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Reconstructive REVIEW

OFFICIAL JOURNAL OF THE

Joint Implant Surgery and Research Foundation

Strategic Alliance with

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OFFICIAL JOURNAL OF THE

JISRF

Joint Implant Surgery and Research Foundation

Strategic Alliance with

An Announcement From:

Dr Rami M Sorial FRACS FAOrthA

President, Asia Pacific Arthroplasty Society & Associate Editor-in-Chief, Pacific Rim, Reconstructive Review

&

Timothy McTighe, Dr. H.S. (hc)

Executive Director, JISRF,

& Editor-in-Chief, Reconstructive Review

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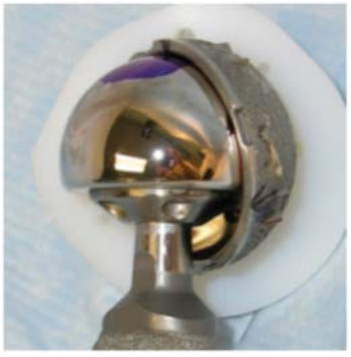
Ian Clarke, PhD & Thomas K. Donaldson, MD



Metal on metal retrieval

Levels of Evidence

Reconstructive Review has adopted the American Academy of Orthopaedic Surgeons (AAOS) Levels of Evidence for Primary Research Question. These guidelines will now be part of the review process for manuscript submission.

Levels of Evidence For Primary Research Question[1]

	Types of Studies			
	Therapeutic Studies – Investigating the results of treatment	Prognostic Studies – Investigating the effect of a patient characteristic on the outcome of disease	Diagnostic Studies – Investigating a diagnostic test	Economic and Decision Analyses – Developing an economic or decision model
Level I	• High quality randomized trial with statistically significant difference or no statistically significant difference but narrow confidence intervals • Systematic Review[2] of Level I RCTs (and study results were homogenous[3])	• High quality prospective study[4] (all patients were enrolled at the same point in their disease with ≥ 80% follow-up of enrolled patients) • Systematic review[2] of Level I studies	• Testing of previously developed diagnostic criteria on consecutive patients (with universally applied reference "gold" standard) • Systematic review[2] of Level I studies	• Sensible costs and alternatives; values obtained from many studies; with multiway sensitivity analyses • Systematic review[2] of Level I studies
Level II	• Lesser quality RCT (e.g. < 80% follow-up, no blinding, or improper randomization) • Prospective[4] comparative study[5] • Systematic review[2] of Level II studies or Level 1 studies with inconsistent results	• Retrospective[6] study • Untreated controls from an RCT • Lesser quality prospective study (e.g. patients enrolled at different points in their disease or <80% follow-up.) • Systematic review[2] of Level II studies	• Development of diagnostic criteria on consecutive patients (with universally applied reference "gold" standard) • Systematic review[2] of Level II studies	• Sensible costs and alternatives; values obtained from limited studies; with multiway sensitivity analyses • Systematic review[2] of Level II studies
Level III	• Case control study[7] • Retrospective[6] comparative study[5] • Systematic review[2] of Level III studies	• Case control study[7]	• Study of non-consecutive patients; without consistently applied reference "gold" standard • Systematic review[2] of Level III studies	• Analyses based on limited alternatives and costs; and poor estimates • Systematic review[2] of Level III studies
Level IV	Case Series[8]	Case series	• Case-control study • Poor reference standard	• Analyses with no sensitivity analyses
Level V	Expert Opinion	Expert Opinion	Expert Opinion	Expert Opinion

1. A complete assessment of quality of individual studies requires critical appraisal of all aspects of the study design.
2. A combination of results from two or more prior studies.
3. Studies provided consistent results.
4. Study was started before the first patient enrolled.
5. Patients treated one way (e.g. cemented hip arthroplasty) compared with a group of patients treated in another way (e.g. uncemented hip arthroplasty) at the same institution.
6. The study was started after the first patient enrolled.
7. Patients identified for the study based on their outcome, called "cases"; e.g. failed total arthroplasty, are compared to those who did not have outcome, called "controls"; e.g. successful total hip arthroplasty.
8. Patients treated one way with no comparison group of patients treated in another way.

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Reconstructive Review

A Journal Published by the Joint Implant Surgery & Research Foundation

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Charles Bechtol, MD

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Please direct any requests for inclusion, editorial comments or questions to Timothy McTighe, Dr. HS (hc), Executive Director, JISRF, 46 Chagrin Plaza #117, Chagrin Falls, Ohio 44023, tmct@jisrf.org.

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- Basic Science
- Case Reports
- Clinical/Surgical
- Commentary
- Controversial Issues (i.e. modularity, tapers, MoM)
- Reviews
- Letters to the Editor
- Surveys

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Articles submitted will need to be divided into separate files including cover page and manuscript. Figures, images, and photographs should be submitted separately.

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  - Title
  - Abstract (**ALL ARTICLES MUST INCLUDE AN ABSTRACT**)
  - Introduction
  - Materials and Methods
  - Results
  - Discussion
  - References (for styles please refer to the website http://www.nlm.nih.gov/bsd/uniform_requirements.html)
- *Figures, Images and Photographs* - Please do not embed figures, images, and photographs in the main manuscript. They should be uploaded as individual files.

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- Live Area: 7.25" x 9.25"
- No Bleeds

Ad Specification

- Full color or black and white - available sizes:
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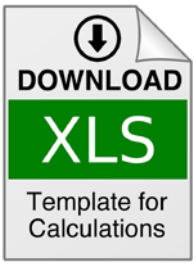
Margin-of-safety Algorithm Used with EOS Imaging to Interpret MHRA Warning for 46-48mm MOM Arthroplasty

Clarke I [1], Lazennec J [2]

Abstract

The Medical Healthcare Products Regulatory Agency (MHRA June-2015) warned of higher risks with 46-48mm sizes of BHR hip resurfacing arthroplasty (HRA). The most common condemnation of adverse results in MOM bearings has been termed edge loading. We originally developed a margin-of-safety (MOS) algorithm to define edge loading of cups in simulator studies. This method integrated simulator wear-patterns with respect to cup diameters and cup designs. The algorithm's simplicity lay in the fact that with wear-patterns and rim-profile angles predetermined, the only input required was the cup inclination-angle. The algorithm demonstrated that the margin-of-safety decreased in smaller cups due to the tribo-mechanics of spherical CoCr bearings, a previously unrecognized feature. For the 46mm and 48mm cups highlighted in the MHRA alert, the critical cup inclinations where edge-wear became a risk occurred at 65-66°, revealing an insignificant difference with respect to diameters. The MOS-algorithm also indicated that lower lateral-inclination angles were particularly beneficial, i.e. a 46mm cup positioned at 50° inclination would exhibit a higher margin of safety than either 48mm or 50mm sizes positioned at 55° inclination. This evidence supported clinical studies that recommended BHR cup inclinations up to 50-55° and lower as optimal for reducing metal-ion concentrations. In a patient with normal spine mobility, our EOS imaging demonstrated that the inclination in the 46mm cup steepened by 9° from standing to the seated position while margin-of-safety was reduced by 50%. Our 2nd patient with a stiff spine sat with the same component orientations as in his standing posture. Thus MOM impingement and subluxation in different functional postures may also provoke rim-damage mechanisms. Here the combination of EOS imaging and the MOS-algorithm may aid understanding of such risks. Thus the margin-of-safety algorithm confirmed and helped explained the relative risks in the 46mm and 48mm cups highlighted



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2 Department of Orthopaedics, La Pitie Hospital, UPMC University, Paris, France

by the MHRA. The algorithm's stratification by cup rim-profile, inclination angle and cup diameter may assist the surgeon determine which patients may be more at risk for edge wear with the smaller BHR cups. The ARC, CPR and MOS algorithms can be downloaded here (Excel file).

Keywords: *BHR Resurfacing Arthroplasty, cup inclination, edge wear, MHRA alert, EOS, MOM*
Level of Evidence: *AAOS Therapeutic Level V*

Introduction

Clinical studies of metal on metal (MOM) bearings used in hip resurfacing arthroplasty and total hip arthroplasty frequently described high rates of failure. [1-4] The most common condemnation of MOM performance has been termed "edge-loading". [1,5-12] Studies implicated small MOM diameters, sub-hemispherical cup designs, surgical positioning, and hip-joint excursion. Nevertheless the BHR resurfacing system continues to receive acclaim as very successful when applied correctly to young patients with the right indications, even in patients with the small BHR devices. [13-15] However, a recent Medical Device Alert by the Medical Healthcare Products Regulatory Agency (MHRA, June 2015, UK) singled out female patients and 46-48mm BHR devices as representative of unacceptable risks but with no guidelines provided (Fig. 1). Thus the surgeon may have a dilemma in determining


GOV.UK

Medical safety alert

Metal-on-metal (MoM) hip replacements - guidance on implantation and patient management

From: Medicines and Healthcare products Regulatory Agency
Published: 25 June 2015
Issued: 25 June 2015

- Do not implant BHR devices in:
  - female patients
  - patients requiring femoral heads sized 46mm or smaller
- Only use 48mm BHR heads in the specific circumstance of intra-operative downsizing from a pre-operatively templated 50mm to a measured 48mm at the time of surgery
- Return all unused BHR femoral heads sized 46mm and smaller and their corresponding acetabular and dysplasia cups to the manufacturer
- Follow up patients implanted with BHR hips that fall within the scope of this medical device alert ie:
  - all symptomatic patients
  - all female patients
  - all patients implanted with head sizes 46mm or smaller

Fig.1. Medical Healthcare Products Regulatory Agency (MHRA) issued a medical device alert (MDA-2015/024, 25th June 2015) identifying higher risks with BHR sizes 46-48 mm

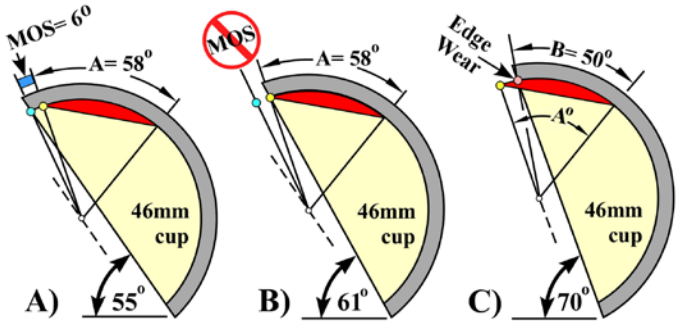

Fig. 2. Effect of cup inclination on wear-pattern (angle-A) and margin-of-safety (MOS), A) at 55 ° inclination the cup wear-pattern has a 58° arc and MOS has a 6° arc, B) adding 6° additional inclination reduces MOS to zero, and C) adding another 9° inclination reduces the cup wear-pattern to a 50° arc and edge wear presents. This edge-wear definition would be EW = 9/58 = 16%".

which of his patients with smaller BHR devices may be at risk.

The key to assessing edge-wear lies in defining the 'margin for error' [9] or, as will be termed here, the 'margin-of-safety' (Fig. 2). During the bearing's run-in phase, the cup wear-pattern grows rapidly, typically to greater than 400mm^2 area. [16,17] As long as this habitual wear-pattern is separated from the cup rim by an adequate margin-of-safety (MOS), edge wear is unlikely (Figs. 2a, 3a). At a steeper angle the margin-of-safety decreases to zero and places the patient at risk for edge wear (Fig. 2b). At even steeper angles the cup rim will cross over the habitual wear-pattern area and edge wear ensues (Figs. 2c, 3b). This is believed to create severe stress-concentrations, compromise fluid-film lubrication, and thereby contribute to extreme wear. [6,10,11,18,19] The Petersen Tribology Laboratory of Loma Linda University (LLU) developed a margin-of-safety algorithm that integrated simulator wear-patterns with respect to cup diameters and cup designs. The

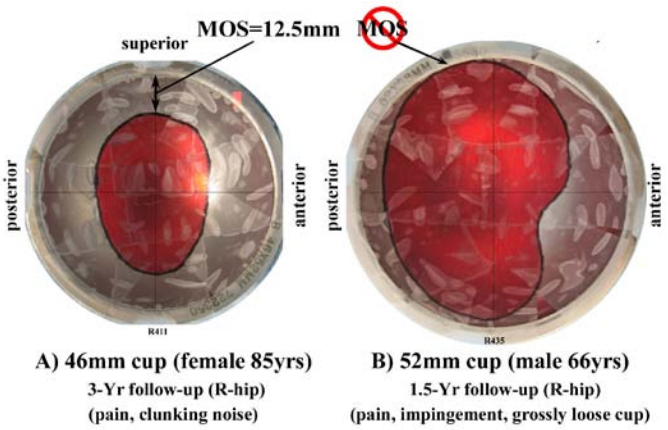

Fig. 3. Wear-patterns (colored red for photography) in MOM retrieval studies showing, (a) margin of safety superior to central wear-pattern, and (b) wear-pattern juxtaposed to cup rim indicating edge-wear.

algorithm has been used to validate edge-loading in studies of steep cup scenarios. [20] While size of cup wear-patterns appeared to be an important parameter, this was not considered in prior studies. Clinical methods for assessing cup coverage have included the "Arc of Cover" distance [9] and the "Contact Patch to Rim" (CPR) distance. [1] These concepts measured the distance from the cup rim to either the vertical reference plane or to a 14° medially-directed axis, respectively (Fig. 4a). A third method termed "Contact Patch Edge to Rim" distance (CPER) combined a 14° medially-directed reference axis with a "contact patch" calculation (Fig. 4b). [6] While such measurements provided stratification of risk, [6,21-23] they did not provide the surgeon with the neccessary details to assess risk of edge-wear directly.

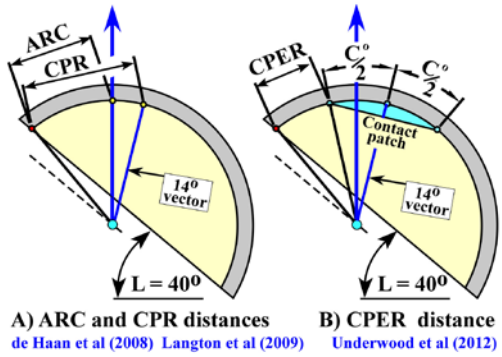

Fig. 4. Schematic of methods used to describe cup coverage on antero-posterior images, a) "Arc of Cover" (ARC) [9] and "Contact Patch to Rim" (CPR) [1] distances, where 'ARC' defines a chord to be comparable to CPR-distance method, and b) "Contact Patch Edge to Rim" (CPER) [6].

There has also been little understanding of how patient postures change the position of artificial hip-joints. The majority of measurements have been made from radiographic or CT images taken with the patient in the supine position. However, hip dislocation is a frequent mode of failure and the sitting position is one where most impingements and posterior dislocations occur. At La Pitie Hospital (Paris, France), the orthopedic group developed EOS imaging (author JYL) to investigate various patient postures. The EOS™ imaging system is capable of simultaneously capturing two orthogonal antero-posterior (AP) and lateral images, thus typically providing full pelvic visualization in standing, sitting, and other positions. [24,25] The first objective of this report was to study the margins-of-safety (MOS) in 46-48mm diameter BHR mentioned in the MHRA warning. The conventional ARC and CPR methods were also compared (Fig. 4a). The second objective was to compare MOS and CPR data for standing and sitting positions in two patients, both with 46mm diameter MOM.

Methods

To avoid confusion with "contact patch" data and other commonly used terms (Fig. 4), the wear area produced in hip simulator studies will be defined as the Cup Area Pattern (CAP). CAP areas in MOM simulator studies typically ranged 411- 480mm^2 by the end of the 5-million cycle tests. [16,17,26] The corresponding wear-pattern angles (Fig. 2: angle-A) were calculated using standard equations for spherical geometry. These were plotted with respect to cup diameter and extrapolated by linear regression to cover the 36-60mm diameter range. The extent of cup rim-coverage is also believed to be an important parameter. [1,8-12] In this study we utilized the rim-profile angle (Fig. 5: P) to define loss of coverage in the load-bearing area of the cup. Cup-profile angles (P) were derived from published cup-face angles (F) provided for five MOM systems [6] and calculated using,

Equation-1 (Fig. 5):
2*P = 180 – F

The rim profile angles were extrapolated over the 36-60mm diameter range by linear-regression techniques. CPR and MOS data were calculated using the 14° medially-directed vector. [1] For a cup positioned with lateral-inclination L-angle (Fig. 5) the summation follows as,

Equation-2 (Fig. 5):
L + P + MOS + A/2 = 104°

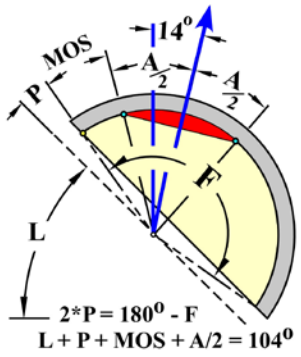

Fig. 5. Illustration of cup geometry defining inclination angle (L), rim-profile angle (P) and wear-pattern angle (A) with respect to a 14° medially directed load vector.

Note with resultant loading in simulator studies being in the vertical plane, equation-2 would simply be summated to 90°. The MOS-algorithm also provided a definition for edge-wear (EW), whereby,

Equation-3 (Figs. 2b, c):
EW% = 100*(A – B)/A

The critical cup inclination angle (*L) with margin-of-safety diminished to zero can be determined by setting MOS=0 in equation-2,

Equation-4 Critical inclination (Fig. 2b):
$*L = 104° - (P + A/2)$

Clinical studies of cup coverage have used varied criteria (Fig. 4) and therefore equation-2 can simply be extended as follows,

Equation-5 (Figs. 4a):
$L + P + ARC = 90°$ [9]

Equation-6: (Figs. 4a, 5):
$L + P + CPR = 104°$ [1]

Equation-7: (Fig. 4b):
$L + P + CPER + C/2 = 104°$ [6]

Using angles for margin-of-safety calculations greatly simplifies the analysis (Fig. 5). As required, MOS and CPR angles can be converted to 'distance' measurements,

Equation-8a:
MOS distance (mm) = DIA*sin(MOS/2)

Equation-8b:
CPR distance (mm) = DIA*sin(CPR/2)

A set of sample calculations are included for ARC, CPR and MOS indices (Table 1) - the template for ARC, CPR and MOS calculations can be downloaded here (Excel file). It is noted that the original equation for "Arc of Cover" calculated the distance along the cup surface, i.e. length of the circular arc. [9] In this study, the ARC distance (equation-5) defined the chord of a circle in order to be compatible with the CPR method (Fig. 4). The CPER innovation (equation-7) added contact-patch size, which reduced the rim-distance prediction compared to CPR data. However, following the run-in wear process, patient hip-function will have enlarged the wear-pattern area much beyond the size of the contact patch. [16]

The EOS imaging presents patients in various functional positions for analysis of pelvic and femoral rotations and for comparison of implant positions. Differences between standing and sitting postures were compared in two patients, one with normal spinal mobility and the second with considerable stiffness due to spinal pathology. Both had 46mm THA (Metasul™ , Zimmer, Warsaw IN) with a 5° rim-profile angle (P). Cup inclination angles and CPR distances were calculated and compared with the MOS-algorithm for sitting versus standing postures.

Results

The data from simulator studies demonstrated that wear-pattern angles decreased linearly with increasing cup diameter (Fig. 6). The wear pattern in a 36mm BHR-type cup had a 66.7° angle, which decreased to 58.2° in a 46mm cup and to 56.6° in a 48mm cup. The largest cup considered (60mm) had the smallest wear-pattern angle (46.4°),

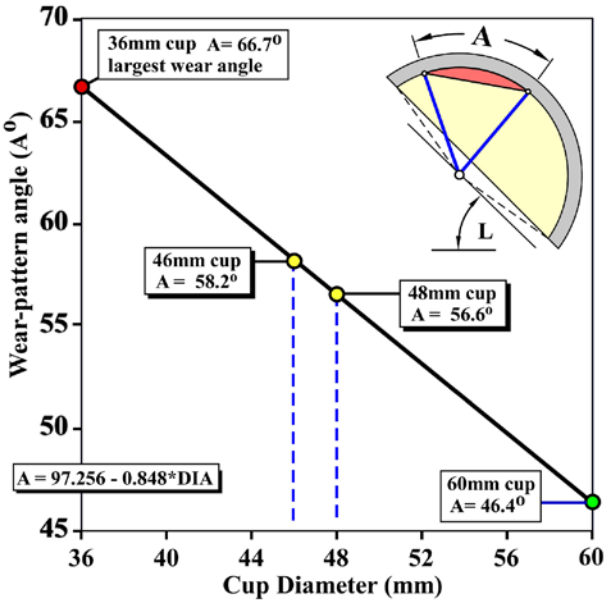

Fig. 6. Trending of wear-pattern angles (A) derived from linear regression of data from hip simulator wear-patterns. [20]

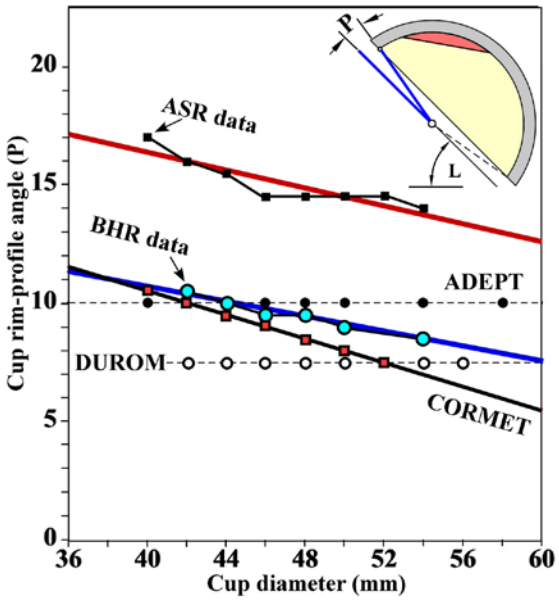

Fig. 7. Trending of rim-profile angles (P) derived from data on cup-face angles (F). [6]

which compared to the 36mm cup, represented an overall reduction of 20.3°.

The rim-profile angle (P) defined how much hemispherical coverage was reduced in the load-bearing region (Fig. 7). These data will be labeled 'BHR-type' since some values may not reflect the vendor's actual specification (Table 1). The CORMET design provided the most coverage while the ASR provided least. The ADEPT and DUROM cups had constant profile angles whereas the ASR, BHR and CORMET profile angles decreased linearly with increasing diameter (Fig. 7).

Differences produced by wear-pattern and rim-profile angles were illustrated by comparing 46mm and 56mm cups (Fig. 8). Wear-pattern areas covered 418 and 458 mm^2 in the small and large cups, respectively. However the wear-pattern angle was larger (58.2°) in the small cup than in the large cup (49.8°). The rim-profile angle (P) was also larger in the smaller cup (9.7° vs 8.1°). The combined effect of these angles (Fig. 8) reduced the safety margin in the small cup (MOS=15.2°) by 5.8° compared to the large cup (MOS=21°).

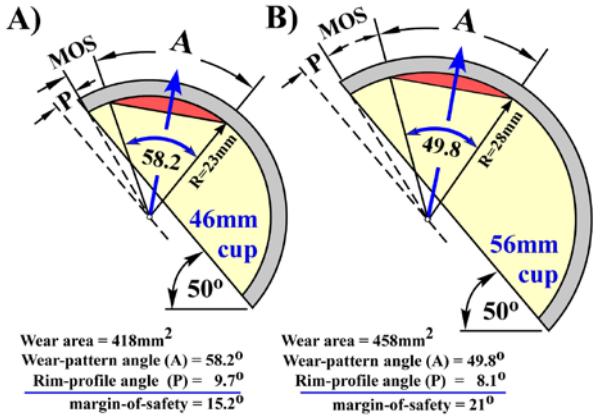

Fig. 8. Comparison of wear-pattern angles (A) and margins-of-safety (MOS) produced in 46mm and 56mm cups at same inclination angle.

Comparing cups at 65° inclination the methods predicted that safety margins increased linearly with component size (Fig. 9a). The ARC and CPR methods had similar slope but differed in magnitude due to the 14° difference in their reference axes (Fig. 4). The CPER had the same reference axis as CPR method but subtracted the half-width of the contact patch, this reduction making it similar in magnitude to the ARC method. The MOS-algorithm revealed that 36-46mm diameter cups had edge-wear while the 48mm size achieved a safety margin represented by only 1.3° (Fig. 9a). The MOS trend showed the lowest magnitude but steepest slope due to the inclusion of simulator wear-patterns. The critical inclination angles (equation-4) were 65.2° and 66.3° for 46 and 48mm diameters respectively (Fig. 9b). Comparing MOM diameters and inclina-

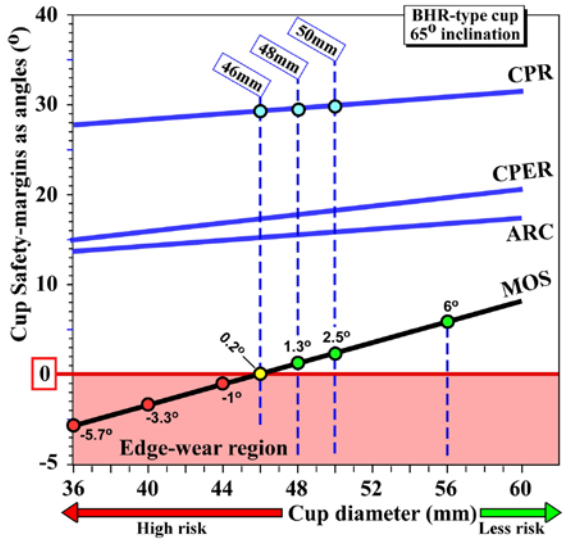

Fig. 9a.

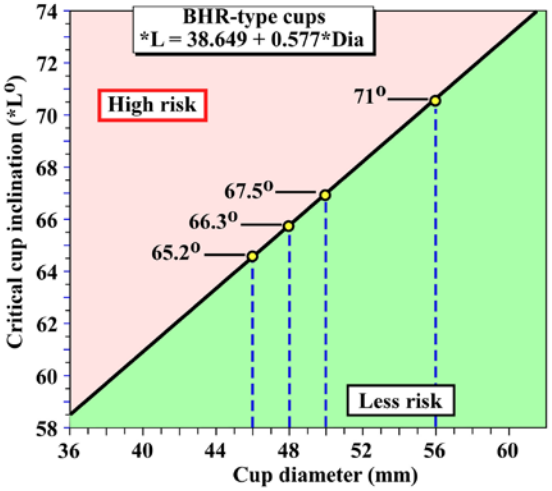

Fig. 9b.

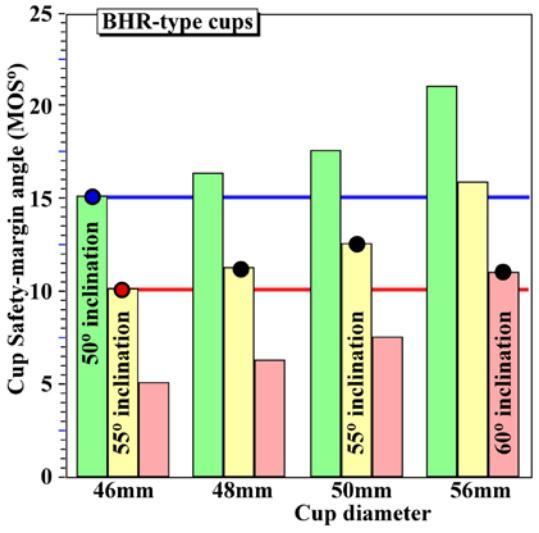

Fig. 9c

Fig. 9. Comparisons of safety predictions in BHR-type cups,
(a) ARC, CPER, CPR and MOS angles for 36-60mm diameter cups, all at 65° cup inclination,
(b) Critical inclination angles (equation-4) predicted for 36-60mm diameter cups
(c) Margins of safety predictions (MOS, angles) for small cups sizes 46-50mm versus the 56mm size and compared using cup inclinations 50, 55 and 60°.

tion angles, the 46mm cup at 50° inclination exhibited a greater safety-margin than the 48mm and 50mm cups at 55° inclination. At the same inclination, the 46mm cup exhibited a safety-margin only slightly lower than 48mm and 50mm sizes. The MOS-algorithm predicted that rim distances in 48 and 50mm cups would be 0.5mm and 1.1mm, respectively (Fig. 10). The CPR method produced 11.6-12.3mm distances for critical cup sizes 46-48mm, which as indicated were above the 10mm clinical threshold (Fig. 10).

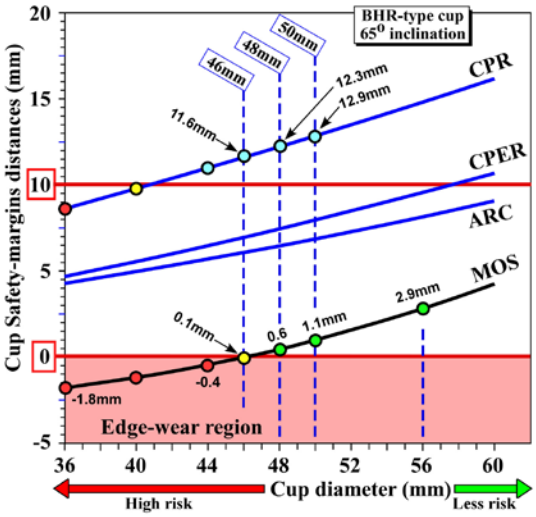

Fig. 10. Comparison of safety margins (distances) predicted by four methods (ARC, CPER, CPR, MOS) for a cup inclination of 65°.

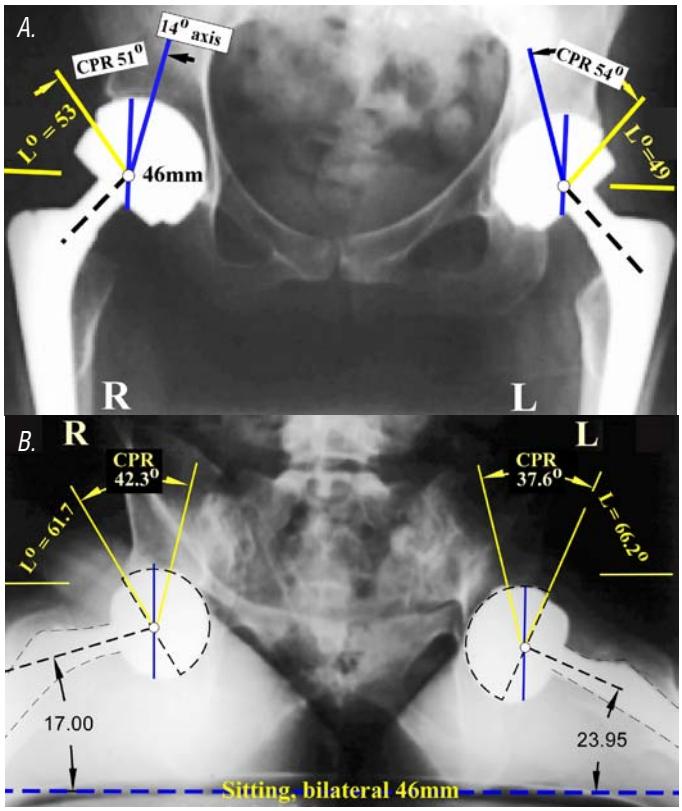

Fig. 11. EOS images for case with bilateral 46mm THA and good pelvic mobility in (a) standing and (b) sitting.

In standing posture, EOS imaging revealed that the cup in the right hip of patient-1 had a 53° lateral inclination that increased to 62° in sitting (Fig. 11). The CPR angles were correspondingly reduced from 51° to 42° and calculated MOS angles reduced from 16.6° to 8.1°. In contrast, patient-2 had essentially the same cup inclinations in both standing and sitting positions and thus CPR and MOS angles varied little (Fig. 12).

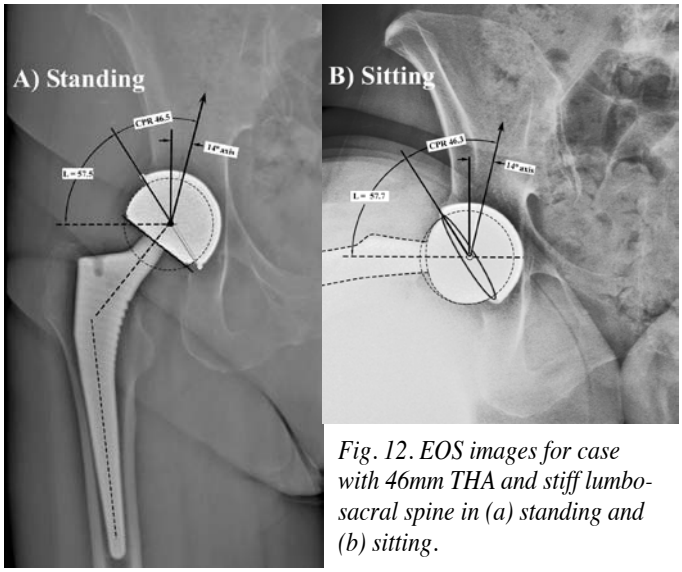

Fig. 12. EOS images for case with 46mm THA and stiff lumbosacral spine in (a) standing and (b) sitting.

Discussion

The margin-of-safety method appears to be the first to integrate wear-patterns and cup rim-profiles to define "edge-wear". Its simplicity lies in the fact that using the predetermined wear-patterns and rim-profile angles, the only input required is cup inclination (Table 1). This algorithm revealed that critical cup inclinations, where edge-wear becomes a risk, were defined solely by cup-profile and wear-pattern angles (equation-4). The former represents the cup-design parameter while the latter represents tribo-mechanics of spherical CoCr bearings. For the BHR cups highlighted in the recent MHRA warning, the MOS algorithm predicted that the 46mm cup was most at risk at 65° and higher inclinations while the difference in safety margin between 46 and 48mm cups was represented by only 1.1°. Thus cup diameters appeared to be a relatively weak indicator of safety margin. The MOS-algorithm predicted that the margin of safety would actually be higher in a 46mm cup positioned with 5° lower inclination than in 48mm or 50mm size cups. Thus the margin-of-safety algorithm confirmed and explained the relative risks of 46mm and 48mm cups highlighted in the MHRA alert. Conversely, for a 46mm cup angled 5° higher than its critical incli-

nation (in Fig. 9b), the resulting definition for edge wear (equation-3) would simply show that A-B = 5° where angle-A = 58.2° (Table 1) and EW% = 5/58.2 = 8.6%.

The margin-of-safety algorithm has been validated in hip simulator tests. [20,27] However for clinical applications there are limitations to a mathematical depiction of edge-wear. The main assumption was that cup wear-patterns in hip simulators would be predictive of those in patients. It is to be anticipated that the CoCr tribo-mechanics in spherical bearings will be similar in vivo and in vitro. The major difference is that component positioning and hip functions are well defined in a simulator test and also non-variant. In contrast, surgical positioning of femoral and acetabular components and subsequent hip function represent a complex set of variables. In particular the head:neck ratios in the resurfaced hip joints may have variable effects such as impingement and subluxation. [28] In this regard our MOM retrieval studies documented that cup wear-patterns were much larger in failed MOM cases (Fig. 3b). [29]

Clinical studies of BHR cases recommended cup inclinations up to 50-55° as optimal for reducing the metal-ion concentrations but also indicated that lower angles could risk anterior impingement. [1,30] The 46mm and 48mm BHR-type cups described here demonstrated critical cup inclinations at 65-66° (equation-4). This evident shift of perhaps 10° may represent the difference between mathematical precision and clinical reality. The MOS-algorithm defined the proximity of the wear pattern to the cup rim at varied 'inclination' angles. Other mathematical methods integrated the angles of cup anteversion and lateral-inclination to provide a more complete component description. [6,23] However, all current methods were based on an assumption of a 14° reference axis for the hip-joint reaction force (Fig. 4) - taken from a biomechanics study of patients in single-legged stance. [31] In reality we have little or no understanding of which patient posture(s) will produce an edge-wear condition. Thus while the MOS-algorithm can indicate the safety margin in that cup design and with that diameter, it is likely that this is representative of the "ideal' patient (Fig. 3a). Thus mathematical treatments may underestimate the risk of edge-wear, particularly in young and active individuals (Fig. 3b).

The MOS-algorithm has provided the first demonstration that small cups inherently had the least margin of safety due to their wear-pattern angles being proportionally greater than in large cups. This tribo-mechanical effect was not intuitively obvious, considering that wear patterns increased in size with increased cup diameter. [29] However as shown by example, a 46mm cup featured a larger wear-pattern angle than a 56mm cup and thus the margin-of-safety was reduced accordingly (Figs. 6, 8). Adding to the risk was the reduced coverage in some design of small cups (Fig. 7). Thus smaller cups inherently have smaller safety margins, a fact which has become well identified in clinical and retrieval studies. [1,8-10,18]

The dilemma apparent is that steep-cup algorithms (Fig. 9, 10) are based only on a scenario of adverse edge-loading during gait, i.e. in the habitual load-bearing area of the cup (Fig. 4). However the apparent desirability of positioning cups with reduced lateral-inclination may may result in other risks, such as posterior impingement, subluxation and anterior edge wear. [1,32] In our patient with normal spine mobility, EOS imaging demonstrated that cup inclination steepened by 9° in the seated position, with the margin-of-safety being reduced by 50%. Thus the risk is that MOM impingement and subluxation while in sitting

Diameter BHR-type	36mm	38mm	40mm	42mm	44mm	46mm	48mm	50mm	52mm	54mm	56mm	58mm	60mm
Inclination (L)	50	50	50	50	50	50	50	50	50	50	50	50	50
Angle (A/2)	33.4	33.4	33.4	33.4	33.4	33.4	33.4	33.4	33.4	33.4	33.4	33.4	33.4
Angle (P)	11.3	11.0	10.7	10.3	10.0	9.7	9.4	9.1	8.7	8.4	8.1	7.8	7.4
L+P	61.3	61.0	60.7	60.3	60.0	59.7	59.4	59.1	58.7	58.4	58.1	57.8	57.4
P+A/2	44.7	43.5	42.4	41.1	40.0	38.8	37.7	36.5	35.3	34.1	33.0	31.8	30.6
L+P+A/2	94.7	93.5	92.4	91.1	90.0	88.8	87.7	86.5	85.3	84.1	83.0	81.8	80.6
MOS (°)	9.3	10.5	11.6	12.9	14.0	15.2	16.3	17.5	18.7	19.9	21.0	22.2	23.4
ARC (°)	28.7	29.0	29.3	29.7	30.0	30.3	30.6	30.9	31.3	31.6	31.9	32.2	32.6
CPR (°)	42.7	43.0	43.3	43.7	44.0	44.3	44.6	44.9	45.3	45.6	45.9	46.2	46.6
MOS (mm)	2.9	3.5	4.1	4.7	5.4	6.1	6.8	7.6	8.5	9.3	10.2	11.1	12.2
ARC (mm)	8.9	9.5	10.1	10.8	11.4	12.0	12.7	13.3	14.0	14.7	15.4	16.1	16.8
CPR (mm)	13.1	13.9	14.8	15.6	16.5	17.3	18.2	19.1	20.0	20.9	21.8	22.8	23.7

Table 1. Sample calculations for BHR-type cups using 50° cup inclination as an example, where equation-2 indicates MOS = 104 – (L+P+A/2), equation-5 has ARC = 90 – (L+P), and equation-6 has CPR = 104 – (L+P) and from. Angular data were converted to distances using equations 8a and b.

or other postures could provoke rim-damage mechanisms. [7,33,34] Such a release of large metal particles could then provoke an aggressive 3rd-body wear mechanism during gait. [20,34] These risks in implant orientation combined with patient positional variation are poorly understood. EOS imaging combined with the MOS-algorithm should help in the exploration of such postural variations.

In conclusion, the margin-of-safety algorithm demonstrated the risk factors inherent in 46-48mm BHR-type devices described in the June MHRA alert. The MOS-algorithm facilitated an understanding of how cup design, diameter and inclination affected the margin-of-safety. In patient studies the cup size and rim profile are pre-determined and thus the only input needed for ARC, CPR and MOS determinations is the cup's lateral inclination (Table 1). These data also indicated that cups with less steep inclinations (45-55°) effectively raised the available margin of safety, even in 46-48mm size cups. It is hoped the MOS-algorithm will provide surgeons with a suitable instrument to evaluate how the MHRA warning affects their clinical practice.

Disclosure Statement

One or more of our authors have disclosed information that may present potential for conflict of interest with this work. For full disclosures refer to last page of this journal.

References

1. Langton DJ, Sprowson AP, Joyce TJ, Reed M, Carluke I, Partington P, Nargol AV. Blood metal ion concentrations after hip resurfacing arthroplasty: a comparative study of articular surface replacement and Birmingham Hip Resurfacing arthroplasties. J Bone Joint Surg Br 2009;91-10:1287-95.
2. Hart AJ, Sabah S, Henckel J, Lewis A, Cobb J, Sampson B, Mitchell A, Skinner JA. The painful metal-on-metal hip resurfacing. J Bone Joint Surg Br 2009;91-6:738-44.
3. Mabilleau G, Kwon YM, Pandit H, Murray DW, Sabokbar A. Metal-on-metal hip resurfacing arthroplasty: a review of periprosthetic biological reactions. Acta Orthop 2008;79-6:734-47.
4. Vendittoli PA, Mottard S, Roy AG, Dupont C, Lavigne M. Chromium and cobalt ion release following the Durom high carbon content, forged metal-on-metal surface replacement of the hip. J Bone Joint Surg Br 2007;89-4:441-8.
5. Kwon YM, Mellon SJ, Monk P, Murray DW, Gill HS. In vivo evaluation of edge-loading in metal-on-metal hip resurfacing patients with pseudotumours. Bone Joint Res. 2012;1-4:42 -9.
6. Underwood RJ, Zografos A, Sayles RS, Hart A, Cann P. Edge loading in metal-on-metal hips: low clearance is a new risk factor. J Eng in Med 2012;226-3:217 - 6.
7. McHugh D, Currier J, Kennedy F, Collier J, Van Critters D. Plastic Deformation from Edge Loading is common on Retrieved Metal-on-Metal Hips and Can Be Predicted With Finite Element Analysis. In: Kurtz SM, Greenwald SA, Mihalko WM, Lemons JA, eds. Metal-On-Metal Total Hip Replacement Devices, 2013:235-50.
8. Morlock MM, Bishop NE, Zustin J, Hahn M, Ruther W, Amling M. Modes of Implant Failure After Hip Resurfacing: Morphological and Wear Analysis of 267 Retrieval Specimens. J Bone Joint Surg Am 2008;90:89 -95.
9. De Haan R, Pattyn C, Gill HS, Murray DW, Campbell PA, De Smet K. Correlation between inclination of the acetabular component and metal ion levels in metal-on-metal hip resurfacing replacement. J Bone Joint Surg Br 2008;90-10:1291-7.
10. Jeffers JR, A, Taylor A, Tuke M. The problem with large diameter metal-on-metal acetabular cup inclination. Bulletin of the NYU Hospital for Joint Diseases 2009;67 -2:189 - 92.
11. Shimmin AJ, Walter WL, Esposito C. The influence of the size of the component on the outcome of resurfacing arthroplasty of the hip. Journal of Bone and Joint Surgery BR 2010;92 -B:469 - 76.
12. Griffin WL, Nanson CJ, Springer BD, Davies MA, Fehring TK. Reduced articular surface of one-piece cups. A cause of runaway wear and early failure. Clin Orthop Relat Res 2010;468:2328 - 32.
13. Matharu GS, McBryde CW, Pynsent WB, Pynsent PB, Treacy RBC. The outcome of the Birmingham Hip Resurfacing in patients aged < 50 years up to 14 years post-operatively. Bone Joint J 2013;95-B:1172-7.
14. De Smet K. Revisions of hip resurfacings from an independent specialist center. ISTA 28th Annual Congress. Vienna, Austria, 2015.
15. Daniel J. Mortality and implant revision rates following hip resurfacings and hip replacements. ISTA 28th Annual Congress. Vienna, Austria, 2015.
16. Leslie I, Williams S, Brown C, Isaac G, Jin Z, Ingham E, Fisher J. Effect of bearing size on the long-term wear, wear debris, and ion levels of large diameter metal-on-metal hip replacements-An in vitro study. J Biomed Mater Res B Appl Biomater 2008;87-1:163-72.
17. Bowsher JG, Clarke IC, Williams PA, Donaldson TK. What is a "normal" wear pattern for metal-on-metal hip bearings? J Biomed Mater Res B Appl Biomater 2009;91-1:297-308.
18. Brodner W, Grubl A, Jankovsky R, Meisinger V, Lehr S, Gottsauner-Wolf F. Cup inclination and serum concentration of cobalt and chromium after metal-on-metal total hip arthroplasty. J Arthroplasty 2004;19-8 Suppl 3:66-70.
19. Wang L, Williams S, Udofia I, Isaac G, Fisher J, Zhongmin J. The effect of cup orientation and coverage on contact mechanics and range of motion of metal-on-metal hip resurfacing arthroplasty. J Eng in Med 2012;226-11:887-6.
20. Clarke IC, Burgett-Morena MD, Donaldson TK, Smith EJ, Savissar C, Bowsher JG. Validation of clinical edge-wear in 'Steep-cups' using 40 - 70 degrees dynamic inclinations in novel MOM simulator study. ISTA 28th Annual Congress. Vienna, Austria, 2015.
21. Amstutz HC, Le Duff M, Johnson AJ. Socket position determines hip resurfacing 10-year survivorship. Clinical Orthopaedics and Related Research 2012;470:3127 - 33.
22. Yoon JP, Le Duff MJ, Johnson A, Takamura KM, Ebramzadeh E, Amstutz CA. Contact patch to rim distance predicts metal ion levels in hip resurfacing. Clin Orthop Relat Res 2013;471:1615-21.
23. Matthies AK, Henckel J, Cro S, Suarez A, Noble PC, Skinner J, Hart AJ. Predicting Wear and Blood Metal Ion Levels in Metal-on-Metal HIp Resurfacing. J Orthop Res 2014;32-1:167-74.
24. Lazennec JY, Rousseau MA, Rangel A, Gorin M, Belicourt C, Brusson A, Catonne Y. Pelvis and total hip arthroplasty acetabular component orientations in sitting and standing positions: measurements reproductibility with EOS imaging system versus conventional radiographies. Orthop Traumatol Surg Res 2011;97-4:373 - 80.
25. Lazennec JY, Rousseau MA, Brusson A, Folinais D, Amel M, Clarke IC, Pour AE. Total Hip Prostheses in Standing, Sitting and Squatting Positions: An Overview of Our 8 Years Practice Using the EOS Imaging Technology. Open Orthop. J. 2015;9:26-44.
26. Lee R, Essner A, Wang A. Tribological considerations in primary and revision metal-on-metal arthroplasty. J Bone Joint Surg Am 2008;90 Suppl 3:118-24.
27. Clarke IC, Donaldson TK, Savisaar C, Bowsher JG. New algorithm permits accurate depiction of cup-wear patterns in clinical and simulator studies. ISTA 28th Annual Congress. Vienna, Austria, 2015.
28. Bengs BC, Sangiorgio SN, Ebramzadeh E. Less range of motion with resurfacing arthroplasty than with total hip arthroplasty. Acta Orthop 2008;79-6:755-62.
29. Clarke IC, Donaldson TK, Burgett MD, Smith EJ, Bowsher J, Savisaar C, John A, Lazennec JY, McPherson E, Peters CL. Normal and Adverse Wear Patterns Created In-vivo on MOM Surfaces - a retrieval study representing four vendors. In: Kurtz SM, Greenwald SA, Mihalko WM, Lemons JA, eds. Metal-on-Metal Total Hip Replacement Devices. Vol. STP1560. West Conshohocken, PA: ASTM International, 2013 157-92.
30. Langton, DJ, Jameson, SS, Joyce, TJ, Gandhi, JN, Sidaginamale, R, Mereddy, P, Lord, J, Nargol, AV. Accelerating failure rate of the ASR total hip replacement J. Bone Joint Surg. Br 2011; 93-8: 1011 – 1016.
31. Bergmann G, Deuretzbacher G, Heller M, Graichen F, Rohlmann A, Strauss J, Duda GN. Hip contact forces and gait patterns from routine activities. J Biomech 2001;34-7:859-71.
32. Esposito CI, Walter WL, Roques A, Tuke MA, Zicat BA, Walsh WR, Walter WK. Wear in alumina-on-alumina ceramic bearings. A retrieval analysis of edge loading. J Bone Joint Surg Am 2012;7:901-7.
33. Halim T, Burgett M, Donaldson TK, Savisaar C, Bowsher JG, Clarke IC. Profiling the third-body wear damage produced in CoCr surfaces by bone cement, CoCr, and Ti6A14V debris: A 10-cycle metal-on-metal simulator test. J Eng in Med 2014;Proc. IMechE -H:1-11.
34. Halim T, Clarke IC, Burgett-Moreno M, Donaldson TK, Savisaar C, Bowsher JG. A Simulator Study of Adverse Wear with Metal and Cement Debris Contamination in metal-on-metal (MOM) Hip Bearings. J Bone Joint Research (UK) 2015;4:29-3

Glossary of Terms

A:
Angle used to represent cup wear-pattern

C:
Angle used to represent size of contact-patch

F:
Angle describing the sub-hemispherical bearing surface

P:
Profile angle representing loss of bearing surface in load-bearing region of cup

L:
Lateral inclination angle of cup

*L:
Critical cup inclination (equation-4)

ARC:
Distance measured from cup rim to the vertical plane, analogous to the "Arc of Cover" [9]

CAP:
Area of cup wear-pattern produced in a hip simulator

CPR:
"Contact Patch to Rim" chord distance from cup rim to a 14° medially-directed axis [1]

CPER:
"Contact Patch Edge to Rim" chord distance [6] measured from cup rim to edge of contact patch (as centered on a 14° medially-directed axis)

Edge wear:
An adverse wear condition produced when the cup rim is able to cross the habitual wear-pattern in a MOM bearing

EW%:
definition for edge wear in MOS-algorithm (equation-3)

Margin-of-safety:
A narrow region that can be present between cup rim and the edge of the wear-pattern

MOS:
Margin-of-safety measurement (distance, angle: equations 2 and 8a)

Wear-pattern:
Habitual wear zone produced by patient's hip function

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A Minimum 2-Year Follow-up Using Modular Trabecular Metal Tibial Components in Total Knee Arthroplasty

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Abstract

Introduction: Early failure of tibial components remains a concern in total knee arthroplasty (TKA). Loss of fixation with cemented implants continues to be problematic in young, active patients. We sought to determine outcomes in patients receiving trabecular metal (TM) implants in a single-surgeon community hospital setting.

Methods: A retrospective analysis was performed on 167 consecutive primary TKAs performed on 133 patients utilizing a TM tibial implant with a minimum two years follow-up.

Results: Failure due to aseptic loosening occurred in 4 of the 167 cases (2.4%). Local and systemic complication rates were low. Length of hospital stay and tourniquet time data were also reported.

Conclusion: Overall complications were low in our cohort of patients receiving TM implants. Longer follow-up is necessary to determine if the outcomes we observed are sustained over time.

Keywords: *total knee arthroplasty; uncemented; cementless; trabecular metal; porous tantalum*
Level of Evidence: *AAOS Therapeutic Level IV*

Introduction

Among the many ways by which total knee arthroplasty (TKA) fail and require revision, early aseptic failure of tibial implants continues to be a major concern for most surgeons [1,2,3]. In the cemented TKA literature, aseptic loosening rates continue to remain between 1 - 7 % in most reported series [4,5,6,7,8]. Although cemented TKA remains the gold standard, the bone cement interface represents a biologically static construct. Mechanical forces that overwhelm the strength of this interface will lead to failure without the biologic capacity for repair [9]. Biologic fixation of an implant to bone, if achieved, has the theoretical

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advantage of biologic repair throughout the life of the implant if the surrounding host bone maintains the ability for fracture repair and remodeling. Cementless implants were developed to capitalize on this potential [10,11,12,13].

Early cementless porous-coated implants had several design flaws such as low porosity, suboptimal frictional characteristics, and increased modulus of elasticity as compared to bone [14]. Trabecular metal (TM) tibial components (Zimmer Inc.) were introduced in 1999 with the aim of overcoming the limitations of earlier porous coated cementless designs. The TM material is composed of tantalum, a chemically stable and inert metal with a high fatigue strength that makes it ideal for orthopaedic implants [14]. During development, the polyethylene tray is firmly attached to the TM material through direct compression molding. The TM tibial baseplate is additionally composed of two hexagon-shaped tantalum pegs that are press fit into holes drilled in the tibia to maximize bony ingrowth potential. Trabecular metal has demonstrated significant bony ingrowth and has been successfully used previously in tumor reconstruction, spinal fusion, and treatment of avascular necrosis of the femoral head [14]. With a porosity of up to 80% and a high coefficient of friction against cancellous bone, TM has great potential for biologic fixation [15]. The high porosity provides the ideal environment for bony in-growth and vascularization [16].

The advent of TM and early studies demonstrating better initial stabilization and comparable survival rates when compared to cemented tibial implants has led to a gradual increase in clinical use. The purpose of this study was to report our experiences using TM tibial components in a high volume, single-surgeon community hospital practice with a minimum of two years follow-up.

Methods

The study used prospectively collected data on all patients undergoing TKA with TM tibial baseplates performed by a single fellowship-trained orthopedic surgeon at a large community hospital. The study included all primary TKAs using TM tibial implants performed between October 2008 and May 2011, for a total of 167 TKAs performed on 133 patients. All patients consented for the procedure.

The initial Institutional Review Board approval for the study and data collection was obtained in 2004 and has been renewed annually. Data were collected prospectively using standardized data collection forms and protocols, and maintained in a designated database. Data were collected preoperatively and postoperatively, with the database continually updated with complications and follow-up data on all patients within the database. Standardized data collection forms were used to collect data on patient characteristics. The study inclusion criteria included any patient seen by the surgeon during the study time period for primary TKA with a TM tibial implant, including patients requiring hardware removal prior to primary arthroplasty. Patients undergoing revision TKA were excluded from this study.

The senior author (CKN) performed all operations. All tibial implants were posterior stabilized modular components. Monoblock components were not used during this study. All trabecular metal tibial implants were by Zimmer (NexGen Trabecular Metal Tibial Tray).

All TKAs in this study were performed in a large community hospital and the study was observational in nature. The decision to use the modular TM tibial baseplate was made by the surgeon based on intraoperative assessment of bone quality. As there are no established quantitative measures or guidelines for surgeons to follow regarding the indications or contraindications for the use of trabecular metal implants, the surgeon (CKN) based his decision regarding the appropriateness of TM use on the visual inspection of bone porosity, age of the patient, bony defects present, and palpable assessment of bone density. The patella was routinely resurfaced and cemented. All femoral components were cemented.

All patients received the same preoperative and postoperative protocols. The schedule for follow-up consisted of a standard total knee postoperative protocol, which consisted of scheduled appointments at 2 weeks, 6 weeks, 3 months, 6 months, 1 year, and 2 years following surgery. Radiograph images were taken at each follow-up appointment to monitor implant fixation (Figure 1a-1c) and revision TKA was performed when necessary (Figure 1d). Beyond 2 years post-TKA, follow-up appointments were scheduled at 5 years or at the patient's preference.

All patients had hip-to-ankle radiographs prior to surgery and at 6-weeks follow-up to assess preoperative deformity and final outcome regarding implant position and mechanical alignment. All patients also had standard anteroposterior (AP), lateral, and merchant views done preoperatively and at each follow-up appointment. All patients had standard AP and lateral immediate postoperative radiographs taken in the recovery room following surgery.

Intraoperative complications, perioperative complications, and complications which occurred throughout the entire clinical follow-up period were prospectively collected and entered into a database. All pertinent surgical information including anesthesia type, tourniquet times, implant sizes and brand as well as patellar thickness pre- and

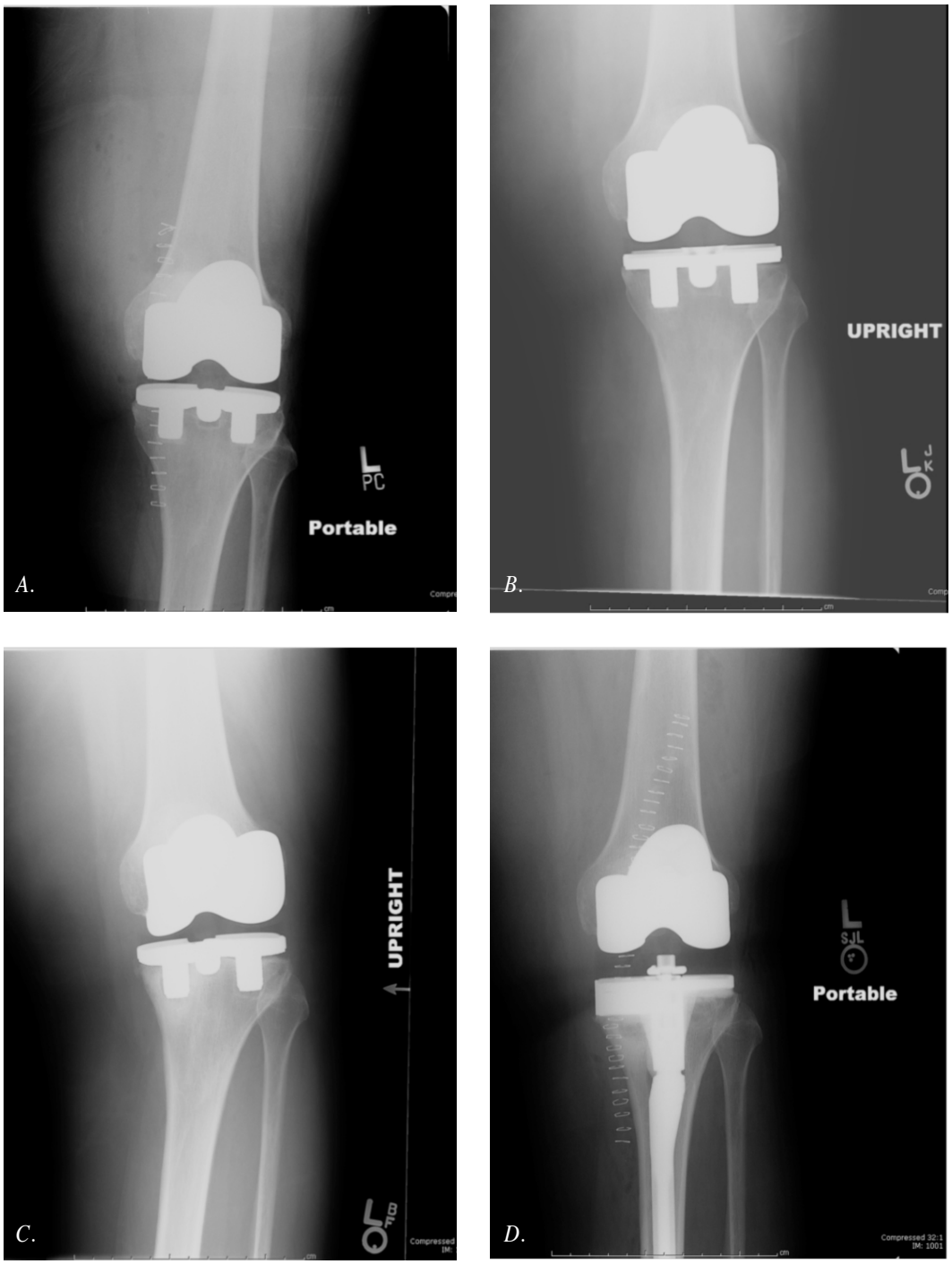

Figure 1. Radiograph images of TKA with TM tibial implants. Images taken (a) prior to discharge, (b) at 6 weeks follow-up, (c) at 8 months follow-up, and (d) following revision TKA.

post-resurfacing were entered into the database. Preoperative knee range of motion, as well as immediate postoperative range of motion following wound closure and dressing application, was also recorded.

Aseptic failure was recorded per knee and was defined by either a grossly unstable radiograph or a bone scan positive for increased activity at the bone-implant interface with accompanying clinical symptoms. Clinical symptoms, which included the presence of progressive pain, chronic pain, or start-up pain, were investigated with laboratory tests to rule out infection including C-reactive protein, sedimentation rates, and aspirations where clinically indicated. Radiographic evidence of failure included gross subsidence of an implant, a lack of bony integration as determined by the lack of spot welding, or the presence of radiolucent lines or areas of osteolysis beneath the tibial baseplate. The onset of failure was defined as the day of diagnosis by the operating surgeon.

Results

Patient Characteristics

Table 1 reports patient demographics and average follow-up time. Sex was reported as a percentage of males receiving TM implants. Mean age, body mass index (BMI), American Society of Anesthesiologists (ASA) Physical Status, and follow-up were also recorded.

Local Complications

Table 2 presents data on failure due to aseptic loosening and additional local complications recorded per knee (n=167). These include deep venous thrombosis (DVT), peroneal nerve palsy, deep infection, superficial infection, wound dehiscence, structural implant failure, and fracture. Overall, the incidence of local complications was low.

Systemic Complications

Table 3 presents data on systemic complications recorded per patient (n=133). Systemic complications included myocardial infarction (MI), pulmonary embolism (PE), and death. Overall, incidence rates of systemic complications were low.

Tourniquet Time and Length of Stay

Tourniquet time was analyzed and recorded "per TKA" whereas length of stay (LOS) was analyzed and recorded "per surgery". The average tourniquet time was 47.6 minutes (range 0-90 minutes). No tourniquet was used in two knees undergoing TKA with a TM tibial component.

The LOS (per surgery) was 2.81 days (SD=1.3 days, range 1-9 days) with the median length being 2.0 days.

Implant Survival

The failure time was defined as the time between the date of the TKA and the earliest clinical or radiographic indication of aseptic failure. All 4 cases (100%) of aseptic failure occurred within 1 year (two failures at 1 month, one case at 2 months, and one case at 8 months). The mean time to aseptic failure following TKA was 3.5 months (range: 1-8 months).

X-Ray Review Analysis

While we understand that the KSS and radiographic data is valuable in demonstrating clinical efficacy, we do not have a completed data set to perform the analysis to include in this paper.

Table 1: Patient Characteristics

Variable	TM Baseplate (n=133)
Male	83 (62.4%)
Age (years)	65.5 ± 8.9
BMI	31.9 ± 5.4
ASA Physical Status	2.2 ± 0.5
Follow-up (months)	33.9 ± 8.4

Note: Data are presented per patient. The values presented for age, BMI, ASA, and follow-up are the means and standard deviations.

Table 2: Local Complications

Complication	TM Base plate (n=167)
Aseptic Loosening	4 (2.4%)
DVT	4 (2.4%)
Peroneal Nerve Palsy	0
Deep Infection	4 (2.4%)
Superficial Infection	0
Wound Dehiscence	0
Structural Implant Failure	0
Fracture	0
TOTAL	12 (7.2%)

Note: Data are presented per TKA.

Table 3: Systemic Complications

Complication	TM Base plate (n=133)
Death	0
MI	0
PE	1 (.8%)
TOTAL	1 (.8%)

Note: Data are presented per patient.

Discussion

This study reports our experiences with TKA in patients receiving cementless TM tibial components using prospectively collected data on 167 TKAs performed on 133 patients. Data was collected in a large volume, single-surgeon practice over a three year period with a minimum two years of follow-up. In our series, the early aseptic failure rate in patients undergoing TKA with TM tibial components was 2.4%.

Despite the biologic promise of trabecular metal, there is relatively little reported experience utilizing TM tibial implants compared to the overwhelmingly large data available regarding cemented TKA. Initial research by Bobyn et al demonstrated low complication rates yet had a limit-

ed number of patients and an undefined follow-up period [17]. Helm et al followed 105 patients for three years and found no radiolucencies, with only one revision of the tibial component (1%), which was attributed to a trauma [18]. Ghalayini et al reported similar results at 6 years [19]. Unger et al followed 108 patients for two years and had no revisions or clinical or radiographic failures [20]. Kamath et al reported on 100 consecutive patients younger than 55 at a minimum of 5 years and found no significant difference to a matched cemented group and noted no failures due to fixation [21].

Aseptic loosening of the tibial component remains a primary cause of revision surgery in TKA. Multiple studies have reported aseptic loosening to account for between 3% and 60% of TKA failures depending on the length of follow-up [22,23,24,25,26,27]. Research comparing aseptic failure rates in cementless TM tibial components to cemented tibial components is limited. A study by Dunbar et al [2] used radiostereometric analysis to evaluate migration of the tibial components, and found the proportion of components "at risk" of aseptic loosening to be 0% in patients with a TM tibial component and 19% in patients with cemented tibial components at 2 years follow-up. A similar study at 5 years follow-up demonstrated solid fixation and stabilization of the TM tibial components with 0% of TM components at risk of aseptic loosening [28]. Hayakawa et al reported no cases of implant loosening in their series of 29 TM tibial component TKA patients [29]. Fernandez-Fairen et al similarly reported no cases of aseptic loosening in any of their 69 TM tibial component and 63 cemented tibial component patients [30]. A recent randomized control trial comparing cemented and TM tibial component survivorship found that patients receiving TM tibial implants had a lower 5-year risk of aseptic loosening than patients receiving cemented tibial implants [31]. Survivorship and functionality were comparable between the two groups.

In our study, there were four cases (2.4%) of aseptic loosening in patients receiving TM tibial components. In addition, all of our patients were seen at a minimum of two years following surgery during which time the majority of failures would be expected [2,32]. Indeed all four cases of aseptic loosening occurred within 8 months. Two cases of aseptic failure occurred prior to 1-month follow-up. Both cases had varus subsidence of the tibial plate indicating aseptic loosening as the primary mechanism of failure.

The mechanism by which aseptic failures occur in TM tibial implants may also be postulated by observations in our study. Earlier reports demonstrated that the majority of aseptic failures cases occurred within the first two years following TKA [32]. We report similar results in our series, as all 4 cases of aseptic failure occurred within 8 months following surgery. This finding may shed light on the mechanism by which aseptic loosening occurs in TM TKA. Trabecular metal implants allow for dynamic bone remodeling at the bone-implant interface if biologic fixation succeeds. Aseptic failure with TM implants would be expected early if osseointegration fails, which was observed in our study. On the other hand, cemented implants form a static interface with bone, which can gradually break down and loosen over time, resulting in a greater incidence of aseptic loosening over time. More prospective, randomized studies looking at the survival of these implants over the long-term should be done to evaluate their longevity.

Tourniquet time can be used as a way to measure surgery time, as well as a means to quantify efficiency. Since TM tibial components do not require cement, time spent on preparing the cement can be saved. Furthermore, there are disadvantages to prolonged operative and tourniquet times in addition to the added operating room costs. These include increased blood loss, tourniquet associated ischemia, increased incidence of infection, and delayed wound healing [33]. However, the cost benefit gained in the shorter operating time may be slightly offset by the higher cost of the TM tibial component.

There have been reported drawbacks to the use of TM in TKA. In a case report of an 80 year-old man receiving a TM tibial component, it was hypothesized that a patient's advanced age may cause reduced regenerative ability of bone, and thus diminished effectiveness of the TM tibial component [34]. This hypothesis raises the important question: how do orthopedic surgeons determine who is an appropriate candidate for a TM implant? We may never be able to identify specific characteristics that give us reliable answers, but this limited study appears to support the use of TM baseplates in younger male patients.

The primary potential study limitation was the observational nature of the study. The surgeon used his clinical judgment to determine if a patient was suitable to receive a TM tibial implant. As a result, the patients in this series were relatively young (65.5 years), and predominantly male (62.4%). However, previous studies have demonstrated higher TKA failure rates in younger patients [35] and in males [36,37]. Based on the findings of these previous studies, as well as the low aseptic failure rate in our series of patients, one could postulate that TM implants may be an effective alternative for younger, active patients. Randomized trials with long-term follow-ups comparing TM to cemented tibial implants are necessary to determine the clinical worth of TM.

Conclusion

The demand for knee replacements is expected to continue to rise, particularly in younger patient populations [38,39]. Biologic fixation of implants has theoretical advantages over static fixation strategies such as cement. We report an aseptic loosening rate of 2.4% in our cohort of TKA patients receiving TM implants. Additional local and systemic complications were rare. A substantial amount of research is still required to determine if TM implants will provide improved longevity in TKA patients.

References

1. Bourne RB, Finlay JB. The influence of tibial component intramedullary stems and implant-cortex contact on the strain distribution of the proximal tibia following total knee arthroplasty: an in vitro study. Clin Orthop Relat Res. 1986;208:95–99
2. Dunbar MJ, Wilson DAJ, Hennigar AW, Amirault JD, Gross M, Reardon GP. Fixation of a trabecular metal knee arthroplasty component. A prospective randomized study. J Bone Joint Surg Am. 2009;91:1578–1586
3. Cawley DT, Kelly N, Simpkin A, Shannon FJ, McGarry JP. Full and surface tibial cementation in total knee arthroplasty: a biomechanical investigation of stress distribution and remodeling in the tibia. Clin Biomech (Bristol, Avon). 2012;27:390-397
4. Foran JR, Whited BW, Sporer SM. Early aseptic loosening with a precoated low-profile tibial component: a case series. J Arthroplasty. 2011;26:1445-1450
5. Barrington JW, Sah A, Malchau H, Burke DW. Contemporary cruciate-retaining total knee arthroplasty with a pegged tibial baseplate. Results at a minimum of ten years. J Bone Joint Surg Am. 2009;91:874-878
6. Miller CW, Pettygrow R. Long-term clinical and radiographic results of a pegged tibial baseplate in primary total knee arthroplasty. J Arthroplasty 2001;16:70
7. Weeden SH, Ogden SB. Early loosening of MIS tibial implants in primary TKA. American Academy of Orthopaedic Surgeons Annual Meeting. New Orleans, LA; 2010
8. Anderson DR, Anderson JT. High incidence of aseptic loosening following MIS total knee arthroplasty at short- term follow-up. American Academy of Orthopaedic Surgeons Annual Meeting. Las Vegas, NV; 2009
9. Lewis G. Properties of acrylic bone cement: state of the art review. J Biomed Mater Res. 1997;38:155-182
10. Soballe K, Hansen ES, Brockstedt-Rasmussen H, Bunger C. Hydroxyapatite coating converts fibrous tissue to bone around loaded implants. J Bone Joint Surg Br. 1993;75:270-278
11. Hofmann AA, Evanich JD, Ferguson RP, Camargo MP. Ten- to 14-year clinical followup of the cementless Natural Knee system. Clin Orthop Relat Res. 2001;388:85-94
12. Baldwin JL, El-Saied MR, Rubinstein RA Jr. Uncemented total knee arthroplasty: report of 109 titanium knees with cancellous-structured porous coating. Orthopedics. 1996;19:123-130
13. Hofmann AA, Heithoff SM, Camargo M. Cementless total knee arthroplasty in patients 50 years or younger. Clin Orthop Relat Res. 2002;404:102-107
14. Patil N, Lee K, Goodman SB. Porous tantalum in hip and knee reconstructive surgery. J Biomed Mater Res B Appl Biomater. 2009;89:242-251
15. Bobyn JD, Stackpool GJ, Hacking SA, Tanzer M, Krygier JJ. Characteristics of bone ingrowth and interface mechanics of a new porous tantalum biomaterial. J Bone Joint Surg Br. 1999;81:907-914
16. Karageorgiou V, Kaplan D. Porosity of 3D biomaterial scaffolds and osteogenesis. Biomaterials. 2005;26:5474–5491
17. Bobyn JD, Poggie RA, Krygier JJ, Lewallen DG, Hanssen AD, Lewis RJ, Unger AS, et al. Clinical validation of a structural porous tantalum biomaterial for adult reconstruction. J Bone Joint Surg Am. 2004;86A:123-129
18. Helm AT, Kerin C, Ghalayini SR, McLauchlan GJ. Preliminary results of an uncemented trabecular metal tibial component in total knee arthroplasty. J Arthroplasty. 2009;24:941–944
19. Ghalayini SR, Helm AT, McLauchlan GJ. Minimum 6year results of an uncemented trabecular metal tibial component in total knee arthroplasty. The Knee. 2012;19:872-874
20. Unger AS, Duggan JP. Midterm results of a porous tantalum monoblock tibia component. J Arthroplasty. 2011;26:855–860
21. Kamath AF, Lee GC, Sheth NP, Nelson CL, Garino JP, Israelite CL. Prospective results of uncemented tantalum monoblock tibia in total knee arthroplasty: minimum 5-year follow-up in patients younger than 55 years. J Arthroplasty. 2011;26:1390-1395
22. Fehring TK, Odum S, Griffin WL, Mason JB, Nadaud M. Early failures in total knee arthroplasty. Clin Orthop Relat Res. 2001;392:315-318
23. Bozic KJ, Kurtz SM, Lau E, Ong K, Chiu V, Vail TP, Rubash HE, Berry DJ. The epidemiology of revision total knee arthroplasty in the United States. Clin Orthop Relat Res. 2010;468:45-51
24. Sharkey PF, Hozack WJ, Rothman RH, Shastri S, Jacoby SM. Insall Award paper. Why are total knee arthroplasties failing today? Clin Orthop Relat Res. 2002;404:7-13
25. Vessely MB, Whaley AL, Harmsen WS, Schleck CD, Berry DJ. The Chitranjan Ranawat Award: Long-term survivorship and failure modes of 1000 cemented condylar total knee arthroplasties. Clin Orthop Relat Res. 2006;452:28-34
26. Peters CL, Hennessey R, Barden RM, Galante JO, Rosenberg AG. Revision total knee arthroplasty with a cemented posterior-stabilized or constrained condylar prosthesis: a minimum 3-year and average 5-year follow-up study. J Arthroplasty. 1997;12:896-903
27. Garcia RM, Hardy BT, Kraay MJ, Goldberg VM. Revision total knee arthroplasty for aseptic and septic causes in patients with rheumatoid arthritis. Clin Orthop Relat Res. 2010;468:82-89
28. Wilson DA, Richardson G, Hennigar AW, Dunbar MJ. Continued stabilization of trabecular metal tibial monoblock total knee arthroplasty components at 5 years measured with radiostereometric analysis. Acta Orthop. 2012;83:36–40
29. Hayakawa K, Date H, Tsujimura S, Nojiri S, Yamada H, Nakagawa K. Mid-term results of total knee arthroplasty with a porour tantalum monoblock tibial component. Knee. 2014;21(1):199-203
30. Fernandez-Fiaren M, Hernandez-Vaquero D, Murcia A, Torres A, Llopis R. Trabecular metal in total knee arhtroplasty associated with higher knee scores: a randomized controlled trial. Clin Orthop Relat Res. 2013;471:3543-3553
31. Pulido L, Abdel MP, Lewallen DG, Stuart MJ, Sanchez-Sotelo J, Hanssen AD, Pagnano MW. Trabecular Metal Tibial Components Were Durable and Reliable in Primary Total Knee Arthroplasty: A Randomized Clinical Trial. Clin Orthop Relat Res. 2014 Apr 1.
32. Piedade SR, Pinaroli A, Servien E, Neyret P. Revision after early aseptic failures in primary total knee arthroplasty. Knee Surg Sports Traumatol Arthrosc. 2009;17:248-253
33. Cheng, T., Zhang, G., & Zhang, X. (2011). Imageless Navigation System Does Not Improve Component Rotational Alignment in Total Knee Arthroplasty. Journal of Surgical Research, 171(2), 590–600.
34. Tigani D, Sabbioni G, Raimondi A. Early aseptic loosening of a porous tantalum knee prosthesis. Chir Organi Mov. 2009;93:187-191
35. Harrysson OL, Robertsson O, Nayfeh JF. Higher cumulative revision rate of knee arthroplasties in younger patients with osteoarthritis. Clin Orthop Relat Res. 2004;421:162–168
36. Singh JA, Kwoh CK, Richardson D, Chen W, Ibrahim SA. Gender and surgical outcomes and mortality after primary total knee arthroplasty: A risk-adjusted analysis. Arthritis Care Res (Hoboken). 2013
37. Gioe TJ, Novak C, Sinner P, Ma W, Mehle S. Knee arthroplasty in the young patient: survival in a community registry. Clin Orthop Relat Res. 2007;464:83-87
38. Jain NB, Higgins LD, Ozumba D, Guller U, Cronin M, Pietrobon R, Katz JN. Trends in epidemiology of knee arthroplasty in the United States, 1990-2000. Arthritis Rheum. 2005;52:3928-3933
39. Losina E, Thornhill TS, Rome BN, Wright J, Katz JN. The dramatic increase in total knee replacement utilization rates in the United States cannot be fully explained by growth in population size and the obesity epidemic. J Bone Joint Surg Am. 2012;94:201-20

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Surgeon Assessment of Gapping Versus Kinetic Loading Using Intraoperative Sensors During TKA

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Abstract

Purpose: The purpose of this study was to determine if using a sensor-equipped tibial insert would reduce medial (MED) and lateral (LAT) gapping and create more equivalent compressive forces in the MED and LAT compartments.

Methods: 7 orthopedic surgeons each performed bilateral TKA on complete lower extremity cadaveric specimens. Left TKA was performed first without the use of the instrumented tibial insert. With trial components placed, the patella was reduced and joint capsule closed with towel clips. Surgeons performed varus and valgus stress tests on each knee and the mm of MED and LAT gapping were recorded. Compressive forces in the MED and LAT compartment were measured at 10°, 45°, and 90° of flexion. Sensor-assisted TKA was then performed on the right knee and compressive forces and gapping were again recorded. MED, LAT, and total mediolateral (ML) gapping and MED and LAT compressive forces were compared between conventional TKA and sensor-assisted TKA with paired t-tests.

Results: Sensor-assisted TKA resulted in significantly reduced MED (1.2 vs. 1.9 mm, $p<.001$), LAT (0.8 vs. 1.4 mm, $p = 0.003$), and total ML gapping (2.0 vs. 3.4 mm, $p<.001$). There were no differences in the MED and LAT compressive forces between conventional and sensor-assisted TKA. However, sensor-assisted TKAs demonstrated greater MED compartment forces as the knee was flexed whereas conventional TKAs had greater LAT forces.

Conclusions: Sensor-assisted TKA significantly reduced MED and LAT gapping with the knee in 20° of flexion. Future clinical studies are needed to determine the most appropriate compressive forces in the MED and LAT compartments.

Keywords: *total knee replacement, ligament balancing, laxity, instability, Kinetic Sensors*
Level of Evidence: *AAOS Therapeutic Level II*

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Introduction

Independent of mechanical axis restoration and joint line inclination, proper balance of the soft tissues of the knee has become one of the primary principles in achieving successful total knee arthroplasty (TKA). [10] A balanced extension gap is routinely achieved by releasing structures on the tight or concave side of the knee deformity. For example, medial structures are released to balance a varus knee and, with a valgus knee, lateral structures are released. The inability to achieve proper varus-valgus balance of the knee may result in patient discomfort and/or dissatisfaction secondary to either restricted range of motion or mediolateral instability. [4,14] Furthermore, unequal contact forces between the medial and lateral compartments could increase the risk of accelerated wear and/or premature failure of the polyethylene. [22]

Due to the potentially increased risks of a poor clinical outcome or revision, instrumented methods to assist surgeons when balancing the knee have been developed. An electronic load-sensing tibial trial system has been developed to quantify the magnitude and location of compressive forces in the medial and lateral compartments. The sensor replaces the standard tibial trial insert and fits exactly into the tibial tray, and is used only during the trialing process (Figure 1). Dual kinetic loading plates coupled

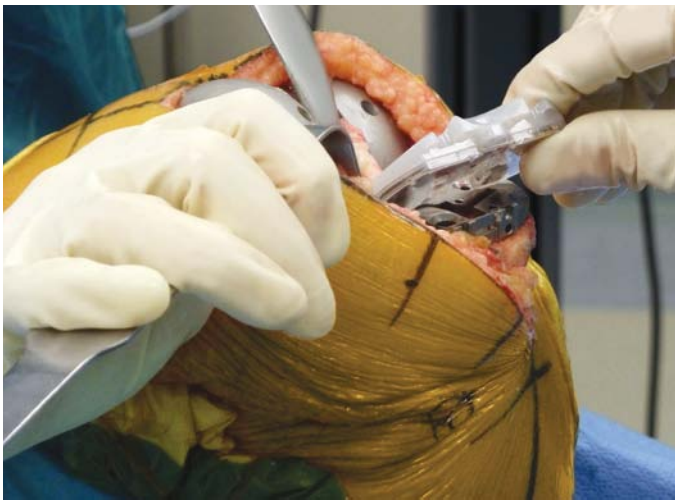

Figure 1. Sensor-equipped tibial insert being placed.

with a microprocessor relay loading values and femoral contact point position in real-time to a display screen. All sensor data is displayed graphically and superimposed on a virtual sensor image (Figure 2). Peak loading values and tibiofemoral contact point position in the medial and lateral compartments are displayed separately, and can be tracked through the full range of motion. The sensor system also captures the relative rotational alignment of the tibial tray, in relation to the femur, by measuring the peak

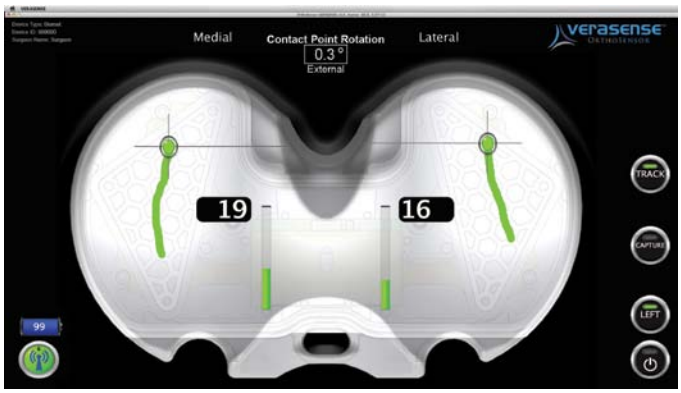

Figure 2. An example of the real-time force readings provided by the software's graphical user interface. In this example, the knee is well balanced with 19lbf in the medial compartment and 16 lbf in the lateral compartment.

contact point position in the medial and lateral compartment.

In theory, by providing surgeons with real-time information about mediolateral force asymmetries throughout the full range of motion, instrumented balancing systems may allow for more consistently balanced TKAs. For the current study, we questioned whether use of a load-sensing tibial trial system would allow surgeons to more consistently balance the knee with reduced medial and lateral gapping. We also questioned whether the use of the load-sensing tibial trial would result in more symmetrical medial and lateral compressive forces throughout the range of motion. We hypothesized that sensor-assisted TKAs would demonstrate significantly lower medial and lateral gapping, as well more symmetrical compressive forces in the medial and lateral compartments than conventional TKAs.

Materials and Methods

Seven orthopaedic surgeons participated in this laboratory study, and only the lead author had prior clinical experience with the sensor-equipped tibial insert and TKA implant system utilized in this study. Five surgeons were board certified with seven to 30 years of clinical experience, and two were orthopedic residents (R5 and R4). Each surgeon was asked to perform bilateral posterior cruciate ligament (PCL)-retaining TKA on a complete lower extremity specimen. The cadaveric specimens (5 female, 2 male; Mean age = 60 years (range 31 to 78), Mean weight = 70.9 kg (range 43.2 to 113.6 kg)) were delivered to the laboratory facility in a thawed state, and the study procedures were performed over a six-hour period. None of the specimens had a history of previous knee surgery. Two specimens had bilateral degenerative changes in the knee joints at the time of surgery; however, the other speci-

mens were considered normal. One specimen with varus deformity had Outerbridge grade 4 degenerative changes to the medial and patellofemoral compartments with grade 3 changes in the lateral compartment. One specimen with valgus deformity had tricompartmental Outerbridge grade 4 changes. Each surgeon first performed a cruciate-retaining TKA on the left knee using either a medial parapatellar or subvastus approach. Measured resection techniques were utilized to determine rotation of the femoral component, and all surgeons utilized similar TKA instrument sets and trial components (Vanguard Complete®, Biomet, Warsaw, IN).

Study measurements were made once the surgeon had made all bony cuts, balanced the soft-tissue as necessary, and trial components had been placed. The tibial trial was pinned in place and a sensor-equipped tibial insert (VERASENSE™ , OrthoSensor, Inc., Dania Beach, FL, Figure 1) was inserted in the standard tibial trial component. The sensor-equipped tibial insert featured the same articulating surface as the true polyethylene liners. Force sensors located throughout the tibial insert allowed for compressive loads in the medial and lateral compartment to be displayed wirelessly on the monitor of the accompanying tower unit. With the surgeon blinded to the measurements, the compressive forces in the medial and lateral compartments were recorded with the knee in 10°, 45°, and 90° of flexion. An evaluator that did not perform any of the surgical procedures recorded all study measurements, and pressure measurements were made with the patella reduced and the capsule closed with towel clips. Force readings were provided by the system in pounds force (lbf), and were displayed in 1 lbf increments. The amount of force asymmetry was calculated by subtracting the lateral compartment forces from the medial compartment measures. As such, negative symmetry values were indicative of greater forces in the lateral compartment and positive values associated with greater medial forces.

All seven surgeons were then asked to manually estimate the mm of medial and lateral gapping when performing varus and valgus stress tests for each of the seven specimens. Medial and lateral gapping were assessed with knee flexed to approximately 20° with the patella reduced and capsule closed with towel clips. The study surgeons manually estimated medial and lateral gapping in 0.5 mm increments. While it is common to intraoperatively manually grade mm of gapping with the knee in full extension and 90° of flexion, varus and valgus stress tests were performed at approximately 20° in this study as gapping measurements at this knee angle have been associated with patient-reported pain and function. [7] Medial and lateral gapping were recorded individually, and the total mediolateral gapping was calculated as the sum of both directions. Surgeons were blinded to the compressive loads and the other surgeons' gapping measurements.

Following a senior peer instructional seminar session on the clinical use of the sensor-equipped tibial insert, surgeons performed a sensor-assisted TKA on the right knee of each specimen. Surgeons were asked to again perform TKA as they normally would, but with the goal of balancing the compressive loads in the medial and lateral compartment to within 15 lbs (6.8 kg) through the use of the instrumented tibial trial. In addition to fully releasing specific structures to improve intraoperative balance, surgeons were free to use their preferred methods of soft tissue balancing such as pie-crusting or multiple needle puncturing. [9,17] Once the surgeons were satisfied with both implant alignment and soft-tissue balance, the medial and lateral gapping measurements were made, and the medial and lateral compressive forces were again recorded at 10°, 45°, and 90° of flexion.

Statistical Analyses

Paired, two-tailed t-tests were utilized to compare medial, lateral, and total mediolateral gapping between conventional and sensor-assisted TKA. Paired, two-tailed t-tests were also utilized to compare the medial and lateral compressive forces as well as the mediolateral symmetry at 10°, 45°, and 90° of flexion between conventional and sensor-assisted TKA. Statistical analyses were performed with SPSS Statistics v21 (IBM, Armonk, NJ), and $p < 0.05$ was considered statistically significant.

Results

Medial, lateral, and total mediolateral gapping were significantly reduced when using the instrumented tibial trial (Table 1). While the medial and lateral compressive forces, and mediolateral symmetry did not statistically differ between conventional and sensor-assisted TKA at 10°, 45°, or 90° of flexion ($p > 0.05$, Table 2), there was a shift from greater lateral compressive forces without the sensor to greater medial forces when using the device as the knee was flexed (Figure 3).

Discussion

The primary purpose of this study was to determine if the use of a load-sensing tibial trial would reduce medial

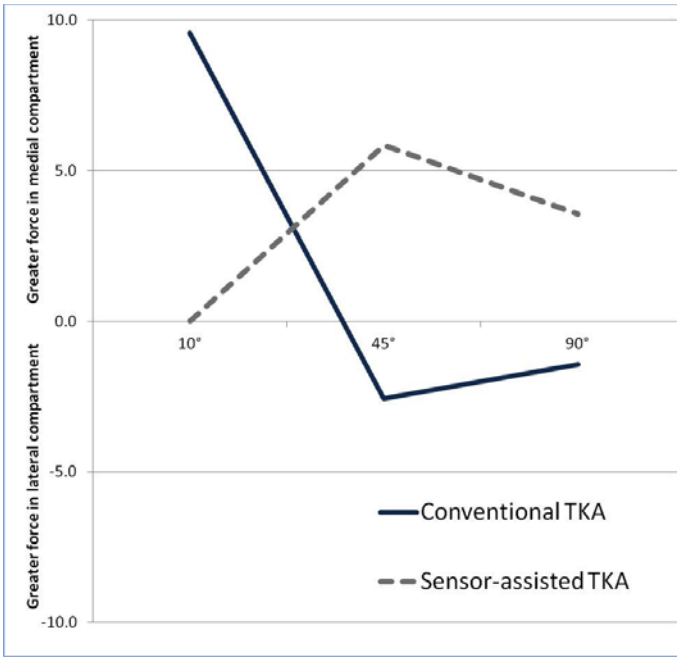

Figure 3. As the knee was flexed from 10° to 90°, there was a shift from greater compressive forces (lbf) in the lateral compartment forces during conventional TKA whereas the sensor-assisted TKAs had greater medial forces as the knee was flexed. The mean difference between the medial and lateral compartment forces at 10°, 45°, and 90° are presented for the two types of TKA. Zero represents equivalent forces in the medial and lateral compartments, positive values are indicative of greater forces in the medial compartment, and negative values are indicative of greater forces in the lateral compartment.

	Conventional TKA	Sensor-assisted TKA	p
Medial Gapping	*1.9 ± 1.4	*1.2 ± 0.9	< 0.001
Lateral Gapping	*1.4 ± 1.3	*0.8 ± 0.9	0.003
Total Mediolateral Gapping	*3.4 ± 2.1	*2.0 ± 1.4	< 0.001
Medial Compressive Force			
10° knee flexion	20.3 ± 39.4	7.3 ± 8.4	0.38
45° knee flexion	6.3 ± 6.2	10.6 ± 12.6	0.33
90° knee flexion	5.6 ± 5.3	9.9 ± 10.5	0.33
Lateral Compressive Force			
10° knee flexion	10.7 ± 8.5	7.3 ± 6.7	0.52
45° knee flexion	8.9 ± 3.8	4.7 ± 5.8	0.14
90° knee flexion	7.0 ± 5.0	6.3 ± 5.0	0.85

*significantly different ($p < 0.05$)

Table 1. Comparison of medial, lateral and total mediolateral gapping (mm ± standard deviation), as well as medial and lateral compressive forces (lbf ± standard deviation) between conventional and sensor-assisted TKAs.

	Cadaver							
	1	2	3	4	5	6	7	Mean
Conventional TKA								
Medial gapping	1.7	1.4	0.1	2.9	3.9	2.1	1.3	1.9
Lateral gapping	2.9	1.0	0.7	1.2	1.0	2.1	1.2	1.4
Medial compressive force	8	0	2	6	12	16	0	6.3
Lateral compressive force	3	11	6	12	14	8	8	8.9
Sensor-assisted TKA								
Medial gapping	0.3	1.2	1.1	1.9	2.1	0.9	0.9	1.2
Lateral gapping	0.3	0.3	1.8	0.7	1.1	0.9	0.4	0.8
Medial compressive force	35	0	3	8	5	20	3	10.6
Lateral compressive force	1	0	0	13	0	8	11	4.7

Table 2. Midflexion medial and lateral gapping (mm) and compressive forces (lbf) of the conventional and sensor-assisted TKAs performed in each cadaveric specimen. Gapping and compressive force measurements were taken at 20° and 45° of knee flexion, respectively.

and lateral gapping. Our hypothesis was supported, as medial gapping was significantly reduced from 1.9 mm to 1.2 mm ($p < 0.001$) and lateral gapping was significantly reduced from 1.4 mm to 0.8 mm ($p = 0.003$). The secondary hypothesis was that the mediolateral compressive forces would be more symmetrical when using the load-sensing tibial trial. This hypothesis was not supported, as no statistical differences in medial forces, lateral forces, or mediolateral asymmetry were noted between conventional and sensor-assisted TKA.

It was; however, interesting that there appeared to be a shift from greater lateral forces at higher flexion angles with conventional TKA to greater medial forces with sensor-assisted TKA. In the native knee, lateral laxity is greater than medial laxity, and is in part responsible for allowing lateral femoral rollback as the knee is flexed. [20] Having slightly greater compressive forces in the medial compartment with greater lateral laxity during TKA may promote more normal kinematics with a medial pivot and lateral femoral rollback. [5,8] In the current study, sensor-assisted TKAs demonstrated this pattern, with equivalent medial and lateral forces at 10°, but greater in the medial compartment at 45° and 90°. On the contrary, conventional

TKAs had greater forces in the medial compartment at 10°, but were greater in the lateral compartment at 45° and 90°.

While the results of the current study demonstrate improved mediolateral gapping with the use of the instrumented tibial trial, the clinical use of similar devices may allow the orthopedic community to identify the balancing techniques that best promote a successful clinical outcome. To date, there is no clear consensus in the literature whether a truly balanced knee should be the goal, or if a knee with subtle lateral laxity is more likely to have a successful outcome. Proponents of a truly balanced often cite the improved range of motion and lift-off of less than 1 mm that have been associated with a well-balanced TKA. [14,23] Conversely, patients have been reported to prefer a TKA with mild to moderate mediolateral laxity than a truly balanced knee. [11] Edwards et al. first reported that Hospital for Special Surgery scores were greater for lax knees than those without mediolateral laxity. [3] Similar results have been reported by Liebs et al., stating that patients with a larger lateral gap in extension demonstrated significantly greater WOMAC pain scores than those that had increased medial gap. [13]

The debate over whether to truly balance the knee or to try to recreate the increased lateral laxity of the normal knee will undoubtedly continue and is beyond the scope of this study. Regardless of what the target balance should be, the fact remains that mediolateral laxity is multifactorial, especially when the knee is flexed. Mediolateral laxity, as well as the individual compressive forces in the medial and lateral compartments, are influenced many factors including: posterior slope of the tibial component [18], internal rotation of the tibial component [16], the condition or presence of the posterior cruciate ligament [15], and the number of releases performed to balance the extension gap. [1] Since there are many factors that influence mediolateral laxity and compressive forces, intraoperative tools that enable surgeons to make informed decisions about soft tissue balance and implant orientation throughout the range of motion are required.

This study was not without limitation. First, the ability to generalize these cadaveric results to the clinical setting will be limited. Mediolateral laxity changes as osteoarthritis progresses [19], but the majority of the knees in this study did not have degenerative changes. As such, we expect that the specimens used in this study may not have been as technically challenging to balance as an osteoarthritic knee. This may be one potential underlying reason for why no differences in mediolateral forces were noted between conventional and sensor-assisted TKAs. For example, 5/7 conventional TKAs had mediolateral symmetry within the target range of ± 15 lbs at 10° of flexion. While this improved to 7/7 within the target range for the sensor-assisted TKAs, the potential benefit of using the sensor may have been masked by the lack of preoperative asymmetry between the medial and lateral compartments usually common to osteoarthritic joints. Second, manual gapping measurements were the primary outcome variable used to evaluate the effect of using the load-sensing tibial trial. Manual measurements of joint gapping are the most common clinical method to diagnose mediolateral instability, and are included as part of the Knee Society Knee Scoring System. [21,6] While inter-surgeon agreement in the amount of gapping may be inherently limited, previous authors have reported that varus and valgus laxity can be accurately measured [2] and that surgeons can reliably apply varus and valgus torques. [12] However, to mitigate potential errors associated with inter-surgeon agreement, we designed the study so that each surgeon's exam of the sensor-assisted TKAs was compared to that surgeon's gapping measurements of the conventional TKAs. Third, the current study utilized only PCL-retaining TKA, and further study is necessary to determine if similar results would be demonstrated when using PCL-substituting designs. Finally, this laboratory study was the initial experience with the sensor-equipped tibial insert for five of the seven surgeons. As with any new technique or technology, a learning curve is to be expected and was not controlled for as part of this laboratory study. The relative lack of familiarity of the implant system for a majority of the surgeons may have also had a debatable effect on balance, based on the relationship between the system's instrumentation and final gap sizes. Several surgeons found the final cuts to be more generous than what they were used to, thus leading to slightly greater joint laxity in extension.

In conclusion, the use of a sensor-equipped tibial insert resulted in significantly reduced medial and lateral gapping in this laboratory study. Future studies are needed to determine if similar findings are seen in the clinical setting, and large-scale prospective studies are needed to determine the TKA balancing techniques that best promote a successful clinical outcome.

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Disclosure Statement

One or more of our authors have disclosed information that may present potential for conflict of interest with this work. For full disclosures refer to last page of this journal.

References

1. Christensen CP, Stewart AH, Jacobs CA (2013) Soft tissue releases affect the femoral component rotation necessary to create a balanced flexion gap during total knee arthroplasty. J Arthroplasty 28 (9):1528-1532
2. Clarke JV, Wilson WT, Wearing SC, Picard F, Riches PE, Deakin AH (2012) Standardising the clinical assessment of coronal knee laxity. Proc Inst Mech Eng H 226 (9):699-708
3. Edwards E, Miller J, Chan K-H (1988) The effect of postoperative collateral ligament laxity in total knee arthroplasty. Clin Orthop Related Res 236:44-51
4. Fehring TK, Valadie AL (1994) Knee instability after total knee arthroplasty. Clin Orthop Relat Res 299:157-162
5. Fujimoto E, Sasashige Y, Masuda Y, Takashi H, Eguchi A, Masuda T, Sawa M, Nagata Y (2013) Significant effect of the posterior tibial slope and medial/lateral ligament balance on knee flexion in total knee arthroplasty. Knee Surg Sports Traumatol Arthrosc DOI http://dx.doi.org/10.1007/s00167-012-2059-6
6. Healy WL, Della Valle CJ, Iorio R, Berend KR, Cushner FD, Dalury DF, Lonner JH (2013) Complications of total knee arthroplasty. Standardized list and definitions of The Knee Society. Clin Orthop Related Res 471:215-220
7. Jacobs CA, Christensen CP (2015) Intraoperative lateral gapping associated with improved subjective pain and function scores 2-5 years after TKA. Paper presented at the Orthopaedic Research Society 2015 Annual Meeting, Las Vegas, NV, March 28-31, 2015
8. Kobayashi T, Suzuki M, Sasho T, Nakagawa K, Tsuneizumi Y, Takahashi K (2012) Lateral laxity in flexin increases the postoperative flexion angle in cruciate-retaining total knee arthroplasty. J Arthroplasty 27 (2)
9. Koh IJ, Kwak D-S, Kim TK, Park IJ, In Y (2014) How effective is multiple needle puncturing for medial soft tissue balancing during total knee arthroplasty? A cadaveric study. J Arthroplasty 29 (12):2478-2483
10. Krackow KA (1995) Surgical principles in total knee arthroplasty: alignment, deformity, approaches, and bone cuts. In: Callaghan JJ, Dennis DA, Paprosky WG, Rosenberg AG (eds) Orthopaedic Knowledge Update: Hip and Knee Reconstruction. American Academy of Orthopaedic Surgeons, Chicago, IL, pp 269-276
11. Kuster MS, Bitschnau B, Votruba T (2004) Influence of collateral ligament laxity on patient satisfaction after total knee arthroplasty: a comparative bilateral study. Acta Orthop Trauma Surg 124:415-417
12. LaPrade RF, Heikes C, Bakker AJ, Jakobsen RB (2008) The reproducibility and repeatability of varus stress radiographs in the assessment of isolated fibular collateral ligament and grade-III posterolateral knee injuries. An in vitro biomechanical study. J Bone Joint Surg (Am) 90-A:69-76
13. Liebs TR, Kloos S-A, Herzberg W, Ruther W, Hassenpflug J (2013) The significance of an asymmetric extension gap on routine radiographs after total knee replacement. A new sign and its clinical significance. Bone Joint J 95-B (4):472-477
14. Matsuda Y, Ishii Y, Noguchi H, Ishii R (2005) Varus-valgus balance and range of motion after total knee arthroplasty. J Bone Joint Surg (Br) 87-B:804-808
15. Matsumoto T, Kubo S, Muratsu H, Matsushita T, Ishida K, Kawakami Y, Oka S, Matsuzaki T, Kuroda Y, Nishida K, Akisue T, Kuroda R, Kurosaka M (2013) Different pattern in gap balancing between the cruciate-retaining and posterior-stabilized total knee arthroplasty. Knee Surg Sports Traumatol Arthrosc 21:2338-2345
16. Matsuzaki T, Matsumoto T, Kubo S, Muratsu H, Matsushita T, Kawakami Y, Ishida K, Oka S, Kuroda R, Kurosaka M (2013) Tibial internal rotation is affected by lateral laxity in cruciate-retaining total knee arthroplasty: an intraoperative kinematic study using a navitation system and offset-type tensor. Knee Surg Sports Traumatol Arthrosc DOI http://dx.doi.org/10.1007/s00167-013-2627-4
17. Meneghini RM, Daluga AT, Sturgis LA, Lieberman JR (2013) Is the pie-crusting technique safe for MCL release in varus deformity correction in total knee arthroplasty? J Arthroplasty 28 (8):1306-1309
18. Oka S, Matsumoto T, Muratsu H, Kubo S, Matsushita T, Ishida K, Kuroda R, Kurosaka M (2013) The influence of the tibial slope on intra-operative soft tissue balance in cruciate-retaining and posterior-stabilized total knee arthroplasty. Knee Surg Sports Traumatol Arthrosc DOI http://dx.doi.org/10.1007/s00167-013-2535-7
19. Okamoto S, Okazaki K, Mitsuyasu H, Matsuda S, Iwamoto Y (2013) Lateral soft tissue laxity increases but medial laxity does not contract with varus deformity in total knee arthroplasty. Clin Orthop Related Res 471:1334-1342
20. Okazaki K, Miura H, Matsuda S, al e (2006) Asymmetry of mediolateral laxity of the normal knee. J Orthop Sci 11:264-266
21. Scuderi GR, Bourne RB, Noble PC, Benjamin JB, Lonner JH (2012) The new Knee Society Knee Scoring System. Clin Orthop Related Res 470:3-19
22. Wasielewski RC, Galante JO, Leighty RM, Natarajan RN, Rosenberg AG (1994) Wear patterns on retrieved polyethylene tibial inserts and their relationship to technical considerations during total knee arthroplasty. Clin Orthop Relat Res 299:31-43
23. Wasielewski RC, Galat DD, Komistek RD (2005) Correlation of compartment pressure data from an intraoperative sensing device with postoperative fluoroscopic kinematic results in TKA patients. J Biomech 38 333-339

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"Table-less" and "Assistant-less" Direct Anterior Approach to Hip Arthroplasty

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Abstract

In recent years, specialized, non-sterile, traction table systems have facilitated Direct Anterior Approach (DAA) hip arthroplasty. To combat the potential downsides of these traction systems, a sterile, intra-operative retractor option has emerged as a means to access the surgical site more easily, minimize soft-tissue trauma, and reduce the degree of required human assistance. This chapter describes the setup, surgical approach, and early results of a retractor system (the Phantom MIS Anterior Hip Retractor system [TeDan Surgical Innovations, Inc. {TSI}, Houston, Texas, US Patent # 8,808,176 B2]), which uses a standard operating table, allows preparation of both lower extremities free in the surgical field, is compatible with fluoroscopy, and aids in both acetabular and femoral exposure, preparation, and implantation. Early outcome data indicates that this system significantly minimizes the need for surgical assistance, while allowing for safe and effective DAA performance, facilitating the procedure for high-volume surgeons and shortening the learning curve for surgeons new to the procedure.

Keywords: *hip arthroplasty, hip replacement, hip reconstruction, direct anterior approach*
Level of Evidence: *AAOS Therapeutic Level IV*

Introduction

Since Keggi's initial introduction of the technique to the United States, many studies have demonstrated the validity of direct anterior approach (DAA) hip arthroplasty using a standard operating table [1,2,3,4]. With more surgeons opting to use the DAA for total hip arthroplasty, technology is affording new opportunities to perform the procedure more efficiently and cost-effectively—without specialized traction mechanisms and with fewer surgical assistants. Benefits of using the standard operating table, as opposed to a traction apparatus, include the ability to prepare the entire operative (and contralateral) limb in the surgical field, improved control and feel of the limb, and and prevention of transmission of excessive, potenitally dangerous forces to the bone and soft tissues. Downsides to using the standard operating table include the need for multiple assistants and difficulties with femoral exposure and preparation, with the potential for additional soft tissue trauma, component

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malposition, and accentuation of the DAA learning curve.

The described technique (Phantom MIS) involves a patented "table-less" approach (use of a standard operating table without a limb traction apparatus), in which a specialized, self-retaining, table-mounted, retractor system facilitates exposure of the femur and acetabulum, while allowing for fluoroscopic visualization and prepping of the entire operative limb and contralateral limb in the field on a standard operating table (TeDan Surgical Innovations Inc., Houston, TX, US Patent # 8,808,176 B2). An evolution of previous table mounted self retaining retractor designs used in general abdominal surgery, this self-retaining retractor system employs the use of stable, adjustable surgical arms with attachable retractors, allowing surgeons to perform the entire procedure on a standard operating table with minimal (or no) additional surgical personnel. The system aims to address obstacles of the DAA, while maintaining "table-less" advantages of decreased expense, decreased storage requirements, compatibility with standard OR equipment, simple mechanics, controlled forces, improved feel, and ability to prep both legs into the surgical field. Subsequent benefits of this system may include decreased soft tissue and bone trauma, improved component positioning, improved limb length symmetry, decreased need for surgical assistance, and potential shortening of the learning curve.

The purpose of this study is to evaluate the clinical results of the Phantom MIS DAA retractor system in 50 cases performed by a single surgeon (DCA) early in the surgeon's learning curve in order to determine if the system is a safe and effective means to facilitate DAA hip replacement by surgeons relatively new to the procedure.

Materials and Methods

SURGICAL TECHNIQUE

Equipment

- A standard operating stable that bends at the knee (Skytron® or similar)
- TSI® Phantom Anterior Retractor System
- Standard fluoroscopy or digital radiography unit (if desired)
- 0–1 surgical assistants
- Standard total hip arthroplasty instruments equipment
  - o Wheatlander retractors, alice clamps, oscilating saw, cork screw, and acetabular / femoral preparation instrumentation

Positioning

- Secure the traditional table's "head" extension piece to the "foot" of the table.
  - o The patient is placed supine with the pelvis centered on the table and with the table's bending joint 3 inches distal to the level of the patient's hip joint

Preparation

- Hindquarter prep on the operative side, the non-operative is prepped to above the knee (alternatively, both hindquarters may be prepped for bilateral cases).
  - o Impervious drapes initially secure the perimeter, both lower extremities are covered with stockinettes, which are then wrapped with Coban.
  - o A traditional hip drape with pouches is passed over both limbs, with a 6-inch slit cut to accommodate non-operative limb (Figure 1a); for bilateral cases, two U-drapes with a central perineal towel can be used (Figure 1b).

Figure 1a. Example of draping for unilateral case

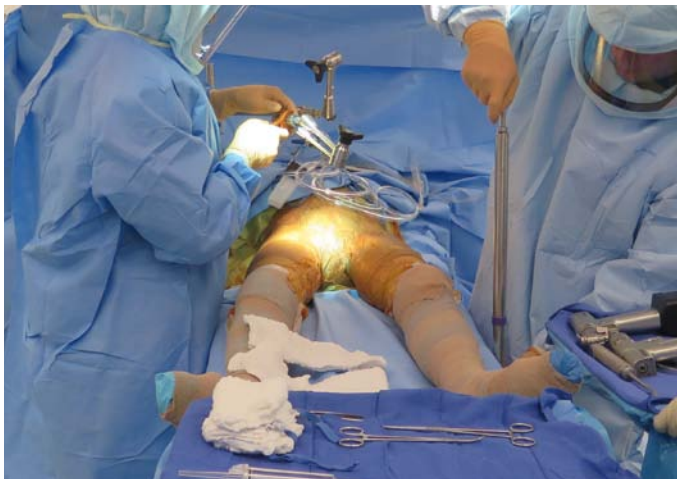


Figure 1b. Example of draping for bilateral case

- The skin is re-prepped with another surgical prep stick, the incision line is marked with the sterile marking pen, and Ioban is placed to completely cover all skin. Outer gloves are then changed.

Retractor System Set Up

- The Yellow Post Clamp (YC) is applied to the non-operative side of the table 12" – 24" proximal to the hip joint, over the sterile drapes. The Trident (T) is placed over the Yellow Post Clamp, directed toward the incision, and locked into place, with the red Trident prong directed toward the patient's head and the blue Trident prong directed toward the patient's foot (Figure 1c). The Blue Elbow (BE) is secured to the distal Trident (blue) prong, and the Yellow Accessory Arm (YA) and Blue Accessory Arm (BA) are then secured to the corresponding middle Trident (yellow) and Blue Elbow attachment points, respectively; these Yellow and Blue Accessory Arms will hold retractors on the side opposite the surgeon.

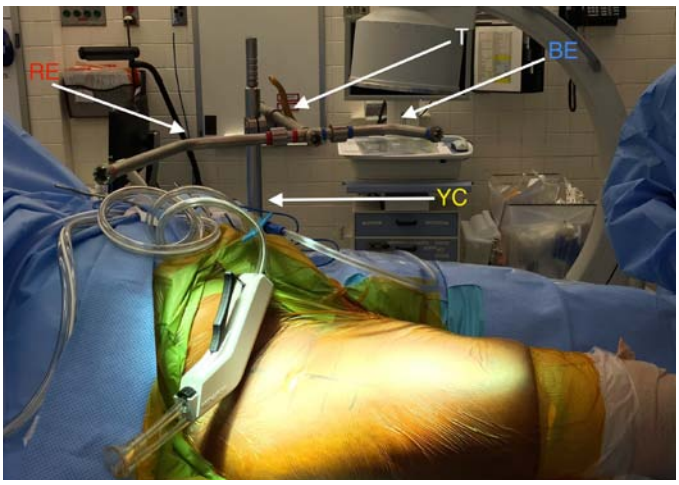


Figure 1c. Yellow Post Clamp and Trident application

- Two options allow a retractor to be placed on the surgeon's side of the incision:
  - o Option 1 (Figure 1d and 1e): The Red Elbow (RE) may be attached to the proximal (red) Trident prong, which then attaches to the Red Accessory Arm (RA). This arm can reach over and hold a retractor on the surgeon's side.

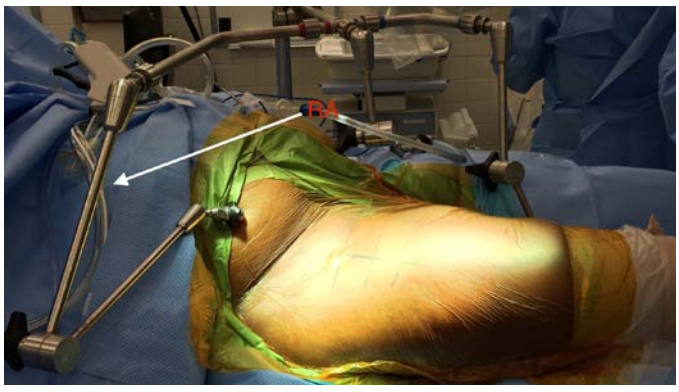


Figure 1d. Option 1: the additional proximal retractor is placed on the non-operative side of the table through the Red Elbow attachment

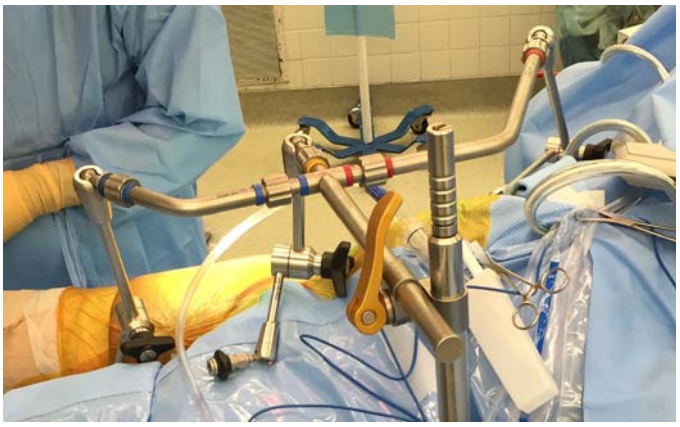


Figure 1e. Option 1: the additional proximal retractor is placed on the non-operative side of the table through the Red Elbow attachment (another view)

  - o Option 2 (Figure 1f): The Purple Post Clamp (PC) is applied to the side rail operative side of the bed, 12" distal to the hip joint, over the sterile drapes. The Ball Joint Angle Arm (JA) is then applied to this mounting post, which then attaches to the Purple Accessory Arm (PA). This arm can hold a retractor of the surgeon's side.

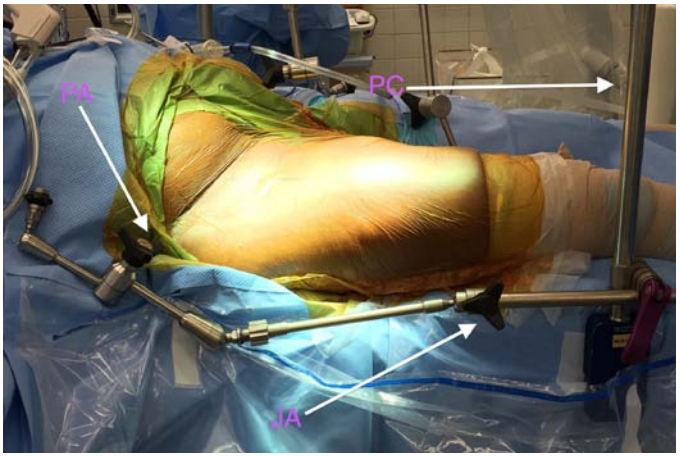


Figure 1f. Option 2: the additional proximal retractor is placed on the operative side of the table through the Purple Post Clamp and Ball Joint Angle Arm

Surgical Approach

- The incision starts 1 cm distal and 2 cm lateral to the anterior superior iliac spine (ASIS) and extends 8–12 cm distally and laterally toward the lateral knee, with the lower extremity in the neutral position (Figure 2a). If the limb is externally rotated during incision, the path will be inadvertently directed medially, and the lateral femoral cutaneous nerve branches will be at risk. The fascia over the tensor fascia lata (TFL) muscle is incised and elevated off of the TFL muscle medially (staying in this sheath protects the lateral femoral cutaneous nerve and allows for easy identification of the interval) (Figure 2b).

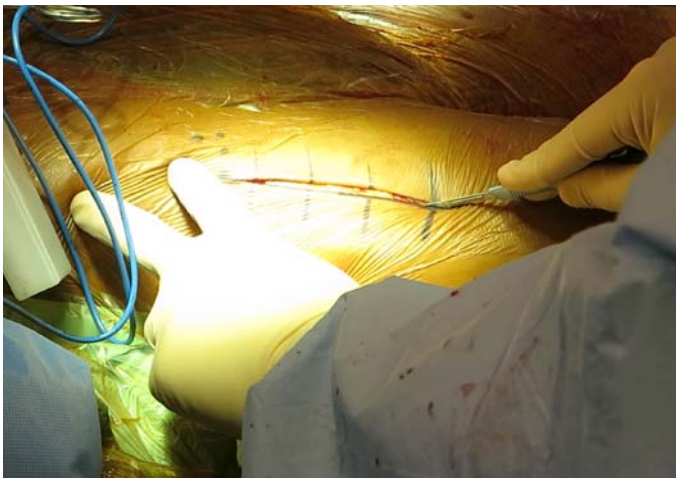


Figure 2a. The initial surgical incision

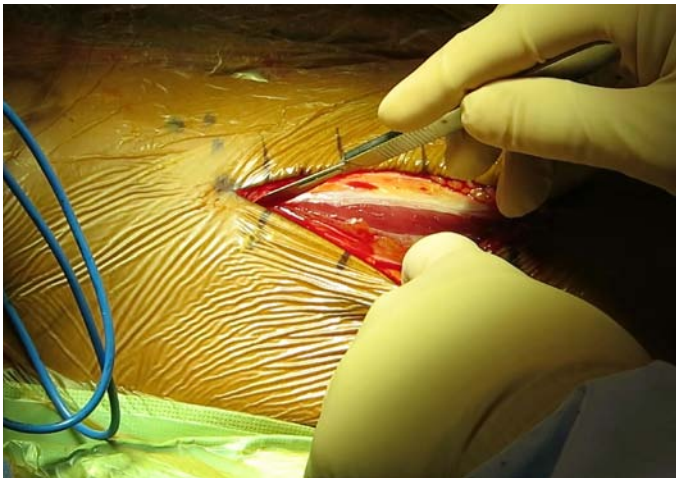


Figure 2b. The approach with entry into the TFL sheath

- o The interval between TFL and sartorius is developed with finger dissection, staying within the TFL sheath, and held open with a self-retaining wheatlander retractor (abducting the hip will loosen the TFL and further open this interval); the lateral femoral circumflex vessels are then identified and ligated (the authors prefer using silk ligature, but electrocautery is also an option) (Figure 2c).

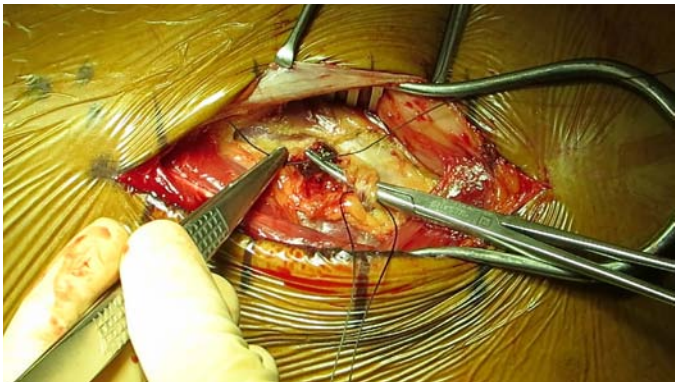


Figure 2c. Exposure of the superficial interval with ligation of the lateral femoral circumflex vessels

- o Medially, a Straight (20º) Hohmann Retractor is placed around the femoral neck, between the medial hip capsule and rectus femoris, and secured to the Yellow Accessory Arm; laterally, a Right-Angled Hohmann Retractor is placed around the femoral neck, between the lateral hip capsule and gluteus medius, and secured to the Red (option 1) or Purple (option 2) Accessory Arm (Figure 2d).

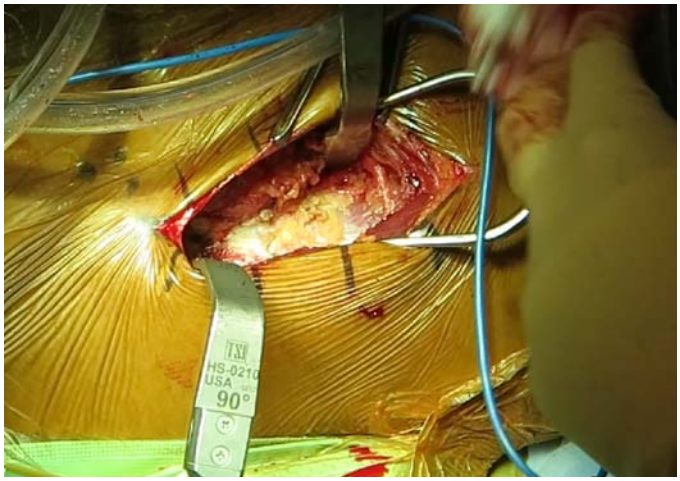


Figure 2d. Exposure of anterior hip capsule

- o The pre-capsular fat is removed, and the indirect head of rectus is elevated medially for capsular exposure; an "I" shaped capsulotomy is performed. The authors prefer to preserve the capsule for lateral coverage / closure; alternatively, the capsule may be resected.

Neck Osteotomy and Femoral Head Extraction

- Medially, a Straight (20º) Hohmann Retractor is placed directly around the medial femoral neck; laterally a Right-Angled or 70º Hohmann Retractor is placed directly around the lateral femoral neck.
- The inferomedial femoral neck capsule is released to the level of the lesser trochanter; palpation of the lesser trochanter, in addition to fluoroscopy, facilitates osteotomy position in accordance with preoperative templating (Figure 3a).
- The oscillating saw is used to create the femoral neck cut. An additional femoral neck cut can be made 5–10 mm proximal to the initial cut, creating an intercalary segment, which can then be removed to allow for easier head extraction.
- The hip joint can be slightly flexed to facilitate delivery of the femur posteriorly. Posteriorly, a Straight (20º) Hohmann Retractor is placed between the posterior femoral head and the femur, carefully delivering the femur further posterior; Anteriorly a Curved (70º) Hohmann Retractor is placed between the femo-

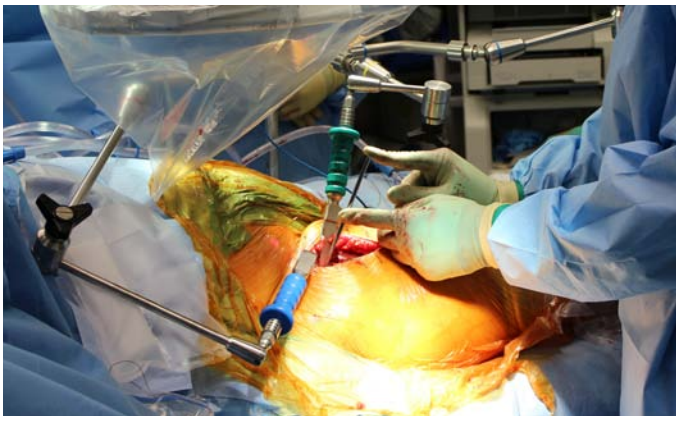


Figure 3a. Exposure of the femoral neck and localization of femoral neck osteotomy

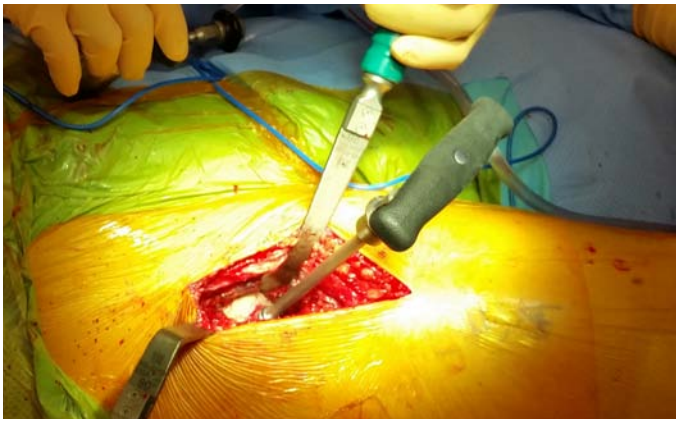


Figure 3b. Removal of the femoral head

ral head and the acetabulum. A corkscrew or threaded Steinman pin is placed into the femoral head through the cartilage or femoral neck cortex (Figure 3b).

- Capsular attachments around the base of the head are released with electrocautery. Careful rotation of the femoral head can facilitate this release. With traction on the head, the ligamentum teres can be identified and transected, facilitating removal. Care is taken with rotation and extraction not to injure the TFL, rectus femoris, or sartorius.

Acetabular Exposure

- A Curved (70º) Hohmann Retractor is placed over the anterior wall of acetabulum, between the anterior wall and iliopsoas (with great care not to over-retract to avoid femoral nerve injury); this retractor is secured to the Yellow Accessory Arm.
- A Curved (70º) Hohmann Retractor is placed between the inferior border of acetabulum (cotyloid fossa) and transverse acetabular ligament (with great care not to over-retract to avoid obturator nerve injury), and secured to the Blue Accessory Arm.
- A Straight (20º) Hohmann Retractor is placed between posterior wall of acetabulum and the femur (with great care to stay close to the bone to avoid sciatic nerve injury), and secured to the Red Accessory Arm (Option 1 [Figure 4a]) or Purple Accessory Arm (Option 2 [Figure 4b]).

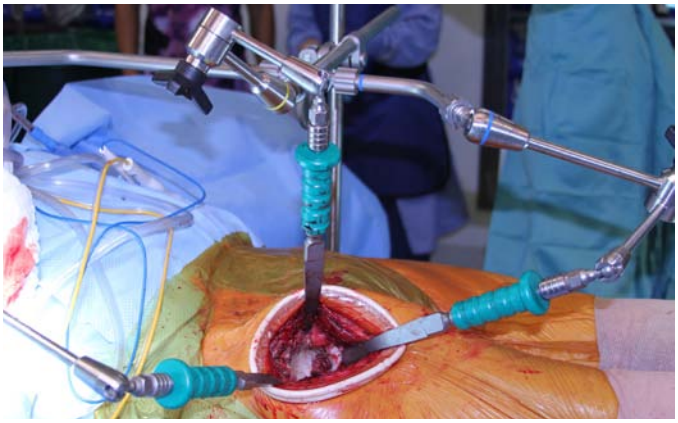


Figure 4a. Acetabular exposure using Option 1 (posterior wall retractor is secured from non-operative side of table)

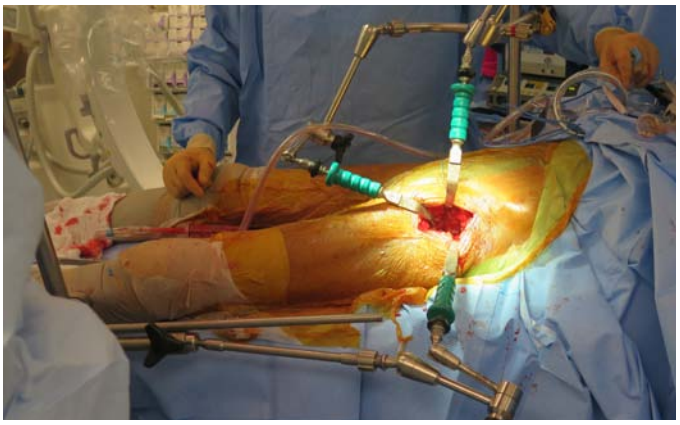


Figure 4b. Acetabular exposure using Option 2 (posterior wall retractor is secured from operative side of table)

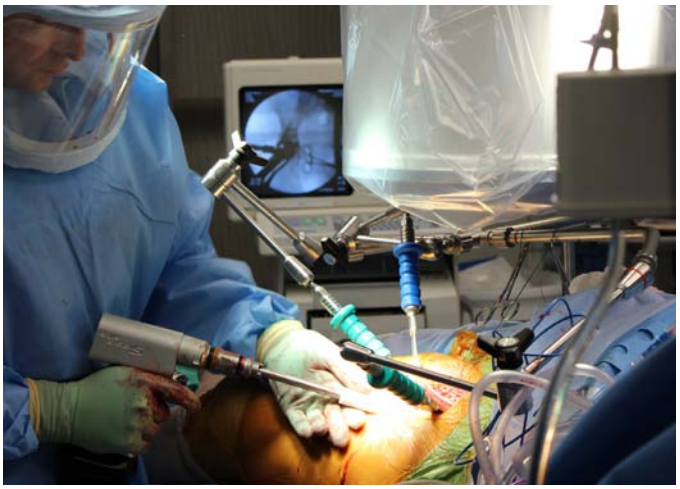


Figure 4c: Acetabular exposure and preparation, allowing fluoroscopy, without any other surgical assistance

- The acetabulum is reamed in usual fashion. The authors prefer to ream to the base of the cotyloid fossa, at 40 degrees of abduction and 20 degrees of antever-

sion, without raising the joint line (closely following native acetabular position); fluoroscopy or digital radiography can be used as a guide, but great care must be taken to assure a true AP pelvis radiographic position when judging acetabular alignment (Figure 4c).

Femoral Exposure

- If not previously placed, the Purple Post Clamp is now applied 12" distal to the hip joint to the side rail of the table, over the sterile drapes, on the operative side of the table; the Ball Joint Angle Arm is then applied to this mounting post, which then attaches to the Purple Accessory Arm, and the Red Elbow and Red Accessory Arm are removed (if previously placed). The Extension Bar is then placed over the Purple Post Clamp.
- The legs of the table are dropped 15–60 degrees (obtaining extension at the hip); the non-operative leg is placed on a well padded sterile Mayo stand. With the limb in the neutral position, the Femoral Hook is carefully placed around the proximal posterior femur from the lateral direction, distal to the vastus ridge, proximal to the gluteus maximus insertion, over (not through) the vastus lateralis, hugging the bone posteriorly. The operative limb is then adducted and externally rotated, keeping the knee straight to decrease anterior soft tissue tension.
- One or two retractors are placed around the medial femoral neck and secured to the Yellow and / or Blue Accessory Arms. A serrated Cobra Retractor or Curved Pointed (double-pronged) Retractor is initially placed over the greater trochanter, between TFL and gluteus medius. The Femoral Hook is attached to the Femoral Lift (FL), which is attached to the Extension Bar (EB) (Figure 5a). The capsule at the lateral femoral neck is removed, and the posterior femoral neck capsule is released. The trochanteric retractor can now be placed between the greater trochanter and gluteus medius, retracting the TFL and gluteus medius, while assisting with femoral elevation.
- The femur is carefully elevated by turning the finger dial on the Femoral Lift (1 click = 1 mm elevation). The posterolateral femoral neck capsule is further released under tension; the conjoined tendon (the gemelli and obturator internus) insertion at the medial greater trochanter is identified and either released fully, released partially, or preserved; the piriformis tendon at the medial tip of the greater trochanter and the obturator externus at the distal medial greater trochanter are preserved (Figure 5b & 5c).

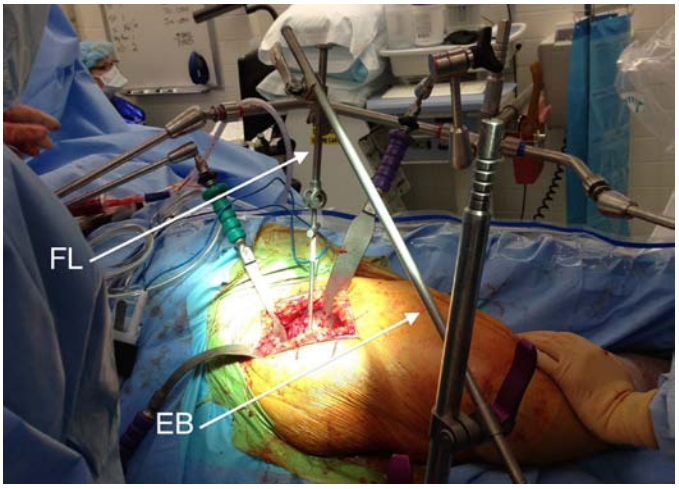


Figure 5a: Femoral exposure and preparation, using the Femoral Lift, without any other surgical assistance

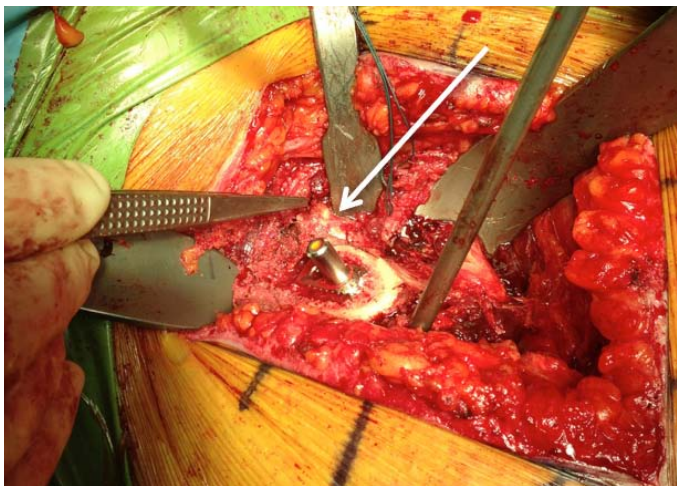


Figure 5b: Exposure of the proximal femur and associated insertions of the oburator internus and superior / inferior gamelli

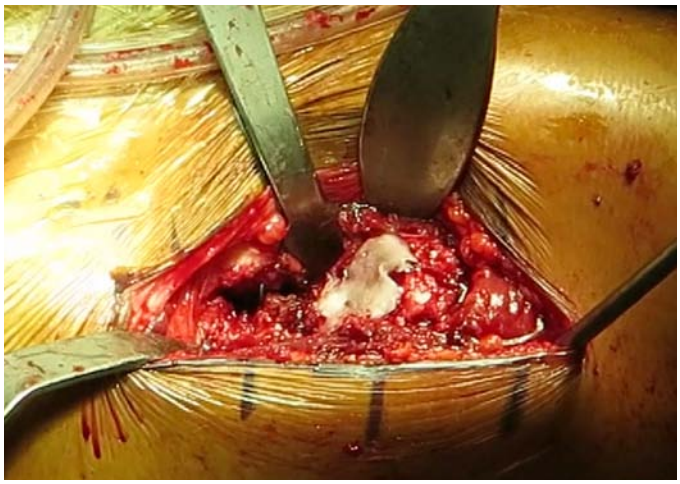


Figure 5c: Exposure of the proximal femur

- The femur is elevated gradually as careful releases are performed, without excessive tension; the femur is delivered only to the extent necessary for appropriate broach and stem insertion (Figure 5d). Traditional straight broach handles and long femoral stems can be used with this technique (Figure 5e).

Figure 5d: Femoral broaching with double-offset broach handle

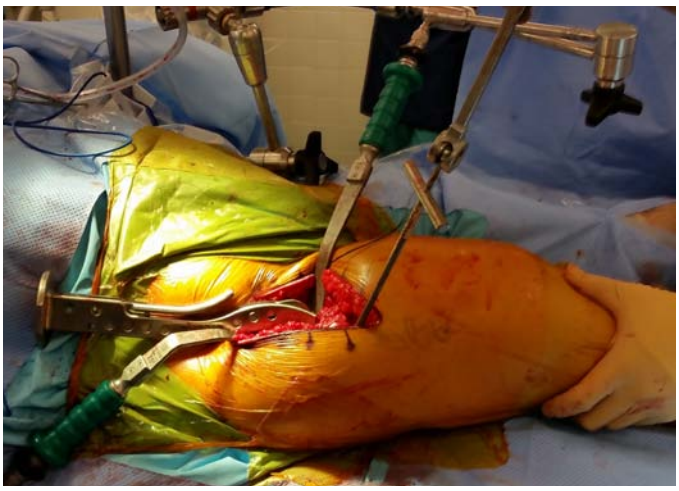


Figure 5e: Femoral broaching with standard straight (non-offset) broach handle

Femoral Trialing and Implantation

- Femoral component trialing is then performed. Fluoroscopy or intra-operative digital radiography can verify appropriate implant position. Manual joint reduction with feel of soft tissue tension helps verify appropriate stability. Direct comparison to the prepped contralateral limb allows for consistently reproducible limb length equality (Figure 6a). The hip can be easily taken through a full, unimpeded range of motion in all planes.

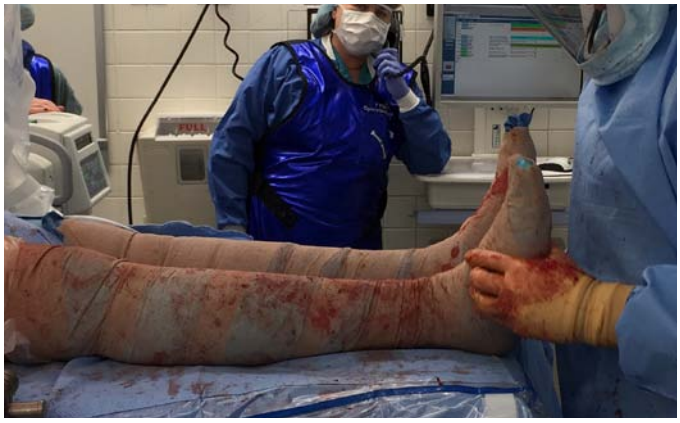


Figure 6a: Femoral broach and head trialing with contralateral limb length comparison

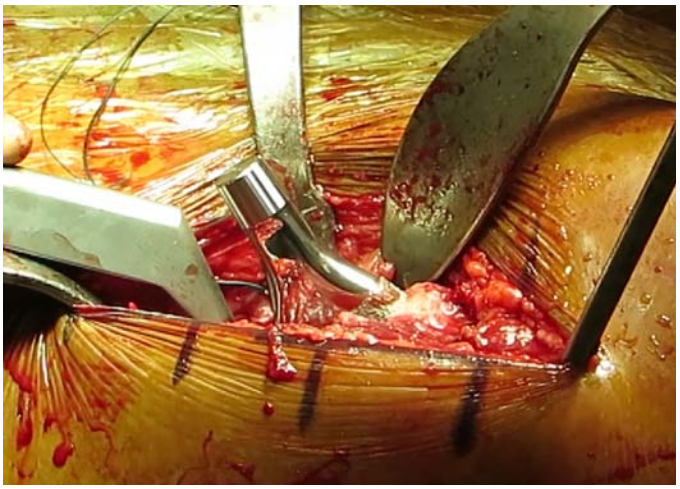


Figure 6b: Femoral stem implantation

- Femoral stem implantation is then performed with standard technique according to the type of stem used (Figure 6b).

Wound closure

- The authors prefer to preserve the hip joint capsule and subsequently close it with interrupted, braided absorbable #1 suture (Figure 7a).

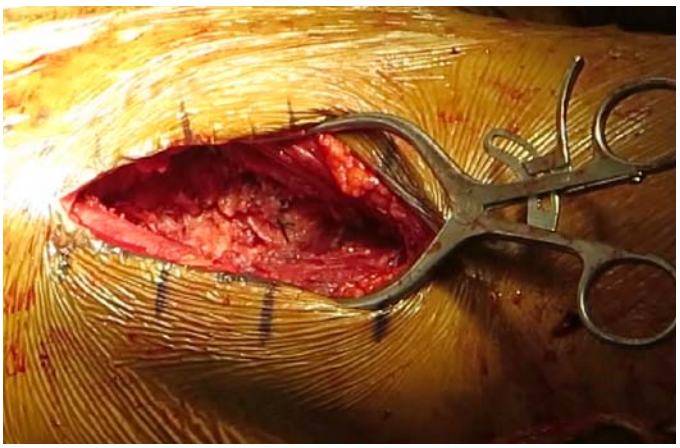


Figure 7a: Preservation and closure of preserved anterior hip joint capsule

- The fascia over TFL is closed with interrupted, braided absorbable #0 suture, with care not to ensnare branches of the LFCN anteriorly.
- The skin is closed with subdermal and subcuticular suture, and the soft tissues remain healthy and untraumatized (Figure 7b). The incision is dressed with incisional sealant (Dermabond® [Ethicon US, LLC, Cincinnati, OH]) in addition to a skin-friendly occlusive antimicrobial dressing (Aquacel® Ag [Convatec, Inc., Skillman, NJ]).

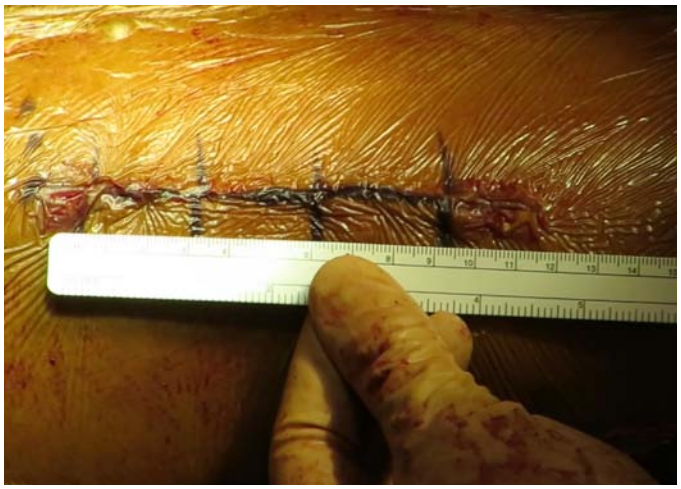


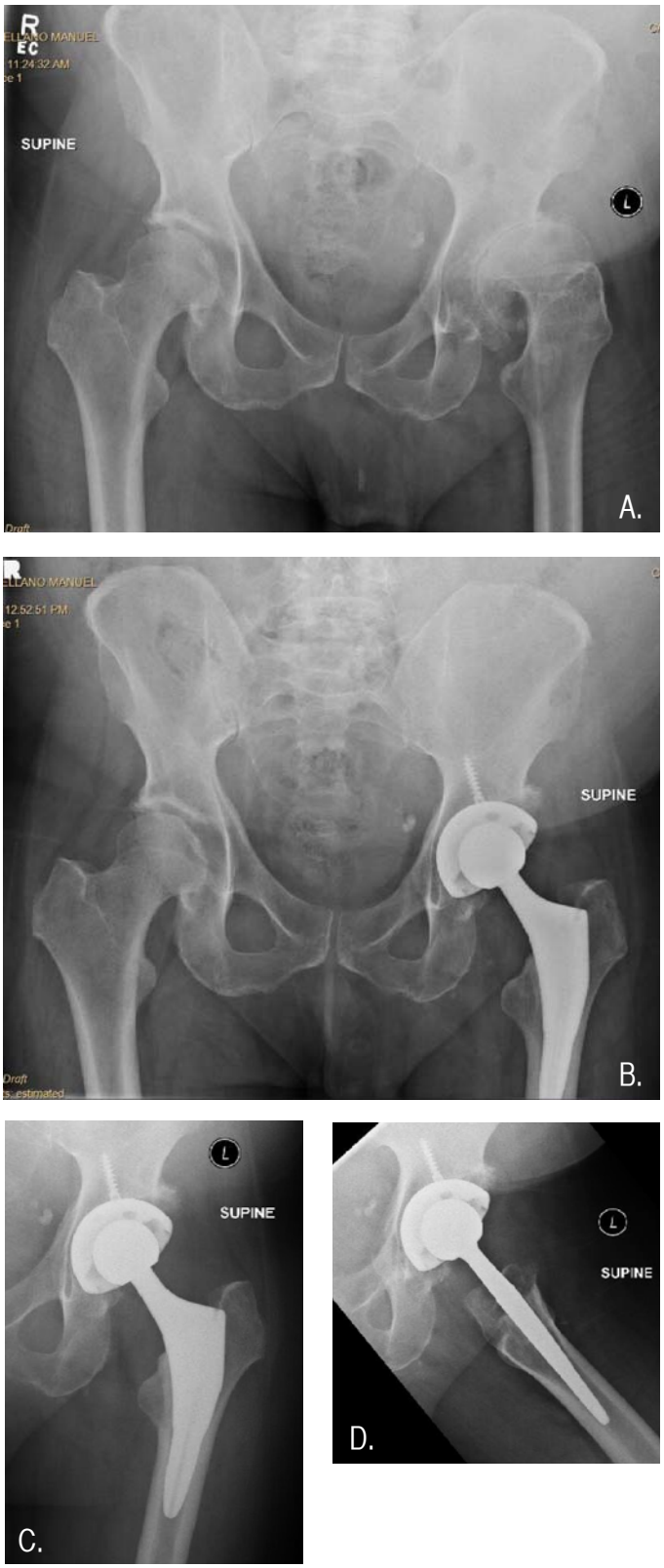
Figure 7b: Soft tissue status and incisional length after completion of the procedure

Postoperative care and rehabilitation

- The patient is treated with protected weight bearing as tolerated with crutches or a front-wheeled walker if a press fit femoral stem is used, or full weight bearing as tolerated with assistive devices only as needed if a cemented femoral stem is used.
- No hip precautions (anterior or posterior) are instituted.
- The sealed, occlusive dressing is left in place and not changed for 7–10 days (patients are allowed to shower).

STUDY DESIGN

Fifty consecutive DAA THA surgeries performed by a single surgeon (DCA), early in the surgeon's DAA learning curve, using the TSI Phantom MIS retractor system on a standard operating table, were retrospectively reviewed. Mean patient age was 67.7 years (range 45–97), with 35 females and 15 males. The underlying pathology consisted of osteoarthritis [23], femoral neck fracture [14], congenital dysplasia [6], avascular necrosis [4], and metastatic carcinoma [3] (Figures 8a-d). Follow up averaged 26.6 months. Thirty-seven of the cases performed were total hip arthroplasties and 13 were hemi-arthroplasties. Thirty-two of femoral stems were press fit, the remaining were cemented, and all cups were press fit. Cases were then evaluated according to outcome measures of surgical time, estimated blood loss, number of assistants used, intra-operative releases, component position, and complications.



Figures 8a-d: Preoperative and postoperative radiographs of one of the study patients (Ortho Development Corporation, Inc., Draper, UT)

Results

Surgical time averaged 116.3 minutes (range 79–180), and estimated blood loss averaged 223 cc (range 50–600),

without use of transexamic acid or pro-coagulants. The mean number of surgical assistants was 0.9 per case, with 5 (10%) of the cases using no assistant. Length of stay averaged 2.9 days (range 1–5).

With regard to intra-operative femoral releases, partial conjoined tendon release was performed in 15 cases and complete release in 32 cases; three cases were performed with no release of the conjoined tendon. Thirty-seven of 50 cases (74%) were performed without any piriformis release; the remaining cases involved partial piriformis release in 8, and complete piriformis release in 5.

Absolute radiographic limb length discrepancy averaged 0.2 mm (0–3.5 mm). Mean radiographic coronal femoral stem alignment was 0.13° with respect to neutral (range 0° [neutral]–2° [varus]). In four cases (8%), the stem rested in 1° varus, and in 1 case (2%), the stem rested at 2° varus. The remaining stems (90%) rested at 0° (neutral) coronal alignment (including the last 25 cases). Mean acetabular abduction angle was 39.8°, and in 36 of 37 THA cases (97%), the cup fell within the 35° – 45° range. In one case early in the series, the acetabular abduction angle was 50° (case # 15).

With regard to complications, there were no dislocations (0%) and no infections (0%). There was one intra-operative non-displaced proximal femur fracture early in the series (case #9) in a patient with severe osteoporosis using press fit femoral stem. This patient was still allowed to bear weight as tolerated without restrictions immediately, and healed without limp or any problems. The patient's contralateral hip was replaced later in the series (case #50) using cemented femoral stem, with no complications. There was one case of femoral stem subsidence at 3 months postoperatively in a patient with severe osteoporosis and neuropathy, in which a press fit femoral stem was used and immediate weight bearing was allowed. This case was treated with revision, without further problems. There was one case of lumbosacral plexopathy, diagnosed by neurology consultation as secondary to epidural hematoma caused by traumatic spinal block, which resolved spontaneously without intervention. One patient who underwent cemented hip hemiarthroplasty for femoral neck fragility fracture sustained a Vancouver C periprosthetic fracture of the distal femur (12 cm distal to the femoral stem tip) 6 months after surgery. The patient was treated successfully with percutaneous plate fixation and healed without further complication or disability.

Discussion

DAA to hip arthroplasty carries many distinct advantages, which are balanced by difficulties with femoral exposure [5]. Given the technical challenges, a distinct and possibly lengthy learning curve has been well described with regard to surgeons newly adopting the procedure [6,7]. In attempt to combat these challenges, traction-based table systems have emerged to facilitate the approach. These "table" systems certainly improve the ease of the procedure, but carry downsides of excessive forces, expense, space requirements, need for additional operative personnel, and complex mechanics requiring maintenance. Therefore, the "table-less" technique to DAA has re-emerged as a viable option, addressing traction-related concerns, but carrying downsides of difficulties with femoral exposure and implantation, potential soft tissue trauma, and need for multiple assistants.

The Phantom MIS technique of "table-less" DAA consists of a table mounted retractor system with a femoral lift assembly applied to a standard operating table, aiming to maintain "table-less" advantages, while minimizing the downsides. The ability to prepare both lower extremities in the surgical field allows for direct clinical limb length comparison and minimizes limb length discrepancy, as evidenced by the close symmetry of limb lengths seen in this study. Preparing both extremities also facilitates the "feel" of reduction and assessment soft tissue tension, allowing complete, passive joint range of motion; this ability helps improve appropriate implant choice during trialing. The system's self-retaining retractor features free up the hands of surgical assistants to do other more meaningful work during the case, and make the procedure possible even if no surgical assistant is available, as evidenced by 10% of the cases in this study performed without any surgical assistant (other than the scrub technician). As personnel costs increase and implant surgery reimbursements decrease, this decreased reliance on additional operating personnel may become a distinct advantage.

The manual femoral elevation system exposes the femur well, while providing controlled forces and feel of tension, which may decrease soft tissue trauma, nerve stretch, and fracture risk, which was demonstrated by the well-positioned femoral implants and low complication rates seen in this study. The system also allows for cemented femoral stem implantation. The unparalleled acetabular exposure, while still allowing use of fluoroscopy, facilitates cup positioning, as evidenced by the consistent, appropriate acetabular shell position in this series. The low dislocation rate (0%) seen in this study may be in part attributable to the stability conferred by the DAA approach, and also the lack of excessive releases, preservation and repair of the anterior joint capsule, and appropriate implant position, which are all facilitated with the Phantom MIS system. This sys-

tem can also be applied to traction tables in order to minimize the need for assistance and to aid with exposure in these cases. Additional advantages of the system include attachable, small, cold LED lights that illuminate the deep surgical field, further improving the ease of the surgery. Any retractors with a hole at the proximal handle tip can be used with the system, and custom retractors of any sort can be easily manufactured and applied.

Conclusion

A specialized hip retractor system (Phantom MIS) affords surgeons the opportunity to perform DAA procedures on a standard operating table with limited assistance. This system offers many potential benefits when compared to traction-related technique, including decreased expense, decreased storage requirements, compatibility with standard operating equipment, simple mechanics, controlled forces, improved feel, decreased reliance on additional personnel, and ability to prep both lower extremities into the surgical field. The systems allows for incorporation of the best of both "table" and "table-less" techniques, while maintaining the benefits of each. Traditional hip arthroplasty principles still apply, and careful attention to technique and respect for soft tissues and bone is always required. A retrospective review of surgeries using the Phantom MIS Hip Retractor system demonstrates that the system can be safely and effectively applied to the DAA procedure, even early in a surgeon's learning curve. The series indicates that DAA for hip arthroplasty with a standard operating table was greatly facilitated with this specialized retractor system, requiring only a single assistant, and even allowing for the procedure to be performed without any surgical assistance. The Phantom MIS retractor system technique facilitates appropriate DAA hip arthroplasty outcomes, with apparent shortening of the learning curve, while minimizing potential complications.

Disclosure Statement

One or more of our authors have disclosed information that may present potential for conflict of interest with this work. For full disclosures refer to last page of this journal.

References

1. Light TR, Keggi KJ. Anterior approach to hip arthroplasty. Clin Orthop Relat Res. 1980 Oct;(152):255-60.
2. Kennon RE, Keggi JM, Wetmore RS, Zatorski LE, Huo MH, Keggi KJ.Total hip arthroplasty through a minimally invasive anterior surgical approach. J Bone Joint Surg Am. 2003;85-A Suppl 4:39-48.
3. Lovell TP. Single-incision direct anterior approach for total hip arthroplasty using a standard operating table. J Arthroplasty. 2008 Oct;23(7 Suppl):64-8.
4. Berend KR, Lombardi AV Jr, Seng BE, Adams JB. Enhanced early outcomes with the anterior supine intermuscular approach in primary total hip arthroplasty. J Bone Joint Surg Am. 2009 Nov;91 Suppl 6:107-20.
5. Matsuura M, Ohashi H, Okamoto Y, Inori F, Okajima Y. Elevation of the femur in THA through a direct anterior approach: cadaver and clinical studies. Clin Orthop Relat Res. 2010 Dec;468(12):3201-6.
6. Seng BE, Berend KR, Ajluni AF, Lombardi AV Jr. Anterior-supine minimally invasive total hip arthroplasty: defining the learning curve. Orthop Clin North Am. 2009 Jul;40(3):343-50.
7. Masonis J, Thompson C, Odum S. Safe and accurate: learning the direct anterior total hip arthroplasty. Orthopedics. 2008 Dec;31(12 Suppl 2).

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CASE REPORT
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Pendulum Test: A Highly Accurate and Simple Physical Examination Maneuver to Identify Hip Pathology

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Abstract

Background: Patients with hip pathology often complain of various symptoms, e.g. pain or discomfort of low back, lower extremity, hip, groin, thigh, buttock or knee. Physicians may be distracted by these complaints, and misdiagnose and mistreat hip pathology. To avoid this, the pendulum test, which is performed with a patient seated on the examination table and hips and knees are flexed at 90 degrees, while the examiner passively swings the patient's lower extremity in and out as a pendulum, has been employed for all patients with the complaint of low back, hip and knee.

Objective: The efficacy and the accuracy of the pendulum test were evaluated.

Patients and methods: Consecutive 40 patients, who had complained pain or discomfort of low back, lower extremity, hip, groin, thigh, buttock and knee were examined by the pendulum test.

Results: Eighteen patients were positive for the pendulum test, and all of them correlated to the hip pathology.

Conclusions: The pendulum test was confirmed to be easily performed and reliable in detecting the hip pathology. Therefore, this test is highly recommended for the differentiation of patients with low back, hip and knee complaints.

Keywords: *pendulum test; hip joint; internal and external rotation; physical examination*
Level of Evidence: *AAOS Therapeutic Level IV*

Introduction

The physical examination of hip joints includes evaluation of the range of motion with some classical procedures, e.g. Patrick's test and Thomas test. Positive results of the test are often followed by the diagnostic imaging examinations, i.e. the roentgenogram, CT scanning and MR imaging. Patients with hip pathology, however, do not always complain of hip pain. The pain or discomfort of low back, lower extremity, groin, thigh, buttock or knee are all com-

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mon complaints, which may be caused by hip pathology. Moreover, the hip joint is deep-seated and difficult to be palpated compared to the spine and the knee. For these reasons, the physicians sometimes misdiagnose and treat the wrong part of the body, instead of hip joint.

To avoid this inaccuracy, we have been employed the pendulum test, for all patients with complaints of low back, hip and knee pain or discomfort as an accurate maneuver to identify the presence of the hip pathology. This test has been used as one of the maneuver to diagnose and manage patients prior to hip surgery [1]. We have found that this test is highly efficient for the diagnosis of even early stage hip pathology. The objective of this study was to document the efficacy of the pendulum test to detect the hip pathology for the patients with low back, hip and knee pain.

Maneuver of Pendulum Test

Once a patient is suspected of pathology involving lumbar spine, hip or knee joints, after taking the detailed clinical history, we perform the pendulum test at the beginning of the physical examination. The patient is sitting on the edge of the examination table, bilateral hips and knees are flexed at 90 degrees and the feet are off the ground. The examiner sits in front of the patient, holds the knee gently with one hand, and grabs the ipsilateral ankle with the other hand. Then, the examiner gently swings the patient's lower extremity in and out as a pendulum (Fig. 1). This in and out motion demonstrates external and internal rotation of the hip joint, respectively. Usually this test is performed on the asymptomatic side as a base line, before examining the contralateral limb.

The test is regarded as positive, when a patient demonstrates discomfort, pain, or a noticeable difference in the range of motion in the hip joints. If it is accompanied by pain or discomfort on the ipsilateral hip or groin, it indicates the existence of hip joint pathology. If the hip rotation is limited, especially the internal rotation, this is the evidence of hip anatomically advanced pathology.

Patients and Methods

Consecutive 40 patients in our outpatient clinic, who had complained pain or discomfort of low back, lower extremity, hip, groin, thigh, buttock, and knee were examined.

Patients were 25 to 103 years old, average was 68 ± 15 years old, and were 14 males and 26 females. Of 40 patients, the chief complaints were; 21 with knee pain or discomfort, 8 with groin pain, 3 with hip pain, 1 with low

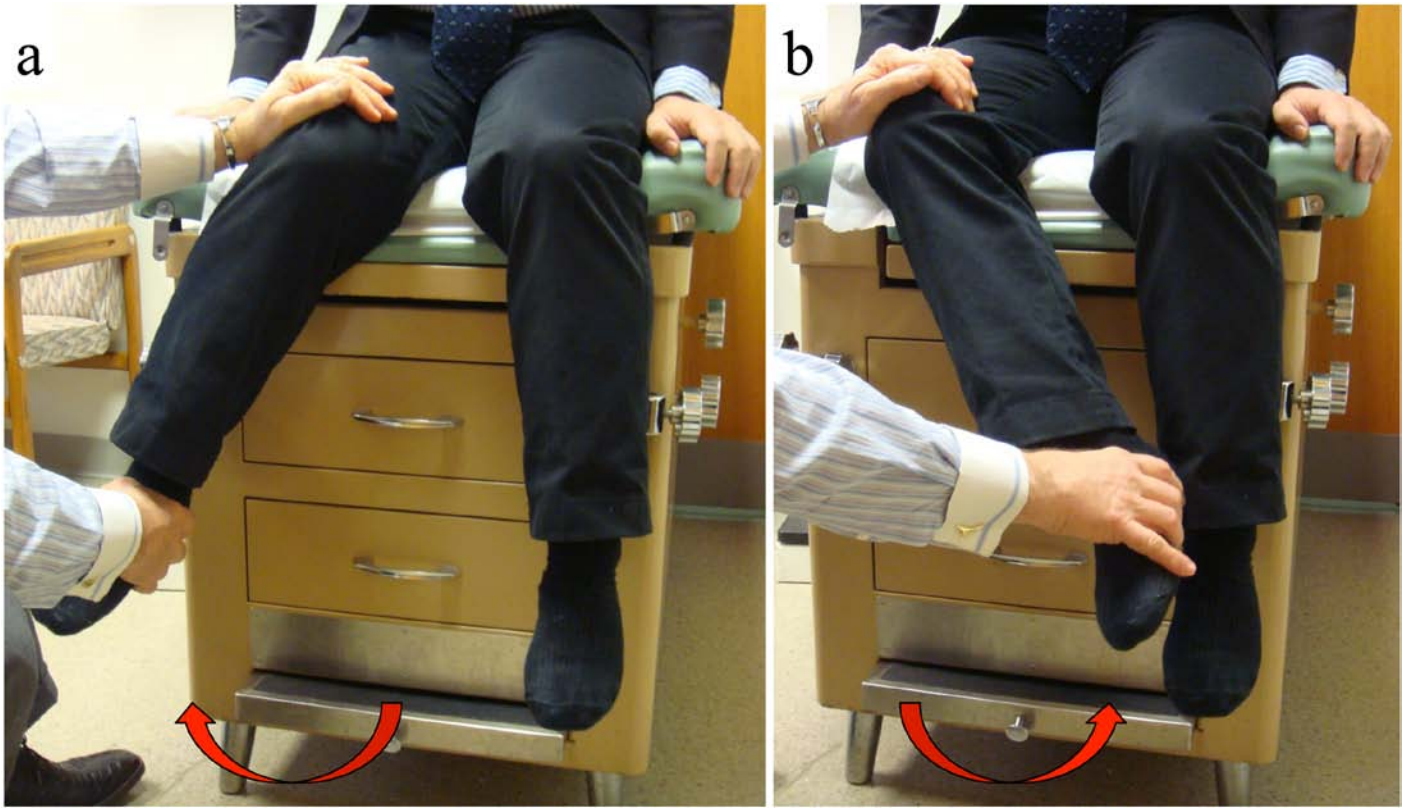

Fig. 1 : Maneuver of the pendulum test. The internal rotation (a) and external rotation (b) of hip joint under the flexion at 90 degrees of the hip and knee is demonstrated.

back pain, 1 with lower back and lower extremity pain, 2 with low back and hip pain or discomfort, 1 with low back and groin discomfort, 1 with groin, thigh and buttock discomfort, 1 with buttock and lower extremity pain, and 1 with lower extremity pain.

This study was approved by Institution Review Board (IRB). No funding or financial benefits provided to the authors for the project from any source.

Results

Twenty two patients were negative for the pendulum test and 18 patients were positive. There were 21 patients who presented with a complaint of knee pain or discomfort. Of these, 2 had a positive pendulum test. They were found to have aseptic loosening post total hip arthroplasty and osteoarthritis (OA) of the hip. All 8 patients with groin pain and 3 patients with hip pain had a positive pendulum test. All were shown to have diagnosed with hip related diseases. Eight patients had a complaint of low back pain, together with the pain of hip, groin, thigh, buttock or lower extremity. Three had a negative pendulum test and 5 had a positive test. Especially for these cases, the pendulum test was extremely an effective tool for differentiating hip from low back pathologies in spite of their complex presentation. Although some cases had both OA of the spine and the hip, it was possible to distinguish which was the more critical complaint in these patients. Consequently, all patients with the positive pendulum test correlated to the hip pathology.

Case reports

CASE 1

A patient was a 66 years old male, and the chief complaint was intermittent discomfort of bilateral knees while walking, greater in the right than left. He had suffered an insidious increase in symptoms for one year, without any history of prior trauma. Because of the tenderness of the medial side of both knees, he was diagnosed as internal derangement of the knees, however, the knee joints had a full of range of motion without swelling or effusion. Moreover, there was no objective finding consistent with OA of the knee evaluated by the roentgenogram and MR imaging examinations. The conservative treatment of the knees had not been effective, and thus he was referred to our clinic for a second opinion evaluation. Although his knees were examined in great detail, the referring physician had performed no examination for the hips.

He presented independently ambulating without a cane, however, his right lower extremity was slightly externally rotated while walking. The pendulum test was performed, and he complained of discomfort in both hip joints, greater in the right than left, especially when the right with internal rotation. The arc of movement was decreased bilaterally more in the right compared with the left. Therefore, hip pathology was suspected. The roentgenogram findings of the hip joints showed the early OA with a slight osteophyte formation and a joint space narrowing (Fig. 2), confirming the efficacy of pendulum test.

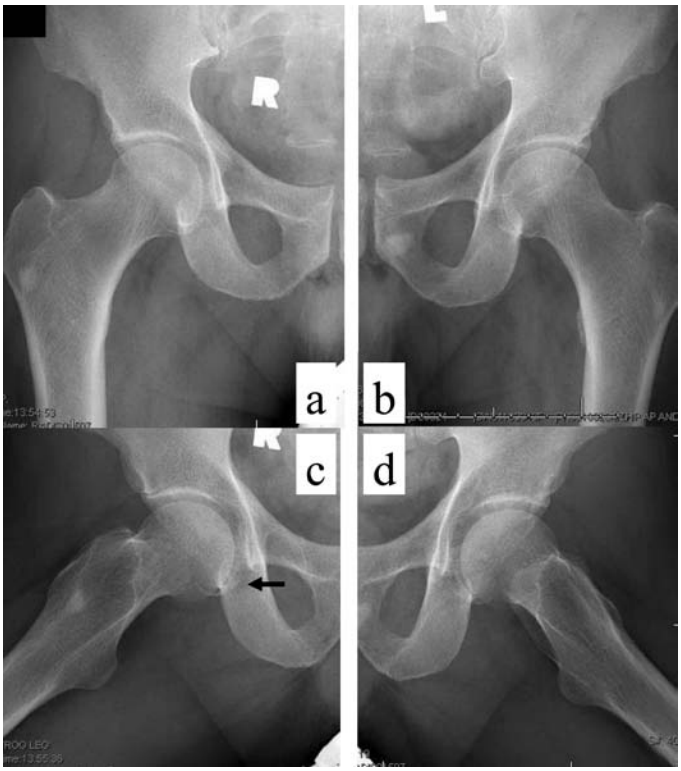

Fig. 2 : The roentgenogram findings of anterior-posterior view (a, b) and lateral view (c, d) of bilateral hip joints. Osteophyte formation and joint space narrowing were slightly detected in the right hip at the lateral view (arrow).

CASE 2

A patient was a 55 years old male with a chief complaint of left groin pain. He had developed increasing intermittent discomfort in the left groin, aggravated with activities and restricting range of motion over many years. He was status post spinal fusion of the fifth lumbar and first sacral vartebras. The primary doctor suspected the cause of the groin discomfort was due to increasing demand on hip range of motion following the spinal fusion. However, the hip joints had not been evaluated. The patient presented to our institution for a second opinion evaluation.

With the pendulum test, the patient complained of the discomfort with internal rotation of the hip, greater in the

left than right. Further the test showed limitation of internal rotation of both hip joints. He was asymptomatic on the right, and the limitation was more severe on the left, however, the internal rotation was also limited on the right. The roentgenogram evaluation showed that mild OA on the left hip and minimal OA in the right hip, besides the post status of spinal fusion surgery (Fig.3, 4), again confirming the diagnostic accuracy of the pendulum test.

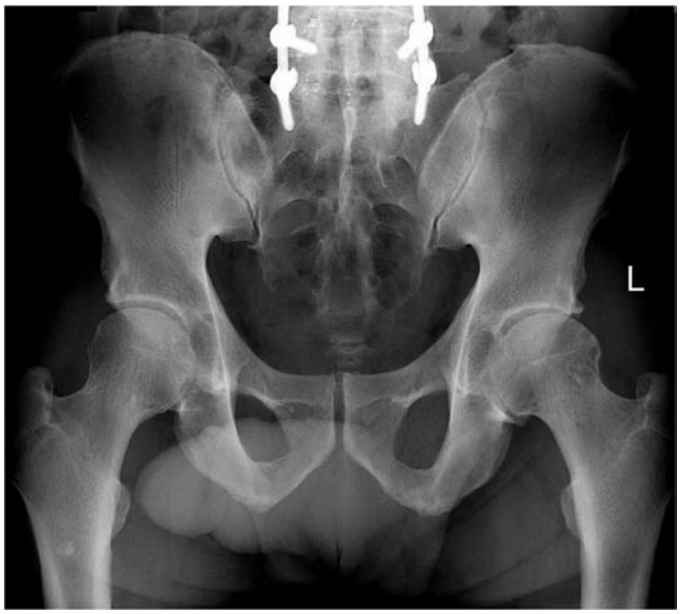

Fig. 3 : The roentgenogram findings of pelvis, post spinal fusion surgery.

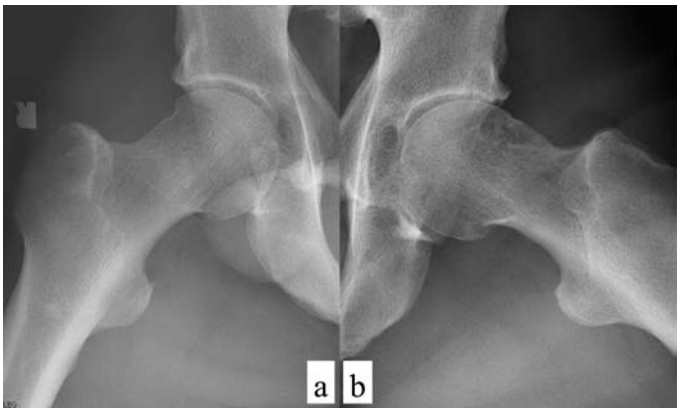

Fig. 4 : The roentgenogram findings of lateral view (a, b) of bilateral hip joints. Mild OA on the left hip and minimal OA in the right hip were detected.

Discussion

In outpatient clinics, physicians are often misled by the location of the patients' complaints of pain or discomfort. Although the pathology emanates from the hip joint, patients sometimes complain of the low back, thigh or knee joint pain. For this reason, physicians may focus on the complaint sites, and unfortunately have their attention drawn away from the true site of pathology, leading to misdiagnosis and mistreatment. Conversely, even if a physician suspects hip pathology, and begins with an examination of the hip joint, patients who complain of low back or knee joint may feel uncomfortable and distrustful, and may lose confidence in the physician believing their complaints come from the symptomatic sites of which they are complaining.

The lumbar spine, hip and knee joints are anatomically related and work synergetically during activity of daily living. Because of its simplicity, accuracy, and efficacy, we routinely perform the pendulum test, with the patient seated, at the beginning of physical examination for patients with low back, hip and knee complaints. This test is easily performed without the patients' awareness that the hip joints are being assessed. Thus, we could evaluate hip joints accurately with the patients' in a relaxed condition. Once the pendulum test is positive, the meaning of the test is explained as an evaluation of hip joints, and further physical and imaging examinations of hip joints are continued.

The hip as a "ball-and-socket" joint provides no geometric resistance to the rotational torque. Thus, rotational movement is totally dependent upon a static ligamentous structure (especially the iliofemoral ligament) and the dynamic action of the gluteus medius. The iliofemoral ligament, also is known as the Y-shaped ligament, is the largest ligament in the body and tightens with internal rotation [2,3]. When the hip joint is inflamed, synovial liquid increases, the capsular ligaments become swollen, and the intra-articular pressure rises. These reactions cause tightening of the capsule and are manifested as acute groin discomfort. To reduce the symptom, patients will reflexively assume an external rotational posture to relax the capsular ligaments [2]. As a consequence of their external rotational positioning of the lower extremity, the ipsilateral knee is subjected to increase torsional stress, as seen in the first case. The knee is not designed to tolerate this torsion force because the knee is a "hinge" joint. This transfer of rotation force from the damaged hip to the otherwise normal knee causes pain and stress at both the medial and the patellofemoral components of the knee. We diagnosed this first case as OA of the hip joint, with pain at the knee due to secondary mechanical stress. In the second case, both the patient and the physician believed the groin pain had caused by the restricted lumbar motion following the spinal fusion surgery. However, the pendulum test was positive, proving the groin pain was due to OA of the hip.

There have been many tests described for the evaluation of the hip. The Patrick's test, also known as the Faber test,

is often performed to evaluate with the hip and the sacroiliac joint. The tested hip is simultaneously flexed, abducted, externally rotated, and extended with the subject supine by the examiner. While holding the contralateral anterior superior iliac spine, the ipsilateral knee is stressed to lowered towards the table. If the knee does not lower to the table, it is suspected as a hip flexion contracture or protective iliopsoas spasm. If the ipsilateral hip pain is reproduced, it is suggestive of the hip joint disorder. If the pain is elicited on the contralateral side, it is suggestive of the sacroiliac joint disorder. The Thomas test is used to demonstrate a hip flexion contracture. The patient brings one knee to the chest with subject supine. If the patient's contralateral hip flexes, it indicates the tightness of iliopsoas, tensor fascia latae, or rectus femoris. Femoroacetabular impingement (FAI) is a condition of subtle developmental abnormalities of the hip [4,5]. The flexion-internal rotation-adduction impingement test to detect FAI is performed by the examiner with the subject supine. If the pain is reproduced, it is suggestive of FAI. The accuracy of these tests has been proven [6-9].

These examinations of the hip joint require the patient to lie supine and prone on the examination table. However, it is difficult to assume these postures for the patients with low back, hip or knee symptoms, flexion contracture of the hip joints, or after some surgical procedures. Therefore, a test for hip pathology with a patient seated, offers much advantage. OA of the hip starts with the deterioration of the internal rotation [10,11]. The most frequent location for FAI is the anterior rim area and the most critical motion is the internal rotation of the hip at 90 degrees flexion [12]. Thus, the internal rotation is the important morton to detect the early stage of OA and FAI, which can be accurately demonstrated by the pendulum test. It is also maybe performed in patients after total hip replacement and femoral head replacement without the risk of dislocation.

A limitation of this study is a small number of patients evaluated. However this test has been performed on many patients in our institution. We have been satisfied with the ease with which it can elicit the hip discomfort due to a diseased hip joint, even at a very early stage of OA. This is the first article to discuss the examination maneuver based on the anatomy and pathology of the hip joints. The pendulum test was considered to be a very accurate and useful maneuver in the evaluation of hip joints, even when patients have a simultaneous pathology at low back, hip or knee.

Conclusions

We have found that limited rotation, particularly internal rotation, of the hip joint while a patient is seated with the hip and knee flexed at 90 degrees is extremely predictive of hip pathology. The positive pendulum test highly correlated to the hip pathology.

References

1. Stone M, Assessment of the difficult primary hip replacement, Curr Orthop. 2008 Jun 22;3:165-172
2. Gray H, Articulations of the lower extremity, Gray's Anatomy, Fifteenth edition, 1995, 240-246.
3. Martin HD, Savage A, Braly BA, Palmer IJ, Beall DP, Kelly B. The function of the hip capsular ligaments: a quantitative report. Arthroscopy. 2008;24(2):188-195.
4. Myers SR, Eijer H, Ganz R. Anterior femoroacetabular impingement after periacetabular osteotomy. Clin Orthop Relat Res. 1999;363:93-99.
5. Ganz R, Parvizi J, Beck M, Leunig M, Notzli H, Siebenrock KA. Femoroacetabular impingement: a cause for osteoarthritis of the hip. Clin Orthop Relat Res. 2003;417:112–120.
6. Theiler R, Stucki G, Schütz R, Hofer H, Seifert B, Tyndall A, Michel BA. Parametric and non-parametric measures in the assessment of knee and hip osteoarthritis: interobserver reliability and correlation with radiology. Osteoarthritis Cartilage. 1996;4(1):35-42.
7. Cibere J, Thorne A, Bellamy N, Greidanus N, Chalmers A, Mahomed N, Shojania K, Kopec J, Esdaile JM. Reliability of the hip examination in osteoarthritis: effect of standardization. Arthritis Rheum. 2008;15;59(3):373-381.
8. Martin RL, Sekiya JK., The interrater reliability of 4 clinical tests used to assess individuals with musculoskeletal hip pain. J Orthop Sports Phys Ther. 2008;38(2):71-77.
9. Lee KM, Chung CY, Kwon DG, Han HS, Choi IH, Park MS. Reliability of physical examination in the measurement of hip flexion contracture and correlation with gait parameters in cerebral palsy. J Bone Joint Surg Am. 2011;19;93(2):150-158.
10. Croft PR, Nahit ES, Macfarlane GJ, Silman AJ. Interobserver reliability in measuring flexion, internal rotation, and external rotation of the hip using a plurimeter. Ann Rheum Dis. 1996;55(5): 320–323.
11. Holla JF, van der Leeden M, Roorda LD, Bierma-Zeinstra SM, Damen J, Dekker J, Steultjens MP. Diagnostic accuracy of range of motion measurements in early symptomatic hip and/or knee osteoarthritis. Arthritis Care Res. 2012 Jan;64(1):59-65.
12. Ganz R, Leunig M, Leunig-Ganz K, Harris WH. The etiology of osteoarthritis of the hip: an integrated mechanical concept. Clin Orthop Relat Res. 2008;466(2):264-272.

4TH ANNUAL

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SCHEDULE

THURSDAY, NOVEMBER 5

1:00 PM	TSA I
2:25 PM	rTSA
3:45 PM	Break
4:15 PM	Point-Counterpoint Debates
5:15 PM	What Would You Do: Case-Based Presentations
6:00 PM	Opening Reception

FRIDAY, NOVEMBER 6

7:00 AM	Live Surgery
8:00 AM	Instability
9:25 AM	Break
9:55 AM	Point-Counterpoint Debates
10:40 AM	Rotator Cuff
12:00 PM	Industry-Sponsored Luncheon Workshops
1:20 PM	Perioperative Management of the Shoulder Patient
2:40 PM	How I Do It
3:20 PM	Break
3:50 PM	What Would You Do: Case-Based Presentations

SATURDAY, NOVEMBER 7

7:00 AM	Surgical Skills Cadaver Workshops
	Small-Group Discussions: Case-Based Reviews
10:30 AM	Fractures and Dislocations
11:50 AM	Industry-Sponsored Luncheon Workshops
1:10 PM	Total Shoulder Arthroplasty II
2:30 PM	How I Do It
3:10 PM	Break
3:40 PM	Point-Counterpoint Debates
4:25 PM	What Would You Do: Case-Based Presentations
5:10 PM	Adjourn

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COMMENTARY
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Safety Issue of Hip Resurfacing, A Commentary

McTighe T [1], Acknowledgments to: Clarke I, Lazennec J

I had the pleasure of attending the recent International Society For Technology in Arthroplasty (ISTA) Annual Meeting held in Vienna, Austria September 30 - October 3, 2015. This years President was Robert M. Streicher, PhD supported by Program Director Joseph Fetto, MD. They along with their entire educational team put on an excellent symposium.

For those that are not acquainted with this group I encourage all that are interested in joint replacement to take time next year to join Stephen Murphy, MD, who will be hosting, as the 2016 President, the annual meeting in Boston.

One session that I particularly enjoyed was the session on Friday afternoon titled Hip Arthroplasty in the Patient Under 50: Long Term Clinical Series Moderated by Thomas Gross and Koen de Smet. There were twelve excellent papers presented in this session on results with Hip Resurfacing Arthroplasty. In fact, if one had only heard those papers and new nothing about the recent controversy one would wonder why more Resurfacing was not being done today! This leads into our Commentary on "Safety Issue of Hip Resurfacing."

Hip Resurfacing (HR) development of the 1970s was an attempt to address the failures of conventional cemented stems. Those early HR designs failed because problems with maintaining bone under the resurfaced femoral head, and loosening of the socket with substantial acetabular bone loss. However technology, knowledge and surgical techniques have evolved over the past 45 years. The more recent designs like the Birmingham Hip Resurfacing (BHR) focused on metal to metal bearing surfaces. These devices are under attack and maybe they should be. However, lets not ignore the significant amount of information and potential improvements in both design technology and surgical techniques that have come about over the past few years.

The Medical Healthcare Products Regulatory Agency (MHRA June, 2015) warned of higher risks with 46-48mm sizes of BHR hip resurfacing arthroplasty (HRA). For the 46mm and 48mm cups highlighted in the MHRA alert, the critical cup inclinations where edge-wear became a risk occurred at 65-66º, revealing an insignificant difference with respect to diameters.

This warning brings with it a level of confusion and implies that the critical factor is small sizes (46-48) when in fact the real risk is not the size of the implant but the inclination (position) of the implant.

Our lead paper in this edition is titled "Margin-of-safety Algorithm Used with EOS Imaging to Interpret MHRA Warning for 46-48mm MOM Arthroplasty" authored by Clark and Lazennec.

Timothy McTighe, Dr. HS (hc)

The level of evidence in this paper brings about some very significant findings. "For the 46mm and 48mm cups highlighted in the MHRA alert, the critical cup inclinations where

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edge-wear became a risk occurred at 65-66°, revealing an insignificant difference with respect to diameters. The MOS-algorithm also indicated that lower lateral-inclination angles were particularly beneficial, i.e. a 46mm cup positioned at 50° inclination would exhibit a higher margin of safety than either 48mm or 50mm sizes positioned at 55° inclination. This evidence supported clinical studies that recommended BHR cup inclinations of 50-55° or lower as optimal for reducing metal-ion concentrations."

Was the MHRA alert released without all the factors being properly reviewed and expressed? Does this alert cloud the issue of risk factors? Does this alert bring more attention to the legal community that may act hastily causing more concern; anxiety and expense to a heath care community already under attack? Does this alert provide clearly defined guidelines as to when surgical intervention should be considered?

I suggest not, however, our featured paper (Clark and Lazennec) provides an algorithm that can provide a simple and reproducible tool to help guide surgeons on how the MHRA warning may affect their clinical outcomes.

Over the years we have seen that when new designs come to the general market if the surgeon and companies do not fully understand the design principles and the required technique to ensure proper indications, implant position and precautions, patients are at risk.

Papers presented at the 2015 ISTA Meeting demonstrated that MOM HR works well in the hands of the "Experts." This then raises the question do the "Experts" always tell the truth when they are proclaiming excellent results how do we judge? Full disclosure of potential conflicts is our best practice for this concern.

Do we need Expert HR Centers?

How do we define Expert HR Centers?

How do we define Expert HR surgeons?

Who and what criterion defines the expert surgeons who are permitted to perform HR?

Will manufactures support HR technology that is plagued with current financial risks?

Should we be advocating for an indemnification from the patient that since he or she is part of the decision making process they lose their rights for punitive damages in cases of clinical failure?

The question raised now is who should decide on what and when to use. There has been debate that maybe only those that do a significant amount of any given procedure should be able to use or do the procedure. Then there is the argument of some type of additional training process or certification should entitle the surgeon to have access to this technology. If that route is taken who decides? Does the training come from industry, from CME activities, from Professional Societies from additional Fellowships or from an honest discussion between patient and surgeon with full disclosure on the merits and risks of the procedure along with a full discussion of the training of the individual experience the surgeon has with this technology. One would think this happens as a matter of routine practice.

There needs to be a balance between the designers, the developers, the distributors and all guided by the Professional Educational and Scientific Societies. When this breaks down we then see the government and legal sharks jump into the mix. In my opinion, bias as it is, I believe we can continue to make improvements in design, material and surgical technique however, I do not believe our government or our insurance industry has the same focus. Their focus is to say this technology is now a commodity and there is no difference between devices or training. They are trying to bring both surgeons and designers down to the lowest common denominator and say there is no difference so all-pricing for both should be at a commodity price point. Example: An active 65-year-old male on Medicare cannot sit with his surgeon to decide what type of implant is best for him. Lets say both surgeon and patient wish to use a ceramic on ceramic bearing or a Metal on Metal HR. Can he in the U.S. pay the cost differential and have the technology of his choice? The answer is no it is against the law. We need to fight to maintain the authority that medical decisions are a joint decision process between surgeon, patient and supported by proper medical societies.

The clinical evidence is in and clearly demonstrates that current HR can be done safely when there is full understanding of the design principals and the required technique to ensure proper implant position.

Clarke and Lazennec's paper supports what we already know that surgical prosthetic placement is the major criteria for good outcomes. A small cup correctly placed can be better for the patient than a large cup incorrectly placed.

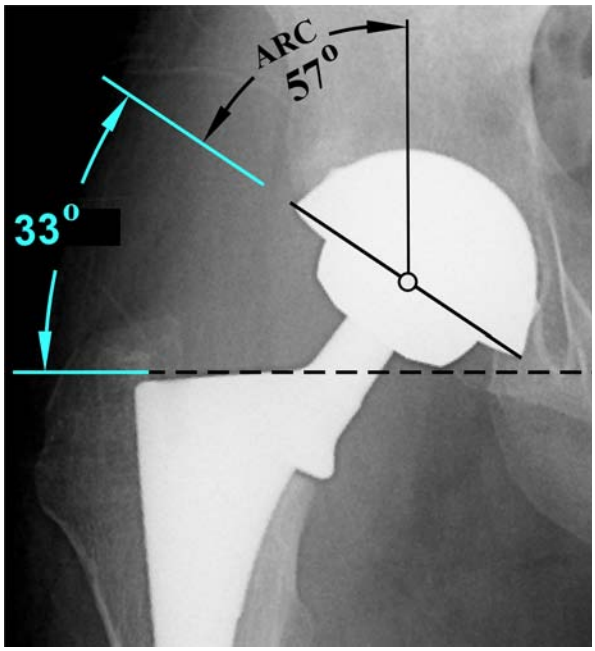

Fig. 1. 38mm M2a (Biomet, Warsaw IN)

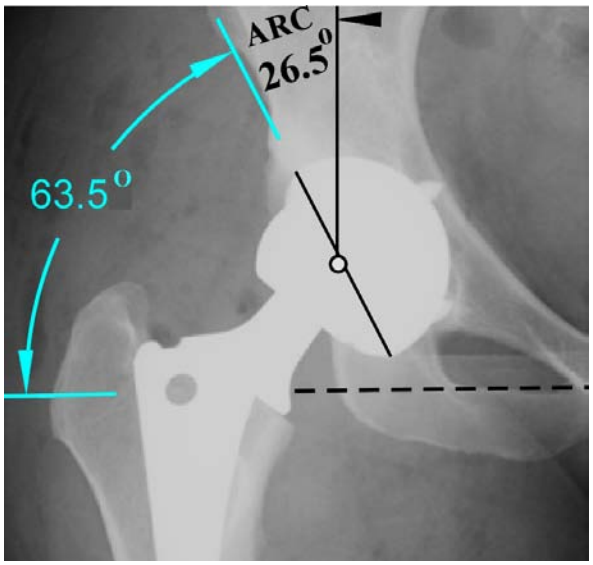

Fig. 2 36mm Pinnacle (Depuy, Warsaw IN).

A simple case survey (using the ARC parameter) illustrates the difference in cup coverage due to the angle of lateral inclination. A 33°-inclined cup allows for ARC-coverage of 57° whereas a 63.5°-inclined cup reduces the ARC-coverage to 26.5°. Case-1 had a 38mm M2a (Biomet, Warsaw IN) and case-2 had a 36mm Pinnacle (Depuy, Warsaw IN). Patient-1 was a 17-year-old male revised after 7 years for hip pain and a noisy bearing but with notably low metal ions. Patient-2 was a 51-year-old female revised at 5 years with a painful hip and high metal ions. Such case analyses are quite complex and the surgeon needs a simple instrument to isolate the effects of cup design, diameter and inclination in deciding whether edge wear should be a real consideration. It may be that the MOS-algorithm can serve as that instrument.

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LETTER TO THE EDITOR http://dx.doi.org/10.15438/rr.5.3.124

Letter to the Editor

Keggi J [1]

Tim McTighe's comments are timely and apt in his article "Safety Issue of Hip Resurfacing". As a profession we struggle now more than ever with the tension between healthcare and practice of medicine. The former involves government policy, regulation, budgetary items and corporatization. The latter is the application of scientific knowledge and personal interaction to the art of healing. In the modern world it is difficult to have one without the other, but we must remain vigilant.

The process of developing and deploying new technology in medicine necessarily involves introducing some failures. It is our intellectual goal and ethical duty to try to minimize those failures. Nonetheless, greater understanding and new improvements evolve from understanding both the successes and problems of a particular technology. We do not yet have the ideal implant for every patient, but the choices surgeons have today are the product of countless cycles of development. The components we implant and the techniques we use today are vastly improved when compared to the tools and technology of the prior decades. Many of the greatest advances in medicine and modern life have come from the work of individuals and industry working together. Whether driven by compassion, competition, scientific curiosity or profit (or any combination thereof), innovators working in the private sector have delivered previously unimaginable improvement in the quality of our lives.

The core of the practice of medicine is the physician-patient relationship. This is also the avenue for the introduction of new technology. This is the setting where an individual patient with his particular medical condition, activities, preferences and concerns can have a full discussion of the options with someone who can interpret his circumstances in the light of medical science and develop a specific plan. It requires a practitioner to be up to date scientifically and also transparent, as Tim suggests, regarding one's experience and commercial relationships. It requires the patient to be informed and participatory in the process. The scientific community, as exhibited in this issue's Featured Article by Clarke and Lazennac, delves into detailed basic science and clinical questions. Industry has the responsibility of providing proper training with specific new technologies. Our professional societies and CME organizations have been outstanding as a forum for additional training and for presenting results. Registries and data collection agencies can provide aggregate outcomes as well.

However, we are now being pushed from care that is individual and potentially excellent to care that is population-based and "good enough". While registries and government agencies can provide "big data" that can be illuminating, the rules of implementation, the process of implant selection and the delivery of care must remain well within medicine itself and within the doctor-patient relationship. Care that satisfies certain checkboxes or published clinical guidelines is becoming the norm. Such care can bring consistency but also reflects the increasing institutionalization and depersonalization of medicine. It is our challenge and responsibility to continue to provide to our patients on an individual basis the best that medicine has to offer despite changes in employment models, healthcare financing and increasing regulation. It is the hard work of individuals, researchers, the professional societies, industry and those who contribute to Reconstructive Review and other forums that drive this process forward for the benefit of patients worldwide.

John M. Keggi, MD

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This phase will include an expansion of our world renowned executive health and wellness practice, The Greenbrier Clinic, which will be bolstered by a world-class sports medicine program, including an orthopedic surgery center and athletic performance/rehabilitation facility, all led by the Founder of the American Sports Medicine Institute, Dr. Jim Andrews and Chair of Cleveland Clinic Innovations, Thomas Graham. Rounding out the Institute's services will be a first-in-class plastic and cosmetic surgery and Lifestyle Enhancement Academy, helping people look and feel their best. Physicians, universities, research foundations, medical journals and other healthcare industry leaders, all of whom are on the cutting edge of medical technology, research and care, have committed to join the project and establish an international research and education destination or "think tank" to stimulate research, drive innovation, force change and redefine how the world approaches health, wellness and longevity.

The Institute's facility, designed by Willie Stokes, will feature Georgian architecture similar to the resort's façade, a replica of the Springhouse, the site of the famous sulphur springs and special guests suites for patients and their families. Jack Diamond, President and CEO, and Mark Krohn, COO, are leading the development of this exciting project and are actively looking for other physicians and medical thought leaders to be involved.

For more information, please contact:

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Disclosure for Authors

Article 1, page 13.
Clarke [4] - consultant to Stryker and WMT; Lazennec [1]

Article 2, page 23.
Zandee van Rilland [1]; Varcadipane [1]; Geling [1]; Murai Kuba [1]; Nakasone [1]

Article 3, page 29.
Meere [4] - consultant to OrthoSensor, Inc.; LaMont [1]; Baez [1]; Kang [1]; Rasquinha [1]; Anderson [4] - employee of OrthoSensor, Inc.; Jacobs [1]

Article 4, page 35.
Allison [4] - royalty payments, TeDan Surgical Innovations, Inc., royalty payments, Ortho Development Corporation, Inc., royalty payments, Exactech, Inc., speaker fees, Convatec, Inc., stockholder, Carbo-Fix, Ltd.; Menendez [4] - royalty payments, TeDan Surgical Innovations, Inc.; Brien [1]; McTighe [1]

Article 5, page 45.
Oshima [1], Fetto [1]

Article 6, page 51.
McTighe [1]

Article 7, page 55.
Keggi [1]

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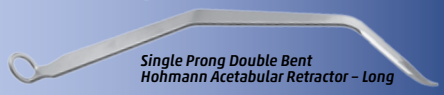

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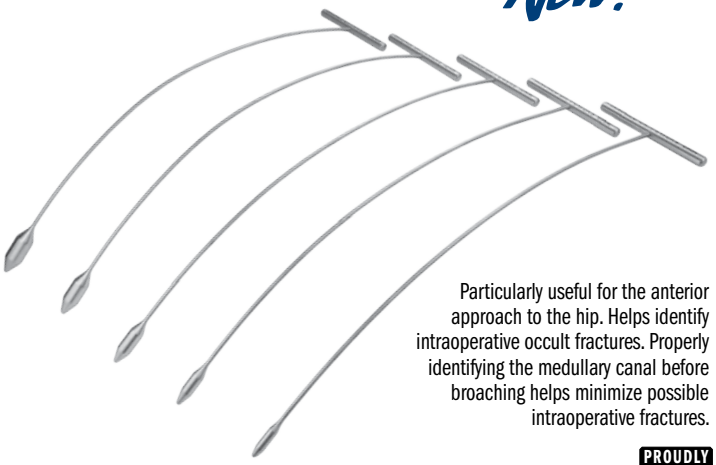

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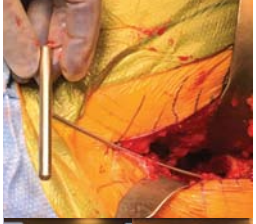

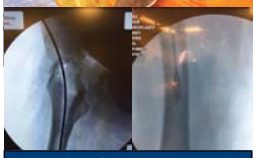

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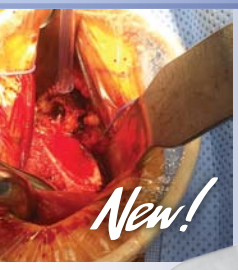
Also available individually:
4189-06 [6 mm] *Overall Length: 14.25" (36,2 cm)* *Handle Length: 3.5" (8,9 cm)*
4189-06 [8 mm] *Overall Length: 14.25" (36,2 cm)* *Handle Length: 3.5" (8,9 cm)*
4189-06 [10 mm] *Overall Length: 14.25" (36,2 cm)* *Handle Length: 3.5" (8,9 cm)*
4189-06 [12 mm] *Overall Length: 14.25" (36,2 cm)* *Handle Length: 3.5" (8,9 cm)*
4189-06 [14 mm] *Overall Length: 14.25" (36,2 cm)* *Handle Length: 3.5" (8,9 cm)*



Hope Direct Anterior Femoral Retractor

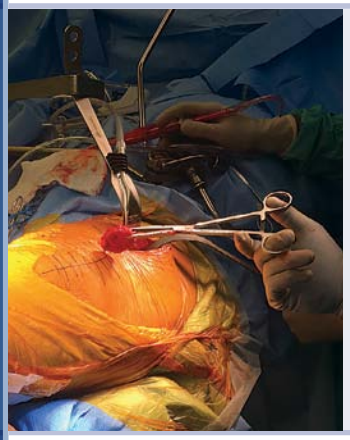
Designed by Charles A. Hope, MD

Designed to aid in exposure of the calcar femorale for proximal femoral exposure and broaching

New!

PROUDLY MADE IN THE USA

PRODUCT NO:
5838 *Overall Length: 11" (27,9 cm)* *Blade Width: 1" (2,54 cm)*



Powers Modified Kocher Clamp

Designed by Mark Powers, MD

Heavier design allows for a firmer grasping of bone and soft tissues

New!

PRODUCT NO:
1814 *Overall Length: 8.25"* *Law Length: 2.5"*

PROUDLY MADE IN THE USA

Bozeman Anterior THA Femoral Elevator

Three Sizes Now Available!

Designed by Daniel M. Gannon, MD

Designed to elevate the femur anteriorly, providing exposure to allow broaching of the femoral canal and final placement of the femoral component, during direct anterior approach THA

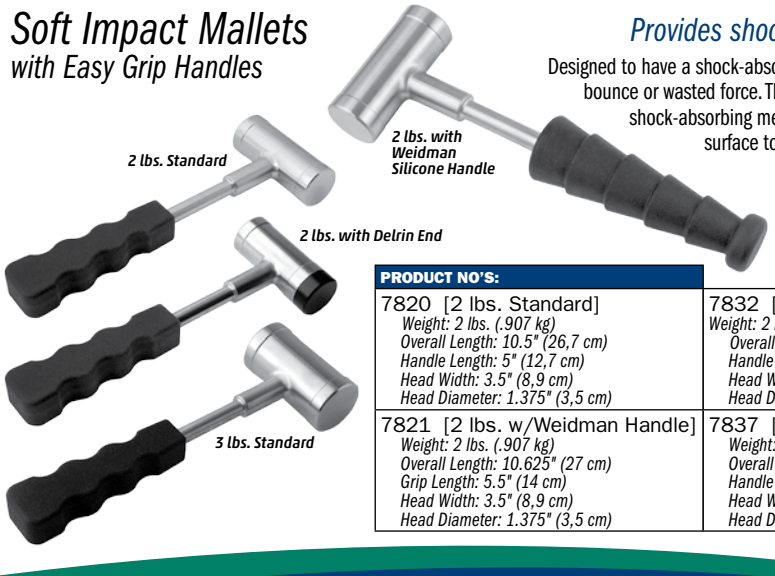
PRODUCT NO'S:
6144 [Small] *Overall Length: 11.5"* *Blade Neck Width: 26.1mm* *Blade Flared End Width: 30.1mm*
6146 [Medium] *Overall Length: 13.5"* *Blade Neck Width: 29.8mm* *Blade Flared End Width: 34.7mm*
6145 [Large] *Overall Length: 15.5"* *Blade Neck Width: 33.6mm* *Blade Flared End Width: 39.3mm*

PROUDLY MADE IN THE USA

Soft Impact Mallets with Easy Grip Handles

Provides shock-absorbing force

Designed to have a shock-absorbing force, providing less bounce or wasted force. The mallets are filled with a shock-absorbing media and has a flat striking surface to keep the mallet centered on an instrument.



PROUDLY MADE IN THE USA

PRODUCT NO'S:	
7820 [2 lbs. Standard] *Weight: 2 lbs. (.907 kg)* *Overall Length: 10.5" (26,7 cm)* *Handle Length: 5" (12,7 cm)* *Head Width: 3.5" (8,9 cm)* *Head Diameter: 1.375" (3,5 cm)*	7832 [2 lbs. w/Delrin End] *Weight: 2 lbs. (.907 kg)* *Overall Length: 10.5" (26,7 cm)* *Handle Length: 5" (12,7 cm)* *Head Width: 3.5" (8,9 cm)* *Head Diameter: 1.375" (3,5 cm)*
7821 [2 lbs. w/Weidman Handle] *Weight: 2 lbs. (.907 kg)* *Overall Length: 10.625" (27 cm)* *Grip Length: 5.5" (14 cm)* *Head Width: 3.5" (8,9 cm)* *Head Diameter: 1.375" (3,5 cm)*	7837 [3 lbs. Standard] *Weight: 3 lbs. (1.35 kg)* *Overall Length: 11" (27,9 cm)* *Handle Length: 5" (12,7 cm)* *Head Width: 3.5" (8,9 cm)* *Head Diameter: 1.875" (4,8 cm)*

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