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High accuracy of a new robotically assisted technique for total knee arthroplasty: an in vivo study

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Abstract

Purpose Over the last decade, robotic TKA gained popularity for improving the accuracy of implant positioning and reducing outliers in limb alignment comparing to conventional jig-based TKA. Hypothesis of this study was that this newly designed robotically assisted system will achieve a high level of accuracy for bone resection. Purpose of the study was to evaluate the accuracy of the system.

Methods For this study, 75 knees in 75 patients were operated using a new, robotic system (ROSA[®] Knee System; Zimmer Biomet, Warsaw, IN) with a Posterior Stabilized Total Knee Arthroplasty (Persona[®] Knee System). The planned, validated and measured angles and cuts for the distal and posterior femur, for the proximal tibia and for the final coronal alignment on long standing x-rays were compared.

Results A statistically significant difference was found only between the average planned and the average validated angle for femoral flexion, tibial coronal axis, medial and lateral cuts; the average difference was in any case below 1 mm or under 1 degree with SD < 1. No statistical difference was found between planned validated and measured cuts. Average difference between planned HKA and measured was 1.2 ± 1.1 . No statistically significant difference was found.

Conclusions The results of this study demonstrated that using this new surgical robot in total knee arthroplasty it is possible to perform accurate bone cuts and to achieve the planned angles and resections.

Keywords Robotic surgery · Total knee arthroplasty · Navigation · Computer assisted surgery · In vivo · Accuracy

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Introduction

Different authors investigated the outcome of total knee arthroplasty (TKA) and demonstrated that up to 20% of the patients are not satisfied with their knee function after TKA [4, 9, 10, 13, 20] Pain, instability, and limitation of the range of motion are the most commonly reported symptoms among unsatisfied patients, while the major causes reported of unsuccessful TKA are inadequate alignment and errors in balancing [4, 9]. With the aim of improving outcomes, there is an increasing focus on different alignment options [17] and soft-tissue balancing techniques [18]. As standard instrumentations might not be accurate enough to achieve either of these, balancing tools, patient-specific instrumentations (PSI) and, more recently, computer and robotic-assisted TKA have been introduced to help surgeons to adopt hybrid techniques and, at the same time, to optimize alignment, reducing the number of outliers [6, 13, 14, 21].

Computer navigation provides patient-specific anatomical data with recommendations for bone resection and optimal implant positioning, but the computer system does not actively control or restrain the motor skill of the operating surgeon. Over the last decade, robotic TKA gained popularity for improving the accuracy of implant positioning and reducing outliers in limb alignment comparing to conventional jig-based TKA [13, 14]. Robotic tools are classified in fully active versus semi-active systems [5]. Fully active robotic systems work autonomously to perform the planned femoral and tibial bone resections. Semi-active robotic systems enable the surgeon to maintain the overall control over bone resections and implant positioning, but provide live intraoperative feedback to limit deviation from the preoperative and intraoperative surgical plan [5]. The Rosa[®] (Zimmer-Biomet Warsaw IN) robotic-arm system is a new robotic system that incorporates robotic placement of the cutting jigs and dynamic ligament balance evaluation. This system can be considered as a collaborative robotic system with the robot helping in placing the cutting jig, while the surgeon is in full control of sawing through the jig [19].

The aim of this study was to analyse the accuracy of this new system to perform the planned bone cuts and angles in an imageless procedure. The primary hypothesis was that the robotic system was reliable in terms of accuracy of planning, execution and validation of the bone cuts and angles. To demonstrate this hypothesis, the planned validated and measured bone cuts and angles were compared. This is, to our knowledge, the first validation study performed in vivo with the Rosa[®] system.

Materials and methods

From March 2020 to December 2020, 85 consecutive patients requiring TKA to treat primary osteoarthritis were enrolled in a prospective study; the first 10 cases were excluded as included in the learning curve period [9, 10], so the data of 75 procedures are presented. Mean age at the time of surgery was 70.6 (\pm 12) years with a mean body mass index (BMI) of 29 kg/m² (\pm 14), 37 were females. All surgeries were performed by the same surgical team (including the two senior authors and one younger author, all experienced in computer assisted knee surgery). In all patients the same implant was used (Persona PS, Zimmer Biomet, Warsaw, IN). All the procedures were performed with the assistance of ROSA Knee System (Zimmer Biomet, Warsaw, IN) using the imageless option. Planning was generated from landmarks taken on the femur and tibia after arthrotomy. Landmarks are standard landmarks for navigation systems and include centre of the femoral head, femoral canal entry point, trochlear groove, anterior cortex, epicondyles, distal and posterior femoral condyles, malleoli, medial and lateral tibial plate, tibial canal entry, cruciate ligaments' insertions and tibial tuberosity. An intraoperative plan was defined and validated according to the surgeon's preference as for the final alignment decided, and then, bone resections were performed with the assistance of the robot. All the cuts were verified by the tools offered by the Rosa system and, for each bone cut, the resection thickness was measured using a dedicated Vernier calliper with a 0.5 mm accuracy as described



Fig. 1 Intraoperative planning: resections are calculated on the acquired bony landmarks and ligament assessment to obtain the desired balance and HKA axis



Fig. 2 Live validation system

by Biant [3]. For the evaluation of the reproducibility of HKA planned alignment the following X-ray assessment was conducted: preoperatively full-leg and lateral X-ray view obtained for each single patient. Postoperatively, full-leg weight bearing X-rays were obtained for every patient on the second day after surgery and at 3 months follow up as a standard protocol in our institution. Radiographic measurements were done with the use of Carestream Vue PACS v11.3.4 (Carestream Health, Inc, Rochester, NY).

Robotic procedure

The robotic procedures were performed as described by Parratte in a previous publication [19].

In summary, the intraoperative planning is performed by the surgeon, using the dedicated software, to determine the ideal resection thickness and angles to obtain a balanced and well-aligned TKA (Fig. 1 shows the calculated resections once the desired extension gap balance is achieved). All the planned values are automatically recorded by the system. The planned measurements are entered into the ROSA system and verified perioperatively in situ during the surgery. The robotic arm positions and holds the universal cutting jig in the desired location as determined by the surgical plan.

Once the cutting jig is set in the correct position it is pinned to the bone and the surgeon performs the cuts. After femoral and tibia resections, the surgeon can verify and validate the cuts with a specific validation tool (Fig. 2) in this study the cuts were also measured and with a calliper. Once the first two cuts are performed, the extension gap evaluation can be performed and verified either with a static spacer or with a balancing tool (Zimmer Fuzion® spacer block or tensor). The flexion gap and the rotation of the femoral component are then re-assessed in the planning system with a rotational that is based on the ligament tension assessed with the Zimmer Fuzion® system (spacer block or tensioner). The robotic arm is used to position the drilling holes for the dedicated classic 4-in-1 posterior referenced cutting jig that sets the anterior-posterior position and rotation of the femoral component, according to the planning. The remaining femoral cuts are then performed. After the cuts are performed, posterior condyles cuts thickness is measured with a calliper and flexion knee balance is evaluated with the robot and Fuzion balancing tool. The preparation of the tibial metaphysis and the patella are performed with a standard instrumentation. Trial implants are then inserted, and the final axis of the leg is recorded and compared with the intra-operative plan.

The study didn't aim for a specific HKA; the HKA was intraoperatively planned to obtain balanced gaps, ranging $\pm 3^{\circ}$ from the MA (Mechanical Axis) in the majority of cases (in the present study in 1 case the final target was set at + 5° from the MA); one of the aims of the study was to compare and validate the planned intra-op HKA and the post-op HKA.

Statistical analysis

To confirm the reliability of the measurements, interobserver, and intraobserver comparisons were performed on the pre- and post-op X-rays evaluation (HKA was measured in the pre-op and at the 3 months follow up X-rays evaluation). For each parameter studied (cuts and angles: planned with the ROSA system, measured with a dedicated Vernier calliper or calculated on the X-rays and validated with the ROSA system) descriptive statistics (mean and standard deviation) were calculated. For each paired samples the average error was calculated (mean of the differences between coupled data calculated for every patient) and a dedicated t test was performed. A confidence interval of 95% was set a priori for the t test. Statistical significance was set at P < 0.05 for all statistical tests. All statistics were performed using Excel software (version 2016; Microsoft, Redmond, WA).

Results

Average results (\pm standard deviation SD) of the planned, measured and validated cuts and angles together with their histogram are presented in Tables 1 and 2 respectively.

A comparison between the average measures of the planned and the validated (obtained with the validation tool of the system) data provided by the ROSA system (femoral and tibial cuts, femoral flexion and axis, tibial slope and axis) as well as between the planned, validated and measured cuts thicknesses (with the calliper) and angles (and on the post-operative X-rays) was performed and reported on Tables 3 and 4.

Results CUTS (mm)	Average p (APC) $\pm S$	Average planned cutsAv(APC) ± SD(A)		s Average measured cuts (AMC) \pm SD
Femoral				
Distal medial resection	10.2 ± 1.4		10 ± 1.8	10.1 ± 1.3
Distal lateral resection	8.9 ± 1.3		8.7 ± 1.7	8.9 ± 1.5
Posterior medial resection	10.9 ± 1.5			10.4 ± 1.4
Posterior lateral resection	9.2 ± 1.6			9.4 ± 1.1
Tibial				
Lateral side	9.6 ± 1.4		8.9 ± 1.8	8.5 ± 2.1
Medial side	7.2 ± 2.1		6.6 ± 1.9	7.8 ± 2
12 10 8 6 4 2 0 Femoral distal Femoral distal	emoral Eemoral	Tipial lateral	ial medial	
relificial distar relificial distar po medial lateral po resection resection r e Average planned cuts l	APC) Average valida	resection re	esection	

Results Angles (°)	Average planned a $(APA) \pm SD$	Average validated (AVA)±SD	angle Average measured angle (AMA)±SD
Femoral			·
Flexion	2.7 ± 1	2.0 ± 1	2.2 ± 1
Varus/valgus	1.3 ± 1	1.4 ± 1.1	1.0 ± 1.1
Tibia.			
Slope	3 ± 0.3	2.8 ± 0.8	2.6 ± 1
Varus/valgus	0.5 ± 0.7	1.1 ± 1.2	1.1 ± 1.1
3.5 3 2.5 2 1.5 1 0.5 0 Femoral flexion	Femoral Varus/valgus ed angle (APA) Average valida irred angle (AMA)	e Tibial varus/valgus	

Table 2Average values ofthe angles, planned (APA)—validated with ROSA system(AVA)-measured on the x-rays(AMA) with histogram

A statistically significant difference was found only between: the average planned and validated angle of the femoral flexion, the average planned and validated angle of the tibial coronal axis and the value of the planned and verified thickness of the medial and lateral tibial cuts. The average difference was in any case below 1 mm or under 1 degree with SD < 1. No statistically significant difference for any of the other measures was found (Tables 3 and 4). Long standing weight bearing Postoperative X-rays, were performed at 3 months follow up as

Table 3Average difference(mean of the differencesbetween the two measurementsfor each patient), and SD(standard deviation) withhistogram between: averageplanned cuts (APC); averagevalidated cuts (AVC) andaverage measured cuts (AMC)

Statistical analysis CUTS		ГS AF	APC/AVC		APC/AMC	APC/AMC		AVC/AMC	
		Av	erage dif- ence ± SD	P value	Average dif- ference \pm SD	P value	Average dif- ference ± SD	P value	
Femoral									
Distal med	ial resectio	on 0.7	2 ± 0.7	n.s	0.8 ± 0.57	n.s	0.9 ± 1	n.s	
Distal later	al resection	n 0.6	6 ± 0.6	n.s	0.9 ± 0.7	n.s	1.1 ± 0.8	n.s	
Posterior n	nedial resea	ction			0.4 ± 0.6	n.s			
Posterior la	ateral resec	tion			0.6 ± 0.5	n.s			
Tibial									
Lateral resection		0.9	0±0.,9	< 0,05	1.8 ± 1.6	n.s	1.6 ± 1.5	n.s	
Medial resection		0.8	8 ± 0.9	< 0,05	1.9 ± 1.7	n.s	1.5 ± 1.5	n.s	
	A	PC/AVC AP	C/AMC ■AVC,	/AMC					
P:0,45 P:0,91	P: 0,12 P: 0,84 P: 0,25	F: 0.31	P: 0,89	P: <0,05 P: 0,08 P: 0,08	P: 40 05				
FEMORAL DISTAL MEDIAL RESECTION	FEMORAL DISTAL LATERAL RESECTION	FEMORAL POSTERIOR MEDIAL RESECTION	FEMORAL POSTERIOR LATERAL RESECTION	TIBIAL LATERAL REECTION	TIBIAL MEDIAL RESECTION				

Table 4Average difference(mean of the differencesbetween the two measurementsfor each patient), and SD(standard deviation) withhistogram between: averageplanned angles (APA); averagevalidated angles (AVA) andaverage measured angles(AMA)

Statistical analysis angles		APA/AVA		APA/AMA		AVA/AMA	
	Ā	werage \pm SD	Р	Average \pm SD	Р	Average \pm SD	Р
Femoral							
Flexion	0	$.8 \pm 0.8$	< 0.05	0.1 ± 1.2	n.s	0.2 ± 0.9	n.s
Varus/valgus	0	.5±0.6	n.s	0.6 ± 0.5	n.s	0.6 ± 0.1	n.s
Tibial							
Slope	0	.5±0.6	n.s	0.03 ± 1.9	n.s	0.1 ± 1.7	n.s
Varus/valgus	0	$.7 \pm 0.9$	< 0.05	0.3 ± 1.8	n.s	0.4 ± 1.8	n.s
S0.0- :4	APA/AVA	APA/AMA AVA/	AMA SOO - id PE TI	P:034			

a standard protocol at our institution. The distribution of the post-op HKA alignment around the mechanical axis is represented in Fig. 3. The post-op coronal alignment was calculated and compared with the pre-op and the intra-op planned measures. The average difference between planned HKA and measured was 1.2 ± 1.1 . No statistically significant difference was found (Table 5).



Fig. 3 Distribution of the HKA axis measured at the 3 months follow up X-rays

Discussion

This is a preliminary feasibility study. The primary hypothesis was that with the robotic assisted system in use in our institution (ROSA Zimmer-Biomet), based on a robotic assisted positioning of the cutting jig, a high level of accuracy of cuts, angular values and post-op limb alignment would be achieved.

The most important finding of the present study is that this new Robotic System demonstrated high accuracy in performing the planned cuts and angles in vivo. First, the cuts, planned and verified with the robotic validation tool, available from the robots' surgical reports, were compared. The differences were less than 1 mm for both the femur and the tibia with a standard deviation of less than 1. Using a traditional saw system for cutting the bone, this result is justifiable with the thickness of the blade itself. A statistically significant difference was found only between the planned and validated cuts of the tibia, but no statistically significant difference was registered between planned and measured or measured and validated cuts.

The difference between planned and obtained angles both for the femur (flexion and coronal axis) and the tibia (slope and coronal axis) was less than 1 degree with a standard deviation of less than 1. A statistically significant difference was found only between the average planned and validated angle of the femoral flexion and of the tibial coronal axis and was in any case below 1 degree with a SD of less than 1. This data can be justified by a manual error of the surgeon when applying the validation tool on the bone surface: the flat tool, applied on the bone surface have a small degree of freedom and the measure can be influenced by the rough surface of the bone.

The reliability of the robot in reproducing the planned HKA was verified with the axis measured on long length x-rays at the 3 months follow up: the mean difference was 1.2 ± 1.1 . No statistically significant difference was found.

 1.2 ± 1.1

Table 5Planned and measured HKA axes on long standing X-rays and average difference (in degrees) between planned and post-op measuredHKA (mean of the differences between the HKA measurements for each patient) and SD (standard deviation), with histogram

Results HKA (°)	HKA preop	НКАР	HKAM3
Average	175.8	178.2	179.0
SD	8.6	1.6	1.3
Statistical analysis HKA	НКАР/НКАМ3		
<i>P</i> value			n.s

Average difference \pm SD

Results HKA

Results (°): HKA preop; HKAP: HKA planned; HKAM3: HKA measured 3 months.



All These findings are relevant to support the reliability of the robotic system.

Most of the recent studies presented in the literature on robotic surgery focus on alignment of the components and post-operative HKA axis [16, 22, 23].

Aiming to a specific degree of alignment requires precise systems to study the preoperative conditions and obtain the planned axis, and with these targets an accurate robotic system may be very helpful. In this study, the average error was $1.2 \pm 1.1^{\circ}$.

The results of the present study confirm, in vivo, those obtained and validated by Parratte et al. [19] in their cadaveric study where they performed 30 TKA on 15 frozen cadaveric specimens with the ROSA Knee System (Zimmer Biomet) using 3 different implants: the femoral and tibial coronal and sagittal alignment error showed a standard deviation of less than 1 (SD < 1), measured with the Optical Navigation System (ORTHOsoft, Zimmer Biomet, IN). The authors also described a difference between planned and measured bone resections (as well with a calliper) with a SD < 1, which is again a result similar to the one obtained in vivo in the present study.

Finally, they described a mean hip-knee-ankle axis difference of 0.03 ± 0.87 between the measured and the planned axis, with a rate of malalignment > 3° of 0%.

This study is also in line with the one presented by Figueroa et al. [8]who focused on the reliability in reproducing the planned cuts with a robotic-arm system that incorporates robotic placement of the cutting jigs. In their study Figueroa et al. [8] presented 173 TKA performed with an imageless passive robotic TKA. They compared intraoperative recorded cuts with postoperative CT scans for each case. They described a mean difference for HKA predicted and measured of $0.4 \pm 2.4^{\circ}$ more varus, with 83% HKA angles within a difference of 3 degrees.

In a recent publication, Collins [7] showed results comparable to those presented in this study using the Navio Robotic System (Smith and Nephew) with a 93% accuracy on the coronal alignment. In their study Sires et al. present the results using the Mako total knee robotic arm-assisted surgery (Stryker, Kalamazoo, MI) in 37 consecutive cases of TKA; they measured angular and thickness average difference between the planning and the results obtained with a navigated probe system. They described for the femoral component a mean absolute difference from the plan of 0.38 mm for the distal femoral cut, of 0.46° for varus/valgus and of 0.55° for flexion. For the tibial cuts the mean absolute difference was 0.37 mm, with 0.53° for valgus/varus and 0.59° for the anterior/posterior slope.

Hamp et al. [11] also showed greater accuracy with a Robotic Arm Assisted TKA (MAKO, Stryker, Kalamazoo, MI) comparing to a traditional technique in an in-vitro study on 12 knees, and recently Held [12] showed improved compartment balancing using a Robotic assisted system (Navio, Smith and Nephew) for total knee arthroplasty.

The results of the present study are also in line with those presented by these ones.

In a recent systematic review and meta-analysis, Zhang [26] showed that Robotic TKA (RATKA) demonstrated improved accuracy of component positioning and patient-reported outcomes with a very short learning curve for operating time (between 7 and 11 cases), comparing to traditional techniques.

Same results were previously showed by Kayani [14]that demonstrated improved accuracy in bone cuts and implant positioning with a robotic arm assisted TKR, a short learning curve of 7 cases, and no effect on the accuracy of implant positioning.

Moreover, two recent studies show an improved accuracy in implant positioning using a robotic system, although only the meta-analyses published by Agarwal [1] outlines an associated improvement on patient's outcomes. In fact, the data published in the overview performed by Kort [15] show concerns and inconclusive results in terms of improvements of clinical scores or reduction of complications and revisions. On the other side, in a recent publication Yamamura [24] showed only fair-to-moderate accuracy in terms of bone cuts using a CT-based Patients Specific Instrumentation (PSI) system, confirming the disappointing results with PSI, in terms of accuracy, previously presented by An et al. [2] with an MRI-based system. Zambianchi also showed low accuracy of two different PSI systems [25].

All these studies showed that the limitations in accuracy of PSI systems were mainly related to the positioning of the cutting jigs despite a correct planning [2, 24, 25]. The use of a Robotic Arm may be helpful to overcome these limitations improving the positioning of the cutting jig and the accuracy of the bone cuts.

This study has several limitations: first, the absence of any clinical evaluation of the patients, but the aim of the study was to validate the in vivo the accuracy of the system in terms of bone resections and alignment, and not to compare these data with any clinical evaluation. Second limitation is the fact that all procedures were imageless even if the system have an image-based option. The reasons for this choice are mainly two: first, the study have been conducted during the first and second wave of covid-19 outbreak and patients had limited access to hospitals, so it was logistically complicated and risky to organize the pre-op study for the image-based planning, second because once completed the learning curve with the image-less technique we decided to validate this technique before starting a new learning curve.

On the other hand, this last limitation results in a strength as the high level of accuracy demonstrated by the imageless procedure implies different logistic and economic advantages such as a reduced number of hospital access for the patients, no dedicated pre-op x-ray examination and no waiting time for the approved pre-op planning by the company.

This, it is, to our knowledge, the first study validating the accuracy of this specific robotic system in vivo.

More research is needed to assess whether the improvement of accuracy correlates with better results in patient satisfaction and overall survival rates of total knee replacements.

Conclusions

The results of this study demonstrate that a high degree of accuracy can be obtained using this new robotically assisted TKA system based on robotically positioned and stabilized cutting jigs.

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Declarations

Conflict of interest Prof Francesco Benazzo declares a teaching contract with the manufacturer (Zimmer Biomet); all other authors declare no conflict of interest related to the present study.

Ethical approval No IRB approval was necessary for this study, as a standard and approved technique was applied and no sensible data are presented.

Informed consent All patients signed an informed consent for the surgical procedure.

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