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Abstract

Total knee arthroplasty is a successful procedure. However, there is still area for improvement as up to 15-20% of patients remain unsatisfied. Robotic-assisted surgery (RAS) may improve patient outcomes by providing a reproducible way of obtaining neutral mechanical alignment of the limb, which has been shown to reduce early revisions and correlate with patient reported outcomes after surgery.

We prospectively enrolled 106 patients undergoing robotic-assisted TKA by a single surgeon performing a measured-resection femur-first technique using the OMNIBotic system. Patients completed a KOOS and New Knee Society Score (KSS) pre-operatively and at 3, 6, 12, and 24 months (M) postoperatively. Changes in the five KOOS sub-scales were compared to available literature data from the FORCE – TJR cohort, as well as to individual studies reporting on conventional and computer-assisted TKA.

When compared to FORCE-TJR 6-month (M) and 2-year (Y) data, the RAS cohort had significantly higher improvements at 6M for pain (40.5 vs. 31.1, p<.001) and at 2Y for all five KOOS sub-scores. The larger improvement was due to the RAS cohort having lower baseline KOOS scores than the FORCE-TJR cohort, except for the Sports-Recreation sub-score, which was similar pre-operatively but significantly higher post-operatively for the robotic cohort. Rates of dissatisfaction with knee pain level and function using the KSS after RAS were 3.0%, 1.0%, and 2.7% at 6, 12, and 24M postoperatively, respectively.

Despite having poorer joint function and higher pain pre-operatively, robotic-assisted TKA patients achieved excellent self-reported outcomes, with significantly higher levels of improvement through two years post-surgery when compared with large national cohort studies. Further controlled clinical studies are warranted to determine if these results translate to other groups of surgeons, centers and patients.

1 Introduction

Total knee arthroplasty will continue to grow in incidence in the coming years, yet patient satisfaction with the procedure is still variable. With current literature showing satisfaction of around 80-85% (1-4), there is still significant room for improvement. Prior studies have shown that correcting varus/valgus alignment within 3 degrees of neutral has improved outcomes for patients in terms of

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early revisions and functional outcomes score (5-8). The multitude of deformities that can be present at time of surgery also add to the challenge of obtaining consistent results (9). As the demand for this procedure grows, we must continue to work towards better outcomes for our patients.

A potential solution to this problem is augmenting the surgical endeavor in a way that allows the surgeon to be more precise with his or her instrumentation, and obtain real time feedback of intraoperative decisions (7, 10-12). This is where robotics and computer assisted surgery may provide a significant benefit. The early results of this technology have been mixed when compared to conventional total knee arthroplasty, with increased operative time, excellent reproducible alignment, but overall little change in patient outcomes (13-15). Yet, the field has continued to expand and improve, with the goal of making a highly functional and reproducible total knee procedure without significantly increasing cost or surgical time (16-20). The OMNI robotic total knee arthroplasty system aims to address these issues and hopes to improve long-term patient outcomes.

We report on the three and six month and one and two year follow up in an ongoing singlesurgeon study using the OMNIBotic total knee arthroplasty (TKA) system. Post-operative patient reported functional outcomes scores are compared to prior scores in the literature on computerassisted and conventional TKA.

2 Methods

We prospectively evaluated 106 patients who underwent total knee arthroplasty using the OMNIBotic Computer Assisted Total Knee System over a 2-year period (11, 12). The system was used in a measured-resection femur-first technique and included use of a miniature bone-mounted robotic cutting-guide. The system acquires hundreds of datapoints using real-time three-dimensional mapping of the articular surface (11, 12). Patients underwent primary knee replacement with a standard medial parapatellar incision using the OMNI Apex CR/Ultra-Congruent total knee system. The patients had a standard post-operative protocol which consisted of weight bearing as tolerated and physical therapy. The post-operative outcomes were evaluated using the Knee injury and Osteoarthritis Outcome Score (KOOS), New Knee Society Score (KSS), and Veterans RAND -12 (VR-12) outcome measures. The patients were evaluated prior to the surgery and at 3, 6, 12 and 24 months post-operatively. Changes in the five KOOS subscales were compared to available literature data from FORCE – TJR (21, 22), a large, prospective, national cohort of TJR patients, as well as to individual studies (23-25) reporting on conventional and computer assisted TKA patient outcomes. A two tailed t-test was used to identify statistically significant differences between the groups. Variance in PROM score improvements were assumed to be equal to the robotic cohort when variance values were not available in the literature data. We also evaluated post-operative patient satisfaction with their procedure.

3 Results

Patients who underwent Robotic assisted surgery (RAS) for TKA reported significantly improved outcomes at 3, 6, 12 and 24 months (M) from pre-operative baseline values (tables 1 and 2). The improvement in KOOS subscales were generally higher for RAS when compared to conventional total knee arthroplasty (Conv.) at 3M for pain (32.6 RAS vs 19.7 Conv., p - value < 0.001), Symptoms (27.1 RAS vs 7.0 Conv., p-value <0.001), ADL (32.9 RAS vs 20.9 Conv., p-value < 0.001), SportsRec (20.0 RAS vs 7.6 Conv., p-value = 0.02), and QOL (40.9 RAS vs 27.8 Conv., p-value = 0.01) (Table 1). The improvement in KOOS subscales continued to be higher for RAS when compared to Conv. out to the 2Y mark as well. For pain (45.9 RAS vs 38.2 Conv., p - value = 0.001), Symptoms (39.6 RAS vs 32.1 Conv., p-value = 0.002), ADL (41.7 RAS vs 31.1, p-value < 0.001),

SportsRec (44.4 RAS vs 33.9 Conv., p-value = 0.005), and QOL (56.5 RAS vs 42.8 Conv., p-value <0.001) (Table 1).

When compared to the FORCE-TJR registry cohort 6M and 2-year (Y) data, the RAS cohort had significantly higher improvements at 6M for pain and at 2Y for all five sub-scores (table 1). The larger improvement in the RAS group was mainly due to the RAS cohort having lower baseline KOOS scores than the FORCE-TJR group, except for the Sports and Recreation sub-score, where the RAS group had a similar pre-operative but significantly higher post-operative score. Improvements in 2011 KSS patient satisfaction and functional scores at 6M were 11 and 10 points greater than those reported for conventional TKA (p-values of <0.001 for both subgroups). A mean of 31 pts for the Patient Satisfaction score indicates that on average patients were 'Satisfied' with their knee function and pain level. Rates of dissatisfaction with knee pain level and function using the KSS after RAS were 3.0%, 1.0%, and 2.7% at 6, 12, and 24M postoperatively, respectively.

4 Discussion

Robotic assisted TKA provides a way to reproducibly obtain a neutral alignment of the lower limb and aims to improve patient outcomes (10, 15, 17). The results showed increasing and sustained improvements in patient reported outcome scores and in all KOOS subscales through the first two years with use of a robotic TKA system. It also appears that patients were more satisfied after robotic knee arthroplasty when compared to prior total knee surgery results seen in the literature (4, 26, 27). This information shows how robotic assisted TKA may help to improve patient outcomes in both the short and mid-term.

In terms of study limitations, there is relatively short follow up of only 2 years. However, studies have shown that most of the expected improvement in pain and function following TKA can be seen at 6 months postoperatively, with moderate additional improvement up to the 2 year timepoint (28). Additionally, no control cohort from the same surgeon or same institution is included for comparison. The senior surgeon author who performed these cases (JAK) however only performs robotic knee replacement surgery and does not perform conventional (manual) surgery, which makes a conventional same-surgeon control cohort difficult to obtain. A third limitation is that a systematic review of the literature was not performed for comparison data. We did however compare our data with that of a large national cohort that is believed to be largely representative of the standard of care for TKA across the United States (20). Finally, we did have a drop out of patients within the study, with 75 patients reporting outcomes at 2Y, down from 104 patients at the 3M mark. However, we are still collecting final data, and expect the RAS 2.7% KSS dissatisfaction rate to drop even lower as we finalize our 2Y follow up.

5 Conclusion

Robotic assisted TKA shows excellent results in terms of patient reported outcomes through 2 years post-operatively in our study. It appears that these patients have improved outcome scores when compared to conventional total knee arthroplasty during this period. Further long-term data needs to be considered to draw major conclusions, however, robotic assisted TKA provides a promising avenue in the quest for continued patient satisfaction and patient outcomes for total knee arthroplasty, with 2-year data now available.

	RAS-TKA								Gøthesen 2014 [21]				Roos 2003 [23]		Li 2017 [19]		Lyman 2018 [20]			
	Pre-Op	3M	6M	1Y	2Y	ΔPre-op & 3M		∆ Pre- op & 1Y	∆ Pre- op & 2Y	ΔPre & 3		P value 3M	P value 3M	∆ Pre-op & 6M	P value 6M	∆ Pre- op & 6M	P value 6M	∆ Pre- op & 2Y	P value 1Y-2Y	P value 2Y-2Y
KOOS										Conv.	CAS	∆RAS vs	∆RAS vs	Conv.	∆RAS vs	Reg.	∆RAS vs	Reg.	∆RAS vs	∆RAS vs
Subscale	n=106	n=104	n=101	n=101	n=74					n= 90	n= 92	∆Conv.	∆CAS.	n=97	∆Conv.	n=2,792	∆Reg	n = 1114	∆Reg	∆Reg
Pain	42.6	75.3	82.8	85.5	86.7	32.6	40.5	43.8	45.9	19.7	27.4	<.001*	0.06	41	0.86	31.1	< 0.001*	38.2	0.002*	0.001*
Symptoms	45.2	72.4	78.0	80.1	83.4	27.1	32.8	35.5	39.6	7.0	13.1	<.001*	<.001*	25	0.01*	-	-	32.1	0.087	0.002*
ADL	45.3	78.6	83.8	86.1	86.1	32.9	38.5	41.5	41.7	20.9	26.3	<.001*	0.01*	36	0.38			31.1	<.001*	<.001*
SportRec	20.5	40.7	49.7	59.7	64.2	20.0	29.0	39.0	44.4	7.6	21.1	0.02*	0.84	32	0.57			33.9	0.133	0.005*
QOL	21.1	62.2	67.5	72.4	76.5	40.9	46.6	52.2	56.5	27.8	35.0	0.01*	0.01*	40	0.01*	-		42.8	<.001*	<.001*

Table 1 – KOOS subscale scores for robotics assisted total knee arthroplasty (RAS -TKA) and literature data (*p<0.05)

Months (M), Years (Y), Conventional TKA (Conv.), Computer-assisted TKA (CAS), Registry Data (REG), Robotics Assisted Total Knee Replacement (RAS), Knee Injury and Osteoarthritis Outcome Score (KOOS)

Table 2 – 2011 Knee Society Scores (KSS) for RAS-TKA and literature data (*p<0.05)

				Uefuji 201							
	Pre-Op	3M	6M	1Y	2Y	Δ Pre- op & 3M	Δ Pre- op & 6M	Pre-Op	6M	∆ Pre- op & 6M	P value 6M ΔRAS vs
2011 KSS	n=106	n=104	n=101	n=101	n=75	n=104	n=101	n=52	n=52		∆Conv.
Expectation (15 pts)	14.0	10.2	10.2	10.5	10.1			12	10	-	-
Satisfaction (40 pts)	12.1	29.4	31.2	32.3	32.8	17.3	19.20	14	22	8	<.001*
Functional (100 pts)	36.7	62.2	67.3	70.5	71.5	25.3	30.5	44	64	20	<.001*
Objective	22.0	72.9	73.8	74.7	74.7	50.9	51.8	-	-	-	-

Months (M), Years (Y), Conventional TKA (Conv.), Computer-assisted TKA (CAS), Registry Data (REG), Robotics Assisted Total Knee Replacement (RAS), Knee Society Score (KSS)

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