ISSN 2331-2262 (print) • ISSN 2331-2270 (online)

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The Reconstructive Review (ISSN 2331-2262 print, ISSN 2331-2270 online) will be published four times a year by the Joint Implant Surgery & Research Foundation, 46 Chagrin Plaza #117, Chagrin Falls, Ohio 44023.

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- Live Area: 7.25" x 9.25"
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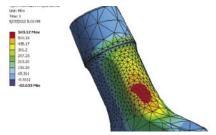
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REVIEW

http://dx.doi.org/10.15438/rr.8.2.209

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Understanding Iliotibial Band-Sparing Total Hip Arthroplasty: Alternatives to Traditional THA Approaches

Nevins R¹, Sagers²

Abstract

Excellent long term results in total hip arthroplasty (THA) are achievable through a variety of surgical techniques. However, the push for cost savings and higher patient expectations has shifted the focus to improving short term outcomes such as length of stay and in-hospital narcotic requirements. While approximately 87% of surgeons worldwide continue to prefer traditional posterolateral (PL) or lateral approaches for arthroplasty, [1] alternative approaches that spare the iliotibial band have emerged over the last several years in hopes of improved outcomes. This review explores the iliotibial band-sparing approaches, their advantages and disadvantages, and provides an overview of their published results.

The Iliotibial Band

The Iliotibial band (ITB) is a group of vertically oriented fibers consisting of a superficial, intermediate and deep layer that converge from their origins at the iliac tubercle, iliac crest and the superior acetabulum and insert on the lateral femoral condyle and tibia. Huang et al, who dissected 40 cadaver specimens and examined the ITB and investing structures at the hip, describe the insertion of the superior fibers of the gluteus maximus as a posterior reinforcement of the ITB. [2] These fibers do not insert at the greater trochanter, but rather join the continuation of the tensor fascia latae and the remaining fibers of the inferior gluteus maximus to insert at the linea aspera via the lateral intermuscular septum. [2-4] (FIG-URE 1)

Much study and emphasis has more recently fobeen cused on the function of the ITB at the knee, where it functions to create a rigid support pillar to allow for asymmetric standing. [3-5] However, Inman attempted to qualify and quantify its contribution to standing and gait at the hip as early as 1947. He proposed that the ITB provides nearly half of the torque necessary to keep the pelvis level

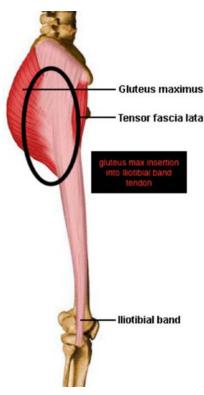


Figure 1: Approximately 75% of gluteus maximus insertion is into the iliotibial bad. Image courtesy of dept. washington.edu

Keywords: iliotibial band; total hip arthroplasty; minimally invasive *Level of Evidence*: AAOS Therapeutic Level V and is one of the final restraints to prevent further sagging when the pelvis is allowed to sag unilaterally. [6] The result of disrupting this checkrein to hip abduction during single leg stance has been shown in literature evaluating lateral THA approaches, with the incidence of Trendelenburg gait as high as 31%. [7]

Direct Anterior Approach

The Direct Anterior (DA) Approach is the most popular and studied of the ITB sparing approaches. The intermuscular, internervous interval of the approach, with the plane extending between the tensor fascia latae (TFL) and the sartorius muscles, was originally described in 1881 by Hueter, [8] and subsequently modified by Smith-Petersen in 1917. [9] It was not routinely used in THA until 1980 when Light and Keggi published their results, which showed a low complication rate, although average length of stay (LOS) was 12.8 days in their study. [10] Over the last 20 years, renewed interest in the DA approach has been driven by the search for a less invasive approach with faster recovery.

The DA approach can be performed using either specialized tables or a standard operating table, depending on surgeon preference. Specialized tables allow traction boots to be used and may allow for more precise positioning and control of the extremities during the surgery. When using a standard table, a bump may be placed beneath the patient at the level of the anterior superior iliac spine (ASIS) to allow relative extension of the hip to allow for better exposure during femoral preparation. In addition, the table itself can be flexed in a way to allow for additional hip extension if the patient is positioned at the crease of the table.

While placement of the incision may vary slightly with surgeon preference, it generally extends from approximately 3 cm inferior and 3 cm lateral to the ASIS, extending distally over the TFL muscle belly. Dissection of the fascial planes of the TFL is carried out to ensure proper muscular intervals and avoid medial dissection near the femoral neurovascular bundle. After separating the TFL from the sartorius, the TFL is retracted laterally, retractors are placed extracapsularly over the superior and inferior femoral neck as well as the lateral edge of the intertrochanteric ridge. (FIGURE 2) The fat overlying the anterior hip capsule is removed, and the attachment of the reflected head of the rectus femoris is released from the anterior acetabulum. Capsulotomy or capsulectomy is then performed and the joint exposed by placing the retractors intracapsularly. The femoral neck cut is made and the head is extricated. The acetabulum is then prepared and the cup placed, often-

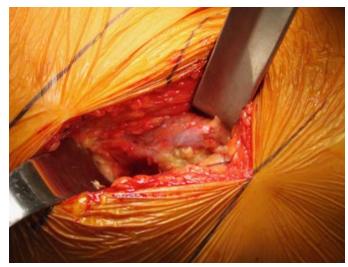


Figure 2: DA Approach superficial dissection is performed between TFL and sartorius. Image courtesy of Dr. Aaron Salyapongse

times under fluoroscopic guidance to ensure proper positioning. The femoral shaft is then presented by extending, external rotating and adducting the hip. Specialized bone hooks and offset broaches have been designed to assist in presenting the femur out of the incision. [11] Early teaching of the technique also described a release of the posterolateral capsule at the greater trochanter to allow for further translation; however, several authors now recommend releasing the conjoined tendon to the level of the obturator internus and, when necessary, the piriformis, to facilitate adequate exposure. $[\underline{12},\underline{14}]$ After femur preparation is complete, trialing, final implantation and stability testing takes place. The wound is closed in the standard fashion. While individual protocols vary, many DA surgeons do not place formal restrictions on mobility for their patients postoperatively.

Outcomes of the DA approach have been favorable, particularly in the early postoperative period. Barrett et al performed a randomized trial comparing DA and PL approaches performed by the same surgeon. The DA patients had less pain, were discharged sooner, and were able to walk greater distances during the first and second postoperative days in comparison to the PL approach patients. However, the longer-term outcomes were equal at 6 months between the two groups. [15] Restrepo et al performed a randomized study comparing the DA and direct lateral (DL) approach and had similar improved short term outcomes in the DA group. [16] Berend performed a large retrospective study comparing the DA and the less-invasive DL approach. The LOS between the groups was not significantly different, but the percentage of patients discharged home, the Harris Hip Scores and Lower Extremity Activity Scores were all significantly higher in the DA vs. the DL group. [17] Several studies support these findings,

$[\underline{18}-\underline{22}]$ while others refute them. $[\underline{23}]$

Initially described and advertised as a "tendon sparing" approach (focused on sparing the short external rotators (SER) in comparison to the posterolateral approach), releases of the piriformis and conjoined tendon better facilitate femoral preparation during the DA approach. [12-14] Meneghini performed a cadaveric study comparing muscle damage incurred by DA and PL approaches and reported that release of the piriformis and conjoined tendon was necessary in 50% of their dissections in order to achieve adequate femoral exposure. [14] This, however, does not appear to compromise the potential for accelerated recovery. Rodriguez et al compared 60 patients that had the DA approach THA using a release of the posterior superior hip capsule, the piriformis, and the superior portion of the conjoined tendon to 60 patients who underwent THA using the mini-incision posterolateral (PL) approach. The patients who had the DA approach had faster return to function in the early postoperative period compared to the PL group, consistent with other reports on the DA approach that do not explicitly describe these tendon releases. [13] This suggests that the DA approach's preservation of the SERs may not be the main factor contributing to accelerated recovery, [24] but may instead be the preservation of the ITB.

The DA approach is not without risk of intraoperative and postoperative complications, especially in the operations performed in the learning curve period. [25,26] While relatively rare, the most common complications include intraoperative femoral fracture or perforation, acetabular fracture, lateral femoral cutaneous nerve (LFCN) palsy, and dislocation. Ankle fracture has also been reported with the use of traction tables for positioning. [27]Because of the location of the incision, superficial wound complications are also an issue, especially in patients with higher BMI. [28] These complications are more common (as high as 9-13%) [29] in the first 50-100 cases, designated as the learning curve, [26, 29-30] with early revision rates as high as 6%. [30] These complication rates appear to decrease according to surgeon experience, with complication risk profiles similar to that of other hip approaches after the learning curve. [21,31,32] Additionally, risk of complications and expertise required both increase when using the DA approach for complex or revision cases, although it can be successfully performed. [33] The risk of an increased rate of these complications during the learning curve as well as the decreased extensibility of the approach remain deterrents for some surgeons to pursue the potential improved short term outcomes afforded by the approach, especially when long term outcomes have not been proven to be significantly better. [17, 34, 35]

SuperCap[®] / Direct Superior Approach[®]

In 2002, Dr. Stephen Murphy first described the Supercapsular THA (SuperCap[®] Microport Orthopedics Inc., Arlington, TN, USA). This single-incision technique shifts the traditional posterior superficial dissection slightly proximal, preserving the ITB at the greater trochanter

(FIGURE 3). Other modifications have been introduced (Direct Superior[®] Stryker Inc., Kalamazoo, MI, USA), but share in common the use of a superior capsulotomy and specialized instrumentation in an effort to avoid releasing the SER tendons.

Patients are placed in the lateral decubitus position on a standard operating table. The operative leg is placed in flexion, internal rotation, and adduction by placing the foot on a Mayo stand. The incision is typically in line with the femoral shaft just superior to the greater trochanter, extending proximally be-

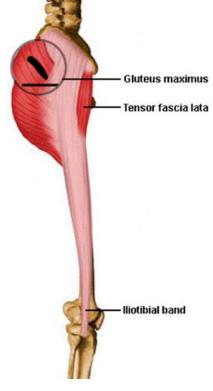


Figure 3: ITB-Sparing techniques: all superficial dissections do not violate ITB tendon. Image courtesy dept. washington.edu

tween 6-8 cm. Blunt dissection is performed to split the gluteus maximus in line with its fibers until the interval of the posterior border of the gluteus medius and the piriformis is identified. The piriformis and conjoined tendon attachments are preserved, if possible. Alternatively, the Direct Superior[®] or Northern approach uses the traditional PL approach deep interval (between the gluteus medius and the conjoined tendon with release of the piriformis and superior SERs) with the same ITB-sparing superficial dissection. [36] The gluteus minimus is reflected anteriorly from the superior capsule and the capsule incised along the superior aspect of the femoral neck, extending to the acetabulum.

Retractors placed along the anterior and posterior femoral neck allow complete visualization of the proximal femur. The proximal femur is prepared in line with the femoral shaft with the femoral head and neck in situ. This theoretically distributes stresses during femoral preparation, decreasing the risk of intraoperative femur fractures, and avoids overstretching the attached short external rotators that occurs with surgical dislocation. Acetabular preparation is performed using specialized instrumentation in the form of angulated reamers (FIGURE 4) and offset cup



Figure 4: Angled reamer used to avoid violation of ITB tendon. Image courtesy Dr. Brandon Gough

inserters, with or without the use of CT guided navigation to aid in positioning. While these instruments are required for preparation of the bony structures, any implant system can be inserted during the procedure. The capsulotomy is closed in a normal fashion after trialing, implantation and in-situ reduction, and the piriformis insertion, if released, is repaired. Closure of the remaining layers is performed in the standard fashion. [<u>37</u>]

The tissue-preserving nature of the superior approach affords the stability of the traditional transgluteal approach while decreasing the potential risk of gait abnormalities and pain associated with the traditional posterior approach, presumably by preserving the ITB. This allows patients to routinely be placed into an accelerated rehabilitation protocol, permitting them to bear weight almost immediately after surgery without traditional hip precautions. [<u>37,38</u>]

In a study of 218 consecutive patients undergoing total hip arthroplasty using this technique in 2010-2011, 87% of patients were discharged within 2 days of surgery, and 99% of all patients were discharged home, with only 1 readmission for a GI bleed related to use of NSAIDs postoperatively. There was only 1 reoperation at 8 months postoperatively, an irrigation and debridement for continued pain with no evidence of infection. [38] Capuano reported on 463 patients including 275 primary elective THA and 188 femoral neck fracture patients that underwent THA using this technique. 375 patients (75%) could walk with full weight bearing on the operative leg within 6 hours of the procedure. There was a 1% complication rate (1 dislocation, 2 malpositioned cups, 2 loosened cups), all within the first 20 cases. There were no further complications reported after the first 20 cases. [39]

PATH[®]

First reported by Dr. Penenberg in 2004, PATH[®] (Microport Orthopedics Inc., Arlington, TN, USA) utilizes the deep interval of the traditional PL approach, but differs from the traditional approach by shifting the superficial dissection superiorly to avoid disruption of the ITB at the greater trochanter. Rather than using an angulated reamer of SuperCap[®]/Direct Superior[®], acetabular reaming is accomplished by inserting a cannula through a portal in the soft tissues just posterior to the proximal femoral shaft, avoiding the ITB at the trochanter. This allows for direct visualization of the acetabulum during reaming, as well as the use of straight reaming handles for more familiar reaming control.

The patient is placed in the lateral decubitus position on a peg board, anterior on the table with the foot on a Mayo stand to allow for flexion, adduction and internal rotation of the leg. The incision starts at the proximal edge of the greater trochanter and extends proximally, angled 30-45 degrees posteriorly. After incision of the overlying fascia, the gluteus maximus is bluntly dissected in line with its fibers. The interval is developed between the gluteus medius and the conjoined tendon. The piriformis insertion is identified and it is released along it's footprint, preserving as much length as possible for later repair. If necessary, the superior portion of the conjoined tendon may also be released for increased exposure. A posterior capsulotomy is performed, in line with the femoral neck, to the level of the acetabular rim before it is curved anteriorly along the posterior wall toward the lateral rim, creating a "J-shaped" capsulotomy. In the originally described approach, the hip was dislocated to allow for the femoral neck cut. However, in recent years, modifications (PATH II) allow for the femoral neck cut to be performed in-situ. Intracapsular Hohmann retractors are placed anterior and posterior to the femoral neck cut to expose the osteotomy site and protect soft tissues. A napkin ring of bone is typically removed as proximally on the neck as possible to facilitate head extrication, or, depending on surgeon preference, a single osteotomy with en bloc extrication may be performed. With a more posterior capsulotomy, a small (3-4mm) corner of the posterolateral greater trochanter without muscular attachment may impede the femoral neck osteotomy at the appropriate angle. This small piece of bone may be removed via cheilectomy to facilitate the osteotomy.

The hip is then slightly flexed and maximally internally rotated and the femur is prepped and broached. Once broaching to the appropriately sized implant is completed, a "cleanup" neck cut is performed using the inserted broach as a cutting guide. The appropriate depth and angle of the neck cut is determined by referencing the distance between the shoulder of the broach and the tip of the greater trochanter and comparing to preoperative templating. This allows for reliable and reproducible implant positioning.

The leg is then returned to the starting position for acetabular preparation. Large Hohmann acetabular retractors are used to provide visualization. A cannula is introduced through a downstream portal using an over-the-top guide, using the native acetabulum to direct placement. The cannula is directed through the soft tissues posterior to the femur and towards the acetabulum. Once the cannula is in place, an 8mm reamer driver is inserted into the cannula and the reaming basket inserted and assembled in situ through the main exposure to perform reaming under direct visualization (FIGURES 5,6). The acetabular component is then inserted and impacted into a position of stability, with full visualization of the bony rim and cup during the insertion. Trialing is completed, intraoperative x-rays may be taken, range of motion and stability is tested, and final implants are inserted. The posterior capsule, piriformis and conjoined tendons are then repaired and the incision closed in the standard fashion. [40]

Penenberg reported on 250 consecutive patients, without excluding patients for BMI or complexity, and followed them for two years. All patients were placed into an accelerated rehabilitation protocol, and 83% of patients were using a cane or no assistive device for ambulation at discharge. There were no dislocations, infections, or deep vein thrombosis in the group. Femoral and acetabular components were within the accepted limits in 96% and 97% of patients, respectively. [40]

Rasuli and Grofton analyzed the learning curve of the



Figure 5: Small posterior incision and accessory portal with cannula in place allows for reaming and impacting cup without violation of ITB



Figure 6: Cannula provides excellent inline access to reamer basket without violating ITB and with minimal release of piriformis and external rotators

PATH procedure, showing reproducible acetabular anteversion and abduction (13.1 +/- 7.1 degrees, 42.9 +/- 7.6 degrees), mean operative time of 114 minutes, and 2 complications in the first 50 cases (intraoperative femoral fracture in case 10 and a posterior dislocation at 6 weeks in case 26). [41] This relatively short learning curve demonstrates the safety of the procedure, likely due to the familiarity of the dissection to trained surgeons, while still affording the benefit of accelerated recovery after surgery. In addition, the incision and intervals are extensile and easily convertible to the standard posterior approaches.

SuperPATH®

Developed by Dr. James Chow, the SuperPATH® (Mi-

croport Orthopedics Inc., Arlington, TN, USA) approach is a combination of certain aspects of the SuperCap/Direct Superior[®] and PATH[®] techniques, using the interval, capsulotomy, and femoral preparation of the Superior approach, but using the cannulated portal and straight acetabular reaming instruments that PATH[®] introduced. [41] The patients are similarly placed in the lateral decubitus position on a peg board, with the patient anterior on the bed to allow for a flexed, adducted, internally rotated position of the operative leg. The incision and dissection of Super-PATH[®] are similar to SuperCap[®], with the interval between the gluteus medius and the piriformis being developed and attempted preservation of the piriformis and conjoined tendon insertions. After the capsulotomy is performed in approximately the 11:00 position, the femur is prepared in situ by "canoeing" a space into the femoral neck to allow for subsequent broach placement. The final broach is left in place for the femoral neck cut, similar to the technique described in PATH[®], using the distance between the broach shoulder and the tip of the greater trochanter as a reference. The head is removed en bloc. The acetabulum is then prepared in a similar fashion to that described above in the PATH[®] approach. Once trialing is completed and final implants are placed the hip is reduced. Stability and range of motion is tested, and the capsule and soft tissues are repaired before standard closure is performed. [42]

This approach was developed to allow for the perceived advantages of the each of its predecessors, preserving the iliotibial band and external rotators, with in-line axial femoral preparation prior to the femoral neck cut as in the SuperCap[®] approach and allowing for consistent acetabular reaming through the accessory portal as in the PATH[®] approach.

Results of the combined technique are similar to the other "micro" approaches. Chow et al reported on the first 110 patients, including the learning curve, and all patients had well placed femoral and acetabular components at 2 year follow-up, with an average hospital stay of 1.7 days. All patients were placed in a comprehensive management program including preoperative medical optimization and counseling, as well as accelerated rehabilitation postoperatively. Of note, no IV narcotics were required or used in the postoperative period. Chow also reported 4 complications related to the surgery in the first 330 patients (1.2%) to undergo the operation, with 2 calcar fractures, 1 nondisplaced acetabular fracture, and 1 failure of cup fixation. [43,44]

Gofton et al reviewed 479 SuperPATH[®] patients across 3 centers and evaluated readmission and discharge disposition rates. There was an all-cause readmission rate of 2.3% after an average LOS of 1.6 days. 91% of patients were discharged home routinely, 3.8% home with home health, and a combined 4.7% to skilled nursing and acute inpatient rehab facilities (4.1% and 0.6%, respectively). [<u>41</u>] Gofton then analyzed the cost reduction using these results compared to the patients receiving a THA via a lateral approach by another surgeon at the same institution and found a 28.4% cost reduction in favor of SuperPATH. [<u>45</u>]

Discussion

Overall, hip arthroplasty is a surgical procedure with excellent long term outcomes, no matter the approach, so long as the components are well-placed and well-seated. Each traditional approach has its pros and cons, which have been extensively studied and improved upon with better techniques and technology over the last several decades. Because of the consistent long-term results, increasing attention has been placed on short term recovery with accelerated rehabilitation programs, multimodal pain management, and tissue preserving approaches. Results of early attempts at minimally invasive THA were generally unacceptable; however, continued innovation and exploration of tissue-preserving intervals, including the ones discussed in this review, have resulted in promising short-term outcomes with consistent medium and long-term results.

It was previously thought that the DA approach showed accelerated recovery due to sparing the SER tendons in comparison to the traditional posterolateral approach. However, recent descriptions of the technique using conjoined tendon releases without compromises in outcomes [24] suggest that the SER preservation may not be the true source of improved postoperative pain. One possible explanation for the shorter recovery may be that the DA approach spares the proximal ITB at the greater trochanter. The ITB-sparing approaches described above, while differing slightly in dissection planes, preservation of SER attachments, and instrumentation, share the preservation of the ITB in common with the DA approach. The evidence showing that early postoperative pain and function are similar between the approaches suggests that the ITB preservation may be the key common factor.

Penenberg proposes that preservation of the ITB in this area preserves the gluteus maximus attachment at the ITB, and that the sparing of this attachment is what contributes to decreased pain and improved function in the early postoperative period (personal communication). This sparing of the ITB makes these approaches distinctly different from traditional posterior and mini-posterior approaches, as neither truly spares this portion of the ITB and the gluteus maximus insertion. The authors of this review concur with this hypothesis, although further biomechanical study is needed to further define the role this structure plays.

When all is said and done, there is no conclusive evidence that one approach to THA is superior to another. The above-mentioned techniques offer different options to perform this common procedure in a manner that preserves the ITB and the insertion of the superior gluteus maximus. While the anterior approach is much more extensively studied, the learning curve and potential complications reported in the literature may deter surgeons from adopting the technique into practice. The other techniques mentioned here offer an alternative to the DA approach with promising short and medium-term results reported in the literature.

The decision on which approach to use in daily practice should be a function of the surgeon's training and experience. That said, the senior author of this review utilizes the PATH approach for the following reasons: 1) the ITB and gluteus maximus tendon sparing nature of the approach, which appears to influence early postoperative pain and function, 2) the small learning curve, likely due to the familiarity of the anatomy, approach, and orientation from a previously-used posterior approach, 3) the ease of use of the instrumentation introduced by this technique, 4) the extensile nature of the approach, should the need arise, allowing standard posterior approach access to the femur and acetabulum, and 5) the avoidance of common complications of the DA approach, such as LFCN injury, femoral perforation during broaching, and wound infections due to the incision being made in the groin area.

We recognize the need for increased clinical data to further demonstrate the safety and efficacy of these relatively new techniques. Longer term data is currently being collected. Further reporting of these results is warranted and merits discussion in the future.

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SUBMISSION HISTORY

Submitted August 9, 2018 Reviewed December 12, 2018 Accepted December 17, 2018 Published December 21, 2018

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AUTHOR DISCLOSURES

The authors declare that there are no disclosures regarding the publication of this paper.

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REVIEW

http://dx.doi.org/10.15438/rr.8.2.213

Coronal Alignment in TKA: Traditional Principles Versus New Concepts

Parisi T¹, Jennings J^{1,3}, Dennis D^{1,2,3,4}

Abstract

Background: Up to 20% of total knee arthroplasty (TKA) patients are not satisfied with their outcome, and coronal alignment is considered an important variable in attaining a well-functioning TKA. Neutral mechanical alignment is not necessarily the anatomic norm and has led some surgeons to advocate a shift in defining and attaining the optimal coronal component alignment. Our aim was to review the different coronal alignment paradigms of TKA and summarize the historical and contemporary outcomes of different alignment techniques.

Methods: A systematic review was performed in March 2017 via PubMed using the search terms: coronal alignment, kinematic alignment, and total knee replacement using Boolean "and" in-between terms. Relevant results were then reviewed, analyzed and summarized

Conclusions: Early clinical outcomes of kinematically aligned TKAs are promising, but long-term clinical results are unknown. Clinical, laboratory, and retrieval studies suggest that mechanical varus in TKA, especially involving the tibial component, may result in earlier failure. Kinematic alignment with boundaries may be an optimal strategy for patients with pre-operative constitutional varus or congenital tibia vara.

Keywords: total knee arthroplasty; kinematic alignment; coronal alignment; mechanical alignment *Level of Evidence*: AAOS Therapeutic Level III

Background

The importance of coronal alignment in total knee arthroplasty

Coronal alignment is considered an important variable in attaining a well-functioning TKA. [1-4] Proper alignment improves soft tissue balance and decreases mechanical and shear stresses placed on the implant fixation interface as well as on articular bearing surfaces. [4– 6 Malalignment results in decreased functional outcomes and survivorship, and has been implicated as a cause of early failure due to wear and loosening, [2,4-10] particularly in older implants of non-highly crosslinked polyethylene. [11] Most surgeons follow the tenet that post-operative alignment should be within 3° of a neutral mechanical axis. [4-6,9,12-16] However, up to 20% of TKA patients are dissatisfied, [17, 18] with some evidence that coronal alignment plays a role in patient satisfaction. [19,20] As such, substantial research and resources have been invested in defining optimal mechanical alignment, [21-24] as evidenced by recent developments in computer navigation, patient-specific instrumentation, and support for kinematically-aligned TKA. [25–27]

Anatomy and Alignment: Traditional Theories

Definition of the anatomical framework is required to understand different theories of coronal alignment (Table 1, Figure 1). Native knee alignment varies throughout the

AXES	DEFINITION
Vertical Axis	Is referenced from a vertical midline extending distally from the center of the pubic symphysis. It determines overall alignment of the lower extremity. [26]
Anatomic Axes	Anatomic axes of lower extremities always are drawn proximal-to-distal and bisect the intramedullary canals. [27] Any femoral or tibial diaphyseal deformity, either congenital, developmental, or traumatic, can markedly deviate the anatomic axes. [3,26]
- Anatomic Femoral Axis	Is typically approximately 9° of valgus compared to midline, and 5° to 7° valgus to the mechanical axis. $[3,14,26]$
- Anatomic Tibial Axis	Is typically in approximately 3° of varus compared to the vertical axis and approximates the mechanical axis. [3,14,26]
Mechanical Axis	Is defined by a line drawn from the center of the femoral head to the center of the talus, and typically is approximately 3° valgus to the vertical axis. [3,27,26]
- Mechanical Femoral Axis	Runs from the center of the femoral head to the intercondylar notch. $[3,14,26]$
- Mechanical Tibial Axis	Runs from the center of the proximal tibia to the center of the talus. $[3,14,26]$
AXES	DEFINITION
Hip-Knee- Ankle Angle (HKA)	Is created via intersection of the mechanical axis of the femur and tibia. It is typically just under 180° , and passes just medial to the tibial spine. [3,28]
Anatomic Femorotibial Angle (AFT)	Is formed by intersection of the anatomic femoral axis and the joint line and is typically approximately 6° of valgus.
Mechanical Femorotibial Angle (MFT)	Is formed between the mechanical femoral (3° valgus) and tibial axes (3° varus), resulting in 0°, or so-call neutral mechanical alignment. [$3,14,26$] The MFT is essentially the same as the HKA. [29]
Femorotibial Angle (FTA)	Is the lateral angle created between the anatomic axes of the femur and tibia. On average, it is 178° in men and 174° in women. [3,27]

population, and neutral mechanical alignment, defined as 0°, is not always observed in healthy, non-arthritic patients. [12] Hsu et al. [28] found the hip-knee-ankle angle (HKA) of normal adults was actually 1.2° of varus and only 2.2% had a HKA of 0°. Fahlman et al. [29] found only 11% of 143 patients had bilateral mechanically-neutral knees, with 49% aligned in mechanical varus, and 22% aligned in mechanical values. In asymptomatic adults, constitutionally varus knees (HKA > 3° varus) has been found in up to 32% of men and 17% of women. [31] Conversely, in a popula-

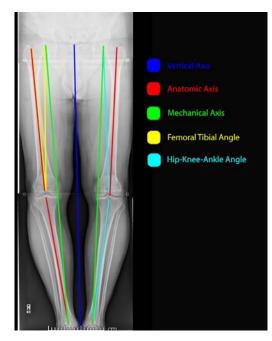


Figure 1: Illustration, demonstrating the different axes of the knee. The dark-blue line represents the vertical axis extending distally from the center of the pubic symphysis. The red lines represent the anatomic axes overall, as well as of the femur and tibia. Anatomic axes of lower extremities always are drawn proximal-to-distal and bisect the intramedullary canals. The anatomic femoral axis is typically approximately 9° of valgus compared to midline, and 5° to 7° valgus to the mechanical axis. The anatomic tibial axis is typically in approximately 3° of varus compared to the vertical axis and approximates the mechanical axis. The green line represents the mechanical axis, defined by a line drawn from the center of the femoral head to the center of the talus, and typically is approximately 3° valgus to the vertical axis. The yellow lines represent the femoral tibial angle which is formed by the intersection of the anatomic femoral axis and the joint line and is typically approximately 6° of valgus. The light-blue line represents the hip-knee-ankle angle which is created via intersection of the mechanical axis of the femur and tibia, and is typically just under 180°, and passes just medial to the tibial spine.

tion of symptomatic osteoarthritic patients, 71% had varus alignment with a mean HKA of -9.0°. [30] Additionally, Vandekerckhove et al. [52], have shown that constitutional varus does contribute to a higher incidence of osteoarthritis in the general population.

Anatomic Alignment

The premise of anatomic alignment is that optimal component position should recreate the anatomic joint line based on long-standing roentgenograms to attain an axis extending from the center of the knee to the femoral head and ankle joint. [31] This alignment technique attempts to place the joint line parallel to the ground during the bilateral limb stance phase of normal gait. [31] However, given

that surgeons accurately place components within 3° of the desired target less than 70% of the time with conventional TKA instrumentation, aiming for 2-3° of varus may result in outliers which could predispose to early failures. [32]

Mechanical Alignment

Mechanical alignment is performed by cutting both the femur and tibia perpendicular to their respective mechanical axes. [33] This results in a TKA femoral-tibial angle of approximately 5°-7° of valgus with the purpose of creating even load distribution across the joint. [35] Advocates of mechanical alignment feared that anatomic alignment would increase medial loads and risk medial tibial component fixation failure. [35]

Restoration of mechanical alignment to 0° may increase component longevity and has demonstrated a 3% loosening rate when the mechanical axis crossed the middle 1/3rd of the prosthesis versus 24% when the mechanical axis was shifted medially or laterally.5 Similarly, Fang et al. [12] found neutral mechanical alignment had a lower failure rate (0.5%) than varus (1.8%) or valgus (1.5%). Other authors have reported similar findings.20,36 This is supported in wear analysis of TKA retrievals. [5,7,11,19,22,30,37,38] Lastly, BMI may play a role in failure of the tibial component. Berend et al. [9] found a 168 times higher failure rate if the tibia component was positioned in varus (\geq 3°) in conjunction with a BMI >33.7 kg/m2.

Conversely, other studies have not demonstrated significant survivorship differences for TKAs placed outside of the $0\pm3^{\circ}$ traditional "safe zone". [22,24,34–36] Parratte et al. [22,30] found no differences in 15 and now 20-year survival of mechanically aligned knees $(0^{\circ}\pm 3^{\circ})$ versus those marginally outside of these parameters $(4^{\circ}-6^{\circ})$. Bonner et al. [34] stratified TKA patients into "aligned" $(0^{\circ}\pm3^{\circ})$ and "malaligned" (deviation $> 3^{\circ}$) groups and found slightly higher 15-year survival in the aligned group, although the difference was not statistically significant. [34] Similarly, Morgan et al. [35] found no difference in survivorship of TKAs independent of neutral, valgus or varus AFT. Matziolis et al., [24] found no outcome differences in TKAs aligned in mechanical varus versus those in neutral. A review of TKAs performed on patients with pre-operative varus gonarthrosis showed no functional difference between TKAs aligned in post-operative mechanical varus versus neutral, as well as no difference in revision rates. [37] Similarly, Hadi et al. [38] did not find increased revision rates of malaligned TKAs measured using the mechanical axis, but did find an association between malalignment and revision rate using an anatomical axis. Lastly, some evidence suggests patients placed in mechanical varus

have an increase in satisfaction after TKA. Vanlommel et al. [<u>36</u>] evaluated TKAs in pre-operative varus and found those left in mild mechanical varus (3° to 6°) had superior post-operative Knee Society (KSS) and Western Ontario and McMaster Universities Arthritis Index (WOMAC) scores compared to knees corrected to neutral or those left in increased varus (> 6^{\circ}).

Even if mechanically aligned on static radiographs, there is evidence that dynamic loading of a mechanically neutral TKA may not be balanced. [39–41] Miller et al. [39] found static neutral mechanical alignment ($0^{\circ}\pm3^{\circ}$) in 13 of 15 knees, but only 7 of 15 had balanced dynamic loading with gait testing. In cadaveric knee analysis, Delport et al. [42] showed decreased physiological strain in collateral ligaments when TKAs were restored to $\pm2^{\circ}$ of constitutional alignment versus neutral mechanical alignment.

Kinematic TKA Alignment

History and Definition of Kinematic Alignment

Kinematic alignment TKA technique evolved from kinematic studies. [43,44] Its basic principle is attempted restoration of a patient's pre-arthritic anatomy and axes of the knee, while creating a balanced TKA throughout the entire arc of motion. Specifically, it attempts to three-dimensionally align the distal and posterior femoral joint lines of the femoral component to the original primary transverse axis of the femur and joint line of the tibia to a patient's pre-arthritic state. [18] This could be achieved by transforming the arthritic knee to its pre-arthritic state via 3D modeling from a preoperative CT scan or MRI, [45] or by, more simply, performing tibial resection in 2°-3° of varus. [21] It proposes three axes which govern the movement of the patella and tibia with respect to the femur: a primary transverse axis within the femur about which the tibia flexes and extends, a second transverse axis in the femur, parallel and proximal to the first and about which the patella flexes and extends, and a third axis in the tibia which is longitudinal and perpendicular to the others (Figure 2). [45]

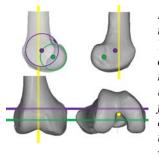


Figure 2: Illustration, demonstrating the three kinematic axes of the knee. Yellow line indicates the longitudinal axis in the tibia about which the tibia rotates on the femur. The green line indicates the transverse axis in the femur about which the tibia flexes and extends. The magenta line indicates the transverse axis in the femur about which the patella flexes and extends. The goal of kinematic alignment is to co-align the transverse axes and restore any difference in symmetry and coronal laxity between full extension and 90° of flexion of the normal knee. [45,46] As such, the thickness of all femoral bone resections including worn cartilage and bone from the saw kerf is equal to the thickness of the femoral component. [45] Restoration of the pre-arthritic joint line level and obliquity to minimize soft tissue releases, may provide the patient with a more "naturally feeling" knee and improve patient satisfaction as theorized by proponents of kinematic alignment.

To perform kinematic alignment, use of patient-specific instrumentation, computer navigation, or measurement calipers is required to achieve the desired level of precision needed for bone cuts. [47] If even small errors in resection occur, resulting in excessive tibial varus (>5°), one risks premature tibial component failure. [47] Additionally, most kinematic alignment surgeons utilize PCL-retaining TKAs. [47]

Proposed Advantages and Disadvantages of Kinematically Aligned TKA

Theoretical Advantages

Bellemans et al. [48,49] have suggested that restoring patients with constitutional varus to neutral mechanical alignment may not optimize outcomes. Using kinematic alignment principles to instead resect the tibia in a few degrees of varus and re-establish the obliquity and location of the pre-arthritic joint line, in theory, should require less soft tissue releasing and result in a more "natural feeling" TKA. [47] Vanlommel et al. [36] showed that pre-operatively varus-deformed knees that were left in mild mechanical varus (3° to 6°) at TKA had superior post-operative functional scores compared to knees corrected to mechanical neutral $(0^{\circ}\pm 3^{\circ})$.

Theoretical Disadvantages

Due to the risk of over-correction and cutting the tibia in excessive varus, surgeons performing kinematic alignment should consider using computer navigation or patient specific instrumentation to maximize precision. [47] A recent meta-analysis showed that mechanical axis malalignment greater than $\pm 3^{\circ}$ occurred 31.8% of the time using conventional TKA alignment techniques, versus 9.0% using computer navigation. [32]

Additionally, there is a three-decade history of satisfactory results with mechanically aligned TKAs in subjects with a wide range of limb alignment and arthritic deformities. Increased polyethylene stresses associated with malalignment has been shown by numerous reports to result in premature TKA failure. [5,7,9,11,15,50,51] Three laboratory studies have shown that 3°-5° of mechanical varus leads to uneven load distribution with increased compressive loading and medial wear. [6,53,54] Additionally, three retrieval analyses suggested that overall varus TKA alignment is correlated with increased wear and damage. [55-57] Two of three suggested if the tibial component was placed in varus but overall mechanical alignment was in neutral, then there was no increase in wear or damage. [55,56] D'Lima et al. [57] reported increased wear anytime the tibia was in varus, even if overall alignment was neutral. Additionally, cadaveric studies have consistently found that varus alignment causes increased posteromedial strain and medial loading pressures with decreased loads to implant failure. [13,16,58] Ritter et al., demonstrated increased failure rates with mechanical varus >2.5°, and as previously mentioned, Berend et al., demonstrated a 168 time increase in failure with a tibia in mechanical varus and BMI >33.7. [9,14] As such, the predominance of studies suggest that mechanical varus in TKA, especially involving the tibial component, may result in earlier TKA failure.

Techniques of Kinematically Aligned TKAs

Traditional Kinematic Alignment Techniques

Kinematically alignment technique using patient-specific femoral and tibial cutting guides was developed and described in 2005. [45] It required special software to create and transform a patient's arthritic knee to its non-arthritic state via a 3D model generated by magnetic resonance or computed tomography imaging. This was then used to create patient-specific cutting guides based on kinematic alignment principles. To eliminate the expense of patient-specific instrumentation and allow for broader use of kinematic alignment, Howell revised his technique to use modified generic instrumentation, and educated estimations of cartilage and bone wear. [26,59] Femoral implant placement is based on the primary transverse axes about which the tibia and the patella flex and extend. The distal femoral cutting guide is manually placed just posterior to the notch apex, flush with the 'unworn' side and manually raised away from the 'worn' side to correct for wear. The goal is to perform a resection equal to the distal thickness of the femoral component with symmetric medial and lateral condylar thickness minus the thickness of the estimated cartilage and bone erosion on the worn side). For example, if the component width is 9mm and the surgeon estimates 2mm of cartilage and 1mm of osseous wear, 9mm is resected from the unworn side versus 6mm from the worn condyle (Figure 3). The posterior referenc-

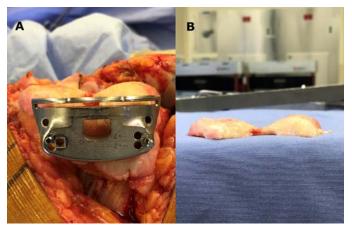


Figure 3A & 3B: Intraoperative photographs demonstrating placement of the distal femoral cutting guide (A) and subsequent distal femoral condylar resected bone (B) with a goal of resection width equaling the distal femoral component thickness and similar condylar thicknesses considering the thickness of cartilage and bone loss from the worn condyle.

ing guide is set at neutral rotation to assure an equal resection thickness of the posterior aspects of the medial and lateral condyles because typical posterior cartilage wear is minimal (Figure 4). Chamfer cuts are made to match the best-fitting femoral component.

The tibial cutting guide is set according to native varusvalgus alignment and, like the femur, is adjusted so resection of the 'worn' side is thinner than the 'unworn' side by the amount of estimated wear present. Posterior tibia slope is set to neutral (duplicating native posterior tibial slope) to preserve the PCL insertion (Figure 5).

To balance the knee, a stepwise algorithm is proposed (Figure 6). [45] Generally, the first step is to confirm symmetric and equal bony cuts measured via caliper once corrected for cartilage, bone wear, and saw-blade kerf. [45]

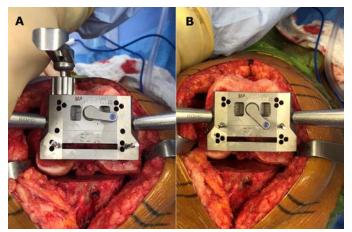


Figure 4A & 4B: Intraoperative photographs of the AP cutting block positioned for kinematic alignment (A); equal posterior condylar bone resections) versus traditional alignment (B) seeking external rotation of the femoral component relative to the posterior condylar axis.

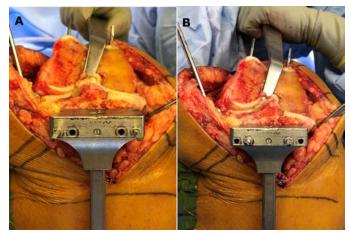
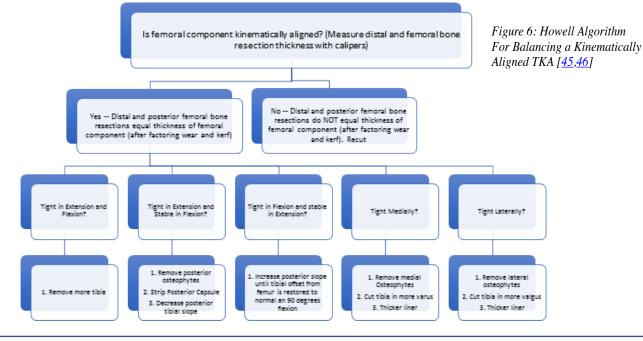


Figure 5A & B: Intraoperative photographs of the tibial cutting jig positioned for kinematic alignment (A); equal medial and lateral condylar resections considering wear) versus traditional mechanical alignment in which less bone is resected medially (B).



Sagittal balancing technique is similar to mechanical alignment with typical steps to address a TKA tight in flexion and or extension. Coronal balance, however, is quite different. Although both begin with the removal of osteophytes, if a TKA is tight medially in a kinematically aligned knee, the next step would be to cut the tibia in more varus rather than perform soft tissue releasing. [45] Similarly, if the knee is too tight laterally, rather than pie-crust the arcuate ligament and iliotibial band, kinematic alignment suggests re-cutting the tibia in more valgus. [45]

Kinematic Alignment Using Computer Navigation

Kinematically aligning TKAs using computer navigation has been described as well. [60] Distal femoral and proximal tibial resection amounts are set to equal TKA implant thickness. Cartilage and bone loss is assessed by comparing intact areas. If subchondral bone is exposed, it is considered to represent 3 mm of cartilage loss and coronal resection angles are adjusted accordingly. $[\underline{60,61}]$ If partial thickness cartilage loss is present, it is estimated intraoperatively, and again, resection angles are adjusted. In their technique, Hutt et al. suggest keeping resections within a "safe range" of either combined coronal orientation within $\pm 3^{\circ}$ of neutral or limiting the lateral distal femoral and medial proximal tibial angles to $\pm 5^{\circ}$. [60] All cuts are confirmed by caliper measurements intraoperatively. Posterior femoral condylar resections are completed using a posterior referencing technique set to neutral rotation to only resect the thickness of implant posterior condyles and match each patient's native femoral rotation. In their series of 100 TKAs completed using this technique, only 5% required any ligamentous release and at mean follow-up of 2.4 years, the mean HKA angle was 0.5° varus (from 4.6° varus pre-operatively), and WOMAC and KOOS scores improved. [60] They concluded that kinematically aligned TKA using computer navigation is reproducible and offers good short-term results, and pending long-term studies, may be a viable option to partially correct extreme anatomy that may perform unsatisfactorily with traditional mechanical alignment. [60]

Kinematic Alignment with Boundaries

Many surgeons today would agree that coronal alignment plays an important role in the survival and clinical outcomes of TKA. Continued debate occurs as to what the ideal alignment should be as well as the best method to obtain it. [62-64] Some experts suggest that ideal alignment is probably patient specific and a fixed amount of varus or valgus resection is not ideal. [62] Some surgeons have begun performing variations of classic kinematic alignment as described by Howell, [50] limiting the technique

to patients with substantial varus alignment, such as constitutional varus or congenital tibial vara. In these patients, surgeons limit varus tibial resection to a maximum 3° to avoid excessive medial tibial loads and restrict distal femoral valgus resection to a range of $2-8^{\circ}$ ($5^{\circ}\pm3^{\circ}$ of valgus) with the goal of removing a similar amount of bone from medial and lateral distal femoral condyles. While classic kinematic alignment proposes equal posterior condylar resection, some surgeons will vary the thickness of medial vs. lateral posterior resections to assure gap balance in flexion. These variations from classic kinematic alignment have been referred to by some as "kinematic alignment with boundaries." They are briefly mentioned here to reflect the thoughts of surgeons interested in challenging the traditional concept of aligning all TKAs to neutral mechanical alignment. The authors cannot recommend or dispute these alignment variations as valuable data with their use are not yet available.

Outcomes of Kinematically Aligned TKAs

Unfortunately, there are no clinical studies evaluating the long-term clinical outcomes of kinematically aligned TKAs. Howell et al. [25] has published a 31-month followup of 214 kinematically aligned knees divided into three groups based on the mechanical axis: TKAs in >3° varus, TKAs in >3° valgus, and TKAs in the neutral range of 0°±3°. Postoperatively, all had similar WOMAC and Oxford Knee Scores (OKS), and there were no catastrophic failures or need for TKA revision for loosening, instability or wear, even with tibial varus outliers to 9°. Similarly, Dossett et al. [65] performed a randomized control trial (RCT) comparing 88 TKAs, 44 which underwent kinematic alignment and 44 which underwent mechanical alignment. At two-years, those who underwent kinematic alignment had statistically significant improvement in WOMAC, KSS, and OKS scores as well as higher mean flexion and less pain than those with mechanical alignment. In a multicenter patient questionnaire study, patients who had a kinematically aligned TKA were three-times more likely to state their knee felt more 'normal' compared to those with a mechanically aligned TKA. [66]

More recently, studies have not been able to find any clinical difference in kinematically versus mechanically aligned TKAs. Howell et al. [67] re-evaluated 219 kinematically aligned knees at a mean follow-up of 6.3 years, again showing no difference in functional outcomes, WOMAC, or OKS. Kinematically aligned knees had a 97.5% survivorship with one deep infection, one loose tibial component, and two loose patellar components. Similarly, Young et al. [68] performed a RCT of 99 TKAs,

comparing mechanical to kinematically aligned TKAs. At 2 years, no difference was observed in OKS, WOM-AC or Forgotten Joint scores between the two groups, nor was there any difference in complication rates. HKA axis did not differ between groups, but kinematically aligned TKAs had 1.9° more tibial varus and 1.6° more femoral valgus than the mechanically aligned group. Interestingly, a recent retrospective review of 361 consecutive primary TKAs found that in knees with preoperative varus alignment, those that were corrected to mechanical neutral actually had improved median KSS when compared to those left in residual varus. [69]

Finally, a meta-analysis including 877 kinematically aligned TKAs with a mean follow-up duration of 37.9 months found a cumulative survivorship of 97.4%.70 There was a 1.2% revision rate for patellofemoral problems, but kinematic versus conventionally aligned TKAs demonstrated no differences in complication rates. Additionally, the kinematic group had a higher combined postoperative KSS (mean difference of 9.1 points). Authors concluded that overall survivorship or complication rates do not differ, but that functional outcomes favor kinematically aligned TKAs in the short term.

Kinematic Alignment: Questions Remaining

Will placement of the tibial component in varus affect long-term wear and fixation?

There are a number of previous studies that have shown inferior results of TKAs with the tibial component positioned in varus alignment. [9,37,54,71] Since we know that constitutional varus contributes to a higher incidence of knee osteoarthritis in the non-implanted knee, will the varus positioning of the tibial component similarly cause accelerated medial wear of the polyethylene bearing after TKA? While current clinical studies of kinematically aligned TKAs have not shown higher rates of tibial loosening, radiographically noticeable polyethylene wear or osteolytic lesions, these studies have limited follow-up duration. Longer term data, as well as fluoroscopic, in-vivo, weight bearing kinematic analyses, are needed to truly assess the longevity and functional outcomes overtime.

Will removal of one or both cruciate ligaments during TKA affect the precision of the transverse axes utilized for implant positioning in kinematically aligned TKA?

Kinematic alignment in TKA strives to restore native flexion-extension and longitudinal rotation axes of the tibiofemoral joint. [44] However, the work performed by Hollister, et al. [49] was performed on native cadaveric knees that still had intact anterior cruciate (ACL) and posterior cruciate ligaments (PCL). The ACL is typically sacrificed during TKA, and a substantial number of surgeons implant posterior cruciate substituting (PS) TKAs. Will sacrificing the PCL change the flexion-extension and longitudinal rotation axes Hollister described?

A study of nine cadaver knees pre- and post- ACL reconstruction found significant changes in the longitudinal axes of rotation after ACL reconstruction with a relatively large (2.1 mm) medial translation. [72] Smaller changes were also present in the anterior to posterior axis (0.3 mm shift posteriorly) as well as the internal-external rotation axis (0.5° of internal rotation). [72] This intuitively makes sense as posteromedial wear is common in osteoarthritic knees after ACL attenuation. [73] Kinematic analysis of ACL deficient native knees has shown increased mean contact stresses especially posteromedially. [74] What is unclear is whether the varus alignment from kinematically aligned TKAs, accentuated by the lack of the ACL, will increase the medial tibial load enough to predispose kinematically aligned TKAs to earlier failure. Similarly, a PCL deficient knee also experiences increased tibiofemoral contact stresses in the medial compartment. [75] While the main implementers of kinematic alignment implant cruciate retaining (CR) prostheses, a significant proportion of surgeons implant PS TKAs. [47] As such, it also stands to question whether performing kinematic alignment in PS implant designs will lead to increased contact stresses and earlier failure. These data stimulate the question of whether kinematic alignment is a concept best suited to bicruciate-retaining TKA.

Internal rotation of femoral and tibial components has been frequently observed with use of kinematic alignment in TKA. Will these rotational variances have long-term effects on patellar tracking, wear, or fixation in addition to limiting postoperative knee flexion?

In the kinematically aligned TKA, the optimal rotation of the femoral component in the axial plane is based on restoration of the posterior femoral joint line of the pre-arthritic knee. This is in-contrast to conventional techniques of determining rotation by placement perpendicular to the anterior-posterior axis, parallel to the transepicondylar axis (TEA), or parallel to the resected tibia with each collateral ligament equally tensioned. [76–78] In an MRI study of 114 kinematically aligned TKAs, the mean posterior femoral axis was found to be 4° internally rotated when compared to the TEA. [79] A separate analysis of 101 kinematically aligned TKAs found femoral rotation to range from -3° internal to 2° external, and tibial rotation to vary from -11° internal to 12° external. [80] This same analysis found a weak negative association between internal malrotation

and OKS and WOMAC scores. [80] Internal rotation of the femoral and/or tibial components in TKA has been associated with increased patellofemoral complications, anterior knee pain, premature polyethylene wear, arthrofibrosis, and early failure. [81–86] Although early clinical outcome studies have shown promising results for kinematically aligned TKAs, the most common reason for revision was patellofemoral complications (1.2%). [70] These included patellar instability, and anterior knee pain requiring lateral patellar facet excision. While these failures are likely multifactorial, it does bring up the concern that kinematically aligned TKAs may have a higher incidence of patellar problems because of the relatively higher incidence of internal femoral and tibial component rotation. Additionally, Boldt, et al. [87] observed a clear correlation between arthrofibrosis and placement of the femoral component internally rotated relative to the TEA.

Does kinematic alignment work well for all knees requiring TKA?

Does this concept work for all implant designs? Is it still safe to use this method in knees with severe angular deformity and ligamentous attenuation? It is known that the ACL serves as a secondary stabilizer of the lateral flexion gap. Flouroscopic studies of PCL-retaining TKAs have shown that femoral condylar lift-off predominately occurs laterally, believed secondary to loss of the stabilizing effect of the ACL. [88] Lateral femoral condylar lift-off increases medial condylar loads. If the tibial component is already positioned in varus, will this, in conjunction with loss of the ACL result in medial tibial overload and premature failure?

Summary/Conclusions

While extensive long-term data supporting reliable clinical outcomes and survivorship of mechanically aligned TKAs exists, there continues to be up to 20% of TKA patients who are not satisfied with their functional outcomes. While this reality is likely multifactorial in nature, and not solely due to knee alignment, it is also known that neutral mechanical alignment is not necessarily the anatomic normal. This has led some surgeons to advocate a paradigm shift in defining optimal component alignment. While short-term clinical and functional outcomes of kinematic alignment are promising, long-term clinical results and survivorship are still needed to make any lasting conclusions. Patients with large deformities in pre-operative alignment may benefit from a kinematic alignment with boundaries technique. Additionally, with increasing scrutiny of how health-care dollars are spent, it is unclear whether the adoption of expensive technology (i.e., computer navigation, patient-specific instrumentation, etc.) which may facilitate the precision required to attain ideal results with kinematic alignment, will be supported without long-term clinically superior results.

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SUBMISSION HISTORY

Submitted October 23, 2018 Reviewed December 10, 2018 Accepted December 10, 2018 Published December 31, 2018

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AUTHOR DISCLOSURES

The authors declare that there are no disclosures regarding the publication of this paper.

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ORIGINAL ARTICLE

http://dx.doi.org/10.15438/rr.8.2.212

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Dual Antibiotic Therapy with Vancomycin and Cefazolin for Surgical Prophylaxis in Total Knee Arthroplasty

Cohen-Rosenblum A¹, Crutcher M¹, Gui J¹, Novicoff W¹, Nelson S¹, Browne JA¹

Abstract

Background: Perioperative administration of intravenous antibiotics is a routine part of total knee arthroplasty. Antibiotic selection is a matter of controversy, and the potential risks and benefits associated with each antibiotic selection need to be considered. The objective of this study is to examine the effects of routine dual antibiotic prophylaxis with both cefazolin and vancomycin on infection and renal failure after primary total knee arthroplasty (TKA) compared with cefazolin alone.

Methods: We performed a retrospective review of primary TKA patients for two years before and two years after routine dual antibiotic prophylaxis was implemented at our institution. 1502 patients were included (567 cefazolin-only and 935 dual prophylaxis).

Results: 2 patients (0.4%) in the cefazolin-only group had a deep surgical site infection, compared with 13 patients (1.4%) in the dual prophylaxis group (p=0.06). 46 patients (8.1%) in the cefazolin-only group had postoperative renal failure, compared with 36 patients (3.9%) in the dual prophylaxis group (p=0.0006).

Discussion and Conclusion: Our results did not support the routine use of vancomycin in primary total joint arthroplasty to decrease periprosthetic joint infection. However, we also did not see any clear harm due to renal failure in the routine use of dual antibiotic prophylaxis.

Background

Since its controversial introduction over 50 years ago, perioperative administration of intravenous antibiotics has become a routine part of total joint arthroplasty and is proven to reduce the risk of infection [1-4]. The recommended number and combination of specific antibiotics continues to be a matter of debate. The 2013 Proceedings of the International Consensus on Periprosthetic Joint Infection found a strong consensus that a first or second-generation cephalosporin should be used for routine surgical prophylaxis, as well as strong consensus against the routine use of vancomycin given the lack of convincing evidence available [5]. However, with the increased prevalence of methicillin-resistant Staphylococcus aureus (MRSA) having emerged over the past 2 decades, vancomycin is increasingly used for prophylaxis in primary and revision total joint arthroplasty [6-9].

Vancomycin is a glycopeptide antibiotic that inhibits bacterial cell wall synthesis, and has been found to be effective in the prevention of MRSA surgical site infections [10]. It is commonly used for surgical prophylaxis for patients with a β -lactam allergy or MRSA colonization, either alone or in combination with another antibiotic with

Keywords: antibiotic prophylaxis; primary total knee arthroplasty; infection; renal failure *Level of Evidence*: AAOS Therapeutic Level III broader coverage such as clindamycin or an aminoglycoside [10-12]. However, vancomycin has relatively weak antibacterial activity against methicillin-sensitive Staphylococcus aureus (MSSA). Vancomycin is also associated with nephrotoxicity and ototoxicity, as well as the development of vancomycin-resistant enterococci [13,14]. A 2015 study found that total joint arthroplasty patients receiving dual antibiotic prophylaxis with vancomycin and cefazolin had a higher incidence of acute kidney injury than those treated with cefazolin only [15].

There are relatively few studies comparing antibiotic prophylaxis with cefazolin alone with routine dual prophylaxis with cefazolin and vancomycin in total joint arthroplasty. A 2012 retrospective review by Sewick et al. of almost 2000 primary total joint arthroplasty patients found no reduction in surgical site infections after the addition of vancomycin to cefazolin for surgical prophylaxis [16]. A 2018 retrospective review of neary 1900 patients by Burger et al. found that the addition of vancomycin to cefazolin for surgical prophylaxis [16]. A 2018 retrospective review of neary 1900 patients by Burger et al. found that the addition of vancomycin to cefazolin at least 45 minutes prior to skin incision reduced deep infection rates in primary hip and knee arthroplasty with a low risk of renal impairment [17].

Given the potential risks of vancomycin administration and the relative paucity of comparative data, the purpose of this study was to investigate infection rates and nephrotoxicity in total knee arthroplasty patients before and after the adoption of routine dual-antibiotic prophylaxis by our institution. Our hypothesis was that there would be a decrease in periprosthetic joint infection and an increase in acute kidney injury during the dual prophylaxis period.

Materials and Methods

Following Institutional Review Board approval, we retrospectively reviewed all patients who had undergone primary total knee replacements performed from January 2010 to June 2014. In July 2012 our institutional protocol switched from using cefazolin alone to dual-antibiotic prophylaxis with cefazolin and vancomycin for total joint arthroplasty, allowing the division into two groups: 1) cefazolin only and 2) vancomycin and cefazolin. Primary total knee arthroplasty patients from this time period receiving a different combination of antibiotics were excluded. Prior to incision, patients in the cefazolin-only group received a weight-based dose of cefazolin, with patients less than 70kg receiving 1g, 70-120kg receiving 2g, and over 120kg receiving 3g. Those in the dual prophylaxis group received a weight-based dose of cefazolin and 1 gram of vancomycin. Both groups received 2 additional doses of intravenous cefazolin in a 24-hour period starting 8 hours

after the procedure. No additional postoperative dose of vancomycin was given to patients in the dual prophylaxis group.

Electronic medical records were reviewed for age, sex, ethnicity, body mass index (BMI), American Society of Anesthesiologists (ASA) class, pre and post-operative creatinine, readmission within 90 days, return to the operating room for another procedure, and occurrence of superficial or deep surgical site infection. Surgical site infection was defined according to the World Health Organization definition as "infections anatomically associated with a surgical procedure performed in an operating room and not present prior to the operation" [18]. Superficial surgical site infection (SSI) was considered to have occurred in any patient with abnormal superficial incisional signs such as redness or swelling, prolonged drainage, or for whom the surgeon administered any postoperative oral antibiotics. This diagnosis of SSI was made by the individual attending surgeon based upon clinical experience. Deep infection was considered to have occurred in any patient returned to the operating room in the 90-day postoperative period for hematoma, drainage, wound dehiscence, or purulence. A culture-negative deep infection was defined as a periprosthetic infection that had met Musculoskeletal Infection Society criteria for periprosthetic joint infection without positive cultures [19]. Patients with an elevation in postoperative creatinine were subcategorized into different stages of renal failure according to the Acute Kidney Injury Network staging system from 1 to 3 [20].

Statistical analysis of the two groups was performed using Pearson's chi-square test. In addition, logistic regression was used to control for demographic differences between groups. Power analysis showed that we needed at least 435 patients in each group to be able to detect a 50% difference in infection rates between groups (combining superficial and deep infections) with 80% power.

Results

1502 primary total knee arthroplasty patients were included in the study, with 567 patients in the cefazolin-only group (65.4% female) and 935 patients (63.0% female) in the cefazolin and vancomycin group. Complete demographic data is shown in Table 1. 58 patients (10.2%) in the cefazolin-only group had a superficial surgical site infection, compared with 86 patients (9.2%) in the cefazolin and vancomycin group (p=0.53). 2 patients (0.4%) in the cefazolin-only group had a deep surgical site infection, compared with 13 patients (1.4%) in the cefazolin and vancomycin group (p=0.06). The 2 deep infections in the ce-

	Cefazolin Only (n=567)		Cefa Vancom	p-value	
	n	(%)	n	(%)	
Gender					
Male	196	(34.6)	346	(37.0)	p = 0.347
Female	371	(65.4)	589	(63.0)	
Ethnicity					
White	436	(76.9)	766	(81.9)	p = 0.021
Black	89	(15.7)	135	(14.4)	
Other	42	(7.4)	34	(3.6)	
ASA class					
1	3	(0.5)	7	(0.7)	p = 0.000
2	426	(75.1)	591	(63.2)	
3	137	(24.2)	332	(35.5)	
4	1	(0.2)	5	(0.5)	
BMI					
<18.0	3	(0.5)	1	(0.1)	p = 0.020
18.0- 24.99	44	(7.8)	121	(12.9)	
25.00 to 29.99	157	(27.9)	259	(27.7)	
30.00 and higher	359	(63.8)	554	(59.3)	
BMI					
Average BMI ± SD (standard deviation)	33.8 ± 7.5		32.3 ± 6.7		p = 0.000
Age					
Average age (years) ± SD	62.5 ± 10.5		64.4 ± 10.2		p = 0.572

fazolin-only group were culture negative. Of the 13 deep infections in the cefazolin and vancomycin group, 4 were culture negative, while the remaining specimens grew positive cultures for methicillin-sensitive Staphylococcus aureus (MSSA) (4 patients), MRSA (2 patients), Streptococcus agalactiae (2 patients), Enterobacter cloacae (1 patient), and Escheria coli (1 patient, coinfected with MRSA).

46 patients (8.1%) in the cefazolin-only group had postoperative renal failure, compared with 36 patients (3.9%)in the cefazolin and vancomycin group (p=0.0006). There were no statistically significant differences in 90-day readmission or return to operating room for further procedures (Table 2). Logistic regression analysis revealed an association between BMI and deep infection (p=0.0146), and that female sex, ASA class 1 and 2, and being in the vancomy-

Table 2. Adverse Outcomes of TKA Patients, 2010-2014
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	Cefazolin Only (n=567)		Cefa Vancon	p-value		
	n	(%)	n	(%)		
Superficial infection	58	(10.2)	86	(9.2)	0.5275	
Deep infection	2	(0.4)	13	(1.4)	0.0606	
Readmission within 90 days	22	(3.9)	25	(2.7)	0.2215	
Return to surgery	13	(2.3)	16	(1.7)	0.4435	
Renal failure (stages merged)	46	(8.1)	36	(3.9)	0.0006	
Stage 1	43	(7.6)	33	(3.5)	-	
Stage 2	2	(0.4)	2	(0.2)	-	
Stage 3	1	(0.2)	1	(0.1)	-	

cin and cefazolin group were protective against postoperative renal failure. Complete results of logistic regression analysis are found in Tables 3 and 4.

Discussion

We hypothesized that the group receiving dual antibiotic prophylaxis with vancomycin and cefazolin would have a decreased incidence of periprosthetic joint infection and an increase in acute kidney injury compared with the cefazolin group. In fact, somewhat counterintuitively, our data showed a trend towards deep infection in patients receiving dual antibiotic prophylaxis that did not reach statistical significance, as well as a statistically significant decrease in postoperative renal failure.

A review of the existing data involving vancomycin and surgical site infection in total joint arthroplasty shows mixed results. As mentioned previously, the 2012 study by Sewick et al. directly comparing cefazolin monotherapy and dual prophylaxis with vancomycin and cefazolin found no significant change in surgical site infections (p=0.636) [16]. In contrast, the 2018 study by Burger et al. demonstrated a reduced rate of PJI with dual prophylaxis but only when the infusion of vancomycin was administered at least 45 minutes prior to skin incision [17]. Harold et al. and Lamplot et al. both noted a decrease in infection rates when a dual antibiotic approach was incorporated into a multifaceted aseptic protocol to reduce the rates of PJI which also included modified instrument care, preop-

	p-value	OR Point Estimate	OR Confidence Interval
Vancomycin and cefazolin compared with cefazolin only	0.0634	4.221	(0.923, 19.306)
Female compared with male	0.6235	1.341	(0.415, 4.331)
Ethnicity compared with white			
Black	0.9359	1.055	(0.287, 3.877)
Other	0.9776	<0.001	(<0.001,>999.999)
ASA class 1&2 compared with 3&4	0.2037	0.493	(0.165, 1.468)
Age	0.8696	1.329	(0.044, 39.793)
BMI	0.0146	34.317	(2.011, 585.638)

Table 3: Results of Logistic Regression of TKA Patients with Deep Infection, 2010-2014

erative nasal mupirocin and altered surgical skin preparation [21, 22].

Smith et al. retrospectively reviewed two groups of primary total joint arthroplasty patients who only received cefazolin and those who only received vancomycin for surgical prophylaxis, and found decreased rates of both periprosthetic joint infection overall and MRSA infection in the vancomycin only group [8]. Ponce et al. retrospectively reviewed over 18,000 primary total joint arthroplasties and found an increased rate of surgical site infection in patients without penicillin allergy receiving vancomycin only for prophylaxis compared with cefazolin only (2.6% vs. 1.3%, p<0.01). There was no statistically significant difference in the surgical site infection rates for patients receiving vancomycin only compared with vancomycin and cefazolin (2.6% vs. 1.6%, p=0.17) [23]. Tan et al. found a similar rate of deep infection in primary total joint arthroplasty patients treated with vancomycin monotherapy for ß-lactam allergy compared with non-allergic patients receiving cefazolin, but a comparatively increased risk of Gram-negative infection [24].

Kheir et al. found a higher rate of periprosthetic joint infection in primary total joint arthroplasty patients receiving vancomycin only compared with cefazolin only, noting that only 28% of the patients in their vancomycin-only group received appropriate weight-based dosing of 15 mg/kg, and that the two periprosthetic infections that occurred in the underdosed group were both caused by MRSA [25]. In our study, all patients receiving dual antibiotic prophylaxis received 1g of vancomycin irrespective weight, which likely caused a portion likely caused a portion of patients to be underdosed. This could theoretically explain why the dual prophylaxis group did not have a lower rate

Table 4: Results of Logistic Regression of TKA Patients with RenalFailure, 2010-2014

	p-value	OR Point Estimate	OR Confidence Interval
Vancomycin and cefazolin compared with cefazolin only	0.0001	0.400	(0.250, 0.641)
Female compared with male	0.0001	0.381	(0.238, 0.610)
Ethnicity compared with white			
Black	0.2393	1.433	(0.787, 2.609)
Other	0.9504	1.035	(0.355, 3.019)
ASA class 1&2 compared with 3&4	0.0027	0.477	(0.294, 0.773)
Age	0.1248	3.345	(0.716, 15.636)
BMI	0.0025	6.625	(1.943, 22.581)

of infection compared with the cefazolin-only group. Vancomycin underdosing may also have contributed to the low rate of renal failure in the dual prophylaxis group, counter to our hypothesis that there would be an increase in renal failure in patients receiving a potential nephrotoxic medication. In addition, there may have been a selection bias in the dual prophylaxis group against patients at higher risk of renal failure for receiving vancomycin in the first place.

Limitations of this study include its retrospective design and the inclusion of only total knee arthroplasty patients. It is possible that our study is underpowered to show a difference in a relatively rare outcome such as postoperative infection. Also, we did not include close follow-up of postoperative renal failure patients with details such as rate of return to baseline renal function.

Conclusions

Our results, with the numbers available, did not support the routine use of vancomycin in primary total joint arthroplasty to decrease periprosthetic joint infection. However, we also did not see any clear harm due to renal failure in the routine use of dual antibiotic prophylaxis. Further research should be done to investigate whether routine dual antibiotic prophylaxis with vancomycin should continue to be used routinely for surgical prophylaxis in total joint arthroplasty, or if an algorithm-based antibiotic stewardship program should be adopted to restrict its use to selected subgroups of patients.

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SUBMISSION HISTORY

Submitted August 22, 2018 Reviewed November 9, 2018 Accepted November 20, 2018 Published December 31, 2018

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AUTHOR DISCLOSURES

The authors declare that there are no disclosures regarding the publication of this paper.

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ORIGINAL ARTICLE

http://dx.doi.org/10.15438/rr.8.2.215

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Is Utilizing a Modular Stemmed Tibial Component in Obese Patients Undergoing Primary Total Knee Replacement Cost-Effective?

Martin JR¹, Otero JE², Beaver WB¹, Springer BD¹, Griffin WL¹

Abstract

Background: There has been recent enthusiasm for the use of modular stemmed tibial components in obese (BMI \geq 35kg/m2) patients undergoing primary total knee arthroplasty (TKA). This has been mainly driven by studies demonstrating statistically significant increases in the rates of aseptic tibial loosening (ATL) in this patient population. However, to our knowledge, no study has specifically evaluated the cost effectiveness of this current recommendation.

Methods: The following study was performed utilizing previously obtained data on the incidence of ATL in obese patients undergoing primary TKA. This data was then utilized to create a cost calculator that can evaluate the price point at which the use of a stemmed tibial component in all obese patients would be less than or equal to the costs of revision surgery if a stemmed implant was not utilized.

Results: Utilizing historical data with a revision rate of 4% for aseptic loosening of the tibia on obese patients, a cost calculator was developed. The cost calculator requires the input of expected or known incidence of ATL utilizing a stem extension and the expected or known costs of revision for ATL.

Conclusion: The following cost calculator quickly determines a price point at which the use of a tibial stem offsets the costs of revision surgery. While this study may not provide an exact cost-effectiveness of modular stem fixation due to model limitations, it will hopefully initiate the

discussion for providing more cost-effective individualized care for this patient population.

Background

Obesity is currently an epidemic, affecting approximately one third of adults in the United States [1]. The average body mass index (BMI) in patients undergoing primary total knee arthroplasty (TKA) continues to increase. Numerous studies have demonstrated significantly worse outcomes in obese patients undergoing primary TKA [2– 5]. More recently, several studies have begun to identify obesity as a risk factor for aseptic loosening of the tibial component after primary TKA [6–8]. Abdel noted an approximately doubled risk of aseptic tibial loosening (ATL) in this patient population at 15 year follow-up [7]. They noted that increased implant fixation with the use of a tibial stem may decrease the rate of ATL in patients with a BMI ≥ 35 kg/m2.

The introduction of a modular tibial stem significantly increases fixation of the tibial component. One study noted that the addition of a short tibial stem decreases proximal tibial cement-bone interface compressive stresses by

Keywords: obesity; total knee arthroplasty; cost calculator; stemmed tibial component; cost-effectiveness *Level of Evidence*: AAOS Therapeutic Level IV 136% and cement-bone shear stress by 92% [9]. However, the use of a tibial stem has not been demonstrated to significantly improve outcomes in obese patients undergoing TKA [10]. Additionally, the incidence of ATL in obese patients that receive a modular tibial stem is unknown. Despite limited clinical evidence, there has been increased use of tibial stems in obese patients undergoing primary TKA to decrease the incidence of ATL.

Utilization of a tibial stem has several limitations including increased surgical time, increased difficulty of revision of the implant, and cost. The addition of a tibial stem is not available with all tibial baseplates. Some implants may require conversion from the standard primary tibial tray to a revision tibial tray. Conversion to a revision tibial tray may substantially change implant costs based on the cost differential of the primary and revision implant pricing. Currently, there is almost no data available if utilizing a modular stemmed tibial component for obese patients undergoing primary TKA is cost-effective. Therefore, the following study was designed to develop a cost-calculator that would evaluate the price point at which the use of a tibial stem would offset the cost of revision surgery in obese patients (BMI \geq 35 kg/m2) undergoing primary TKA. The cost calculator was then applied to a high volume arthroplasty center to determine the projected costs at this institution. While the following cost calculator only represents a very basic model of cost-effectiveness, the primary goal for this study is to begin the discussion in providing cost-effective personalized medicine for obese patients undergoing primary TKA.

Materials and Methods

The following study was performed utilizing historical data on the incidence of ATL in patients undergoing primary TKA [7]. This dataset included retrospectively collected information from 1998 to 2012 utilizing a variety of contemporary total knee arthroplasty designs. Four major implant manufacturers were included, specifically DePuy (Warsaw, IN), Stryker (Mahwah, NJ), Zimmer (Warsaw, IN), and Smith and Nephew (Memphis, TN). Stratifying aseptic loosening by BMI, obese patients had a statistically significant increased rate of aseptic loosening at 15 years (4.26% vs. 2.16%) and a hazard ratio 2.3 (p=0.003). It should be noted that some primary implants have different implant geometry or stem lengths which may not have significantly higher rates of tibial loosening in obese patients, and this particular implant was not included in the study design11.

The four percent incidence of ATL in obese patients at

15 years, with contemporary total knee arthroplasty designs, was then utilized as the main determinant for building the cost calculator. The following formula was utilized to determine if the costs of the addition of a tibial stem were cost effective:

$$t = Cost^{non-stemmed} - Cost^{stemmed}$$

t represents the cost of the tibial stem. Cost^{non-stemmed} represents the cost for revision surgery assuming the historical incidence of 4% for all obese patients undergoing primary TKA without a stemmed tibial component. Cost^{stemmed} represents the cost for revision surgery based on the incidence of revision when utilizing a stemmed tibial component in all patients.

For simplification of the scoring calculator, variables that could be easily identified at most institutions, including the incidence of ATL when a stemmed tibial component and the cost of revision for aseptic loosening were utilized. More sophisticated modeling would likely consider variables that are more challenging to quantify such as quality adjusted life years, pain scoring, vocational absences, costs of complications, etc. However, the aim of this study was only to determine at what price point the cost of the tibial stem offsets the cost of revision for ATL.

A scoring calculator was then developed that would calculate the cost of a tibial stem by allowing the user to insert two variables; 1. the incidence of ATL when a modular tibial stem was utilized, and 2. the cost of revision surgery for ATL. An example was then utilized to demonstrate how the calculator might be applied. Additionally, the calculator was applied to a high volume joint center to determine if the costs of the modular tibial stem offset the costs of revision for aseptic loosening at each institution. It should be noted that at our institution, a short (<40 mm) supplemental cemented tibial stem was utilized for additional fixation. No long constructs or cementless designs were included.

Results

A scoring calculator was developed utilizing price points of revision surgery beginning at \$5,000 and increasing by \$5,000 intervals up to \$50,000. The rates of aseptic loosening were listed from 0% to 4.5%. An aseptic loosening rate of 4% identified the point at which the use of a tibial stem could not add any additional cost to the total implant price or it would no longer be cost effective. Additionally, 4.5% was included only for completeness. It was not believed that the use of a tibial stem would result in a higher rate of aseptic loosening. For the creation of the table, the revision rate in patients that did not receive a stem was assumed to be 4%. The following tibial stem cost calculator can be seen in Table 1.

Case Example

The cost calculator can be utilized to determine the cost-effectiveness of the stem when the incidence of aseptic loosening of the tibial implant is known as well as the cost of revision surgery for aseptic loosening of the tibia. Therefore, if a hospital has

	Cost of Revision for aseptic loosening (dollars)										
Aseptic loosening Incidence (%)	5000	10000	15000	20000	25000	30000	35000	40000	45000	50000	
0	200	400	600	800	1000	1200	1400	1600	1800	2000	
1	150	300	450	600	750	900	1050	1200	1350	1500	
1.5	125	250	375	500	625	750	875	1000	1125	1250	
2	100	200	300	400	500	600	700	800	900	1000	
2.5	75	150	225	300	375	450	525	600	675	750	
3	50	100	150	200	250	300	350	400	450	500	
3.5	25	50	75	100	125	150	175	200	225	250	
4	0	0	0	0	0	0	0	0	0	0	
4.5	-25	-50	-75	-100	-125	-150	-175	-200	-225	-250	

a known incidence of 1.5% for ATL when a tibial stem is utilized and the costs for a revision for aseptic loosening are \$30,000 per revision; the tibial stem would need to be less than \$750. If the stems cost any more than \$750 the cost of revision for ATL would be less than the total costs for the use of stems.

$$t = Cost^{non-stemmed} - Cost^{stemmed}$$

$$t = 4\%(\$30,000) - 1.5\%(\$30,000)$$

$$t = \$1,200 - \$450$$

$$t = \$750$$

High Volume Center

The following institution has less than a 1% incidence of ATL when utilizing a tibial stem. Therefore, 1% ATL was utilized for the following calculation. The cost of revision surgery for ATL is approximately \$45,000/revision (based on average hospital collections). Therefore, the cost calculator demonstrates that the cost of the tibial stem should be \$1,350. However, at this institution, the costs for the tibial stem are \$2,000/stem. Therefore, each additional case where a tibial stem is utilized represents an additional \$650/case in costs.

$$t = 4\%(\$45,000) - 1\%(\$45,000)$$

$$t = \$1,800 - \$450$$

$$t = \$1,350$$

Discussion

Obesity remains a substantial risk factor for complications and worse outcomes following primary TKA [4,12-15]. Many studies have associated obesity with increased implant loosening rates, but there remains a paucity of data regarding the economic considerations in this patient population [6,8]. A recent study by Abdel et. al. has recommended considering the use of a stemmed tibial component in obese patients undergoing primary TKA [7]. While this may potentially reduce the incidence of ATL in this patient population, we believe that this practice may significantly increase the cost of joint replacements if appropriate implant pricing has not been considered. Therefore, the following study provides a framework for implant pricing to begin the discussion of improving cost-effectiveness in obese patients undergoing primary TKA.

Recent studies have demonstrated that the average BMI in patients undergoing primary TKA has continued to rise [16]. The average BMI is approaching 35 kg/m2. If a modular stemmed tibial component was utilized in all patients with a BMI \geq 35 kg/m2, approximately 50% of patients would require this implant. If cost-effectiveness is not considered, there is a potential for these implants to add excessive additional costs. This would be contradictory to the current emphasis that has been placed on cost-containment in total joint replacement. Therefore, this study critically analyzes the costs of utilizing a stemmed tibial component in obese patients undergoing primary TKA with a goal of providing more cost-effective individualized care.

The cost-effectiveness of the tibial stem in this model is dependent on multiple factors. First, the incidence of ATL is extremely important. The lower the incidence of ATL in the obese population implanted without stems, the greater the number needed to treat to prevent this complication and therefore increased costs. Next, the incidence of aseptic loosening in obese patients in which a tibial stem was utilized can dramatically alter the cost-effectiveness. In an ideal scenario, the use of a tibial stem would prevent all cases of tibial loosening. However, realistically, there will be a small percentage of patients that still develop ATL in this patient population. Preferably, this percentage would not be greater than the incidence of loosening in patients where a tibial stem was not utilized. One final consideration would be the cost of revision surgery for aseptic loosening. The more expensive the revision surgery, the more cost-effective the stem can potentially become.

Current pricing for tibial implants is commonly negotiated between hospital systems and the implant manufacturers. A thorough understanding of each implant's revision options is therefore necessary. Some implant models, can readily incorporate a stem on their primary tibial tray. However, other tibial implants are not modular and require conversion to a revision tibial tray. There may be substantial cost differences between adding a stem and changing to a revision tibial tray. Therefore, the modularity or ability to accept a tibial stem must be factored into the cost-effectiveness of supplemental tibial stem fixation. It should be noted that decreasing 90-day complication and readmission rates is one of the main focuses of many hospital systems. However, preventing aseptic loosening years later may be overlooked in many discussions on implant pricing but should be considered.

As was identified in the clinical example, the cost of a tibial stem was not cost-effective based on this simplified cost calculator. The high volume center had an increased cost of \$650/stem. It is possible that other variables, including quality of life, could have been modeled into the cost-analysis and provided more favorable results for the use of a modular tibial stem. However, there is currently limited clinical evidence that supports the benefits for the use of a tibial stem. Therefore, further reductions in the price of a tibial stem may be necessary to increase the costeffectiveness of these implants. Considering that the average BMI is now approaching 35 kg/m2, approximately 300,000 of the estimated 600,000 annual TKAs will likely require a tibial stem. The use of tibial stem may increase the costs by approximately \$200 million utilizing this data. However, the main objective of this study is not necessarily to recommend for or against the use of modular tibial stems. The goal is to initiate the discussion of cost-effectiveness of global use of these stems in all obese patients, with a focus on individualized care.

Currently, there is a small margin for cost-effectiveness of the tibial stem based on this model. When implant costs rise above a certain threshold, the tibial stem can add substantial costs to the surgery. Unfortunately, as the average BMI in patients undergoing primary TKA increases, this will further increase the costs. Therefore, more selective utilization of tibial stems in obese patients may further improve cost-effectiveness of the implant. Fehring et. al. recently identified smaller implant size and obesity to be associated with aseptic tibial varus collapse [8]. He noted that higher tibial stress appears to be a risk factor for this failure mechanism and recommended consideration of a stem for additional fixation at a critical tibial stress threshold of 300,000 Pa. Subsequently, Martin et. al. noted that preoperative varus deformity may also be associated with aseptic tibial varus collapse [6]. Screening patients for risk factors associated with ATL (smaller implant size and preoperative varus deformity) will improve the cost-effectiveness of the tibial stem.

While this study represents the first attempt to demonstrate the cost-effectiveness of utilizing a tibial stem in obese patients undergoing primary TKA, there are several limitations. First, this study utilizes a basic model that attempts to determine the cost-effectiveness of utilizing a stemmed tibial component. The modeling process has inherent limitations and is not as accurate as a randomized prospective trial. However, the time and cost-savings of the model are notable and does spark the debate of the cost-effectiveness of modular stem fixation in obese patients undergoing primary TKA. Unfortunately, this model does not address all of the variables but may lead to improved modeling in the future. Second, implant pricing is not universal. Higher volume centers will likely be able to obtain implants at a reduced cost. This can impact the cost-effectiveness models by increasing the price of the implants as well as the cost of revision. Third, the rate of ATL is based on historic controls. Higher rates of aseptic loosening will increase the cost-effectiveness of the tibial stem. Additionally, the ability of the modular tibial stem to prevent ATL is not known. As the rate of revision for aseptic loosening of the stemmed tibial component approaches the rate of aseptic loosening without a stem, the additional costs of the stem will eventually become cost-ineffective at any price. Finally, this study attempts to simplify the complexities of calculating cost-effectiveness. It is very challenging to determine an exact cost associated with revision surgery. The costs represented in this study do not factor in patient's debility before or after surgery, secondary effects of caregivers, the need for nursing/rehab facility use, or post-operative complications that are not captured in the 90-day global period, or the costs of work absences [17,18]. As these other variables are included, the cost-effectiveness of the modular tibial stem will likely increase as well. The authors acknowledge this as a substantial limitation, and understand that further investigation is necessary on this topic to build more accurate models. However, with the recent push for cost-containment in arthroplasty surgeries, there will be greater scrutiny on the costs of implants. Therefore, this study offers an introductory view into the cost-effectiveness of tibial stems.

Conclusion

Utilization of a tibial stem in obese patients has been advocated as a method for decreasing the rates of aseptic loosening in primary TKA. Currently, there are few clinical studies that have demonstrated a significant reduction in aseptic loosening with a modular stemmed tibial component. However, theoretical benefits have led many surgeons to adopt this methodology. The following cost calculator was proposed as a method for rudimentarily calculating the cost-effectiveness of utilizing a tibial stem. This study is not meant to specifically determine implant pricing, but rather to re-evaluate clinical practices in order to provide more cost-effective individualized medicine. We therefore would recommend more selective utilization of tibial stems in obese patients undergoing primary TKA whenever possible to improve the cost-effectiveness of these implants.

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SUBMISSION HISTORY

Submitted October 24, 2018 Reviewed November 15, 2018 Revised December 11, 2018 Accepted December 17, 2018 Published December 31, 2018

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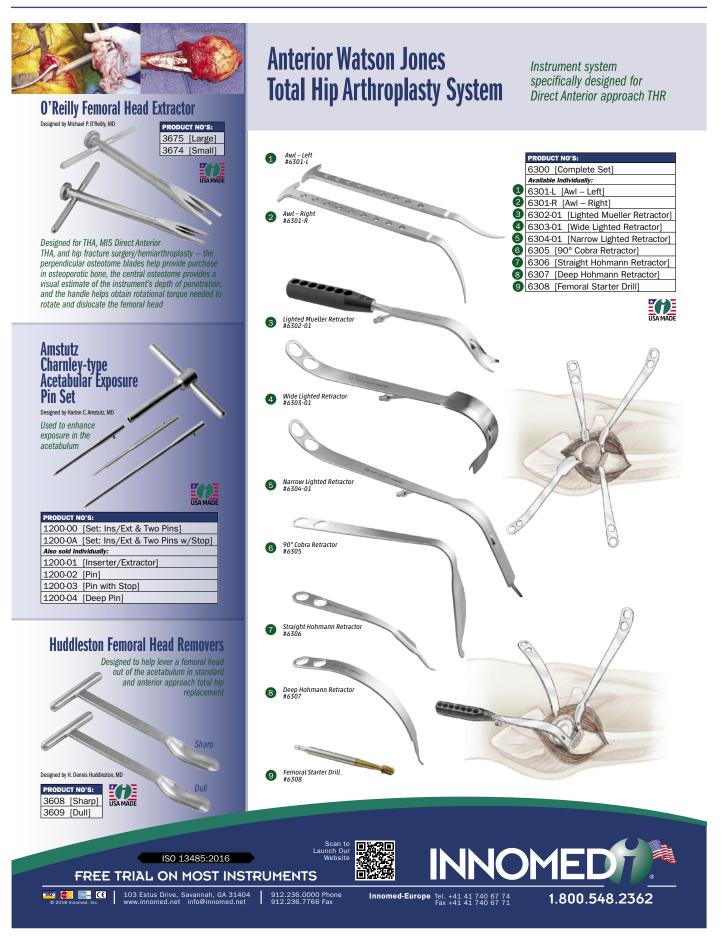
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AUTHOR DISCLOSURES

The authors declare that there are no disclosures regarding the publication of this paper.

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ORIGINAL ARTICLE

http://dx.doi.org/10.15438/rr.8.2.216

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Perioperative Complications Following One-Stage Bilateral and Unilateral Total Hip Arthroplasty via Direct Anterior Approach

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Abstract

Background: A single stage bilateral total hip arthroplasty (BTHA) utilizing the direct anterior approach (DDA) has been reported to have a similar incidence of perioperative complications as unilateral total hip arthroplasty (THA). However, previous studies have included various surgeons with differences in contraindications, protocol, technique and/or experience.

Questions/Purposes: The purpose of this retrospective review was to compare perioperative outcomes in single-stage bilateral and unilateral total hip arthroplasties via the direct anterior approach performed by a single, fellowship trained, high volume arthroplasty surgeon.

Methods: A retrospective review was completed on consecutive single-stage bilateral total hip arthroplasties performed between 2009 and 2017 and compared to consecutive unilateral total hip arthroplasties performed between 2014 and 2016. Perioperative data and complications occurring within 90 days were collected for all included patients. Student t-tests were performed to detect differences between bilateral and unilateral surgical variables.

Results: A total of 349 patients (531 hips) were included, consisting of 182 BTHA patients (364 hips) and 167 unilateral THA patients. Patients undergoing unilateral THA had significantly lower operating time, shorter length of stay, lower estimated blood loss, lower rate of transfusions and higher rate of home discharge compared to BTHA (p<0.001). Complications were present in four

unilateral THA patients, three requiring revision, and nine BTHA patients, three requiring revision.

Conclusions: There was no difference in complications, as well as no perioperative mortalities or systemic complications, within 90 days following surgery between unilateral and bilateral patients. Based on these results, single-stage DAA BTHA is a safe procedure to perform, and did not appear to result in higher rates of complications when compared to patients receiving a DAA unilateral THA.

Background

Total hip arthroplasty (THA) is commonly performed for the treatment of osteoarthritis, with previous research citing good clinical outcomes and survivorship, as well as consistently high patient satisfaction outcomes. These positive outcomes have increased with the introduction of the minimally invasive direct anterior approach (DAA), providing shorter recovery time, improved pain control and increased functional scores following surgery. However, previous research has reported up to 25% of patients undergoing THA for the treatment of osteoarthritis will re-

Keywords: total hip arthroplasty; complications; direct anterior approach *Level of Evidence*: AAOS Therapeutic Level III quire a contralateral THA [1,2], with 10% of those patients having met the criteria for bilateral THA (BTHA) at initial presentation [3,4].

A two-stage THA, in which two unilateral surgical procedures are performed, has historically been preferred due to the decreased risk of single event large blood loss, venous thromboembolic events and delays in recovery time [5]. However, current research supports the use of onestage BTHA, in which the surgical procedure is performed under one anesthetic event, reporting shorter operating times and potentially more symmetrical post-operative limb lengths [6-10]. Additionally, single-stage BTHA patients have previously been reported to have faster recovery time, with improved hip flexion and performance in activities of daily living [11].

Previous research evaluating the single-stage BTHA utilizing a DAA has reported low incidence of perioperative complications and rates of transfusions [12,13]. When comparing unilateral DAA THA and one-stage DAA BTHA, no differences were reported in perioperative complications, length of stay and discharge disposition [14]. However, sample sizes were small and data was pooled from various surgeons with differences in contraindications, protocol, technique and/or experience. The purpose of this retrospective review was to compare perioperative outcomes in single-stage DAA BTHA and unilateral DAA THA performed by a single, fellowship trained, high volume arthroplasty surgeon at a single multispecialty community institution.

Materials and Methods

This institutional review board approved study was a retrospective chart review of DAA THAs performed by a single, fellowship trained arthroplasty surgeon. Consecutive single-stage DAA BTHA performed between 2009 and 2017 were evaluated and compared to consecutive unilateral THAs performed between 2014 and 2016. For both groups, inclusion criteria for this review was all elective THAs performed for radiographic and clinical evidence of symptomatic hip osteoarthritis, rheumatoid arthritis or avascular necrosis in one or both hips. Patients with severe congenital deformity or dysplasia were not excluded. Patients undergoing THA for femoral neck fractures were excluded. A total of 349 patients (531 hips) were included, consisting of 182 BTHA patients (364 hips) and 167 unilateral THA patients. Demographic information for both groups is presented in Table 1.

All patients received a cementless total hip replacement performed through a direct anterior approach as described by Matta et al. [15,16] using a specialized fracture table (Hana®, Mizuho OSI, Union City, CA) and intraoperative fluoroscopy. For single-stage BTHA, the left hip was usually performed first. Patients received either general anesthesia, spinal anesthesia or a paravertebral block at the discretion of the attending anesthesiologist. All patients received an intraarticular injection mixture of Ropivicaine, Toradol and epinephrine in the amount appropriate for their weight as determined by the anesthesiologist. All

	Unilateral								Bilateral							
	Males						Fema	les	Males			Females				
	n = 79					n = 8	n = 88			n = 81			n = 101			
	Mean		SD	Range	Mean		SD	Range	Mean	Mean SD Range		Mean		SD	Range	
Age	65.6	±	9.6	(39,86)	67.5	±	11.0	(89,23)	61.7	±	10.5	(25,85)	64.6	±	11.3	(25,92)
Weight (kg)	79.4	±	17.9	(37.6,142.4)	71.9	±	16.9	(39.9,130.1)	84.5	±	13.9	(49.0,123.8)	64.7	±	11.9	(41.3,119.3)
Height (cm)	169.2	±	10.2	(148.6,195.6)	163.3	±	9.7	(146.1,190.0)	174.6	±	8.4	(147.3,190.5)	159.1	±	8.4	(137.2,175.3)
BMI	28.2	±	5.2	(18.5,47.7)	26.1	±	5.1	(16.9,39.0)	27.7	±	4.0	(18.0,38.1)	25.6	±	4.7	(17.6,45.1)
ASA																
1	1				0		0			2						
2	38				47		42			70						
3	40					40				39		28				
4	0					1				0				1		

Table 1. Demographic information for all patients and by gender

n = number of patients in group; SD = standard deviation; kg = kilograms; cm = centimetersBMI = body mass index; ASA = American Society of Anesthesiologist classification patients received a multimodal preoperative pain control protocol which consisted of 200 mg of oral Celebrex, 500 mg of oral Tylenol and 10 mg of OxyContin prior to surgery. All patients received appropriate prophylactic antibiotics just prior to surgery and for 24 hours following surgery. All patients received 325 mg of Aspirin twice daily following surgery for deep vein thrombosis chemoprophylaxis unless they could not tolerate Aspirin or if risk factors such as previous deep vein thrombosis or pulmonary embolism necessitated chemoprophylaxis with Lovenox or other anticoagulants. Following surgery, as needed oral narcotic medications and 500 mg - 1000 mg of oral acetaminophen were given every six hours. Intravenous narcotic medications were used only if pain exceeded the oral pain medications given.

All patients had physical therapy initiated on the day of surgery and twice daily while hospitalized. Immediate full, unrestricted weight bearing was allowed. Patients did not have hip precautions and were specifically educated before surgery that they could perform any hip motions that they felt safe and comfortable to do at any time following surgery. Decision on time of discharge and disposition were made as a team (which included the physical therapist) and was dependent on the physical performance and ability to safely and independently perform activities of daily living and stair negotiation. Discharge to home, acute inpatient rehabilitation or skilled nursing level transfer was decided based on the functional abilities of the patient following surgery.

Patients were seen two weeks following surgery to assess wound healing, then at six weeks, three months, six months, one year and two years following surgery with plans for follow up every five years thereafter. Immediately following surgery, patients had supine anteroposterior radiographs taken in the recovery bay. Weight bearing anteroposterior pelvis radiographs as well as frog leg lateral views were taken at the six week visit. Repeat films were done at the six month evaluation and at one year and two years following surgery. Patients with unusual pain or clinically abnormal symptoms had appropriate evaluations as indicated by the specific complaints.

Surgical data reviewed included operative times (skin incision to skin closure), estimated intraoperative blood loss, postoperative or intraoperative rate of blood transfusions, length of hospital stay and discharge disposition. Perioperative complications were defined as any complication arising within 90 days following surgery. All serious postoperative complications that required repeat surgery were recorded prospectively. Thigh pain and groin pain that persisted past six weeks following surgery were also recorded prospectively and monitored. Any serious medical complications such as myocardial infarctions, cerebrovascular events, deep vein thrombosis or pulmonary emboli were likewise reported. Readmissions for any reason were also recorded within 90 days following surgery.

Demographic information for both groups were organized by gender. Descriptive statistics, including means and standard deviations, for all surgical based outcomes were determined for all patients by group. Student t-tests were performed to detect differences between BTHA and unilateral THA surgical variables, with a significance level of p<0.05.

Results

Patients undergoing unilateral THA had significantly lower operating time, shorter length of stay, lower estimated blood loss, lower rate of transfusions and higher rate of home discharge compared to BTHA (p<0.001) (Table 2). Complications were present in four unilateral THA patients, three requiring revision, and nine BTHA patients, three requiring revision (Table 3).

Discussion

Although previous studies have demonstrated the safety and efficacy of BTHA performed through the DAA [4,17], the single surgeon design of current study provides uniformity in protocol, technique and surgeon experience, thus providing a more accurate evaluation of perioperative outcomes. In the current study, complications were present in 2.1% of unilateral THA and 2.5% of BTHA, with no perioperative mortalities or systemic complications, to include cardiac or cerebrovascular events, deep vein thrombosis or pulmonary embolism.

Table 2. Comparison of surgical variables by group

	Unilat	eral	THA	Bilate	p-value		
	n	= 16	7	n =			
	Mean		SD	Mean		SD	
ORT (min)	75.2	±	12.3	170.1	±	38.0	<0.001
LOS (days)	2.1	±	0.9	2.6	±	0.1	<0.001
EBL (cc)	239.2	±	76.6	402.8	±	99.4	<0.001
Home Discharge	86.0%			67	<0.001		
Transfusion	6	6.6%		12	<0.001		

THA = total hip arthroplasty; SD = standard deviation n = number of patients; ORT = operating room time min = minutes; LOS = length of hospital stayEBL = estimated blood loss; cc = cubic centimeters

	Patient	Gender	Age	BMI	ASA	ORT (mins)	LOS (days)	Complication	Revision Required
Unilataral						(mms)	(uays)		Kequiteu
Unilateral									
	1	Female	57	27.5	3	98	2	Intraoperative Femur Fracture	No
	2	Female	73	20.8	3	63	3	Periprosthetic Femur Fracture	Yes
	3	Female	83	27.3	2	73	7	Periprosthetic Femur Fracture	Yes
	4	Female	54	17.7	2	105	2	Dislocation	Yes
Bilateral									
	1	Male	66	21.2	3	60	3	Deep Infection	No
	2	Female	67	20.3	2	193	4	Intraoperative Femur Fracture	No
	3	Female	77	24.6	3	137	4	Periprosthetic Femur Fracture	Yes
	4	Male	64	23.4	2	128	2	Superficial Infection	No
	5	Male	70	31.6	2	91	4	Periprosthetic Femur Fracture	Yes
	6	Male	25	25.1	2	147	1	Superficial Infection	No
	7	Female	41	25.1	1	251	3	Dislocation	No
	8	Female	77	25.4	2	181	3	Periprosthetic Femur Fracture	Yes
	9	Female	71	24.8	3	164	2	Superficial Infection	No

Table 3. Surgical Complications

BMI = body mass index; ASA = American society of Anesthesiologist physical status classification; *ORT* = operating room time in minutes; *LOS* = length of stay in days

In addition to being a large, single surgeon cohort, the inclusion criteria for this study was widely inclusive and single-stage DAA BTHA was offered to all patients with bilateral involvement regardless of age or comorbidities. This is different than previous studies, in which patients were excluded from single stage bilateral consideration based on age, preoperative anemia, pulmonary disease, renal disease and history of cardiac events [4,12-14,18]. In the current study, patients experiencing a complication did not represent the extremes in age, BMI or ASA category, challenging the concern inferred by previous studies that patients in these categories should be excluded from one-stage BTHA.

All surgical outcome measures were significantly different between unilateral THA and BTHA, as expected. Operating time for BTHA patients was approximately 85 minutes per hip compared to 75 minutes for unilateral THA, with the extra time most likely due to the redrapping of the patient. Length of stay was statistically significantly longer for BTHA than unilateral THA but clinically insignificant, and more unilateral THAs were discharged directly home, highlighting the increased short term functional limitations expected in the BTHA patients. Remarkably, nearly 70% of single stage DAA BTHA patients were able to discharge directly home after an average hospital stay of only 2.6 days.

There were a number of limitations in the current study.

First, this was a retrospective evaluation of two surgial procedures. However, all procedures were performed by the same surgeon with the same standard of care protocol for each patient, limiting the influence of surgical technique and protocol on the outcomes. Additoinally, patients were not excluded from the study based on commorbidities, therefore, eliminating the patient selection as a potential bias in the results. Secondly, no long term follow up or patient outcome measures were collected in this study so no conclusion can be made about function or patient satisfaction following surgery. However, the purpose of this study was to descibe only perioperative complications occuring during the two procedures, determining if the single-stage BTHA was a safe option of patients with bilateral symptoms.

Conclusion

In this retrospective comparison, perioperative complications were present four unilateral THA patients, three requiring revision, and nine BTHA patients, three requiring revision, within 90 days following surgery. As expected, unilateral THA patients had significantly lower operating time, shorter length of stay, lower estimated blood loss, lower rate of transfusions and higher rate of home discharge compared to BTHA. Uniquely different than previous research, exclusion criteria did not differ between the unilateral THA and BTHA groups. All patients with bilateral hip arthritis were offered single stage BTHA regardless of age or comorbidities. This is the first study to report a complication comparison in a large cohort of patients undergoing BTHA via the DAA by a single surgeon, without excluding patients of advanced age or presence of co-morbidities. Based on these results, single-stage DAA BTHA is a safe procedure to perform, and did not appear to result in higher rates of complications when compared to patients receiving a DAA unilateral THA.

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SUBMISSION HISTORY

Submitted October 26, 2018 Reviewed November 11, 2018 Revised December 10, 2018 Accepted December 13, 2018 Published December 31, 2018

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AUTHOR DISCLOSURES

The authors declare that there are no disclosures regarding the publication of this paper.

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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.

	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 Review2 of Level I RCTs (and study results were homogenous3) 	 High quality prospective study4 (all patients were enrolled at the same point in their disease with ≥ 80% follow-up of enrolled patients) Systematic review2 of Level I studies 	• Testing of previously developed diagnostic criteria on consecutive patients (with universally applied reference "gold" standard) • Systematic review2 of Level I studies	 Sensible costs and alternatives; values obtained from many studies; with multiway sensitivity analyses Systematic review2 of Level I studies 						
Level II	 Lesser quality RCT (e.g. < 80% follow-up, no blinding, or improper randomization) Prospective4 comparative study5 • Systematic review2 of Level II studies or Level 1 studies with inconsistent results 	• Retrospective6 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 review2 of Level II studies	• Development of diagnostic criteria on consecutive patients (with universally applied reference "gold" standard) • Systematic review2 of Level II studies	 Sensible costs and alternatives; values obtained from limited studies; with multiway sensitivity analyses Systematic review2 of Level II studies 						
Level III	• Case control study7 • Retrospective6 comparative study5 • Systematic review2 of Level III studies	• Case control study7	• Study of non-consecutive patients; without consistently applied reference "gold" standard • Systematic review2 of Level III studies	• Analyses based on limited alternatives and costs; and poor estimates • Systematic review2 of Level III studies						
Level IV	Case Series8	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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