

REVIEW ARTICLE

# Surgical innovation and safety: femoroacetabular impingement and the IDEAL collaborative framework

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Submitted 16 June 2015; Revised 0 Month 0000; revised version accepted 25 October 2015

## ABSTRACT

Operative treatment of femoroacetabular impingement (FAI) is a relatively new, yet rapidly expanding surgical innovation. Although the practice of surgery is inherently innovative, there is no clear distinction between minor technical variation and true modification that warrants testing. This raises important questions about how new procedures should be evaluated before being broadly disseminated. The IDEAL Collaborative is a consortium that promotes safe and responsible translation of research into clinical practice. The collaborative has delineated the typical stages of evolution of new interventional technologies, and the type of study designs appropriate for each stage. This report examines the surgical treatment of FAI as a case study of the IDEAL framework and discusses both missed and future opportunities for critical assessment.

## INTRODUCTION

Surgery is inherently innovative, yet there is no clear boundary to distinguish minor variation in technique from true modification that warrants testing. Unlike new drug development, there is no regulatory framework to guide the investigation of novel surgical techniques. This presents uncomfortable, yet pertinent questions about how new procedures can be safely developed, tested and evaluated before they are disseminated to other surgeons. If we fail to address these questions, we may surrender the opportunity to external regulators who will make judgments that may impede progress and innovation. Indeed, this has occurred in several states in the US where Health Technology Assessment (HTA) committees have ruled against coverage of surgery for femoroacetabular impingement (FAI). The IDEAL Collaborative is a consortium that promotes safe and responsible integration of new technologies in surgery. The IDEAL Framework defines the typical stages through which new interventional technologies pass, and the study designs suitable

for each stage. The rapid expansion of FAI treatment is a good model to examine the stages of surgical innovation and opportunities for critical appraisal as defined by the IDEAL group.

## SURGICAL INNOVATION AND THE IDEAL COLLABORATIVE

Surgical innovation has been defined as a procedure that includes at least one of the following: (i) a different risk profile from standard practice, (ii) the need for new training, (iii) the use of a different anatomical approach, (iv) the potential for increased cost and (v) outcomes that have not yet been described [1,2]. FAI is a unique example of innovation in that there has been recent evolution in our understanding of the disease itself concomitant with advancement of the surgical treatment described by Ganz *et al.* [3] in 2001. FAI meets the definition on all points with the added complexity that there previously was no 'standard practice' with which to compare.

Recognizing that there is no regulatory framework for the evaluation and integration of new technologies in surgery, a group of clinicians and methodologists convened for three conferences between 2007 and 2009 as part of the Balliol Colloquium on Surgical Innovation and Evaluation. This group, the 'IDEAL collaborative', described the stages of surgical innovation in a manner analogous to the four phases of drug development necessary for FDA approval [4]. They reviewed current practices and, importantly, outlined the opportunities for critical assessment at each stage. The following is a summary of their recommendations published in a three-part series in the *Lancet* [4–6] (Table 1).

### Stage 1—idea/innovation

In the first stage, innovators develop their technique in cadaver or animal models and begin to test the procedure in a few patients. Typically, results from this stage are published in case reports and articles trumpeting new techniques. The obvious risk is that the safety of novel techniques is unknown, and patients and hospitals may be unaware that new procedures are being tested. The IDEAL group recommends that organizations or specialty associations develop surgical innovation registries, which surgeons can query to see if similar work is being conducted and learn from the early experience of others. The group emphasizes the importance of informing hospitals and patients about the new procedure and recommends that the process require application to an institutional review board (IRB) to review the rationale, plan and method of study for the new procedure. The collaborative recognizes that although this involves infrastructure and cultural change, it is a necessary step to ensure safety and proper oversight. One mechanism to drive change is for journal editors to require proof of IRB approval as a condition for publishing new techniques, similar to the documentation of human subjects research approval that is currently necessary for other study types.

In the example of FAI, Mikulicz first reported surgical treatment of SCFE-like deformities in 1903 and a failed case was noted in the English literature in 1909 [7,8]. Smith-Petersen described the anterior approach to the hip in 1936 as a means to address pathologic impingement between the proximal femur and acetabulum [9]. Although abnormal femoral morphology was associated with premature osteoarthritis for decades, it remained a largely unsolved clinical problem until Ganz and colleagues published their technique for surgical hip dislocation (SHD) in 2001 [3,10–13]. They had initially noted impingement after femoral neck fracture malunion and as a consequence of anterior overcoverage in periacetabular

osteotomy [14,15]. Following publication of the SHD technique, intra-operative observations delineated the pathomechanism of impingement and chondral injury that could lead to osteoarthritis [16]. In line with IDEAL group's conception of this stage, the technique evolved from cadaver studies investigating the blood supply to the femoral head [17]; the novelty of the technique lay in providing complete access to the hip joint, while minimizing the risk of femoral head osteonecrosis.

### Stages 2a/b—development and exploration

In stage 2a, the focus is on further confirming the safety of the procedure in a small group of patients (<30) as the innovators improve along their learning curve and modify technical aspects of the procedure. In the current state, new techniques are largely unregulated and often reported as case series'. Again, the IDEAL group recommends that surgeons submit prospective development protocols to an IRB to ensure objective oversight of the procedure. Once the main technique is established, stage 2b, the exploration stage begins, in which the indications for the procedure are refined and adoption is occurring among other surgeons. In this phase, the IDEAL group emphasizes the importance of transparency about complications as a means to caution other surgeons about potential dangers. Mentoring and learning curve evaluation are essential as the procedure is disseminated. At this stage, results from a larger number of patients (2–300) are needed before a randomized-controlled trial (RCT) is feasible.

For FAI, the original SHD report captured the development stage, documenting the experience in 213 patients followed shortly thereafter by further studies establishing the safety of the procedure and 5-year results [3,18,19]. Soon, other surgeons adopted the procedure and published their case series' [20,21]. FAI is unique in that understanding of the pathomechanics evolved in concert with early spread of the SHD technique [16]. Within 5 years after publication of the SHD technique, there was renewed interest in limited open approaches and adaptation of arthroscopic techniques to treat FAI, along with reports of potential complications [22–31].

At this juncture, the IDEAL group emphasizes creation of disease-based, rather than procedural-based prospective research databases that include patients undergoing alternative or conservative care to generate an overall picture of management of the patient populations. There have been several missed opportunities with respect to FAI at this stage, such as, lack of consensus about surgical indications and patient selection criteria, lack of standardized outcome definitions and measurement tools, and no formula to assess procedure quality and surgeon

**Table I. Stages of surgical innovation**

<i>Stage</i>	<i>1 IDEA</i>	<i>2a DEVELOPMENT</i>	<i>2b EXPLORATION</i>	<i>3 ASSESSMENT</i>	<i>4 LONG-TERM STUDY</i>
Purpose	Proof of Concept	Development	Learning	Assessment	Surveillance
Number and types of patients	Single digit, highly selected	Few (<30); selected	Many; broadening indications	Many; expanded (well defined) indications	All eligible
Number and types of surgeons	Very few; innovators	Few; Innovators and some early adopters	Many; innovators, early adopters, early majority	Many; early majority	All eligible
Procedure	Evolving; procedure inception	Evolving; procedure development	Evolving; procedure refinement; community learning	Stable	Stable
Method of analysis	Structured Case Reports	Prospective development studies	Disease-based research database, feasibility RCT	RCT or alternative designs, if necessary	Registry, routine database, rare-case reports
Goals/outcome measure	Proof of Concept; technical achievement; disasters, dramatic successes	Mainly safety; technical and procedural success	Safety; clinical outcomes; short-term outcomes, patient-reported outcomes (PROs), feasibility	Clinical outcomes, mid- and long-term outcomes; patient-reported outcomes; cost-effectiveness	Long-term outcomes, quality assurance, rare events reporting
Ethical approval	Sometimes	Yes	Yes	Yes	No
FAI Experience and Pitfalls	SHD technique developed after cadaveric study	Early results reported by innovators and early adopters	Expansion of alternative FAI procedures; No consensus on PROs, indications, or patient selection criteria; No method for training, learning curve assessment	Wide adoption of hip arthroscopy; No consensus on PROs, indications, or patient selection criteria; No procedural or surgeon quality measures; RCTs for arthroscopy versus conservative management pending	British Hip Society registry; most procedures and surgeons unmonitored

Adapted and reprinted from The Lancet, Vol. 374, McCulloch P, Altman DG, Campbell WB et al., No Surgical Innovation without Evaluation: the IDEAL Recommendations, 1097–104, 2009, with permission from Elsevier. [5].

performance [5]. In addition, there is no established course for training or mentoring surgeons new to the technique—a pertinent issue in view of the potential complications associated with the hip arthroscopy learning curve [32–35].

### Stage 3—assessment

The third stage marks a critical point when the effectiveness of the new procedure is ready to be measured against the current standard. At the same time, adoption of the technique is expanding among surgeons, while patient

awareness and demand for the procedure are increasing. The IDEAL group recommends that RCTs be the default study design, though there may still be a role for well-conducted prospective case series. The group clarifies that there may be challenges in which randomized trials may not be ethical or feasible and there may be recruitment difficulties. If these studies are not conducted, however, there is danger that broad acceptance may occur before the technique is proven. Extrapolating Malcolm Gladwell's idea of information diffusion, it is estimated that 10–20% adoption among surgeons marks the 'tipping point' beyond which, even if unproven, the procedure may be destined for widespread dissemination and formal assessment may no longer be possible [36–38]. The IDEAL group suggests that multi-center studies may be necessary to achieve adequate power, though this requires collaboration that can be difficult to achieve, especially considering the competitiveness of a new technique [39,40].

Currently, the surgical treatment of FAI is at the cusp of stage 3. The time of exploration is ending and there is a need for rigorous critical assessment. This stage again highlights FAI as a unique example in that the evolution of the SHD technique helped clarify FAI as a disease-entity, and there was no prior standard treatment to compare. Many level 3 and 4 reports and several systematic reviews of open, limited open and arthroscopic treatment cautiously conclude that, in the absence of substantial osteoarthritis, surgery results in decreased pain and improved function [19,21,40–44]. Several studies have attempted to compare approaches, but these reports are limited by irreconcilable heterogeneity in patient selection, criteria for failure and the outcome instruments used to measure results [41,42,45–48]. There is only one published study that attempted prospective randomized allocation of patients between SHD and arthroscopy [49]. Of the 200 patients who met inclusion criteria for the study, 162 declined to participate, and only 10 of 28 subjects agreed to be randomized. The authors concede that the popularity of hip arthroscopy forced closure of the trial due to patient unwillingness to undergo SHD [49]. However, even in the absence of efficacy data, there has been an exponential increase in hip arthroscopy rates [50–53]. As adoption rates are near the tipping point, there is danger that clinical equipoise may be lost and RCTs may no longer be possible. It has been noted that treatment trends for FAI outstrip the available evidence [54]. Several randomized trials comparing hip arthroscopy to conservative management or physical therapy have been registered with the US National Institute of Health, including an ambitious multi-center study to compare arthroscopic osteochondroplasty

and lavage to lavage alone, but the widespread acceptance and utilization of hip arthroscopy will make comparison to SHD very challenging [55,56].

Fortunately, leaders in FAI treatment recognized the need for multi-center collaboration and formed the ANCHOR (Academic Network of Conservation Hip Outcomes Research) and MAHORN (Multicenter Arthroscopy of the Hip Outcomes Research Network) groups, which have expanded knowledge in the field [57–60]. Moving forward, it will be important to generate higher quality data to prove the efficacy and durability of FAI treatment [61]. This will require collaboration among all FAI surgeons, rather than separate efforts from open versus arthroscopic surgeons.

#### Stage 4—LONG-term study

In stage 4, the new procedure is well established, and the focus turns to monitoring for long-term outcomes and rare events. The IDEAL group suggests that registries be maintained, which can provide more detailed information about factors that contribute to variation in outcomes, such as patient subgroup variables, alternative aftercare regimens and differences in surgeon performance. For FAI, the British Hip Society has established a Nonarthritic Hip Registry to track FAI procedures [62]. Elsewhere, the majority of FAI surgeons and procedures are unmonitored.

#### RESPONSIBILITY FOR OVERSIGHT

It is not clear who should be responsible to oversee new innovations in surgery. Options range from institution-based review committees or specialty-driven surgical registries to regional or state health technology committees [1,2,63]. A hospital-based HTA program in Calgary provides a successful model for safely and responsibly integrating innovation in surgery [1]. With the explicit goal to guide adoption of new technologies, while improving patient care in a manner supported by evidence-based decisions, the program intends to 'bridge the gap' between evidence and practice. Reporting on their 5-year results in Alberta, the authors were surprised to note that no innovation application had been outright rejected. Their aim was to manage risk without stifling innovation—rather than denying proposals, they offered qualified, conditional approvals that varied in proportion to the uncertainty and risk of the new technology. These constraints ranged from single case approval to procedures requiring clinical audit or formal trial approval. The group attributes the success of the program to having a collaborative, multi-disciplinary team with ample surgeon input, and they recommend it as a model that can be transferred to other hospitals or regional health centers.

If physicians are not proactively involved in the oversight process, external regulators who prioritize cost-control over progress and improved patient care may assume the task. In August 2011, the Washington State Health Care Authority Health Technology Clinical Committee (HTCC) ruled that there is insufficient evidence to warrant coverage of surgical treatment for FAI [64]. As a result, state employees and those injured on the job are uniformly denied coverage of surgery for FAI without an option for appeal. Citing the Washington HTA decision, the Oregon Health Authority Health Evidence Review Commission (HERC) made a similar decision to deny coverage in August 2012 [65]. The HERC overturned this decision in January 2014, noting that, despite insufficient evidence of efficacy, the change was based on the existing prevalence of FAI treatment, the difficulty of recruiting patients for research and the lack of alternative effective treatment for patients who have failed conservative treatment and meet specific criteria for surgery [66]. In their review of the medical literature, the Washington HTCC posed six questions:

Is there a consistent or agreed upon case definition for FAI? What is the evidence of reliability and validity of these case definitions?

What are the expected treatment outcomes of hip surgery for FAI? Are there validated instruments related to hip surgery outcomes?

What is the short and long-term evidence of efficacy and effectiveness of hip surgery (open or arthroscopic) compared with no surgery for FAI?

What is the evidence of the safety of hip surgery for FAI compared with no surgery?

What is the evidence that hip surgery for FAI compared with no surgery has differential efficacy or safety issues in sub-populations, e.g. gender, age, psychosocial comorbidities, payer-type, provider-type?

What evidence of cost implications and cost-effectiveness of hip surgery compared with no surgery exists for FAI?

These are worthy questions, and the Washington HTCC was not incorrect in concluding that the available evidence was inadequate. However, they erred in the timing of their decision, which failed to take into account the unique features of FAI as a novel disease-entity and the natural stages of evolution of surgical innovation. In contrast, a committee from the National Institute for Health and Clinical Excellence (NICE) in the United Kingdom reviewed the same literature and came to a different

conclusion, ruling in favor of coverage for open and arthroscopic surgery for FAI [67,68]. The NICE is a special health authority, independent of the government, which produces evidence-based guidelines and health technology appraisals to ensure value and quality of care in the National Health System. Their guidelines for FAI specify that only surgeons with specialized training and expertise in open and arthroscopic treatment of FAI perform these procedures. In addition, details of all patients undergoing surgery should be reported in the Nonarthroplasty Hip Registry, a national registry that was established by the British Hip Society in October 2011 after unanimous vote of its membership recognized the value of this type of accountability [62].

Even with improved safeguards for new technologies in surgery, it is doubtful that there will be specific constraints on surgeons who want to try these techniques. It rests with the integrity of the individual to decide what amount of training he/she needs to perform these procedures safely and what degree of transparency is appropriate with patients who undergo surgery early in one's learning path.

## SUMMARY

In the last 15 years, improved understanding of the pathomechanics of FAI and options for surgical treatment have revolutionized the care of patients with non-arthritis hip pain. FAI provides an excellent case study to explore the stages of surgical innovation outlined by the IDEAL collaborative. This exercise demands reflection on lessons learned and necessary steps for the future, particularly as the popularity of hip arthroscopy reaches the tipping point of widespread adoption. In addition, this review highlights the need for hip preservation surgeons to consider how best to ensure safety, adequate training and high-quality evaluation for other procedures that entail substantial risk and challenging learning curves [69–71]. Finally, the FAI experience is a reminder that clinicians need to be proactive in working to ensure the safety and efficacy of new technologies or risk forfeiting responsibility to external regulators.

## CONFLICT OF INTEREST STATEMENT

None declared.

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