

Two Year Outcomes of Robotic Arm Unicompartmental Knee Arthroplasty

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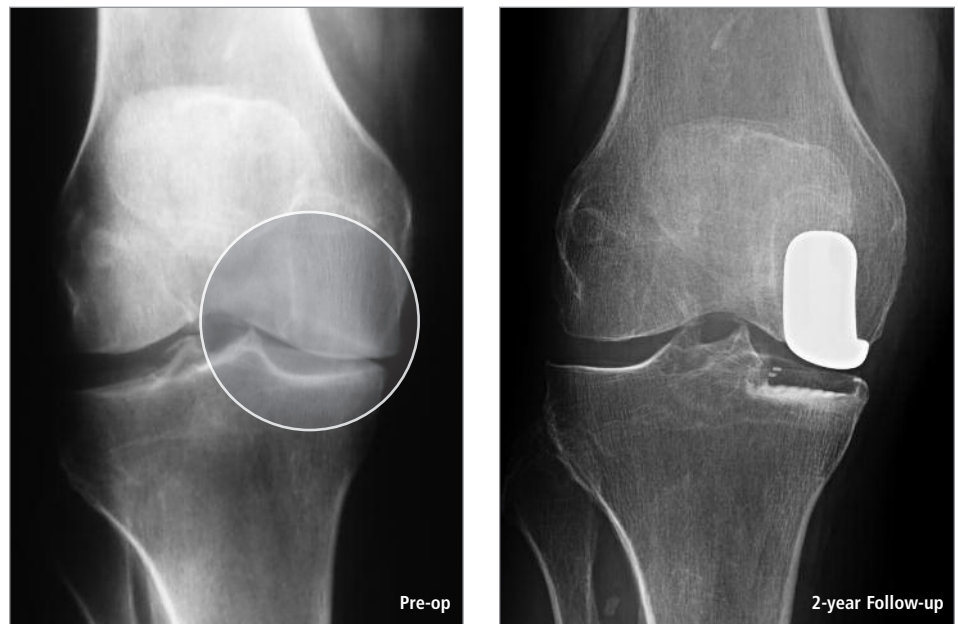
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Clinical outcomes of UKA procedures are sensitive to malalignment of the components, and thus show significant variability in the literature. The original MAKOplasty® procedure addresses isolated medial compartment osteoarthritis with the classic indications of UKA. Using precision planning through patient specific 3D modeling and reconstruction, the MAKOplasty® robotic arm gives the surgeon control of resurfacing the knee joint, allowing for consistent precision according to the previously chosen plan. Through the precise preparation of bone surfaces and inter-component alignment, MAKOplasty® is designed to significantly increase accuracy and decrease malalignment, thus increasing post-operative physical and function outcomes. This paper evaluates two year clinical outcomes of this novel surgical procedure.

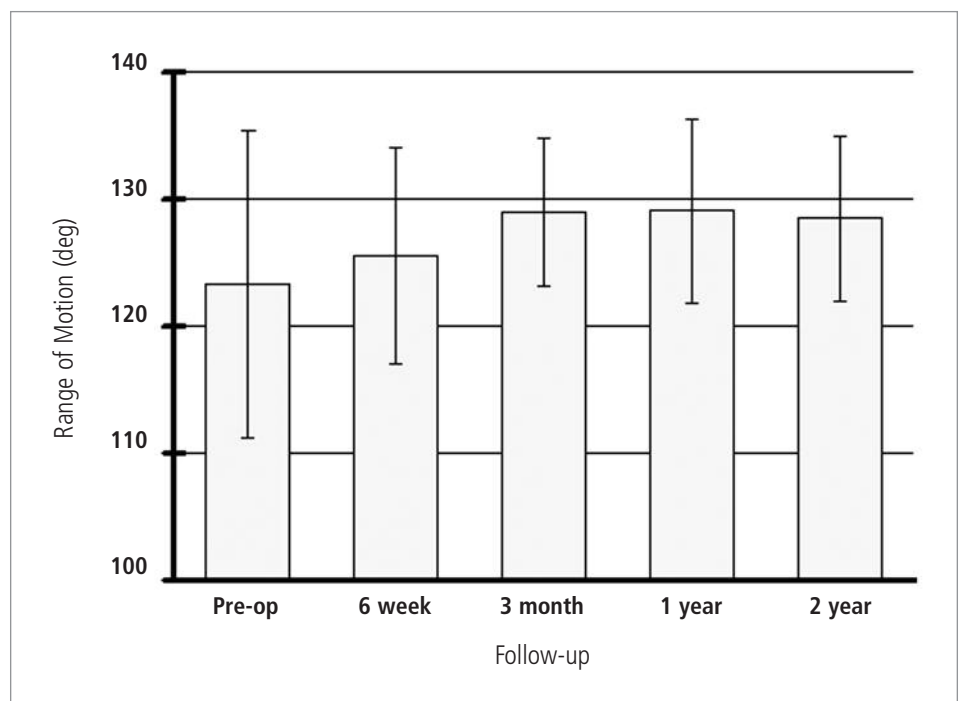
Figure 1: Resurfacing UKA components with an all-poly inlay tibial component.



Clinical Outcomes

The first seventy-three (42 male, 31 female) patients (average age: 71 ± 10 yrs) to receive a robotic arm assisted UKA (first procedure June 2006), the average follow-up was 30 months (range: 24 to 40 months). The average patient BMI was $29 \pm 5 \text{ kg/m}^2$ with 38% categorized as obese. The tibial component for all patients was an all-poly inlay design (Figure 1). At two year follow up, it was found that the average range of motion significantly increased to $129 \pm 6.5^\circ$ compared with $123.3 \pm 12.1^\circ$ pre-operatively ($p < 0.05$, Figure 2). Post-operative Knee Society Knee and Functional scores also increased from 43.8 to 96.75 ($p < 0.0001$) and 63.9 to 80 ($p < 0.0001$), respectively (Figure 3).

Figure 2: Progression of improvements in range of motion.

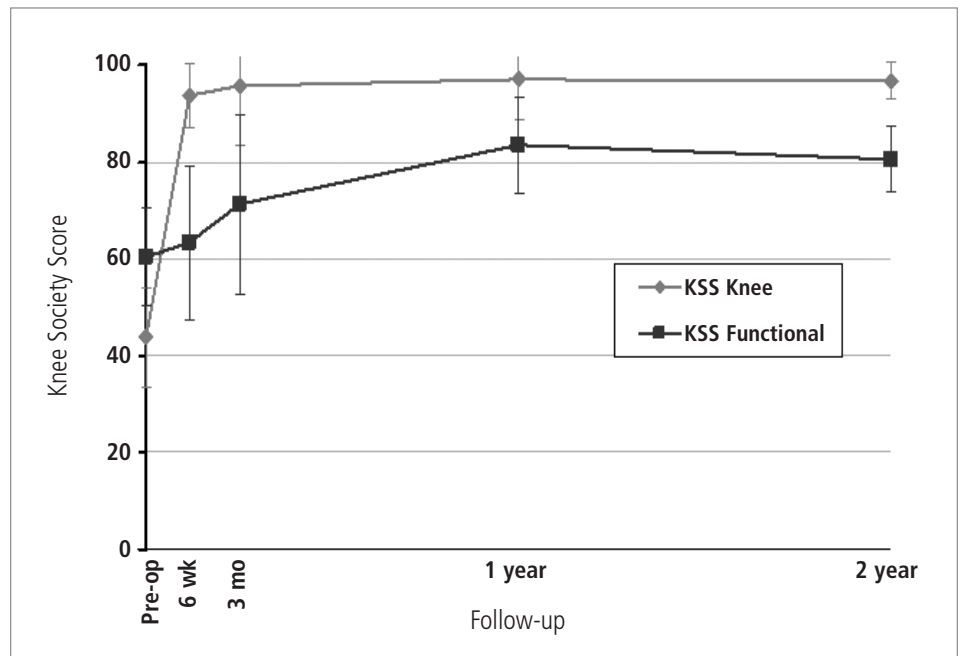


Complications:

Of the 73 two year post-operative patients, two have been revised, for a

two year clinical failure rate of 2.34%. Both revisions were due to loosening of the tibial component and occurred 23.6 and 17.5 months, respectively, after the index procedure. The first patient was revised to a TKA. The second patient was revised to a unicompartmental onlay tibial component. At 17.5 months, this patient (age 50, BMI 27.2) presented with weight bearing pain in the medial compartment. Upon explantation of the inlay component, the surgeon observed perfect cement-to-bone integration and noted that the failure was due to debonding of the undersurface of the poly to the cement. Optimal alignment of the femur to the tibia remained intact and the patient showed no signs of progressing OA disease. The bone preserving nature of the original MAKOplasty® procedure allowed the surgeon to convert the patient to an onlay component with minimal bone resection instead of conversion to a TKA. (Figures 4a and 4b). Since this initial series of patients, a cement channel has been added to the inlay design to improve cement fixation effectiveness. In addition, the

Figure 3: Knee Society Scores at each follow-up visit.



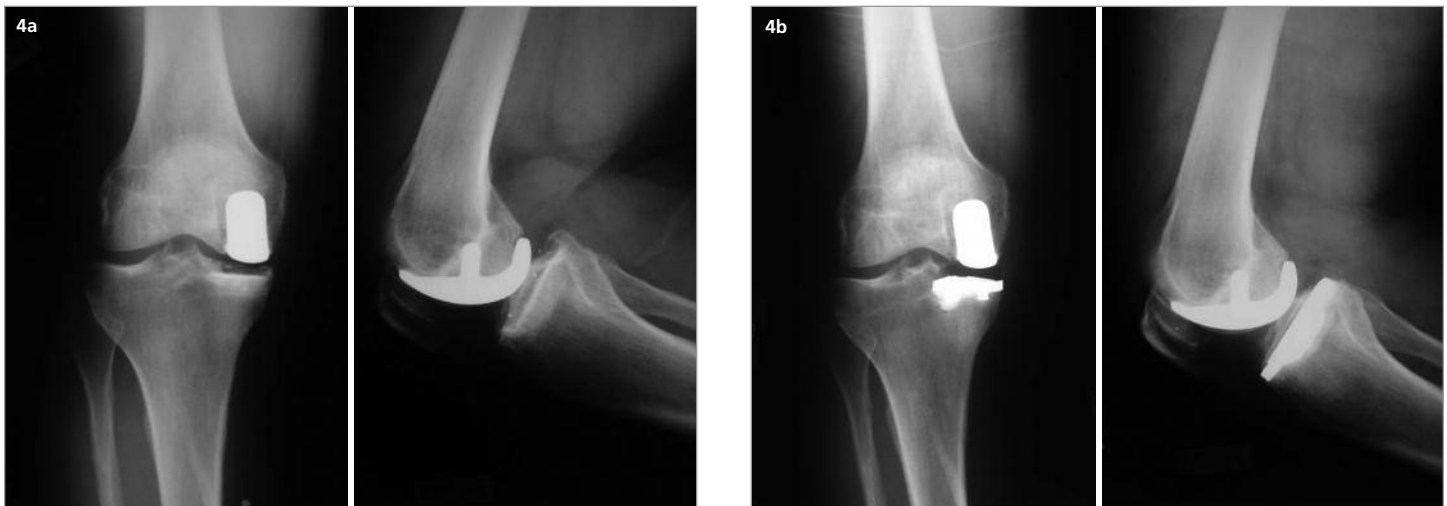
undersurface of the tibial component has since been removed and replaced with a dovetail channel to improve lift-off resistance of the tibial inlay (Figure 5). This new design has shown to

be 10 times stronger in laboratory push out tests (data on file).

Conclusions:

This initial series of robotic arm guided

Figures 4a and 4b: Original MAKOplasty® inlay component (4a) allowed the surgeon to convert the patient to an onlay procedure (4b).



UKA implantations provided significant improvement in the post-operative function of patients in every functional measurement with only two revisions to date, one for improper patient selection and the other for design issues that have been significantly improved. The introduction of new procedures and technologies in medicine is routinely fraught with issues associated with learning curves and unanticipated pitfalls. Because the explicit objectives of this novel technology are to optimize surgical procedures to provide more safe and more reliable outcomes, these favorable results provide the potential for significant improvements in orthopedic surgery.

Figure 5. Tibial inlay design.

