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Original article

Using a patient-specific cutting guide enables identical knee osteotomies: An evaluation of accuracy on sawbones

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ABSTRACT

Purpose: It was hypothesized that using a Patient-Specific Cutting Guide (PSCG) would allow the creation of sawbones model osteotomies, identical in the 3 planes and the hinge parameters, that can be used for biomechanical studies. The aim of the study was to evaluate the accuracy of the PSCG system and to introduce and assess the new hinge parameter; the hinge area.

Methods: Six identical sawbones tibia models were identically set up for identical osteotomy cuts by the same surgeon in the same session and with identical instruments. A medical scanner was used to evaluate the 3D configuration of all the specimens. The analyzed parameters included the cutting angles in both the coronal and sagittal planes (degrees) and the hinge and the slicing areas (cm²), and the hinge thickness (mm). The values were statistically evaluated for average, standard deviation, 95% confidence index, and delta to the expected values were calculated.

Results: The mean values for the coronal and sagittal angles were $110.5^\circ \pm 1^\circ$ and $89.8^\circ \pm 0.8^\circ$, respectively. The 95% confidence index level ranged between 0.1° , and 0.8° in both the coronal & the sagittal planes. The mean values for the hinge thickness, the hinge area, and the slicing area were 12.7 ± 1.5 mm, 4.2 ± 0.9 cm², and 18.3 ± 1.2 cm², respectively.

Conclusion: In the presented study, it can be demonstrated that mechanically identical osteotomy specimens, with regard to the cutting planes and hinge parameters, can be reliably created using the PSCG. The identical specimens can be used for biomechanical research purposes to further expand our knowledge of the factors affecting osteotomy outcomes.

Level of evidence: IV.

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1. Introduction

High Tibial Osteotomy (HTO) is gaining high popularity and effectiveness in the management of patients with cartilage injuries and concomitant varus malalignment of the knee, with success reported when properly indicated and performed [1–3]. The majority of the complications and dissatisfaction are attributed to HTO biomechanics [4] and can result in a total knee arthroplasty conversion. A possible complication of opening wedge osteotomy is the lateral hinge fractures which can occur intra-operatively or post-operatively [5,6].

The use of Patient-Specific Cutting Guide (PSCG) reduces statically-significantly the postoperative outliers in HTO [7] and seems to increase surgical accuracy for osteotomies around the knee as shown both in clinics [8,9] and on sawbones [10]. Furthermore, the preservation of

the lateral hinge is a key factor for surgery success and can be enhanced by using protective systems coupling a PSCG and the introduction of K-wires. K-wires aims at controlling the accurate positioning of the PSCG, guiding the sawblade, and limiting the depth cut acting as a stopper for the saw stroke [11–13].

For osteotomies, the desired correction is defined pre-operatively through a virtual surgery based on 3D reconstruction from a CT scan. The accuracy of correction is generally defined as the difference between that planned correction (target) and the correction really achieved which is post-operative and commonly measured via a CT scan [7]. Then, cutting errors could be affected both by bone cutting techniques and the cutting guide [14] particularly by its positioning [15].

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Though the spread of the use of PSCGs is increasing, there is still some skepticism concerning the reproducibility of accurate cuts with PSI [16]. To date, no elements are published allowing reproducible composite specimens creation for experimental osteotomies investigations.

We hypothesized that by using the PSCG, similar osteotomies can be created on multiple specimens with identical characteristics both for the cuts, in terms of 3 cutting planes, and the hinge, in terms of thickness, size, and orientation.

The primary outcome of the study was to evaluate the trueness (as the mean deviation to the planned target) and precision (as the standard deviation) of the PSCG and to assess the variability caused by the positioning and handling during the cutting steps of the surgeon.

The secondary outcome was to assess our newly proposed hinge parameter, the hinge area, and the ability to create it identically in multiple specimens to further study and analyse other predictors of lateral hinge fractures. A CT-based measurement method and a 3matic measurement protocol were used to highlight the 3D discrepancies between the planned cuts and the performed cuts.

2. Materials and Methods

The study design involved six identical sawbone-tibias (4th generation composite bone with a solid foam core, medium size, Sawbones®) that underwent the same biplanar HTO cut on the same experimental setup and during the same half-day. To eliminate any expertise variability, all steps were performed by a single high-volume knee osteotomy surgeon in the same session. Identical positioning of the PSCG, K-wire insertion, and biplanar osteotomy cuts utilizing the same measurements (Fig. 1) were performed. All cuts were created utilizing the same power tool, a conventional saw (System 8 Stryker Precision® saw) with a saw blade thickness of 1.2 mm.

After the sawbone was fixed into vise clamps, the PSCG was secured to the proximal and medial side of the tibia by creating 2 drill tunnels; one parallel to and just distal to the cutting plane. And the other one is directed from the medial distal to the proximal lateral. Two K-wires (\varnothing 2 mm) were inserted in the drill tunnels serving as cutting stops. This configuration allowed the preservation of a 12mm-thick hinge in the lateral cortex.

Then, all specimens were scanned at the same time on a medical scanner (Revolution Frontier, GE MEDICAL SYSTEMS, Sainte-Marguerite Hospital, Marseille, France). Measurements parameters were: 300 mA and 120 kV with a slice thickness of 0.62 mm. Each slice

was composed of 512×512 pixels, with 0.72 mm per pixel. The DICOM images were imported in Mimics 22.0 (Materialise®, Leuven, Belgium) for segmentation. Then, the 3D geometry of each tibia was imported and reconstructed in 3-Matic 14.0 (Materialise®, Leuven, Belgium). The tibias were meshed with the function “adaptive mesh” which gave a uniform mesh and a mean length of 1 mm for the elements.

The following constitutes a reproducible and numerical measurement method to assess geometrics HTO parameters that were performed with 3-Matic 14.0. Based on the methods [17,18], a specific coordinate system was created for each tibia. The centers of the tibial plateau and the distal tibiotalar joint were defined. The center of the tibial plateau was obtained by fitting two circles on the tibial plateau, then a transverse line (AB) was created, bisecting the tibial plateau and passing through the center of each circle. The midpoint of this line represents the center of the tibia (center C) (Fig. 2(1)). The center of the distal surface was obtained by fitting one circle on the distal tibiofemoral joint. The center of the distal tibiotalar joint was defined as the center of a circle fitting the area (center D) (Fig. 2(2)).

The mechanical axis of the tibia was defined by a line passing through the center of the tibial plateau (center C) and the center of the tibiotalar joint (center D). Then, 3 reference planes were created. A coronal plane was defined by the plane passing through the mechanical axis and the transverse tibial plateau line (Fig. 2(4)). A sagittal plane was defined by the plane perpendicular to the coronal plane and passing through the mechanical axis (Fig. 2(3)). And an axial plane passes through the center of the tibial plateau and is perpendicular to both the coronal and sagittal planes.

This study evaluated:

- the cutting angle in the coronal plane as the angle between the cutting plane and mechanical axis: a plane X parallel to the sagittal plane was created at the medial hinge point. In first intention, the cutting plane were drawn using 3 points method (operator sensitive). Later, this was replaced by creating 2 planes at the upper and lower planes of the cut respectively in green and red (Fig. 3(1)). The angle between each cutting plane and plane X was calculated (Fig. 3(2)): angle measured with the upper cut plane);
- the cutting angle in the sagittal plane: the anteroposterior orientation of the cut was defined, then utilizing the same planes from the coronal method, angular deviations from the mechanical axis were assessed to measure the cutting angle. (Fig. 3(3)).

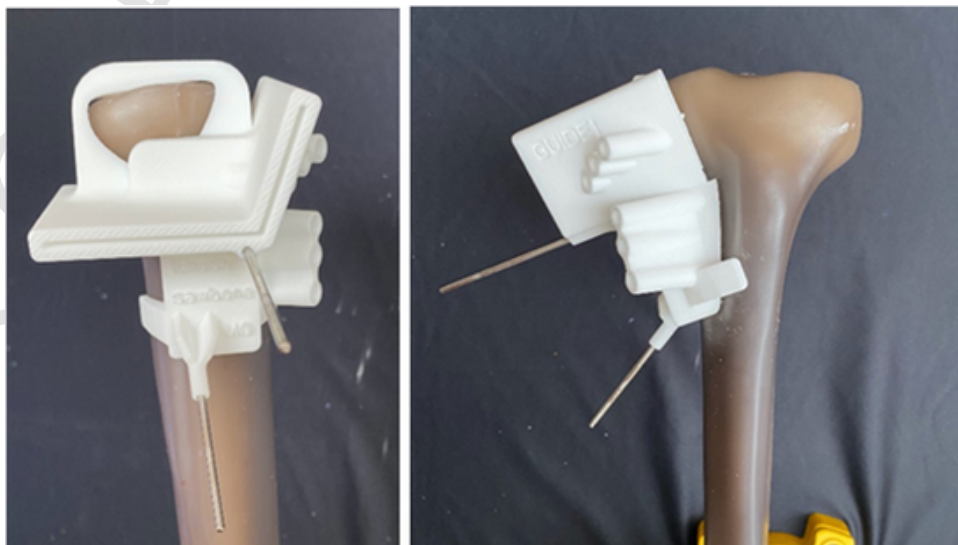


Fig. 1. Sawbone with the specimen-specific guide secured in place with 2 K wires.

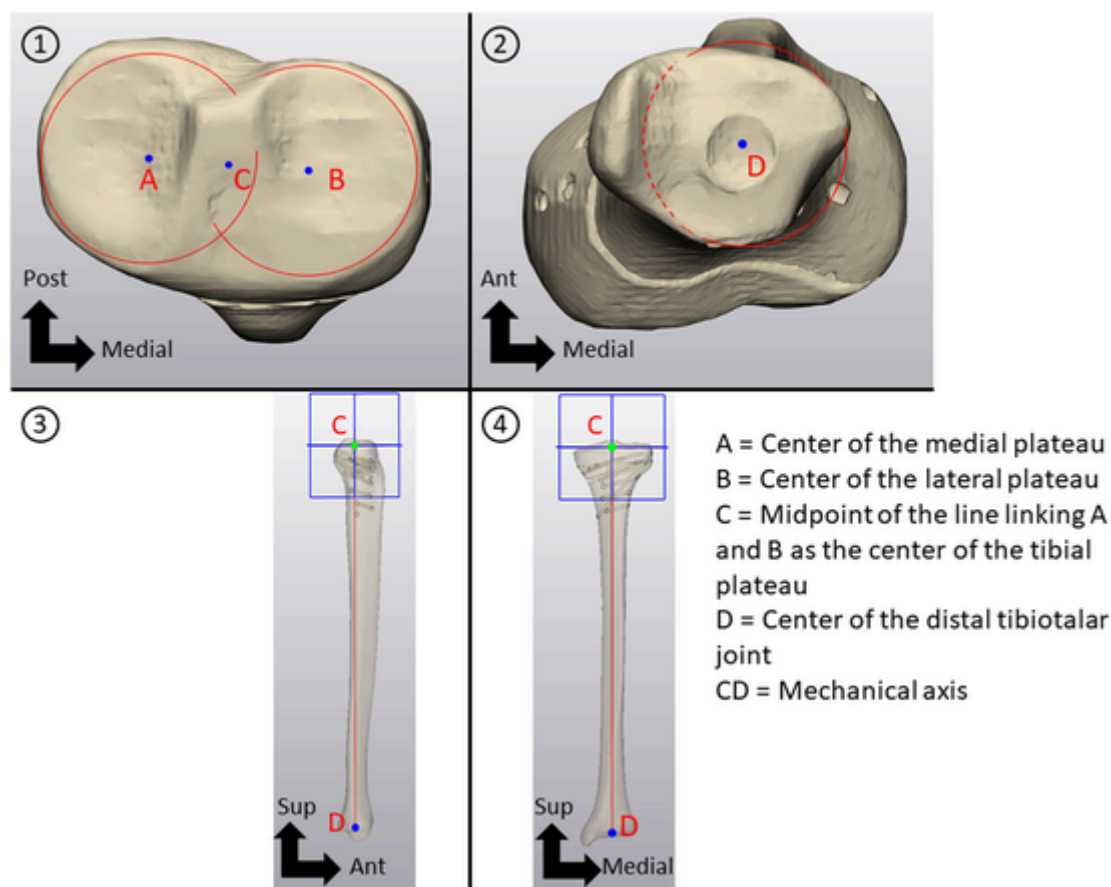


Fig. 2. 3D tibia reconstruction and mechanical axis creation process. 1: the two circles corresponding to the lateral and medial condyles of the tibial plateau, center A and B respectively. The midpoint of the AB line is represented by point C, which is considered the center of the tibial plateau; 2: determination of center D of the distal tibiotalar joint; 3 and 4: the mechanical axis (in red) joining C and D in a sagittal view and a coronal view.

Some hinge-related parameters were assessed with the hinge zone demonstrated using 3Matic (virtually cut with extension to the medial cortex); the hinge thickness which is the distance between the medial side of the hinge K-wire and the lateral cortex (Fig. 3(4)) double-headed red arrow). And the hinge area (a novel parameter proposed in our study): is the surface area calculation of the hinge elements (Fig. 3(4), green area) and the slicing area (blue area) is also calculated.

For all data, the average and Standard Deviation (SD) were calculated. Based on the standard deviations, a 95% confidence index was calculated for the measurements of the cutting angles in the coronal and sagittal planes. A delta comparison to the expected values, 110° frontal angle, 90° sagittal angle, and 12 mm hinge-wire thickness was calculated. A ± 2 mm and $\pm 2^\circ$ tolerance threshold were chosen.

3. Results

Firstly, the measurement of the cutting angles in the coronal and sagittal plane are reported. The total results for all measurements in the coronal and sagittal planes (steps 2 and 3 respectively) are shown in Table 1. The mean values were $110.5^\circ (\pm 1^\circ)$ and $89.8^\circ (\pm 0.8^\circ)$ for the coronal angle and sagittal angle, respectively (Table 2). Only the mean angle in the coronal plane of tibia 1 exceeded the 2° tolerance threshold. As the measurements are repeated on each column with the upper angle and lower angles, we could calculate a confidence index for the measurement on 3Matic associated the measurement uncertainty with a range of $[0.1^\circ; 1.2^\circ]$. Concerning the global accuracy of the cut using a PSCG, the calculation of the 95% confidence index level gives 0.8° and 1.1° for coronal and sagittal angles (Table 2).

For the hinge thickness, the mean value was 12.7 mm (± 1.5 mm). The mean value for hinge area was $4.2 \text{ cm}^2 (\pm 0.9 \text{ cm}^2)$ (Table 3). The mean value for the slicing area was $18.3 \text{ cm}^2 (\pm 1.2 \text{ cm}^2)$. Then, the calculation of the relative hinge area gave $18.6\% (\pm 4.3\%)$. Two specimens exceeded the 2 mm threshold but 100% of specimens were within 2.6 mm (Table 4).

4. Discussion

The main goal was to assess the accuracy of bony cuts obtained by the using of PSCG in a controlled environment. In our study, the accuracy of the PSCG was comparable to or even better than the accuracy reported by Xia et al. [19], in evaluating the SkyWalkers surgical robot for total knee arthroplasty on saw bone models. Xia et al. reported the mean angle deviation between the planned and the achieved osteotomies to be not more than $1.03^\circ \pm 0.55^\circ$. With a maximal angle deviation at each osteotomy plane $\leq 2.03^\circ$. Whereas, our results showed the mean cutting angles deviation between the planned and achieved osteotomies was 1.0° for the coronal plane and 0.8° for the sagittal plane, with the maximal angle deviation reported as 2.1° for the coronal plane and 1.2° for the sagittal plane. Additionally, we reported at least 67% of angle deviation at each plane was within 1° , 83% within 1.5° , and 100% within 2.5° . This is more accurate than the results reported by Xia et al., with at least 45%, 95%, and 100% of the angle deviation at each osteotomy plane within 1° , 2° , and 3° , respectively.

Chaouche et al. [8], investigated the accuracy of the PSCG for open wedge HTO in a cohort of 100 patients. The reported results demonstrated more accuracy for the PSCG than our results both in the coronal plane; with a mean delta hip knee-ankle angle of $1^\circ \pm 0.9^\circ$, and in the

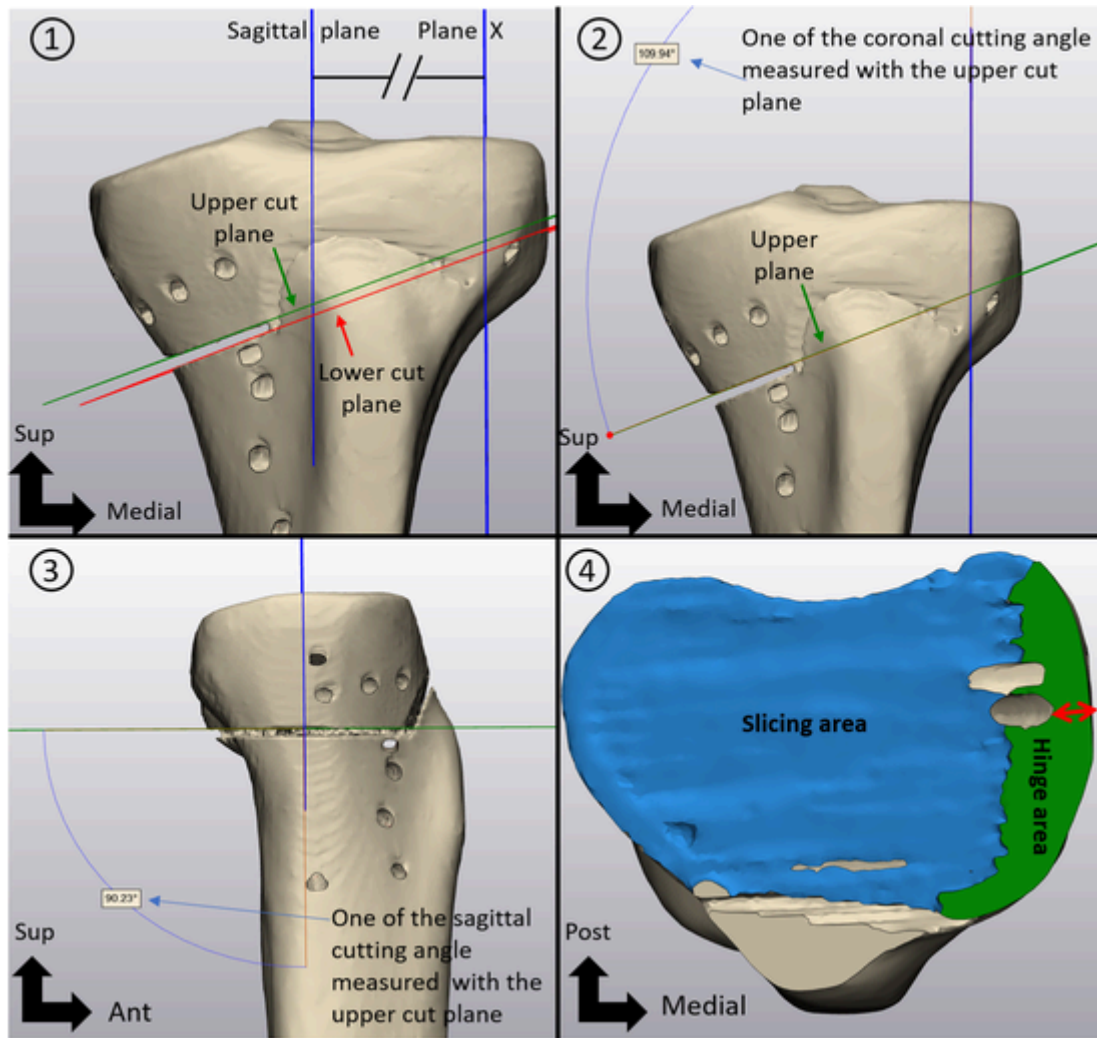


Fig. 3. Measurements of the coronal and sagittal angle and hinge area. 1 and 2: show the coronal angle measurements with an upper cut plane (in green), a lower cut plane (in red), and a new plane (plane X) strictly parallel to the sagittal plane and the mechanical axis (in dark blue); 3: represents the sagittal angle between the upper plane (in green) and the mechanical axis (in blue); 4: shows the cutting plane the sliced area in blue and the hinge area in green.

Table 1

Results for the cutting angle in the coronal and sagittal plane and measurement variability.

Parameters (in°)	Tibia 1		Tibia 2		Tibia 3		Tibia 4		Tibia 5		Tibia 6	
	Coronal	Sagittal	Coronal	Sagittal	Coronal	Sagittal	Coronal	Sagittal	Coronal	Sagittal	Coronal	Sagittal
Upper angle 1	111.9	90.9	109.6	90.1	110.1	88.4	109.9	90.2	109.3	91.5	111.1	89.5
Upper angle 2	111.9	90.7	109.2	89.2	110.0	88.6	110.0	90.2	108.3	90.2	111.0	88.8
Lower angle 1	112.2	90.9	110.6	89.1	111.2	89.3	110.1	90.0	109.6	90.0	111.3	88.4
Lower angle 2	112.0	90.8	110.9	90.0	111.3	89.0	110.0	89.8	109.5	89.8	112.0	89.2
Mean angle	112.1	90.8	110.1	89.6	110.7	88.8	110.0	90.1	109.1	90.4	111.3	89.0
SD	0.1	0.1	0.8	0.5	0.7	0.4	0.1	0.2	0.6	0.8	0.4	0.5
95% Confidence index	± 0.2	± 0.1	± 1.2	± 0.8	± 1.1	± 0.6	± 0.1	± 0.3	± 0.9	± 1.2	± 0.7	± 0.8
Delta comparison	2.1	0.8	0.1	0.4	0.7	1.2	0.0	0.1	0.9	0.4	1.3	1.0

sagittal plane; with a mean delta posterior plateau tibial angle of $0.4^\circ \pm 0.8^\circ$. However, the results reported in our study are still even better than the allowed error range of 2-3° for patient-specific guides as per Gauci's review [20].

Patient-specific instrumentation in HTO can yield even higher accuracy. Mao et al. [21], reported significantly high accuracy for the 3D printed patient-specific instrumentation in performing medial open wedge HTO when prospectively compared to the conventional methods. The correction error for the patient-specific instrumentation versus the conventional method was for the mechanical femorotibial angle

$0:2^\circ \pm 0:6^\circ$ vs. $1:2^\circ \pm 1:4^\circ$, $p = 0:004$), and for the mechanical medial proximal tibial angle was $0:1^\circ \pm 0:4^\circ$ vs. $2:2^\circ \pm 1:8$.

Additionally, patient-specific instrumentations help achieve accurate cuts regardless of the surgeon's level of experience. However, the variability in positioning the guide itself can affect the accuracy. Antoniadis et al. [16] in a sawbones study, evaluated the accuracy of the tibial cuts using patient-specific instrumentation and reported a total error in guide positioning in the coronal plane (varus-valgus angle) of $0.74^\circ \pm 0.49^\circ$ and the in the sagittal plane (tibial slope angle) of $2.51^\circ \pm 1.58^\circ$. Meanwhile, they reported the total deviation between

Table 2

Global accuracy of the cutting process.

Angle	Mean (°)	SD (°)	Ua (°)	Δx (°)	Delta comparison	Specimens number within 0.5° (%)	Specimens number within 1° (%)	Specimens number within 1.5° (%)	Specimens number within 2° (%)	Specimens number within 2.5° (%)
Coronal	110.5	1.0	0.4	1.1	0.5	33	67	83	83	100
Sagittal	89.8	0.8	0.3	0.8	0.2	50	67	100	100	100

Target values were 110° for the coronal angle and 90° for the sagittal angle. At least 67% of angle deviation at each plane was within 1°, 83% within 1.5° and 100% within 2.5°.

Table 3

Results for the hinge thickness and hinge area.

Parameters	Tibia 1	Tibia 2	Tibia 3	Tibia 4	Tibia 5	Tibia 6	Mean	SD
Slicing area (cm ²)	19.3	17.4	17.7	20.3	17.1	18.2	18.3	1.2
Hinge area (cm ²)	3.2	5.3	4.5	3.0	4.9	4.0	4.2	0.9
% of Hinge area	14.4	23.5	20.2	12.9	22.4	18.2	18.6	4.3
Hinge thickness (mm)	12.5	11.6	14.5	12.0	14.4	11.0	12.7	1.5
Delta comparison (mm)	0.5	0.4	2.5	0.0	2.4	1.0	0.7	1.0

Table 4

Deviation of the hinge thickness from the 2 mm-threshold.

Distance to a targeted hinge thickness value of 12 mm	Specimens number within 0.5 mm (%)	Specimens number within 1 mm (%)	Specimens number within 1.5 mm (%)	Specimens number within 2 mm (%)	Specimens number within 2.6 mm (%)
	33	50	67	67	100

At least 50% of hinge thickness deviation was within 1 mm, 67% within 1.5 mm and 100% within 2.6 mm.

the pin guide and the achieved osteotomies to be $1.21^\circ \pm 0.53^\circ$ in the coronal plane (varus-valgus angle), and $0.50^\circ \pm 0.47^\circ$ in the sagittal plane (tibial slope angle). The results reported in our study are comparable with Antoniadis et al. results.

We reported a mean hinge thickness of 12.7 ± 1.5 mm. Dessyn et al. [11], in a cadaveric study evaluating the protective effect of an additional K wire for increasing resistance to hinge fracture, reported a mean hinge thickness of 10 ± 1 mm. In our study, we further investigated the preserved hinge area as a factor directly related to hinge's mechanical strength and it is the first time for this parameter to be introduced. The mean value of the preserved hinge area was $4.2 \text{ cm}^2 \pm 0.9 \text{ cm}^2$ with an associated relative standard deviation of 22%. Whereas, the hinge thickness parameter was less dispersed with a relative standard deviation of 11%. This demonstrates that the hinge thickness parameter does not ideally reflect the state of stress in the hinge. The hinge area is not a parameter available to the operating theatre but rather a variable for ex-vivo/in-vitro biomechanical studies where identical, controlled, and reproducible samples are required. It deals with the maximum stress passing through the hinge area and directly predicts the mechanical strength of the hinge.

This study has a number of limitations, in particular it is a non-comparative study. There was no control group such as a group performed with freehand cut without the use of PSCG which could have highlighted the higher accuracy of the PSCG. Only 6 sawbones models were involved in the study, however, two variables were controlled which are; the surgeon's level of experience as only one surgeon performed all the osteotomies, and the other controlled variable was the validation of the metrology process (measurement of inter-operator deviations). This is an experimental study on sawbones models, however, it can be transferred to ex-vivo cadaveric models. There were no surrounding soft tissues, so no challenges in positioning the PSCG which could contribute to the errors in positioning or stability of the guide. Additionally, the results are not 100% perfect due to variability in PSCG

positioning, sawblade elasticity, and the quality of the power tool (usually, after 3–4 complete cuts, the power of the tool is diminished in comparison with the first performed cuts.).

Despite the low clinical value of the study, it highlights two important issues. Firstly, without using the PSCG, specimens involved in mechanical studies will probably be significantly different to allow efficient comparison of variable surgical strategies. Secondly, even with controlling all other variables, the precision of the PSCG in creating identical specimens is still not 100% perfect, however, they have been demonstrated to be superior to free-hand cuts or even navigation. To our knowledge, this is the first study of its kind. We have validated the use of PSCG in basic sciences surrounding HTO. Hinge parameters are used as a postoperative outcome measure. The hinge area, the parameter that we introduced, will be useful for any CT-based analysis of hinge-related issues.

5. Conclusion

In our study, the reliability and accuracy of the PSCG system in creating similar osteotomies identical in the 3 planes and the hinge parameters have been highlighted. The hinge area has been introduced as a new parameter that is directly related to the mechanical strength of the hinge.

Disclosure of interest

The authors declare that they have no competing interest.

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Authors' contribution

M.O. had conceived the design of this study perform the cuts. M.O. and M.P. supervised the process. S.A. had performed the data acquisition. S.A. and V.T. had conceived the measurement methodology and data analysis. S.A. and A.M. performed statistical analysis. S.A., V.T., M.P. and M.O. participated to draft the manuscript. V.T., M.P., M.O. and A.M. had revised the manuscript. All authors have read and approve the final submitted manuscript.

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