**RESULTS**

Our study sample comprised 1000 patients (54% male, 46% female, median age 21 [range 12–26] yr) with acute appendicitis confirmed both intraoperatively and with histology during the 5-year period from January 2008 to December 2012. Medical care was sought on average 4.2 days after the onset of symptoms. Half of the patients presented from rural areas and the other half from urban areas. A total of 490 patients were considered to have generalized peritonitis at presentation, and the remaining 510 patients presented with localized peritonitis or non-specific abdominal pain. Intraoperative findings were as follows: 405 (40.5%) had inflamed, nonperforated appendices and 595 (59.5%) had perforated appendices. Of the cohort with perforated appendicitis 177 (29.7%) had perforation-associated localized intra-abdominal sepsis, and 418 (70.2%) had perforation-associated generalized intra-abdominal sepsis. In all, 234 (23.4%) patients required temporary abdominal closure, and 406 (40.6%) patients required revision laparotomy for residual sepsis. Ninety-five (9.5%) patients required postoperative intensive care admission owing to perforation and generalized sepsis. The mean length of stay in intensive care was 6 days. The remaining patients were admitted to the general surgical wards. Overall complications were as follows: 82 (8.2%) patients had hospital-acquired pneumonia, 57 (5.7%) had acute kidney injury, 142 (14.2%) had wound sepsis, and 20 (2.0%) experienced other complications. Overall mortality was 1.3%.

Table 1 compares the outcomes of acute appendicitis at our institution with those in institutions in the developed world.11

**Alvarado score**

For the entire cohort of 1000 patients, Alvarado scores were 1–4 in 20.9%, 5–6 in 35.7% and 7–10 in 43.4%, indicating low, intermediate and high clinical probability, respectively. The frequency of occurrence of each item on the Alvarado score and relative clinical probabilities are shown in Tables 2 and 3. Figure 1 provides a summary of the Alvarado scores for all patients with acute appendicitis.

**Subgroup analysis**

For the purpose of subgroup analysis, a total of 510 patients (65.5% male, 34.5% female, median age 19 [range 11–25] yr) who did not have generalized peritonitis on presentation were analyzed separately. A total of 393 of 510 (77.1%) patients had inflamed, nonperforated appendices and 117 (22.9%) had perforated appendices associated with localized intra-abdominal sepsis.

The Alvarado scores of all 510 patients were 1–4 in 5.5%, 5–6 in 18.1% and 7–10 in 76.4%, indicating low, intermediate and high clinical probability, respectively. The frequency of occurrence of each item on the Alvarado score and relative clinical probabilities are

| Table 1. Comparative data between the US Department of Defense and our institution |
|---------------------------------|-----------------|-----------------|
| Comparative data                | US Department of Defense | Edendale Hospital |
| Year                            | 1997            | 2008–2012       |
| Patients, no.                   | 4950            | 1000            |
| Centres, no.                    | 147             | 1               |
| Patients/centre/yr, no.         | 25              | 200             |
| Perforation rate, %             | 24              | 60              |
| Mortality, %                    | 0.08            | 1               |
| Intensive care unit, %          | NA              | 10              |
| Reoperation rate, %             | 0.5             | 23              |
| Temporary abdominal closure, %  | NA              | 41              |
| NA = not available.             |                 |                 |

| Table 2. Alvarado score for all patients with acute appendicitis in, n = 1000 |
|---------------------------------|-----------------|---------------|
| Alvarado score                  | No. (%)         |
| 1                               | 20 (2.0)        |
| 2                               | 25 (2.5)        |
| 3                               | 44 (4.4)        |
| 4                               | 120 (12.0)      |
| 5                               | 155 (15.5)      |
| 6                               | 202 (20.2)      |
| 7                               | 110 (11.0)      |
| 8                               | 120 (12.0)      |
| 9                               | 135 (13.5)      |
| 10                              | 69 (6.9)        |

| Table 3. Clinical probability according to Alvarado score, n = 1000 |
|---------------------------------|-----------------|---------------|
| Score                           | Clinical probability | No. (%)      |
| 1–4                             | Low              | 209 (20.9) |
| 5–6                             | Intermediate     | 357 (35.7)  |
| 7–10                            | High             | 434 (43.4)  |
shown in Tables 4 and 5. Figure 1 provides a summary of the Alvarado score with separate subgroup analysis.

The Alvarado scores of the 393 patients with inflamed, nonperforated appendices were 1–4 in 6.9%, 5–6 in 21.9% and 7–10 in 71.2%, indicating low, intermediate and high clinical probability, respectively. The frequency of occurrence of each item on the Alvarado score and relative clinical probabilities are shown in Tables 6 and 7.

The Alvarado scores of the 117 patients with perforated appendices (localized sepsis) were 1–4 in 0.9%, 5–6 in 5.1% and 7–10 in 94.0%, indicating low, intermediate and high clinical probability, respectively. The frequency of occurrence of each item on the Alvarado score and relative clinical probabilities were shown in Tables 6 and 7.

**Discussion**

Acute appendicitis is an important clinical problem in South Africa, and the incidence appears to be increasing among the general population.\(^1\),\(^3\) It is associated with long delays to definitive surgery, major morbidity and high cost.\(^1\),\(^2\) While there is evidence to suggest that patients do not present early and that a great deal of the morbidity is related to the presence of barriers to care, there is a concern that even once contact with the health system has been made, clinical failure to recognize the condition exacerbates the delays.\(^5\) There are a number of structural reasons for the high incidence of clinical failure that revolve around junior staff working in areas of limited resources with inadequate supervision.\(^14\) However, it has been suggested that the clinical presentation of the disease in South Africa is also different to that in the developed world.\(^1\),\(^11\) Abdominal tuberculosis; HIV; and other tropical diseases, such as typhoid, amoebiasis and pediatric diarrhea, may all mimic acute appendicitis.\(^12\) In our previous study on acute appendicitis, only a small proportion of our patients presented with the classic migratory abdominal pain.\(^3\) The most common symptoms encountered were all nonspecific, and these findings were similar to those previously reported in Durban, South Africa.\(^15\) The nonspecific nature of these symptoms has implications for the clinical assessment of black African patients. The present results seem to support our suspicion that the presentation of acute appendicitis among the South African population is different to that in the developed world.\(^1\),\(^16\)

**Limitations**

There are a number of limitations to our study. As the Alvarado score was applied retrospectively to patients already known to have the disease, there is a significant
potential for selection bias, and it is quite possible that the average Alvarado score of patients in our study is higher than that of patients presenting to our institutions with nonspecific abdominal pain who did not receive surgery.

We are interested in developing a triage tool for rural hospitals. The concept would be to create tick-box-style clerking sheets in district hospitals that would enable junior doctors to score each patient presenting with abdominal pain. Patients meeting a specific score could then be triaged for urgent referral to a regional institution with surgical capacity. However, before the widespread introduction of the use of the Alvarado score in our setting, we need to prospectively investigate its applicability in our institutions. We have increasingly used tick-box-style clerking sheets to improve the quality of care in our setting. This is taken directly from the aviation industry, which makes frequent use of tick-box-style checklists to improve safety. The assessment of abdominal pain may be amenable to such an intervention, and a major attraction of the Alvarado Score is that it can be tabulated into a routine clerking sheet. However, our study has shown that using the Alvarado score, more than one-quarter of all patients with proven acute appendicitis would have been classified as having a low to intermediate probability of the disease being present and that slightly less than 5% of these patients would have been discharged home despite having the disease. The implications of this finding for staff in rural district hospitals are unclear. These individuals are usually busy generalists with limited access to advanced imaging who are unable to undertake the operations themselves. There appear to be 3 options available to them: discharge, admit or transfer the patient. Our results suggest that approximately 20% of patients who have the disease may have been admitted to a district hospital for ongoing observations. Yet we know from our previous research that there is already a delay in transferring patients from district to regional hospitals, so this may simply exacerbate the problem. A further 5% of patients with the disease would have been sent home. Similarly, we know that a substantial number of patients are in fact incorrectly sent home from a district-level facility despite the presence of the disease. The concern with the Alvarado score remains that in our under-resourced hospitals its use may exacerbate rather than improve the current situation.

**CONCLUSION**

Acute appendicitis remains a common clinical diagnostic problem, and in our environment it is associated with significant delays and poor clinical outcomes. The widespread use of the Alvarado score as a clinical prediction tool has its merits, but its applicability in the black South African population is unclear, with a significant proportion of patients with the disease being potentially missed. This is likely to be related to a much wider range of pathologies and atypical clinical presentations. Future prospective research must be undertaken to validate the Alvarado score, with a possible modification, in order to improve its relevance in our environment.

**Competing interests:** None declared.

**Contributors:** All authors designed the study. V. Kong acquired the data, which V. Kong, S. van der Linde, J. Handley and D. Clarke analyzed. V. Kong and J. Handley wrote the article, which all authors reviewed and approved for publication.

**References**

Health-related quality of life following decompression compared to decompression and fusion for degenerative lumbar spondylolisthesis: a Canadian multicentre study

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Background: Decompression alone (D) is a well-accepted treatment for patients with lumbar spinal stenosis (LSS) causing neurogenic claudication; however, D is controversial in patients with LSS who have degenerative spondylolisthesis (DLS). Our goal was to compare the outcome of anatomy-preserving D with decompression and fusion (DF) for patients with grade I DLS. We compared patients with DLS who had elective primary 1–2 level spinal D at 1 centre with a cohort who had 1–2 level spinal DF at 5 other centres.

Methods: Patients followed for at least 2 years were included. Primary analysis included comparison of change in SF-36 physical component summary (PCS) scores and the proportion of patients achieving minimal clinically important difference (MCID) and substantial clinical benefit (SCB).

Results: There was no significant difference in baseline SF-36 scores between the groups. The average change in PCS score was 10.4 versus 11.4 (p = 0.61) for the D and DF groups, respectively. Sixty-seven percent of the D group and 71% of the DF group attained MCID, while 64% of both D and DF groups attained SCB. There was no significant difference between D and DF for change in PCS score (p = 0.74) or likelihood of reaching MCID (p = 0.81) or SCB (p = 0.85) after adjusting for other variables.

Conclusion: In select patients with DLS, the outcome of D is comparable to DF at a minimum of 2 years.
Degenerative lumbar spondylolisthesis (DLS) is a common spinal disorder that can lead to substantial back and/or leg pain. It is also a very common reason for spinal surgery in individuals older than 65 years. The estimated incidence of DLS is 12.7% with an overall prevalence of 6% that increases between the fifth and eighth decades of life. For symptomatic patients, the recent Spine Patient Outcomes Research Trial (SPORT) — DLS study has demonstrated that surgical management is superior to conservative care at 2 and 4 years post-intervention.

From a surgical perspective, since the controlled study by Herkowitz and Kurz demonstrated a high failure rate following decompression (conventional midline laminectomy) alone (D), decompression and fusion (DF) has become the surgical treatment of choice for patients with DLS. A recent systematic review by Martin and colleagues concluded that “decompression and spinal fusion may lead to better clinical outcome compared to decompression alone.” The contemporary management of DLS is reflected in the SPORT — DLS study in which 95% of patients underwent fusion, the majority of which (74%) were instrumented fusions.

Degenerative spondylolisthesis, however, represents a spectrum of pathology from very stable collapsed discs to maintained disc height with significant translation on loading dynamic imaging studies. Clinical symptoms also vary, with the patient experiencing either classical bilateral neurogenic claudication symptoms and/or unilateral/bilateral lumbar radiculopathy/sciatica. Physicians and surgeons experienced in the treatment of patients with this condition recognize this broad clinical presentation, which is a consideration given recent randomized controlled trials (RCTs) evaluating “similar patients” from an experimental and control perspective. By carefully delineating these potential subgroups the question arises as to whether all cases of DLS require fusion and, if so, whether instrumentation may or may not be required as an adjunct to fusion. The importance of this question is further amplified when one considers the additional morbidity associated with instrumented spinal fusion in elderly patients and the scarcity of health care resources for this growing segment of the population.

The development of less destructive midline anatomy-sparing decompressive techniques have created renewed interest in D rather than DF for certain patients with “stable” DLS. The literature to date has demonstrated good efficacy of the less invasive decompressive techniques in treating simple lumbar spinal stenosis (LSS), but to our knowledge no comparative study in a pure cohort of patients with DLS has been conducted. The purpose of the present study was to assess the outcomes of anatomy-preserving D in a select subgroup of patients with DLS compared with those of a multicentre cohort of patients with DLS who underwent DF.

**Methods**

We conducted a Canadian multicentre ambispective (retrospective review of prospectively collected data) cohort study. We sought to determine whether the 2-year postoperative improvement in health-related quality of life (HRQoL) outcomes for D was equivalent to that of DF for the management of focal (1–2 level) stenosis and associated DLS with similar clinical presentation. The study was approved by each institution’s research ethics board.

**Patient population**

Inclusion and exclusion criteria were applied to prospective surgical databases collecting HRQoL outcome measures from 6 academic spine centres across Canada. We included patients with DLS who had 1- or 2-level surgery for whom baseline and 2-year primary outcome data were available. All patients had failed at least 6 months of nonoperative care. Exclusion criteria were other causes of spinal stenosis (e.g., congenital, post-traumatic, degenerative scoliosis), multilevel surgery (> 2 levels), previous surgeries (at the symptomatic or adjacent level; a prior discectomy was allowed) or multilevel coronal and/or sagittal plane deformity.

**Surgical technique**

Indication for surgery and type of surgery was as per the individual surgeons’ practices.

Decompression alone was performed at 1 centre only (Toronto Western Hospital [TWH]). This technique was chosen for patients with neurogenic claudication/mechanical radiculopathy (i.e., leg-dominant symptoms that were relieved by postural change and/or rest), no (or tolerable) mechanical back pain, facet anatomy favourable to facet-sparing (i.e., undercutting) decompression, up to a 25% (grade I) spondylolisthesis, and no obvious dynamic instability on imaging. Radiographic dynamic instability was defined as an increase in spondylolisthesis by 4–5 mm or more demonstrated on supine to standing or flexion-extension imaging. Preoperative disc height was not considered in the decision for D. It entailed a midline-sparing, bilateral decompression from a unilateral approach using a tubular retractor system (METRx Medtronic) that has been previously described by Kelleher and colleagues.

At the time of surgery (2000–2006) all 8 surgeons from the 5 other academic centres performed DF for all patients with symptomatic DLS. This group represents the broader structural presentations of DLS, including the more “stable” patients amenable to D as well as those with more complex structural pathology (e.g., grade II or greater listhesis and/or more complex coronal or sagittal plane spinal alignment) for which DF may be indicated. The primary indications for surgery were leg-dominant pain and, to a much lesser extent, back and leg pain. Fusion for back-dominant pain...
was rarely performed by any of the surgeons. All fusions were instrumented using pedicle screws with posterolateral and/or interbody fusion.

Data collection

Data included the patient characteristics of age and sex. The preoperative and postoperative (2 yr minimum) Medical Outcomes Study Short-Form General Health Survey (SF-36) was administered. Data were obtained from site-specific prospective surgical registries collecting patient-reported HRQoL (SF-36) data. Varying definitions of what constituted an adverse event and different methods for reporting all or selected events precluded comparison of adverse events.

Outcome measures

The SF-36 physical component summary (PCS) score was the primary outcome measure. Primary analysis included comparison of the degree of change between pre- and postoperative PCS scores and the proportion of patients from each cohort reaching minimal clinically important difference (MCID) and substantial clinical benefit (SCB) for PCS, as defined for degenerative spinal surgery.26 Our secondary analysis compared the 2-year postoperative change in scores on the 8 SF-36 subscales and the mental component summary (MCS) score.

Statistical analysis

We performed univariate analysis using an unpaired Student t test for continuous variables and a Pearson χ² test for categorical variables. Multivariate analysis was performed to control for any significant baseline difference between cohorts.

A priori power analysis

Using historical standard deviations for PCS in this population, with α (type I error rate) set 0.05 and power at 80%, we determined that 50 patients per group would be required to detect an MCID for PCS between groups.

Results

A total of 179 patients underwent surgery for the diagnosis of spinal stenosis with DLS. Decompression alone was performed in 46 patients (57% single-level), whereas DF was performed in 133 patients (64% single-level). The baseline demographic and clinical characteristics of the groups are presented in Table 1. The D group was on average 5 years older (p = 0.003) and had 15% fewer women (p = 0.044) than the DF group. The mean time from surgery was equivalent between the groups (p = 0.69). The D group had slightly more 2-level procedures than the DF group (43% vs. 36%, respectively). Baseline SF-36 values are presented in Table 2. There was no significant difference in baseline SF-36 scores between the groups; however, 3 SF-36 components nearly reached significance: MCS, general health (GH) and mental health (MH; all p = 0.06). With the exception of GH, there was significant improvement pre- to postoperatively in all SF-36 subscales and summary scores for both the D and DF groups (Table 3).

Comparison between the subgroups of D and DF patients from the only centre performing D (TWH) are shown in Table 4. There was no significant difference between the D and DF groups’ baseline and 2 year SF-36 scores (data presented for only the PCS, physical functioning [PF] and bodily pain [BP] scores; no difference was noted for any other subscales). The results of patients who underwent DF at TWH were also compared with those of patients who underwent DF at the other centres. There was no significant difference between the D and DF groups’ baseline and 2 year SF-36 scores (data presented for only the PCS, PF and BP scores; no difference was noted for any other subscales).

Table 1. Demographic and clinical characteristics of the study sample

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Group</th>
<th>p value*</th>
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<tr>
<td></td>
<td>Decompression alone, n = 46</td>
<td>Decompression and fusion, n = 133</td>
</tr>
<tr>
<td>Age, yr</td>
<td>67.80 ± 8.66</td>
<td>62.47 ± 10.83</td>
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<tr>
<td>Sex, female</td>
<td>27 (59)</td>
<td>98 (74)</td>
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<tr>
<td>% with 1-level surgery</td>
<td>26 (57)</td>
<td>85 (64)</td>
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<tr>
<td>Time from surgery</td>
<td>29.95 ± 14.34</td>
<td>29.17 ± 10.36</td>
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<tr>
<td>Baseline PCS score</td>
<td>28.90 ± 7.90</td>
<td>30.00 ± 7.00</td>
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<tr>
<td>Baseline MCS score</td>
<td>42.90 ± 12.70</td>
<td>46.80 ± 11.80</td>
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</table>

MCS = mental component summary; PCS = physical component summary; SD = standard deviation.

* Two sample Student t test (mean) or Pearson χ² test (percentage).

Primary outcome

With regard to the numeric mean change in overall physical HRQoL (PCS) there was no significant difference in the mean change in PCS for D and DF (10.4 v. 11.4, p = 0.61). Similarly, the number of patients reaching MCID

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(4.9 point change in PCS) was 68% for D and 73% for DF ($p = 0.58$). The number of patients reaching SCB (6.2 point change in PCS) was 64% for D and 66% for DF ($p = 0.81$). The results of multivariate analysis are shown in Tables 5–7. The multivariate analysis demonstrated that baseline age ($p = 0.039$) and PCS ($p < 0.003$) were independent predictors of change in PCS and likelihood of reaching MCID and SCB for PCS. Older patients and those with higher baseline PCS scores (i.e., better physical HRQoL) had less change in PCS and were less likely to reach MCID and SCB for PCS. There was no significant difference in change in PCS or likelihood of reaching MCID or SCB for PCS between the D and DF groups when adjusted for other variables (all $p > 0.74$).

**Secondary outcome**

The mean change in SF-36 subscale and component summary scale scores are presented in Table 3. Overall, there was no significant difference between the D and DF groups in the pre- to postoperative change in any of the subscales or the MCS (all $p > 0.19$).

**DISCUSSION**

The results of our study demonstrate that in a select subgroup of patients with DLS (i.e., those with leg-dominant symptoms and what is typically termed a “stable DLS”) D can achieve the same significant improvement in HRQoL as DF.

The generally accepted clinical belief that DF is superior to D for the surgical management of DLS was recently supported by a systematic review by Martin and colleagues. Historically superior outcomes of DF versus D are demonstrated in patient-reported outcomes, postoperative increase in listhesis (instability) and reoperation rates. However, in contrast to the present study, a distinct “stable cohort” of patients with DLS was

<table>
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<th>Table 2. Baseline and postoperative SF-36 subcomponent scores</th>
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<td>SF-36 component</td>
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<tr>
<td>Physical component summary</td>
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<td>Mental component summary</td>
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<tr>
<td>Physical functioning</td>
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<td>Mental health</td>
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SD = standard deviation. *Two-sample Student t test comparing pre- and postoperative values.

<table>
<thead>
<tr>
<th>Table 3. Two-year change in health-related quality of life, SF-36 components</th>
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<td>SF-36 component</td>
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SD = standard deviation. *Two-sample Student t test.
not identified and a midline anatomy-sparing minimally invasive approach was not used.7,8,27,28,33 A traditional laminectomy does not preserve any of the midline structures and also may not be facet-preserving. Consequently, a traditional laminectomy has a higher likelihood of increased postoperative instability, clinical failure and revision rate over time, particularly in the DLS patient population.7,14 However, several small series in which facet-preserving techniques were used also suggest that DF was still superior for this patient population.28,30,32,35

The findings of the present study are contrary to those in most of the literature and to surgeon belief. Although limited in number, there are a few published studies that contradict the studies favouring fusion and that support the findings of the present study. Matsudaira and colleagues31 demonstrated no difference in outcome between midline-sparing (bilateral laminotomy), facet-preserving decompression \( n = 18 \) and decompression and instrumented posterolateral fusion \( n = 19 \) 2 years after surgery in patients with grade 1 DLS.31 In the recently published SPORT — DLS study, 19 patients underwent D and 344 patients underwent DF.36 As reported by Tosteson and colleagues,36 the quality-adjusted life years (QALY) gained by the 19 patients who had D was the same as that in the DF cohort 2 years post-surgery.36 Unfortunately, no details regarding selection criteria for those undergoing D are provided in these studies.

It is our belief that, from a structural and clinical perspective, all patients with asymptomatic DLS are not equal. Symptomatic patients typically present with 3 clinical scenarios (back-dominant pain, leg-dominant pain and equal back and leg pain) and a stable or unstable (i.e., mobile) low-grade (I-II) listhesis. Regardless of outcome, it would appear that the 2 main selection criteria used in this study are consistent with those of other contemporary studies where D was applied in the DLS population: leg-dominant symptoms and stable (< 3–5mm of movement) grade 1 spondylolisthesis.14,31,32,37 Essentially, these patients present with unilateral or bilateral neurogenic claudication symptoms, much like patients with LSS.38 Two studies using these selection criteria for this patient population have demonstrated no difference in outcome between midline-sparing (bilateral laminotomy), facet-preserving decompression \( n = 18 \) and decompression and instrumented posterolateral fusion \( n = 19 \) 2 years after surgery in patients with grade 1 DLS.31

### Table 4. SF-36 component scores: Decompression alone versus decompression and fusion in Toronto Western Hospital patients, and decompression and fusion in Toronto Western Hospital patients versus all sites

<table>
<thead>
<tr>
<th>Factor</th>
<th>Decompression alone, ( n = 46 )</th>
<th>Decompression and fusion, ( n = 25 )</th>
<th>All sites depression and fusion, ( n = 108 )</th>
<th>p value†</th>
<th>pH test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline PCS</td>
<td>28.9 ± 8.0</td>
<td>31.2 ± 7.6</td>
<td>31.2 ± 7.6</td>
<td>0.25</td>
<td>0.25</td>
</tr>
<tr>
<td>2 year PCS</td>
<td>39.0 ± 11.7</td>
<td>42.8 ± 9.7</td>
<td>42.8 ± 9.7</td>
<td>0.16</td>
<td>0.16</td>
</tr>
<tr>
<td>Change in PCS</td>
<td>10.4 ± 10.8</td>
<td>12.1 ± 9.4</td>
<td>12.1 ± 9.4</td>
<td>0.51</td>
<td>0.51</td>
</tr>
<tr>
<td>PCS MCID, %</td>
<td>65</td>
<td>76</td>
<td>76</td>
<td>0.70</td>
<td>0.70</td>
</tr>
<tr>
<td>PCS SCB, %</td>
<td>61</td>
<td>72</td>
<td>72</td>
<td>0.63</td>
<td>0.63</td>
</tr>
<tr>
<td>Baseline PF</td>
<td>24.8 ± 20.6</td>
<td>31.1 ± 23.7</td>
<td>31.1 ± 23.7</td>
<td>0.27</td>
<td>0.27</td>
</tr>
<tr>
<td>2-year PF</td>
<td>52.2 ± 30.7</td>
<td>62.2 ± 25.0</td>
<td>62.2 ± 25.0</td>
<td>0.14</td>
<td>0.14</td>
</tr>
<tr>
<td>Change in PF</td>
<td>27.3 ± 31.2</td>
<td>31.1 ± 24.7</td>
<td>31.1 ± 24.7</td>
<td>0.58</td>
<td>0.58</td>
</tr>
<tr>
<td>Baseline BP</td>
<td>26.2 ± 19.5</td>
<td>30.3 ± 18.4</td>
<td>30.3 ± 18.4</td>
<td>0.38</td>
<td>0.38</td>
</tr>
<tr>
<td>2-year BP</td>
<td>57.3 ± 25.2</td>
<td>59.2 ± 20.7</td>
<td>59.2 ± 20.7</td>
<td>0.73</td>
<td>0.73</td>
</tr>
<tr>
<td>Change in BP</td>
<td>32.8 ± 23.6</td>
<td>29.0 ± 25.4</td>
<td>29.0 ± 25.4</td>
<td>0.54</td>
<td>0.54</td>
</tr>
</tbody>
</table>

BP = bodily pain; MCID = minimal clinically important difference; PCS = physical component summary; PF = physical functioning; SCB = substantial clinical benefit; SD = standard deviation; TWH = Toronto Western Hospital.

*Unless otherwise indicated.
†Two-sample Student t test.
‡MCID for PCS = 4.9.
§SCB for PCS = 6.2.

### Table 5. Multiple linear regression results for change in physical component summary score, \( n = 175 \)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Coefficient (95% CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, yr</td>
<td>-0.20 (-0.34 to -0.05)</td>
<td>0.009</td>
</tr>
<tr>
<td>Sex, female</td>
<td>-1.21 (-1.66 to 2.24)</td>
<td>0.49</td>
</tr>
<tr>
<td>Baseline PCS</td>
<td>-0.47 (-0.70 to -0.25)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Baseline MCS</td>
<td>0.06 (+0.07 to 0.19)</td>
<td>0.35</td>
</tr>
<tr>
<td>Decompression and fusion</td>
<td>0.60 (+0.29 to 4.17)</td>
<td>0.74</td>
</tr>
</tbody>
</table>

CI = confidence interval; MCS = mental component summary; SD = standard deviation.

### Table 6. Logistic regression results for MCID on physical component summary score, \( n = 125 \)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Odds ratio (95% CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, yr</td>
<td>0.96 (0.93–1.00)</td>
<td>0.039</td>
</tr>
<tr>
<td>Sex, female</td>
<td>0.80 (0.36–1.82)</td>
<td>0.60</td>
</tr>
<tr>
<td>Baseline PCS score</td>
<td>0.91 (0.87–0.96)</td>
<td>0.001</td>
</tr>
<tr>
<td>Baseline MCS score</td>
<td>1.02 (0.99–1.05)</td>
<td>0.13</td>
</tr>
<tr>
<td>Decompression and fusion</td>
<td>1.11 (0.48–2.55)</td>
<td>0.81</td>
</tr>
</tbody>
</table>

CI = confidence interval; MCID = minimal clinically important difference; MCS = mental component summary; SD = standard deviation. *MCID for PCS = 4.9.
criteria have directly assessed the outcome of D alone for DLS compared with LSS patients without DLS. Sasai and colleagues demonstrated that the outcomes of midline facet-preserving D in select patients with DLS (n = 23) was similar to those of patients with LSS (n = 25) without spondylolisthesis at a minimum of 2 years (mean follow-up was 4 yr). Most recently, Kelleher and colleagues demonstrated comparable outcomes at 2 years with D in the same subset of DLS patients as those in our study compared with patients with LSS without spondylolisthesis.

By applying the aforementioned selection criteria (see methods), D for this defined subset of patients with DLS has several obvious advantages. From the perspective of elderly patients, reduced surgical morbidity and recovery time with similar clinical outcomes are clearly desirable. From a health care system perspective, the reduced duration of surgery, length of hospital stay and cost of D versus DF translate to cost savings or increased service delivery (i.e., more patients treated) for the same cost. However, before wide adoption of D for a subgroup of patients with DLS can be considered, the generalizability and sustainability of the alternative technique must be demonstrated. Although a keyhole technique was used in our study (i.e., the preferred access of the specific surgeon using this approach), others have demonstrated similar findings with more conventional access and a bilateral technique. The postoperative increase in radiographic listhesis demonstrated in the studies of Kelleher and colleagues, Matsudaira and colleagues and Sasai and colleagues (1.7% to 8.4%) is concerning regarding long-term sustainability. However, these studies all noted that an increase in listhesis did not correlate with an inferior clinical outcome or higher reoperation rate 2–4 years postoperatively. Furthermore, the revision rates in these studies (4% at 48 month follow-up) are comparable to that reported in the literature for contemporary DF in this population. Regardless, the clinical and economic impact of any potential difference in the long-term revision rate of these cohorts requires further investigation. Although not part of the present study, the TWH patients reported in Table 4 are part of an ongoing observational study with follow-up ranging from 5 to 13 years. In this group, the longer term revision rate for those who underwent D was 11% (n = 5 [3 with same site and 2 adjacent segment procedures]; 3 of these patients required a subsequent DF and 2 had repeat D; mean time to revision was 61.2 months) and 36% for those with DF (n = 9 [2 with same site and 7 with adjacent segment procedures]; all had a repeat DF; mean time to revision was 62.1 months). It must be emphasized that the primary DF group at this centre would represent the more unstable and complex anatomic presentations of DLS. Given the possibility of therapeutic equipoise, the question of D versus DF for a defined subpopulation of patients with DLS lends itself ideally to an RCT. However, as demonstrated by the ongoing controversy of instrumented versus noninstrumented fusion for DLS, an RCT demonstrating minimal difference without long-term follow up is unlikely to change the established practice of fusion for most — if not all — patients with DLS who require surgical intervention.

**Limitations**

The major strength of our study is that it assesses an alternative surgical management strategy (D) in a highly selected subpopulation of DLS patients compared with a generalizable multicentre cohort of DLS patients with similar clinical presentation in whom this selection criteria was not applied and who all received DF. To our knowledge, this study also represents the largest comparative study of its kind and presents clearly defined selection criteria and surgical principle for D in the DLS population. The methodological limitations of this study are related to the retrospective nature of our data abstraction from prospective databases. The potential confounding effects of patient and surgeon selection biases, differential complication rates and differences in surgical technique (mix of posterolateral or interbody instrumented fusion) for the DF cohort cannot be accounted for, but may reinforce the generalizability of our control group. In addition, all the other participating surgeons in this study performed DF for DLS patients. Patients who received DF at the centre performing selective D demonstrated similar results compared with the rest of the DF cohort as well as compared with the D cohort, suggesting a similar treatment effect can be achieved for the selected subgroup from within the same centre. The experimental group (D) was a highly selected subpopulation of patients with DLS and was thus not generalizable to the current literature. In addition, these patients underwent a specific minimally invasive decompression technique that

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**Table 7. Logistic regression results for SCB on physical component summary score, \( n = 114 \)**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Odds ratio (95% CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, yr</td>
<td>0.96 (0.92–0.99)</td>
<td>0.010</td>
</tr>
<tr>
<td>Sex, female</td>
<td>1.07 (0.95–2.28)</td>
<td>0.87</td>
</tr>
<tr>
<td>Baseline PCS score</td>
<td>0.93 (0.88–0.97)</td>
<td>0.002</td>
</tr>
<tr>
<td>Baseline MCS score</td>
<td>1.01 (0.98–1.04)</td>
<td>0.41</td>
</tr>
<tr>
<td>Decompression and fusion</td>
<td>0.93 (0.42–2.05)</td>
<td>0.85</td>
</tr>
</tbody>
</table>

CI = confidence interval; MCS = mental component summary; PCS = physical component summary; SCB = substantial clinical benefit; SD = standard deviation.

*SCB for PCS = 6.2.

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**Table 8. Comparison of degenerative spondylolisthesis patients in SPORT trial sample versus present sample: change in SF-36 physical functioning and bodily pain scores**

<table>
<thead>
<tr>
<th>SF-36 component</th>
<th>Group</th>
<th>( \Delta ) score</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>SPORT, ( n = 324 )</td>
<td>Present, ( n = 179 )</td>
</tr>
<tr>
<td>Physical functioning</td>
<td>26.6</td>
<td>29.7</td>
</tr>
<tr>
<td>Bodily pain</td>
<td>29.9</td>
<td>30.1</td>
</tr>
</tbody>
</table>

SPORT = Spine Patient Outcomes Research Trial.
has not been assessed for generalizability, thus introducing the possibility of a technique-based surgeon and procedural bias. Furthermore, the baseline demographic characteristics were not equal between cohorts. The D group was on average 5 years older, included fewer women and had more 2-level procedures than the DF group. Furthermore, the D group had a trend toward lower baseline MCS, GH and MH scores (Table 2, p = 0.06). However, these differences would more likely bias against the D group. As noted in the results, multivariate analysis controlling for age, sex and baseline PCS and MCS scores did not alter the outcome between those with D and DF. However, we did not control for other potential confounders, such as medical comorbidities, smoking status, fusion techniques (i.e., posterolateral vs. interbody fusion) or percent of spondylolysis-thesis. Although we cannot comment on all possible confounders, the older age and less intensive procedure performed in the D cohort would suggest they were probably more likely to have other medical comorbidities, which would again cause bias toward a lower SF-36 outcome in that group. Finally, it is possible that a superior result could have been obtained for the DF cohort if all patients underwent more contemporary interbody fusion using less invasive techniques. To date, however, studies comparing minimally invasive surgery to open fusion for spondylolysis-thesis at 2 years or greater have demonstrated equivalence in clinical outcome. Furthermore, if we compare our overall DLS cohort to the as-treated surgical cohort from the SPORT — DLS study, the mean age, sex, preoperative and 2-year postoperative PF and BP scores between our studies are very similar (Table 8). Consequently, with the aforementioned limitations considered, it seems that our cohorts and overall outcomes are consistent with those of a contemporary surgical DLS population.

CONCLUSION

The present study demonstrates that for a specific subpopulation of patients with DLS (i.e., those with leg-dominant symptoms and a radiographically stable grade I spondylolysis-thesis), undergoing an anatomic midline-sparing microdecompression alone can achieve the same improvement in HRQoL as that of DF for the overall DLS population at 2 years postoperatively. The routine implementation of D for this defined subpopulation of patients with DLS could result in fewer surgical complications, improved reactivation and potentially less health care utilization in a growing segment of society. Therefore, further multicentre prospective evaluation and longer term follow up is probably warranted.

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Competing interests: Y.R. Rampersaud is a paid consultant of Medtronic. C. Fisher is a paid consultant of Medtronic and Nuvasive and has received grants from Medtronic, AO Spine and the Orthopaedic Research and Education Foundation. M. Dvorak and E. Abraham are paid consultants of and have received speaker fees and travel assistance from Medtronic. W. Oxner has received honoraria and speaker fees from Medtronic. No other competing interests declared.

Contributors: All authors designed the study and acquired the data. Y.R. Rampersaud and C. Fisher analyzed the data. Y.R. Rampersaud wrote the article, which all authors reviewed and approved for publication.

References


Oncoplastic reduction using the vertical scar superior-medial pedicle pattern technique for immediate partial breast reconstruction

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Background: Oncoplastic breast reduction in women with medium to large breasts has reportedly benefited them both oncologically and cosmetically. We present our experience with an oncoplastic breast reduction technique using a vertical scar superior-medial pedicle pattern for immediate partial breast reconstruction.

Methods: All patients with breast tumours who underwent vertical scar superior-medial pedicle reduction pattern oncoplastic surgery at our centre between September 2006 and June 2010 were retrospectively studied. Follow-up continued from 12 months to 6 years.

Results: Twenty women (age 28–72 yr) were enrolled: 16 with invasive carcinoma and 4 with benign tumours. They all had tumour-free surgical margins, and no further oncological operations were required. The patients expressed a high degree of satisfaction from the surgical outcome in terms of improved quality of life and a good cosmetic result.

Conclusion: The vertical scar superior-medial pedicle reduction pattern is a versatile oncoplastic technique that allows breast tissue rearrangement for various tumour locations. It is oncologically beneficial and is associated with high patient satisfaction.

Breast cancer is the most common malignancy affecting women in the western world.1,2 The surgical treatment for breast cancer has continuously undergone profound changes over the past 3 decades, and the medical community currently endorses breast-conserving therapy (BCT) as the gold standard approach for most women with early-stage breast cancer.1,2 The combination of partial mastectomy and postsurgical radiation therapy has sometimes resulted in poor cosmetic results, characterized by deformation and...
noticeable asymmetry of the shape and size of the operated breast.\textsuperscript{3–7} This occurs more often when the tumour:breast size ratio is high. Several studies have shown a direct correlation between the magnitude of parenchymal and cutaneous excision and cosmetic outcome.\textsuperscript{3–7}

Improvements in diagnostic technology and mammographic screening as well as increased use of preoperative local or systemic therapies have extended the indications for BCT.\textsuperscript{1,2} Several oncoplastic breast surgery techniques have been introduced in an attempt to optimize the balance between the risk of local recurrence and the cosmetic outcome of BCT.\textsuperscript{3–14} The combined plastic surgery techniques of tissue replacement or rearrangement provide a wider local excision while achieving better breast shape and symmetry.\textsuperscript{3–23}

Although macromastia has been considered a contraindication for BCT owing to difficulties in administering radiation therapy at the surgical site, it has become standard procedure for a select group of patients with both breast cancer and breast hypertrophy.\textsuperscript{15–22} The combination of a tumour resection in a reduction pattern with a contralateral breast resection was first developed in the late 1980s and has been reported by many authors.\textsuperscript{15–23} An increasing number of reports have stated that bilateral breast reduction in conjunction with tumour-directed breast-conserving therapy is a surgical technique that can potentially improve the effectiveness of radiation therapy, alleviate neuropathic symptoms that may accompany macromastia and enhance the patients’ perceptions of their bodies after surgery.\textsuperscript{15–23} Numerous surgical techniques for oncoplastic breast resection have been described in the literature, and many of them have variably overlapping technical details, all of which can cause some confusion when evaluating and comparing the published results.\textsuperscript{15–23}

Our objective was to describe our experience with the vertical scar superior-medial pedicle reduction pattern approach for immediate oncoplastic reconstruction surgery on BCT deformities. The indications, advantages and limitations of the technique are discussed, and the simplicity of a single reduction technique for accommodating the different breast tumour regions is emphasized.

**METHODS**

All patients who underwent BCT and immediate reconstruction using the vertical scar superior-medial pedicle reduction pattern oncoplastic surgery at the Tel-Aviv Sourasky Medical Center and a private clinic between September 2006 and June 2010 were included in this series. We retrospectively collected and evaluated data on their demographic characteristics, oncologic findings, hospital admissions and postoperative outcomes. Oncologic information included tumour type, size and location; axillary lymph-node surgery; and adjuvant chemo- and radiotherapy. All breast specimens had been marked and weighed, and surgical margins were assessed by pathology to determine if the tumour had been fully excised and whether the margins were tumour-free.

Each patient was closely followed postoperatively by her plastic and general surgeons as well as by her oncologist. Cosmetic outcome was determined based on patient satisfaction and by grading from 5 independent reviewers, all of whom were plastic surgeons. Categories for evaluation included breast shape, nipple position and breast/nipple symmetry. Each were given a score on a scale of 1 to 4 (1 = poor, 2 = satisfactory, 3 = good, 4 = very good). The patients graded their satisfaction on a scale of 1 to 4 (1 = regret the decision, 2 = disappointed, 3 = satisfied, 4 = very satisfied). Data were collected retrospectively from outpatient charts.

**SURGICAL TECHNIQUE**

The patients were seen preoperatively by a multidisciplinary breast surgery team, and a plastic surgeon was consulted because of large breast volume, ptosis or tumour size and location. Patients with macromastia and tumours not located in the superior-medial pole of the breast were considered candidates for an oncoplastic breast reduction technique using the vertical scar superior-medial pedicle pattern for immediate reconstruction. Tumour size and location, surgical scars, resection area and axillary dissection were planned and discussed among the participating specialists after reviewing all relevant breast imaging.

Tumour location was marked on the breast skin. Nipple location was spotted 1–2 cm below the inframammary fold on the central meridian of the breast. A mosque pattern was marked around the new nipple location, and the medial and lateral margins of the skin resection were patterned using the Lassus manoeuvre.\textsuperscript{24–26} The superior-medial pedicle was marked with a width of 6–8 cm, depending on the volume of the breast and planned tissue resection. The base width of the pedicle included 5 cm of the medial pillar on the vertical limb 1–3 cm from the medial part of the mosque. The pedicle was oriented more medially than superiorly when the distance between the new and old nipple was shorter. Tumour resection was achieved through the skin resection markings of both the general surgeon and the plastic surgeon. Skin undermining beside the tumour bed was performed in order to permit wide glandular resection. After resection, tissue extensions were taken from all tumour bed dimensions, and the tumour bed margins were marked by surgical clips to facilitate locating the original tumour bed for the expected radiation boost. The tumour specimens were marked and weighed. Axillary dissection, when needed, was performed through a separate axillary incision.

Once the tumour had been removed, its location dictated the reduction pattern, resection and insetting. For tumour defects located in the inferior pole of the breast, the remaining skin and glandular tissue were resected according to the previous reduction pattern markings, and the pedicle was rotated superiority to its new position. The medial and lateral pillars were then shaped and plicated. For tumours that were located in the lateral pole of the breast, the pedicle was harvested with
additional glandular tissue from the inferior pole that filled the defect in the lateral area once the pedicle had been rotated superiorly (Fig. 1). Centrally located tumours that required resection of the nipple/areola complex (NAC) were marked by an inverted “V” instead of the mosque design, positioning the tip of the “V” at the planned new nipple position. The pedicle stub (resected NAC) was harvested with additional glandular tissue from the inferior-medial pole, which was rotated to the central area of the breast for better breast projection (Fig. 2). Lateral fullness was addressed by thorough undermining and emptying of the lower-lateral triangles during the procedure. No lateral liposuction was performed.

The resected breast tissue was added to the weight of the tumour specimen for determining total tissue removal. The contralateral breast underwent reduction in the superior-medial pattern. We usually tried to reduce the normal breast by 10% more than the affected breast in order to achieve better symmetry after radiation therapy.

The patient was then positioned upright for final assessment of symmetry, flap moulding and breast shape. Three drains were inserted (1 in each breast and 1 in the axilla after dissection) and the incisions were sutured. The surgical scars were protected with gauze pads, and a sports bra was fitted comfortably over the entire surgical field.

RESULTS

A total of 20 women with breast tumours underwent surgery by means of the vertical scar superior-medial pedicle reduction pattern oncoplastic surgery technique. Their mean age was 46.6 (range 28–72) years. Reconstructions were done immediately by the plastic surgeon after tumour removal by the general surgeon. The participants’ demographic and clinical characteristics are summarized in Table 1. Sixteen patients (80%) had invasive carcinomas and the other 4 patients (20%) had benign breast tumours (2 fibroadenoma, 1 cystosarcoma phylloides and 1 lipoma). Eighteen patients (90%) underwent unilateral oncoplastic reconstruction and 2 patients had bilateral oncoplastic reconstruction. Contralateral breast surgery (n = 18) included 16 with reduction/mastopexy, 1 with contralateral mastectomy and immediate tissue expander reconstruction and 1 with no surgery, yielding a total of 39 operated breasts. The tumour locations are displayed in Figure 3. One patient had unilateral NAC resection because of tumour location. Duration of surgery averaged 3 hours and 30 minutes (range 2.5–5.5 h), and hospital stay averaged 3.5 (range 2–8) days.

The oncological data are summarized in Table 2. Eleven of the 16 patients with malignant disease underwent axillary lymph node dissection, and 5 patients underwent sentinel lymph node biopsy that was negative for metastasis, both performed from a separate axillary incision. Five patients had chemotherapy before surgery (Table 2) and 8 had it after surgery. All patients with malignant tumours received postoperative radiation therapy. Radiotherapy was administered after chemotherapy and included daily fractionated doses up to a total of 45–50 Gy and an additional boost of 10 Gy to the primary tumour bed.

All patients had tumour-free surgical margins, and no further oncological operations were required. One patient had invasive ductal carcinoma that reached 0.5 cm from
the surgical margin; extension biopsies taken from that area during surgery were negative. No residual tumour was seen on the pathological specimens of 2 patients after they had undergone preoperative neoadjuvant chemotherapy (complete pathological response).

The postoperative follow-up period averaged 34.7 (range 12–72) months. One patient was lost to long-term follow-up because she lived abroad. Postoperative complications included dehiscence of the upper vertical scar and lateral fat necrosis in 1 patient, who was successfully

Fig. 2. A 46-year-old patient with infiltrating ductal carcinoma (IDC) of her right breast located under the nipple/areola complex (NAC) (A, B). The patient underwent right lumpectomy, including the NAC, leaving a large central defect (C). Glandular tissue from the inferior-medial pole based medially was rotated to the central area of the breast to fill in the defect (D). The left breast was reduced simultaneously. Postoperative pictures (E, F) 1 year after surgery and radiation therapy to the right breast.

Table 1. Patient characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>No. (%) or mean [range]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, yr</td>
<td>46.6 [28–72]</td>
</tr>
<tr>
<td>Comorbidities</td>
<td></td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>3 (15)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>2 (10)</td>
</tr>
<tr>
<td>Asthma</td>
<td>1 (5)</td>
</tr>
<tr>
<td>Body mass index</td>
<td>29 [22–36]</td>
</tr>
<tr>
<td>Smoker</td>
<td>2 (10)</td>
</tr>
<tr>
<td>Premenopausal</td>
<td>15 (75)</td>
</tr>
<tr>
<td>Previous breast surgery</td>
<td>1 (5)</td>
</tr>
</tbody>
</table>
treated conservatively. There were no surgical complications in the contralateral healthy breast. Two patients underwent revision surgery unrelated to radiation therapy: 1 for improved areolar symmetry and the other for re-reduction of the oncoplastic breast owing to asymmetry of the implant-reconstructed contralateral breast (Fig. 4).

The patients reported a high degree of satisfaction with the surgical outcome in terms of improved breast shape, volume, and position, all of which were retained after radiation therapy. Eighteen patients were either very satisfied or satisfied with their results, while 2 patients were disappointed (1 owing to breast asymmetry between the oncoplastic-reduced breast and an implant-reconstructed contralateral breast [Fig. 4] and 1 owing to hypertrophic scarring on the healthy breast). None of the 18 women regretted having undergone the surgery. The independent observers’ evaluation of the 19 patients who completed follow-up was that most of the patients had a very good to good surgical outcome regarding breast shape, NAC position and breast symmetry (Table 3).

**Discussion**

Breast conservative surgery in combination with postoperative radiation therapy has become the gold standard for early-stage breast cancer. In select patients, the lumpectomy defect and adjuvant radiation therapy can cause substantial breast deformity in shape, size and NAC position. Poor cosmetic results of BCT have been reported in 5%–40% of patients. The management of secondary breast deformities from partial mastectomies can be challenging, particularly when operating in a radiated field, and increasing attention is being paid to long-term cosmetic results. Immediate breast repair before adjuvant radiotherapy has been shown by many studies to be oncologically safe and esthetically beneficial. The breast reduction pattern

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**Table 2. Oncological data**

<table>
<thead>
<tr>
<th>Factor</th>
<th>No. (%) or mean [range]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tumour type, n = 22</td>
<td></td>
</tr>
<tr>
<td>Malignant IDC</td>
<td>18 (82)</td>
</tr>
<tr>
<td>Nonmalignant</td>
<td>4 (18)</td>
</tr>
<tr>
<td>Tumour location, n = 22</td>
<td></td>
</tr>
<tr>
<td>Inferior pole</td>
<td>13 (59)</td>
</tr>
<tr>
<td>Lateral pole</td>
<td>8 (36)</td>
</tr>
<tr>
<td>Nipple/areola complex</td>
<td>1 (5)</td>
</tr>
<tr>
<td>Tumour size, cm; n = 22</td>
<td>3.5 [1–12]</td>
</tr>
<tr>
<td>Tumour specimen weight mean, g</td>
<td>255 [50–600]</td>
</tr>
<tr>
<td>Total tumour + reduction resection, g</td>
<td>534 [50–1265]</td>
</tr>
<tr>
<td>Total contralateral breast reduction, g; n = 16</td>
<td>642 [50–1146]</td>
</tr>
<tr>
<td>Neoadjuvant chemotherapy, n = 16</td>
<td>5 (31)</td>
</tr>
<tr>
<td>Adjuvant chemotherapy, n = 16</td>
<td>8 (50)</td>
</tr>
<tr>
<td>Malignant tumour staging, n = 16</td>
<td></td>
</tr>
<tr>
<td>T1, &lt; 2 cm</td>
<td>8 (50)</td>
</tr>
<tr>
<td>T2, 2–5 cm</td>
<td>6 (37.5)</td>
</tr>
<tr>
<td>T3, &gt; 5 cm</td>
<td>2 (12.5)</td>
</tr>
<tr>
<td>Tumour receptors, n = 16</td>
<td></td>
</tr>
<tr>
<td>Estrogen positive</td>
<td>10</td>
</tr>
<tr>
<td>HER2-positive</td>
<td>5</td>
</tr>
</tbody>
</table>

HER2 = human epidermal growth factor receptor 2; IDC = infiltrating ductal carcinoma.
The oncoplastic breast reduction technique for partial mastectomy reportedly has numerous advantages: it permits wider resection margins with a higher probability of negative tumour margins; breast tissue rearrangement is done using local tissue, with no other donor sites or foreign body materials, obliterating the lumpectomy tissue dead-space; the reduced breast has better radiation-field efficiency and less radiation fibrosis during radiation therapy compared with larger breasts; and long-term breast surveillance imaging is technically easier and more precise in reduced breasts.\textsuperscript{15–23} Furthermore, removal of additional breast tissue through reduction techniques allows examination of contralateral breast tissue for occult breast lesions and theoretically makes sense in terms of reducing the risk of breast cancer.

The reduction of the normal contralateral breast in parallel with the oncoplastic reduction pattern reconstruction results in smaller-sized breasts that are aesthetically more pleasing, have better symmetry and provide relief from back and neck pain for patients with large, heavy and pendulous breasts.\textsuperscript{10–23} There are various management algorithms and approaches for reduction pattern oncoplastic surgery, including different skin reduction patterns, NAC pedicles and breast tissue rearrangement.\textsuperscript{15–21} Our experience with the vertical scar superior-medial pedicle reduction pattern approach to oncoplastic breast surgery was highly rewarding. This technique is based on the Hall-Findlay vertical reduction mammoplasty\textsuperscript{24} and has several advantages over other reduction pattern oncoplastic techniques. It is relatively simple and has a short learning curve. It involves a straightforward glandular resection and shorter skin incisions, resulting in a shorter duration of surgery.\textsuperscript{24} Furthermore, the superior-medial pedicle offers a reliable NAC for different breast sizes as well as versatility for different tumour locations and tissue rearrangement.\textsuperscript{24–26} The tumour location in this series was in the inferior and lateral poles of the breast, with 1 patient having a tumour under the NAC (Fig. 1). The vertical scar we used has low skin vascular compromise, sparing the long inframammary horizontal scar of the traditional wise pattern. Long-term follow-up findings demonstrated high patient satisfaction as well as high scoring for breast shape, NAC position and breast symmetry by independent observers (Table 3).

Local recurrence is an important consideration in oncoplastic surgery. In our series, the average tumour specimen weighed 255 g, compared with institutional norms of about 40–50 g with the nononcoplastic approach, thus reducing the risk for local recurrence.\textsuperscript{4} All our patients had tumour-free surgical margins; there was no need to widen the margins in any of them. However, in the event that there had been positive margins, they could have been managed either by completion mastectomy and reconstruction or re-excision, depending on a variety of patient- and surgeon-related factors and preferences as well as pathological findings. There is minimal downside to conversion to mastectomy and reconstruction. The skin is spared and immediate reconstruction is performed.

Early postoperative complications were limited to partial dehiscence of the vertical scar and lateral fat necrosis in 1 patient that was successfully treated conservatively. The vertical scar was closed secondarily before radiation therapy was initiated. There was no incidence in which adjuvant treatment was delayed due to surgical complications. Two patients underwent revision surgery: 1 for periareolar scars and another for rereduction of the oncoplastic breast.

### Table 3. Outcome evaluation by independent observers*

<table>
<thead>
<tr>
<th>Outcome parameter; score range</th>
<th>No. of patients</th>
<th>Mean (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast shape</td>
<td>3.1 (2.3–3.8)</td>
<td></td>
</tr>
<tr>
<td>Very good (n = 4) to good (n = 3)</td>
<td>14</td>
<td></td>
</tr>
<tr>
<td>Good (n = 3) to satisfactory (n = 2)</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Satisfactory (n = 2) to poor (n = 1)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Nipple/areola complex position</td>
<td>3.1 (2.4–3.6)</td>
<td></td>
</tr>
<tr>
<td>Very good (n = 4) to good (n = 3)</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td>Good (n = 3) to satisfactory (n = 2)</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Satisfactory (n = 2) to poor (n = 1)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Breast symmetry</td>
<td>2.9 (2.0–3.8)</td>
<td></td>
</tr>
<tr>
<td>Very good (n = 4) to good (n = 3)</td>
<td>14</td>
<td></td>
</tr>
<tr>
<td>Good (n = 3) to satisfactory (n = 2)</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Satisfactory (n = 2) to poor (n = 1)</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

*5 observers.

**Fig. 5.** A 39-year-old patient with infiltrating ductal carcinoma (IDC) of her right breast located at the upper-lateral pole (A). She underwent right lumpectomy with vertical scar superior-medial pedicle reduction pattern oncoplastic surgery and left breast reduction. Postoperative picture (B) 1 year after surgery and radiation therapy to the right breast.
revision surgery was needed as a consequence of postoperative radiation therapy or owing to breast shape (e.g., fat necrosis, breast fibrosis) or symmetry. Because the shape of the breast is generally preserved, cases of postradiation asymmetry can be treated with minor adjustments to the contralateral nonradiated breast rather than by reconstructing a deformity in the radiated breast.

Limitations

There are several limitations associated with the vertical scar superior-medial pedicle reduction pattern technique. Tumours located in the superior and medial poles require modifying the NAC pedicle to an inferiorly or laterally based pedicle. Furthermore, the vertical scar limits skin resection in the vertical aspect, leaving skin puckers, rippling and a mid-inferior dog-ear that can potentially cause scar dehiscence and takes weeks to straighten out and improve. Breast tissue rearrangement can cause internal scar tissue and fat necrosis that sometimes require tissue sampling to rule out recurrent cancer. However, overall we found the technique to be safe and effective without significantly affecting postoperative cancer surveillance.15

Conclusion

Our experience was that the vertical scar superior-medial pedicle reduction pattern was a simple, reliable and highly versatile technique with the other recognized benefits of reduction pattern oncoplastic surgery. It was associated with tumour-free oncolological margins, high patient satisfaction and pleasing aesthetic results. Judicious patient selection, coordinated planning and meticulous intraoperative management are the keys to favourable surgical outcome. We encourage the education of patients and physicians about the benefits of oncoplastic surgery for BCT.

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Competing interests: None declared.

Contributors: Y. Barnea, D. Barsuk, T. Menes, A. Zaretski, D. Leshem, J. Weiss, S. Schneebaum and E. Gur designed the study. Y. Barnea and A. Inbal acquired the data, which Y. Barnea analyzed. Y. Barnea and A. Inbal wrote the article, which all authors reviewed and approved for publication.

References

End-to-end ductal anastomosis is a physiologic biliary reconstruction that is commonly used in liver transplantation and less frequently in the surgical treatment of iatrogenic bile duct injuries. Currently, end-to-end ductal anastomosis is the biliary reconstruction of choice for liver transplantation in most adult patients. In recent years, it has also been performed for liver transplantation in children and in select patients with primary sclerosing cholangitis. The procedure is also performed in some patients with iatrogenic bile duct injuries, as it establishes physiologic bile flow. Proper digestion and absorption as well as postoperative endoscopic access are possible in patients who undergo end-to-end ductal anastomosis. It allows endoscopic diagnostic and therapeutic procedures in patients following surgery. This anastomosis is technically simple and associated with fewer early postoperative complications than the Roux-en-Y hepaticojejunostomy; however, end-to-end ductal anastomosis is not possible to perform in all patients. This review discusses the indications for and limitations of this biliary reconstruction, the technique used in liver transplantation and surgical repair of injured bile ducts, suture types and use of a T-tube.

End-to-end ductal anastomosis is a physiologic biliary reconstruction that is commonly used in liver transplantation and general surgery, including the treatment of iatrogenic bile duct injuries (IBDI). End-to-end ductal anastomosis and Roux-en-Y hepaticojejunostomy (HJ) are the 2 most common biliary reconstructions, and the former is the most common in patients who have had liver transplantation, including those with primary sclerosing cholangitis (PSC). In recent years, the traditional method of HJ has been challenged by end-to-end biliary reconstruction in these patient groups; however, in patients with IBDI, HJ is performed most frequently.

End-to-end ductal anastomosis has many advantages: it is physiologically simpler and associated with fewer early postoperative complications than HJ. End-to-end ductal anastomosis establishes physiologic bile flow; therefore, proper digestion and absorption are possible following this procedure. Postoperative endoscopic access is also possible, facilitating different diagnostic and therapeutic procedures. Despite its advantages, it is not possible to perform end-to-end ductal anastomosis in all patients.1–5

End-to-end ductal anastomosis in biliary reconstruction: indications and limitations

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L’anastomose termino-terminale du canal biliaire est la technique de reconstruction biliaire physiologique la plus couramment utilisée lors de la greffe du foie; elle est moins souvent utilisée pour le traitement chirurgical des blessures iatrogènes affectant le canal biliaire. À l’heure actuelle, l’anastomose termino-terminale est la reconstruction biliaire privilégiée lors d’une transplantation hépatique chez la plupart des patients adultes. Ces dernières années, on y a également eu recours pour la greffe hépatique chez les enfants et dans certains cas de cholangite sclérosante. L’intervention est également effectuée chez certains patients présentant des traumatismes iatrogènes affectant le canal biliaire, puisqu’elle permet la circulation physiologique de la bile. Une digestion et une absorption adéquates, de même qu’un accès endoscopique postopératoire sont donc possibles chez les patients qui subissent une anastomose termino-terminale. Elle facilite les interventions diagnostiques et thérapeutiques endoscopiques chez les patients après la chirurgie. Cette anastomose est simple au plan technique et associée à moins de complications durant la période postopératoire immédiate comparativement à l’hépaticojunostomie Roux en Y. Toutefois, l’anastomose termino-terminale n’est pas réalisable chez tous les patients. La présente analyse aborde les indications et les limites de cette reconstruction biliaire, la technique utilisée lors de la greffe hépatique et lors de la réparation chirurgicale des canaux biliaires lésés, les types de sutures et l’utilisation d’un tube en T.
The aim of this paper was to present the use of end-to-end ductal anastomosis in patients undergoing liver transplantation and gastrointestinal surgery. This review also discusses the limitations in using this biliary reconstruction method and describes a surgical technique of end-to-end ductal anastomosis.

**End-to-end ductal anastomosis in liver transplantation**

Biliary anastomosis is referred to as the Achilles’ heel of liver transplantation. The noted incidence of biliary complications is 5%–15% after deceased donor liver transplantation (DDLT) and 20%–34% after right-lobe live donor liver transplantation (LDLT). Nowadays, different methods of biliary reconstruction are used: Roux-en-Y HJ, end-to-end ductal anastomosis and side-to-side ductal anastomosis. Other biliary reconstructions, such as cholecystoduodenostomy, cholecystojejunostomy or the gallbladder conduit technique, were used in the early experience of liver transplantation, but they were associated with a high risk (up to 70%) of septic complications. Also, many gallbladders had to be removed because of cystic duct obstruction. Subsequently, HJ was introduced as the standard technique in liver transplantation, and it was a common method of biliary reconstruction for a long time. End-to-end ductal anastomosis was performed as the standard biliary reconstruction after DDLT, whereas HJ was the standard technique performed after LDLT. This trend has changed because of the disadvantages of HJ: longer duration of surgery and higher risk of bacterial contamination due to construction of the Roux-Y limb. Moreover, the re-established bilioenteric continuity is not physiologic and does not allow endoscopic access after liver transplantation. Currently, end-to-end ductal anastomosis is the standard biliary reconstruction for both DDLT and LDLT in adults. This method is preferable because of an intact sphincter Oddi that can prevent septic cholangitis due to ascending infections. Moreover, the procedure facilitates subsequent endoscopic diagnostic and therapeutic procedures in patients with biliary complications after liver transplantation. However, end-to-end ductal anastomosis with a small duct (< 4 mm in diameter) is associated with a higher risk of biliary strictures than HJ.4,7,8

**Hepaticojejunostomy versus end-to-end ductal anastomosis in liver transplantation**

There are a number of studies comparing HJ and end-to-end ductal anastomosis in liver transplantation in the literature. Kasahara and colleagues5 compared different biliary reconstructions in 321 recipients of right lobe LDLT. Biliary reconstruction was performed with HJ in 121 patients, end-to-end ductal anastomosis in 192 patients, and combined HJ and end-to-end ductal anastomosis in 8 patients. They found that end-to-end ductal anastomosis showed a significantly lower incidence of leakage and a higher incidence of stricture. However, 74.5% of the stricture was managed with endoscopic treatment. It should be emphasized that in recent years, the traditional method of HJ has been challenged by end-to-end ductal anastomosis biliary reconstruction even in patients undergoing liver transplantation owing to PSC. Damrah and colleagues9 compared HJ and end-to-end ductal anastomosis after liver transplantation in patients who had PSC. They used end-to-end ductal anastomosis when the recipient’s common bile duct was free of gross disease. Morbidity, mortality, disease recurrence and graft and patient survival were comparable between the groups. Based on these results, the authors recommended end-to-end ductal anastomosis for select patients with PSC as the first option for reconstruction. Similar results have been presented in other studies.10–12

**End-to-end ductal anastomosis in pediatric liver transplantation**

Currently, end-to-end ductal anastomosis is the biliary reconstruction of choice in adults. Its pediatric feasibility has rarely been reported. Tanaka and colleagues13 compared 14 patients who underwent end-to-end ductal anastomosis and 46 patients who underwent HJ; the incidence of biliary leakage was 7.1% and 8.7%, respectively, and that of stricture was 28.6% and 10.9%, respectively, but the differences were not significant. The authors observed that, compared with the HJ group, biliary stricture in the end-to-end ductal anastomosis group tended to require revision surgery with HJ and longer treatment with percutaneous transhepatic biliary drainage. Based on these results, the authors recommended HJ as the preferable reconstruction in children. They recommended that end-to-end ductal anastomosis should be considered when making a new Roux-Y limb is impossible or troublesome owing to abdominal dense adhesion or short bowel syndrome. Liu and colleagues14 analyzed results of end-to-end ductal anastomosis in 7 children undergoing LDLT using a left-lobe graft. The authors concluded that end-to-end ductal anastomosis biliary reconstruction without external stent tube in patients undergoing left-lobe LDLT was feasible in a select group of children with normal extrahepatic bile ducts. In smaller recipients with larger grafts, the use of a transanastomotic biliary tube could prevent anastomotic kinking, although the authors suggested HJ as a better method of biliary reconstruction for this condition. Other studies have also confirmed the usefulness of end-to-end ductal anastomosis for liver transplantation in select pediatric patients.15–18

**End-to-end ductal anastomosis in the surgical treatment of iatrogenic bile duct injuries**

Iatrogenic bile duct injuries are still an important problem in gastrointestinal surgery. Noninvasive, percutaneous
radiological end endoscopic techniques are recommended as initial treatment of IBDI. When these techniques are not effective, surgical management is considered. The goal of surgical treatment is to reconstruct the proper bile flow to the alimentary tract. The long-term results depend on the type of biliary reconstruction performed. Different biliary reconstructions have been reported in the surgical treatment of IBDI: Roux-en-Y HJ, end-to-end ductal biliary anastomosis, choledochoduodenostomy, Lahey HJ, jejunal interposition hepaticoduodenostomy, Blumgart (Hepp) anastomosis, Heinecke–Mikulicz biliary plastic reconstruction and Smith mucosal graft.\(^\text{23,24}\)

**Hepaticojejunostomy versus end-to-end ductal anastomosis in the surgical treatment of IBDI**

Currently, Roux-en-Y HJ is the most common surgical reconstruction of IBDI.\(^\text{2,3}\) Most authors have reported a preference for HJ owing to the lower number of postoperative anastomosis strictures with HJ than with end-to-end ductal anastomosis. The latter procedure is seldom performed in patients with IBDI because of a higher incidence of postoperative anastomosis strictures (up to 80%) compared with HJ.\(^\text{2,3}\) However, after HJ, bile flow into the alimentary tract is not physiologic because the duodenum and upper part of the jejunum are excluded from bile passage. Roux-en-Y HJ is associated with different disturbances in the release of gastrointestinal hormones leading to maldigestion and malabsorption.\(^\text{1,2,22,21}\) Significantly lower weight gain in patients who had HJ than in those who had end-to-end ductal anastomosis was observed in a previous study.\(^\text{1}\) Moreover, a higher number of duodenal ulcers has been observed in patients undergoing HJ, and this may be associated with a loss of the neutralizing effect of the bile, including bicarbonates and the secondary gastric hypersecretion. Control endoscopic examination and endoscopic dilatation of strictured biliary anastomosis is not possible after HJ.\(^\text{1,2}\) End-to-end ductal anastomosis should be considered the treatment of choice in select patients with IBDI because it is a more physiologic procedure than HJ; however, HJ should be considered in patients in whom end-to-end ductal anastomosis is not possible.\(^\text{1}\)

It has been shown that good long-term results can be achieved in a select group of patients following end-to-end ductal anastomosis. Gazzaniga and colleagues\(^\text{21}\) performed end-to-end ductal anastomosis in the immediate repair procedures only when the injury did not exceed one-third of the duct circumference and was not located more than 2 cm below the ductal confluence (Strasberg E2), or when injury was detected during the primary operation. In this series, injuries were type E2 in 18 patients, type E3 in 29 patients, and type E4 in 15 patients. Direct repair is not recommended when more than one-third of the bile duct circumference is injured. It cannot be carried out when the lesion involves the bifurcation of 1 or both hepatic ducts (Strasberg E3/E4). In such cases a Roux-en-Y HJ is the only procedure available to repair the damage. Reuver and colleagues\(^\text{21}\) recommended end-to-end ductal anastomosis in patients with injuries detected preoperatively when there was not extensive tissue loss. In patients with extensive tissue loss, particularly in those with more proximal injuries within the hepatic bifurcation or intrahepatic lesions, the authors recommend no primary repair. Kohneh and colleagues\(^\text{19}\) achieved better results with end-to-end ductal anastomosis (100%) than with HJ (71.4%) during early repair procedures (<30 d after the initial trauma). They performed end-to-end ductal anastomosis in patients with bile duct injuries classified as type II (Bismuth) or E2 (Strasberg). In the Department of Digestive Tract Surgery, Katowice, Poland, end-to-end ductal anastomosis reconstruction was performed when bile duct loss was 0.5–4 cm. Excision of the bile duct structure, dissection and refreshing of the proximal and distal stumps as far as the tissues are healthy and without inflammation, and the use of nontraumatic, monofilament-interrupted sutures 5–0 yielded good long-term results comparable to the results achieved with HJ. Recurrent stricture was observed in 5.3% of patients after HJ and 9.6% after end-to-end ductal anastomosis.\(^\text{1}\) Another study revealed that quality of life was also comparable after HJ and end-to-end ductal anastomosis. Moreover, it should be emphasized that physical functioning was significantly better in patients who underwent end-to-end ductal anastomosis than in those who underwent HJ.\(^\text{3}\) Another essential advantage of end-to-end ductal anastomosis is the possibility of control endoscopic examination and therapeutic procedures in patients after biliary reconstruction. End-to-end ductal anastomosis strictures can be easily dilated endoscopically in contrast to HJ. Fewer early complications have been observed after end-to-end ductal anastomosis than HJ; the complications were associated with opening of the alimentary tract and a higher number of performed anastomoses (biliary-enteric and enteroenteric) in patients who underwent HJ.\(^\text{1}\)

It should be noted that end-to-end ductal anastomosis has some limitations and cannot be performed in patients with all bile duct injuries; it is not possible to perform the procedure in patients with complex vasculobiliary injuries. According to Strasberg and Helton,\(^\text{26}\) a vasculobiliary injury (VBI) is an injury to both a bile duct and a hepatic artery and/or portal vein; the bile duct injury can be caused by surgical trauma, ischemic in origin or both, and can or cannot be accompanied by various degrees of hepatic ischemia. Injury of a right hepatic artery (RHA) is the most frequent type of VBI. There are contradictory reports regarding the association between the outcome of bile duct injuries and RHA injuries in the literature. Strasberg and Helton\(^\text{26}\) reviewed studies on VBI. Koffron and colleagues\(^\text{27}\) reported an associated injury of the artery in 61% of patients with recurrent strictures after primary bile duct repair. Schmidt and colleagues\(^\text{28}\) reported that the presence of combined vascular and bile duct injuries and injury at or above the level of the biliary bifurcation were significant independent predictors of poor outcome in...
patients undergoing Roux-en-Y HJ. Madariaga and colleagues\textsuperscript{29} described early necrosis of a biliary anastomosis requiring right hepatic lobectomy in the presence of an RHA injury. Sarno and colleagues\textsuperscript{30} noted that patients with concomitant VBI had worse outcomes after bile duct injury repair. In contrast to the aforementioned studies, Alves and colleagues\textsuperscript{31} reported comparable incidence of postoperative complications in patients with and without arterial injury. Stewart and colleagues\textsuperscript{32} did not report any influence of arterial injury on long-term results following biliary reconstruction, but RHA injury was associated with a higher incidence of postoperative abscess, bleeding, hemobilia, hepatic ischemia, and the need for hepatic resection. Results of RHA injury and vasculobiliary injury involving both RHA and bile duct are different. It is associated with the arterial blood supply of the extrahepatic biliary tract.

In an injury to the RHA without biliary injury, occlusion of the RHA results in ischemia of the right liver, but blood flow is restored by preformed collateral arterial shunts. In a combined vasculobiliary injury involving the RHA, E1–3 injuries leave the hilar shunt (hilar plexus) open but obstruct the longitudinal shunt (axial arteries at 3, 9 and 12 o’clock) and may induce greater hepatic ischemia than RHA occlusion only, and E4 injuries induce greater ischemia than right hepatic injuries alone by obstructing the important hilar shunt and the longitudinal shunt. Therefore, it is not possible to perform end-to-end ductal anastomosis in patients with complex vasculobiliary injuries that require Roux-en-Y HJ and, frequently, hepatic hepatectomy or liver transplantation. \textsuperscript{26,30}

**TECHNIQUE OF END-TO-END DUCTAL ANASTOMOSIS**

**General principles**

Two main conditions must be met for proper healing of each biliary anastomosis. The anastomosed edges should be healthy; there should be no inflammation, ischemia or fibrosis; and the anastomosis should be tension-free and properly vascularized.\textsuperscript{13} Dissection and refreshing of the proximal and distal stumps as far as the tissues are healthy and without inflammation should be performed. However, careful dissection is required to save intact axial arteries within a wall of the common bile and hepatic ducts.\textsuperscript{14} Biliary reconstruction should be performed when no active inflammation process is present, particularly in patients with IBDI, who frequently have ischemia, fibrosis and inflammation within the bile ducts.\textsuperscript{1} Ischemia, either associated with graft preservation injury or inflammation due to rejection, has also been observed during liver transplantation.\textsuperscript{15} Both proximal and distal ductal stumps should be dissected and approximated without tension. End-to-end ductal anastomosis could be recommended for patients when the maximal length loss of the bile duct is 4 cm. The sutured ends have to be healthy and without inflammation and ischemia. The diameter of both anastomosed ends has to be comparable. In the Department of Digestive Tract Surgery, if there was a difference between a diameter of anastomosed ends, the narrower end was incised longitudinally in the anterior surface to extend it. End-to-end ductal anastomosis repair was not carried out in bile ducts that were too narrow (diameter < 4 mm). The approximating of both ends is possible because of a wide Kocher manoeuvre (mobilization of the pancreatic head with the descending, horizontal and ascending part of the duodenum out of the peritoneum). Patients undergoing a first or, exceptionally, second bile duct repair can be a candidate for end-to-end ductal anastomosis. Hepaticojejunostomy should be performed in patients who do not satisfy the aforementioned criteria.\textsuperscript{1}

**Suture type**

Both continuous (CS) or interrupted (IS) and absorbable (polydioxanone) or nonabsorbable (prolene or polypropylene), 5–0, 6–0 or 7–0 sutures are used for end-to-end ductal anastomosis in patients undergoing liver transplantation.\textsuperscript{4,14,15,16} Initially, IS was the standard for these patients; CS was not adopted for end-to-end ductal anastomosis owing to concern for higher stricture rates than IS. Continuous sutures are quicker to perform than IS. Castaldo and colleagues\textsuperscript{15} compared CS and IS for end-to-end ductal anastomosis in patients undergoing liver transplantation. The authors reported comparable results with both surgical techniques. There was no difference in biliary complications, graft survival or patient survival between the analyzed groups. The overall biliary complication rate was 15%. There was no difference in the proportion of leaks (CS 7.3% v. IS 8.5%) or strictures (CS 9.8% v. IS 5.1%) between groups. The nontraumatic, monofilament-interrupted 5–0 suture is the technique of choice for end-to-end ductal anastomosis in patients with IBDI.\textsuperscript{1}

**T-tube use**

The use of a T-tube in end-to-end ductal anastomosis remains controversial. There are contradictory reports in the literature regarding the feasibility of biliary drainage for end-to-end ductal anastomosis in patients undergoing liver transplantation and those undergoing IBDI repair. The advantage of biliary drainage is to limit the inflammation and fibrosis that occur after the surgical procedure. Therefore, some authors believe that the presence of the biliary tube prevents anastomosis stricture.\textsuperscript{1,28} The disadvantage is the higher risk of postoperative complications.\textsuperscript{1} Scatton and colleagues\textsuperscript{17} compared the incidence of biliary complications after liver transplantation in patients undergoing end-to-end ductal anastomosis with or without T-tube in a large multicentre, prospective, randomized trial. The study included 108 patients divided into 2 groups: patients with ($n = 90$) or without ($n = 90$) a T-tube who underwent surgery in 6 French liver transplantation centres. The authors
reported an increased biliary complication rate in the T-tube group, that was linked to minor complications. The incidence of biliary fistula was 10% in the T-tube group and 2.2% in the group without a T-tube. Therefore, the authors did not recommend the performance of end-to-end ductal anastomosis with a T-tube in patients undergoing liver transplantation. Recently, López-Andújar and colleagues compared the incidence and severity of biliary complications due to liver transplantation after end-to-end ductal anastomosis with or without a T-tube in a single-centre, prospective, randomized trial. The study involved 95 patients with a T-tube and 92 patients without a T-tube. Significantly fewer anastomotic strictures were reported in the T-tube group (n = 2 [2.1%]) than in the non-T-tube group (n = 13 [14.1%]). No difference in anastomotic bile leakage was observed between the groups. The authors concluded that complications in the T-tube group were less severe and required less aggressive treatment than those in the non-T-tube group. The incidence of anastomotic strictures was higher in patients without T-tubes. The authors recommended using a rubber T-tube for end-to-end ductal anastomosis during liver transplantation in risky anastomosis and when the bile duct diameter is less than 7 mm. Contradictory meta-analyses regarding the usefulness of a T-tube in end-to-end ductal anastomosis can also be found in the literature. Sotiropoulos and colleagues pooled the outcomes of 1027 patients undergoing end-to-end ductal anastomosis with or without T-tube in 9 of 46 screened trials by means of fixed- or random-effects models. In this meta-analysis, the patients without T-tubes had fewer episodes of cholangitis and peritonitis, and they demonstrated a favourable trend for fewer overall biliary complications. Anastomotic bile leaks or fistulas, end-to-end ductal anastomosis revisions, dilatation and stenting, hepatic artery thromboses, retransplantation and death due to biliary complications were comparable in between the groups. Therefore, the authors did not recommend the use of a T-tube for end-to-end ductal anastomosis in patients undergoing liver transplantation. In contrast, Huang and colleagues reviewed 5 randomized control trials (RCTs) and 8 comparative studies. They suggested that the insertion of a T-tube reduced the incidence of biliary stenosis without increasing the incidence of other biliary complications. Based on these results, the use of a T-tube for end-to-end ductal anastomosis in patients undergoing liver transplantation could be recommended.

The use and duration of biliary drainage in patients with IBDI is controversial. The advantage of biliary drainage is limitation of the inflammation and fibrosis occurring after the surgical procedure. In some authors’ opinions, the presence of the biliary tube prevents anastomosis stricture. The disadvantage of biliary drainage is a higher risk of postoperative complications. The duration of drainage is also controversial. According to most authors, the optimal duration for biliary drainage is about 3 months. Investigations showed that longer duration of biliary drainage did not provide a greater advantage. The 2 main types of biliary drainage using T-tube can be distinguished: external T-drainage (Fig. 1A) and internal Y-drainage (Fig. 1B). External T-drainage involves using a typical T-tube with insertion of its short branches into the bile duct and conducting of its long branch through the abdominal wall outside. It can be removed percutaneously after healing of the end-to-end ductal anastomosis. Internal Y-drainage involves insertion of short branches of the T-tube into both the right and left hepatic ducts, splinting of the anastomosis and conducting of its long branch into the duodenum by the papilla of Vater. This drainage can be removed endoscopically after healing of the end-to-end ductal anastomosis. It should be emphasized that the internal Y-drainage is less traumatic (does not involve additional incision of the bile duct wall) than the external T-drainage. Therefore, it should be recommended as the drainage of choice in end-to-end ductal anastomosis.

Complications of end-to-end ductal anastomosis

An anastomostic fistula and stenosis are the 2 common postoperative complications following end-to-end ductal anastomosis. In patients who have had end-to-end ductal anastomosis, endoscopic control and treatment of these complications are possible. In anastomotic leakages and strictures, endoscopic retrograde cholangiopancreatography (ERCP) with stenting or stricture balloon dilatation is the first-line treatment. Percutaneous transhepatic biliary drainage can also be performed. Yoshiya and colleagues described the use of rendezvous ductoplasty to treat biliary anastomotic stricture after LDLT. Biliary anastomotic stricture was classified according to ERCP findings after normal pressure contrast injection: type I (n = 32) in which the stricture was visualized; type II (n = 13) in which the common hepatic duct and graft intrahepatic

![Fig. 1: Types of biliary drainage using T-tube. (A) External T-drainage. (B) Internal Y-drainage.](image-url)
ducts were visualized, but the stricture was not visualized; or type III ($n = 8$) in which the stricture and graft intrahepatic ducts were not visualized. The number of attempts to pass the guidewire through the stricture was significantly lower in type I than type II or type III. The treatment success rate was 78.1% for type I, 38.5% for type II, and 50.0% for type III. Rendezvous ductoplasty was the first successful treatment in a higher proportion of types II and III patients than type I patients (66.7% vs. 6.3%). Cumulative treatment success rates were not significantly different between the rendezvous ductoplasty and the non-rendezvous ductoplasty groups. Hsieh and colleagues described aggressive endoscopy-based treatment with maximal stent placement that allowed 100% resolution of all biliary anastomotic strictures after LDLT without the need for surgical intervention or retransplantation. When less invasive (using endoscopy and interventional radiology) treatment is not successful, surgery is needed. 

**Conclusion**

End-to-end ductal anastomosis is used for biliary reconstruction in patients undergoing liver transplantation and surgical repair of IBDI. The use of end-to-end ductal anastomosis in patients undergoing liver transplantation is more common than in those undergoing surgical treatment of IBDI. The achievement of good long-term results is possible in patients undergoing both treatments. End-to-end ductal anastomosis should be considered as the biliary reconstruction of choice because it is more physiologic than HJ and it is associated with fewer early postoperative complications.

**Competing interests:** None declared.

**References**


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Systematic review on the inclusion of patients with cognitive impairment in hip fracture trials: a missed opportunity?

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Background: More than 320 000 hip fractures occur annually in North America. An estimated 30% of this population have cognitive impairment. We sought to determine the extent to which patients with cognitive impairment or dementia have been included in randomized controlled trials (RCTs) assessing hip fracture management.

Methods: We conducted a systematic search of 3 electronic journal databases of articles published between January 2000 and June 2010. Studies were screened in duplicate to collect English-language RCTs assessing operative interventions for femoral head, neck or intertrochanteric fractures. We systematically collected descriptive data and used the \( \chi^2 \) test for comparison between groups as appropriate.

Results: We screened 1201 abstracts, 72 of which were eligible for inclusion in our review. Femoral neck and intertrochanteric fractures were equally represented. Thirty-three (46%) studies did not report the inclusion or exclusion of patients with cognitive impairment. Nineteen (26%) studies explicitly included cognitively impaired patients, whereas 20 (28%) excluded them. Only 2 trials (3%) reported outcomes specific to cognitively impaired patients. Fourteen trials (19.4%) reported the use of a validated cognitive assessment tool. None of the trials that reported inclusion of cognitively impaired patients were from North American centres.

Conclusion: One in 3 patients with hip fractures have concomitant cognitive impairment, yet 8 of 10 hip fracture trials excluded or ignored this population. The ambiguity or exclusion of these patients misses an opportunity to study outcomes and identify factors associated with improved prognosis.

Contexte : On dénombre plus de 320 000 fractures de la hanche chaque année en Amérique du Nord et on estime que 30 % de ces personnes ont une atteinte cognitive. Nous avons voulu déterminer dans quelle mesure les patients qui souffrent d’une atteinte cognitive ou de démence ont été inclus dans les essais randomisés et contrôlés (ERC) portant sur la prise en charge de la fracture de la hanche.


Résultats : Nous avons passé en revue 1201 résumés, dont 72 répondaient à nos critères d’admissibilité. Les fractures du col du fémur et intertrochantériennes étaient représentées en proportions égales. Trente-trois études (46 %) ne faisaient aucune mention de l’inclusion ou de l’exclusion des patients souffrant d’atteinte cognitive. Dix-neuf (26 %) études incluaient expressément des patients souffrant d’atteinte cognitive, tandis que 20 (28 %) les excluaient. Seulement 2 essais (3 %) ont fait état de résultats spécifiques aux patients souffrant d’atteinte cognitive. Quatorze essais (19,4 %) ont déclaré utiliser un outil d’évaluation cognitive validé. Aucun des essais ayant mentionné l’inclusion de patients souffrant d’atteinte cognitive ne provenait de centres nord-américains.

Conclusion : Un patient victime d’une fracture de la hanche sur 3 souffrait concomitamment d’une atteinte cognitive et pourtant, 8 essais sur 10 portant sur la fracture de la hanche ont exclus ou ignoré cette population. L’ambiguïté vis-à-vis de ces patients ou leur exclusion est une occasion manquée d’étudier les paramètres et de relever les facteurs associés à un pronostic plus favorable.
More than 320 000 hip fractures occur annually in North America. As hip fracture is a condition most common among elderly individuals, its societal burden is expected to grow as the North American population continues to age. By 2040, the number of individuals older than 65 is forecasted to increase from 34.8 million to 77.2 million, resulting in an annual hip fracture incidence of greater than 580 000. Dementia — a chronic form of cognitive impairment — is prevalent in the elderly population as well, and co-occurrence of this condition with hip fracture is not infrequent. By some estimates, 30% of patients who sustain a hip fracture also have cognitive impairment or dementia.

There is early evidence to suggest that patients with dementia typically experience poorer functional outcomes and increased morbidity and mortality following a hip fracture. Identifying strategies to optimize outcomes in hip fracture patients with dementia is therefore critically important; however, the extent to which this issue is addressed in orthopedic surgery randomized controlled trials (RCTs) has not been well-elucidated. Exclusion of patients with dementia from surgical RCTs could potentially undermine the applicability of trial results to this sizeable subgroup.

We conducted a systematic review to analyze the inclusion of patients with cognitive impairment and dementia in hip fracture RCTs conducted over the course of the past decade. This information will provide an important consideration to both clinicians managing hip fracture patients with dementia and researchers designing future hip fracture RCTs.

METHODS

We performed a systematic review of RCTs involving hip fracture operative treatments to determine the extent to which patients with cognitive impairment or dementia were included. We used applicable components of the PRISMA 2009 checklist as a framework for this review.

Eligibility criteria and study selection

Criteria for inclusion in this review were established a priori, and all studies satisfied the following parameters: RCT study design; assessment of an operative intervention for femoral head, femoral neck, or intertrochanteric fractures; publication in English; original publication; and publication date between January 2000 and June 2010.

We used a 2-step review process to screen and select eligible trials. The first step entailed a review of all titles and abstracts yielded by our search strategy. Studies meeting the inclusion criteria and those with equivocal eligibility were retrieved for full-text review and data retrieval.

Search strategy

We performed a systematic search of the medical literature to identify all relevant RCTs published between January 2000 and June 2010. Two investigators searched 3 electronic medical databases (Medline, Embase, PubMed) using the following search terms: “hip fracture” OR “femoral neck fracture” OR “femoral head fracture” OR “intertrochanteric fracture” OR “subcapital fracture” alongside appropriate database subject headings (i.e., MeSH, Emtree). Given the eligibility criteria outlined, we placed the following limits on the searches: publication in the English language, RCT and publication in January 2000 or later. We included a systematic PubMed search as a supplementary query to ensure no pertinent trials were overlooked. This search was done with limits to predetermined journals that were judged to be high-yield: The Journal of Bone & Joint Surgery (American and British volumes), Clinical Orthopaedic and Related Research, Acta Orthopaedica and The Journal of Orthopaedic Trauma.

Data extraction

Standardized data extraction forms were developed a priori. For each study, characteristics of the trial, including geographical location, sample size, number of centres, mean patient population age and sex ratios, were recorded. Furthermore, we documented the fracture type and operative interventions assessed, as well as the significance of the results of the primary outcome measure.

For each trial, we evaluated whether patients with dementia or other forms of cognitive impairment were explicitly included or explicitly excluded. We also recorded the cognitive assessment tool used to make a diagnosis for inclusion or exclusion. If inclusion status could not be ascertained based on the published manuscript or if no mention was made regarding the strategy for cognitive assessment, then we considered it “not reported.” Finally, for studies including patients with dementia, we determined whether a subgroup analysis was performed and assessed the results of such analyses. For studies excluding patients with dementia, we recorded if a rationale for exclusion was provided, and if so, we noted the reason provided.

All data extraction was done in duplicate, and any discrepancies were resolved by consensus among the reviewers.

Statistical analysis

We systematically collected descriptive data and used the χ² statistical test for comparison between groups as appropriate. Our primary variable of interest was the number of patients with dementia in each trial.
studies that included patients with dementia compared with those that excluded patients with dementia.

**RESULTS**

Our search identified a total of 1201 studies published between January 2000 and June 2010 for screening of titles and abstracts. Of the 1201 studies, 92 trials were deemed potentially eligible and retrieved for full text review. Of these studies, 72 were included for final review (Fig. 1).

**Study characteristics**

The majority of studies were conducted in Europe (79%) and involved a single centre (65%). Sample sizes ranged from 19 to 569 patients. An equivalent number of studies assessed the management of femoral neck fractures \( n = 36 \) and intertrochanteric fractures \( n = 36 \). More than half (51%) of the studies compared methods of internal fixation, 22% compared methods of arthroplasty, and 15% compared arthroplasty to internal fixation. Studies reported significant findings 18% of the time (Table 1).

**Inclusion of patients with dementia**

Among the 72 RCTs included in this review, 19 studies included both cognitively intact and impaired patients, and 1 of these studies reported dementia or cognitive impairment as the focus of the paper.

Nineteen studies (26%) explicitly included patients with cognitive impairment and 20 studies (28%) explicitly excluded such patients, as stated in their methodology or as evident in the paper. None of the RCTs that reported inclusion of cognitively impaired patients were from North American centres. There were no significant differences between RCTs that included or excluded these patients in terms of patient age, number of centres, or operative procedures compared. Of the 19 studies that included this patient population, 10 specified dementia as the form of cognitive impairment, whereas the remaining 9 did not. Thirty-three studies (46%) failed to report the inclusion or exclusion of patients with cognitive impairment from their trials (Fig. 2 and Table 2).

Fourteen of 72 trials (19.4%) reported the use of a validated cognitive assessment tool. This included formal tests, such as the Mini-Mental State Exam (MMSE). A single additional trial used a cognitive assessment tool that was not validated.

Of the 19 studies including patients with cognitive impairment, only 2 studies highlighted outcomes of this population. The first study tested surgical interventions in cognitively impaired patients only, while the second conducted a subgroup analysis on this population. With respect to the 20 studies excluding patients with cognitive impairment, 11 studies compared methods of internal fixation and arthroplasty, and 9 studies compared arthroplasty to internal fixation.

**Table 1. Characteristics of RCTs**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Studies, no. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Geographical location</td>
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<tr>
<td>Europe</td>
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<tr>
<td>South Asia</td>
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<td>Other</td>
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<tr>
<td>No. of centres</td>
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</tr>
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<td>Sample size</td>
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<tr>
<td>&lt; 50</td>
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</tr>
<tr>
<td>50–100</td>
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<tr>
<td>100–150</td>
<td>19 (26)</td>
</tr>
<tr>
<td>&gt; 150</td>
<td>22 (31)</td>
</tr>
<tr>
<td>Type of fracture</td>
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<tr>
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</tr>
<tr>
<td>Femoral neck</td>
<td>36 (50)</td>
</tr>
<tr>
<td>Intertrochanteric</td>
<td>36 (50)</td>
</tr>
<tr>
<td>Type of treatment</td>
<td></td>
</tr>
<tr>
<td>IF v. IF</td>
<td>37 (51)</td>
</tr>
<tr>
<td>Arthroplasty</td>
<td>16 (22)</td>
</tr>
<tr>
<td>HA v. HA</td>
<td>11 (15)</td>
</tr>
<tr>
<td>THA v. HA</td>
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<tr>
<td>THA v. THA</td>
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<tr>
<td>Arthroplasty v. IF</td>
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<tr>
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<td>14 (19)</td>
</tr>
<tr>
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<td>45 (63)</td>
</tr>
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</table>

HA = hip arthroplasty; IF = internal fixation; RCT = randomized controlled trial; THA = total hip arthroplasty.

**Fig. 1.** Systematic search strategy for article inclusion. RCT = randomized controlled trial.
impairment, only 6 (30%) attempted to provide a rationale within the published manuscript for the exclusion of such patients. Reasons were the patients’ inability to provide informed consent (1 study) and the aim of evaluating outcomes in an active or a mentally competent subpopulation (5 studies).

**Discussion**

Our systematic review evaluated 72 RCTs in an attempt to delineate the degree to which patients with cognitive impairment and dementia are being incorporated into orthopedic trials on hip fracture management. Our results indicate that patients with cognitive impairment are seldom included (26%) and are rarely the focus (1%) of RCTs evaluating operative hip fracture management. Furthermore, validated screening tools for cognitive impairment are rarely used in those studies that purport to explicitly include or exclude these patients. Finally, we were able to identify only 2 trials that evaluated interventions specifically for patients with cognitive impairment. One of these studies included only patients with cognitive impairment, while another conducted a subgroup analysis for this patient population. Previous literature has provided contrasting results. In a systematic review of 17 RCTs conducted over a period of 20 years, Herbert-Davies and colleagues found that 13 (76%) RCTs explicitly included patients with dementia, while 4 (24%) explicitly excluded this patient population. A possible explanation for this discrepancy is that the authors evaluated only RCTs that reported sufficient data on the number of patients with dementia. Studies offering a quantitative description of patients with dementia are certainly more likely to include such patients. Our review was more comprehensive to the extent that our analysis was based solely upon reporting of inclusion and exclusion status, irrespective of further quantitative reporting.

An assumption that outcomes are similar in patients with and without cognitive impairment is not supported by the evidence. For instance, Panula and colleagues reviewed the charts of 428 hip fracture patients in a Finnish hospital registry and correlated these to the official cause of death statistics in Finland. The investigators found that patients with dementia

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**Table 2. Inclusion and exclusion by study characteristics**

<table>
<thead>
<tr>
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<th></th>
<th></th>
<th>p value</th>
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<td>Dementia patients excluded</td>
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</tr>
<tr>
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<td></td>
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<tr>
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<td>6</td>
<td>21</td>
<td>0.27</td>
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<td>1</td>
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<tr>
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<td>4</td>
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<td>10</td>
<td>13</td>
<td>22</td>
<td>0.43</td>
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</table>

IF = internal fixation.
who sustained hip fractures had a more than 3-fold increased risk of death than those with dementia in the general population. Similarly, in a chart review of 495 hip fracture patients in the United States, Bentler and colleagues demonstrated that patients with dementia were 45% more likely to die postinjury than patients without dementia.

Some early evidence indicates that patients with cognitive impairment may actually have different intervention-specific outcomes as well. An RCT performed by Johannson and colleagues comparing total hip arthroplasty to internal fixation for hip fracture demonstrated an inversion of outcomes among hip fracture patients with cognitive impairment. Specifically, the investigators found a 5% reoperation rate with internal fixation and a 32% dislocation rate after arthroplasty in patients with cognitive impairment. This pattern was reversed in cognitively intact patients, who experienced a 60% reoperation rate after internal fixation and a 12% dislocation rate after arthroplasty. Purposely studying patients with cognitive impairment would help identify such differences, thereby better informing orthopedic practice.

Limitations

Our study has several strengths. As mentioned, we used a systematic search strategy to identify eligible studies and applied this search across 3 medical databases to collect a large sample of 72 RCTs. Two reviewers extracted all data independently and in duplicate. We were able to capture a broad range of studies with respect to geographic location, type of hip fracture and operative intervention. Unfortunately, our study did have the limitation of excluding 8 potentially relevant articles owing to inaccessibility. Given our large sample size and the findings of our study, it is unlikely that the inclusion of such studies would have substantially altered our results.

CONCLUSION

The ambiguity and outright exclusion of patients with cognitive impairment in RCTs challenges the apparent external validity of these trials. The selection of certain primary outcomes, such as patient-reported questionnaires, may necessarily preclude inclusion of patients with cognitive impairment in an RCT. However, given the size of this subpopulation, we believe that exclusion without explanation is no longer acceptable. We propose a “call for inclusion” of patients with cognitive dysfunction to identify interventions that improve survival and function in this patient population.

Competing interests: None declared.

Contributors: All authors designed the study. S. Mundi and H. Chaudhry acquired the data, which all authors analyzed. S. Mundi and H. Chaudhry wrote the article, which M. Bhandari reviewed. All authors approved the final version for publication.

References

Technique to achieve the symmetry of the new inframammary fold

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SUMMARY
The literature outlines several surgical techniques to restore inframammary fold definition, but symmetry of the fold is often left to irreproducible procedures. We report our personal technique to restore the symmetry of the inframammary fold during multistep breast reconstruction.

In multistep breast reconstruction, the inframammary fold is often distorted as a result of imperfect tissue expansion. The literature outlines several surgical techniques to restore inframammary fold definition, but symmetry of the fold is often left to irreproducible procedures. We report our personal technique to restore the symmetry of the inframammary fold during multistep breast reconstruction.

The surgeon begins by drawing the midline with the patient in an upright position. The physiologic inframammary fold is pointed outward, and a perpendicular line is drawn from its lower point (point A) to the midline (point B). From point B, a second line is drawn until it reaches the lower point of the contralateral inframammary fold (point C). From point C, a perpendicular line to the midline is drawn. The surgeon moves the new inframammary fold upward the exact distance between point B and the projection of point C on the midline (Fig. 1, panel 1, x-distance).

During this surgical procedure, an appropriate dermo-adipose flap must be raised to extend the dissection beyond the future inframammary fold. Moving up the new inframammary fold along the x-distance, the CB segment becomes perpendicular to the midline, reaching the same height as the contralateral fold (Fig. 1, panel 2). In order to obtain adequate symmetry of the medial portion of the inframammary fold, the surgeon first draws the BA segment followed by a bisector line drawn from the inner corner (point B) toward the inframammary fold (i.e., the x-distance from point B to the inframammary fold). A new line, equal to the x-distance, is drawn perpendicular to the bisector line (Fig. 1, panel 3).

During surgery, the new inframammary fold has to be fixed at the lateral extreme of this segment, ensuring the same position as the contralateral fold (Fig. 1, panel 4). To ensure symmetry of the lateral part of inframammary fold, the surgeon draws a line from point A to the anterior axillary line (point D), creating the y-distance (Fig. 1, panel 5). A bisector line is drawn from point D toward the inframammary fold, creating the x-distance. On the contralateral side, a new segment is drawn from point C to the anterior axillary line (point D, y-distance), followed by a bisector line (x-distance; Fig. 1, panel 5). During surgery, the new inframammary fold lateral extreme must be fixed at the apex of the bisector line (Fig. 1, panel 6).

The restoration of a well-defined fold during reconstructive or cosmetic surgery is a fundamental step toward an excellent result. It is
common opinion that the optimum conformation of an inframammary fold is an angle of 90°; a variation of this angle results in less definition.3,4 Of equal importance to definition is the symmetry between inframammary folds. Symmetry is often left to “at a glance” procedures without scientific basis.

Our method is simple, quick to perform, reliable and reproducible, allowing the surgeon to perform an inframammary fold to restore and ensure symmetry to the contralateral breast.

To our knowledge, no previous reports on this issue have been published in literature.

Competing interests: None declared.

References


Clinical scenario

You are a young general surgeon in a community practice. A new consultation is scheduled in your clinic: a 60-year-old woman presenting with chronic venous ulcers on both legs. She has no other notable medical history. Over the previous 5 years, she had a number of debridements and skin grafts performed by a surgeon who recently retired. She is very frustrated by her odor-ous oozing ulcers and is embarrassed to visit her family. You review the records at your hospital but cannot find much useful information. You do not know why her previous surgeries and nonsurgical treatments have failed. You know that venous ulcers have different etiologies, such as persisting edema, superinfections or concomitant arterial insufficiency. You decide to review the literature guidelines that give specific recommendations on the management of venous ulcers to ensure an option on the treatment algorithm has not been overlooked.

Literature search

As described in a previous article in the “users’ guide to the surgical literature” series, you begin with a Medline search. The terms “venous ulcer” and “guideline” are entered separately. Based on medical subject heading (MESH) terms, Medline prompts inclusion of the terms “leg ulcer/” or “varicose ulcer/” and “guideline” or “practice guideline,” respectively. These terms are combined and results limited to the English language, yielding 10 articles. Three of them do not relate to venous ulcers, and 3 were published before the year 2000. Two are nonspecific for ulcers, and 1 focuses on prevention. You select the article entitled, “Guidelines for the treatment of venous ulcers,” which appears to address your question. You print the guideline and review it before your next visit with the patient.

Introduction

Clinical practice guidelines (CPGs) are defined in the literature as “systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.” They distill a large body of literature on a topic into a format that is high-yield and easy for physicians to use.

Worldwide, surgeons perform 200 million procedures annually. There is constant effort to optimize this complex and expensive health care facet. Surgeons are faced with difficult management decisions while balancing evidence-based recommendations. When trial evidence exists, it often cannot be perfectly applied to specific patient presentations. It is difficult to independently condense primary research for each patient. Moreover, health care providers and insurers are increasingly concerned with quality improvement and cost effectiveness. Guidelines aim to balance these factors and direct consistent
and reliable care. The number of surgical guidelines available in the literature is increasing. However, CPGs vary in their quality and sometimes deviate from high methodological rigor. It is necessary for surgeons to be able to appraise CPGs before deciding to adopt their recommendations.

Since 1990, CPGs have been an increasingly popular tool influencing physician practice. More than 20 tools to interpret and appraise CPGs have been published; the latest is the AGREE-II instrument (appraisal of guidelines for research and evaluation). It was originally released in 2003 to address guideline development, reporting and evaluation. Two further studies, have refined the instrument, now recognized as the methodological standard in guideline evaluation.

In this article, we discuss a practical approach to the appraisal of a CPG: Box 1 contains the key items readers should consider when using a CPG in surgery. As in previous users’ guide to the surgical literature articles, we use a condensed framework to approach a guideline from a surgical perspective. This will provide surgeons with a practical approach to interpreting and applying recommendations in a CPG, using the guideline by Robson and colleagues as an example.

Are the recommendations valid?

Is there a clear statement of a clinical problem?

Like other publications, CPGs address a defined problem in a specific group of patients. Surgeons must always consider whether the CPG recommendations can be applied to their own patients. The PIPOH items (patient population, intervention(s), professionals/patients, outcomes to be considered, health care setting) are suggested in the ADAPTE process (www.adapte.org) to frame the content and clinical question in a guideline. Readers should use these categories to decide if the recommendations presented are representative of their patient and treatment goals. Surgeons are cautioned in applying CPGs not designed for their patient populations. Subtle differences in any category can alter the CPG’s applicability.

Box 1. Users’ guides for an article on clinical practice guidelines

I. Are the recommendations valid?

1. Is there a clear statement of a clinical problem?
2. Who was involved in guideline development (i.e., authors, reviewers, patients, readers)?
3. How is the guideline reviewed?
4. What literature are recommendations based on?
II. What recommendations are made?
5. Are useful recommendations presented?
6. How do authors move from evidence to recommendations?
III. Will the results help me in caring for my patients?
7. Were all outcomes considered (surgical outcomes versus natural course of disease)?
8. Will I be able to implement these recommendations?

Robson and colleagues summarize the management of venous ulcers in 8 categories: diagnosis, compression, infection control, wound bed preparation, dressings, surgery, adjuvant agents and long-term maintenance. However, the guideline does not include specific PIPOH criteria. For example, the authors need to be more specific in Recommendation #6.3: “Less extensive surgery on the venous system, such as superficial venous ablation, endovenous laser ablation, or valvuloplasty, especially when combined with compression therapy, can be useful in decreasing the recurrence of venous ulcers (Level I).” The reader must carefully consider patient population and health care setting in this recommendation. Venous ulcers are associated with comorbidity. If our hypothetical patient had diabetes or an inflammatory disorder, interventions would differ. Further, procedures such as endovenous laser ablation may not be available in every health care setting.

Who was involved in guideline development? (ie. authors, reviewers, patients, readers)

No guideline is developed in isolation, free from potential bias. These biases may be subconscious and difficult to detect. Surgeons must critically consider how and why the guideline has been created. What inherent biases may the authors have? Organizing committees and professional organizations beyond those listed in the authorship may have reviewed the guideline. While reviewing evidence and providing recommendations, each group will have their own influence. Who are the people in these roles? Who are they representing? What is their expertise? Guideline panels and authorship are often sponsored by the pharmaceutical industry in some capacity.

The authorship should be analyzed for surgical input. Review by a surgical association or publishing in a surgical journal demonstrate evaluation with surgical familiarity. Even when presented with the same research evidence, professional groups can differ in their recommendations. Shaneyfelt and colleagues identify examples in breast and prostate cancer: a cancer interest group may support adoption of new, costly population screening interventions despite limited effectiveness, whereas public health groups may not view the intervention as a cost-effective strategy in the general population.

Robson and colleagues’ work is developed by the Wound Healing Society, with grant support from its educational/charitable arm, the Wound Healing Foundation. The guideline is published in Wound Repair and Regeneration by the Wound Healing Society. The guideline has been developed and published by the same association, indicating a potential conflict of interest. Further, CPGs authored by research/care societies may be of lower quality than those published by guideline societies. The CPG by Robson and colleagues lists its authors and their affiliations and positions. The group is composed of academicians, private practice physicians, podiatrists, nurse clinicians,
research nurses, industrial scientists and an epidemiologist. The diverse author group reflects the multidisciplinary approach to chronic wounds and helps to reduce professional bias. However, little detail is given to the roles of each professional, and there is no mention of surgeons.

How is the guideline reviewed?
Surgeons should scrutinize the review and revision process of CPGs. Like any other publication, CPGs are subject to peer review. Beyond the guideline’s sponsoring association and authors, surgeons should be sure that independent experts are involved. This includes experts in medical and research methodology and possibly patient groups. The process should be transparent. Commentary and editing from the review panel should be included or available in a supplement. Prior to dissemination, guidelines may be pilot tested on small patient samples to ensure applicability. Authors should describe the process of reviewing and updating the guideline on an ongoing basis. Some groups establish a team monitoring for new evidence, whereas others provide a predetermined schedule of updates to their guidelines. Guidelines with extensive readership and consistent new research findings (e.g., ACCP and ACLS guidelines) often schedule new releases.

In Robson and colleagues’ work, specific revision methodology is lacking. There is no indication the Wound Healing Society has reviewed the guideline, despite their sponsorship. Details of expert review, review scales, specialties/disciplines of reviewers and edits suggested during the review process would all be pertinent to the surgeon. Without insight into who approved the CPG, it is difficult to discern the potential biases that would impact surgical decision making. No procedure is defined for revision. Given that leaders in the ever changing field of wound management provided this CPG, surgeons should expect a schedule of updates.

Editorial independence and funding should be declared with all forms of research. Surgeons should be critical in assessing the interests of governing bodies or pharmaceutical/equipment sponsors. The translation of primary literature to clinical recommendations requires judgment. Surgeons must ensure this judgment is not biased. For example, does a company marketing dressings have any stake in these recommendations? Do involved professional organizations have a monetary or public interest? The interests of authors, Wound Repair and Regeneration and the Wound Healing Society are not discussed in the CPG by Robson and colleagues. It is difficult to interpret the biases authors may impose on the CPG outside of credentials listed. No information is available for financial or research support of members. Robson and colleagues succeed in not emphasizing the use of brand name products. Instead it indicates the evidence-based properties of a dressing that improve wound care.

What is the evidence base?
Authors should use appropriate methodology to support their recommendations. A transparent and structured methodology reflects rigorous development. This is evaluated stepwise, beginning with the search strategy, appraising evidence and grading recommendations. Similar to the rigor of a systematic review, a good CPG will reflect a body of high-quality research with coherent results. Quality of referenced studies should be clear. Issues with blinding, allocation concealment and equal expertise among groups are unique challenges in surgical RCTs. Unfortunately, CPGs in surgery can rarely depend solely on high-level evidence (systematic reviews, randomized controlled trials [RCTs]). In some surgical areas, observational studies and case reports may be the only evidence available, and these must be analyzed for confounding and bias. Often the available evidence is not of high quality. However, guidelines addressing questions without available high-quality evidence are still important in guiding physician decision making. Moreover, these complex situations require a transparent and rigorous methodology.

Guidelines should include, either in the text or supporting documentation, a statement detailing the development process. The availability of this process is a good predictor of the CPG’s overall rigor. Search strategies should incorporate multiple databases and a search of grey literature (unpublished sources, such as conferences and thesis work). Explicit inclusion and exclusion criteria should be defined, and the assessment of the validity of the evidence should be reproducible and consistent among studies. A lag time exists between guideline development and publication. The CPG by Robson and colleagues was developed in October 2005 and published in the November/December 2006 issue of Wound Repair and Regeneration. In some rapidly changing specialties, it is possible that new evidence becomes available within this lag time.

The CPG by Robson and colleagues includes a methods section. While databases are listed, no search terms are specified to ensure a reproducible search methodology for the references cited. Without search terms, transparency is difficult to establish. Robson and colleagues specify that their methodology differs from that of previous publications, including laboratory/animal studies and findings extrapolating from treatment of other ulcers. Beyond this, their process for selecting evidence is vague.

Robson and colleagues succeed in defining the level of evidence for each recommendation. For example, they cite the following literature for Recommendation #2.1: “Cullum N, Nelson EA, Fletcher AW, Sheldon TA. Compression for venous leg ulcers. The Cochrane Database of Systematic Reviews. (2001 Issue 2) The Cochrane Collaboration. John Wiley & Sons Ltd. [STAT, 23 RCT].” This illustrates that the recommendation is based on a meta-analysis of 23 RCTs and provides readers with a reference to the original data. Recommendations are followed by
contributing references, each marked with 1 of 8 levels of evidence: STAT (Statistical analysis, meta-analysis, consensus statement by commissioned panel of experts), RCT, LIT REV (literature review), CLIN S (clinical case series), RETRO S (retrospective series review), EXP (experimental laboratory or animal study), TECH (technique or methodology description) or PATH S (pathological series review). Of the 41 grouped recommendations made, 5 do not reference RCT or higher levels of evidence: 1.3, 1.4, 4.3, 5.4 and 6.4. While RCTs, systematic reviews and meta-analyses represent the top of the level of evidence hierarchy, there is no discussion of the merits of each reference. Preferably, the RCTs should each be evaluated for individual methodological quality, especially given the unique issues in surgical trials.

What recommendations are made?

Are useful recommendations presented?

Surgeons use guidelines for specific and practical evidence-based advice to direct patient care. An RCT measuring physician practice finds specific recommendations leading to more appropriate and fewer inappropriate clinical tests when compared with unspecific recommendations. For surgical CPGs and decision making, choices for patient care can often be reduced to a decision tree (e.g., nonoperative v. procedure X v. procedure Y). From a surgical standpoint, attention to this paradigm is critical. Given a patient presentation, readers will turn to CPGs to illustrate both when a procedure should be performed and which procedure should be performed if different options exist.

In Robson and colleagues’ work, recommendations are specific in most cases. For example, their Recommendation #1.4 states, “Apparent venous ulcers that have been open continuously without signs of healing for 3 months or that do not demonstrate any response to treatment after 6 weeks should be biopsied for histological diagnosis (Level III),” and Recommendation #1.1 states, “Gross arterial disease should be ruled out by establishing that pedal pulses are present on physical examination and/or that the ankle: brachial index (ABI) is > 0.8. (Any ABI < 1.0 suggests a degree of vascular disease and compression therapy is usually considered to be contraindicated with an ABI < 0.7) […] (Level I).” These 2 examples reflect objective recommendations for venous ulcers.

The clarity of other recommendations could be improved. For example, Recommendation #4.1 states, “Examination of the patient as a whole is important to evaluate and correct causes of tissue damage. This includes factors such as (A) systemic diseases and medications, (B) nutrition, and (C) tissue perfusion and oxygenation (Level II).” What specific diseases and medications are most important for venous ulcers? What components of a nutrition workup are relevant? What typically needs to be supplemented? This information should be provided from the primary literature. The guideline succeeds in presenting surgical, nonsurgical and preventative surgical options for venous ulcers where applicable.

How do authors move from evidence to recommendations?

Arriving at a guideline recommendation is complex, combining best evidence, clinical decision making and patient preferences. Good CPGs will provide simple, straightforward care recommendations despite the complexities behind them. When authors use a systematic method to arrive at a judgment, recommendations are more clear and accurate in guiding practice. Using this methodology, CPG authors should provide a strength or grade for each recommendation. This provides surgeons an indication of the confidence authors have in the literature, level of evidence and real-world effectiveness behind each of their recommendations. While CPG authors use a variety of methods to grade recommendations, use of a consistent and transparent methodology allows CPGs to be compared across different fields and specialties. The GRADE methodology is used widely, including the Cochrane Collaboration and UpToDate. The GRADE methodology uses a simple system to categorize the quality of evidence into 4 levels (high, moderate, low and very low) and strength of recommendations (strong or weak). Authors interpret methodology, heterogeneity, directness, precision and publication bias of each primary paper. For example, the Society for Vascular Surgery adopts the GRADE framework and has a transparent methodology in forming their rigorous, patient-important guideline recommendations.

Robson and colleagues do not describe the strengths and limitations in the body of evidence for each recommendation. There is no formal tool used to illustrate the quality of each paper cited. A classification is used to indicate the strength of each recommendation. This helps illustrate the judgment process for each recommendation. However, the authors do not include patient values in their judgment:

- “Level I: Meta-analysis of multiple RCTs or at least 2 RCTs support the intervention of the guideline. Another route would be multiple laboratory or animal experiments with at least 2 clinical series supporting the laboratory results.”
- “Level II: Less than Level I, but at least 1 RCT and at least 2 significant clinical series or expert opinion papers with literature reviews support the intervention. Experimental evidence that is quite convincing, but not yet supported by adequate human experience, is included.”
- “Level III: Suggestive data of proof of principle, but lacking sufficient data, such as meta-analysis, RCT or multiple clinical series.”

The suggestion in the guideline can be positive or negative at the proposed level (e.g., meta-analysis and 2 RCTs stating intervention is not of use in treating venous ulcers). A high level of evidence may not lead to a strong
recommendation. For example, Recommendation #7b.4 states, “Negative pressure wound therapy may be useful prior to a skin graft flap by helping promote the development of granulation tissue in the wound base, or postoperatively by preventing shearing and removing exudates. However, its reported experience in venous ulcers is limited (Level II).” Despite high-level evidence there has not been an illustration of clinical effectiveness, and the impact of therapy may outweigh its potential benefits to patients.

A classification of each recommendation’s strength is missing. Grading recommendations based on this system would allow for comparisons among recommendations in this guideline. No consensus methodology (e.g., Delphi method) is included. Without explicit methodology, it is difficult to ascertain how the CPG committee arrived at their recommendations. Insight on how decisions were made is necessary for surgeons to apply findings in their own decision making. The aforementioned GRADE methodology provides structure to the review process and limits the bias of “expert opinion” where evidence is unclear.

**Will the results help me care for my patients?**

**Are all outcomes considered?**
The process used to select the relevant outcomes and importance of these outcomes must be explicit and sensible. The importance of a certain outcome is directly related to what a patient cares about most. Therefore, CPG authors need to describe the methods with which the outcomes were chosen and a description of the process used to decide on the importance of each outcome. Information on who was involved in outcome choice as well as how values were assigned to outcomes should be apparent in the guideline.

Surgical decision making, like other recommendations, can often be reduced to analysis of benefit versus risk and harm. Guidelines should identify not only the interventions of interest, but also sensible alternatives. Surgeons must consider whether the benefits of the treatment discussed outweigh not only the side effects and risks of treatment, but also the implications of another treatment or no treatment. For example, under what circumstances does the benefit of diagnostic laparoscopy outweigh the risk? In a CPG for basal cell carcinoma, authors weigh surgical excision against curettage and desiccation, cryotherapy, radiation, chemotherapy and carbon dioxide laser. Considerations include the clinical situation, availability of equipment and patient values/risk profiles among other variables.

Robson and colleagues provide a thorough approach to workup and treatment of venous ulcers. Surgical CPGs are sometimes guilty of focusing on the surgical aspects of care while ignoring other aspects of patient management. The nonsurgical multidisciplinary approach is well defined for workup, allowing readers a guide to the workup and preoperative preparation of a venous ulcer. Operative interventions should be compared more directly. For example, Recommendation #6.3 states, “Less extensive surgery on the venous system, such as superficial venous ablation, endovenous laser ablation, or valvuloplasty, especially when combined with compression therapy, can be useful in decreasing the recurrence of venous ulcers (Level I).” This recommendation should be scrutinized because authors can expand on the specific indication of each procedure compared with traditional deep ligation of multiple perforating veins and previously mentioned subfascial endoscopic perforator surgery. This approach to surgical decision making would be helpful to readers.

**Will I be able to implement these recommendations?**

Moving from primary evidence to CPGs, authors consider the potential barriers in offering these procedures to patients. When using a guideline, surgeons interpret recommendations in their own setting. An academic tertiary care centre and community hospital have different patient populations, resources and support personnel. Applicability and assessment of barriers is often overlooked, especially in surgery. Guidelines are expected to illustrate how recommendations can be applied in the settings the authors intended.

Robson and colleagues describe the necessary components for proper management of venous ulcers. While the CPG touches on the multidisciplinary care required in the preoperative workup, operative/postoperative management and follow-up, the barriers and difficulties in this process are not specifically discussed. The CPG focuses solely on interventions. Practically, surgeons are most often limited by the resources available to them. Using a CPG, surgeons must consider if their own resources would support recommendations. Are new, expensive dressings more effective in treatment? Questions of cost-effectiveness and economic analysis are increasingly important to answer.

**Resolution**

Although Robson and colleagues’ work is not specific to a particular population or any comorbid conditions, you have no reason to believe that it is not applicable to your patient. You consider the recommendations in this guideline in a stepwise manner. A biopsy of the ulcer first rules out malignancy. A quantitative biopsy rules out clinically important bacterial contamination. You proceed to debride the ulcer in your clinic to minimize the bacterial medium. Home care services are used for daily moist dressing in addition to compression to minimize edema. Two weeks later, the ulcer has a clean base, and you perform a split thickness skin graft. With weekly outpatient follow-up, the patient’s surprise the ulcer proceeds to heal for the first time in 5 years. This is not the end of the story though. You recommend that the patient should continue applying the compression dressings for life to avoid recurrence.
Competing interests: None declared.

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Use of a novel energy technology for arresting ongoing liver surface and laceration hemorrhage

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Persistent hemorrhage from liver capsular injuries has remained a technical challenge without an optimal solution. This report discusses an easy to use device that is commonly used within elective hepatic surgery and can be successful in arresting ongoing surface and laceration bleeding in patients with solid organ injuries.

Hepatic hemorrhage is often life-threatening and difficult to arrest. While the algorithm for the treatment of ongoing liver bleeding is well described,1 technical considerations for stopping persistent hepatic surface/capsule bleeding are not. Traditional techniques include coagulation by high voltage cautery using a Bovie, topical hemostatic application and/or the delivery of ignited argon gas.2 This form of bleeding is particularly troublesome when a surgeon unpacks a previously damage-controlled liver injury that had not been wrapped with a nonstick, plastic barrier.

Several patients (11) at the Foothills Medical Centre (FMC) have now been treated with a novel device that is commonly used for elective liver transection among hepatobiliary surgeons (Aquamantys; Medtronic). This instrument utilizes bipolar radiofrequency energy, which acts to ignite/boil dripping saline from a small, easy to manipulate handpiece instrument. This device is also excellent at sealing small to medium-sized bile ducts, thereby preventing subsequent bile leaks and collections.

The 11 patients treated at FMC had multiple injuries (mean injury severity score 28) and required initial damage control packing with a return to the operating room within 24–72 hours once their physiology and biochemistry was stabilized. All livers had been initially packed with standard laparotomy sponges and subsequently oozed substantial volumes of blood from the liver capsule and/or laceration itself when unpacked. Coagulation and cautery with the Aquamantys device stopped the hemorrhage in all 11 patients immediately. Anecdotally, the local effect of the Aquamantys device on the injured liver and associated hemorrhage was very similar to its effect during elective surgery on cirrhotic patients. In all cases, the 6.0 tip (round and blunt), as opposed to the 9.5 tip (sharp), was used. Interestingly, surgeons at FMC have also successfully used its deep tissue sealing ability for a splenic laceration in 1 patient with multiple injuries.

The Aquamantys instrument has the potential to arrest ongoing hepatic surface/capsular bleeding as well as moderate hemorrhage associated with the liver laceration itself. Despite an impressive history and near ubiquitous use within the elective hepatic surgery arena, to my knowledge, this represents the first discussion of a potential use for this technology in injured patients. Further experience and study is required.

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WHAT WOULD I WANT FOR MY SURGERY?

Team-oriented. Communicative. Transparent. These are words that we want all patients to use when describing their operating teams. Teams that embody these characteristics likely work well together and make few mistakes. But creating a standardized surgical culture that encourages these qualities has proven challenging.

Implementing the surgical safety checklist can grow this culture by framing how an operating team communicates; in turn, this can minimize avoidable risks (like infections and allergic reactions) that endanger patients. It makes sense. A recent study, however, found no correlation between the surgical checklist and patient mortality. Does this mean that there is no value in its application?

In British Columbia, a variety of stakeholders from the surgical community have responded to this study with the hope of highlighting the value of good teamwork and communication in the operating room. There is tremendous value to the checklist beyond its statistical significance. It ensures that common objectives are being effectively communicated. It empowers all health professionals to speak up if they notice a potential error. It gives patients a voice in determining their own care.

Since there is very little education on teamwork for health professionals, past studies promoting the benefits of the checklist should not be discounted. Our group also suggests that hospitals invest resources and expertise to provide teams with coaching and training. This investment will undoubtedly foster the use of tools like the checklist.

The next time that you are in the operating room, imagine that it is you laying on the table. Would you want to have a high-functioning team performing your surgery? The answer is obvious. The checklist can help operating teams work better together. We hope our paper (Available at http://bcpsqc.ca/clinical-improvement/surgical-checklist/what-would-you-want-for-your-surgery/) offers constructive ideas on how Canada’s surgical community can move forward as it aims to improve care for patients.

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A CENTURY OF BREAST SURGERY: FROM RADICAL TO MINIMAL

We read the recent article “What is the effect of screening mammography on breast cancer incidence” with great interest. The introduction of breast screening programs has opened many new uncertainties on the ideal management of women with early breast cancer. This is especially true of in situ disease, as it is clear that a proportion of these women may be overtreated. We feel your readers may be interested in the history of breast cancer treatment and the changes in surgical techniques as a background for considering breast cancer incidence over time. This history is especially pertinent in light of only marginal reductions in the rate of late-stage cancer presentation, suggesting the screening program is unlikely to eliminate the need for more extensive surgery for later-stage presentation. In this letter we provide this historic surgical background.

In the last century, breast surgery has undergone dramatic changes in dogma; it serves as a prime example of how surgeons have made progress by challenging the limits of contemporary doctrine. The origins of breast surgery for cancer can be traced back to the 16th century. It was not until 1894, however, that an American surgeon, William Stewart Halsted (1852–1922), published his surgical technique for breast cancer surgery in the form of the Halsted (radical) mastectomy. This technique involved excising the breast, lymph nodes and pectoralis major and minor, leaving only skin covering the ribs. This extensive en bloc tissue resection resulted in considerable disfigurement and morbidity from the resultant weakened arm function and disabling lymphedema. Despite this, the vogue toward more extensive surgery continued into the midtwentieth century with a “bigger is better” approach. In fact, an American surgeon, Owen H. Wangensteen, was quoted as saying “Today, it should be said, I believe, the Halsted operation for cancer of the breast is outmoded: it is not radical enough.” These newer operations involved extending the radical surgery dissection into the neck and mediastinum by suprarectal mastectomy. This made no difference on patient outcomes; subsequent survival rates did not change in light of more aggressive surgery.

In 1948, Patey and Dyson (London) advocated for taking a step back with pectoralis major–sparing surgery by using modified radical mastectomy for breast cancer. The modified radical mastectomy became popular and slowly replaced more extensive surgery by the 1980s. Patey argued that the excision of pectoralis major did not add any significant benefit but did contribute to poor cosmetic outcomes and intraoperative blood loss. In this post-
World War II era and particularly from the 1970s, advances in adjuvant therapy (such as hormonal, chemotherapy and radiotherapy) have been combined with less radical surgery to achieve similar survival rates compared with early more radical surgery.

The 1970s marked the age of large-scale randomized controlled trials (RCTs) assessing the extent of surgery with objective outcomes. The Alabama Breast Cancer Project, Manchester Trial, the Cardiff–St. Mary’s trial and several others compared more versus less extensive surgery. In 1971, the National Surgical Adjuvant Breast and Bowel Project B-04 was initiated and was to be the largest RCT on the subject. The trial included 1079 women with clinically negative axillary nodes who underwent radical mastectomy, total mastectomy without axillary dissection but with postoperative irradiation, or total mastectomy plus axillary dissection only if their nodes became positive. There is now 25-year follow-up data from this study, which validated other studies showing no advantage from radical mastectomy.6

The true era of breast-conserving surgery is accredited to Umberto Veronesi, an Italian oncologist who progressed the idea of removing only the involved part of the breast (quadrantectomy). This was a radical idea at the time. An RCT of 701 women recruited from 1973 to 1980 and followed up for 20 years showed that the long-term survival rate among women who undergo breast-conserving surgery (with radiotherapy) was similar to that among women who undergo radical mastectomy. The evolution and mini-mization of breast surgery is being echoed in the field of surgery to the axilla. A number of contemporary studies have focused on the role of management of the sentinel lymph node biopsy (Z0011, Amaro, Supremo), stepping away from conventional axillary clearance.

The future of breast surgery is bright. The next decade will be marked by shifts in paradigm toward less (with narrower acceptable margins) but more focused surgery to both the breast and axilla in light of advances in newer radiotherapy and chemotherapy regimens. This is especially true with earlier stage cancer detection, which this data demonstrates.1

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References
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As of 2016, the CHUM will offer a renewed hospital experience in its new facility located in downtown Montréal.

The CHUM is an active member of the Réseau universitaire intégré de santé (RUIS) of the Université de Montréal. The institution gathers over 10,000 employees; close to 1,000 doctors, dentists and pharmacists; approximately 1,400 researchers, investigators and other members of the Centre de recherche du CHUM (CRCHUM); as well as 650 volunteers. With its major contribution in training doctors and health professionals in Québec, the CHUM welcomes close to 6,000 students and interns each year. The CHUM’s annual budget ranges around $830 million. Its main areas of expertise are cancer, neurosciences, cardiovascular and metabolic, transplantation, functional musculoskeletal, imagery, leading medical technologies, genetics and biomarkers, as well as immunology and infectiology.

CHUM IS RECRUITING A DIRECTOR FOR ITS DEPARTMENT OF SURGERY

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Summary of the role and responsibilities

The Director of the Department of Surgery will have the unique opportunity to participate and influence the creation of the new CHUM. They will be able to plan a service offering in the most modern infrastructures. They will have to promote the academic mission and vision of excellence of their department.

The ideal candidate must have an academic profile and a good understanding of the academic mission and vision of excellence of their department.

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CHAIRE DE RECHERCHE FRANCIS-GLORIEUX SUR LES MALADIES MUSCULO-SQUELETTIQUES PÉDIATRIQUES
Département de chirurgie pédiatrique
Hôpitaux Shriners pour enfants, Université McGill

Nous sommes à la recherche d’un scientifique hautement qualifié dans le domaine des maladies musculo-squelettiques pédiatriques (M.D. ou Ph.D. ou M.D., Ph.D.) pour être nommé titulaire de la Chaire de recherche Francis-Glorieux sur les maladies musculo-squelettiques créée par l’Hôpital Shriners pour enfants de Montréal et la Faculté de médecine de l’Université McGill. Le titulaire sera un scientifique de renomme internationale appelé à diriger une équipe de recherche très dynamique à l’Hôpital Shriners pour enfants du Canada. Le nouvel Hôpital Shriners pour enfants et son centre de recherche ouvriront leurs portes en 2015. Les installations abriteront un laboratoire de travaux pratiques de 2322 mètres carrés, un centre de recherche clinique de 185 mètres carrés, une petite installation réservée aux animaux, un laboratoire d’analyse du mouvement, une vaste salle de conférence et un laboratoire d’enseignement de techniques chirurgicales. Le nouvel hôpital Shriners sera adjacent à l’Hôpital de Montréal pour enfants, au Centre universitaire de santé McGill et à l’Institut de recherche avec lesquels il travaillera en étroite association. Le candidat devra jouir d’une réputation internationale dans le domaine de la recherche, bénéficier d’un financement soutenu par des organismes soumis à l’examen des pairs et avoir publié des travaux de recherche dans le domaine de la régénération osseuse ou des cellules souches. Le candidat devra posséder le leadership, la vision et l’expertise nécessaires pour faire avancer la recherche sur les maladies musculo-squelettiques et l’enseignement au Département de chirurgie pédiatrique.

Le candidat devra :
• attester d’une carrière universitaire dans le domaine de la médecine régénérative et de la recherche sur les cellules souches, ce domaine touchant à la recherche sur les maladies musculo-squelettiques;
• posséder une expérience de premier plan dans le domaine de la médecine régénérative et notamment en recherche sur les cellules souches;
• avoir une vision claire de l’évolution constante de la recherche sur les maladies musculo-squelettiques et avoir une capacité démontrée de partager sa vision, d’encourager les autres à prendre part à des activités de recherche au centre de recherche Shriners et de favoriser une approche interdisciplinaire en matière de recherche à l’Hôpital Shriners pour enfants, à l’Hôpital de Montréal pour enfants du Centre universitaire de santé McGill et à l’Université McGill;
• posséder une expérience de la gestion d’un centre de recherche serait un atout.

Le candidat doit être professeur agrégé ou professeur titulaire.

L’Université McGill souscrit à la diversité et à l’équité en matière d’emploi. Elle accueille favorablement les demandes d’emploi des femmes, des peuples autochtones, des minorités visibles, des minorités ethniques, des personnes handicapées, des personnes de toutes orientations et identités sexuelles et d’autres personnes qui pourraient contribuer à une plus grande diversité. On encourage tous les candidats qualifiés à postuler, la priorité sera toutefois accordée aux Canadiens ainsi qu’aux résidents permanents.

Date limite de présentation des candidatures : le 30 septembre 2014.

Faire parvenir une lettre d’intérêt signée, un curriculum vitae et les noms de trois répondants à la personne suivante :
Dr Jean-Pierre Farmer, président du Comité de recherche
Chef du département de chirurgie pédiatrique, Université McGill
a/s josee.lamarre@muhc.mcgill.ca

FRANCIS GLORIEUX CHAIR IN PEDIATRIC MUSCULOSKELETAL RESEARCH
Department of Pediatric Surgery
Shriners Hospital, McGill University

We are seeking a highly qualified scholar in pediatric musculoskeletal research (MD or Ph.D. or MD, Ph.D.) to assume the Francis Glorieux Chair in Musculoskeletal research at Shriners Hospital, McGill University’s Faculty of Medicine. It is anticipated that the prospective chair holder will be a world class scholar who will lead a vigorous research team at the Shriners Hospitals for Children – Canada. The new Shriners Hospital and its research centre will open its doors in 2015 and will include a 25,000 sq. ft. wet laboratory, a 2000 sq. ft. clinical investigation unit, a small animal facility as well as a motion analysis laboratory, a large conference room and a surgical skills laboratory. The new Shriners facility will be adjacent to, and partner with, the Montreal Children’s Hospital and the McGill University Health Centre and its Research Institute. It is expected that the candidate will have an international research reputation, including a track record of sustained funding from peer-review agencies, evidence of prior research publications in the field of bone regeneration/stem cell research and is expected to provide leadership, vision and expertise that will advance musculoskeletal research and teaching in the Department.

Candidates must have:
• Demonstrated academic accomplishments in regenerative medicine and stem cell research as it applies to musculoskeletal research;
• Leadership experience in bone regeneration, and specifically stem cell research;
• A clear vision of the evolving nature of musculoskeletal research and a demonstrated ability to share their vision and to encourage others to partake in research activities in the Shriners research centre and to foster an interdisciplinary approach to research with the Shriners Hospital for Children, the Montreal Children’s Hospital, McGill University Health Centre and McGill University;
• Experience in the administrative aspects of a research centre would be an asset.

Candidates should hold the academic rank of Associate or Full Professor.

McGill University is committed to equity in employment and diversity. It welcomes applications from Aboriginal persons, persons with disabilities, ethnic minorities, persons of minority sexual orientation or gender identity, visible minorities, women and others who may contribute to diversification. All qualified applicants are encouraged to apply; however, Canadians and permanent residents will be given priority.

Application deadline date: September 30, 2014.

Please forward signed letter of interest, C.V. and names of three referees to:
Dr. Jean-Pierre Farmer, Chairman, Search Committee
Chair, Department of Pediatric Surgery, McGill University
a/s josee.lamarre@muhc.mcgill.ca
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