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Does preoperative 3D CT planning helps in predicting the component size determination and alignment in automatic robotic total knee arthroplasty (RA-TKA)☆

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A R T I C L E I N F O

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A B S T R A C T

Purpose: Image-based Robotic Total knee Arthroplasty (RA-TKA)was developed with the purpose of enhancing the accuracy in determining the component sizes preoperatively and helping surgeons in minimizing errors and improve patient outcomes. The research aims to find the reliability of robotic-assisted TKR based on images in determining the correct component sizes using preoperative three-dimensional (3D) computer tomography.
Method: After ethical approval, we conducted a prospective study from March 2022 to December 2022. A total of 100 knees underwent image-based RA-TKA having grade 4 Osteoarthritis knee (Kellegren Lawrence classification). A single senior surgeon performed on all patients. Postoperative implant sizes and fit were assessed by five radiographic markers by an independent observer.
Results: In our study, we found the mean age was (64.96 ± 7.3) years, with female to male ratio of 43:22. The preoperative 3D CT accuracy is 100% for femoral component sizing and 97% for the tibial component. There was a statistically significant improvement in varus deformity from preoperative 7.370 ± 3.70° to 1.24 0 ± 0.910° after surgery., p = 0.001. Improvement in flexion deformity correction was from preoperative 6.50 ± 6.30 to postoperative 1.640 ± 1.770, p = 0.001.
Conclusion: Our study concludes that the use of pre-operative 3D CT helps in predicting the component sizes, minimizes surgical time, and enhances implant position accuracy, as well as improves postoperative limb alignment in the coronal and sagittal planes.

Authors contribution

Dr Pramod Bhor:Conceptualization and Supervision.; Dr Sawankumar pawar:methodology and writing. ; Dr:Dnyanada Kutumbe - Data Curation.; Dr Arvind Vatkar: Writing – review and editing. ; Dr Sachin kale:Formal analysis.; Dr Rahul Jagtap: Software.

1. Background

Patients undergoing Total knee arthroplasty (TKA) with 15 years follow–up have an 81%–92% rate of implant survival making it a largely successful procedure.[1,2] Although dissatisfaction is seen in 10–20% of patients,[3,4] several factors influence outcomes after TKA, of which alignment and component positioning are important factors that influence component loosening and instability.[5] In an attempt to improve patients' satisfaction and survival of implants, several upgrades were tried in terms of implant design[3] and navigation technology. The acceptable standard margin of error for limb alignment in the coronal or frontal plan is between two-three degrees from neutral alignment.[6,7] The technology used such as computer-aided surgery (CAS) to a certain extent improved the mechanical alignment postoperatively[8,9] but the alignment outside ± three degrees with CAS is between 4 and 21%.[8,10] So, CAS failed to show improved survival of implants in clinical studies with implant overhang seen in 27% of cases leading to post-TKA knee

Abbreviations: CAS, Computer-aided surgery; CT, Computer Tomography; TKA, Total knee arthroplasty..

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pain.[6,7]

Achieving accurate implant sizes of the femur and tibial component with alignment in coronal or frontal plan and its placement showed improved knee balancing in extension and flexion, improved implant longevity, and patient-reported outcome measure.[11,12]

Robotic-assisted total knee arthroplasty has been invented to produce more precise knee component alignment and implant placement. Robotic-assisted surgery entails the production of a preoperative patient-specific model that corresponds to a surgical plan. However, there is a paucity of evidence on the effectiveness and dependability of automated robotic-assisted TKA in implant sizing and intraoperative efficacy in sagittal and coronal deformity correction.

Hence, the aim of our study was to assess utility of "CT-based three-dimensional template in patient undergoing RA-TKA" in estimating femur and tibia implant sizes preoperatively.

2. Material and methods

Study pattern- Prospective study to assess the effectiveness of 3D CT in identifying the component sizes of both tibia and femur prior to surgery in patients seeking RA-TKA.

Data Source - Patients operated between March 2022 to December 2022 after getting approved by the Human Research Ethics Committee (IEC/2023/OAS/01).

Patient selection- The trial included all patients who agreed to robotic-assisted total knee arthroplasty diagnosed with primary stage 4 Kellgren and Lawrence osteoarthritis and rheumatoid arthritis between March 2022 and December 2022.

Exclusion criteria include 1) Patients undergoing revision TKA.2) Non-consented patients 3) whose CT segmentation was not possible. The sample size was estimated to be 103 for a 90% reduction in implant size and position error with α error of 0.05 and beta error of 0.20 with the power of a study is 80%.

3. Data collection

Demographic data like Age, Sex, BMI, and investigations like preoperative, and post-operative radiographs, and wound complications (like pin track infection, intraoperative ligament injury, and periprosthetic fracture) were collected from the surgery operative data. Postoperative radiographs were assessed by an independent observer for the position and size of the implant and alignment in sagittal and coronal plans. The independent observer was not part of the RA-TKA operative team.

4. Surgical technique and post-operative care

All surgical patients had a CT scan of an operating limb in three axial planes: the hip region, knee joints, and ankle. The resulting images were retrieved and sent to the j-planer for segmentation in order to accomplish spatial matches with the patient's leg and the three-dimensional structure utilized in the operating SW (jSUI). A trained company employee and operating surgeon performed the planning, after which the surgical plan was saved, attached to the robotic arm's USB connector, and uploaded to the operational SW(jSUI) (figure-1a,1b,1c). Following Preoperative Planning and work-up, each patient got an IV administration of Cefuroxime 1.5 g as well as tranexamic acid 1 g m 30 min preceding the skin incision. In unilateral situations, spinal anesthesia was considered, as was combination spinal-epidural anesthesia in bilateral cases. For all cases, a tourniquet was utilized. All patients underwent surgery using a traditional midline incision and a medial parapatellar arthrotomy using a measured resection approach. Within the same incision, an optical tracking system is implanted in the femur. It is positioned anteromedial and 10–12 cm from the joint line on the tibia. The surgeon then completed the registration procedure to ensure that the 3D image of the patient corresponded to the original operation location. Following the registration process, the robot evaluates the data, and balancing is done intraoperatively for desired gap check, A 1 mm difference between the medial and lateral gap in an extension and flexion of 90° has been approved and regarded as a balanced knee, while the patient gets connected to the robot and stabilized for surgery. Finally, an automatic Cuvis-Joint Robot (Meril Opulent, Republic of Korea) precisely cuts the bone with respect to the dimensions, position, angle, and alignment of the implant decided beforehand in the presurgery preparation phase. The implant trial has been completed, and the plane of alignment has been validated. Following that, the final implants were cemented in place, the surgical site was thoroughly irrigated, and the tourniquet was deflated. In all cases, enough hemostasis was established before closure, and the insertion of a suction drain was postponed. An independent observer[13] evaluated postoperative implant sizes and fit using five radiographic markers (Figure-2a & 2b). Regional

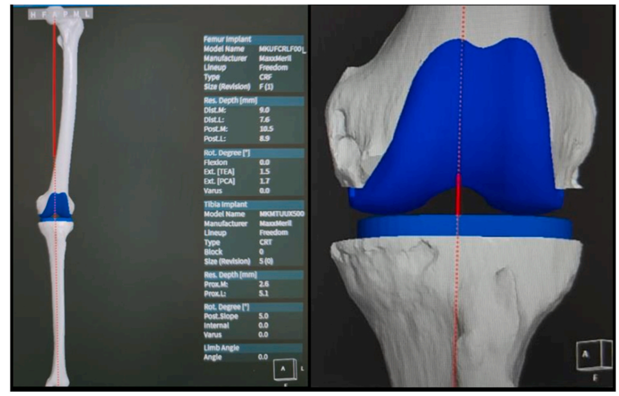

Fig- 1a. preoperative size determination by robotic software.

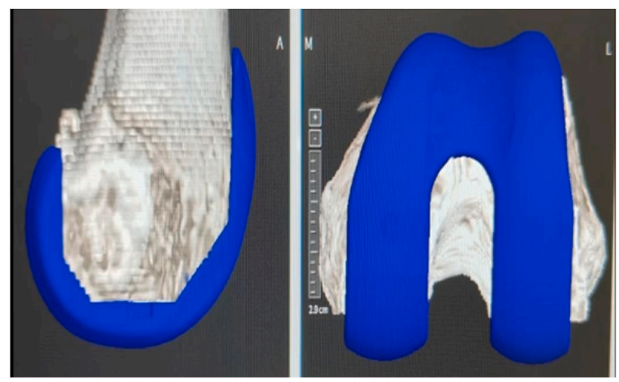

Fig-1b. Femur preoperative size.

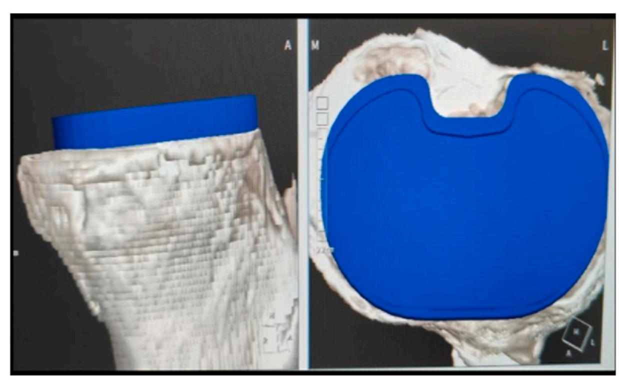

Fig-1c. Tibia preoperative size.

Fig. 2A. Preoperative Skiagram of the patients with severe varus deformity which required upsizing of tibia component from 1 to 2.

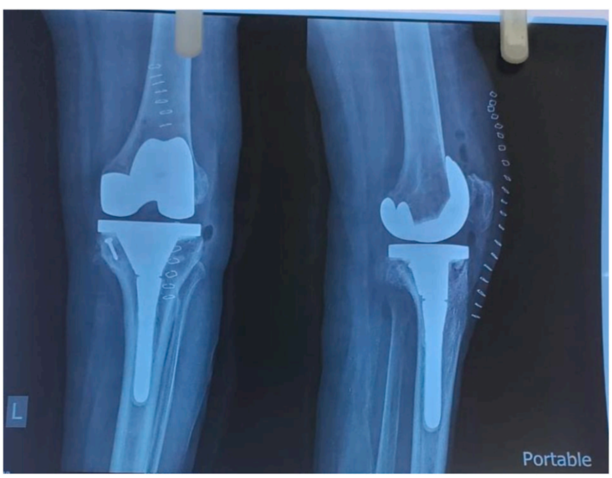

Fig. 2B. Postoperative Skiagram of the patients with severe varus deformity which required upsizing of tibia component from 1 to 2.

blocks were used to treat pain following surgery. Enoxaparin (40 IU) was administered subcutaneously every day till the day of discharge, with the first dosage assigned 24 h after surgery to prevent deep vein thrombosis, while patients were able to walk after 6 h on postoperative day 0. All patients were given rivaroxaban 10 mg once a day until the sutures were removed, which took about 12–14 days from the time of surgery. All of our patients were monitored regularly on a monthly and three-month basis after surgery, and any complications were noted.

5. Statistical methods

Microsoft Excel was used to collect and compile the data. Epi info [Version 7.2; CDC, Atlanta] was used for the analysis. The qualitative factors were calculated as percentages. The mean and standard deviation were used to express normal quantitative data. The independent samples *t*-test was used to determine the difference between the two means. The chi-squared or Fisher's Exact test was used to determine the difference between the two proportions. The analysis was two-tailed throughout, with the significance threshold set at 0.05. Intraclass correlation was used to examine inter- and intra-observer variability.

6. Results

In our study, we found the mean age was (64.96 $\pm$ 7.3) years, with a female-to-male ratio of (43:22) as seen in (Table 1). 35 Patients underwent bilateral robotic-assisted total knee Arthroplasty and 30 patients for the unilateral knee (Table 1). The preoperative 3D CT accuracy is 100% for femoral component sizing and 97% for the tibial component. In two patients the tibia was sized 2 instead of size 3 for medial tightness during the trial of implant, and in one patient it was sized to 2 instead of size 1 for severe varus deformity of 27 deg with a bone defect which was reconstructed with two screws and cement (Figure-2a & 2b). The mean improvement in varus deformity from (preoperative- 7.370 $\pm$ 3.70 to post-operative- 1.24 0 $\pm$ 0.910, p = 0.001) was a statistically significant improvement (Figure-3). Improvement in flexion deformity correction was from preoperative 6.50 $\pm$ 6.30 to postoperative 1.640 $\pm$ 1.770, p = 0.001, which is also a statistically significant improvement. (Table-2).

Surgery complications- There was 1 case of tibia pin tract delayed healing for which re-suturing was done under local anesthesia. Apart from this, there was no other complication at 90 days postoperatively. Peek's criterion revealed that no femoral or tibial implant was undersized or large.

7. Discussion

The purpose of this study was to look into the usefulness of RA-TKA in precisely calculating femoral and tibial implant sizes using preoperative CT-based three-dimensional templating and postoperative limb alignment within the sagittal and coronal planes, as well as complications. The study's main finding demonstrates how using pre-operative 3D CT aids in precisely forecasting component sizes.

Long-term implant longevity and clinical outcomes are determined by the size and position of the femur and tibia implants. Zhang J et al.[14] performed a meta-analysis and a systematic review to examine the precision of component placement, alignment, and balancing methods and noticed that RA-TKA enhanced component positioning accuracy and patient-reported outcomes. Previous research showed that a femoral implant an overhang is responsible for 27% of clinically severe knee pain.[15] In their analysis of the literature, Petersen W et al.[16] discovered that component malpositioning is the explanation for patella maltracking and anterior knee discomfort after TKA. Undersizing the femur component can result in mid-flexion instability and anterior notching of the femur, which increases the possibility of periprosthetic fracture, whereas oversizing the femur can result in joint overstuffing and patellofemoral pain.[17] The undersized tibial component causes subsidence and failure, but concern about overhang can cause pain from soft tissue irritation.[18,19]

Moon YW et al.[20] demonstrated comparable results. In their cadaveric examination, they concluded that robotic-assisted TKA has superior precision in component alignment as compared to the conventional approach. Sires JD et al.[21] found that the accuracy of intraoperative component alignment using MAKO-assisted TKA was comparable to CT-based assessment. Yang HY et al.[22] observed that robotic-assisted TKA minimizes the occurrence of leg alignment outliers when compared to traditional TKA. Moreover, several other studies revealed that RATKA could improve clinical results by increasing component positioning accuracy in TKA.[23–25]

This is our early experience to investigate the effectiveness of a preoperative 3D CT scan contemplating in properly identifying femoral and tibial implant sizes, as well as limb alignment.

Our research has a few drawbacks. The outcomes of robotic-assisted TKA were not assessed in comparison with conventional TKA in the study populations. In our investigation, the sample size was modest. This

Table 1
Table shows the demographic data of our study.

Gender	Male- 22	Female- 43
Age	Mean - 64.96 years	
Number Knee replacement	Bilateral- 35	Unilateral- 30

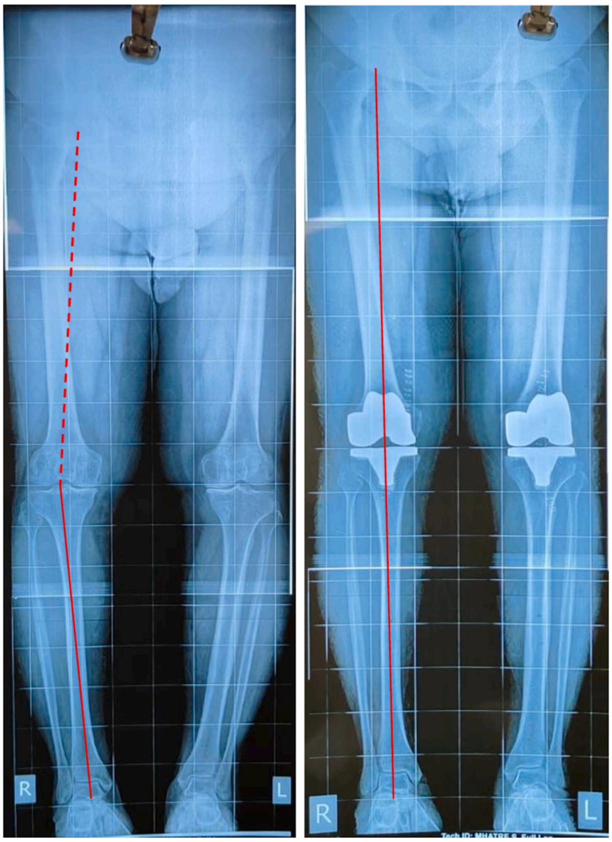

Figure-3. Preoperative and Postoperative limb alignment.

Table 2
Table shows the correction of varus and fixed flexion deformity (FFD) after surgery in our study.

	No of planned sizes	Actual no sizes implanted
Femur	100	100 (100% Accuracy)
Tibia	100	97 (97% Accuracy)
Preop varus	7.30 ± 3.70	P = 0.001
Postop varus correction	1.240 ± 0.910	
Preop FFD	6.50 ± 6.30	P = 0.001
Postop FFD correction	1.640 ± 1.770	

study only includes brief follow-up periods. Long-term follow-up of such investigations is essential to understand implant survivability outcomes.

8. Conclusion

Our study concludes that the use of pre-operative 3D CT helps in predicting the component sizes and thereby reducing the surgical time and improving the accuracy of implant positioning and also improves the patient's limb alignment postoperatively in both coronal and sagittal plane. Long-term multi-centric trials will help to find the outcomes in terms of component life and stability.

Ethics approval

This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the Ethics Committee of institute (IEC/2023/OAS/01).

Conflicts of interest

None.

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Informed consent

Informed consent was obtained from all individual participants for robotic TKA included in the study.

Declaration of Generative AI and AI-assisted technologies in the writing process

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"None"

References

1 Stiehl JB, Hamelynck KJ, Voorhorst PE. International multi-centre survivorship analysis of mobile bearing total knee arthroplasty. *Int Orthop*. 2006;30(3):190–199. https://doi.org/10.1007/s00264-005-0053-z.
2 Scuderi GR, Insall JN, Windsor RE, Moran MC. Survivorship of cemented knee replacements. *J Bone Joint Surg Br*. 1989;71(5):798–803. https://doi.org/10.1302/0301-620X.71B5.2584250.
3 Liu J, Yang Y, Wan S, et al. A new prediction model for patient satisfaction after total knee arthroplasty and the roles of different scoring systems: a retrospective cohort study. *J Orthop Surg Res*. 2021;16(1):329. https://doi.org/10.1186/s13018-021-02469-4. Published 2021 May 20.
4 Lombardi Jr AV, Berend KR, Adams JB. Why knee replacements fail in 2013: patient, surgeon, or implant? *Bone Joint Lett J*. 2014;96-B(11 Supple A):101–104. https://doi.org/10.1302/0301-620X.96B11.34350.
5 Sharkey PF, Hozack WJ, Rothman RH, Shastri S, Jacoby SM. Insall Award paper. Why are total knee arthroplasties failing today? *Clin Orthop Relat Res*. 2002;404: 7–13. https://doi.org/10.1097/00003086-200211000-00003.
6 Nayak M, Kumar V, Yadav R, et al. Coronal alignment of the lower extremity: a gender-based radio-graphic analysis in Indian patients. *Indian J Orthop*. 2020;54(4): 504–512. https://doi.org/10.1007/s43465-020-00050-5. Published 2020 Mar 10.
7 Oswald MH, Jakob RP, Schneider E, Hoogewoud HM. Radiological analysis of normal axial alignment of femur and tibia in view of total knee arthroplasty. *J. Arthroplasty*. 1993;8(4):419–426. https://doi.org/10.1016/s0883-5403(06)80042-2.
8 Bäthis H, Perlick L, Tingart M, Lüring C, Zurakowski D, Grifka J. Alignment in total knee arthroplasty. A comparison of computer-assisted surgery with the conventional technique. *J Bone Joint Surg Br*. 2004;86(5):682–687. https://doi.org/10.1302/0301-620x.86b5.14927.
9 Bae DK, Song SJ. Computer assisted navigation in knee arthroplasty. *Clin. Orthop. Surg*. 2011;3(4):259–267. https://doi.org/10.4055/cios.2011.3.4.259.
10 Confalonieri N, Biazzo A. Computer-assisted surgery in total knee replacement: advantages, surgical procedure and review of the literature. *Acta Biomed*. 2019;90 (1):16–23. https://doi.org/10.23750/abm.v90i1.6319. Published 2019 Jan 22.
11 Nisar S, Palan J, Rivière C, Emerton M, Pandit H. Kinematic alignment in total knee arthroplasty. *EFORT Open Rev*,. 2020;5(7):380–390. https://doi.org/10.1302/2058-5241.5.200010. Published 2020 Aug 1.
12 Zeng HB, Ying XZ, Chen GJ, et al. Extramedullary versus intramedullary tibial alignment technique in total knee arthroplasty: a meta-analysis of randomized controlled trials. *Clinics*. 2015;70(10):714–719. https://doi.org/10.6061/clinics/2015(10)10.
13 Peek AC, Bloch B, Auld J. How useful is templating for total knee replacement component sizing? *Knee*. 2012;19(4):266–269. https://doi.org/10.1016/j.knee.2011.03.010.
14 Zhang J, Ndou WS, Ng N, et al. Robotic-arm assisted total knee arthroplasty is associated with improved accuracy and patient reported outcomes: a systematic review and meta-analysis [published correction appears in Knee Surg Sports Traumatol Arthrosc. *Knee Surg Sports Traumatol Arthrosc*. 2022;30(8):2677–2695. https://doi.org/10.1007/s00167-021-06464-4, 2021 Apr 18.
15 Bonanzinga T, Gambaro FM, Iacono F, Marcacci M. Sub-optimal femoral fit in total knee arthroplasty, a systematic review of human femoral data vs off-the-shelf contemporary femoral components. published correction appears in J Exp Orthop. 2023 May 25;10(1):54 *J Exp Orthop*. 2023;10(1):41. https://doi.org/10.1186/s40634-023-00607-x. Published 2023 Apr 10.
16 Petersen W, Rembitzki IV, Brüggemann GP, et al. Anterior knee pain after total knee arthroplasty: a narrative review. *Int Orthop*. 2014;38(2):319–328. https://doi.org/10.1007/s00264-013-2081-4.
17 Shekhar A, Chandra Krishna C, Patil S, Tapasvi S. Does increased femoral component size options reduce anterior femoral notching in total knee replacement? *J Clin Orthop Trauma*. 2020;11(Suppl 2):S223–S227. https://doi.org/10.1016/j.jcot.2019.03.006.

18 Abram SG, Marsh AG, Brydone AS, Nicol F, Mohammed A, Spencer SJ. The effect of tibial component sizing on patient reported outcome measures following uncemented total knee replacement. *Knee*. 2014;21(5):955–959. https://doi.org/10.1016/j.knee.2014.05.010.

19 Fehring TK, Fehring KA, Anderson LA, Otero JE, Springer BD. Catastrophic varus collapse of the tibia in obese total knee arthroplasty. *J Arthroplasty*. 2017;32(5): 1625–1629. https://doi.org/10.1016/j.arth.2016.12.001.

20 Moon YW, Ha CW, Do KH, et al. Comparison of robot-assisted and conventional total knee arthroplasty: a controlled cadaver study using multiparameter quantitative three-dimensional CT assessment of alignment. *Comput Aided Surg*. 2012;17(2): 86–95. https://doi.org/10.3109/10929088.2012.654408.

21 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*. 2021;34(10):1133–1137. https://doi.org/10.1055/s-0040-1701447.

22 Yang HY, Seon JK, Shin YJ, Lim HA, Song EK. Robotic total knee arthroplasty with a cruciate-retaining implant: a 10-year follow-up study. *Clin Orthop Surg*. 2017;9(2): 169–176. https://doi.org/10.4055/cios.2017.9.2.169.

23 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. https://doi.org/10.1016/j.arth.2018.03.042.

24 Cho KJ, Seon JK, Jang WY, Park CG, Song EK. Robotic versus conventional primary total knee arthroplasty: clinical and radiological long-term results with a minimum follow-up of ten years. *Int Orthop*. 2019;43(6):1345–1354. https://doi.org/10.1007/s00264-018-4231-1.

25 Liow MHL, Goh GS, Wong MK, Chin PL, Tay DK, Yeo SJ. Robotic-assisted total knee arthroplasty may lead to improvement in quality-of-life measures: a 2-year follow-up of a prospective randomized trial. *Knee Surg Sports Traumatol Arthrosc*. 2017;25(9): 2942–2951. https://doi.org/10.1007/s00167-016-4076-3.