REVIEW ARTICLE

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How should new orthopaedic implants be introduced: an example and recommendations for best practice

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Abstract

Continued advancements in orthopaedics have led to the development of many new implants; many of these are being utilized in clinical practice with little or no evidence base for their safety or effectiveness. Highly publicized failures in orthopaedic technology have led to an increased awareness of this issue in both medical and non-medical circles. In most cases, the significant harm caused to the public could have been avoided by the appropriately staged implementation of new implants. This review comments on the current literature regarding the optimal practice for the introduction of new orthopaedic technology. The authors' experience with the failed ESKA Adapter Short-stem/Modular Hip is described; the methodology used for its evaluation is used as a basis to discuss what was successful about the process and also give warning on what could be improved upon. The ideal practice requires new orthopaedic implants to be evaluated by high-volume surgeons in specialist orthopaedic hospitals. These studies should include biomechanical studies, radiostereophotometric analysis, implant retrieval and outcome assessment. Results and complications should be reported early to the appropriate joint registry and regulatory body. Once a suitable evidence base has developed, the implant can be distributed into wider clinical practice or withdrawn. These recommendations aim to protect the patient and public from harm while allowing surgical innovation to still continue.

Introduction

Orthopaedic implants and their regulation has been a topical discussion in recent years,[1–3] both in medical circles as well as in the media. The failure of some metal on metal hip replacements such as the DePuy ASR (DePuy, Warsaw, IN, USA)[4–6] has been widely reported in the media leading to a greater interest in implant safety from both patients and the general public.

Increasingly, in Australia, surgical innovation is occurring without an adequate evidence base to support it.[3] From years 2000 to 2011, there were nearly 300 deaths and over 2000 serious injuries related to medical devices in Australia.[7] The Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) was in part set up to identify and flag prostheses that have a higher than expected revision rate.[8,9] Two of the most recent Australian Orthopaedic Association annual scientific meetings (2012 and 2014)[10] have had the regulation and evidence for orthopaedic implants as theme topics.

A 2011 analysis of the AOANJRR showed that no hip or knee arthroplasty introduced in Australia between 2003 and 2007 had improved outcomes over those currently being used. Of those introduced, 30% were associated with significantly worse outcomes.[11] Other studies worldwide have shown a similar link with poorer outcomes being associated with new arthroplasty designs.[12–14]

Australia is not alone in this issue. The 2013 National Joint Registry of England, Wales and Northern Ireland reported that of the 86 488 implanted hip arthroplasties in the UK in 2012, only 69% of uncemented stems and 3% of uncemented cups met the UK Orthopaedic Data Evaluation Panel benchmark rating.[15] Nearly one-fourth of all hip replacement implants available in the UK have no evidence at all for their clinical effectiveness.[16]

The risks of using implants with little evidence available to support their clinical effectiveness need to be evaluated against the perceived technological benefits. Innovation should be encouraged; however, clearly defined and nationally recognized strategies should exist to bring new implants into the public/patient domain with patient safety and protection being the major prerequisite.

For the purpose of this commentary, a review of the literature was undertaken. With this information and using the authors'

experience in Australia with the ESKA Adapter Short-stem/Modular Hip (EAH) (ESKA, Lubeck, Germany), this paper provides recommendations for how new implants should be introduced. The journey from initial concept through to the final withdrawal of this stem is described and the process is used as a basis to give advice (as well as warning) on the optimal methodology for the introduction of new orthopaedic implants, both in Australia and worldwide.

Concept

The EAH was marketed as having two distinct theoretical advantages over contemporary total hip arthroplasties – a short stem and modularity of the neck. The short stem should allow less broaching of the proximal femur, maintain distal femoral bone stock and decrease proximal stress shielding in the femur. The modularity of the neck would allow patient-specific customization of the prosthesis to a degree that was not possible with non-modular stems.

Independent biomechanical assessment

Prior to embarking on a clinical pilot study using the EAH, independent mechanical testing was undertaken at the Medical Physics Department of the Royal Perth Hospital, Perth, Western Australia. von Mises stress distributions created by both the EAH and its long stem counterpart were evaluated in sawbones to validate the fundamental concept of short-stem design. Results confirmed no significant differences in proximal stress distributions with either long or short stems (the long stem appearing almost obsolete) supporting the fundamental hypothesis behind short-stem design (Figs S1, S2).

Pilot clinical/RSA study

The EAH is a fully porous stem coated with 'Spongiosa' metal for secondary osseointegration. In order to assess early clinical outcomes and to investigate early *in vivo* migration properties of the EAH, a radiostereophotometric analysis (RSA) study was undertaken. RSA studies are considered as the gold standard in the evaluation of early migration properties of new hip replacements.[17,18]

After full ethics approval, a non-randomized, prospective cohort RSA study was undertaken. The EAH was implanted in 35 consecutive patients with 1-mm diameter tantalum RSA beads inserted in a standard manner (Fig. S3). In all cases, an uncemented shell (ESKA BS shell) and polyethylene liner were used. RSA analysis was performed independently at 3, 6, 12 and 24 months post-surgery in a unit highly experienced with this technique. Independent assessment of patient outcome was performed in the Joint Replacement Assessment Clinic at the Royal Perth Hospital using the validated Harris Hip Score, Short Form (36) Health Survey and Western Ontario and McMaster Universities Osteoarthritis Index.

No perioperative complications occurred. At follow-up within the first 12 months, three patients were investigated for ongoing pain associated with caseous masses/pseudotumours around the EAH implant. This was surprising given that metal-on-polyethylene bearings were used; however, histological analysis confirmed these lesions to be aseptic lymphocytic vasculitis-associated lesions (ALVALs).[19,20]

All patients underwent revision surgery to a ceramic-on-ceramic bearing with good result. Retrieval analysis of the prostheses was performed at the Medical Physics Department of the Royal Perth Hospital. This showed significant corrosion and fretting at the neck stem taper (Fig. S4) and represented one of the first described examples of 'trunnionosis'. A mathematical finite element analysis (FEA) study subsequently showed that the dual modularity of the ESKA hip was causing increased stress at the medial aspect of the neck and trunnion (Fig. S5).

After identifying issues with trunnionosis and pseudotumour formation/ALVAL, the entire study cohort was tested for whole blood cobalt and chromium levels. No further cases of pseudotumours have been identified to date and the RSA study was abandoned after revision of the third ALVAL case despite stem subsidence not being an issue in this cohort.

Reporting and withdrawal of prosthesis

These early results were reported to the AOANJRR. These data in conjunction with the results of other centres were analysed. The AOANJRR data showed that the EAH had a higher than expected rate of revision – 12.1% at 5 years.[21,22] The EAH was initially flagged as an 'at-risk' implant and subsequently in 2012 the implant distributor withdrew the EAH in Australia.

In total, 6 years passed from the introduction of the EAH in 2005 to it being completely withdrawn in Australia. Over this time, 742 EAHs were registered as being implanted in Australia.[21,22]

Discussion

The study cited in this paper was published as one of the first identifying the risk of corrosion and metal ion release in modular neck-stem hip arthroplasties.[23] It also provides an excellent and transparent timeline of how orthopaedic implants using small cohort studies, under the close scrutiny of a tertiary research environment, should be introduced in order to minimize the risk to the public. This methodology is outlined in Figure 1. The optimal introduction of new implants should be under the supervision of specialist orthopaedic/tertiary level university teaching hospitals where resources such as implant retrieval analysis, histological/biochemical analyses, biomechanical studies, outcomes assessment and RSA can be overseen.

Evidence supporting the idea that joint arthroplasties undertaken by high-volume surgeons and by high-volume centres have improved outcomes is increasing[24–26] and it is well proven that there is a definite learning curve when a surgeon uses a new prosthesis or technique.[27–30] Surgeons and centres highly experienced in a procedure are best equipped to overcome this learning curve quickly, and minimize any potential harm to patients. Past British Orthopaedic Association president Tim Briggs has previously proposed this idea[31] suggesting that the five UK specialist orthopaedic hospitals should play a key role in the evaluation of new implants. Only evaluating implants by high-volume surgeons in high-volume centres does affect the generalizability of the results of a new implant – this trade-off does not outweigh the benefit to patient

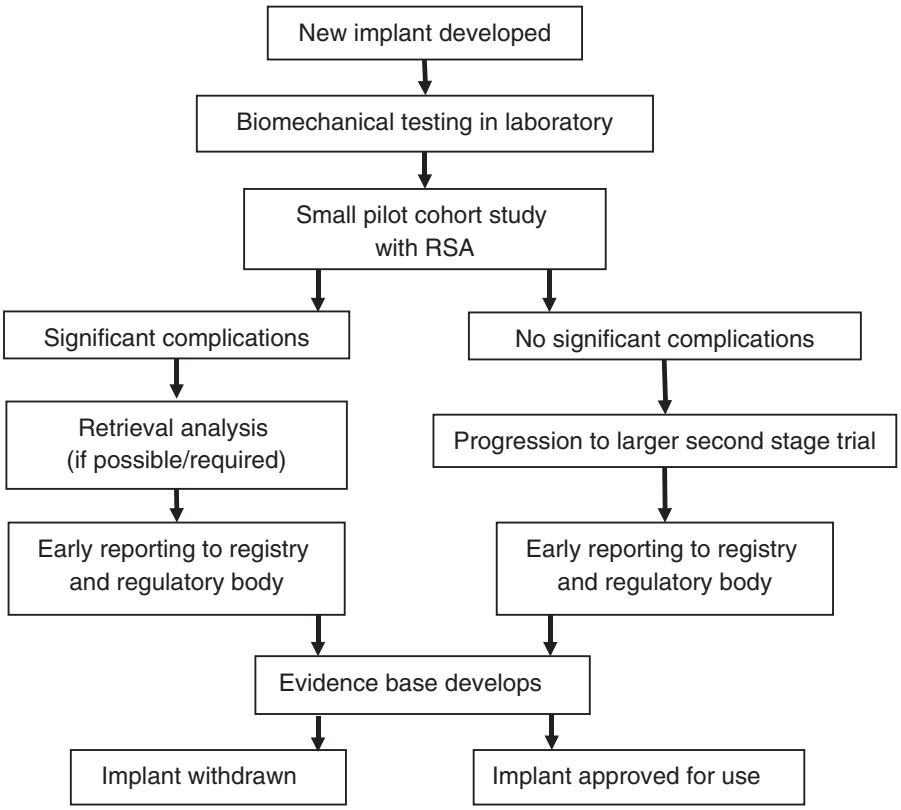

Fig. 1. Optimal methodology for the introduction of new orthopaedic implants.

safety. It also reduces the risk of mistakenly labelling a potentially beneficial technology as unsafe, due to difficulty overcoming the learning curve. Once the safety of a new implant has been established, its efficacy in smaller centres should be assessed as second stage study coordinated by the original investigating hospital using a hub and spoke model.

RSA studies play an important role in the evaluation of new implants. They allow for very accurate information to be obtained using only a small sample size, minimizing the risk to the public. Short-term RSA results showing early migration have been shown to be highly predictive of long-term outcomes[32,33] and in both Australasian and Swedish registry data, implant models that have been RSA tested perform better, having a one-third reduction in revisions when compared with those that have not.[34] However, there are still reasons for late implant migration that would not be detected by RSA (such as polyethylene wear) which should be kept in mind.

When introducing a new orthopaedic implant, independent biomechanical studies should be performed. Doing this independently is important to eliminate the bias present in (likely industry sponsored) studies undertaken during the implant's development. FEA is a mathematical tool that allows the simulation of orthopaedic interventions. In the aerospace industry, FEA is used as a predictive tool; however, its use in orthopaedic practice it is less precise and plays a more indicative role.[35] Although still useful in preclinical tests, access to FEA is most valuable to an investigator in the analysis of complications. Retrieval of implants and their analysis is also crucial in the investigation of complications. Retrieval analysis can yield information about why implants fail *in vivo*[36] that biomechanical testing cannot.

In Australia, new implants and medical technology are regulated by the Therapeutic Goods Administration (TGA). The TGA has often been more effective than equivalent bodies internationally. Australia has had approximately 30 deaths per year related to medical devices, while the USA in 2006 had over 2700.[7] This represents a greater than five times *per capita* increase. In 2012, the TGA reclassified hip, knee and shoulder replacements as Class III medical devices[37] meaning they are now subject to greater scrutiny before being approved. This was in part a response to the failure of the DePuy ASR and recommendations from the Australian Orthopaedic Association.[6] Australia's post-market surveillance for arthroplasty is very sensitive, largely due to the AOANJRR. This was the first joint registry worldwide to develop a standardized process for the identification of poorly performing prostheses.[9] Australia was the first country to have DePuy ASR recalled;[6] similarly, the EAH was identified early as an outlier and subsequently withdrawn in Australia.

The outcomes of new implants, whether positive or negative, need to be reported. This is critical when it comes to complications and should be done promptly and transparently. In Australia, this process is assisted by both the AOANJRR as well as the TGA. Additionally, the results need to be published in the literature. This is not always simple when it comes to negative results. In orthopaedics,[38,39] and in medicine in general,[40] negative results are less likely to be published which can cause a publication bias. It is critical that this information is circulated throughout the wider medical community so that unsuccessful ideas are not unnecessarily attempted again. Complications are not usually reported well in the orthopaedic literature.[41] The complications related to the use of the

EAH were novel and easy to publish; however, this is not always the case.

Most complications that arise from the *in vivo* use of new implants are not easily predicted. Very minimal changes in design can lead to unanticipated side effects.[42] A pilot study evaluating an implant should be sufficiently powered to answer accurately the question being studied but it should also have the ability to identify and report unexpected complications. This may not happen without the appropriate specialized facilities and feedback mechanisms being in place. The controlled implementation of the EAH in this paper identified an unforeseen complication which was then fed back to the appropriate regulatory body.

It is well known that hip and knee arthroplasty surgery is highly cost effective.[43] That said, the incremental benefit from any technological improvement will not necessarily be cost effective. A cost analysis undertaken in the USA suggests that for a new knee replacement to be cost effective it needs to reduce the revision rate by over 50%.[44] Given that evidence suggests there has been no improvement (or even an increase) in the revision rate[11,12] from the introduction of new arthroplasties in recent years, the appropriate staged implementation of new implants is crucial. The costs of complications and poorly performing prostheses are very high, while the potential for benefit is low.

There are aspects of this paper's methodology that could be improved upon. The EAH had more than one major new feature that was being tested: the dual modular neck and the short-stem concept (and also to a degree the Spongiosa metal porous coating). It was only the failure of the dual modular neck that resulted in the complications seen in this study. The viability of these other features is not known as the implant was withdrawn and the RSA study abandoned before this could be determined. If these new advances were introduced incrementally, then the identified modularity issue could have been avoided while the possible benefits of the short stem and coating may have been perpetuated. Australia wide, 742 EAH hips were reported by the AOANJRR as implanted prior to it being withdrawn.[21,22] This represents a large number of patients that have been exposed to harm in order to evaluate the EAH. Given that substantial issues with the EAH were identified in this study of only 35 patients, the process of acting on identified issues needs to be expedited. Many EAHs would have been implanted without using this paper's controlled methodology, delaying the reporting of complications. This reaffirms the recommendation that all new orthopaedic implants should be introduced in a stepwise manner as clinical trials – if this was the case across Australia, significant morbidity from the EAH could have been prevented.

Guidelines have been published for the safe introduction of new surgical techniques and technology. The Ballioli Collaboration's IDEAL recommendations[45] are the most commonly cited. The evaluation of surgical innovation requires a different approach to advances in other aspects of medicine (such as drug development) for a multitude of reasons.[46] Learning curves and operator skill are among these and the IDEAL recommendations try to address these issues. Further improvements to the IDEAL recommendations have been made to help deal with the ethical dilemmas created and also highlight the importance of registries in follow-up.[47] Ahn *et al*. also suggest that prospective series and registries are the most effective way to safely evaluate new orthopaedic technology as the 'gold standard' of prospective double-blind randomized controlled trials are not always feasible.[48] Other authors such as Briggs *et al*. and Nelissen *et al*. have strongly advocated for the phased introduction of new orthopaedic implants.[31,34]

This paper's advice, in contrast to the IDEAL recommendations, is solely aimed at evaluating new orthopaedic implants. This allows the suggestions to be specific and practical in order to deal with the unique complexities of orthopaedic surgery – such as biomechanical assessment and the increasing dependence of registries in evaluating prostheses. Unlike a guideline, the EAH is a real example of the careful evaluation of a new orthopaedic implant. This allows real-world validation of both what was effective as well as what could have been improved. The EAH's subsequent failure was detected and managed without substantial cost to Australian patients and public; both the methodology of the study as well as Australia's regulatory environment and post-market surveillance allowed this to occur. A researcher looking to follow this paper's recommendations needs to be aware of their own country's reporting and identification processes for failed medical devices, as they may not be as sensitive or as robust as those in Australia.

Conclusion

The problem of how to best introduce and evaluate new orthopaedic implants is not yet solved. This is only going to become more challenging as technology becomes more complex and multiple non-arthroplasty orthopaedic implants are introduced. It is easy for surgeons and patients to feel that newer technology will be better; however, both need to be aware that this is not always the case.

Guidelines should not be so restrictive that they prevent innovation. Forsaking new technology completely to avoid all possible risks to the public will reduce the quality of health care in the long run. There needs to be a middle ground found where new implants can be evaluated and introduced in a safe and regulated manner. There also needs to be a responsive transparent mechanism whereby at-risk implants can be flagged and withdrawn if required. Allowing surgeons and smaller hospitals to 'have a go' at using a new implant without an evidence base is not acceptable.

The EAH is an example of how this can be done well, and also highlights aspects that could have been done better. The discovery of trunnionosis was identified early and with less cost to the public in Australia than many other failed orthopaedic implants. The process described is evidence based and unlike many other published guidelines the recommendations of this review are validated by their real-world application.

The methodology discussed in this paper can be used as practical guidelines for the introduction of new orthopaedic implants. This requires high-volume surgeons in specialist orthopaedic hospitals to conduct small pilot studies that include mechanical and biomechanical engineering analysis. This should be followed by careful monitoring of the patients with early reporting and disclosure of complications to the appropriate joint registry and regulatory body. The resources and expertise required to conduct such trials are not available to smaller or low-volume centres, but they could feasibly

be part of a larger second stage study coordinated by one of these centres using a hub and spoke model. Given the significant costs (both in health outcomes and to the health budget) of inappropriate prosthesis implantation, having strict guidelines will benefit both the individual patient and the community as a whole.

Conflicts of interest

None declared.

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Supporting information

Additional Supporting Information may be found in the online version of this article at the publisher's web-site:

Figure S1. Sawbones model for the evaluation of von Mises stresses (prior to implantation of stems).
Figure S2. Quantitative von Mises stress distribution for (a) long-stem ESKA and (b) EAH (ESKA Adapter Short-stem/Modular Hip; note zero stresses around distal aspect of long stem in (a)).
Figure S3. Post-operative radiograph showing implanted EAH (ESKA Adapter Short-stem/Modular Hip) with tantalum beads.
Figure S4. Photograph showing retrieved EAH (ESKA Adapter Short-stem/Modular Hip). Note wear pattern on trunnion.
Figure S5. Finite element analysis showing increased stresses at the modular trunnion/stem interface.