

Contents lists available at [ScienceDirect](#)

The Knee



Survivorship and patient satisfaction of robotic-assisted medial unicompartmental knee arthroplasty at a minimum two-year follow-up

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ARTICLE INFO

Article history:

Received 29 July 2016

Received in revised form 28 November 2016

Accepted 8 December 2016

Available online xxxxx

Keywords:

Unicompartmental knee arthroplasty

UKA

Robot

Robotic

Survivorship

Satisfaction

ABSTRACT

Background: Successful clinical outcomes following unicompartmental knee arthroplasty (UKA) depend on lower limb alignment, soft tissue balance and component positioning, which can be difficult to control using manual instrumentation. Although robotic-assisted surgery more reliably controls these surgical factors, studies assessing outcomes of robotic-assisted UKA are lacking. Therefore, a prospective multicenter study was performed to assess outcomes of robotic-assisted UKA.

Methods: A total of 1007 consecutive patients (1135 knees) underwent robotic-assisted medial UKA surgery from six surgeons at separate institutions between March 2009 and December 2011. All patients received a fixed-bearing metal-backed onlay implant as tibial component. Each patient was contacted at minimum two-year follow-up and asked a series of five questions to determine survivorship and patient satisfaction. Worst-case scenario analysis was performed whereby all patients were considered as revision when they declined participation in the study.

Results: Data was collected for 797 patients (909 knees) with average follow-up of 29.6 months (range: 22–52 months). At 2.5-years of follow-up, 11 knees were reported as revised, which resulted in a survivorship of 98.8%. Thirty-five patients declined participation in the study yielding a worst-case survivorship of 96.0%. Of all patients without revision, 92% was either very satisfied or satisfied with their knee function.

Conclusion: In this multicenter study, robotic-assisted UKA was found to have high survivorship and satisfaction rate at short-term follow-up. Prospective comparison studies with longer follow-up are necessary in order to compare survivorship and satisfaction rates of robotic-assisted UKA to conventional UKA and total knee arthroplasty.

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1. Introduction

Unicompartmental knee arthroplasty (UKA) is an increasingly popular surgical treatment for isolated medial compartment osteoarthritis (OA) of the knee [1]. Many distinct advantages of UKA compared to total knee arthroplasty (TKA) have been reported

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<http://dx.doi.org/10.1016/j.knee.2016.12.001>

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Please cite this article as: Pearle AD, et al, Survivorship and patient satisfaction of robotic-assisted medial unicompartmental knee arthroplasty at a minimum two-year follow-up, *Knee* (2016), <http://dx.doi.org/10.1016/j.knee.2016.12.001>

including lower perioperative morbidity [2,3], lower risk for infection [4], less blood loss [5], accelerated recovery [6,7] and improved range of motion [2,7]. A recent cost-effectiveness study demonstrated that medial UKA is preferable to TKA with decreased lifetime costs and improved quality of life in patients over 65 years of age [8].

In spite of these advantages, UKA may be an underutilized procedure [9,10]. This may be partially explained by concerns about short and long-term survivorship of UKA compared to TKA. Registry data demonstrated that 10-year survivorship of UKA (85–90%) is lower than TKA survivorship (95%) [11–13]. Recent literature also showed, however, that UKA performed in high-volume centers has a higher survivorship compared to low-volume UKA centers [14,15]. Several authors have shown that good results with UKA can be achieved by reporting a 10-year survivorship over 95% in high-volume UKA centers [16–19].

Recently, robotic-assisted surgery has been shown to reliably improve lower leg alignment [20–24], soft tissue balancing [25] and implant positioning [26–29] when compared to conventional UKA surgery. Since failure of UKA is commonly associated with technical errors of malalignment, instability and implant malpositioning [30–35], one would expect better results with robotic-assisted surgery; however early and long-term survivorship data of robotic-assisted UKA are lacking [36]. Therefore, the purpose of this multicenter study was to determine survivorship and patient satisfaction of robotic-assisted UKA at short-term follow-up.

2. Methods

2.1. Study design

In this prospective multicenter study, all patients were included who received a medial UKA with a fixed-bearing metal backed onlay tibial component between March 2009 and December 2011 (Figure 1). These patients represent the initial series of robotic-assisted MCK Medial Onlay UKAs (MAKO Surgical Corp., Ft. Lauderdale, FL, USA) performed by six surgeons, starting from the implant release date of March 2009. This corresponded to the release of the Robotic Arm Interactive Orthopedic (RIO) System (MAKO Surgical Corp., Ft. Lauderdale, FL, USA), a third generation robot-guided surgical instrument. Prior to this study, all surgeons participated in a knee course, in which the surgeons practiced robotic-assisted medial UKA on two to five cadaveric knees. Because half of the participating surgeons had previous robotic experience with UKA, this series included the robotic technology learning curve for three surgeons, and the implant learning curve for all six surgeons, both defined as the first 30 cases with the new technique and implant. The participating surgeons exhibited varying procedural volumes for robotic-assisted UKA during the study period, ranging from 4.6 to 15.8 procedures per month. The surgical indications for medial UKA were left to the discretion of the individual surgeons. This study was approved under the Western Institutional Review Board (WIRB) for all centers.

2.2. Robot characteristics

Accuracy of the RIO system has previously been well characterized. Mechanical alignment with this system is accurate within 1.6° of the preoperative plan [37], soft tissue balancing is accurate within 0.53 mm of the preoperative plan at all flexion angles [25] and component positioning is accurate for the femoral component within 0.8 mm and 0.9° of the original plan and for the



Figure 1. The MCK Medial Onlay UKA is shown with the femoral component, tibial component and the ultra-high-molecular-weight polyethylene (UHMWPE) insert.

tibial component within 0.9 mm and 1.7° of the preoperative plan in all directions [28]. Robotic-assisted UKA surgery has been shown to be more accurate and reliable when compared to manual UKA surgery [26,29,36,38].

2.3. Data collection

In order to collect data on survivorship and patient satisfaction, a research coordinator contacted all patients by phone to complete a survey at a minimum of two years postoperatively. Patients were asked a series of questions to determine their implant survivorship and overall satisfaction with the function of their operated knee. The questions included a confirmation of the patient's surgeon and implant and whether they have had their implant removed, revised, or reoperated for any reason. If the patient answered yes, the patient was asked for the date and reason of revision or reoperation, and whether or not they returned to their original surgeon. If the patients answered no, the patient was asked to rate their overall satisfaction with their operated knee on the following five-level Likert scale: "very satisfied", "satisfied", "neutral", "dissatisfied", or "very dissatisfied". Phone contact for each patient was attempted three times before they were considered lost to follow-up.

Patients were classified in different age groups (i.e. ≤ 59 years, 60–69 years, 70–79 years and ≥ 80 years) with age defined as age at time of surgery. Patients were also classified in different body mass index (BMI) groups according to the World Health Organization (i.e. normal weight (18.5–24.9), overweight (25.0–29.9), class I obesity (30.0–34.9) and class II–III obesity (≥ 35.0)). The annual revision rate was used to compare these different age and BMI groups. This parameter is defined as the "revision rate per 100 observed component years" and is calculated by dividing the number of failures by the total observed component years. This outcome corrects for different follow-up intervals and number of implants and therefore enables comparison between different groups or studies. This method is frequently used by other studies reporting UKA revision rates [39–42].

2.4. Statistical analysis

All statistical analyses were performed using SAS Software for Windows 9.3 (SAS Institute Inc., Cary, NC, USA). In order to assess robotic-assisted UKA survivorship, revision for any reason was determined. Additionally, a "worst-case" analysis was performed whereby all patients who declined to participate in the follow-up survey considered as revision, which has been reported in orthopedic studies [17,43]. Survivorship from surgery to revision was calculated and graphed according to the Kaplan–Meier method and reported with 95% confidence interval (CI) [44]. The log-rank test was then used to compare survivorship between surgeons. Independent t-tests were used to assess the learning curve of all surgeons by comparing revision rate in the first 30 cases to revision rate in the remaining cases. To our best knowledge, no statistical method can be used to assess differences in annual revision rate as stated by other studies [39,40,42,45]. All tests were two-sided and a p-value of < 0.05 was used to determine statistical significance.

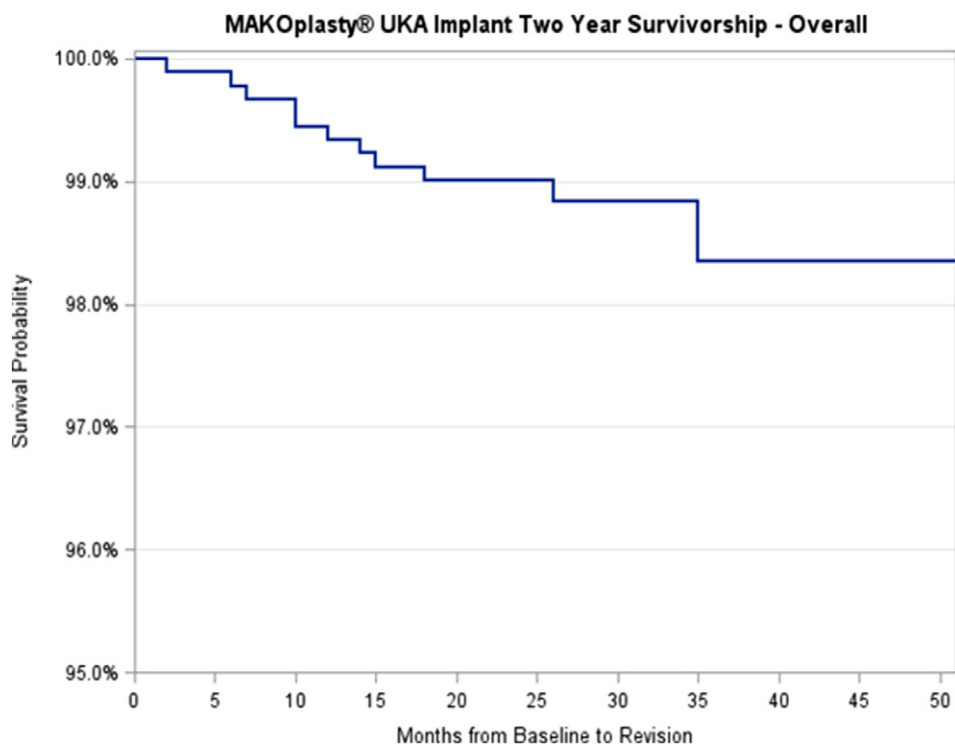


Figure 2. The Kaplan–Meier curve shows the survivorship of this cohort of 909 UKAs.

Table 1

Revisions per 100 observed years (annual revision rate) in different age groups.

Age group	Mean age	Number of UKA	Mean follow-up (months)	Number of revisions	Total observed years	Annual revision rate
≤59 years	54.3	154	29.2	4	374.5	1.07
60–69	65.3	323	29.1	3	784.4	0.38
70–79	74.7	303	30.2	3	761.8	0.39
≥80 years	83.1	129	29.9	1	321.9	0.31
Total	69.1	909	29.6	11	2242.2	0.49

UKA indicates unicompartmental knee arthroplasty.

3. Results

A total of 1007 consecutive patients (1135 knees) underwent robotic-assisted medial UKA surgery. Thirty-five patients declined study participation, 15 patients were deceased, and 160 patients were lost to follow-up (i.e. could not be contacted). A total of 797 patients (909 knees) were successfully enrolled in the study, yielding an 80% follow-up rate. A total of 443 males (56%) and 352 females (44%) were included (gender was missing in two patients). Of all patients, 685 patients (86%) received unilateral UKA while 112 patients (14%) received bilateral UKA. Average age (\pm standard deviation (SD)) at surgery was 69.1 ± 9.5 years (range: 39–93 years) and the average BMI was 29.4 ± 4.9 (range: 19–48; BMI was missing in 18 patients). Average follow-up was 29.6 months (range: 22–52 months).

Eleven revisions (three males, eight females) were reported in 909 knees, which resulted in a survivorship of 98.8% (95% CI: 97.8%–99.3%) at mean follow-up of 2.5 years (Figure 2). The annual revision rate was 0.49 revisions per year (Table 1). Fifteen patients reported reoperations in which no original implant component was removed. Worst-case scenario analysis (with patients who declined to participate considered as failure) revealed a survivorship of 96.0% (95% CI: 94.7%–97.0%). Modes of failures were unexplained pain in five patients (45%), aseptic loosening in three patients (27%), infection in one patient (nine percent), tibial subsidence in one patient (nine percent) and OA progression in one patient (nine percent). Reasons for reoperation included soft tissue tears and cement debridement but were not further specified.

When comparing annual revision rates in different age groups, it was found that patients older than 80 years had the lowest annual revision rate (0.31), while patients younger than 60 years had the highest annual revision rate (1.07) (Table 1). When comparing annual revision rate in different BMI groups, the highest revision rate was found in patients with a BMI above 35 (1.36) while patients with normal weight (BMI 18.5–24.9) had the lowest annual revision rate (0.28) (Table 2).

Of all patients without revision, 71% reported feeling very satisfied with their overall operated knee function and 21% of patients were satisfied, while three percent reported feeling dissatisfied and one percent reported feeling very dissatisfied. Four percent of patients were neither satisfied nor dissatisfied (Figure 3).

No significant differences were seen between the surgeons concerning revision or reoperation (Figure 4). For all surgeons, no significant learning curve was detected with regard to revision or reoperation (all $p > 0.05$).

4. Discussion

This is the first large prospective, multicenter study that has assessed survivorship and satisfaction rate of robotic-assisted UKA. At short-term follow-up, a survivorship of 98.8% in 797 patients (909 knees) was found, while worst-case scenario analysis, with all patients declining participation considered as revised, revealed a survivorship of 96.0%. Furthermore, 92% of the patients were either very satisfied or satisfied with their overall knee function.

When comparing our survivorship with other large cohort studies and registry studies that report two to three year survivorship of UKA over the last decade, we found high survivorship (98.8%) in our large multicenter cohort compared to other cohort studies (average other studies 97.0%, Table 3 [17,18,46–50]). Indeed, to our knowledge, the UKA survivorship rate of 98.8% is the highest reported rate in the literature at this early time point of any large cohort studies (Table 3 [11,12,51,52]). In this study, a patient satisfaction rate of 92% was found at 2.5-year follow-up, which is similar to other cohort studies that reported UKA satisfaction scores of overall knee function at two-year follow-up (91.5%, Table 4 [53–62]) and higher than the satisfaction rates of registry data (85.0%, Table 4 [12,52,63]).

Table 2

Revisions per 100 observed years (annual revision rate) in different BMI groups.

BMI	Mean BMI	Number of UKA	Mean follow-up (months)	Number of revisions	Total observed years	Annual revision rate
Missing	0	18	33.8	0	50.7	0.00
18.5–24.9	23.1	143	29.5	1	351.3	0.28
25.0–29.9	27.5	401	29.5	4	986.1	0.41
30.0–34.9	32.2	228	29.5	2	561.3	0.36
≥35.0	38.0	119	29.6	4	293.2	1.36
Total	29.4	909	29.6	11	2242.2	0.49

UKA indicates unicompartmental knee arthroplasty.

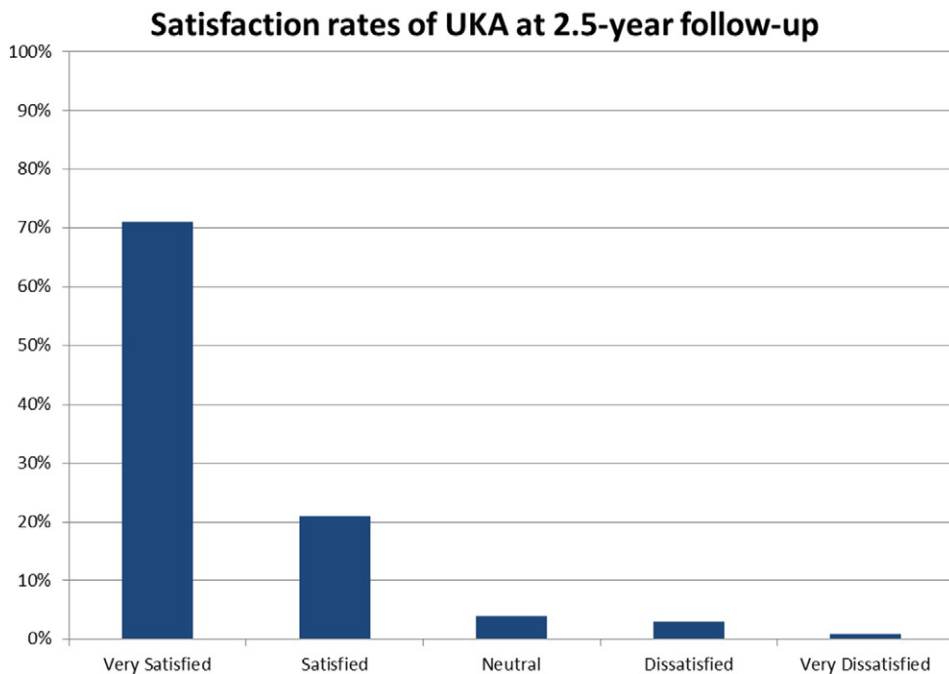


Figure 3. Patient satisfaction results at two-year follow-up are shown with 92% of patients reporting either very satisfied or satisfied regarding the overall function of their operated knee.

A possible explanation for the low revision rate of robotic-assisted UKA at short-term follow-up is the ability of robotic-assisted surgery to control surgical variables. Early failures following UKA are associated with technical errors of implant malpositioning and lower limb malalignment [30–34,64]. Previous reports have demonstrated that robotic-assisted UKA can

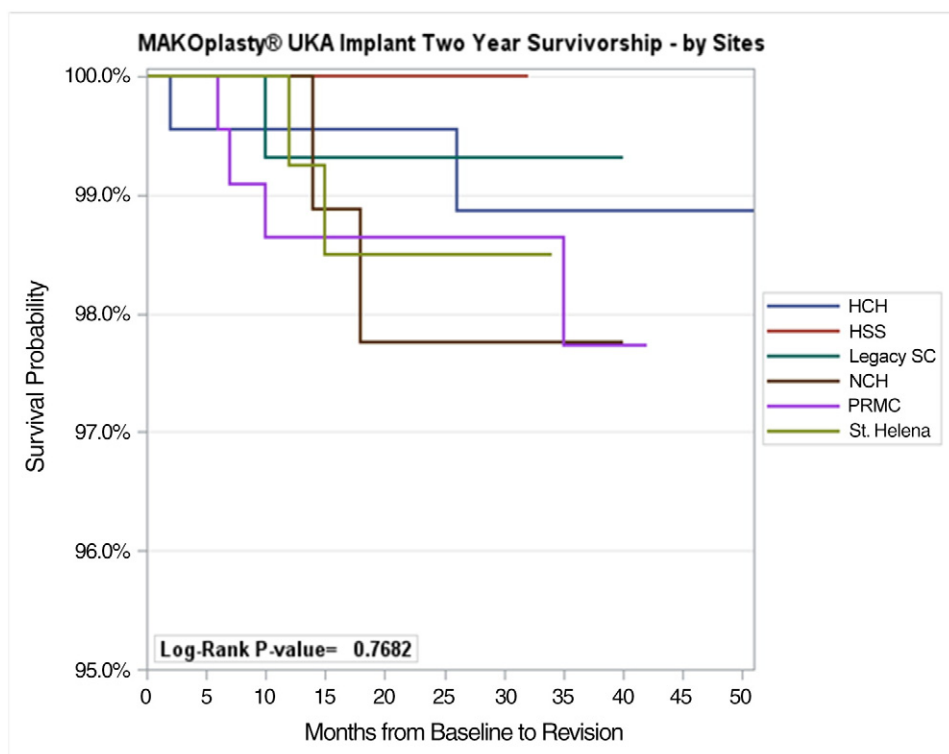


Figure 4. Kaplan–Meier curve is shown with the six centers that performed UKA procedures. No significant differences were seen between the centers ($p = 0.768$).

Table 3

Studies and annual registries reporting two to three year UKA survivorship.

Author/country	Year published	Start cohort	End cohort	UKA (n)	Survivorship at two to three year follow-up
Cohort studies					
Eickmann et al. [46]	2006	1984	1998	411	96.0%
Hamilton et al. [47]	2014	2001	2004	517	97.0%
Liebs and Herzberg [48]	2013	2002	2009	401	94.7%
Lim et al. [49]	2012	2001	2011	400	97.4%
Pandit et al. [18]	2011	1998	2009	1000	98.0%
Vorlat et al. [50]	2006	1988	1996	149	97.8%
Yoshida et al. [17]	2013	2002	2011	1279	98.3%
Annual registries					
Australia [11] ^a	2014	1999	2013	41,250	95.1%
New Zealand [12] ^a	2013	2000	2012	7388	96.1%
Sweden [13] ^a	2013	1999	2012		95.3%
United Kingdom [52]	2013	2003	2010	30,795	95.6%
Cohort studies					97.0%
Annual registries					95.5%

UKA indicates unicompartmental knee arthroplasty.

^a These registries reported combined medial and lateral UKA survivorship with predominantly medial UKA.

reduce variation in implant positioning in cadaveric studies [26] and improve postoperative implant positioning in patients undergoing UKA compared with conventional manual techniques [27–29]. Additionally, it has been shown that lower limb realignment is reliably controlled by robotic-assisted techniques [20–22,29]. As such, our favorable survivorship data using robotic assistance could be explained by improved control of surgical technique compared with manual approaches, which may decrease the risk of early aseptic loosening due to malpositioning and early disease progress secondary to overcorrection of lower leg alignment (Figure 5). Indeed, a recent systematic review showed that aseptic loosening (36%) and OA progression (20%) are the most common failure modes in medial UKA [35], which were less frequently seen in this study (27% and nine percent, respectively, Figure 6). However, as some patients declined participation, a “worst-case” survivorship of 96.0% was calculated which would be consistent with prior cohort studies. In this “worst-case” survivorship scenario, clinical benefit of robotic-assisted UKA versus manual techniques would not be confirmed. Therefore, additional clinical outcome studies of robotic-assisted UKA are clearly necessary to corroborate our findings.

In this study cohort, an overall annual revision rate of 0.49 was found and the annual revision rate was higher in patients younger than 60 years (1.07). This finding is similar to several registries that reported higher revision rates in younger patients [41,65–67]. The higher demands and activity level in younger patients could explain the differences in revision when compared to older patients (0.31). Additionally, a higher annual revision rate in patients with obesity was noted. In our study, patients with normal weight had an annual revision rate of 0.28 while patients with class II–III obesity had an annual revision rate of 1.36; these findings are similar to current literature findings. Haughom and colleagues showed in a database analysis of 2316 UKAs that BMI was a significant risk factor for revision [68], while Kandil and colleagues showed in a national database study of 15,770 UKAs that obesity and morbid obesity were risk factors for complications and revisions [69]. Interestingly, Bonutti et al. [70] and Berend et al. [71] showed that a higher BMI was associated with higher revision rate at two to three year

Table 4

Cohort studies and annual registries reporting satisfaction of patients following medial UKA in excellent/good and fair/poor.

	Year	No of UKA	Mean FU (year)	Excellent/good	Fair/poor
Cohort studies					
Bhattacharya et al. [53]	2012	131	4.3	93.1%	6.9%
Biswal and Brighton [54]	2010	116	5.7	91.4%	8.4%
Gleeson et al. [55]	2004	101	2.0	77.5%	22.5%
Pietschmann et al. [56]	2013	131	4.2	93.1%	6.9%
Saxler et al. [57]	2004	355	5.5	92.0%	8.0%
Schroer et al. [58]	2013	83	3.6	87.0%	13.0%
Streit et al. [59]	2015	107	5.0	94.4%	5.6%
Von Keudell et al. [60]	2014	141	6.1	94.3%	5.7%
Walker et al. [61]	2014	109	4.4	94.5%	5.5%
Wong et al. [62]	2014	51	4.3	98.0%	2.0%
Annual registries					
New Zealand [12]	2015	2034		88.0%	12.0%
Sweden [63]	2000	21,164		83.0%	17.0%
United Kingdom [52]	2014	25,982		84.1%	15.9%
Cohort studies				91.5%	8.5%
Annual registries				85.0%	15.0%

UKA indicates unicompartmental knee arthroplasty; FU, follow-up.

Please cite this article as: Pearle AD, et al, Survivorship and patient satisfaction of robotic-assisted medial unicompartmental knee arthroplasty at a minimum two-year follow-up, *Knee* (2016), <http://dx.doi.org/10.1016/j.knee.2016.12.001>

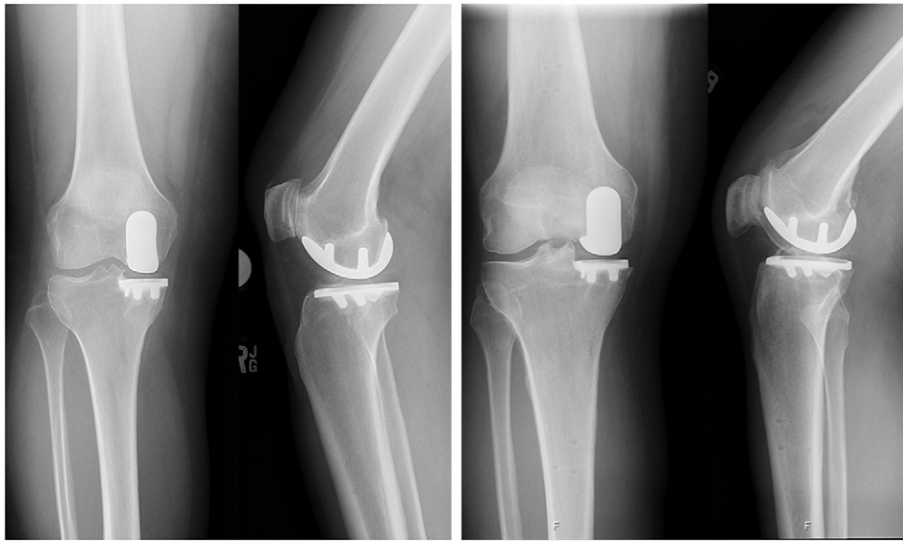


Figure 5. Well-fixed components are shown at two-year follow-up.

follow-up, while other studies could not find a correlation between BMI and revision rates at long-term follow-up [72–77]. Our findings of increased annual revision rate in younger and obese patients in spite of the presumed standardization of the surgical technique with the robotic assistance confirm that these modifiable (BMI) and non-modifiable (age) factors influence survivorship in UKA. From our data, it is not possible to assess if robotic UKA surgery has lower revision rates in patients with younger age or higher BMI when compared to conventional UKA. Comparative studies of manual and robotic UKA are necessary to assess revision rates in these specific patient groups.

Multiple studies have demonstrated that conclusions related to the cost-effectiveness of UKA, TKA and high tibial osteotomy (HTO) are highly sensitive to annual revision rates [8,78–80]. For example, it has been demonstrated that UKA is cost-effective compared to TKA if the annual revision rate is <4.0 per year in 78 year old patients [78]. In patients between ages 50 and 60, UKA becomes the preferred cost-effective treatment for medial compartment OA compared to TKA and HTO when the annual conversion rate drops below 2.0 per year [79]. Our findings of annual conversion rates of 0.39 per year in the 70–79 year old age group and 1.07 per year in the under 60 year old age group fall well below the threshold values to ensure that UKA is the preferred, cost-effective treatment in both these young and old age groups. Furthermore, Moschetti et al. compared cost-effectiveness of robotic-assisted UKA with manual UKA [80]. The authors used a two-year failure rate of 1.2% for robotic-assisted UKA and 3.1% for manual UKA, similar to the findings in this study and pooled manual UKA studies (Table 3), respectively. Taking robotic equipment costs into consideration, these authors found that robotic-assisted UKA is a cost-effective procedure when compared to manual UKA if the case volume exceeds 94 cases per year. These numbers indicate that robotic-assisted UKA is currently cost-effective in high-volume centers. Taken together, these studies suggest that the use of robotic technologies that

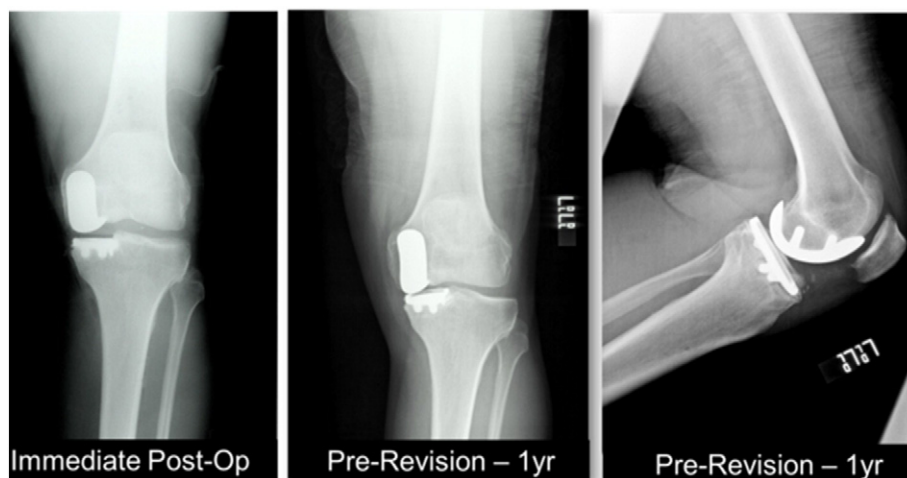


Figure 6. Immediate postoperative and at one-year follow-up radiographs are shown of a patient with a revised UKA. Loosening of the tibial baseplate at the anterior side is evident at one-year follow-up.

control UKA surgical technique and improve survivorship may change conclusions regarding the cost-effectiveness of various procedures for treatment of isolated medial compartment degenerative joint disease.

There are several limitations to this study. The most important limitation is that 20% of patients were lost to follow-up. Most of these patients could not be included because they could not be reached by serial phone calls. However, a small percentage of patients declined to participate, which includes a potential bias. Therefore, a worst-case scenario survivorship analysis was performed, which showed comparable survivorship to that reported in registries and most manual cohort studies. A follow-up rate of 80% is not unexpected in a multicenter study of this scale performed in the United States (US) [81–85]. With a follow-up rate of 80%, this study still reports the survivorship and satisfaction rate of 909 robotic-assisted UKA procedures and is, to our knowledge, the largest US multicenter study reporting outcomes following UKA surgery. Findings in this study report that outcomes of robotic-assisted UKA surgery are between superior to similar to conventional UKA and therefore future studies are necessary to further compare outcomes of both procedures. A second limitation was that this study only assessed survivorship and satisfaction rate of robotic-assisted UKA surgery, while functional and radiographic outcomes were not obtained. Several other studies have previously reported radiologic outcomes and accuracy of robotic-assisted UKA surgery [25,26,28,29,37,38]. In addition, several recent studies have reported the short-term functional outcomes of robotic-assisted surgery [86–88]. A third limitation was that due to the nature of a multicenter study and the different surgeon case volumes, standardization of surgical indication was not part of the study design and no distinct exclusion criteria were specified for this study. However, because surgical indications were left to the discretion of the multiple surgeons in the study, these outcomes may be generalizable to the robotic UKA experience in the US. A fourth limitation was that medical notes were not reviewed and that all data was patient-reported, which may contain a potential bias. Lastly, follow-up was relatively short and long-term follow-up is needed. This study is ongoing with patient contact planned at five and ten years postoperatively.

5. Conclusion

In this multicenter study, robotic-assisted UKA was found to have high survivorship and high satisfaction rate at short-term follow-up. Since worst-case scenario analysis revealed similar survivorship to manual UKA, prospective comparative studies with longer follow-up and high follow-up rate are necessary in order to further compare survivorship and satisfaction rates of robotic-assisted UKA to conventional UKA and to TKA.

Conflict of interest

The participating institutions received funding from MAKO Surgical Corporation for performing this study. Author ADP, TMC, TAB and MWR have received personal funding from MAKO Surgical Corporation over the last three years.

Acknowledgments

We would like to thank Kaitlin Carroll, BS, for her assistance in writing the manuscript and thank Jon Douchis, MD, and Fredrick Buechel Jr. as surgeons who performed surgery in a subset of patients. Finally, we would like to thank Michael Conditt and Sharon Branch from Stryker (Stryker Corporation, Kalamazoo, MI, USA) for their assistance in performing this study.

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