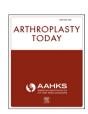
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Original Research

Robotic-Assisted Total Knee Arthroplasty Improves Accuracy and Reproducibility of the Polyethylene Insert Thickness Compared to Manual Instrumentation or Navigation: A Retrospective Cohort Study

Yoan Bourgeault-Gagnon, FRCSC^a, Lucy J. Salmon, BAppSci (Physio), PhD^{a, b}, Matthew C. Lyons, MBBS, FRACS^{a, *}

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ABSTRACT

Background: Increased accuracy and lower rates of component positioning outliers have been associated with better long-term survival and functional outcomes of total knee arthroplasty (TKA). This study investigates the accuracy of robotic-assisted TKA compared to navigation-assisted and manual instrumentation techniques, using polyethylene tibial insert thickness as a surrogate.

Methods: Consecutive primary TKA by a single surgeon were retrospectively reviewed and divided in 3 groups: manual instrumentation, navigation-assisted, and robotic-assisted (RA-TKA). Polyethylene insert thickness, deviation from planned thickness, and rate of outliers were compared between the 3 groups using nonparametric analysis of variance, Kruskal-Wallis tests, and Bonferroni corrections. Logistic regression analysis was performed to identify predictors of polyethylene thickness ≥ 9 mm. The learning curve for RA-TKA was evaluated with a box plot graph of groups of 10 consecutive cases.

Results: There were 474 patients in manual instrumentation TKA, 257 in navigation-assisted TKA and 225 in RA-TKA, with median polyethylene thicknesses of 6.0 (interquartile range 5.0-7.0), 6.0 (interquartile range 5.0-6.0) millimeters, respectively (P<0.001 RA-TKA compared to both other groups). Polyethylene inserts with a thickness ≥ 9 mm were used in 28 (5.9%) manual instrumentation TKA, 13 (5.1%) navigation-assisted TKA, and 1 (0.4%) RA-TKA (P=.004). Independent predictors for polyethylene thickness ≥ 9 mm included surgical technique, left side, and male sex. A learning curve of <30 cases was observed before consistent polyethylene thickness was achieved in RA-TKA.

Conclusions: Tibial polyethylene insert thickness, as a surrogate of surgical accuracy, is more reproducible in robotic-assisted than in navigation-assisted or manual-instrumentation TKA. The learning curve to reach high levels of reproducibility with this technique is relatively short.

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Introduction

There is no consensus on the best alignment philosophy or surgical technique for total knee arthroplasty (TKA) as satisfaction rates remain similar, with a recurrent 20%-25% of dissatisfied patients [1,2], and equivalent revision rates. Irrespective of the

intended alignment, accuracy and precision of the surgical technique are essential to deliver optimal and predictable results [3].

With advancing technology, multiple tools intended to improve the accuracy of implant positioning have been developed. Computer-assisted surgery, or navigation-assisted surgery (NA-TKA), was conceived to decrease the number of outliers in coronal plane resections [3]. Robotic-assisted TKA (RA-TKA) is progressively becoming more popular, also aiming for improved accuracy and precision in surgical technique. A number of robotic systems have been developed, ranging from "passive" to "semiautonomous" and finally to "fully autonomous" versions [4]. Currently, several clinical

^a North Sydney Orthopaedic and Sports Medicine Centre, Wollstonecraft, NSW, Australia

^b University of Notre Dame Medical School, Sydney, NSW, Australia

^{*} Corresponding author. North Sydney Orthopaedic and Sports Medicine Centre, The Mater Clinic, Suite 2, 3-9 Gillies St, Wollstonecraft, NSW 2065 Australia.

studies [5-9] and a few systematic reviews [10-16] have demonstrated improved radiologic accuracy when using robotic systems, compared to conventional instrumentation, reducing limb alignment outliers. However, less data have been published on the results obtained with the VELYS Robotic-Assistance System (Depuy Synthes, Raynham, MA) [17], which is a recently distributed imagefree semiassisted robotic-arm TKA system. Doan et al [18] have shown, in a cadaveric study of 40 specimen, smaller resection errors and less outliers in VELYS RA-TKA compared to M-TKA.

While accuracy was measured with mechanical hip-knee-ankle angle [7,8,11,18,19], sagittal, coronal, and rotational implant positioning [7,8,11,18,19] or component size prediction [7] in most of the aforementioned studies, polyethylene (PE) thickness [6,8] is also an important marker of accuracy. Historically, with non-cross-linked PE, a thickness of 10 mm or less had been associated with rapid wear and an increased rate of revision [20,21]. With the improvement in cross-linking and sterilization of the PE inserts, the question has shifted from "what is the minimal polyethylene thickness?" to "what is the impact of thicker polyethylene inserts?" Three different authors have demonstrated that thicker tibial bearings were associated with greater revision rates, using cutoffs varying between \geq 13 mm and \geq 16 mm [20,22,23]. The required PE thickness is primarily dictated by the thickness of resected bone, the initial soft tissue laxity and the need for ligament releases. The authors therefore hypothesized that the divergence from plan and the necessity to use a thicker PE may indicate a more technically complex procedure [20,22,23].

In the current study, the primary objective was to investigate the accuracy of the RA-TKA technique vs the NA-TKA and the conventional manual instrumentation TKA (M-TKA) techniques, using PE tibial insert thickness as a surrogate. The primary outcome measures were deviation from the planned PE thickness, and prevalence of TKA with PE thickness of >9 mm. Our hypothesis was that RA-TKA would be more accurate than NA-TKA and that both would be more accurate than M-TKA. The secondary objectives were 2-fold; to identify predictors of increased PE thickness and to evaluate the learning curve needed to become precise with the RA-TKA technique.

Material and methods

Patient selection

This retrospective cohort study was approved by a local institutional review board (HREC reference number: LNR/13/SVH/73). All participants provided informed consent. Eligible patients were identified from an internal prospective database. The inclusion criteria were adults undergoing primary TKA for osteoarthritis, with an Attune prosthesis (Depuy Synthes, Raynham, MA), under

the care of the senior author (ML) between June 2015 and April 2023 for a total of 956 patients.

Patient demographic details, including age, sex, surgical side, and body mass index (BMI), as well as surgical and implants details, were prospectively collected. Only Attune TKAs were included to minimize confounders. All types of PE inserts were included (cruciate retaining, posterior stabilized and medial stabilized). The procedures were divided into 3 groups: M-TKA, NA-TKA, and RA-TKA.

Patient characteristics

Of the 956 patients included in the study, 474 were allocated to the M-TKA group, 257 to the NA-TKA group and 225 to the RA-TKA group. The population consisted of 51.8% women, had a median age of 68.3 years, had a median BMI of 30.0 (interquartile range [IQR], 27-33) kg/m2, and included 47.8% of left-sided surgeries and 31.3% of patients with ASA grades 3 and 4. Patients characteristics according to their groups are tabulated in Table 1. All characteristics are similarly distributed between groups, except BMI, which is significantly lower in the RA-TKA group than in the M-TKA group, with values of 29 (IQR, 27-32) kg/m2 and 30 (IQR, 27-34) kg/m2, respectively (P=.046).

All cases done between June 2015 and October 2016 were performed with a conventional manual instrumentation technique. The Brainlab Knee3 (Brainlab, Munich, Germany) navigation system was first used by the senior author in October 2016. The VELYS robot was then introduced in November 2021. When all options were available, the decision to use manual, navigated or robotic techniques was influenced by the patients' expectations, previous surgeries, the system's availability and the surgeon's preferences. This was not randomized.

The primary outcomes were the (a) median deviation from planned PE thickness (mm) and (b) the prevalence of PE thickness outliers between M-TKA, NA-TKA and RA-TKA groups.

The planned PE thickness was 5 mm for every case. The deviation from planned thickness was calculated by subtracting the surgical PE thickness to the 5-mm thickness that was aimed for. The PE outliers were defined as those having a thickness of ≥ 9 mm, in accordance with the study by Rajamäki et al [22] who used a ≥ 13 mm cutoff in their population of PFC Sigma, NexGen and Triathlon TKAs. The Attune AOX PE are labeled with the exact PE thickness at their thinnest point, with sizes of 5, 6, 7, 8, 10, 12, 14, 16, 18 and 20 millimeters [24]. Conversely, the PFC Sigma, NexGen, and Triathlon PE [25] are labeled with the total thickness of the tibial baseplate combined with the PE, like many other implants [26]. Since the Attune tibial baseplate's thickness is 4 mm, we considered a combination of the Attune tibial baseplate added to the PE thicknesses

Table 1 Patient characteristics.

Variable	M-TKA	NA-TKA	RA-TKA	P
Number of patients, n	474	257	225	
Median age, y (IQR)	68.6 (62-74)	68.2 (62-75)	69.6 (63-75)	.103
Women, n (%)	256 (54.0)	123 (47.9)	116 (51.6)	.282
Left side, n (%)	227 (47.9)	125 (48.6)	105 (46.7)	.909
Median BMI, kg/m ² (IQR)	$30(27-34)^{a}$	29 (27-34)	$29(27-32)^a$.046
ASA grades 3 and 4 (%)	121 (33.8)	78 (30.7)	63 (28.1)	.345

^a Denotes a subset of statistically significant categories (Kruskal-Wallis test).

ASA, American Society of Anesthesiology Classification; BMI, body mass index; IQR, interquartile range; M-TKA, manual instrumentation total knee arthroplasty; NA-TKA, navigation-assisted total knee arthroplasty; RA-TKA, robotic-assisted total knee arthroplasty; SD, standard deviation.



Figure 1. Computer-assisted surgery ligament Tensor (Depuy Synthes, Raynham, MA), a joint tensioning device imparting 120 N of force to the medial and lateral compartments.

when comparing implants, that is, a 10-mm Attune PE insert is considered equivalent to a 14-mm NexGen PE .

Operative technique

The tourniquet was used in most surgeries for the duration of the procedure, or at least during cementation, unless there was an absolute contraindication. A midline or a curved medial parapatellar incision was used. A medial parapatellar arthrotomy was performed. The Intuition instrumentation (Depuy Synthes, Raynham, MA) was used for every case, in association with the specific technique's additional instruments, which consisted of the Velys System instrumentation or the Brainlab Knee3 instrumentation. The type of PE (posterior stabilized fixed bearing, cruciate retaining rotating platform, or medial stabilized fixed bearing) as well as the decision to use cement fixation or not were individualized for each patient and were not standardized between groups.

A conventional measured resection technique was employed for the M-TKAs, starting with the distal femoral cut using an intramedullary guide set at 9 mm unless a flexion contracture was noted, and then the 4 other femoral cuts using the 4-in-1 femoral cutting. The distal femoral cut was carried out with 5°-7° degrees of valgus relative to the intramedullary guide axis, based on the preoperative alignment film measurements. The femoral rotation was determined with a posterior referencing guide, aiming for 3°-5° of external rotation relative to the posterior condylar axis, influenced by the preoperative lower limb alignment. The proximal tibial cut utilized an extramedullary guide, with 9 mm taken from the high side. The knee range of motion, stability and flexion and extension gaps were measured and, if asymmetric, soft-tissue releases were performed, followed by bony recuts when needed.

In the NA-TKAs and RA-TKAs, the tibial and femoral pins and trackers were set up after incision, capsulotomy, and adequate initial exposure. Anatomic landmarks were then identified with the navigation probe and integrated by the system in order to intraoperatively plan the aimed resections. A functional alignment philosophy was used with a tibia first osteotomy. Osteophytes were resected at this stage. A joint tensioning device, the Computer Assisted Surgery Ligament Tensor (Depuy Synthes, Raynham, MA), imparting 120 N of force to the medial and lateral compartments was inserted and taken through a range of motion (see Fig. 1). The femoral position was then virtually manipulated to optimize soft

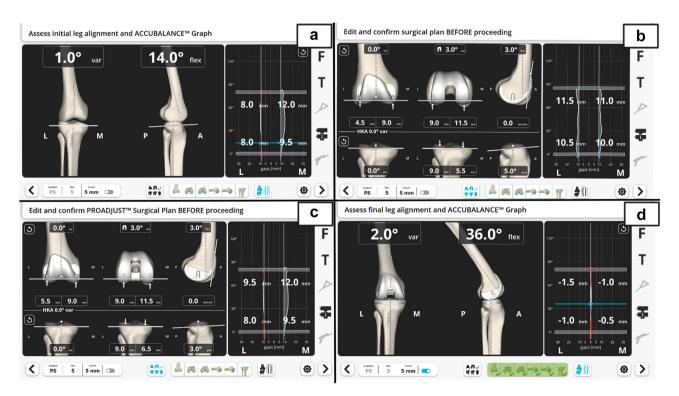


Figure 2. Virtual Soft Tissue Balancing and Femoral Component Manipulation Using the VELYS Navigation System (Depuy Synthes, Raynham, MA). (a). Initial leg alignment and balance. (b) Components alignment and soft tissue balance after tibial cut and before virtual femoral manipulation (CAS Ligament Tensor in place). (c) Components alignment and soft tissue balance after tibial cut and after virtual femoral manipulation (CAS Ligament Tensor in place). (d) Final leg alignment and balance. CAS, computer-assisted surgery.

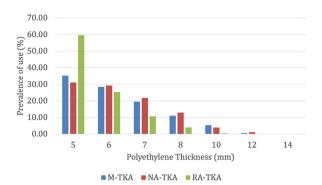


Figure 3. Polyethylene thicknesses prevalence. M_TKA, manual instrumentation total knee arthroplasty; NA_TKA, navigation-assisted total knee arthroplasty; RA_TKA, robotic-assisted total knee arthroplasty.

tissue balance with minimal releases (see Fig. 2). After fixation of the definitive femoral and tibial implants, a tibial insert trial was inserted. Range of motion and soft-tissue balance were tested manually and confirmed with the navigation system before choosing the definitive PE insert's thickness.

Data analyses

Statistical analysis was performed with SPSS (IBM, version 29). P values < .05 were considered statistically significant. PE thickness and deviation from planned thickness constitute ordinal variables but were considered in the statistical analyses as continuous variables, for purposes of simplicity and validity and because of the number of ordered categories [27]. Normality testing of continuous data was assessed with Shapiro-Wilks tests. Nonparametric descriptive statistics were presented as medians and IQR for continuous variables such as age, BMI, PE thickness and deviation from plan, and counts and percentages for categorical variables, such as surgical side, sex and American Society of Anesthesiology grade. Groups were compared with 1-way parametric analysis of variance and nonparametric analysis of variance testing with Kruskal-Wallis test for continuous variables as an omnibus test and Bonferroni post hoc paired comparisons for significant variables. Difference in proportions of patients between groups were assessed with the Pearson's Chi-square test.

A logistic regression analysis was performed to identify predictors of increased PE thickness of more than 9 mm. Variables included in the regression model were technique group (M-TKA, NA-TKA and RA-TKA), sex (men/women), operative side (left/right), BMI (continuous variable), and age (continuous variable).

A box plot analysis of RA-TKAs split in subgroups of 10 cases was used to illustrate the learning curve.

Results

PE thickness

The median PE thickness in the M-TKA, NA-TKA, and RA-TKA groups were 6.0 (IQR, 5.0-7.0), 6.0 (IQR, 5.0-7.0), and 5.0 (IQR, 5.0-6.0) millimeters, respectively. The difference between the RA-TKA group and both other groups was statistically significant, with P values \leq .001. The distribution of PE thickness is shown in Figures 3 and 4.

Accuracy assessment

The prevalence of TKA PE thickness outliers (defined as ≥ 9 mm) (P=.004) and mean deviation from planned thickness ($P\leq.001$) are statistically lower in the RA-TKA group compared to both other groups (Table 2).

Risk factors for PE thickness >9 mm (lower accuracy)

Out of the 956 cases, 943 (98.6%) could be used for the logistic regression analysis. The 13 cases not included were missing baseline BMI data. Statistically significant predictors of increased PE thickness (\geq 9 mm) included the use of the manual instrumentation technique (odds ratio [OR] = 14.8, confidence interval [CI] 2.0-110.1, P = .008), the use of the navigation-assisted technique (OR = 11.6, CI 1.5-89.9, P = .019), male sex (OR = 2.0, CI 1.0-3.8, P = .039), and left-sided surgery (OR = 2.0, C.I. 1.1-3.9, P = .033). BMI and age were not statistically significant predictors of a higher prevalence of PE thickness of \geq 9 mm.

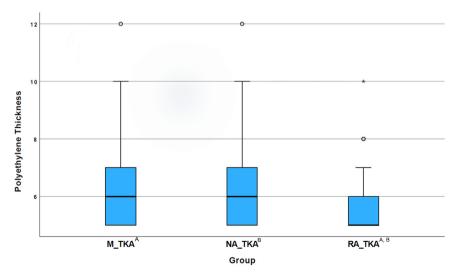


Figure 4. Distribution of polyethylene thicknesses as a function of surgical technique. M_TKA, manual instrumentation total knee arthroplasty; NA_TKA, navigation-assisted total knee arthroplasty; RA_TKA, robotic-assisted total knee arthroplasty.

 Table 2

 Accuracy assessment of the different techniques used.

Polyethylene thickness	M-TKA	NA-TKA	RA-TKA	P
Number of outliers ≥9 mm (%)	28 (5.9) ^a	13 (5.1) ^b	1 (0.4) ^{a,b}	.004ª
Mean deviation from planned	1.3 (1.4) ^c	1.4 (1.4) ^d	$0.6 (0.9)^{c,d}$	$\leq .001^{a}$
thickness (SD), mm				

M-TKA, manual instrumentation total knee arthroplasty; NA-TKA, navigation-assisted total knee arthroplasty; RA-TKA, robotic-assisted total knee arthroplasty; SD. standard deviation.

Each subscript letter denotes a subset of statistically significant categories.

Learning curve of RA-TKA

The 225 RA-TKA cases were subclassified in groups of 10 consecutive cases, in order to illustrate the senior surgeon's learning curve when introducing this new technique into his practice. The first 3 groups of cases, that, 30 cases, show a greater mean PE thickness per case and greater variations compared to the rest (see Fig. 5).

All RA-TKA cases were analyzed in consecutive groups of 10 cases, illustrating the PE thickness used in function of the experience with the technique.

Discussion

This retrospective cohort study of 956 TKAs confirmed that the RA-TKA technique was more accurate than the M-TKA or NA-TKA techniques. This was shown by the 12-15 times lower odds of PE thickness outliers, as well as the lower deviation from planned thickness, when compared to the 2 other groups. However, contrarily to what was hypothesized, no difference was found between the NA-TKA and M-TKA techniques for PE thickness or prevalence of PE thickness outliers.

Our results align with those obtained by Deckey et al, which showed a significantly lower deviation from planned PE thickness in RA-TKA compared to M-TKA, with deviations of 1.4 mm and 2.7 mm, respectively. On their part, even if the study by Nam et al [6] did not demonstrate a statistically significant difference between PE sizes used in the conventional group and the robotic-assisted

group, their results still showed a greater number of outliers in the conventional group, with 0% (0/154) liner outliers in the RA-TKA group vs 2.6% (4/156) in the M-TKA group, when using 16 mm or more as the definition of outliers. Since Triathlon TKA (Stryker, Mahwah, NJ) implants were used in all cases, for which a PE thickness of 16 mm is considered equivalent to a 12-mm Attune PE and a 13 mm is considered equivalent to a 10-mm Attune PE, the number of outliers in their studied population of Triathlon TKAs would be of 24 (15.6%) in the M-TKA group vs 15 (9.8%) in the RA-TKA group [6] if a 13-mm cut-off was used [22]. These findings and the results of this study collectively suggest that RA-TKA techniques reduce the variability seen in tibial PE thickness.

We believe that the ability to intraoperatively adjust the resection planning, that is, depth and orientation of resections, in accordance with the tested ligamentous balance is the main reason for the difference in accuracy between these techniques. The difference found between RA-TKA and NA-TKA in our project has not been described previously and may be related to, in varying proportions, differences in the planning software used, cumulative surgeon's experience or by a more accurate way of transferring the planned parameters to the actual resections.

Using a conventional manual jig-assisted technique increased the odds of PE thickness of 10 mm or greater by a factor of 15 times, while a computer-navigated TKA technique increased the odds by a factor of 11 times, relative to the RA-TKA technique. Male sex (OR, 2.0) and left surgery side (OR, 2.0) were also associated with PE thickness >9 mm in our analysis but were weaker predictors when compared to surgical technique, and their practical significance remains uncertain. Our hypothesis for the role of surgical side is that the surgeon's laterality might have a minor but yet notable impact on cutting accuracy. Manual and computer-navigated techniques are by far the most statistically significant predictors of PE thickness outliers.

PE thickness has been associated with outcomes in previous studies [20,22,23,28,29], with combined tibial baseplate plus PE insert thickness values as low as 13 mm (equivalent to Attune PE thickness of 10 mm) being associated with increased revision rates [22]. PE thickness itself may not increase the risk of failure, but it probably illustrates the complexity of the case. Surgeon's use thicker PE inserts in different situations, such as a patient with ligamentous laxity, a deep tibial cut, femoral over-resection, or sub-

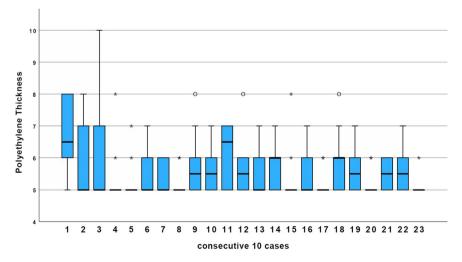


Figure 5. Robotic-assisted total knee arthroplasty technique learning curve.

^a Statistically significant difference (≤0.05).

optimal mediolateral balance. These may result in postoperative mediolateral instability, proximalized joint line or relative overconstraint, each of which may in turn affect the implant's longevity. Accuracy and reproducibility with PE insert thickness is therefore essential and using a robotic-assisted technique represents a reliable option to achieve that.

Our results show that less than 30 cases were needed to obtain a consistent variability between cases, or inflection point, in terms of PE thickness. Previous studies evaluating the learning curve associated with RA-TKA have primarily focused on operative time, showing that 7-11 cases were needed to reach the inflection point of proficiency [5,11]. Cumulative experience has not been reported to impact implant positioning, joint line restauration or lower limb axis [5], but in our study did improve PE liner thickness accuracy.

Potential limitations

First, we acknowledge that the chronological difference between groups could theoretically influence the surgeon's experience and results. However, the large group sizes and inclusion of the initial cases for each group, where the learning curve is the steepest, in the analysis minimizes that risk of bias.

Second, all cases had been performed by a single surgeon which reduces generalization potential. The learning curve therefore represents a specific surgeon's experience and may not be globally applicable. The same can be said for the implant (Attune Knee System) and the robotic-assistance system used (VELYS Knee Solution). Caution is advised when extrapolating the results to other implants or robotic-assistance devices.

Third, initial coronal alignment was not considered in the potential risk factors and confounders because of the high variability in measurement techniques (navigation system analysis vs preoperative imaging) and rates of missing data between groups in the database. We have assumed that the surgeon's patient cohort maintained a similar distribution in terms of preoperative alignment throughout the study period.

Conclusions

Tibial PE insert thickness, which is a marker of technical and cutting accuracy, is more reproducible in robotic-assisted than in navigation-assisted or manual instrumentation TKA, with significantly less outliers when the robot is used. The learning curve to reach high levels of reproducibility with this technique is relatively short.

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Conflicts of interest

Matthew C Lyons declares having worked/working as a paid consultant or paid presenter or speaker for Corin (Corin Group, Cirencester, Gloucestershire), Depuy (Depuy Synthes Inc Services, Raynham, Massachusetts, US), Johnson & Johnson (Johnson & Johnson Services, Inc, New Brunswick, New Jersey, US), and Zimmer Biomet (Warsaw, IN). He also declares having received research support from Depuy (Depuy Synthes Inc Services, Raynham, MA). He declares holding stock or stock options in NavBit and 360 MedCare. No direct funding or benefits were received for this project. All other authors declare no potential conflicts of interest.

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CRediT authorship contribution statement

Yoan Bourgeault-Gagnon: Conceptualization, Methodology, Visualization, Writing — original draft, Writing — review & editing. **Lucy J. Salmon:** Data curation, Formal analysis, Methodology, Project administration, Software, Writing — review & editing. **Matthew C. Lyons:** Conceptualization, Resources, Supervision, Writing — review & editing.

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