Technological innovation in orthopaedic surgery: balancing innovation and science with clinical and industry interests

Romain Seil¹ · Olufemi R. Ayeni^{2,3} · Michael T. Hirschmann^{4,5}

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Romain Seil

Olufemi R. Ayeni

Michael T. Hirschmann

Over the last decades, many technological innovations have been introduced in orthopaedic surgery (i.e. computer aided surgery, CASPAR, ROBODOC, hip resurfacing, various ligament reconstruction procedures, new osteotomy techniques, hip arthroscopy, etc.). Whereas some of them rapidly made their way towards general acceptance, many of them silently disappeared after a few years [9].

The reason for this was that in most cases, initial theoretical advantages could not be confirmed clinically, or the promising results could not be reproduced on a large-scale basis by peers. Another factor may be the lack of financial resources to keep pursuing ongoing evaluation of the initially promising concept. Nevertheless, on rare occasions, new technology had to be recalled due to damage to the patients [1, 3, 7, 8].

Interestingly, it is a common pattern that previously unsuccessful technologies or surgical techniques are reintroduced with minor technological changes after some years. The same theoretical concepts which constitute the basis of a new, but vanished technology reappear in a modified version.

The principles applied to promote a new product or technology within the surgical community remains the same. Typically, this effort is driven by industry partners, who are under constant pressure to produce innovative products and or key opinion leaders who aim to build their career or reputation while improving patient care.

✉ Romain Seil
rseil@yahoo.com

¹ Centre Hospitalier Luxembourg-Clinique d'Eich and Sports Medicine Research Laboratory, Luxembourg Institute of Health, Luxembourg, Luxembourg

² Division of Orthopaedic Surgery, Department of Surgery, McMaster University, Hamilton, Canada

³ Department of Health Research Methods, Evidence, and Impact, McMaster University, Hamilton, Canada

⁴ Department of Orthopaedic Surgery and Traumatology, Kantonsspital Baselland (Bruderholz, Liestal, Laufen), Bruderholz, Switzerland

⁵ University of Basel, Basel, Switzerland

Clearly, it is often difficult for us, orthopaedic surgeons, to make a decision if and when to implement innovations into the daily clinical practice. The individual surgeon can choose between not adopting these novel developments, which might mean less possibilities of self-marketing, but also less risk of damage to the patient due to eventual procedure-related complications, or adopting and implementing these into clinical practice. This difficult challenge is nicely highlighted in an article discussing success and personal innovative pressure of orthopaedic surgeons [12]: “In the clinical setting, I have been unwilling to introduce “innovative” techniques to supposedly fix “problems” that I have not personally encountered in my patients. This has allowed me to steer clear of metal-on-metal articulations, modular necks, and hip resurfacing, and to not subject my surgical schedule (or my patients) to the learning curve of the 2-incision and anterior hip approaches, despite my having taken courses to achieve cadaveric proficiency”.

In this critical process of decision making, a surgeon is generally confronted with two lines of information.

The first is a commercial one, and is proposed by the developing and distributing company. The surgeon is directly exposed to the marketing materials often promotional in nature with an intent to increase sales. The second line of information represents the latest scientific literature

showing advantages of the innovation over previous, often long-standing clinical proven technology or technique. Initially, available scientific literature is often difficult to interpret. A fact that is readily apparent at the early phase of the introduction of technology or technique as objective, but potentially biased information is available from developers or early adopters (Fig. 1).

When analyzing this literature, surgeons must be aware of the limitations, conflicts of interest and other sources of bias. The readers should be aware of these factors prior to clinical decision making (Fig. 2).

In addition, us surgeons need to question the relevance of the innovation for patient-, surgeon- and procedure-related factors in terms of outcomes.

As an example, total knee arthroplasty (TKA) is chosen. Here, individual patient-related factors are characteristics like age, BMI, activity level, psychological status, the type and degree of knee osteoarthritis, the patient's knee morphology, alignment, preoperative joint mobility. Furthermore, factors such as individual healing potential and compliance with postoperative rehabilitation are important. Surgeon-related factors include the level of training and proficiency, the experience, the individual case-load, personal performance at the day and moment of surgery, but also pre-operative planning of the procedure. Procedure-related

Fig. 1 Representation of global adoption of a new surgical technique, e.g. hip arthroscopy as a treatment for femoroacetabular impingement (FAI) illustrating increased adoption over time [2]

Fig. 2 Representation of three main categories of surgical variables, e.g. after total knee arthroplasty (technology A). Adding second technology to the procedure increases the surgical outcome variables and may increase its complexity instead of simplifying the procedure

factors include the type of approach, intra- and perioperative pain management, control of blood loss and finally the type of implant, its principle and design. Although this list is not complete and exhaustive, it probably contains the main elements influencing outcomes after knee arthroplasty.

Adding a new, complex technology like a robot or computer assisted surgery [5, 10, 13] to TKA with its inherent complication potential and learning curve means multiplying the number of confounding factors and outcome variables. Considering basic mathematics, mixing three categories of outcome-related factors such as the above-mentioned ones leads to six different outcome combinations ($3 \times 2 \times 1$). Adding a fourth dimension increases the number of outcome possibilities from 6 to 24 ($4 \times 3 \times 2 \times 1$).

Clearly, this means that when a new technology is added to a first one, a certain degree of complexity is added. Often this makes it necessary to evaluate a very large number of patients to isolate the effect of a single variable change and create reliable scientific evidence. Likewise, the surgeon needs to realize that the groups of patients which are presented in an early study need to be comparable in order to avoid comparing “apples to oranges”. As an example, a comparison of outcomes after robotic or computer assisted knee surgery to conventional surgery need identical study groups (regarding pre-operative planning) which is not the case in most studies. As such, different planning procedures amongst groups would limit the comparability or generalizability of the results.

Recently, the Australian Knee Arthroplasty Registry has released surprising findings. A long-term analysis of more than 60,000 TKA revealed a 45% higher risk of revision for posterior stabilized TKAs in comparison to minimally stabilized TKAs [11]. This adds significant knowledge to a field in which eminence based teaching and cultural differences

have prevailed for decades when it came to implant choice [4, 6]. In fact, this example shows how long it takes and how difficult it is to find answers for an apparently simple question like the optimal implant choice in TKA, implicating only a single of the above-mentioned factors.

We need to be aware that there are no single answer to such complex questions like the benefit of additional technology to routine knee arthroplasty. Hence, we should always apply Hippocrates’ principle of “no harm” first. If a decision on implementing an innovative technology or technique is made, scientific follow up and careful evaluation of patients must be guaranteed. The scientific development of innovative technology should not be finished upon its transfer into clinical practice. Therefore, implementation of innovation must become a science, not a fashion or a commercially driven process. The first steps in this direction have been made in some countries with the introduction of Orthopaedic Data Evaluation Panel (ODEP) and “beyond compliance” systems. In ODEP hip, knee and shoulder prostheses are benchmarked against agreed standards at regular time points. Furthermore, in 2011 a “beyond compliance” system was initiated, which additionally follows implants from the time of CE marking (indicating conformity with health, safety, and environmental protection standards for products sold within the European Economic Area) to the first ODEP rating. Clearly, these registries help surgeons identify implants at risk of premature failure earlier and prevent doing harm to the patient. However, currently these systems are only in place in few countries and only follow-up implanted prostheses. Innovations in other fields or technological innovations are not included here. Innovations are essential to improve patient care but with innovation comes a responsibility to keep patients’ interest first.

Compliance with Ethical Standards

Conflict of interest The author declares that they have no conflict of interest.

Ethical approval This article does not contain any studies with human participants or animals performed by any of the authors.

Informed consent For this type of study informed consent is not required.

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