



# **Outcomes of Initial Series of MAKOplasty® Unicompartmental Knee Arthroplasty**

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## Introduction

Unicompartmental knee arthroplasty (UKA) is a procedure to replace only one tibiofemoral compartment of the diseased knee, most commonly the medial compartment. Popularity and usage in the 1980s faded following reports of high early conversion rates to total knee arthroplasty [Laskin 1978, Insall 1980]. However, by the late 1990s interest in UKA heightened due to the many potential advantages such as bone preservation, reduced operating room time, better post-operative range of motion, improved gait and greater patient satisfaction. Despite this interest, significant issues still exist today with early failure of both the femoral component [Mariani 2007, Furnes 2007, Schai 1998, Skyrme 2002, Bartley 1994, Hodge 1992] and the tibial component [Furnes 2007, Berend 2005, Collier 2006].

It has been documented that early failures are primarily due to inaccurate positioning of components leading to overcorrection or undercorrection of the final limb alignment [Kasodekar 2006; Barrett 1987; Emerson 1991; Herzog 1991]. Malalignment of the leg is associated with increased polyethylene wear [Hernigou 2004-A], disease progression to the opposite compartment [Hernigou 2004-A; Jeer 2004; Sarangi 1994; Ridgeway 2002], and implant loosening [Koshino 1991]. Malalignment of the femoral component is known to cause femoral fracture [Sandborn 1987] and tibial component loosening [Assor 2006]. Excessive posterior slope (>7 degrees) of the tibial component is associated with tibial component loosening [Hernigou 2004-B], rupture of the ACL [Hernigou 2004-B], and increased bone stresses [Sawatari 2005]. Thus, while providing the opportunity for many clinical

advantages, the technical difficulties associated with accurately aligning the implanted components have prohibited widespread clinical success of UKA.

MAKOplasty® combines the precision planning of patient specific three dimensional modeling and reconstruction with the use of a robotic arm giving the surgeon absolute control of resurfacing the knee joint, allowing for consistent precision according to the plan chosen by the surgeon. Through precise preparation of bone surfaces and inter-component alignment, MAKOplasty® offers the possibility of realizing all the potential advantages of UKA while simultaneously alleviating the issues related to poor alignment and technical difficulty. The purpose of this study was to assess the functional and radiographic outcomes of the initial series of this new procedure.

## Materials and Methods

Forty-three MAKOplasty® procedures were performed in 42 patients (1 bilateral) for treatment of isolated medial compartment osteoarthritis by two orthopedic surgeons. The patient group consisted of 23 women and 19 men. Demographic information was available for a subgroup of 24 patients. The 12 men and 12 women in this group had

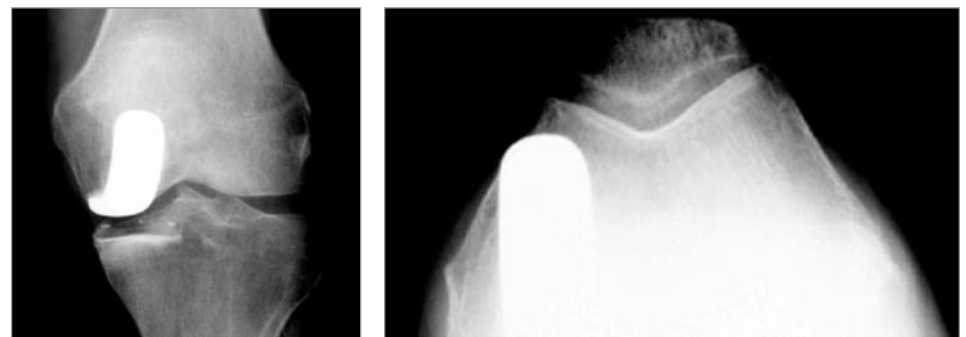
Fig 1. Radiographic Measurements of Component Alignment



an average age of  $73 \pm 11$  yrs (range: 49 to 97 yrs), an average height of  $67 \pm 3$  in and weight of  $185 \pm 37$  lbs, corresponding to an average BMI of  $29 \pm 5$ . Thirty-eight percent of these patients were classified as obese.

A pre-operative CT scan was taken of each patient and the three dimensional reconstructions of the femur and the tibia along with models of the implanted components were used by the surgeon to create an optimized pre-operative plan determining the size, the orientation and the placement of the components relative to the bones. This plan was then realized intra-operatively by computer guided control of the cutting and burring instruments attached to a robotic arm,

Fig 2. Patient with slight medial overhang due to internal rotation of femoral component



which takes the place of traditional intra-operatively aligned instruments and creates the cut bony surfaces as planned pre-operatively to which the implants are cemented. Unicompartmental arthroplasty components were then cemented into the femur and the tibia. The tibial component was an all polyethylene inlay design.

Standard lateral and AP radiographs were taken for all patients 2 weeks post-operatively and evaluated by a single independent orthopedic surgeon. Eight different aspects of component to host bone alignment were assessed (Figure 1) as either acceptable or unacceptable based on the ranges in Table 1. From each of the two radiographic poses, a position and an orientation were assessed for the tibial and the femoral component. In addition, pre- and post-operative (3 month) data were collected from the subgroup of 24 patients on their Knee Society Score, WOMAC Osteoarthritis Index, SF-12 health survey and range of motion.

## Results

The average flexion significantly increased at three months post-operatively to  $126 \pm 6^\circ$  compared with  $121 \pm 8^\circ$  pre-operatively ( $p < 0.001$ ). Post-operative KSS and WOMAC total scores significantly improved from  $95 \pm 16$  to  $150 \pm 27$  ( $p < 0.001$ ) and  $41 \pm 15$  to  $21 \pm 17$  ( $p < 0.001$ ), respectively. Quality of life, as measured by the SF-12 Physical Summary also significantly improved from  $30 \pm 9$  to  $39 \pm 12$  ( $p < 0.001$ ). Table 2 summarizes the results. MAKOpasty® significantly improved every measured clinical outcome.

Radiographically, we identified as an outlier any specific measurement outside a particular range set by a clinical advisory

board of orthopedic surgeons. Of the 344 radiographic measurements, only 4 (1%) were identified as outliers (Table 3). Three of those were a slight medial overhang of the femoral component. Upon review of the Merchant view radiographs from these cases, this overhang was actually only overhang of the most anterior (extension) portion of the implant due to slight internal rotation of the femoral component (Figure 2). The fourth outlier was an overstuffing of the joint space with a femoral component that appears to be one size too large.

## Conclusions

The goal of the MAKOpasty® procedure

is to accurately and reproducibly resect bone relative the pre-operative plan to facilitate the implantation of a medial unicompartmental arthroplasty. This study examined the early clinical results of 25 implantations and the radiographic results of 43 implantations from the initial series of the implementation of this new technology. This initial series of MAKOpasty® UKA procedures provided significant improvement in the post-operative function of patients in every functional measurement. As this is a new procedure, it is difficult to compare these results with published long-term studies as functional outcomes tend to continually improve throughout the first year

Table 1. Acceptable Positioning Guide for Each Component

Femoral Component	Minimum	Ideal	Maximum
A - Flexion/Extension	4° flexion	10° flexion	15° flexion
B - Proximodistal Position	1mm distal of bone	2mm distal of bone	3mm distal of bone
E - Varus/Valgus	0° valgus	5° valgus	10° valgus
F - Mediolateral Position	no med overhang	ideal coverage	No lat overhang

Tibial Component	Minimum	Ideal	Maximum
C - Posterior Slope	0° posterior	4° posterior	7° posterior
D - Proximodistal Position	3mm prox of bone	2mm prox of bone	4mm distal of bone
G - Varus/Valgus	10° varus	3° varus	Neutral
H - Mediolateral Position	2mm min fr. cortex	2mm min fr. cortex	2mm from eminence

Table 2. Summary of Clinical Outcomes

Functional Metric	pre-op	post-op	p-value
ROM	$121 \pm 8^\circ$	$126 \pm 6^\circ$	$p < 0.001$
Knee Society Score	$95 \pm 16$	$150 \pm 27$	$p < 0.001$
Sf-12 Physical Summary	$30 \pm 9$	$39 \pm 12$	$p < 0.001$
WOMAC total	$41 \pm 15$	$21 \pm 17$	$p < 0.001$
WOMAC pain	$8 \pm 4$	$4 \pm 3$	$p < 0.001$
WOMAC stiffness	$4 \pm 1$	$2 \pm 1$	$p < 0.001$
WOMAC physical function	$29 \pm 11$	$15 \pm 13$	$p < 0.001$

Table 3. Summary of Radiographic Outcomes

	AP Radiograph		Lateral Radiograph	
	ML Position	Varus/Valgus	PD Position	Flexion/Slope
Femoral Component	40/43	43/43	42/43	43/43
Tibial Component	43/43	43/43	43/43	43/43

post-operatively. The results presented in this report, even though at only 3 months post-operatively, are as good or better than both long term [Bourne 2007] and early [Hartley 2002] results of TKA in terms of the change pre- to post-operatively in the WOMAC, SF-12 PCS and ROM. Assessing the alignment of the components radiographically revealed that the initial series of MAKOplasty® procedures resulted in very few outliers (1%). This is particularly impressive as these patients were from the inaugural series of patients undergoing a technologically innovative procedure. The introduction of new procedures and technologies in medicine are routinely fraught with issues associated with learning curves and unanticipated pitfalls. Because the objectives of the MAKOplasty® procedure are to provide more safe and more reliable outcomes, these favorable results with UKA using this new technology provide the potential for significant improvements in orthopedic surgery.

#### References

Assor M, Aubaniac JM. Influence of rotatory malposition of femoral implant in failure of unicompartmental medial knee prosthesis. *Rev Chir Orthop Reparatrice Appar Mot.* 92(5):473-84. 2006.

Barrett WP, Scott RD. Revision of failed unicompartmental knee arthroplasty. *J Bone Joint Surg Am.* 69(9):1328-35. 1987.

Bartley RE, Stulberg SA, Robb WJ, Sweeney HJ. Polyethylene wear in unicompartmental knee arthroplasty. *Clin Orthop Relat Res.* 299:18-24. 1994.

Berend KR, Lombardi AV Jr, Mallory TH, Adams JB, Groseth KL. Early failure of minimally invasive unicompartmental knee arthroplasty is associated with obesity. *Clin Orthop Relat Res.* 440:27-37. 2005.

Bourne RB, McCalden RW, MacDonald SJ, Mokete L, Guerin J. Influence of patient factors on TKA outcomes at 5 to 11 years follow up. *Clin Orthop Relat Res.* Nov;464:27-31. 2007.

Collier MB, Eickmann TH, Sukezaki F, McAuley JP, Engh GA. Patient, implant, and alignment factors associated with revision of medial compartment unicompartmental arthroplasty. *J Arthroplasty.* 21(6 Suppl 2):108-15. 2006.

Emerson RH, Head WC. Failure mechanisms of unicompartmental knee replacement: the impact of changes in operative technique and component design. *Semin Arthroplasty.* 2(1):23-8. 1991.

Furnes O, Espehaug B, Lie SA, Vollset SE, Engesaeter LB, Havelin LI. Failure mechanisms after unicompartmental and tricompartmental primary knee replacement with cement. *J Bone Joint Surg Am.* 89(3):519-25. 2007.

Hartley RC, Barton-Hanson NG, Finley R, Parkinson RW. Early patient outcomes after primary and revision total knee arthroplasty. A prospective study. *J Bone Joint Surg Br.* 84(7):994-9. 2002.

[A] Hernigou P, Deschamps G. Alignment influences wear in the knee after medial unicompartmental arthroplasty. *Clin Orthop Relat Res.* (423):161-5. 2004.

[B] Hernigou P, Deschamps G. Posterior slope of the tibial implant and the outcome of unicompartmental knee arthroplasty. *J Bone Joint Surg Am.* 86-A(3):506-11. 2004.

Herzog R, Morscher E. Failures of knee joint prostheses. An analysis of knee prostheses and component revisions, 1980-1987. *Orthopade.* 20(3):221-6. 1991.

Hodge WA, Chandler HP. Unicompartmental knee replacement: a comparison of constrained and unconstrained designs. *J Bone Joint Surg Am.* 74(6):887-83. 1992.

Insall J, Aglietti P. A five to seven-year follow-up of unicompartmental arthroplasty. *J Bone Joint Surg Am.* 62(8):1329-37. 1980.

Jeer PJ, Keene GC, Gill P. Unicompartmental knee arthroplasty: an intermediate report of survivorship

after the introduction of a new system with analysis of failures. *Knee.* 11(5):369-74. 2004.

Kasodekar VB, Yeo SJ, Othman S. Clinical outcome of unicompartmental knee arthroplasty and influence of alignment on prosthesis survival rate. *Singapore Med J.* 47(9):796-802. 2006.

Koshino T, Morii T, Wada J, Takahashi S. Unicompartmental replacement with the Marmor Modular knee: operative procedure and results. *Bull Hosp Jt Dis Orthop Inst.* 51(2):119-31. 1991.

Laskin RS. Unicompartmental tibiofemoral resurfacing arthroplasty. *J Bone Joint Surg Am.* 60(2):182-5. 1978.

Mariani EM, Bourne MH, Jackson RT, Jackson ST, Jones P. Early failure of unicompartmental knee arthroplasty. *J Arthroplasty.* 22(6 Suppl 2):81-4. 2007.

Ridgeway SR, McAuley JP, Ammeen DJ, Engh GA. The effect of alignment of the knee on the outcome of unicompartmental knee replacement. *J Bone Joint Surg Br.* 84(3):351-5. 2002.

Sandborn PM, Cook SD, Kester MA, Haddad RJ Jr. Fatigue failure of the femoral component of a unicompartmental knee. *Clin Orthop Relat Res.* (222):249-54. 1987.

Sarangi PP, Karachalios T, Jackson M, Newman JH. Patterns of failed internal unicompartmental knee prostheses, allowing persistence of undercorrection. *Rev Chir Orthop Reparatrice Appar Mot.* 80(3):217-22. 1994.

Sawatari T, Tsumura H, Iesaka K, Furushiro Y, Torisu T. Three-dimensional finite element analysis of unicompartmental knee arthroplasty-the influence of tibial component inclination. *J Orthop Res.* 23(3):549-54. 2005.

Schai PA, Suh JT, Thornhill TS, Scott RD. Unicompartmental knee arthroplasty in middle-aged patients: a 2-6 year follow-up evaluation. *J Arthroplasty.* 13(4):365-72. 1998.

Skyrme AD, Mencia MB, Skinner PW. Early failure of the posterior-coated anatomic cemented unicompartmental knee arthroplasty. *J Arthroplasty.* 17(2):201-5. 2002.