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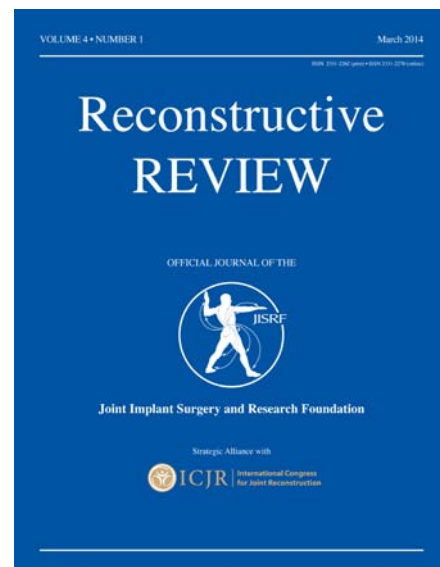
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In Memory of

Tony N. Aram MD

October 7, 1963 - June 17, 2014

Dr. Tony Aram will be remembered not only as a great surgeon, but a great friend and colleague to many. He lived an exemplary life of devotion, honor, humbleness and dedication to his family, friends and his profession.

Dr. Aram unexpectedly passed away Tuesday morning, June 17, 2014 of natural causes at his home. Tony Aram touched the lives of countless patients and friends over several years in practice. He devoted his life to the betterment of everyone else and for that so many are grateful.

Tony Aram, M.D. built a culture of radically caring for patients while utilizing the most advanced medical technology. In his pursuit, he became known community-wide for pushing the limits in Orthopaedics to achieve radical results.

We will forever remember his smile and lively personality that would bring light to any situation. He will be sorely missed.

The legacy of Dr. Tony Aram will live on, as the practice he built, Advanced Orthopaedics and Sports Medicine Institute (AOSMI), will continue to serve and treat patients in the Washington, D.C./metro area. After several years of searching for a Doctor to join the practice, and prior to his passing, Dr. Aram hand selected Dr. Asheesh Gupta to join the practice. Dr. Gupta will carry on the mission and vision that AOSMI was so diligently founded on many years ago.

Tony was a significant part of the Joint Implant Surgery & Research Foundation (JISRF) and participated in both our Tissue Sparing Implant (TSI™) Study Group and was part of our Editorial Board for JISRF's journal Reconstructive Review. He will be fondly remembered and we will miss the passion he had for both orthopaedics and his personal and professional friendships. You were a good man Tony and you will always be remembered and missed.

Timothy McTighe, Dr. H.S. (hc)
Executive Director, JISRF

Reconstructive Review

A Journal Published by the Joint Implant Surgery & Research Foundation



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CASE REPORT

Osseointegration Implant Post Coupling With External Prosthetic Limb

Continuation of Previous Case Reports “Stage III”

Ronald W. Hillock, MD[†]; Danny L Tatum, BCP[‡]; Edward Dolegowski, PT[§]

Abstract

An ongoing update of the progress case report for the first patient treated with the Longitude™ osseointegration prosthesis implanted in an amputated residual femur is presented. The patient was given an intensive physical therapy program of strengthening and conditioning in anticipation of coupling to the external prosthesis. A custom prosthesis was fabricated based on the Plie' 2.0 microprocessor knee system. The patient was then successfully trained on use and care of the prosthesis for ambulation without any complications.

Keywords: Amputation, Osseointegration

Acknowledgement: Design concept by Concept Design & Development, LLC (CDD, LLC); Development and Manufacturing by Signature Orthopaedics, LTD; Centennial Hills Hospital Medical Center, Las Vegas, NV; and Institutional Review Board (IRB) by Joint Implant Surgery & Research Foundation.

Background

As previously reported, the index patient for the Longitude™, Osseointegration implant (OI) is a 65-year-old female. Longitude™ is a prototype custom OI prosthesis system manufactured by Signature Orthopedics USA, Las Vegas, Nevada, USA. The second stage procedure, coupling of the femoral stem implant through the skin with the abutment device was completed on 12/18/2013. The treatment team now presents the patient's progress through coupling with an external limb prosthesis.

An intensive therapy program was initiated in anticipation of progressing to wear and use of the OI implant coupled to an external limb prosthesis. The process of fabrication of a prosthetic limb was started immediately following the completion of the stage II procedure.

there were few pain related issues following the second surgery and subsequent rehabilitation program. All pain medications were discontinued by the 5th week post-surgery. Phantom limb pain had resolved prior to the second stage surgery. Phantom limb sensation has become less symptomatic though it is still present.

The stoma at the terminal aspect of the residual limb, at the implant skin junction, was dressed on a daily basis. The patient was encouraged to take over all dressing and wound care related activities. As anticipated, the stoma initially bled for the first 10 days following surgery. A dressing consisting of a 4 cm x 4cm segment of Silverlon with a central post cut out was applied and changed twice daily. This was backed by absorptive sterile gauze dressing (see figures 1 and 2). Eventually the patient began adapting a commercially manufactured disposable sterile pad mar-

Treatment following stage II

Pain control was easily covered with oral hydrocodone;

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Figure 1: The stoma with silicon basket and dressing in place.



Figure 2: Anteroposterior view of the stoma.

keted for lactating females. The breast pads are circular, conical and fit the silicon basket designed for this function. A simple modification of cutting a hole for the central post is required. As the stoma matured, the drainage diminished to a minimal volume of serous fluid.

On day 32 following the second surgery, increased pain with purulent drainage was noted at the stoma site. The skin did not have any erythema about the stoma or lymphatic streaking present. There was no adenopathy. What had been a serous drainage increased in volume and a foul odor developed. The abutment device was initially covered with a silicon sleeve at the skin implant junction. The sleeve was removed in the outpatient setting without any difficulty under a local anesthetic. Stoma care was altered to include twice-daily cleansing with hydrogen peroxide. The patient was given a 10-day course of oral Cephalexin 500mg every 6 hours. The drainage returned to clear serous material without odor and the pain resolved completely within 4 days of starting oral antibiotics. The patient elected to continue twice-daily hydrogen peroxide cleaning from that day forward.

During the recovery period following the surgery, the patient reported emotional distress and anxiety. Though she had been counseled on the planned outcome extensively, the reality of the metal abutment protruding through the skin of the limb was more psychologically distressing than had been anticipated. Through many counseling sessions with the operative surgeon, the patient adjusted to the implant and she returned to baseline emotional status. A referral to a mental health professional was offered but declined. The patient declined all offered antidepressant medications.

During the period of time following the second surgery, an individual within her community who had undergone an OI implant in another country contacted the patient. The advice and encouragement provided by another OI patient was invaluable. Her emotional well being as well as progress with coupling and weight bearing was improved by the peer-to-peer level communication and support.

Therapy prior to coupling

While awaiting fabrication of the final external prosthesis, the patient initiated a prescribed therapeutic exercise program. The goals of therapy were to maximize the residual limb strength and flexibility at the hip, to maximize the intact limb's strength, flexibility and proprioception and to improve overall balance while also increasing the patient's aerobic capacity.

Strength and conditioning of the residual limb was addressed through a series of prone lying on a padded bolster (see figure 3). Isotonic hip abduction and extension exercises with resistance applied through cuff weights or TheraBand™ in both the laying and standing positions was also used (see figures 4, 5 and 6). Balance was addressed through single limb standing on both stable and



Figure 3: Image of the patient practicing prone extension stretching while laying face down.



Figure 4: Isotonic hip abduction applied via TheraBand™ in standing position.



Figure 5: Isotonic hip extension applied via TheraBand™ in standing position.

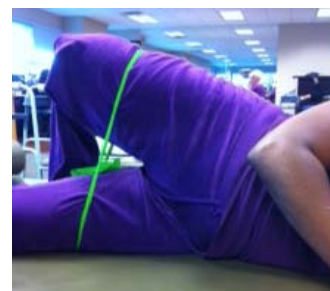


Figure 6: Isotonic hip abduction applied via TheraBand™ in lying position.



Figure 7: Image of the patient strengthening balance via single limb standing on intact limb.



Figure 8: Image of the patient strengthening the intact limb via leg press exercises.

unstable surfaces without upper extremity support to maximize limb proprioception (see figure 7). The strength of the intact limb was improved with resistance exercises on the leg press (see figure 8). Aerobic fitness was improved through a program of upper body ergometry and recumbent cycling.

Prosthesis design and fabrication

A custom compression garment with a terminal hole for the OI implant was worn most of the time while awaiting fabrication of the external prosthesis.

To aid in the transition to the final prosthesis, a “stubby trainer” prosthetic device was fabricated (see figure 9). This device consisted of a rocker bottom terminal sole with a non-skid rubber surface at the level of the contralateral knee. The stubby trainer was used to begin weight bearing through the OI construct on a hydraulic platform table set at the appropriate height. The patient could bear 50% weight without discomfort immediately on fitting (see figure 10). She rapidly progressed to full weight bearing through the stubby trainer within 2 weeks. The only complaints during this phase were related to hip muscle cramping and fatigue.

During the stubby training phase it was noted that the direct skeletal coupling resulted in a voluntary 90° arc of motion in the internal and external rotation plane. This factor was taken into consideration during the fabrication of the final limb prosthesis.

The final external limb prosthesis was fabricated with the following components. The abutment device was fitted with a terminal adaptor that linked with an offset coupler. The offset coupler was designed to allow for 360° of rotation with up to 15mm of offset (see figures 11, 12 and 13).

The prosthetic knee system selected was the Plie' 2.0, manufactured by Freedom Innovations (See figure 14). The Plie' 2.0 knee is designed for K3 or K4 level performance, with enhanced durability features. One key feature of the Plie' 2.0 is the fact that it is water resistant. Additionally, the Plie' 2.0 knee microprocessor uses an externally exchangeable battery system, allowing the user to have back-up charged batteries while active in the community. Other microprocessor-powered knee systems have an integrated battery system that cannot be changed by the user, requiring the time consuming process of plugging into an external power source for recharging.

The prosthetic ankle was built with a 4R39 torsion adaptor, manufactured by Otto Bock, Duerstadt, Germany. This component was selected to allow for up to 12° of rotation torsion with the foot securely planted to the

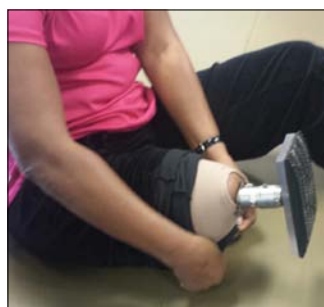


Figure 9: The stubby trainer prosthetic device is attached to the patient in order to begin weight bearing via the osseointegration construct.



Figure 10: The patient bearing weight on a hydraulic platform table set at the appropriate height.



Figure 11: Anteroposterior view of coupler.



Figure 12: Medial view of coupler.



Figure 13: Posterior view of coupler.



Figure 14: Image of the final prosthesis device.

ground. The prosthetic foot selected was the Multiflex Endolite™, manufactured by Blatchford Inc, Basingstoke, UK. The patient had requested the option of an adjustable heel angle to allow for footwear other than flat-soled shoes. The Multiflex Endolite foot is adjustable for up to a 2.5 cm heel lift.

Post coupling therapy program

The patient was fitted with her external limb prosthesis and took her first steps using parallel bars for sup-

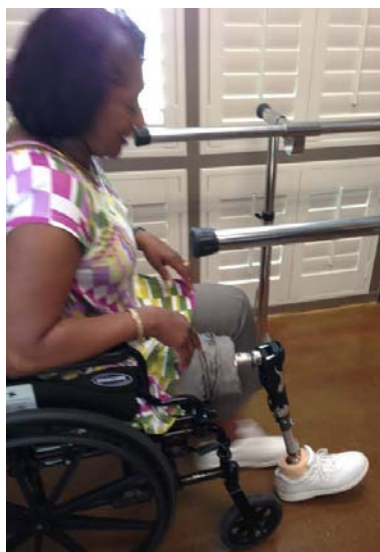


Figure 15: The patient training with the coupled final prosthetic device.

port with no problems, roughly 4 months following the second surgery. She initially reported cramping and pain in the hip musculature. Peer to peer advice and encouragement was given, the patient was counseled that this was a normal sensation and had been experienced by others on initial weight bearing. She was able to remain ambulated with upper limb support on parallel bars for a distance of 3 m., turn and then returned 3 m. (see figure 15). She was able to couple and uncouple the prosthesis from the abutment after 10 minutes of instruction without any difficulty.

The goals of physical therapy with the external limb prosthesis were to improve endurance and strength while continuing to work on balance. A prescribed exercise program with the prosthesis was designed to work through gait on level surfaces, uneven surfaces, stairs, and curbs with a long-term goal of ambulation without any assistive device.

The prosthetic offset coupler was initially set at 0/0, no rotational correction, and no offset correction. As the patient ambulated, she reported single limb stance on the prosthetic limb associated with a sensation of medial shifting center of gravity causing her to feel off-balance. An adjustment of 5mm of lateral offset with 0 rotation was then set and the patient reported feeling balanced with gait.

The patient began wearing the prosthesis under supervision of the prosthetist for the first 3 hours of use over 2 therapy sessions. She then advanced to progressive wear as tolerated, increasing duration of wear on a daily basis with a goal of full time wear while ambulatory throughout her activities of daily living. As of this publication she has been routinely using the prosthesis in the home, bracing against furniture or using a walker for support. The gait pattern has progressed to a fluid heel toe motion with the microprocessor deactivated in a passive mode. She has begun training with the microprocessor activated, though not yet fully using the advantage of the computerized knee to its full potential. The patient reports wearing the prosthetic limb OI construct for 4 to 6 hours per day in therapy and during home exercise.

Initially the patient experienced back pain as well as

pain in the hip musculature. With progressive training and exercise the pain has improved. Peer to peer advice has been invaluable and the patient is now training through these pains. The only medications required for pain during this phase have been over the counter NSAIDs. Of note she has not reported thigh pain or pain at the stoma with or without the external prosthesis attached.

As reported in other OI implant systems, the patient reported feeling skeletal vibrations with heel strike of prosthetic foot to floor impact, a sensation that has been termed “osseoperception” in prior reported literature.

Discussion

All aspect of this patient’s care has been designed with the goal of coupling the OI implant to an external prosthesis. Through a collaborative effort between the operative surgeon, the prosthetist, physical therapist and the patient, a coordinated program was developed and implemented. Peer to peer mentoring and advice has been beneficial to the patient’s progress. The patient experienced minor setbacks along the course of treatment. The patient has progressed to using the OI coupled prosthetic limb in activities of daily living. With continued effort, the treatment team is confident the patient will achieve independent functions. Prior to the first surgery the patient expressed a desire to return to occupational function as a health care professional. With continued focus therapy, we are cautiously optimistic that she will attain that status.

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ORIGINAL ARTICLE

Management of Medial Collateral Ligament Injury During Primary Total Knee Arthroplasty: A Systematic Review

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Abstract

Medial collateral ligament injury during primary total knee arthroplasty is a recognised complication potentially resulting in valgus instability, suboptimal patient outcomes and a higher rate of revision or reoperation. Options for management include primary repair with or without augmentation, reconstruction or immediate conversion to prosthesis with greater constraint, in conjunction with various postoperative rehabilitation protocols. Inconsistent recommendations throughout the orthopaedic literature have made the approach to managing this complication problematic. The objective of this study was to review the available literature to date comparing intraoperative and postoperative management options for primary total knee arthroplasty complicated by recognised injury to the medial collateral ligament. This systematic literature review was prospectively registered with PROSPERO (#CRD42014008866) and performed in accordance with PRISMA guidelines including a PRISMA flow diagram. Five articles satisfied the inclusion criteria. Each was a retrospective, observational cohort or case series with small numbers reported, inconsistent methodology and incompletely reported outcomes. Four of the five studies managing medial collateral ligament injury during total knee arthroplasty (47/84 patients) with direct repair with or without autograft augmentation reported good outcomes with no revision or reoperation required for symptomatic instability over a follow-up period of 16 months to almost 8 years. The fifth study with a follow-up to 10 years and a high rate of conversion to unlinked semi constrained total knee arthroplasty implant (30/37 patients) reported a greater incidence of revision due to instability, in patients in whom the medial collateral ligament injury was directly repaired without added constraint. Overall balance of evidence is in favour of satisfactory outcomes without symptomatic instability following direct repair with or without augmentation of an medial collateral ligament injury recognised intraoperatively during total knee arthroplasty. An implant with greater constraint may have reduced longevity in younger, more active patients through aseptic loosening. In elderly or less mobile patients, and in situations where the medial collateral ligament repair is deemed poor quality or incomplete, an implant with greater constraint would seem prudent. In patients where direct repair with or without augmentation was used, a period of 4-6 weeks of unrestricted rehabilitation in a hinged knee brace should be followed.

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Introduction

Intraoperative disruption to the medial collateral ligament (MCL) during total knee arthroplasty (TKA) is an uncommon but recognised complication reported in 0.8-8% of TKAs [1-5]. Failure to achieve long term coronal plane stability in a primary TKA may significantly influence outcomes by shortening an implant's longevity through accelerated wear, negatively affecting patient satisfaction and functional scores and ultimately leading to reoperation or early revision.

Medial collateral ligament injury during TKA is generally considered to be an iatrogenic complication [3]. Morbid obesity has been considered a risk factor contributing to intraoperative avulsion of the tibial insertion of the MCL during difficult exposure [4].

No consensus has been reached on the ideal management of recognised MCL injury during primary TKA, with options considered intraoperatively such as primary repair, immediate reconstruction or changing the implant to increase constraint. Primary repair can be attempted by direct suture apposition of a midsubstance MCL laceration, anchor or screw with post fixation of an avulsed MCL insertion, or fixation of the avulsed insertion through a transosseous bridge [2]. Augmentation of a repaired MCL has also been described with semitendinosus tendon [6] or quadriceps tendon free graft in cases with a residual gap after repair, poor quality tissue or if there was suspicion of the repair stretching postoperatively [7].

Coronal plane instability has been shown in cadaveric studies to be significantly affected by release of the deep and superficial components of the MCL [8]. Conversion of a posterior cruciate sparing implant to a posterior stabilised component in this study after release of the MCL and posterior cruciate ligament (PCL), did not provide any significant restraint to valgus laxity. Unlinked varus-valgus constrained prostheses have been advocated for the treatment of intraoperative disruption of the MCL and resultant valgus laxity [9-11]. There is reluctance, particularly in young active patients to using implants with greater constraint due to increased stresses transferred to the implant-cement and implant-bone interfaces, osteolysis, accelerated polyethylene wear and risk of subsequent aseptic loosening [12].

Furthermore, there is no agreement as to the ideal postoperative management of patients following MCL repair with or without augmentation, reconstruction or conversion to implants with additional constraint. Casting, provision of hinged bracing, degrees of freedom in bracing, weightbearing status and duration of postoperative treatment of each method are varied.

The aim of this systematic literature review was to compare predetermined patient outcomes following repair or reconstruction of recognised MCL injury during primary TKA to cases where additional constraint was used as part of the management of valgus laxity over at least 12 months from time of index operation.

Methods

The review protocol for this systematic review was registered with the International Prospective Register of Systematic Reviews (PROSPERO: <http://www.crd.york.ac.uk/PROSPERO/>) #CRD42014008866 prior to screening articles against eligibility criteria.

This study was designed to identify in the literature, patients of any age undergoing primary total TKA who sustain a recognised intraoperative injury to the MCL. Primary repair with or without augmentation or reconstruction of the injured MCL by any means was compared to intraoperative increase in constraint, to a prosthesis with unlinked high polyethylene post on tibial insert or linked hinged prosthesis, with concurrent repair or reconstruction of the MCL. Adequate minimum follow-up was considered to be 12 months given reported postoperative outcome scores would reflect clinically significant instability, pain or loss of function.

Intraoperative injury to the MCL reflects an unplanned complication of a primary TKA. Randomised trials were not anticipated so both retrospective and prospective original peer reviewed observational studies were considered with a minimum of 5 patients. Isolated case studies, technique guides, expert recommendations and duplicate publications were excluded.

Patients with preoperative valgus knee malalignment of greater than 10 degrees undergoing primary TKA were excluded due to the chronicity of the resultant MCL laxity. Revision TKA was included as an exclusion criterion due to difficulty in approach, high likelihood of needing complex releases and additional constraint or augmentation due to bone loss at the time of implant removal.

Exclusion criteria also included lack of basic patient demographics, subjective and objective measures taken at follow-up, duration of follow-up and any unexplained loss to follow-up.

LITERATURE SEARCH STRATEGY

A search strategy was developed to locate original human non-cadaveric journal articles across a wide range of databases without limits to language. MEDLINE online database was searched with limits from 1946 to 1st Febru-

ary 2014, EMBASE database was searched from 1974 to 1st February 2014. Proquest, CINAHL, PEDro, Cochrane Central Register of Controlled Trials (CENTRAL) and Google scholar were searched without early time limit, up until 1st February, 2014. An independent trained research librarian with experience in searching electronic databases performed the original comprehensive literature search with nominated search strategy and key words (Table 2).

Conference Proceedings, Unpublished trials, Industry reports, a manual search of table of contents from relevant chapters of major current orthopaedic textbooks, a manual search of table of contents from major orthopaedic journals (JAAOS, JBJS-Am and The Bone and Joint Journal, CORR, J Arthroplasty, Acta Orthopædica, Orth Clinics Nth America) and reference lists from screened selected articles were all cross checked for additional relevant references.

Authors of studies included in the qualitative synthesis were contacted for any longer term follow-up data not reported in these studies, in particular revision rate and reoperation for any reason.

DATA EXTRACTION

Three blinded reviewers (AK, HLO, BZ) examined all retrieved titles and abstracts and selected studies for full text

review. Full text articles were retrieved and two reviewers (PDT, AS) independently selected studies based on predetermined inclusion/exclusion criteria (Table 3) and recorded data such as study aims and design, sample size, patient demographics, methodology, type of prosthesis used, intervention, outcome parameters, complications, revision/reoperation rate and follow-up on a standardised proforma developed. Discrepancies were resolved by consensus, with a third reviewer (BZ) as necessary.

Individual selected studies were rigorously assessed for risk of bias. Pre-trial bias was

assessed by analysing study design, methods of patient recruitment, outcome measures, blinding methods and protocols for data collection. Information bias was assessed in each study by noting standardised patient interactions, prospective or retrospective collection and analysis of data, transfer bias and rigorous accounting of patient follow-up, clarity on description of the mechanism of recognised MCL injury and method of treatment, use of validated outcome measures and performance bias. Post trial bias analysis was analysed by noting any effects of citation bias, confounding variables and an attempt was made to determine factors affecting generalisation of the results, in particular

Table 2: Search Strategy used for Medline and Embase Databases

Search strategy for Medline and Embase (Ovid MEDLINE 1946 to Feb Week 1 2014, Embase 1974 to 2014 Week 4)
1. exp medial collateral ligament/
2. medial collateral ligament.tw.
3. medial ligament/
4. MCL/
5. valgus instability/
6. instability.tw.
7. or/1-6
8. avulsion.tw
9. injury.tw
10. iatrogenic.tw
11. laceration.tw
12. or/8-11
13. exp total knee arthroplasty/
14. exp total knee replacement/
15. knee arthroplasty.tw.
16. knee replacement.tw.
17. or/13-16
18. repair.tw.
19. reconstruct\$.tw.
20. augment.tw.
21. constrain\$.tw.
22. ((varus valgus) or (varus-valgus)).tw
23. or/18-22
24. 7 and 17
25. 12 or 23
26. animal/ not human/
27. 24 and 25
28. 26 and 27
29. remove duplicates from 28

Table 1 - Predetermined Study Eligibility Criteria

<i>Inclusion Criteria</i>
1. Original peer reviewed published journal articles
2. Either retrospective or prospective
3. Observational studies or better
4. Minimum 5 patients in case series/cohort
5. Primary TKA
6. Clearly documented implant type and surgical approach during TKA used
7. Intraoperative recognition of acute MCL injury - midsubstance/origin/insertion
8. Thorough description of MCL injury repair and/or reconstruction technique
9. Method of augmentation with detailed surgical technique
10. Implant used where additional constraint was selected
11. Postoperative management and duration including weight bearing status, support with cast/brace
12. At least 12 months follow-up
13. Documentation and follow-up of predetermined outcome measures
<i>Exclusion Criteria</i>
1. Non human studies
2. Isolated case studies
3. Technique/opinion papers and expert recommendations
4. Duplicate publications (latest one only was considered eligible)
5. Patients with preoperative >10 degrees valgus or recognised preoperative MCL incompetence
6. Incomplete reporting of late reconstruction, reoperation rate or revision TKA
7. Lack of study population demographics
8. Inadequate or insufficient follow-up
9. Incomplete reporting of predetermined outcome measures
10. Unexplained loss to follow-up

Table 3. Predetermined outcomes

<i>Objective Measures:</i>
1. Standardised knee score (eg. Oxford/Knee Society Score)
2. Knee range of motion (ROM)
3. Varus-valgus stability
4. Anteroposterior stability
5. Radiographic signs of loosening/instability
6. Reoperation rate
7. Revision operation
<i>Subjective Measures:</i>
1. Pain score
2. Patient satisfaction score
3. Symptomatic instability

the degree of internal and external validity.

Detailed follow-up of cases of MCL injury during primary TKA was expected due to the nature of the complication and importance of tracking outcomes through standardised examinations and validated outcome scores. Given the expected low case numbers, variability in study methodology anticipated and variety of methods used to manage intraoperative MCL injury, a descriptive synthesis of selected articles was anticipated.

STATISTICAL ANALYSIS

A meta analysis of the studies selected for detailed analysis was not feasible due to heterogeneity, lack of randomisation, small numbers and varying methodology. A descriptive analysis was favoured given lack of directly comparable results.

Results

A comprehensive literature database search identified 105 potentially relevant studies. A manual search of relevant literature uncovered a further 4 studies, of which 3 were duplicate references. Screening of titles and abstracts of the 106 shortlisted studies excluded 82 papers and the remainder full text articles were sourced for detailed anal-

ysis.

A further 19 full text articles were excluded with reasons summarised in PRISMA flow diagram (Diagram 1). The remaining 5 published articles were subjected to detailed analysis with a comprehensive proforma.

The studies selected were on primary cemented TKA and had clearly documented an acute MCL injury recognised intraoperatively and the management chosen. The pooled results cover 84 patients across 5 studies.

One study was excluded from incidence calculation as it did not record the total number of TKA [13]. The remaining 4 studies totalled 69 MCL injuries affected over 5355 TKA operations in those studies which documented total number of TKA [1-3, 7]. This corresponds to an overall incidence of 1.5%.

The 5 studies selected for review were retrospective case series with well documented procedures and method of management of MCL injury (Tables 4, 5). Implant brand and model used were generally reported (Table 6). However all 5 papers had significant pre-trial bias in selection and channelling, bias during the trials and potential confounding variables not described or discussed.

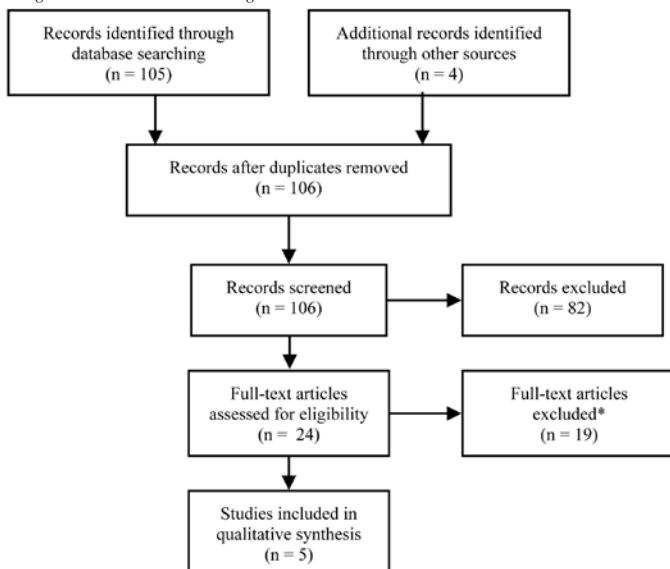
Mean age across the studies was similar, ranging from 58 to 67 years. BMI was reported in 3 of the studies, with averages consistently above 30, in the range for obese. There were predominantly females in 4 of the 5 studies, gender was more equally distributed in the fifth study [1].

Each patient affected was accounted for and there was minimal loss to follow-up. Postoperative management was well documented in all studies however a complete set of objective outcome parameters was only reported in one series [3]. All 5 studies documented revision rate and Knee Society Scores.

Only one paper treated MCL laxity with increased constraint [1]. Within this study, 30/37 (81%) TKAs required immediate intraoperative revision to a semi constrained, non linked prosthesis (TCIII, DePuy). The intraoperative findings such as degree and region of MCL injury, and reasons for selecting increased constraint were not reported. Among the 84 TKAs that were treated for MCL injury, 28/84 (33.3%) were midsubstance and directly apposed and repaired with non absorbable sutures, 15/84 (17.9%) were treated non operatively with an increased thickness of polyethylene insert of 2-4mm [13]. The MCL injury was augmented with superficial, partial thickness quadriceps tendon autograft harvested in 5/84 (6.0%). Overall, 13/84 (15.5%) were avulsions from the tibial or femoral insertions and were repaired with staple, anchor or post fixation and 30/84 (35.7%) were treated with conversion to unlinked, semi-constrained (high post) prosthesis.

Four studies [2, 3, 7, 13] that used direct repair, aug-

Diagram 1: PRISMA Flow Diagram



* Reasons for full text articles excluded:

- MCL injury recognised intraoperatively in <5 patients reported (7)
- Instability/failure of MCL secondary to trauma after TKA (2)
- Case series with MCL incompetence due to excessive valgus laxity (3)
- Descriptive overview, not a clinical study (3)
- Conference proceeding, not peer reviewed journal publication (1)
- Cadaveric study (1)
- Opinion paper (1)
- Postoperative radiology after TKA based study (1)

mentation or increasing polyethylene thickness reported no further revision for symptomatic instability or aseptic loosening within 16-95 months (47/84 TKA, 56%). The patients who developed instability after repair of a MCL injury and use of a PS TKA in the fifth study were all diagnosed and revised to a unlinked semi-constrained implant within 12 months of the index TKA (4/7, 57%). Implant type was varied and ranged from CR to PS and across several designs. The higher rate of revision in one series did not appear to result from choice of implants used [1].

Knee Society Scores were generally good (70-79) to excellent (80-100) in patients where MCL was repaired with or without augmentation in 4 studies [2, 3, 7, 13]. In

the other study, there were statistically significant reductions in Knee Society Pain and Function scores comparing patients who underwent TKA and sustained an MCL injury to controls, regardless of method treated, however on subgroup analysis the patients treated with increased constraint had scores similar to controls [1].

Postoperatively, most patients across the 5 studies were allowed to bear weight as tolerated without any activity restrictions. Immobilisation for 1 week, followed by restricted weight bearing with a crutch was used in all TKA routinely in one series [7], with the addition of hinged knee brace in TKA complicated by MCL injury for 4 weeks. Casting immobilisation for up to 4 weeks was used in 4

Table 4. Characteristics of included studies

Authors	Study Type	Oxford CEBM Level of Evidence	Number Affected (total case series)	Mean Age	BMI**	M : F	Prosthesis ^	Intervention	Postop protocol	Follow-up
Stephens et al [3]	Retrospective	4	9 (total 1105)	58	43.3 (29.1-55.7)	2 : 7	CR	Direct repair of midsubstance laceration	WBAT, no brace	8/9, minimum 22 months
Koo and Choi [13]	Retrospective	4	15 (*)	63.9 (56-73)	-	2 : 13	PS in 13 (Scorpio-PS (4), Genesis II (4), Nexgen LPS (5), AGC-PS (1)) CR in 2	Detached tibial insertion, thicker insert used	WBAT, no brace	Minimum 2 years
Jung et al [7]	Retrospective	4	7 (2 excluded due to MCL directly repaired) (2000)	67	30.3 +/- 5.7	1 : 4	PS	2 directly repaired MCL (excluded), 5 augmented with superficial quadriceps autograft	Immobilised 1 week then restricted weight bearing with crutch, Hinged knee brace, full ROM 4 weeks&	16 months
Leopold et al [2]	Retrospective	4	16 (600)	63 (47-86)	32.5 (20-49)	4 : 10	CR (12), PS (4) where severe flexion/varus preop	Direct repair midsubstance laceration (12). Suture anchor or screw post fixation of insertion avulsion (4).	WBAT, Hinged knee brace, full ROM 6 weeks	14/16, 45 months (24-95)
Lee and Lotke [1]	Retrospective	4	37 (28 MCL transection, 9 tibial avulsion) (1650)	60	-	18 : 19	PS (7), VVC (30)	Direct suture repair (5), Tibial avulsion stapled (9), VVC (30)	WBAT, no brace (33/37), 4/37 with PS TKA were cast for 4 weeks	34/37, 54 months (36-120)

* Overall number of TKA performed over 8.5 years not reported

** Body Mass Index calculated as (Mass in kg)/(height in m)². Units are presented as kg/m²

- Indicates not documented

^ Prosthesis type - CR (Cruciate Retaining), PS (Posterior Stabilised), VVC (Varus Valgus Constrained, non linked/semi-constrained)

& Postoperative protocol differed from controls only by use of a hinged knee brace.

Table 5. Outcomes Assessed

Authors	Postop KSS score	Postop KSS Function score	Satisfaction score	Knee ROM	Varus-Valgus instability	Antero-posterior instability	Radiographic signs loosening	Reoperation rate	Revision Rate	Symptomatic instability
Stephens et al [3]	91.5	73.3	None unsatisfied	0-120.5	Nil	Nil	Nil	1/9 for AVN patella	1/9 for sepsis	Nil
Koo and Choi [13]	91 +/- 6.78	82.50 +/- 13.57	-	0-130	1 of 15 >5deg valgus on stress xray	Nil	Nil	Nil	Nil	Nil
Jung et al [7]	87 +/- 3.7	85 +/- 3.5	-	3 - 129	Nil	-	-	Nil	Nil	Nil
Leopold et al [2]	93 (78-100)	-	-	2 - 108	Nil	Nil	2 had <1cm non progressive lucencies under medial tibial component	1 manipulation for flexion stiffness then polyethylene change for sepsis	Nil	Nil
Lee and Lotke [1]	81	74	-	-	-	-	-	-	4/7 PS knees revised for instability at average 7 months (3-12) - increased constraint 3/30 semi constrained revised (1 for sepsis, 2 for aseptic loosening)	-

- Indicates not documented

of 7 TKA that were treated with PS implant after repair/augmentation of the MCL injury [1], but this was not reported to be a factor in the higher rate revision. While 4 of 7 PS TKAs revised for instability in this series, casting amongst these patients was not reported. An unrestricted hinged range of motion brace in the postoperative period was used in 23/84 (27.4%) for between 4-6 weeks.

Discussion

Injury to the MCL during primary TKA may be caused during tibial or medial femoral condylar bone resection [1, 14]. Avulsion of the tibial or femoral insertions of the MCL may occur during high flexion in exposing the knee joint, inappropriately placed medial joint line retractors or by overly vigorous varus-valgus stressing of implants to assess stability.

Iatrogenic injury to the MCL during TKA is an uncommon but serious complication that can result in symptomatic instability, aseptic loosening of the implant, early implant failure and subsequent revision [1]. Risk factors for MCL injury during TKA include morbid obesity [4] and severe varus deformities in patients who have undergone previous knee surgery or that have considerable medial condyle bone defects [6]. Management options to achieve

Table 6. Prostheses Utilised

Authors	Implants used in TKA, number of patients
Stephens et al [3]	CR - PFC Sigma (Depuy, Warsaw, Indiana), 9
Koo and Choi [13]	Scorpio PS (osteonics, Allendale, New Jersey) 4 Genesis II PS (Smith & Nephew, Memphis, Tennessee) 4 NexGen LPS (Zimmer, Warsaw, Indiana) 5 AGC PS (Biomet, Warsaw, Indiana) 1 Series 7000-CR (osteonics, Allendale, New Jersey) 1
Jung et al [7]	Posterior stabilised, implant details not recorded, 7
Leopold et al [2]	NexGen CR or Miller-Galante II CR (Zimmer, Warsaw, Indiana) 12 Nexgen LPS or Insall-Burstein-II PS (Zimmer, Warsaw, Indiana) 4 (PS used if severe varus or flexion contracture)
Lee and Lotke [1]	PS - PFC Sigma (Depuy, Warsaw, Indiana) or Scorpio PS (Stryker, Mahwah, New Jersey), 7* VVC (TCIII, Depuy), 30

* Four of 7 patients revised for instability within 12 months post index TKA

coronal plane stability range from inserting a thicker polyethylene liner [13], direct repair with or without autograft quadriceps or semitendinosus tendon augmentation or conversion to an implant with greater constraint [1-3, 6-8, 15].

Use of a unlinked, semi constrained prosthesis with a greater degree of varus-valgus stability from a metal reinforced, high tibial post can lead to increased force transmission and shearing at the bone cement interface compared to PS or CR TKA [16]. However, survivorship of unlinked, semi constrained primary TKA with either cemented or uncemented stems has been shown to be from 80-90% up to 10 years [9-12], particularly in the elderly or patients with low physical demands [16].

Collateral ligament reconstruction alone as a subsequent operation for the treatment of the unstable TKA has been shown to be ineffective [15]. Several factors were considered including artificial forces in a TKA, typically older age of the patient, poor quality tissue to repair and underlying disease process such as inflammatory arthropathy. Recognition of MCL injury and prompt action by any means to address the MCL incompetence intraoperatively is essential.

One of 5 case series reported in this review reported revision for instability [1]. The PCL has been reported to be a secondary stabiliser to valgus stress in the native knee [17, 18]. Preservation of the PCL in a TKA using a CR implant may impart a degree of additional stability in the coronal plane postoperatively. Communication with the authors of the selected studies and unpublished data located did not show any further revisions of the current cases reported for instability.

In summary, due to the variable methodology, high degree of selection and reporting bias inherent in retrospective case series and the potential for confounding error as well as incomplete reporting and low numbers in the selected 5 studies, we were unable to reach a definitive recommendation for all patients. While semi constrained TKA implants have shown good clinical outcomes up to 10 years, there is the potential for increased rates of aseptic loosening and implant failure, particularly in younger, fitter and more active patients. A less constrained (PS/CR) implant may be acceptable if a good quality direct repair with or without augmentation is possible. When an unlinked semi constrained TKA prosthesis is not available, direct repair with or without augmentation is an acceptable alternative. In cases where the MCL repair is prone to stretching, tissue quality is poor, or in the elderly, conversion to a semi constrained unlinked implant is preferable.

Postoperative management can be commenced without activity or weight bearing restriction. In direct repair with or without augmentation, the addition of a unlocked hinged knee brace for 4-6 weeks would seem prudent.

Longer term studies with larger number of patients and more detailed consistent follow-up are required to compare direct repair with or without augmentation of the MCL to

survival of unlinked semi constrained prostheses in the setting of acute MCL injury during TKA.

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ORIGINAL ARTICLE

Total Hip Stem Classification System

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Abstract

The aim of this paper is to review the influx of short stems for total hip arthroplasty. Not all short stems are created equal concerning fixation points for implant stability and length of engagement of the device in the proximal femur. Some devices are stabilized in the head, neck, metaphysis and metaphysis/diaphysis. Depending on stabilization and engagement area different short stems can have different indications, contraindications and clinical outcomes. As a result of our findings JISRF developed a classification system based on implant stabilization point and overall stem length.

Keywords: short stems, head stabilized, neck stabilized, metaphyseal stabilized, metaphyseal diaphyseal stabilized

Introduction

The use of short stems is growing. Initial short and mid-term follow up studies of a number of these stems suggest that stable, durable fixation and excellent clinical outcomes can be achieved. As a result, a very large number of short stem designs are available. However, there does not exist a classification system [1,2,3,4] for uncemented short stem implants that would allow comparisons of clinical and radiographic results. The purpose of this paper is to propose an updated classification system based upon the

length of the stem and the method by which the stem seeks to achieve stability.

A number of advantages have been argued to justify the design and clinical usage of short stems [5,6]. Elimination of femoral proximal-distal mismatch, tissue preservation (hard & soft), facilitation of less invasive surgical exposures, less invasive surgical violation into the femoral canal, less violation into the trochanteric bed, improved proximal bone remodeling, less intraoperative blood loss, less postoperative rehabilitation, less instrumentation and less inventory cost [7,8].

All of these advantages are worthwhile if they can be proven to be benefits to the clinical outcome and increased survivorship of the device. The real question is can these shorter length devices obtain long-lasting stability of the implant without diaphyseal anchoring [9].



Figure 1. A variety of short stems are available in the global market.

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The influx of short stem designs can be confusing as a result of many different design philosophies. Learmonth in 2009 attempted to broadly divide conservative implants into three categories: [3]

1. Femoral Neck Implants:

These are the most conservative of the short-stemmed prostheses. A wedge shaped cylindrical implant is impacted into the femoral neck to provide initial stability. Long-term stability is then provided by bone ingrowth. It is important to have reasonable bone quality and relatively normal anatomy of the proximal femur.



Figure 2. Example: The Silent Stem.

2. Stems Engaging the Lateral Cortex:

Engaging the lateral cortex resists the turning moment generated on weight bearing and improves the stability of conservative prostheses in the coronal plane. The implant is designed to load the medial cortex of the femoral neck.

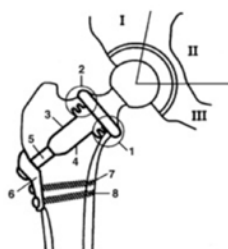


Figure 3. Example: The Thrust Plate Implant.

3. Stems Using the Lateral Trochanteric Flare:

Engagement of the lateral flare on the prosthesis to the corresponding region of the greater trochanter aids in both torsional and axial stability of the implant.



Figure 4. Example: The Mayo Stem.

We have found this classification too broad in its description and it does not address the sub-classifications of designs. The Joint Implant Surgery and Research Foundation (JISRF) advocate a stem classification system by primary stabilization contact regions to help identify, differentiate, and catalog short-stemmed total hip replacements. This classification system should help clarify the design principles inherent with each type and provide some guidance when researchers and other investigators are reporting on the outcomes of the various implant styles. The basic categories of classification include the following: head stabilized, neck stabilized, metaphyseal stabilized, and conventional metaphyseal/diaphyseal stabilized.

The classification system is officially structured as follows:

1. Head Stabilized
 - A. Hip Resurfacing
 - B. Mid-Head Stem
2. Neck Stabilized
 - A. Short Curved Stems
 - B. Short Lateral Engaging Stem
 - C. Neck Plugs or Neck Only
3. Metaphyseal Stabilized
 - A. Taper Stems
 - B. Bulky/Fit and Fill Stems
4. Conventional Metaphyseal/Diaphyseal Stabilized

Some of these devices are not available in the United States (U.S.) and some are new with regard to clinical performance. As a result this paper makes no assumption as to clinical outcome or benefits to certain product features. This is intended to point out certain trends for hip reconstruction and provide a base for development of the “JISRF Stem Classification System”.



Figure 5. Stabilization Zones for Classification System.

Trends

Conservative approaches to hip development (devices and surgical approaches) are the main focus in total hip arthroplasty at the moment [3,10]. The recent Metal on Metal concerns has reduced current alternate hard on hard bearing development [11]. The focus is on improved polyethylene material matting with improved ceramic heads and more conservative stem designs.

Recent reports with certain convention style stems have raised concerns over the use of modularity at this neck stem junction. Neck stem modular tapers are being used in six of the twenty-five devices we reviewed with success. It is important to remember not all modularity is created equal. Application of modularity in certain designs like neck sparing have, significantly reduced stresses at the modular neck stem junction compared to both conventional monoblock and modular designs [12,13].

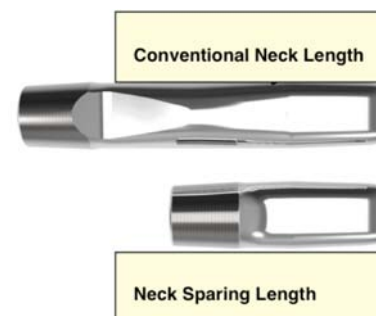


Figure 6. Comparison of Modular Necks (Standard Neck vs. Neck Sparing Design).

The European experience, with certain styles of conservative designs, is years ahead of our experience in the U.S., so it is reasonable to look towards Europe for both trends and early to mid-term clinical results [14].

JISRF Stem Classification System

HEAD-STABILIZED PROCEDURES (JISRF CLASSIFICATION 1A & 1B)

Head-stabilizing procedures are classified as either hip resurfacing or mid-head resection (e.g., Birmingham Mid Head Replacement (BMHR)).

Hip Resurfacing (Jisrf Classification 1A)

This procedure is bone conserving as most of the femoral head is retained. The femoral head is shaped to accept a low-wear metal sphere, and most devices feature a stem component for alignment guidance.



Figure 7. Example of Hip Resurfacing

Mid-Head Resurfacing (JISRF Classification 1B)

This device was developed as an alternative to traditional hip resurfacing for patients whose femoral head structure or bone quality was inadequate for resurfacing.

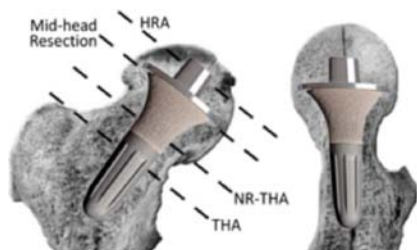


Figure 8. Example of Mid-Head Resection Resurfacing

NECK-STABILIZED PROCEDURES (JISRF CLASSIFICATION 2A, B & C)

In his now classic paper, “Why Resect the Neck,” published in a 1986 issue of the Journal of Bone and Joint Surgery, Michael Freeman was the first to advocate for sparing the neck. [36] Since the 1980s, Freeman has developed a number of neck-sparing stems to be used with and without bone cement. However, his stems have featured a conventional straight-length stem

Short Curved Neck-Sparing Stem (JISRF Classification 2A)

Recently, new designs are following in Pipino’s Biodynamic™ stem style of saving the femoral neck. These designs feature a short curved stem that finds its stabilization contact region in the femoral neck and saves considerable bone in the medial



Figure 9. Example of TSI™ Neck Preserving Short Curved Stem

calcar region. In addition, the curvature of the stem prevents violation of the lateral trochanteric region. The shorter stem also reduces blood loss by not reaming the femoral canal distally. These style stems generally have a variable stem length between 90 and 135 mm. This might not appear much shorter than conventional cementless stems (110 to 150 mm) however, the shorter curved neck sparing stems penetrate on average one to two centimeters less distally in the femoral canal.

One important factor to remember about neck sparing stems is the increase risk factor for mechanical impingement especially with retained osteophytes attached to the femoral neck. In addition if you cannot get to a 32mm head diameter we would recommend a dual mobile style versus using a smaller fixed head diameter. Alternatively, a different stem design may be indicated in these smaller patients.

Short Lateral Flare Engaging Stem (JISRF Classification 2B)

The authors have seen lateral flare engaging conventional cementless stems such as the Revallation® Stem (JISRF Classification 4), but we have only seen one short neck-preserving stem that engages the trochanteric lateral flare (Proxima™ Implant).



Figure 10. Example Post-op view of Proxima Stem

Neck Plugs or Neck Only Implants (JISRF Classification 2C)

Several modified neck-sparing designs have recently been introduced that are only inserted into the femoral neck region. These have been referred to as “neck plugs or neck only” and are limited to international clinical experience. They appear to be a hybrid design between the short curved neck-sparing stem and the mid-head device by McMinn (BMHR). Surgeons who have been interested in hip resurfacing and robotics appear to be drawn to this design style. While results are short-term, interest appears to be growing with the decline of hip resurfacing.



Figure 11. Example of TSI™ Neck Plug

Models of neck plugs in development or currently on the market include the Silent Hip from DePuy, launched in 2009; the Primoris Neck Replacement from Biomet; the Spiron™ Hip by ARGE Medical Technics; the CUT™ Stem by Orthodynamics; and the TSI™ Hip by Concept Design & Development, LLC. All of these devices

es have a common theme: engagement in the femoral neck and a 12/14 head neck taper. As many of these models are still in development, details on precise specifications and early clinical results are available for only three models of neck plugs: the Spiron™ Hip, the CUT™ Stem, and the Silent™ Hip.

SHORT METAPHYSEAL STABILIZED STEMS (JISRF CLASSIFICATION 3A AND 3B)

Short metaphyseal stabilized stems comprise the largest segment of short stems in the United States, compared with the neck-stabilized stems that dominate the European market. The first generation of short stems in the United States were truncated conventional tapered stems. This may be due in part to the nature of design and surgical technique. This style stem uses the same neck resection as conventional cementless stems and does not require an additional learning curve or modification of surgical technique. It also does not require any additional engineering modifications at the proximal portion of the stem. Some early reports from Europe on metaphyseal stems are beginning to recommend a higher neck resection to reduce stem subsidence and torsional instability.

Tapered Stems (JISRF Classification 3A)

One common design of short metaphyseal stabilized stems is the coronal wedge taper. Typically, this implant design is a modified version of a conventional stem length. The implant provides a tight wedge taper in the coronal plane and is relatively flat in the sagittal plane. The flat-plane design allows the surgeon to adjust stem version as needed. Coronal wedge taper stems provide a very tight wedge taper fit between the lateral femoral cortex and the medial femoral neck. This requires removal of the lateral femoral neck cortex. Most wedging occurs at the meta-diaphyseal junction of the proximal femur. Medial to lateral cortical contact is essential. The anterior to posterior fill is not anatomic. Consequently, the anterior and posterior surfaces are primarily in contact with cancellous bone.



Figure 12. Example of short metaphyseal style tapered stem.

Bulky or Fit and Fill Stems (JISRF Classification 3B)

These stems often feature anatomical shaped stems (left and right) with a percentage of anterversion (6° to 12°) built into a monoblock neck/stem configuration. They fit and fill most of the metaph-



Figure 13. Example of short metaphyseal style bulky stem.

yseal area. Some designs feature an enhanced lateral flare for enhanced stability.

Pitfalls and Liabilities of Short Stems

Use of short stem technology for primary THA comes with caveats. Shorter stems are generally less stable at initial press fit (compared with their longer stem counterparts). Surgeons, therefore, will compensate by forcing a “tighter” initial press fit. Surgical technique that emphasizes a robust press fit can lead to proximal femoral fracture. We have empirically seen this phenomenon with a variety of short stem designs. Conversely, if the surgeon adopts a less aggressive press fit technique to mitigate the risk of proximal neck fracture, the short stem may settle and become mechanically loose because the stem is less inherently stable to rotational loads compared with longer stem implants. This ultimately narrows the “sweet spot” for press fit technique. For some surgeons, learning the sweet spot for a particular short stem may entail a long learning curve. When considering short stem implants, one should, at a minimum, consider implanting these devices in an instructed cadaver course scenario.

Short stem designs that rely mostly on femoral neck fixation are susceptible to failure if the femoral neck is thin and osteoporotic. Rotational hip stress combined with cantilever bending forces can overstress the native neck bone, leading to bone fatigue. As a result, the hoop stresses that keep the implant stable are lost and the stem loses mechanical fixation and settles. To mitigate this problem, the authors believe all short stems must be limited in weight bearing for 4 to 6 weeks. A 50% weight load to the implant is recommended. This will give the femoral neck enough time to heal and biologically bond to the prosthesis. With the push towards ultra-short lengths of stay and “rapid recovery” protocols, this point must be continually emphasized to the health care team and patient.

Conclusion

Short femoral stems have been of interest to surgeons and implant designers for decades. Many varieties of short stem (JISRF classification 2 and 3) have been introduced over the years with the goal of reducing the soft tissue dis-

EXAMPLE: CONVENTIONAL METAPHYSEAL / DIAPHYSEAL STABILIZED STEMS (JISRF CLASSIFICATION 4)

Figure 14. AML® Stem



section associated with standard metaphyseal-diaphyseal stabilized (JISRF classification 4) length stems. Some short stems are also bone sparing, by preserving the medial femoral neck, the lateral femoral neck, or both.

The broad category of short stems actually encompasses several subtypes. The JISRF classification is recommended as a means to accurately assess the clinical performance of these subgroups. Neck/stem modularity plays an important role in some short stem implant systems in order to facilitate anatomic restoration. Avoidance of complications at the modular junction is a function of specific design parameters, especially when considering dissimilar metals. Short stems can be successfully implanted via all standard approaches to the hip, including anterior, lateral, and posterior approaches.

Short stems can facilitate surgical technique for THA. Specifically, when one is using Direct Anterior Approach (DDA), the neck-sparing curved design significantly facilitates cases of stem insertion. Less trochanteric levering reduces the risk of proximal femur fractures. Furthermore, with larger-sized patients, proximal extension of the incision is avoided. When utilizing a posterior hip approach, surgeons must note that a true neck-sparing implant provides a distinct advantage for soft tissue closure. Specifically, the capsular envelope is not extensively removed. This allows for a more robust closure of the posterior hip capsule, which may translate to improved posterior hip stability. Furthermore, since a majority of the femoral neck is preserved, the short external complex is successfully closed in a consistent fashion. This adds an additional soft tissue layer that is protective.

Short stems have a definite role in modern total hip arthroplasty, as greater emphasis is being placed on soft-tissue and bone-sparing techniques and as refinements continue in the understanding of proximal femoral fixation and the biomechanics of head/neck and neck/stem modularity.

Metaphyseal short stems have significantly less surface contact area compared with conventional length stems and as a result, they might have less torsional and axial resistance. Neck-retaining short stems provide additional axial and torsional stability and reduced stress at the implant bone interface and may be a consideration in the more active patient profile. Bone quality and the patient's physical activity should be considered prior to the selection of short-stem devices. Short stems both of older generations

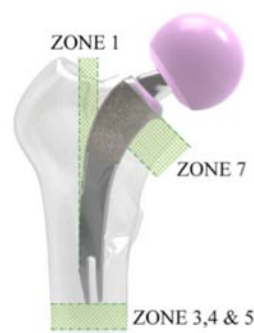


Figure 15. Example of bone saving Gruen Zones with a Short Curved Neck Preserving Stem

and new can and do work. Many short stem designs have considerably different style features that may alter bone remodeling. Bony adaptation around new implants might have different time frames before these changes occur. Only detailed follow-up will render the results.

Knowing the design and the required technique is vital in order to fit the device properly to the patient. The variations of short stems available call for caution in their overall use until there is better understanding of how dependent



Figure 16. Post-op x-ray comparing conventional cementless stem to a short curved neck preserving style stem.

these stems are on individual stem features, bone quality, and surgical techniques. Overall, the authors are cautiously optimistic and continue advocating their selective use.

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ORIGINAL ARTICLE

Improving Pre-Operative Flexion in Primary TKA: A Surgical Technique Emphasizing Knee Flexion with 5-Year Follow-Up

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Abstract

This study prospectively reviews a consecutive series of 228 primary total knee arthroplasty (TKA) procedures utilizing a technique to optimize knee flexion. The main features include: (1) the use of a “patellar friendly” femoral component and reduced thickness patellar components, (2) patient individualized adjustment of the femoral component rotation set strictly to the anterior-posterior femoral axis, (3) a rigorous flexion compartment debridement to remove non-essential posterior femoral bone with a Z-osteotome, and (4) incorporation of a rapid recovery protocol with features to promote knee flexion.

Results were categorized into three groups: low pre-op flexion (90 degrees and below), regular pre-op flexion (91-125 degrees), and high pre-op flexion (126 degrees and above). Average flexion in the low flexion group improved by 20 degrees at 6 weeks, 28 degrees at 3 months, 31 degrees at 1 year, and 30 degrees at 5 years. In the regular flexion group, average flexion improved by 2 degrees at 6 weeks, 10 degrees at 3 months, 12 degrees at 1 year, and 13 degrees at 5 years. Finally, in the high flexion group, average flexion decreased by 7 degrees at 6 weeks, regained preoperative levels at 3 months, and increased by 3 degrees at 1 year and 4 degrees at 5 years.

In summary, a technique that emphasizes patellofemoral kinematics can consistently improve flexion in TKA in short and long-term follow-up.

Keywords: Total knee arthroplasty, range of motion, high flexion, surgical technique, implant design, AP Axis

Level of Evidence: AAOS Therapeutic Study Level III

Introduction

Primary total knee arthroplasty (TKA) is a very successful procedure that significantly improves quality of life. [11,15,28] The established goals of pain relief and preservation of patient function are accomplished in most patients in intermediate to long term follow up. [12,27] With the ever-increasing size of the baby boomer population, recent emphasis has been focused on improving patient outcomes, including knee flexion. [19,26] Newer concepts include less invasive surgical techniques, coor-

dated in-hospital and postoperative rapid recovery programs, and reduction in overall use of allied health resources. [6,7,13,20] These ideas are predicated upon the concept of reducing net patient costs, which ultimately reduces overall national healthcare costs. To be effective, any change in the short term goals must be consistently

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reproducible and must show an improvement compared to established methods in the long term.

This study prospectively reviews our work to maximize postoperative knee flexion in primary TKA. We utilize several concepts within our approach to high flexion which include: (1) the use of a “patellar friendly” high flexion design femoral component, (2) a modified surgical technique that places higher emphasis on patellofemoral alignment, (3) the removal of posterior femoral bone with a Z-osteotomy, and (4) a rapid recovery protocol that we have developed over a period of two years. This study reviews a consecutive series with this established protocol, prospectively followed to 5 years post-op.

Methods

The Vanguard® Complete Knee System (Biomet; Warsaw, Indiana) was utilized for primary total knee replacement patients treated by the senior author between October 2004 and February 2007. A cruciate retaining femoral component was used in all cases. When the posterior cruciate ligament (PCL) was incompetent, attenuated, or released, an anterior stabilized tibial component was implanted. When the PCL was intact, a standard polyethylene insert was used. If excess translation in flexion occurred, a congruent insert was utilized. All tibial components were modular metal base plates with a cruciate keel. An all-polyethylene 3 peg reduced thickness patellar dome was placed in all cases. Implants were cemented with Palacos® cement (Heraeus Kulzer GmbH; Wehrheim, Germany) without antibiotics.

All surgeries utilized a “less invasive surgery” technique with an anterior-medial incision. The deep arthroscopy started at the inferior-medial aspect of the tibial tubercle and typically ended 2.0 centimeters (cm) superior to the patella. Bone preparation employed reduced sized instrumentation (Microplasty™, Biomet; Warsaw, Indiana) with posterior femoral referencing. An intramedullary guide system was used for distal femoral preparation and an extramedullary guide system was employed for proximal tibial preparation. A fixed “4 in 1” reduced size cutting block was used for the femoral cuts, with 5 cm long medial and lateral pins. For femoral component sizing and preparation, a modified posterior femoral condyle referencing system was used. Rotation of the femoral component strictly adhered to the anterior-posterior axis (AP axis) as defined by Whiteside. [3,21,30] The AP axis was carefully determined by utilizing a newly developed AP axis jig (figure 1). The base of the jig fit into the intercondylar notch at the most lateral aspect of the insertion of the PCL on the



Figure 1. Photograph of AP axis jig that is used intra-operatively to determine the anterior-posterior axis of the femur. The small triangle in the lower part of the jig is placed in the intercondylar notch at the most lateral insertion of the PCL ligament. The sliding upper portion of the jig is placed in the deepest portion of the trochlear groove. In cases of patellofemoral dysplasia, surgeon discretion was allowed for placement of the trochlear portion of the jig.

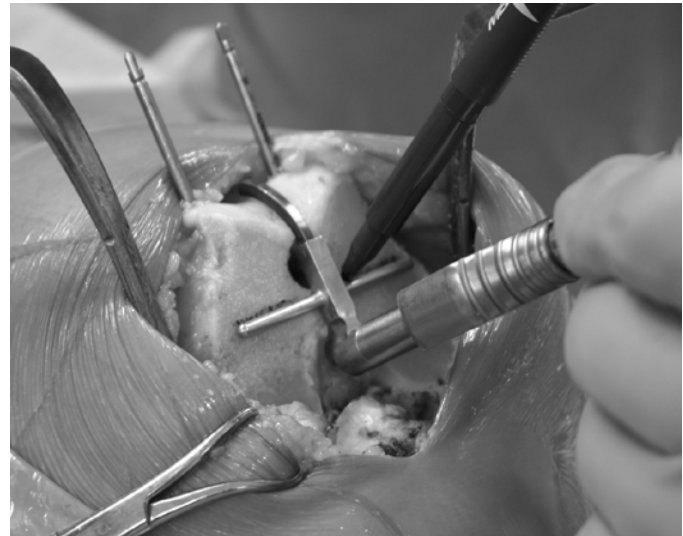


Figure 2. Intra-operative application of AP Axis Jig. As defined by Whiteside [30], the jig is placed at the most lateral portion of the PCL. The upper part lies in the patellar groove. The two side posts are perpendicular to the AP axis line. A marker is used to make a line on the distal cut of the femur. This defines the rotation for the femoral component.

femur. The jig was then positioned into the base of the trochlear groove. The perpendicular line was marked on the cross bars of the jig with a blue marking pen (figure 2). The AP sizing jig employed a variable rotation axis to adjust femoral component rotation parallel to the marked blue line (figures 3a & 3b). Femoral component rotation was set from zero to nine degrees of external rotation.

Femoral component sizing was chosen to ensure that the lateral prosthetic trochlear flange was no thicker than the resected lateral trochlear bone. If the measured trochlear bone thickness was less than the 7 millimeter (mm) metallic flange thickness, the femur was downsized by one size. The goal was to place the anterior flange flush with the anterior femoral cortex. When needed, a femoral blend or small notch (up to 2 mm) cut was accepted. Posterior femoral condyle osteophyte removal was an important step. Any bone extending beyond the prosthetic femoral condyle was removed with a z-shaped osteotome to prevent flexion impingement (figures 4a & 4b).

Coronal plane balancing was accomplished with a trial femoral component and a tibial trial component without a keel. Releases were performed to achieve full knee exten-

Figures 3a-3b. Modified Femoral Sizing Jig.

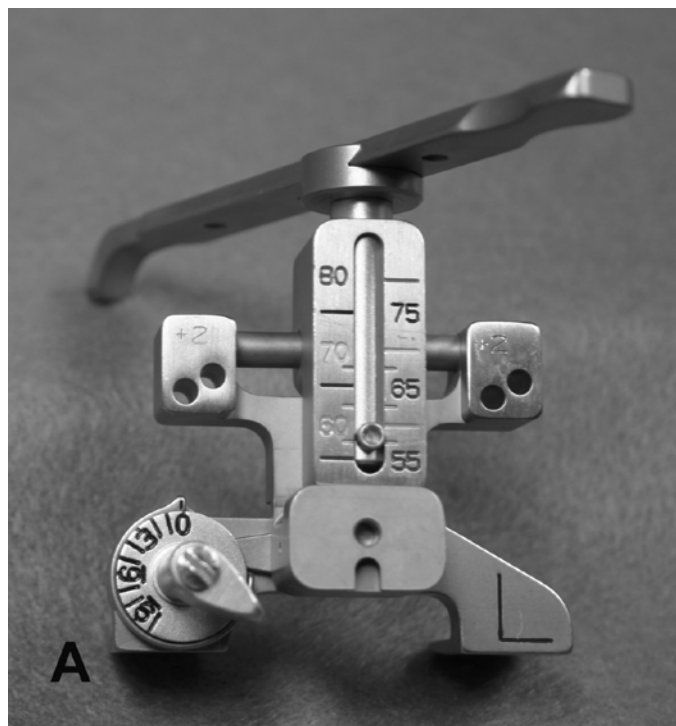


Figure 3a. Photograph of modified sizing jig. The jig uses the posterior femoral condyles for referencing. This jig uses posterior metallic pads to define the posterior femoral condyles. These pads are used to measure anterior to posterior height. However, instead of a fixed femoral rotation (usually between 3 to 5 degrees), this instrument utilizes a rotation dial to rotate the jig parallel to the reference line drawn in figure 2.

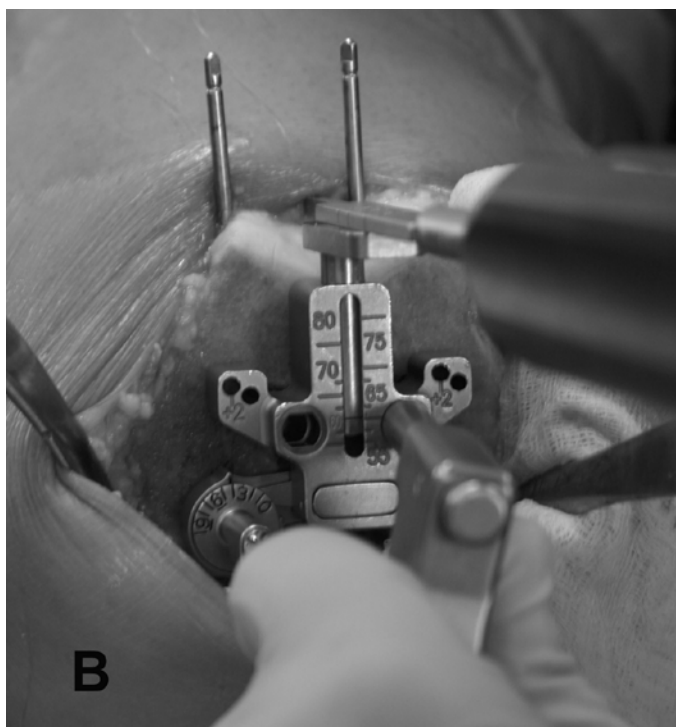


Figure 3b. Intra-operative placement of the AP sizing jig. Rotation is carefully set parallel to the rotation reference line. By using this method, we believe patellofemoral tracking is optimized for deep knee flexion. Notice in this case, external rotation was set at four degrees.

Figures 4a-4b. Z-osteotome for posterior femoral bone debridement.

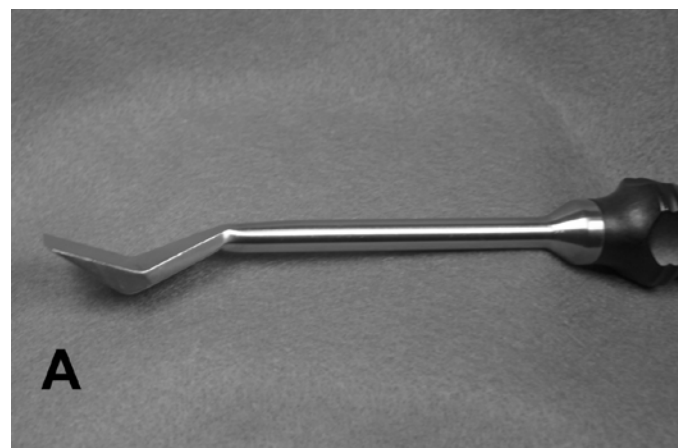


Figure 4a. Demonstrates design of Z-osteotome for posterior femoral condyle debridement. The current design shown is the 5th ideation. This tool allows removal of bone that would extend beyond metallic femoral condyles. The blade is short enough so as not to notch the posterior femoral cortex or damage the posterior femoral capsule.

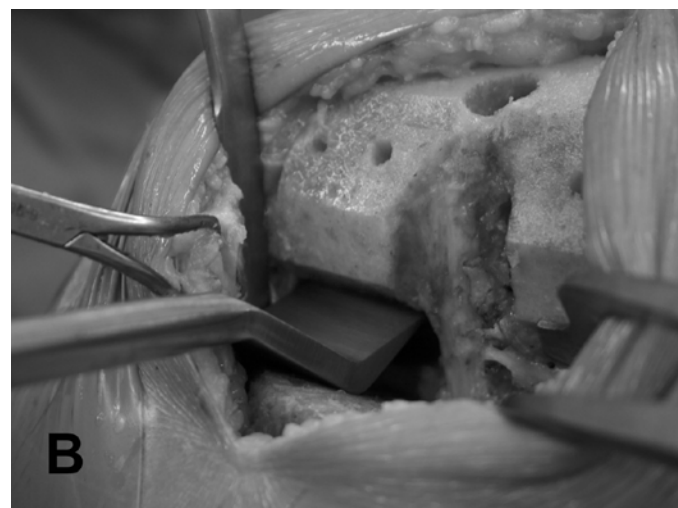


Figure 4b. Shows the application of Z-osteotome for posterior femoral bone debridement. The osteotome is placed on the cut posterior femoral condyle at a position just behind the end of the metallic femoral component. The cut bone is removed with a curved rongeur.

sion. Medial-lateral (ML) balance was tested in full extension and 90 degrees of flexion. Posterior tibial slope was individualized to parallel the medial compartment slope. Tibial component rotation was adjusted and marked at end flexion. This ensured optimal mating of the femoral and tibial components in deep flexion.

Patellar resurfacing technique strictly enforced restoration of patellar height without overstuffing. All patellar components were the modified thin design with reduced polyethylene thickness (see table 1). This assured that in every case the patella was not “overstuffed.” Resurfacing also emphasized maximal patellar bone coverage from superior to inferior. The patellar dome was placed against the medial edge. Any remaining unresurfaced bone was

Table 1. Thickness Change between Standard and Modified Patellar Components

Patellar Diameter	Patellar Thickness (mm) Modified Thin Design	Patellar Thickness (mm) Standard Design
28mm	5.8	8.0
31mm	5.8	8.0
34mm	7.8	8.5
37mm	9.8	10.0

Figures 5a-5c. Technique of lateral patellar bone reduction. The unresurfaced patellar bone on the lateral side is removed to reduce lateral reticular tension.



Figure 5a. Demonstrates placement of largest diameter low profile component which covers the patella from superior to inferior. The patella is placed next to the medial rim.

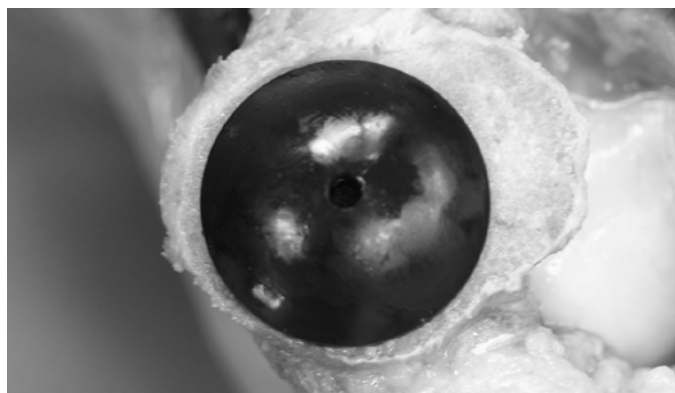


Figure 5b. The unresurfaced lateral patellar bone is dissected with an electrocautery and is removed with a large rongeur and trimmed with a small rongeur. With bone resection, lateral retinacular tissues about the patella are relieved.

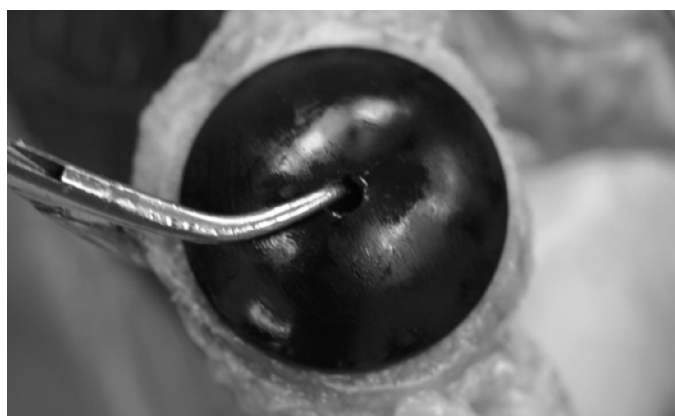


Figure 5c. Shows the final result. The bone removal relaxes the peripatellar retinaculum and allows the patella to more easily track in the middle of the trochlear groove. In this case, 1.1cm of lateral patellar bone was removed.

removed with a lateral patellar bone reduction technique (figure 5).

Prior to closure, the pericapsular tissues were injected with a “joint cocktail” of 50cc with a 23 gauge spinal needle. The joint cocktail consisted of 100mg ropivacaine (Naropin®, Astra Zeneca; Wilmington, Delaware), 0.1mg epinephrine (Hospira; Lake Forest, Illinois), 80mg methylprednisolone acetate (DepoMedrol®, Pharmacia and Upjohn Co; Kalamazoo, Michigan), and 60mg ketorolac (Toradol®, Bedford Laboratories; Bedford, Ohio) mixed with sterile saline to achieve a volume of 50cc. Knee closure was performed at 90 to 95 degrees of flexion, including the skin. The skin was closed with a subcuticular closure with 4.0 Monocryl™ suture (Ethicon Inc; Somerville, New Jersey). A 7mm silastic drain was placed in every case. A pneumatic thigh tourniquet was used in every case, at a pressure of 275mm Hg. The tourniquet was released after skin closure when the sterile dressing was applied.

Postoperatively, a rapid recovery protocol was employed. [6] Surgeries were performed with a spinal anesthetic. Early ambulation, when possible, was started on the day of surgery. Inpatient physical therapy focused on gait training, safety, and home tasks, rather than knee flexion. Controlled passive motion (CPM) devices were never used. Patients were typically discharged between postoperative days 2 to 4. Outpatient physical therapy was prescribed for six to twelve weeks. Physical therapy was discontinued when the goals of end extension, flexion (typically 125 degrees), strength, and safety were consistently achieved by the patient.

Primary deep vein thrombosis (DVT) prophylaxis was pneumatic foot compression devices (Huntleigh FP 5000, Huntleigh Healthcare; Eatontown, New Jersey), thigh high graduated compression stockings (T.E.D® Stockings, Tyco Healthcare Group LP; Mansfield, Massachusetts), early ambulation, and oral aspirin (325mg) twice daily. Aspirin and graduated compression stockings were continued for six weeks. Patients with a known history of thrombophlebitis or pulmonary embolus (PE) were treated with 40mg subcutaneous enoxaparin sodium injection (Lovenox®, Sanofi-Aventis; Bridgewater, New Jersey) twice daily for three weeks, starting postoperative day one. Patients who were previously on warfarin (Coumadin®, Bristol-Meyers Squibb Co; Princeton, New Jersey) for atrial fibrillation were restarted on warfarin therapy.

Knee range of motion was measured in a 16-inch high chair, with the foot touching the floor. A standardized goniometer with 7-inch arms was employed. Routine patient follow up was scheduled at 6 weeks, 3 months, and annually. A decision for manipulation was made at the 6-week follow up interval. Pre-operative, operative, and post-op-

erative data was prospectively collected and maintained on a patient database in Microsoft Access® (Microsoft Corporation; Redmond, WA) and analyzed at regular intervals.

Results

Between October 2004 and February 2007, 201 patients (231 knees) underwent primary total knee arthroplasty utilizing Vanguard Complete Knee System components. Of these, three patients (3 knees) were excluded secondary to complications occurring prior to the six-week follow up visit. One patient died several weeks after hospital discharge of sepsis following emergency abdominal surgery. One patient required a revision for periprosthetic fracture after a fall and one required revision for posterior instability secondary to traumatic PCL rupture following a fall. Four patients (4 knees) did not return for follow up in our office. Three of these patients lived far from our office, decided to return to their primary orthopedic surgeon, and were doing well. One patient was a resident in a skilled nursing facility and declined to come in for office evaluation. This patient was satisfied with her knee replacement. Six patients (7 knees) had incomplete data. Two patients (3 knees) were missing 6-week data. Four patients (4 knees) were missing three-month data.

There were 148 female (65%) and 80 male (35%) patients. The mean age was 65 (range 20 to 98). The diagnosis was degenerative joint disease in 213 knees, post-traumatic arthritis in 9 knees, and rheumatoid arthritis in 6 knees. Deformity was absent in 62 knees, 42 knees had valgus deformities (defined as ≥ 12 degrees mechanical alignment), and 124 knees had varus deformities (defined as \leq zero degrees mechanical alignment). Of the 228 procedures included in this study, 129 (57%) were performed on the right knee and 99 (43%) on the left knee.

Average pre-operative flexion was 114 degrees (range 70-140) and average pre-operative flexion contracture was 10 degrees (range 10 degrees of hyperextension to 32 degrees of flexion contracture). Average flexion achieved was 116 degrees at 6 week follow-up (range 65-142), 125 degrees at 3 month follow-up (range 80-152), 128 degrees at 1 year follow-up (range 85-152), and 128 degrees at 5 year follow-up (range 95-145). Average flexion contracture was 8 degrees at 6 weeks (range 0-22), 4 degrees at 3 months (range 0-24), 1 degree at 1 year (range 0-12), and 1 degree at 5 years (range 0-24).

Knee range results were then analyzed in three separate groups: low pre-op flexion (90 degrees or less), regular pre-op flexion (91-125 degrees), and high pre-op flexion (126 degrees and above). In the 15 cases with low

pre-operative flexion, average preoperative flexion was 83 degrees. In this group, average pre-operative flexion contracture was 17 degrees (range 0-32). Average flexion achieved was 103 degrees at 6 weeks (range 80-125), 111 degrees at 3 months (range 80-130), 114 degrees at 1 year (range 85-125), and 113 degrees at 5 years (range 95-124). Average flexion contracture was 8 degrees at 6 weeks (range 0-16), 5 degrees at 3 months (range 0-12), 0 degrees at 1 year (range 0-0), and 1 degree at 5 years (range 0-10).

In 188 cases with regular pre-operative flexion, average pre-op flexion was 114 degrees. In this group, average pre-operative flexion contracture was 11 degrees (range 10 degrees of hyperextension to 30-degree flexion contracture). Average flexion was 116 at 6 weeks (range 65-142), 124 degrees at 3 months (range 102-142), 126 degrees at 1 year (range 105-150), and 127 degrees at 5 years (range 110-145). Average flexion contracture was 8 degrees at 6 weeks (range 0-22), 4 degrees at 3 months (range 0-24), 1 degree at 1 year (range 0-12), and 1 degree at 5 years (range 0-20).

Twenty-five cases were in the high pre-operative flexion group, with an average of 132 degrees. Pre-operative flexion contracture in this group was 6 degrees (range 0-15). Average flexion decreased at 6 weeks to 125 degrees (range 105-140), was equal to pre-operative flexion at 3 months (range 120-152), and increased to 135 degrees (range 120-152) at 1 year and 136 degrees (range 130-145) at 5 years. Average flexion contracture increased at 6 weeks to 8 degrees (range 0-14), but decreased to 4 degrees (range 0-13) at 3 months, 1 degree (range 0-10) at 1 year, and 1 degree (range 0-5) at 5 years.

Complications within this series included four patients (1.7%) with knee instability. One patient required revision to a salvage hinge prosthesis eight weeks post-operatively for global knee instability. Pre-operatively, the leg was moderately weak from a stroke. During the patient's rehabilitation, the knee became globally unstable including hyperextension. One patient experienced flexion instability with a subluxation event. This patient was revised with an anterior stabilized insert eleven weeks post-operatively, and subsequently has no instability. One patient experienced a subluxation event on the second post-operative day. This patient had in place an anterior stabilized insert, and was treated definitively with a controlled motion brace for six weeks. This patient has no residual instability. One patient experienced mild posterior subluxation (loose flexion gap) but decided against revision. Three knees (1.3%) required manipulation. All three patients achieved and maintained adequate flexion after manipulation.

There were seven (3%) incidents of wound complica-

tions. There was one case of a partial wound dehiscence after a fall that was repaired surgically, along with knee lavage. One patient had an evacuation of a deep hematoma. There were four cases of cellulitis that responded fully to antibiotic therapy. There was one irrigation and debridement for wound drainage and cellulitis that was concerning for a deep infection. This completely resolved following administration of intravenous antibiotics, and deep cultures were negative.

One patient required a repair of an extensor mechanism rupture following a fall. One patient had a DVT that responded to treatment with warfarin. One patient had a documented PE that was initially treated with heparin. The patient subsequently developed a small knee hematoma, and heparin was discontinued. She had no further problems following placement of an inferior vena cava filter. One patient required a blood transfusion prior to hospital discharge. One patient had a non Q-wave myocardial infarction on post-operative day two, and was treated medically following cardiac catheterization.

Discussion

In the following 20 years, the baby boomer population will mature and place significant pressure on the American Healthcare system. [26] Budgetary constraints will inevitably place restrictions upon reimbursement to hospitals, physicians, and allied healthcare professionals. In the realm of joint replacement surgery, we have already seen the curtailment of physical therapy visits allowed for Medicare and Medicaid patients.

At our center, we have focused on methods to deliver a cost effective, efficient “product” to patients requiring knee replacement surgery. The goal was to provide a knee replacement procedure that was “easy” on the patients and minimized perioperative care.

This study demonstrates that in the early post-operative period, knee flexion can be consistently maintained at 6 weeks and 3 months. At the 6-week follow up interval, the low pre-op flexion group gained an average 20 degrees of flexion, the regular pre-op flexion group gained an average 2 degrees of flexion, and the high pre-op flexion group lost 7 degrees of flexion. At the 3-month follow up the low pre-op flexion group maintained their increased flexion with an average increase of 28 degrees. The regular pre-op flexion group went on to gain an average of 10 degrees. The high pre-op flexion group returned to their average pre-operative flexion. Furthermore, these early gains in pre-operative flexion were maintained at 1 year and at 5 years in all groups. The improved flexion achieved in all groups we

believe is attributable to several factors: (1) prosthetic design, (2) surgical technique, and (3) facilitated perioperative rehabilitation. [4,5]

The Vanguard® femoral component design is one that is considered “patellar friendly.” The component is asymmetrical and laterally angulates the patellar groove by 6.5°. The lateral anterior flange thickness is relatively thin (7mm) which prevents an inordinate rising of the patella. Moreover, the trochlear groove is deep, which also prevents excess rising of the patella.

Another important factor was the ease of prosthetic sizing of the femur. The average incremental change in femoral component size is small (2.5mm). In addition, the AP to ML ratio of the femur is optimized to accommodate worldwide variations in distal femoral bony architecture. These two factors allowed more precise femoral sizing in both male and female populations without overhang.

The reduced thickness patellar components (modified thin design) allowed us to recreate patellar height without overstuffing. Overstuffing of the patellar height frequently occurs in smaller patients where the patellar thickness, not infrequently, measures 18-21mm. [22] This is a special problem to us given our diverse population within the United States. In this group, cutting the patella to a standard 15mm thickness and placing a typical 8mm patellar dome will increase patellar height and retinacular tension. Increased retinacular tension is perceived as pain, and, therefore, the patient will self-limit knee flexion range. [29] In this series, there was no case of overstuffing of the patellofemoral joint.

The other major factor optimizing knee flexion is surgical technique. [2,8,17,25,28,29] In this series, the described technique was developed over a period of three years and represents a significant paradigm shift for the authors. The current technique places emphasis on defining the patellofemoral plane of knee motion and then recreating that plane with the prosthetic femoral component. The tibial component is then mated in deep flexion to avoid flexion conflict. The above ideals do not displace the basic tenets of mechanical alignment and ligament balancing. Instead, coronal and sagittal knee balancing occurs after defining the flexion arc as determined by the AP axis method. The philosophy driving this technique is that the patellofemoral arc is an established patient parameter that, when created, provides the easiest route to knee flexion. [1,2,9,22] Any change in this plane makes patellofemoral balancing more difficult. Thus, recreating this plane will optimize patellar tracking and ultimately enhance knee flexion. In this series, femoral rotation was set between zero and nine degrees. Some would argue that a rotation from zero to three degrees is counterintuitive. This is thought to cause

lateral patellar maltracking, frequently necessitating a lateral retinacular release. However, in this series no formal lateral releases were required. This underscores the idea that native femoral rotation is not a fixed variable, but rather a range, following a bell curve. This is supported by the work of Poilvache, which describes natural femoral external rotation between 0.16 and 8.12 degrees. [24] We believe that postoperative rehabilitation is facilitated by not performing lateral releases. A lateral retinacular release is painful and causes significant knee swelling. This limits knee flexion and lengthens the rehabilitation period.

In this study a rapid recovery protocol was utilized. The protocol includes several techniques that we feel promote knee flexion. Closure of all soft tissues of the knee in flexion is known to improve flexion range and reduce hospital stay. [8,10,14,16,18] Although we cannot independently quantitate its effect, the injection of the pericapsular tissues with a "joint cocktail" does, in our opinion, facilitate early functional recovery. The pericapsular injection of pain medication and anti-inflammatory agents allowed our patients to transition routinely to oral narcotics and avoid intravenous patient controlled analgesia (PCA) pumps. We believe the combination of preemptive analgesia, intra-operative pericapsular injection, and post-operative oral analgesia maximized patient vigor, allowing patients to walk with confidence and participate in activities requiring greater knee flexion. [8,29]

During the post-operative period, patients continued with outpatient physical therapy. This was unchanged from our previous protocol. However, we received consistent feedback from our primary therapist regarding the ease with which patients regained flexion. Because of the varied geographical location of our patients, we could not objectively record the amount of physical therapy required for our patients. In some of our larger physical therapy clinics, the time to discharge from physical therapy has decreased significantly, from a typical 10-14 weeks to just 4-10 weeks currently.

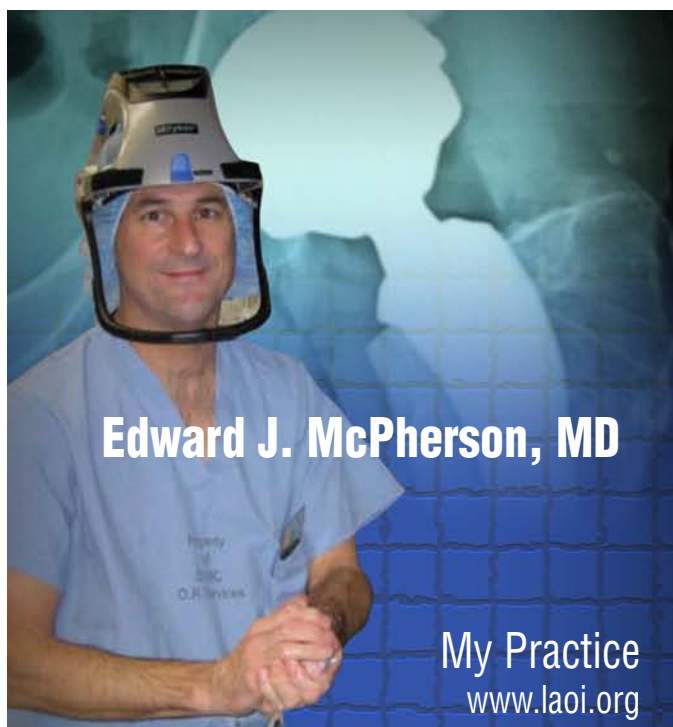
In this series, a considerable number of patients (N=4) suffered posterior flexion instability. For the most part, this can be explained by surgeon error. Prior to this series, the operating surgeon implanted exclusively posterior stabilized knee implants for a five year period. The change to a cruciate retaining construct was based upon disenchantment with patient complaints of knee crunch, clicks, and rattling in posterior stabilized knees. In this series, we accepted more generous flexion gaps than we should have allowed (a posterior stabilized bias). Furthermore, in the early part of this series, anterior stabilized tibial inserts were not yet available. We believe the combination of anatomic tibial slope, lax flexion gaps, and lack of anterior sta-

bilized inserts was the cause of flexion instability. Based upon this experience, we more aggressively utilize the anterior stabilized insert if the PCL is at all attenuated. [9,23]

In summary, this study shows that knee flexion after TKA can be improved consistently without utilizing excess allied healthcare resources. We realize this is just one method and other prosthetic designs and techniques may accomplish similar goals. However, we emphasize several ideas that can be universally applied to improve flexion. First, the surgeon should never overstuff net patellar height. Increased patellar height increases retinacular tension, which can reduce knee flexion. Second, adjusting tibial component rotation with the knee at end flexion in our experience is a helpful technical point to promote knee flexion. Lastly, adjusting femoral component rotation using only the AP axis is an acceptable technique. By recreating the sagittal arc of the knee via the AP axis technique, we have found reproducible knee flexion without incurring significant kinematic conflict or patellar maltracking. Furthermore, this technique can be utilized in less invasive incisions where other femoral landmarks are frequently obscured. We feel these techniques deserve further evaluation and will continue to follow this series of patients to determine long term outcomes for this prosthesis design, surgical technique, and recovery protocol.

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As an Orthopaedic surgeon in Los Angeles, CA, I'm grateful to practice medicine in an area with exceptional healthcare. My choice is to practice at St. Vincent Medical Center. My research is in collaboration with JISRF, Founded here in L.A. in 1971 by Prof. Charles O. Bechtol, MD.

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CASE REPORT

Subgroup Analysis of Topical Tranexamic Acid in Total Knee Arthroplasty

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Abstract

Evidence continues to accumulate for the efficacy of tranexamic acid (TXA) use in primary total knee arthroplasty (TKA). An essential question that remains is to determine which specific subgroups of patients undergoing TKA will benefit from TXA use and if surgeons should be more selective in its administration. We performed a retrospective cohort study involving 187 TKA patients who received intra-articular (“topical”) TXA, and compared these to 168 historical controls who did not receive TXA. These patients were then subdivided into groups based on gender, age, BMI, and preoperative hemoglobin for analysis. All patients, despite their demographics, saw an improvement in primary outcome measures without a detectable increase in complications. Based on these data, there are no restrictions on the use of TXA. Obese patients, females, and those over 65 years of age undergoing total knee arthroplasty may benefit from TXA most consistently.

Introduction

Topical or intraarticular tranexamic acid (TXA) has garnered recent attention for its ability to reduce transfusion rates [1,2,3,4] reduce length of stay [5], and reduce cost [1,6,7] following total joint arthroplasty. Our institution has seen and reported similar results [8]. The essential question that remains is to determine which specific subgroups of patients undergoing total knee arthroplasty (TKA) will benefit from TXA use and if surgeons should be more selective in its administration. We performed a retrospective cohort study involving 187 TKA patients who received intraarticular (“topical”) TXA, and compared these to 168 historical controls who did not receive TXA. These patients were then subdivided into groups based on gender, age, BMI, and preoperative hemoglobin for analysis.

The purpose of this study was to retrospectively identify patient characteristics that will more accurately justify the utilization of topical TXA in TKA; the ultimate goal is for a surgeon to correctly identify patients preoperatively (prospectively) who will most consistently benefit from

topical TXA administration. A secondary goal was to identify patients that were unlikely to benefit from TXA and thereby limit unnecessary use and improve cost saving.

Methods

Following IRB approval, 355 primary, consecutive TKA performed by 5 orthopaedic surgeons at a single institution between March 2012 and March 2013 were retrospectively reviewed. September 1st 2012 marked the day that each of these surgeons began to administer topical TXA to all total joint patients intraoperatively. The months of August and September of 2012 were excluded from the study to prevent overlap of the experimental and control groups. The proportion of patients was similar between the two cohorts for each surgeon. Bilateral and revision knees were excluded from the study.

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Patients all underwent general anesthesia, tourniquet use, and received local 10cc of 0.5% Marcaine without epinephrine at the operative site after wound closure. All patients received preoperative antibiotics within 1 hour of surgical incision, typically cefazolin, vancomycin if MRSA history present, or clindamycin if significant cephalosporin allergy. Following release of the tourniquet, electrocautery hemostasis, and capsular closure, one gram of TXA in 10cc of normal saline was injected intraarticularly into the knee. Standard postoperative DVT prophylaxis was used including TEDS, SCDs and chemical prophylaxis. One surgeon used postoperative aspirin for chemical DVT prophylaxis while the other four used Coumadin. No intraoperative drains were placed. No changes were made to each surgeon's individual surgical and postoperative protocols between the control and experimental groups. No primary, unilateral total joint patients were excluded from TXA use. Hemoglobin levels were obtained each day during hospitalization and the lowest of these was used for analysis. Transfusion was triggered by a hemoglobin of less than 8 g/dL for all patients in both control and experimental groups. Each chart was reviewed via the electronic medical record and the following variables were obtained: age, gender, BMI, transfusions, preoperative hemoglobin within 30 days of operation, postoperative hemoglobin, operative time, tourniquet time, days in hospital, 30 day readmission, disposition to home or subacute nursing facility, and complications of UTI, pneumonia, MI, DVT, stroke and death within 30 days. All readmissions were recorded regardless of the reason. Not all readmission reasons qualified as complications in our analysis. No routine screening for DVT/PE was performed. Symptomatic DVT was confirmed by ultrasound.

Statistical analysis was used to confirm the significance of the results. The chi square test was used for discrete variables. Independent t-tests were used for continuous variables. Statistical significance was defined as $P < 0.05$.

Results

The total 355 cases were analyzed based on gender, age, BMI and preoperative hemoglobin. Age was divided by older or younger than 65 years. BMI was divided by obesity, defined as 30 and above. A division at 12 g/dL was used for preoperative hemoglobin. The number of cases for each group is contained in Table 1.

Overall, TXA effectively reduced the transfusion rate, increased postoperative

hemoglobin levels, decreased the change in hemoglobin, and increased home disposition. These effects were not evenly distributed however. The total summary without subdivision can be found in Table 2. Tourniquet time, EBL, days in hospital, surgical time, complication rate and readmission rate were similar between the groups unless otherwise stated.

GENDER

Females had a significant difference in their postoperative hemoglobin, delta hemoglobin, and disposition. The transfusion rate change was not statistically significant, a reduction from 16.5% to 7.3%, $p = 0.064$. See Table 3 for all subgroup outcome values. Women experienced one UTI, one DVT and three readmissions in the control group; the TXA group experienced 1 MI and 5 readmissions.

Males were noted to have a significant difference in their postoperative hemoglobin and transfusion rate. Male disposition and delta hemoglobin did not significantly differ. Males experienced 1 UTI and 4 readmissions in the control group; the TXA group experienced no complications and 2 readmissions.

BMI

Patients with a BMI of less than 30 showed a significant difference in their postoperative hemoglobin, delta hemoglobin, and transfusion rate. Their disposition did not dif-

Table 1. The total number of patients in each subgroup is presented before and after TXA.

Subgroup	Before TXA	After TXA
Age <65	75	86
Age >65	93	101
BMI <30	69	82
BMI >30	85	105
Female	109	109
Male	59	78
Hgb <12	17	15
Hgb >12	128	154

Table 2. Outcome measurements for TXA intervention in all TKA patients before division into subgroups.

Outcome	Before TXA	After TXA	P Value
Disposition home	95 (56.5%)	132 (70.6%)	0.0059
Disposition SNF	73 (43.5%)	55 (29.4%)	0.0059
Readmission	7	7	0.8379
Complications	3	1	0.2622
Delta Hgb	4.4+/-1.1	3.7+/-1.6	0.0001
Postoperative Hgb	9.2+/-1.2	10.2+/-1.8	0.0001
Patients Transfused	25 (14.9%)	8 (4.3%)	0.0018
Units Transfused	41	20	0.0041
Length of stay	3.2	3.2	0.7606

Table 3. Subgroups divided by age, gender, BMI, and preoperative hemoglobin (Hgb), before and after TXA use.

Subgroup	Before TXA	After TXA	P Value
Age <65			
-Transfusion	7 (9.3%)	2 (2.3%)	0.0864
-Delta Hgb	4.31+/-1.13	3.76+/-1.06	0.0034
-Postoperative Hgb	9.48+/-1.25	10.2+/-1.33	0.0005
-Disposition home	50 (66.7%)	58 (67.4%)	0.4297
Age >65			
-Transfusion	18 (19.4%)	6 (5.9%)	0.0132
-Delta Hgb	4.30+/-1.2	3.74+/-0.95	0.0013
-Postoperative Hgb	9.01+/-1.18	10.28+/-2.20	0.0001
-Disposition home	45 (48.4%)	70 (69.3%)	0.0024
BMI <30			
-Transfusion	14 (20.3%)	5 (6.1%)	0.0214
-Delta Hgb	4.56+/-1.23	3.99+/-0.99	0.0015
-Postoperative Hgb	8.95+/-1.30	10.15+/-1.23	0.0001
-Disposition home	41 (59.4%)	58 (70.7%)	0.1451
BMI >30			
-Transfusion	9 (10.6%)	3 (2.9%)	0.0415
-Delta Hgb	4.12+/-1.07	3.65+/-0.97	0.0032
-Postoperative Hgb	9.43+/-1.14	10.26+/-2.23	0.0021
-Disposition home	42 (49.4%)	74 (70.5%)	0.0031
Female			
-Transfusion	18 (16.5%)	8 (7.3%)	0.0636
-Delta Hgb	4.19+/-1.18	3.51+/-1.67	0.0016
-Postoperative Hgb	8.84+/-1.01	9.60+/-1.17	0.0001
-Disposition home	53 (48.6%)	71 (65.1%)	0.0138
Male			
-Transfusion	7 (11.9%)	0 (0%)	0.0028
-Delta Hgb	4.49+/-1.09	4.08+/-1.47	0.0863
-Postoperative Hgb	9.85+/-1.26	11.08+/-2.23	0.0002
-Disposition home	42 (71.2%)	62 (79.5%)	0.3966
Hgb <12			
-Transfusion	8 (47.1%)	5 (33.3%)	0.6067
-Delta Hgb	3.17+/-1.25	2.98+/-1.03	0.6447
-Postoperative Hgb	7.84+/-0.80	8.27+/-1.01	0.1997
-Disposition home	4 (23.5%)	6 (40.0%)	0.3158
Hgb >12			
-Transfusion	14 (10.9%)	1 (0.6%)	0.0003
-Delta Hgb	4.47+/-0.99	3.86+/-0.94	0.0001
-Postoperative Hgb	9.43+/-1.14	10.46+/-1.86	0.0001
-Disposition home	78 (60.9%)	109 (70.8%)	0.0566

fer significantly. The control group had 3 readmissions and 1 UTI complication. The TXA group required 5 readmissions, 1 MI complication.

Patients with a BMI greater than 30 had a significant difference in their delta hemoglobin, disposition, postoperative hemoglobin and their transfusion rate. The control group had 3 readmissions, 1 symptomatic DVT and 1 UTI.

The TXA group suffered no complications, but two readmissions.

AGE

Those patients over 65 years had a significant difference in delta hemoglobin, postoperative hemoglobin, transfusion rate, and disposition. In the control group 3 patients were readmitted and 3 had postoperative complications: 2 UTIs, and 1 symptomatic DVT. In the TXA group there were 5 readmissions and 1 MI.

For patients younger than 65 years the delta hemoglobin, postoperative hemoglobin were both significant. The transfusion reduction and disposition were not significantly changed. There were no readmissions in the control group, two in the TXA group. There were no complications in this group.

PREOPERATIVE HEMOGLOBIN

Patients that preoperatively had a hemoglobin of 12 g/dL or greater showed a significant difference in delta hemoglobin, postop hemoglobin and transfusion rate. Disposition did not differ significantly. The control group contained 3 readmissions and 1 UTI. The TXA group had 4 readmissions and no complications.

Patients with a preoperative hemoglobin less than 12 showed no significant difference in their delta hemoglobin, postoperative hemoglobin, transfusion rate or disposition. The control group had 4 readmissions, 1 UTI and 1 symptomatic DVT. The TXA group had 3 readmissions and 1 MI. Refer to Table 3 for a subgroup summary of outcomes.

Discussion

Topical administration of tranexamic acid is becoming more widely used, however the method used to apply it and discerning which specific patients will benefit most from its use has not been clearly established in the literature. The goal of this study was to present an effective method of topical tranexamic acid administration and rigorously examine the subgroups of patients within the study population to determine which patients TXA is most likely to benefit.

There are several weaknesses of this study, including

its retrospective design. Patients were followed for 30 days postoperatively in the electronic database. Any complication that presented either after this time period or to a different healthcare facility was not recorded. The study includes five different surgeons with their own slightly different TKA surgical protocols; however, the method of TXA administration was standardized. Importantly, some of the subgroups may be underpowered to detect significant differences, particularly the preoperative hemoglobin <12 g/dL group which contained a notably lower case volume in the series.

The data is consistent with the current literature [9,10,11,12,13] revealing significant differences with topical TXA use: a transfusion rate reduction of 10.6%, delta hemoglobin decrease by 0.7g/dL, increased postoperative hemoglobin by 1g/dL, and increased disposition to home by 14.1%. See Table 2 for primary outcomes of all patients.

Ritter et al found no difference in outcomes based on gender following total knee arthroplasty [14]. The gender cohorts in our study responded to TXA differently. Females saw a significant difference in postoperative hemoglobin, delta hemoglobin, and disposition. Their transfusion rate reduction of 9.2% approached significance ($P = 0.064$). Males dropped to a transfusion rate of zero following TXA implementation; however this did not significantly affect their delta hgb or their disposition. Only 49% of females compared to 71% of males in the control group went home. Following TXA implementation, 65% of females were able to go home, compared to 80% of males. A large percentage of males went home postoperatively despite transfusion requirements or postoperative hemoglobin. This discrepancy may be due to gender differences in postoperative care expectations or may relate to overall postoperative hemoglobin level, which was higher in males. TXA had a significant impact on female disposition and increased male disposition home but not significantly.

Suleiman et al concluded that there was no difference in postoperative complications in total knee arthroplasty when comparing cohorts based on BMI [15]. The BMI cohorts in our study mirrored their results showing no difference in complications. Both groups significantly benefited from TXA implementation. Patients who were not obese did not see a significant increase in home disposition. At baseline without TXA, non-obese patients were 10% more likely to be discharged home (59% compared to 49% in obese individuals). With TXA use, both obese and non-obese patients went home at the same rate, 70% and 71%, respectively.

Kennedy et al found that complications were higher in the elderly following TKA [16]. The patients over 65

years old in our study were more likely to suffer complications following TKA than those under 65 regardless of TXA administration. Those over 65 benefitted significantly from TXA in all outcome measurements: lower transfusion rates, lower delta hemoglobin, higher postoperative hemoglobin and higher home disposition. Patients under 65 had a significantly higher postoperative hemoglobin and lower delta hemoglobin, however this did not significantly affect their transfusion or disposition rate, likely due to their ability to compensate for relative anemia.

Friedman et al found a direct correlation between preoperative hemoglobin and transfusion requirement following total knee arthroplasty [17]. Our data confirms this finding, showing that patients with a preoperative hemoglobin of less than 12g/dL had a 47% transfusion rate. This rate dropped to 33% after TXA implementation; however this was not statistically significant. This particular cohort may have too few patients to detect a difference, as no outcome measures were significantly affected. Patients with a preoperative hemoglobin over 12g/dL went from a 10.9% transfusion rate to 0.6%, ($P = 0.0003$) following the use of TXA. Home disposition approached significance in this group ($P = 0.0566$), an increase from 60.9% to 70.8%.


Overall, patients who are obese or over the age of 65 are most likely to benefit from TXA use. Females had a relatively greater clinical response to TXA use than their male counterparts. Patients with preoperative anemia (Hgb <12) would theoretically seem to benefit from TXA but our study was underpowered to assess this accurately, warranting further study in anemic patients undergoing TKA. All patients, despite their demographics, saw an improvement in primary outcome measures without a detectable increase in complications. Based on these data, there are no restrictions on the use of TXA. Obese patients, females, and those over 65 years of age undergoing total knee arthroplasty may benefit from TXA most consistently.

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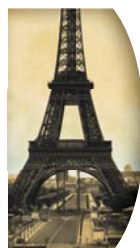
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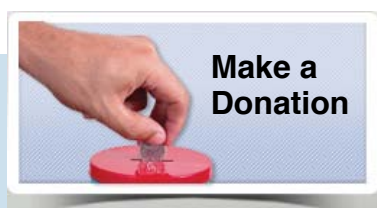
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Disclosure for Authors

Article 1, page 13.
Hillock [1], Tatum [1], Dolegowski [1]
Article 2, page 17.
Della Torre [1], Stephens [1], Lii Oh [1], Kamra [1], Zicat [1], Walker [1]
Article 3, page 24.
McTighe [1], Keggi [1], Stulberg [1], Keppler [1], Brazil [1], McPherson [1]
Article 4, page 29.
McPherson [1], Portugal [1], Dipane [1], Sherif [1]
Article 5, page 37.
Tuttle [1], Anazonwu [1], Rubin [1]

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Future Site Selected For This Cutting-Edge Medical Initiative



Since 1948, the Greenbrier Clinic has been recognized as an industry leader in executive health and wellness through utilizing advanced diagnostics in the early diagnosis, prevention and treatment of disease. Building upon that history of medical excellence, Jim Justice, Chairman and owner of the Greenbrier Resort, has announced the creation of the Greenbrier Medical Institute. The institute's 1st phase is projected to cost about \$250 million, employ more than 500 people and include 3 buildings.

This phase will include an expansion of our world renowned executive health and wellness practice, The Greenbrier Clinic, which will be bolstered by a world-class sports medicine program, including an orthopedic surgery center and athletic performance/rehabilitation facility, all led by the Founder of the American Sports Medicine Institute, Dr. Jim Andrews and Chair of Cleveland Clinic Innovations, Thomas Graham. Rounding out the Institute's services will be a first-



in-class plastic and cosmetic surgery and Lifestyle Enhancement Academy, helping people look and feel their best. Physicians, universities, research foundations, medical journals and other healthcare industry leaders, all of whom are on the cutting edge of medical technology, research and care, have committed to join the project and establish an international research and education destination or "think tank" to stimulate research, drive innovation, force change and redefine how the world approaches health, wellness and longevity.

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

For more information, please contact:

Mark E. Krohn, Chief Operating Officer
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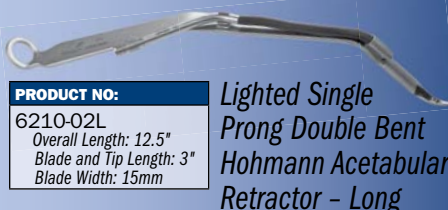
PRODUCT NO'S:

6120-L [Narrow]
Overall Length: 11.75"
Handle Length: 6.5"
Blade Width: 19mm

6130-L [Standard]
Overall Length: 12"
Handle Length: 7"
Blade Width: 33mm

6135-L [Deep]
Overall Length: 14.5"
Handle Length: 7"
Blade Width: 33mm

Lighted Cobra
Retractors



PRODUCT NO:

6210-02L
Overall Length: 12.5"
Blade and Tip Length: 3"
Blade Width: 15mm

Lighted Single
Prong Double Bent
Hohmann Acetabular
Retractor - Long



PRODUCT NO:

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Overall Length: 12"
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Combines the two most
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The tool has a blunt blade tip on one end to help with separation of
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and leverage

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PRODUCT NO'S:

4535-01 [Extra Deep Modified
Narrow Hohmann]
Overall Length: 11.625"
Blade Width: 16.4mm

4550-01 [Extra Deep Modified
Blunt Hohmann]
Overall Length: 13.25"
Blade Width at End: 11mm

4558-01 [Extra Deep Hohmann]
Overall Length: 11.5"
Blade Width: 16.7mm

6450-01 [Extra Deep Single
Prong Soft Tissue]
Overall Length: 13.75"
Blade Width: 22.3mm

6570-01 [Extra Deep Single
Prong Acetabular]
Overall Length: 13.75"
Blade Width: 22.3mm

7115-03 [Extra Deep Bent
Hohmann]
Overall Length: 12.125"
Handle Length: 9.75"
Depth from Bend: 6.25"
Blade Width: 19mm

Listed in order of appearance at left.

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PRODUCT NO'S:

7318-00 [Complete System]

7318-01 [Frame]
Length: 14.5"
Maximum Width: 12"

7318-02 [Small Narrow Blade]
Blade Width: 1.25"
Blade Depth: 1.25"
Overall Length: 8.5"

7318-03 [Small Wide Blade]
Blade Width: 2"
Blade Depth: 1.25"
Overall Length: 8.5"

7318-04 [Medium Narrow Blade]
Blade Width: 1.25"
Blade Depth: 2.25"
Overall Length: 8.5"

7318-05 [Medium Wide Blade]
Blade Width: 2"
Blade Depth: 2.25"
Overall Length: 8.5"

7318-06 [Medium Malleable Blade]
Blade Width: 1.25"
Blade Depth: 2.25"
Overall Length: 8.5"

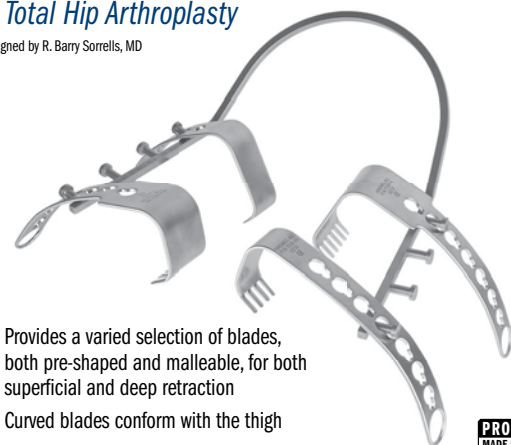
7318-07 [Large Narrow Blade]
Blade Width: 1.25"
Blade Depth: 3.25"
Overall Length: 8.5"

7318-08 [Large Wide Blade]
Blade Width: 2"
Blade Depth: 3.25"
Overall Length: 8.5"

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- ▶ Curved blades conform with the thigh
- ▶ Self-retaining and easily adjustable

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- (2) Small Retractors
 - (1) Narrow
 - (1) Wide
- (3) Medium Retractors
 - (1) Malleable Narrow
 - (1) Narrow
 - (1) Wide
- (2) Large Retractors
 - (1) Narrow
 - (1) Wide



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