

# Mako Total Knee key clinical studies

|             | Title   | Journal   | Year | Author(s)  | Institution(s)  | Conclusion   |
|-------------|---|---|------|--|---|--|
| Accuracy    | Robotic-arm assisted total knee arthroplasty more accurately restored the posterior condylar offset ratio and the Insall-Salvati Index compared to the manual technique; a cohort-matched study                               | Surgical Technology International   | 2019 | Sultan AA, Khlopas A, Sodhi N, Bhowmik-Stoker M, Chen A, Orozco F, Kolisek F, Mahoney O, Smith LS, Malkani A, Molloy RM, Mont MA | Cleveland Clinic, Cleveland, Ohio; Rothman Institute, Philadelphia, Pennsylvania; OrthoIndy, Indianapolis, Indiana; Athens Orthopaedic Clinic, Athens, Georgia; Shea Orthopedic Group, Louisville, Kentucky; Lenox Hill Hospital, New York City, New York | "Patients who underwent TKA using robotic-arm assisted technology had smaller mean differences in PCOR which had been previously shown to correlate with better joint ROM at 1-year following surgery. In addition, these patients were less likely to have values outside of normal Insall-Salvati Index, which meant they may be less likely to develop patella baja, a condition in which the patella would impinge onto the patellar component, potentially leading to restricted flexion and overall ROM."  |
| Accuracy    | Robotic assisted total knee arthroplasty demonstrates greater component placement accuracy compared to manual instrumentation: results of a prospective multi-center evaluation   | Presented at International Society for Technology in Arthroplasty (Toronto, Canada)                                   | 2019 | Mont MA, Kinsey T, Zhang J, Bhowmik-Stoker M, Chen A, Orozco F, Hozack W, Mahoney O  |   | This study showed improved accuracy to plan for RA-TKA compared to manual TKA. "Compared to manual TKA, RA-TKA cases were typically 47% more accurate for tibial component alignment, 59% more accurate for tibial slope, and 36% more accurate for femoral component rotation (percent differences of median absolute deviations from plan). As optimal component position in TKA affects joint kinematics and may positively influence implant longevity, it is important for surgeons to maximize the opportunity to direct component positioning."   |
| Accuracy    | Robotic-arm assisted total knee arthroplasty demonstrated greater accuracy and precision to plan compared with manual techniques  | J Knee Surg<br>DOI: <a href="https://doi.org/10.1055/s-0038-1641729">10.1055/s-0038-1641729</a> .                     | 2018 | Hampp EL, Chughtai M, Scholl LY, Sodhi N, Bhowmik-Stoker M, Jacofsky DJ, Mont MA   | Cleveland Clinic; Lenox Hill Hospital; CORE Institute   | In a cadaveric study that compared RA-TKA to manual TKA (M-TKA), "RA-TKA bone cuts were as or more accurate to plan based on nominal median values in 11 out of 12 measurements. RA-TKA bone cuts were more precise to plan in 8 out of 12 measurements. RA-TKA final component positions were as or more accurate to plan based on median values in five out of five measurements. RA-TKA final component positions were more precise to plan in four out of five measurements... When compared with M-TKA, RA-TKA demonstrated more accurate and precise bone cuts and implant positioning to plan." |
| Soft tissue | Iatrogenic bone and soft tissue trauma in robotic-arm assisted total knee arthroplasty compared with conventional jig-based total knee arthroplasty: a prospective cohort study and validation of a new classification system | Journal of Arthroplasty<br>DOI: <a href="https://doi.org/10.1016/j.arth.2018.03.042">10.1016/j.arth.2018.03.042</a> . | 2018 | Kayani B, Konan S, Pietrzak JRT, Haddad FS   | University College Hospital, London, UK; Princess Grace Hospital, London, UK  | "There was reduced bone and periarticular soft tissue injury" in patients undergoing RA-TKA compared to conventional TKA.  |

# Mako Total Knee key clinical studies (continued)

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|----------|--|--|------|--|---|---|
| Outcomes | Do total knee arthroplasty surgical instruments influence clinical outcomes? A prospective parallel study of 150 patients  | Presented at ORS   | 2019 | Bhowmik-Stoker M, Faizan A, Nevelos J, Tippet B, Clark G                                       | St. John of God, Perth, Australia   | Compared to computer navigated TKA, patients who received RA-TKA had significantly improved post-op pain, reduced total morphine consumption, and a reduced length of stay.   |
| Outcomes | Robotic-arm assisted total knee arthroplasty is associated with improved early functional recovery and reduced time to hospital discharge compared with conventional jig-based total knee arthroplasty: a prospective cohort study | Bone and Joint Journal<br><br>DOI:10.1302/0301-620X.100B7.BJJ-2017-1449.R1 | 2018 | Kayani B, Konan S, Tahmassebi J, Pietrzak JRT, Haddad FS                                       | University College Hospital, London, United Kingdom; Princess Grace Hospital, London, United Kingdom  | When comparing robotic-arm assisted TKA (RA-TKA) to conventional instrumented TKA, RA-TKA was associated with: less postoperative pain, reduced postoperative hemoglobin levels, less time to straight leg raise, less inpatient PT sessions, less time to hospital discharge, and improved maximum knee flexion at discharge.                                |
| Outcomes | Multicenter analysis of outcomes after robotic-arm assisted total knee arthroplasty  | Presented at the Knee Society Meeting                                      | 2018 | Hozack W, Chen A, Khlopas A, Mahoney O, Mont M, Murray T, Orozco F, Higuera Rueda C, Stearns K | Rothman Institute; Brigham and Women's Orthopaedic Center; Cleveland Clinic; Athens Orthopaedic Clinic; Lenox Hill Hospital                 | The data indicated RA-TKA patients had greater improvement in their functional activity walking and standing scores at both 4-6 weeks and 6 months follow-up (p=0.019 and p=0.017, respectively) when compared to conventional TKA patients. Additionally, RA-TKA patients had higher overall functional activity improvements at 1-year follow-up (p=0.020). |
| Outcomes | Does robotic-arm assisted surgery improve early outcomes in total knee arthroplasty?   | Presented at ORS   | 2018 | Bhimani S, Bhimani R, Feher A, Malkani A   | University of Louisville, Louisville, KY; Jewish Hospital, KentuckyOne Health, Louisville, KY   | The RA-TKA group had significantly lower VAS pain scores at rest and with activity compared to the manual instrument TKA group at 6-week follow-up.   |
| Outcomes | Patient satisfaction outcomes after robotic-arm assisted total knee arthroplasty: a short-term evaluation  | J Knee Surg<br><br>DOI: 10.1055/s-0037-1607450                             | 2017 | Marchand RC, Sodhi N, Khlopas A, Sultan AA, Harwin SF, Malkani AL, Mont MM                     | Ortho Rhode Island, Wakefield, RI; Cleveland Clinic, Cleveland, OH; Mount Sinai West Hospital, New York; KentuckyOne Health, Louisville, KY | The RA-TKA cohort had a significantly lower mean pain score and greater patient satisfaction than the manual TKA cohort. The results from this study showed that patients who underwent RA-TKA demonstrated better overall patient satisfaction and functional outcome scores.  |
| Cost     | Health care utilization and payer cost analysis of robotic arm assisted total knee arthroplasty at 30, 60, and 90 days   | J Knee Surg<br><br>DOI: 10.1055/s-0039-1695741                             | 2019 | Mont MA, Cool C, Gregory D, Coppolecchia A, Sodhi N, Jacofsky D                                | Lenox Hill Hospital; Baker Tilly; The CORE Institute  | RA-TKA patients had overall lower average 90-day EOC cost to payer (Medicare) compared to conventional TKA. Cost savings were driven by: reduced index facility costs, lower LOS, discharge destinations, and decreased readmissions.   |

# Mako Partial Knee key clinical studies

|              | Title   | Journal   | Year | Author(s)  | Institution(s)  | Conclusion  |
|--------------|---|---|------|--|---|---|
| Accuracy     | Improved accuracy of component positioning with robotic-assisted unicompartmental knee arthroplasty: data from a prospective, randomized controlled study | Journal of Bone and Joint Surgery<br><a href="https://doi.org/10.2106/JBJS.15.00664">DOI: 10.2106/JBJS.15.00664</a>         | 2016 | Bell SW, Anthony I, Jones B, MacLean A, Rowe P, Blyth M          | Glasgow Royal Infirmary, UK   | Mako Partial Knee demonstrated improved accuracy of component positioning to plan compared with conventional surgical techniques (Oxford).  |
| Survivorship | Clinical outcomes of robotically assisted UKAs at 3 years follow-up   | Presented at The Partial Knee Meeting (Bruges, Belgium)   | 2018 | Catani F   | Universita degli Studi di Modena e Reggio-Emilia, Italy   | Mako Partial Knee survivorship at 3-year follow-up was 99.2% for medial UKA (n=388) and 100% for lateral UKA (n=67).  |
| Survivorship | Midterm survivorship and patient satisfaction of robotic-arm assisted medial unicompartmental knee arthroplasty: a multicenter study                      | Journal of Arthroplasty<br><a href="https://doi.org/10.1016/j.arth.2018.01.036">DOI: 10.1016/j.arth.2018.01.036</a>         | 2018 | Kleebblad LJ, Borus TA, Coon TM, Douchis J, Nguyen JT, Pearle AD | Hospital for Special Surgery, New York; Rebound Orthopedics & Neurosurgery, Portland, OR; Coon Joint Replacement Institute, CA; NCH Orthopedics, FL | Mako Partial Knee showed 97% survivorship at midterm 5-year follow-up in this multicenter study (n=432). Mako Partial Knee 5-year survivorship was similar to conventional primary total knee and far superior to manual partial knee in the 2018 Australian Joint Registry Report. Mako Partial Knee also showed 91% of patients were either very satisfied or satisfied with their knee function at 5-year follow-up. |
| Survivorship | Australian Hip, Knee & Shoulder Arthroplasty Registry 2018  | AOANJRR 2018<br><a href="https://aoanjrr.sahmri.com/annual-reports-2018">https://aoanjrr.sahmri.com/annual-reports-2018</a> | 2018 | N/A  | Australia   | Mako Partial Knee showed 1.2% revision rate at 1-year follow-up in the 2018 Australian Registry, whereas Oxford cemented showed 2.2% revision rate.   |

# Mako Partial Knee key clinical studies (continued)

|                 | Title  | Journal  | Year | Author(s)   | Institution(s)  | Conclusion  |
|-----------------|--|--|------|---|---|---|
| <b>Outcomes</b> | An assessment of early functional rehabilitation and hospital discharge in conventional versus robotic-arm assisted unicompartmental knee arthroplasty | Bone Joint J<br><br>DOI: <a href="#">10.1302/0301-620X.101B1.BJJ-2018-0564.R2</a>          | 2019 | Kayani B, Konan S, Tahmassebi J, Rowan FE, Haddad FS                            | University College London Hospital; Princess Grace Hospital                             | In a single surgeon study comparing consecutive Mako Partial Knee (n=73) vs. manual Oxford uni (n=73), Mako Partial Knee patients demonstrated: reduced post-op pain (p<0.001), decreased analgesia requirements (p<0.001), shorter time to straight leg raise (p<0.001), decreased number of PT sessions (5 vs. 9, p<0.001), improved max knee flexion at discharge (p<0.001), and reduced mean time to hospital discharge (29 hours). |
| <b>Outcomes</b> | Outcomes of robotic-arm assisted medial unicompartmental knee arthroplasty: minimum 3-year follow-up   | European Journal of Orthopaedic Surgery & Traumatology                                     | 2019 | Dretakis K, Igoumenou VG<br><br>DOI: <a href="#">10.1007/s00590-019-02424-4</a> | Hygeia Hospital, Athens, Greece; National and Kapodistrian University of Athens, Greece | At minimum 3-year follow-up, Mako Partial Knee patients (n=51) showed no implant failure or implant-related complication or revision surgery, as well as excellent overall patient satisfaction for 96.1% of patients (patients reported very satisfied or satisfied).  |
| <b>Outcomes</b> | Robotic-arm assisted vs. conventional unicompartmental knee arthroplasty: the 2 year clinical outcomes of a randomized controlled trial                | J Arthroplasty<br><br>DOI: <a href="#">10.1016/j.arth.2018.02.050</a>                      | 2018 | Gilmour A, MacLean AD, Rowe PJ, Banger MS, Donnelly I, Jones BG, Blyth M        | Glasgow Royal Infirmary, Scotland, UK; University of Strathclyde, Scotland, UK          | For more active patients, Mako Partial Knee patients had significantly better outcomes at 2 years compared to manual Oxford uni patients as measured by the AKSS (p=0.017), OKS (p=0.036), FJS (p=0.017), and Stiffness VAS (p=0.019).  |
| <b>Outcomes</b> | Robotic-arm assisted versus conventional unicompartmental knee arthroplasty: exploratory secondary analysis of a randomized controlled trial           | Bone and Joint Research<br><br>DOI: <a href="#">10.1302/2046-3758.611.BJR-2017-0060.R1</a> | 2017 | Blyth MJG, Anthony I, Rowe P, Banger MS, MacLean A, Jones B                     | University of Strathclyde, Glasgow, UK  | Mako Partial Knee patients reported 55.4% lower post-op pain compared to manual patients (Oxford) from day one to week eight (p=0.04) and had better AKSS scores compared to manual patients at 3 months post-op. Key factors associated with achieving excellent clinical outcomes on the AKSS were: a pre-op activity level >5 on the UCLA activity score and use of robotic-arm assisted surgery.                                    |
| <b>Cost</b>     | Revision analysis of robotic-arm assisted and manual unicompartmental knee arthroplasty  | J Arthroplasty<br><br>DOI: <a href="#">10.1016/j.arth.2019.01.018</a>                      | 2019 | Cool CL, Needham KA, Khlopas A, Mont MA   | Baker Tilly, NY; Cleveland Clinic, OH; Lenox Hill Hospital, NY                          | This study demonstrated that patients who underwent Mako Partial Knee had fewer revision procedures, shorter length of stay, and incurred lower mean costs during the index admission and at 24 months post-op.   |

# Mako Total Hip key clinical studies

|          | Title   | Journal  | Year | Author(s)   | Institution(s)  | Conclusion   |
|----------|---|--|------|---|---|--|
| Accuracy | Accuracy of component positioning in 1980 total hip arthroplasties: a comparative analysis by surgical technique and mode of guidance       | The Journal of Arthroplasty<br><a href="#">DOI: 10.1016/j.arth.2015.06.059</a> | 2018 | Domb B, Redmond J, Louis S, Alden K, Daley R, LaReau J, Petrakos A, Gui C, Suarez-Ahedo C | American Hip Institute  | Robotic-guided surgery was more accurate to plan than other techniques and modes of guidance in placing the acetabular component within the Lewinnek and Callanan safe zones.  |
| Accuracy | Variance in predicted cup size by 2-dimensional vs 3-dimensional computerized tomography-based templating in primary total hip arthroplasty | Arthroplasty Today<br><a href="#">DOI: 10.1016/j.artd.2016.09.003</a>          | 2017 | Osmani F, Thakkar S, Ramme A, Elbuluk A, Wojack P, Vigdorchik J                           | NYU Langone Medical Center, Hospital for Joint Disease  | CT-guided planning more accurately predicted hip implant cup size when compared to the significant overpredictions of digital and acetate templating. CT-guided templating may also lead to better outcomes due to bone stock preservation from a smaller and more accurate cup size predicted than that of digital and acetate predictions. |
| Accuracy | Precision of acetabular cup placement in robotic integrated total hip arthroplasty  | Hip International<br><a href="#">DOI: 10.5301/hipint.5000289</a>               | 2015 | Elson L, Douchis J, Illgen R, Marchand R, Padgett D, Bragdon C, Malchua H                 | Massachusetts General Hospital; Creekside Medical Center; South County Hospital; Hospital for Special Surgery | Intraoperative robotic assistance allowed for precision of preparation and position of the acetabular cup to plan during total hip arthroplasty.   |
| Accuracy | Accuracy of cup positioning and achieving desired hip length and offset following robotic THA   | Presented at CAOS  | 2014 | Jerabek S, Carroll K, Marratt J, Mayman D, Padgett D                                      | Hospital for Special Surgery  | Robotic THA provided excellent accuracy and precision with regard to planned cup position, hip length and offset.  |
| Accuracy | Comparison of robotic-assisted and conventional acetabular cup placement in THA: a matched-pair control study                               | Clinical Orthopaedics and Related Research                                     | 2013 | Domb B, Bitar Y, Sadik A, Stake C, Botser I   | American Hip Institute<br><a href="#">DOI: 10.1007/s11999-013-3253-7</a>                                      | Use of robotic system allowed for improvement in placement of the cup in both Lewinnek and Callanan safe zones.  |
| Accuracy | Haptically guided robotic technology in total hip arthroplasty: A cadaveric investigation   | Sage Publications<br><a href="#">DOI: 10.1177/0954411912468540</a>             | 2013 | Nawabi D, Conditt M, Ranawat A, Dunbar N, Jones J, Banks S, Padgett D                     | Hospital for Special Surgery  | In a cadaveric study, the robotic-assisted system was significantly more accurate to plan than manual implantation in reproducing COR and cup orientation.   |

# Mako Total Hip key clinical studies (continued)

|                          | Title  | Journal   | Year | Author(s)   | Institution(s)   | Conclusion  |
|--------------------------|--|---|------|---|--|---|
| <b>Bone preservation</b> | Robotic-arm assisted total hip arthroplasty results in smaller acetabular cup size in relation to the femoral head size: a matched-pair controlled study | Hip International<br><a href="#">DOI: 10.5301/hipint.5000418</a>      | 2017 | Suarez-Ahedo C, Gui C, Martin T, Chandrasekaran S, Lodhia P, Domb B       | American Hip Institute   | Using acetabular cup size relative to femoral head size as an approximate surrogate measure of acetabular bone resection, these results may suggest greater preservation of bone stock using RTHA compared to CTHA.                             |
| <b>Outcomes</b>          | Robotic-assisted total hip arthroplasty: clinical outcomes and complication rate   | Int J Med Robot<br><a href="#">DOI: 10.1002/rcs.1912</a>              | 2018 | Perets I, Walsh J, Close M, Mu B, Yuen L, Domb B                          | American Hip Institute   | “Mako Total Hip reported the highest Forgotten Joint Score (FJS) for THA in literature, no leg length discrepancies, and no dislocations.”  |
| <b>Outcomes</b>          | Conventional vs robotic-arm assisted total hip arthroplasty (THA) surgical time, transfusion rates, length of stay, complications and learning curve     | Journal of Arthritis<br><a href="#">DOI:10.4172/2167-7921.1000272</a> | 2018 | Heng Y, Gunaratne R, Ironside C, Taheri A                                 | Joondalup Health Campus, Australia; Curtin University, Australia | The observed reduction in LOS, comparable surgical times and potential for fewer complications may outweigh the increased initial cost associated with the robotic system.  |
| <b>Outcomes</b>          | Robotic-assisted total hip arthroplasty: outcomes at minimum two year follow up  | Surgical Technology International                                     | 2017 | Illgen R, Bukowski B, Abiola R, Anderson P, Chughtai M, Khlopas A, Mont M | University of Wisconsin; Cleveland Clinic                        | RA-THA improved acetabular component accuracy and reduced dislocation rates compared with mTHA.   |
| <b>Outcomes</b>          | Improved functional outcomes with robotic compared with manual total hip arthroplasty  | Surgical Technology International                                     | 2016 | Bukowski B, Anderson P, Khlopas A, Chughtai M, Mont M, Illgen R           | University of Wisconsin; Cleveland Clinic                        | The rTHA cohort demonstrated significantly higher mean postoperative UCLA scores, higher mean postoperative mHHS scores, and a greater percentage of patients with mHHS of 90 to 100 points compared with mTHA at a minimum one-year follow-up. |

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