MAKO View

Current insight and experience on MAKOplasty® for healthcare professionals

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INSIDE this issue

MAKO View is a publication dedicated to providing information, data, perspective and opinions on healthcare and economics related to the new orthopedic solution, MAKOplasty®. In this issue we focus on partial knee surgical options and new data.

Reference:
1 Conditt, M. (2008). Outcomes of Initial Series of MAKOplasty® Unicompartmental Knee Arthroplasty.

More Precision and New Capabilities

Editorial

In June of 2006, the first MAKOplasty® procedure is successfully performed. An initial series of 25 implantations and 43 radiographs finds significant improvement in post-operative function for all functional measures at three months and very few outliers (1%) in a radiographic assessment of the alignment of components[1]. During this time, unicompartmental knee arthroplasty (UKA) resurges. The need arises for more precise bone preparation and implant placement for UKA.

MAKOplasty®, powered by the robotic arm system, offers an innovative solution that enables precise and consistent resurfacing and implant placement. Pre- and intra-operative three-dimensional planning, tactile technology, and virtual instrumentation assist the surgeon to achieve a naturally balanced and aligned knee.

Late 2008 and in 2009, several peer reviewed journals and scientific sessions report the experience with MAKO's robotic arm system. Publications include Journal of Arthroplasty, Journal of Bone and Joint Surgery, and the American Journal of Orthopedics. Findings are consistent that MAKOplasty® offers accuracy, bone and tissue conservation, and improved patient function.

Released in 2009, the RIO® System adds operational advancements, user flexibility and a new platform for expanding applications. The release of the RESTORIS® MCK MultiCompartmental Knee System goes beyond medial UKA. It extends the consistent, reproducible, precision of MAKOplasty® to the treatment of the lateral or patellofemoral compartments and bicompartmental treatment of the medial and patellofemoral compartments.

Over 2300 MAKOplasty® procedures have been performed across 36 sites as of December 31, 2009. Early data on patient satisfaction is strong as shown in Table 1, page 3. Physician satisfaction is growing as Dr. Frederick F. Buechel, Jr. of Naples, Florida, states, "I am really a believer in the technology, watching my patients do things in a week that my total knees take 6-12 months to achieve. My patients are the true benefactors of this technology, and I believe this will transform the treatment of knee arthritis."

MAKOplasty® Lateral Procedure

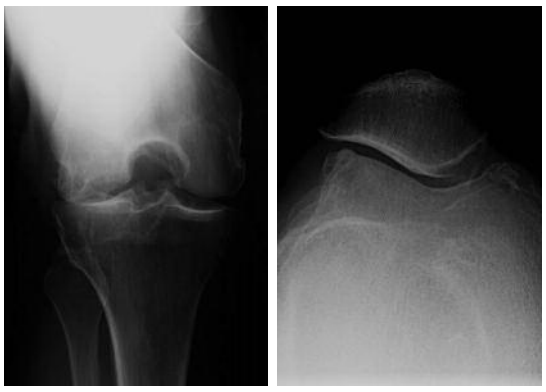
By John H. Velyvis, M.D.

John H. Velyvis, M.D.
Eisenhower Medical Center
Rancho Mirage, CA

The patient is a 49 year old male who presents with bilateral knee pain, worse on the right side. He has had many years of disabling pain. Both knees have had patellar realignment procedures in the early 1970s. In addition, two more procedures were done on the right knee: In 1978, a large osteochondral lesion was excised and then in 1979, a bone spur was removed, both open procedures.

The patient feels that his right leg is shorter than his left. He has tried physical therapy and he has been using a brace. Neither has helped much. His pain is severe and disabling - he rates it at 9 to 10 out of 10. He limps, feels popping and grinding in the knee, cannot stand for long periods or walk long distances. He has trouble sleeping and cannot kneel or squat without severe discomfort. He takes

Pre-op



Post-op

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Case Study: **Bicompartmental MAKOplasty® Procedure**

By Stefan Kreuzer, M.D.

Stefan Kreuzer, M.D.
Foundation Surgical Hospital
Houston, TX

A 66 year old male presented with right knee pain in the medial and anterior compartments. The patient is a former paratrooper and still maintains a highly active lifestyle by working out on a regular basis, cycling, and golfing. Conservative treatments provided him with minimal reduction in symptoms at which point he was ready to discuss surgical interventions. On physical exam his range of motion was 0-110 degrees of flexion. He had significant tenderness to palpation around the patella and pain with deep knee flexion. There was mild laxity with valgus stress and a negative Lachman. His pre-operative radiographs demonstrated loss of medial joint space, patellofemoral OA, and a normal lateral compartment (Figure 1). The combination of his lifestyle, desire to remain active, physical exam, bone quality, and pre-operative xrays made him an excellent candidate for Bicompartmental MAKOplasty®.

The procedure was performed at our surgical center in the afternoon and he was up and walking with the physical therapists before discharge the following day. He was discharged with pain pills and NSAIDS as needed and continued outpatient physical therapy for four weeks. He reported a post-op pain of five and stopped using the pain medication on post-op day two. His post-operative course has been uneventful with minimal knee pain two weeks out and range of motion 0-115 degrees. He cycles every other day for a minimum of 10 miles up to 20 miles. He is a member of a cycling club that goes for rides as long as 42 miles. He also tries to golf at least once a week. His immediate post-operative films (Figure 2) show excellent placement of the components with minimal bone loss.

Figure 1. Pre-op

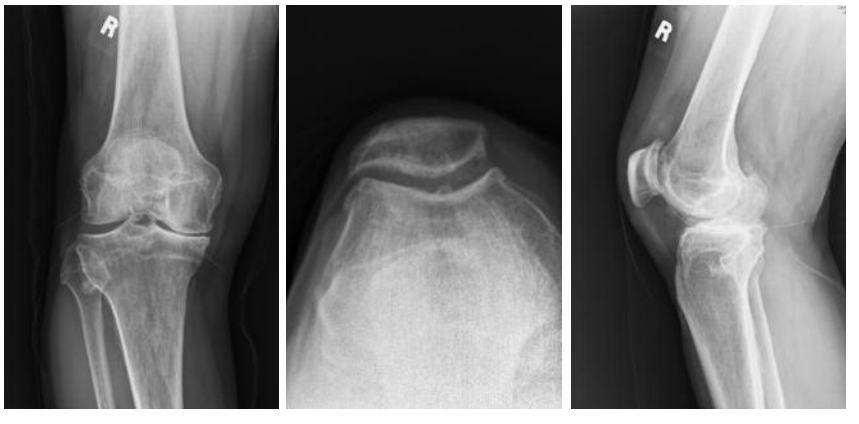
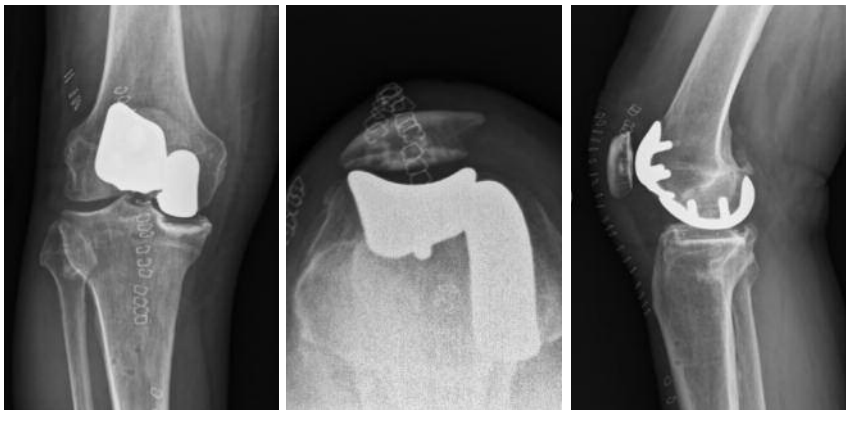


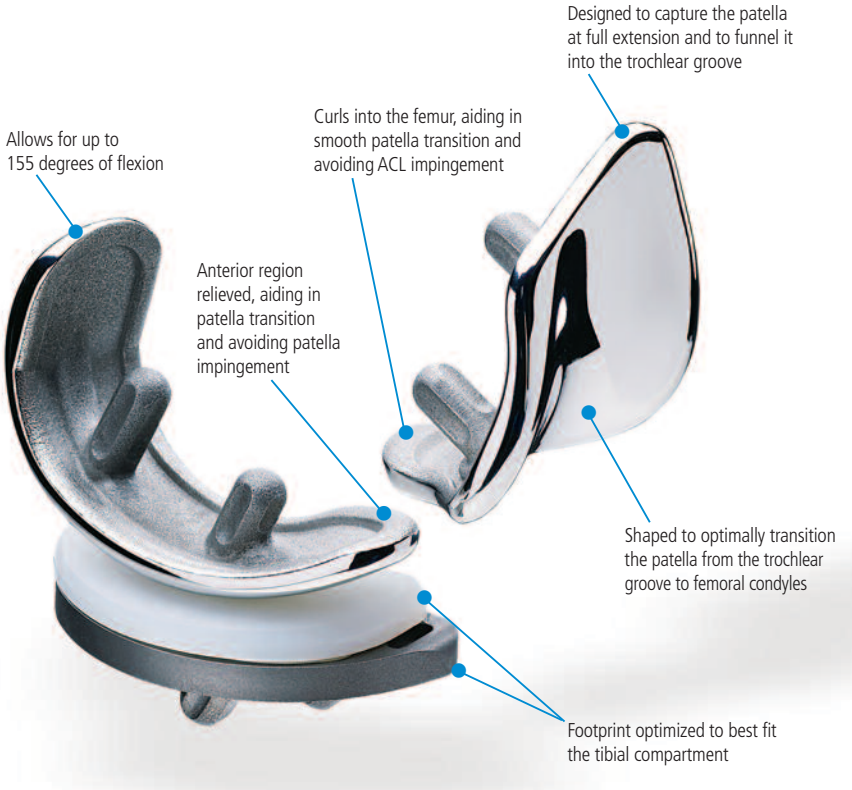
Figure 2. Post-op

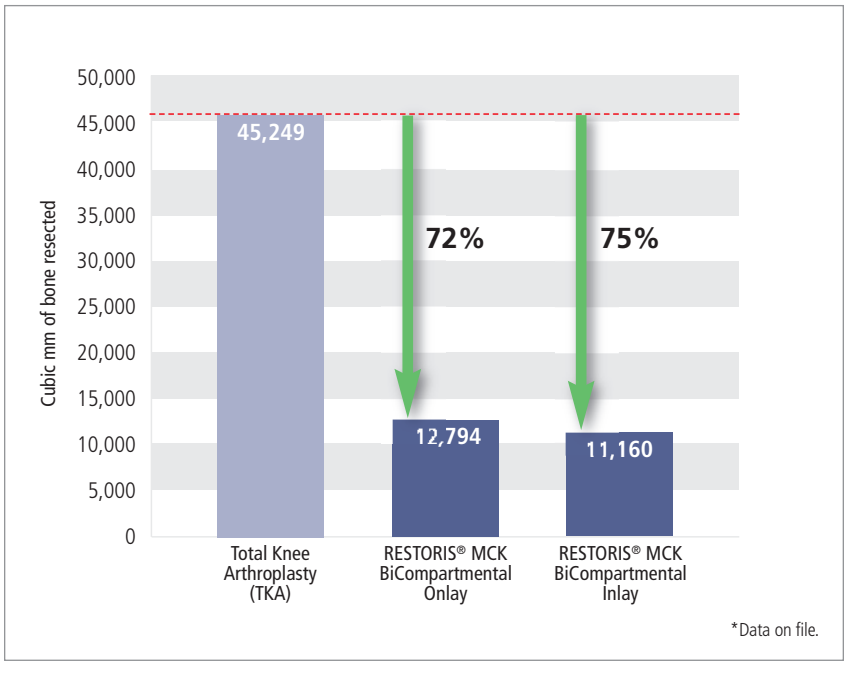


Implant Design: RESTORIS® MCK

The trochlear and femoral components were designed to provide a continuous support surface for the patella as it crosses over the critical transition zones between compartments. Using the advanced pre-operative and intra-operative planning capabilities of the RIO®, the RESTORIS® MCK components can be precisely placed to target the disease without damaging critical soft tissue, while freed from the confines of conventional instrumentation.

Femoral, Patellofemoral and Tibial Components





- **Bone Conservation**
  Resurfacing technique provides stable implant fixation while preserving the ability to revise to a primary TKA if the disease progresses

- **ACL and PCL Preservation**
  Bicompartmental solution retains both the ACL and PCL to retain function and the natural feel of the knee

MAKOplasty® Shaping Economic Success:
Capturing Knee Markets with Robotic Arm Technology

Surgeons are attracted to RIO® for its ability to expand treatment options and surgical patient volumes. Hospitals seek new technologies to develop centers of excellence and expand market reach. The MAKOplasty® solution provides benefits to all stakeholders and enables competitive and market advantages while demonstrating positive financial returns.

Table 1.

Measuring Patient Satisfaction

As part of the MAKO joint registry, a qualitative survey measures patient satisfaction with MAKOplasty®. Initial responses indicate positive patient satisfaction, greater confidence with the use of robotic arm technology, and a trend to seeking physicians who perform MAKOplasty®. Data collection is ongoing.

Would you recommend MAKOplasty® to a friend or family member?

Post-op

2 weeks (n=133)	6 weeks (n=153)
Yes: 97%	Yes: 98%
No: 3%	No: 2%

Are you more or less comfortable knowing that your surgery was performed with the MAKO robotic arm system?

(n=258)

I feel more comfortable: 79%

It doesn't matter to me: 21%

Did you pick your surgeon specifically because he performed MAKOplasty®?

(n=258)

Yes: 55%

No: 45%

MAKOplasty® Economic Case Profile - Single Surgeon Success

Eisenhower Medical Center - John H. Velyvis, M.D.

Opportunity:

- Add RIO® robotic arm system to enhance technology leadership in the region
- Offer earlier treatment options for suffers of osteoarthritis of the knee
- Build upon the Eisenhower Orthopedic Center of Excellence

Solution:

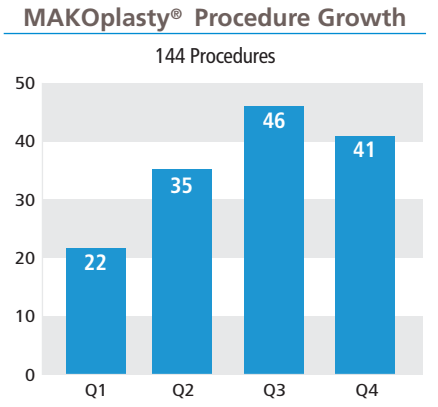
- MAKOplasty® program to attract new patients to Eisenhower Medical Center

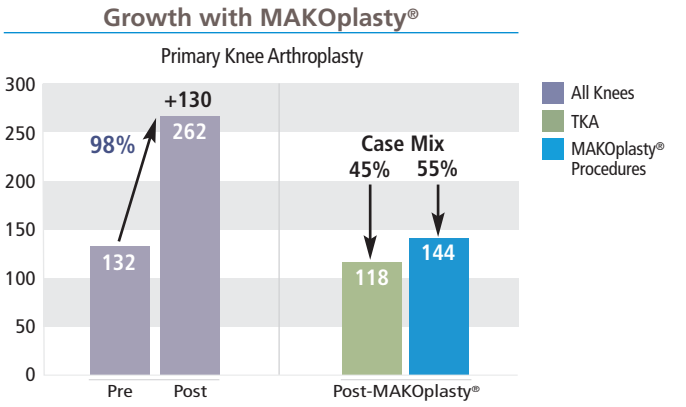
Result:

- Rapid MAKOplasty® adoption; 144 procedures in first year
- Significant growth in practice - 98% in all Primary Knee Arthroplasty (130 cases)
- Strong partial knee case mix, 55% MAKOplasty®

Primary Knee Arthroplasty growth: 98%

130 incremental cases year over year





First MAKOplasty® procedure was performed in November 2008.

MAKOplasty® Economic Case Profile - Two Year Review

Holy Cross Hospital

Opportunity:

- Build upon Orthopedic Center of Excellence
- Incorporate cutting edge technologies to provide the highest level of patient care
- Create a concrete competitive advantage

Solution:

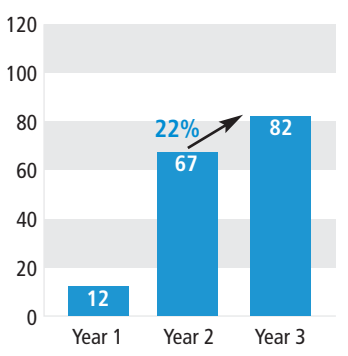
- MAKOplasty® program as key differentiator of Orthopedic Center of Excellence

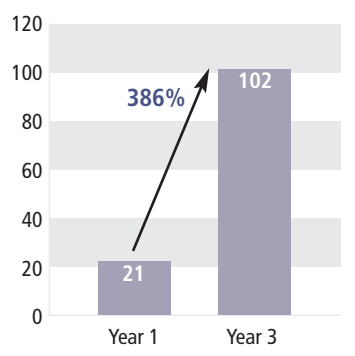
Result:

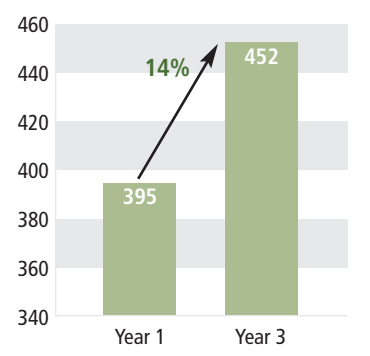
- MAKOplasty® year over year growth, 22% growth in year two
- Unicompartmental Knee Arthroplasties (UKA) more than tripled
- Total Knee Arthroplasties (TKA) benefit from "Halo Effect" with 14% growth

Primary Knee Arthroplasty growth: 33%

138 incremental cases year 3 versus year 1







First MAKOplasty® procedure was performed in June of year 1.

All procedural and economic data presented on this page are provided by individual hospitals; not independently validated by MAKO.

Two Year Outcomes of Robotic Arm Assisted UKA

By Martin W. Roche, M.D.

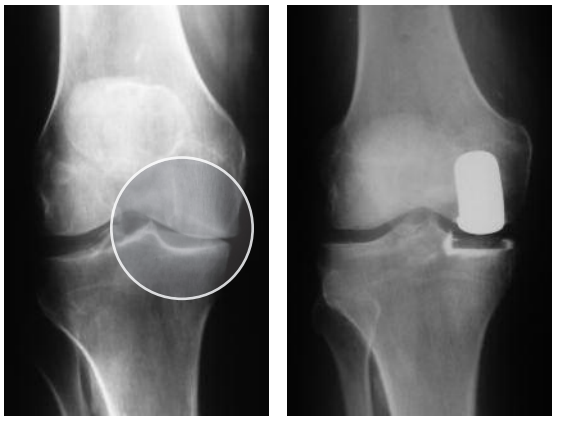
Martin W. Roche, M.D.
Holy Cross Hospital
Fort Lauderdale, FL

Clinical outcomes of UKA procedures are sensitive to malalignment of the components, and thus show significant variability in the literature. The 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 mal-alignment, thus increasing post-operative physical and function outcomes.

The first seventy-three (42 male, 31 female) patients (average age: 71 ±10yrs) to receive a robotically assisted UKA enrolled in an IRB approved outcomes registry. The average follow-up was 28 months (range: 21–38 months). The tibial component for all patients was an all-poly inlay design. At two year follow up, it was found that the average range of motion significantly increased to 129±6.5° compared with 123.3±12.1° pre-operatively ($p<0.05$). Post-operative Knee Society Knee and Functional scores also increased from 43.8±9.9 to 96.75±2.35 ($p<0.0001$) and 63.9±11.8 to 80±14.0 ($p<0.0001$), respectively.

Of the 73 two year post-operative patients, two have been revised, for a two year clinical failure rate of 2.34% at an average follow-up of 24.4 months. Both revisions were due to loosening of the inlay tibial component and occurred 23.6 and 17.5 months, respectively, after the index procedure. The first revised patient was revised to a TKA. The second patient was revised to a unicompartmental onlay tibial component.

Pre-op **Two year**



This initial series of robotic arm guided UKA implantations provided significant improvement in the post-operative function of patients in every functional measurement with only two revisions to date, likely for improper patient selection. 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.

MAKOplasty® Lateral Procedure

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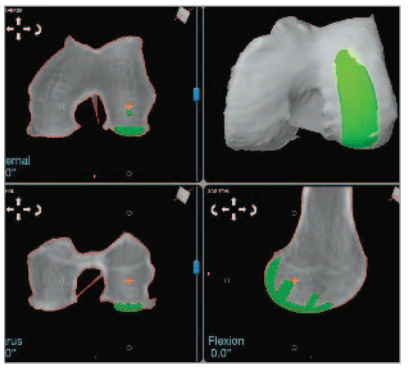
Patient-specific planning



ibuprofen and oxycontin. He has seen two other orthopedic surgeons recently. He received one cortisone injection with minimal pain relief.

The patient is currently employed and is on his feet frequently through out the work day.

Physical examination: The patient stands 6 ft. 4 in. and weighs 218 lbs. He has a correctable valgus deformity of both knees of approximately 5 to 7 degrees off mechanical axis, with well healed scars from prior open procedures on both knees. There is no effusion or significant soft tissue swelling. Palpation reveals pain in the lateral joint line of both knees, more severe pain in the right knee. Range of motion is 0 to 150 degrees with moderate to severe pain in deep flexion in the right knee, and mild pain in deep flexion in the left knee. The quads and hamstrings strength are normal.

The patella has normal tracking without significant crepitus or pain on motion, normal retinacular laxity, normal Q angle, and negative apprehension test. Ligament exam is normal with Lachman, pivot shift and anterior drawer testing. No posterior sag. No opening or pain on varus or valgus stress at full extension and 30 degree of flexion. No sensory deficits. Reflexes are normal.

"MAKO has again taken a difficult, heavily instrumented procedure and made it much simpler to perform with accurate and reproducible results."

John H. Velyvis, M.D.
Eisenhower Medical Center, Rancho Mirage, CA

Pre-operative X-rays were taken with standard four views of the knees: standing AP, standing tunnel/notch, lateral, and patella sunrise views. These demonstrate valgus deformity of about 5 to 7 degrees off mechanical axis with bone-on-bone arthritis of both left and right knees in the lateral compartment, mainly in the standing tunnel views. The patellofemoral articulation has small patellofemoral rim osteophytes without narrowing, and normal tracking.

The patient was scheduled for lateral partial knee resurfacing with MAKOplasty® robotic arm assistance. We performed the procedure and the patient did extremely well, experiencing very little pain post-operatively. The patient was able to participate in physical therapy later the same day. He stayed overnight and stayed for 2 more therapy sessions before going home the day after surgery. He used very little pain medication and did not require a walking assist once he got home. Physical therapy guided him at home for 2 weeks before discharging him. He has done very well and is extremely happy with his MAKOplasty® procedure. He would do it again, and may return for a MAKOplasty® procedure on his left knee in the future. He would recommend the lateral MAKOplasty® procedure to his friends and family.

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