AGC
Total Knee System

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Foreward

Total knee replacement is one of the most predictable procedures performed in orthopaedic surgery. The reliability of pain relief and improvement in function after total knee replacement is well documented. The AGC posterior-cruciate retaining total knee replacement has been demonstrated in numerous studies with 15-year survivorship of over 98%. The AGC total knee replacement uses a non-constrained design with flat-on-flat geometry. The excellent long term survivorship is due in part to the one piece configuration that incorporates metal backing of the tibial component with direct compression molding of the polyethylene hence eliminating any backside wear.

In June 2007, an International Symposium on total knee arthroplasty was convened in Marabella, Spain celebrating the 20 year anniversary of the AGC total knee replacement. Topics presented in the symposium include the 20 year follow up of AGC Total Knee Replacement, an update on total knee arthroplasty with 4.4 mm of tibial polyethylene, a comparison of cemented and cementless AGC total knee replacement with and without hydroxyapatite fixation. To date, the AGC total knee replacement continues to enjoy an almost unparalleled clinical success in total knee replacement. This symposium represents an update on the international clinical and biomechanical studies on the AGC TKR.

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Proceedings of the International Symposium on Current Topics in Knee Arthroplasty
Selected Scientific Exhibits

20 year Follow-up of the AGC Total Knee Replacement

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Abstract

The long-term success of total knee replacements (TKR) is multifactorial including patient, surgical, and implant factors. The purpose of this study was to examine the 20 year follow-up of the cemented AGC TKR. 7760 AGC TKR's were performed from 1983-2004 and knees with minimum 2 year follow-up were studied. The 20 year survivorship was 97.8% with no implants being revised for polyethylene wear or osteolysis. Age over 70 was associated with increased survival (99.6%) ($p<0.0001$) while pre operative valgus alignment (95%) ($p=0.0056$) decreased survivorship. Age less than 55 ($p=0.1288$) pre op varus alignment ($p=0.7068$) osteonecrosis ($p=.0601$) rheumatoid arthritis ($p=0.2468$) and gender ($p=0.6660$) were not statistically associated with failure. We attribute the success of the AGC implant to its relatively unconstrained articular geometry and the durability of a non-modular metal backed tibial component with compression molded polyethylene.

What do you say to a patient who asks "how long will my total knee replacement (TKR) last and are there any predisposing factors that may lead to or hinder my knee's success or failure?" Present day, long term literature deals with the original Total Condylar total knee replacement designs that were implanted over 20 years ago and demonstrate success rates between 91% and 98% [1-9] Rand and Ilstrup in 1991 examined 9200 TKR's and noted four variables that were significantly associated with excellent long term survival of a TKR; a primary total knee arthroplasty, a diagnosis of rheumatoid arthritis, age greater than 60 and the use of a cemented condylar prosthesis with a metal backed tibial component. Utilizing these variables their survivorship of over 97% was achieved at 10 years[10]. Again in 2003 Rand et al noted an age >70, rheumatoid arthritis, and retention of the posterior cruciate ligament with a cemented metal backed tibial prosthesis offered the greatest chance for success.[11] We published our 15 year survival rates using the AGC non-modular total knee replacement with compression molded polyethylene in 2000 and noted a 98.6% survival rate.[12] The purpose of this paper is to report the 20 year survival rates of the AGC prosthesis and note if there are any other factors that may help or hinder the survival of the prosthesis.

Materials and methods

Between September 15, 1983 and December 31, 2004, 7760 primary cemented AGC (Anatomic Graduated Components, Biomet, Inc, Warsaw, Indiana) TKR's were performed. 482 patients were lost to follow-up (6.8%). A minimum follow-up of 2 years was selected and the remainder ranged from 2-22 years with a mean of 6.9 years. There were 536 AGC total knee replacements utilizing an all polyethylene tibial component [13], leaving 6726 total knee replacements in 4408 patients which forms the study group for this study. 2118 patients underwent bilateral TKR, one of which had a constrained condylar total (Zimmer, Warsaw, Indiana) knee replacement. Infections, fractures, and asymptomatic radiographic patellar loosening were excluded for the survivorship analysis.

The surgery was performed by six surgeons utilizing similar surgical techniques and instrumentation and all patients underwent the similar postoperative rehabilitation. The AGC was the most common implant utilized at our center for the past 24 years however selection criteria for this implant were not defined and was surgeon selection throughout the study, most often independent of deformity or diagnosis. Preoperative antibiotics were routinely administered and thromboembolic prophylaxis was intravenous heparin and TED hose and has been previously reported[14]. The average age at operation was 69.9 years (range 23 to 93) and 2664 (60.5%) were females. The diagnosis leading to TKR was osteoarthritis in 96%, rheumatoid arthritis in 3%, and osteonecrosis in 1% (Table 1). During this study period 1920 (28.6%) of the 6726 knees or 1278 (29.0%) of the 4408 patients died. The remainders of the variables are noted in Table 1.

The AGC TKR utilized in this study is a cemented posterior cruciate ligament retaining prosthesis with a metal backed, non-modular tibial component of compression molded polyethylene (Himont 1900 resin). The articular geometry is nonconforming with a relatively flat on flat coronal plane design which allows complete size interchangeability. (Figure 1) All the patellae were resurfaced with a cemented all polyethylene patellar component.

Knee Society Scores (KSS)[15], pain scores, and functional scores (stairs, walking, gait, stability, ROM) as well as Knee society radiographic scores[16] were collected at each follow up visit. (Figure 2) Follow up visits were scheduled for 6 months, 1 year and every two years thereafter. Time to failure was collected. Kaplan Meier Survivorship analysis was performed with aseptic loosening or revision of any component as the endpoint. Failure mechanisms were recorded and have been previously reported[17]. Variables associated with revision were analyzed by Cox proportional hazards regression with a significance level of 0.05. Patient variables tested were age, pre operative alignment, gender, diagnosis and bilaterality for association with prosthesis survival.

Results:

The pre and post operative variables and KSS are noted in Table 2 with statistically significant improvement in all variables ($p<0.0001$ and $p=.0044$ for flexion). The tibial radiolucencies averaged 6 % and did not change over the time for any zones (Table 3). Osteolysis was not noted in any follow up at any time, excluding the above tibial radiolucency, which when present did not change. The overall survival rate at 20 years was 97.8% with revision of the tibia or femur as the endpoint. The survival rate for the tibial component was 98.3% and for the femoral component 99.4%. Using Cox regression (Table 4), age over 70 years was 4.6 times less likely to fail ($p< 0.0001$), and preoperative valgus alignment (11 to 40) was 2.8 times more likely to fail ($p= 0.0056$). Age 55 and under was not statistically a factor associated with failure ($p= 0.1190$) nor was preoperative varus alignment ($p= 0.8451$), nor osteonecrosis ($p=.0601$), nor rheumatoid arthritis ($p= 0.0990$) or gender ($p= 0.7717$).

There were 18 failures associated with an infection. 13 were successfully treated with a two stage excisional arthroplasty and antibiotic spacer procedure. 2 required a repeat two staged exchange with delayed reimplantation, 2 required an above knee amputation, and none underwent fusion.

There were 48 tibial revisions, 11 femoral revisions, and 11 patellar revisions. (Table 5).

Discussion

Despite the many prostheses presently on the market there are very few published long-term results at 20 years except for the total condylar type prosthesis[1-9] with posterior cruciate retention (98.6%) (5,6) and with implants that substitute for the posterior cruciate ligament (91%, 92.9%, and 90.7%)[1-4]. The survival of the press fit condylar prosthesis (PFC, DePuy, Warsaw, Indiana) with cruciate retention was reported to be 92.6%[8] and with posterior cruciate substitution was 91.5%[7] both at 15 years of follow-up. In our study, the AGC TKR was found to have an overall survivorship of 97.8% at 20 years with no implants being revised for polyethylene wear or osteolysis. This demonstrates the importance and value of non-modular implants on long-term survivorship of TKR's.

Other authors have found polyethylene wear to be a leading cause of failure leading to revision in TKR[18]. Osteolysis, a problem often associated with articular and backside polyethylene wear has been noted with TKR's which utilize modular tibial components[19]. With the AGC TKR this has not been a problem that we have noted to date. We hypothesize that this is related to the fact that the tibial prosthesis is metal backed, non-modular and with compression molded polyethylene which may be more resistant to backside wear, oxidation, and the negative impact of locking mechanism deterioration in vivo[19]. Other "modern" strategies to reduce polyethylene wear have included all polyethylene tibial components[20], mobile bearing TKR's[21], improved locking mechanisms however none have documented the long term survivorship equal to the AGC TKR in use since 1983.

In this study, we found two variables affected the survival of the AGC TKR at a follow-up of 20 years: age over 70 increased survivorship (99.6% survival), while preoperative valgus decreased survivorship (95.1%). Variables examined that were not independently associated with success or failure were age less then 55, preoperative varus, rheumatoid arthritis, bilateral procedures, BMI, or gender. Even though there is a statistical difference noted, because this is such a large series of total knee replacements, the survival was greater than 98% for all variables except osteonecrosis and preoperative valgus which still had a survival of 96% and 95% respectively.

It is obvious from the data that the cause for failure, even though they are less than 1%, are not directly related to the prosthesis but due primarily to patient selection and surgical technique. We have previously reported on the influence of varus alignment combined with an increased BMI on failure[17] as well as late instability in valgus knees with a planovalgus foot[22]. This prosthesis, however, was not found to be the weak link in this 20 year study.

This study confirms the findings of Rand, et al who found, considering implant factors, that a PCL retaining, metal backed, non-modular, cemented TKR, with an all polyethylene patellar component had the highest survivorship in their analysis of over 11,000 TKR's. Few implants utilized today implement this strategy for improving long term survivorship through non modularity.

Limitations of this study include the fact that the data was collected prospectively and analyzed retrospectively. Further, no clear selection criteria for this implant were established and may have allowed a selection bias. A small percentage of patients were lost to follow-up and their status is unknown. Finally the surgical technique has been modified over time including intramedullary instrumentation, femoral component rotation, lateral release rates, and type of cement. The effect of these modifications over the 20 year period of the study remains unknown.

To answer our leading question, utilizing a cruciate retaining non-modular cemented AGC total knee replacement one can easily tell anyone that the survival rate over 20 years is 98% and that polyethylene wear of the implant is quite uncommon with the design features of this implant.

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Table 1 Demographics

		n	%
AGE	55 and under	379	6%
	56 - 70	2856	43%
	71 and over	3363	51%
Pre Op Alignment	Varus (4 to -25)	4564	78%
	Normal (5 to 10)	771	13%
	Valgus (11 to 40)	509	9%
Gender	Male	2719	40%
	Female	4007	60%
Diagnosis	OA	6427	96%
	RA	214	3%
	ON	68	1%
	other	17	0%
Bilaterality (knees)	Unilateral	2491	37%
	Simultaneous Bilateral	4235	63%

Table 2 Clinical values pre and post operatively

	Pre operative		Post operative		
	mean	std	mean	std	p-value
Knee score 0	44.6	+/-17.6	84.3	+/-12.4	<.0001
Fun score 0	43.4	+/-14.9	76.4	+/-22.6	<.0001
Pain 0	12.9	+/-13.8	46.9	+/-8.2	<.0001
Stairs 0	29.9	+/-7.4	36.8	+/-10.4	<.0001
Walk 0	19.1	+/-8.5	41.3	+/-13.4	<.0001
Flexion 0	114.4	+/-10.0	115.1	+/-9.5	0.0044
Extension 0	-1.6	+/-5.2	-1.0	+/-4.3	<.0001
Alignment 0	0	+/-7.7	4.8	+/-2.9	<.0001

Table 3 Radiolucencies

All noted initially and did not change over time

6M	1Y	3Y	5Y	7Y	10Y	12Y	15Y
3.3%	5.3%	7.0%	7.8%	7.9%	6.7%	7.8%	9.2%

Radiolucency n=6726 % with tibial

Table 4 Variables relationship to survival

Cox Regression		
Significant	p-value	Hazard Ratio
Age over 70 (age 71 and older)	<0.0001	4.6 (times less likely to fail)
Pre op Valgus	0.0056	2.8 (times more likely to fail)
Not Significant		
Osteonecrosis	0.0601	
Age 55 and under	0.1288	
RA	0.2468	
Gender	0.6660	
Pre op Varus	0.7068	
Bilateral Procedure	0.9801	

Table 5 - Survivorship Analysis for all variables

	Survivor Tables (n=6726)				
	5 yr	10 yr	15 yr	20 yr	Success
n-count (# remaining)(n=6726)	n= 4441	n= 1552	n= 342	n= 36	
Cemented AGCs	0.9945	0.9884	0.9780	0.9780	55 fails 99.2% success
Tibial Fails	0.9948	0.9901	0.9828	0.9828	48 fails 99.3% success
Femoral Fails	0.9993	0.9970	0.9939	0.9939	11 fails 99.8% success
Cemented, Age <=55	0.9798	0.9703	0.9703	-	7 fails 98.2% success
Cemented, Age >=56 and <=70	0.9921	0.9830	0.9642	0.9642	39 fails 98.6% success
Cemented, Age >=71	0.9979	0.9956	0.9956	0.9956	9 fails 99.7% success
Diagnosis, OA	0.9946	0.9885	0.9768	0.9768	52 fails 99.2% success
Diagnosis, ON	0.9636	0.9636	0.9636	0.9636	2 fails 97.1% success
Diagnosis, RA	1.0000	0.9919	0.9919	0.9919	1 fail 99.5% success
Gender, Males	0.9950	0.9878	0.9757	0.9757	22 fails 99.2% success
Gender, Females	0.9941	0.9888	0.9794	0.9794	33 fails 99.2% success
Alignment0, Varus <=4	0.9953	0.9899	0.9839	0.9839	32 fails 99.3% success
Alignment0, Neutral >=5 and <=10	0.9971	0.9904	0.9814	0.9814	5 fails 99.4% success
Alignment0, Valgus >=11	0.9930	0.9785	0.9513	0.9513	9 fails 98.2% success

Figure 1: The Anatomic Graduated Component (AGC) total knee replacement, noting the compression molded, non modular tibial component

Figure 2: A78 year old white female, 20 years post operative left AGC total knee replacement.

Total Knee Arthroplasty with 4.4 mm of Tibial Polyethylene

An Update

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Abstract

A previous study included 313 patients with 387 one piece, 8mm tibial components implanted in them. All tibial prostheses were manufactured with 4.4 mm of polyethylene directly molded to a 3.6 mm cobalt chrome metal baseplate. From this group, 116 patients underwent bilateral total knee arthroplasties with an 8mm tibial component on one side and a tibial component with at least 6.4 mm of polyethylene on the other side. This study aims to update the results of the previous study. The followup for this study averaged 11.8 years. At the latest follow-up, the average Knee Society knee score was 81.0 points and the average pain score was 46.4 points. No polyethylene wear or osteolytic lesions were identified radiographically. There were seven knees with tibial radiolucencies found at the bone cement interface measuring between 1 & 2 mm. Three prostheses were removed due to infection. Metallosis and polyethylene failure of metal backed patellae occurred in five knees. There were three loose metal backed patellae and two loose all polyethylene patellae. There was one case of tibial component failure. Survival rates for failure defined as loosening or revision of any component for any reason were found to be 98.9%, 97.5%, 95.1%, and 93.2% for 5, 10, 15, and 18-year followups respectively. Survival rates for failure defined as aseptic component failure were found to be 100%, 100%, 99.1%, and 99.1% for 5, 10, 15, and 18 year followups respectively. No statistical differences were identified between the knee components with thicker (at least 6.4 mm) or thinner (4.4 mm) polyethylene.

Introduction

A problem for the total knee arthroplasty is polyethylene wear, which may lead to implant loosening and resultant failure. Revision surgery for the failed arthroplasty may be problematic as well because of the degradation of periprosthetic bone, which occurs due to the polyethylene wear. Polyethylene wear is a multifactorial process, and one of the factors attributed to wear is the thickness of the polyethylene.[1] A thickness of 8 mm is generally preferred and suggested as a minimum as it has been shown to decrease contact stress and lessen the chance of implant failure.[2,3]

Previously, our institution hypothesized that a thinner tibial polyethylene will provide excellent results using flat-on-flat, nonconstrained, compression molded tibial components.[4] The midterm results from that study showed that with a 4.4 mm polyethylene and lower conformity total knee arthroplasty, there were no radiographic indications of wear, loosening, or revision for reasons other than infection. 10 year survivorship was greater than 94%. The present study aims to provide updated results of this study.

Materials and Methods

A consecutive series of 1247 primary posterior cruciate retaining total knee arthroplasties (Anatomic Graduated Components, Biomet, Warsaw, IN) were performed at the author's institution between January 1983 to December 1989. Of these total knee arthroplasties, 387 AGC total knee prostheses were implanted with 8 mm thick tibial components (combined metal and polyethylene). A 4.4 mm polyethylene was directly compression molded to a 3.6 mm CoCr metal baseplate and central stem in production of all tibial prostheses. The sagittal plane articulation was flat on flat and nonconstrained despite having a coronal plane articulation between the femoral and tibial components that conformed anteriorly.

The total knee arthroplasties were primarily performed for the treatment of osteoarthritis in 84.7% of patients. At time of surgery, patients were an average age of 70.6 years. Women were composed of 65% of patients (Table 1).

From the 1247 patients, 232 patients underwent simultaneous bilateral AGC total knee replacements. In 116 patients, an 8 mm (4.4 mm of polyethylene) tibial prosthesis was implanted on one side, and the other side had at least a 10 mm thick tibial component. Eighty-seven knees had tibial components of 10 mm (6.4 mm of polyethylene). Twenty six knees had 12 mm thick tibial components (8.4 mm of polyethylene). 16 mm tibial components were used in 3 knees. Women composed of 57% of the patients. The average age of these 116 patients at time of surgery was 70.1 years (range, 31-89 years).

Surgical technique and clinical evaluation methods are mentioned in the previous study.[4] In addition, radiographs were examined retrospectively for polyethylene thickness changes of at least 2 mm and for osteolysis. The follow-up average for this study was 11.8 years (range, 3-22 years) for the 313 patients. No patients were lost to follow-up and 42 patients died during the follow-up period due to reasons not associated with the total knee arthroplasty. Follow-up of the patients with bilateral knee replacement was an average of 10.9 years (range, 2-24).

Statistical analysis in this study included the Student's *t* test, Log-rank test, and Kaplan Meier survival rates at 5, 10, 15, and 18 years with the help of the Statistical Analysis System (Cary, NC).[5] Failure was defined as loosening or revision of any component for any reason.

Results

At the latest follow-up, the average Knee Society knee score was 81.0 points and the average pain score was 46.4 points (Table 2). Fourteen knees had extension of 5° or less and 22 knees had extension of greater than 5°. Average flexion was 108.3°

There was no identified polyethylene thickness change, and additionally, the radiographs did not indicate any cases of osteolysis. Average postoperative alignment was 5.1° valgus (range, 10°-20° valgus). No cases had a change in AP alignment of greater than 2°, and this change was thought to be within the error of measurement. At latest followup, there were seven knees (1.9%) with tibial radiolucencies found at the bone cement interface measuring between 1&2 mm. Three knees had Zone 1 tibial radiolucencies and three knees had Zone 3 tibial radiolucencies. Two of the seven knees had radiolucencies found in Zones 4 and 6. One knee had a radiolucency in Zone 5. Five of the seven patients were free of pain at latest follow-up. The other two patients had little pain. There were no tibial or femoral component aseptic loosening identified clinically or radiographically.

Three prostheses were removed due to infection at greater than 6 months post operatively. Metallosis and polyethylene failure of metal backed patellae occurred in five knees and necessitated a revision of those knees. In addition, there were three loose metal backed patellae and two loose all polyethylene patellae. There was one case of tibial component failure. Survival rates for failure defined as loosening or revision of any component for any reason are shown in Table 3 and were found to be 98.9%, 97.5%, 95.1%, and 93.2% for 5, 10, 15, and 18 year follow-ups respectively. Survival rates for failure defined as aseptic component failure were found to be 100%, 100%, 99.1%, and 99.1% for 5, 10, 15, and 18 year follow-ups respectively.

A comparison of the Knee Society knee and pain scores at final followup for patients with an 8 mm thick tibial prosthesis on one side and a 10 mm thick or greater tibial component on the other side is provided in Table 4. No statistical differences were identified between the scores of the two groups.

Over the duration of the study, the proportion of prostheses that failed was found to be 4 out of 116 for the 8 mm group and 1 out of 116 for the greater than 8 mm group. The 8 mm group had one late infection, two failed metal backed patellae and one case of metal synovitis. The 10 mm and larger group had one metal backed patella fail. There were no cases of femoral or tibial loosening in either group.

Discussion

In the previous study, there was no radiographic wear detected of the tibial component, loosening, or revision for reason other than infection.[4] Average follow-up was greater than 10 years. Average knee score was 81.4 points and average pain score was 47.2 points. The present study has similar average scores of 81.0 and 46.4 points respectively. There were no cases of osteolysis, which has been a concern associated with tibial polyethylene wear.[6] As well, there was no polyethylene wear detected radiographically. The scores between the group with 4.4 mm of polyethylene and the group with 6.4 mm or greater of polyethylene were not significantly different. As was mentioned previously, the construction of the polyethylene contributes greatly to its effectiveness and the amount of wear it will endure.[7-9]

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TABLE 1. Demographic Data	
Patient Data	**Number**
AGC TKRs Jan1983 - Dec 1989	1247 knees
AGC TKRs w/ 8mm Tibia	387 knees
Patients	313
Gender (patients)	
Female	204 (65.2%)
Male	109 (34.8%)
Age (patients)	
Average	70.6 years
Range	23-90 years
Diagnosis (knees)	
Osteoarthritis	328 (84.7%)
Rheumatoid arthritis	36 (9.3%)
Osteonecrosis	15 (3.9%)
Other	8 (2.1%)
Followup (patients)	
Average	11.8 years
Range	3-22 years
Standard Deviation	4.4 years

TABLE 2. Clinical Results	
Score or Measurement	**Result**
Knee Score	
Average	81.0 points
Range	5 - 100 points
Standard Deviation	16.8 points
Pain Score	
Average	46.4 points
Range	0 – 50 points
Standard Deviation	8.9 points
Range of Motion	
Average extension	1.0 ° flexion
(Range)	(-10 to 25° flexion)
Average flexion	108.3°
(Range)	(70 – 140° flexion)

TABLE 3. Kaplan-Meier Survival		
Interval	**Number of Knees**	**Rate**
5-Year	296	98.9% [97.1%, 99.6%]
10-Year	195	97.5% [95.0%, 98.7%]
15-Year	88	95.1% [91.1%, 97.3%]
18-Year	28	93.2% [86.6%, 96.6%]

Failure was defined as a revision for any reason or loosening of any component.
[ ] = 95% confidence interval

TABLE 4. Simultaneous Bilateral AGC Total Knee Replacements		
Score	**8 mm Group**	**10-16 mm Group**
Knee Scores (p = 0.2176)		
Average	85.9 points	88.5 points
Range	50 - 100 points	47 – 100 points
Standard deviation	12.8 points	11.5 points
Pain Scores (p = 0.1982)		
Average	47.3 points	48.5 points
Range	10 – 50 points	30 - 50 points
Standard deviation	7.4 points	3.9 points

The AGC Total Knee Replacement- Cemented versus Cementless Hydroxyapatite fixation

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Abstract

We carried out a prospective randomised controlled trial comparing 2 different methods of fixation for the Anatomical Graduated Components (AGC) total knee replacement (TKR). Cemented fixation was compared with hydroxyapatite coated (HAC), cementless fixation. 210 patients (254 knees) were studied. Patients were followed up and assessed with the Hospital for Special Surgery Scores (HSS). There was no significant difference in mean HSS score ($p>0.05$) between the 2 methods of fixation with a mean follow-up of 8.1 years (range 6-12 years). Survival was 99% for cemented and 98% for HAC. Our study shows excellent long-term results for AGC TKRs with both cemented and HAC cementless fixation.

Introduction

The cemented posterior cruciate retaining Anatomical Graduated Components (AGC) knee prosthesis (Biomet, Warsaw, Indiana) is considered to be the gold standard Total Knee Replacement (TKR) because of its longevity and effectiveness at symptom relief. Excellent survival rates of 98% at 15 years[1] are reported, with multiple other studies supporting this[2,3,4]. The Swedish Knee Arthroplasty Register reports a survival of 97.5% at 10 years[5]. The prosthesis is a posterior cruciate retaining design with flat on flat articular geometry. The tibial component is monoblock using direct compression moulding of the polyethylene. These features eliminate backside wear and minimise articular surface polyethylene wear. This is believed to be the reason for the success of this prosthesis[3].
The design of the AGC knee has remained unchanged since 1983, with both cementless and cemented versions available. The vast majority of studies reported in the literature used cement for prosthesis fixation[2,3,4,6]. The cementless version is identical to the cemented but undergoes a plasma sprayed, porous coating of titanium (thickness 635-888μm, porosity 35%, pore size of 90-180μm). The only study of this cementless AGC prosthesis showed a 97% survival at 10 years. However, this fell to 87% success when pain and radiographic loosening were considered[7].

In 1994, a HAC version was introduced. A second plasma-spray coating of hydroxyapatite (thickness 40-70μm, purity 99.5%, crystallinity 50-70%) is added after the initial porous-coating (Figure 1). This offers the benefit of a biological fixation of the implant to the skeleton and early secondary fixation. At the time of the initiation of the study there were encouraging reports of HAC fixation of hip prosthesis[8]. More recently similar results have been reported for TKRs [9,10,11].

Our aim was to determine whether the HAC cementless AGC produced comparable results to the gold standard cemented version. We carried out a prospective randomised trial to assess this.

Materials and Methods

Ethical approval was granted by the Conquest Research and Ethics committee. 210 patients (254 knees) were recruited from March 1994 until February 2001. A random number table was used to determine the choice of implant fixation. The inclusion criteria set for the study were patients up to the age of 75 years and with a clinical diagnosis of osteoarthritis confirmed on x-ray, requiring primary knee arthroplasty.

Surgery was performed under the supervision of the senior author (ABM), but by several surgeons, including trainees. All operations were performed through a medial parapatellar approach using a standard technique with the position of the femoral component related to the posterior condyles. Lateral patellar release was not required for any cases. Antibiotic prophylaxis was given at induction before the tourniquet was inflated (cefuroxime 1.5g) with 2 further post operative doses (750mg at 6 & 12 hrs). Of the 210 patients, 44 were bilateral (13 of which were synchronous). The patella was resurfaced in 156 cases.

Hospital for Special Surgery Scores (HSS) for the knee12 and radiographs were recorded pre operatively, at 6 weeks post operatively, 6 months, 1 year and annually in a dedicated clinic run by a research physiotherapist. The HSS score measures pain, function, range of motion, deformity and laxity. The score is out of 100, with the higher the score, the better the result (Table 1). Statistical analysis was with SPSS version 12.0.01 for windows with a p value <0.05 selected to determine statistical significance.

Results

210 patients were recruited with 254 TKRs performed. 44 cases were bilateral, with 13 of these synchronous. The male to female ratio of patients was 112 to 98. 118 knees were cemented with 136 HAC, cementless. The mean age was 67.5 years, with a range of 47 to 75 years. The mean follow-up was 8.1 years with a range of 6 to 13 years. Currently, we have 167 still on the trial (76 cemented, 91 HAC) (Table 2).

There was no significant difference in HSS scores between the 2 methods of fixation at any stage post operatively (Table 3, Figure 2) (p>0.05). Their mean HSS scores were identical (Table 4).

Radiographic Analysis

• Migration of tibial component

Observed in 2 cementless HAC cases revised for tibial loosening. No cemented cases.

• Radiolucencies

Radiolucencies were observed in 18 cemented knees and 5 HAC. All radiolucencies were < 2mm and non progressive. The normal radiological appearance of an HAC prosthesis was bony in-growth under the tibial trays with a radiodense line around the uncoated stem. This is due to micromovement of the stem and is not indicative of loosening (Figure 4).

Revisions

HAC Group

- 2 knees for early aseptic tibial loosening (Figures 4 & 5) due to malalignment and undersizing of the tibial component respectively.
- 1 knee for infection (2 stage revision).

Cemented Group

- 1 knee for infection (2 stage revision).

Other Complications

- 2 patella buttons revised (sheared through central peg – lead to satisfactory results after revisions).
- 1 intraoperative fracture (HAC) – proximal tibial fracture fixed with single screw with no clinical problems.
- 1 periprosthetic fracture (HAC) - 2 years post-op, distal femoral fracture fixed with 2 cannulated screws with satisfactory outcome.

- 1 Patella dislocation (cemented).
- 14 Required manipulation under anaesthetic for stiffness (6 cemented, 8 HAC).

Cost Difference

The net increased cost of the HAC prosthesis is £561 more than the cemented version taking into consideration the expense of cement and its mixing system. This increased cost can be partially offset by the reduced operating time of the HAC knee.

Discussion

Our study demonstrates excellent results for the AGC with both methods of fixation. Survival at a mean follow-up of 8.1 years (range 6-12 years) is 99% for cemented fixation and 98% for hydroxyapatite, with mean HSS scores of 85 for both post-operatively. Excluding infection which is unrelated to the method of prosthesis fixation, the survival rate is 100% for cemented and 99% for HAC. Both methods exhibited satisfactory results, with no significant difference in HSS scores at any point following surgery ($p>0.05$).

Although not statistically significant, the two cases of aseptic loosening in the HAC group have concerned the authors. We propose two possible mechanisms for these early failures of malalignment and undersizing of the tibial component described in Figures 4 and 5. Early clinical failure has been reported with varus tibial component malalignment ≥3.0 degrees, even in cemented TKRs [13,14]. Although a similar outcome could have occurred in a cemented AGC, there may be an increased risk of aseptic tibial loosening due to malalignment in cementless AGCs. A much larger study would be required to demonstrate this.
Undersizing of the tibial component is a risk factor for migration and aseptic loosening, particularly in osteoporotic bone. Correct sizing should ensure that the rim of the prosthesis sits on cortical rather than purely cancellous bone. With cementless fixation, correct sizing is probably even more important and undersizing may increase the risk of early failure.
In conclusion, our study shows excellent long-term results for AGC TKRs with both types of fixation. There was no significant difference in clinical outcome between HAC and cemented. However, we do feel that cementless fixation requires a more precise surgical technique and that errors, such as malalignment or undersizing of the tibial component may be more likely to progress to failure.

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Tables and Figures

Figure 1. The Hydroxyapatite coated AGC Total Knee Replacement.
The whole of the internal surface of the femoral component is coated but only the tray of the tibial component. Coating of the stem was felt to be unwise in case of the need for implant removal.

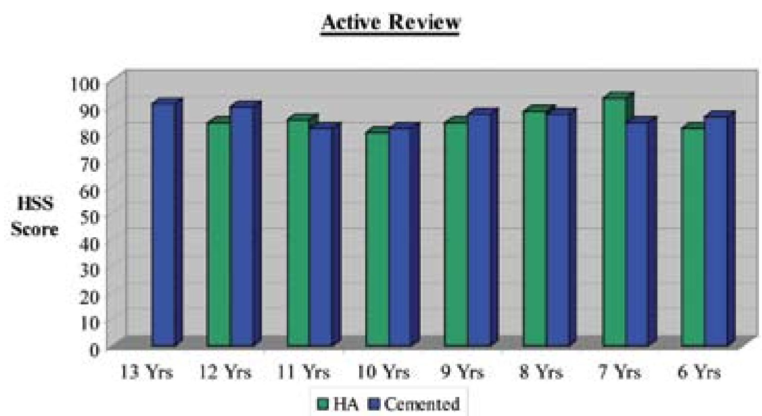

Figure 2 Chart showing Hospital for Special Surgery (HSS) scores for all patients currently under clinical review.

Figure 3. 5 year follow-up radiographs of HAC AGC knee. The normal radiological appearance of an HAC prosthesis was bony ingrowth under the tibial trays with a radiodense line around the uncoated stem. This due to micromovement of the stem and is not indicative of loosening.

Figure 4a. Aseptic loosening of tibial component with varus malalignment. This 60 year old gentleman had bilateral HAC TKRs performed. The left side resulted in aseptic loosening which we believe was due to malalignment of the tibial component.

Figure 4b. This required revision of the tibial component to a Maxim stemmed tibial component (Biomet, Warsaw, Indiana) with an AGC modular bearing, whilst the right primary HAC AGC Knee was satisfactory. There was no microbiological growth from peri-operative samples.

Figure 5a. HAC AGC knee with undersized tibial component. A 55 year old woman had bilateral, non synchronous, HAC TKRs performed. The right tibial component was undersized and progressed to aseptic loosening.

Figure 5b. Initial revision surgery was by conversion to a cemented AGC tibial component, although clinical outcome was unsatisfactory.

Figure 5c. A further revision was carried out to a constrained Maxim cemented TKR with a satisfactory outcome. There was no microbiological growth from peri-operative samples.

Table 1 Hospital for Special Surgery Scores (HSS) for the knee12.

Score (out of 100)	Outcome
> 85	Excellent
70-85	Good
60-70	Fair
<60	Poor

Table 2. Patient outcomes

	Patella Resurfaced	Died	Lost to Follow-up	Revision
Cemented (n=118)	53	27	14	1
HAC (n=136)	57	31	11	3

Table 3 Hospital for Special Surgery (HSS) scores for all patients recruited to study. (Patients with follow-up less than 6 years were either lost to follow-up or died).

Years	Cemented		HAC	
	No	Mean	No	Mean
13	2	91		
12	1	90	2	84
11	2	82	3	85
10	16	82	10	78
9	14	87	24	84
8	19	87	23	88
7	17	85	20	89
6	14	87	22	83
Less than 6	32	84	29	88

No significant difference (p>0.05 Student's t test).

Table 4 Mean Hospital for Special Surgery (HSS) scores for all patients.

	Cemented (n=118)	HAC (n=136)
Mean Pre-op HSS score	55.5	58.2
Mean Post-op HSS score at last review	85	85

No significant difference (p>0.05 Student's t test).

Twenty-Year Survivorship of Cementless Anatomic Graduated Component (AGC) Total Knee Replacement

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Abstract

Introduction

There is a renewed interest in cementless total knee replacement (TKR) due to improved biomaterials, desire for decreased surgical times and the potential increased longevity of cementless fixation. This study reports the long term results of a cementless TKR system.

Methods

Seventy-three cementless TKRs were performed in 47 patients from 1984 to 1986. There were 42 TKRs in women and 31 TKRs in males. The mean age of the patients was 59 years (range, 18 to 79) at surgery. Surgery was performed for a diagnosis of osteoarthritis in 59 knees, rheumatoid arthritis in 8 and osteonecrosis in 3 knees. The TKR system comprised a cobalt chrome femoral component, a monoblock porous plasma sprayed tibial component and a metal backed patella. All three components were implanted without cement and the tibial component was inserted without screws. Clinical and radiographic follow was performed at routine intervals for a minimum 10 years.

Results

Fifty three knees obtained a minimum of ten years clinical and radiographic follow-up. Twenty four knees were followed a minimum of twenty years and no patient was lost to follow-up. Fifteen failures occurred and included 12 revisions for failed metal backed patella components and metallosis. Two tibial components failed due to aseptic loosening at 1.1 and 2.2 years, and one knee suffered a hematogenous infection at 11 years. Excluding the failed metal backed patella failures and single failure for infection, the cumulative Kaplan-Meier Survivorship for the cementless tibial component was 96.8% at 20 years. There were no femoral component failures.

Discussion

Cementless TKR is an attractive option for those with disabling knee gonarthrosis, particularly the younger patient. After eliminating the well documented metal backed patella failures, this cementless knee system utilizing a monoblock tibial component without screws demonstrated excellent long term survivorship out to 20 years follow up. This outcome and survivorship data is invaluable and should be strongly considered in the design of the next generation of modern cementless total knee replacement.

Level of Evidence: IV

Introduction

Cementless fixation in total knee replacement (TKR) has enjoyed limited use in the U.S. over the past decades due to failures in the early generation of implant designs.[1-6] While cemented fixation for TKR remains the gold standard[7-12], aseptic loosening continues as a common failure mechanism[13-16], particularly in young patients. This persistent failure mechanism, in addition to the clearly established trend of performing TKR in younger more active patients, has promoted a renewed interest in cementless total knee replacement.

The majority of cementless total knee arthroplasty systems have endured limited success due predominantly to failed metal backed patellar components with subsequent metallosis.[10,17-31] Osteolysis secondary to these failures, as well as modularity and screw fixation, have typically required removal and revision of all three components in the knee replacement. Despite these early failures, certain cementless total knee arthroplasty designs have demonstrated excellent long-term results equal to those of cemented knee replacement [32-35]. The tibial component of the successful fixed-bearing designs have all typically utilized supplemental screw fixation[33-35] ,however, it remains unknown whether this adjuvant screw fixation is a requisite for successful long-term outcomes in cementless TKR. We report the long term results and 20 year survivorship of a cementless fixed bearing TKR system utilizing a tibial component without screw fixation.

Materials and Methods

Seventy three cementless total knee replacements were performed in 47 patients from 1984 to 1986. Twenty six patients underwent bilateral knee replacements (52 knees) and 21 patients underwent unilateral TKR. The mean patient age was 59 years (range, 18 to 79 years) at surgery. The mean Body Mass Index of the 47 patients was 26 (range, 21.3 to 31.0). There were 26 females and 21 males. Surgery was performed for a diagnosis of osteoarthritis in 59 knees, rheumatoid arthritis in 8 and osteonecrosis in 3 knees.

All the total knee replacement surgeries were performed through a median parapatellar approach and the posterior cruciate ligament was preserved in all cases. Bone cuts were made with a standard saw without irrigation. No irrigation was used on any cancellous bone surfaces and the cementless femoral, tibial and patellar components were implanted without bone slurry or autograft. The cementless total knee replacement system used was the cruciate retaining Anatomic Graduated Component (AGC) (Biomet, Warsaw, IN). The femoral component was composed of cobalt chrome with a plasma sprayed porous titanium surface on the distal and chamfer cut undersurfaces (Figure 1A). The anterior and posterior condyle undersurfaces were coated with a thinner layer of plasma sprayed porous titanium with less surface roughness designed to minimize stress shielding of the anterior and posterior femoral condyles (Figure 1A). The tibial component was a metal backed monoblock design with a central stem and compression molded polyethylene. The metal tibial base was composed of cobalt chrome with a plasma sprayed porous coating on the undersurface and an “I beam” cross section stem that was glass bead blasted (Ra=0.45 microns) (Figure 1B). The tibial bone preparation included an interference fit of the tibial stem and supplemental screw fixation was not used or available with this tibial component. The patella component was cementless, metal backed and a monoblock design with a single fixation peg. The patellar metal base was composed of titanium, with a porous plasma sprayed undersurface and a single fixation peg with a Ra=8.6.

Patients were kept non weight bearing for 8 weeks postoperatively and then allowed to progress to full weight bearing. The patients were allowed and encouraged to perform full range of motion exercises to maximize flexion and terminal extension during the non weight bearing time period. Clinical and radiographic evaluation was performed on all patients at six months, one year, three years, five years and then every five years thereafter for a minimum of 10 years. The Knee Society functional knee and pain scores were recorded. Serial anteroposterior and lateral radiographs were obtained and reviewed for any measurable interval changes. A detailed radiographic analysis of the component alignment and subsidence was performed with an additional emphasis of critically evaluating the tibial and femoral component prosthesis bone interface for radiolucencies, sclerotic halo lines and evidence of osseointegration.

All statistical analyses were performed by Kaplan-Meier survivor analysis, and statistically significant p-values were reported by Cox proportional hazards regression. The data was analyzed in SAS version 9 (Cary , NC), and the level of significance was set at .05.

Results

Fifty three knees obtained a minimum of ten years clinical and radiographic follow-up and 24 knees obtained a minimum twenty years follow-up (Table 1). No patient was lost to follow-up. Nine patients died prior to 10 year follow-up and eleven patients died after obtaining the minimum 10 year follow-up without revision or failure. The average length of follow-up for those knees that were not lost to death or revised due to failure was 19.9 years (range, 12.6 to 21.6 years).

The preoperative mean Knee Society score improved from 55.8 +/- 10.0 (range, 26-72) to 91.0 +/- 14.0 (range, 55-100) at final follow-up. Function Scores improved from a preoperative mean of 28.5 +/-16.4 (range, 10-70) to a mean value of 76.3 +/-27.8 (range, 20-100) postoperatively. The mean preoperative pain score improved from 31.1 +/-9.2 (range, 10-45) to 48.7 +/- 3.0 (range, 40-50) at final follow-up. The average preoperative knee flexion improved slightly from a preoperative mean value of 116.6 +/- 16.9 degrees (range, 65-140) to 118.3 +/-15.4 degrees (range, 65-150) postoperatively.

Fifteen failures requiring revision occurred and included 12 revisions for failed metal backed patella components and metallosis. The mean time to failure of the 12 metal backed patellar components was 8.8 years (range, 1.4 to 19.4 years). The patellar component failures occurred via severe polyethylene wear through with metallosis and damage to the femoral implant requiring revision total knee arthroplasty involving all three components. All tibial components in the knees revised for patellar component failure were well fixed without loosening at the time of revision surgery. Two tibial components failed due to aseptic loosening at 1.1 and 2.2 years, respectively. One knee suffered a hematogenous infection and required reoperation at 11 years. Excluding the failed metal backed patella failures and single failure for infection, the cumulative Kaplan-Meier Survivorship for the cementless tibial component was 96.8% at 10 and 20 years (Figure 2). There were no femoral component failures in this series. (Table 1)

Radiographic Analysis

There were 14 tibial radiolucencies (19.2%) present on the 2 month radiographs. These radiolucencies were all 1 mm or smaller and located either underneath the tibial base plate of the medial or lateral plateau. At one year radiographic follow-up, only 2 of 14 (14.2%) radiolucencies remained. One of the two persistent radiolucencies encompassed both the medial and lateral tibial plateau and was associated with pain consistent with failure of ingrowth and aseptic loosening. That patient underwent revision TKR at 1.1 years. The other persistent radiolucency involved the medial plateau and slowly decreased over time. It no longer existed at 5 years and remained absent at the 15 year radiographic follow-up with evidence of osseointegration underneath the medial tibial baseplate. There were variable degrees of lucent area under the anterior flange of 20 of 73 femoral components noted at the 2 month follow-up, consistent with incomplete seating of the anterior flange on the anterior femur. This lucency remained at final follow-up in all 20 of the 73 knees but was not progressive or associated with any evidence of loosening. There were 8 radiolucencies located at the posterior condyle noted on the 2 month radiograph. These radiolucent lines were all 1 mm or less, persisted until final follow up and were non progressive in all cases. There were no radiolucent lines present on the distal condyle, anterior chamfer or posterior chamfer undersurface of the femoral component on any component at 2 month follow-up or at final follow-up.

Fifty three of the 73 total knee tibial components (72.6%) were aligned from neutral to 4 degrees of varus with respect to the anatomic tibial axis. Nine of 73 (12.3%) tibial components were between 5 and 10 degrees of varus and 11 of 73 (15.1%) were malaligned greater than 11 degrees of tibial varus. One of the tibial failures occurred in the group within 4 degrees of tibial varus and one failure occurred in those components aligned between 5 and 10 degrees of varus. There were no failures in the malaligned tibial components greater than 11 degrees of varus.

Discussion

Despite the long-term success of traditional cemented total knee arthroplasty[7-11], a renewed interest in cementless total knee replacement has emerged. The interest in cementless fixation as a more durable and long lasting interface is a result of total knee replacement being performed in younger patients with more active lifestyle than those patients in the past. In addition, economic and health resource factors present in modern healthcare warrant the more efficient cementless fixation that avoids the additional surgical time necessary for cement to cure, while minimizing the surgery duration and subsequent infection risk. The emergence of new biomaterials, such as hydroxyapatite[36,37], porous tantalum[38-41] and highly porous titanium[42], have contributed to the resurgence of interest in cementless fixation in total knee arthroplasty. Despite the potential advantages, cementless fixation remains controversial, particularly in the U.S., due to past failures in the early generation of implant designs.[1-6] However, these failures are attributable to various design flaws such as poor quality polyethylene, patch porous coating to allow tibial osteolysis[43,44], fatigue fracture of the femoral component[45] and failed metal backed patellar components with subsequent metallosis.[10,17-31] Berger et al reported a 48% failure rate requiring reoperation for failed Miller-Galante (Zimmer, Warsaw, IN) cementless patellar components with the two failure mechanisms being failure of ingrowth and excessive polyethylene wear and metallosis.[1] Our series is consistent with the previously published reports that document high failure rates with metal backed patellar components. Twelve of the 73 cementless AGC total knee replacements in this series were revised due to severe polyethylene wear of metal backed patellar components and subsequent metallosis. However, upon closer inspection and long term follow-up of the entire cohort of patients, successful long term cementless fixation and survivorship was demonstrated in the tibial and femoral components.

It has been reported that cementless tibial fixation is most reliably achieved with supplemental screw fixation to augment initial tibial component stability and minimize the subsequent deleterious micromotion.[46,47] However, reports exist that document failure of component ingrowth and metaphyseal osteolytic lesions predominating around tibial screw tracks.[1,6,48] In a series of 131 consecutive cementless Miller-Galante-1 (Zimmer, Warsaw, IN) total knee replacements with a tibial component undersurface consisting of a porous fiber metal mesh and screw augmentation, the authors documented a discouraging 8% tibial aseptic loosening rate due to failure of ingrowth and a 12% incidence of small osteolytic lesions around screw holes at a mean 11 year follow-up[1]. The incidence of screw track osteolysis is reported to be greater than 30% in some cementless tibial component designs[6,48] and has been attributed to the screw holes allowing egress of joint fluid and particulate debris to the proximal tibial metaphysis. The tibial component design in this series of cementless AGC (Biomet, Warsaw, IN) knee replacements has achieved excellent fixation and long-term osseointegration without supplemental screw fixation. The authors believe the low incidence of tibial osteolysis and the excellent 96.8% 20-year survivorship are the result of a tibial component design that incorporates a PCL retaining, non constrained articulation with a monoblock, porous plasma sprayed tibial undersurface, a smooth central stem without supplemental screws and compression molded polyethylene. Only two tibial components failed in this series, both of which were revised at 1.1 and 2.2 years postoperatively. Withstanding these two failures, this tibial component faired well with excellent long-term osseointegration and success, despite being placed in varus alignment somewhat frequently (Figure 3).

Cementless femoral components have generally performed well in long-term outcomes, both in hybrid and cementless TKR systems.[33,35,49] This success is likely related to the inherent stability of press fit obtained with the chamfer cuts in multiple planes required for implantation. However, stress-shielding and a decrease in bone mineral density in the anterior aspect of the distal femur has been observed in response to successful osseointegration[50]. The cementless AGC femoral component was designed to avoid this detrimental stress shielding by applying the roughest, most biologically friendly porous plasma sprayed titanium on the distal and chamfer undersurfaces, while leaving the anterior and posterior condylar surfaces with a less rough grit blasted titanium surface (Figure 1A). The low incidence of osteopenia and osteolysis in the anterior distal femur at greater than 10 years follow-up in this series demonstrates the clinical success of that intended design feature.

Despite the early design failures and complications reported with cementless total knee replacement, there are a number of designs that have obtained successful long term results similar to cemented total knee replacement with 10 year survival rates greater than 95%.[33-35,51-53] The majority of this limited number of long-term studies involve cruciate retaining designs that utilize supplemental tibial screw fixation. In contrast, the results of this series document excellent long-term success of cementless total knee arthroplasty without supplemental tibial screw fixation with a 20 year survivorship of 96.8%. Our data is supported by Schroder et al, who reported a 97% survivorship rate at 10 years with the cementless AGC (Biomet, Warsaw, IN) with only two cases of tibial component aseptic loosening, both of which occurred within 3 years of implantation. The authors reported only a single case of osteolysis which was small, non-progressive and located in the lateral tibial plateau.[53]

The limitations that exist in this study involve the retrospective nature of the investigation. However, all patient data was obtained prospectively into a large database as the clinical and radiographic follow-up intervals were achieved. An additional limitation is the rather small cohort of patients. However, despite this small cohort of 73 patients, the authors feel the scientific merit of the study is maintained by the comprehensive data analysis that is afforded by no patient being lost to follow-up at a minimum 10 years, as well as a substantial number of patients (twenty four) obtaining 20 year follow-up.

In conclusion, this study documents that excellent long-term fixation and outcomes can be obtained with cementless total knee arthroplasty without supplemental screw fixation. Failure of metal backed patellar components continues to be the dominant failure mechanism in cementless TKR and warrants caution when considering cementless fixation in knee replacement. The authors believe the success of this cementless AGC total knee replacement is due to the unconstrained PCL retaining design, with a monoblock, stemmed tibial component with compression molded polyethylene. With the emergence and development of new biomaterials such as porous tantalum and highly porous titanium, as well as improved surgical instrumentation and technique, cementless total knee replacement likely represents the optimal long-term fixation and success, particularly in the young active patient.

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Figure Legend

Figure 1A: The AGC (Biomet, Warsaw, IN) femoral component demonstrating the plasma sprayed porous titanium coating on the cobalt chrome implant. Note the anterior condyle undersurface with less surface roughness.
Figure 1B: The AGC (Biomet, Warsaw, IN) tibial component undersurface demonstrating the smooth central "I-Beam" shaped stem and plasma sprayed porous titanium coating.
Figure 2: Survivorship Curve of the cementless AGC (Biomet, Warsaw, IN) total knee replacement minus patellar component failures and reoperation for infection demonstrating 96.8% 20-year survivorship.
Figure 3: Twenty one year follow-up AP (A) and lateral (B) radiographs of a cementless AGC total knee replacement. Excellent long-term radiographic osseointegration of the femoral and tibial components is apparent without evidence of loosening or osteolysis.

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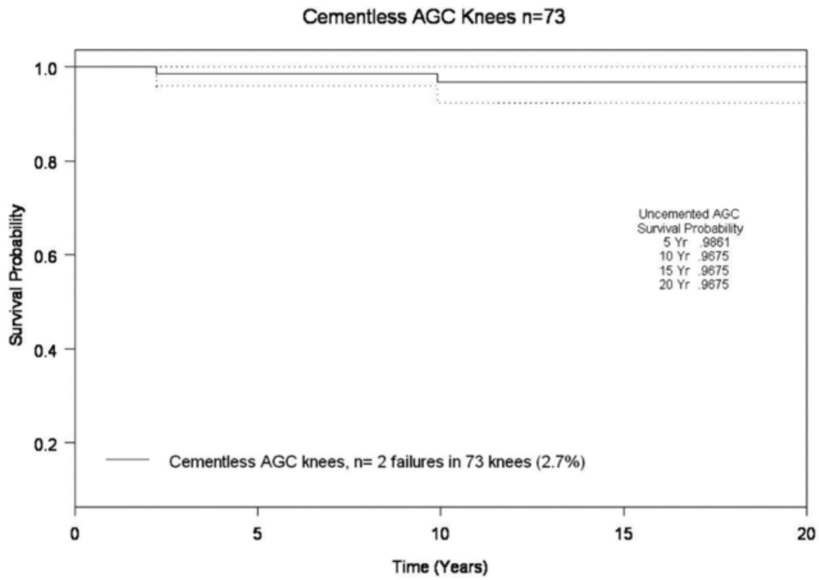

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A comparison in proximal tibial strain between metal backed and all polyethylene AGC total knee arthroplasty tibial components

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Abstract

Background

Loading in TKA is multifactorial and dependent upon alignment, ligament balance, patient, and implant factors. Abnormal loading has been linked to clinical failure; however the respective contribution of each factor to failure is not well known. This study defined the effect of metal backing on loading patterns in the proximal tibia.

Methods

Composite tibiae were implanted with metal backed and all polyethylene AGC TKA tibial components and coated with photoelastic material allowing full field dynamic strain quantification. Changes in strain were measured in twenty four proximal tibial regions under neutral and simulated varus alignment.

Results

Significant shear strain increases ranging from 109% ($p<.0001$) to 457% ($p<.0001$) were measured in various anterior regions of tibiae implanted with all polyethylene tibial components when compared with metal backed components loaded in neutral loading distribution. Posteriorly, strains significantly increased ranging from 46% ($p=.0157$) to 484% ($p=.0011$). In simulated varus loading distributions, significant increases in measured strain ranging from 76% ($p=.0458$) to 335% ($p<.0001$) were measured anteriorly and between 40% ($p=.0010$) to 587% ($p=.0054$) posteriorly for all polyethylene tibial components vs. metal backed components.

Conclusions

Higher strains were observed on composite tibiae implanted with all polyethylene tibial components than implanted with metal backed tibial components in all statistically significant measurement regions. In both balanced and varus loading models, metal backed tibia components reduced the incidence of stress concentrations on the surface of the proximal 30 mm of the tibia.

Clinical Relevance

Higher observed strains in the proximal tibia observed with all polyethylene tibial components could possibly explain increased clinical failure rates observed with this TKA design.

Introduction

Metal backed tibial components in total knee arthroplasty (TKA) currently dominate the orthopaedic market due to intraoperative flexibility afforded by modularity[1]. Metal backing was first used in TKA as a method to potentially improve loading distributions over the tibial plateau at the interface between the prosthesis and the supporting cancellous bone compared to all polyethylene designs[2]. Many clinical studies have compared metal backed and all polyethylene tibial components with variable survivorship[1,3,4,5,6,7]. We have found decreased clinical survivorship with all polyethylene[4] Anatomic Graduated Component (AGC) TKA's (Biomet, Inc, Warsaw, Indiana) compared to the non-modular metal backed[5] design at 10 year follow-up, 68% vs. 98%, respectively. Loosening or bony collapse beneath the medial plateau accounted for 74% of failures in our AGC all polyethylene cohort [4]. However, metal backed tibial components require greater bone resection to accommodate the added thickness of the metal tray and maintain the same UHMWPE thickness which effects early implant migration and may influence long term survivorship[1,3,8]. The purpose of this study was to compare AGC all polyethylene tibial components with metal backed tibial components in neutral and varus loading conditions in vitro to characterize the shear strain loading patterns. We hypothesize that increased strains in the proximal tibia with an all polyethylene tibial component in this TKA design may correlate to bony overload in the medial compartment; possibly accounting for the increased observed rates of clinical failures in the all polyethylene group.

Materials and Methods

Metal backed and all polyethylene AGC Total Knee Systems were used in this study. Sawbones® Third Generation composite tibiae (Pacific Research Laboratories, Inc., Vashon WA) designed to replicate the mechanical properties of cadaveric bone were chosen as test specimens to minimize interspecimen sizing and bone density variability[9]. The composite tibia models are manufactured with a glass fiber and epoxy resin cortical region surrounding a polyurethane foam core with a midshaft intramedullary canal. Five left tibiae for each prosthesis type were implanted by a board certified orthopedic surgeon 5 mm below the joint line with appropriately sized AGC tibial components in neutral alignment. Cuts in all tibiae were verified in order to minimize variation in slope and component rotation. Modular, AGC metal backed tibial components with 10 mm thick UHMWPE tibial tray inserts were compared to 10 mm thick all polyethylene AGC tibial components. A 70 mm AGC femoral component was fitted to a custom loading apparatus allowing axial compressive loads to be applied directly from the femoral component to the tibiofemoral interface at both a 50:50 and an 80:20 medial:lateral condylar distribution (Fig. 1). The femoral component was positioned onto the tibial component, replicating full extension of the lower leg at the knee during stance phase. Loads on each condyle of the femoral component were measured with subminiature load cells (Honeywell Sensotec, Columbus, OH) installed within the custom loading apparatus [10]. Each tibia was potted distally in a hard polyester resin and mounted with a universal joint to a materials testing machine (MTS Systems Corporation, Eden Prairie, MN) while a static axial load of 2700 N (4X assumed body weight of 70 kg) was applied to reproduce typical forces seen at the tibiofemoral joint during normal gait[11] (Fig 2). Four trials for each test specimen were conducted with no evidence of fracture or fatigue.

For strain measurement purposes, a photoelastic coating was molded and bonded to the proximal third of the tibia following procedures from the manufacturer and prior validation studies[10,12]. Photoelastic resin (Vishay Micro Measurements, Raleigh, NC) was cast into 2 mm thick sheets which were then molded to the proximal tibia and permanently adhered with a reflective epoxy (Vishay Micro Measurements, Raleigh, NC). A section of the coating was retained and measured in ten random locations to determine a mean coating thickness for strain calculation.

Shear strain measurements on the surface of the proximal tibia reflect stress patterns in the underlying bone. The photoelastic method of shear strain analysis was chosen for this study because of its ability to provide a full field view of strain on the surface of the proximal tibia[12]. Since the exact location of peak shear strains in the tibia were not known in advance, a full field analysis was preferable to a point analysis provided by a strain gage.

A twenty four region grid was created on around the entirety of the proximal tibia for strain measurement. Three rows were outlined at 1 cm increments distal to the tibial plateau (0-1 cm, 1-2 cm, and 2-3 cm) while eight columns were marked longitudinally around the tibial perimeter with an apparatus ensuring repeatable region positioning between each specimen. Measurement region rows were designated as proximal, middle, and distal, while columns were designated as anteromedial central (AMC), anteromedial peripheral (AMP), anterolateral central (ALC), anterolateral peripheral (ALP), posteromedial central (PMC), posteromedial peripheral (PMP), posterolateral central (PLC), and posterolateral peripheral (PLP). Shear strain measurements in each measurement region were taken using a reflection polariscope (Vishay Intertechnology, Raleigh, NC). A polarized white light source was reflected off the tibia and shown through the analyzer window of the polariscope (Fig. 3). Coloration bands, termed isochromatic fringes, were induced in the photoelastic coating due to changes in the index of refraction of the material when strains are induced on the surface of the tibia during axial loading. These isochromatic fringes were quantified by a single observer into microstrain using a process of null compensation.

Statistical Analysis was performed using the SAS System (SAS Institute Inc., Cary, NC). To determine the effect of loading pattern, the data was grouped in two ways: metal backed and all polyethylene. Linear mixed effects regression, with loading pattern as the fixed effect and tibial specimens as the random effect, was used to determine statistical differences in strain between 50:50 loading and 80:20 loading. To determine the effect of prosthesis type, the data was grouped in four ways: metal backed and 50:50 loading; metal backed and 80:20 loading; all polyethylene and 50:50 loading; all polyethylene and 80:20 loading. In all of the above models, each of the twenty four strain areas on the tibiae were modeled independently.

Results

Least square means of shear strain values in each of the twenty four measurement regions on the proximal tibia are reported for the 50:50 and 80:20 loading distributions in Table 1 and Table 2 respectively. In this study, there were no measurement regions in any experimental group or loading condition that showed statistically significant higher shear strains in the metal backed implanted tibiae when compared to the all polyethylene implanted tibiae (Fig. 4 and Fig. 5). The highest values of shear strain were measured in the central regions of the posterior tibiae implanted with all polyethylene components and loaded with both 50:50 and 80:20 medial:lateral condylar distributions.

In 50:50 loading, as seen in Figure 4, the majority of anterior and posterior measurement regions showed significantly higher shear strains in the all polyethylene experimental group. Mean shear strains as high as 1501 μm were measured in balanced condylar loading from 1-2 cm below the level of resection in the PLC region of the all polyethylene experimental group, a statistically significant increase of 70% ($p=0.0092$) from the metal backed PLC region. The greatest percent difference in strains between the two groups in 50:50 loading were seen in the PMC and PLC measurement regions from 0-1 cm below the level of resection. All polyethylene TKA were noted to have 192% higher shear strain in the PMC region ($p<0.0001$) and 484% higher shear strain in the PLC region ($p=0.0011$) compared to metal backed components. While in 80:20 loading, the majority of posterior regions and five of the twelve anterior measurement regions showed significantly higher strains in the all polyethylene implanted tibiae, as shown in Figure 5. The greatest percent increase in strain from metal backed to all polyethylene implanted tibiae was found from 0-1 cm below the level of bone resection in the PLC region at 587% (p=0.0054).

Discussion

We have previously reported a 98% fifteen-year survival rate with the non modular metal backed AGC total knee prosthesis, in a study of 4,583 knees, while we found only a 68% ten-year survival rate in a study 536 knees with AGC all polyethylene tibial components [4,5]. Taylor et al.[13] stated that excessive stresses in the proximal tibia could lead to prosthesis migration and cancellous bone failure which is the most common failure mechanism observed for AGC all polyethylene implants.[4] The biomechanical findings of this current study with significantly higher stains observed with all polyethylene tibial components parallels the increased survival rate of metal backed AGC and the much lower survival rate of all polyethylene AGC components. Prosthetic malalignment has been shown to be a cause of early TKA failure[5,14]. Tibial component varus has been shown through in vitro photoelastic studies[10] to demonstrate significantly increased surface strain in the medial tibial bone which interestingly correlates with clinical failure mechanisms we have observed noting the combined effect of greater than three degrees of tibial component varus alignment and increased body mass index (BMI) on failure through medial bone fatigue and component loosening.[14] Furthermore, Paganelli et al.[15] found in finite element analysis that the location and magnitude of the loading at the tibial plateau can be significantly altered by component alignment. In addition, malalignment has been shown to result in significantly lower loads to failure during in vitro testing [16]. Based on these clinical and prior in vitro findings, we considered it important to load the tibiae in both balanced and simulated varus malalignment to better understand the effects of metal backing on the load transmission to the tibia.

Finite element studies have shown that metal backing reduces system stresses in the PMMA bone cement, as well as in the underlying cancellous bone[6,7]. Under varus loading conditions, with 80% of the total compressive load supported by the medial condyle, metal backing was shown to reduce the strain on multiple regions of the proximal tibia (Fig 5.) which were most notably seen in posterior tibia and strains were significantly reduced across both the medial and lateral aspects of the bone. Intuitively, strains in both the groups of tibiae experienced higher strains on the medial tibia while in varus loading. Metal backing did not equalize strain across the entire posterior tibia during neutral and simulated varus loading, but did reduce strain laterally as well as medially. Overall, in every measurement region with a statistically significant difference in shear strain, higher strain was measured in the all polyethylene implanted tibiae compared to metal backed components. Statistically significant increases in strain from 126 μm (p=.0131) to 745 μm (p=.0011) and from 40% (p=.0010) to 587% (p=.0054) were seen in the all polyethylene experimental group. We believe this may correlate with the higher failure rates we have observed in the AGC all polyethylene cohort[4] compared to the metal backed cohort[5] from our institution.

This study utilized composite tibiae as a method to replicate the mechanical characteristics of cadaveric tibiae and to increase study uniformity. Tibial interaction with the fibula and other dynamic factors such as quadriceps or other muscular forces were not accounted for and may limit widespread clinical application.

These findings may or may not be applicable to other prosthetic systems other than the AGC and its relatively flat on flat coronal plane geometry. Photoelastic strain measurement provided the ability to measure strains on any area of the surface of the proximal tibia, since the location of the peak strains is initially unknown. However, with this method, only shear strain measurements were taken[12]. Shear strain values in this study are useful for comparison of intra study experimental groups, yet are difficult to compare with strain measurements in other literature[12].

In conclusion, striking differences were found in the two experimental groups. The purpose of this study was to document the effects on the underlying and supporting bone in the proximal tibia from the use of a metal backing in the tibial component. While the use of metal backing does increase the amount of bone resection required for TKA, this study shows that in the composite tibial model, across the entire surface of the proximal tibia, metal backing maintains, and more frequently reduces strain on the surface of the bone and correlates with higher clinical survivorship observed with the metal backed AGC[5] compared to the all polyethylene tibial components[4].

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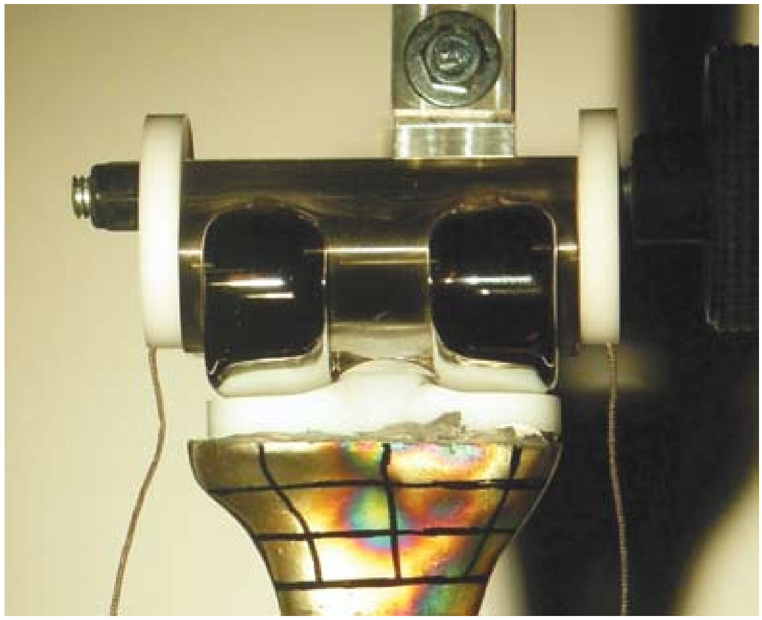


Figure 1: Custom loading apparatus for the application of 80:20 medial:lateral condylar loading distribution via AGC femoral component. Device design courtesy of Richard R. Glisson, Orthopaedic Research Laboratories, Duke University Medical Center, Durham, North Carolina.

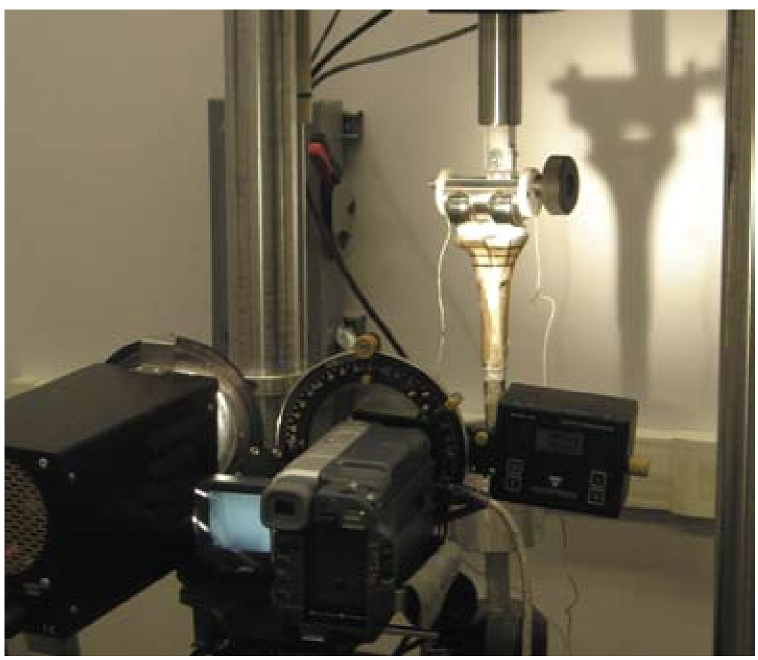


Figure 2: Reflection polariscope and null compensator for quantitative strain measurement. Test specimens were mounted on a tabletop servohydraulic materials testing machine for compressive loading.

Figure 3: Schematic of photoelastic shear strain measurement test setup. White light is polarized and then reflected off of the coated tibia. Coloration bands on the tibia corresponding to quantifiable strain are viewed through the analyzer lens. (Image used with permission from Vishay Inter-Technology, Inc. "Introduction to Stress Analysis by the PhotoStress Method" TN-702-2).

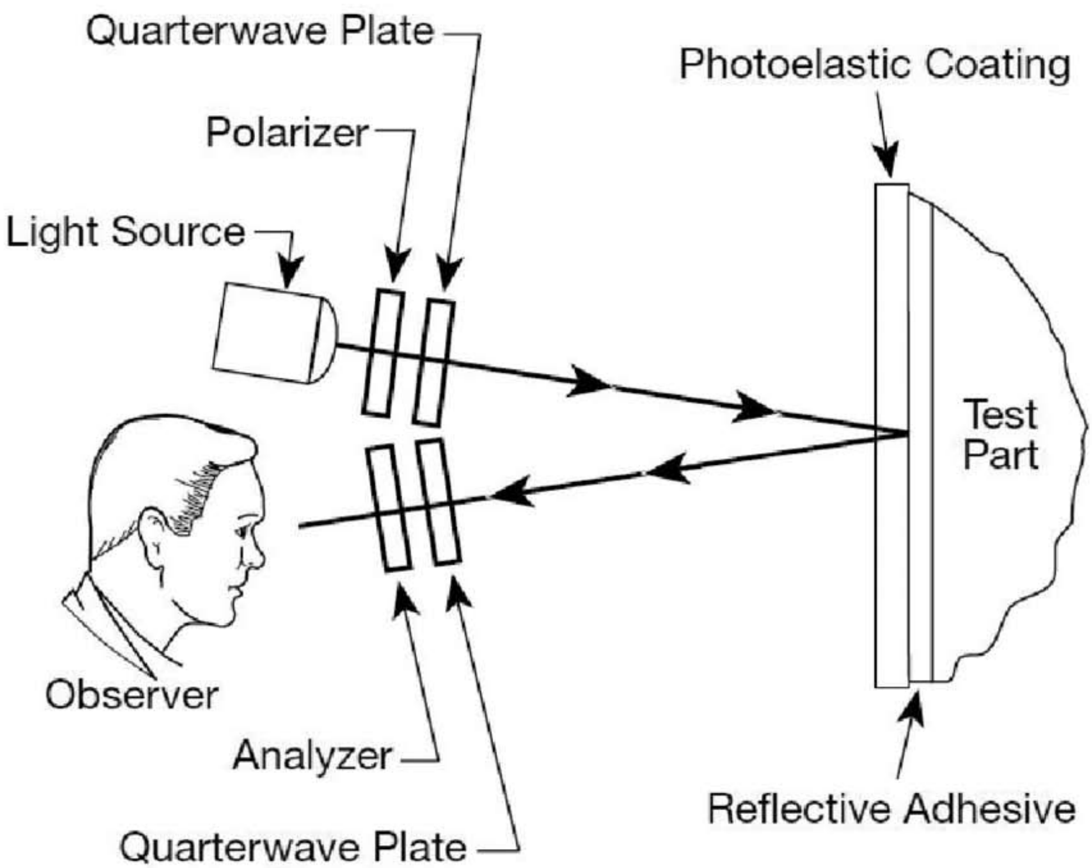
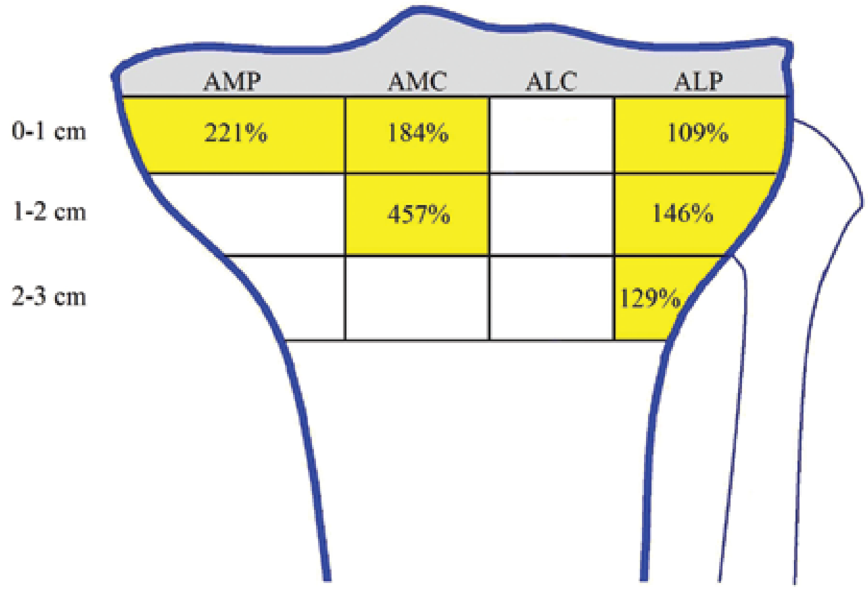


Figure 4: Percent increase in strain from metal backed AGC® to all polyethylene AGC® in 50:50 loading distribution. Yellow shaded columns are statistically significant increases ($p<0.05$) in A: the anterior proximal tibia, B: the posterior proximal tibia.

4A



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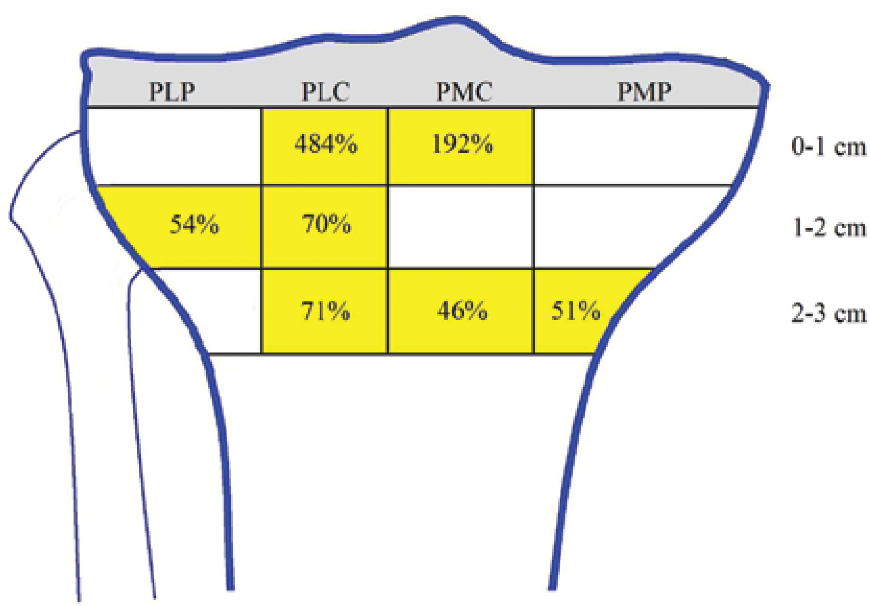

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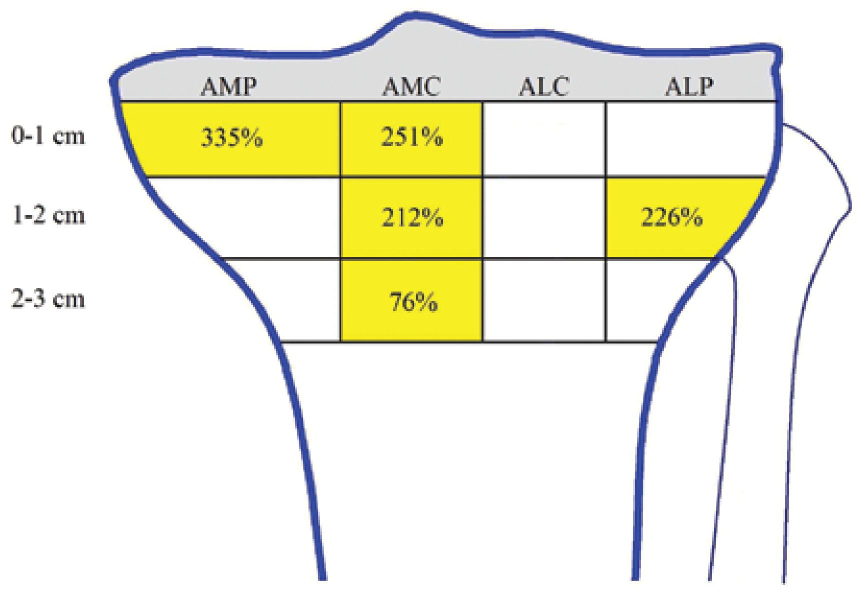
5A



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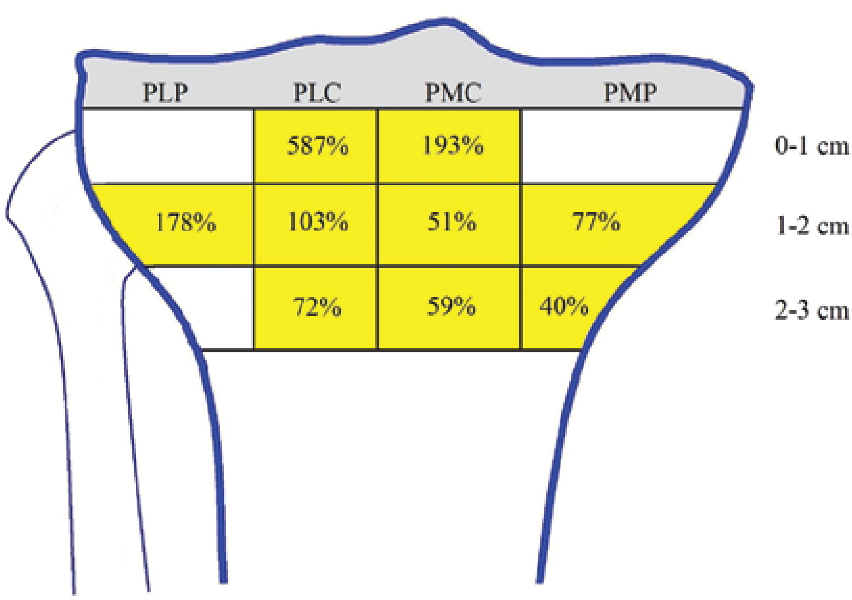

Table 1:

Least mean square averages of strain measurements (μm) with a 50:50 loading distribution in each of the 24 measurement regions at 1 cm increments from the tibial plateau.

All polyethylene					Metal backed				
	AMP	AMC	ALC	ALP		AMP	AMC	ALC	ALP
0-1 cm	183	287	195	479	0-1 cm	57	39	278	229
1-2 cm	230	351	119	634	1-2 cm	157	63	214	258
2-3 cm	119	139	255	569	2-3 cm	98	69	196	248
	PMP	PMC	PLC	PLP		PMP	PMC	PLC	PLP
0-1 cm	269	450	899	176	0-1 cm	154	154	154	125
1-2 cm	296	768	1501	869	1-2 cm	198	546	882	563
2-3 cm	464	1059	1040	929	2-3 cm	308	723	607	745

Table 2:

Least mean square averages of strain measurements (μm) with a 80:20 loading distribution in each of the 24 measurement regions at 1 cm increments from the tibial plateau.

All polyethylene					Metal backed				
	AMP	AMC	ALC	ALP		AMP	AMC	ALC	ALP
0-1 cm	583	643	144	145	0-1 cm	128	183	113	45
1-2 cm	501	743	198	225	1-2 cm	341	238	242	69
2-3 cm	572	520	272	193	2-3 cm	396	296	310	178
	PMP	PMC	PLC	PLP		PMP	PMC	PLC	PLP
0-1 cm	751	597	653	122	0-1 cm	382	204	95	95
1-2 cm	859	1229	1223	431	1-2 cm	485	816	603	155
2-3 cm	990	1303	847	504	2-3 cm	709	818	492	382

Notes