УДК 616.728.2-089.843(045)=111

Anatomical large femoral heads: early complications and mid term results

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Purpose: mechanical complications such as malrestoration of hip anatomy still impede surgical results and patient satisfaction after THA. Anatomical femoral «mega-heads» are a novel approach which enables a surgeon to use a large diameter metal on metal implant to restore hip anatomy. Ability to place femoral head eccentrically on the femoral taper results in possible anteversion, retroversion, offset and lengthening. Our hypothesis is that use of this device will result in more accurate anatomical restoration and clinical results. Methods: 64 anatomical mega-head arthroplasties were evaluated. Preoperative planning was done in order to determine the desired position of the head, restore the anatomy and avoid leg lengthening. Patients were observed at an average of 50-months for both subjective and objective outcomes. Radiograph analysis assessed anatomical restoration. Results: 51 of the 64 hips were available for follow up. In 35 the head was placed eccentrically. In 20 the positioning was inferior, 6 — posterior, 3 — anterior, 1 — superior, and 4 inferior and posterior. Harris Hip and SF-36 scores improved significantly (P < 0.001). Mean radiographic limb and offset discrepancy were 0.1 and 0.01mm respectively. Six patients (11.7 %) underwent revision surgery; elevated metal ion levels and pseudotumor (3), acetabular component loosening (2), and unexplained hip pain (1). Conclusions: The novel anatomical femoral mega-head allows versatility in restoration of normal hip anatomy. Mid-term follow-up showed a higher than anticipated rate of complications for this cup design and reduced longevity of the implant. Novel ways need to be explored to allow such versatility in restoring hip anatomy. Key words: total hip arthroplasty, anatomical large head, anatomical center of rotation, mega-head, mid term results.

Цель: неадекватное восстановление анатомии тазобедренного сустава (ТБС) негативно влияет на результаты тотального эндопротезирования. Использование анатомических мегаголовок бедренной кости в паре трения «металл-металл» является новым подходом, позволяющим восстановить анатомию ТБС. Расположение головки бедренной кости эксцентрично на конусе бедра с уменьшающимся сечением приводит к возможности антеверсии, ретроверсии, офсет и удлинению. Предполагаем, что применение такого устройства обеспечит более точное восстановление анатомии ТБС и улучшит клинические результаты. Методы: оценены объективные и субъективные результаты 64 операций эндопротезирования с применением анатомических мегаголовок в среднем в течение 50 мес. Перед операцией определяли необходимое положение головки, восстановление анатомии и избежание удлинения конечности. Результаты: в динамике проанализировали 51 из 64 прооперированных суставов. В 35 случаях головка располагалась эксцентрично,в 20 – книзу, в 6 – кзади, в 3 — кпереди, в 1 — кверху, в 4 — книзу и кзади. Отмечено значительное улучшение показателей шкалы Harris'a для ТБС и SF-36 (P < 0,001). Средние показатели рентгенологических различий конечностей и офсет были 0,1 и 0,01 мм соответственно. У 6 пациентов (11,7 %) выполнено ревизионное хирургическое вмешательство: у 3 больных выявлен повышенный уровень содержания ионов железа и псевдоопухоль, у 2 — расшатывание вертлужного компонента, у 1 — боли в ТБС. Выводы: новые анатомические мегаголовки бедренной кости обеспечивают универсальность в восстановлении анатомии ТБС. Промежуточные результаты свидетельствуют о более высоком, по сравнению с предполагаемым, уровне осложнений для данного дизайна головки и сниженной долговечности имплантата. Необходим поиск новых путей для получения универсальности восстановления анатомии ТБС. Ключевые слова: тотальное эндопротезирование тазобедренного сустава, анатомически большая головка, анатомический центр ротации, промежуточные результаты.

Key words: total hip arthroplasty; anatomical large head; anatomical center of rotation; mega-head; mid term results

Introduction

One of the major challenges in performing a Total Hip Arthroplasty is restoration of native hip anatomy for better surgical results. Complications, such as dislocations (occur in about 3 % of cases), postoperative fractures (1 % of cases), leg length inequality (symptomatic in up to 27 % in some series), abductor mechanism weakness and device failure can be attributed in part to inaccurate restoration of native hip anatomy [1–3].

Human hip has great anatomical variability regarding size, version, neck length, valgus/varus position and offset [4]. Each prosthesis design has a different degree of freedom in fitting a specific anatomy — different sizes, different neck lengths, standard vs. high offset design. Modularity was utilized to conform further characteristics of the femur, but there were reports of failure at the interface between the different modular parts [5–7]. Methods to increase accuracy of cuts and implant positioning, such as pre-op planning (digital/manual templating), intra-operative measurements and navigational techniques are combined as well as surgical technique (e.g. level of osteotomy and version determination by angle of insertion into the femur) all play a crucial role [8]. However those options do not always suffice and may lead to a sub-optimal result due to patient's specific anatomy. Attention to each of the anatomical variables is essential. The global offset is the sum of the femoral offset and the lateralization of the hip's center of rotation, and its preservation allows restoration of the abducting musculature and the lever arm, increased stability and range of motion and decreased wear [9]. Version refers to the orientation of the neck in reference to the coronal plane of the femur and is denoted as ante, neutral or retroversion and its restoration is essential in achieving stability [10]. Leg length inequality over 1 cm can cause patient discomfort and dissatisfaction, and lengthening of over 2 cm may increase the risk of sciatic nerve palsy [11, 12]. Short neck lengths requiring low femoral neck osteotomies can cause early loosening and fractures.

The anatomical femoral mega-head is a novel approach (DePuy Synthes, Warsaw, Indiana, USA), which enables a surgeon to replicate normal anatomy of each hip and increase versatility during surgery. Owing to large head size, the head can be placed eccentrically over the taper in any direction, each resulting in a specific change in biomechanics (Fig. 1). Displacing the head to the anterior or posterior direction causes change in ante or retro-version, with displacement limited by the head size (range ±10 degrees). When applying the eccentric displacement to the inferior or superior position the result is a change in offset and in limb length (table 1). The anatomical large head can also be set with greater neck length. Digital preoperative planning on Anteroposterior and Axial radiographs

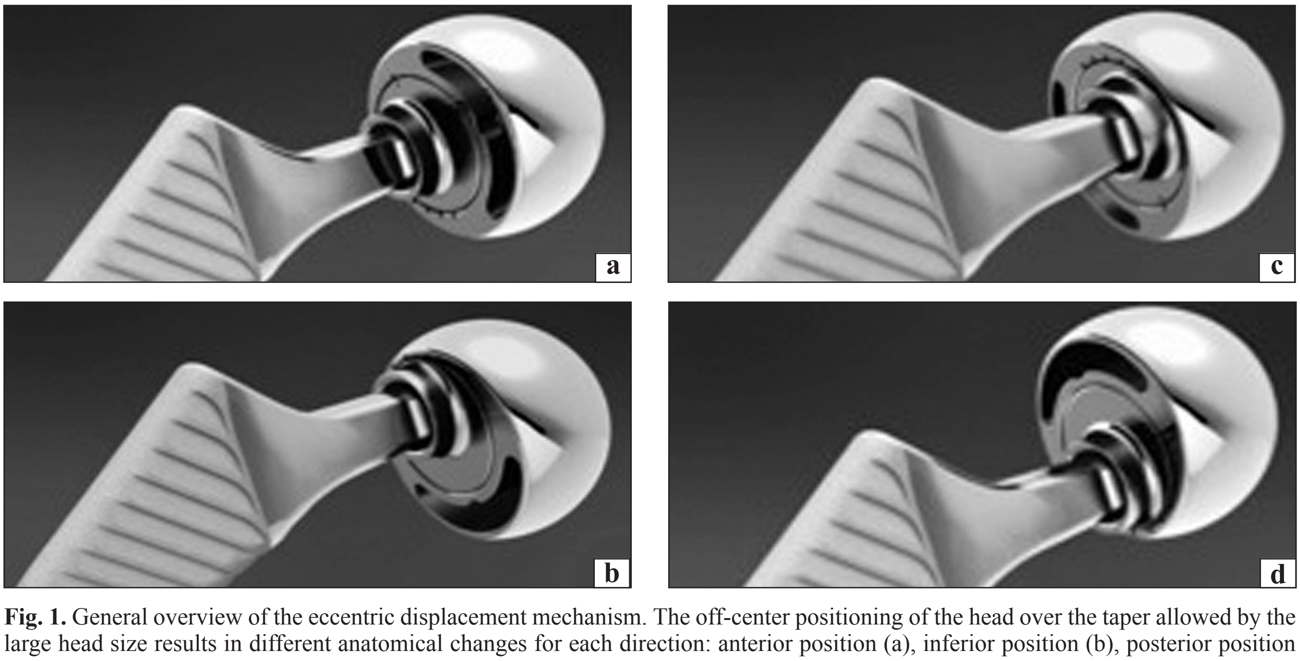

Fig. 1. General overview of the eccentric displacement mechanism. The off-center positioning of the head over the taper allowed by the large head size results in different anatomical changes for each direction: anterior position (a), inferior position (b), posterior position (c), superior position (d)

Table 1

Versatility of the anatomical femoral mega-head and the resulting anatomical changes

Head Size	Direction of displacement	Maximal displacement (mm)	Resulting change in joint anatomy per 1mm	Range
Up to 45 mm	Anterior/ posterior	4	1.3–1.5º change in version	± 5º
	Superior	7	0.7 mm in offset	± 5.6 mm
	Inferior	11		
46 mm and larger	Anterior/ posterior	8	1.3–1.5º change in version	± 10º
	Superior	11	0.7 mm in offset	± 9.1 mm
	Inferior	15		

Note. Different head sizes offer different ranges for implant versatility, which also differ in the range for different directions. The distance of off-center displacement is translated into changes in the resulting anatomy.

is done in order to determine the desired position of the head for optimal anatomical restoration, with intra operative measurements and modifications to achieve the best result. Moving the taper from the center of the head is made possible by the large head size. The use of metal on metal implants offered a few theoretical advantages — elimination of the Polyethylene liner wear, increased stability due to increased head size and range of motion [13–15]. However, as clinical experience grew, new problems appeared. Elevated blood metal ion levels, local tissue responses to metal debris, and unacceptable rates of failure, eventually leading to discontinuing of further use for several implants [16–18], as well as the evolving field of taper neck trunionosis [19, 20].

The possible advantage of this system is its versatility and ability to restore precisely the anatomy of the native hip, especially addressing extreme variations (varus, valgus and extremely short/long neck hips), thus reducing complications deriving from the mechanical changes in the joint — leg length discrepancy, muscle strength, dislocations etc [21–23]. The versatility is obtained without use of a modular neck system, which may increase the risk of hardware failure at the modular junction and modular taper neck trunionosis [5, 6].

The aims of the study were to investigate short to mid-term safety and longevity of the prosthesis, as implied by rate and cause of failures, to assess the anatomical restoration achieved as compared to the native contra-lateral hip and resulting surgical outcomes as assessed by the common validated methods used for hip arthroplasty [24, 25].

Material and methods

This study is a cross sectional prospective case series of total hip arthroplasty patients using a novel device. The study protocol was approved by the institutional review board and all patients signed informed consent before participating. Between the years 2006 and 2009, 64 total hip arthroplasties for 61 patients using the anatomical large head (Depuy Synthes, Warsaw, Indiana, USA) were performed by a single surgeon (S.D.) at two institutions. The inclusion criteria were derived from pre-op planning using the TraumaCad® software (version 2.3, Voyant Health, PetachTikva, Israel) (Fig. 2). The implant was chosen specifically

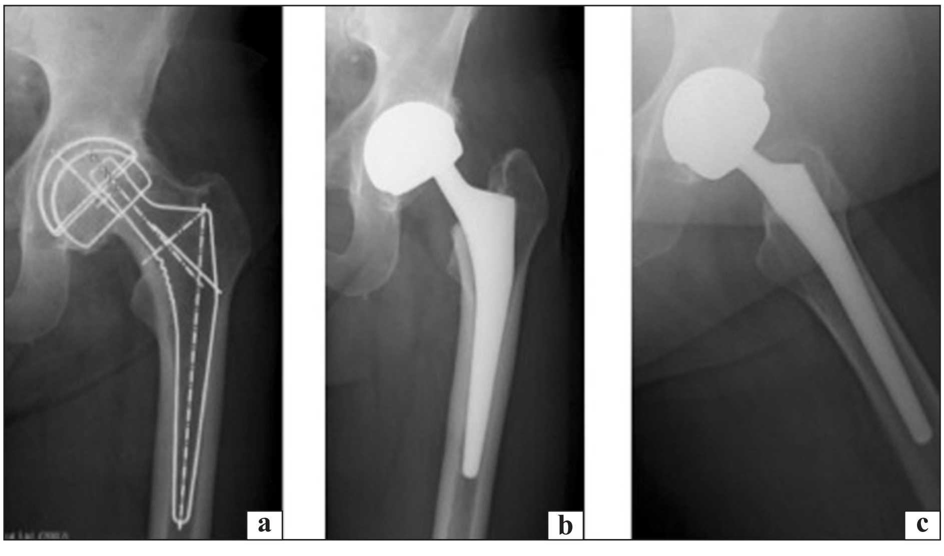

Fig. 2. Pre-operative planning and post-operative imaging: a) pre-operative planning on antero-posterior imaging of a patient with extreme varus alignment of the hip; b) post-operative antero-posterior X-rays demonstrating posterior eccentric positioning chosen to increase offset; c) axial post-operative X-rays showing anterior positioning intended to increase anteversion and stability

Table 2

Patient demographics

Patient Factor	Number (range)
Age (range)	62.8 (26–88)
Male	13
Female	35
Bilateral Procedures	3
Total Procedures	51
Follow-up time (months)	33.6 (14–63)
Diagnosis	
Primary Osteoarthritis	42
Osteonecrosis	4
Developmental Dysplasia	5

Note. Patient population characteristics.

Table 3

Surgical data for the cohort

Operation side (Rt/Lt/Bil)	23/22/3
Surgical Approach: – Antero-Lateral – Postero-Lateral	 43 8
Femoral Head Size (mm)	45.8 (43–47)
Acetabular Implant Size (mm)	50.8 (46–58)
Lateralized/Non Lateralized Stems	19/32

Note. The surgical variants in the cohort, including surgical approaches, implant sizes and positions, not including the eccentric displacement unique to the mega-head.

for cases in which preoperative planning suggested that usage of other available prosthesis would result in inadequate anatomical restoration — i.e. 1. Leg length discrepancy, 2. Insufficient restoration of offset, 3. The need for a very low neck osteotomy, 4. Inability to lateralize a high offset stem due to small femur size. Examples of anatomical variations encountered were extreme varus or valgus positions of the native hip and extremely short femoral necks. Patients included in the study were a consecutive cohort where the anatomical head implant was used.

51 of the hips (48 patients) were available for follow-up and were included in the final cohort (table 2). 13 patients were lost to follow-up. Three patients passed away due to reasons unrelated to the surgery, none of them had previously reported dissatisfaction with the results of the surgery. Mean age was 62.6 years (range 26–88 years), 38 patients were female (79.1 %) and the mean follow up time was 50 months (range 14–89 months). Three patients had bilateral staged arthroplasties. Most patients were operated on due to primary osteoarthritis (42 patients, 82.3 %), followed by avascular necrosis (5 patients, 9.8 %) and developmental dysplasia of the hip (4 patients, 7.8 %).

43 operations were performed using the posterior approach (84.3 %) and the rest using the anterior-lateral approach (table 3). The acetabular shell used was the cementless ASR XL component (Articular Surface Replacement, Depuy Synthes, Warsaw, Indiana, USA) with cup sizes 46–58 mm (average 50.8), all cups were press fitted. Corail's cementless femoral stems (Depuy Synthes, Warsaw, Indiana, USA) [sizes 8–14 (avg. 11.1)] were used, with 19 (37.2 %) employing lateralized stems. The heads used were Anatomical femoral large heads (Depuy Synthes, Warsaw, Indiana, USA) made from cast Cobalt Chrome alloy (as with previous ASR heads), with sizes used ranging 43–47 mm (median 45 mm). No bone grafts were used for any of the procedures. All patients received standard and identical infection and DVT prophylaxis and post-op rehabilitation regiment.

Patients were assessed clinically and radiographically. Follow-up visits with recent antero-posterior and axial radiographs were made at 6 weeks, 3 months, 6 months, 1 year, and yearly thereafter. Radiographs were examined by 3 of the authors, and were assessed for signs of wear, osteolysis, loosening (including radiolucent lines, subsidence, implant migration and change of position), heterotopic ossification (stratified using the Brooker Criteria), acetabular coverage and increased cup inclination [26]. Anatomical restoration was measured on the antero-posterior radiographs and was compared to the contralateral hip. In staged procedures, pre-operative planning and anatomical restoration was done compared to the first operation. The parameters measured were leg length difference and global offset using bony landmarks in previously mentioned techniques [9, 27, 28]. Leg length was measured as the distance from the proximal/distal tip of the lesser trochanter to a line going through the distal tips of the lower pubic rami and the offset was measured as the distance

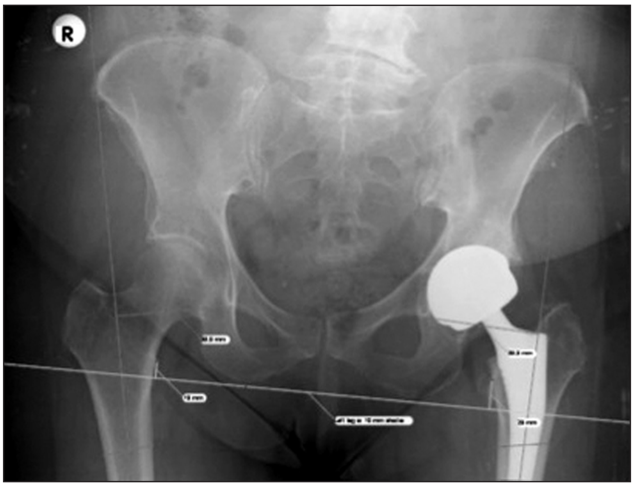

Fig. 3. Anatomical measurements. Anatomical restoration of leg length and offset as measured using the TraumaCad® software. Calibration is done using the known implant size

Table 4

Eccentric displacement of implants

Direction of Displacement	Number (average, mm)
Inferior	20 (4.35)
Anterior	6 (3.2)
Posterior	4 (5)
Superior	1 (4)
Neutral Position	16
Postero-inferior	4 (3.5, 3.5)

Note. Data about final post-operative positions of implants. The majority were put in the inferior position set to increase offset. As each mm of inferior positioning results in 0.7 mm increase in offset, the average increase was 3.04 mm.

from the center of the head to the long axis of the femoral shaft (Fig 3). Patients were assessed clinically using the Harris Hip Score, Short Form — 36 for quality of life, and Pain Visual Analogue Score, comparing preoperative and last follow up scores [24]. Patients were also examined for gait abnormalities, active assisted range of motion, abductor weakness (the Trendelenburg test and active abduction) [29], and leg length discrepancy (subjectively, objectively with maleolar pelvic distance and heightened soles to correct the difference if existing). The rate of complications was noted for intra-operative fractures, bleeding, infection, DVT/PE, dislocations, post-op fractures, snapping hip and bursitis. Management of metal bearing related complications (elevated metal ion levels and MRI findings) was performed according to national published protocols [17].

Data analysis was done using the Statistica Software (version 8.0, Tulsa, Oklahoma, USA). All anatomical variables were compared to the contra-lateral side. Data is presented as mean, range and standard deviation. We used the paired t-test to compare continuous clinical variables. P value was set to ≤ 0.05 for statistical significance.

Results and discussion

Eccentric positioning was utilized in 35 of the hips (68.6 %) to accommodate the native hip anatomy. Inferior positioning to increase offset was used in 20 hips, followed by anterior positioning (6 hips), posterior positioning (4 hips), superior positioning (1 hip) and 4 hips with a combination of posterior and inferior positioning (table 4). Harris hip scores, available for 48 hips, improved significantly from 40.7 (±13.5 SD) pre-operatively to 86 (±17.5 SD) at the last follow-up ($p < 0.001$). Short Form — 36 scores, available for 43 hips, improved significantly from 46.1 (±16.7 SD) pre-operatively to 80.5 (±13.7 SD) at the last follow-up, evident in both components (mental and physical) of the quality of life assessment ($p < 0.001$ for all scores) (table 5).

Visual Analogue scales for pain improved significantly from an average of 9 (range 7–10) pre-operatively to 0.8 at last follow-up ($p < 0.001$). On physical

Table 5

Subjective Clinical outcomes

Clinical variant	Preoperative	Postoperative at Last Follow-up
Pain (Visual Analogue Scale)	9 (7–10, ±0.98)	0.8 (0–6, ±1.4)
Harris Hip Score	40.7 (10–73, ±13.9)	86 (35–95,±17.8)
Excellent	—	25 (52.1 %)
Good	—	8 (16.7 %)
Fair	1 (2.1 %)	5 (10.4 %)
Poor	46 (97.9 %)	10 (20.8 %)
SF-36 Total	46.1 (14–77, ±16.5)	80.5 (42–100, ±13.7)
SF-36 Physical Component	37.2 (14–77, ±18.6)	79.2 (42–100, ±17.5)
SF-36 Mental Component	58.2 (14–77, ±19.7)	82.8 (42–100, ±12.2)

Note. Results of Harris Hip Scores, Short Form 36 and Pain Visual Analogue Scales. Improvement in all scores and components was statistically significant ($P < 0.001$).

Table 6

Clinical outcome — objective assessment

Range of Motion	Operated Hip (degrees, average, standard deviation)	Non Operated Hip (degrees, average, standard deviation)
Abduction	35.5 (±9.8)	34 (±10.8)
Adduction	28.6 (±7.8)	26.4 (±8.5)
Flexion	109.8 (±12.2)	107.9 (±13.4)
Internal Rotation	44.3 (±14.9)	36.9 (±18.6)
External Rotation	31.1 (±12.1)	29.5 (±10.8)

Note. Comparison of ranges of motion for the operated and non-operated hip. There was no statistically significant difference between the groups.

examination, patients showed good ranges of motion, usually comparable to the non-operated hip (table 6). Four patients (7.8 %) had abductor weakness as demonstrated by a positive Trendelenburg sign, of which only two had gait disturbances. Two patients (3.9 %) complained on leg length inequality, of which only one had objective evidence of LLD demonstrated both clinically (6 mm) and radiographically (6 mm) and balanced by a shoe insert. Two patients suffered from a self-limiting trochanteric bursitis, and one patient suffered from a snapping hip syndrome.

There were no intra-operative fractures, abnormal hemorrhage, surgical site infections, DVT/PE, dislocations or post-op periprosthetic fractures. Six patients (11,7 %) underwent revision surgery for various reasons — three for metal bearings associated complications (elevated blood metal ion levels and pseudotumors), two for aseptic loosening (one evident by scintigraphy and one by X-rays) and one due to hip pain with normal serum ion levels and normal MRI (intra-operatively there was a fluid collection and the cup was revised). Two more patients are planned for revision surgery, one for a late infection and another for symptomatic pseudotumor.

Recent radiographs were available for 47 of the hips (92.1 %). One patient as mentioned had acetabular aseptic loosening with radiolucent lines in Charnley and Delee's zones 1–3. Three patients (5.8 %) had radiolucent lines of less than 1 mm thickness in zone 1. One patient (1.9 %) had increased acetabular inclination of 63 0. Five patients (9.8 %) showed heterotopic ossification (Brooker classes I–II 4 hips, Brooker class III 1 hip) and none required treatment for it. No patients showed femoral stem subsidence, pedestal formation or stress related bone formation.

Anatomical restoration was measured on digital antero-posterior radiographs using the TraumaCad® software and was compared to the contra-lateral hip. Adequate radiographs were available for 48 hips to calculate length difference and for 38 hips for measuring offsets, due to different hip rotations that effected the measurements. Mean leg length discrepancy was 0.1 mm (±3.5, range –9.9 — +8.3). There was no statistically significant difference between leg lengths (P = 0.85, t= –0.186). Mean difference between offsets was 0.01 mm (±4.4, range –6.2 — +13.2). There was no statistically significant difference between offsets (P = 0.99. t = 0.006).

Discussion

Total hip arthroplasty has been proven to yield excellent results with significant improvement in patients' physical and emotional status. Insomuch that this surgery eventually earned title of «The operation of the 20th century» [30]. However, attempts are still made to improve clinical results by utilizing new implant designs and surgical techniques [31]. Extreme variants in patients' anatomy still pose a significant challenge. Trying to replicate the anatomy of a varus hip, even when using a coxa vara stem, can still demand a very low neck osteotomy. The standard hip implant, when used on a varus hip, can cause significant elongation of the limb and patient discomfort. The concept of the eccentric displacement allowed by the big femoral head offers the adaptability to most hip anatomy, more than any other current implant. An additional important advantage is that the versatility is achieved while using a proven single (rather than modular) piece, avoiding the inherent weakness of the modular taper junction.

Although preoperative digital templating has been proven to be accurate in predicting size of implants used, hip replacements are still being done without preoperative templating and sizing [8]. The anatomical femoral mega-head can be utilized to achieve accurate anatomical restoration. It is constructed in a way that allows variable displacement of the taper from the center of the head, both in direction and in distance. Therefore, digital preoperative templating, for which we used the TraumaCad® software, is necessary to predict the correct positioning of the femoral head.

As a result of the anatomical restoration achieved during the procedures, our series showed very low rates of complications owing to mechanical imbalance: no dislocations and no cases of leg length difference over 10 mm. Revision surgery was required in 6 patients. The indications for revisions were associate with the known and published complications of metal on metal heads and the ASR cup specifically (elevated blood ion levels, pseudotumors, aseptic loosening) and do not seem to be related to the unique femoral head design.

There are several implications to be considered due to the unique asymmetric design of the implant. One of the possible pitfalls is implant failure due to change of the loads and stresses across the femoral head and stem. However there were no signs of femoral loosening within our mid-term follow-up. Questions about possible trunionosis due to the large femoral head sizes will need to be examined with further follow up. Another theoretical implication of the asymmetry of the implant is soft tissue or osseous impingement. Possible clinical manifestations include reduced range of motion, instability, accelerated wear and unexplained pain. However, ranges of motion with the studied patient cohort were comparable to the contralateral hip with no statistically significant difference (table 6).

Study limitations include a relatively high number of patients lost to follow-up and unable to be included in the study and inaccurate measurements due to low quality imaging in some patients (less than 8 %). Further research will be needed to determine if clinical results are comparable to other implants in long-term follow-up. Additional questions that must be evaluated are similar to the ones in Metal on Metal implant bearing — level of serum ions, systemic effects, local tissue response and level of metal wear resulting from asymmetrical design.

The presented novel anatomical femoral mega-head is a new concept for hip implant design. Unacceptable clinical results caused a decline in the use of ASR and its removal from the market [32]. The novel concept of placing the taper not directly in the center of the head, the asymmetrical location of the trunion is made possible through the use of a large diameter femoral head. This concept may be applied in the future, possibly in implants with other designs or ones with different bearing materials. Special consideration should be given to different tribological characteristics to meet the changed load mechanics of the hip joint.

Acknowledgments

All coauthors have seen and agree with the contents of the manuscript.

Each author certifies he or she has no commercial associations that might pose a conflict of interest in connection with the submitted article.

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DOI: http://dx.doi.org/10.15674/0030-59872016115-22 The article was received at editorial office 10.02.2016

РАННИЕ ОСЛОЖНЕНИЯ И ПРОМЕЖУТОЧНЫЕ РЕЗУЛЬТАТЫ ПРИ ЭНДОПРОТЕЗИРОВАНИИ С ПРИМЕНЕНИЕМ АНАТОМИЧЕСКИХ МЕГАГОЛОВОК БЕДРЕННОЙ КОСТИ

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