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Accuracy of tibial cuts with patient-specific instrumentation is not influenced by the surgeon's level of experience

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Abstract

Purpose It was hypothesized that surgeon's experience as well as bone density play a significant role in achieving accurate cuts with patient-specific instrumentation (PSI). The aim of this study was to compare the accuracy of the tibial cuts in different bone densities made by a highly experienced orthopedic surgeon on one hand and a less experienced orthopedic surgeon on the other.

Methods Tibial models from three different sawbone densities were developed for this study. Each surgeon performed 21 cuts. A coordinate measuring machine was used to analyse the cuts. The K-Cohen test was performed to evaluate the results. The analyzed parameters were guide positioning and deviation from the guide cut to the tibial cut, including varus/valgus angle, the tibial slope, cut height, planarity (mm^2), and rugosity (mm).

Results There was a significant difference in the positioning of the tibial cut guide between the two surgeons for the tibial slope ($p < 0.05$), while no difference was observed for the varus/valgus angle (n.s.) and the cut height (n.s.). No significant difference in the tibial cut was observed between the surgeons for the tibial slope angle (n.s.), varus/valgus angle (n.s.), planarity (n.s.), and rugosity (n.s.). In the different bone types, no significant difference was observed for the tibial slope (n.s.) and varus/valgus angle (n.s.), while planarity and rugosity showed significant differences ($p < 0.05$). Our study showed no significant difference in the tibial cuts for the tibial slope, varus/valgus angle, planarity, and rugosity between the two surgeons.

Conclusions In the present study, it could be demonstrated that accuracy of the cuts is ensured by PSI not depending on the surgeon's experience and the bone mineral density. This speaks to its clinical significance: PSI might be suited for less experienced surgeons to reduce outliers in total knee arthroplasty (TKA).

Keywords Patient-specific instrumentation · Total knee arthroplasty · Tibial cut accuracy

Abbreviations

CT	Computer tomography
MRI	Magnetic resonance imaging
PSI	Patient-specific instrumentation
R_a	Rugosity
TKA	Total knee arthroplasty

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Introduction

Total knee arthroplasty (TKA) is an effective method for the treatment of knee osteoarthritis [20]. Despite the fact that the majority of patients report improvement with their pain symptoms and function after TKA, up to 20% of patients are not satisfied after the surgery according to registry data [2, 8, 31]. Numerous studies have shown that achieving neutral limb alignment and optimal component positioning is crucial for the success of the surgical procedure [5, 14]. Malalignment of the implants after primary TKA has been found to be the primary reason for revision in 7% of revised TKAs [28, 30] and has been associated with decreased implant survival [28] and inferior patient-reported outcomes [22]. However, other factors such as instability, patellar maltracking, or even patient-related factors (age, general health, preoperative Oxford Knee Score and EQ-5D, comorbidities, or simply their expectations) have been found to have an impact on the final outcome [1].

Optimal placement of the prosthetic components is a major issue for the orthopedic surgeon performing a TKA, and a lot of research and development is aimed at improving the likelihood of achieving optimal alignment. In recent years, patient-specific instrumentation (PSI) has been introduced, in which the cutting blocks are custom-made for each patient using bone models based on computer tomography (CT) or magnetic resonance imaging (MRI) [13, 33]. The cutting blocks are prepared to fit uniquely on the distal femur and the proximal tibia providing accurate cuts. The potential benefits of PSI, besides the reproducibility of accurate cuts, are reduced surgical time, improved overall cost effectiveness, and low complication rates [9, 25, 26].

While PSI is garnering increasing scientific and practical interest, numerous authors have reported improved alignment and component positioning [3, 11, 12, 24, 25]. The PSI systems can be cost effective, since they reduce surgical time and the number of trays required during a surgery. PSI may be more attractive compared to computer-navigated or robotic surgeries, since they require an additional and costly time for registration [19, 26, 32]. On the other hand, there are also reports that show no benefit or even unsatisfactory results from PSI [6, 10, 29, 35]. There is still some skepticism concerning the reproducibility of accurate cuts with PSI. The parameters influencing the bad outliers have not been fully investigated. In particular, the potential benefit of PSI for surgeons of varying levels of experience has not been investigated to our knowledge. Furthermore, the influence of bone quality in terms of its density has not been considered so far.

Thus, the purpose of the present study is to compare the accuracy of tibial cuts in terms of deviation from the planned cut, between a highly experienced orthopedic surgeon and a less experienced orthopedic surgeon in different bone densities. We hypothesized that using PSI generates accurate tibial cuts and that this accuracy is not influenced by the surgeon's level of experience.

Materials and methods

Forty-five sawbone tibial models were prepared using the same mold. Due to the lack of data for this kind of experiment, a sample size of 38 was calculated based on the hypothesis of a difference of 1.5° with a standard deviation of 1.5° for tibial slope and varus/valgus between the two surgeons. To have three balanced groups of bone density, seven samples were added. Different cortical and cancellous foam densities (20 samples) were proposed by the manufacturer (Sawbones Inc., Malmo, Sweden). Prior to testing, we performed a dual-energy X-ray absorptiometry analysis of the available sawbone models and sorted the suitable combinations for cortical and cancellous bone out. Three different densities of cortical and cancellous bone were selected with the aim of reproducing normal, osteoporotic, and young active bone. The 3D reconstruction of the bone model was used to create the MyKnee patient-specific tibial cutting guides (Medacta International SA, Castel San Pietro, Switzerland).

Two surgeons performed the tibial cuts: one highly experienced (NH) with over 30 years in practice and a less experienced surgeon (AA) in the last year of his residency. Each surgeon placed the cutting guide, fixed it with three pins hammered in by hand, and made the tibial resection on 21 bone models (seven bone models for each density) in random order. A randomization list was prepared using a dedicated online software (http://www.sealedenvelope.com). The surgeons were blind to the bone density of the tibia they were cutting: all the bones looked identical in regards to shape and color.

Once all the resections were done, the cutting guides were left in place and the bones were put in a specific support, manufactured based on the bone shape with the aim of fixing all models in the same position. The error in the positioning of the guide was measured as the difference between the plane defined by the cutting slot, which should ideally represent the resection suggested by the guide, and the angles between the vector normal to the slot plane and the tibial anatomic axis defined in the preoperative planning (90° varus–valgus and 93° tibial slope). The variability added by the surgeon during the execution of the cut was measured comparing this plane to that obtained after the resection.

A coordinate measuring machine (CMM, Mod. Carl Zeiss Contura G2 (700 × 700 × 600 mm) validated by Accredia Lat 177 CMM 164/17) was used to measure and reproduce the plane defined by the slot of the cutting guide (a), the real plane of the resection (b), and the resection height and the profile of the cut bone (c). The planes observed were calculated starting from three points recorded by the machine on the surface of a measuring block positioned in the cutting guide slot and on top of the tibia (Fig. 1).

The position of the cutting guides in terms of the varus/valgus angle, the tibial slope, and the resection depth measured on the plane drawn from the guide slot were compared between the two surgeons. The aim was to verify if the surgeon's level of experience can influence the positioning of the guide. The guide plane (a) was then compared with the actual plane obtained after the resection (b) to evaluate the deviation of the cut from that expected (Fig. 2).

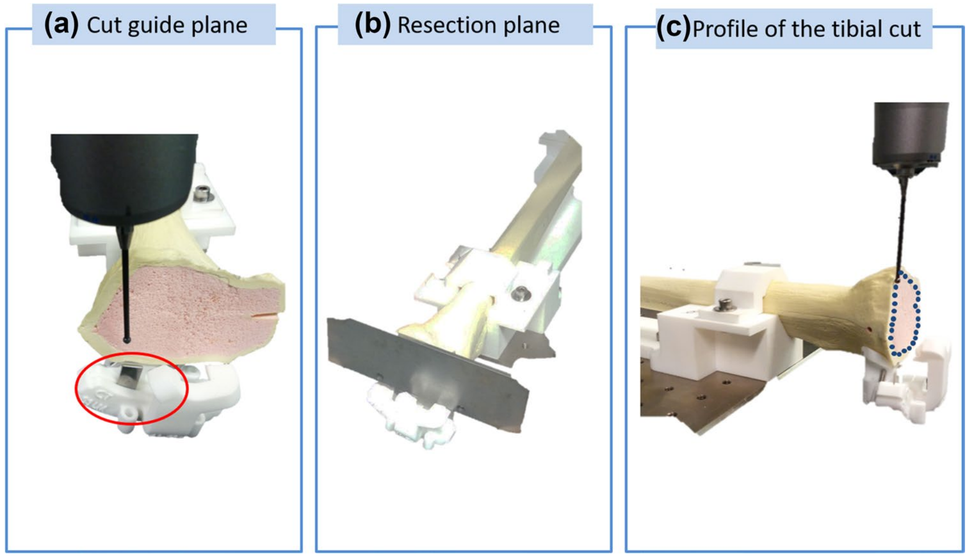

Fig. 1 Guide plane (**a**) was then compared with the actual plane obtained after the resection (**b**) to evaluate the deviation of the cut from the expected. After cutting the profile of the tibial surface was measured by a coordinate measuring machine (**c**)

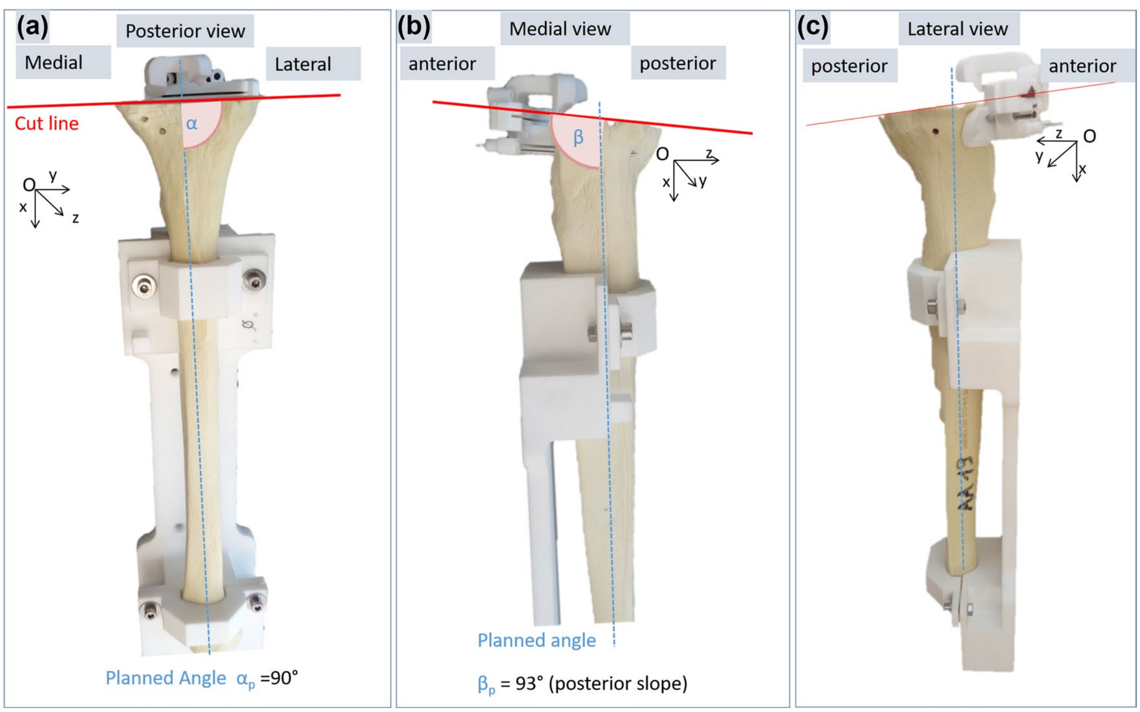

Fig. 2 Position of the cutting guides in terms of varus/valgus angle (**a**), tibial slope (**b**), and resection depth measured on the plane drawn from the guide slot (**c**) was compared between the two surgeons with the aim to verify if the surgeon experience can influence the positioning of the guide

The planarity and rugosity were calculated starting from the reconstruction of the resected tibial surface. The coordinate measuring machine recorded the 3D position of a series of 50 points along the outline of the tibial resection surface. The distance from each of these points to the plane that simulated the tibial tray plane was calculated. The areas of trapezoids were calculated using the distances of the two points on the plane as the base and the distance between the two points as the height (Fig. 3). Planarity is defined by the sum of these areas that, in other words, represent the lateral area of a cylinder built by the projection of the points on the resection plane. In an ideal situation when the actual resection plane coincides with the simulated plane, each of said trapezia would have a surface area of 0.

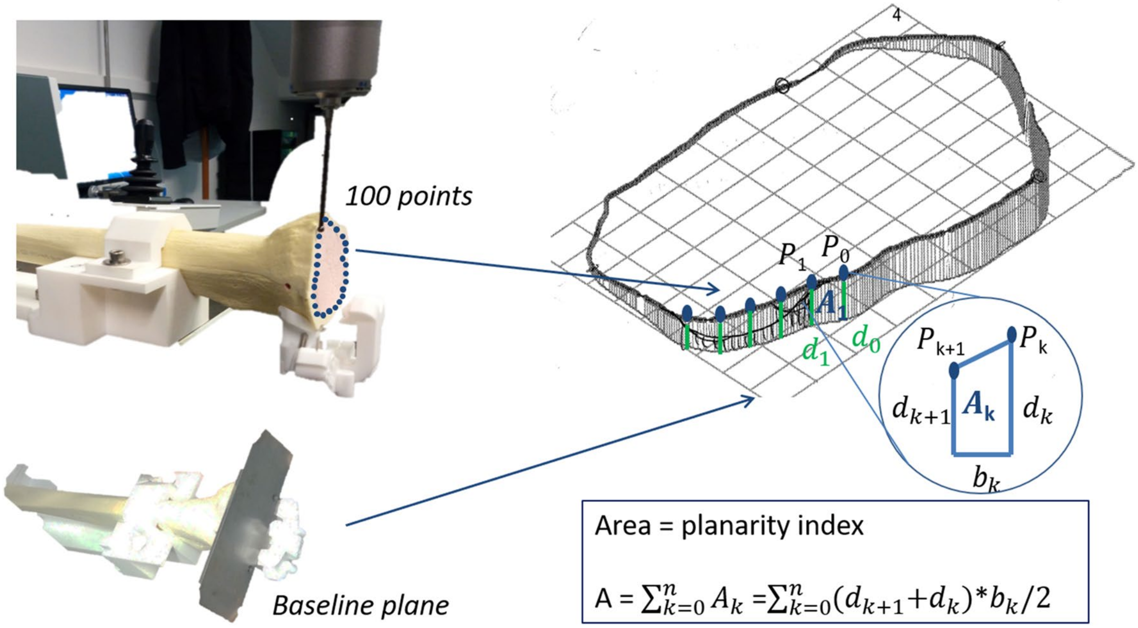

Fig. 3 Planarity was estimated by the area of the cylinder built by the projection of the points on the resection plane

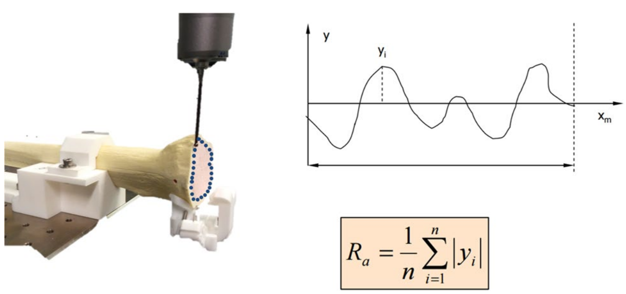

Fig. 4 Rugosity (R_a) was defined as the arithmetic average value of the absolute deviation of the surface above and below the mean line

Rugosity (R_a) was defined as the arithmetic average value of the absolute deviation of the surface above and below the mean line (Fig. 4).

The influence of bone density on the recorded parameters was evaluated to test the hypothesis that the bone density can affect the final cut.

No IRB approval was sought as this was an in-vitro study with no patient involvement. Each author certifies that his or her institution approved the protocol for this investigation and that all investigations were conducted in conformity with ethical principles of research.

Statistical analysis

Twenty-one bone cuts were performed in each group to detect any significant difference in the accuracy of the cuts made by the highly experienced and the less experienced surgeon. A post hoc power analysis was performed after the tests on the secondary outcomes (bone density influence) with a power of 90%. For the calculation of the sample size, no clinically significant difference or standard deviation was available in literature. Hence, the hypothesis of a difference of 1.5° and a standard deviation of 1.5° for tibial slope and varus/valgus were made to estimate a difference between the two surgeons (experienced versus less experienced). Alpha 0.05 and beta 0.85 were used for a two-sided test. The data collected for each parameter in each group were tested for normality using a Shapiro test. The difference between the groups was tested using a Student's *t* test for independent samples in the case of normal distribution of the values, or with a Mann–Whitney test in the case of non-normal distribution. The analysis of variance was performed with the ANOVA or the Kruskal–Wallis tests to assess the influence of bone density on the outcomes. A *p* value of 0.05 was considered in all the statistical analyses.

Results

The comparison between the surgeons (Table 1)

Guide positioning

Regarding the positioning of the tibial cut guide for the tibial slope, there was a significant difference between the surgeons with the error tibial slope angle $|\beta_p - \beta_g|$ (°)

Table 1 Comparison of junior (AA) and senior (NH) surgeon for guide positioning, depth of cut, deviation between pin guide and tibial cut, planarity, and rugosity

	Error tibial slope angle (°)			Error varus/valgus angle (°)			Depth of the cut (mm)			Deviation pin/cut—tibial slope (°)			Deviation pin/cut—varus/valgus (°)			Planarity (mm^2)			Rugosity (mm)		
	Mean	SD	*p* value	Mean	SD	*p* value	Mean	SD	*p* value	Mean	SD	*p* value	Mean	SD	*p* value	Mean	SD	*p* value	Mean	SD	*p* value
AA	1.76	1.47	<0.05	0.61	0.36	n.s.	2.5	0.71	n.s.	1.21	0.58	n.s.	0.54	0.46	n.s.	41.4	17.8	n.s	0.12	0.06	n.s.
NH	3.25	1.31		0.86	0.56		2.24	0.54		1.21	0.47		0.46	0.47		44.3	15		0.12	0.06	

being 1.8° (SD ± 1.5°) for AA and 3.3° (SD ± 1.3°) for NH ($p < 0.05$). The error varus/valgus angle $\left|\alpha_g\right|$ (°) was 0.6° (SD ± 0.4°) for AA and 0.9° (SD ± 0.6°) for NH. This difference was not statistically significant (n.s.).

Depth of the cut

Surgeon AA had a mean error depth cut $\left|d_p - d\right|$ (mm) of 2.5 mm (SD ± 0.7 mm), while the figure was 2.2 mm (SD ± 0.5) for surgeon NH. The difference was not statistically significant (n.s.).

Deviation between the pin guide and the tibial cut

The deviation between the pin guide and the tibial cut for the tibial slope angle $\left|\beta_g - \beta_t\right|$ (°) was 1.2° (SD ± 0.6°) for surgeon AA and 1.2° (SD ± 0.5°) for surgeon NH, displaying no statistically significant difference (n.s.). The deviation between the pin guide and the tibial cut for the varus/valgus angle $\left|\alpha_g - \alpha_t\right|$ (°) was 0.5° (SD ± 0.5°) for surgeon AA and 0.5° (SD ± 0.5°) for surgeon NH. This difference was also not statistically significant (n.s.).

Planarity and rugosity

The planarity of the cut was 41 mm^2 (SD ± 18 mm^2) for surgeon AA and 44 (SD ± 15 mm^2) for surgeon NH. The difference was not statistically significant (n.s.). The rugosity of the cut was 0.12 mm (SD ± 0.06 mm) for surgeon AA and 0.12 mm (SD ± 0.06 mm) for surgeon NH showing no statistically significant difference (n.s.).

The comparison of the bone types (Table 2)

Deviation guide pin from the tibial cut

The mean deviation of the guide pin from the tibial cut concerning the tibial slope angle $\left|\beta_g - \beta_t\right|$ (°) was 1° (SD ± 0.7°) for athletic bone, 1.2 (SD ± 0.5) for normal bone, and 1.4 (SD ± 0.3) for osteoporotic bone. The difference between the bone types was not statistically significant (n.s.). Regarding the varus/valgus angle $\left|\alpha_g - \alpha_t\right|$ (°), the mean deviation for athletic bone was 0.4° (SD ± 0.4°), 0.6° (SD ± 0.5°) for normal bone, and 0.4° (SD ± 0.3°) for osteoporotic bone. This difference was not statistically significant.

Planarity and rugosity

The planarity error of the tibial surface was 51 mm^2 (SD ± 15 mm^2) for athletic bone, 45 mm^2 (SD ± 16 mm^2) for normal bone, and 34 mm^2 (SD ± 14 mm^2) for osteoporotic bone. The difference in the planarity error between

Table 2 Comparison between bone types for deviation between pin guide and tibial cut, planarity, and rugosity

	Deviation pin/cut—tibial slope (°)			Deviation pin/cut—varus/valgus (°)			Planarity (mm^2)			Rugosity (mm)		
	Mean	SD	*p* value	Mean	SD	*p* value	Mean	SD	*p* value	Mean	SD	*p* value
Athletic bone	1.02	0.67	n.s.	0.43	0.35	n.s.	51.1	15.1		0.16	0.07	
Normal bone	1.23	0.53		0.64	0.52		45	16.1	n.s.	0.13	0.05	n.s.
Osteoporotic bone	1.36	0.33		0.42	0.26		33.5	13.5	< 0.05	0.09	0.04	< 0.05

athletic and normal bones (n.s.) and between normal and osteoporotic bones (n.s.) was not statistically significant. However, the difference between athletic and osteoporotic bone ($p < 0.05$) was statistically significant. The rugosity of the tibial surface was 0.16 mm (SD ± 0.07 mm) for athletic bone, 0.13 mm (SD ± 0.05 mm) for normal bone, and 0.09 mm (SD ± 0.04 mm) for osteoporotic bone. The difference between athletic and normal bones was not statistically significant (n.s.). The difference between athletic and osteoporotic bones ($p < 0.05$) and between normal and osteoporotic bones ($p < 0.06$) was statistically significant.

Discussion

The most important finding of the present study was that PSI can provide accurate cuts after placement of the guide, independent from the surgeon's experience and the bone mineral density.

The optimal placement of the components in knee arthroplasty is a major issue and PSI is a relatively new tool for improving that positioning. The current literature presents controversial data concerning mechanical alignment through the use of PSI with outlier rates (more than 3° deviation) ranging from 3 to 49% [3, 4, 6, 10, 18, 23, 34]. A reason for this discrepancy is possibly the use of different systems.

Another possible outlier that—to our knowledge—has not been investigated so far is the influence of the surgeon`s level of experience. With conventional arthroplasty, it seems obvious that the experience of the surgeon plays a crucial role in the placement of the components as the correct alignment of the components can be a challenging step for an inexperienced surgeon or low volume surgeon. Studies have shown that there is an association between the surgeon's level of experience and the surgical outcome of total knee arthroplasty with an emphasis on the patients with rheumatoid arthritis [16, 17, 27]. A survival analysis of 1084 knees of Oxford unicompartmental knee arthroplasty, comparing consultant and trainee surgeons, showed an overall higher reoperation rate in the trainee group [7]. However, the study also concluded that good results can be achieved by trainee surgeons if performed in a high volume center [7].

The most important finding of the present study is that PSI can provide correct and reliable cuts, independent of the experience of the surgeon. When considering the tibial cutting guide position on the bone surfaces, statistically significant differences in the analyzed parameters were not observed, except for in the tibial slope.

Errors obtained by excluding the guide position were comparable among the two surgeons without any significant difference. This means that once the guide is positioned, the surgeon's experience does not influence the final cut. The errors in slope and varus/valgus angles obtained were lower than 1.5°, hence clinically not significant. The maximal errors obtained in varus/valgus and tibial slope angles were similar to those obtained in a study performed with open and slotted guides [32]. In that study, contrary to our findings, the expert group of surgeons exhibited significantly less variance in varus/valgus angles.

Neither planarity nor rugosity was influenced by the surgeon's level of experience.

Another important finding of the present study is that PSI can provide accurate cuts, independent of the bone density in terms of varus/valgus and slope angles. For this purpose, sawbones of three different cortical and cancellous densities was produced. The deviation of the guide pin from the tibial cut showed no statistically significant difference for the varus/valgus angle and the tibial slope. Our results can be compared to previous reports on computer-navigated TKAs that have shown that osteoporotic knees have a more valgus position of the tibial component compared to non-osteoporotic knees, indicating that osteoporosis may affect the position of the tibial component [21]. A matched control study with 235 cases comparing the component positions in navigated versus conventional TKA suggested that the poor fixation of the tracker pin, especially in the case of osteoporotic bone, can be a potential source of error leading to poor limb alignment or component position [15].

A significant influence of bone density was seen when analyzing the planarity and rugosity of the cut surfaces. The planarity achieved on osteoporotic bones was significantly greater than that obtained on athletic bone. As a result, rugosity was lower in osteoporotic bone rather than in athletic bone. This may be due to the reduced force applied to obtain the cut.

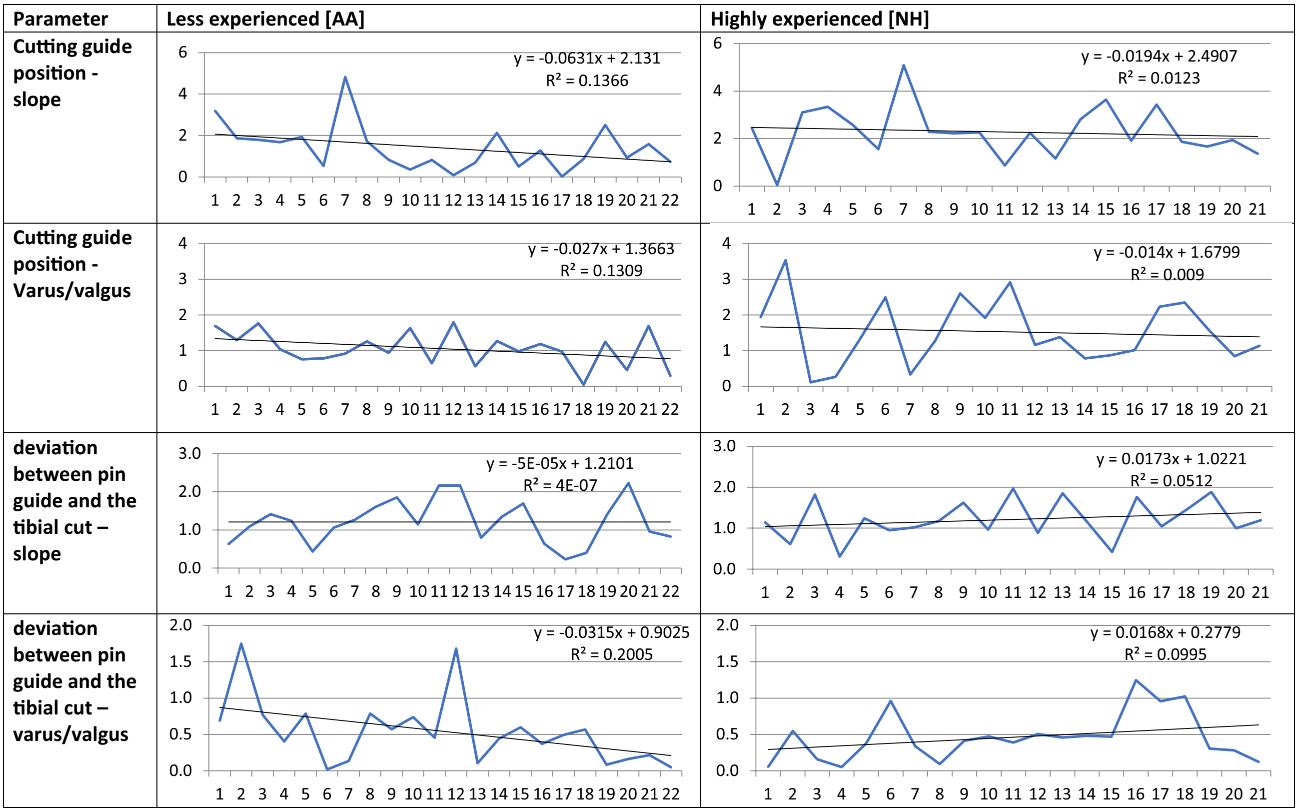

Fig. 5 Linear regression of the learning curves of the evaluated parameters. *x*-axis indicates the procedure (1–22) for the less experienced (left column) and the highly experienced surgeon (right column); *y*-axis indicates the accuracy of the cut (°)

The current literature lacks information on whether bone mineral density affects the accuracy of the tibial cuts using PSI. The present study is the first to examine this question. The planarity and rugosity parameters have widely been neglected in similar studies. This is the first study to examine the association between the planarity and rugosity of the tibial cut, the experience of the surgeon, and the bone mineral density. To the best of our knowledge, the influence of planarity and rugosity on the final implant position is unknown. This may not have any effect on the position of cemented implants, but planarity and rugosity could be relevant when cementless components are used. The alteration of the surface, where the cementless component is placed, could modify the final position of the implant and, therefore, its final angles.

The present study does have some limitations. This is an ex vivo biomechanical study performed on sawbones with different cortical bone and cancellous bone density. The surrounding soft tissue (which may be a reason for possible misplacement of the cutting block) was not simulated and thus not evaluated in our study. Nevertheless, we assume that with careful preparation of the soft tissue, an accurate positioning of the cutting block can be achieved. The sawbones used for this study were prepared with the same mold, but the final finishing of the surfaces was made manually to eliminate flaws. This could have affected the precision of the positioning of the guides. Furthermore, only two surgeons were performing the cuts. More surgeons with different levels of experience in TKA would add power to this experimental study. The surgeons performed all the cuts in a single session. The execution of the same cut on the same bone may result in a learning effect. We observed a learning effect for both surgeons in regard to cutting guide positioning. Furthermore, the less experienced surgeon improved during the cutting procedures especially in regard to varus/valgus deviation, while the experienced surgeon decreased his accuracy for this parameter (Fig. 5). Furthermore, the psychological approach of an experienced surgeon during a real surgery could be different from a less experienced surgeon. This condition cannot be reproduced properly in a laboratory setting. Another limitation could be the bone exposure. In this experimental setting, the bone models' stability, visibility, and accessibility are better than those achieved in a surgical field. This allows the surgeon to check and correct the cut during the procedure.

Despite the study's limitations, the present data indicate that PSI can ensure accurate cuts independent of the surgeon's experience and that bone mineral density can influence the planarity and the rugosity of the cut surface. Patient-specific instrumentation might be suited for less experienced surgeons to reduce outliers in TKA.

Conclusion

This study demonstrates that surgeon experience does not improve the quality of the tibial cut when using patient-specific guides for TKA in a sawbone model. The accuracy of the tibial cut is also not influenced by the bone quality when using PSI. That PSI can provide accurate cuts independent of the surgeon's experience was proven by our results.

Author contributions AA performed the cuts as one of the surgeons and was mainly responsible for writing the manuscript. RSC and MOS helped with the statistical evaluation of the data and revised the manuscript. DB offered the infrastructure and technical equipment for the study. NH first conceived of the study, performed the tibial cuts, and revised the manuscript. All authors have read and approved the final submitted manuscript.

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Compliance with ethical standards

Conflict of interest RSC, MOS, and AA declare that they have no conflict of interest. NH is a consultant and receives royalties from Medacta International SA (Castel San Pietro, Switzerland). DB is employee of Medacta International SA.

Ethical approval No IRB approval was sought as this was an in-vitro study with no patient involvement. Each author certifies that his or her institution approved the protocol for this investigation and that all investigations were conducted in conformity with ethical principles of research.

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