Design Considerations for the Next Generation Hip Resurfacing Implant

Commentary

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Received: 7 September 2016/Accepted: 18 November 2016/Published online: 19 December 2016
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Abstract The current generation of hip resurfacing consists of a metal-on-metal ball and monoblock socket of minimal thickness. Although results in certain patient subgroups have been excellent at up to 15 years of follow-up, other subgroups have had poor results. The hard-on-hard bearing is susceptible to edge-loading conditions and may produce excessive metallic debris; furthermore, other patients have had allergic reactions to the metal byproducts. In both situations, there can be clinical failures from adverse local tissue reactions. As such, the role of hip resurfacing has diminished over the last decade because of these issues. Developing the next generation hip resurfacing is essential to address these problems, and there are multiple design considerations in doing so. The choice of materials will be of prime concern, with the decision to use a hard-on-soft or hard-on-hard articulation. The dimensions of the resurfacing implant also pose a challenge, because of the requirement to preserve the bone. Fixation of the implant is another area of interest, in order to maximize implant longevity.

Keywords hip resurfacing · hip arthroplasty · alternative bearings · implant design

Introduction

Hip resurfacing is an alternative to traditional total hip arthroplasty that involves the removal of the arthritic surfaces of the femoral head and acetabulum, and then implantation of two components to recreate the joint surfaces.

Because the amount of the bone removed is quite small, hip resurfacing allows for the preservation of the femoral bone, which is appealing in younger, active patients.

Since the implanted material matches the amount of removed bone, hip resurfacing implants are necessarily thin. The current generation of hip resurfacing implants is approximately 3-mm thick at both the acetabular and femoral sidewalls.

The current generation of hip resurfacing implants is metal-on-metal, which has been found to create problems in some patients because of excess production of metal debris or allergic reaction to the metal particles. As such, surgeons and patients are eager to use different materials in hip resurfacing, which could solve these problems.

History

Hip resurfacing, also known as surface arthroplasty of the hip, was first invented in the 1970s by Drs. Amstutz, Wagner, and Freeman [2]. Each of these surgeons came up with the concept independently, as an attempt to preserve the bone in younger patients requiring total hip arthroplasty. The concept was simple: preserve the bone on the femoral side, in order to preserve the option of a stemmed total hip replacement in the future.

The original hip resurfacing implants were made of a cemented, cobalt-chrome femoral head and a cemented, all-

Electronic supplementary material The online version of this article (doi:10.1007/s11420-016-9536-2) contains supplementary material, which is available to authorized users.

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polyethylene acetabular component [1]. Unfortunately, because the polyethylene component was necessarily thin to accommodate such a large femoral head, there was rapid volumetric wear. The rapid wear led to premature osteolysis, causing an early failure rate of 66% at 5 years [18]. As such, the procedure was largely abandoned due to material failure.

In the early 1990s, Derek McMinn applied the concept of a metal-on-metal (MOM) total hip arthroplasty to hip resurfacing [27]. He believed that a cobalt-chrome femoral head and socket could avoid the problems of polyethylene wear and osteolysis that plagued the prior generation of implants, while maintaining the thin geometry necessary for hip resurfacing. He based the metal-lurgy of the device upon that previously used in successful total hip replacements such as the Ring and McKee-Farrar prostheses [27].

After several years of experimenting with different fixation strategies, McMinn eventually settled upon a porous ingrowth acetabular component and a cemented femoral implant [27]. To date, McMinn and others have reported excellent results in patients up to 15 years [7, 8, 26, 32].

Problems with the Current Resurfacing Designs

In 2008, the Oxford group reported on a new finding in patients who had undergone MOM resurfacing—swelling and masses around the resurfaced joint, which they termed “pseudotumor” [28]. The patients who experienced pseudotumor often had pain and diminished function and required revision of their hip resurfacing, often with poor results.

Also coming to light at a similar time were reports of edge loading and metallosis involving hip resurfacing devices [10, 11, 22]. It was realized that the large diameter metal-on-metal bearing, while forgiving in position for dislocation, was very unforgiving with regard to wear. Thus, an overly vertical or anteverted socket could lead to the excess production of metal debris [24].

Furthermore, metal-on-metal joints must have precise machining and good design in order to achieve proper fluid-film lubrication, which is essential for the maintenance of low wear. Unfortunately, a widely used MOM total hip device, the Articular Surface Replacement (Johnson & Johnson, Warsaw, Indiana), was found to have multiple design flaws that led to accelerated wear and its eventual recall from the worldwide market [23].

Finally, it was also recognized that a minority of patients had an apparently immunological response to the metal debris within the joint, a histologic finding that was termed aseptic lymphocytic vasculitis-associated lesion (ALVAL) [9]. This response could also lead to soft-tissue masses, osteolysis, and component loosening.

These soft tissue reactions have been termed adverse local tissue reaction (ALTR) and adverse reaction to metal debris (ARMD). In analyzing factors for soft tissue reactions to hip resurfacing, female sex has been found to be a risk factor [13], and as such, few women are receiving hip resurfacing in 2016.

Design Considerations for the Next Generation Resurfacing Implant

One of the most important considerations in designing the next generation hip resurfacing implant is the thickness of the head and the socket; namely, the difference between the outer diameter of the acetabular component and the outer diameter of the femoral head. This is because it is directly related to the amount of the bone that must be removed in order to resurface the joint.

Presently, with MOM hip resurfacing, the differential between the socket and the head is 6 mm; hence, the acetabular component wall is 3-mm thick. To achieve a proper fit of the socket, without the excessive removal of the acetabular bone, the femoral head often has to be downsized from the native head size. A cadaveric study comparing the amount of bone removed from the acetabulum in a total hip vs. hip resurfacing found no difference when using this technique [31].

Because of the thinness requirement for the socket, it is currently a monoblock design. A modular design, where a liner would interlock with an outer substrate, would increase the thickness of the acetabular component.

It may be possible to increase the differential between the outer socket and head to 8 mm; however, any increase beyond that would likely violate the principles of bone preservation. Too large of a differential between the head and socket dimensions would result in either a poor head/neck ratio and even possibly neck notching or excessive removal of the acetabular bone.

Materials

In general, a bearing articulation can either be hard-on-soft or hard-on-hard, each of which has pros and cons. The benefit of a hard-on-hard articulation is that when fluid film lubrication is achieved, the wear rates can be extremely low. However, as has been realized with MOM bearings, a hard-on-hard articulation is more susceptible to problems when there is edge loading. Furthermore, it can be more at risk with impingement situations—for example, a ceramic-on-ceramic total hip arthroplasty (THA) can chip or fracture. Thus, a hard-on-hard articulation has to be installed more precisely to avoid edge loading and impingement. A hard-on-soft articulation, on the other hand, is more forgiving of these two scenarios. Although edge loading and impingement can still occur, the soft acetabular surface will likely deform and wear faster, but would not likely fail as catastrophically as a hard surface.

Given the problems surrounding the soft tissue response to MOM hip resurfacing, it is desirable to eliminate the generation of metal debris. In order to do so, a completely different material, such as ceramic, must be used to articulate against itself or the metal head must articulate against another, softer material such as polyethylene.

Highly cross-linked polyethylene (XLPE) has been in use in total hip arthroplasty for over a decade and appears to dramatically reduce polyethylene wear and osteolysis [12, 21]. Additionally, XLPE has been made thinner and thinner, in order to accommodate larger femoral ball size, without an apparent increase in linear wear [19, 20]. A metal ball and XLPE liner,

i.e., a hard-on-soft combination, would be attractive in the next generation resurfacing, as it would mitigate edge loading. Whereas a MOM joint with edge-loading produces excess metal debris, an edge-loaded XLPE acetabular implant might wear more quickly. However, the current literature demonstrates that edge-loaded XLPE appears to be quite forgiving. Edge-loading scenarios have also been tested in a simulator with XLPE and it appears to be much more resistant to wear than conventional PE [15]. In a resurfacing implant, with the dimensional restrictions to minimize bone loss, the XLPE may need to be as thin as 1–2 mm. This is a concern, of course, in terms of longevity when placed in young, active patients.

Ceramic-on-ceramic could be another material combination for the next generation resurfacing implant. Ceramic can be made into the requisite shape; however, concerns exist over the brittle nature of ceramic. With excessive edge loading, ceramic has been known to fracture [6]. Furthermore, the possibility of squeaking also exists. An early attempt at a ceramic-on-ceramic resurfacing implant resulted in fracture in all cases [25] and was abandoned. However, the newest generation of delta ceramics are more fracture resistant [4, 16] and could potentially be used for a resurfacing head and acetabulum.

Another consideration when designing a resurfacing implant is deformation upon implantation, particularly that of the socket. A hard-on-hard bearing requires a certain diametrical clearance in order to achieve fluid-film lubrication. What has been realized is that an acetabular socket can deform when implanted into the bone [5, 17], leading to an alteration in the diametrical clearance. This must be accommodated for in the design of the head and socket, so as to avoid equatorial seizing. This is relevant for a polyethylene socket as well, since the material is more flexible and will likely undergo more deformation than a harder bearing.

Future Materials

Oxidized zirconium (tradename oxinium™, Smith and Nephew, Memphis, TN) is a unique material also known as ceramicised metal. It is manufactured by infusing zirconium metal with oxygen under high temperatures and pressures, leading to a zirconium oxide outer layer of about 5-µm thick. Furthermore, there is a transitional layer between the zirconium oxide and zirconium metal of approximately 2 µm. The outer layer of ceramic gives it the hydrophilic nature and hardness of a ceramic ball, without the possibility of fracture. Oxidized zirconium, when coupled with XLPE, has had outstanding results in the Australian National Joint Registry [3].

There is the next generation of oxidized zirconium, termed Oxinium diffusion hardened (ODH). Through a proprietary process, the oxidized zirconium layer has been made more robust, with a thicker transitional layer (20 µm), leading to an even harder, more wear-resistant material [29]. This ODH material is now being tested against ODH liners in an investigational device exemption study.

ODH could potentially be used for the next generation resurfacing head, further eliminating cobalt-chrome from the system. It could be paired with XLPE or even itself, creating either a hard-on-soft or hard-on-hard articulation.

Fixation

Currently, the resurfacing acetabulum is press-fit, with an in-growth backside surface of either cobalt-chromium beads or titanium plasma spray. The challenge with the next generation resurfacing will be to apply a fixation surface to the new material. As the current resurfacing socket is monoblock, it is likely that the next generation will also have to be monoblock in order to avoid excessive thickness. There are currently monoblock PE and delta ceramic components in use in THR [30].

The femoral component of today's resurfacing is typically cemented. However, there have been uncemented, press-fit femoral components, which obviate the need for cement and theoretically could have greater longevity. One such implant has had excellent results in the midterm [14]. As the THA market has moved toward cementless fixation, it seems likely that so too will the resurfacing market.

Conclusion

The next generation of hip resurfacing implants must avoid the problems that have arisen with the current generation of MOM implants; namely, soft tissue reactions to the metal wear particles. On the other hand, results of MOM hip resurfacing have been excellent in certain patient subgroups, with 98% survivorship at 15 years, in men under the age of 65. It will be difficult for the next generation of implant to match these results! However, there have been significant problems in certain patients, such as smaller-sized women. Thus, the challenge is to match the good results of the current resurfacing implants and expand them to all patient groups. It may turn out that MOM hip resurfacing endures for larger, male patients and the next generation resurfacing is used for patients who might encounter problems with MOM hip resurfacing.

As previously discussed, there are several considerations in the design of the next generation resurfacing: bearing materials, implant thickness, and fixation. At this point, because of what has been learned with the current generation of implants, the next generation will be tested, using hip simulators, under conditions of impingement, edge loading, and deformation. That is to say, because a new hip resurfacing implant design will be highly scrutinized by regulatory agencies, surgeons, and patients alike, it will be subjected to a higher level of pre-clinical testing than any other previous resurfacing implant.

Compliance with Ethical Standards

Conflict of Interest: Edwin P. Su, MD reports personal fees from Smith and Nephew, Inc. outside the work.

Human/Animal Rights: This article does not contain any studies with human or animal subjects performed by the any of the authors.

Informed Consent: N/A

Required Author Forms Disclosure forms provided by the authors are available with the online version of this article.

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