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Reconstructive REVIEW

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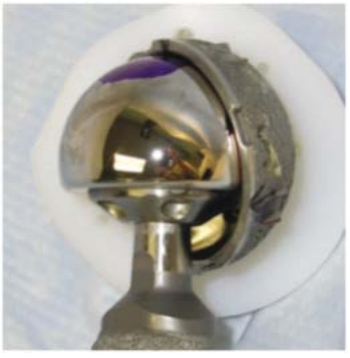

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Reconstructive Review

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

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ORIGINAL ARTICLE https://doi.org/10.15438/rr.11.1.235

Cementless Highly Porous Titanium Tibial Base Plate in Total Knee Arthroplasty – 5-year Survivorship

Shah, S[1]; Coulshed, N[2]; Sorial, R[3]

Abstract

Background: TKA in more active and young patients has prompted the interest in more durable and biological methods of Osteo-integration with cementless components. With the emergence of improved biomaterials like porous titanium the search for a cementless TKA with long-term durability may have ended. This is a retrospective study of 492 consecutive TKAs using cementless tibial fixation with a comprehensive ANJRR review for failure at 5.9 years and clinical and radiological results in a subgroup.

Method: We studied 492 TKAs performed consecutively by a single surgeon between 1st Jan. 2010 and 31st Dec. 2015 using a cementless, fixed bearing tibial tray (porous–Regenerex, Vanguard, Zimmer-Biomet) and a cementless femoral component (Vanguard) with no exclusion criteria. A joint registry review through the Australian National Joint Replacement Registry (ANJRR) was performed on the whole cohort. The surviving patients were followed up for clinical outcomes and radiological assessment completed on a subgroup of patients accessible during the study period (Level II evidence).

Results: The average Knee Society Score at final follow-up was 89.33, average pre-op being 42.06. Average post-op WOMAC score was 43.45 and average pre-op was 77.78. On radiological examination, only one patient had osteolysis and subsidence of the tibial base plate. In our series 9 patients were revised, out of which only 4 patients had the tibial tray and femoral component revised and 5 patients had patella resurfacing or liner exchange. Overall survivorship of the cementless tibial component is excellent with a survivorship of 99.4% at 5.9 years based on the ANJRR analysis.

Conclusions; Cementless tibial fixation using a porous titanium tray can provide stable bone ingrowth fixation on the tibial side with excellent and predictable medium-term outcomes.

Background

Cemented and cementless tibial components are two different options for tibial fixation in Total Knee Arthroplasty. Cemented tibial fixation is common and proven durable in long term studies [1]. Cementless tibial components were introduced over the last 30 years with some variable results with the main concerns being aseptic loosening and long-term survival. Several radiostereometric studies have shown migration of cemented tibial trays due to bone resorption at cement-bone interface, which is of concern in young active patients [2]. With the favorable outcome from cementless hip arthroplasty, there has been resurgence in interest around cement-less fixation in TKA [3]. Hybrid fixation like cementless femur and cemented tibia in TKA has shown equivalent results in terms of du-

Keywords*: cementless tibia; Regenerex; cementless total knee arthroplasty; Vanguard*
Level of Evidence*: II*

rability and survival to cemented TKA. Clinical outcomes and histological evidence have shown porous surfaces provide the ideal scaffold for bone ingrowth [4]. Highly porous metals have been used successfully in revision TKA and so may be an attractive fixation option for primary tibial trays. Regenerex® is a highly porous titanium construct with large pore size and interconnecting porous structure with good biomechanical properties including compressive strength and modulus of elasticity very similar to normal trabecular bone. Material biomechanical properties like roughness help in friction fit and initial stability and high porosity enhances bone ingrowth, thus increasing implant survival [5].

While there are several studies demonstrating favorable outcomes with cementless tibial components in TKA, many have strict inclusion criteria and rely on careful patient selection to achieve these outcomes. Our study had no exclusion criteria and aimed to examine and report on the early clinical and radiologic outcomes as well as midterm survivorship of the cementless porous titanium tibial tray in a cohort of 492 consecutive cases (492 patients).

Our hypothesis was that this cementless tibial tray would demonstrate excellent early durability and survivorship, as well as excellent clinical and radiological outcomes.

Materials and Methods

Retrospective analysis of 492 patients comprised 295 females (60.0%) and 197 males (40.0%). The average age of patients was 66.5, range 42-91 years. The average preoperative mechanical axis measured 3.9o varus (23o varus – 17o valgus).

All TKA cases operated by single surgeon from the 1st January 2010 to the 31st December 2015 were included in this study (N=492 cases). Institutional ethics approval was sought and granted for this project (Ref. H11998). The clinical data set is incomplete, with only 477 patients having a complete pre-operative assessment and 318 with a minimum 6-month post-operative assessment or greater data set. The reasons for this include failure to collect data at time of consultation (15 cases) or patient's election not to participate or return for follow up after 6 weeks for logistic reasons (159 cases).

All the patients who underwent primary total knee arthroplasty are included in data collection. There were no exclusion criteria based on patient characteristics including age, BMI, indication for TKA, type of arthritis, metabolic bone disease or previous osteotomy. All the surgeries were performed at two centers (Macquarie University Hospital and Nepean Private Hospital, NSW, Australia).

Submission to National Joint Replacement Registry

A submission was made to the Australian National Joint Replacement Registry (ANJRR) for the whole cohort of patients, to review the revision rates and reasons for revision for each patient whether performed by the senior author or performed at another facility. A comparison of the revision rates of the cementless tray with all TKAs using other cementless tibial trays and all TKAs using a cemented tibial tray.

The Australian National Joint Replacement Registry (ANJRR) report included data of all 492 cases in its analysis. This is viewed as a benefit of the registry review as it ensures inclusion of all patients in the analysis who had the index surgery including those who elected not to return for further follow up and who may have had revision surgery at an alternate institution

The ANJRR has an over 99% data compliance, allows analysis of surgeon's performance including full demographics of the surgeon's practice, reasons and types of revisions, a list of prostheses they use, hospitals where they treat their patients and revisions by year of implantation [7].

Patient Assessment

All 492 patients are assessed pre-operatively and then routinely seen at 6 weeks, 6 months, and 5 years post-operatively or at any interim time they elect to return for an assessment and clinical evaluation. The American Knee Society (AKS) score, Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and Flexion score is collected for each patient. The most recent or current scores are derived from their most recent follow-up appointments and/or score sheet mail out. For both Knee and Function AKS scores, a score of >80 was considered excellent, 70-79 good, 60-69 fair, and <60 poor.

Radiological Assessment

X-rays were done for all 492 patients pre-operatively, post-operatively, at 6 months and at 5-year follow-up. Radiological evaluation was performed on the 297 patients who either returned follow-up x-rays following mail out request or attended for follow-up during the time of the study period with routine x-rays between August 2016 to July 2017 using Knee Society Radiological evaluation and scoring system for TKA [6]. Each X-ray was examined for radiolucent lines, osteolysis and subsidence of the implant (fig.1, 2, 3). Radiolucent lines were measured in millimeters. Lucent lines of 1mm or more were recorded. Osteolysis is any progressive lesion of bone loss beneath the

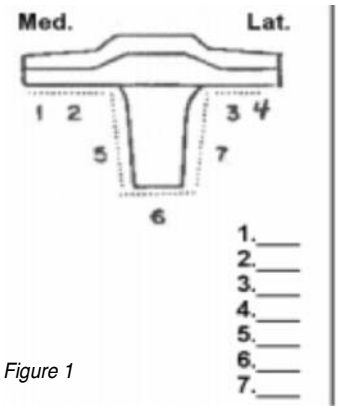
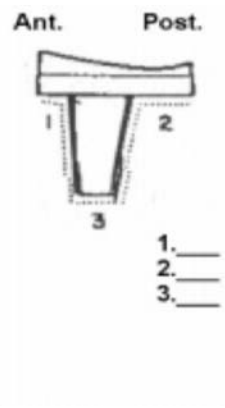


Figure 1



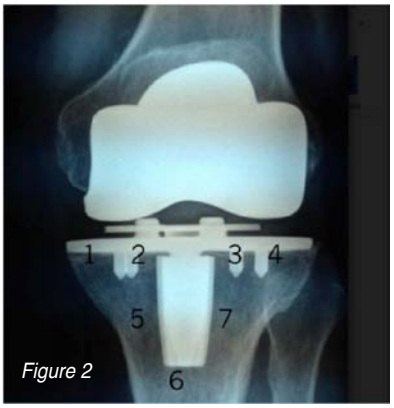


Figure 2

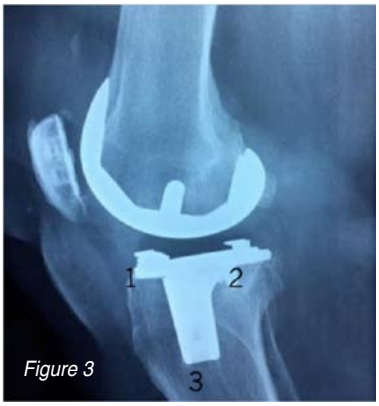


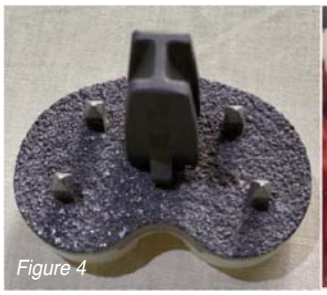
Figure 3

Figures 1, 2 and 3: showing zones around Tibia for radiological evaluation after TKA. (From Knee Society Radiological Evaluation)

implant (tibial base plate). Subsidence can be defined as a change in position of an implant (tibial base plate) due to bone loss at implant bone interface.

Implants

The implant used is the Regenerex ® Cementless Tibial tray, part of Vanguard Total Knee system manufactured by Zimmer-Biomet, Warsaw, Indiana, USA. It has highly porous titanium undersurface with an average porosity of 67% and average pore size of 300 microns (fig. 4,5). It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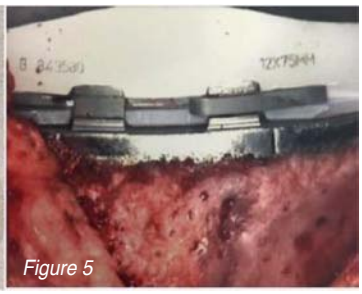


Figure 5

Figure 4 and 5: showing highly porous titanium under surface and implant bone interface

is not coated with hydroxyapatite unlike some other cementless total knee systems [8]. The tray has central stem and 4 square non-porous peripheral pegs to improve fixation (fig. 6). The polyethylene insert used was posterior cruciate retaining in most of the patients. The ultracongruent insert was used in a small number of patients where the PCL was deficient or was sacrificed for balance. The Vanguard Porous Hydroxyapatite coated cementless femoral component was inserted for all cases and a cemented polyethylene patella button was used to resurface the patella only in selected cases of advanced patella wear.

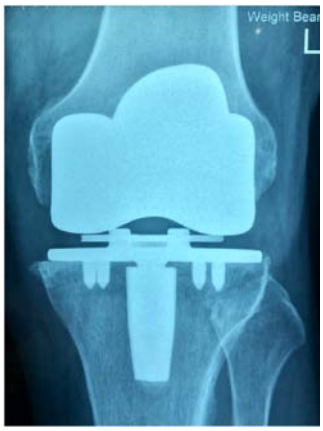


Figure 6: X-ray showing stable interface with Regenerex tibial tray.

Surgical Technique

A standard medial para-patella approach was used in all cases and tibial base plate was inserted in accordance with the manufacturer's recommended technique. The first 260 cases were implanted using a tourniquet. The remaining cases were implanted without tourniquet due to a change in surgical protocol with the introduction of tranexamic acid. One gram of tranexamic acid was given intravenously immediately prior to the incision, as well as 3 grams in 30mls normal saline placed topically after implantation. It is of advantage to perform whole surgery without tourniquet, as it gives chance to achieve accurate haemostasis prior to implantation given the best visibility of posterior capsule. Also, it prevents post-operative swelling, bruising and delayed articular recovery [9]. In addition, studies have failed to demonstrate any relationship between tourniquet use and implant survivorship in TKA [10].

Statistical Analysis

AKS scores, WOMAC index and flexion range were recorded pre-operatively, at 6 weeks and 6-months post-operatively and at their most recent follow up. All patients were included regardless of the completeness of their data set to provide the best representation of the cohort and avoid selection bias. Mean and standard deviation values were calculated for WOMAC index, AKS and flexion scores at each follow-up interval. Pre-operative values were compared separately with both the post-operative values and current follow-up using paired samples T-tests. Kaplan-Meier curves were calculated using the data from the ANJRR to compare the relative survival (defined as revision of any kind) of our study cementless tibial trays and other cemented TKAs. All statistical analysis was conducted using SPSS. The permissible upper limit of significance accepted is at 0.05 (5%) probability level.

Results

Clinical Parameters

The average follow-up time for all patients was 4 years, with a range of 1 year 4 months to 7 years 1 month. At each assessment interval the AKS (Knee and function) scores, WOMAC index and Flexion scores were recorded for each of the patients seen. The following table illustrates this data, comparing the pre-operative, post-operative and current values. The first p value indicates the statistical significance between pre-operative and post-operative scores, the second p value the significance between the post-operative and current values.

Table 1. Clinical results

Clinical Parameter	Follow-up point	Mean ± Std. Dev	p value
WOMAC	Pre-op	77.78 ± 14.37	-
	Post-op	43.45 ± 16.56	<0.001
	Current	38.43 ± 15.08	0.005
AKS Knee Score	Pre-op	42.06 ± 17.86	-
	Post-op	82.53 ± 16.60	<0.001
	Current	89.33 ± 15.48	<0.001
AKS Function Score	Pre-op	45.65 ± 18.34	-
	Post-op	75.73 ± 22.77	<0.001
	Current	75.85 ± 23.95	0.953
Flexion range	Pre-op	104.08 ± 13.84	-
	Post-op	116.89 ± 10.55	<0.001
	Current	118.10 ± 13.22	0.144

At each follow-up interval there was a significant improvement from baseline in all-clinical parameters and notably there was a statistically significant improvement between the 6-month post-operative and current follow-up scores for both the WOMAC index and AKS Knee scores. At current follow-up 85% of knees were rated excellent, 5% good, 4% fair and 6% poor. Therefore 90% of TKAs were rated as good/excellent and the flexion range also significantly improved to an average of 118 degrees.

Radiological Results

Radiographs of 297 patients who submitted their x-rays during the study period were analysed. Lucent zones around the tibial tray were documented in 13 patients (5%). A summary of the lucent zones as measured, and their location is shown in Table 2.

One patient had radiologic evidence of significant subsidence, shown in figure 7,8. This patient had lucent lines totalling 9mm across the different zones and was clinically loose. The femoral component also demonstrated significant osteolysis below the implant and was loose. This patient was not reporting any significant pain and was still functional without support and has to date declined proposed revision surgery. No other patient X-rays demonstrated lucent zones sufficient to suggest implant loosening. Note that the routine knee x-rays of the remaining patients have all been reviewed by the senior author during routine follow-up outside the study period and documented to be stable, but this was not used for reporting here.

Table 2. Lucent zones around the tibial implant

AP zones	1.0mm	1.5mm	2.0mm	2.5mm	3.0mm
1	5	-	-	-	-
2	2	-	-	-	-
3	2	-	-	-	-
4	6	2	1	-	-
5	-	-	-	-	-
6	-	-	-	-	-
Lateral					
1	4	-	1	-	-
2	2	-	1	-	-
3	1	-	-	-	1

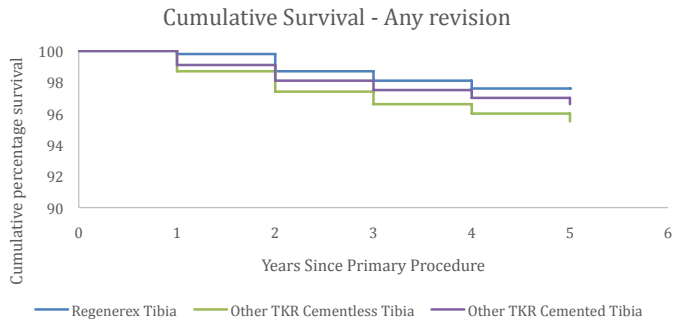
Registry Results

The Australian National Joint Replacement Registry (ANJRR) data reported that of the 492 cases submitted, only 9 patients (1.7%) required revision of their knee replacement and all had their revision surgery between 12 and 36 months following the index procedure. The revision procedures in these 9 patients were identified as 2 patients who had only their polyethylene insert revised, 2 patients who had their patella resurfaced, 1 patient who had both the polyethylene insert and patella resurfaced, 1 patient who had a cement spacer and 3 patients who had full revision of their total knee replacement (tibial & femoral components). The reasons for revision in these 9 patients included 1 for infection, 1 for loosening/lysis, 2 for patella pain, 1 for instability, 3 for arthrofibrosis and 1 other (reason not provided). At 5 years follow-up there was a cumulative revision rate of 0.6% (CI 0.1, 2.4) for all tibial implant revisions.

Kaplan-Meier Analysis

Survivorship with tibial revision as the end point was 99.4% (CI 97.6, 99.9) at 5 years. Survivorship for the tibial implant with aseptic loosening requiring revision, as an endpoint was 99.8%. This is illustrated in figures 2 and 3, respectively.

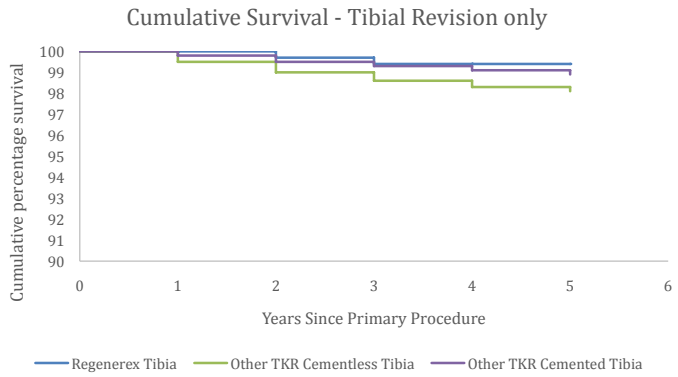
Curve 1 Kaplan Meier Curve – Survival of entire implant



In comparison to other cementless implants using any revision procedure as an end point our series showed slightly higher survival (Hazard ratio =1.68, CI 0.87-3.22, P=0.121), but this was not statistically significant. The absolute difference in favour of our study tibial component is 2.1% (95.5% vs. 97.6%). Similarly, comparison of our cementless tibial component with other cemented tibial implants showed higher survival but no significant difference at 5 years (HR=1.42, CI 0.74-2.73, P=0.293).

Hazard Ratio - In survival analysis the hazard ratio (HR) is the ratio of the hazard rates corresponding to the conditions described by two levels of an explanatory variable.

Curve 2 Kaplan Meier Curve – Survival of Tibial Implant

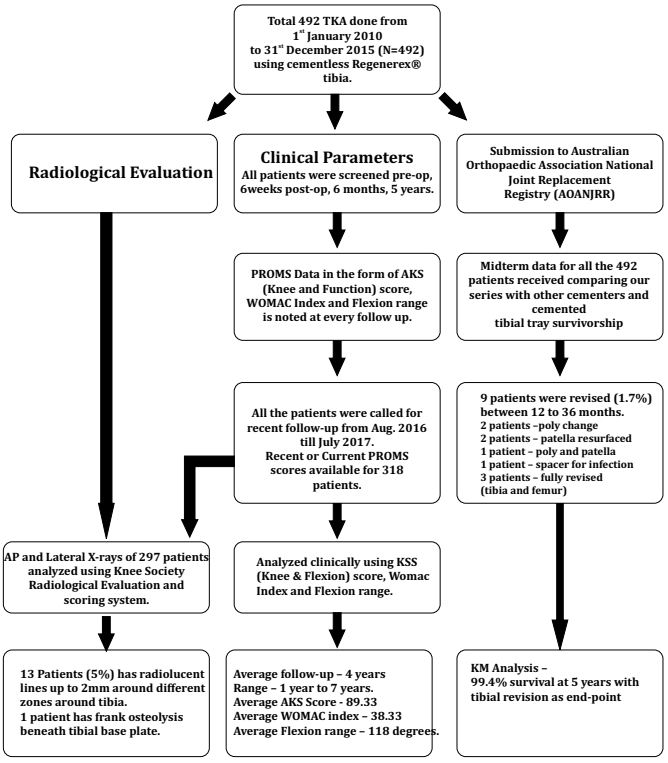


With revision of the tibial implant as an endpoint there is an absolute but non-significant difference in favour of our cementless tibial implant at 5 years. Other cementless implants compared to the Regenerex tibia produces a hazard ratio of 1.92 (CI 0.62-5.96, P=0.258). Cemented tibias compared to the Regenerex tibia yields a hazard ratio of 1.27 (CI 0.41-3.94, P=0.679).

Discussion

Our retrospective study of 492 cementless TKAs drew on comprehensive data from an ANJRR analysis and combined with a clinical review of patients returning for follow up during the study period. At most recent follow-up

Flow Chart of the Study



patients reported an average AKS knee score of 89, with 85% of knees being rated as excellent. This is consistent with the previous study comparing it to the PPS implant where it demonstrated excellent clinical outcomes in the short term. These results demonstrate a high rate of patient satisfaction with the study implant and are comparable to other implants with excellent survival rates [11].

Radiologic analysis of 297 patients demonstrated some evidence of lucent lines in only 5% of cases, most commonly in zone 4. One case demonstrated radiologically significant change with extensive osteolysis and subsidence at 12 months (fig. 7 and 8) but despite radiographic evidence of implant failure this patient had few symptoms and declined revision surgery.

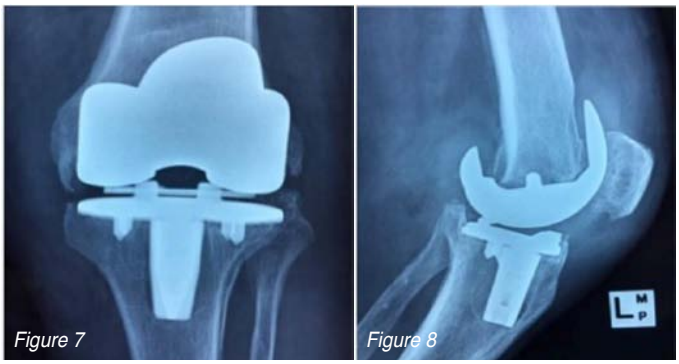


Figure 7 and 8: showing tibial subsidence due to early failure of biological ingrowth

The failure of early cementless implants is multifactorial, however can be largely attributed to early designs not achieving sufficient early fixation and the implant interface not adequately replicating trabecular bone structure to encourage long term bony ingrowth. These early implants were designed with beaded technology or fibre-mesh technology for their implant-bone interface, which had low-porosity. They also used screws to achieve early fixation. The first fully cementless implant using porous bead technology was the PCA TKA (Howmedica Corporation, Rutherford, New Jersey). It suffered from a high failure rate, most commonly due to tibial implant related failures. Moran et al reported a 19% failure rate at 5 years, predominantly due to collapse of the anteromedial portion of the tibial plateau [12]. Another study looking at the fibre-mesh technology in the Miller-Galante-I implant (Zimmer Inc, Warsaw, Indiana, USA), demonstrated aseptic loosening of the tibial component in 8% of cases, partial lucency around the tibial component in 53% of cases and 12% osteolysis rate around screws used for adjuvant fixation [13]. As well as aseptic loosening and osteolysis, stress shielding and polyethylene wears and patellar failures all plagued early implant designs [14,15].

After catastrophic failure of earlier cementless designs, screw-based fixation has been replaced by pegged tibial designs, eliminating screw-holes and providing an increased surface area for implant fixation, while simultaneously removing potential points where osteolysis can occur due to polyethylene debris entering cancellous bone surfaces [16,17].

Improved surface design, and the addition of Hydroxyapatite coating have yielded excellent results with several cementless designs [18]. The Natural Knee (Zimmer Inc., Warsaw, Indiana, USA) with a cancellous-structured titanium implant yielded a 95.1% survival rate for the tibial implant [19]. More recently, there has been the introduction of highly porous titanium and tantalum-based implant interfaces, which replicate both the porosity and compressive strength of cancellous bone.

Dunbar et al. [20] reported on early clinical and radiostereometric (RSA) analysis results comparing cementless trabecular metal tibia with conventional cemented tibia. They reported no revisions or failure at 2years. RSA helped in measuring the migration of the tibial component. It suggested migration of trabecular metal group during initial post-operative period and stabilised by one-year period.

Niemelainen et al. [21] of the Finnish Registry reported on revision and re-operation data for cementless trabecular metal tibia by patient age. Three categories i.e. age <55, 55 to 65 and age>65 showed 97%survival, revision for aseptic loosening being the end point.

Minoda et al. [22] reported 6-year follow-up in a matched cohort comparing cementless trabecular metal tibia with conventional cemented tibia. They have used Dual Energy X-ray absorptiometry in conjunction with plain radiographs for assessment of bone density and implant migration. They reported bone density in proximal tibia well preserved in trabecular metal group and same durability as cemented tibia.

The implant examined in our study represents another new baseplate technology, using highly porous titanium. Porous titanium offers benefits of a high coefficient of friction to stop early movement and a high porosity and biocompatible scaffold to encourage early bone growth. This is supported by a recent paper, evaluating the bone remodelling around this implant, demonstrating an increase in bone mineral density below the lateral plateau, and no change below the medial plateau [23].

There is limited published data examining the outcomes of this prosthesis specifically and include a RCT comparing the Vanguard Regenerex implant to a Vanguard Porous Plasma Sprayed (PPS) implant [24] in 61 patients with follow-up including RSA up to 24 months. The Regenerex implant had a statistically significant higher subsidence rate at 24 months on RSA, but lower migration rate between 12 and 24 months. There was no difference in clinical outcomes scores at 4 years and no implants in either arm required revision. This study suggests the tibial prosthesis provides a stable migration pattern with good clinical outcomes scores in the short term but did not perform any better than an older established implant [25]. The study was also slightly underpowered as only 21 patients in the PPS group and 22 in the Regenerex group completed follow-up.

In these series, survivorship of the tibial Implant is excellent with a survivorship of 99.4% at 5.9 years based on a comprehensive ANJRR data analysis. Three revisions of the tibial implant were performed, in each case part of revision of the entire TKA (femoral and tibial implants). One revision was for infection (fig. 9, 10), one for pain and one

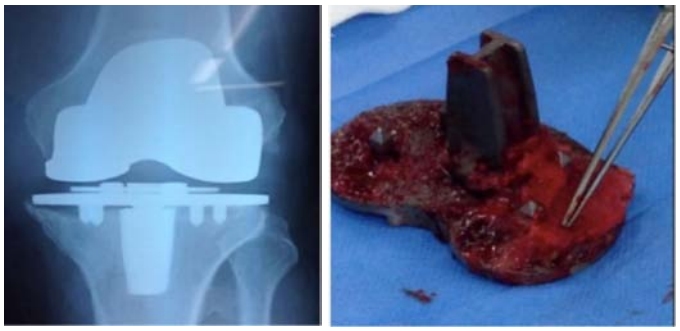


Figure 9 and 10 showing osteolysis on medial side under tibia (zone 1, 2) and retrieval of same tibia for infection showing good ingrowth on lateral side

for loosening/lysis. Survivorship with tibial aseptic loosening as an endpoint is 99.8%.

Comparison of this cohort with ANJRR data demonstrates excellent survivorship, comparable to cemented TKA which still remains the gold standard. Time-matched comparisons with revision for any reason as an endpoint between TKR with cemented tibias and this cohort produced a Hazard Ratio (HR) of 1.42 (CI 0.74-2.73, P=0.293), demonstrating a non-significant trend in favour of the study tibial tray. Comparison with other cementless tibial TKA vs. this cohort had an HR of 1.68 (CI 0.87-3.22, P=0.121) again demonstrating a non-significant trend favouring this implant. Comparison using tibial revision as an endpoint demonstrated similar non-significant trends in favour of this implant with hazard ratios of 1.27 (0.41-3.94, P=0.679), 1.92 (0.62-5.96, P=0.258) for cemented tibias and cementless tibias.

There are very few studies reporting on clinical outcome and survivorship of the Regenerex implant and most of them are underpowered. This study combines clinical outcome, radiological assessment along with registry-analysed data for the enrolled cohort with no exclusion criteria.

Limitations of the study

Being a retrospective study with data collected prospectively, there is a potential for cofounding bias due to -

- Incomplete data set due to difficulties in having patients return for clinical follow up or return to have follow up x-rays particularly if they have no symptoms. A more complete data set of outcome scores and radiographic analysis was aimed for to match the complete ANJRR analysis.
- Radiographic evaluation of whole cohort was not done as all patients did not attend follow-up during study period or failure to respond to mailout request.
- Patient selection criteria might be different for other series or in data provided by ANJRR.

Conclusion

In conclusion, this is an early to mid-term follow up study reporting on survivorship for a highly porous titanium tibial cementless implant used consecutively in all patients without exclusion criteria. It provided reliable results (clinical and radiological) and durable fixation with PROMS data reflecting a 90% good/excellent result and a 5.9-year tibial tray survivorship of 99.4% as per the ANJRR analysis. It is too early to predict that this highly porous coating of tibial implant will contribute to a long-term survivorship in cementless TKA. Another study is underway aiming to answer the questions whether these results are maintained at over 10 years.

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AUTHOR AFFILIATIONS

1 Dr Smit Shah DNB Orth, M.S. Orth, D.Orth
Consultant Orthopaedic Surgeon, Nanavati Superspeciality Hospital, Vile-Parle (W) Mumbai

2 Nicholas Coulshed MBBS (Hons I)
Conjoint Associate Lecturer UNSW, South Western Sydney Clinical School, NSW, Australia

3 Dr Rami Sorial FRACS, FAOrthA
Associate Professor and Head of Department, Orthoapedics, Nepean Hospital, Derby St, Penrith, NSW 2750

(Direct inquires to Smit Shah, drshahsmit@gmail.com)

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Intravenous versus Intra-Articular Tranexamic Acid in Primary Total Hip Arthroplasty: A Prospective Randomised Double Blinded Non-Inferiority Trial

Hasan, A [1]; Campbell, D [1,2]; Lewis, P [1,2]

Abstact

Background: Tranexamic acid (TXA) has been shown to be effective in reducing post-operative blood loss after hip replacement surgery. Clinicians can be reluctant to administer intravenous (IV) TXA to high risk patients and intra-articular (IA) administration has been proposed as an alternative mode of delivery. This study was conducted to compare the efficacy of IV versus IA administration of TXA.

Methods: This prospective, double blinded, randomised non-inferiority trial, compared 69 patients undergoing primary total hip arthroplasty (THA) who received either 3 doses of 15mg/kg of IV TXA or 3 g of IA TXA after capsular closure. The primary outcomes were change in Hb and the rate of blood transfusion. The secondary outcome was the rate of VTE.

Results: The mean haemoglobin level change from pre-operative to day 1 post-operative for the IV group was 26.7g/L and for IA group was 27.3g/L. No statistically significant difference was detected between the two groups (p=0.82). No patients required a transfusion or developed a VTE.

Conclusions: IA administration of TXA can be equally effective as IV in the reduction of blood loss and the prevention of post-operative anaemia in primary THA.

Background

Tranexamic acid (TXA), an antifibrinolytic agent that has been in clinical use since the 1960s, has become commonly used in orthopaedic surgery over the last decade, often as a component of a multimodal blood loss management strategy. Post operative anaemia is common following hip arthroplasty surgery with some studies reporting transfusion rates of 24.4% prior to the introduction of TXA [1]. Allogeneic transfusions are associated with complications including immunosuppression, perioperative infections and transfusion-related reactions [2,3]. Among patients with acute coronary syndromes, there is an increased risk of myocardial infarction and death [4,5]. Furthermore, anaemia may slow a patient's postoperative rehabilitation and prolong the length of hospital stay with additional costs [6].

Intravenous (IV) administration of TXA during arthroplasty surgery has been shown to decrease peri-operative blood loss, thereby reducing transfusion rates [7-10]. The decreased transfusion requirements and length of stay is cost effective and the routine use of TXA is recommended [11,12].

Keywords: *Tranexamic Acid, Hip Arthroplasty, Intravenous, Intra-Articular, Topical, Blood Loss*
Level of Evidence: *II*

The proposed advantages of a single dose IA (intra-articular) TXA administration include targeted therapeutic delivery with lower plasma concentration of TXA [13] potentially mitigating the risk of systemic adverse events and eliminating the requirement for repeated post-operative IV administration. Common medical conditions such as previous venous thromboembolism, renal impairment, cerebrovascular and myocardial disease preclude universal administration of IV TXA despite no evidence of risk to these patients [14]. This population with medical co-morbidities would benefit from the prevention of post-operative anaemia.

IA administration of TXA has been compared to IV use in total hip arthroplasty with variable results [12,15,16]. North et al and Xie et al observed that IA was not as effective as IV administration at reducing post-operative haemoglobin drop [12,16]. However, all 3 studies observed equal transfusion rates amongst the IV and IA cohorts [15]. All three studies used only a single dose of IV TXA. It is standard at our institution to give 3 doses at 8 hourly intervals, a multi-dosing approach which has been associated with improved effectiveness [7]. Given the uncertainty in the literature, this study aims to confirm if IA can be an effective and equal substitute for IV multi-dose administration.

The purpose of this prospective, randomised non-inferiority trial was to compare the efficacy of intravenous (IV) versus intra-articular (IA) administration of TXA in patients undergoing primary total hip arthroplasty by comparing the post-operative haemoglobin (Hb) change and transfusion requirement.

Materials & Methods

Patients

The study design was a prospective double blinded, randomised non-inferiority trial. Between June 2016 and October 2017, patients were recruited from Wakefield Orthopaedic Clinic, a metropolitan private hospital. All patients undergoing primary total hip arthroplasty for osteoarthritis were included. Independent Ethics Board approval was granted from the Calvary Health Care Adelaide Human Research Ethics Committee (Ref no. 16-CHREC-F001) and the trial was registered with the Australian New Zealand Clinical Trials Registry (ACTRN 12616000907448).

Exclusion criteria included those with acquired defective colour vision, previous subarachnoid haemorrhage, active intravascular clotting, or hypersensitivity to TXA (which are the product specified contra-indications), as well as those with a hypercoaguable tendency (history of arterial or venous thromboembolic disease such as CVA, DVT or PE, or fibrinolytic disorder requiring anti-fibrinolytic treatment), coagulopathy (PLT <150, INR >1.4) or cognitive impairment. Patients on continued anticoagulation agents were excluded to eliminate this confounding factor. Patients with renal impairment (creatinine >120mmol/L) were also excluded to keep the administered dose the same for all patients. The exclusion criteria was based on previous similar studies investigating the effectiveness of TXA in order to produce a comparable cohort.

A consistent blood management protocol was used. The protocol included pre-operative Hb assessment and optimization if required. All patients were advised to cease anti-inflammatory medications and health supplements ten days prior to surgery. Spinal anaesthetic was used with normotensive or hypotensive control. Normothermia was maintained. TXA was administered to all patients at 15mg/kg approximated to 1g aliquots which translated to a total dose of 3g for all patients. Post operative Hb was measured on the morning the day after surgery. We adhered to an evidence-based transfusion protocol, whereby patients were transfused if they had a Hb <70g/L, or Hb <100 g/L with symptoms of cardiovascular or cerebrovascular ischemia [17,18].

All surgeries were performed by 2 experienced arthroplasty surgeons using their usual surgical technique and implant. Drains were not used. VTE prophylaxis included bilateral pneumatic calf compression devices and 100mg Aspirin commencing day 1 post-operative for a minimum of four weeks. Median length of stay was 4 days for both surgeons. Both surgeons had similar surgical techniques and post-operative protocols.

Randomisation and Administration

Allocation was determined using an electronic randomizer in blocks of 20 and envelopes were then numbered consecutively. Envelopes were opened by the anaesthetist in the operating theatre who prepared the treatment and placebo IV and IA solutions. Patients were assigned to one of two groups; the IV group received IV TXA 15mg/kg 8 hourly for three doses commencing at induction of anaeasthesia plus a placebo of 40ml normal saline injected intra-articular in a single sterile syringe. The IA group received 3g of TXA mixed with 40ml normal saline in a single sterile syringe that was administered IA plus a placebo of similar volume IV normal saline. IA application was performed by injecting the 40mL solution intra-articular after capsular closure. The second and third doses of IV solution (TXA or saline) was prescribed by the anaesthetist and administered by the ward nurses. The surgeon and patient remained blinded throughout this process.

Outcomes

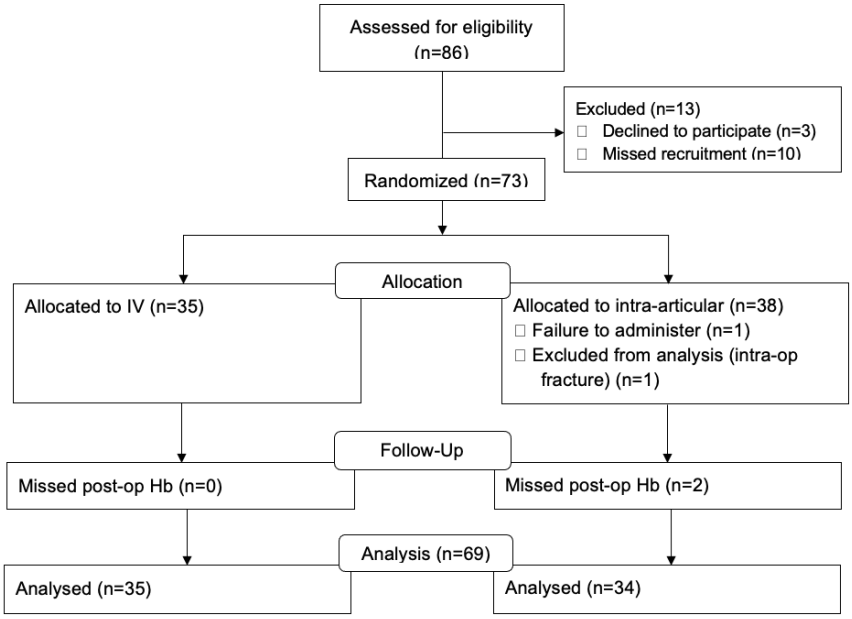
The primary outcome was the Hb change comparing preoperative Hb and day 1 post-operative Hb. Secondary outcomes were the rate of transfusion and the incidence of inpatient venous thromboembolism. A restrictive investigation protocol was routine practice and patients were investigated with limb venous ultrasonography if they demonstrated clinical symptoms and signs of VTE.

Statistical Analysis

Sample size was calculated using a two-sample means test, setting a non-inferiority margin for Hb change of 8g/L with a standard deviation of 12.6g/L. These parameters have been used by others [19,20]. In order to achieve 90% power at the 0.05 level of significance, 32 patients per study arm were required.

Unadjusted and adjusted linear regression models were performed to detect a statistically significantly different (P value <0.05) change in Hb. Fisher's Exact Test was used to find an association between TXA treatment group and transfusion requirement.

Figure 1. Participant flow



Results

Patient Cohort

Of the 86 patients deemed eligible, 13 patients were excluded and the remaining 73 patients were randomised to either IV or IA application (Figure 1). The final analysis consisted of 35 patients in the IV and 34 patients in the IA treatment arm.

The patient demographics and surgical parameters are listed in Table 1. The two cohorts were similar. The average age was 67.6 years. The majority of hip arthroplasties were uncemented, performed via a posterior approach.

Haemoglobin change

There was a mean Hb drop of 26.7g/L for the IV group and 27.3 g/L for the IA group (Table 2). An unadjusted linear regression of Hb change versus TXA treatment group, adjusting for Hb pre-surgery, did not show a statistically significant difference in Hb change between the 2 cohorts (P value=0.7665). An adjusted linear regression of Hb change versus TXA treatment group, adjusting for Hb pre-surgery, age, BMI, surgeon, approach, stem fixation and operation time was performed. Adjusting for these variables, there was no statistically significant difference

Table 1: Baseline Characteristics of Study Population

	IV (n= 35)	IA (n=34)	Total (n=69)
Patient Demographics			
Male	14	14	28 (41%)
Female	21	20	41 (59%)
Average age	70.0 ± 10.2	65.2 ± 10.5	67.6 ± 10.5
BMI	27.7 ±	29.1 ± 6.1	28.4 ± 5.5
ASA			
1	2	3	5 (7%)
2	20	16	36 (52%)
3	13	14	27 (41%)
4	0	1	1 (1%)
Surgical Parameters			
Surgeon 1	25	26	51 (74%)
Surgeon 2	10	8	18 (26%)
Posterior	33	30	63 (91%)
Anterior	2	4	6 (9%)
Uncemented	30	30	60 (87%)
Cemented	5	4	9 (13%)
Average op time			
(mins)	72.6 ± 18.4	74.5 ± 15.1	73.5 ± 16.8

Table 2: Outcomes of the Two Groups – Mean and Standard deviations

	IV (n=35)	IA (n=34)	P value
Pre-op Hb (g/L)	138.1 ± 10.5	137.6 ± 12.0	0.86
Post-op Hb (g/L)	111.5 ± 13.3	110.3 ± 14.7	0.73
Hb drop (g/L)	26.7 ± 12.2	27.3 ± 11.8	0.82
Transfused	0	0	0.00
DVT	0	0	0.00

in Hb change between the two treatment groups (P value=0.6298).

Transfusion and Venous thromboembolism rate

None of the patients in this study required a transfusion. Additionally, none of the patients developed an inpatient venous thromboembolism.

Discussion

We found that IA TXA was equally effective as IV administration in total hip arthroplasty in restricting post-operative blood loss as measured by drop in Hb. In this study a single 3g dose of IA TXA administered during surgery was not inferior to the three separate 15mg/kg doses of IV TXA. There was no clinically significant difference in the post-operative haemoglobin decrease, post-operative haemoglobin value or transfusion requirements.

Strategies to limit blood loss associated with arthroplasty surgery are increasingly used by arthroplasty surgeons and TXA is commonly used for coagulation cascade manipulation [1]. Multiple studies have been published with universal demonstration of its clinical efficacy, however the ideal route and timing of administration are less clear. IA administration is a potential option to mitigate systemic TXA effects. Wong et al found the plasma concentration of TXA after topical application was 70% less than the same dose of TXA administered by IV injection [13]. While there is good evidence to support the use of TXA in all patients, with no evidence of adverse effects, there is some reluctance for routine use of IV TXA amongst clinicians less familiar with the data due to theoretical concerns of a prothrombotic effect.

No clinical studies, meta-analyses or registry studies have demonstrated an association with an increased risk of VTE or arterial thrombosis [21] but many clinical trials have excluded patients considered to be of increased risk. Whilst there is no data to suggest an increased risk with universal TXA use [14], the converse is less clear: i.e. whether there is an increased risk of medical complications by withholding TXA in the 'high risk' patient group. Two recent clinical studies addressing the use of TXA in the 'high risk' group have not demonstrated an increased complication rate [22,23]. IV TXA was not associated with an increased risk of VTE in patients with a history of VTE [22]. Further, a Danish registry study has demonstrated not only a reduced risk of arterial thrombosis (myocardial infarction and ischaemic stroke), but reduced rate of all-cause mortality, if TXA is still administered in these patients [24].

Despite the paucity of evidence of harm, Patel et al [25] observed that TXA was considered a contraindication in over 25% of patients. Further, Ho et al [26] observed 6% of patients had a failure of a universal administration protocol citing concern from clinical staff (such as anaesthesia) and were denied TXA treatment.

There are limited prospective studies assessing the efficacy of intra-articular TXA in hip arthroplasty patients and comparison of these is difficult due to the variety of doses and dosing regimens used. Konig et al and Wei and Wei used three separate 1g injections instilled after acetabular preparation, after femoral broaching and before/after fascial closure [15,27]. Wei and Wei reported 3g IA was equally effective as the same dose IV at reducing total blood loss (958 ml [IV] vs 963ml [IA]) and the transfusion rate (5.94% [IV], 5.88% [IA]), but did not report on the effect on Hb change [15]. North et al used a lower dose of 2g TXA, and bathed the wound with TXA after component placement and observed an inferior blood sparing effect when compared to the IV group (Hb drop 3.1g/dL [IV] vs 3.5g/dL [IA], transfusion rate 11% [IV] vs 18% [IA] [12]. Xie et al observed a significantly smaller Hb change in a 1.5g IV dose group compared to 3g IA group (2.98g/dL [IV] vs 3.36g/dL [IA]) [16]. They also showed a combination of 1g IV and 2g IA administration was more effective than either IA or IV in isolation (Hb drop 3.89g/dL[IV and IA]) [16]. Similarly, Yi et al found that a combination of IV and IA administration was more effective that IV delivery alone at reducing postoperative bleeding and the transfusion rate (16% [IV] vs 2% [IV and IA] [28].

This study found an overall smaller Hb change and transfusion rate across both treatment groups compared to previous studies which may be the result of the effectiveness of our strict blood management protocol. Unlike North et al and Xie et al, we found IA application was not inferior to IV in preventing post-operative anaemia.

This study design differs from others being a non-inferiority trial comparing a single 3g TXA IA injection following capsule closure (a contemporary dosage regime) to three 15mg/kg IV doses (the manufacturer recommended regime). This is also consistent with the method used in a study of knee arthroplasty patients (3g TXA IA compared to three divided IV doses) which also demonstrated no difference in blood loss [29,30].

We acknowledge the limitations of this study. This study was powered to detect a primary outcome of the day 1 postoperative fall of Hb level setting a non-inferiority margin of 8g/L that was validated with a post hoc analysis. The requirement for blood transfusion could not be studied due to the low frequency of this event (as anticipated with the inclusion of TXA and a contemporary blood manage-

ment protocol) [17]. Similarly we did not design the study to detect medical or surgical complications and we did not compare clinical outcomes. Our results on VTE rate are consistent with previously published data; it is a relatively uncommon event and difficult to demonstrate a statistically significant association with any route of TXA administration.

Conclusion

This study shows IA administration is an effective alternative to IV administration for TXA. IA administration may have a particular place for patients where there are concerns about possible systemic side-effects from IV use.

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AUTHOR AFFILIATIONS

Afsana P Hasan, MBBS[1]; David Campbell, MBBS, PhD, FRACS, FAOrthA[1,2]; Peter Lewis, MBBS, FRACS, FAOrthA[1,2]

1 Centre of Orthopaedics and Trauma Research, University of Adelaide, Adelaide, South Australia, Australia

2 Wakefield Orthopaedic Clinic, Adelaide, South Australia, Australia

(Direct inquires to Afsana Hasan, afsana.hasan@gmail.com)

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Low Transfusion Rate Attainable in Anterior Approach Total Hip Arthroplasty Utilizing a Modern Protocol

Gondusky, J[1]; Campbell, B[2]; Coulson, C[3]

Abstact

Background: Transfusion is a known risk of total hip arthroplasty (THA). It has been associated with a multitude of medical complications and increased cost. Prior studies report transfusion rates associated with THA, with wide variation, but most cannot differentiate the surgical approach utilized. The anterior approach (AA) for THA has been associated with increased operative time, complications, and blood loss, but little data exists regarding the actual transfusion rate associated with the approach.

Methods: We performed a retrospective review of 390 consecutive, elective, primary unilateral AA THA procedures. Patient demographic, clinical and perioperative data was analyzed. A modern perioperative pathway, including a simple protocol to limit blood loss, is defined.

Results: The group consisted of a typical inpatient arthroplasty population, with wide ranges of age, body mass index (BMI), and health status. The average age was 64.05 years (+ 10.67, range 27-94). BMI averaged 29.76 kg/m2 (+ 5.98, range 16-47). The majority of patients were American Society of Anesthesiologists (ASA) class 2 (45.6%) or 3 (50.3%), with 10 patients ASA 4 (2.6%). Average preoperative hemoglobin was 13.48 g/dL (+ 1.47, range 9.1-18.2). Operative time averaged 91.22 minutes (+ 14.2). 83.3% of patients received a spinal anesthetic. Most patients were discharged on postoperative day one (93.1%) to home (99%). Estimated blood loss averaged 264mL (+ 95.19, range 100-1000). No patient required perioperative transfusion or readmission for symptomatic anemia within 30 days postoperative.

Conclusion: A modern protocol we utilize and define is capable of limiting blood loss and transfusion risk in anterior approach total hip arthroplasty.

Background

Substantial blood loss and the resultant need for perioperative transfusion is a known risk of most major surgical procedures, including total hip arthroplasty (THA). Transfusion is associated with risks to the patient, and significant cost to the healthcare system [1-6]. Mitigating the risk of this complication should be one of the goals of successful primary THA.

Wide variation exists in the reported rate of transfusion in primary, elective THA. Modern studies report transfusion rates between 0 – 39.2% [1-4,6-20]. In large scale studies of the topic, wide variation is noted amongst hospitals. This is attributed to differences in procedural volume and length of stay [6,15]. The most recent, large patient volume analyses, demonstrate a transfusion rate range from 11.8 – 22.2% [4,6,10,12,15]. Notably, some of these studies highlight a concerning trend toward an increased rate of transfusion over time [4,6].

Transfusion is not without risk. Hemolytic and allergic

Keywords*: anterior approach; direct anterior; primary total hip arthroplasty; total hip arthroplasty; transfusion; blood loss*
Level of Evidence*: IV, Retrospective Case Series*

reactions, circulatory overload, acute lung injury, and disease transmission have been reported [1-3]. In addition, transfusion has been associated with immunomodulatory effects and increased risk of perioperative infection, including surgical site and respiratory infection. In joint arthroplasty, transfusion has been associated with increased hospital length of stay (LOS), likelihood of discharge to a skilled nursing facility (SNF), mortality, and cost [1,2,4-6]. Estimates of hospital cost associated with a single transfusion in knee arthroplasty patients was found to be $1777 [20]. In an era where quality outcomes have been linked to payment via bundled care arrangements, and there is increased movement of THA to outpatient centers without transfusion capability, it is important to avoid this medical, logistical and financial risk.

The anterior approach (AA) for THA has been associated with increased operative time, blood loss, and complications, especially during the procedural "learning curve." [21-30]. A continued increase in operative time and blood loss with AA THA, relative to the posterolateral approach, has been suggested even beyond the learning curve [31]. The blood loss reported in series outside of the learning curve for AA THA averages 320 – 463mL, with a range of 50 – 2000mL [28,31-34]. Learning curve studies reveal a reported maximum estimated blood loss (EBL) range up to 2718 mL [22]. While self-reported EBL can be an unreliable and subjective metric, transfusion rate is objective and has been shown to be associated with increased perioperative risk and cost, but it too can be confounded by autologous pre-donation, patient selection bias, or the use of variable transfusion triggers [1-6,20]. Transfusion data is rarely reported with information regarding the approach utilized for elective THA. No large-scale study exists which reports transfusion data for AA THA. Smaller studies available are confounded by autologous transfusion [24,35] or selection bias [34]. Given data that suggests blood loss is higher with the AA, it could be suspected that the AA THA transfusion rate may be higher than that reported regardless of approach, but little objective and unbiased data is available.

Determining the rate and preventing the occurrence of transfusion in AA THA is important to improve patient care and quality outcomes, move AA THA toward the outpatient setting, and minimize cost. The goal of this study was to determine the rate of transfusion in a consecutive series of AA THA patients typical of an inpatient setting. We also attempt to define a simple, modern protocol to reduce perioperative blood loss and transfusion risk about AA THA.

Materials and Methods

Once institutional review board approval was obtained, we queried the hospital's electronic medical records to identify consecutive patients who underwent primary, unilateral, elective THA via the anterior approach (AA) by a single surgeon between January 2018 and November 2019. A total of 390 cases were identified. No patients were excluded. Conversion and revision cases were not included.

The surgeon is a high volume, fellowship trained arthroplasty surgeon beyond the learning curve, with no strict contraindications to AA THA (no primary THA via an alternative surgical approach was performed during the study period). All surgeries were performed on a table allowing leg manipulation (hana, Mizuho OSI, Union City, California). The surgical technique utilized is as per that described previously [36].

All patients underwent standard preoperative lab testing, including hemoglobin/hematocrit (Hg/HCT) and coagulation levels. No blood pre-donation, or preoperative iron or other supplemental medical treatment was utilized. There was no absolute exclusion criteria based on preoperative anemia. Standard discontinuation of preoperative anticoagulants was done according to specialist consultant, primary care, or anesthesia recommendations. Preoperative primary care clearance was obtained. Specialist clearance was obtained as needed, most commonly for significant cardiac history.

Intraoperatively, no blood collection or autotransfusion device was utilized. Hemostasis was obtained with standard bovie electrocautery, with meticulous hemostasis the goal at each surgical plane. The specific surgical steps deemed most important to minimizing blood loss are defined within Table 1 and the Discussion section.

Use of spinal anesthesia was preferred and planned. All patients received intravenous (IV) tranexamic acid (TXA), one gram at the initiation of the case and one gram IV during final closure. Intravenous dexamethasone (10mg) was also given at the start of the procedure to aid in control of pain and nausea. This was withheld in insulin dependent diabetic patients or those with high preoperative blood sugar if felt optimal, in coordination with the anesthesia team. No specific hypotensive anesthesia protocol was employed. Generally, hypotensive anesthesia was attempted and preferred, but logistically this varied by anesthesia provider and patient. At the conclusion of the case, a total of 90 mL mixture of ropivacaine (60mL, 0.5%) and ketorolac (1cc, 30mG/mL), diluted in normal saline, was instilled into the hip capsule and subcutaneous tissues. Standard perioperative antibiotics were given. Postoperative DVT prophylaxis was predominantly aspirin (ASA),

81 or 325 mg twice a day for four weeks, started within hours postoperatively. No drains were utilized. Closure proceeded with capsule, fascia, subcutaneous and skin. Skin closure was with absorbable subcuticular suture and a skin glue strip, followed by application of a water impermeable dressing. The perioperative aspects felt most important to limit excessive blood loss and transfusion are summarized in Table 1.

Table 1. Protocol Steps to Minimize Blood Loss and Transfusion Rate in Anterior Approach THA

Preoperative	• Optimize preoperative hemoglobin • Ensure preoperative coagulation labs normal, check LFTs if indicated • Discontinue NSAIDs and anticoagulant medicines according to guidelines and specialist recommendations
Intraoperative	• Intravenous and/or topical TXA use • Neuraxial anesthesia favored over general endotracheal • Standard bovie electrocautery • Meticulous surgical hemostasis* • Bone wax use on the cut femoral neck, as needed • Blood pressure management • Minimize operative time • Avoid drain use • Adequate preoperative and intraoperative hydration
Postoperative	• Choose an optimal anticoagulant agent • Nursing-based fluid resuscitation protocol for hypotension • Utilize evidence-based transfusion triggers [37]

LFTs, liver function tests; NSAIDS, nonsteroidal anti-inflammatory drugs; TXA, tranexamic acid
**see notes in the article text regarding sequential surgical steps recommended to achieve optimal hemostasis*

Postoperatively, all patients received internal medicine hospitalist consultation for management of medical issues. These providers and the surgical team assessed the patient clinically for concern of symptomatic hypotension. Routine postoperative labs were not ordered. Parameters for the treatment of hypotension were standardized and allow for the nursing staff to administer 500mL fluid boluses at blood pressure thresholds. Our transfusion triggers are as recommended by established clinical practice guidelines, with consideration of transfusion for Hg of 8g/dL or less, or for symptoms of chest pain, orthostatic hypotension, tachycardia unresponsive to fluid resuscitation, and in the setting of congestive heart failure [37]. Any of these scenarios were discussed in conjunction with our hospitalist colleagues to determine if transfusion was deemed in the best interest of the patient.

A standard multimodal pain control pathway was followed, utilizing local ice, oral acetaminophen, IV nonsteroidal anti-inflammatory (NSAID), IV dexamethasone (10mg AM POD #1), and limited narcotics. NSAIDs were withheld in patients with chronic kidney disease (CKD), or based on the judgement of the treating team, if gastrointestinal bleeding risk was considered higher than average. This variable was not discretely recorded.

Patient demographic, clinical and perioperative data were collected, including the following: age, gender, height, weight, body mass index (BMI) , American Society of Anesthesiologists Physical Status (ASA PS) classification, preoperative hemoglobin and hematocrit, estimated intraoperative blood loss, operative time, anesthesia type, length of hospital stay (LOS), perioperative (within 30 days) transfusion or readmission for symptomatic anemia, venous thromboembolic event (VTE) prophylaxis utilized, and discharge disposition.

All statistical analyses were performed using standard software (Microsoft Excel, vers 16.36, 2020). Continuous variables were described using means and standard deviations. Categorical variables were summarized using frequencies and percentages.

Results

During the study period, 390 consecutive elective primary AA THA were performed by a single surgeon and included in the data analysis. Patient age, gender, height, weight, BMI, and ASA class are reported in Table 2. A wide range of patient age, BMI and ASA score is seen, reflecting a heterogenous population of surgical inpatient candidates. This includes some at higher risk for periop-

Table 2. Patient Demographics

Number of patients (n)			390	
Age (mean + SD, years)			64.05 + 10.67 (range 27 – 94)	
Sex (n [%])				
Male			171 (44%)	
Female			219 (56%)	
Height (mean + SD, inches)			67.09 + 3.88	
Weight (mean + SD, kilograms)			86.56 + 19.71	
BMI (mean + SD, kilograms/meters [2])			29.76 + 5.98 (range 16 – 47)	
ASA PS Class	**1**	**2**	**3**	**4**
(n [%])	7 (1.8)	178 (45.6)	196 (50.3)	10 (2.6)

SD, standard deviation; BMI, body mass index; ASA PS, American Society of Anesthesiologists Physical Status Classification System

erative complication given the extremes of age, BMI and ASA score. Preoperative and operative data is presented in Table 3.

No patient required a blood transfusion, or readmission for symptomatic anemia, within the first 30 days postoperative. Preoperative Hg averaged 13.48 g/dL. The lowest preoperative Hg (9.1 g/dL) was seen in a patient cleared by their surgeon after lung wedge resection. He underwent routine THA, had no postoperative labs checked and did not require treatment of symptomatic hypotension or require transfusion perioperatively.

Blood loss was surgeon-reported in consultation with the anesthesia team. This averaged 263.88 mL. Three patients had blood loss over 500 mL. Two were large, obese and technically challenging males with prolonged operative times. One of these, who recorded the maximum reported blood loss of 1000 mL, was large (58-year-old male with BMI 40.84) and had massive destructive change. Spinal anesthesia was utilized. The prolonged operative time (109 min) and noted slow ooze from bone preparation was felt to be the reason for the excessive blood loss. His preoperative Hg was 13.3 and he did have postoperative labs checked. His postoperative day one Hg was 10.9. He remained asymptomatic and did not require treatment, being discharged on postoperative day (POD) #1. The second large male was a similar scenario: 45-year-old male, 195.6cm and 181.4kg, BMI 47.43, GETA, operative time 174 min, EBL 800cc, and DC POD #1 without issue. The remaining patient with reported EBL over 500mL was an elderly female with chronic obstructive pulmonary disease (COPD), ASA 3 and with poor bone quality. Spinal anesthesia was utilized, and EBL was 600mL. She did not have postoperative labs checked and did not require treatment, with uneventful discharge POD#1.

Table 3. Perioperative and Operative Data

	Mean	Std Dev	Minimum	Maximum
Preop Hg (g/dL)	13.48	1.47	9.1	18.2
Preop HCT (%)	40.52	4.05	26.6	53.20
Operative Time (minutes)	91.22	14.2	61	176
EBL (mL)	263.88	95.19	100	1000
Transfusion (n)	None required within 30 days postoperative			
Anesthetic (n [%])	**Spinal**	**General**		
	325 (83.3)	65 (16.7)		
VTE Prophylaxis (n [%])	**ASA**	**Other**		
	377 (96.7)	13 (3.3)		
LOS – Discharge Day (n [%])	**POD 0**	**POD 1**	**POD 2**	**POD 3-6**
	1 (<1)	363 (93.1)	14 (3.6)	12 (3.1)
Discharge Disposition (n [%])	**Home**	**SNF**		
	386 (99)	4 (1)		

SD, standard deviation; Hg, Hemoglobin; HCT, Hematocrit; EBL, estimated blood loss; mL, milliliter(s); VTE, venous thromboembolic; ASA, Aspirin; LOS, Length of Stay; POD, post-operative day; SNF, skilled nursing facility

Operative time as derived from the nursing record denotes incision until final dressing placed and shows an average of 91.22 minutes with a fairly narrow distribution (standard deviation +/- 14.20 minutes).

The majority of patients received a spinal anesthetic (83.3%). The cases in which spinal anesthesia was not utilized were due to patient request for general endotracheal anesthesia (GETA), failed attempt at adequate spinal block, or relative contraindication to use (high lumbar spinal fusion or timing of chronic anticoagulation cessation). Of note, mean EBL in patients receiving spinal anesthesia was slightly lower at 259.5 mL (standard deviation +/- 93.1 mL) versus 286.2 mL with GETA (standard deviation +/- 103.0). The majority of patients also received Aspirin for VTE prophylaxis (96.7%), and were discharged on POD #1 (93.1%) to home (99%). Most patients who received an alternative to aspirin for VTE prophylaxis were resuming a chronic anticoagulant.

Discussion

Excessive blood loss and transfusion are known risks of THA. Reported rates of transfusion in more recent, large studies range from 11.8 – 22.2% [4,6,10,12,15]. There is some evidence that the overall rate of transfusion is actually increasing [4,6]. These large studies do not qualify transfusion risk based on the approach utilized for THA.

The anterior approach for THA has been associated with increased operative time, complications, and blood loss relative to other approaches [21-30]. One would suspect an increased transfusion rate associated with the approach given this increased reported blood loss, but no data exists which demonstrates this clearly. Multiple series report blood loss associated with AA THA [21-28,31-34]. Only three studies were identified which report transfusion data [24,34,35]. Alecci et al compared results of

THA performed by the AA (n=221) versus a lateral approach (n=198). They reported a 19.5% rate of transfusion in the AA group, but this included patients who received either allogenic or autologous blood [35]. Woolson et al [24] noted a high complication and transfusion rate in the learning curve with the AA for five low volume surgeons. They reported a high mean blood loss (858 mL). They noted an average total transfusion of 2.4 units per patient with most receiving pre-donated blood (most received 1-3 units, average of 1.7 units). The overall transfusion rate is high but not reported, and confounded by autologous predonation [24].

Toy et al [34] present a modern study of 145 AA THA performed in an outpatient surgery center. They report a transfusion rate of 0.7% (1/145). They also note one patient with acute blood loss anemia that required overnight monitoring, but who did not require transfusion. This data is important in that it notes a low transfusion rate with modern AA THA at an outpatient center with a surgeon outside of the procedural learning curve. It adds to growing evidence that the procedure can be performed safely in this setting. The transfusion data in the study, however, is pertinent to the study population. It may not be translatable to the higher risk inpatient setting, as their patients were selected as acceptable candidates for outpatient THA. Their selection criteria included parameters of preoperative HCT > 30, age < 70, and BMI < 35. Their actual patient data reveal an average age of 55 years, and BMI of 29.7. They used a similar TXA protocol as the present study, as well as an albumin bolus during surgery [34]. Their results are comparable to our low rate of transfusion achievable with modern AA THA, but their selection criteria make the transfusion data less applicable to inpatient scenarios.

Understanding the risk factors for transfusion is important to limiting its occurrence. Studies have shown that in THA, increased transfusion rate has been associated with increased weight, lower preoperative Hg, increasing age, lower BMI, higher ASA score, longer operative time, higher surgical EBL, lower surgeon procedural volume, anesthetic type (neuraxial favored), African American race, Medicaid status, and surgery at smaller, rural and nonacademic centers [3,4,6,7,11,12,15]. Optimizing any of these modifiable risk factors could help minimize transfusion risk.

Transfusion carries significant risk to the patient, and financial detriment to the healthcare system. Patient risk can range from mild to, rarely, life-threatening, and has been well-documented and previously discussed [1-3]. The occurrence of transfusion in, specifically, joint arthroplasty has been linked to increased LOS, likelihood of discharge to a SNF, and increased cost [1,2,4-6]. Reported cost for a unit transfusion of blood ranges from $700 - $1,500 [38,39], and the impact of transfusion on overall admission cost at $1,731 and $1,777 in separate studies [4,20]. With transition to the outpatient setting, and bundled care arrangements attempting to link quality outcomes to cost, it is important to avoid this complication.

Following a simple, modern perioperative pathway we have shown the ability to minimize blood loss and the need for transfusion. The basics of this simple pathway emphasize good surgical technique, optimal anesthetic, and the adjunct use of tranexamic acid (TXA) (Table 1).

Surgical cautery devices have been designed to minimize blood loss, with some advanced bipolar sealer devices purporting a lower drop in Hg after THA [40]. We used a standard bovie electrocautery device. The anatomical sites of bleeding the surgeon has to take the utmost care to coagulate, in order of surgical procedural progression, include: isolation and cautery of the ascending branch and accompanying veins of the lateral circumflex artery; slow and meticulous release of the capsule at its attachment to the proximal femur (especially at the inferior neck where more robust vasculature can be present); upon neck cutting, careful attention to minimize past-pointing with the saw blade, causing posterior vascular injury; upon femoral head removal performed in-situ, levering of the head through manipulation of the corkscrew device medially and distally, thus allowing for visualization of the release and coagulation of the previously unobservable posterior capsular structures (as opposed to avulsion of this tissue from the head); after femoral head removal, attention focused to the posterior capsule where disrupted bleeders from the head removal process may be visualized and coagulated; bone wax placement on more aggressively bleeding cancellous bone at the site of the femoral neck cut; upon acetabular preparation, slow and meticulous foveal tissue removal with gentle traction and coagulation systematically; and overall rapid and efficient progression of all surgical steps. This efficiency is particularly important during acetabular preparation and femoral broaching. If bony bleeding occurs during these steps, it cannot be coagulated, and implantation of trial or definitive devices expeditiously can pressurize the bone to limit bleeding. As noted, occasionally, after the femoral neck cut, finger-pressurized bone wax is utilized to reduce bleeding from the femoral cancellous bone. This is primarily done to aid acetabular visualization, as blood can pool at the inferior acetabulum, but in situations with brisk bleeding from the femoral neck the practice can limit overall blood loss. This bone wax is removed at the beginning of the femoral preparation using a curette. A meticulous surgical technique cannot be overemphasized.

Neuraxial anesthesia has been shown to limit blood loss in THA [3,10,18]. In a study of 5,914 cases of both THA and TKA, Turcotte et al found a transfusion rate of 5.8% with GETA versus 1.6% for neuraxial (p<.001). They note that the proposed physiologic reason for this difference seems to be decreased arterial and venous blood pressure, as well as decreased peripheral blood pressure at the actual site of the surgical wound [18]. The use of TXA has also become standard of care for THA, with the American Association of Hip and Knee Surgeons (AAHKS) publishing endorsed, evidence-based, clinical practice guidelines for TXA use in total joint arthroplasty in 2019 [41].

This study is not without limitations. It is a retrospective chart review of electronic medical records, with the inherent limitations associated with such a review process. We recognize too that our EBL data is limited by the self-reported nature of this value. The value was surgeon self-reported with anesthesia team input, but we recognize that these values are never extremely accurate. In addition, it has been recognized that calculation of blood loss through preoperative and postoperative lab values provides a more precise way to account for both operative as well as "hidden" blood loss. Hidden blood loss is noted to account for 26 – 60% of total blood loss in hip and knee arthroplasty [3]. We did not routinely check postoperative labs, this not only prevented us from calculating blood loss, it also could have meant that patients with anemia were missed clinically. Nonetheless, we feel that this practice is consistent with most modern THA scenarios, and relevant to increasingly short LOS and cost containment measures (minimizing unnecessary lab draws). Given the overall case number, transfusion data, and lack of readmission for symptomatic anemia, we feel our protocol is supported.

Conclusion

Transfusion is a known risk in total hip arthroplasty. It has been associated with a multitude of medical complications, increased cost to the healthcare system, and logistical concerns in the outpatient setting. Little data exists regarding the transfusion rate in anterior approach total hip arthroplasty, although many reports suggest increased blood loss relative to other approaches. Our data supports the simple, modern protocol we present as capable of limiting blood loss and transfusion risk in anterior approach total hip arthroplasty.

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AUTHOR AFFILIATIONS

1 Dr Joseph Gondusky MD
Hip and Knee Arthroplasty Surgeon
Jordan-Young Institute, Virginia Beach, VA

2 Dr Benjamin Campbell MD
Thomas Jefferson University, Philidelphia, PA

3 Christian Coulson
Eastern Virginia Medical School, Norfolk, VA

(Direct inquires to Joseph Gondusky, josephgondusky@gmail.com)

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A New Cementless Total Hip Arthroplasty – A Multicentre Prospective Minimum 2 Year Follow-up Clinical Outcomes Study

Pandey, R[1]; Coffey, S[2]; Sorial, R[2]

Abstact

Background: Cementless implants were introduced approximately three decades ago in order to address aseptic loosening of cemented hip prostheses with the aim of early mobilisation, better functional result and bone stock preservation. The primary objective of this study is to introduce a new cementless HA coated implant and report its minimum 2 year follow up results.

Material & Method: This is a prospective, multi-centre, consecutive series, clinical outcomes study with 75 patients. Inclusion criteria for the study were age 21- 85 years, BMI <40, osteoarthritis of the hip.

Patients were operated using a standard posterolateral approach. The Paragon stem and the Global cup were implanted in a cementless method. Patients were reviewed at 6 weeks, 6 months and two years postoperative. At each visit AQoL 6D, VAS Pain, Oxford Hip Score were recorded. Post-operative X-Rays were reviewed at immediate post-operative, 6 months and two years.

Results: Mean duration of surgery was 63.1 min with range of 40-120 min. AQoL over time changed from pre-op mean 50.51 to a 2 year mean 35.06. Oxford hip score improved from pre-op mean of 19.93 (SD 8.13) to post-op 6wks mean 33.5 (SD 8.64) and plateaued at 41.3 (SD 6.75) at 6 months and 42.2(SD 6.28) at 2 years. VAS pain trajectories, showing a clear downward trend from pre-op to postoperative assessments. At a minimum 2 year clinical follow up there is a 100% survivorship of the Paragon stem and 98.7% survivorship of the total hip construct overall for any reason.

Discussion & Conclusion: The combination of Paragon stem and Global cup incorporates proven features of successful implants. The unique feature of lateral tension grooves and progressive neck dimension with dual offset options offers promising early results with early follow up of a minimum of 2 years and is a good cementless THA option.

Background

Total hip arthroplasty is a proven procedure for treatment of end stage debilitating hip disease. Since its inception implants have undergone various modifications in design and method of fixation.

The primary objective of THA is to provide a painless, mobile, stable hip with minimal limb length discrepancy. In addition to these short term goals, efforts have been made to prolong survivorship by modifying implant morphology, fixation methods and bearing surfaces. This is particularly relevant in the younger or high demand population.

Cementless implants were introduced approximately three decades ago in order to address aseptic loosening of cemented hip prostheses [1] with the aim of early mobilisation, better functional result and bone stock preservation.

Keywords*: Total hip replacement; Oxford hip score; Cementless hip ; Paragon; Early outcomes*
Level of Evidence*: IV*

They have shown good result with combination of both cementless stem and cup [2].

Since the introduction of cementless tapered, rectangular cross-sectioned implant by Zweimuller, approximately 700,000 of this design stems have been implanted worldwide [3] and have shown good results after 15 years [4,5,6].

Biplanar wedge design was introduced to provide axial and rotational stability through the rectangular dual longitudinal taper and compaction of cancellous bone creating contact between the femoral cortex and the corners of the stem. Hydroxyapatite coating was introduced to promote bone ongrowth, providing durable secondary fixation and has shown good results in implant survivorship [7].

Cementless hemispherical Titanium press fit acetabular component design has excellent outcomes and survivorship even in more difficult patient populations [8,9,10].

This study introduces the Paragon cementless stem and Global cup (Corin, Cirencester,

UK)The Paragon stem is a monobloc, titanium, fully HA coated rectangular biplanar wedge design with compression grooves on the medial, anterior and posterior metaphyseal surfaces and unique tension grooves on the lateral metaphyseal surface. It is available in two offset options and progressive neck dimensions. TGA approval was granted in 2012.

The Global cup is a pure titanium macro ingrowth surface with a 3-dimensional dual layer of sintered HA.

The primary objective of this study is to introduce a new cementless HA coated implant and report its minimum 2 year follow up results.

Material and Methods

A prospective, multi-centre, consecutive series, clinical outcomes study was undertaken from July 2014 to March 2016. A total of 75 patients were included in the study, performed by 2 investigators at 2 different sites during the study period. 3 patients were excluded from the study due to loss to follow up. The study was approved by the ethics committee at Nepean Hospital (HREC-2019/ETH01509 ID 43890)

Inclusion criteria for the study were age 21- 85 years, BMI <40, osteoarthritis of the hip, individuals physically and mentally willing and able to comply with post-operative scheduled clinical and radiographic evaluations and rehabilitation.

Exclusion criteria were active infection in the hip joint, previous total hip replacement or hip fusion of the affected hip joint, neuromuscular or neurosensory deficiency, systemic disease (i.e., moderate to severe osteoporosis, Paget's disease, renal osteodystrophy),immunologically suppressed or receiving steroids in excess of physiologic dose requirements, pregnant or scheduled for a simultaneous bilateral primary total hip arthroplasty.

Demographic details, medical history, physical review, body mass index (BMI) and laboratory investigations were collected pre-operatively. Patient reported outcomes parameters were recorded and collected prospectively.

Surgical Procedure

Patients were operated on using a standard posterolateral approach. The Paragon stem and the Global cup were implanted in a cementless method according to the manufacturer's published surgical technique (Corin Group Paragon Stem System Surgical Technique).

Implant details, operative time, operative and postoperative complications were recorded. All patients received routine antibiotic (cephazolin 3 doses) and DVT prophylaxis (rivaroxaban 10 mg daily for 30 days).

Post-operatively all the patients were mobilised from the 1st post-operative day, weight bearing as tolerated under the supervision of a physiotherapist until discharge.

Patients were reviewed at 6 weeks, 6 months and two years postoperative. At each visit AQoL 6D, VAS Pain, Oxford Hip Score were recorded. Post-operative X-Rays were reviewed at immediate post-operative, 6 months and two years (Table1).

Post-operative complications, limb length discrepancies and any revisions were documented.

Finally, an AOANJRR (Australian Orthopaedic Association National Joint Replacement Registry) data analysis was requested on the patient cohort to ensure they had not had a revision procedure performed at time of write up and to determine 4 year survivorship of implant study group in the registry as compared to national data for all total hip replacement implants.

Statistical methods

Adequate sample size was selected for the study. Descriptive analyses of OHS, AQoL-6D and VAS pain were performed, by tabulating the median and range (min, max), and mean and standard deviation of the scores at the preoperative and three post-operative assessments.

Graphic representations of the data included spaghetti plots of the individual trajectories over time, box-plots, and mean and error bars (standard error of the estimated mean).

Repeated measures analysis of variance (rANOVA) was then conducted, to assess the overall within-subject changes of scores over time.

Table 1 – Table showing sequential follow up visits and parameters measured

				Follow-up Phase		
	Pre-op	**Intra-op**	**1 wk (hospital)**	**6 wks (+/- 2 wks)**	**6 mths (+/- 1 mth)**	**2 yrs (+/- 2 mths)**
	(Not > 2 months prior to surgery) Visit 1	**(Day 0) Visit 2**	**(Day 0-7) Visit 3**	**Visit 4**	**Visit 5**	**Visit 6**
Eligibility, Consent	X	-	-	-	-	-
Patient Demographics, Medical history1, Physical examination1	X	-	-	-	-	-
Concomitant Medication	X	-	-	-	-	-
Weight, Height	X	-	-	-	-	-
Laboratory2	X	-	-	-	-	-
Leg length	X	-	-	X	-	-
Operative Details	-	X	-	-	-	-
Adverse Events / Complications	-	X	X	X	X	X
AP & Lateral Radiographs	X	-	X	X	X	X
AQoL Questionnaire, Oxford Hip Score Pain VAS	X	-	-	X	X	X

In case of a statistically significant effect in rANOVA, post-hoc paired t-tests were performed, to test which assessments were different from other assessments. These tests were adjusted for multiple comparisons with Bonferroni correction.

Results

Out of the 72 patients included in the study, 34 were males (47.2%) and 38 were females (52.7%) with mean age 65.1 (36.6 – 83.7). Left side in 40 cases (55.5%) and right in 32 cases (44.4%). Body mass index had a mean of 29.03 (Range 18.8-39.8, SD 4.63). The age range - sex relation and side - sex relation is depicted in graphs (figure 1,2). Bone quality was assessed as Dorr type A in 14 (19.4%), type B in 51 (70.8%) and type C in 7 (9.7 %).

Implant specifications such as stem size, cup size, liner, and head sizes are depicted in series of graphs (figure 3a, b, c, d).

Mean duration of surgery was 63.1 min with range of 40-120 min. An additional procedure was required in 8 cases. Two cases required acetabular bone grafting, three patients required repair of abductor tendons and three patients required adductor tenotomy for severe contractures.

One patient required a cerclage cable for a linear crack of the calcar at broaching. The stem remained stable and the patient progressed without complication using routine post-operative physio protocol. One acetabular cup was difficult to insert due to thread difficulties with the inserter. The cup was inserted and remained stable without further

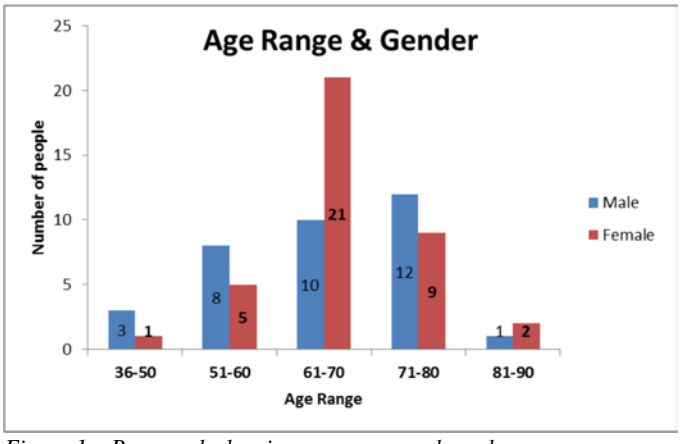

Figure 1 – Bar graph showing age range and gender

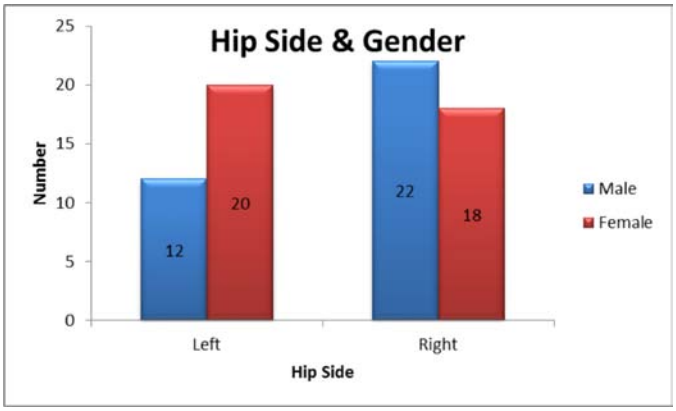

Figure 2 - Bar graph showing side and gender

Figure 3 – Series of bar graphs showing

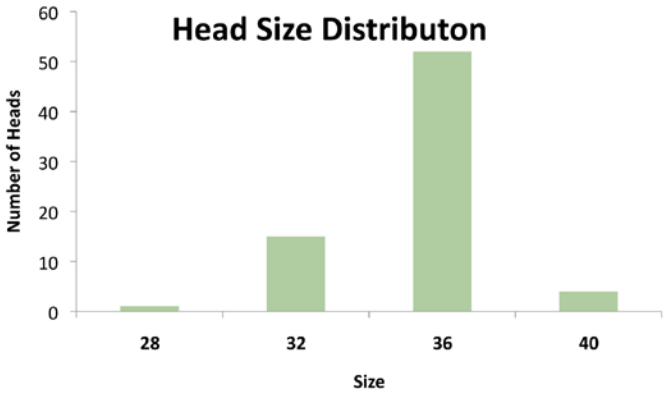

Figure 3a – femoral head size distribution

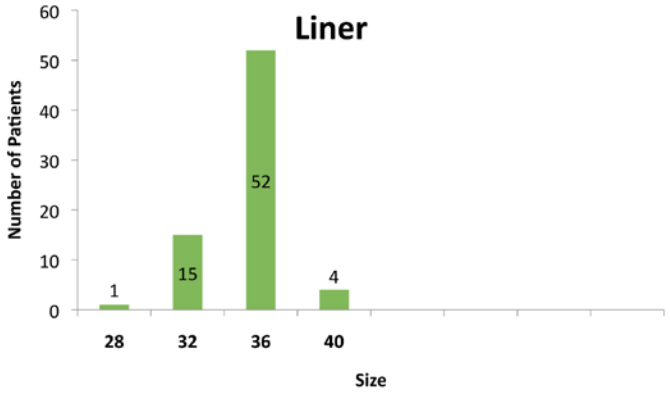

Figure 3b – Liner size distribution

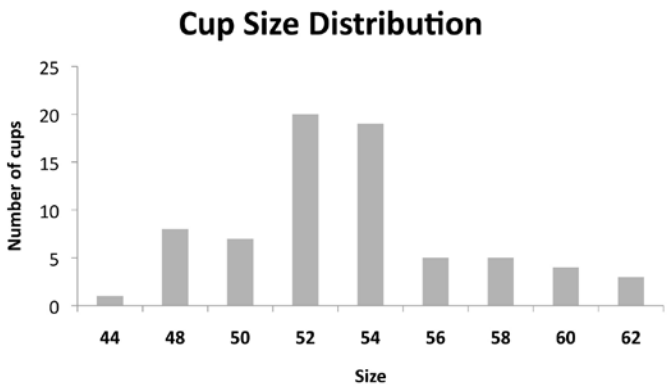

Figure 3c – Acetabulum cup size distribution

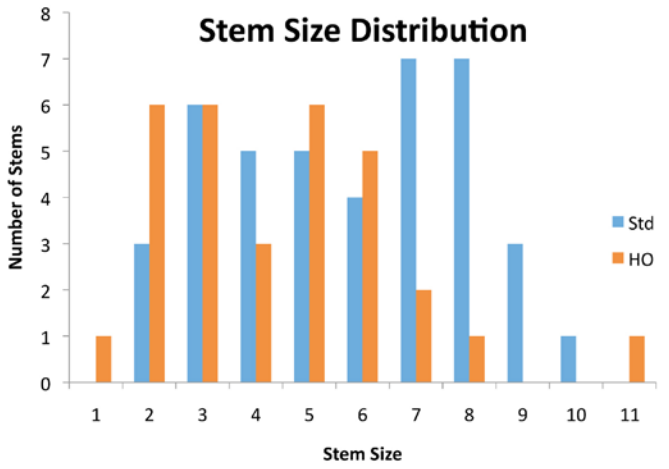

Figure 3d – Femoral stem size and offset distribution

complication.

One patient underwent a cup only revision for groin pain from psoas impingement after returning to heavy physical work within 6 weeks of surgery. The stem remained stable and left in situ. Three of the original group of patients were lost to follow-up, however no further revisions have been recorded following a data analysis by the AOANJRR. Only the one acetabular component was revised in the whole series. The revisions per 100 Observed Years of our study group is 0.40 (0.001, 2.24) as compared to 0.65 (0.64, 0.66) of all primary THAs in the registry. Also, the cumulative percentage revision rate of this implant combination in our study group at 4 years is 1.4, which is well below the average of 3 in all other THR implant combinations nationally.

Limb length at 6 weeks was equal in 65 cases (90.2%) with minimal discrepancy around 5 mm in the remaining seven cases.

Oxford Hip Score

This was measured over a period of time and is shown in table 2. Mean and error plot of individual OHS trajectories, showing a clear upward trend from pre-op mean of 19.93 (SD 8.13 to post-op 6wks mean 33.5 (SD 8.64), 41.3 (SD 6.75) at 6 months and 42.2(SD 6.28) at 2 years. (Figure 4).

Repeated measures analysis of variance showed a statistically significant effect of time on the Oxford Hip Score, $F(3, 189) = 216.14$, $p < 0.0001$.

After Paired samples t-tests (with Bonferroni correction) adjusted for multiple testing, there was a statistically significant difference in the OHS from pre-op to post-op 6wks ($p < 0.0001$) and from post-op 6wks to post-op 6mths ($p < 0.0001$), but not after post-op 6mths.

Table 2 – Serial Oxford hip score mean measurement.

Time	N	Minimum	Median	Maximum	Mean	Std Dev
pre-op	72	4.00	20.00	40.00	19.93	8.13
post-op 6wks	72	9.00	35.00	47.00	33.50	8.64
post-op 6mths	72	22.00	45.00	48.00	41.83	6.75
post-op 2yrs	64	22.00	45.00	48.00	42.83	6.28

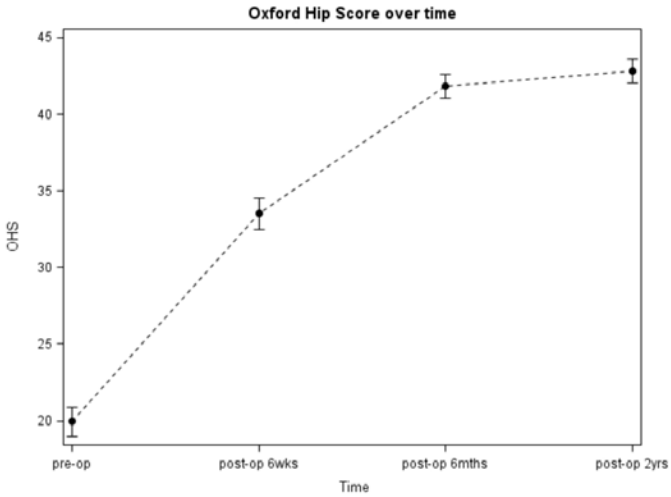

Figure 4 - Mean and error plot of individual OHS trajectories

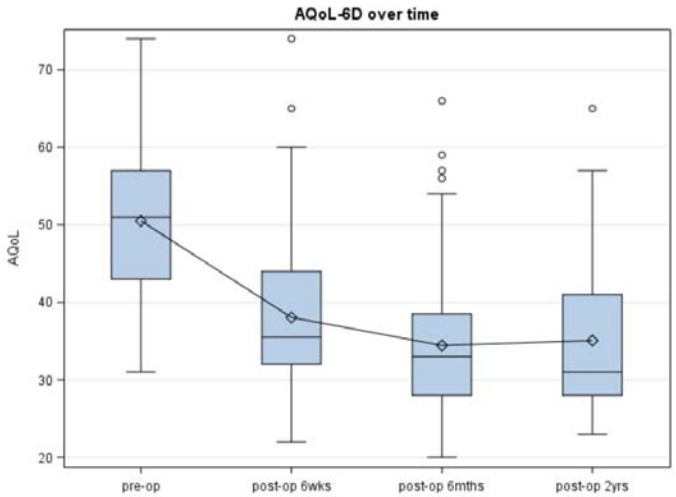

Figure 6 - Box-plots of AQoL-6D

AQoL-6D

AQoL over time changed from pre-op mean 50.51 (SD 10.80), at 6 weeks mean 38.06 (SD 9.85), at 6 months mean 34.44 (SD 9.37) and at 2 years mean 35.06 (SD 9.77).

Spaghetti plot of individual AQoL-6D trajectories, showing a general downward trend from pre-op to postoperative assessments (and a few outliers with an increase) (Figure 5).

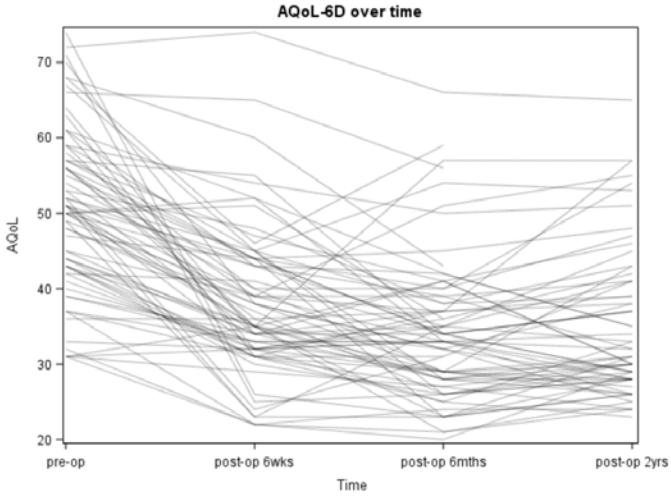

Figure 5 - Spaghetti plot of individual AQoL-6D trajectories

Box-plots of AQoL-6D, summarising the distribution of AQoL-6D at the different assessments (Figure 6).

There was a statistically significant effect of time on the AQoL-6D, $F(3, 186) = 77.80$, $p < 0.0001$.

After adjusting for multiple testing, there was a statistically significant difference in the AQoL-6D from pre-op to post-op 6wks and from post-op 6wks to post-op 6mths, but not after post-op 6mths.

Visual Analogue Scale for pain

VAS pain over time changed from pre-op mean 64.47(SD 21.48), at 6 weeks mean 16.21 (SD 21.64), at 6 months mean 10.49 (SD 12.80) and at 2 years mean 14.86 (SD 21.06)

Box – plot showing VAS pain trajectories, showing a clear downward trend from pre-op to post-op 6wks and a plateau in the following postoperative assessments (and a few outliers with an increase) (Figure 7).

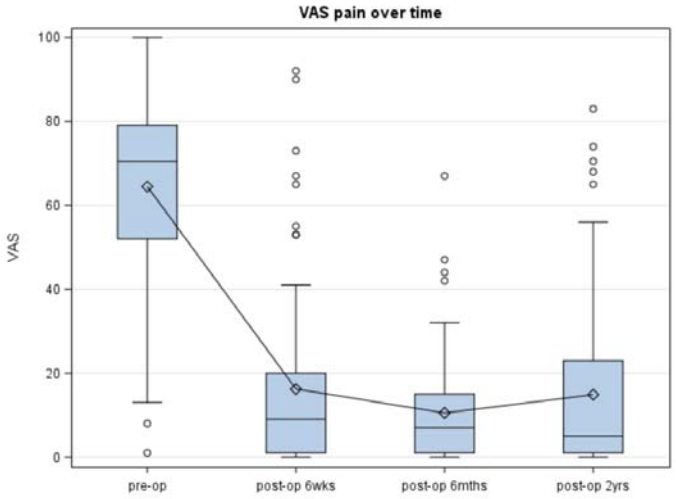

Figure 7 - Box – plot showing VAS pain trajectories

There was a statistically significant effect of time on VAS pain, $F(3, 168) = 152.49$, $p < 0.0001$.

After adjusting for multiple testing, there was a statistically significant difference in VAS pain from pre-op to post-op 6wks ($p < 0.0001$), but no differences in the subsequent follow-up assessments($p < 0.1767$, $p = 0.4103$)

Discussion

Total hip arthroplasty designs have evolved over last few decades. Cementless femoral stem design has evolved over the last few decades with numerous features common to successful stems. Fully HA coated, dual taper, titanium ingrowth or ongrowth stems have become standard of care. Durable fixation can be expected for many years and long-term loosening is rarely seen in successful combination of stem, cup and bearing surface.

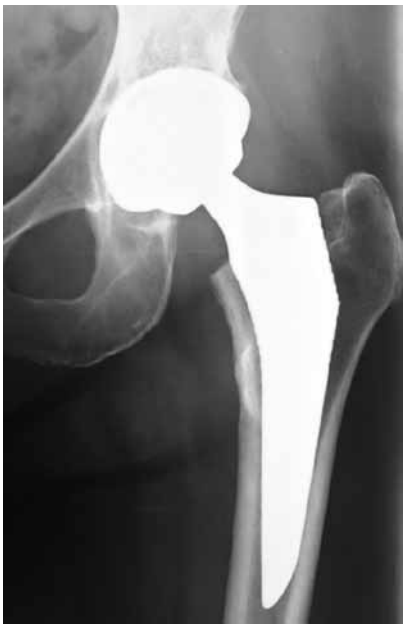

Figure 8 – Post operative X ray of Paragon and Global combination

Figure 9 – Photograph of implant showing; 9a - AP view showing Design features; 9b - Lateral view showing design features

The combination of Paragon stem and Global cup (Figure 8) incorporates proven features of successful implants. The unique feature of lateral tension grooves and progressive neck dimension with dual offset options adds potential benefits in obtaining excellent leg length and offset control, whilst minimising trochanteric osteoporosis (Figure 9 a,b).

Thigh pain has been reported in cementless stems. Gielis et al [11] compared mid-thigh pain results using short stem design vs wedge design. They reported lower rates of mid-thigh pain using short stems 14% as compared to 24% in wedge design. In our study at two year follow-up no patient complained of mid-thigh pain. This suggests that durable fixation and minimal stiffness mismatch is a feature of the clinical use of this stem.

Extensive work has been done on design to reproduce normal physiological loading of the femur and a patent design of incorporation of tension grooves on the lateral aspect of the stem to mimic lateral tensile trabeculae present around greater trochanter (Figure 10). Also, there are medial compressive grooves presently seen in many successful designs to reproduce compressive trabeculae around calcar region.

Figure 10 – Photograph of paragon stem showing lateral tensile grooves

Boxy cross section of the implant along with vertical ribs on the stem provides rotational stability. Polished offset distal tip prevents distal impingement of the stem tip on cortex and subsequent thigh pain.

Periprosthetic fracture has been reported in cemented and cementless designs, with some morphological differences between the two. Common fracture patterns in cementless stems is Vancouver 2B. To date there have been no post-operative periprosthetic fractures in this series. Colacchio et al [12] have shown better results of newer wedge design with medial curvature and lateral distal offset design in terms of periprosthetic fractures.

The Global Acetabular Cup is a cementless, press-fit, primary hip arthroplasty acetabular component. The design is a highly porous hemispherical Titanium alloy with HA coating. The Global cup is designed to engage either Delta ceramic or highly crosslinked polyethylene (HXLPE) liners. It has a circumferential locking groove and anti-rotation feature which adds locking support for the polyethylene liner. There is provision for 3 dome screws which may be placed at surgeon discretion. Advantage of placement of screw in quadrant fashion as described by Wasielewski et al [17] is well known and provides option in special circumstances.

Eskelinen et al [13] in their study from the Finnish Arthroplasty Register reported good endurance of press-fit porous-coated cups against aseptic loosening in young patients. They have reported few cases of revision in their study due to use of ultra-high molecular weight polyethylene and not highly cross-linked polyethylene. In our study there has been no revision due to loosening. One case was revised due to psoas impingement and the new acetabular component was repositioned. This implant specifically uses either highly cross-linked polyethylene or ceramic liners. There are multiple studies which have shown good long-term results with the hemispherical design [14,15].

In literature few designs have shown higher incidence of liner dissociation and fracture due to use of peripheral lugs or thin liner rims [18,19]. The Global cup uses a circumferential locking groove for snap-fit, along with taper design of the cup to enhance liner engagement. Similar designs have shown good results [20].

In this study, early clinical and radiological results of this implant combination are promising. The demographics of the patients in this series is consistent with general hip arthroplasty. A broad age and BMI range is represented with similar male/female distribution.

Revision rate in this study is quite low and only in 1 case there was revision required that to because of psoas tendon impingement. Overall survivorship of implant in this early result is 98.6% with revision for any reason taken as endpoint and 100% implant failure taken as end point.

Tetsunaga et al [21] in their study of early outcome of Summit stem in Japanese population has shown comparable results to our study with overall survivorship of implant as 100 percent, but in their study there are 3 patients of thigh pain, which is attributed to distal fixation of the stem. Due to optimal length of our stem and distal offset design, in this study there was no case of thigh pain.

Oxford hip score was used in this study as a measure of clinical outcome and there is marked improvement in the score from pre-operative mean of 19.3 which is severe arthritis to 42.83 at 2-year follow-up. These results are statistically significant p <.0001. This is consistent with other well performing implants. The point to note is that there is not much difference between the 6 month and 2-year scores. This may illustrate that overall result of the implant is good once the stem is well fixed. Although these are early results and further follow up is required.

AQol 6d questionnaire was used to assess the improvement in quality of life. It takes approximately 2-3 minutes to complete which patients find easy [22,23]. The scores improved statistically significantly from pre-op mean of 50.51 to 34.44 at 6 months post-op and remained almost similar at 2 years. This followed the trend of Oxford hip scores and results are encouraging.

VAS is a universal method to grade amount of pain experienced by the patient. VAS score changed statistically significantly from Pre-op mean 64.47, SD 21.48 to 6 weeks post-op mean 16.21, SD 21.64. The score generally decreased over a period of time. But there were few outliers, one patient complained of pain in knee, which lead to increase in VAS score.

Our current AOANJRR data analyses obtained in September 2019, demonstrates implant combination of Paragon stem & Global cup has excellent results with 100% survival of the Paragon stem and 98.7% of Global cup at 4 years. One case of cup revision for this series was due to groin pain from psoas impingement. The cumulative percentage revision rate of this implant combination is 1.4 at 4 years, which is well below the national average of 3 for all other THR combinations.

Our study also has its shortcomings. Whilst the sample size of 72 patients is good, higher numbers and longer follow-up would enhance the validity of the results. The cases were operated on by two design surgeons and further analysis of other case series or registry data will add to broader outcomes. Third this is not a randomised controlled trail. Future studies are required which are randomised controlled trials with larger sample size, longer follow up and heterogeneous group of patients and surgeons.

Conclusion

This implant combination of the Paragon stem and the Global cup has shown promising early results with early follow up of a minimum of 2 years, with a 100% survivorship of the stem and 98.7% survivorship overall for any reason and is a good cementless option in THA.

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AUTHOR AFFILIATIONS

1 Dr Rohit Pandey MD
MS (ORTHO), DNB (ORTHO), MNAMS, MBBS, MacNep Arthroplasty Fellow
Nepean Hospital, NSW, Australia

2 Dr Simon P Coffey MD
MBBS (Hons) FRACS (Orth) FAOA
Nepean Hospital and Macquarie Hospital, NSW, Australia

3 Dr Rami Sorial
A/Prof (FRACS, FAORTHA)
Nepean Hospital and Macquarie Hospital, NSW, Australia

(Direct inquires to Rohit Pandey, docrohit87@gmail.com)

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Range of Motion Comparison Following Total Knee Arthroplasty with and without Patella Resurfacing

Jackels, M[1]; Andrews, S[2]; Matsumoto, M[1]; Mathews, K[3]; Nakasone, C[2]

Abstact

Background: Despite significant evaluation, no consensus has been reach for best clinical practice for resurfacing the patella during total knee arthroplasty. Further complicating the ability to reach a conclusion is the inclusion of several different implant types used in previous research.

Questions/Purpose: The purpose of this study was to compare post-TKA outcomes between two cruciate retaining implants with or without patella resurfacing.

Methods: This retrospective review included 289 patients (380 knees) with a minimum six-month follow-up. All patients received a CR implant, with either a symmetric or an asymmetric tibial baseplate. Post-TKA knee flexion was categorized as <120° and ≥120° and knee extension classified as 0° or >0° and required knee manipulations were noted. Descriptive, nonparametric statistics were performed and a multivariate logistic regression was performed to determine risk of poor range of motion and manipulations.

Results: Age was significantly lower in the resurfaced group (p=0.001) and the resurfaced group had longer tourniquet time (p=0.003). The symmetric-resurfaced group had ≥120° of flexion and full extension in 72% and 98.7% of patients, respectively. Compared to symmetric-resurfaced, all other groups had a significantly greater risk of not reaching 120° of knee flexion (p<0.05). There were no significant differences in the risk of requiring a MUA between groups (p>0.06).

Conclusions: The effect of resurfacing the patella on post-TKA outcomes may be influenced by tibial implant design. Compared to all other combinations, a symmetric tibial baseplate and resurfaced patella resulted in the highest percentage of patients reaching ≥120°, with a low incidence of manipulations.

Background

The reported rate of patellar resurfacing during primary total knee arthroplasty (TKA) has ranged from 3% in Sweden to 98% in the United States, remaining essentially unchanged over the last decade [1]. This large range highlights the variation of surgeon opinion and decades of research has provided little to no conclusive evidence for best standard of practice for patella resurfacing. Evidence against routine patella resurfacing primarily includes cadaveric and anatomic studies, reporting abnormal kinematics, contact areas and loading characteristics [2-8]. Conversely, several meta-analyses conclude a lower incidence of anterior knee pain and fewer revisions following routine patella resurfacing but fail to report consistent clinically meaningful differences [9-14].

Previous joint registry evaluations have alluded to the influence of implant design on outcomes following TKA

Keywords*: range of motion; total knee arthroplasty; patella resurfacing*
Level of Evidence*: III*

with or without patella resurfacing [15-18]. The lack of consensus is likely due to the myriad of implant designs available and from which research has been conducted, which include fundamental differences in function and stability. However, previous research has suggested that cruciate retaining (CR) implants with patella resurfacing may result in a lower incidence of anterior knee pain and fewer revisions when compared to posterior stabilized implants [12,13,19]. Unfortunately, even within CR implant research, multiple implant designs are present and broad application is limited.

A primary design difference in CR implants is the presence of either a symmetric or an asymmetric tibial baseplate, with modern designs commonly implanted with an ultra-congruent (UC) tibial insert. Despite the wide use and high success of these implants [20,21], the influence of patella resurfacing and subsequent clinical outcomes, specifically post-operative knee range of motion (ROM), remain uncertain. Therefore, the purpose of this study was to compare post-TKA knee range of motion for patients with a minimum six month follow up between CR implants with symmetric and asymmetric tibial baseplates, with or without patella resurfacing.

Materials and Methods

This institutional review board approved, retrospective review included a consecutive cohort of 289 patients (380 knees) having undergone primary TKA for the treatment of osteoarthritis between January 2016 and January 2019 and had a minimum six month post-operative clinical assessment. All procedures were performed by a single, high volume fellowship trained orthopedic surgeon at a community hospital with nearly 10 years of fast track arthroplasty type delivery of care. The standard of care for primary TKA included the use of a tourniquet and a medial parapatellar approach with eversion of the patella and removal of the patellar fat pad for visualization. The posterior cruciate ligament was sacrificed in all procedures. Balancing of the knee was performed utilizing standard spacer blocks and alignment rods to assess intraoperative alignment and extension and flexion gap balance. Medial or lateral soft tissue releases were performed if necessary to obtain balance. Reduction of bony osteophytes were also performed where necessary to achieve proper knee balance. Extension and flexion gap balancing was performed in an identical manner for both systems as both systems are nearly identical in design regarding the femoral components. Patellar tracking was tested with extension and flexion of the knee without pressure on the patellae. The study surgeon routinely uses two implant types to perform TKA. Both systems have nearly identical femoral designs utilizing a multi-radius femoral component with similar trochlear designs. The major difference between the two systems are largely related to the design of the tibial baseplate. Therefore, over the study period, the two CR implants were used without preference for patient demographics or disease progression. Although not part of a formal randomization process, patients were randomly assigned by the surgeon without regard for patient demographics, severity of arthritis or deformity present to receive either a symmetric tibial baseplate (Balanced Knee® System, Ortho Development Corporation, Draper, UT) or an asymmetric tibial baseplate (Persona®, Zimmer Biomet, Warsaw, IN). Both systems were used with the corresponding UC tibial insert.

Until September 2017, the senior surgeon would have been classified as "usually" resurfacing the patella, with over 90% of patients undergoing patella resurfacing [17]. Due to lack of definitive data to support or condemn either practice regarding the patellae, the senior surgeon switched to a "rarely" patella resurfacing classification following September 2017, during which time less than 10% of patients underwent patella resurfacing [17]. During this time, patella resurfacing was rarely performed regardless of the condition of the native patellae. In all cases of patella resurfacing, pre- and post-patella resurfacing measurements were taken using a caliper to measure the thickest portion of the patella prior to resection of the articular surface and then following completion of cemented fixation of an all polyethylene symmetric dome shaped patella.

Following TKA, immediate and unrestricted, full weight bearing was allowed as tolerated, with no knee ROM restrictions. Physical therapy evaluation and treatment began on the day of surgery and continued twice daily until cleared for discharge. All patients received outpatient rehabilitation beginning within a week of hospital discharge and continued for six weeks. Standard physical therapy ROM goals were to equal or exceed preoperative ROM, with a minimum goal of 120° of flexion targeted if possible. Patients with (1) less than 90° of flexion, (2) greater than 10° of a flexion contracture and/or (3) greater than 30° loss of total motion from preoperative ROM measurements at the six week post-TKA clinic visit were considered candidates for manipulation under anesthesia (MUA). Immediately following MUA, physical therapy was prescribed for five consecutive days, followed by three times per week until therapy goals were met or further progress in ROM could not be achieved.

Patient demographics were collected for each patient at the time of surgery, including age, body mass index (BMI) and American Society of Anesthesiologists' (ASA) clas-

sification determined by the core group of anesthesiologists experienced in arthroplasty care. Pre- and post-operative knee flexion and extension were recorded by the senior surgeon or physician assistant. The decision for MUA was typically made between 6 weeks and three months following TKA, therefore, would have been noted prior to the six month clinic visit.

Data were analyzed across four groups, designated by tibia component design and patella resurfacing status, including asymmetric-resurfaced, asymmetric-non-resurfaced, symmetric-resurfaced and symmetric-non-resurfaced. Range of motion was evaluated both as a continuous variable and as a categorical variable, including knee flexion categorized as less than 120° and equal to or greater than 120° and knee extension classified as 0° or greater than 0°. Categorical classification of range of motion was based on standard post-operative range of motion targets, in which 120° of knee flexion and 0° of knee extension are established patient goals. Post-operative ROM data were taken from the last clinic visit attended, with a minimum of six month follow up required. Group differences in categorical data were evaluated by Chi Square tests. Continuous data were non-parametric as determined by the Kolmogorov-Smirnov test; therefore, Kruskal-Wallis tests were performed to determine group differences. Multiple Mann-Whitney Tests were performed to determine differences between asymmetric and symmetric for resurfaced and non-resurfaced patella. A multivariate logistic regression was performed for post-operative ROM and MUA, with symmetric tibial and resurface patella as the reference category for all analyses. Results were presented at odds ratios (OR) and 95% confidence intervals (CI). All statistical analyzes were performed using SPSS vs 25 with a significance level of $p<0.05$.

Table 1. Patient Characteristics and Perioperative Variables by Group

Patella	Resurfaced		Non-Resurfaced		
Tibia	Asymmetrical (N=53)	Symmetrical (N=125)	Asymmetrical (N=123)	Symmetrical (N=80)	p-value
Age (years)*	67.5 (8.2)	68.1 (8.4)	71.4 (7.7)	71.4 (9.5)	0.001
BMI (kg/m2)*	30.8 (6.1)	30.7 (5.8)	28.8 (5.6)	29.7 (5.8)	0.099
Gender*					
Male	10 (25.0%)	43 (43.9%)	41 (43.6%)	22 (38.6%)	0.178
Female	30 (75.0%)	55 (56.1%)	53 (56.4%)	35 (61.4%)	
Procedure					0.252
Unilateral	27 (50.9%)	71 (56.8%)	65 (52.8%)	34 (42.5%)	
Bilateral*	13 (29.1%)	27 (43.2%)	29 (47.2%)	23 (57.5%)	
Tourniquet Time	40.5 (8.6)	40.2 (10.8)	37.7 (9.6)	37.4 (10.9)	0.003
Surgical Time					
Unilateral	66.1 (12.0)	71.8 (21.5)	63.6 (12.6)	65.9 (16.8)	0.048
Bilateral*	172.5 (18.9)	167.0 (20.6)	153.9 (15.5)	154.2 (18.9)	0.005

* = bilaterals included once, therefore, sample size is number of patients
Presented at Mean (standard deviation) or Frequency (% of total)
N = number of knees

Results

Overall, the average age of all patients was 69.73 (8.5) years old and average BMI was 29.88 (5.8). Group descriptive are presented in Table 1, with significant main effects noted in age (p=0.001), tourniquet time (p=0.003) and surgical time for both unilateral (p=0.048) and bilateral (p=0.005) procedures. There was no significant difference between tibial baseplate groups for resurfaced and non-resurfaced patella (Mann-Whitney).

No significant group differences were present in pre-operative ROM (Table 2). Group differences were present for all post-operative ROM variables, including knee flexion ($p<0.001$) and knee extension (p=0.003), with symmetric-resurfaced having the greatest flexion and extension. Additionally, knee flexion was significantly greater in symmetric-resurfaced compared to asymmetric-resurfaced ($p<0.001$). Knee extension was significantly less in symmetric-non-resurfaced compared to asymmetric-non-resurfaced (p=0.010). Categorically, ROM goals were most commonly met with symmetric-resurfaced for flexion (72%) and symmetric-non-resurfaced for extension (98.7%). Range of motion goals were least commonly met with symmetric-non-resurfaced for flexion (51.2%) and asymmetric-non-resurfaced for extension (89.4%). There was not significant group difference for MUAs, however, asymmetric-non-resurfaced had the greatest occurrence, with 8.9% of patients requiring MUA.

Compared to symmetric-resurfaced, all other groups had a significantly greater risk of not reaching 120° of knee flexion ($p<0.05$) (Table 3). Additionally, asymmetric-non-resurfaced had a significantly greater risk of not reaching full extension compared to the symmetric-resurfaced

Table 2. Functional Outcomes by Group - Mean(SD)/Frequency/(%)

Patella	Resurfaced		Non-Resurfaced		
Tibia	Asymmetrical (N=53)	Symmetrical (N=125)	Asymmetrical (N=123)	Symmetrical (N=80)	p-value
Pre-Flex	114.5 (14.2)	117.9 (14.2)	115.4 (14.9)	114.9 (14.6)	0.196
Pre-Ext	3.8 (5.5)	3.9 (7.5)	4.2 (6.9)	4.0 (5.3)	0.802
Post-Flex	113.3 (10.9)	119.8 (10.2)*	115.5 (10.2)	114.1 (12.5)	<0.001
Post-Ext	0.6 (2.9)	0.2 (1.8)	1.2 (4.0)	0.1 (0.6)^	0.003
PostFlex<120	23 (43.4%)	35 (28.0%)	50 (40.7%)	39 (48.8%)	0.017
PostExt>0	3 (5.7%)	2 (1.6%)	13 (10.6%)	1 (1.3%)	0.004
MUA	1 (1.9%)	4 (3.2%)	11 (8.9%)	2 (2.5%)	0.062

Pre = preoperative; Post = postoperative; Flex = knee flexion; Ext = knee extension
N = number of knees; MUA = manipulation under anesthesia; SD = standard deviation
* = significantly greater than asymmetrical-resurfaced (p<0.001) (Mann-Whitney)
^ = significantly less than asymmetrical-non-resurfaced (p=0.010) (Mann-Whitney)

Table 3. Odds for Obtaining Post-Operative Functional Goal

	Tibia	Patella	OR (95% CI)	p-value
Post-Flexion*	Symmetrical	Resurfaced	Reference	
	Symmetrical	Non-Resurfaced	0.409 (0.227-0.735)	0.003
	Asymmetrical	Resurfaced	0.507(0.260-0.990)	0.047
	Asymmetrical	Non-Resurfaced	0.568 (0.334-0.966)	0.037
Post-Extension^	Symmetrical	Resurfaced	Reference	
	Symmetrical	Non-Resurfaced	1.285 (0.115-14.403)	0.839
	Asymmetrical	Resurfaced	0.271 (0.044-1.671)	0.160
	Asymmetrical	Non-Resurfaced	0.138 (0.030-0.623)	0.010
MUA	Symmetrical	Resurfaced	Reference	
	Symmetrical	Non-Resurfaced	1.289 (0.231-7.208)	0.772
	Asymmetrical	Resurfaced	1.719 (0.188-15.753)	0.632
	Asymmetrical	Non-Resurfaced	0.337 (0.104-1.088)	0.069

OR = odds ration; CI = confidence interval; MUA = manipulation under anesthesia
* = functional goal was above 120° of knee flexion by six months
^ = functional goal was above 0° of knee extension by six months
** OR below 1 indicates increased risk for poor outcome compared to reference

group. There were no significant differences in the risk of requiring a MUA between groups.

Discussion

Previous research has failed to provide adequate evidence to recommend for or against resurfacing the patella during TKA. The use of several different implant designs has further limited the ability for previous research to isolate the influence of patella resurfacing. Therefore, the current study aimed to evaluate the influence of patella resurfacing on post-operative ROM outcomes, using two distinctly different CR implants with an UC insert. The results of the current study indicate that resurfacing the patella when using a symmetric tibial implant provided the best post-operative knee flexion outcomes, with 72% of patients successfully achieving the established clinical goal of greater than 120° of knee flexion. Although this combination resulted in the second best knee extension outcomes, only two patients (1.6%) did not achieve full extension and only four patients (3.2%) required MUA.

Previous research and meta-analyses commonly use post-operative ROM as the primary outcome in the evaluation of patella resurfacing [9-13]. The results of those studies concluded that a resurfaced patella significantly increased post-operative ROM, particularly knee flexion. Interestingly, the results of the current study clearly indicate that post-operative knee flexion in patients with a resurfaced patella was dependent on the type of tibial implant used. Specifically, symmetric-resurfaced patients had the greatest knee flexion (average 119.8°) while asymmetric-resurfaced patients had the lowest knee flexion (average 113.3°). Although knee flexion was not significantly different in the non-resurfaced group between tibial implants, failure to achieve full extension following TKA was significantly greater in the asymmetric-non-resurfaced group. The lack of full knee extension in this group led to 10.6% of patients not meeting their post-operative ROM goals and 8.9% of those patients required a MUA, which was the most of all groups.

Significant differences in post-TKA ROM were noted between the four groups and, in the context of clinical goals of 120° of knee flexion and 0° of knee extension, these small differences in ROM are likely clinically relevant. Compared to symmetric-resurfaced, the risk for not achieving 120° of knee flexion was significantly greater

for all other groups. More specifically, the combination of a symmetric tibial baseplate with a resurfaced patella provided the best environment for a patient to obtain 120° of knee flexion. This distinction was not as clear for extension, as only the asymmetric-non-resurfaced patients had a significantly greater risk for not achieving full knee extension compared to symmetric-resurfaced. These results, coupled with the low incidence of MUA, suggests that when using a CR implant and UC insert during TKA, the use of a symmetric tibial baseplate and resurfacing the patella may provide the best post-operative range of motion outcomes.

As expected, resurfacing the patella significantly increased both tourniquet and surgical time for both unilateral and bilateral TKAs. Unfortunately, the increase in tourniquet and surgical time was accompanied by an increasing patient BMI, with positive correlations between these variables previously described in literature [22]. Nonetheless, the difference in tourniquet time of less than three minutes was clinically insignificant. Even with the compounding tourniquet time for bilateral patients, surgical time increased an average of only 16 minutes.

There are a few limitations regarding this study. This was a retrospective chart review evaluating only post-operative range of motion outcomes. The lack of formal randomization for this study could have introduced a selection bias when resurfacing the patella. However, the lack of group differences in pre-operative ROM adds confidence to our results. Secondly, only ROM outcomes were collected during patient clinic visits with no patient reported outcomes to supplement these results. Furthermore, the condition of the patella was not graded at the time of surgery; therefore, no comment can be made regarding the relationship between severity of patellofemoral arthritis at the time of surgery, patella treatment and post-operative ROM. Lastly, while the femoral components used in the current study are nearly identical in design, there are very subtle design differences that could have had an impact on the results presented. However, it is the similarity of the femoral designs of the two systems studied here used with significantly different baseplate designs that may strengthen these findings as the tibial baseplate design was the only major difference between the systems. Ongoing, prospective research at the current institution includes a randomization of patients and collection of both patella grading and patient reported outcomes.

Conclusion

Based on the results of the current study, the effect of resurfacing the patella on postoperative ROM may be influenced by tibial implant design. In the current study, the combination of a symmetric tibial baseplate and a resurfaced patella provided the best overall post-operative ROM, with a low incidence of MUAs. Additionally, all other surgical combinations provided either a similar risk or an increased risk for not achieving full ROM. These preliminary results should be further evaluated before a definitive recommendation can be made for patella resurfacing.

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AUTHOR AFFILIATIONS

1 Melissa K. Jackels, MS; Maya Y. Matsumoto, BA
John A. Burns School of Medicine University of Hawai'i at Manoa, 651 Ilalo Street Honolulu, HI

2 Samantha N. Andrews, PhD; Cass k. Nakasone, MD
(1) Straub Medical Center, 888 S. King St., Honolulu, HI (2) John A. Burns School of Medicine, University of Hawai'i, Manoa, 651 Ilalo Street Honolulu, HI – Department of Surgery

3 Kristin Mathews, MS
Straub Medical Center, 888 S. King St., Honolulu, HI

(Direct inquires to Samantha Andrews, samantha.andrews@straub.net)

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Early Term Radiographic Follow-Up of the Trident Tritanium Acetabular Component

DeBoer, D[1]; Hodrick, J[1]; Christie, M[1]

Abstact

Background: The purpose of this study was to evaluate the two year clinical and radiographic outcomes of patients undergoing a primary total hip arthroplasty (THA) using the Trident Tritanium primary Cup.

Methods: 197 patients who underwent a direct anterior THA using a Tritanium acetabular component between 2011 and 2015 were retrospectively reviewed by two surgeons from a single institution. The investigators, along with an independent physician, separately reviewed radiographs blinded to clinical data looking for radiolucent lines adjacent to the acetabular cup using the Charnley-DeLee zones. Clinical results were measured using acetabular revision surgery as an end point for failure. According to the American Academy of Orthopaedic Surgeons Levels of Evidence, this study was consistent with a Level III Therapeutic study.

Results: 101 (48.73%) subjects did not exhibit any radiolucent lines around the acetabular component. 53 (26.90%) subjects displayed radiolucency in only one zone. 27 (13.71%) subjects displayed radiolucency in two zones, and 16 (8.12%) displayed radiolucency in all three zones. Radiolucency was most prevalent in zone 1 at 2 years with 83 (42.13%) subjects displaying radiolucency. There were seven (2.54%) acetabular failures within two years of the index surgery. Of those 7 subjects, 3 displayed radiolucency in 1 zone, 2 displayed radiolucency in >1 zone, and 2 displayed radiolucencies >1 mm.

Conclusion: In our study, the Tritanium Cup demonstrated a 2.54% failure rate for aseptic loosening at 2 year follow-up. In addition, 51.27% of patients displayed a radiolucent line in at least one Charnley-DeLee zone. We also observed a progression of radiolucencies between the 6 month radiographs and the 2 year radiographs.

Background

The purpose of this review is to report a retrospective analysis of radiographic and clinical outcomes of a modern acetabular component with an ultra-porous biologic fixation surface. Specifically we are reporting to add to the body of literature regarding the Stryker Trident Tritanium (Stryker, Mahwah, NJ) acetabular component. There have been mixed reports on the short and midterm clinical and radiographic outcomes of patients undergoing total hip arthroplasty (THA) using the Trident Tritanium primary acetabular shell [1-8]. In 2013, Naziri et al. reported on patients undergoing primary hip replacement surgery using the Tritanium cup and showed 100% survival of the acetabular component at an average of 36 months follow-up [1]. A subsequent multicenter study with 12 centers and 255 cases demonstrated a 99.6% survivorship at 3-year follow-up [5]. Additionally, a six to ten year follow-up study of 62 patients undergoing revision hip arthroplasty using the Tritanium cup demonstrated 98% implant survivorship [2]. However, authors of more recent published studies voiced concerns regarding diminished implant lon-

Keywords: *Primary Total Hip Arthroplasty; Biologic Fixation; Titanium; Acetabulum; Ultra Porous Surface; Treatment Outcome; Follow-Up Study; Radiography; Retrospective Study*
Level of Evidence: *IV*

gevity and poor clinical outcome scores in primary THA [9,8,3]. Carli et al. reported only two failures in 104 primary hips at a 5-year minimum follow-up study, but the radiographic analysis showed potentially pending failures with 40% of patients having radiosclerotic lines in 2 or more DeLee zones [3]. They also noted poorer functional outcomes in this same patient cohort, including lower postoperative Harris Hip Scores (HHS).

These concerns result from this acetabular shell being a member of a relatively new class of acetabular components that utilize an ultraporous metal substrate for the biologic fixation surface. Theoretically, these porous metal biologic fixation surfaces are designed to resemble trabecular bone and increase the rate of biologic fixation [10]. These surfaces can be manufactured to maintain an elastic modulus similar to trabecular bone and reduce stress shielding [11]. They also have a greater surface frictional coefficient to improve initial implant stability [12]. However, the long-term survivorship of implants manufactured with these newer technologies is unknown.

The purpose of this study is to report the radiographic results in primary THA of patients that received a Trident Tritanium acetabular component at a minimum of 2 year follow-up.

Materials and Methods

Between June 2012 and November 2015, we identified 200 consecutive patients that underwent primary total hip arthroplasty using a Tritanium acetabular component [13]. Three patients did not return for the minimum 2-year follow-up visit and were excluded from the review. This left 197 patients in the investigational cohort. This study received an Institutional Review Board (IRB) exemption letter for retrospectively reviewing a standard of care protocol for total joint arthroplasty. All patients included in the study met the normal criteria for primary total hip replacement and were in compliance with the labeling for the device. Exclusion criteria (Table 1) included age less than 18 years old or greater than 79 years old, a body mass index (BMI) greater than 40 kg/m2, or a patient with a diagnosis of inflammatory arthropathy. Patients were also excluded if they had a prior organ transplant, history of active joint sepsis, carcinoma in the last 5 years, neurological disease (e.g. Parkinson's disease), psycho-social disorders that would limit rehabilitation, or deficient bone stock requiring use of a structural acetabular bone graft. Patient follow-up data was collected at 6 weeks, 3 to 6 months, 1 year, and minimum of 2 years post-operatively.

Table 1. Exclusion Criteria

Criteria
Age < 18 yrs. old or > 79 yrs. old
BMI > 40 kg/m2
Diagnosis of inflammatory arthropathy
Prior organ transplant
History of active joint sepsis
Carcinoma within last 5 years (prior to surgery)
Neurological disease (ex. Parkinson's disease)
Psychosocial disorders
Deficient bone stock requiring acetabular bone graft

Tritanium Acetabular Component

All surgeries were performed using the Trident Tritanium Acetabular Cup System (Figure 1), which provides a variety of cup inserts and size options. The Tritanium components are cementless, made of titanium, available with a clusterhole pattern for adjunct fixation, and are available in sizes 48-80 mm. The shells offer the option of Alumina Ceramic, Crossfire, or X3TM polyethylene inserts. Tritanium is the name of the surface coating on the underlying Trident shell. This surface manufacturing process begins with a mixture of a proprietary sacrificial pore former, polymeric binding agent, and commercially pure titanium powder [14]. The resulting material is molded and compacted at high pressure and low temperature to form a "green-state structure." The structure is machined to the desired form, mated to a titanium substrate, and treated to remove the pore former and binding agent. The process is completed by sintering the titanium particles to each other and the underlying substrate.

Figure 1. Tritanium Acetabular Cup

Surgical Procedure

All surgeries were performed by two fellowship trained surgeons (DKD, JTH) through a direct anterior approach using a Hana table. C-arm fluoroscopy was utilized in all procedures to aid with acetabular component positioning. Acetabular preparation was performed according to manufacturer protocol using the Stryker CuttingEdgeTM spherical reamers. Under-reaming the acetabulum by 1 mm was the preference for all cases; however, a few patients re-

Table 2. Demographics

	Sample Size (N)	Mean Value	Standard Deviation
Age	197	62.38	9.50
BMI	197	28.49	4.70
Gender (M:F)	(87:110)		
Pre-Operative Diagnosis			
Osteoarthritis	175		
Post-Traumatic Arthritis	2		
Avascular Necrosis	20		

Table 3. Number of Patients with Radiolucencies at Various Time Intervals

	6 Months	1 Year	2 Years
Zone 1	43	53	83
Zone 2	12	10	32
Zone 3	8	23	40
TOTAL	51	59	96
1 Zone Affected	41	36	53
2 Zones Affected	8	19	27
3 Zones Affected	2	4	16

Table 4. Cup Failure Cases

Patient	Age	BMI	Failure Type or Loosening	Time to Failure (months)	6 Month Radiolucencies	1 Year Radiolucencies	2 Year Radiolucencies	Latest Post-Op Pain Score
1	46.8	32	Aseptic	51	None	None	Zone 1,2,3	0
2	66.1	36	Aseptic	18	Zone 1	Zone 1	N/A	3
3	55	27	Aseptic	18	None	None	N/A	4
4	77.1	30	Aseptic	7	None	N/A	N/A	N/A
5	53.3	27	Septic	27	None	Zone 1	N/A	7
6	65	29	Aseptic	38	None	None	Zone 1	5
7	79	26	Aseptic	15	Zone 1	Zone 1,2	N/A	10

ceived line to line reaming, at the surgeon's discretion, due to sclerotic bone. Cup positioning was determined by fluoroscopic images and reamer handle alignment rods with the goal of 40o of abduction and 20o of anteversion. One surgeon (DKD) preference was to use a single dome screw for adjunct acetabular fixation in all cases, while the other surgeon (JTH) assessed bone quality and used 0, 1, or 2 screws as he deemed necessary for initial stable fixation. Table 5 shows the breakdown in number of screws used in all cases. X3TM crosslinked polyethylene liners were used in all 197 cases. A 32 or 36mm ceramic femoral head was used in all cases. Patients with a 52mm acetabular component or smaller received a 32 mm head ball. Patients with a 54mm acetabular component or larger received a 36 mm head ball.

Table 5. Number of Cases with Adjuvant Screw Fixation

	Number of Cases
0 Screws Used	5
1 Screw Used	179
2 Screws Used	13
TOTAL	197

Clinical Analysis

Although the clinical outcomes were not primary focus of this review, patient variables such as age, sex, race, BMI, post-operative pain scores, and revision for aseptic loosening were recorded. In addition, intraoperative and post-operative complications were noted.

Radiographic Analysis

Radiographs taken at 6 weeks, 3 to 6 months, 1 year, and a minimum 2 year follow-up were analyzed by 3 orthopedic surgeons and were blinded to clinical outcome. All patients received a standing anteroposterior pelvis x-ray, anteroposterior hip, and lateral hip x-ray at each follow-up visit. Radiographs were inspected for the presence of radiolucent lines, the locations of which were documented using acetabular zones described by DeLee and Charnley [15]. Radiographs were also assessed for bone-implant gaps of 1 mm or greater. Three surgeons independently evaluated all radiographs and discrepancies in the presence or size of the radiolucency were resolved if 2 of 3 surgeons agreed. If no agreement in radiographic interpretation was reached, radiographs were re-evaluated sequentially at the available 6 week, 3 to 6 month, 1 year, and 2 year x-rays to determine if a trend existed and consensus could be reached. Using this method, all discrepancies in radiographic findings were resolved for patients in this study.

Results

There were 197 patients that underwent a primary total hip replacement using a Trident Tritanium acetabular component with adjuvant screw fixation and received radiographs at a minimum of 2 year follow-up. Patient demographics are shown in Table 2. There were 87 males and 110 females. The average age was 62.4 +/- 9.5 years and the average BMI was 28.5 +/- 4.7 40 kg/m2. Primary diagnoses included osteoarthritis in 175 patients, avascular necrosis in 20 patients, and post-traumatic arthritis in 2 patients. There were no significant intra-operative complications reported in this cohort.

There were 7 patients (Table 4) that were revised for acetabular loosening using revision surgery as the criteria for failure. Six patients (3.04%) had aseptic implant loosening and 1 patient (0.51%) experienced septic loosening; they had a history of alcoholism and developed stage 3 avascular necrosis. The patient underwent an uncomplicated primary total hip replacement but continued to report mild to moderate pain throughout the entire post-operative period. They have since had a progression of acetabular radiolucencies in 2 DeLee zones, increased uptake on Tc99 bone scan, and a hip aspiration that revealed greater than 100,000 WBCs. This patient ultimately grew Propionibacterium acnes from his hip aspirate, underwent a 2-stage revision for prosthetic joint infection, and has had no further sequalae related to his revision hip replacement.

In case 3, the patient continued to have groin pain for almost the entire post-operative period (about 18 months). The patient was felt to have suspected iliopsoas impingement syndrome and surgical exploration of the hip demonstrated a loose acetabular component despite the lack of radiolucent lines. In case 4, the patient had a posterior column fracture noted 6 weeks post-operatively from the index arthroplasty. A trial of restricted weight bearing was unsuccessful. A revision of the acetabular component with plating of posterior column was performed 7 months post-operatively. At the time of the revision surgery, the acetabular component was removed easily with no significant acetabular bone loss and sclerotic bone beneath the acetabular component.

The remaining six patients had isolated acetabular failures due to aseptic loosening. The average age of this group was 63.2 +/- 12.2 years and the average BMI was 29.5 +/- 3.4 kg/m2, which were not statistically different from our total cohort demographics. The average time to failure was 24.7 months. Four of these six patients did not have a radiolucent line at 6 months, but follow-up radiographs demonstrated a progression of their radiolucencies prior to implant failure. Two of the six patients had 1 zone of radiolucency at their 6-month visit. Of these two patients, one had a progression to 2 zones of radiolucency prior to failure; the other patient had a progression of 1 zone from 1 millimeter to 2 millimeters prior to failure. All six patients reported continued pain after surgery. The average Visual Analog Scale (VAS) Pain score for these six patients was 5.2 at final follow-up. Adjuvant screw fixation on the acetabular component was not standardized. Of the six aseptic failures, one patient had 2 screws, one patient had 0 screws, and the remaining four patients had 1 screw placed at the index surgery.

Radiographic Analysis

The number of patients with various radiolucencies at different time intervals are shown in Table 3. The total number of patients with radiolucent lines was 51 of 197 (26%) at 6 months, 59 of 197 (30%) at 1 year, and 96 of 197 (49%) at 2 years. The majority of patients with radiolucencies were noted to be in zone 1; there were 43 patients with zone 1 radiolucencies noted at 6 months, 53 noted at 1 year, and 83 noted at 2 years. Zone 3 was the next most frequently noted location of radiolucency; there were 8 patients with zone 3 radiolucencies noted at 6 months, 23 noted at 1 year, and 40 noted at 2 years. Zone 2 radiolucencies were observed least frequently; there were 12 patients with zone 2 radiolucencies at 6 months, 10 noted at 1 year, and 32 noted at 2 years.

Radiolucent lines were observed in either one or multiple zones at the different time intervals. At 6 months, there were 41 patients (21%) with 1 zone involved, 8 patients (4%) with 2 zones involved, and 2 patients (1%) with 3 zones involved. At 1 year, there were 36 patients (18%) with 1 zone involved, 19 patients (10%) with 2 zones involved, and 4 patients (2%) with 3 zones involved. Finally, at 2 years, there were 53 patients (27%) with 1 zone involved, and 27 patients (14%) with 2 zones involved, and 16 patients (8%) with 3 zones involved.

Discussion

In this study, the overall aseptic failure rate for isolated Tritanium acetabular implants at 2 years post-operatively was 3%. These results are similar to those reported in national registries such as the Australian Joint Registry, which reported a 2.5% failure rate at 2 years, and the English National Registry, which reported a 1.63% failure rate at 3 years [16, 17]. Furthermore, the aseptic loosening rates, using revision surgery as an endpoint for failure, reported on 1,038 primary THA patients with mid-term follow-up (24 - 72 months) were less than 2% for all studies

using a Tritanium acetabular component [6].

Concerns have also been raised about the number of patients with post-operative radiolucent lines around the acetabular component. Carli et al. were the first to report a concern regarding this issue in 2017 [3]. This study's 1 year radiographs demonstrated 30.3% of cases with radiolucent lines in 2 or more DeLee zones, of which 8.2% had radiolucent lines in 3 zones. During minimum 5 years follow-up, these numbers increased to 40.0% and 17.1%, respectively. Additionally, Carli et al. compared the Tritanium cup patients to a cohort of patients receiving a conventional Trident hydroxyapatite (HA) coated acetabular implant [3]. The functional outcomes of the Tritanium cohort were statistically worse than the Trident HA group, suggesting impending failures in the Tritanium patients.

Yoshioka et al. also compared a group of Tritanium cup patients to a cohort of Trident HA cup patients [8]. Each group contained 130 cases with an average follow-up slightly more than 3 years. The Tritanium cup group had at least 1 zone radiolucent line in 36% at 3 months and 60% at 3 years; in comparison, the Trident HA group experienced at least 1 zone of radiolucency in 2.5% at 3 months and in 0.8% at 3 years. They reported no difference in clinical outcome between groups at final follow-up of at least 3 years.

Another ultra-porous acetabular component that has been reviewed is the Dynasty Biofoam cup (MicroPort Orthopedics, Arlington, TN, USA). Carli et al. compared 92 patients (96 cups) implanted with the Biofoam cup to 93 patients (96 cups) using a traditional Trident peripheral self-locking (PSL) cup [18]. They also noted a large number of radiolucent lines on radiographs at a minimum follow-up of 2 years. A significantly greater number of Biofoam components exhibited radiolucencies in 2 zones (27.2%) and 3 zones (12.0%) compared to 0% of the Trident shells ($p<0.05$).

We also observed a significant number of patient radiographs with post-operative radiolucencies. In our study, at least 1 zone of radiolucency was detected in 26% of patients at 6 months, 30% at 1 year, and 49% at 2 years. Furthermore, the number of patients with radiolucencies increased over time. Our data showed that 21% of patients had 1-zone involvement on 6 month radiographs, which increased to 27% of patients at 2 years. Likewise, the number of patients with 2 or more zones of involvement increased over time. At 6 months, 2-zone of involvement was noted in 4% of patients and 3-zone involvement was noted in 1% of patients; these values increased to 14% and 8% at 2 years, respectively. This concerning number of radiolucencies warrants more frequent follow up for these patients. Our practice is to see all patients annually for the first 5 years.

There are several limitations to our study. The surgical technique was not standardized as to the number of acetabular screws used during the procedure. Although all implants were initially stable, only one patient with 2 acetabular dome screws went onto failure. This was a retrospective review of radiographic data without patient reported outcomes or functional clinical outcome measures. Furthermore, the study did not have the statistical power to determine whether age, BMI, diagnosis, or sex were clinically significant. A long-term prospective, randomized clinical study comparing traditional ingrowth surfaces to newer, highly porous surfaces will be necessary to determine the clinical significance of the progression of radiolucencies observed on post-operative radiographs.

Another limitation to this study was the exclusion of femoral component data from the final analysis. The three reviewing surgeons did not specifically report on radiolucencies around the femoral component; however, analysis did include a notation for femoral subsidence. In this study, there were no femoral components that demonstrated any degree of subsidence.

Conclusion

The Trident Tritanium cup and its ultra-porous titanium biologic fixation surface exhibited a large number of patients with radiolucent lines, 96 out of 197 patients (48.73%), around the prosthesis at 2 year follow-up. Further study with longer follow up will be required to ascertain the clinical significance of these radiolucencies and determine whether biologic fixation predictably occurs with this newer biologic surface. Our data does support the more recent studies showing a progression of the radiolucencies in some patients with Stryker Trident Tritanium acetabular components.

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AUTHOR AFFILIATIONS

1 Dr David DeBoer MD; Dr Jeffrey Hodrick MD; Dr Matthew Christie
Southern Joint Replacement Institute, 2400 Patterson St Suite 100, Nashville, TN

(Direct inquires to David DeBoer, david@sjri.com)

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Overnight or Short Stay Joint Replacements in the Public and Private settings: An Australian Experience

Qurashi, S[1]; Bajwa, S[2]; Aktas, S[2]; Bestic, W[3]; Chinnappa, J[4]

Abstact

Background: In today's post COVID 19 world, many healthcare systems have been pushed past the brink of economic sustainability. With Total Hip (THR) and Knee Replacements (TKR) being some of the biggest ticket items, the need to adopt methods that improve quality of care & reduce unnecessary costs, is imperative. In this context, we report our experience with a Short Stay / Overnight joint replacement model using an ERAS (Enhanced Recovery After Surgery) Protocol which promotes rapid post-operative recovery and a decreased LOS without an increase in complications or readmission rates.

Method: Retrospective collection of clinical & demographic data was undertaken for 114 consecutive patients undergoing primary THR or TKR by a single surgeon between 1 January 2018 and 19 March 2020 at 2 hospitals (1 public, 1 private). The data was analyzed for LOS, complications & readmission rates within 90 days after surgery.

Results: In THR (n=93) and TKR (n=21), mean LOS was1.54 nights (range 0 - 4). 8 patients were discharged to a rehabilitation facility, the remaining 106 were discharged home. 2 patients were readmitted within 90 days of surgery - one with a periprosthetic fracture and the other for an unrelated respiratory illness.

Conclusion: The implementation of a Short Stay model and associated ERAS protocols in both the public and private hospital settings reduced LOS without a concomitant increase in postoperative complications or readmission rates.

Background

Joint replacement is the definitive treatment for end stage arthritis. With a 105% increase in demand for primary TKR & 73% for primary THR over the past 10 years [1], an estimated 65,569 patients will require a TKR & 39,567 a THR annually by 2030 at a cost of AUD 2.38 billion to the healthcare system [2]. This is a major cost to our health system at the best of economic times. Now consider COVID 19 and the resultant AUD $3.6 billion viral black hole in the Australian economy, the need to be judicious with our healthcare spending is more important than ever [3].

The concept of 'Short stay', 'Overnight', or 'Outpatient' joint replacement surgery has been very talked about in the European and American [4] circles for some years now, but is not an established practice in Australia. Whilst the overseas health system designs are very different, the incentive in Australia has primarily been quicker functional recovery for the patient and less emphasis on the economic motivations. However, our problems on the economic side are no less significant. Elective surgery waitlist blowouts, government funding cuts and now the virus has put a tremendous amount of pressure on our already stretched public system. On the private front, cost of surgery, rehabilitation, and everything that goes with it is astronomical. As per insurance data, the cost of joint replacement in

Keywords*: Enhanced recovery after surgery, Knee replacement, Hip replacement, Arthroplasty, Cost-effectiveness*
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NSW and ACT can be around AUD $30,000-35,000. Out of this, almost half is attributed to post surgery Length of Stay (LOS) stay and rehabilitation [5].

LOS is a conventional index of performance, a quality metric [6] at a clinical and also at an economical level. This is due to its objective nature and ease at which it can be measured. In joint replacement surgery, it is a measure of cost as well as efficiency and more recently, found to be associated with better patient satisfaction [7] and reduction in nosocomial complications as well as readmission rates [6,8].

From an economic standpoint, a major push to reduce LOS stems from healthcare systems employing the Medicare Diagnosis Related Group (DRG) style reimbursement models, whereby the cost of an extended LOS is borne by the hospital and providers [9]. With extended LOS being a significant cause of hospital inefficiencies and expense, many stakeholders are attracted to the idea of cost savings associated with decreased LOS.

On the other hand, concerns about shortening the LOS revolve mainly around a fear of increased complications or readmissions. A landmark study by Meyers et al [10] promoted a week long hospitalization after joint replacement surgery as a norm. This was widely adopted by healthcare systems across the globe in an attempt to prevent post-operative complications. However, in 2021, with newer evidence emerging and advances in perioperative interventions, the above recommendation may be obsolete. There is stronger evidence to show that LOS can be reduced without increasing readmission rates [6,8].

Additionally, an extended stay in rehabilitation has been shown to be associated with increased costs in addition to increased complications, increased readmission rates and no benefits with regards to patient functional scores and satisfaction rates following hip and knee arthroplasty [11].

In this context, it is imperative to establish healthcare practices that optimize patient care and expedite functional recovery without an increase in morbidity associated with joint replacement surgeries while also reducing the economic burden on healthcare services.

ERAS is a series of evidence based perioperative interventions used in a multimodal, integrated clinical care pathway to achieve accelerated functional recovery [12,13]. It requires the multidisciplinary team including anaesthetists, surgeons, nurses and physiotherapists to adhere to a specifically designed protocol following these principles.

The aim of this investigation is to study if our Short Stay model using a predefined ERAS Protocol achieved reduced LOS (Primary outcome measure) without an increase in complications or hospital readmission rates (secondary outcomes).

Materials and Methods

After approval from Hunter New England Ethics Committee (Ref: EX202005-03), all patients undergoing elective THR or TKR at St. Luke's Hospital (Private) and Canterbury Hospital (Public) between January 2018 to March 2020 under the care of lead investigator were identified and studied retrospectively. The exclusion criteria were defined as follows: history of malignant hyperthermia, history of allergy to anaesthetic agent, history of substance abuse, impaired cognitive function. A combination of preoperative (patient education and carbohydrate loading), intraoperative (minimizing opioid use, avoiding regional anaesthesia that inhibits mobilization, early analgesia and anti-emetic use) and postoperative (cryocompression, early mobilization, early oral feeding and multimodal analgesia) measures were used in our ERAS protocol. The full details of our ERAS Protocol are provided in Appendix A.

All TKRs (cemented) were performed with standard medial parapatellar approach by the senior author (SQ). All THR were performed using the SuperPATH approach also by the senior author (SQ) with either hybrid or uncemented implants depending on patient factors.

Patient demographics (Age, Gender, BMI, Preoperative Hemoglobin, Postoperative Hemoglobin, LOS and Complications) were retrospectively collected. Patients health status was graded as per ASA Grading system from Grade I (Healthy) to Grade V (Moribund) [14]. All patients had planned follow ups at 2, 6 weeks postoperatively for Xray and clinical evaluation (Wound status, Range of Motion and functional status).

Outcome measures

The primary outcome measure was LOS postoperatively, defined as the number of nights in the hospital from the date of surgery. The secondary outcome measures were complications (wound complications, falls during post-operative period, periprosthetic fracture, neurovascular injury, infection, dislocation, venous thromboembolism, any infections, or any other complication associated with surgery and readmission into the hospital after discharge for any cause within 90 days of surgery.

Statistical Analysis

The sample size was determined with convenience sampling using 'Sample size calculator- The survey system'. Using 5 cases per month over an enrolment period of 25 months, 112 patients were required for a 95% Confidence Interval with a 5% margin of error. Demographics and baseline characters were evaluated using the geometric mean.

The primary and secondary outcome measures are presented as medians and ranges. The continuous variables in secondary outcome measures were assessed for normality. Statistical analysis of the data was performed using Graph Pad Prism for MacOSX, GraphPad Software, California, USA.

Results

We recruited 114 consecutive THR and TKR's from 1st January 2018 to 18th March 2020. 72 patients underwent surgery in the public system at Canterbury Hospital (54 THR and 18 TKR) while 42 patients were at St. Luke's Private Hospital (39 THR and 3 TKR). This was a total of 93 patients undergoing THR and 21 patients undergoing TKRs. No patients met the exclusion criterion and hence every patient in this time frame was included in the study. Table 1 represents the patient demographics.

Table 1- Patient Demographics

	THR (Range)	TKR (Range)	Total (114)
Age (Years)	62.52 (33-82)	71.39 (56- 82)	64.15
Sex (Female)	47/93	12/21	59/114
BMI	28.19(18.2- 45.9)	30.72 (20.4- 39.9)	29.46
ASA Grading			
Grade I	13	2	15
Grade II	57	14	71
Grade III	22	5	27
Grade IV	1	0	1

Length of Stay

The mean LOS for patients undergoing THR was 1.45 nights (Range: same day discharge - 4) and in patients undergoing TKR was 1.90 nights (Range: 1 - 4). The combined mean LOS was 1.54 nights. (Table 2). 87 of all THR patients and 19 of TKRs were discharged home to continue physiotherapy autonomously. The remaining patients opted to pursue physiotherapy at a rehabilitation center (Table 2). All of the patients that were discharged to a rehabilitation unit had indicated their intention to do so preoperatively instead of a deemed requirement post surgery.

Most patients were ready for discharge after 1 night post operatively (as per our discharge criteria). In patients that stayed longer, the reason for delayed discharge were: postoperative vomiting (n=1), wound ooze requiring application of PICO incisional suction dressing(n=1), urinary retention requiring catheterization overnight (n=1), fall during hospitalisation (n=1- this patient remained asymptomatic however imaging was performed to exclude pathology and more physiotherapy instructional sessions on maneuvering walking aids were provided delaying planned discharge) and delay in organising logistics for interstate / regional travel or awaiting a rehab bed (n=4). In the last group, the reasons were primarily social or logistical even though they had been cleared by physiotherapy/ allied health as well as medical staff. Regardless of the cause of delay, all patients were discharged within 4 nights of surgery. It is also worth noting that if patients felt that they were not ready (social reasons), they were allowed to stay even if they had been cleared for safe discharge.

Complications

Two patients had to be readmitted unexpectedly after presenting to the Emergency Department (ED) - one had a periprosthetic fracture and the other presented with an unrelated respiratory viral illness (table 2).

Table 2- Complications

	THR (Range)	TKR (Range)	Total (114)
Length of Stay (Nights)	1.45 (Same day discharge- 4)	1.90 (1-4)	1.54
Discharge Status			
Home	87/93	19/21	106/114
Rehabilitation Center	6/93	2/21	8/114
Preoperative Hemoglobin	140.5 (107- 178)	138 (111- 158)	139.3
Postoperative Hemoglobin	114.3 (86- 142) (1 post op Inj Ferratin 1000mg)	115.6 (97-143)	114.9
Readmissions (within 30 days of surgery)	1 (Peri-prosthetic Fracture)	1 (Viral infection)	2
Complications			
Fall during Hospitalisation	1 (No complications)		1
Infections			
Stitch Abscess/ Wound Complications		1 (Stitch Abscess)	1

The patient with the periprosthetic fracture had been discharged essentially pain free on day one post surgery and independently mobile on crutches. Towards late afternoon of day 3 she contacted the surgeon's rooms to advise that she started getting pain that afternoon after being asymptomatic earlier. This had become severe so she was ad-

vised to present to the hospital and a CT scan showed an undisplaced femoral calcar fracture. She was treated non-operatively with partial weight bearing for 4 weeks, with sequential radiographs demonstrating a stable implant. She was discharged from the hospital a few days later. At 6 week follow-up, she was independently mobile with no walking aids, no pain and no radiological abnormalities.

One patient had an unplanned visit to the outpatient clinic with a minor stitch abscess which did not require an admission after settling with oral antibiotic treatment.

No patient required a blood transfusion and one asymptomatic patient required a ferritin injection postoperatively for a low haemoglobin (Hb). The mean preoperative Hb was 140.5 gm/L (Range: 107- 178) in THR group and 138 gm/L (range: 111- 158) in the TKR group with a combined mean of 139.3 gm/L. The mean postoperative Hb was 114.3 gm/L (range: 86- 142) in the THR group and 115.6 gm/L (range: 97- 143) in TKR group with a combined mean of 114.9 gm/L.

Discussion

A number of studies [15-17] promoted Short Stay programs / ERAS protocols to be effective in reducing the LOS without increasing the morbidity or hospital expenditure and thereby giving an accelerated recovery in the perioperative period. Our study confirms that Short Stay / ERAS can be implemented in both public and private hospitals in the Australian healthcare landscape and achieve LOS much lower than what is quoted in the literature as being associated with such models. A large number of our patients were deemed suitable for discharge within 1-2 nights postoperatively according to our discharge criteria.

However, for successful application of such a protocol, a truly multidisciplinary collaborative involvement is essential. Efficient implementation of the protocol at every level may be difficult especially if staff are used to long standing conventional practices with other surgical teams in the same institution .

After preoperative patient education and hospital admission, the type of anaesthetic recipe played a vital role. Systemic evaluation preoperatively, intraoperative tranexamic acid, controlled hemostasis and adrenaline in LIA helped minimise blood loss. Emphasis on reduction of PONV (Postoperative Nausea & Vomiting) & POCD (Postoperative Cognitive Dysfunction) compared to other studies [18] due to our use of short acting drugs such as fentanyl, midazolam, vercuronium and propofol helped quicken anaesthetic recovery. Generous use of LIA reduced immediate postoperative pain and minimised the need for long acting opioids. These interventions along with the absence of surgical drains [19] and urinary catheters [20] facilitated early mobilisation, as did avoidance of routine spinal analgesia [21] and nerve blocks with associated quadriceps weakness [22]. The choice of postoperative analgesic regimen facilitated patient capability during physiotherapy. From the time the patient woke up, oral Oxycodone and/or SR Topentadol were used regularly as well as rescue medicines if needed. Prompt oral intake were encouraged with minimum use of IV fluids.

With ERAS protocols, ward practices including nursing care and physiotherapy / allied staff and administrative practices were all adjusted. Multiple inefficient administrative practices also contribute to delay in discharge [23]. One such administrative practice was a surprising find, whereby there was a reluctance of private hospitals to engage in the 'short stay' model. This was constantly blamed on their individual contracts with the health funds, even citing financial penalties (from health funds) or reduced 'case payments' for a discharge earlier than their stipulated number of nights, four nights being the one most often quoted. This reluctance drained its way down from management levels and into nursing and allied staff practices making it obstructive to short stay plans in some instances. The basis of these practices originated from administrators and insurers being focused on reducing implant costs and other smaller savings rather than the major expenses such as LOS and rehabilitation costs for fear of complications and readmissions. We know now that the data used to justify this stance is not applicable in 2021. ERAS has shown to effectively reduce hospital related costs, perioperative morbidity and improve patient satisfaction in the literature [24] and consistent with our experience. Moreover, we also know that blanket inpatient rehabilitation for all, another practice that is sold to patients as being 'a must for all' has been shown to achieve the contrary outcome, with increased readmission rates, costs and complications and no improvements in patient functional scores or satisfaction [11].

We aimed to demonstrate that an accelerated pathway for arthroplasty can work well with the involvement & training of the whole team. With Short Stay, LOS was chosen as the primary measuring outcome as it is the most important reflective index of hospital costs and an overall measure of team efficiency. LOS is a parameter of concern to each physician but also is a tool to reduce the overall burden of healthcare costs to governments around the globe.

Compared to large scale comparative studies in the recent past (Traditional vs Short Stay / ERAS principles) in Arthroplasty [25], our complication rates are far lower in

mortality (0.1% vs None in our study), with lower LOS and blood transfusion (9.8% vs None). Our findings are similar to another Australian study investigating their use of local anaesthetic infiltration to allow a rapid recovery protocol following hip and knee replacements in the private sector with significant associated cost savings [15]. Our readmission rates of THR (1%) and TKR (4%) are slightly lower (3.9% and 6% respectively) with similar mean LOS.

The limitations of our study are our small sample size and retrospective nature of the study. It was also difficult to evaluate the impact of our surgical technique (SuperPATH in Hip Arthroplasty) on ERAS or its individual components. We did not undertake any analysis of the patient satisfaction scores or a health cost analysis which would be components to study in future prospective trials to better establish the effects of the Short Stay protocol & its individual components.

Conclusion

With the partnership of motivated staff and educated patients, Short Stay / ERAS protocols can be implemented in patients undergoing joint replacements in Australian public and private hospitals alike to improve the outcome parameters without any adverse effect on complication rates or readmissions.

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Appendix A: ERAS Protocol

Preoperative:

- Preoperative Joint Replacement education/counselling in the clinics by the Chief operating surgeon to the patient and their immediate family / partner.
- Preoperative assessment done by the anaesthetist in charge to discuss the anaesthetic walk through for the procedure.
- Premedication-Oral analgesic was given preoperatively. Avoid sedatives (Benzodiazepines, Neuroleptics or Opioids given preoperatively)
- Preoperative fasting of 6 hours with clear fluids allowed till 2 hours preoperatively. Preoperative carbohydrate loading.
- Preoperative warming of patient with warmers and blankets was implemented from ward to preoperative anaesthetic bay.

Intraoperative:

- General anaesthesia as a standard approach. No nerve blocks that impair motor function and early mobilisation.
- Minimum use of opioids.
- Drugs used:
  - Midazolam
  - Propofol for induction then TCI
  - Fentanyl approx. 300mcg for entire case (50mcg intubation, 100mcg pre incision, 100mcg during, 50mcg prior to wake up)
  - Vecuronium 20mg intubation and 10mg bolus as required during case
  - Paracetamol 1g then chart QID for 5 days post operative
  - Parecoxib 40mg then chart NSAID for 3-5 days post operative
  - Tramadol 200mg pre incision
  - Ketamine 50mg pre incision
  - Dexamethasone 8mg
  - Ondansetron 8mg and chart PRN post operative
  - If other indicators for PONV then add metoclopramide 20mg and cyclizine 50mg
  - Sugammadex 200mg

- 1g Tranexamic Acid IV 15 minutes before incision followed by 2 doses post-operatively at 8 and 16 hours post-operation
- Cefazolin 2g post intubation then chart 3 x doses q8h post operative
- IVF 1L intraop with second litre started before end of case. 3 x 1L post op (q5h, q8h, q12h)
- Continued intraoperative warming by warmed IV infusion & air warming.
- No indwelling catheters and no drains during or after surgery.
- Application of intermittent pneumatic compression device (IPCD) to the leg opposite to surgical side.
- Local Infiltrative Analgesia (LIA) of Ropivacaine (0.2%) + adrenaline after arthrotomy, during the procedure and closure.

Postoperative:

- No PCA/ No IDC (tethers patient to bed and increases risk of infection)
- Discontinue IV fluids after surgery when the vital parameters are stable. Start oral feeds early.
- Antiemetic prophylaxis.
- Ice packs for 30 minutes every 2 hours as cryo-compression.
- DVT Prophylaxis with intermittent pneumatic compression devices (IPCD), compression socks and enoxaparin (LMWH) SC injections for 10 days post-operation.
- Multimodal analgesia: Regular Paracetamol + NSAID, Tapentadol SR 50mg BD for 3-4 days and Tapentadol IR 50mg q4h PRN. Oxycodone for PACU 1mg q5mins max 5-8mg depending on patient
- Patient goes home with post op pain sheet and scripts
- Early postoperative (recovery room) oral carbohydrate supplementation
- Patients are reviewed on ward end of list to ensure they have mobilized
- Physiotherapy initiated on day of surgery. Patient were made to walk with a walking frame on the day of surgery. Mobilisation Protocol: Mobilisation within 24 hours
- POD 0: Assisted walking, bed to chair transfer.
- POD 1: Independent walking (with gutter crutches), stair climbing and independent transfers.
- Early hospital discharge (<5 days). Discharge criteria was identified to be when the patient mobilized independently, was able to climb stairs and do an independent bed to chair transfer, provided medical indices were normal and patient comfortable.

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AUTHOR AFFILIATIONS

1 Sol Qurashi, MD; The Hip and Knee Clinic, Harbourcity Orthopaedics, Sydney, NSW, Australia; Nepean Hospital, Penrith, NSW, Australia; Canterbury Hospital, Campsie, NSW, Australia

2 Supreet Bajwa, MD; Sam Aktas, MN; The Hip and Knee Clinic, Harbourcity Orthopaedics, Sydney, NSW, Australia

3 William Bestic, MD; Royal North Shore Hospital, St. Leonard's, NSW, Australia

4 Jason Chinnappa, MD; Sydney Orthopaedic And Sports Injury Service, Sydney, NSW, Australia

(Direct inquires to Sol Qurashi, info@harbourcityorthopaedics.com.au)

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Addressing a Complex Proximal Femoral Deformity With Custom Cutting Guides Using 3D-Computer Design Software: A Case Report and 2-year Follow-Up

Hanson, Z[1]; Davis, D[1]; Robison, J[1]; Minter, J[2]

Abstact

We report a case of a 23-year-old female with a history of congenital proximal femoral deformity and malunion of a prior proximal femoral corrective osteotomy, who presented seeking treatment for debilitating end-stage arthritis of her hip. Consideration for total hip arthroplasty (THA) for this patient was complicated by her young age and the complexity of her proximal femoral deformity. A 3-dimensional bone model of the patient's femur was created using digital reconstructive software based on preoperative CT-imaging and used to plan our corrective osteotomy and arthroplasty component specifications. Using the detailed characterization of the femoral morphology, custom cutting guides were designed to fit uniquely into the correct position and ensure a high degree of accuracy with our osteotomy cuts. This unique case highlights the use of 3D-modeling software and printing technology for detailed surgical planning and precise execution in patients with complex deformities or otherwise abnormal anatomy.

Background

Proximal femoral deformity (PFD) may refer to varus or valgus femoral neck-shaft angles, rotational malalignments, leg-length discrepancies or any combination. In adults, PFD may be caused by a number of congenital (e.g., fibrous dysplasia, coxa vara, developmental dysplasia) or acquired etiologies (e.g., infection, fracture malunion, prior proximal femoral osteotomy). [1,2] Regardless of etiology, PFD alters lower extremity mechanical alignment and creates abnormal joint surface stress, leading to accelerated joint surface wear and early arthritis [3–7].

One of the most important treatment goals in these patients is early deformity correction with proximal femoral osteotomy (PFO) to restore mechanical alignment of the lower extremity, provide pain relief, improve gait and overall function. [8] Even after early intervention, many of these patients go on to develop significant hip osteoarthritis at a relatively young age, in which case arthroplasty may be considered. Standard hip replacement techniques and prostheses are typically unsuitable for patients with significant PFD; abnormal femoral morphology may limit adequate component placement and the altered mechanical alignment can lead to accelerated component wear and increased rates of aseptic loosening. Performing adjunctive proximal femoral osteotomies in these patients can restore bony anatomy, simplifying the procedure and improving arthroplasty implant survival.

Proximal femoral deformity correction is technically

Keywords: *Proximal Femoral Deformity, Patient-Specific Instrumentation; Proximal Femoral Osteotomy, 3D printing osteotomy template, Three-Dimensional*
Level of Evidence: *V*

challenging and surgical planning must consider osteotomies to address malalignment, often in multiple planes, as well as choice of hardware to facilitate the degree of surgical correction. [9–13] Even after thorough preparation it can be difficult to accurately replicate the degree of correction planned preoperatively. Advances in computer technologies has led to surgeons seeking support through navigation systems, digital planning tools, and more recently, 3D digital reconstruction and 3D printing techniques to more effectively plan and improve surgical precision to achieve more reliable outcomes.

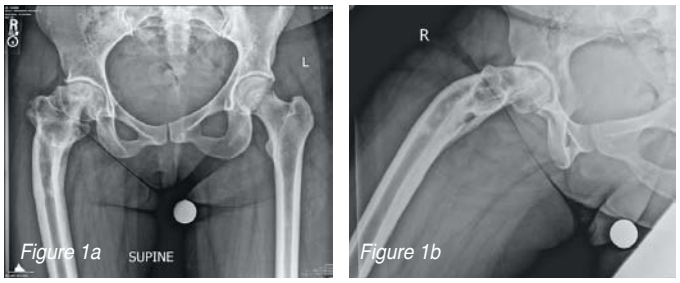

Figure 1. Preoperative radiographs showing (a) an anteroposterior view of the pelvis and (b) a cross-table lateral view of the patient's right hip. Radiographs show marked coxa varus and proximal femoral retroversion, with associated posteroinferior displacement of the femoral head in relation to the femoral neck and shaft consistent with history of SCFE.

Case History

A 23-year-old female presented to our clinic with the complaint of constant right-sided groin and thigh pain, which worsened with activity. Her symptoms had developed gradually and progressed in severity over several years. At the time of presentation, she reported difficulties activities of daily living including stair climbing and application of shoes and socks to the affected extremity, and a maximum ambulatory distance of a quarter mile. The patient's history was significant for severe right-sided femoral deformity due to a slipped capital femoral epiphysis (SCFE), for which she had undergone in-situ pinning and attempted deformity correction with a Southwick (subtrochanteric) osteotomy at an outside medical facility. Of note, the patient also had significant pelvic tilt and spinal deformity due to scoliosis. All retained femoral hardware had been removed years prior to our initial encounter.

On physical exam the patient's right hip exhibited significantly restricted range of motion with approximately 60 degrees of flexion, 20 degrees of abduction, 15 degrees of adduction, 15 degrees of external rotation and 0 degrees of internal rotation. On strength examination of the hip, the patient exhibited 4/5 strength with hip abduction, adduction and hip flexion. Limb lengths were measured from umbilicus to medial malleolus and determined to have approximately 3 cm of discrepancy (96 cm on the right and 99 cm on the left). She had a short limbed, antalgic, non-Trendelenburg gait. Interestingly, the patient exhibited hyper-mobility at her elbow, wrist and knee joints bilaterally.

Radiographs demonstrated a complex multi-angular deformity with severe osteoarthritis of the right hip. Evidence of this patient's original SCFE deformity is seen on plain films (Fig. 1), which demonstrate coxa vara and proximal femoral retroversion. An extension deformity has developed due to posteroinferior displacement of the femoral head in relation to the femoral neck. The metaphysis of the anterolateral neck has formed a CAM-type lesion due to abutment against the anterior acetabulum. Dense sclerotic cortical bone is noted with gross shortening of the extremity and associated pelvic tilt. The degree of femoral retroversion and anterior metaphyseal abutment here are consistent with the restrictions to hip flexion and internal rotation seen on clinical exam.

The patient presented after having delayed surgery as long as possible, though she was now at a point where her pain and functional limitations warranted intervention. While the degree of arthritis present warranted treatment with joint reconstruction, the complexity of her deformity prohibited conventional arthroplasty techniques; her abnormal canal morphology increased the risk for intraoperative complications (e.g., fracture), poor fit of standard components and, in combination with her altered joint mechanics, early implant failure.

To address these concerns, surgical treatment would involve deformity correction with proximal femoral osteotomies and subsequent total hip arthroplasty. Given the complexity and multi-plane nature of the deformity, 3-dimensional (3D) surgical planning using CustomLINK (Waldemar Link GmbH and Co.; Hamburg, Germany) was used to more accurately plan osteotomy cuts that provide the desired angular correction. Based on fine-cut CT images (coronal and sagittal reformations), digital reformatting software was used to generate a 3D-model of the right hemipelvis and femur (Fig. 2). A dedicated engineering team was available to assist with osteotomy planning, design custom-cutting guides and provide input on implant size and design.

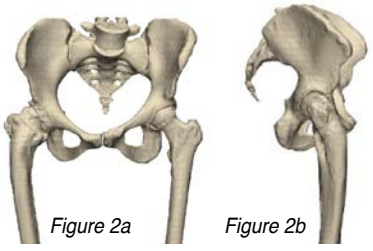

Figure 2. Anterior (a) and lateral (b) views of the 3-dimensional reconstructed model based on fine-cut CT imaging of the pelvis and proximal femur.

In collaboration with the engineering team, a single osteotomy was planned at a location which would provide optimal angular correction (Fig. 3). Planning a single osteotomy cut was ideal, provided it achieved sufficient deformity correction, because it allowed for a simplified, "one and done" design for a cutting jig. A custom cutting-guide based on this patient's unique bony topography was designed using 3D printing technology and used to help ensure the angular correction planned preoperatively was replicated during surgery (Fig. 4).

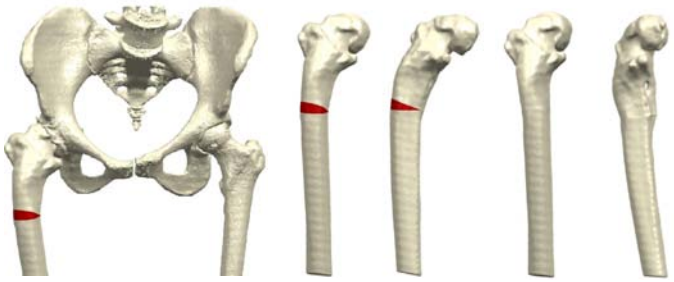

Figure 3a Figure 3b Figure 3c

Figure 3. Preoperative 3-dimensional planning for the proximal femoral corrective osteotomy shows the planned wedge osteotomy denoted in red on the (a) anterior view of the pelvis and (b) anterior and lateral views of the isolated femur. By digitally removing the osteotomy wedge, the final alignment based on the projected correction can be assessed in multiple planes (c).

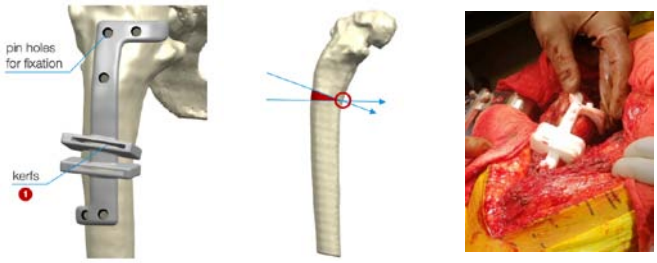

Figure 4a Figure 4b Figure 4c

Figure 4. Proposed design (a) for a custom-cutting jig with pin holes to secure the guide in its pre-planned location and saw blade guides oriented to obtain the desired angular correction. The saw guides were designed to accommodate a specific saw blade kerf to minimize toggle and maximize precision of the cuts at the projected angles (b). (c) An intraoperative photograph of the custom- cutting guide in position along the anterolateral aspect of the proximal femur. The guide was fabricated with medical-grade resin using 3-dimensional printing technology.

Planning the reconstructive portion of the case was done based on the predicted femoral model after the osteotomy (Fig. 3). An MP-Link modular stem (Waldemar Link GmbH and Co.; Hamburg, Germany), a Wagner-type stem, was chosen to bypass the abnormal proximal metaphysis and osteotomy site to obtain fixation in the distal, well-preserved femur. A modular stem (rather than a monoblock) was chosen in this case as we felt the ability to make height and version adjustments with a modular device was of added benefit compared to a one-piece stem. Together with the engineering team, implant specifications including optimal stem placement, size and version were determined preoperatively (Fig. 5). This advanced planning allows for what amounts to a virtual surgery.

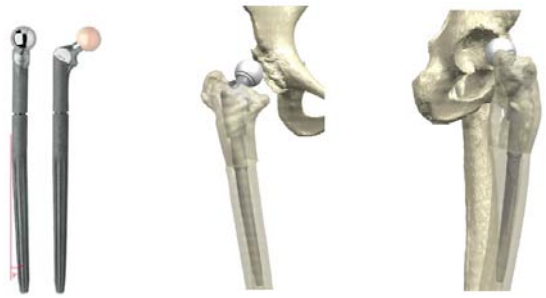

Figure 5a Figure 5b Figure 5c

Figure 5. (a) The proposed implant design included a stem with a 3-degree built-in angle to match that of the femur, as well as projected stem length, proximal and distal stem diameter, neck length and neck shaft angle. Anterior (a) and lateral (b) views showing the optimal position of the proposed implant within the femur after corrective alignment had been obtained.

The surgery was made difficult due to the prior surgical procedures, dense scar and contractures. Simple mobilization of the soft tissues, scar resection and tenotomies (psoas insertion and proximal adductors as well as the external rotators) allowed improved visualization. The custom cutting guide utilized for the osteotomy conformed to the patient's anatomy over the anterolateral femur in the preplanned site (Fig. 4). The custom jig was secured with smooth, trocar tipped 3.2 mm pins for fixation and the osteotomy was performed; after our osteotomy the bone ends were directly apposed which confirmed the adequacy of our cuts. The patient's cortical bone was extremely sclerotic and required the use of a high-speed drill to prepare the proximal canal. Standard reamers for the femoral implant were passed onto the distal segment beyond the osteotomy site. Once the final femoral implant was seated with bony apposition noted the osteotomy site, demineralized bone matrix putty was applied with a contoured plate and cable construct applied. The patient had an uneventful recovery and was allowed to fully weight bear and participate in physical therapy.

Postoperatively the patient had 2 out of 10 pain which went on to resolve completely. She had no residual groin or thigh pain. At 2 years postoperatively, the patient can walk unlimited distances and stair climb with an alternating gait. Her limb length inequality is significantly improved at 1.5 cm compared to 3 cm preoperatively. On exam she has 80 degrees of hip flexion, 20 degrees of abduction, 10 degrees

adduction, 20 degrees of external rotation and 10 degrees of internal rotation. Her hip muscular strength is now graded at 5/5.

Imaging 2-years postoperatively reveal a well fixed and aligned THA, though with persistent diastasis noted at the osteotomy site. It should be noted that at the time the intraoperative cuts were made, the bone edges were noted to be well-opposed, though the patient's bone in this area was sclerotic and noted to have poor bleeding quality. Postoperative radiographs demonstrated gradual resorption of bone around the osteotomy site, with the most recent radiographs showing persistent diastasis with incomplete bridging, though close inspection does find bridging bone across along the titanium grit blasted stem. We suspect that because of the poor bone quality noted in this area in conjunction with stress shielding from the diaphyseal-fitting stem, the patient may not ever develop quality bridging in this area (Fig. 6).

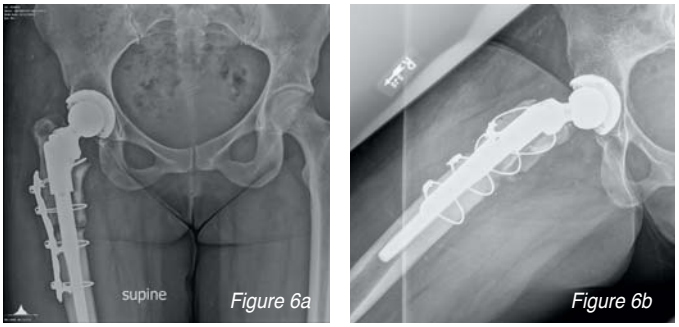

Figure 6. Radiographs showing an (a) anteroposterior view of the pelvis and a (b) cross-table lateral view of the right hip obtained 2 years postoperatively. Imaging shows the implants remain in good position and good diaphyseal fit and bony on-growth distally without evidence of loosening. Osteotomy gap remains visible though scant bridging callous can be seen adjacent to the femoral stem.

Discussion

Proximal femoral deformities can lead to serious functional deficits and joint pain ultimately requiring treatment with end-prosthetic reconstruction. For cases with severe deformity, corrective osteotomy and THA are both needed. Corrective osteotomy can restore normal bone and soft tissue anatomy and re-establish mechanical alignment of the lower extremity. [14] THA can relieve pain and improve the limb function. [15]

3D-imaging software utilizes preoperative CT imaging to construct a 3D model which can be a valuable resource for virtual preoperative surgical planning as well as allow for preoperative collaboration with an engineering team for biomechanical validation of surgical plan. 3D surgical planning in conjunction with 3D printing technology has allowed for the development of custom surgical templates and choice of optimal implant specifics based on biomechanical evaluation. [16] The importance of a properly aligned corrective osteotomy in this case cannot be overstated for this young patient, as it will affect the long-term viability of her THA implants.

Choice of osteotomy size and position is key in providing optimal angular correction without creating a new deformity, and requires both thorough surgical planning and precise execution. [17] The optimal osteotomy should involve a minimal number of cuts and aim to re-establishing neck-shaft angle and restore the lower limb mechanical axis. [18] While classic freehand techniques have traditionally been used for corrective osteotomies, results tend to have larger deviations from the target correction as compared with patient-specific cutting guides (PSGs). PSGs assists in locating the correct osteotomy plane, as the guide fits uniquely into the correct position determined preoperatively. PSG for osteotomies have been associated with higher precision compared to freehand techniques, decreased radiation exposure, shorter operative times and decreased overall blood loss. [19–22]

In this case, a single lateral closing wedge osteotomy was planned in a position to address malalignment in both the coronal and sagittal planes. After osteotomy planning, custom cutting jigs were designed to fit the unusual deformity in this patient and allowed for accurate replication of our planned osteotomy and the desired degree of correction.

Use of long-stemmed femoral implants has been advocated in patients with PFD, particularly those with associated poor bone quality, in order to decrease the risk of aspetic loosening and early failure. [15] This can be challenging depending on the degree of deformity and the morphology of the medullary canal. 3D reconstructive imaging can be used to better characterize the sites of maximal deformity, the length of affected bone, overall bone quality, and determine canal diameter at multiple levels.

For this patient, preoperative 3D planning was used to determine our optimal component size and stem length given the predicted post-correction morphology of the femoral canal. Determining implant specifications preoperatively rather than intraoperatively decreases overall operative time and decreases the risk for cortical perforation or fracture during canal preparation. [15]

Despite the surgical advantages of 3D planning and printing patient specific instrumentation, the cost and time required for use should be considered. A 3D planning service and the production of custom resection guides as described above may cost between $4,000 and $7,500 de-

pending on the complexity and number of required parts. The time spent on collaboration between surgeon and production team may take 4–5 weeks to fabricate the required instruments. [21] While the upfront costs are significant, use has been shown to offset some surgical costs related to operative time and fluoroscopy use, [23] as well as the potential savings provided by avoiding complications and revision surgery. Implant costs for revision of the femoral component alone may cost nearly $10,000, with overall costs to the hospital being more than double that. [24, 25]

Summary

3D design software for THA is a valuable resource for planning proximal femoral corrective osteotomies as well as determining implant size and design specifications in patients with proximal femoral deformities. 3D printing patient-specific cutting guides can help improve the accuracy of osteotomy cuts to reproduce the same degree of correction outlined in the surgical plan. The additional cost and time investment for these resources is worthwhile in patients with severe deformity and high surgical complexity.

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AUTHOR AFFILIATIONS

1 Zachary C. Hanson, MD; Donald D. Davis, MD; J. Weston Robison, MD
Wellstar Atlanta Medical Center, 303 Parkway Dr NE, Atlanta, GA

2 Jon E. Minter, DO
Orthopaedic Surgeon, Northside Total Joint Specialists, Alpharetta , GA

(Direct inquires to Zachary Hanson, zchg47@gmail.com)

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Intrapelvic Pseudotumor Causing Neuropathy and Vascular Obstruction After Revision Total Hip Arthroplasty: A Case Report

Sweet, M[1]; Snoap, T[2]; Roehr, B[2]; Roberts, J[2]

Abstact

Background: There is a growing body of recent literature regarding the occurrence of pseudotumors associated with modular junctions and various bearing surfaces after total hip arthroplasty (THA). Revision surgery is often technically challenging and high complication rates have been reported. The optimal management of these patients and outcomes after operative treatment remain poorly understood.

Methods: We report the case of a 77-year-old male with progressive unilateral lower extremity swelling, pain, and neuropathy 9 years after revision THA for polyethylene liner wear. Imaging and biopsy confirmed a massive intrapelvic pseudotumor exerting compressive effects. Radiographs demonstrated extensive femoral and pelvic osteolysis without evidence of component loosening. Debulking of the intrapelvic portion of the pseudotumor was performed via the lateral window of the ilioinguinal approach with component retention.

Results: Debulking of the intrapelvic mass resulted in resolution of symptoms. One year postoperatively the patient reported pain free ambulation using a walker and no recurrence of symptoms. Radiographs demonstrated stable THA components in comparison with preoperative films.

Discussion and Conclusion: This case demonstrates a rare finding of intrapelvic pseudotumor causing neurovascular compression after revision THA. Clinicians should be aware of intrapelvic pseudotumor as a possible cause of limb swelling and neuropathy, and that debulking of the mass is a potential treatment option in the setting of well-fixed implants.

Background

Adverse local tissue reaction (ALTR) is being increasingly encountered in the setting of failed total hip arthroplasty (THA). Recent literature has focused on increasing our understanding of the biologic mechanisms that induce ALTR, as well as summarizing available evidence regarding the diagnosis and management of patients with this problem, which is recognized to lead to poorer outcomes [1–4]. Briefly, ALTR is a pathological biological tissue response that occurs in association with a joint replacement resulting from chronic immune response to wear debris. ALTRs include variable amounts of osteolysis, tissue necrosis, fluid collection, and soft tissue masses. 'Pseudotumors' are a form of ALTR, referring to benign, aseptic soft tissue masses which develop in the vicinity of a THA, and may be cystic, solid, or both [4–7]. The term pseudotumor is commonly used in reference to metal-on-metal

Keywords*: Pseudotumor; Total Hip Arthroplasty; THA; Pelvic Mass; Adverse Local Tissue Reaction; Femoral Nerve Neuropathy*
Level of Evidence*: IV*

(MoM) THA, however, these masses have been associated with various types of THA bearing surfaces [1,4,5,8–11]. Pseudotumors most commonly present in the periarticular tissues and can be asymptomatic or may be a source of chronic pain due to soft tissue destruction or compressive effects. Here, we report the case of a patient with a large symptomatic pseudotumor with both intrapelvic and extrapelvic components after revision THA. The intrapelvic component resulted in vascular obstruction and femoral neuropathy, which successfully resolved after debulking of the mass. The patient was informed that his case would be submitted for publication, and he provided consent.

Case Presentation

A 77-year-old male was referred to our institution for evaluation of right lower extremity edema, neuropathy, and pain associated with a right pelvic mass. The patient had previously undergone a ceramic-on-polyethylene primary THA in 1992 with a DePuy AML cementless femoral stem, ceramic femoral head, and Duraloc acetabular cup with a Hylamer liner (DePuy Orthopaedics Inc, Warsaw, IN). This was subsequently revised in 2010 by head and liner exchange for polyethylene wear and osteolysis. The acetabular liner was replaced with a Duraloc Marathon polyethylene acetabular liner (10 degree, +4 mm offset, 36 mm inner diameter, 56/68 mm outer diameter) and the ceramic head was revised to an M-Spec metal femoral head (36 mm diameter, 14/16 taper, +0 offset; DePuy Orthopaedics Inc, Warsaw, IN). Both the index and revision THAs were performed at outside institutions. He had no history of prosthetic joint infection.

The patient had a medical history of well-controlled diabetes mellitus (HbA1c <6.0), peripheral vascular disease, and atrial fibrillation managed with Coumadin. His pertinent surgical history included a right femoral-peroneal in-situ bypass graft, right L3-4 laminectomy, both within three years of presentation, and bilateral THAs. His body mass index was 26.9 kg/m^2 and he ambulated functional distances using a walker.

In early 2019, the patient began experiencing worsening buttock and groin pain, anterior thigh paresthesias, and diffuse swelling in the right lower extremity. His initial workup for radiculopathy was performed by his neurosurgeon. An MRI of the lumbar spine obtained incidentally revealed a large right-sided pelvic mass (Fig. 1). A computed tomography (CT) scan demonstrated a heterogenous mass in the right hemipelvis which measured approximately 13 x 10 x 26 cm in dimension (Fig. 2). A CT-guided biopsy was performed and revealed fibrinous and necrotic tissue

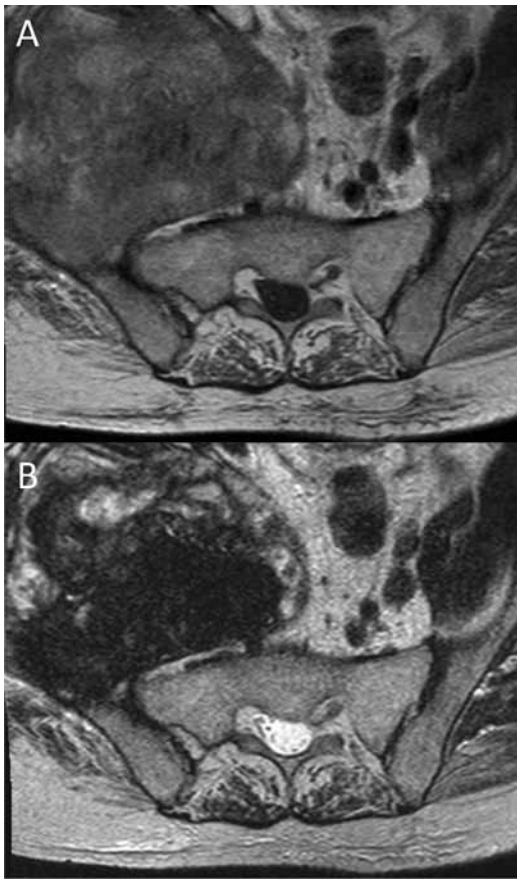

Figure 1: Axial T1-weighted (Fig. 1-A) and T2-weighted (Fig. 1-B) MRI images of the pelvis demonstrating a large heterogenous mass in the right iliac fossa with compression of the pelvic cavity.

with extensive histiocytic infiltrates and few foreign body giant cells. No organisms were cultured, no malignant cells were identified, and no metallic debris was seen. The patient was then referred to a regional academic medical center for evaluation by an orthopaedic oncologist. His case was presented at their multidisciplinary tumor board, and it was felt the mass was due to particulate disease related to his THA. He was then referred to our institution for definitive treatment.

Radiographs obtained during our initial evaluation demonstrated severe osteolysis involving both the proximal femur and acetabulum, with complete destruction of the superior pubic ramus (Fig. 3). The cementless stem and acetabular cup appeared well-fixed to bone with an intact superior rim and no obvious superior or medial migration of the cup. On physical examination, he had diffuse pitting edema throughout the right lower extremity to the thigh, and a mass-like fullness in the right gluteal region. He stated it felt as if he was "sitting on a tennis ball in the right hip." There was no palpable mass over the iliac crest.

The mass had become very debilitating to the patient, and his primary complaint was significant swelling in the right lower extremity. Preoperatively, multiple lengthy discussions were held with the patient and his family on separate occasions. His imaging was reviewed, and the risks, benefits, and alternatives to both operative and non-opera-

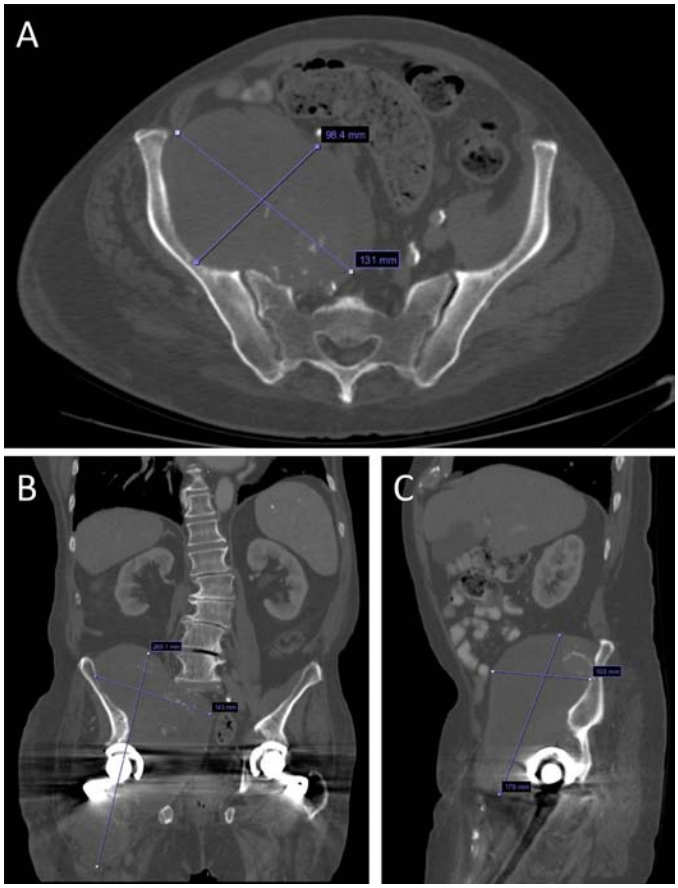

Figure 2: Preoperative axial (Fig. 2-A), coronal (Fig. 2-B), and sagittal (Fig. 2-C) CT images demonstrating a heterogenous destructive mass with scattered peripheral and internal calcification measuring approximately 13 x 10 x 26 cm in dimension involving the right hemipelvis from the iliac fossa to midline. The lesion is causing mass effect on the intrapelvic structures and envelops the right acetabulum and hip prosthesis, extending into the posterior musculature of the right thigh. The mass communicates through a region of extensive osteolysis in the superior pubic ramus to the periprosthetic area.

tive treatment were thoroughly discussed. The complexity of his diagnosis and surgical options were explained, including the risks of progression of his osteolysis and further bone loss making acetabular and femoral reconstruction more challenging than his current situation. Furthermore, his left THA, which also had significant radiographic osteolysis, was discussed. However, he was asymptomatic on the left side and deferred operative treatment. Ultimately, the patient clearly expressed his treatment goals, which entailed undergoing the least amount of surgery that could potentially alleviate some of his symptoms of swelling and paresthesia's. He had low functional demands and understood surgery would not be curative and there was a possibility of recurrence. After thorough discussion, he elected to proceed with debulking with the goal of relief of his compressive symptoms. Preoperatively, the decision was made to debulk only the intrapelvic portion of the mass, as it was felt to contribute to most of his symptoms. The case was reviewed with our vascular surgery colleagues who were available during the procedure.

In December 2019, the patient underwent debulking of the pseudotumor using the lateral window of the ilioinguinal approach. The anterior abdominal musculature was reflected medially off the iliac wing to expose an encapsulated mass adjacent to the iliacus muscle. This was incised, and more than 1L of thick, blood-tinged debris was evacuated (Fig. 4). The acetabular component was palpable

Figure 4: Intraoperative photograph taken through the lateral window demonstrating the porous coated shell visible through the inner table (white arrow) after debulking of the intrapelvic pseudotumor (Fig. 4-A). Clinical photograph of solid debris evacuated from within the fibrous wall of the mass (Fig. 4-B).

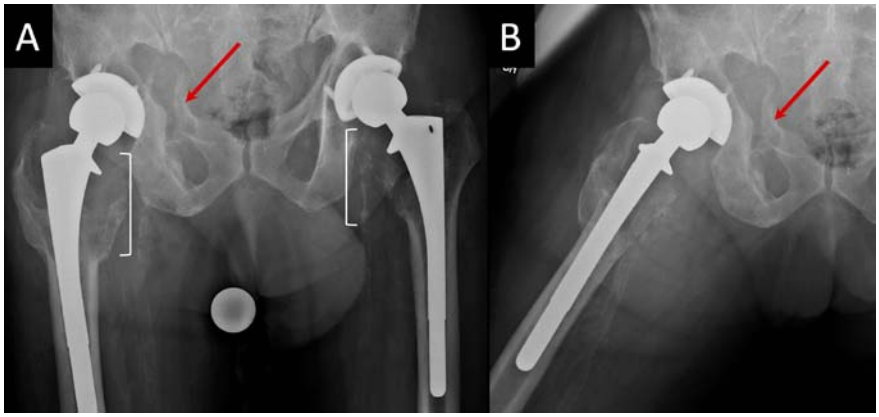

Figure 3: Preoperative anteroposterior pelvis radiograph (Fig. 3-A) and frog-leg lateral radiograph (Fig. 3-B). There is extensive osteolysis involving both the proximal femur (demarcated in white brackets) and acetabulum on the right with less severe osteolysis on the left. There is complete destruction of the right superior pubic ramus (red arrows). There is an intact superior rim of the right acetabulum without obvious component loosening or migration.

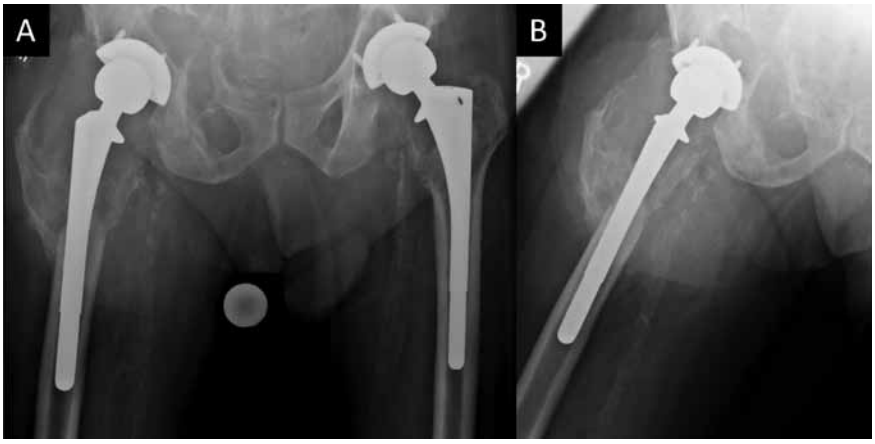

Figure 5: One-year postoperative anteroposterior pelvis radiograph (Fig. 5-A) and frog-leg lateral radiograph (Fig. 5-B).

through the cystic cavity and noted to be stable and well-fixed to bone. Due to the thickness of the debris, it was not possible to express further debris from within the leg. The patient had an uneventful recovery and was discharged to a rehabilitation facility.

One year postoperatively, the patient reported no pain or subjective limp, and was very pleased with the results of his surgery. His swelling had resolved, paresthesias were improved, and he was able to sit comfortably. He continued to use a walker for ambulation. Repeat radiographs demonstrated stable THA components in comparison with preoperative films (Fig. 5). He requested to defer any further operative treatment, unless his extrapelvic symptoms worsened.

Discussion

Pseudotumor is an uncommon complication of THA, and the true prevalence is unknown [4,6]. In a meta-analysis, Wiley et al. reported a 0.6% estimated incidence of pseudotumor after MoM THA or resurfacing arthroplasty [12]. Higher prevalence has been reported in asymptomatic patients and after prolonged follow-up, suggesting growth of pseudotumors over time [13–16]. The rate of revision THA due to symptomatic pseudotumor has been reported to be 0.5% in non-MoM THAs and 2- to 3-fold higher in MoM THA [6,7,12,16,17]. Intrapelvic masses associated with a THA are rare, and have been reported in roughly 30 published cases [18–49]. Pseudotumors associated with THA may be asymptomatic, and identification may occur during routine investigations for another reason. While unexplained pain is typically the presenting symptom, unilateral limb swelling [25–27,29,45], sciatic nerve neuropathy [21], femoral nerve neuropathy [28,30,31], venous thrombosis [32–35], and ureteral obstruction [36,37] have been reported in several case reports.

While the observed differences in biologic response to prosthetic debris vary between patients, particles of all types of metals, polyethylene, and ceramic debris have been shown to induce a biologic response and initiate osteolysis [50]. Our patient presented 27 years after his index THA and 9 years after his revision THA with extensive osteolysis and pseudotumor formation, which we suspect developed in response to wear debris related to his index THA liner. The accelerated wear, risk of osteolysis, and early failures of Hylamer liners, which were introduced in the early 1990s, are well-documented in the literature [51–54]. However, there is limited long-term follow-up information available on patients who have received this bearing surface. This data is important and an additional unique aspect of this patient's case worth highlighting.

The authors acknowledge several limitations associated with the perioperative workup for this case. The patient had undergone an extensive preoperative workup at several outside facilities prior to his evaluation in our office for definitive treatment, and thus a component of the decision making in this case relied on the quality of his medical records. Although the patient's clinical presentation, symptoms, outside laboratory studies, and previous biopsy results were not suggestive of a prosthetic joint infection, a full infectious workup would have ideally been performed at our institution. Additionally, while his pseudotumor and osteolysis were felt to be related to polyethylene wear, rather than metallosis, obtaining serum metal ion levels (cobalt and chromium) would have been prudent. Finally, unfortunately histological slides are discarded after a holding period at our institution and were not available to for image review of this case. Retaining a digital collection of intra-operative soft tissue specimens collected by institutions would be of value for patient care and retrospective case review.

Interestingly, our patient developed symptoms after previously undergoing a right sided lumbar spine decompression and right lower extremity vascular bypass. To our knowledge, this is the first case report to describe a pseudotumor in a patient with a history of operative spine and vascular surgery for symptoms in the ipsilateral extremity. The case presented also represents one of the largest pseudotumors documented in the literature.

The treatment decision for addressing symptomatic pseudotumors is challenging and options include aspiration, removal of the source of wear debris by component

revision or liner exchange, or resection with or without revision THA [3,4,26,39]. Bolognesi et al. provided a framework for the evaluation and treatment of patient with MoM THAs, and a recent consensus statement from the AAOS and AAHKS provides guidance for the evaluation and treatment of ALTR in metal-on-polyethylene THAs [2,7]. However, there is a paucity of data available to guide the evaluation and management of ALTR in patients who have previously been revised. We are aware of only three previous reports documenting enlargement or recurrence of a pseudotumor after revision THA and removal of the source of wear debris [31,55,56]. Revision THA for pseudotumor is recognized to have poor outcomes and high complication rates due to bone loss and periarticular soft tissue damage compromising stability [57–59].

To the best of our knowledge, there has been only one case reporting management of an intrapelvic pseudotumor with excision only [23]. However, in this case the patient refused a revision surgery and follow-up was not reported [23]. Most studies reporting intrapelvic pseudotumors document resection of the mass during revision THA, rather than for symptomatic treatment. In our case, debulking of the solid intrapelvic portion of the mass was performed to relieve compressive effects taking into careful consideration the patient's goals and functional demands. The decision to retain the acetabular cup was based on clinical and radiographic evaluation. The current case documents the potential for symptomatic relief after debulking of an intrapelvic pseudotumor.

In conclusion, clinicians need to be aware of pseudotumors as a differential diagnosis in patients with a history of THA who present with unilateral limb swelling, pain, or neuropathic symptoms. A multidisciplinary approach is advocated with close communication between musculoskeletal radiologists, musculoskeletal oncologists, pathologists, orthopaedic surgeons, and vascular surgeons. Debulking of the solid intrapelvic mass is a potential treatment option after revision THA in the setting of well-fixed components. Continued, long-term observation is warranted as re-accumulation of debris and recurrence of symptoms may occur.

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AUTHOR AFFILIATIONS

1 Dr Matthew C. Sweet, MD
Department of Orthopaedic Surgery, Western Michigan University Homer Stryker M.D. School of Medicine, Kalamazoo, MI

2 Tyler Snoap, MD; Bernard A. Roehr, MD; Jason W. Roberts, MD
Bronson Methodist Hospital, Kalamazoo, MI

(Direct inquires to Matthew Sweet, Matthew.Sweet@med.wmich.edu)

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Metal-on-Metal Total Hip Arthroplasty: Current Recommendations and Lessons Learned

Liu, J[1]; Hart, A[2]; Holderread, B[1]; Clyburn, T[3]

Abstact

Metal-on-metal (MoM) hip arthroplasty was re-popularized in the 1990s to resolve osteolysis and wear associated with metal-on-polyethylene products. Despite early success, registries began reporting high failure rates due to adverse reactions to metal debris (ARMD), manifesting as pseudotumors, hip effusions and osteolysis. Evaluation includes clinical exam, advanced imaging, and blood metal ions and infectious markers. This review provides physicians with an evidence-based update on the 1) clinical workup and management of patients with existing MoM implants, 2) risk and prognostic factors associated with suboptimal results and 3) the precipitating events and lessons learned applicable to future orthopedic prosthesis.

Background

Complications associated with metal-on-metal (MoM) hip implants have been documented since the 1950s when the first generation of MoM implants was introduced. [1] Unfavorable outcomes such as prosthetic loosening, metallic debris, and metal hypersensitivity resulted in a shift to using polyethylene implants in the mid 1970s. [2] However, polyethylene wear-induced osteolysis and loosening called for an improved prosthetic. [3] Thus, in the late 1990s, second-generation MoM devices were re-introduced with the rationale of producing less wear and dislocation due to thinner cups and larger heads. [1,4] Early clinical trials and hip simulations in the early 2000s showed excellent outcomes resulting in the massive implantation of over a million MoM hips worldwide. [2] Despite preliminary success, international registries began detecting higher then acceptable revision rates and complications later in the decade, and voluntary recall by several manufacturers (Table 1). [4] The high failure rates of MoM implants is caused by the release of metal ions secondary to mechanically induced corrosion. [5] The generation of metal ions triggers the secretion of cytokines leading to the

Table 1. Recall dates of MoM hip replacement systems by manufacturer

Hip Replacement System	Manufacturer	Date of Recall
Durom Acetabular Component	Zimmer	July 22, 2008
ASR XL Acetabular	DePuy	August 24, 2010
R3 Metal Liners, R3 Acetabular Cup	Smith & Nephew	June 13, 2012
Rejuvenate, ABG II Modular	Stryker	July 6, 2012
Biomet M2a Magnum Hip	Zimmer Biomet	February 9, 2015
Profemur Z Hip Stem, Profemur Neck Varus/ Valgus CoCr	Wright/ Microport	November 15, 2016

***Keywords**: metal-on-metal, total hip arthroplasty, clinical management, literature review, lessons learned*
***Level of Evidence**: V*

formation of pseudotumors and other adverse local tissue reactions (ALTR). [5] Joint failure associated with pain, large sterile effusions of the hip and/or macroscopic necrosis/metallosis are consequences of adverse reaction to metal debris (ARMD). [6] While rare, systemic toxicity associated with blood metal ions can result in hypothyroidism, tinnitus, neurosensory deficits and cardiomyopathy. [7]

The monitoring and management of patients with problematic MoM requires a step-by-step algorithmic approach including history and physical, blood metal ions (Co, Cr), and imaging (radiography, ultrasonography, and MRI). Optimal management requires evaluating specific patient and implant risk factors on a case-by-case basis. Current studies evaluating revision outcomes have identified specific surgical approaches and factors associated with improved results. MoM implants are now rarely used, however, many patients have a MoM prosthesis that requires surveillance or revision.

Orthopedic registries, retrieval analysis, and collaboration between surgeons have been essential to understanding MoM failures. We continue to examine the deficits in the surveillance and market clearance of MoM implants to understand and learn from past mistakes. The focus of this review is to provide physicians with an evidence based update on the 1) clinical workup and management of MoM total hip arthroplasty, 2) patient and implant risk factors associated with suboptimal results and strategy for improved revision outcomes, and 3) actions that resulted in the widespread introduction and recall of MoM hips and the lessons learned that can be applied to the novel orthopedic prosthesis in the future.

Clinical Evaluation

It is important to obtain the original surgical date, location, indication, perioperative complications, and make and model of the prosthetic. [8] Patients presenting with hip pain should be asked to characterize the temporal onset, duration, severity, location, and quality of the pain to further qualify the diagnosis. [9] Radiation of pain to the greater trochanter and down the thigh is a common presentation that may result in an antalgic gait. [10] Other symptoms are feeling fullness of the hip, swelling, squeaking, crackling, or clunking with movement of the hip. [9] History of a dermal reaction to metal jewelry has been associated with a greater risk for MoM hip hypersensitivity reactions. [9] History of reduced range of motion (ROM) especially with abduction rarely accompanied by a periprosthetic rash, may indicate a reaction to metal debris. [2] Delayed wound healing, inflammation, and infection are suggestive of early joint sepsis. [11] Positive findings require further infectious work-up including erythrocyte sedimentation rate and C-reactive protein (ESR/CRP) levels, synovial fluid white cell counts, and cultures. [9] Physical exam includes palpation for soft tissue masses, assessment of active and passive ROM, identification of pain points, and muscle strength in flexion, extension, abduction, and adduction. A comprehensive neurovascular examination is necessary to rule out associated neurogenic and vascular pathologies. [9]

The Role of Blood Metal Ions

a. Recommendations for Blood Metal Measurements

Screening for cobalt and chromium metal ion levels became common around the time the DePuy Articular Surface Replacement (ASR) total hip prosthetics were recalled in August 10, 2010. Initial studies supported using a threshold of 7 ppb as a trigger for further work-up. [12] Recent studies have shown that the cut-off level of 7 ppb has low sensitivity and found that a cut-off of 4.97 ppb provides optimal sensitivity and specificity. [13] There is no ideal threshold of blood metal ions levels used for action because low levels are not specific in detecting ARMD and high levels risk ignoring some cases of ARMD. [14] However, a 7 ppb threshold has been most widely used and consistent with the latest United Kingdom Medicines and Healthcare products Regulatory Agency (MHRA) recommendations. [15] In 2017, the MHRA also issued an updated recommendation that female hip resurfacing and males with femoral head implant diameter ≥48mm should undergo lifetime annual serum metal ion screening regardless of symptomology. [16] In contrast, the U.S. Food and Drug Administration (FDA) states that there is insufficient evidence to recommend routine blood metal ion testing for patients with no radiograph evidence or clinical symptoms of failure. [17] A current study showed that annual blood Co and Cr have limited discriminant capacity in diagnosing metallosis and there was no significant increase in metal ions beyond 7 years. [18] In consideration of the current evidence, we suggest using the widely used threshold of 7ppb for initial work-up and discontinuation of routine serum testing for asymptomatic well-functioning implants.

b. Systemic Toxicity

Several case reports were published in the past decade describing systemic toxicity due to metal ion release. [4] Bradberry et al. found that the presentation of MoM systemic toxicity may include hypothyroidism, tinnitus, optic atrophy, sensory deficits, and/or cardiomyopathy, not attributed to other pathologies. [7] Clinical features may develop months to years following original implant placement though revision is generally curative of symptoms.

[7] Gillam et. al found a three-fold increase in rates of hospitalization admission for heart failure post-MOM total hip arthoplasty. [19] However, this topic remains controversial as other studies have found no increased risk for cardiac failure in MOM patients compared to a non-MOM cohort. [20] Zywiel et al. concluded that systemic symptoms were associated with cobalt levels greater than 100 ppb and that systemic toxicity was extremely unlikely in the context of low cobalt levels. [21] We recommend that patients should be revised with urgency when patients present with a failed MoM arthroplasty, systemic symptoms and extremely elevated blood metal ions (>100 ppb). [21]

Role of Advanced Imaging

a. Plain Radiography

Plain radiography to assess component position, loosening, osteolysis, bone quality, and femoral neck erosion due to impingement (Fig 1a,e,f). [22,23] Radiographs are indicated in all symptomatic patients with MoM replacements or resurfacings. [24] Radiographs should be compared to evaluate osteolysis and component loosening. [4] Additionally, it is important to assess for osseointegration of the implant as metal ions induce local inflammation and excessive fibrous tissue formation that may prevent osteoblasts from anchoring the implant with strong bone growth (Fig 1g). [25]

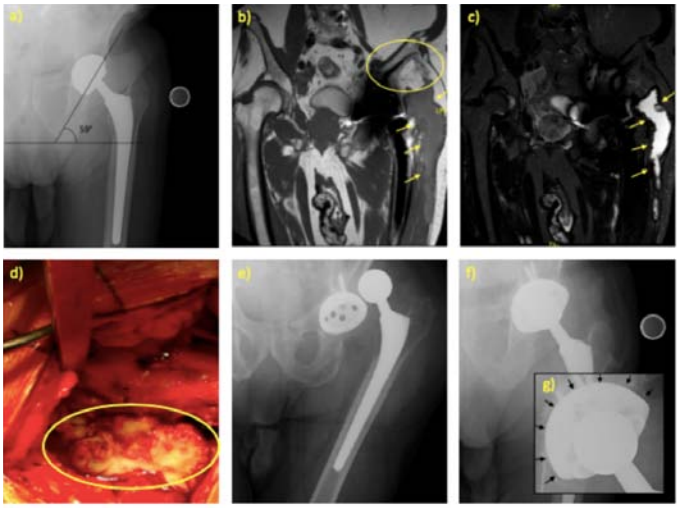

Figure 1. 82-year-old patient with a well-functioning left total metal on-metal Biomet M2A hip implanted in 2005. Patient presents in 2018 with pain, "fullness of hip" and clicking for the past 3-5 months. The work-up included elevated ESR/CRP and elevated cobalt and chromium levels. We present a series of radiographs and MRI images in Figures 1a-f describing his clinical management. a) Plain radiographs show no acute disease with inclination angle of 59°. The patient required revision of the cup, liner, and head. b) T-1 weighted MRI reveals substantial abductor muscle damage (yellow circle) and pseudotumor of the left hip that overlying the quadricep muscles (marked by yellow arrows). c) T-2 weighted MRI reveals the borders of the saturated pseudotumor (marked by yellow arrows). d) Intraoperative image reveals large pseudotumor that extends superficially (yellow circle). e) The same patient dislocated 4 months after revision likely secondary to abductor muscle damage. The stem was well ingrown. f) The patient was unstable after reduction and converted to a Biomet Freedom Constrained Liner. g) We suspect failure of osseointegration into the porous cup evidenced by a continuous 1 mm lucent (marked by arrows).

b. Ultrasonography

Ultrasound may be utilized for initial evaluation of the soft tissues due to its low cost, safety, and easy accessibility. [24] Literature supports the efficacy of ultrasound in detecting tendinous pathologies and periarticular fluid collections. [26] Unlike MRI, ultrasound is not susceptible to metal artifact distortion and has few contraindications. [4] However, ultrasound is operator dependent, requiring expert interpretation, and is limited in sensitivity and evaluation of deeper structures. [27] It is also more challenging to compare serial ultrasounds for surveillance. [26] In practice, ultrasound is generally utilized as an initial screening tool and may serve as a valuable supplement to more definitive modalities. [4]

c. MARS-MRI

With the introduction of metal artifact reduction sequence (MARS), MARS-MRI is the most sensitive and specific modality for diagnosing MoM hip pseudotumors. [28] MARS-MRI can assess for extracapsular and extrinsic cause of hip pain, such as iliopsoas tendonitis, bursitis, nerve compression, and spine pathology as well as abductor muscle integrity. [27] Beyond detection, an expert musculoskeletal radiologist can use MARS-MRI to characterize the location, size, and quality of soft tissue masses and joint effusions (Fig 1b,c). [22] Pandit et al. found that the two most common imaging abnormalities were either a cystic mass, lateral or posterior to the joint or a mainly solid mass, lying anteriorly and involving the psoas muscle. [29] However, the presence of a pseudotumor may be equally likely in a painful hip compared to a well-function hip and is not necessarily an indication for revision surgery. [30] For monitoring, MRI is crucial in collaboration for second opinions and evaluating pseudotumor size progression and invasion of adjacent neurovasculature. Additionally, rapid muscle atrophy due to an accelerated metal-wear induced inflammation is associated with worse revision outcomes and long-term prognosis compared to non-MoM cohorts. [29] Serial MRI can detect sensitive changes in soft tissue pathology and guide surgeons in performing timely revisions that may preserve abductor muscle and patient mobility. [31]

Associated Risk Factors

a. Patient Risk Factors

Liow et al. state that female gender, dysplasia, metal

hypersensitivity, and low body mass index are associated with increased failure rates of MoM hips. [2] Kovovich et al. also reported increased wear and local tissue reactions associated with bilateral implants, high dose corticosteroid therapy, renal insufficiency, metal sensitivity, severe obesity, and high activity. [4] A retrospective analysis by Amstutz et al. reported equal outcomes in male and female hip implants when other risk factors were removed. A recent study of 661 patients found no association between activity level and survivorship and recommended that patients may continue full activity in well-functioning metal hip replacements. [32] With the existing controversy in patient risk factors, further clarification is needed to supplement the management of MoM patients.

b. Implant Risk Factors

Large femoral head sizes have been associated with higher fretting and failure rates of metal hip arthroplasty. [33] Wear in the trunnion-head modular interface, known as trunnionosis, is a common mechanism of failure and affected by larger femoral head sizes increasing torsional forces at the trunnion. [33] Retrieval studies have found that increased femoral head diameter in THA produce increased fretting while corrosion is associated with length of implant time. [34] Early corrosion has also been associated with certain implants such as the Stryker Rejuvenate modular-neck stem design. [35] Flexural rigidity of the neck, trunnion length, trunnion diameter, and taper angle all affect the force distribution at the taper junction. [33] Weiser et al. recommend minimizing femoral head sizes, utilizing more rigid stems and trunnions, and meticulous cleaning and firm head impaction to reduce the risk of trunnionosis. [36] Additionally, edge loading accelerates wear rate as high inclination angles (>55°) result in elevated contact pressure at the articulating surface, which was found by Hart et al. to be the most important predictor of wear rate (Fig 1a and Fig 2a). [37,38] Compared to the ASR hip resurfacing, ASR total hip arthroplasty has higher risk for development of moderate-to-severe pseudotumors. [39] Additionally, a contact patch edge to rim (CPER) distance of less than 10 mm has been correlated with edge-loading and excessive wear (Fig 2b). [40] Due to the variability in implant design, consideration of implant components and risk factors improves patient specific care.

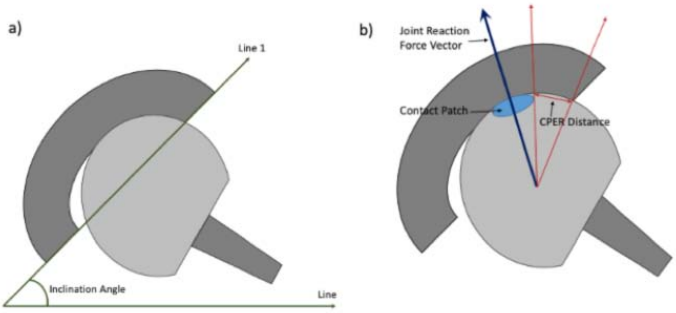

Figure 2. a) Illustration of inclination angle determined by angle between Line 1 (drawn across rim of the cup) and Line 2 (a horizontal reference across ischial tuberosities). b) Illustration of contact patch edge to rim (CPER) Distance. Joint reaction force vector represents balance of moment arms of body weight and abductor tension.

Revision Surgery

Symptomatic patients with pseudotumors that are solid, large, invasive, and destructive of soft tissue and bony structures require timely revision surgery. [41] In contrast, asymptomatic patients with normal imaging and blood ion levels (<4.5 ppb) most likely do not require revision and can be conservatively monitored. [41] However, patients with MoM implants require more robust guidelines for management. Liow et al. conclude that poor revision outcomes are seen in patients with prerevision radiographic loosening, solid lesions/abductor deficiencies on MRI, and high grade intra-operative tissue damage. [42] Matharu et al. suggest a posterior surgical approach when possible, revision of all MoM hip components, and use of a large diameter (>36 mm) ceramic-on-polyethylene or metal-on-polythene articulations to optimize revisions. [43] The hip anatomy should be reconstructed properly as Garcia-Rey et al. concluded that abductor muscle weakness is one of the greatest risk factors for dislocation. [44] Limited revision by conversion to dual mobility in MoM patients with cups in good position and condition have had positive early outcomes. [45] Straightforward patients may be revised with bearing replacements of the acetabular shell and metallic head. [46] However, complicated patients with severe metallosis of the acetabular cavity may require revision with pelvic plating. [47] Pseudotumors that invade soft tissue may require assistance from vascular surgeons for excision while bony osteolysis and trunnionosis may require custom implants and femoral stem replacement. [48] It is important to monitor patients for osseointegration of the implant pre- and post-revision as cellular damage secondary to metallosis can disrupt osteoblast function and bone growth (Fig 1g). [25] Wyles et al. found a high infection rate associated with revision of failed MoM hip replacements, especially in patients presenting with ARMD pre-revision. [49] Thus, post-operative patients should be monitored carefully for short-term infection and long-term complications. We need further reports from multi-center studies and retrospective registry cohorts to establish definitive thresholds for revision, modifiable intra-operative factors, and prognostic risk factors. [41]

Lessons Learned and Future Recommendations

MoM bearings were re-introduced in hip arthroplasty with the hope of addressing the consequences of polyethylene wear, hip dislocation and osteolysis. [50] Initial clinical evidence and laboratory evidence were promising as early in vitro simulations showed significantly reduced wear of tested MoM hip prosthetics (1 mm^3/million cycles, compared to wear of metal-on-polyethylene prosthetics, 30-100 mm^3/million cycles). [51] These findings instigated a widespread, mass implantation of MoM hips with disastrous outcomes. Thus, we realize that preclinical testing, joint simulation, and analytic modeling are insufficient in predicting the performance of orthopedic implants. [52] Hart et al. highlight precipitating factors including false confidence from hip simulations, immaturity of national registries, late implementation of implant retrieval centers, and inadequacy of clinical follow-up studies. [53]

a. The Role of Registries

The joint replacement registries of Australia, England, and Wales first established higher failure rates in MoM hips, resulting a massive recall of ASR and ASR XL metal implants by Depuy, Johnson and Johnson in 2010. [53] The detection was too late to prevent the ensuing catastrophe, leading us to question the efficacy of such registries. Retrospectively, we realize that National Joint Registry of Wales and England, established in 2002, had relatively poor compliance and consent, and immaturity in dealing with failed implants at the time. [53] Registries are also unable to predict or prevent the poor implants from entering markets and are limited to monitoring and reacting failing products. [54] Maturing registries today have implemented mandatory compliance from practicing surgeons and improved protocols for safety measurements. [54] The U.K developed improved guidelines for the introduction of new prosthesis in response and Tucker et al. suggested that a standing committee and universal protocol should oversee the introduction and performance of existing and new implants. [54]

b. Implant Retrieval

The integration of implant retrieval centers was essential to identifying the mechanisms of failure of MoM hip implants. With the increased compliance of surgeons, current studies have identified mechanical components, surrogate markers such as blood metal ions, and positional factors associated with failed implants. [53] The role of retrieval analysis in our management of MoM hips suggests that early retrieval protocols should be in place prior to the introduction of novel orthopedic implants.

c. Rec ommendations for Regulation

Beyond surveillance, we must assess the regulatory entities and barriers in place to prevent the entry of suboptimal products. Though it is important to foster medical innovation, patient safety was severely compromised with metal hip prostheses. [55] Upon investigation, Howard et al. found that many companies bypassed the FDA premarket approval (PMA) market clearance pathway with a less stringent 510(k) pathway, using existing but outdated metal hip predicates. [55] We now realize that the 510(k) pathway is insufficient for the evaluation of high risk orthopedic prostheses. [55] Additionally, they found that FDA post-market surveillance was insufficient and more stringent, longer duration post-approval studies should have been mandated in metal hip implants. [55] Finally, certain manufacturers withheld failed FDA approvals and continued to market their products in other countries. [55] Thus, Howard et al. conclude that regulatory approval information should be made accessible to all stakeholders including surgeons, patients, and hospital administrators in the future. [55] Upon investigation of the protocols in place, it is evident that regulatory bodies need to serve a more involved and robust role in the assessment of novel orthopedic prosthesis.

Summary

Currently, we recommend a step-by-step algorithmic approach with clinical exam, serum studies, and imaging for evaluating MoM patients. [8] Inconsistent practice between different orthopedic centers calls for further international guidance and multi-disciplinary panels to improve consensus in decision making. [56] We hope that the integration of more mature registries and retrieval centers with updated regulatory protocols can prevent the massive implantation of suboptimal prosthetics in the future. While the use of total metal hips is now largely outdated, the lessons we learned can be widely applied to prevent a similar catastrophe from occurring again. [53]

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AUTHOR AFFILIATIONS

1 Dr Jonathan Liu, MD; Dr Brendan Holderread, MD
Texas A&M Health Science Center, 8441 Riverside Pkwy, Bryan, TX

2 Dr Alister Hart, MD
Royal National Orthopaedic Hospital, Brockley Hill, Stanmore HA7 4LP, United Kingdom

3 Dr Terry Clyburn, MD
Houston Methodist Hospital, 6565 Fannin St, Houston, TX

(Direct inquires to Jonathan Liu, jliu0422@tamu.edu)

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A Literature-Based Resource for the Development of Outpatient Arthroplasty Patient Selection Criteria

Gondusky, J[1]; Pahapill, R[2]; Coulson, C[2]

Abstact

Total joint arthroplasty (TJA) is moving towards the outpatient setting. Teams must develop patient selection criteria to ensure appropriate candidates are treated at the optimal site of care. Protocols and recommendations have been developed to aid care teams in developing patient selection criteria, but these come from multiple disparate sources. We review the available literature on patient selection criteria and optimization in the outpatient TJA population, and synthesize this information into a workable format for care design. We hope to provide a resource to stakeholders that can be tailored to their unique outpatient facility.

Background

Total joint arthroplasty (TJA) is moving toward the outpatient setting. The change has been facilitated by improved perioperative protocols and anesthesia techniques, and increasingly embraced by patients, surgeons, and insurers. Adaptation of protocols from the hospital inpatient to the outpatient setting requires a focused effort on the part of the care team to develop pathways that ensure continued safety, quality, satisfaction, and cost containment. An aspect of this care design needs to be a thoughtful consideration of who to select for candidacy at an outpatient facility. We attempt to provide a review of the available literature on patient selection criteria for outpatient TJA, and we synthesize this data in attempts to provide a reference to care teams attempting to create selection criteria appropriate for their unique facility. In addition, given its applicability to patient selection, we present a review of modifiable risk factors that affect TJA outcome, as well as patient optimization opportunities.

Materials & Methods

A review of published material related to outpatient, rapid discharge or same day TJA was queried, with specific focus on outpatient surgery, same day discharge, and patient optimization. We searched the PubMed database for articles published between January 1, 2015, and December 31, 2019, in order to focus on relevant, modern studies. Articles that included a specific focus on outpatient surgery, same day discharge, and patient optimization about the TJA episode were included. Articles focusing on upper extremity surgery, or without defined tangent variables allowing for comparison, such as generic opinion articles, were excluded (Fig. 1). The most relevant available articles were individually determined and reviewed, with a goal of enough focused studies analyzed to ensure adequate breadth of the topic. [1-19] Articles were grouped into those providing data on selection criteria, failed dis-

Keywords: *Total joint arthroplasty, outpatient, same day discharge, selection criteria, patient optimization*
Level of Evidence: *IV*

charge, or patient optimization. Studies focused on selection criteria were reviewed, with selection variables extracted. These were compared across studies. The relative paucity of studies and overall low levels of evidence did not allow for a true weighting of variables as is possible in more robust systematic reviews. Hence, the studies were synthesized grossly to be able to present an overall review of published literature on the topic. Inclusion and exclusion criteria for selection were grouped according to variable for attempted presentation in a consolidated format. Optimization and discharge failure data were synthesized and are presented descriptively.

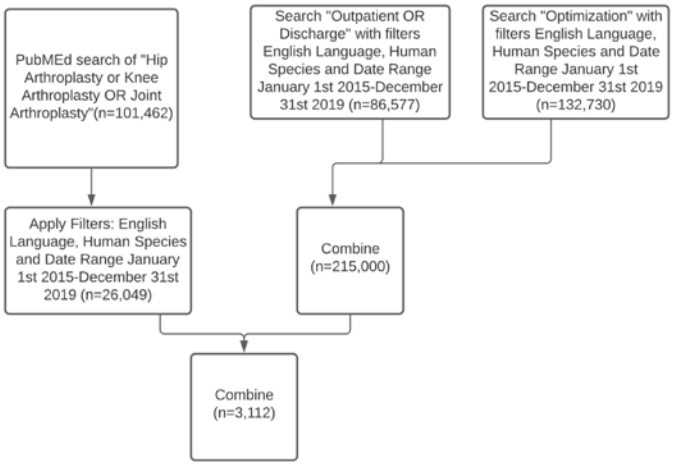

Figure 1: Search methodology for relevant articles

Results

Multiple authors have reported on their results with outpatient TJA. [1-19] Some studies select patient inclusion and exclusion criteria, and then determine the results of patient outcomes based on this selection. Others attempt to define appropriate criteria based on a retrospective review of successful day of surgery discharge after TJA. Scoring systems have also been promoted to aid the team in appropriate selection of the outpatient TJA candidate. [7,8] Given the heterogeneity of the literature on the topic, we attempted to provide some synthesis to guide stakeholders.

Certain variables are consistently addressed in the literature. These are summarized in Table 1. Many authors note specific but less universal recommendations for exclusion. These are valuable for consideration and are presented in Table 2.

Table 1: A list of variables consistently noted by various authors.

Patient Variable	Range of Exclusion
Age (yrs.)	>65-75 [1,2,4,9]
ASA Class*	≥3 [1,9-11]
BMI (kg/m2)	>35-40 [1-3,9,10,12]
Preoperative Hemoglobin (g/dL), Hematocrit	<10-12 [1-3,9,11], <30% [4]
Glucose on Day of Surgery (mg/dL)	>180-200 [9,12,13]
Hemoglobin A1C (%)	>7.5 [11,14]
Timed Up and Go Test (s)	>10 [5]
Creatinine (mg/dL)	>2 [14]
Sodium (mEq/L)	<126 [14]
Potassium (mmol/L)	<3 [14]
STOP-BANG score for Obstructive Sleep Apnea (OSA)	>5 [9]

Table 1 reveals variable exclusion ranges noted by some authors. *ASA 3 was considered appropriate criteria for outpatient TJA by most authors. In a review of 3,444 charts, over 1/3 of ASA 3 patients were otherwise deemed eligible for TJA in the ambulatory surgical center when their composite screening criteria were utilized. [10]

Table 2: A list of general exclusion criteria noted by some authors.

Other General Exclusion Criteria to Consider
Revision Surgery [1,2]
Bilateral Arthroplasty [1,2]
Inability to Ambulate Without a Walker [1,2]
Significant Cardiopulmonary History [1-4,9-11] (see article text for definition)
History of Thromboembolic Event [4,9-11]
Chronic Anticoagulation [3,9]
Presence of Obstructive Sleep Apnea [3,9,10,15]
Chronic Liver Disease (Childs class B or worse) [9]
Cerebral Vascular Disease [9]
Chronic pre-operative opioid use/addiction [1,2]
Inadequate assistance at home after discharge1/lack of support [2,3,15]
Cognitive Deficiencies [15]

Significant cardiopulmonary history is important to define, as many patients present with some history of diagnosis in these systems, and one needs tangible guidelines to aid selection criteria. This is defined in the reviewed studies as "no history of cardiopulmonary disease that would necessitate inpatient monitoring after surgery", [1] no CABG or stent placement within the last 6 months, [4] no history of coronary arterial disease or arrhythmias, [3]

no history of MI or CAD with PCI or CABG within the last one year, [10] and no oxygen or COPD/asthma steroid dependency. [9]

Reasons for failed day of surgery discharge can help modify selection criteria and focus efforts on care design. A review of available literature reveals some common issues. Fraser et al. noted the importance of preoperative education and planning, as most of their patients failed same day discharge due to patient preference, with patient concern about being "tired, safety concerns at home, or a long drive home". [1] They also found a significant correlation with failure and the number of patient-reported allergies, anxiety, depression, OSA and rheumatoid arthritis (RA). From a medical standpoint, they had a large percentage fail due to dizziness, vasovagal episodes, and/or hypotension. [1] DeCook noted discharge delays being predictable due to hyper or hypotension, over sedation, urinary retention, nausea or vomiting, pain and social support issues. [19] Richards et al. reported that out of 7 failures, 5 were due to hypotension, one due to pain, and one urinary retention. [5] Goyal et al. reported similar issues limiting day of surgery discharge with overall 24% failing. Older women had the most significant issue with prolonged length of stay in their study. [2]

A review of optimization strategies is also valuable to consider in determining care design and selection criteria. A few authors present excellent and comprehensive reviews of the topic. [13,14,16-18] While a thorough review of patient optimization is beyond the scope of this article, we believe the basic variables addressed are worthy of note, in order to alert the care team for their consideration. These are presented in Table 3.

Yu et al, Boraiah et al and Kim et al describe a surgeon-led screening and optimization initiative. [16-18] They identify eight risk factor categories that are modifiable. These 8 categories include infection, smoking, obesity/malnutrition, cardiovascular disease, history of VTED, neurocognitive/psychiatric substance-related problems, physical deconditioning, and diabetes/malnutrition. [16] Using their protocol, they noted a lower readmission rate, cost and skilled nursing facility discharge (SNF DC). [16]

Discussion

Primary TJA should be "successful" and reproducible. "Success" should be defined as reflecting the "triple aim" initiative promoted by the IHI institute for HC improvement: better care for individuals (quality/satisfaction/patient experience), better health for populations, and lower per capita costs. As a huge annual healthcare expenditure, that has proven to be of value to society, [21,22] progressing TJA to the outpatient setting should be seen as a way to fulfill this "triple aim."

Care design is critical to successful implementation of an outpatient arthroplasty program. Patient selection criteria represent an important aspect of the care design pathway. Since it is impossible to extricate patient optimization and risk factor modification from the selection decision-making process, it would seem to make sense to consider these aspects of patient care at the time of considering patient selection criteria. It would also be important to consider why patients fail in the outpatient setting in order to understand how proposed selection criteria or preoperative pathways may need to be altered in order to achieve outpatient arthroplasty success. It is also important to constantly consider one's particular facility. Patient mix, available resources, proximity to higher levels of care, and many other facets differ between outpatient facilities. Each of these patient selection criteria variables need to be considered in light of one's circumstances. Because of this, a one-size fits all criteria will never be appropriate. Initial patient selection criteria should be formalized based on thoughtful consideration of variables in light of the facility circumstances and should always be reviewed and modified as needed.

Failure of planned day of surgery discharge provides a list of care design aspects to optimize. [1,2,5,19] These heed the importance of protocols that address postoperative pain, urinary retention, nausea/vomiting prevention and hypotension. They also highlight the importance of preoperative education, focusing on the need for a coach/support staff at home, as well as the patient understanding of the logistics and time-course of the operative day's events.

Tables 1 and 2 can be used as a starting point for care teams to consider in creation of their patient selection criteria. As noted, the criteria variables can be best modified by teams with awareness of their unique circumstances. We recommend that a multispecialty group, including representatives from surgery, anesthesia, nursing, therapy and administration are present to provide input for discussion, and that thoughtful and logical selection criteria are formalized. These can then be implemented with careful tracking and refined within a multispecialty quality control process.

Table 3 presents optimization strategies for variables. These are valuable and the extent of which a care team desires to implement these aspects should be determined. For instance, a robust and high-volume program may have the ability to institute care design pathways for many of these issues, including obesity management, psychopa-

Table 3: Variables to be considered for optimization during development of patient selection criteria.

Variable	Potential Problem Range	Considerations for Optimization
BMI (kg/m2)	Exact cutoff remains controversial. [17]	Recommend nutrition counseling, [13] endocrinology consult, [13] referral to bariatrics [16]
Hemoglobin A1c (%)	>7-7.5 [13, 14], >8 [16]	Refer to diabetic management/ endocrinologist/nutritionist [13,16]
Fasting Blood Glucose (mg/dL)	>180 [16]	
Hemoglobin (g/dL)	<9.9 [13] <11 (female) or <12 for (male) [14]	Consult hematology/anemia working group [13]
Transferrin (mg/dL)	<200 [13]	Nutrition consultation or supplementation [13]
Total Blood Count (/mm3)	<1500 [13]	
Albumin (g/dL)	<3.5 [13]	
Platelet count (per microliter)	<100,000 or >600,000 [14]	Consult hematology
INR	>1.25 [14]	
Sodium (mEq/L)	<128 [14]	Consult nephrology
Potassium (mmol/L)	<3.5 [14]	
Creatinine (mg/dL)	>1.5 [14]	
UTI	Positive	Treat UTI [13]
OSA Screen	Known OSA or STOP-BANG intermediate or high risk [14]	Refer to sleep medicine
MRSA History	Positive	Nasal mupirocin and preoperative vancomycin, [13] weight-based Vancomycin [16] S. Aureus decolonization before surgery [17]
HIV	Positive	Optimize with specialist [16]
HCV	Positive	Optimize with specialist. [16] Consider liver function tests
Cigarette Use	Current Smoker	Refer to smoking cessation program [13,16,17]
Alcohol Use	>2 Drinks Per Day with Daily Use [14]	Alcohol Intervention [16]
Venous Thromboembolic Disease (VTED)	History of PE, DVT, activated protein C resistance, high factor VIII or lipoprotein A levels. [16]	Consult vascular medicine / hematology. [13] Patients with history of VTED receive aggressive anticoagulation. [16]
Cardiopulmonary Disease	Significant PVD, CAD, CHF, uncontrolled HTN, arrythmia, CVA, recent CABG/MI/stent, COPD. [13,16]	Cardiology Referral [13] Perioperative use of Beta Blockers [17,20]
Narcotic Abuse	Longer than three months [13]	Optional Referral to Pain Medicine, [13] Drug Intervention [16]
Psychiatric Disease [17]	Depression: Patient Health Questionnaire (PHQ-2)>2. [14] (PHQ-9)>6. [16] Generalized Anxiety Disorder (GAD) item 2>2. [14]	Consult Primary Care [13] Depression intervention/catastrophizing therapy. [16] Cognitive Behavioral Therapy [17] Consider referral to psychiatry
Ambulatory Status	Patient is non-ambulatory or needs assistance with transfers. [16]	Refer to physical and/or occupational therapy to educate patient on fall prevention, facilitate "pre-habilitation". [16,17]
Immune Modifying Therapy	Positive	Consult Rheumatology [13]
Lower Extremity Skin Check	Presence of at least "Small Wound", [14] lymphedema, severe varicosities or dermatologic condition	Clinical decision-making by surgeon, refer to wound therapy as needed
Dental Screen	Positive Screen [14]	Dental examination [13]

Abbreviations: Urinary Tract Infection (UTI), Obstructive Sleep Apnea (OSA) Pulmonary Embolism (PE), Deep Venous Thrombosis (DVT), Peripheral Vascular Disease (PVD), Coronary Artery Disease (CAD), Congestive Heart Failure (CHF), Hypertension (HTN), Cerebrovascular Accident (CVA), Coronary Artery Bypass Graft (CABG), Myocardial Infarction (MI), Chronic Obstructive Pulmonary Disease (COPD)

thology and nutrition optimization. However, other programs may desire a focus on only cardiac optimization when needed, and an otherwise standard list of inclusion and exclusion criteria. More robust scoring systems can also be considered and will, necessarily and practically, be resource dependent.

Conclusion

Patient selection criteria are an important aspect of care design within a successful outpatient arthroplasty program. A review of outpatient TJA selection criteria, optimization strategies, and etiology of failed same day discharge is presented. We hope the synthesis of this data provides a starting point and valuable reference for care teams to aid creation of their specific, facility-appropriate, outpatient arthroplasty selection criteria.

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AUTHOR AFFILIATIONS

1 Dr. Joseph Gondusky, MD
Jordan-Young Institute, 5716 Cleveland St #200, Virginia Beach, VA

2 Richard Pahapill, MD; Christian Coulson, MD
Eastern Virginia Medical School, 825 Fairfax Ave, Norfolk, VA

(Direct inquires to Dr. Joseph Gondusky, josephgondusky@gmail.com)

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Life Lost Too Soon: Navy Corpsman from Ohio Killed in Afghanistan Attack August 26, 2021

McTighe, T[1]

Navy Corpsman Maxton "Max" W. Soviak, HM3 (22 years old) of Berlin Heights, Ohio, was one of the 13 U.S. service members killed while supporting non-combatant evacuation operation in Kabul, Afghanistan.

Max was advanced to the rank of Hospital Corpsman Third Class "as a result of his brave actions in support of fellow service members," according to a Navy statement. He was also posthumously awarded the Purple Heart and Fleet Marine Force Corpsman warfare badge.

He enlisted in September 2017 and attended Hospital Corpsman School in San Antonio, Texas, before postings in Guam and at Camp Pendleton.

Soviak lived in Berlin Heights and graduated from Edison High School in 2017, where he also wrestled and played football.

The Soviak family said Maxton was proud of being part of a state champion wrestling team and a final four state playoff football team two years in a row, "but he was most proud to be a Navy Corpsman and a 'devil doc' for the Marines."

Navy Corpsman Maxton "Max" W. Soviak
January 22, 1999 - August 26, 2021

I wanted to take this opportunity to pass on my condolences to the Soviak Family, and friends. Seeing and reading about Max made me think how blessed I have been since Max and I started out with very similar paths to adulthood.

Like Max, I joined the U.S. Navy out of High School (Euclid High). We were both from Northern Ohio. Max being from Berlin Heights and I was from Euclid, Ohio. He joined during the Afghan war in 2017 and I joined during the Vietnam Conflict in 1969. Max went on to attend the Hospital Corpsman School in San Antonio, Texas. I did my Hospital Corps School at Great Lakes, Illinois. Max went on to posting in Guam and at Camp Pendleton before serving in Afghanistan. I went on to posting at Key West Naval Hospital prior to my training at Marine Corps Base Camp Lejeune, NC, and Camp Lejeune Naval Hospital (HM-0000) and Field Medicine Service School (HM- 8404) Camp Lejeune NC. The Field Medical Service Technician (FMST) course is designed for E1 to E6 Hospital Corpsmen. Training has a mix of classroom and field training. Emphasis is placed on learning field medicine by using the principles of Tactical Combat Casualty Care (TCCC).

Max served in the final days of a long drawn out war,

and too often we see our loved ones die at the final stages of a terrible conflict. I was luckier than Max – I did not have to serve in a combat situation. I missed out of serving in Vietnam since my brother was also enlisted (Army) and serving in Vietnam. He was blessed with being able to come home after his tour of duty.

Max served for four years and was advanced to the rank of Hospital Corpsman Third Class. I was discharged after my four years (1973) as a Third Class Petty Officer.

Max did not have the opportunity to see where his Navy training would have take him. I, on the other hand, benefitted because my Navy experience prepared me for a 50 year career in Orthopaedic medicine.

There is little doubt in my mind that Max would have gone on to make many contributions in the medical field. Naval training in the health care field is the best in the world and Max lived and died making a difference. Max also made me think of my Father, Francis V. McTighe (Army/Air Corps) who served in World War II as a Medic and was part of Operation Overlord, the battle began on June 6, 1944, also known as D-Day, when some 156,000 American, British and Canadian forces landed on five beaches along a 50-mile stretch of the heavily fortified coast of France's Normandy region. My Dad was also blessed to come home after his service.

Max, you make me proud. You will be remembered by many.

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AUTHOR AFFILIATIONS

1 Timothy McTighe, Dr HS (hc); Joint Implant Surgery & Research Foundation, 46 Chagrin Shopping Plaza, #117, Chagrin Falls, OH 44022 US

(Direct reprint requests to Timothy McTighe, tmct@jisrf.org)

AUTHOR DISCLOSURES

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

Signature Orthopaedics France
L'Arobase - 2 Rue Georges Charpak
81100 CASTRES
FRANCE

T: +33 (0)5 63 73 51 83
F: +33 (0)5 63 73 51 84

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Signature Orthopaedics Europe
88 Harcourt St Dublin Ireland
T+353 1 691 5293F+353 1 691 5010

Signature Orthopaedics Australia
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T+61 2 9428 5181 F+61 2 8456 6065
info@signatureortho.com.au
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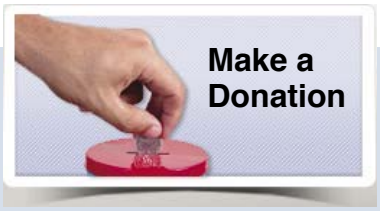

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Levels of Evidence

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

	Types of Studies			
	Therapeutic Studies – Investigating the results of treatment	**Prognostic Studies – Investigating the effect of a patient characteristic on the outcome of disease**	**Diagnostic Studies – Investigating a diagnostic test**	**Economic and Decision Analyses – Developing an economic or decision model**
Level I	• High quality randomized trial with statistically significant difference or no statistically significant difference but narrow confidence intervals • Systematic Review2 of Level I RCTs (and study results were homogenous3)	• High quality prospective study4 (all patients were enrolled at the same point in their disease with ≥ 80% follow-up of enrolled patients) • Systematic review2 of Level I studies	• Testing of previously developed diagnostic criteria on consecutive patients (with universally applied reference "gold" standard) • Systematic review2 of Level I studies	• Sensible costs and alternatives; values obtained from many studies; with multiway sensitivity analyses • Systematic review2 of Level I studies
Level II	• Lesser quality RCT (e.g. < 80% follow-up, no blinding, or improper randomization) • Prospective4 comparative study5 • Systematic review2 of Level II studies or Level 1 studies with inconsistent results	• Retrospective6 study • Untreated controls from an RCT • Lesser quality prospective study (e.g. patients enrolled at different points in their disease or <80% follow-up.) • Systematic review2 of Level II studies	• Development of diagnostic criteria on consecutive patients (with universally applied reference "gold" standard) • Systematic review2 of Level II studies	• Sensible costs and alternatives; values obtained from limited studies; with multiway sensitivity analyses • Systematic review2 of Level II studies
Level III	• Case control study7 • Retrospective6 comparative study5 • Systematic review2 of Level III studies	• Case control study7	• Study of non-consecutive patients; without consistently applied reference "gold" standard • Systematic review2 of Level III studies	• Analyses based on limited alternatives and costs; and poor estimates • Systematic review2 of Level III studies
Level IV	Case Series8	Case series	• Case-control study • Poor reference standard	• Analyses with no sensitivity analyses
Level V	Expert Opinion	Expert Opinion	Expert Opinion	Expert Opinion

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

Reconstructive Review Disclosure Statement

The following information will be published on each paper.

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Joint Implant Surgery and Research Foundation
46 Chagrin Shopping Plaza, #117
Chagrin Falls, Ohio 44022
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