OMNI

OMNIBotics®
Clinical Summary
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OMNIBotics® Clinical Summary
Contents

OMNI Research
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Introduction

The present report is a summary of historical and ongoing clinical studies of the OMNIBotics® surgical platform and OMNI total joint arthroplasty components. The goals of these studies are to investigate the potential clinical, surgical, and economic benefits of OMNI's robotic-assisted arthroplasty products.

The OMNIBotics system aims to improve surgical and patient outcomes through:

1) enhanced patient specific 3D intra-operative planning without pre-operative imaging,
2) active ligament balancing,
3) robotic-assisted bone resections, and
4) quantitative, active insert trialing.

Early clinical research at OMNI was directed at validating the accuracy and precision of the OMNIBotics platform [1-11], quantifying surgical efficiency and the learning curve [5,6,8,10], and demonstrating the utility of the system for routine and complex TKA cases [6,10]. Initial cadaver studies demonstrated significantly improved bone-cutting precision, implant placement and time savings over conventional cutting guides [1,2]. Koenig et al. assessed surgical accuracy and efficiency in their first 100 patients and reported final leg alignment within 3° of neutral to the mechanical axis in 98% of cases [5,10].

Moreover, the learning curve required only an additional 7 minutes of tourniquet time on average over the first 25 cases (56 vs 49 minutes) and accuracy was not affected during the learning curve period. In a subsequent study the authors reported that severe varus and valgus deformities ≥10° could be corrected to within 3.5° of neutral in all cases, while these more difficult cases added only 3-5 minutes of surgery time [6]. In a clinical study involving 81 patients, Clark and Schmidt reported 9 minutes faster computer times, 0.5° higher accuracy, and a 0.6 day shorter hospital stay when using OMNIBotics versus a competitive navigation system [8].

OMNIBotics® Active Spacer™

In 2017 OMNI introduced a new, innovative technology for robotic-assisted ligament balancing, the OMNIBotics® Active Spacer™ [19-26]. The Active Spacer is the only commercially available system that integrates robotically controlled ligament tensioning with implant planning and robotic-assisted bone resection.

Pre-clinical investigations carried out during the development of the technology demonstrated that the system was effective at equalizing the flexion and extension gaps, as well as predicting the gaps throughout the entire range of motion prior to making resections with an accuracy better than 2mm [19-22]. Early clinical data shows that post-operative balance can be planned throughout the ROM to within 0.4±1.1mm (mean ± standard deviation) [23]. A prospective multi-center study is currently underway to investigate the effects of the active spacer on ligament balancing and the associated improvements in patient reported outcomes.

The remainder of this report provides a summary of recent and ongoing clinical research studies being performed on OMNI's robotic-assisted technologies, including the Active Spacer.

Validation of a Laxity Prediction Algorithm for Gap-Balancing Total Knee Arthroplasty [23]

Introduction

Gap balancing in total knee arthroplasty (TKA) has traditionally focused on achieving equal and symmetric gaps in flexion and in extension. Gap measurements are not typically performed in mid-flexion which can result in increased mid-flexion laxity even when the gaps in extension and flexion are equal and symmetric. TKA surgeons often rely on experience to determine the bone cuts necessary to achieve a desirable gap outcome which is not reproducible across surgeons. A tool that allows for quantitative prediction of post-operative gaps prior to bone resections may help to better define optimal patient-specific balance targets and achieve more consistent outcomes in TKA. In this study, the accuracy of a virtual gap algorithm used to predict the post-op laxity profile as a function of the measured pre-operative laxity and the virtual femoral component plan was evaluated.

Methods

Thirty-one patients (33 knees total, mean age: 72±11, BMI: 27.3±8.3) undergoing total knee arthroplasty with a tibial-cut first technique were included in this study. After resecting the proximal tibia and the posterior cruciate ligament, but prior to resecting the femur, the knee joint was tensioned using a novel robotic assisted ligament tensioning tool (OMNIBotics® Active Spacer™, Fig 1). The gap profiles were measured using the navigation system as the limb was manually taken through a range of flexion while the Active Spacer applied a load between 80-100N. The native gap was defined as the distance between the tibial resection and the closest point on the articulating surface of the native femur on the medial and lateral sides at each degree of flexion (Fig 2A). A virtual gap algorithm was used to determine the predicted post-operative gap profile based on the native gap acquisition and the planned implant alignment (Fig 2B). The iBlock robotic cutting-guide was used to perform the femoral cuts based on the planned implant position. After inserting a femoral trial component, the active spacer was reinserted into the joint. The same loading profile used for the native gap acquisition was repeated. The post-operative gap was measured as the distance from the tibial resection to the closest point on the femoral trial (Fig 2C). The predictive error was calculated as the difference between the measured post-operative gap and the predictive gap at each flexion angle. The mean and standard deviation of the medial and lateral prediction error were calculated for all knees. Paired t-tests were used to identify significant differences between the predicted and measured post-operative gap across the flexion arc.

Results

The average discrepancy between the predicted and post-operative gaps was 0.4±1.1mm and 0.3±0.8mm for the medial and lateral gaps respectively. The maximum error was 2.0mm on the medial side and 1.8mm for the lateral side. Differences between the predicted and the measured post-op gaps on the medial or the lateral side were not statistically significant for all flexion angles ($p>0.8$).

Discussion

Predicting post-operative knee laxity using a dynamic pre-op gap acquisition under controlled tension and a 3D femoral implant plan was found to be accurate and reproducible to within 1-2mm

throughout the range of flexion. The prediction algorithm assumes that all femoral cuts are made to the plan. However, surgeons typically accept bone resections that are within 1mm of the plan which may explain some of the variation between the predicted and the actual gaps.

Significance/ Clinical Relevance

Computerized implant planning algorithms now enable prediction of post-operative soft-tissue balance and gaps throughout the range of knee motion prior to performing any femoral resections. This allows for optimization of femoral component placement to achieve a desired gap or knee laxity profile throughout the range of flexion and not only in flexion and extension. The laxity predictions have been shown to be accurate to within 1-2mm when coupled with a computer-controlled ligament tensioner.

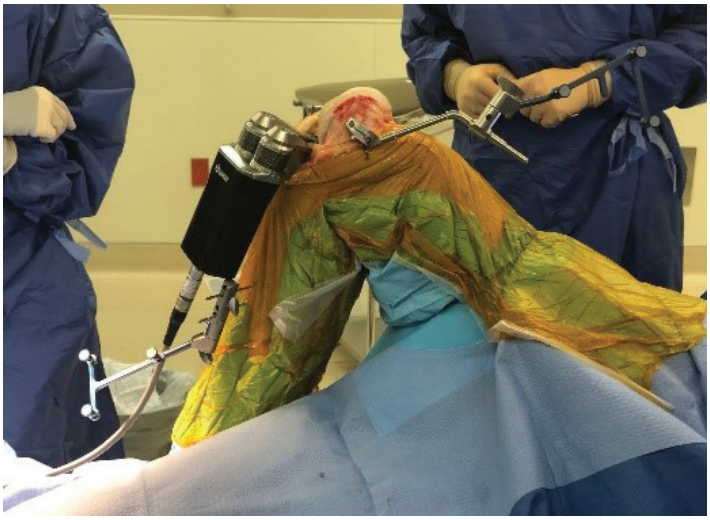

Fig 1. The surgical setup showing the tracking arrays and the Active Spacer

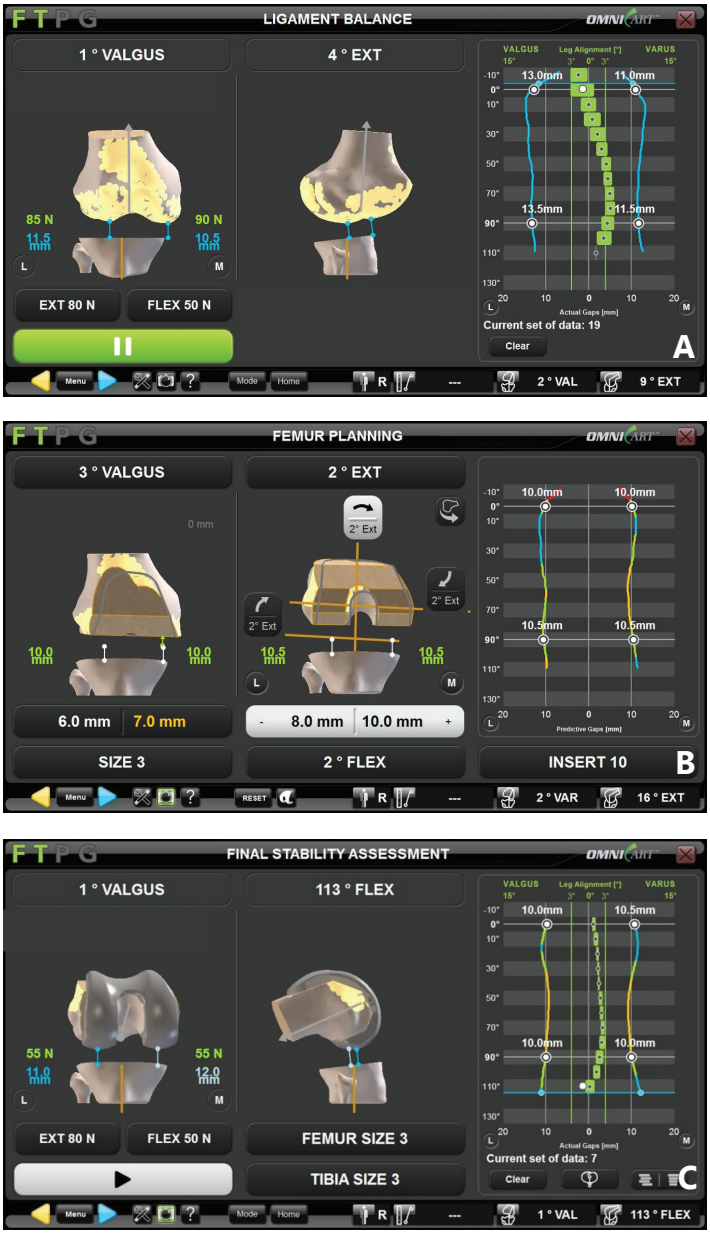

Fig 2. Screenshots from the OMNIBotics system showing (A) native gap balancing collection screen, (B) femoral planning screen and (C) implants gap acquisition screen

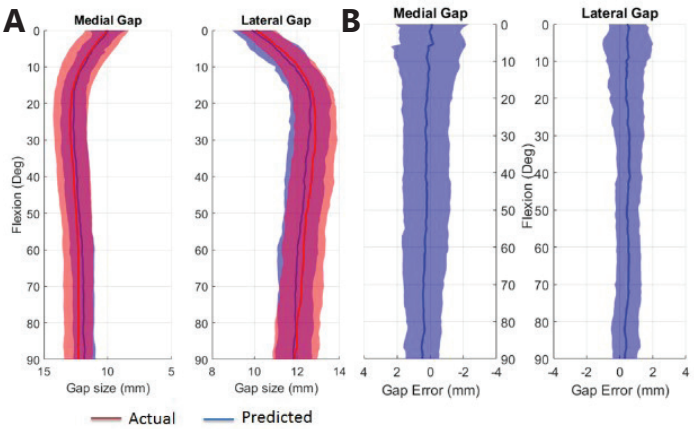

Fig 3. (A) The tibiofemoral medial and lateral gap for the predicted post-operative gap (blue) and measured post-operative gap (red) (B) the error between the predicted gaps and the post-operative gaps

The Effect of Gap Balancing at 0° Versus 10° of Flexion on Extension and Mid-flexion Laxity in Total Knee Arthroplasty [24]

Introduction

The gap-balancing technique in total knee arthroplasty aims to produce a balanced knee throughout the range of motion, by using the native flexion and extension gaps to plan the femoral bone resections and alignment. Previous studies have shown that the native gaps increase significantly in the first 10° of flexion, however, likely due in part to the tension in the posterior capsule and the knee screw-home mechanism as the joint is brought into full extension. Therefore, planning at 0° flexion could result in a different femoral plan than planning at 10° of flexion. In addition, the effect of the planning angle on the resultant gaps throughout the arc of flexion has not been previously characterized. This study aims to quantify the change in the post-operative tibiofemoral gap throughout the arc of flexion when varying the planning extension angle.

Materials and Methods

32 knees from 32 patients (mean age: 72±11, BMI: 27.3±8.3) were implanted with a posterior cruciate sacrificing TKA using a robotic-assisted tibial-cut first gap-balancing technique. The proximal tibia was resected perpendicular to the mechanical axis and the knee joint was tensioned using a novel ligament tensioning tool that applies computer controlled tension to the ligaments throughout the arc of flexion (OMNIBotics® Active Spacer™, Fig 1). The gap profiles were measured using the navigation system as the ligaments were actively tensioned and the limb was manually taken through a range of flexion. The system applied a load ranging between 80-100N of tension equally to each of the medial and lateral compartments. The femoral implant position and size was then planned to have equal and symmetric knee gaps in extension and flexion. Patients were divided into two sequential groups: Group A, the knee was planned to have equal and symmetric gaps at 0° and 90° (18 consecutive knees), Group B the knee was planned to have equal and symmetric gaps at 10° and 90° (14 consecutive knees). The femur was resected and a femoral trial was inserted and the postoperative gaps were measured throughout the arc of flexion while the Active Spacer applied equal tension to the ligaments. The mean and standard deviation of the post-operative gaps profiles throughout the range of flexion were calculated for each group. T-tests were used to identify significant differences between group A and group B from 0° to 10° of flexion in 10° increments.

Results

In both group A and group B, the post-operative extension and flexion gaps were balanced to within 1mm of each other on average (Fig 2). Significantly larger gaps were seen in mid-flexion for group A than for group B however, with a maximum laxity increase of 3-4mm occurring around 25-30° in group A. The gap profiles between 20-60° were significantly different from the gaps at 0° and 90° in group A, but not in group B.

Discussion

Gap planning at 10° and 90° of flexion produced comparatively equal and symmetric gaps from 10° to 90° post-operatively, and resulted in similar gap patterns to those reported in the native knee, while planning at 0°and 90° produced larger laxity in mid-flexion. Gap planning at 10° resulted in smaller gaps and increased tension at full extension,

however. In some cases, this may result in a flexion contracture requiring a posterior capsule release or distal femoral recut to achieve full extension. Planning at 0° resulted in larger gaps and lower joint forces at full extension, but increased knee laxity in mid-flexion which may contribute to mid-flexion instability.

Significance/ Clinical Relevance

Gap planning at 0° or 10°of extension produced different post-operative gap profile patterns throughout the range of knee motion in TKA. Planning for equal and symmetric gaps at 0° resulted in increased laxity in mid-flexion while planning at 10° resulted in a tighter knee in full extension. Depending on the clinical circumstances of the case, the implications of planning at both 0° and 10° in gap balancing TKA should be taken into consideration. Further studies will be beneficial in determining the applicability in specific clinical scenarios.

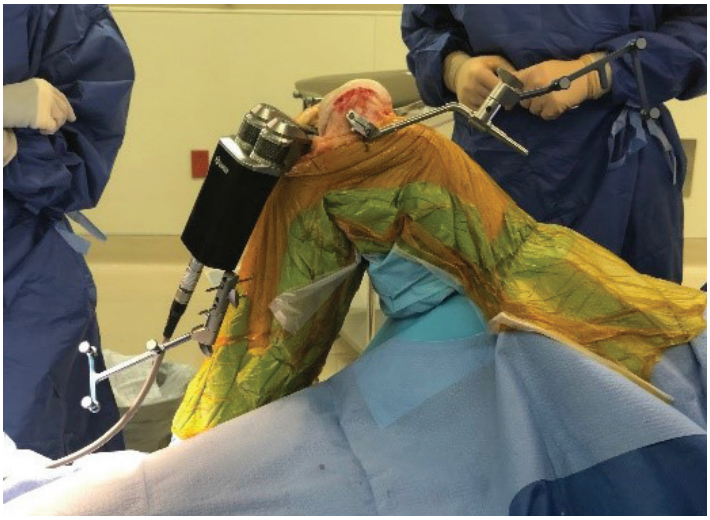

Fig 1. Intra-operative photo showing the Active Spacer inserted in the knee

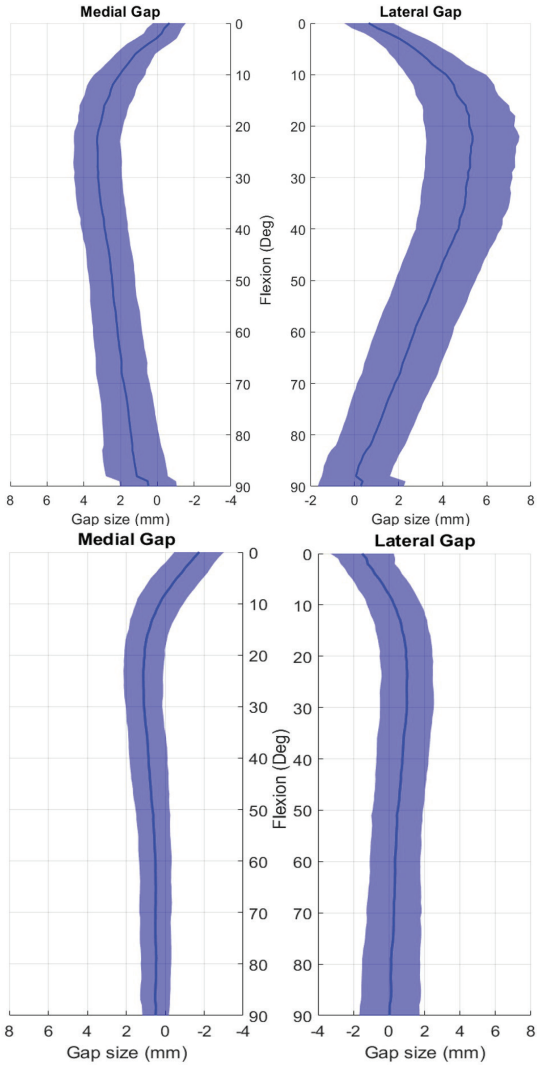

Fig 2. Post-operative gap profiles measured in knees that were planned to have equal gaps at 0° (upper, Group A) and at 90° (lower, Group B)

Does an Increase in Distraction Force Uniformly Increase Tibiofemoral Gaps? [25]

Introduction

The goal of gap balancing total knee arthroplasty (TKA) is to achieve a balanced and rectangular joint space with equatorial forces across the medial and lateral compartments in both flexion and extension. Currently surgeons use manual spacer-blocks and typically rely on their feel to tension the ligaments with no pre-defined forces. Understanding the relationship between the applied force and the resulting joint distraction could help identify the optimal force to appropriately tension the ligaments to achieve a balanced knee, create more objective decision making during TKA and potentially improve patient satisfaction. The objective of this study was to quantify the change in knee joint gaps under different tension levels.

Methods

14 knees in 14 patients (8 male, 60±8 age, 33± 4BMI) were registered using computer navigation in preparation for robotic-assisted total knee arthroplasty using the OMNIBotics® System (Raynham, MA). The PCL was resected, and then navigation was used to make the tibial cut at 0 degrees of varus/valgus. A novel ligament tensioning tool that applies computer controlled tension to the ligaments throughout the arc of flexion (OMNIBotics® Active Spacer™) was inserted into the joint space (Fig 1). The knee was manually extended from 90° flexion to full extension while the active spacer applied an equal load of 70N, 90N and 110N in three separate trials both medially and laterally. The tibiofemoral gaps were recorded using the navigation system.

The tibiofemoral gaps from the 70N loading cycle was chosen as the baseline. The difference relative to the baseline was calculated for the 90N and 110N load cycle gaps. Average and standard deviation was calculated for the fourteen patients. Paired t-tests were used to identify significant differences in the tibiofemoral gaps between the three load levels and from medial to lateral.

Results

The baseline tibiofemoral gaps increased with flexion from 0° to 10-20° flexion, at which point they remained consistent for the rest of the flexion range (Fig 2). On average, the baseline medial gaps were smaller than the lateral gaps by 2.8mm ($p<0.05$). Increasing the applied load resulted in an increase in the tibiofemoral gaps (Fig 3). The difference was small in early extension but became significant past 10° of flexion ($p<0.05$). The increase in gaps between 70 and 90N was larger than the increase in gaps between 90 and 110N. At 90° flexion, increasing the applied load resulted in smaller increase in the medial gaps compare to the lateral gaps.

Discussion

Increasing the distraction force resulted in larger tibiofemoral gaps, however the change in joint gaps was not uniform across the flexion range. Similar results have been observed in previous studies. The knee has less laxity in early extension due to tension in the posterior capsule. This explains the smaller variation in early extension. The larger difference in gaps between 70N and 90N compared to the difference between 90N and 110N is likely due to the non-linear force elongation curve of the ligaments, while mediolateral differences are likely due to the different structural properties and higher stiffness of medial versus lateral collateral ligaments

structures. This indicates that an increase in distraction force can affect femoral implant rotation as well as resection level in the gap balancing technique.

Significance/ Clinical Relevance

Understanding the effect of increasing the tension force on tibiofemoral gaps and its relation to the ligament stress-strain curve will aid in determining the optimal bony cuts that appropriately tension soft tissues in order to achieve a balanced knee

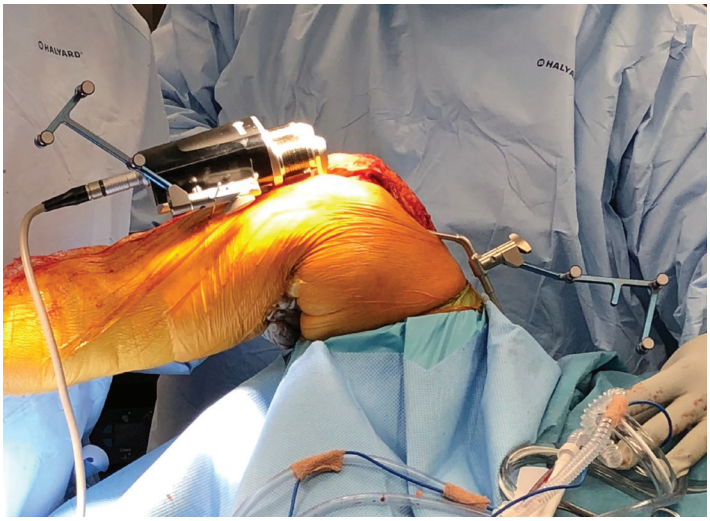

Fig 1. The surgical setup showing the tracking array and the Active Spacer

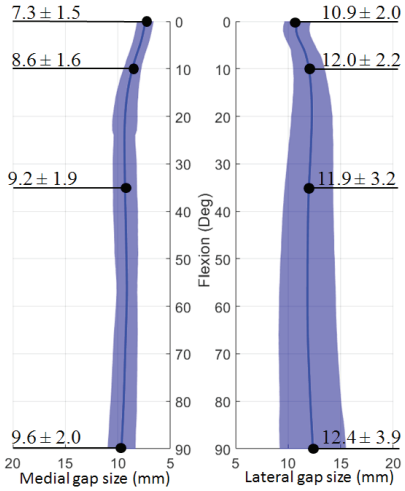

Fig 2. The average and standard deviation of the medial and lateral tibiofemoral gaps under 70N of tension

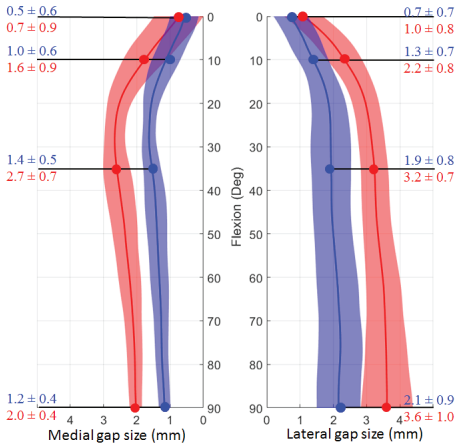

Fig 3. The average tibiofemoral gap difference using 90N of tension (blue) and 110N of tension (red) relative to the baseline. Shaded areas represent ± one standard deviation

Ligament Tension and Balance After Robotic-Assisted TKA – Dynamic Changes with an Increasingly Applied Force

[26]

Study Objective

To quantify gap distraction post-operatively with incrementally increasing distraction force.

Methods

The OMNIBotics® Active Spacer™ applied 80N of tension in flexion and 100N in extension and a gap balancing algorithm allowed planning of the femoral bone cuts in fourteen patients. After placement of the femoral trial, the Active Spacer was reinserted into the knee in place of the tibial insert. The knee was extended from 90° flexion to full extension while applying equal medial and lateral loads of 70N, 90N and 110N in three separate trials. Tibiofemoral gaps at 70N of applied tension were plotted as the baseline gaps and the difference relative to baseline was calculated for 90N and 110N.

Results

Mediolateral gaps were symmetric within 1.3mm across the flexion range (Fig 1a). Baseline gaps were smallest in extension and increased by 3.2mm medially and 1.6mm laterally from 0° to 35° of flexion. Gaps were unchanged past about 30° of flexion. Compared to baseline, medial gaps averaged 1.3mm and 2.2mm larger while the lateral gaps were 1.6mm and 2.6mm larger for 90N and 110N loads, respectively ($p<0.05$, Fig 1b). The difference in gaps between the 70N and 90N loads (1.5mm average) was larger than the difference between the 90N and 110N loads (1mm). At 90° flexion, increasing load resulted in asymmetric gap distraction with a smaller increase in medial gaps compared to lateral gaps by about 0.5mm.

Discussion

Using a gap balancing technique with a novel integrated tensioning device, the resulting knee balance was within 1.3mm mediolaterally throughout the ROM. There was a non-linear increase in knee joint distraction with applied tension. The smaller joint distraction with increased tension implies an increase in knee stiffness from 70N to 110N. This data provides a better understanding of the relationship between joint distraction, ligament tension and knee stiffness post TKA, which can aid in informed decision making and optimal soft tissue tensioning during TKA.

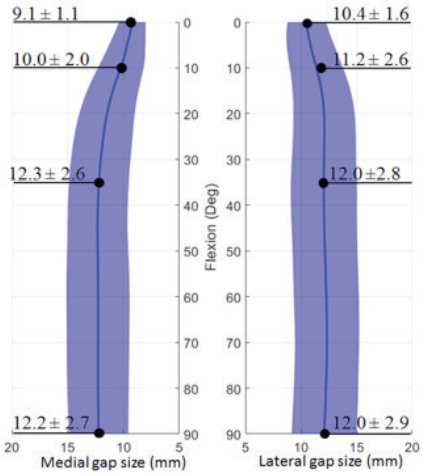

Fig 1a. The average (blue line) and standard deviation (shaded area) of the medial and lateral tibiofemoral gaps under 70N of tension

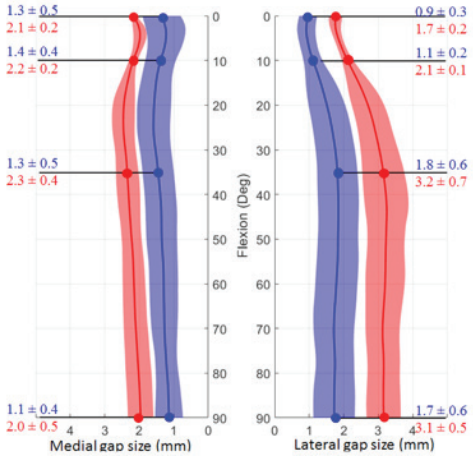

Fig 1b. The average tibiofemoral gap difference using 90N of tension (blue) and 110N of tension (red) relative to the baseline. Shaded areas represent the standard deviation.

OMNIBotics® Versus Manual Knee Outcomes- Robotics And Navigation 2-Year Follow-Up In Navigated TKR, Results Of A Multi-Centre Study [13-15]

Objectives

Compare clinical patient-reported outcomes of OMNIBotics versus manually instrumented total knee arthroplasty.

Methods

This is an ongoing multicenter study involving 892 APEX Knee™ cases at 8 sites in Europe. Knee Society Scores (KSS), WOMAC and SF -12 scores are being collected at 1, 3, 12, and 24 months follow-up.

KSS-Functional Scale				
	Pre-Op	1 month	3 months	1 year
OMNIBotics (n = 343)	43,45	74,43	90,53	96,40
Conventional (n=549)	42,32	55,40	76,64	78,68

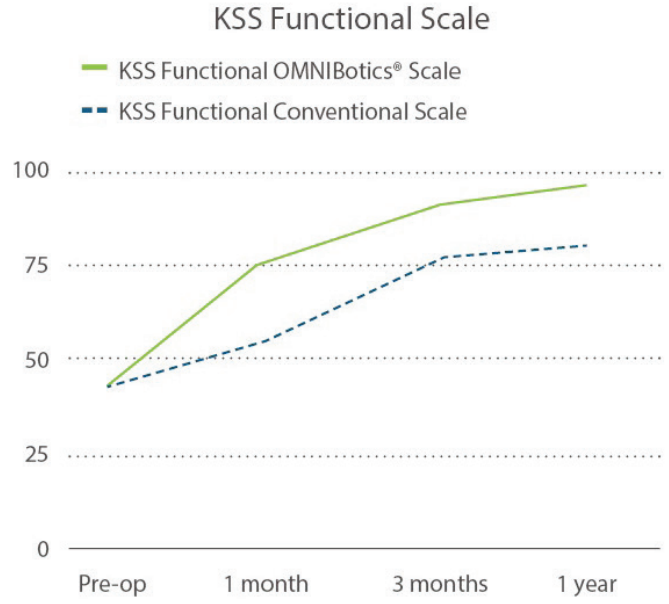

Fig 1. OMNIBotics resulted in significantly higher Knee Society Functional Scores when compared to manual instrumentation

Conventional and OMNIBotics groups consisted of 549 and 343 patients, respectively, with similar demographics in each group (gender, age, BMI).

Results

The improvement in KSS functional scores was significantly higher in the OMNIBotics group than in the conventional group (Fig 1). WOMAC Pain, Stiffness, and Function, and SF-12 Physical Scores also demonstrated significantly greater improvement in the OMNIBotics group. Surgery time was 3:20 minutes longer with OMNIBotics than with conventional instruments.

Conclusions

Use of OMNIBotics demonstrated improved clinical outcomes in terms of knee function, pain, stiffness and quality of life over conventional manual instrumentation in this large multicenter trial, with minimal added surgery time.

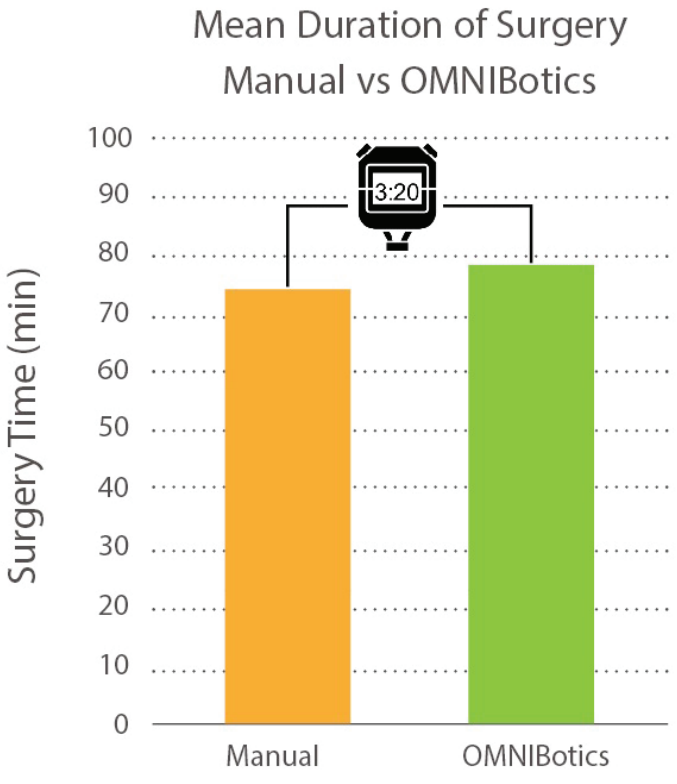

Fig 2. Surgery duration with OMNIBotics was close to time neutral, taking only 3:20 minutes longer than conventional surgery

OMNIBotics® Reduces Manipulation Rates [16]

Introduction

Arthrofibrosis remains a dominant post-operative complication and reason for returning to the OR following total knee arthroplasty. Trauma induced by ligament releases during TKA soft tissue balancing and soft tissue imbalance are thought to be contributing factors to arthrofibrosis, which is commonly treated by manipulation under anesthesia (MUA).

Objectives

We hypothesized that a robotic-assisted ligament balancing technique where the femoral component position is planned in 3D based on ligament gap data would result in lower MUA rates than a measured resection technique where the implants are planned based solely on boney alignment data and ligaments are released afterwards to achieve balance. We also aimed to determine the degree of mechanical axis deviation from neutral that resulted from the ligament balancing technique.

Methods

301 consecutive primary TKA cases performed by a single surgeon were reviewed. The first 102 consecutive TKA cases were performed with a computer-navigated femur-first measured resection technique (Stryker Navigation with Smith and Nephew GEN II). The subsequent 199 consecutive cases were performed with a robotic-assisted tibia-first ligament balancing technique (OMNIBotics with APEX Knee™). CPT billing codes were reviewed to determine how many patients in each group underwent post-operative MUA. Post-operative mechanical alignment was measured in a subset of 50 consecutive patients in the ligament balancing group on standing long-leg radiographs by an independent observer.

Results

Post-operative MUA rates were significantly lower in the ligament balancing group than in the measured resection group (Fig 1). 91.3% of knees were within 3° and 100% (46/46) were within 4° of neutral alignment to the mechanical axis post-operatively in the ligament balancing group (Fig 2).

Conclusions

Ligament balancing femoral based planning in TKA resulted in a significantly lower post-operative manipulation rate than in the measured resection approach, while maintaining highly accurate overall alignment to the mechanical axis.

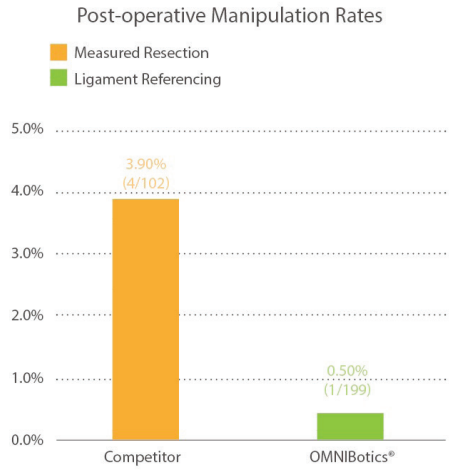

Fig 1. Post-operative manipulation rates were significantly lower in the OMNIBotics ligament balancing group than in the Stryker navigation measured resection group (p=0.05)

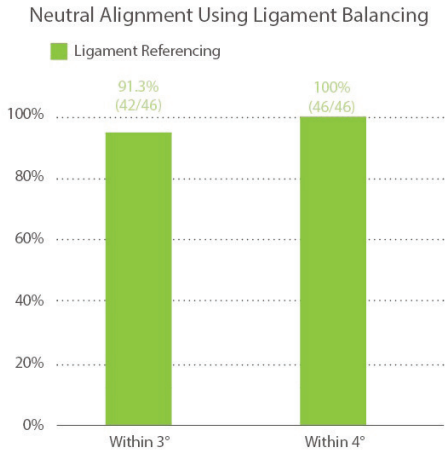

Fig 2. 91.3% and 100% of knees were within 3° and 4° of neutral alignment using OMNIBotics with ligament balancing

Early Patient Satisfaction and Surgical Efficiency of Robotic-Assisted TKA

**** Winner of the 2016 Transatlantic Orthopaedic Congress Award of Excellence for an Oral Scientific Poster: Knee***

[17,18*]

Introduction

There is increasing pressure on healthcare providers to demonstrate competitiveness in quality, patient outcomes and cost. Robotic and computer-assisted total knee arthroplasty (TKA) have been shown to be more accurate than conventional TKA, thereby potentially improving quality and outcomes, however these technologies are usually associated with longer procedural times and higher costs for hospitals.

Objectives

The aim of this study was to determine the surgical efficiency, learning curve and early patient satisfaction of robotic-assisted TKA with a contemporary imageless system (OMNIBotics®).

Methods

The first 29 robotic-assisted TKA cases performed by a single surgeon having no prior experience with computer or robotic-assisted TKA were reviewed.

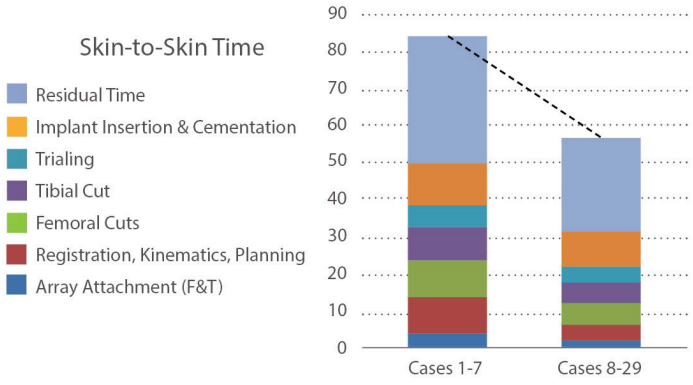

Fig 1. Skin-to-skin time decreased from 84min to 57min (p=0.0008) after 7 cases

Skin-to-skin time was measured and computer surgical logs were reviewed to analyze every step of the procedure. Patients completed surveys at 3 months to determine their overall satisfaction with their surgical joint.

Results

All time metrics decreased significantly after the first 7 cases, except the residual time (Fig 1). Mean skin-to-skin time significantly decreased from 83.7min to 57.1min (p=0.0008) beyond 7 cases, and hip center to final cut validation time decreased from 30.2min to 20.3min (p=0.0002). 21 out of 29 patients completed questionnaires. 85.7% were "Fully satisfied" and 14.3% were "Partly satisfied". No patients were 'Not Satisfied' (Table 1). Cost analysis showed there were no capital costs associated with acquisition of the robotic system and per case cost was equal to conventional TKA.

Conclusion

Improvements in surgical efficiency and quality are becoming increasingly important in today's healthcare environment. The results of this study indicated equal cost, a short learning curve and comparable procedure times to conventional TKA. The Patient Reported Outcomes with this group of patients was very high compared to rates reported in the literature.

Early Patient Satisfaction: Robotic-Assisted TKA					
	n	f/u time	Not Satisfied	Neutral	Fully Satisfied
Current Study	29	3m	0% (0/29)	14.3% (5/29)	85.7 (21/29)
Bourne CORR 2010	1703	1yr	11.6%	7.7%	80.6%
Heck CORR 1998	330	>2yr	9.0%	3.0%	88.0%
Baker JBJS(Br)2007	8095	>1yr	7.0%	11.2%	81.8%
Noble CORR 2006	253	>1yr	14.0%	11.0%	75.0%
Robertsson Acta 2000	27.372	2-17yr	8.0%	11.0%	81.0%

Table 1. Robotic-assisted TKA demonstrated lower dissatisfaction rates than those for conventional TKA reported in the literature

Prospective Study on Patient Satisfaction and Outcomes in Robotic TKA – Study Update [27]

Objectives

This is a prospective study evaluating clinical outcomes, patient reported outcomes (PROMs), and patient satisfaction in robotic-assisted total knee arthroplasty.

Methods

106 TKA patients at Winthrop University Hospital (Mineola, NY) were consented pre-operatively and will be followed up for at least two years, with longterm follow-up planned up to 10 years for PROM's and survivorship. New Knee Society Scores (KSS-2011), KOOS, VR-12 are being collected pre-op, 3M, 6M and annually. Complications, re-admissions, blood loss, length of stay, discharge location, pain management, surgery time, and leg and component alignment are also being tracked.

Interim Results

106 patients have been enrolled to date with 3M, 6M and 1 year follow-up available on 104, 101 and 72 patients, respectively. Mid-study results show significant improvements in knee function, pain reduction, satisfaction, and quality of life, and compare favorably to other studies in the literature (Tables 1 and 2).

TKA Case Details		
	Average	Range
Age at Surgery	69	47-88
BMI	29.83	19.8-41.4
Skin to Skin Time	1:09:51	0:53-1:51:00
Tourniquet Time	0:42:52	31-1:25
Length of Stay	2.5 days	1-8

Table 1. Demographic, Operative Time, and LOS Data

WUH OMNIBotics TKA	Pre-OP n=106	3 Month n=104	WUH 3 M Improvement	1 year n=72	WUH 1 Y Improvement	Changes in KOOS scores between Pre-OP & 3 Months	
						n=90	CAS n=90
KOOS- Pain	42	75	33	85	43	20	27
KOOS-Symptoms	45	73	28	79	34	7	13
KOOS-Activities of Daily Living	45	79	34	86	41	21	26
KOOS-SportRec	20	41	21	58	38	8	21
KOOS-QOL	21	62	41	72	51	28	35

Table 2. Comparison of improvement in KOOS scores at 3, 6, and 12 months between OMNIBotics TKAs and conventional and computer-assisted TKAs reported in the literature [1]

WUH OMNIBotics TKA							Literature [2]Uefuji		
PROM	Pre-OP n=106	3 month n=104	6 month n=101	Change at 6 months	1 year n=72	Change at 1 year	Pre-OP	6 month	Change at 6 months
2011 KSS-Symptoms (25 pts)	7	18	20	13	20	13			
2011 KSS-Expectation (15 pts)	14	10	10	-4	11	-3	12	10	-2
2011 KSS-Satisfaction (40 pts)	12	29	31	19	32	20	14	22	8
2011 KSS-Functional (100 pts)	37	62	67	30	70	33	44	64	20

Table 3. Comparison of improvement in 2011 KSS scores at 6 months and 1 year between OMNIBotics TKA patients and published results of conventional TKA patients [2]

Conclusions

The midterm study results, including 1 year post TKA, of this ongoing prospective study show greater improvement in KOOS and 2011 KSS outcome measures in comparison to conventional and CAS-TKA. The KSS Satisfaction score improved by 19 points at 6 months which is double the change in conventional TKA. Patient's remained satisfied 1 year after their TKA demonstrated by an average improvement of 20 points in their KSS satisfaction score.

References

1.Gothesen Ø. et al, Functional outcome and alignment in computer-assisted and conventionally operated total knee replacements A Multicentre Parallel-Group Randomised Controlled Trial. *Bone Joint J* 2014; 96-B:609–18.

2. Uefuji A, et al. Subjective Evaluations of Both Before and After Total Knee Arthroplasty with the 2011 Knee Society Score. Poster presented at: ISAKOS: 2015 June 7-11; Lyon, France.

90-Day Costs and Clinical Results of Robotic-Assisted and Conventional TKA [27]

Introduction

Current CMS reimbursement policy for total joint replacement is aligned with more cost effective, higher quality care. Upon implementation of a standardized evidenced-based care pathway, we evaluated overall procedural costs and clinical outcomes over the 90-day episode of care period for patients undergoing TKA with either conventional (Conv.) or robotic-assisted (RAS) instrumentation.

Methods

In a retrospective review of the first seven consecutive quarters of Bundled Payment for Care Improvement (BPCI) Model 2 participation beginning January 2014, we compared 90-day readmission rates, Length of Stay (LOS), discharge disposition, gains per episode in relation to target prices and overall episode costs for surgeons who performed either RAS-TKA (3 surgeons, 147 patients) or Conv. TKA (3 surgeons, 85 patients) at a single institution. All Medicare patients from all surgeons performing more than two TKAs within the study period were included. An evidence-based clinical care pathway was implemented prior to the start of the study that standardized pre-operative patient education, anesthesia, pain management, blood management, and physical/occupational therapy throughout the LOS for all patients. Physician-specific target prices were established from institutional historical payment data over a prior three year period.

Results

RAS and Conv-TKA procedures exhibited an average gain per episode of $7,600 and $5,579, respectively (Table 1). The average total cost per episode was $2,085 lower for patients receiving RAS-TKA, with the majority of cost savings in reduced SNF usage ($1,481) and readmissions ($944), Table 2. Discharge to home versus Sub-acute Rehabilitation Facilities (SAR's) was 14% higher in the RAS group (62% vs 48%, $p<0.05$).

Conclusions

Implementation of a standardized care pathway across all service departments and physicians resulted in a reduction in overall episode of care costs, with further reductions in cost and discharge to SARs observed with the use of RAS.

	Gain/ Episode	90 Day Re-Admit	% Home	% SAR
RAS-TKR Group (3 Surgeons)				
Surgeon A	$7,603	5%	66%	31%
Surgeon D	$8,838	11%	39%	61%
Surgeon F	$4,292	0%	43%	57%
Group Average	$7,600	5.4%	62%	37%
CONV-TKR Group (3 Surgeons)				
Surgeon B	$6,629	14%	57%	38%
Surgeon C	$6,639	9%	56%	41%
Surgeon E	$1,033	12%	12%	88%
Group Average	$5,579	11.7%	48%	51%

Table 1. WUH BPCI 90 Day Bundle Data – Robotic vs Conventional TKR (Q1, 2014 – Q3, 2015)

	Robotics[1]	Conventional[2]	Difference
Episodes	147	86	
Anchor Inpatient Stay	$16,802	$16,479	$323
SNF	$4,847	$6,327	$[1,481]
IRF	$440	$609	$169
Home Health	$3,878	$3,652	$225
Readmissions	$531	$1,475	$[944]
Outpatient Physical Therapy	$1,461	$1424	$37
Outpatient/ Professional	$985	$1,061	$76
Total	$28,943	$31,028	$[2,085]

Table 2. Breakdown of 90-day episode of care costs

OMNIBotics® Computer-Assisted Total Hip (CATH) Application

OMNI has developed a new computer-assisted total hip (CATH) application that is currently being evaluated clinically under a limited release program CATH is based on OMNI's proprietary OMNIBotics Bone Morphing™ anatomical modeling technology and as such requires no pre-operative CT or MRI scans, eliminating unnecessary radiation exposure to the patient as well as cost and time inefficiencies.

The system provides real-time control of acetabular reaming and final cup impaction orientation with respect to both the anterior pelvic plane and the native acetabular rim plane. Reaming depth with respect to the floor of the fossa, reamer and cup medialization, and final cup impaction depth (seating) are also tracked in real time. Leg length and offset control are provided without requiring a femoral array to be fixed to the femur.

The system is currently compatible with the anterior surgical approach and straight acetabular instruments. New offset instrumentation and compatibility with the posterior approach are expected to be introduced later this year.
Initial results and feedback obtained during the clinical evaluation period are promising, with good correspondence between the intra-operative CATH readings and post-operative radiographs/ intra-operative C-arm, and minimal extra surgical time added in comparison to conventional surgery.

It is envisioned the system will be useful for eliminating the need for using a C-arm intra-operatively, thereby reducing OR time and complexity, and radiation exposure and infection risk. Future clinical research on the OMNIBotics CATH application will focus on proving these benefits as well as the system's ability to improve cup positioning and leg length reproducibility and patient outcomes in comparison to conventionally instrumented techniques.

Fig 1. Intra-operative photograph showing CATH instrumentation and reamer tracking

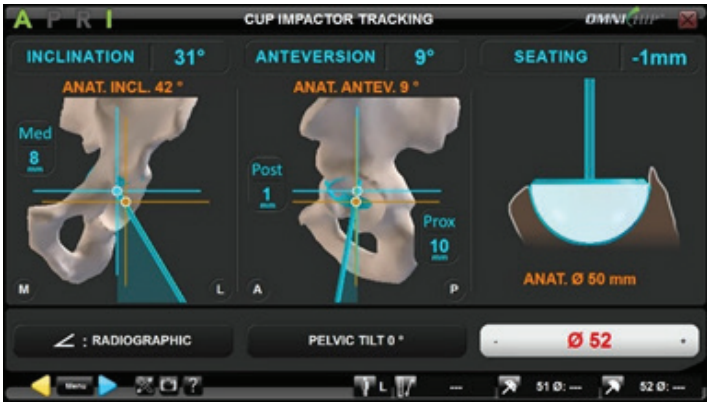

Fig 2. Real time cup impactor tracking with respect to the anterior pelvic plane and native acetabular rim. 3D position and seating depth relative to the last reamed position is also provided

Fig 3. Leg length and offset control are provided without requiring an array to be attached to the femur

APEX Knee™ System Survivorship

Introduction

Survival analysis is an important tool for assessing the outcome of total joint replacement. This paper provides a review of the APEX Knee System survival estimate based on the information known to OMNI, in relation to survival data reported in national registries from Australia, Sweden, and the UK. Survival of the APEX Knee System is based on reports of revisions provided by any source but generally from physicians, hospitals and sales professionals. Although all devices implanted in the US are included, all revisions may not be reported to OMNI.

Kaplan-Meier (K-M) Survival Estimate

The survival estimate for the APEX Knee System (all types combined) is compared below to data published in the Australian, Swedish and UK national registries [1,2,3] for primary knee arthroplasty.

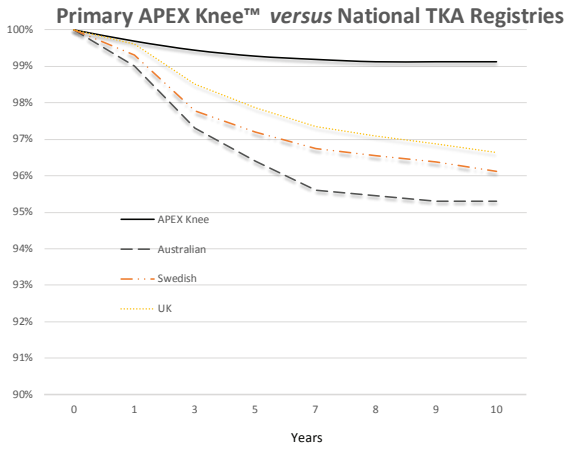

Fig 1. K-M Survival Estimate for the APEX Knee versus National TKA Registries

The Kaplan-Meier Survival Estimate has been calculated separately for the APEX Congruent, Ultra and PS knee and plotted below. The plots include a 95% confidence interval (CI) using Greenwood's method [4].

Discussion

The purpose of this review was to compare APEX Knee System survival to similar products. The survival estimate for the APEX Knee is above 99% at 5 years and at 99% at 10 years. The primary reasons for revision are similar to those reported in the registries including infection, instability, loosening, pain and fracture. This report does not account for non-reporting or competing events that preclude revision such as death.

The APEX Knee System has been shown to have an excellent survival record when compared to registry data for knee systems. Although it cannot be assured that all APEX Knee System revisions are reported to OMNI, reports from all sources are investigated and included in this report.

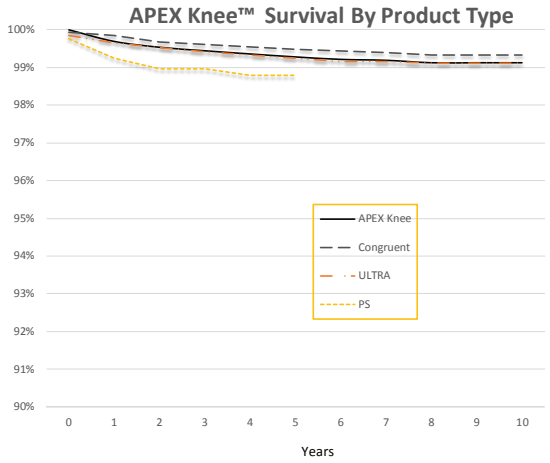

Fig 2. K-M Survival Estimates for the APEX Knee by product type

References

1. Australian Orthopaedic Association Hip and Knee Arthroplasty, Annual Report 2016

2. National Joint Registry of England and Wales, 13th Annual Report 2016

3. Swedish Knee Arthroplasty Register, Annual Report 2014

4. Kaplan EL, Meier P, Nonparametric estimation from incomplete observations. *J Am Stat Assoc* 1958;53:457-81.

A Prospective Comparison of TKA Using an Ultra Congruent, a Condylar-Stabilizing Tibial Insert, and a Posterior Stabilized Tibial Insert: Five-Year Results [28]

Introduction

This study compared the 5-year results of posterior cruciate ligament (PCL)-sacrificing total knee arthroplasty (TKA) to a post and cam-style posterior stabilized (PS) device, a deep-dish, highly-congruent condylar stabilizing (CS) device, and an ultra-congruent (UC) device. The hypothesis was that the clinical and radiographic outcomes would be equivalent.

Methods

CS and PS participants were part of a prospective, randomized trial using the Stryker Triathlon knee, and UC participants were part of a separate prospective, non-randomized protocol using the OMNI APEX Knee™ that was otherwise identical. Participants were assessed preoperatively, and postoperatively at 6 weeks, 6 months, and annually for 5 years by Knee Society Score, SF-36 v2, Lower Extremity Activity Scale (LEAS), and radiographic evaluation.

Results

There were 109 CS/PS participants at 5 years. Two re-operations were required by traumatic events, making implant survivorship 98.6%. There were 48 UC participants that completed the study. One UC subject had a loosened polyethylene insert locking bolt that required surgical intervention 3 years postoperatively. Tourniquet (P = .02) and operative (P = .01) times for the CS and UC groups were significantly shorter than the PS group. Knee Society function scores were better for the UC group than the CS and PS groups at 6 months (p = .04) and 1 year (P = .03); there were no differences for pain and motion scores. There were no significant differences in the SF-36 and LEAS scores at any time period, expect for the LEAS which was higher in UC group than CS group at 5Y (*p < .05). Only tibiofemoral alignment for UC vs. PS preoperatively (P = .04) and ROM between UC vs. CS extension at 4-years were significantly different (P = .03).

Discussion and Conclusion

These data confirm the hypothesis that there are no obvious significant differences in outcomes between the three groups at a 5-year minimum follow-up. The UC device exhibited significantly higher KSS Function scores at 6 months and 1 year, but not at 5 years.

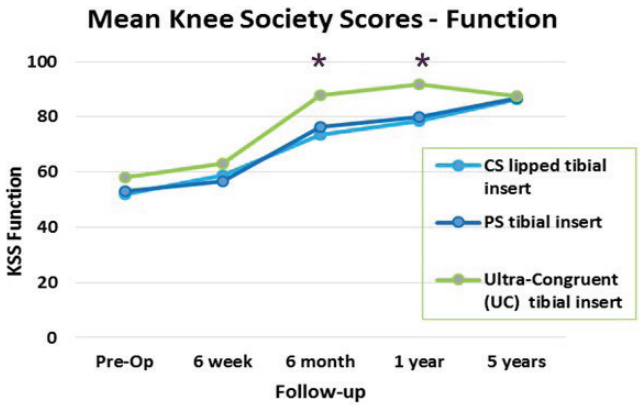

Fig 1. KS function scores were higher for UC group than PS and CS groups at 6M (*p = .04) and 1Y (*p = .03)

References

[1] Koulalis D, O'Loughlin PF, Plaskos C, Kendoff D, Pearle AD. Adjustable cutting blocks for computer-navigated total knee arthroplasty - A cadaver study. J Arthroplasty. 2010 Aug;25(5):807-11.

[2] Koulalis D, O'Loughlin PF, Plaskos C, Kendoff D, Cross MB, Pearle AD. Sequential versus automated cutting guides in computer-assisted total knee arthroplasty. Knee. 2011;18(6):436-442.

[3] Suero EM, Plaskos C, Dixon PL, Pearle AD. Adjustable cutting blocks improve alignment and surgical time in computer-assisted total knee replacement. Knee Surg Sports Traumatol Arthrosc. 2012 Sep;20(9):1736-41.

[4] Suero EM, Citak M, Claps C, Pearle AD, Plaskos C. Variations in ankle registration using two different anatomic landmarks: a radiographic study. Knee Surg Sports Traumatol Arthrosc. 2013 Dec;21(12):2759-63.

[5] Koenig JA, Suero EM, Plaskos C. Surgical accuracy and efficiency of computer-navigated TKA with a robotic cutting guide–report on the first 100 cases. J Bone Joint Surg Br. 2012;94-B(S)-XLIV:103.

[6] Koenig JA, Plaskos C. Influence of Pre-Operative Deformity on Surgical Accuracy and Time in Robotic-Assisted TKA. Bone & Joint Journal. 2013; 95-B (S-28) 62.

[7] Ponder C, Plaskos C, Cheal E. Press-fit total knee arthroplasty with a robotic-cutting guide: proof of concept and initial clinical experience. Bone & Joint Journal. 2013;95 (S-28):61.

[8] Clark TC, Schmidt FH. Robot-assisted navigation versus computer-assisted navigation in primary total knee arthroplasty: efficiency and accuracy. ISRN Orthop. 2013:794827.

[9] Nam D, Maher PA, Rebolledo BJ, Nawabi DH, McLawhorn AS, Pearle AD. Patient specific cutting guides versus an imageless, computer-assisted surgery system in total knee arthroplasty. Knee. 2013 Aug;20(4):263-7.

[10] Plaskos C, Koenig JA, Ponder CE. Robotic-assisted knee replacement surgery. In Medical Robotics: Minimally Invasive Surgery. Edited by P. Gomes. Woodhead Publishing Ltd, Cambridge, UK, 2012 pp 113-158.

[11] Hodgson AJ, Plaskos C. Robotics in orthopedic surgery: proven versus predicted benefits of commercially available systems. In Robotic Surgery: Applications and Advances, Eds. D Kendoff, AD Pearle. Future Medicine Ltd. March 2013, Pages 134-149.

[12] Revenga, C et al. Computer-Assisted Navigation Versus Conventional Total Knee Arthroplasty In A Spanish Multicenter Study. 15th EFFORT Congress, London 2014.

[13] Revenga C et al. Robotics And Navigation. 2-Year Follow-Up In Navigated TKR. Results Of A Multi-Centre Study, 16th EFORT Congress, Prague, 2015.

[14] Revenga C et al. 2-Years Follow-Up Of I-Block: Robotic Assisted Surgery Versus Navigation In Total Knee Arthroplasty. Results In Multicenter Study. 17th EFORT Congress, Geneva 2016.

[15] Hernández-Vaquero D. et al. The Use of PS or CR Models is not Sufficient to Explain the Differences in the Results of Total Knee Arthroplasty. Study of Interactions. British Journal of Medicine and Medical Research, 2016, 12(8):1-9.

[16] Dabuzhsky L, Neuhauser-Daley K, Plaskos C. Post-Operative Manipulation Rates in Robotic-Assisted TKA Using a Gap Referencing Technique. International Society for Technology in Arthroplasty (ISTA), Boston, MA, USA, Oct 2016.

[17] Keggi JM, Plaskos C. Learning Curve and Early Patient Satisfaction of Robotic-Assisted Total Knee Arthroplasty. International Society for Technology in Arthroplasty (ISTA), Boston, MA, USA, Oct 2016.

[18] Keggi JM, Plaskos C. Surgical Efficiency and Early Patient Satisfaction in Imageless Robotic-Assisted Total Knee Arthroplasty. International Congress for Joint Reconstruction (ICJR) Transatlantic Orthopaedic Conference, New York City, NY, USA, Oct 2016.

[19] Plaskos C, Todorov A, Joly C, Dabuzhsky L, Gill P, Jevsevar D, Keggi J, Koenig J, Moschetti W. Sydney S. A Novel Active Spacer System For Ligament Balancing In Robotic-Assisted Knee Arthroplasty – Concept Feasibility And Early Cadaver Results. 14th Annual Meeting of the International Society for Computer Assisted Orthopaedic Surgery, Osaka, Japan, June 2016.

[20] Moschetti WE, Keggi JM, Dabuzhsky L, Jevsevar D, Plaskos C. Dynamic Robotic-Assisted Ligament Tensioning and Gap Balancing in Total Knee Arthroplasty - A Cadaver Study. International Society for Technology in Arthroplasty (ISTA), Boston, MA, USA, Oct 2016.

[21] Moschetti WE, Keggi JM, Dabuzhsky L, Jevsevar DS, Shalhoub S, Plaskos C. Continuous assessment of ligamentous tension during total knee replacement demonstrates an anatomic cause for mid-flexion instability: A cadaveric study. Orthopeadic Research Society (ORS), San Diego, CA, USA, March 2017.

[22] Shalhoub S, Plaskos C, Moschetti WE, Keggi JM, Jevsevar DS, Dabuzhsky L, Keggi JM. Continuous Tibiofemoral Gap Assessment of Ligamentous Laxity Profiles Before and After Robotic Assisted Total Knee Replacement. 15th Annual Meeting of the International Society for Computer Assisted Orthopaedic Surgery, Aachen, Germany, June 2017.

[23] Shalhoub S, Randall AL, Lawrence JM, Keggi JM, Plaskos C. Validation of a Laxity Prediction Algorithm for Gap-Balancing Total Knee Arthroplasty. Orthopaedic Research Society Annual Meeting. New Orleans, LA, March 2018.

[24] Shalhoub S, Plaskos C, Randall AL, Keggi JM, Lawrence JM, The Effect of Gap Balancing at 0° Versus 10° of Flexion on Extension and Mid-flexion Laxity in TKA. Orthopaedic Research Society Annual Meeting. New Orleans, LA, March 2018.

[25] Shalhoub S, Lawrence D, Plaskos C, Lawrence JM. Does an increase in distraction force uniformly increase tibiofemoral gaps? Orthopaedic Research Society Annual Meeting. New Orleans, LA, March 2018.

[26] Shalhoub S, Lawrence D, Plaskos C, Lawrence JM. Ligament Tension and Balance After Robotic-Assisted TKA – Dynamic Changes with an Increasingly Applied Force. World Congress of Biomechanics. Dublin, Ireland, July 2018.

[27] Koenig JA, Plaskos C. Improving Value in TKA with Robotics – Evaluation of Clinical and Economic Results with the OMNIBotics® System. In Robotics in Knee and Hip Arthroplasty: Current Concepts, Techniques and Emerging Uses. Ed. Lonner JH. Springer (In Press) 2018.

[28] Scott DF. A Prospective Comparison of Total Knee Arthroplasty Using an Ultra-Congruent, a Condylar-Stabilizing Tibial Insert, and a Posterior Stabilized Tibial Insert: Five Year Results. AAOS 2018 Annual Meeting. New Orleans, LA, 2018.

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