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Advances in hip arthroplasty surgery: what is justified?

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- Total hip arthroplasty (THA) surgery has shown dramatic changes in terms of increased number of procedures and of technical development in recent years. It has been described as "the operation of the 20th century" for the excellent results, the high satisfaction of the patients and the improvement of the quality of life.
- A lot of variations have been introduced over the last few decades in THA especially in terms of indications (both in younger and older patients), techniques and devices (approaches, tissue preservation, biomaterials and industrial finishing), per-operative management (blood loss and pain control) and post-operative protocols (the so called "fast track" surgery). Looking at all these advances the emerging question is: have all of them been justified both in terms of improvement of the results for the patients and of the cost/benefit ratio from an economical point of view?
- The purpose of this paper is to critically analyse the advantages and the disadvantages of the theoretically proposed "advances in hip arthroplasty" and attempt to understand which are justified of such "advances" nowadays, based on the international and the European perspective with a focus on the author's personal clinical experience.

Keywords: hip; total hip arthroplasty; hip replacement; bearings; approaches; techniques; patient satisfaction; clinical outcomes

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Introduction

Total hip arthroplasty (THA) has been described as "the operation of the 20th century" for the high satisfaction of the patients and the improvement of the quality of life following surgery.[1] More than 1 million THAs are performed worldwide per year. The clinical outcome and the implant functioning are excellent over time with greater than 95% survivorship at ten years as reported by data from National registries[2] and more than 80% of the prostheses survive at 25 years follow-up.[3] The number of implants is projected to increase by 174% in the United States by 2030,[4] but the rise is much higher in emerging countries so that the worldwide number is projected to double within the next two decades.[3]

Despite the good results, a lot of variations have been introduced during the last few years in THA with the aim of further improving the outcome. When a new implant is proposed, the advantage of introducing such a new prosthesis to the market must be carefully evaluated. Anand et al, in an investigation performed at the Australian Joint Replacement Registry, found no benefit to the introduction of new prostheses into the market during a five-year study period. Moreover, they found that 30% of the new implants were associated with a significantly worse outcome compared with existing implants with a minimal duration of five years follow-up.[5] Nieuwenhuijse et al performed a systematic review of clinical trials, comparative observational studies and registry data on new orthopaedic devices. They concluded that "new technologies are being introduced to the commercial market without sufficiently high quality evidence for improved benefit over existing, well proven, and safe alternatives. Moreover, the existing devices may be safer to use in total hip and knee replacement".[6] There are devices, especially stems, with decades of successful results whilst many implants have been rapidly withdrawn from the market. The EFORT Ethical Committee recommends that "we should offer effective treatment based on the best available evidence".[7] Anyway the lesson learnt by the metal-on-metal THA experience have made all the stakeholders more careful in the introduction of hip implants onto the market and hopefully will enable safer innovation for patients, surgeons and manufacturers.[8]

Compared with the past, the focus of attention recently with advances has been more on the reduction of complications, minimisation of the costs and improvement of the patients satisfaction during the surgical journey.[9]

The main changes have regarded the indications, that have increased for both younger and older patients, the surgical techniques (approaches, tissue preservation and

reconstruction), some biomaterials, design and industrial finishing, the per-operative management (blood loss and pain control) and the post-operative protocols (the so called "fast track" surgery). Looking at all these advances the emerging question is: have all of them been justified both in terms of improvement of the results for the patients and of the cost/benefit ratio from an economical point of view?

Overview of advances in THA

What is justified?

Indications, patients' expectations and satisfaction

We observe an increasing number of younger patients requiring THA. The average age remains nearly the same, but the number of younger and older patients is rising. In our Department in the time period between 1984 and 1999 the mean age of the patients operated on for THA was 66 years (20 to 93) and the patients younger than 40 years were 1.1%. Between 2000 and 2010 the mean age remained the same (66 years; 18 to 89) while the younger than 40 years group rose up to 4.2%. This tendency has continued to increase: between 2010 and 2015 the mean age was 64 years (16 to 91), and those younger than 40 years were 5.4%. Social and cultural reasons are behind this phenomenon. Even very old patients who are healthy want to maintain a completely active daily life and ask for joint replacement at the age of 80 or 90 years. Very young people are not willing to wait for a well-functioning hip and do not accept the restrictions in everyday life. The theoretical so-called "new technologies" have made this opportunity possible, promising long-lasting excellent clinical results. But careful indications must be strictly followed as young age is associated with lower mortality and better functional outcome but also with a higher risk of revision at 8 to 15 years.[10] Also the increased risk of complications is 40% for every decade above the age of 65.[11] Only the future will reveal the answer to the question if these widened indications will increase the number of revisions in the future and if this is fully justified for the patients.

In any event, THA is a safe procedure. Patients have impaired long-term self-reported outcomes, they perform worse than the general population, but are much better than those with untreated arthritis.[12] The level of surgical satisfaction is high.[13] 7% of overall dissatisfaction is reported after THA which is a better satisfaction rate than with TKA.[14] Depression and symptomatic arthritis in another major joint are the main reasons for dissatisfaction. Post-operative functional scores, pain relief, and restoration of function are factors influencing the good outcome whilst a major complication is not a predictor of dissatisfaction. But the most relevant factor for satisfaction is the meeting of patients' expectations.[14] As a matter of fact unrealistic expectations are the main cause of dissatisfaction and health-care providers should do more to help their patients to develop realistic expectations about the impact of a TJR.[15] The creation of unrealistic expectations, the lack of information on the future and on the risks linked to an artificial joint and on the behaviours and activities that should be avoided after surgery, are the main "advance" which is not justifiable for the patient.

Length of stay, per-operative journey (anaesthesia and pain control, blood management)

The so called "fast track" surgery or better identified as "rapid recovery" is gaining in popularity. Length of stay (LOS) depends on: age, female sex, living alone, co-morbidity, pre-operative use of walking aids, lower pre- and post-operative haemoglobin levels, higher ASA scores, and the time between surgery and mobilisation.[16,17] The satisfaction is correlated with LOS and is improved by nursing, pain treatment and frequent doctors' rounds. The overall satisfaction is associated with increasing age, being married, low co-morbidities.[16] Patients are generally satisfied with fast track, THA patients more than TKA ones, but older patients with THA are the most satisfied.[18]

A dedicated staff, motivated and informed patients, post-operative pain control, careful and "less traumatic" surgical technique are requested for the purpose of reducing the period of hospitalisation and avoiding useless procedures and costs. Also, at the same time, they are important for improving the satisfaction of the patients and minimising the risks of complications. There are several factors influencing the compliance of the patient, but most important are the mental status and the understanding of the patient and the collaboration of the family. The main obstacles against the optimisation of recovery are cultural: the practice from the past when long recovery with rehabilitation was common, but also the surgeons that have to re-organise their routine slow down this process. Moreover, it is necessary to follow up the patients after the discharge in a safe way. From this point of view social and local organisation are very different in different European countries, but also in the same country. What is not justified is the introduction of rapid recovery or a "fast-track" procedure with a short LOS without a safe protocol and careful follow-up of the patients.

General anaesthesia is reported to have three times the risk of re-admission to hospital compared with spinal anaesthesia.[19] This confirms the advantages of epidural anesthesia versus general with less risk of complications including blood transfusion, stroke and cardiac arrest.[20] Moreover it reduces the post-operative pain and the drug dose in the first hours after operation. Apart from specific health contra-indications and with the consent of the

patients, the routine use of general anesthesia in standard primary THA is not justified nowadays.

The use of tranexamic acid has been very effective in minimising the need for blood transfusions following THA.[21,22] Its increasing use has almost eliminated the need for other blood conservation strategies such as erythropoietin administration, pre-operative autologous donation and intra- or post-operative blood salvation. There is still some debate on which is the better use, locally or generally administrated, whilst one demonstrates that there is no contra-indication for intravenous tranexamic acid in patients with a history of venous thromboembolism.[23] The use of tranexamic acid is nowadays strongly proposed, more than justified.

Surgical Approaches

“New” surgical approaches, mainly the direct anterior approach, have been widely promoted in the last few years. The promotion has been carried out by scientific, mass media and internet advertisement. There is no doubt about the good and comparable results to the other more traditional approaches with this technique in good hands. The question is what is really important in the surgical approach to the hip joint. The abductor muscle function must be preserved as if it is damaged, the outcome is poor and there is not a totally effective solution. The rate of complications must be acceptable, at least balanced with the supposed advantages. The approach should provide a good view of the anatomical landmarks for implant positioning, which is a key point for long-term implant survival, and should be suitable for different types of implants both cemented and cementless. The riskier scenario is when more parameters are changed at the same time: the approach, the technique, and the implant.

Spaans et al analysed their first 46 consecutive minimally invasive (MIS) anterior approaches matched *versus* 46 posterolateral.[24] They reported: longer operative time, higher blood loss, four intra-operative conversions to posterolateral, more complications and the same length of stay in hospital with no functional difference. They conclude that “the complication rate might be unacceptably high for surgeons with already low complication rates in standard THA”.[24] Higgins et al in a meta-analysis concluded that “current evidence comparing outcomes following anterior versus posterior THA does not demonstrate clear superiority of either approach. Until more rigorous, randomised evidence is available, we recommend choice of surgical approach for THA be based on patient characteristics, surgeon experience and surgeon and patient preference”.[25] Respect for the soft tissues, but mainly correct implant position is the most important issue when performing a THA and we need very good reasons to change approach and implant for our patients ... When we have good results in our practice this must be justified and needs a careful training process under the supervision of an expert surgeon.

Bearing options and femoral head size

There is limited evidence regarding comparative effectiveness of various hip implant bearings.[26] RCTs show similar short- to mid-term survivorship among ceramic-on-ceramic (CoC), ceramic-on-highly cross-linked polyethylene (XPE) and metal-on-XPE in patients younger than 65 years.[27] Standard polyethylene (PE), sterilised in Ethylene Oxide and with correct packaging, can show good clinical results even in the long-term.[28] Whilst in large datasets from registries[2] metal-on-conventional PE has a higher risk of revision compared with metal-on-XPE, registry data suggests that “Clinicians should consider the use of XPE when using a polyethylene bearing in THA”.[29] A minimum XPE thickness must be preserved as breakage of the XPE liners has been described especially in steep cups with elevated rims and poor locking mechanism.[30-33]

Ceramic heads are getting increasing popularity compared with metal heads due to trunnionosis reports at the level of the head-neck junction.[34,35] It is probably an overestimated problem, but it must be evaluated when considering the cause of failure of a THA.[36] Retrieval studies show that “by using a ceramic head, CoCr fretting and corrosion from the modular head-neck taper may be mitigated although not completely eliminated”[37] and metal release due to taper fretting and corrosion is reduced.[38] CoC is widely used in young active patients, mainly in some European countries and some centres inside countries.[39]

The answer to the question on which is the best option in young patients between CoC and ceramic (or metal) on XPE is still open and only long-term studies will establish the superiority of one bearing over the others. The infusion of vitamin E in XPE reduces oxidation *in vivo* with the aim of improving the mechanical strength of XPE. Even if attractive from a theoretical point of view, and promising early results have been shown with very low wear even for 36 mm heads,[40] it is necessary to have the confirmation of clinical studies as at the moment there is no evidence of different head penetration with E-poly analysed with radiostereometry.[41]

Head size depends on the bearing. For XPE the range should be from 28 mm to 36 mm in large acetabular cups with enough thickness of the XPE liner and for CoC from 32 mm to 36 mm with 40 mm heads only for selected cases of big acetabula with good thickness of the metal back. Anyway there is a lack of long-term analysis of cost-effectiveness on the use of different bearings. Long-term follow-up are requested, but at the moment we can conclude that the use of big metal-on-metal heads is clearly not justified[42] and has been abandoned by most surgeons,[43] CoC is not cost-effective in the older population,

but should be considered for young active patients and perhaps, at the same price, ceramic-on-XPE could be preferable to metal-on-XPE.

Type of fixation and design

Type of fixation. Huge differences still exist amongst countries in the rate of use of cemented and cementless fixation. In some regions the cemented stems were less than 4% in 2013,[39] in other countries they were more than 68% in the same year.[44] All around the world at the moment there is still a tendency toward the increase of the number of cementless fixation that is in contrast with registries and published data outcome[45] which do not justify this tendency.

There is a quite clear evidence that at least in patients that are 75 years or older cementless fixation has a significantly higher risk of revision compared with hybrid fixation[46] and data from the Finnish Arthroplasty Registry show how uncemented fixation is associated with an increased risk of revision without decreasing the mortality rate in octogenarians.[47] Perhaps in future, due also to the need of reducing costs, an increased use of cemented implants will be justified.

Short stems. The increased indications for THA in younger patients and the higher risk of revision at 8 to 15 years in this population[10] are good reasons for considering bone-preserving stems, able to transmit the load to the proximal femur, to avoid stress-shielding and thigh pain. Feyen and Shimmin in their instructional review on shortened stems comment that "the length of contemporary stems has been based on intuition and historical developments, rather than scientific evidence".[48] The short stem appears to allow a more anatomical reconstruction and thus a more balanced hip.[49] As a matter of fact short stems have substantial difference from one type to the other. Falez et al further developed a classification useful for comparing the different types of short stems.[50] Unfortunately, beyond the good theoretical basis, there is still a lack of data on short stems, and the quality of the currently available evidence is quite low. A high prevalence of stem misalignment, incorrect sizing, subsidence and intraoperative fractures is reported.[51,52] Moreover the more neck which is preserved the more the difficulties can be present in correcting deformities, especially in the case of major problems in controlling leg length, offset and anteversion.[53] Some short stems have already been withdrawn from the market .

Despite the favourable medium-term revision rate, there is still a lack of long-term studies. Clinical evidence from "collum stem" studies is limited. In a systematic review van Oldenrijk et al described how studies did not show a satisfactory overall survival rate, ". While a large number of observational studies on "partial collum" and "trochanter-sparing" stems, demonstrate adequate survival rates at medium-term follow-up".[52] Short stems with documented clinical results are justified, they need correct indications and careful surgical technique. The new ones as well as all new devices need a stepwise introduction.[54]

High porosity cups. Following some good results,[55] thanks to the properties of excellent primary stability due to the outer surface with great grip on the bone and the bone ingrowth capability of tantalum implants,[56] many other companies have been proposing their own products. High porosity titanium cups are not all the same.[57] They differ in technology, structure, pore size and open porosity. These different features can affect the elastic modulus, the mechanical strength, the friction co-efficient of the outer surface and the bone ingrowth capability.

Due to the higher costs and the great difficulty of removal of these implants in case of revision, for example in case of infection, they are probably only justified in revision surgery when poor bone contact and bone loss are major issues[58] or in cases of dysplastic hips or insufficient acetabula with poor bone.[59] The routine use of cups coated with hydroxyapatite is questionable at present.[60]

Computer-assisted navigation and robotics

Navigation and robotics have never played a major role in THA surgery. The reason is simple: while studies demonstrate that the precision of the acetabular cup placement is improved, decreasing the number of outliers, and that leg-length discrepancy is decreased,[61] on the other hand no significant differences in cup inclination, anteversion and incidence of post-operative dislocation as a mean value are demonstrated whilst there is an increased operative time (more than 20 minutes).[61] Other studies show controversial results: intra-operative fluoroscopy and imageless navigation seem equivalent in accuracy and precision to reconstruct leg-length and global and femoral offset,[62] but the acetabular component position tomography analyses were similar whether using the imageless navigation or performing it conventionally,[63] THA navigation does not improve mid-term functional outcome, bony ingrowth and polyethylene wear.[64] Robotic-arm assisted surgery is a promising technique that has improved accuracy in cup placement when compared with conventional surgery and possibly with computer-assisted surgery[65,66] with minimal intra-operative complications, however, whether the radiographic improvements will translate into clinical benefits for patients remains unproven.[67]

The recent reviews[68,69] agree that computer-navigation and even robotic-assisted surgery have disadvantages that may limit their routine use, including high costs and

longer surgery time. Randomised controlled studies with long-term follow-up and future research are needed to prove a cost-effective long term clinical benefit to patients. At the moment the use doesn't look justified in daily clinical practice outside of selected high volume and experienced centres, or for research purposes.

Prevention of complications

The prevention of complication justifies the use of "special" implants in the population at risk.

Even if there is a general tendency toward a decrease of dislocations following THA, it is still the second reason for revision at any time and the first reason for early re-operation.[2] Bigger heads (36 mm *vs* 28 mm) reduce the risk of dislocation.[70,71] Larger heads are more effective in the posterolateral approach,[72] but less in patients at high risk of dislocation or with muscular damage.[73] Dislocation is a multifactorial problem. In cases where one or more risk factors are present, dual mobility cups (DMC) have been a great advance in reducing the dislocation rate.[74] The DMC is not a new device,[75] but the advances are that the modern types of DMC with improved fixation to the bone are safe to use in younger patients.[76] The increasing indications for THA in the younger population anyway still needs a longer follow-up to fully justify the use in this cohort of patients at risk of failure for tribology reasons.

Modularity became a major issue in the last few years. Metal-backed liners and stem-head modularity are considered a standard for implant and nowadays no one will go back to monoblock implants out of all-poly cemented cups. Exchangeable necks have been proposed as a great advance in reconstruction of hip biomechanics. Since the results of the Australian Registry[2] on exchangeable necks compared to fixed ones were published, reporting double revision rate for the modular ones and several recalls from the companies[77], an international discussion around the topic has been going on. Titanium-to-titanium neck–stem taper junction has been reported with cases of fracture,[78] whilst cobalt-chromium-to-titanium has been described with fretting and corrosion at the neck-stem junction with typical adverse local tissue reactions.[79,80] In the last report from the Australian Registry,[2] when considering separately the exchangeable necks cobalt-chromium-to-titanium versus titanium-to-titanium, the latter has a much less revision rate compared with the first one, but still more than the fixed neck implants. Some surgeons and companies have developed guidelines for the safe use of exchangeable necks or modularity according to BMI, sex, level of activity and anatomical parameters. Probably, but still to be proven, this type of implant should be reserved for the cases when it is strictly necessary due to local anatomical abnormalities of the proximal femur as there is a "price" in terms of risk to be paid that must be justified.

Advances have been made in the diagnosis of infected THA as clearer diagnostic criteria and more reliable, even if not completely exhaustive, tests such as leukocyte esterase and alfa-defensin, are available in clinical practice to rule out infections.[81] Chlorhexidine skin disinfection has been reported as more effective in preventing surgical site infection compared to iodine-based agents.[82]

Conclusions

THA is a safe and cost-effective procedure. Great advances have been introduced in the last few years in terms of less invasive surgical procedures, tissue preservation, improved wear resistance of the materials, biocompatibility and bone ingrowth capability of the biomaterials, knowledge and restoration of the hip anatomy and function, perioperative management (pain control and blood loss) and prevention of complications. Especially in the case of new devices each advance must be justified both in terms of clinical benefit for the patient and of costs for the healthcare system. Moreover any supposed advance needs nowadays to be extensively proven as regards safety and security for the patient and for the system. What is "justified" should be based on changes which are safe and secure with well-proven advantages for the patient, with a wise progressive introduction of the novelties in clinical trials.

Many times the continued debate around implant fixation, bearing surfaces and approaches generates great emotion and tremendous tribal rivalries.[83] Professionalism, transparency, regularly review of our own practice by audit and scientifically-based willingness to change personal practice, are the ways to justify advances in our own surgery.

I would conclude the overview of this ICL with this advice from the EFORT Ethical Code: "there should be an end to the haphazard way in which new surgical techniques and products are introduced. Patients may be attracted by the latest trend before it has been properly tried and evaluated. The history of Orthopaedics is littered with widely different procedures which have proved of little value".[84]

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