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 MAKOplasty® clinical perspectives and outcomes.

Heralding in a New Era of Precision Surgery

By Lawrence D. Dorr, M.D.

Surgeons adopt new technology slowly. They want to know if it will truly benefit their patients. It should also improve the surgeon's performance of the operation. Today, the materials used for total hip replacement and total knee replacement are very durable. The limitation to a "lifetime" hip or knee replacement is positioning the components correctly so they do not impinge and that the biomechanical reconstruction is correct.

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Therefore, the frontier for total joint replacement surgery is to perform operations with repeatable and predictable results for all surgeons. Even expert surgeons benefit from quantitative knowledge in the operating room provided by computer navigation. Computer navigation has made results more predictable with total hip or total knee replacement. Human errors caused by manual use of tools, variability of 3-D vision, or judgment still can occur. The use of a robotic system programmed with computer navigation software can eliminate those human errors. The robotic system can control depth of bone preparation and can identify component position in/on the bone. It therefore eliminates the judgment of the surgeon for those factors and makes performance of component placement repeatable and predictable for all operations.

The era of precision surgery is already here. In July 2008 we began the use of a robotic arm system made by MAKO Surgical Corp. The robotic arm is controlled by the surgeon, but it is programmed so that the bone resurfacing is precise. When the bone preparation exceeds the prescribed limit, the robotic arm stops. It will not permit the human error of too little or too much bone preparation. Our first use of the robotic arm system has been with unicompartmental knee replacement. We anticipate the use of the robotic arm system will be extended to multiple operations, initially in the hip and knee.

Can Robotics Enable Advanced Modular Knee Arthroplasty Design?

By Scott Banks
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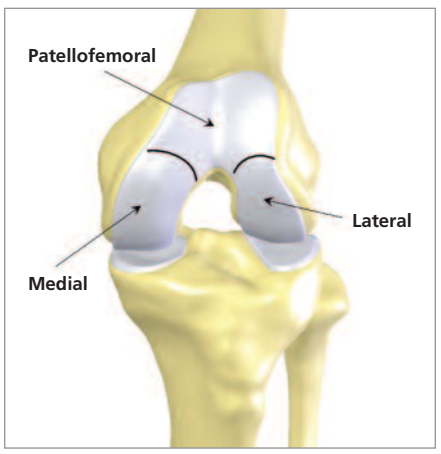

Current robotic systems for surgery can be classified as autonomous (e.g. RoboDoc, [1]), teleoperated (e.g. DaVinci, [2]), and tactile or surgeon-guided (e.g. Acrobot Sculptor, MAKO TGS System). In surgeon-guided systems the surgeon provides power for instrument motion while the robotic arm constrains instrument position and/or orientation within some anatomically registered volume [3]. In the case of knee arthroplasty, a surgeon-guided robotic arm system provides virtual cutting guides for bone removal, with either a saw or burr. This capability provides the potential for accurately sculpted, patient-specific, free form bone resection where less bone is removed than traditional piecewise resections with a saw and cutting jigs. In addition, a surgeon-guided system with dynamic bone position tracking allows the possibility of keyhole surgery, where a patient-specific graphics display provides the surgeon a heads-up virtual visualization of bone removal.

continues on page 4

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Editor's Comment:

The first MAKOplasty® partial knee resurfacing procedure powered by MAKO's surgeon-interactive robotic arm system was performed in June of 2006 by Martin W. Roche, M.D. at Holy Cross Hospital in Fort Lauderdale, Florida. Twenty-eight months later, with 13 hospital sites and over 550 procedures, surgical experience is growing rapidly and early outcomes are very promising.

The regulatory pathway for commercialization has also been rapid. Since receiving (510k) marketing clearance from the FDA in November of 2005 for its version 1.0 robotic arm system, MAKO then released two enhanced versions of the robotic arm system 1.2 and 1.3, in 2008.

MAKO's implant designs are advancing with the system. An inlay resurfacing design was first introduced and onlay knee implants were added to accommodate different patient profiles and surgeon preferences in early 2008. Currently MAKO is introducing it's new RESTORIS™ Unicompartmental Knee System in both inlay and onlay designs. RESTORIS™ offers a common femoral component for intra-operative flexibility when converting from inlay to onlay and bone and tissue preserving designs.

As surgeon adoption of MAKOplasty® continues, a growing number of patients have a new option for treating painful early to mid-stage osteoarthritis of the knee with more precise and consistent results. These results may translate into more natural knee functionality and a rapid return to daily activities. MV

Outpatient UKA

By Michael Conditt, Ph.D.

One area of clinical interest at MAKO Surgical Corp is developing a MAKOplasty® protocol that allows same day hospital discharge. There are several surgical factors that may affect early hospital discharge including operative time, incision length and location, amount of surgical trauma to various components of the knee, general health, blood loss, implant alignment, surgical technique, tourniquet use, and anesthesia. Equally important, but much less well understood, is a disciplined and structured program focusing on patient education and patient support through health literacy, advocacy and aggressive case management.

Consistently achieving same day hospital release following UKA is dependent on well planned pre-, intra- and post-operative guidelines. This begins with pre-operatively providing patients with a class or information session with a detailed explanation of their symptoms, treatment options and details of the MAKOplasty® procedure as well as what to expect during the recovery process. In addition, the entire surgical staff should be educated and made aware of the accelerated discharge protocol.

Figure 1.
Typical MIS UKA Incision.

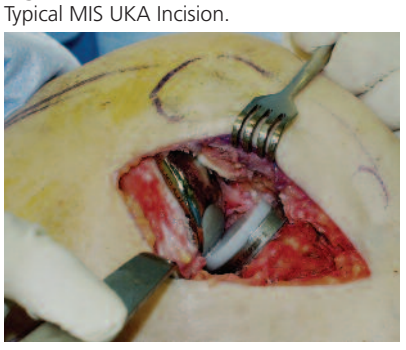

Figure 2.
Intracapsular Anesthetic Injection.

Figure 3.
Active Post-operative Knee Flexion.

Specific doses of pre-emptive analgesics and anti-emetics are introduced pre-operatively as well to decrease inflammation and pain, and to prepare the gastrointestinal tract for the insult of anesthesia, respectively. Intra-operative management for a successful outpatient UKA is focused on the size of the incision (Figure 1), minimizing trauma to the quadriceps, and preventing and treating pain, nausea, and hypovolemia. Intraoperative anesthesia is also administrated as recommended for the patient (Figure 2) and blood management options are discussed specific to the patient.

Post operatively, motion of the knee joint soon after surgery is critical to an accelerated recovery. In addition, the patient should be kept well hydrated to prevent post-operative hypotension and nausea. The following discharge goals must be met by each patient: independent ambulation of 100 feet, active straight leg raise, active knee flexion to 90 degrees (Figure 3), no wound complications, and adequate pain control. Patients must understand that they will not be released from the hospital if these criteria are not fully met, and/or if they feel uncomfortable leaving. Upon successful discharge, patients are instructed to walk as much as possible and perform straight leg raises, quad sets, and ROM exercises three times a day.

The process of an outpatient UKA procedure involves the cooperation and effort of all individuals who interact with the patient. Dedication to these pre-, intra- and post-operative issues and guidelines promise to make outpatient UKA a safe and reliable outpatient procedure.

References

These data are compiled from a review of the clinical approach of John A. Repicci, M.D. and Thomas M. Coon, M.D.

Snapshot: *Clinical Research*

Michael Conditt, Ph.D.
Director of Clinical Research
MAKO Surgical Corp.

One of MAKO's core areas of interest is science-based clinical research, which is under the directive of Michael Conditt, Ph.D.

Dr. Conditt received his Ph.D. in Biomedical Engineering from Northwestern University in 1998. Prior to joining MAKO, Dr. Conditt served as the Director of Research, Institute of Orthopedic Research and Education at the Baylor College of Medicine in Houston, TX. While at Baylor, Dr. Conditt and his colleagues were awarded the prestigious John Insall Award for Outstanding Clinical Research in 2006.

Dr. Conditt holds an exceptional track record in clinical research. Since joining MAKO in December 2007, Dr. Conditt has worked with surgeons using the system and submitted 39 abstracts, twelve of which were accepted as podiums and posters, submitted 13 peer-reviewed manuscripts of which 11 were accepted, completed four white papers, and submitted two book chapters.

When asked what he perceives as primary areas of opportunity in the future for robotics and imaging technologies, Dr. Conditt replied: "The true potential of this technology is in the ability to perform precision procedures currently not possible due to access, visualization or safety issues. In addition, we are able to open our minds and creatively design implants whose geometries are no longer bound by the restrictions imposed by current cutting tools and instrumentation. I believe this will result in truly anatomic, joint resurfacing implants that will replace only the diseased tissues and will result in significant improvements in functional outcomes."

MAKOplasty® Case Report

By Raj Sinha, M.D., Ph.D.

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A 59 year old female presented with progressive medial left knee pain. She previously had a femur fracture that healed with a residual varus deformity. She has attempted to remain active, playing tennis, golf, hiking and skiing. Because of the deformity, she has gone on to develop isolated medial compartment disease (X-rays shown in Figure 1). Due to her desire to remain active, with minimal recovery time and rehabilitation, she opted for a MAKOplasty® procedure.

She qualifies as a good candidate for the procedure because of her isolated one compartment arthritis, excellent bone quality, partially correctable deformity of the joint and good flexion of the knee. In addition, due to her commitment to remaining active, having a "replaced" knee that preserves all of the normal structures in the knee will allow the knee to feel more like a normal knee than if she had a total knee replacement (Figure 2).

The procedure was performed early on a Wednesday morning, and by lunchtime, she was walking with the physical therapists. She had full control of the limb and minimal pain. She was able to be discharged from the hospital the next morning. At that time, she was using only two pain pills per day. She started outpatient physical therapy two days later. By two weeks after surgery, she was walking without any assistive devices and was progressing well with physical therapy. At that time, she felt well enough to travel, deciding to fly to her home in Northern California to continue her therapy. At five months, she had full extension and full flexion (Figure 3) with return to her active lifestyle with minimal pain. Her next check up will be at one year post-op.

Figure 1. Pre-op AP View.

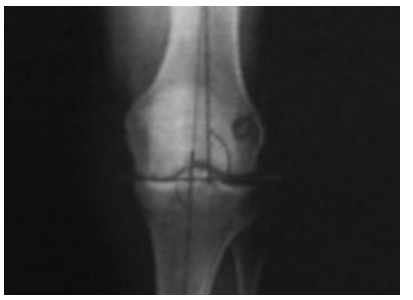


Figure 2. Immediate Post-op AP View.

Figure 3. Five Month Post-op.

MAKOplasty® Center of Excellence: **Connecting the MAKOplasty® Experience**

MAKO Surgical Corp. is committed to advancing the experience on MAKOplasty® and is pleased to announce **MAKOLink.info**, a secured web-based community. It is designed to facilitate knowledge exchange among healthcare professionals and ease of access to MAKO clinical, product and marketing resources.

MAKOLink.info is available to all MAKOplasty® Center of Excellence sites. Members will be able to download reports, access peer-reviewed white papers and research reports, view streaming media and webcasts, review surgical demonstrations and access marketing and educational content. Members will also be able to take advantage of the Discussion Board, a forum designed to facilitate peer-to-peer clinical discussions, shared experiences and communication of best practices.

For more information, send your inquiries to admin@makolink.info.

MAKOLink.info

Poster Sessions Presented at ISTA

One Year Outcomes of Robotic Arm Guided UKA

Roche, M; Augustin, D; Conditt, M A

Purpose:
The purpose of this study was to assess the functional and radiographic outcomes of the initial series of this new procedure.

Conconclusion:
- This new procedure provides comprehensive, three-dimensional planning of UKA components, including soft tissue balancing, followed by accurate resection of the femur and the tibia.
- This preparation allows for precise placement and alignment of the components.
- All patients showed significant improvement in the post-operative function in every functional measurement.
- 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 robotic arm 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.

Robotic Arm Guided UKA is More Accurate than Manually Instrumented UKA

Coon T; Driscoll, M D; Conditt, M A

Purpose:
This study compares the accuracy of UKA component placement and early clinical outcomes with traditional jig-based instrumentation versus robotic arm guided surgery.

Conclusion:
- Tibial component alignment in UKA is significantly more accurate and less variable using robotic arm guided surgery compared to manual, jig-based instrumentation.
- By enhancing component alignment, this novel technique provides a potential method for improving outcomes in UKA patients.

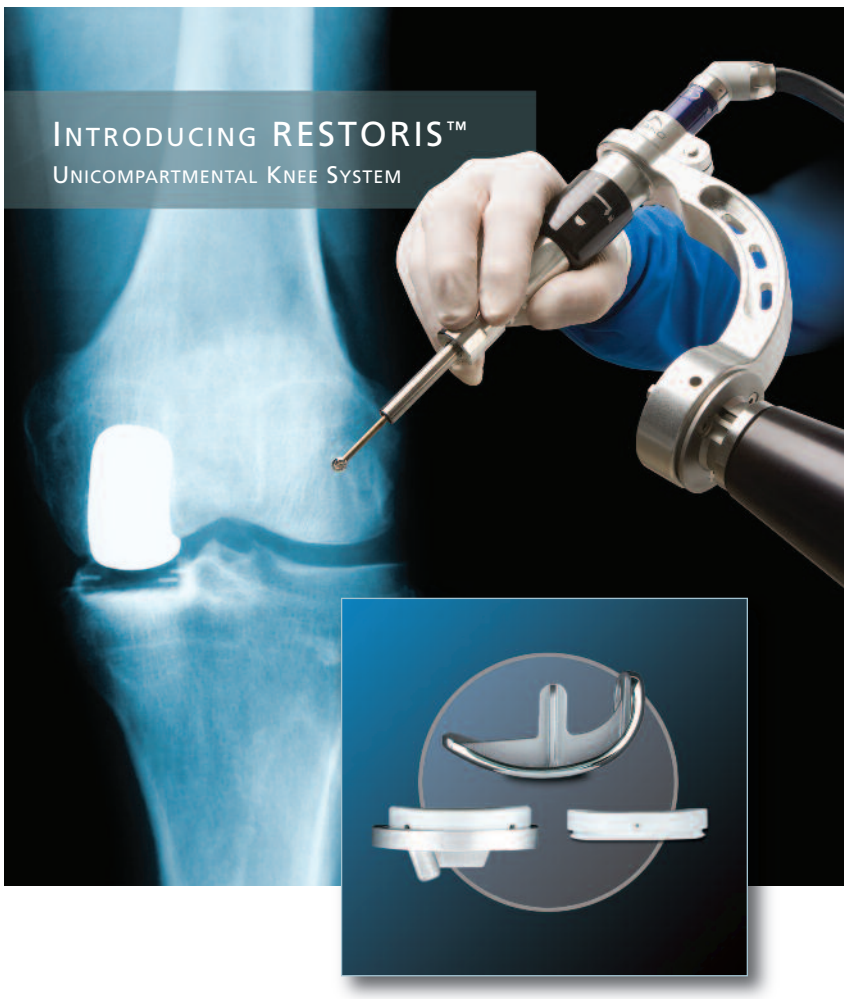
Does Less Medial Tibial Plateau Resection Make a Difference in UKA

Coon T; Driscoll, M D; Conditt, M A

Purpose:
This study assesses the clinical consequences of removing less tibial bone in UKA.

Conclusion:
- Tibial component alignment in UKA is significantly more accurate and less variable using robotic arm guided surgery compared to manual, jig-based instrumentation.
- By enhancing component alignment, this novel technique provides a potential method for improving outcomes in UKA patients.

The complete posters are available in the "Clinical" section of makosurgical.com.



RESTORIS™ Unicompartmental Knee System Is Designed For MAKOplasty®

- Implant designs which preserve critical tissue and bone for improved outcomes
- Intra-operative flexibility in converting from inlay to onlay implants
- Resurfacing implants based on proven clinical designs

New Clinical White Papers Now Available

- Outpatient Unicompartmental Knee Arthroplasty
- An Assessment of Indications for Inlay and Onlay Unicompartmental Knee Arthroplasty

These white papers and other clinical papers are available in the "Clinical" section of www.makosurgical.com.

Can Robotics Enable Advanced Modular Knee Arthroplasty Design?

continued from page 1

The ability to perform accurate, minimal exposure bone resection leads naturally to consideration of alternatives to monoblock total knee arthroplasty components and potentially to a staged, tissue-conserving treatment paradigm for knee osteoarthritis. All else being equal, there might be functional benefit to replacing only damaged compartments, and retaining the normal ligamentous structures, if one can address progression of disease in other compartments without revision of components already in place. Further, it is reasonable to assume that a system of arthroplasty components specifically designed for modular resurfacing and robotic arm guided surgical placement should perform at least as well as those previously implanted with free-hand or rather crudely instrumented techniques.

Surgeon-guided robotic capabilities present a unique opportunity to rethink knee arthroplasty design from a fresh perspective. The essential question to ask is, "With these surgical capabilities, how might you design a system of arthroplasty components to address a specific spectrum of disease in a way that maximizes the benefits of the robotic-surgery approach to the patient and surgeon?" In considering a robot-enabled approach to knee arthroplasty, we developed the following general requirements for the system and its constituent components:

- Anatomically shaped to minimize bone resection
- Implant sizes should fit patients worldwide
- Bi-cruciate retaining
- Fixed bearing
- Modular, separate compartmental components for 1, 2, or 3 compartment disease
- Modular, separate compartmental implants for size interchangeability
- Minimal incision
- Bone preparation using surgeon-guided robotic arm system

MAKO Surgical Corp. and a group of expert surgeons and engineers are working through the design details using the latest computational and experimental tools to draft these designs. Clinical experience with comprehensive and critical follow-up monitoring will prove if this design concept provides a reliable treatment option for the treatment of osteoarthritic degeneration in the cruciate-intact knee.

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