Next-generation soft-tissue-friendly large-diameter femoral head

Kartik Mangudi Varadarajan, PhD*, Michael P. Duffy, MS, Thomas Zumbrunn, MS, David Chan, BS, Keith Wannomae, BS, Brad Micheli, BS, Andrew A. Freiberg, MD, Harry E. Rubash, MD, Henrik Malchau, MD, PhD, and Orhun K. Muratoglu, PhD

Department of Orthopedic Surgery, Massachusetts General Hospital, Boston, MA

Abstract

Large-diameter femoral heads are being used increasingly in total hip arthroplasty (THA) to minimize dislocation risk. However, recent studies have shown that conventional large heads can impinge on native soft tissues, particularly the iliopsoas, leading to activity-limiting anterior hip pain. To address this, a novel soft-tissue-friendly anatomically contoured femoral head (ACH) was developed. This paper describes the design rationale and pre-clinical testing of the ACH implant. The test results demonstrate that anatomical contouring of large-diameter femoral heads for soft-tissue relief can be accomplished without affecting dislocation resistance, femoroacetabular contact area, or wear performance in ceramic-on-polyethylene implants.

1. The clinical need

Over the last decade, the use of large-diameter femoral heads to minimize dislocation risk in total hip arthroplasty (THA) has been growing at a rapid rate. For example, the use of 36 mm and greater diameter ceramic heads increased 10-fold from 2003 (4%) to 2013 (43%). (Data on file with CeramTec.) National Joint Registry data from England and Wales during the 5-year period from 2005 to 2009 showed a five-fold increase in the use of 36 mm and greater diameter femoral heads (5% in 2005 to 26% in 2009) [1]. Reduction in dislocation risk with large-diameter heads has been reported in numerous clinical and biomechanical studies. For example, Lombardi et al. [2] reported a 0.05% dislocation rate in primary THA with 36 mm and greater diameter femoral heads, compared to 0.8% dislocation rate in a previous study utilizing smaller-diameter heads. In revision THA, Garbuz et al. [3] reported a 1.1% dislocation rate with 36- and 40-mm heads, compared to 8.7% dislocation rate with 32-mm heads.

Despite the benefit of improved stability, one of the concerns regarding the use of large femoral heads is the potential for impingement against native soft tissues such as the anterior hip capsule and the iliopsoas muscle/tendon, leading to anterior hip pain (or groin pain). The reported incidence of anterior hip pain following THA ranges from about 0.4% to 18% and commonly occurs during activities such as getting out of a chair or a car [4]. The pain may also be reproduced by active leg raising, resisted flexion, and with external hip rotation or hip extension [5]. The iliopsoas in particular is susceptible to impingement due to its close proximity to the hip joint.

*Address reprint requests to Kartik Manhudi Varadarajan, PhD, 55 Fruit St, GRI-1223, Massachusetts General Hospital, Boston, MA 02114.

E-mail address: kmangudivaradarajan@partners.org (K.M. Varadarajan).

1045-4527/$ - see front matter © 2014 Elsevier Inc. All rights reserved.
http://dx.doi.org/10.1053/j.sart.2014.01.007
Proximally, the iliopsoas articulates with the iliopsoas notch (acetabular margin) on the pelvis and the anterior surface of the native femoral head. Distally the iliopsoas wraps around the femoral head near the femoral head-neck junction before inserting into the lesser trochanter. In a cadaver study, Yoshio et al. [6] showed that the iliopsoas articulates against the native femoral head at flexion angles below 45° (Fig. 1). They also measured peak tension in the iliopsoas muscle and peak contact pressures between the femoral head and the iliopsoas between 0° and 30° of hip flexion [6]. Consequently, while anterior hip pain following THA can occur due to impingement of soft tissues with a prominent prosthetic acetabular rim, it can also occur from soft-tissue impingement with large-diameter femoral head prosthesis.

Bartelt et al. [7] reported a significantly higher rate of groin pain in patients with large-diameter metal-on-metal and hip resurfacing implants compared to those with conventional THA (15–18% vs. 7%). They postulated that this may be related to greater impingement of the iliopsoas with the large-diameter femoral heads. Browne et al. [8] documented severe groin pain resulting from iliopsoas and capsular impingement with the prosthetic femoral head in patients with large metal-on-metal implants. The symptoms were successfully treated with release of the iliopsoas and downsizing of the femoral head. Baumgarten et al. [9] documented the occurrence of groin pain related to iliopsoas impingement with the large femoral head in conventional THA. Pain related to iliopsoas impingement may be treated with release of the iliopsoas tendon, downsizing of femoral head, and steroid injections [4,8,9]. However, release of iliopsoas tendon can result in significant compromise of joint function since the iliopsoas is the dominant flexor of the hip joint. Downsizing of the femoral head can mitigate soft tissue impingement, but it re-introduces

Figure 1 – (A) Left hip from cadaver specimen with superficial soft tissues removed to show iliopsoas muscle and tendon. The iliopsoas travels anteriorly over the femoral head and wraps around the distal femoral head prior to inserting on the lesser trochanter. (B) Sagittal image of a cadaver hip from study by Yoshio et al. showing the iliopsoas tendon articulating with femoral head (P = pelvis, F = femur, arrow indicates iliopsoas femoral head contact). (Adapted with permission from Yoshio et al. [6].) (Color version of figure appears online.)

Figure 2 – (A) Geometric comparison of a conventional large-diameter femoral head and the new anatomically contoured head (ACH). (B) A 36-mm ceramic ACH and a 36-mm ceramic conventional head. (Color version of figure appears online.)
the increased risk of hip dislocation. Steroid injections provide only short-term pain relief and are ineffective in the treatment of severe cases. Thus, there is a significant clinical need for next-generation large-diameter femoral head implants that can reduce the risk of soft-tissue impingement while retaining the benefits of increased joint stability.

To address this, a new soft-tissue-friendly anatomically contoured head (ACH) was developed (Fig. 2). In this paper we describe the design rationale and pre-clinical testing of this novel implant. The hypothesis was that anatomical contouring of the femoral head for soft-tissue relief could be achieved without affecting mechanical performance. This was verified via: (i) dynamic simulations of hip joint dislocation, (ii) finite element analysis of femoroacetabular contact area, and (iii) wear study using hip joint simulator.

2. Design rationale

Conventional large-diameter femoral heads have a spherical articular surface with a constant angular extent ($\beta_{\text{conv}}$) of about 120° (Figs. 2 and 3). In contrast, the native femoral head articular surface has a variable angular extent ($\beta$) at different locations around the femoral neck axis (Fig. 3) [10]. At the anterior-most and posterior-most margins, the angular extent of the native femoral articular surface is about 120°. However, at the distal-medial and proximal-lateral margins, the angular extent of the native femoral articular surface is only about 100°. Therefore, conventional large-diameter femoral heads can overhang beyond the native margin in the shaded region shown in Figure 3. The iliopsoas wraps around the distal portion of the native femoral head-neck junction before inserting into the lesser trochanter (Fig. 1). Consequently, the distal-medial portions of the conventional large-diameter femoral heads can impinge on the iliopsoas. This impingement may be further exacerbated by alteration in soft-tissue tension and the iliopsoas muscle pathway following THA [11]. Such alterations may result from variations in hip joint center, femoral offset, capsular excision etc [11–13]. Hence, even large femoral heads not matching the native head size have potential to cause anterior hip pain [11].

To address the anatomical mismatch and concerns regarding anterior hip pain with conventional implants, a new soft-tissue-friendly anatomically contoured head was developed (Fig. 2). In the ACH implant, the large-diameter profile of a conventional implant is retained in the hemispherical portion above the equator (towards the apex). However, the distal portion of the femoral head below the equator is contoured using a smaller radius to reduce the volume of material exposed to the soft tissue and to provide a smooth transition from the articular surface to the femoral head–neck junction. This reduces the potential for impingement and irritation of soft tissues such as the iliopsoas. The transition from the contoured to the non-contoured region in the ACH implant is marked by the angle $\theta$ ($\theta$~90°, Figs. 2 and 3). The impact of such anatomical contouring on dislocation resistance, femoroacetabular contact area, and wear performance was evaluated via tests described in the next section.

3. Methods

3.1. Resistance to hip dislocation

The impact of anatomical contouring on hip joint stability was evaluated by simulating dynamic hip dislocations in a multi-body simulation software (MSC Adams, Newport Beach, CA). A 36-mm ACH, a 36-mm conventional head, and a 28-mm conventional head were tested under two dislocation modes: (A) Posterior dislocation (at 90° hip flexion) with internal hip rotation and a posterosuperior directed joint force applied to the femoral head center as described by Kluess et al. [14]. (B) Posterior dislocation (starting at 90° hip flexion) with combined hip flexion and adduction and a posteromedial force direction as described by Nadzadi et al. [15]. Impingement-free motion (motion without neck impingement against acetabular liner) and jump distance (head center displacement from the acetabular liner rotation center prior to imminent dislocation) were measured (Fig. 4). The
acetabular cup and femoral components were placed in a nominal position (acetabular cup: 42° abduction, 20° of anteversion; femoral component: 10° anteversion).

3.2. Femoroacetabular contact area

To assess the femoroacetabular contact area, a finite element analysis (FEA) was completed with a 36-mm diameter conventional head and a 36-mm diameter ACH implant. To simulate a worst-case design, a more aggressively contoured version of the ACH implant was used in the FEA. The FEA model included a rigid acetabular shell, plastically deformable UHMWPE acetabular liner, rigid femoral head, and rigid femoral stem. The femoral stem was placed at 0°, 10°, and 20° of anteversion. The acetabular shell and liner were placed in 20°, 40°, and 60° of abduction and 0°, 20°, and 40° of anteversion. The femoral head to acetabular liner radial clearances modeled were 0.06, 0.13, and 0.5 mm. Three loading cases corresponding to peak in vivo loads during walking, chair sit, and deep-knee bend were analyzed [16]. This allowed the study of a range of component positions, manufacturing tolerances, and joint loads during different daily activities.

3.3. Wear performance

ACH and conventional head wear characteristics were assessed with an AMTI 12-station hip simulator test according to ISO 14242-1. Acetabular liners with a 36-mm inner diameter were manufactured from two UHMWPE stocks: (1)
Conventional PE liners from compression-molded GUR 1020 UHMWPE, and (2) VitE-PE liners from 0.1 wt.% Vitamin E-blended GUR 1020 UHMWPE that was e-beam irradiated to 120 kGy at 100°C. All liners were EtO sterilized prior to testing. Three acetabular liners from both material groups articulated against a conventional head and an ACH creating four head-liner groupings. Two additional liners and heads for each head-liner group served as load-soak components to account for fluid absorption. Testing was carried out to a total of 2 million cycles (MC) of simulated gait. Every 0.5 MC interval of simulated gait, liners were cleaned and weighed per ISO 14242-2 in order to gravimetrically assess wear. Wear rate in milligrams per million cycles (mg/MC) was calculated as the linear regression slope of the data.

4. Results

4.1. Resistance to hip dislocation

The dislocation analysis did not show any differences between the 36 mm ACH implant and the conventional 36 mm head (Figs. 5 and 6). The 36 mm ACH and conventional head showed greater impingement-free motion compared to the 28-mm conventional head, with an increase of 7.0° for dislocation mode A and 4.3° for mode B. Similarly, relative to the 28-mm conventional head, the jump distance for the 36-mm ACH and the 36-mm conventional head was increased by 1.6-mm for dislocation mode A and 2.2-mm for dislocation mode B.

4.2. Femoroacetabular contact area

Under all FEA contact simulations, there was no difference between the ACH and conventional head implants (Figs. 7 and 8). The contact area was calculated as the area on the acetabular liner supporting load as determined by the contact pressure. The contact area for both prostheses depended on the radial clearance between the head and the liner (Fig. 8). The average contact area (standard deviation) across all activities and component positions for the conventional head for 0.5, 0.13, and 0.06 mm of radial clearance was 230.5 (70.2) mm², 419.8 (48.7) mm², and 575.4 (60.1) mm², respectively. Similarly, the average contact area across all activities and component positions for the ACH were 230.5 (70.4) mm², 420.1 (48.7) mm², and 575.9 (59.4) mm². A student t-test (P = 0.05) confirmed that the ACH had the same contact area as the conventional head for all radial clearances and component positions.

4.3. Wear performance

Based on 2 MC of wear testing, the linear wear rate of the Conventional PE liners articulating against ceramic conventional head and ACH was 21.4 (4.1) mg/MC and 20.8 (4.2) mg/MC, respectively (Fig. 9). The linear wear rate of the VitE-PE

Figure 6 – Impingement-free motion of each prosthesis for dislocation mode A and B. There is no difference between the 36 mm ACH and the 36 mm conventional head. (Color version of figure appears online.)

Figure 7 – Contact pressure of liner from gait cycle loading with cup at 40° abduction and 20° anteversion. Femoral stem was at 0° anteversion. Maximum contact pressure shown is 8 MPa. (Color version of figure appears online.)
liners articulating against conventional head and ACH was \(-2.5\) (1.6) mg/MC and \(-1.1\) (0.7) mg/MC, respectively. The “negative” wear rates for the VitE-PE liners indicate very low wear rates and weight gain due to fluid absorption.

5. Discussion

While large-diameter heads offer the benefit of increased resistance to hip dislocation [2,3], recent clinical studies also show increased potential for anterior hip pain related to iliopsoas impingement [6–10]. Today, this is particularly relevant due to the growing use of large-diameter heads [2], and poses a significant clinical need for next-generation large-diameter heads that can mitigate the risk of soft-tissue impingement while maintaining increased joint stability. This paper describes a new anatomically contoured femoral head designed to address this clinical need. Preclinical tests were conducted to verify the impact of the soft-tissue-friendly design on dislocation resistance, femoroacetabular contact area, and wear performance in ceramic-on-polyethylene articulation.

During the simulated dislocation tests the ACH implant showed increased dislocation resistance compared to a conventional small-diameter head, while matching the stability of a conventional large head of the same size. This is because, at the point of imminent dislocation, the ACH and conventional large heads contact the acetabular rim above the equator where both implants have identical geometries. These dislocation simulations consider only the joint stability provided by the implants and consequently represent the worst-case scenario.

The FEA study of femoroacetabular contact areas included various radial clearances and component orientations to account for variations in prostheses design, manufacturing tolerances, and surgical placement. The FEA showed no differences in femoroacetabular contact area between the ACH implant and the conventional head articulating against UHMWPE liner. Although not evaluated herein, similar results are expected with ceramic-on-ceramic articulations. This is because the stiffer material combination of ceramic-on-ceramic articulation is expected to produce smaller femoroacetabular contact area that is closer to the joint load vector near the apex/pole of the femoral head and thus farther from the location of anatomical contouring.

The wear test results reinforced the findings of the FEA and showed no difference in the wear rates of ceramic ACH implants and conventional ceramic heads articulating against conventional UHMWPE liners or VitE-stabilized highly cross-linked UHMWPE liners. The “negative” wear rate of the VitE-PE liners was due to the extremely low wear rates coupled with increased fluid absorption in the wear samples, which experienced both relative motion and loads, compared to the load-soak liners, which experienced joint loads only [17]. It is to be noted that the wear data reported herein is based on 2 MC of testing. Typically, in hard-on-soft articulation, the first 0.5 MC is considered the

Figure 8 – Femoroacetabular contact area (average of all component alignments) for different simulated activities and different femoral head-liner clearances. (Color version of figure appears online.)

Weight Change of Acetabular Liners From Simulated Gait

Figure 9 – Wear of conventional non-contoured head (Conv. Head) and anatomically contoured femoral heads (ACH) against conventional PE liners (Conv. PE) and vitE-stabilized highly cross-linked PE liners (vitE-PE). (Color version of figure appears online.)
running-in period, and thereafter the wear volume increases linearly and wear rate remains constant [18]. Therefore, the hip simulator testing up to 2 MC, with three consistent readings at 1 MC, 1.5 MC, and 2 MC, was considered sufficient for this initial study. Future studies will evaluate wear performance over extended duty cycles, as well as wear performance of the ACH implant in ceramic-on-ceramic articulation.

In addition to wear, femoroacetabular friction is another important tribological parameter. While not discussed herein, preliminary tests conducted on a pendulum comparator showed that the ACH implant may provide additional benefits of reduced frictional torque in ceramic-on-ceramic articulation. In these tests, 36-mm ACH heads articulating against ceramic liners showed a 12–19% increase in the number of pendulum swings compared to 36-mm conventional ceramic heads articulating against the same ceramic liners. This additional potential benefit of the ACH design is under further investigation.

6. Conclusions

The anatomically contoured femoral head is a next-generation large-diameter femoral head designed to mitigate the risk for soft-tissue impingement with contemporary implants while retaining their benefits of increased joint stability. Conventional large-diameter heads do not match the native femoral articular extent, leading to potential for soft-tissue (e.g., iliopsoas) impingement with the distal portion of the head. This is addressed in the ACH implant by retaining the large-diameter profile of conventional implant above the equator while contouring the distal portion below the equator using a smaller radius. This contouring reduces the volume of material exposed to the soft tissues and provides a smooth transition from the articular surface to the femoral head to the femoral head-neck junction, thereby reducing potential for impingement and irritation of the soft tissues. Pre-clinical testing of the ACH implant showed that the soft-tissue-friendly design does not affect dislocation resistance, femoroacetabular contact area, or wear performance in ceramic-on-polyethylene articulation.

REFERENCES


