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Reconstructive REVIEW

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JISRF

Joint Implant Surgery and Research Foundation

Strategic Alliance with

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VOLUME 7 • NUMBER 2 June 2017

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Strategic Alliance with

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Dr Rami M Sorial FRACS FAOrthA

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

&

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

Executive Director, JISRF,

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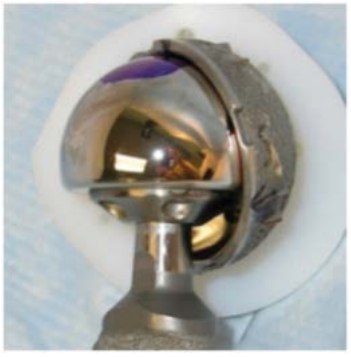

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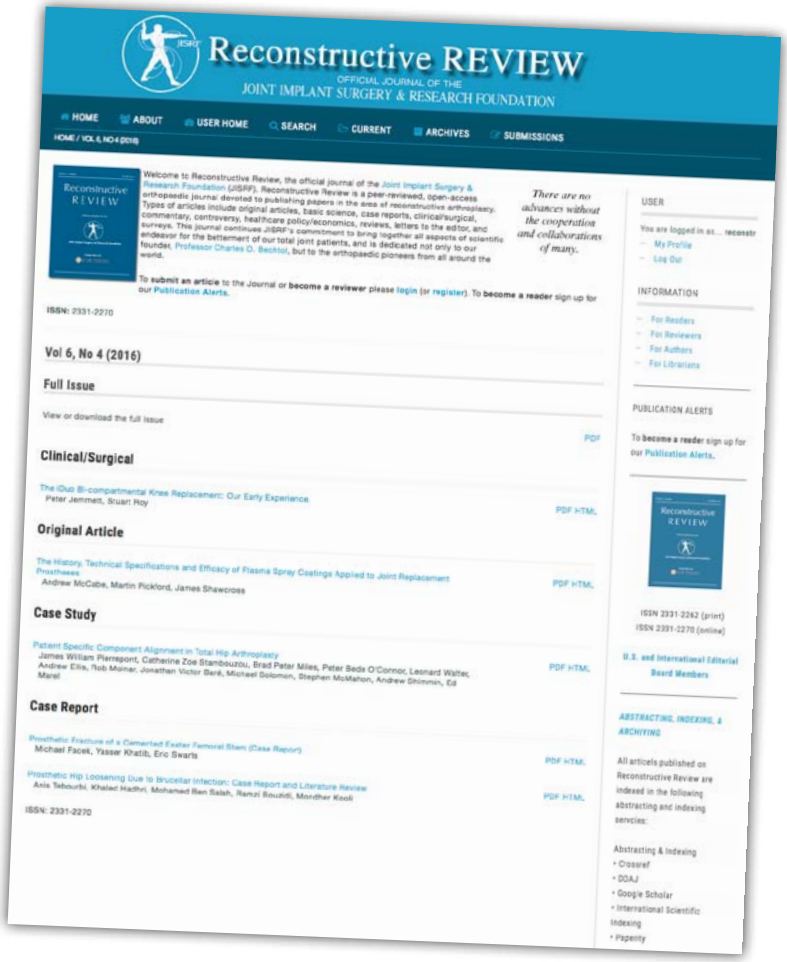

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The Performance of Mixed Manufacturer Metal On Metal Total Hip Replacements

Cook R[1], Latham J[1], Wood R[1]

Abstract

Using a femoral head from one manufacturer on the stem of another manufacturer poses the risk that the taper interface between the components may not contact correctly and the performance of the joint will be impaired. The cohorts in this study are a combination of modular Birmingham Hip Resurfacing (BHR) and Adept femoral heads on CPT stems. The study reviews the geometry of the taper interfaces to establish if the taper clearance angles was outside of the normal range for other taper interfaces. In addition the rates of material loss from the bearings and taper and a ranking of the stem damage were reviewed to determine if the levels of loss were above that seen for other similar joints.

The material loss analysis demonstrated that the rates or levels of loss from the bearings, taper and stem were no different to levels published for manufacturer matched joints and in many cases were lower. The results demonstrate that the taper clearance angles for the mixed manufacturer joints (BHR-CPT: 0.067 to -0.116, Adept-CPT: 0.101 to -0.056) were within the range of other studies and manufacturer matched clearances (0.134 to -0.149).

Using components from different manufacturers has not in this instance increased the level of material loss from the joints, when compared to other similar manufacturer matched joints.

Keywords: *total hip; mix and match; metal on metal*
Level of Evidence: *AAOS Therapeutic Level III*

Introduction

The use of large diameter Cobalt Chromium femoral head components in total hip replacements has come under scrutiny due to the poor performance of these joints in-vivo. In particular the performance of the taper junction between the head and femoral components. The use of mixed manufacturer components has been a particular area of focus, where the manufacturers' variation in angle of their 12/14 tapers can result in different taper clearance angles and contact lengths 1 from those specified by the manufacturers.

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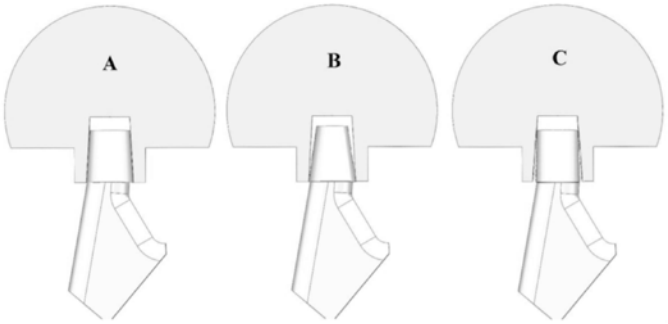

Figure 1. Taper Clearance Angle definition. A. Full length contact, taper angle = trunnion angle, clearance = 0. B. Distal contact, taper angle < trunnion angle, Clearance < 0. C. Proximal Contact, taper angle > trunnion angle, Clearance > 0

The taper clearance angle provides a means of assessing how the male and female components of a taper will contact (Figure 1). A positive clearance indicates that the taper would have contacted at the proximal / narrow diameter end of the taper, while a negative clearance is the opposite, with a distal contact at the larger diameter end of the interface. The angles for the ASR and Articuleze joints presented by Langton et al [2] were 5.670° (5.568° to 5.798°) and 5.639° (5.584° to 5.685°) (taper engagement level identified data) which, when paired with the 5° 43' Corail trunnion [3], provide clearances of -0.047° (-0.149° to 0.081°) and -0.078° (-0.133° to -0.032°) degrees. This range of clearance angles and differences in design specification is further reflected in the study of Kocagöz et al. [1] whose cohort of 50 metal femoral head had a 35:15 split between positive and negative clearance angles. The range of taper clearances within the study [1] was 7.5 to -8 arcminutes (0.125° to -0.133°), with 50% of the values between 5 and -2 arcminutes (0.083° to -0.033°).

This analysis demonstrates that there is no consistent or single design philosophy for taper contacts between manufacturers, with some opting for proximal contacts and positive clearances and others for distal contacts and negative clearances. In the case of the ASR – Corail pairings the variation in the measured angle of the tapers provide both positive and negative clearances on the same trunnion.

The analysis of retrieved joints has highlighted three sources of material loss; the bearing surfaces [4-6], the taper interface [7-11] and the cement-stem interface [12,13] each capable of triggering a reaction significant enough to require revision surgery. The ability of bearing surface wear to cause adverse reactions is clear from the retrieval studies [4-6] focused on resurfacing joints. The ability of the material loss from the taper interface to initiate adverse reactions can be demonstrated by the increasing numbers of failures in metal on polymer bearings [7-11]. The issue of debris from the cement stem interface was demonstrated by the work of Donnell et al. and Bryant et al. on the Ultima hip replacement system [12,13], with Hothi et al. [14] showing that damage was present on seven different designs of cemented stem.

The literature contains a number of retrieval studies where the values of linear [6,15-19] and volumetric loss [15,19-24] from the bearing surfaces of metal on metal joints have been presented (Table 1). However, in most studies, the values for edge-wearing components have not been differentiated from those without edge wear, meaning the values provided are not reflective of the true wear rates for these joints. Only two studies [6,17] provided linear wear rates and only one provides volumetric rates [22] which are representative of the bearing performance of well aligned components in-vivo (mean bearings combined: 1.10mm3/yr).

There are eight studies [2,19,21,23-27] in the literature which have quantified the material loss from the surfaces of female tapers of both manufacturer matched and mixed manufacturer metal on metal joints (Table 2). The published mean volumetric wear rates from these studies range from 0.85 to 0.127 mm3/year, with median values ranging from 0.132 and 0.238 mm3/year (Table 2).

Cook et al. [28] assessed the volume of material lost from the surfaces of cemented stems, showing mean rates of loss between (0.003 and 1.9mm3/yr), however these measures has a +/-16% error due to the both the complexity and variability in the geometry of different components. The accepted method for the characterization of the level of damage to cemented stems is the 5 level ranking developed by Bryant et al. [12]. Two studies have utilized this score, Bryant et al. [12] who provided a mean score of 2.9 for 105 manufacturer matched cemented components, and Hothi et al. [14] who, while not providing an average value, reported 27 of the 36 stems reviewed as having a score of 3 or over.

These previously published values of material loss and ranking obtained from retrieved metal on metal joints, provide the baseline against which the performance of other joints can be compared. The objective of this study is to determine how the levels of material loss from three sites on a group of mixed manufacturer joints relates to other previously reported levels of material loss from manufacturer matched joints. We hypothesize that the level of material loss from the bearings, taper and cement stem interfaces will not exceed that of other joint designs.

Table 1: Linear and Volumetric Wear Rates of the bearings surfaces of metal on metal joints

Study	Number of Hips	Joint Deign		Edge worn : non-edge worn	Time In-Vivo (Years)	Femoral Head		Acetabular Cup		Bearings Combined	
						Linear Rate (μm^3/year)	Volumetric Rate (mm^3/year)	Linear Rate (μm^3/year)	Volumetric Rate (mm^3/year)	Linear Rate (μm^3/year)	Volumetric Rate (mm^3/year)
Matthies et al.[6]	60	Modular THR		Edge Worn: 34	Mean: 2.6 (1 - 6.1)			Median: 16.87 (0.82 - 119.15)			
				Non-edge worn: 26				Median: 0.00 (0.00 - 4.77)			
	60	Resurfacing		Edge Worn: 40	Mean: 3.8 (1 - 10.1)			Median: 11.00 (0.77 - 173.81)			
				Non-edge worn: 20				Median: 0.00 (0.00- 6.18)			
Kwon et al. [16]	9	Resurfacing	Pseudotumour	9:0	Mean: 3.6 (1.1 - 6.6)	Median: 8.1 (2.75 - 25.4)		Median: 7.36 (1.61 - 24.9)			
	22		No Pseudotumour	1:21	Mean: 2.3 (1.0 - 5.8)	Median: 1.79 (0.82 - 4.15)		Median: 1.28 (0.18 - 3.33)			
Underwood et al.[17]	122	Combined	Edge worn	78				Mean: 31.90 (0.77–245.55)			
			Non-edge worn	44				Mean: 0.85 (0-6.18)			
Matthies et al. [18]	72	Combined	Pseudotumour		Mean: 3.1 (1 - 5.75)	Median: 5.3 (0 - 84.1)		Median: 6.8 (0 – 180)			
	33		Control		Mean: 3.3 (1.1 - 7.9)	Median: 2 (0 - 62.1)		Median: 2.2 (0 – 64.3)			
Hart et al. [29]	45	Resurfacing			Mean: 2.7	Median: 8.7		Median: 5.6			
Glyn-Jones et al. [15]	18	Resurfacing	Pseudotumour	7:11	Mean: 3.9 SD: 2.1	Mean: 8.4 SD: 8.7	Mean: 3.3 SD: 5.7	Mean: 16.1 SD: 21.4	Mean: 2.5 SD: 6.3		
	18		Control	6:12	Mean: 2.5 SD: 1.9	Mean: 2.9 SD: 3.9	Mean: 0.8 SD: 1.2	Mean: 1.0 SD: 1.5	Mean: 0.4 SD: 0.8		
Nawabi et al. [19]	94	Combined	Unexplained Pain	8:27	Mean: 3.25 (1.5 - 8.6)					Median: 2.6 (0 - 128.2)	Median:0.3 (0 - 29.3)
			Control	37:22	Mean: 2.5 (1 - 6.5)					Median: 12.8 (0 - 232.1)	Median:1.5 (0 - 94.3)
	10	Resurfacing	Combined		Mean: 1.9 (1.5 - 4.2)					Median: 3.3 (0 - 128.2)	Median:0.3 (0 - 26.2)
	24	THR	Combined		Mean: 3.75					Median: 2.2	Median:0.3
					(1.5 - 8.6)					(0 - 85.6)	(0 - 29.3)
Morlock et al. [22]	12 Heads 17 Cup	Resurfacing	Non-edge worn				Mean: 0.402 SD: 0.584		Mean: 0.584 SD: 1.39		Mean: 1.10 SD: 1.7
Witt et al. [30]	30 Heads 28 Cups	Modular THR	Combined		Mean: 3.5 SD: 1.6		Mean: 1.96 SD: 4.92		Mean: 1.05 SD: 2.25		
Lord et al. [20]	32 Heads 22 Cups	Resurfacing	Combined				Mean: 8.72 (0.21-31.91)		Mean: 11.02 (0.30-63.59)		Mean: 22.66 (0.51 - 95.50(
Hothi et al. [23]	10 S-ROM stem	Modular THR	Combined		Mean: 5.3 (3.3 - 7)						Median: 3.92 (1.20 - 7.81)
	10 Corail stem	Modular THR	Combined		Mean: 4.7 (4.2 - 6.4)						Median: 3.21 Range: 0.87 - 62.12
Matthies et al. [21]	110	Modular THR	Combined		Mean: 3.7 (1 - 7.1)		Mean: 3.10 Median:1.31 (0.06-45.66)		Mean: 2.56 Median:0.62 (0.04-39.62)		
Sidaginamale et al. [24]	116	Modular THR	Combined		Mean: 4.8 (0.6 - 9.1)						Median: 2.02 0.27 – 68.9
	83	Resurfacing	Combined								Median: 7.35 Range: 0.62 - 95.5
This Study	22 BHR	Modular THR	Combined	16 : 8	Mean: 7.5 (4.7 - 9.6)	Mean: 4.5 Median: 2.5 (0.9 - 39)	Mean: 1.99 Median: 0.7 (0.17 - 21.1)	Mean: 7.3 Median: 1 (0.4 - 105.2)	Mean: 2.94 Median: 0.43 (0.11 – 45.2)		Mean: 4.94 Median: 1.15 (0.36 - 66.4)
	22 Adept	Modular THR	Combined	10 : 12	Mean: 6.8 (3.3 - 10.3)	Mean:1.9 Median: 1.4 (0.3 – 9)	Mean: 0.57 Median: 0.28 (0.08 - 4.7)	Mean: 3.9 Median: 1.8 (0 - 29.6)	Mean: 1.41 Median: 0.38 (0 - 16.7)		Mean: 2.07 Median: 0.74 (0.19 - 21.4)
	16 BHR	Modular THR	Non-edge worn		Mean: 7.3 (4.7 - 9.6)	Mean: 1.9 Median: 1.5 (0.9 - 3.6)	Mean: 0.55 Median: 0.4 (0.17 - 1.46)	Mean: 0.9 Median: 0.8 (0.4 - 1.5)	Mean: 0.40 Median: 0.33 (0.1 – 1)		Mean: 0.96 Median: 0.74 (0.36 - 2.28)
	10 Adept	Modular THR	Non-edge worn		Mean: 6.2 (3.3 - 10.3)	Mean: 1 Median: 0.8 (0.3 - 2.1)	Mean: 0.24 Median: 0.21 (0.08 - 0.5)	Mean: 0.9 Median: 0.6 (0 - 2.8)	Mean: 0.37 Median: 0.22 (0 - 1.6)		Mean: 0.41 Median: 0.32 (0.12 - 0.94)

Materials and Methods

Study demographics

The implants reviewed within this study are shown in Table 3. They are mixed manufacturer head and stem combinations formed of cemented collarless tapered cobalt-chrome Zimmer CPT stems paired with either an Adept LDMH (Finsbury Orthopaedics) (n=22) or a BHR large diameter modular head (LDMH) (Midland Medical technologies; Smith and Nephew) (n=22).

Ethical approval was granted by the National Research Ethics Service Committee South Central = Southampton A.

Study	Number of Hips		Head Sizes (mm)	Time In-Vivo (Months)		Taper	
					Cumulative mm^3	Rate (μm^3/year)	Rate (mm3/year)
Nawabi et al. [19]	58	Unexplained Pain: 25	Mean: 46 (38 – 53)			Mean: 1.4 (0 – 18.1)	
		Control: 33	Mean: 45 (38 – 53)			Mean: 0 (0 – 30.6)	
Matthies et al. [21]	110		Mean: 46.2 (38 – 60)	Mean: 44.2 (12 - 85)	Median: 2.02		Mean: 0.85 Median: 0.54 (0 – 4.29)
Hothi et al. [23]	10	S-ROM stem	36	Mean: 63.5 (40 - 84)			Median: 0.132 (0.015–0.518)
	10	Corail stem	36	Mean: 56 (50 - 77)			Median: 0.238 (0.0002–2.178)
Hothi et al. [25]	150	Mixed Manufacturer	Mean: 45.9 (38 - 60)	Mean: 42.2 (7 - 118)	Mean: 1.52 (0.13–25.89)		
Langton et al. [2]	63	ASR XL	Median 45.5 (39 - 57)	Median: 33 (11 - 64)		Median: 5.92 (0.57 to 32.78)	Mean: 0.44 (0.02 to 8.34)
	48	Articuleze (Pinnacle)	36 (+1 40)	Median: 42 (12 - 75)		Median 1.39 (0.24 to 106.6)	Mean: 0.127 (0.01 to 3.15)
Sidaginamale et al. [24]	116	Mixed Pinnacle, ASR and BHR		Mean: 4.8 (0.6 - 9.1)			Median 0.2 (0.01 – 8.34)
Brock et al. [26]	22	ASR Taper - Corail stem		Mean: 51 (+/-23)			Median: 0.714
	12	ASR Taper - S-ROM stem					Median: 0.494
	50	Pinnacle Taper - Corail stem					Median: 0.402
	20	Pinnacle Taper – S-ROM stem					Median: 0.123
Hothi et al. [27]	61	Pinnacle Taper – Corail stem	36mm	Median: 73.5 12-128			Median: 0.36 (0 - 3.45)
	17	Pinnacle - S-ROM stem					Median: 0.06 (0 - 0.52)
	42	Pinnacle – Summit stem					Median: 0.35 (0 – 2.46)
This study	22	BHR	Mean: 45.3 (42 - 52)	Mean: 90 (56 - 115)	Mean: 1.84 Median: 1.91 (0 - 4.2)		Mean: 0.26 Median: 0.22 0 - 0.9
	22	Adept	Mean: 47.1 (42 - 54)	Mean: 81.8 (39 - 124)	Mean: 1.11 Median: 0.58 (0 – 7.85)		Mean: 0.16 Median: 0.08 0 – 1.04

Table 2. Linear and Volumetric Wear Rates from tapers of metal on metal joints

	BHR	Adept
Number of joints	22	22
Time In-Situ (months)	90 (56 - 115)	82 (39 - 124)
Head Size	42mm n = 8 46mm, n = 10 50mm, n = 4	42mm n = 3 44mm n = 1 46mm n = 7 48mm n = 5 50mm n = 5 54mm n = 1

Table 3 Joint Demographics.

Table 4 Mean, Median and range of values of material loss from the implant surfaces

		BHR-CPT	Adept-CPT		BHR-CPT	Adept-CPT		BHR-CPT	Adept-CPT		BHR-CPT	Adept-CPT
Normal Wear: Edge Wear		16:6	10:12									
Clearance (mm)		0.220 0.211 0.16 – 0.33	0.181 0.180 0.13-0.23									
All Samples Cumulative Linear Loss (µm)	Femoral Head	35 18.5 5 - 318	12.6 7.7 2 - 56.5	Acetabular Cup	58 7.3 2.7 - 859	27 11 0 - 190	Bearings Combined			Taper		
All Samples Linear Loss rate (µm/yr)		4.5 2.5 0.9 - 39	1.9 1.4 0.3 - 9		7.3 1 0.4 - 105.2	3.9 1.8 0 - 29.6						
Non-edge Wearing Cumulative Linear Loss (µm)		14 11 5.2 - 24	5.3 5.9 2.3 - 8.6		6 6 3 - 12.8	5.3 4.7 0 - 19.5						
Non-edge Wearing Linear Loss rate (µm/yr)		1.9 1.5 0.9 - 3.6	1 0.8 0.3 - 2.1		0.9 0.8 0.4 - 1.5	0.9 0.6 0 - 2.8						
All Samples Cumulative Volume Loss (mm^3)		15.64 5 1.13 - 172.6	4.62 2.1 0.6 - 30.4		23.38 3.49 0.5 - 369.3	9.18 3.09 0 - 107.1		39.02 9 1.73 - 541.9	13.80 4.97 0.6 – 137.5		1.84 1.91 0 - 4.2	1.11 0.58 0 - 7.85
All Samples Volume Loss rate (mm^3/yr)		1.99 0.7 0.17 - 21.1	0.57 0.28 0.08 - 4.7		2.94 0.43 0.11 – 45.2	1.41 0.38 0 - 16.7		4.94 1.15 0.36 - 66.4	2.07 0.74 0.19 – 21.4		0.26 0.22 0 - 0.9	0.16 0.08 0 – 1.04
Non-edge Wearing Cumulative Volume Loss (mm^3)		3.98 2.8 1.13 - 8.6	1.36 1.45 0.6 - 2.1		2.94 2.20 0.5 - 7.6	1.88 1.57 0 - 6.3		6.92 5.87 1.73 – 13.62	2.26 2 0.6 – 3.92		1.97 2.34 0 - 4.2	0.76 0.47 0 - 1.9
Non-edge Wearing Volume Loss rate (mm^3/yr)		0.55 0.4 0.17 - 1.46	0.24 0.21 0.08 - 0.5		0.40 0.33 0.1 - 1	0.37 0.22 0 - 1.6		0.96 0.74 0.36 – 2.28	0.61 0.32 0.12 – 0.94		0.28 0.30 0 - 0.9	0.14 0.08 0 - 0.4

Material loss assessment

The volumetric material loss measurements for the bearing and taper surfaces of each joint in the study were obtained using a non-contact optical coordinate measuring machine (OrthoLux, RedLux, Southampton UK). The measurement procedure and validation for spherical components can be found in Tuke et al. [31]. Direct assessment of the bearing surfaces was performed with a point cloud density of 1 point per degree circumferentially and 1 point per degree from the pole to the edge. The regions of damage on the bearing surfaces were identified and removed and a sphere fitted to the remaining points. The linear wear was assessed as the maximum linear deviation from the fitted sphere in the center of the wear scar and the volumetric loss measured as the volume beneath the fitted sphere and the assessed surface within the wear scar region.

The taper assessments were performed on a casting of the taper surface. The casting was made using Microset 202 (Microset Products Ltd,

		Vs. CPT Trunnion angle of 5° 40′ or 5.667°		Vs. Zweymuller Trunnion angle of 5° 38′ or 5.633°		Vs. Synergy Trunnion angle of 5° 40′ secs or 5.667°	
Bearing Manufacturer	Retrieved head Taper Angle (Degrees)	Taper Angle Clearance (Degrees)	Taper Angle Clearance (Minutes)	Taper Angle Clearance (Degrees)	Taper Angle Clearance (Minutes)	Taper Angle Clearance (Degrees)	Taper Angle Clearance (Minutes)
Adept n = 22	5.690° 5.696° (5.610° - 5.767°)	0.024° 0.030° (0.101° to -0.056°)	1.463 1.799 (1.799 to -3.333)	0.057° 0.063° (0.134° to -0.023°)	3.443 3.779 (3.779 to -1.353)	-	-
BHR n = 22	5.662° 5.663° (5.551° - 5.734°)	-0.005° -0.005° (0.067° to -0.116°)	-0.314 -0.272 (4.030 to -6.961)	-	-	-0.005° -0.005° (0.067° to -0.116°)	-0.314 -0.272 (4.030 to -6.961)
Metasul	-	-0.034°	-2.04	-	-	-	-

Table 5: Table 3 Mean, median and range of the Taper Angles and Clearance angles.

Nuneaton, UK) replication material which has the ability to reproduce the surface with a resolution of 0.05 µm. The measurements of the taper surface were collected with a point density of 2 points per degree circumferentially and 70 points per mm along the length. The damaged regions of the taper surface and any regions with material deposits were excluded and a cone fitted to the remaining original surface. The volumetric loss was assessed as the volume beneath the fitted cone within the wear scar region. Validation of this method has been published [32] and the limits of agreement (95%) of the material loss were -0.0416 to 0.173 mm3 with a taper angle shown to be within 0.0024°.

Volumetric loss and the angles of the retrieved trunnions was not assessed. The surfaces of the trunnions were perceived to have some level of deformation or damage along their full lengths. This provided no original surface to which to apply a cone fit, meaning any volumetric value or angle assessment would have had unquantifiable and inconsistent levels of error, with the magnitude of the error varying with the level of damage to the trunnion. In order to assess the taper clearance angles, the manufacturers stated trunnion angle for the CPT (5° 40 minutes), as well as the Finsbury orthopedics Zweymuller Alloclassic (5° 38 minutes) [33] and the Synergy stem (5° 40 minutes) were gathered. The Alloclassic stem and the synergy stem represent the manufacturer matched stem parings for the Adept and BHR heads. It is of note that both the BHR and Adept heads were marketed initially without a specified stem pairing and these were subsequently identified as appropriate. In addition the Metasul and Durom female taper (5° 38 minutes) [34] was reviewed in relation to the CPT trunnion to define manufacturers specified taper clearance for this pairing.

Stem grading

The stems were graded using the criteria described by Bryant et al. 2013 [4]. The scale classifies stems into one of five categories based on the area of damage to the stem surface from within the cemented region. The categories are 1: <10%, 2: 10-25%, 3: 25-50% 4: 50-75% and 5: >75% of the surface.

Results

The bearing surface analysis identified 18 out of the 44 joints (BHR = 6, Adept = 12) as being edge worn. The exclusion of the edge wearing joints from the data sets, provided a mean wear rate for the joints in-vivo of 0.24 and 0.55 mm^3/year for the femoral heads and 0.37 and 0.4 mm^3/year for the acetabular cups of the Adept and BHR joints respectively (Table 4). The wear rate of the non-edge worn femoral heads was significantly higher for the BHR joints ($p = 0.006$), but there was no significant difference between the levels from the acetabular cups ($p = 0.865$).

Analysis of the tapers demonstrated a range of levels of material loss. The mean rate of volumetric loss from the Adept and BHR female taper surfaces respectively was 0.16 and 0.26mm^3/year (Table 4). Comparison of the means of the two rate of loss using a 2 sample t-test showed there was no statistically significant difference ($p = 0.179$). There was also no significant difference between the rates of volume loss from the tapers of the joints with edge worn bearings and those without for either the BHR ($p = 0.113$), the Adept pairings ($p = 0.639$) or the two groups combined ($p = 0.444$).

All of the stems examined displayed evidence of damage to their surfaces which would have been within the cement mantle. The mean Bryant score for the BHR and Adept coupled stems was 2.4 and 2.9 respectively. There was no statistically significant difference in the level of stem damage between the BHR and Adept groups ($p = 0.498$), nor was there a significant difference in the stem score for the edge worn and non-edge worn bearings (BHR: $p = 0.481$, Adept: $p = 0.899$, combined: $p = 0.763$).

The assessment of the BHR and Adept female taper surfaces showed a difference in the mean taper angle (5.690° vs. 5.662° respectively). This difference in the taper angle of the two joints was approaching significance ($p = 0.054$). The taper angles of the joints resulted in different taper clearance angles when compared to the manufacturer specified trunnion angle for the CPT (Table 5). The BHR taper angle was similar to that of the CPT trunnion, but provided a negative clearance of -0.005 degrees. In con-

trast the Adept taper provided a positive clearance angle of 0.024°. Based on the taper angles assessed in this study, the manufacturer matched pairings would have provided mean clearances of 0.057° and –0.005° for the Adept-Alloclassic and the BHR-Synergy respectively and -0.034° for the Metasul-CPT, Table 5.

The correlation between the head size, bearing clearance, time in-situ, offset, taper angle and taper clearance vs. ideal CPT (tapers only) on the volume of loss from the bearing surfaces and the taper and the stem grading was investigated. The only significant correlations were found between the BHR taper loss and the head size ($r = 0.438$, $p = 0.042$) and the CPT derived offset with the stem grading of the Adept group ($r = -0.577$, $p=0.019$).

Inter site

When the volume of material loss from the bearings was compared to that of the taper and the stem grading from the whole data set ($n = 44$), only one significant correlation was found between the bearing surface wear and the stem grading (Head $r = -0.435$, $p = 0.007$, Cup $r = -0.333$, $p = 0.044$). However, removal of an edge worn BHR sample which had lost 172.6 mm^3 and 369.3 mm^3 from the femoral head and acetabular cup respectively rendered this relationship non-significant.

Separate analysis considering the different joint designs and the edge worn and non-edge worn joints separately failed to provide any significant correlations between the material lost from the different sites.

Discussion

In order to determine if the bearing surfaces were performing as would be expected, the results from the wear analysis in this study need to be compared to those of previous studies on similar joints. Table 1 contains linear [6,15-19] and volumetric loss [15,19-24] measures from the bearing surfaces of retrieved metal on metal joints. However, in most studies, the values for edge-wearing components have not been differentiated from those without edge wear, meaning the values provided by most studies are not reflective of the true wear rate for these joints. Only three [6,16,17] out of the six studies provided linear wear rate values which are representative of a well aligned components in-vivo and two of those only presented values for the acetabular cups.

The mean linear wear rates of reported by Underwood et al. [17] were higher than those reported in this study. However, Matthies et al. [6] provided median wear rates for 0 µm/year (0 - 4.77) and 0 µm/year (0 - 6.18). The inference of this is that 37 or more of these 74 retrieved joints had no measureable wear. This may be a reflection of the shorter time in-situ of these joints compared to the current study, or a difference in the ability of the roundness machine measurement technique to pick up low levels of wear compared to the RedLux technique. However the maximum linear wear rates presented for these joints are higher than this study.

The mean volume loss rate of the non-edge wearing femoral head components published by Morlock et al. [22] was lower than from the BHR femoral components in this study. However, the mean volume loss rates from the Adept femoral heads, the acetabular surfaces and the bearings combined for both designs from this study were below the values presented.

When the rates of the whole data, incorporating the edge worn values are compared to the rates of loss those of the previous studies [15,19-23,30], the current values sit within the range presented in Table 1.

The volumetric wear rate of the non-edge wearing joints demonstrate that the BHR joints had double the rate of volume loss from the femoral heads compared to the Adept. This difference can be explained in part by the lower clearance (40μm less) of the Adept joints (Table 4). The Adept clearance is high enough to overcome any fears around deformation during insertion [35] and high friction due to lubricant starvation [36], but low enough to reduce the volume lost as a result of the running in wear associated with higher clearance joints [17,37].

There are eight studies [2,19,21,23-27] in the literature which have quantified the material loss from the surfaces of female tapers (Table 2). Matthies et al [21] and Hothi et al [23] provide values for the cumulative loss from the surfaces of 2.02 mm^3 (Median) and 1.52 mm^3 (Mean), higher than the mean and median values in this study for the Adept tapers, but a higher median and lower mean (0.22 mm3 difference) when compared to the BHR joints.

Comparing the material loss values in this study with those of previous studies (Table 2), the loss is beneath that of Matthies et al. [21] obtained from a range of different joint designs, Hothi et al. [23] for Corail – Ultamet head pairings and the ASR XL tapers presented by Langton et al. [2]. Only the mean values for the Articuleze-Pinnacle joints (difference BHR: 0.133, Adept: 0.033 mm^3/year) and the median value for the S-Rom stem – Ultamet head parings were less than those presented here. In both of these studies [2,23] the head sizes were 36mm which is 6mm smaller than the smallest head considered in this cohort, a known variable in the performance of tapers and the S-Rom stem also has an 11/13 taper rather than a 12/14 which may have influenced the performance.

Comparison of the volumes of loss from the bearings to the taper and stem showed no significant correlations, demonstrating that the loss occurring at these individual sites was independent of what was occurring at the other sites. The results also showed no correlation between joint specific variables such as offset, clearance, head size and time in-situ and the levels of material loss.

The clearance angles for the combinations in this study are within the range presented by Kocagöz et al. [1] and the manufacturers, with the average clearance for each group maintaining the positive or negative clearance which would have been specified for that joint design. The clearance angles were not correlated to the volume of loss from the taper, in agreement with the findings of Kocagöz et al. [1] for the visual grading of taper damage vs. taper clearance.

The closer match of angle seen in the current mixed manufacturer taper and trunnions has advantages. The taper engagement length between the two surfaces will be higher than those with a more extreme taper clearance and larger engagement lengths have been shown to reduce the volume loss from the taper [23]. The horizontal lever arm of distally contacting tapers detailed by Langton et al. [2] will be reduced, which has also been linked to heightened volume loss [2] and the gap between the two surfaces at the larger diameter (open) end of the proximally contacting tapers will be reduced, minimizing the access to fluid entering the interface.

It is clear from this study that there is no consensus on what is an appropriate taper clearance angle. The clearance angles for manufacturer matched pairings demonstrate that the Metasul-CPT and BHR Synergy tapers were designed with a negative clearance of -0.034° and -0.005° respectively, while the Adept-Alloclassic pairing had a positive clearance of 0.057°. Different manufacturers have designed for different clearances and contact locations. The clearances within the study by Langton et al. [2] for the ASR-Corail pairings (-0.149° to 0.081°), the BHR-synergy parings (-0.116° to 0.067°) and the Adept-Alloclassic pairings (-0.023 to 0.134) in this study, demonstrate that both negative and positive clearance angles are possible within the same joint design on a particular stem due to the tolerances of the taper manufacturing.

A review of cemented stems within the previous studies [12-14,38-42], demonstrates that damage is identifiable on a range of designs and materials. Using the data available in the Bryant et al. [12] paper, it was possible to demonstrate that there was no significant difference between the mean stem damage rankings in their study and this work ($p = 0.147$).

It is of note that while the performance of the three interfaces with regards to material loss does not differ and is in many cases better than manufacturer matched options. These joints had the potential to suffer from material loss at all three interfaces, which in combination elevated the overall volume of material released into the patient.

Conclusions

This study has shown that the material loss from the bearing, taper and cement-stem interface of these mixed manufacturer total hip replacements is equal to and in many cases lower than that published by other centers for manufacturer matched joints. The taper clearance angles of these mixed manufacturer joint pairings are within the normal range for modular taper connections of manufacturer matched joints and has maintained the proximal or distal nature of the taper which the manufacturer matched joints would have produced. The use of mixed manufacturer joints has not in this instance adversely affected the performance of the joints when compared to other similar manufacturer matched joints.

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Disclosure

The authors declare that there is no conflict of interest regarding the publication of this paper. For full disclosures refer to last page of this journal.

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The Effect of Patellar Denervation by Circumpatellar Electrocautery on Anterior Knee Pain Following Total Knee Replacement – An Experimental Study

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Abstract

Objectives: Anterior knee pain is a common problem in patients who have undergone TKR which causes dissatisfaction among them. There are Various methods for prevention of anterior knee pain following TKR .The objective of this study is to determine the effect of circumpatellar electrocautery on anterior knee pain following TKR and to compare the results with that of those patients who have undergone TKR without circumpatellar denervation.

Methods: This is a cohort study conducted in Dept. of Orthopedics, Govt. Medical College, Kozhikode,kerala, 2014. Total sample size was 90.out of which 2 patients died during the study period. We lost follow up of 7 patients. Among the remaining 81 patients 42 had undergone TKR with circumpatellar denervation using electocautery and 39 without circumpatellar denervation. They were kept under follow up. Patients were followed up postoperatively at 1 month, 3 months, 6 months and at one year. At all postoperative visits, a clinical score was determined using the Knee Society score and the clinical anterior knee pain rating system described by Waters and Bentley.

Results: There is no statistically significant difference in AKP score between both groups.There is a statistically significant difference in the knee society score at 1st month(p value <.001). But there is no difference on further follow up visits.

Conclusion: There is no statistically significant difference between final outcome of patients who underwent patella denervation using circumpatellar electrocauterisation and those without denervation with respect to anterior knee pain among patients who have undergone TKR.

Keywords: *total knee arthroplasty; anterior knee pain; Circumpatellar denervation*
Level of Evidence: *AAOS Therapeutic Level III*

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Introduction

Anterior knee pain is a common problem in patients who have undergone TKR which causes dissatisfaction among them. The reported incidence of anterior knee pain is about 8% [1]. Patellar denervation using circumpatellar electrocautery is a reasonable option in preventing anterior knee pain without any extra cost or technical difficulties.

The etiology of anterior knee pain after replacement is unknown but is thought to be multi-factorial and related to the patella-femoral joint. There are many predictors for anterior knee pain. The young age female sex, severe pain before surgery; low pain threshold is the non-modifiable predictors [2,3,4]. The modifiable predictors are anxiety, depression, problems of pain processing and preoperative expectations [5].

Nerve endings cut during surgery can regenerate and gets blocked in the scar tissue; a painful neuroma can be formed. Hypoxia of nerves produced due to compression between bone, ligaments or the scar tissue leads to abnormal signal conduction to the CNS which can be felt as an abnormal tingling sensation [6]. The cause of anterior knee pain after TKR can be divided into functional and mechanical problems. But in every case an infection should be ruled out.

There are many functional causes for anterior knee pain following TKR. Quadriceps weakness is a major problem after TKR. It can lead to patellar mal-tracking and quadriceps avoidance gait which is characterized by compensatory increased forward inclination of the trunk due to quadriceps weakness[7,8,9]. Another cause for knee pain is knee spine syndrome due to pathologies in lumbar spine causing lordosis and increased pelvic tilt. Patello-femoral instability and mal-tracking is the main cause for postoperative pain and functional limitations in the joint [10]. It can be caused by insufficient soft tissue balancing, component positioning or design of implant [11,12]. Femoral components with a posterior centre of rotation have a favorable influence on anterior knee pain [13]. It was thought that posterior stabilized (PS) prosthesis design leads to lower patella-femoral joint pressures than a cruciate-retaining (CR) design [14]. But no difference was found with regard to postoperative pain between CR prostheses and PS designs in recent studies [15].

Patella baja can cause anterior knee pain but incidence is low [16]. A progressive degenerative arthritic process of patella due to increased pressure on it by the knee prosthesis can cause anterior knee pain [12]. An increased internal rotation mal alignment of either tibial or femoral component or both can lead to lateral tilt of patella and anterior knee pain [17]. The patello-femoral joint contact pressure is increased due to the posterior subluxation of tibio femoral joint [18]. Avascular necrosis or a transient ischemia can produce localized pain over the patella [19]. Patellar fracture is a rare complication after TKR [20]. Patellar clunk and Synovial hyperplasia can cause anterior knee pain [21,22].

There are various methods for prevention of anterior knee pain following TKR like patelloplasty patellar denervation, patellar resurfacing, avoiding patella malt racking, proper implant selection and component position [23]. Routine patellar resurfacing appears to be an option to reduce patello femoral-related pain. But AKP may still be identified in 5% of patients who undergo primary TKR with patellar resurfacing [24].There are evidences to suggest that routine patellar resurfacing is not needed in order to preserve the patella and to reduce the risk of reoperation in resurfaced patients [25].

Immunohistochemical studies have confirmed the presence of substance-P nociceptive afferent fibers in the peripatellar soft tissues [26]. Hence It is suggested that circumpatellar electrocautery would lead to partial denervation and improved pain relief when patellar resurfacing is not possible. It was thought that primary TKR with circumpatellar electrocautery would lead to partial denervation and improved pain relief compared with no electrocautery. As our institution is catering patients from low and middle socioeconomic status population we do not routinely resurface the patella. The primary objective of this study is to determine the clinical effect of circumpatellar electrocautery on anterior knee pain following TKR and to compare the results with that of those patients who have undergone TKR without circumpatellar denervation.

Materials and Methods

This is a cohort study conducted in Dept. of Orthopedics, Govt. Medical College, Kozhikode,kerala,India during the period January 2012 to December 2014 after getting institutional research committee and ethics committee approval. All patients above the age of 55 who have undergone TKR at our institution during above period were included after getting written informed consent. Those patients with inflammatory arthritis, secondary osteoarthritis of knee following trauma.TKR after high tibial osteotomy and patients with any medical disorder which restricted them from walking were excluded from our study. Those patients who have undergone total hip replacement (THR) and revision TKR were also excluded.

Those patients who have met inclusion criteria and those have given written informed consent were included

in the study. Total sample size was 90.out of which 2 patients died during the study period. We lost follow up of 7 patients. Among the remaining 81 patients 42 had undergone TKR with circumpatellar denervation using electocautery and 39 without circumpatellar denervation. Total knee replacement was done using standard surgical technique in both groups.

They were kept under follow up. Patients were followed up postoperatively at 1 month, 3 months, 6 months and at one year. At all postoperative visits, a clinical score was determined using the Knee Society score and the clinical anterior knee pain rating system described by Waters and Bentley [27,28].

The clinical anterior knee pain rating system described by Waters and Bentley

Grade	Rating Description
0	No pain
I	Mild pain which does not intrude on daily activities
II	Moderate pain which is a nuisance
III	Severe pain

Results

Among the 81 patients, 51.9% underwent TKR with patellar denervation. Among patella denervation group, 59.5% were females and in group without denervation 51.3% were females. Among the total patients, 55.6% were females. Statistical analysis done using SPSS software. There is statistically significant improvement in the AKP score and knee society score in both groups at each follow up visit (tables 4 and 5). Although AKP score is gradually improving, there is no statistically significant difference in AKP score between both groups (table 2).There is a statistically significant difference in the knee society score at 1st month(p value <.001). Patients with patella denervation have better knee society score. But there is no difference on further follow up visits (table 3).

Table 1: Age distribution

Age (years)	Patella denervation +ve		Patella denervation –ve		Total	
	No.	%	No.	%	No.	%
55-59	18	42.9	13	33.3	31	38.3
60-69	19	45.2	20	51.3	39	48.1
70 and above	5	11.9	6	15.4	11	13.6
Total	42	100	39	100	81	100

Chart 1: Age distribution

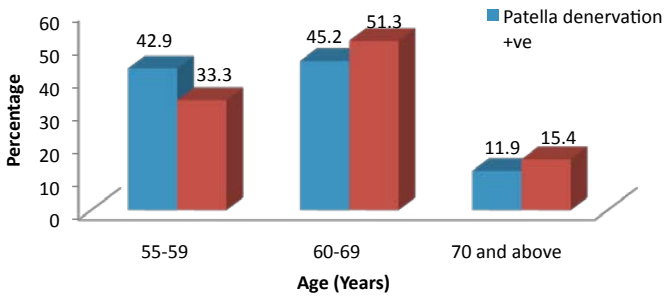
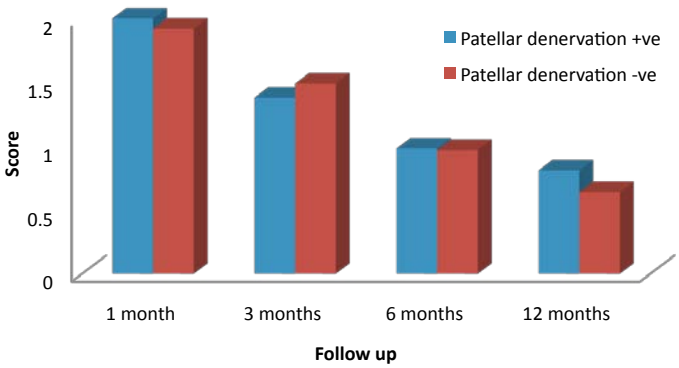


Table 2: Anterior knee pain score. Independent samples 't' test.

Followup	Average AKP score		p value
	Patellar denervation +ve	Patellar denervation -ve	
1 month	2.00 (0.49)	1.92 (0.62)	0.54
3 months	1.38 (3.62)	1.49 (0.50)	0.40
6 months	0.98 (0.71)	0.97 (0.54)	0.99
12 months	0.81 (0.70)	0.64 (0.54)	0.23

Chart 2: AKP score



Discussions

Anterior knee pain after total knee replacement is a major problem. It has been addressed in a number of studies. Unfortunately, many aspects of anterior knee pain after total knee replacement have yet to be fully understood. Many techniques are used to prevent and treat anterior knee pain, including patellar resurfacing but their effectiveness is still controversial. In this study, we tried to assess the effect of circumpatellar denervation among patients who have undergone total knee replacement.

In our study, anterior knee pain is graded using anterior knee pain grading system of Waters and Bentley. Anterior knee pain score was improving in both groups but there was no significant difference between the two groups. Knee society score was compared between the two groups.

Table 3: Anterior society score. Independent samples 't' test.

Followup	Average AKP score		p value
	Patellar denervation +ve	Patellar denervation -ve	
1 month	3.02 (0.41)	3.41 (0.50)	<0.001
3 months	1.98 (0.81)	2.28 (0.76)	0.08
6 months	1.43 (0.63)	1.38 (0.59)	0.75
12 months	1.21 (0.56)	1.18 (0.50)	0.77

Chart 3: Knee society score

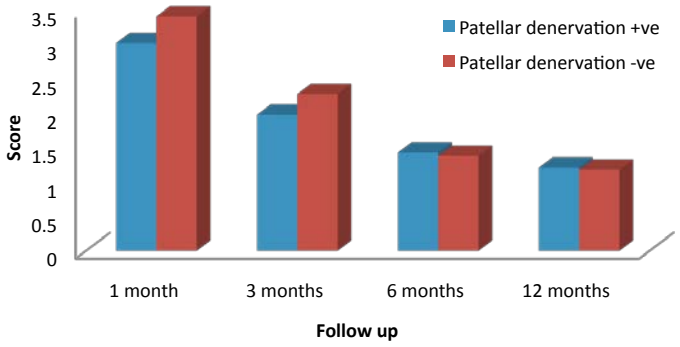


Table 4: Improvement in AKP score on each visit (Average AKP score paired difference). Paired sample 't' test.

	Patellar denervation +ve			Patellar denervation -ve		
	Mean	SD	p value	Mean	SD	p value
1-3 months	0.62	0.54	<0.001	0.44	0.60	<0.001
1-6 months	1.02	0.56	<0.001	0.95	0.76	<0.001
1-12 months	1.19	0.63	<0.001	1.28	0.72	<0.001

Table 5: Improvement in Knee society score on each visit (Average knee score paired difference). Paired sample 't' test.

	Patellar denervation +ve			Patellar denervation -ve		
	Mean	SD	p value	Mean	SD	p value
1-3 months	1.05	0.73	<0.001	1.13	0.57	<0.001
1-6 months	1.59	0.59	<0.001	2.03	0.58	<0.001
1-12 months	1.81	0.50	<0.001	2.23	0.63	<0.001

There was a statistically significant difference at one month but later this difference disappeared. There was a better knee society score among patella denervation group at 1st month.

In a study conducted by Balinga S et al, the outcome following circumpatellar denervation was assessed based on Oxford knee score (OKS) and anterior knee pain using Visual analog scale (VAS). This study showed statistically significant improvement in the OKS and VAS among the patella denervation group [29]. But when the post operative VAS score is compared with the pre op VAS score there was no significant difference in mean improvement in VAS score. Using logistic regression analysis, they found that a low VAS score preoperatively was the predictor of better VAS score than denervation using electro cautery. In another study conducted on 50 patients with bilateral TKR (One side patellar denervation done).
They found out that there was no statistical significant improvement in KSS or WOMAC score with patella denervation [30].

But another study conducted by HPW Van Jonberger in 2008 concluded that in the absence of patellar resurfacing, patellar denervation using electrocautery improves the outcome [31]. A total of 131 patients received patellar denervation and another 131 didn't receive denervation. The relative risk reduction from electrocautery was 40%. The intervention group had a better WOMAC score. (16.3 Vs 21.6, p value 0.04). Knee society score (92.4 Vs 90.4, p value 0.14) was similar in both group. But a randomized control trial conducted by the same author showed that the initial clinical improvement with electrocautery denervation of patella in TKR is not maintained at a mean follow up of 3.7 years [32].

MA Altay and C. Erturk conducted a randomized control study in 2012 which showed that there is a definite advantage with patellar denervation [33]. There were 35 knees each in intervention and control group. In a meta analysis conducted by Tao Cheng et al concluded that there is no strong evidence either for or against circum patellar electrocauterisation compared with non electrocautery in TKR [34]. The clinical outcome of 131 patients followed for more than 9 years were retrospectively assessed and found that patellar non resurfacing techniques including patelloplasty and circumpatellar denervation are similar to patellar resurfacing [35].

So the available studies give conflicting results regarding the effect of patellar denervation. Our study shows that there is no advantage of doing patellar denervation on anterior knee pain or knee society score. This may be due to the fact that etiology of anterior knee pain is multi-factorial. Hence all the causes cannot be addressed by the patel-

lar denervation alone. So we cannot prevent anterior knee pain by doing patellar denervation alone. Apart from factors described in introduction, preoperative expectations and patient education have influence on the postoperative outcome as shown by focused group discussions conducted by us in our TKR patients.

There are some limitations in our study. Here the sample size is small and our follow up period is short. Preoperative severity of knee pain was not included in study. It is a determinant of severity postoperative knee pain.

Conclusion

There is no statistically significant difference between final outcome of patients who underwent patella denervation using circumpatellar electrocauterisation and those without denervation with respect to anterior knee pain among patients who have undergone TKR.

Disclosure

The authors declare that there is no conflict of interest regarding the publication of this paper. For full disclosures refer to last page of this journal.

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A Single Surgeon, 10 Year Experience with the Oxford Partial Knee System: What a Difference Experience, Instruments, Implants, and Technique Can Make

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Abstract

Partial knee (unicompartmental) arthroplasty (PKA) for medial compartment disease of the knee has a long and well documented history of successful results over long periods of follow up. The Oxford Partial Knee Replacement has been available in the U.S. since 2004. After completing an FDA required instructional course, surgeons may use the device. Both the implant and the instruments have evolved since its introduction in 2004. This paper outlines the authors continuous cohort of 249 patients, 286 knees from 2004 to 2014 with minimum 2 year follow up, and reports the results while discussing the impact of experience, instruments and implants, and technique on the outcome of patients in this series. For the aggregate group of 286 knees, there were 17(5.9%) all-cause revisions to TKA, including 2(0.7%) dislocations, resulting in a (83%) survivorship at ten years. The survivorship at ten years for retained implants was 97% if non-implant related causes are not included. At one year, there were 89% excellent and good results, 5% fair, and 6% poor. At two years, there were 93% excellent and good, 1 % fair, and 5.5% poor. The causes for the poor results at one and two years were tibial sided failure or persistent pain. Three (12%) of patients with a poor result at one year had converted to good and excellent at two years. The use of the Oxford Mobile Bearing™ PKA has been shown to be a useful part of the surgeon's surgical armamentarium when dealing with anteromedial osteoarthritis or osteonecrosis of the knee. PKA has been shown to have a lower morbidity and mortality and is cost effective when compared to total knee arthroplasty. The author's experience, as demonstrated in this study, adds validity to the concept that understanding the pathoanatomy of anteromedial osteoarthritis and gaining surgical experience through increased surgical volume, adherence to well documented technique, and the use of a time proven implant, can be accomplished with a high degree of successful outcomes for patients with the appropriate indications.

Keywords: *partial knee arthroplasty, PKA, Oxford Partial Knee Replacement*
Level of Evidence: *AAOS Therapeutic Level III*

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Introduction

Partial knee (unicompartmental) arthroplasty (PKA) for medial compartment disease of the knee has a long and well documented history of successful results over long periods of follow up time in multiple publications and national joint registries [1,2,3,4]. More recent studies have also shown that compared to total knee arthroplasty, PKA carries a lower associated morbidity and mortality and is a more cost effective treatment [29,30,31,32]. White and Goodfellow published the concept and pathoanatomy involved in anteromedial osteoarthritis of the knee, which they believed was the primary indication for PKA [5]. The pathology of anteromedial OA of the knee consists of bone on bone cartilage loss in the anterior and mid medial compartment in association with an intact ACL, MCL, LCL, and functionally normal lateral compartment cartilage which can be demonstrated with a valgus stress radiograph [6].

Controversy still exists regarding indications and contraindications for PKA, particularly with respect to the widely adhered to published criteria set forth by Kozinn and Scott, [7]. Goodfellow began using the Oxford Mobile Bearing™ (OMB) PKA in the late 1980's for anteromedial osteoarthritis, and his early results were published by Murray et al. showing greater than 90% survivorship at 10 years. [8] Other, conflicting non-designing surgeon series, showed inferior results compared to the Oxford groups' series [9,10]. Because of these conflicting results, and to improve outcomes with the OMB device, the Oxford group developed an instructional course to better educate surgeons on the appropriate indications and surgical technique when using the OMB. The Oxford Mobile Bearing™ was released for use in the US in 2004. As a requisite of the release, the FDA required that all surgeons attend an instructional course prior to using the device. The author began using the OMB in 2004.

This study includes all patients (from an IRB approved data bank) operated on between 8/2004 and 9/2014, with a minimum two year follow up. The study period includes 249 patients with 286 knees, which will be analyzed as an aggregate group. A sub-group analysis includes two separate groups. Group I, 133 knees operated between 8/2004 and 9/2009, using the Phase III instruments, technique, and a single peg femur. Group II, 153 knees operated between 10/2009 and 9/2014, using Microplasty™ instruments, technique, and a two peg femur, changes for which the author participated as part of the OMB design team. A total of 10 knees performed using the Oxford Signature custom guides will be included in this group, because the surgical principles are based on the same Microplasty™ technique as utilized for the other patients in Group II.

Materials and Methods

Of the 249 patients in this study, there are 128 females and 121 males. In 239 patients, the diagnosis was anteromedial osteoarthritis and in 10 patients the diagnosis was spontaneous osteonecrosis. The age range for the patients was from 38 to 88 years, with an average of 64.7 years. The right knee was operated in 152 knees and the left in 134 knees. Preoperative extension ranged from 0-12 degrees (average 1.7), and preoperative flexion ranged from 95-145 degrees (average 124). Preoperative KSS scores for pain ranged from 32-89 (average 53.7) and preoperative KSS function scores ranged from 25-90 (average 54.5). Fig. 3.

Preoperative evaluation for all patients included a standing AP radiograph, true lateral, sunrise view, and valgus stress view. Interpretation of these views for appropriate indication for PKA have been published and these indications were adhered to by the author in this series. [10]

The patients in Group I (8/2004-9/2009), consisting of 133 knees, were operated using the Phase III instruments and technique. The femoral component implanted in these patients was a single peg femur. Patients in Group II (10/2009-9/2014), consisting of 153 knees, were operated using newly developed Microplasty™ instrumentation and technique. The femoral component implanted in these patients was a redesigned 2 peg femur. All patients had spinal anesthesia, unless contraindicated. Surgeries were done using the Oxford leg holder, tourniquet control, minimally invasive surgical technique, and with pericapsular field blocks prior to closure. Early in the series, once daily Lovenox was used for DVT prophylaxis, but later switched to BID aspirin. Patients had 23-hour observation stays in the hospital.

Routine follow up was at one month, 3 months, and 1 year. Patients were then advised to follow up annually for 5 years, then a 10-year visit. As many patients who were doing well did not want to come in annually for the first five years, towards the middle of this series patients were advised to have a 10 year follow up visit after a successful 2-year visit, or return at any time if their knee was bothering them. Preoperative KSS scores were completed as well as KSS scores at annual follow up periods.

Radiographs were obtained preoperatively, including a valgus stress radiograph, then at the 4-week postoperative visit, and at the annual exams thereafter. Radiographs were read by the author and over read by a hospital based radiologist. Radiolucencies were classified as physiologic (less

than 1-2 mm and non-progressive) or pathologic (greater than 3 mm and progressive, with or without change in component position). No attempt was made to classify radiolucencies by zone, and implants were recorded as fixed or loose. Failure was defined as revision of the implants for any reason, including those for bearing dislocation and survivorship analysis was based on this definition. Return to the operating room for other causes were not listed as failures, but reoperations. Time to revision was displayed using Kaplan Meier curves. Log-rank test was conducted for comparing the survival curves between the cohorts of Group I and Group II. All tests were 2-sided and statistical significance level was set at 0.05. Statistical analyses were performed using SAS® Enterprise Guide 6.1 (SAS Institute, Cary, NC, USA).

Results

At one year follow up range of motion showed a range of extension from 0-25 degrees with an average of 0.3 degrees. The range of flexion was from 90-155 degrees with an average of 126.5 degrees. KSS pain scores improved with a range of 41-100 with an average of 93.4 and KSS function scores ranged from 40-100 with an average of 89.4. It is important to note that deductions for overall limb alignment were not done in the post op calculation, in that the principle of the surgery is to correct the limb to the pre-disease alignment, which may result in residual varus, and has been shown not to influence overall results [11]. The KSS scores are shown for the patient follow up periods listed as 1, 2, 5, and 10 years. (Fig. 3) At one year, there were 89% excellent and good results, 5% fair, and 6% poor. At two years, there were 93% excellent and good, 1 % fair, and 5.5% poor. The causes for the poor results at one and two years were tibial sided failure or persistent pain. Three (12%) of patients with a poor result at one year had converted to good and excellent at two years. Fourteen (5.6%) of the patients are deceased. Twenty-four (10%) are considered lost to follow up. Four (1.6%) were contacted and stated they did not want to return for a follow up visit, 2 are doing fine, 2 were having some degree of pain.

For the aggregate group of 286 knees, there were 17 (5.9%) all-cause revisions to TKA, including 2 (0.7%) dislocations, resulting in a (83%) survivorship at ten years. The survivorship at ten years for retained implants was 97% if non-implant related causes are not included. (Figs.1 and 2) Eight (2.8% of knees), which represented 47% of revisions were for tibial or femoral mechanical failure. There were 5 (1.7%) tibial sided failures at 15, 17, 24, 32 and 72 months' post index arthroplasty. There were 3 (1.0%)

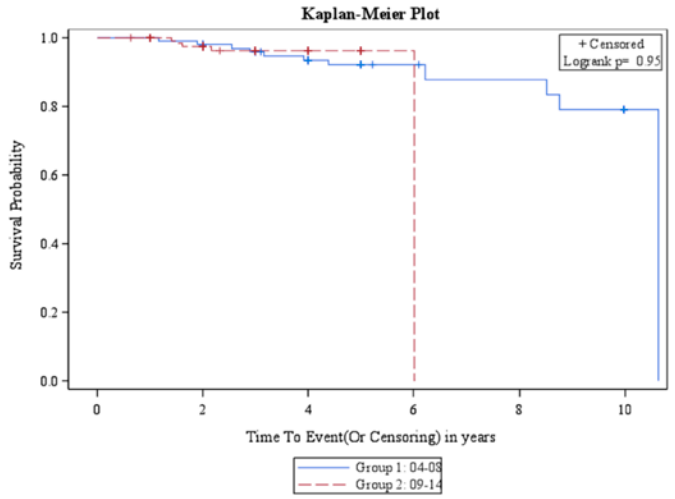

Figure 1. Comparison of Group I and Group II survivorship 10 years

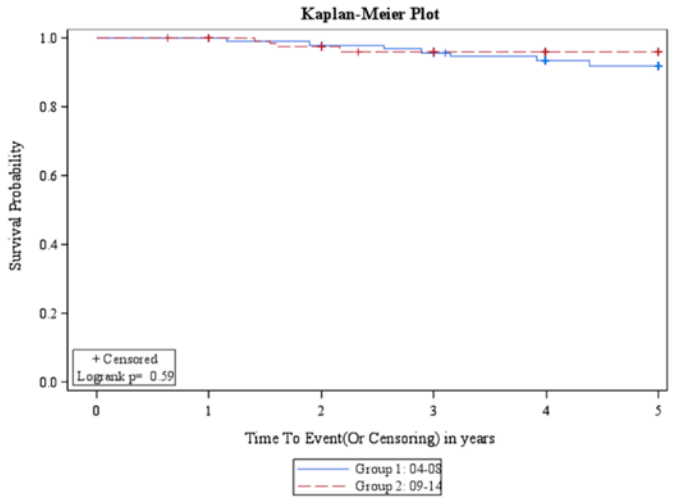

Figure 2. Comparison of Group I and Group II survivorship 5 years

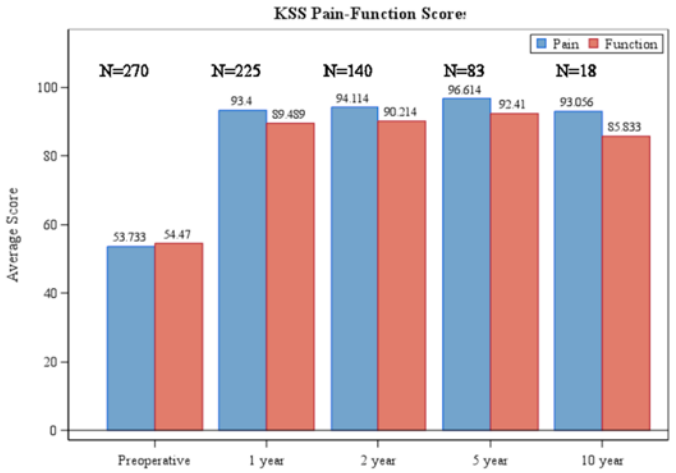

Figure 3.

femoral component loosening at 3, 4, and 10 years. Eight (53%) of revisions were non-implant related: 3 (1.0%) lateral compartment progression, two within 1 year from surgery and 1 at 9 years. One patient developed rheumatoid arthritis at 5 years and the Oxford was revised to a TKA at 6 years. One patient (0.3%) had a periprosthetic femoral fracture at 3 years. One (0.3%) had a late hematogenous infection at 3 years which was managed with a two-stage revision TKA. In this aggregate group, there were 11 (3.8%) return to the OR for non-revision reasons: 2 (0.7%) dislocations; 1 (0.3%) I&D of a hematoma; 1 (0.3%) late sepsis; 1 (0.3%) superficial wound necrosis I&D with STSG; 2 (0.7%) manipulations under anesthesia; 4 (1.4%) arthroscopy for lateral meniscus tear, cement removal, documentation of a loose femoral component, and to document lateral progression, respectively. There were no cases of DVT, PE, MI, or death in the perioperative period.

In the Group II sub-analysis of 153 knees, there were 5 (3.2%) revision/re-operations. Two (1.3%) patients were revised to a TKA: one for a periprosthetic femur fracture and one for lateral compartment progression at 18 months. There were no revisions for implant loosening of either the femur or the tibia. There were 2 (1.3%) bearing dislocations in this group and 1 (0.75%) patient with superficial wound necrosis that required a STSG. These 3 patients were the only non-revision return to the OR in this group. There was a 97% all cause survivorship with revision to TKA as the endpoint for this subgroup at 5 years. For survivorship analysis, bearing dislocation was treated as a revision surgery, as both occurred in Group II. No implant related failures occurred in Group II. Although there was no statistical difference in all cause survivorship between Group I and Group II, all the implant related failures were in Group I. As stated, re-operations for dislocation, both occurring in Group II, were counted as failures, even though they did not result in revision to TKA.

Discussion

Partial knee arthroplasty for anteromedial osteoarthritis of the knee has been shown to be a cost-effective treatment with excellent outcome and durable long term results in multiple studies and reviews of national joint registry data. [1,2,3,4] The description of anteromedial arthritis by White and Goodfellow is the prime indication for the OMB, however spontaneous osteonecrosis is a good secondary indication with excellent outcomes [14,15]. Many surgeons feel that the criteria set forth by Kozinn and Scott are too restrictive, and a recent article more clearly elucidated the unnecessary contraindications for using the OMB. [13]. This article more clearly defined how the status of the patellofemoral joint rarely has an adverse effect on patient outcome, unless there is significant lateral facet disease. A recent consensus statement has attempted to clarify current thought regarding the indications and contraindications for medial PKA [16]. Perhaps the debate regarding the appropriate use of PKA continues, however, in part due to the 2 to 3-fold higher failure rates as compared to TKA reported in several national joint registries [4,22]. Explaining this discrepancy is difficult, as national registries do not collect data as to whether the indications for the procedure or the surgical technique was appropriate for individual patients.

As part of the FDA approval process of the OMB in the US, all surgeons are required to attend an instructional course prior to using the device. The course stresses the importance of appropriate surgical indications and execution of the surgical steps necessary for a successful outcome. There have been several articles that address the effect of surgeon case volume as well as hospital volume on the outcomes in total joint arthroplasty. [17,18,19]. One study showed that surgeons who performed the OMB on 20 to 40 percent of knee replacement candidates, had significantly lower revision rates than those who performed less. [20,21] It stands to reason that surgical case volume is a surrogate for experience, particularly as it pertains to the individual surgeons' outcomes, as shown in the results from the National Joint Registry for England and Wales, which demonstrated higher revision rates in low volume surgeons. This data was also verified by a recent review of data for the UK NJR, which showed very low revision rates for surgeons who were performing PKA on 15 patients per year, and significantly higher rates in those who performed fewer than 5 per year. [4,22]

In the authors opinion, it is not well defined what the individual learning curve is for a given surgeon performing a given surgical procedure, and specifically when using the OMB. Intuitively, facilitating a surgeon becoming proficient at performing a particular surgical procedure can help to improve the outcome. Improvement through educational endeavors that facilitate the understanding of anatomic pathology, the indications for the procedure, and the proper execution of the surgical steps is undeniable. Having instruments used for the procedure that are intuitively practical, efficient to use, and reproducible is a necessary component of surgical success and long term outcome.

In the authors series, Group I patients were operated using Phase III instruments and the single peg femur. The Phase III technique involved making the vertical cut on the proximal tibia adjacent to the lateral edge of the medial femoral condyle. Patients with wide intercondylar notch-

es, particularly females, could end up with tibial resections too far medial thereby necessitating the use of a smaller tibial baseplate. Additionally, without a consistent stylus, the depth of the horizontal tibial cut could lead to over resection of bone. Small and Berend, in their work, using strain measurement techniques, showed the dramatic increase in tibial strain in the proximal medial tibia following PKA. [22,23] They were also able to demonstrate the adverse effect of excessive posterior or anterior slope on strain patterns, as well as the position and rotation of the vertical cut [24]. In Group I patients, the tibial sided failures were associated with tibial cuts that were either too medial or the horizontal cut was excessive (or both), leading to the use of a smaller base plate. The resultant increase in tibial stress is the probable cause for the subsidence and loosening observed in these cases.

In this series, four of the five tibial sided failures occurred early within the first three postoperative years. The cause of this early loosening is described above as it relates to the tibial bone cuts in the Phase I patients. Femoral loosening, although rare, 1.0% in this series, were all in Group I patients, using a single peg femoral component. These patients all had intact tibial components. With the development and implementation of the Microplasty™ instruments, the surgical execution has become easier and more reproducible, as elucidated in a paper by Hurst et al. [26] A significant change in the Microplasty™ technique was the positioning the vertical tibial cut adjacent to the tip of the medial tibial spine at the ACL footprint, instead of the lateral edge of the medial femoral condyle, thus maximizing the tibial baseplate size, increasing tibial plateau coverage, and reducing tibial stress, as elucidated by Small et al.

Of interest, is that none of the patients in Group II have had tibial sided loosening to date, nor have any had any worrisome radiographic radiolucencies or subsidence. On the femoral side, the Microplasty™ instruments have made femoral preparation simpler and more reproducible compared to Phase III [25], It the authors opinion, however, that implementation of the two peg femur is responsible for the reduced femoral loosening to zero in the midterm follow up of Group II patients. Additionally, in Group II, radiographic review has determined that no patients are felt to be at risk for loosening.

In the aggregate group, the all cause revision rate of 5.9% at 10 years is comparable to results found in other published series [2,26,27,28]. In this series, 2.4% of the revisions were for mechanical failure of either the tibial or the femoral component. More importantly, these implant related failures were all in Group I patients which were in the authors early experience with Phase III technique and the single peg femur. The leading cause of non-implant related failure, is lateral compartment progression, occurring in 3 (1.0%) patients, a number which is comparable with published results. [1] To the authors knowledge, there is no preoperative evaluation that can reliably identify those patients at risk for lateral compartment progression following medial PKA, however it is critical to note that the performance of the valgus stress radiograph is essential to documenting the status of the lateral compartment. In a recent publication, the valgus stress view demonstrated lateral compartment collapse in 3 of 78 patients, and thus a contraindication to PKA. [29].

It is important to state that in this series that although the 2 (0.7%) dislocations were considered failures for survivorship analysis, they are not revisions of the implants, as may be reported in some data sets and registries. The rationale for future reporting of bearing dislocation as a reoperation rather than a revision is that the solution for bearing dislocation involves a simple arthrotomy, retrieval of the dislocated bearing, and replacement with a new bearing. It does not involve the removal or exchange of fixed components, or revision to total knee arthroplasty. Therefore, if the rare bearing dislocation was to be considered a non-revision operation, survivorship would be improved 85% in this series.

In this series, the lack of significant perioperative complications, notably DVT, PE, MI, or death, is of significant interest. Lovenox was used initially for DVT prophylaxis and later changed to ASA, with no discernable difference except the return to OR for hematoma evacuation was in a patient on Lovenox prophylaxis. Several recent studies have shown the significant reduction in morbidity and mortality between PKA and TKA [30,31], and the results presented in this series would corroborate those findings. Additionally, in this series, there were no reoperations related to the patellofemoral joint, which reinforces the findings of the many published series cited in this paper.

Conclusions

The use of the Oxford Mobile Bearing™ PKA has been shown to be a useful part of the surgeon's surgical armamentarium when dealing with anteromedial osteoarthritis or osteonecrosis of the knee. PKA has been shown to have a lower morbidity and mortality and is cost effective when compared to total knee arthroplasty. The author's experience with the OMB, as demonstrated in this study, adds validity to the concept that understanding the pathoanatomy of anteromedial osteoarthritis and gaining surgical experience through increased surgical volume, adherence to well documented technique, and the use of a time proven im-

plant, can be accomplished with a high degree of successful outcomes for patients with the appropriate indications. Improved OMB surgical technique, instrumentation, and implant design have resulted in improved outcomes over time within the author's series, with a significant reduction in mechanical loosening of both the femoral and tibial components using later generation designs of the OMB. Lateral compartment disease progression, although infrequent, remains the leading non-implant related cause of long term failure. Future research efforts will need to be directed towards identifying those patients at risk, so they may be counseled preoperatively as to this small but significant risk. Additionally, future studies will be needed to compare other PKA designs and techniques regarding survivorship when comparing multiple surgeons from various locations who utilize PKA in the management of anterior medial OA of the knee and SONK.

Disclosure

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

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Anterolateral Oblique Distal Femoral Osteotomy for the Removal of Well Fixed Cemented Femoral TKA Components

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Abstract

In the setting of periprosthetic joint infection, the complete removal of implants and cement can be challenging with well-fixed, cemented implants about the knee. This can get especially complex in the setting of long cemented femoral component stems. Osteotomies are well described in the proximal femur and tibia for removal of implants and cement. There is little information available on distal femoral osteotomies. We describe an anterolateral oblique distal femoral osteotomy for the removal of well-fixed, cemented components in resection knee arthroplasty that preserves vascularity to the osteotomized segment.

Keywords: *distal femoral osteotomy; revision TKA; complex revision*
Level of Evidence: *AAOS Therapeutic Level III*

Introduction

The removal of well-fixed implants with cemented stems about the knee presents unique challenges in revision and resection knee arthroplasty. [1-3] Extended trochanteric osteotomies and tibial tubercle osteotomy for revision hip and knee arthroplasty have been previously described and used effectively for the removal of implants in these settings. [4-8] Anterior femoral osteotomy in revision knee arthroplasty has been previously described, however many of these reports do not outline the specific technique utilized or markedly compromise blood flow to the osteotomized fragment. [1,9] These techniques were utilized in small groups of patients with limited follow up.

In the setting of periprosthetic infection, all implants and cement mantle should be removed in order to eradicate infection. Removing cement in the femoral canal from

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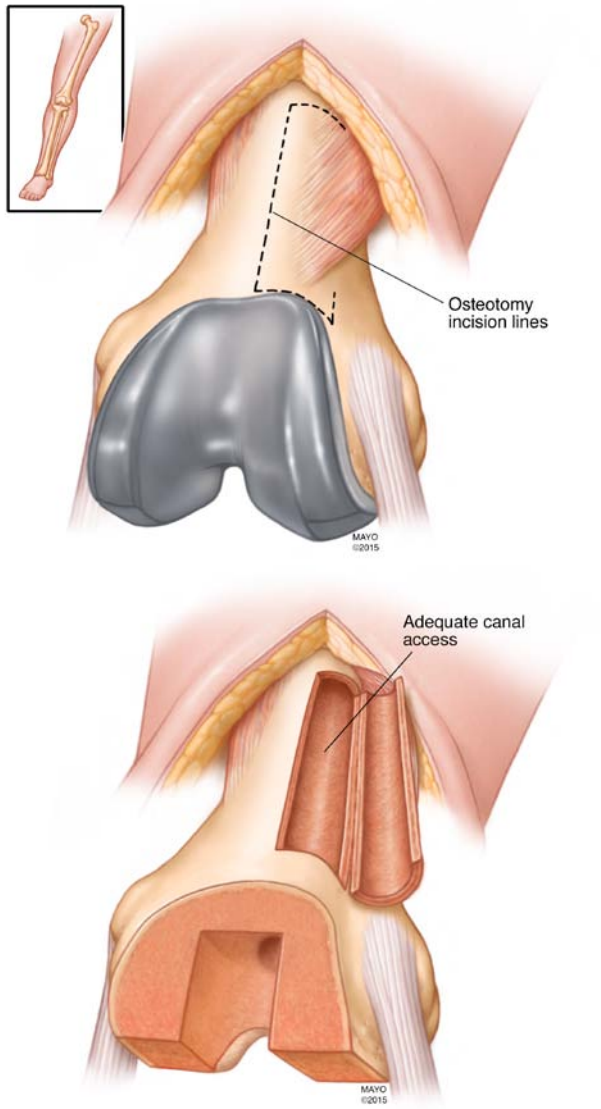
the distal femur is time-consuming, and leaves uncertainty as to whether all cement has been cleared from the femur. A femoral osteotomy can be effective in allowing direct visualization of the femoral canal facilitating the removal of implants, as well as the cement mantle during debridement. This technique is specifically useful in the setting of infection where removal of all foreign material is paramount.

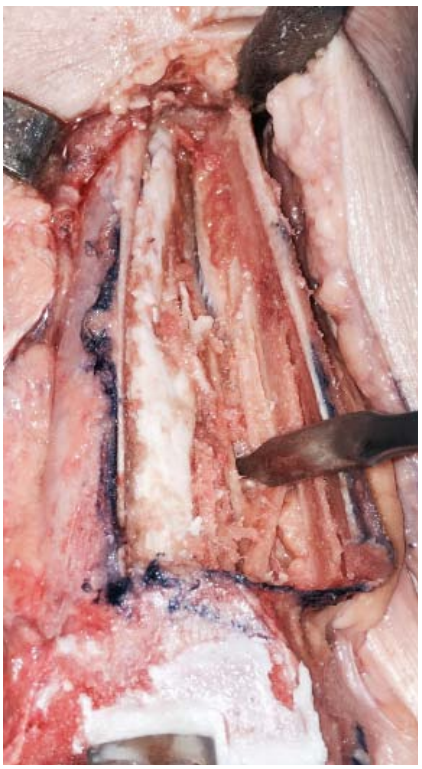
We describe a technique of anterolateral oblique distal femoral osteotomy to remove well-fixed, cemented femoral implants while preserving blood supply to the lateral osteotomized fragment. We have used this technique only in the setting of periprosthetic infection with fully cemented femoral stems, however it may be applicable to other situations in revision arthroplasty.

Technique



Figures 1 and 2.

A standard midline incision with a medial parapatellar arthrotomy is utilized to approach the knee. Synovectomy is performed as necessary; however care is taken not to devascularize the anterolateral aspect of the distal femur. An oscillating saw and osteotomes are used to free up the cement-implant interface along the anterior, posterior, distal, and chamfer portions of the femoral component. An impactor is used to attempt removal of the implant. If the stem is well fixed, or cement is not able to be viewed from the distal femur, then the decision to proceed with osteotomy is made. Sharp dissection is then carried out on the anterior aspect of the femur, while leaving the anterolateral and lateral soft tissue attachments preserved. Using cautery a line is made in the midline of the anterior aspect of the femur and brought out laterally at the proximal most point of the osteotomy. The length of the osteotomy will vary based on the length of the stem and cement mantle. The distal osteotomy site is made just proximal to the anterior phalange of the knee replacement. An oscillating saw is then used to perform the osteotomy entering the femur directly anterior at an oblique angle towards the posterolateral cortex. Osteotomes are then used to book open the fragment and the fragment exits posterolaterally on the femur distally ending at the lateral epicondyle and exiting posterior to the lateral intramuscular septum. Care is taken to assure the lateral and posterior soft tissue envelope is left undisturbed and that the osteotomy hinges laterally without propagating a fracture. (Figure 2) Pre-drilling of the lateral femoral cortex may further reduce the risk of fracture propagation while opening the osteotomy site. Retractors may be placed inside the osteotomized fragment to visualize the canal. Once the osteotomy is performed, direct access to the femoral canal is gained. (Figure 3) If the stemmed implant is still present, a pencil tip burr is used to go circumferentially around the stem to facilitate removal. The implant should be able to be



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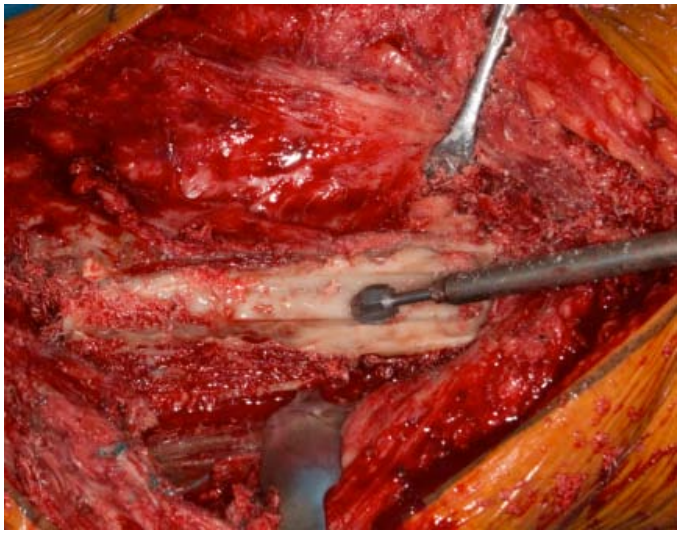

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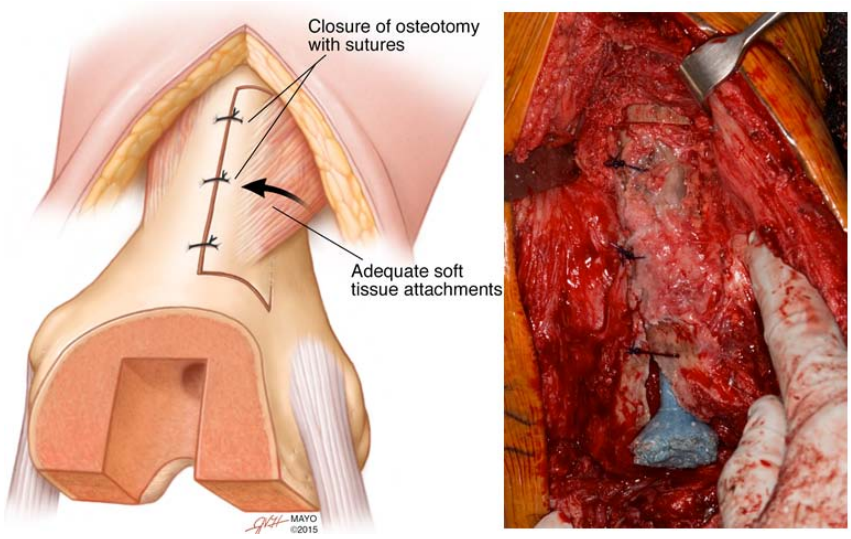

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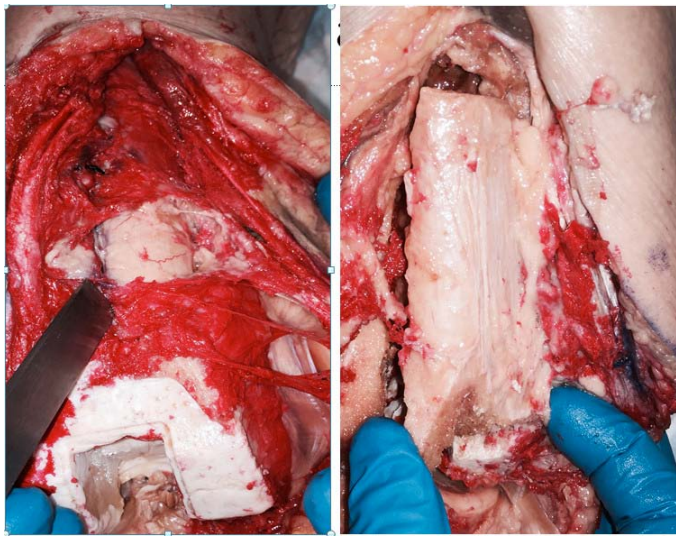

Figure 6.

removed at this time. Often after removal, there may be an abundance of cement mantle still present that must be removed. A high-speed burr is used to remove retained cement in the femoral canal and get to bleeding bone surfaces. (Figure 4) With direct visualization, one can see the cement mantle that is smoothed off that would be otherwise obscured using a distal removal technique. This technique can be performed with or without the use of a tibial tubercle osteotomy to remove the tibial component and cement mantle. Once adequate debridement is performed and all of the cement is removed, a static spacer is utilized. Two dowel rods are fashioned using plastified molds and antibiotic impregnated cement (Vancomycin 3 grams and Gentamicin 3 grams) to be inserted in the femoral and tibial canals. These dowel rods, in addition to a block of cement to support the articulation and fill the space underneath the extensor mechanism form a static spacer for the knee. The osteotomized fragment of the femur is then reduced and fixated using large non-braided, monofilament suture through drill holes in the fragment. (Figure 5) The patient is kept toe-touch weight bearing for 8 weeks until healing of the osteotomy is present on radiographs. Most resection arthroplasty patients routinely have restricted weight bearing during the post-operative period allowing the osteotomy time to heal prior to re-implantation, thus there is no unnecessary delay. At time of reimplantation and healing of the osteotomy, a long stem is used assuring to bypass the osteotomy. Cemented or uncemented stems can be utilized at the time of reimplantation. Hybrid fixation can also be considered with uncemented metaphyseal cones and cemented stems.

Patients and Methods

We have utilized this technique at the time of resection arthroplasty for chronic periprosthetic knee infection in two patients with well-fixed, cemented femoral stems. A comparative qualitative analysis of blood supply to the distal femur was also performed using four fresh-frozen cadaveric knees injected with latex following this anterolateral osteotomy in right and left specimens, an anterior based osteotomy, as well as a control specimen where no osteotomy was performed. Each osteotomy was performed on the cadaveric specimens. The femoral artery was then cannulated and injected with latex dye. We then froze the specimens to allow procurement of the latex. The speci-

mens were then analyzed for blood supply to the distal femur and the osteotomized fragment.

Results

Both patients showed healing of the osteotomy at the time of reimplantation and were successfully reconstructed utilizing stems bypassing the site of the osteotomy. There were no complications using this technique. Both patients were reimplanted using a constrained hinge knee prosthesis. Both are infection free and weight bearing as tolerated at latest follow up. Comparative qualitative analysis of blood supply to the distal femur following the different osteotomy types showed a more robust blood supply when utilizing the anterolateral osteotomy compared to the anterior based osteotomy. (Figure 6) The blood supply to the distal femur in the specimens with the anterolateral osteotomy was similar to the control specimen where no osteotomy was performed.

Discussion

Osteotomy of the femur is often unnecessary in the removal of well-fixed femoral implants, and should be reserved for special circumstances due to its risk of nonunion, fracture propagation, and compromised fixation at revision knee arthroplasty. We present a technique that can be effectively utilized to remove well-fixed femoral components and the cement mantle in resection arthroplasty for periprosthetic knee infection.

One recent report describes an anterior osteotomy entering medially and exiting laterally on the anterior portion of the femur. [9] There are several flaws and differences in this type of osteotomy performed for the removal of well-fixed components. This described osteotomy threatens the vascularity of the osteotomized fragment as this technique makes it difficult to preserve the lateral soft tissue attachments to the anterior based fragment. This is especially disadvantageous in the setting of infection. Previous reports showing the subperiosteal blood supply to the distal femur highlight the lateral cortex and condyle as containing an abundance of intraosseous and extraosseous blood supply. [10,11] The anterior femur is vascularized by branches of the superior medial and lateral geniculate arteries in addition to the anterior soft tissues. An anterior based fragment will compromise this feeding vasculature from the medial and lateral sides of the femur. Furthermore, more soft tissue stripping is needed to complete this type of osteotomy. Our described surgical technique leaves the lateral soft tissue sleeve undisturbed. (Figure 3-3)

The anterior osteotomy described by Merz et al. was fixed using circumferential cables around the distal femur bringing the unnecessary threat of vascular complications to this procedure. Further periosteal stripping around the osteotomy must be performed to properly pass circumferential cables safely which may threaten viability to the osteotomized fragment.

Our technique of large caliber suture fixation has the advantage of superior visualization, adequate stabilization, fragment viability, and is theoretically safer than the previously described technique of osteotomy fixation. (Figure 2-2 and Figure 3-3) We have had no intra-operative complications using this technique. We have found this osteotomy to be a useful technique when removing well-fixed, cemented femoral components during periprosthetic infection.

To date, we have utilized this technique at the time of resection arthroplasty for periprosthetic infection in two patients with well-fixed, cemented femoral stems. Both patients showed healing of the osteotomy at the time of reimplantation and were successfully reconstructed utilizing stems bypassing the site of the osteotomy. Both patients are infection free and weight bearing as tolerated at 2-year follow-up.

Disclosure

The authors declare that there is no conflict of interest regarding the publication of this paper. For full disclosures refer to last page of this journal.

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Posterior Femoral Single Limb Osteotomy for the Removal of Well-Fixed Modular Femoral Neck Components

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Abstract

Modular neck femoral components were introduced to optimize femoral neck anteversion, leg length, offset, and stability in total hip arthroplasty. However, concerns have been raised in recent years regarding early failure of these implants due to corrosion, pseudotumor, as well as fracture of the modular neck. Removing modular neck femoral implants is challenging as removal of the modular femoral neck leaves a proximally coated femoral stem level with the proximal bone of the femoral neck. We describe a posterior femoral single limb osteotomy (posterior cut of an extended trochanteric osteotomy) for the removal of a modular neck femoral component.

Keywords: *femoral osteotomy; THA; revision THA*
Level of Evidence: *AAOS Therapeutic Level III*

Introduction

Modular neck femoral components were introduced to optimize femoral neck anteversion, leg length, offset, and stability in total hip arthroplasty. [1] However, concerns have been raised in recent years regarding early failure of these implants due to corrosion, pseudotumor, as well as fracture of the modular neck. [2-7] Due to these early failure modes, the revision of these femoral components has become more common. Additionally, we have noted that implant removal of well-fixed modular femoral neck implants can be challenging secondary to the modularity of the femoral neck. Extended trochanteric osteotomies have previously been utilized for the extraction of these implants due to the difficulty with removal. [5]

Extended trochanteric osteotomies (ETO) have been described for the removal of well-fixed femoral components in revision total hip arthroplasty. [8-10] While this

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technique has proved useful in the removal of components with good results at mid-term follow up, [8,11,12] stem subsidence, trochanteric migration, nonunion, and fracture of the fragment have been reported. [11-13]

Removing modular neck femoral implants is challenging as removal of the modular femoral neck leaves a proximally coated femoral stem level with the proximal bone of the femoral neck. Without a femoral neck, universal extraction devices and vice grip instruments can not be used. This emphasizes the importance of having implant specific disimpaction equipment available at time of revision in addition to alternative methods for implant removal. We have identified a bone-preserving posterior femoral "single limb osteotomy " that limits the complications associated with an ETO. The purpose of this report was to describe a posterior femoral single limb osteotomy (posterior cut of an extended trochanteric osteotomy) for the removal of a modular neck femoral component.

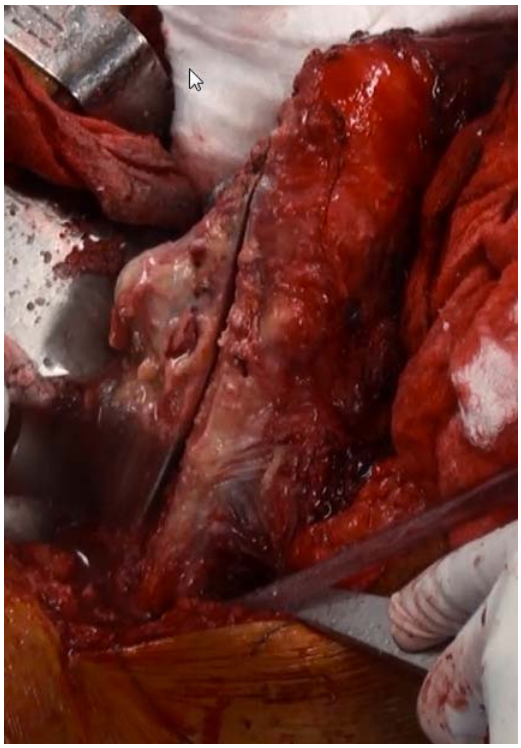


Figure 1.

Surgical Technique

A standard posterior approach to the hip was utilized for this technique. Pericapsular scar was then removed in order to expose the proximal femur. The hip was dislocated posteriorly and the vastus lateralis was elevated distally to expose the posterior aspect of the femur. The modular head and neck were removed with the manufacturers' standard extraction instruments (Stryker, Mawah, NJ, USA). A round tip burr was used to expose the lateral shoulder of the implant to prevent impingement on the greater trochanter during extraction. A standard pencil tip burr followed by a longer pencil tip burr was used to disrupt the bone-implant interface proximally. The standard Stryker Rejuvenate (Stryker Corporation, Mawah, NJ) stem extractor was then placed onto the proximal portion of the implant. A slap hammer was then used to attempt removal of the implant. Traditionally, if this was unsuccessful, an extended trochanteric osteotomy is performed for removal of the implant. In this case, a posteriorly based femoral single limb osteotomy was utilized to open the femur for easier extraction. A microsagittal saw was used to make this osteotomy beginning from the posterior aspect of the greater trochanter extending distally to the templated length (typically 12-14 cm) and represents the posterior limb of a standard extended trochanteric osteotomy. [8-10] (Figure 1) Osteotomes were then inserted to slightly expand the femoral canal diameter. This osteotomy decreases hoop stresses around the femoral implant and may help to disrupt the bone implant interface in well fixed implants.

The stem extractor was again utilized for stem extraction. The femoral single limb osteotomy allows the diameter of the femur to expand decreases hoop stresses facilitating implant removal. (Figures 2 and 3) At the time of closure, two 18 gauge wires are circumferentially passed around the femur and tightened to close the osteotomy. If the implant is still not easily extracted following the posterior osteotomy, the osteotomy can readily be transitioned to a standard extended trochanteric osteotomy.

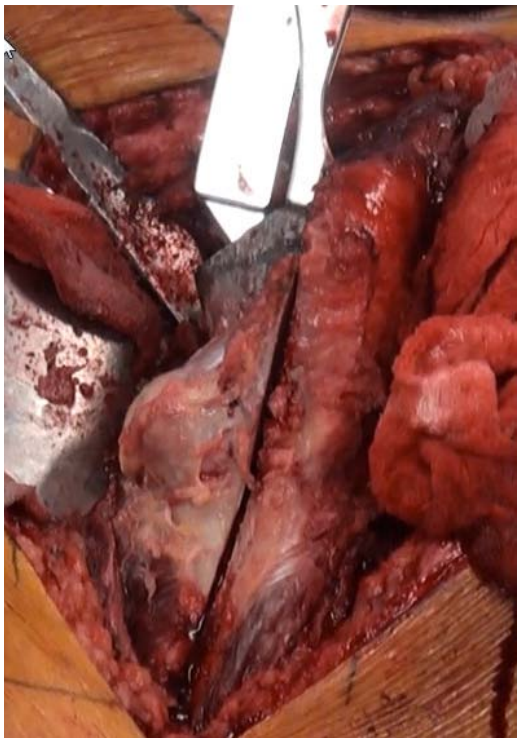
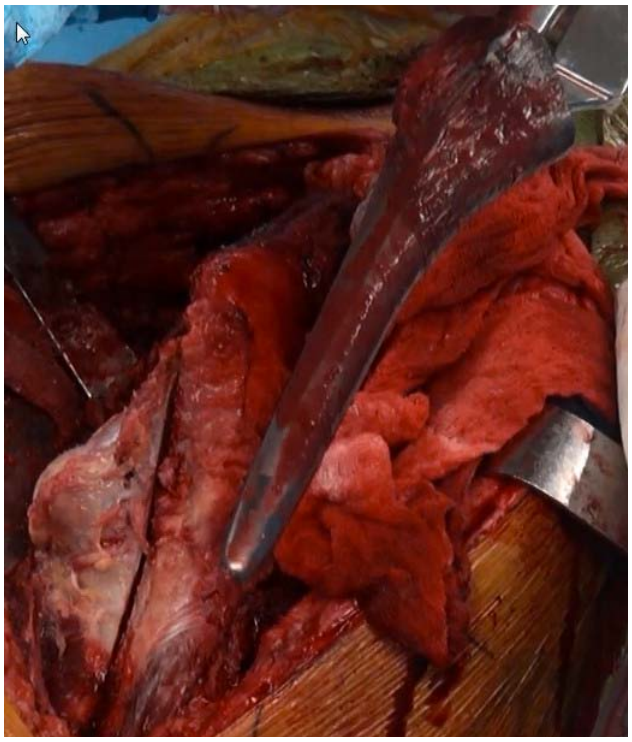


Figure 2.



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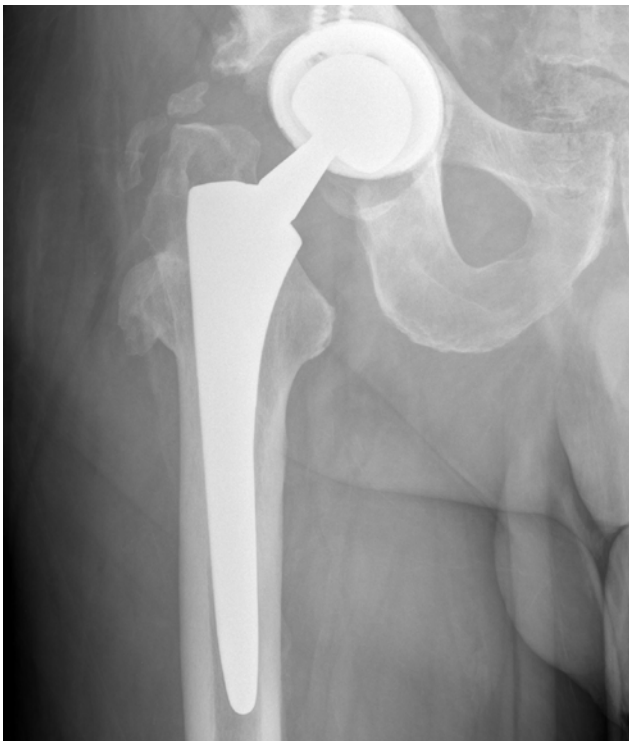

Figure 4.

Case Report

A 60-year-old male 4 years after a right total hip arthroplasty for osteoarthritis presented to our institution with a chief complaint of hip pain. Implanted components consisted of a Tritanium acetabular shell and a Rejuvenate modular neck femoral stem (Stryker, Mawah, NJ, USA). His post-operative course was complicated by a post-operative hematoma, managed non-operatively with no additional sequela. Over the last two years his hip pain had progressively worsened over, requiring a cane for ambulation. Prior work up included ESR, CRP, cobalt and chromium within normal limits and a bone scan suggestive of acetabular loosening. On physical examination he walked with a markedly antalgic gait with a positive Trendelenburg test on the right. Hip pain was reproducible with resisted flexion and internal rotation. Radiographic evaluation showed a well-fixed femoral stem and loosening of the acetabular component. (Figure 4)

On follow-up evaluation, repeat inflammatory markers were significant elevated with ESR 37 (normal 0-22) and CRP 56.8 (normal < 8.0mg/L). Intraarticular hip aspiration contained 3036 total nucleated cells and 85% neutrophils concerning for periprosthetic infection. At time of revision surgery, intraoperative pathology was positive for acute inflammation and a resection arthroplasty was performed. The posterior femoral single limb osteotomy was utilized for removal of the femoral component. (Video) After stem removal and debridement, a temporary antibiotic articulating spacer (Prostalac, DePuy, Warsaw, IN) was placed. (Figure 5) Intraoperative cultures grew methicillin resistant staphylococcus epidermidis. Infectious Disease was consulted and the patient was placed on intravenous vancomycin for 6 weeks. Postoperatively, the patient was made partial weight bearing and was discharged from the hospital on post-operative day 4 (Figure 6).

Discussion

Modular neck femoral stem designs were introduced to address concerns associated with instability after THA. These implants gained popularity due to their ability to independently adjust leg length, offset and version through modularity of the neck segment. In recent years, several failure modes of modular

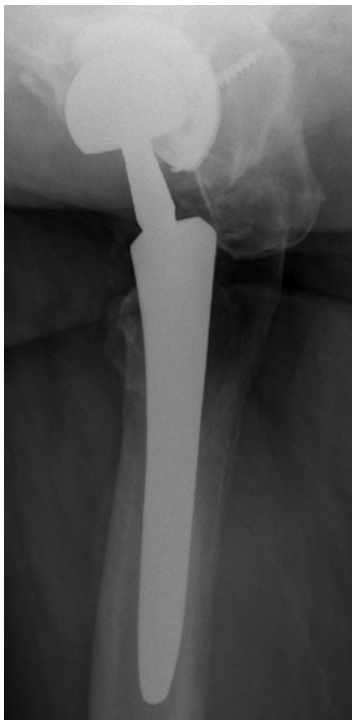

Figure 5.

neck have been identified including modular neck fracture, corrosion, and pseudotumor [2,3,6,7,14]. The corrosion products are similar to those seen with metal-on-metal bearings and trunnion wear associated with metal-on-polyethylene bearings [2,15]. (I would just remove this line) Removal of these modular neck stems can be challenging as removal of the modular neck prevents the use of universal femoral disimpaction devices and an ETO has often been necessary for removal. [5] .The posterior single limb osteotomy described in this paper is bone and soft-tissue preserving and facilitates the extraction of a well-fixed modular femoral neck implant. The benefits of a single limb osteotomy is that it minimizes the risk of fracture of the osteotomy fragment, trochanteric migration, implant subsidence, and trochanteric nonunion associated with an ETO [8,10-13]. A posterior single limb osteotomy also facilitates subsequent fixation as the metaphyseal tube is still intact and does not require reduction. There is also little downside to attempting implant removal after completing the single limb as it can be easily converted to an ETO if necessary. To date, we have been able to successfully remove all modular neck implants utilizing this technique without the need for an extended trochanteric osteotomy.

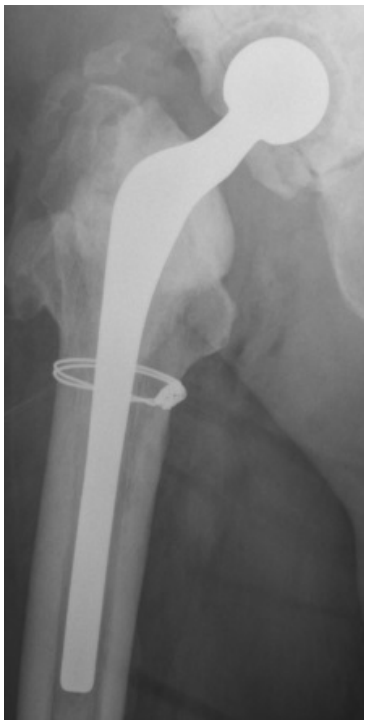

Figure 6.

Bauze et al. [16] previously described a posterior longitudinal osteotomy in the removal of 12 uncemented femoral implants. Ten of these stems had a collar making it difficult to access the medial calcar. The majority of these stems were of older designs no longer in use. The authors found that type of coating (plasma-sprayed or hydroxyapatite), the degree of coating (proximally or fully coated), and length of the stem did not affect the ability to disimpact the stem and all osteotomies healed uneventfully without complication. A single limb osteotomy has also been described for both the direct anterior and direct lateral approaches and with the difference being that the longitudinal split is anterior to that of a standard posteriorly based ETO. [17,18]

In summary, the posterior femoral single limb osteotomy is an effective technique for the removal of proximal ingrowth stems, particularly modular neck femoral stems where engagement of the femoral neck for removal is not possible. There is little downside to this technique as a complete ETO can be performed if necessary. Fully porous coated implants may require a complete ETO, but the authors believe the posterior single limb osteotomy is an effective technique for the removal of all proximally coated monoblock and modular femoral stems.

Disclosure

The authors declare that there is no conflict of interest regarding the publication of this paper. For full disclosures refer to last page of this journal.

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Patient Factors Affecting Surgeon Selection and the Decision to Delay Total Knee Arthroplasty

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Abstract

Background: Delaying total knee arthroplasty (TKA) carries an increased likelihood of poor rehabilitation outcomes. Reasons behind choosing to delay surgery are under investigated. This study explores potential factors related to the decision to delay a TKA procedure and preferences for post-surgical pain management.

Methods: A cross-sectional online survey was conducted among TKA candidates in the US.

Results: 6,298 persons received a screening questionnaire; 2,571 (41%) completed screening with 680 (26%) meeting survey eligibility criteria. 654 of 680 persons (96%) completed surveys. 154 (24%) respondents had delayed TKA. Interference with work and concerns about insufficient post-discharge pain management were found to be significant factors in this decision. A one unit increase in the ten point interference with work scale was associated with a 22% increase in the odds of delaying surgery (OR: 1.219; 95%CI: 1.095-1.356). Surgical candidates concerned about experiencing pain during the first several weeks following surgery had significantly higher odds of delaying surgery (OR: 1.64, 95% CI: 0.881-3.06). Ninety-two percent of respondents indicated they would seek surgeons who offered effective non-opiate pain management options during the first several weeks of the rehabilitation period; 66 percent indicated they would likely switch surgeons for access to a non-opioid pain management approach.

Conclusions: Delaying a TKA is significantly influenced by concerns about interference with work and experiencing an extended period of post-surgical pain during a potentially prolonged recovery period. Access to post-operative pain management methods that reduce or eliminate opioid use during post-discharge rehabilitation and recovery is an important factor in the selection of a joint replacement surgeon.

Keywords*: knee arthroplasty; TKA ;surgical delay; post-operative pain management; non-opiate; surgeon choice*
Level of Evidence*: AAOS Therapeutic Level V*

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Introduction

Total knee arthroplasty (TKA) has been recognized as effective in the treatment of disabling pain caused by severe osteoarthritis (OA) of the knee with significant improvement in patients' quality of life [1]. Knee-replacement surgery is an increasingly common procedure--by 2030 the U.S. demand for primary TKA is projected to grow to 3.5-million [2]. The fastest growth is projected among patients 45-54 years: from 59,000 procedures in 2006 to over 994,000 by 2030 [3].

Deferring surgery decreases the quality of patient outcomes. Postponement can lead to contralateral knee joint and other skeletal damage; weakened or lost function in muscles and ligaments; and greater difficulty or an inability to engage in normal daily activities (e.g., walking, driving, and bathing) [4,5]. The result is an increased likelihood of poor rehabilitation outcomes, further reduced quality of life and a negative impact on emotional well-being [6]. The earlier TKA surgery is performed, the higher the success rate and better the ultimate knee functioning [6]. In addition, following failed conservative treatment—and prior to a delayed surgical intervention—individuals continue experiencing debilitating pain, reduced quality of life, and significant financial burden [6].

Pain following total knee arthroplasty can be severe and opioids are commonly provided to manage postoperative pain. Even as far as one month following TKA, 56% of patients continue taking opioids and 78% continue to complain of moderate to severe pain during ambulation [7]. Among five different surgical procedures (thoracotomy, total knee replacement, total hip replacement, radical mastectomy, lumpectomy) evaluated by Carroll and colleagues TKA patients reported the highest median days to opiate cessation: 47 days post-surgery, with 6% of opioid naive patients continuing to require these analgesics for over 5 months [8]. A large percentage (31% - 84%) of those seeking treatment for opioid addiction report that their abuse ensued following a legitimate prescription from a physician [9,10,11,12]. Finally, patients receiving opioids rather than NSAIDs or Cox-2 inhibitors for chronic non-cancer pain are at a markedly increased risk for falls, cardiovascular events and all-cause mortality [13].

Despite the increasing number of appropriate candidates for TKA, patient acceptance of a surgery recommendation is low. The majority of OA patients ultimately refuse arthroplasty [6], choosing instead to spend an average of 20 years with continuing pain [6]; for young osteoarthritis patients the prospect of continuing pain is 40 or more years [6].

TKA candidates may choose to delay surgery for a variety of reasons. Clinical literature has identified sex and race/ethnicity differences in health beliefs and values that appear to influence patients' decisions about joint replacement surgery [14,15]. Among health beliefs perceptions about pain and concern for interference with activities may be of particular importance. Other identified reasons include ineffectiveness of conservative measures, the perceived lack of safe and effective minimally-invasive surgical options, and concerns that the alternative treatment involves major and irreversible arthroplasty surgery [6].

This study explores patients' perspectives and factors related to the decision to delay a TKA procedure. Surgical candidates suffering from knee osteoarthritis within the United States were surveyed to explore patient perspectives and factors related to the decision to delay surgery.

Materials and Methods

Participants and setting

A cross-sectional survey of individuals aged ≥55 years who were considering a TKA procedure was conducted using an online survey service [16]. Eligible individuals were asked to complete a study-specific survey. Respondents completing the survey were able to direct 50 cents to the charity of their choice from a pre-selected list. Survey questions were presented in sequential order without the ability to return to a previous question to alter a response. This study was determined to be exempt from IRB review [17].

Measures

Demographic Information: Respondent data provided by the survey service included age, gender, annual household income, and education. Age was collected as both a continuous and categorical variable (<18; 18-29; 30-44; 45-60; and >60). Household income was collected as a categorical variable ($0-$24,999; $25,000-$49,999; $50,000-$99,999; $100,000-$149,999; and >$150,000) as was education ("less than high school"; "high school degree"; "some college or associate degree"; "bachelor degree"; and "graduate degree").

Outcome Variables: The primary outcome defined for the study was the decision to delay total knee replacement surgery based on response to the question: "How likely is it that you may have delayed knee replacement surgery due to concerns that pain and/or the side effects of narcotic pain medications may extend your recovery and rehabilitation?" Responses were dichotomized: "Very likely" or "Likely" responses were considered to have delayed total knee replacement surgery; "Unlikely" or "Very unlikely"

responses were considered not to have delayed total knee replacement surgery.

An additional outcome, years considering knee replacement surgery, was based on response to the question "For how many years have you been considering knee replacement surgery?" Responses were dichotomized: ≥ 2 years and < 2 years.

Independent Variables: In addition to demographic information other independent variables included measures related to pain, pain management for TKA surgery and respondent perception of new pain management strategies.

The Brief Pain Inventory [18], a widely used pain assessment tool in clinical settings, was used to assess two aspects of pain—pain severity in the previous 24 hours and interference with every day life. The Brief Pain Inventory (BPI) adopts a scale of 0 to 10 for each measure. For pain severity 0 = complete absence of pain and 10 = worst pain ever experienced. For interference with every day life questions (general activity, mood, walking ability, work, sleep, and enjoyment of life) 0 = no interference and 10 = total interference.

Several questions related to pain management and TKA surgery were included in the survey. One asked respondents to indicate their current pain management strategies. Respondents were also asked about pain concerns that most significantly impacted their decision to have knee replacement surgery (i.e., concerns about pain for the first 3 days following surgery versus concerns about pain within the first several weeks following surgery). Another question asked about their preferred postoperative pain management approach--one that offered "excellent" pain management in the hospital but would likely necessitate the use of opioid analgesics to manage pain following discharge or one that offered "adequate" pain relief in the hospital and would likely reduce or eliminate opioid medications following discharge.

Finally, respondents were asked two questions to assess their perception of a new pain management approach. "How important would it be to your choice of surgeon to know that they have been certified to use a new pain management approach that could lead to a reduction or elimination of narcotic analgesics following TKA surgery?" and "How likely are you to seek a well-qualified knee replacement surgeon who offers a new pain management approach that could lead to a reduction or minimization of narcotic analgesics following TKA surgery?"

Data analysis

Descriptive statistics are reported for age, gender, household income, and educational attainment. Continuous variables are reported as means with standard deviations (mean ± s.d.); categorical variables are reported as percent of respondents.

Associations between the Brief Pain Inventory pain and interference responses and the demographic variables of age, gender, household income and educational attainment were evaluated using the Chi-Square test. For this analysis the 0-10 scales for pain and interference were classified into four categories [19,20]: 0 = "no pain" or "no interference"; 1-4 = "mild pain" or "mild interference"; 5-6 = "moderate pain" or "moderate interference"; 7-10 = "severe pain" or "severe interference".

BPI pain and interference responses were evaluated using Pearson's Correlation Coefficient to assess the relationship and strength of the relationship between variables. A correlation was determined to be strong if the Pearson correlation coefficient was above 0.7; at that level 50% of the variation in one variable is explained by its correlation with the other variable [21].

Logistic regression with stepwise model selection was employed to explore factors potentially significant in predicting the decision to delay a knee replacement surgery and the length of delay. Logistic regression predicts the odds of outcome variables from a set of independent variables [22]; stepwise model selection orders the independent variables in the regression model by a computer algorithm sequentially applying statistical tests [23]. For the logistic regression the primary and secondary study outcomes (decision to delay a TKA and length of delay, respectively) were classified into the two previously defined groups. Exploratory variables for the model included demographic variables (gender, income, education, age), concerns for pain (pain during the three days immediately post-surgery or several weeks following the surgery), and the eight BPI items for pain and interference with every day life.

All statistical analyses were completed using SAS v 9.3 (SAS Institute, Cary, NC, USA). A p-value of < 0.05 was chosen as the threshold for statistical significance.

Results

A total of 6,298 persons were sent a screening questionnaire; 2,571 completed screening and were provided with an eligibility questionnaire; 680 (26%) respondents met the eligibility criteria defined for the study. There were 654 completed surveys for a survey response rate of 96% (654/680).

Demographic Profile: The mean age of survey respondents was 64 ±7 years; 71% of the participants were 60 years or older; 65% of respondents were female (Table 1).

As a group, 55% reported educational attainment of either bachelor or graduate degree; approximately one-third (30%) reporting household incomes of $100,000 or more.

Pain Severity and Interference with Activities: The mean pain level was 5.6 ±2.2 with a median of 6.0. Means for measures of interference with everyday life ranged from a low of 3.5±2.9 for interference with relations to a high of 6.5±2.5 for interference with walking (Table 2). Correlations between the eight BPI items ranged from 0.397 to 0.812 suggesting a moderate to relatively strong correlation (Table 3). In the same correlation matrix, correlations of pain and interference with everyday life ranged from 0.397 to 0.574, a moderate correlation.

Decision to Delay a TKA and Length of Delay: Among the 654 respondents 154 (24%) responded that they had delayed TKA due to concerns that pain and/or the side effects of opioids might extend their recovery and rehabilitation. Logistic regression results indicated that only interference with work scale and age were significant predictors of delay in the stepwise model selection (Table 4). A one unit increase in the interference with work scale is associated with a 22% increase in the odds of delaying knee replacement surgery (95% CI: 1.10-1.36). A one year increase in age is associated with a 1.3% increase in the odds of delaying knee replacement surgery, though this did not reach statistical significance (95% CI: 0.98-1.05).

There were 352 respondents who reported they had been considering knee replacement surgery for at least two years. The factors significant in predicting this secondary outcome were also explored by logistic regression with stepwise model selection (Table 5). A one unit increase in interference with work scale is associated with a 9% increase in the odds of having considered knee replacement surgery for at least 2 years. Patients concerned about experiencing pain during the first several weeks following surgery had significantly higher odds of having considered knee replacement surgery for at least 2 years (OR: 0.59, 95% CI: 0.38 – 0.93.

Pain Management: Among all respondents the use of opioid-containing analgesics to manage knee pain was reported by 22% of respondents; NSAID use by 62%; acetaminophen by 29% and Cox-2 inhibitors by 10%. Approximately 72 percent of the respondents would accept "adequate" rather than "excellent" pain management in the first three days following the surgery if the method would also reduce or eliminate the need to take opioids for pain management during the post-discharge rehabilitation period. The majority of the respondents (74%) were more concerned about pain they were likely to experience within the first several weeks following surgery rather than pain they were likely to experience within the first three post-operative days. Overall 92 percent indicated that a new pain management approach that reduced or eliminated the use of opioid-containing pain medications would be an important factor in their choice of the surgeon they would select to perform their TKA. Even among those who had already identified a surgeon to perform their TKA, 66% would switch to a different surgeon if they could identify another who would offer a pain management approach that reduced or eliminated opioids during the post-discharge rehabilitation and recovery period.

Table 1. Respondent Demographics (n=654)

Measure	Frequency	Percent
Age (mean age:64±7)		
45-60	170	30
>60	413	71
Gender		
Female	382	66
Male	201	35
Household income		
$0 - $24,999	58	13
$25,000 - $49,999	90	20
$50,000 - $99,999	173	38
$100,000 - $149,999	80	17
$150,000 and beyond	61	13
Education		
Less than high school degree	2	< 1
High school degree	37	6
Some college or Associate degree	161	28
Bachelor degree	171	20
Graduate degree	208	36

(Note: sums do not add up to n=654 in some categories due to missing data)

Table 2. Brief Pain Inventory

	Mean (SD)	Median
Pain level	5.6 (2.2)	6.0
Pain Interference with general activity	5.8 (2.4)	6.0
Pain Interference with mood	4.7 (2.7)	5.0
Pain Interference with walking	6.5 (2.5)	7.0
Pain Interference with work	6.0 (2.6)	6.0
Pain Interference with relations	3.5 (2.9)	3.0
Pain Interference with sleep	4.4 (2.9)	4.0
Pain Interference with enjoyment	5.9 (2.8)	6.0

Table 3. Pain Measures Correlation

Interference with:	Pain	General	Mood	Walking	Work	Relations	Sleep	Enjoyment
Pain	1	0.574 *P<0.0001*	0.464 *P<0.0001*	0.550 *P<0.0001*	0.522 *P<0.0001*	0.396 *P<0.0001*	0.510 *P<0.0001*	0.513 *P<0.0001*
General interference	0.574 *P<0.0001*	1	0.660 *P<0.0001*	0.812 *P<0.0001*	0.769 *P<0.0001*	0.566 *P<0.0001*	0.523 *P<0.0001*	0.692 *P<0.0001*
Interference with mood	0.464 *P<0.0001*	0.660 *P<0.0001*	1	0.611 *P<0.0001*	0.618 *P<0.0001*	0.671 *P<0.0001*	0.568 *P<0.0001*	0.713 *P<0.0001*
Interference with walking	0.550 *P<0.0001*	0.812 *P<0.0001*	0.611 *P<0.0001*	1	0.784 *P<0.0001*	0.579 *P<0.0001*	0.530 *P<0.0001*	0.704 *P<0.0001*
Interference with work	0.522 *P<0.0001*	0.769 *P<0.0001*	0.618 *P<0.0001*	0.784 *P<0.0001*	1	0.581 *P<0.0001*	0.521 *P<0.0001*	0.689 *P<0.0001*
Interference with relations	0.396 *P<0.0001*	0.566 *P<0.0001*	0.671 *P<0.0001*	0.579 *P<0.0001*	0.581 *P<0.0001*	1	0.590 *P<0.0001*	0.663 *P<0.0001*
Interference with sleep	0.510 *P<0.0001*	0.523 *P<0.0001*	0.568 *P<0.0001*	0.530 *P<0.0001*	0.521 *P<0.0001*	0.590 *P<0.0001*	1	0.609 *P<0.0001*
Interference with enjoyment	0.513 *P<0.0001*	0.692 *P<0.0001*	0.713 *P<0.0001*	0.704 *P<0.0001*	0.689 *P<0.0001*	0.663 *P<0.0001*	0.609 *P<0.0001*	1

(Note: correlation is presented by Pearson correlation coefficients and the statistical significance P-value)

Table 4. Summary of logistic regression analysis for decision of having delayed knee replacement surgery

Effect	Odds Ratio Estimate	95% Confidence Interval	
Female vs. Male	0.985	0.564	1.722
Income level (High vs. Low)	0.930	0.530	1.634
Education level (High vs. Low)	1.240	0.711	2.162
Age	1.013	0.977	1.051
Interference with work scale	1.219	1.095	1.356
Concerns for pain (3 days vs. several weeks following the surgery)	0.610	0.327	1.135

Table 5. Summary of logistic regression analysis for having been considering knee replacement surgery at least 2 years or longer

Effect	Odds Ratio Estimate	95% Confidence Interval		p value
Female vs. Male	1.005	0.655	1.543	0.9822
Income level (High vs. Low)	0.716	0.454	1.128	0.1498
Education level (High vs. Low)	1.405	0.901	2.191	0.1335
Age	1.026	0.996	1.057	0.085
Interference with work scale	1.086	1.001	1.179	0.0465
Concerns for pain (three days vs. several weeks following the surgery)	0.593	0.379	0.929	0.0224

Discussion

This study provides strong evidence that the decision to delay a TKA is significantly influenced by surgical candidates' concerns about interference with work and experiencing pain for several weeks following TKA. In addition, access to postoperative pain management methods that reduce or eliminate opioid use is an important factor in the selection of a joint replacement surgeon. Considering that over 800,000 TKAs are performed within the United States annually, and that delaying this procedure carries an increased likelihood of poor rehabilitation outcomes, the implications of the results are significant.

Patient concern for interference with work is an important finding: a one unit increase in the interference with work scale was associated with a 22% increase in the odds of delaying TKA. Interference with work was the BPI item with one of the highest mean scores (6.0), and reflects a level of moderate interference. Taken together these results suggest that further investigation of the underlying factors associated with this concern is warranted. The importance of work may be related to income and education levels. It could also be related to perceived and known limitations of currently available knee replacement implants. While there have been numerous improvements in commercially available knee replacement implants, the biomechanics of the knee are not completely replicated by contemporary knee replacements, especially in regards to kneeling and twisting [24].

Previously-published studies have reflected this study's

finding that patients who expressed concern about experiencing pain during the first several weeks following surgery also had significantly higher odds of delaying surgery. Chan and colleagues reported that patients who expressed concern about experiencing pain (first several weeks following surgery) also had significantly higher odds of delaying surgery [25]. TKA is major surgery and pain during the early days of recovery can be severe. Experiencing post-surgical pain has serious implications for post-surgery sequelae including delayed mobilization, greater risk of developing venous thrombosis, coronary ischemia, poor wound healing, longer length of hospital stay, and unnecessary psychological distress, all of which affect patient satisfaction with the surgery [1,25]. The failure to adequately relieve pain is also highly correlated with patient dissatisfaction [26].

The oral analgesics commonly being reported by respondents—primarily opioids combined with NSAIDs or acetaminophen—are not without concerns. Two concerns of particular importance are their use over an extended period and for elderly patients [27,28]. Chronic opioid use leads to the development of tolerance and hyperalgesia [27], has the potential to worsen outcomes in musculoskeletal conditions [27,29] and, in the elderly can lead to delirium and agitation [28]. Chronic use of NSAIDs and acetaminophen both have serious safety concerns—gastric bleeding and liver toxicity, respectively [27,30].

Pain management options that avoid opioid use are not only viewed as desirable by patients—92% of respondents felt that a new pain management approach that reduced or eliminated the use of opioid-containing pain medications was an important factor in their choice of surgeons for TKA; this is consistent with current guidance from the US Food and Drug Administration and health professional societies, each group having expressed concerns about the current use of opioid containing analgesics. Decreasing dependence on opioid analgesics could also reduce surgical candidates' hesitation to proceeding with surgery, and thereby improve the ultimate surgical outcome for millions of individuals.

Finally, given TKA candidate concerns about post-discharge pain management that extends into the rehabilitation phase of recovery, it appears increasingly important to put mechanisms in place to measure and report patient satisfaction not only in regard to how pain is managed during their in-hospital experience, but also in regard to their experience post-discharge. TKA candidates in the valley of decision may be encouraged to learn that pain can be effectively managed during the post-discharge period and therefore be more likely to advance to surgery with less apprehension or delay.

Limitations

There are several limitations to note. This study was a cross-sectional, observational study. Only associations and not causal relationships may be concluded.

Second, though the validity of the Brief Pain Inventory has been established by various studies in assessing cancer or other chronic pains, the validity and reliability of the Brief Pain Inventory in assessing knee pain has not been thoroughly investigated.

Respondents to this study represented well-educated, reasonably middle to high income, American patients who had seriously considered TKA surgery. They may not reflect the perceptions of all TKA surgery candidates.

Finally, the survey invitation, the eligibility process and the survey were administered electronically by an on-line survey service to those who have agreed to participate in SurveyMonkey surveys. This also limits generalizability to the larger population of TKA surgery candidates.

Conclusion

This study suggests that concern about postoperative pain and its interference with work for the first several weeks following discharge is the main driving factor for delaying TKA. There is also significant interest in pain management approaches that reduce or eliminate the need for opioid-containing analgesics among those considering TKA and a willingness by them to seek out a surgeon offering a pain management approach that can accomplish this objective. Surgeons and facilities who adopt effective pain management approaches that minimize opioid use and who report the patient satisfaction associated with these approaches when used during the post-discharge period may benefit from the apparently strong aversion of TKA candidates to this class of analgesics.

Disclosure

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

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Health Care Regulation Spending Trap

McTighe T[1]

Our health care system has faced many challenges over the past 40 plus years. Now these challenges have forced us into a complicated situation that makes it confusing on how best to proceed. Today third party insurance payers make most health care payments. Our premiums are paid into a risk pool-on medical services for other people. Just 12% of health care costs are paid directly by consumers. When the third party payer is perceived as picking up most of the tab, the health care consumers are not as concerned about how much is spent – it's not their money. The result is consumers are disconnected from knowing the cost of goods or services that they are receiving, which ultimately means the normal supply-demand price mechanism isn't going to work, prices will go up. [1]

When someone else is paying 88% of the bill (government & insurance) consumers or patients have all the incentive they need to use as much health care as they can. When consumers share in the cost of their health care purchasing decisions, they are more likely to make those decisions based on price and value.

The RAND Health Insurance Experiment, the largest study ever done of consumer health purchasing behavior, provides ample evidence that consumers can make informed cost-value decisions about their health care. Under the experiment, insurance deductibles were varied from zero to $1,000. Those with no out-of-pocket costs consumed substantially more health care than those who had to share in the cost of care. Yet, with a few exceptions, the effect on outcomes was minimal. A recent study by Amy Finklestein of MIT suggests that nearly half of the per capita increasing health care spending is due to increased health insurance coverage. [2]

So there is little doubt that patients need to be informed, and to be proactive in their health care decisions. But how does that factor affect the many patients who are not capable or have the resources to be proactive and informed?

The Affordable Care Act (ACA) of 2010 was enacted to provide broader health care coverage to the citizens of the U.S. than what was previously available prior to 2010. Good, bad, or indifferent to the Act it is the Law of the Land and has benefited many consumers. Of the 5.45 million who have signed up through the federal exchange (May 2014), 5.18 million (95%) applied for financial assistance in their insurance plans. Only 695,000 people (13%) indicated that they had previous health coverage. So yes, the ACA health bill has cost us taxpayers more money. [3] However I would suggest that the current increase in cost ultimately saves significant dollars over the long run in providing for a healthier patient community.

Increased Job Creation

Since 2010 the healthcare sector has been a leading job-producer. This may be at risk under the current health care environment of this Congress. A report released Friday by the Commonwealth Fund and the Milken Institute School

Keywords: *health, care, costs, consumers, supply, demand*
Level of Evidence: *AAOS Therapeutic Level V*

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of Public Health at the George Washington University found that repealing key provisions of the ACA, including the insurance premium tax credits and Medicaid expansion, could lead to 2.6 million people losing their jobs in 2019. By 2021, nearly 3 million jobs in healthcare and other sectors could be lost.

"Repealing key parts of the ACA could trigger massive job losses and a slump in consumer and business spending that would affect all sectors of state economies," the Milken Institute's Leighton Ku, the lead author of the study, said in a statement. "Cuts in federal funding would not only harm the health care industry and its employees but could lead to serious economic distress for states, including a $1.5 trillion reduction in gross state product from 2019 to 2023."

Table 1.

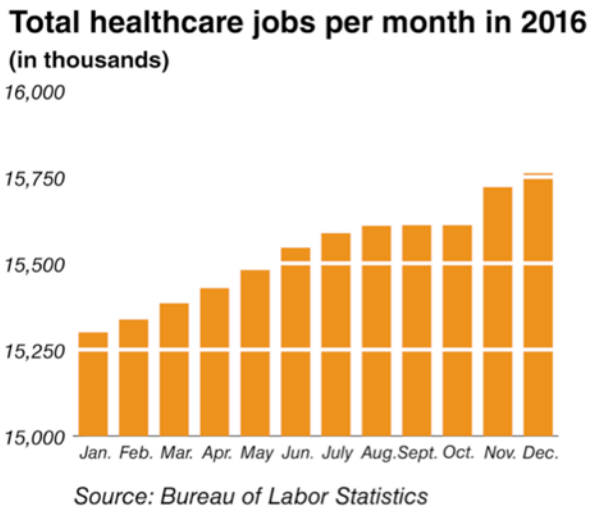
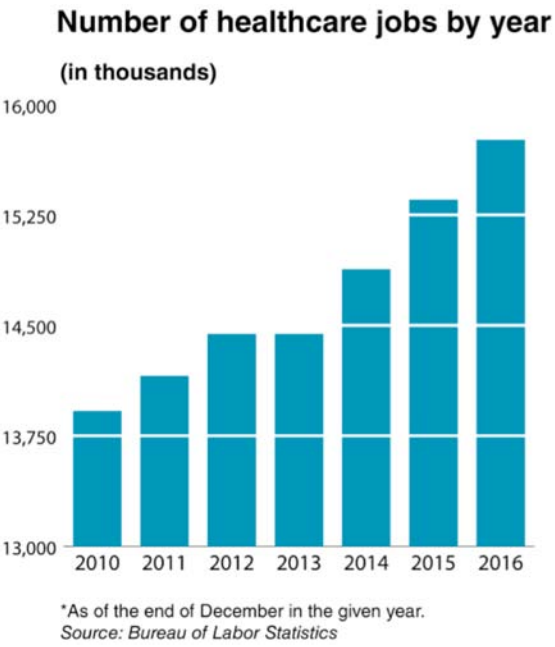


Table 2.



While job growth in the healthcare sector has helped reduce the unemployment rate, it also sped up healthcare spending. The nation's healthcare sector spent $3.2 trillion in 2015, up 5.8% from the year before, driven by coverage expansions under the ACA that led to higher spending for private health insurance, hospital care, physician and clinical services, Medicaid and prescription drugs. As the demand for care under the ACA increased, healthcare organizations responded by adding jobs to cater to those newly insured. Moreover, more care was being reimbursed, so hospitals had more money to spend on hiring (Tables 1, 2).

There is no question that the U.S. health care cost of 17% of GDP is too high as compared to other countries, and we need to slow down annual expenditures. But the question is what are the best potential policies?

Here are a few common sense approaches from my point of view.

- Don't repeal and replace the ACA – fix it by bipartisan cooperation
- Don't repeal the individual shared responsibility payment in the ACA Health Care Law – this brings in much needed revenue to offset Medicaid increases
- Open up more competition in the ACA Heath Care Law – competition reduces cost
- Allow exemptions in Medicare policy for patients to pay for alternative product and treatments currently restricted by law – allows for patients and doctors to be more proactive reducing heath care cost
- Consider Loser Pay Laws in the Heath Care Market – does not restrict contingency legal action
- Make sure Congress is never exempt from the laws it passes

Our current health care situation is not the fault of any one political party. Nor can any one party fix the many problems we face. Let's forget about overall comprehensive action and take immediate incremental steps to help us proceed in the right direction.

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Return to Work Following Total Knee Replacement

Cameron H [1]

Abstract

The length of time to return to work after Total Knee Replacement is often treated as a monolithic entity. Figures produced under such an assumption are interesting but have little practical value in individual cases.

Numerous factors most of which are not under medical control are involved. What is clear however is that the timing of surgery is of considerable importance in a job specific situation and this is under medical control.

Introduction

There have been many attempts to quantify the average time of return to work following total knee replacement as clearly, this information is of value to the patient, the employer, the insurance company, etc. There are a fair number of publications on this issue, but they are of variable quantity and value.

Tilbury (2013) [1] attempted to analyze the data in the literature. They found 796 references. For a variety of reasons such as inadequate numbers, inadequate follow-up, etc. 19 papers only were finally accepted for inclusion.

Even here, there are numerous objections, the main one being that return to work is seen as some monolithic entity into which all patients fit. Clearly, this is not the case and there are numerous factors involved, which may not be seen initially as being terribly significant and, therefore, the data is simply not there when a retrospective chart review is being undertaken.

Total knee replacement is an operation, which requires a certain recovery time. Numerous factors influence this. This has been studied and reported in broad terms only. Lombardi [2] in the U.S. noted the average return to work was about three months, whereas Cameron [3] in Canada found a time twice as long. On comparing notes, it became clear that the main factor was the duration of benefits.

There are a large number of subgroups, who need to be selected out before much can be said about the average length off work following a knee replacement. For example, if the wrong time of year is picked to do the knee replacement and the patient not given adequate time to recover, they may remain off work an inordinate length of time and indeed, they may be forced into retirement, etc. The timing of surgery in many of these jobs is, therefore, of importance. Some of these jobs will be examined and

Keywords: *Total Knee Replacement; return to work; employment influence; timing of total knee replacement*
Level of Evidence: *AAOS Therapeutic Level V*

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the obvious date of prospective surgery pointed out.

Seasonal – Farmers

Depending on geography and the type of farming in general, the farmer should have his knee replaced in November, which will give him a reduce workload until spring. If his knee is replaced in the summer and he will be forced into the unenviable situation of trying to cope with a harvest and a painful knee at the same time, which can be extremely difficult.

Retail

The patient will know and should be asked their busy time. For most, it is winter/spring and they should, therefore, be done in late spring. There are sports stores, however, which tend to be most busy in the spring when customers are outfitting for summer and in fall when they are outfitting for winter. The patient should be able to provide an indicator of when the surgery should be carried out.

Real Estate

Commercial real estate really does not change, but residential does. The busiest time of year is spring so that the real estate sales person should be done in the fall. There is a significant difference between the rural and urban real estate as stairs in the country tend to be more difficult with higher risers and a narrower tread and sometimes access to the property may be difficult.

Landscaping

This used to be seasonal, but most northern landscapers now do snow removal in the winter. There is a fairly narrow window of time in the spring and fall. The fall is preferable. Snow removal is lighter than landscaping.

Construction Industry

This used to be very seasonal as concrete would not set below a certain temperature. Technology, however, has solved that problem and while construction may slow in the winter, it does not stop.

Restaurants

In general, there is no good time for the restaurateur. If the boss is not there, things go missing. Some restaurants experience a slow-down, especially in the summer and some may even close for a few weeks.

Teachers

Teachers have long summer holidays. Teachers should be booked for surgery in the last two weeks in June when the holidays begin, which will give them until September to recover. Early childhood educators/daycare are paradoxically most busy in the summer.

There are many other niche occupations such as commercial diving, trapping, beef cattle farming and Great Lakes Commercial Sailing. A discussion needs to be had with these people regarding the optimum time for surgery.

There are other factors of considerable importance in terms of time to return to work. These observations are obviously generalizations and are certainly not true in every case, but generalizations are just that, i.e. they are generally fairly accurate.

Public versus Private

Public sector workers take far longer to return to work than private sector workers.

Public employees at all levels of government have benefits, which far outweigh those in the private sector. As a rule of thumb, for an identical job, it will take a public sector worker much longer to return to work.

In the private sector, there is always a push to get the patient back to work, which simply does not exist within the public system.

Pension/Retirement

This again tends to be more for public sector type jobs. The patient frequently knows exactly how long they have to work for full pension. Occupations such as nursing, police and fire fighting etc. will frequently request surgery about one year before anticipated retirement as their short term benefits, at least in Canada, accompanied by some long term benefits, will serve as a bridge before old age pension or other pension becomes available. Many of these jobs also allow the banking of sick days of up to one year. This was also true with the large unions in the car plants.

Actors/Entertainers

Elderly entertainers nearing the end of their working life usually have no pension and few savings. They do fortunately, usually have a wide circle of friends for social back-up. If they get a phone call from their agent about a "gig" (job), they may be under enormous pressure to accept it. Fortunately, these parts tend to be of short duration and relatively infrequent and, therefore, while they may delay rehabilitation, most patients cope.

Early Dementia/Placement

Pre-surgical conferences should be held with the family. Advanced dementia is recognized by all so realistic a return to work and or placement conference can be held in the early stage. However, dementia is frequently unrecog-

nized/denied by the family and the surgical team simply does not know. This can become a major problem following surgery. A return to work may be completely unrealistic.

If the patient has lived alone, they may no longer be able to do so. This results in a frantic search for a nursing home. Nursing homes in Canada are in short supply and have very long waiting lists, especially if supplementary financing is not available.

If the patient was in a nursing home, following surgery, they may need an increased level of care and that nursing home may not be appropriate. There is also a policy, which may be peculiar to Canada, which states that if the bed is not occupied within four days, the patient will lose it.

Placement then again becomes a major issue and a source of considerable conflict. The patient cannot stay in an acute hospital, although frequently they do. The staff quickly recognizes the inappropriateness of the situation and pejorative terms such as "bed blocker" begin to be used. Convalescent hospitals will not accept them as they are really not convalescent. The family may come under immense pressure by the hospital to place the patient. Recognizing the futility or impossibility of such a situation, the family, which may be a skip generation, i.e. the grandchildren, may choose to simply walk away. Those working at the sharp edge of medical care find it hard to blame the family.

Placement in these cases is becoming increasingly a major problem, which is not being faced by government at any level. The only government response seems to be to blame struggling nursing homes without providing any increased support or direction.

The Legal Knee

If there is a law suit involved as a result of a car accident, etc., it is important to know the status of the law suit. If the case has not settled and the patient goes back to work, then clearly, the settlement will be less than otherwise would be the case.

The Workmen's Compensation Board Knee

The surgeon must recognize before operating on a Workmen's Compensation Board case that these cases are different from the normal knee case. It is unlike that the patient is going to admit to complete recovery, and will likely continue to complain of pain forever which may be an issue.

The Workmen's Compensation knee has been fairly extensively studied. Clyde (2013) [4]. It seems to be generally agreed that about 70 percent return to work after primary joint arthroplasty versus 44 percent after revision. 67 percent of manual labourers return to work in about 16 weeks versus 85 percent in sedentary jobs.

This is data from the United States of America and as benefits vary considerably from one country to another, it should be seen as a broad indicator only.

Fern Silverman Syndrome [3]

The patient is highly educated, often at university level in her own country, but she has never learned to speak English so can only function within her own culture, which does not allow divorce. She has endless responsibilities including a full-time minimum wage job, all the cooking, all childcare and all homemaking and yard work. She is also responsible for looking after the parents on both sides of the family. After knee replacement, for the first time since marriage none of this is required. The chances of someone caught in this impossible situation returning to work is pretty remote.

Prior Work Status

Those who have not worked in the last few years are unlikely to return to work. Those, who have achieved some sort of a government disability pension, are equally unlikely. Once this exalted status is achieved, the government has no mechanism for further checks and balances.

It used to be thought that 70 percent income replacement would be required, but actually in Canada only 50 percent income replacement if often enough for many people never to return to work.

Neuropathic Pain

Complex regional pain syndrome type 2 is a nerve injury itself. It is extremely uncommon in knee replacement surgery. Type 1 or reflex sympathetic dystrophy [5] is fairly common. The author believes that such a condition exists, but others point out that the early diagnosis is difficult and easily gamed. They suggest that the diagnosis is dubious and can only be entertained in the absence of confounding factors. The chances of a return to work are slim.

Insipient Osteoarthritis

When a poor result presents, it is often instructive to obtain the original x-rays prior to surgery. One is often surprised how little arthritis was present prior to surgery. If there was not much arthritis pain as opposed to perceived pain prior to surgery, an operation is not likely to help and furthermore, even if obvious mechanical problems are present, a revision is equally unlikely to benefit the situation and the patient is equally unlikely to return to work.

Sepsis

This will certainly delay return to work, but fortunately, nowadays is rare.

Psychogenic Pain

There are a variety of psychiatric conditions described, which will certainly influence the return to work. Fibromyalgia was a favourite diagnosis for a quarter of a century. This appears to have been replaced by a new theory of central sensitization. None of these are amenable to any particular treatment. Optimally, a speedy return to gainful employment is preferable, but it is unlikely.

There are full blown psychiatric conditions such as Conversion Disorders and a Somatic Symptom Disorder, which is the new name for a Pain Disorder.

Further Factors of Significance

Socioeconomic factors obviously are of significance Barrack (2014) [6]. Factors such as household income, education and employment, etc. play a significant role. The type of knee implant itself has no effect. Studies done on implants used years ago clearly are outdated.

Discussion

Once these subgroups are removed then one actually ends up with a relatively small number of patients. It is clear that surgery in and of itself, assuming no major complications, is not a significant factor. Return to work cannot be regarded as a monolithic entity and attempts made to quantify it as such will continue to produce data, which may be of some value in the overall sense, but does not really help in the practical sense.

Treatment/Advice

There really is little or nothing, which can be done to alter many of these outcomes. All one can hope to do is recognize them ahead of surgery and make appropriate provision.

One obvious answer in terms of speeding a return to work is a reduction in benefits. This is particularly true in the public system, but given the strength of the public service unions, that is unlikely to change.

A major future problem is likely to be the tidal wave of dementia for which no government at any level appears to be anticipating.

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ICJR/KOA Instructional Course	Oct 20	Seoul, Korea	Henry D. Clarke, MD Dae Bae, MD
5th Annual Shoulder Course Featuring Advanced Concepts™ in Sports Medicine	Nov 3-5	Las Vegas, NV	Richard J. Friedman, MD, FRCSC Raffy Mirzayan, MD John W. Sperling, MD, MBA Joseph D. Zuckerman, MD
ICJR Middle East	Nov 3-5	Dubai, UAE	Samih Tarabichi, MD
ICJR Instructional Course at the 11th International Congress of the COA	Nov 17	Beijing, China	Henry D. Clarke, MD Donald Kastenbaum, MD Yixin Zhou, MD
2017			
9th Annual Winter Hip & Knee Course	Jan 12-15	Vail, CO	Raymond H. Kim, MD Fred D. Cushner, MD Mark W. Pagnano, MD
Current Solutions in Foot & Ankle (a collaboration between ICJR and FORE)	Jan 26-28	Tampa, FL	Michael P. Clare, MD Craig S. Radnay, MD
5th Annual Revision Hip & Knee Course	Apr 6-8	Rochester, MN	Arlen D. Hanssen, MD George J. Haidukewych, MD R. Michael Meneghini, MD
ICJR Japan	Apr 14-15	Tokyo, Japan	Shuichi Matsuda, MD
MAOA Pre-Course: The Knee	Apr 19	Amelia Island, FL	Ryan M. Nunley, MD
5th Annual South/Real Life Orthopaedics Hip & Knee Course	May 18-20	Charleston, SC	Arlen D. Hanssen, MD George J. Haidukewych, MD R. Michael Meneghini, MD

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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.

Levels of Evidence For Primary Research Question[1]

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

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

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Article 1, page 13.
Cook [1]; Latham [1]; Wood [1]

Article 2, page 21.
Zacharia [1]; Paul [1]

Article 3, page 27.
Mauerhan [3] Biomet Consultant, royalties; Rozario [1]

Article 4, page 33.
Fehring [1]; Wyles [1]; Martin [1]; Trousdale [1]

Article 5, page 37.
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Article 6, page 41.
Berend [1]; Zhao [1]; Carlson [2] consulting role in performing the statistical analysis; Stultz [1] Funding for this project was provided by SPR Therapeutics, LLC

Article 7, page 49.
McTighe [1]

Article 8, page 51.
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