

Mako SmartRobotics™ clinical quick guide

Mako Total Knee key clinical studies

| | Title | Reference | Institution(s) | Conclusion | Link |
|----------|--|--|--|--|---|
| Accuracy | CT validation of intraoperative implant position and knee alignment as determined by the Mako Total Knee Arthroplasty System | Sires JD, Wilson CJ. CT validation of intraoperative implant position and knee alignment as determined by the Mako Total Knee Arthroplasty System. J Knee Surg. Accepted manuscript. Published online March 4, 2020. doi:10.1055/s-0040-1701447 | Flinders Medical Centre, Adelaide, South Australia, Australia | This was the first independent study to clinically evaluate the accuracy of intraoperative component alignment through CT validation of the Mako Total Knee System software. Overall, intraoperatively measured component and limb alignment as estimated by Mako Total Knee was comparable to postoperative CT-based measurements (within 1-2 degrees) and mean absolute difference of limb alignment (and standard deviation) was 1.29 degrees (1.25). Postoperative measurements were made off of postoperative CTs and compared to intraoperative values. | https://pubmed.ncbi.nlm.nih.gov/32131103/ |
| Accuracy | Robotic-assisted total knee arthroplasty demonstrates greater component placement accuracy compared with manual instrumentation: initial results of a prospective multicentre evaluation | Mont M, Kinsey T, Zhang J, et al. Robotic-assisted total knee arthroplasty demonstrates greater component placement accuracy compared with manual instrumentation: initial results of a prospective multicentre evaluation. Bone Joint J:Orthop Proc. 2020;102-B(Supp_2):43. | Lenox Hill Hospital; The Athens Orthopaedic Clinic; Stryker Orthopaedics; Brigham and Women's Orthopaedic Center; Rothman Institute, NJ; Rothman Institute, PA | This study showed improved accuracy to plan for robotic-arm assisted TKA (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). | https://online.boneandjoint.org.uk/doi/abs/10.1302/1358-992X.2020.2.043 |
| Accuracy | Accuracy of bone resection in Mako Total Knee robotic-assisted surgery | Sires JD, Craik JD, Wilson CJ. Accuracy of bone resection in Mako Total Knee Robotic-assisted Surgery. J Knee Surg. Accepted manuscript. Published online November 6, 2019. doi:10.1055/s-0039-1700570 | Flinders Medical Centre, Adelaide, South Australia, Australia | On a series of 37 patients, the mean observed difference (and standard deviation) from the surgical plan for distal femoral cuts was 0.38 mm (0.32 mm) deep/proud, for anterior femoral cuts was 0.44 mm (0.27 mm) deep/proud and for tibial cuts was 0.37 mm (0.30 mm) deep/proud. In total, 99 out of 105 (94.29%) of bone resections were within 1 mm of the plan. Mean absolute difference in final limb coronal alignment was 0.78° (0.78°), with 78.13% being ≤ 1.00° of the plan, and 100% being ≤ 3.00° of the plan. These results indicate the ability of the surgeon to accurately achieve preoperatively planned bone resection and final limb coronal alignment using Mako Total Knee. | https://pubmed.ncbi.nlm.nih.gov/31694057/ |

Mako Total Knee key clinical studies (continued)

| | Title | Reference | Institution(s) | Conclusion | Link |
|--------------------|---|---|--|--|---|
| Accuracy | Robotic-arm assisted total knee arthroplasty demonstrated greater accuracy and precision to plan compared with manual techniques | Hampp EL, Chughtai M, Scholl LY, et al. Robotic-arm assisted total knee arthroplasty demonstrated greater accuracy and precision to plan compared with manual techniques. J Knee Surg. 2019;32(3):239-250. doi:10.1055/s-0038-1641729 | 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." | https://pubmed.ncbi.nlm.nih.gov/29715696/#:~:text=Abstract,total%20knee%20arthroplasty%20(MTKA).&text=RATKA%20bone%20cuts%20were%20more,measurements%20(p%20%E2%89%A4%200.05). |
| 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 | Kayani B, Konan S, Pietrzak JRT, Haddad FS. 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. J Arthroplasty. 2018;33(8):2496-2501. doi:10.1016/j.arth.2018.03.042 | University College Hospital, London, United Kingdom; Princess Grace Hospital, London, United Kingdom | "There was reduced bone and periarticular soft tissue injury" in patients who underwent RA-TKA compared to conventional TKA. | https://pubmed.ncbi.nlm.nih.gov/29699827/ |
| Outcomes | Do total knee arthroplasty surgical instruments influence clinical outcomes? A prospective parallel study of 150 patients | Bhowmik-Stoker M, Faizan A, Nevelos JE, Tippet B, Clark G. Do total knee arthroplasty surgical instruments influence clinical outcomes? A prospective parallel study of 150 patients. Presented at: Orthopaedic Research Society Annual Meeting; February 2-5, 2019; Austin, TX | St. John of God, Perth, Australia | Compared to computer-navigated TKA, patients who received RA-TKA had significantly improved postoperative pain, reduced total morphine consumption and a reduced length of stay. | https://www.ors.org/Transactions/65/0329.pdf |

Mako Total Knee key clinical studies (continued)

| | Title | Reference | Institution(s) | Conclusion | Link |
|-----------------|--|--|---|---|---|
| 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 | Kayani B, Konan S, Tahmassebi J, Pietrzak JRT, Haddad FS. 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. <i>Bone Joint J.</i> 2018;100-B(7):930-937. doi:10.1302/0301-620X.100B7.BJJ-2017-1449.R1 | University College Hospital, London, United Kingdom; Princess Grace Hospital, London, United Kingdom | When comparing robotic-arm assisted TKA to conventional-instrumented TKA, RA-TKA was associated with: less postoperative pain, reduced postoperative hemoglobin levels, less time to straight leg raise, fewer inpatient PT sessions, less time to hospital discharge and improved maximum knee flexion at discharge. | https://www.ncbi.nlm.nih.gov/pubmed/29954217 |
| Outcomes | Patient-reported functional and satisfaction outcomes after robotic-arm-assisted total knee arthroplasty: early results of a prospective multicenter investigation | Khlopas A, Sodhi N, Hozack WJ, et al. Patient-reported functional and satisfaction outcomes after robotic-arm-assisted total knee arthroplasty: early results of a prospective multicenter investigation. <i>J Knee Surg.</i> 2020;33(7):685-690. doi:10.1055/s-0039-1684014 | Cleveland Clinic; Lenox Hill Hospital; Rothman Institute; Brigham and Women's Hospital; Athens Orthopaedic Clinic | "At 4 to 6 weeks postoperatively, RA-TKA patients were found to have significantly larger improvements in walking and standing (1.4 vs. -1.2 points; p = 0.019)... advanced activities (1.3 vs. 2.3 points), pain with walking (3.3 vs. 3.2 points), satisfaction score (12.4 vs. 12 points), and expectations score (5.1 vs. 4.4 points) when compared with manual TKA patients. At 3 months, RA-TKA patients were also found to have larger improvements in walking and standing (6.0 vs. 4.8 points), standard activities (11.4 vs. 10.1 points), advanced activities (6.2 vs. 4.6 points), functional activities total score (22.8 vs. 21.2 points), pain with walking (4.3 vs. 4.1 points), total symptoms score (10.5 vs. 10.3 points), satisfaction score (17.0 vs. 15.5 points), and expectations score (4.8 vs. 4.0 points) when compared with manual TKA patients." | https://pubmed.ncbi.nlm.nih.gov/30959541/ |

Mako Total Knee key clinical studies (continued)

| | Title | Reference | Institution(s) | Conclusion | Link |
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| Outcomes (2 years) | New technology for total knee arthroplasty provides excellent patient-reported outcomes: a minimum two-year analysis | Malkani AL, Roche MW, Kolisek FR, et al. New technology for total knee arthroplasty provides excellent patient-reported outcomes: a minimum two-year analysis. Surg Technol Int. 2020;36:276-280. | University of Louisville; Holy Cross Orthopedic Institute; OrthoIndy; Florida Orthopaedic Institute; The Rothman Institute; Long Island Jewish Medical Center; Northwell Health; Cleveland Clinic; Lenox Hill Hospital | Five fellowship-trained, high-volume surgeons at different institutions performed a total of 188 total knee arthroplasty surgeries using Mako Total Knee and had a two-year minimum clinical follow-up. All patients reported excellent postoperative outcomes for Forgotten Joint Score (FJS), Short Form-12 Questionnaire (SF-12) and Knee Society total and subscores (KSS). The mean postoperative SF-12 mental composite score (MCS) and physical composite score (PCS) scores were both 57 points, with 50 as the threshold for norm-based scoring (MCS range: 42 to 69 points; PCS range: 41 to 68 points). The mean FJS was 75 points (range: 14 to 100 points). The mean KSS functional score was 84 points (range: 20 to 100) while the mean Knee Score was 92 points (range: 40 to 100). Similarly, the authors found that the aseptic revision rates were low (n=2, 1.06%, one for unexplained pain, and another for a post-traumatic tibial fracture) with few other postoperative complications (n=7 patients [3.7%]) in this cohort. This analysis found that patients had excellent outcomes across multiple patient-reported outcome measures at a minimum of two-year clinical follow-up after a Mako Total Knee. | https://pubmed.ncbi.nlm.nih.gov/31732961/ |
| Outcomes (adverse events) | Manipulation under anesthesia rates in technology-assisted versus conventional-instrumentation total knee arthroplasty | Malkani AL, Roche MW, Kolisek FR, et al. Manipulation under anesthesia rates in technology-assisted versus conventional-instrumentation total knee arthroplasty. Surg Technol Int. 2020;36:336-340. | University of Louisville; Holy Cross Orthopedic Institute; OrthoIndy; Florida Orthopaedic Institute; The Rothman Institute; Long Island Jewish Medical Center; Northwell Health; Cleveland Clinic; Lenox Hill Hospital | Five fellowship-trained, high-volume surgeons at different institutions performed a total of 188 total knee arthroplasty surgeries using Mako Total Knee. All patients followed similar postoperative rehabilitation starting on postoperative day one. Rates of manipulations under anesthesia (MUAs) were evaluated within and between cohorts. Patients were paired to a consecutive equal number of control patients by each of the specific surgeons for comparison. Additionally, the percent difference of rates was calculated to compare cohorts. All patients were evaluated at a minimum of two-years follow-up time from the index procedure. This study found that patients who underwent robotic-assisted TKA experienced a significant, 4.5-fold decrease in rates of manipulation under anesthesia (p=0.032). | https://www.ncbi.nlm.nih.gov/pubmed/31747712 |

Mako Total Knee key clinical studies (continued)

| | Title | Reference | Institution(s) | Conclusion | Link |
|-----------------------------|--|--|--|--|---|
| Patient satisfaction | Improved patient satisfaction following robotic-assisted total knee arthroplasty | Smith AF, Eccles CJ, Bhimani SJ, et al. Improved patient satisfaction following robotic-assisted total knee arthroplasty. J Knee Surg. Accepted manuscript. Published online November 15, 2019. doi:10.1055/s-0039-1700837 | Kentucky One Health, University of Louisville | One hundred twenty consecutive patients who underwent RA-TKA were compared with a prospective cohort of 103 consecutive patients undergoing TKA with manual jig-based instruments during the same time period. There were no differences between groups with age, gender, baseline Knee Society Score (KSS) knee and function scores, follow-up, and ASA scores. TKAs were performed using same technique, implant design, anesthesia and postoperative treatment protocols. Likert scoring system demonstrated 94% of the patients in the RA-TKA group were either very satisfied or satisfied versus 82% in the manual instruments TKA group (p = 0.005) at one-year follow-up. The RA-TKA group had a better average overall satisfaction score of 7.1 versus 6.6 in the manual instrument group, p = 0.03 at one-year follow-up. KSS function scores for the RA-TKA group were significantly better than those observed in the manual cohort at six weeks and one year postoperatively (p = 0.02, 0.005), and KSS knee scores were significantly better at one year postoperatively (p = 0.046). | https://pubmed.ncbi.nlm.nih.gov/31731324/ |
| Health economics | Robotic-assisted knee surgery: an economic analysis | Pierce J, Needham C, Adams C, Coppolecchia AB, Lavernia C. Robotic-assisted knee surgery: an economic analysis. Presented at: Orthopaedic Research Society Annual Meeting. February 8-11, 2020; Phoenix, AZ. | Baker Tilly, Stryker, University of Miami | This retrospective, longitudinal claims analysis evaluated 90-day episode-of-care (EOC) costs for patients who underwent total knee arthroplasty. Three-hundred and fifty-seven RA-TKAs and 1785 M-TKAs were propensity matched for analysis. Robotic-assisted TKA was associated with shorter length of stay (LOS) and reduced utilization of services. The authors demonstrated that the average 90-day EOC payer costs were \$4,049 less for the robotic-assisted TKA patients when compared to manual TKA patients. These findings may be pertinent to payers as well as providers. | https://www.ors.org/Transactions/66/2350.pdf |
| Health economics | A 90-day episode-of-care cost analysis of robotic-arm assisted total knee arthroplasty | Cool CL, Jacofsky DJ, Seeger KA, Sodhi N, Mont MA. A 90-day episode-of-care cost analysis of robotic-arm assisted total knee arthroplasty. J Comp Eff Res. 2019;8(5):327-336. doi:10.2217/ceer-2018-0136 | Baker Tilly, The Core Institute, Lenox Hill Hospital | TKA procedures were identified in Medicare 100% data. Accounting for baseline differences, propensity score matching was performed 1:5. Ninety-day EOC and index costs, lengths of stay, discharge disposition and readmission rates were assessed. A total of 519 RA-TKAs and 2595 M-TKAs were included. Overall 90-day EOC costs were U.S. \$2,391 less for RA-TKA (p < 0.0001). Over 90% of patients in both cohorts utilized post-acute services, with RA-TKA accruing fewer costs than M-TKA. Post-acute savings can be attributed to discharge destination. RA-TKA incurred an overall lower 90-day EOC cost versus M-TKA. Savings were driven by fewer readmissions and economically beneficial discharge destinations. | https://www.ncbi.nlm.nih.gov/pubmed/30686022 |

Mako Total Knee key clinical studies (continued)

| | Title | Reference | Institution(s) | Conclusion | Link |
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| Health economics | Health care utilization and payer cost analysis of robotic arm assisted total knee arthroplasty at 30, 60, and 90 days | Mont MA, Cool C, Gregory D, Coppolecchia A, Sodhi N, Jacofsky DJ. Health care utilization and payer cost analysis of robotic arm assisted total knee arthroplasty at 30, 60, and 90 days. <i>J Knee Surg</i> . Accepted manuscript. Published online September 2, 2019. doi:10.1055/s-0039-1695741 | 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. The RA-TKA cohort had consistently lower average total episode payment than the M-TKA cohort when compared at 30, 60 and 90 days. At 30 days, 47% fewer RA-TKA patients utilized SNF services (13.5 vs. 25.4%, $p < 0.0001$) and RA-TKA patients had lower SNF costs at 30, 60 and 90 days. RA-TKA patients also utilized fewer home health visits and incurred fewer costs at each time point ($p < 0.05$). Additionally, 31.3% fewer RA-TKA patients utilized emergency room services at 30 days postoperatively, and the RA-TKA cohort had fewer 90-day readmissions (5.2 vs. 7.75%, $p = 0.0423$). Mont et al. concluded that RA-TKA was associated with lower 30-, 60- and 90-day postoperative costs and healthcare utilization. | https://www.ncbi.nlm.nih.gov/pubmed/31476777 |

Mako Partial Knee key clinical studies

| | Title | Reference | Institution(s) | Conclusion | Link |
|------------------------------------|---|--|---|--|---|
| Accuracy and learning curve | The learning curve associated with robotic-arm assisted unicompartmental knee arthroplasty: a prospective cohort study | Kayani B, Konan S, Pietrzak JRT, Huq SS, Tahmassebi J, Haddad FS. The learning curve associated with robotic-arm assisted unicompartmental knee arthroplasty: a prospective cohort study. <i>Bone Joint J.</i> 2018;100-B(8):1033-1042. doi:10.1302/0301-620X.100B8.BJJ-2018-0040.R1 | Princess Grace Hospital and University College Hospital, London, United Kingdom | "Implant placement was significantly more accurate to plan in the posterior tibial slope and joint line height in Mako Partial Knees (n=60) compared to conventional Oxford PKAs (n=60). There was a statistically significant improvement in the planned femoral coronal (p < 0.001) and sagittal (p < 0.001) implant positioning, tibial coronal (p < 0.001) and sagittal (p < 0.001) implant positioning, posterior tibial slope (p < 0.001), and joint line height (p < 0.001) compared with conventional jig-based UKA. Mako Partial Knee was associated with a learning curve of six cases for operating time and surgical team confidence levels, but no learning curve for accuracy of implant positioning." | https://pubmed.ncbi.nlm.nih.gov/30062950/#:~:text=Conclusion%3A%20Robotic%20Darm%20assisted%20UKA,for%20accuracy%20of%20implant%20positioning. |
| Accuracy | Improved accuracy of component positioning with robotic-assisted unicompartmental knee arthroplasty: data from a prospective, randomized controlled study | Bell SW, Anthony I, Jones B, MacLean A, Rowe P, Blyth M. Improved accuracy of component positioning with robotic-assisted unicompartmental knee arthroplasty: data from a prospective, randomized controlled study. <i>J Bone Joint Surg Am.</i> 2016;98(8):627-635. doi:10.2106/JBJS.15.00664 | Glasgow Royal Infirmary, United Kingdom | Mako Partial Knee demonstrated improved accuracy of component positioning to plan compared with conventional surgical techniques (Oxford). | https://pubmed.ncbi.nlm.nih.gov/27098321/ |
| Precision | Robot-assisted unicompartmental knee arthroplasty can reduce radiologic outliers compared to conventional techniques | Park KK, Han CD, Yang I-H, Lee W-S, Han JH, Kwon HM. Robot-assisted unicompartmental knee arthroplasty can reduce radiologic outliers compared to conventional techniques. <i>PLoS One.</i> 2019;14(12):e0225941. doi:10.1371/journal.pone.0225941 | Yonsei University College of Medicine, Seoul, Korea | In a consecutive cohort series of 55 Mako medial UKA patients and 57 manual medial UKA patients, Mako Partial Knee achieved fewer radiologic outliers in terms of mechanical femorotibial angle and coronal alignment of tibial and femoral components (p = 0.022, 0.037, 0.003) and fewer outliers of femoral and tibial component position compared to conventional UKA as studied among an Asian patient population. | https://pubmed.ncbi.nlm.nih.gov/31794587/ |

Mako Partial Knee key clinical studies (continued)

| | Title | Reference | Institution(s) | Conclusion | Link |
|---|--|--|---------------------------------------|---|---|
| Bone preservation | Robotic partial knee arthroplasty demonstrated greater bone preservation compared to robotic total knee arthroplasty | Hampp E, Chang T-C, Pearle A. Robotic partial knee arthroplasty demonstrated greater bone preservation compared to robotic total knee arthroplasty. Presented at: Orthopaedic Research Society Annual Meeting; February 2-5, 2019; Austin, TX. | Hospital for Special Surgery, Stryker | This study found that there was significantly less volume of combined femur and tibia bone resected for a robotic medial partial knee arthroplasty (RA-PKA) compared to a cruciate-retaining (CR) and posterior stabilized (PS) RA-TKA (p<0.05). | https://www.morressier.com/article/0929--robotic-partial-knee-arthroplasty-demonstrated-greater-bone-preservation-compared-robotic-total-knee-arthroplasty/5c8f9097b5d368000-a26b93d |
| Survivorship (midterm) | Australian Orthopaedic Association National Joint Replacement Registry - 2019 Annual Report | Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR). Hip, Knee & Shoulder Arthroplasty: 2019 Annual Report. Adelaide: AOA, 2019. | AOANJRR Registry Report | Mako Partial Knee showed 2.5% revision rate at three-year follow-up in the 2019 Australian Registry, whereas Oxford cemented showed 5.8% revision rate. The cumulative percent revision of primary total knee replacements for the same follow-up was 2.7% for osteoarthritis. | https://aoanjrr.sahmri.com/annual-reports-2019 |
| Survivorship (mid- to long-term) | Mid-term survivorship and patient-reported outcomes of robotic-arm assisted partial knee arthroplasty | Burger JA, Kleeblad LJ, Laas N, Pearle AD. Mid-term survivorship and patient-reported outcomes of robotic-arm assisted partial knee arthroplasty. Bone Joint J. 2020;102-B(1):108-116. doi:10.1302/0301-620X.102B1.BJJ-2019-0510.R1 | Hospital for Special Surgery | This large single-surgeon study (1260 knees in 1062 patients) showed high midterm survivorship, satisfaction levels, and functional outcomes in robotic-arm assisted UKA (RA-UKA). Mean follow-up was 4.7 years (2.0 to 10.8). Five-year survivorship of medial UKA (n = 802) was 97.8%, lateral UKA (n = 171) was 97.7%, and patellofemoral arthroplasty (PFA)/ bicompartamental knee arthroplasty (BiKA) (n = 35/10) was 93.3%. | https://pubmed.ncbi.nlm.nih.gov/31888356/ |

Mako Partial Knee key clinical studies (continued)

| | Title | Reference | Institution(s) | Conclusion | Link |
|---------------------|--|--|---|--|---|
| Survivorship | Clinical outcomes of robotically assisted UKAs at 3 years follow-up | Catani F. Clinical outcomes of robotically assisted UKAs at 3 years follow-up. Presented at: The Partial Knee Meeting; January 30-31, 2018; Bruges, Belgium. | Universita degli Studi di Modena e Reggio-Emilia, Italy | Mako Partial Knee survivorship at three-year follow-up was 99.2% for medial UKA (n=388) and 100% for lateral UKA (n=67). | |
| Outcomes | Robotic-assisted unicompartmental knee arthroplasty has a greater early functional outcome when compared to manual total knee arthroplasty for isolated medial compartment arthritis | Clement ND, Bell A, Simpson P, Macpherson G, Patton JT, Hamilton DF. Robotic-assisted unicompartmental knee arthroplasty has a greater early functional outcome when compared to manual total knee arthroplasty for isolated medial compartment arthritis. Bone Joint Res. 2020;9(1):15-22 doi:10.1302/2046-3758.91.BJR-2019-0147.R1 | Spire Murrayfield Hospital, Edinburgh | Thirty patients who underwent robotic-arm assisted UKA (RA-UKA) were propensity matched to 90 patients undergoing manual TKA (M-TKA); greater knee-specific functional outcome (OKS) and generic health (EQ-5D, FJS) with a shorter length of hospital stay was observed after RA-UKA when compared to M-TKA at six months follow-up. | https://online.boneandjoint.org.uk/doi/full/10.1302/2046-3758.91.BJR-2019-0147.R1 |
| Outcomes | An assessment of early functional rehabilitation and hospital discharge in conventional versus robotic-arm assisted unicompartmental knee arthroplasty: a prospective cohort study | Kayani B, Konan S, Tahmassebi J, Rowan FE, Hadad FS. An assessment of early functional rehabilitation and hospital discharge in conventional versus robotic-arm assisted unicompartmental knee arthroplasty: a prospective cohort study. Bone Joint J. 2019;101-B(1):24-33. doi:10.1302/0301-620X.101B1.BJJ-2018-0564.R2 | University College London Hospital; Princess Grace Hospital | In a single-surgeon study comparing consecutive Mako Partial Knee (n=73) vs. manual Oxford unis (n=73), Mako Partial Knee patients demonstrated: reduced postoperative 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). | https://www.ncbi.nlm.nih.gov/pubmed/30601042 |

Mako Partial Knee key clinical studies (continued)

| | Title | Reference | Institution(s) | Conclusion | Link |
|-------------------------|--|---|---|--|---|
| Outcomes | Outcomes of robotic-arm assisted medial unicompartmental knee arthroplasty: minimum 3-year follow-up | Dretakis K, Igoumenou VG. Outcomes of robotic-arm-assisted medial unicompartmental knee arthroplasty: minimum 3-year follow-up. Eur J Orthop Surg Traumatol. 2019;29(6):1305-1311. doi:10.1007/s00590-019-02424-4 | Hygeia Hospital, Athens, Greece; National and Kapodistrian University of Athens, Greece | At minimum three-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 who reported they were very satisfied or satisfied). | https://link.springer.com/article/10.1007/s00590-019-02424-4 |
| Outcomes | Robotic-arm assisted versus conventional unicompartmental knee arthroplasty: exploratory secondary analysis of a randomized controlled trial | Blyth MJG, Anthony I, Rowe P, Banger MS, MacLean A, Jones B. Robotic arm-assisted versus conventional unicompartmental knee arthroplasty: exploratory secondary analysis of a randomised controlled trial. Bone Joint Res. 2017;6(11):631-639. doi:10.1302/2046-3758.611.BJR-2017-0060.R1 | University of Strathclyde, Glasgow, UK | Mako Partial Knee patients reported 55.4% lower postoperative pain compared to manual patients (Oxford) from day one to week eight (p=0.04) and had better American Knee Society Scores (AKSS) compared to manual patients at three months postoperative. Key factors associated with achieving excellent clinical outcomes on the AKSS were: a preoperative activity level >5 on the UCLA activity score and use of robotic-arm assisted surgery. | https://www.ncbi.nlm.nih.gov/pubmed/29162608 |
| Health economics | Robot-assisted unicompartmental knee arthroplasty for patients with isolated medial compartment osteoarthritis is cost-effective: a Markov decision analysis | Clement ND, Deehan DJ, Patton JT. Robot-assisted unicompartmental knee arthroplasty for patients with isolated medial compartment osteoarthritis is cost-effective: a Markov decision analysis. Bone Joint J. 2019;101-B(9):1063-1070. doi:10.1302/0301-620X.101B9.BJJ-2018-1658.R1 | Royal Infirmary of Edinburgh, Edinburgh, United Kingdom and Freeman Hospital, Newcastle upon Tyne, United Kingdom | A Markov decision analysis showed that RA-UKA is a cost-effective alternative to manual TKA and UKA. The cost per QALY of RA-UKA decreased with reducing length of hospital stay and with increasing case volume, compared with manual TKA and UKA. | https://www.ncbi.nlm.nih.gov/pubmed/31474149 |

Mako Partial Knee key clinical studies (continued)

| | Title | Reference | Institution(s) | Conclusion | Link |
|-------------------------|---|--|--|---|---|
| Health economics | Revision analysis of robotic-arm assisted and manual unicompartmental knee arthroplasty | Cool CL, Needham KA, Khlopas A, Mont MA. Revision analysis of robotic arm-assisted and manual unicompartmental knee arthroplasty. J Arthroplasty. 2019;34(5):926-931. doi:10.1016/j.arth.2019.01.018 | 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 postoperatively. | https://www.arthroplastyjournal.org/article/S0883-5403(19)30045-2/abstract |

Mako Total Hip key clinical studies

| | Title | Reference | Institution(s) | Conclusion | Link |
|----------|--|--|--|--|---|
| Accuracy | Robotic assisted THA performed by surgeons in fellowship training leads to improved accuracy and precision to plan | Borukhov I, Scholl L, Hampp E, Smith R, Byrd Z. Robotic assisted THA performed by surgeons in fellowship training leads to improved accuracy and precision to plan. Orthopaedic Research Society Annual Meeting. February 8-11, 2020; Phoenix, AZ. | University of Texas Health, Houston, TX | In a cadaveric assessment involving six Mako Total Hips and six manual THA hips, the findings of this study suggest that CT preoperative planning and intraoperative robotic technology using the Mako Total Hip application can allow less experienced surgeons to place implant components more consistently in the desired orientation, with comparable accuracy to what has been reported by experienced surgeons. | https://www.ors.org/Transactions/66/1162.pdf |
| Accuracy | Does robotic-assisted total hip arthroplasty improve accuracy of cup positioning? | Lawson JA, Garber AT, Stimac JD, Ramakrishnan R, Smith LS, Malkani AL. Does robotic-assisted total hip arthroplasty improve accuracy of cup positioning? J Hip Surg. 2019;03(04):176-180. doi:10.1055/s-0039-1693480 | University of Louisville; KentuckyOne Health Medical Group; RR Clinical Research Consulting Services | In a retrospective consecutive cohort of 50 manual THAs followed by 50 Mako Total Hips, the study results demonstrated the ability of the Mako System to improve the accuracy and precision relative to plan of acetabular component positioning compared to manual techniques. | https://www.thieme-connect.com/products/ejournals/abstract/10.1055/s-0039-1693480 |
| Accuracy | Assuring the long-term total joint arthroplasty: a triad of variables | Kayani B, Konan S, Thakrar RR, Huq SS, Haddad FS. Assuring the long-term total joint arthroplasty: a triad of variables. Bone Joint J. 2019;101-B(1_Supple_A):11-18. doi:10.1302/0301-620X.101B1.BJJ-2018-0377.R1 | University College Hospital, London, United Kingdom; Princess Grace Hospital, London, United Kingdom | In a prospective cohort study with 50 conventional manual THA patients and 25 Mako Total Hip patients, robotic-arm assisted THA was associated with improved accuracy in restoring the native center of rotation, better preservation of the combined offset and more precise acetabular component positioning within the safe zones of inclination and anteversion compared with conventional manual THA. | https://pubmed.ncbi.nlm.nih.gov/30648491/ |

Mako Total Hip key clinical studies (continued)

| | Title | Reference | Institution(s) | Conclusion | Link |
|----------|---|---|--|---|---|
| Accuracy | Intraoperative placement of total hip arthroplasty components with robotic-arm assisted technology correlates with postoperative implant position: a CT-based study | Nodzo SR, Chang C-C, Carroll KM, et al. Intraoperative placement of total hip arthroplasty components with robotic-arm assisted technology correlates with postoperative implant position: a CT-based study. <i>Bone Joint J.</i> 2018;100-B(10):1303-1309. doi:10.1302/0301-620X.100B10-BJJ-2018-0201.R1 | Hospital for Special Surgery | The system reported accurate values for reconstruction of the hip when compared to those measured postoperatively using CT. The mean deviation from the executed overall hip length and offset were 1.6 mm (sd 2.9) and 0.5 mm (sd 3.0), respectively. There was a significant correlation between mean intraoperative (40.4°, sd 2.1°) acetabular component inclination and mean measured postoperative inclination (40.12°, sd 3.0°, R2 = 0.62; p < 0.001). There was a significant correlation between mean intraoperative version (23.2°, sd 2.3°) and postoperatively measured version (23.0°, sd 2.4°; R2 = 0.76; p < 0.001). | https://pubmed.ncbi.nlm.nih.gov/30295538/ |
| Accuracy | Variance in predicted cup size by 2-dimensional vs 3-dimensional computerized tomography-based templating in primary total hip arthroplasty | Osmani FA, Thakkar S, Ramme A, Elbuluk A, Wojack P, Vigdorichik JM. Variance in predicted cup size by 2-dimensional vs 3-dimensional computerized tomography-based templating in primary total hip arthroplasty. <i>Arthroplast Today.</i> 2017;3(4):289-293. doi:10.1016/j.artd.2016.09.003 | 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. | https://pubmed.ncbi.nlm.nih.gov/29204499/ |
| Accuracy | Accuracy of component positioning in 1980 total hip arthroplasties: a comparative analysis by surgical technique and mode of guidance | Domb BG, Redmond JM, Louis SS, et al. Accuracy of component positioning in 1980 total hip arthroplasties: a comparative analysis by surgical technique and mode of guidance. <i>J Arthroplasty.</i> 2015;30(12):2208-2218. doi:10.1016/j.arth.2015.06.059 | 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. | https://pubmed.ncbi.nlm.nih.gov/26282499/ |

Mako Total Hip key clinical studies (continued)

| | Title | Reference | Institution(s) | Conclusion | Link |
|----------|---|---|---|--|---|
| Accuracy | Precision of acetabular cup placement in robotic integrated total hip arthroplasty | Elson L, Douchis J, Illgen R, et al. Precision of acetabular cup placement in robotic integrated total hip arthroplasty. <i>Hip Int.</i> 2015;25(6):531-536. doi:10.5301/hipint.5000289 | 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. | https://www.ncbi.nlm.nih.gov/pubmed/26391264 |
| Accuracy | Comparison of robotic-assisted and conventional acetabular cup placement in THA: a matched-pair control study | Domb BG, El Bitar YF, Sadik AY, Stake CE, Botser IB. Comparison of robotic-assisted and conventional acetabular cup placement in THA: a matched-pair controlled study. <i>Clin Orthop Relat Res.</i> 2014;472(1):329-336. doi:10.1007/s11999-013-3253-7 | American Hip Institute | The use of a robotic system allowed for improvement in placement of the cup in both Lewinnek and Callanan safe zones. | https://pubmed.ncbi.nlm.nih.gov/23990446/ |
| Accuracy | Haptically guided robotic technology in total hip arthroplasty: a cadaveric investigation | Nawabi DH, Conditt MA, Ranawat AS, et al. Haptically guided robotic technology in total hip arthroplasty: a cadaveric investigation. <i>Proc Ins Mech Eng H.</i> 2013;227(3):302-309. doi:10.1177/0954411912468540 | 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. | https://pubmed.ncbi.nlm.nih.gov/23662346/ |

Mako Total Hip key clinical studies (continued)

| | Title | Reference | Institution(s) | Conclusion | Link |
|--------------------------|---|--|--|---|---|
| Bone preservation | Robotic-arm assisted total hip arthroplasty results in smaller acetabular cup size in relation to the femoral head size: a matched-pair controlled study | Suarez-Ahedo C, Gui C, Martin TJ, Chandrasekaran S, Lodhia P, Domb BG. 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 Int. 2017;27(2):147-152. doi:10.5301/hipint.5000418 | 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 robotic-arm assisted THA (rTHA) compared to conventional THA (cTHA). | https://pubmed.ncbi.nlm.nih.gov/28362049/ |
| Outcomes | Minimum 5-year outcomes of robotic-assisted primary total hip arthroplasty with a nested comparison against manual primary total hip arthroplasty: a propensity score-matched study | Domb BG, Chen JW, Lall AC, Perets I, Maldonado DR. Minimum 5-year outcomes of robotic-assisted primary total hip arthroplasty with a nested comparison against manual primary total hip arthroplasty: a propensity score-matched study. J Am Acad Orthop Surg. Accepted manuscript. Published online February 25, 2020. doi:10.5435/JAAOS-D-19-00328 | American Hip Institute; Vanderbilt University School of Medicine; Hadassah University Hospital | Patients who received rTHA reported favorable outcomes at minimum five-year follow-up. Furthermore, in comparison to a propensity score pair-matched manual THA (mTHA) group, rTHAs reported higher patient-reported outcome scores and had 89% reduced risk of acetabular implant placement beyond the Lewinnek safe zone and 79% reduced risk of placement beyond the Callanan safe zone, compared to manual THA. | https://www.ncbi.nlm.nih.gov/pubmed/32109923 |
| Outcomes | Robotic-assisted total hip arthroplasty: clinical outcomes and complication rate | Perets I, Walsh JP, Close MR, Mu BH, Yuen LC, Domb BG. Robot-assisted total hip arthroplasty: clinical outcomes and complication rate. Int J Med Robot. 2018;14(4):e1912. doi:10.1002/rcs.1912 | American Hip Institute | "Mako Total Hip reported the highest Forgotten Joint Score (FJS) for THA in literature, no leg length discrepancies, and no dislocations." | https://www.ncbi.nlm.nih.gov/pubmed/29761618 |

Mako Total Hip key clinical studies (continued)

| | Title | Reference | Institution(s) | Conclusion | Link |
|-------------------------|--|--|---|--|---|
| Outcomes | Robotic-assisted total hip arthroplasty: outcomes at minimum two year follow up | Illgen RL, Bukowski BR, Abiola R, et al. Robotic-assisted total hip arthroplasty: outcomes at minimum two-year follow-up. Surg Technol Int. 2017;30:365-372. | University of Wisconsin; Cleveland Clinic | In a retrospective review of the initial 100 consecutive manual THAs in clinical practice, the last 100 consecutive manual THAs before Mako THA introduction, and the first consecutive 100 Mako THAs, the authors found Mako Total Hip arthroplasty improved acetabular component accuracy and reduced dislocation rates compared with both manual cohorts. | https://www.ncbi.nlm.nih.gov/pubmed/28537647 |
| Outcomes | Improved functional outcomes with robotic compared with manual total hip arthroplasty | Bukowski BR, Anderson P, Khlopas A, Chughtai M, Mont MA, Illgen RL. Improved functional outcomes with robotic compared with manual total hip arthroplasty. Surg Technol Int. 2016;29:303-308. | 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. | https://pubmed.ncbi.nlm.nih.gov/27728953/ |
| Health economics | Is robotic-arm assisted total hip arthroplasty more cost-saving than manual total hip arthroplasty? A comparative cost-analysis using Markov Model | Maldonado DR, Go C, Kyin C, Shapira J, Rosinsky P, Domb BG. Is robotic-arm assisted total hip arthroplasty more cost-saving than manual total hip arthroplasty? A comparative cost-analysis using Markov Model. Presented at: Orthopaedic Research Society Annual Meeting. February 8-11, 2020; Phoenix, AZ. | American Hip Institute | In the Medicare and private scenarios, rTHA is cost-saving compared to conventional mTHA when considering direct medical costs from a payer perspective. | https://www.ors.org/abstract-search/ |

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