Published Clinical Data Overview

- Health Care Economics
- Accuracy
- Surgical Technique & Robotic Arm Use
- Clinical & Radiographic Outcomes
- Implant Design & Clinical Indications
- Functional & Kinematic Outcomes
MAKOplasty®

Published Clinical Data Overview

MAKOPLASTY CLINICAL RESEARCH PROGRAM

• 43 published peer-reviewed publications, including *Journal of Bone and Joint Surgery, Clinical Orthopaedics and Related Research, The Journal of Arthroplasty* and *The Knee.*
  – 30 Knee
  – 7 Hip
  – 6 Other
• 278 abstracts accepted at peer-reviewed scientific meetings
• Over 65 ongoing studies
• Studies are focused in 6 key areas:
  • Accuracy
  • Clinical and Radiographic Outcomes
  • Functional and Kinematic Outcomes
  • Implant Design and Clinical Indications
  • Surgical Technique and Robotic Arm Use
  • Health Care Economics
PUBLISHED STUDIES – KNEE

30. Effect of arthritis in other compartment after unicompartmental arthroplasty.  
- 144 medial MAKOplasty UKA (134 patients) were assessed to evaluate the impact of residual patellofemoral and lateral OA on clinical outcomes  
- Significant improvement was found in symptoms and scores in spite of other compartment diseases  
- Poorer outcomes were seen in association with comorbidities and long term disability but not when radiographic signs of arthritis in the other compartment were present  
- When symptoms were severe enough to necessitate revision, this was due to OA in the lateral facet of the patellofemoral compartment at the time of medial UKA and not existing lateral compartment disease

29. Comparison of Robot Surgery Modular and Total Knee Arthroplasty Kinematics.  
- The intact kinematics of six cadaveric specimens were measured followed by the kinematics after implantation of bicompartmental PKA, cruciate-retaining (CR) TKA and posterior stabilized (PS) TKA implants  
- Anatomic restoration of the joint surfaces and retention of the cruciate ligaments in bicompartmental knee replacement resulted in more normal kinematics than CR or PS TKA

- An analysis of MAKO’s UKA system and comprehensive summary of its procedural mechanisms  
- All medical innovations in procedures and technologies require a learning curve and unknown potential complications, but the favorable early results from MAKOplasty UKA in optimizing surgical accuracy mean improvements in partial knee arthroplasty

- Review of MAKOplasty robot-assisted UKA with respect to accuracy in restoring limb alignment and functional outcome  
- Discussion of the procedural steps of MAKOplasty including preoperative imaging, preliminary sizing of components, operative setup and robot registration, exposure and bone registration, dynamic soft-tissue assessment, graphic display and burring  
- Promising short-term results with improved surgical accuracy and improved ligament dynamics. Long-term efficacy of functional outcome and implant survivorship need to be studied

- This study of 52 consecutive cases sought to determine whether robotic arm assisted UKA accurately produced ligament tension according to an intra-operative balance plan devised before component implantation  
- Planned dynamic ligament balancing was accurate to within 0.52mm compared to the operative plan  
- 83% of the cases were within 1mm of the plan
25. Is Tibiofemoral Subluxation Correctable in Unicompartmental Knee Arthroplasty?
This study of 274 MAKOplasty UKA presented a novel method used by the authors for measuring tibiofemoral subluxation and suggests that it is a variable that may be present to varying degrees, independent of the patient’s demographic variables or overall mechanical alignment.

24. Does the Type of Tibial Component Affect Mechanical Alignment in Unicompartmental Knee Replacement?
A review of 89 MAKOplasty medial UKA patients (34, inlay tibial component and 55, onlay tibial component) found mean post-operative mechanical alignment significantly closer to neutral in the onlay group (p=0.003).

23. Robotically Assisted Unicompartmental Knee Arthroplasty.
- Describes and analyzes the RIO and its UKA technique
- Highlights the improved accuracy of implantation and exact correlation between preoperative plan and final implant analyzing a positive correlation between implant survivorship and implant alignment, rotation and slope accuracy

22. Unicompartmental knee arthroplasty: Is robotic technology more accurate than conventional technique?
Citak M; Suero EM; Citak M; Dunbar NJ; Branch SH; Conditt MA; Banks SA; Pearle AD. *Knee*. August 2013; 20(4):268-71.
- Comparison of actual implant position and orientation (post-op CT) to preoperative plan in cadaver knees with left side using traditional instrumentation and right side using haptic robotic system
- Surgical RMS errors in femoral component were 1.9mm and 3.7 for robot, 5.4 mm and 10.2 for manual, RMS errors in tibial component were 1.4mm and 5.0 for robot, 5.7mm and 19.2 for manual group

- Evaluation of tibiofemoral translation after posterior slope change with a fixed bearing UKA component in a cadaveric study
- In an ACL deficient knee in this cadaveric study, a decrease in the posterior slope of the insert decreased the anteroposterior tibiofemoral translation in the sagittal plan to a magnitude similar to that of an intact knee

Dunbar, NJ; Roche, MW; Park, BH; Branch, SH; Conditt, MA; Banks, SA. *J Arthroplasty*. May 2012. 27(5):803-808.e1.
- Comparison of the planned to post-operative accuracy of the surgeon’s first 50 robotic arm assisted UKAs
- Femoral and tibial component placement errors determined by comparison of planned implant placement to post-operative CT scans showed an average of less than 1.5mm or 3 degrees along any single axis
Published Clinical Data Overview

Suero, EM; Citak, M; Kraneburg UM; Pearle, AD; Kendoff, DO. *Knee.* January 2012. 10.1016.
   - This case study showed use of MAKOplasty in a challenging UKA case

   - A review of current robotic systems used for orthopedic surgery
   - MAKOplasty PKA was noted to produce accurate implant placement, shorter recovery and rehabilitation and a short learning curve as supported by 8 cited references

Arno, S; Maffei, D; Walker, PS; Schwarzkopf, R; Desai, P; Steiner, GC. *J Arthroplasty.* 2011. 26(8):1396-1403.
   - Examination of 97 TKA cases with medial osteoarthritis to determine the percentage of patients who would have been eligible for a medial UKA
   - 21% of the cases met the classic criteria for UKA with the conclusion that the percentage would have been even higher if the cases had been assessed earlier in the disease process

16. Comparison of Interface Stresses and Strains for Onlay and Inlay Unicompartmental Tibial Components.
   - Finite Element Analysis (FEA) to determine the stresses and strains for both inlay and onlay UKA tibial component options
   - The peak stresses and strains of the all poly inlay are much greater when compared to the metal backed onlay components

15. Future Directions in Knee Replacement.
   - This paper explores opportunities for improvement in knee replacement, including use of partial knee arthroplasty, and suggests that procedures using robotic arm assistance will have optimized position and accuracy

   - A retrospective comparison of postoperative tibial component alignment in consecutive patient populations of robotic arm assisted UKA (n=31) and manually instrumented UKA (n=27)
   - Radiographic comparisons showed higher errors in posterior tibial slope and coronal varus valgus with manual technique
   - The variance in determining posterior slope was 2.6x greater with manual technique

* Application not approved by the FDA.
13. **Robotic-Arm Assisted Unicompartmental Knee Arthroplasty.**

- The early clinical outcomes of UKAs performed with robotic arm assistance were compared with a matched group performed with manual instruments, both with an MIS technique
- Tibial component alignment was found to be more accurate and less variable and consistently less bone was removed with robotic-arm assisted techniques

12. **Arthroscopic Robotic-Arm Assisted Unicompartmental Knee Arthroplasty***

- The potential advantages of robotic-arm assisted UKA through an arthroscopic portal are discussed

11. **Minimally Invasive Robotic-Arm Guided Unicompartmental Knee Arthroplasty**

- A review of the MAKOplasty robotic-arm assisted surgical technique

10. **Indications for Unicompartmental Knee Arthroplasty and Rational for Robotic-Arm Assisted Technology.**

- This article outlines the indications for UKA
- Literature is summarized showing the relationship between component malalignment and implant failure in UKA

9. **Integrating Robotic Technology Into the Operating Room**

- The author describes how the efficiency of the surgical team can help integrate robotic technology into the OR
- His early results suggest a short learning curve and improved radiographic outcomes as compared to manual instrumentation

8. **Robot-Assisted Unicompartmental Knee Arthroplasty**

- The authors’ surgical technique for robotic arm assisted UKA is described

7. **Perioperative Management of Unicompartmental Knee Arthroplasty Using the MAKO Robotic System (MAKOplasty)**

- The perioperative management of robotic arm assisted UKA is described

* Application not approved by the FDA.
6. **Outcomes of Robotically Assisted Unicompartmental Arthroplasty**


   - Early outcomes of MAKOplasty UKA are summarized.
   - A series of 43 robotically-assisted UKA were evaluated via postoperative radiograph (344 individual measures) and revealed to have <1% as outliers.
   - In this patient group, statistically significant improvements were reported in ROM, SF-12 and WOMAC scores, pain, stiffness and physical function.
   - Within a 223 patient registry series of MAKOplasty UKA, the causes of 6 revisions were examined. None of the 6 were for implant loosening or malalignment.
   - The subset of patients at 1 year (n=84) showed significant improvements in ROM and WOMAC scores (p<0.02 and p<0.01, respectively).

5. **Haptic Robotics Enable a Systems Approach to Design of a Minimally Invasive Modular Knee Arthroplasty**


   - This article presents the design rationale for the RESTORIS MCK, a partial knee implant system with modular, unlinked components.

4. **Modular Bicompartmental Knee Arthroplasty with Robotic Arm Assistance**


   - A series of 11 modular bicompartmental arthroplasties were reviewed.
   - 75% of patients were walking without canes by 4 weeks, and mean ROM increased from 125 degrees at 6 weeks to 140 degrees at 6 months.


   - This article develops a cost-effectiveness model for robotic arm assisted UKA.
   - It demonstrates that even the relatively expensive capital equipment cost can be regained within a 2-year period without assuming any increase in market share, which likely grossly underestimates the net positive economic impact of this technology.

2. **The New Arthritic Patient and Arthroplasty Treatment Options**


   - This article summarizes a group of studies showing the clinical benefits of early intervention procedures, including an initial series of 31 patients who underwent robotic arm assisted UKA.
   - These patients recovered their preoperative range of motion and showed significant improvements in measured clinical outcomes at six weeks, including Knee Society scores (p<0.001) and WOMAC physical function and pain scores (p<0.05 and p<0.01, respectively).

1. **Robot-Assisted Unicompartmental Knee Arthroplasty**


   - Report of the first clinical series of robotically-assisted UKA (n=10).
   - Planned and intraoperative tibiofemoral angle was within 1 degree.
   - Postoperative long leg axis radiographs were within 1.6 degrees.
PUBLISHED STUDIES—HIP

7. **Comparison of Robotic-Assisted and Conventional Acetabular Cup Placement in THA: A Matched-Pair Controlled Study.**


   • Single surgeon study of 100 THAs in matched groups (50 robotic arm assisted, 50 conventional)
   • Analyzed radiographically for acetabular cup placement using the Lewinnek Zone (30-50 inclination; 5-25 version) and modified zone described by Callanan (30-45 inclination; 5-25 version)
   • 100% of MAKOplasty cups were placed within the Lewinnek Zone compared to 80% of manual cases (p=0.001)
   • 92% of MAKOplasty cups were placed within the more restricted Callanan Modified Zone compared to 62% of manual cases (p=0.001)
   • Including robotic technology in the OR to improve accuracy did not affect surgically efficiency. There was no statistically significant difference in surgical time (p=0.084) or operating room time (p=0.496)

6. **A Novel Dual Fluoroscopic Imaging Method for Determination of THA Kinematics: In-vitro and In-Vivo Study.**


   • Validation of a novel dual fluoroscopic imaging system (DFIS) to determine THA kinematics both in-vitro and in-vivo. In-vitro study compared THA motion using DFIS technique with radiostereometric analysis in cadaveric hips while in-vivo study compared THA kinematics of two patients during treadmill gait assessing feasibility/repeatability of DFIS
   • In-vitro validation found differences between DFIS and RSA within 0.33±0.81 mm in translation and 0.45±0.65 in rotation
   • In-vivo validation found high repeatability in DFIS suggesting promise of tool in evaluation of in-vivo THA biomechanics

5. **In Vitro Validation of a Non-Invasive Dual Fluoroscopic Imaging Technique for Measurement of the Hip Kinematics**


   • Validation of a non-invasive dual fluoroscopic imaging system (DFIS) for measurements of hip kinematics with bi-lateral hip joint CT scans as bone models and tested static and dynamic conditions of DFIS (compared to radiostereometric analysis)
   • Accuracy ± precision was 0.93±1.3 mm for translations and 0.59±.82 for rotations. Repeatability of DFIS was less than ±0.77 mm and ±0.64 in position and orientation of hip kinematics in static and dynamic positions

4. **Haptically guided robotic technology in total hip arthroplasty – A cadaveric investigation**

   Nawabi, DH; Conditt MA; Ranawat AS; Dunbar NJ; Jones, J; Banks S, Padgett DE. *J Eng Med.* December 2012. [Epub ahead of print].

   • MAKOplasty THA was performed on one side and manual THA on the other side of six cadaveric specimens; surgical plan vs. post-operative placement (CT Scan) was compared
   • MAKOplasty THA cups were within the specified safe zone 100% of the time as compared to 30% for manual THA cups
   • MAKOplasty demonstrated accuracy 4-6 times great than manual techniques in both inclination and version

3. **Robotic Guidance in Total Hip Arthroplasty: The Shape of Things to Come**

   Dorr, LD; Jones, RE; Padgett, DE; Pagnano, M; Ranawat, A; Trousdale, RT. *Orthopedics.* September 2011. 34(9): 652-5

   • This paper highlights the clinical value of robotic arm assisted THA, citing data showing that poor component positions and impingement are the source of increasing mechanical problems with THA
2. **Robotic Assisted Total Hip Arthroplasty Using the MAKO Platform**  
   - This publication summarizes the surgical technique for performing a MAKOplasty THA

1. **Precision Surgery**  
   - This article discusses the importance of component alignment in the prevention of complications and reduction of outliers
PUBLISHED STUDIES—OTHER

6. **Current Concepts in Robotics for the Treatment of Joint Disease**
   - This editorial explores the value of robotics to the surgeon, the patient, the hospital, the regulators and the payers.

5. **Haptic Robot-assisted Surgery Improves Accuracy of Wide Resection of Bone Tumors: A Pilot Study***
   Khan, F; Pearle, A; Lightcap, C; Boland, PJ; Healey JH. *Clin Orthop Relat Res.* 2013 Mar;471(3):851-9
   - Feasibility study to test the hypothesis that haptic robot-assisted technology enhanced primary bone tumor resection
   - Results show that robotic arm resection of osteogenic sarcomas is significantly more accurate than manual techniques
   - In addition, robotic arm preparation of recipient and donor allografts is significantly more accurate compared to manual techniques

4. **A pre-operative approach of range of motion simulation and verification for femoroacetabular impingement**
   - This study demonstrates the accuracy of a pre-operative simulation and prediction of the functional ROM of the hip

3. **The Role of Navigation and Robotic Surgery in Hip Arthroscopy***
   - This paper assesses current robotic systems and discusses their viability in surgical treatment of FAI

2. **A Novel Passive Haptic Device for Simulating a Broad Range of Impedances***
   - This study outlines the engineering concepts for a novel haptic device display

1. **Three-dimensional A-mode Ultrasound Calibration and Registration for Robotic Orthopaedic Knee Surgery.***
   - This paper reports calibration results that show an A-mode ultrasound probe can reach the same accuracy level as a mechanical probe for three-dimensional registration of bony surfaces

* Application not approved by the FDA.