



Patient-specific cutting guides for open-wedge high tibial osteotomy: safety and accuracy analysis of a hundred patients continuous cohort

Samir Chaouche^{1,2} · Christophe Jacquet^{1,2} · Maxime Fabre-Aubrespy^{1,2} · Akash Sharma^{1,2} · Jean-Noël Argenson^{1,2} · Sebastien Parratte^{1,2} · Matthieu Ollivier^{1,2}

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Abstract

Introduction Several recent studies have reported accurate and reliable use of patient-specific cutting guides (PSCG) for medial opening-wedge high tibial osteotomy (OW-HTO); however, a majority of these are small cases series or ex-vivo reports. The hypothesis of this study was that performing an OW-HTO with PSCG results in a reliable and accurate correction with good or satisfactory patient-reported functional outcomes at a mean of two years. We also hypothesized that the use of PSCG would not increase the rate of specific or non-specific complications.

Methods In this single-centre, observational study, a prospective cohort of a hundred patients (age < 60 years with isolated medial knee osteoarthritis and significant metaphyseal tibial vara) were included between February 2014 and November 2017 to investigate the safety and accuracy of OW-HTO using PSCG. The accuracy of post-operative alignment was defined by the difference between the desired correction defined pre-operatively and the correction obtained post-operatively measured on CT scan (Δ HKA, Δ MPTA, Δ PPTA). Functional outcomes were evaluated by the difference between the value obtained in the pre-operative questionnaire and that obtained at the last follow-up (mean 2 years) using the KOOS and UCLA activity scale. Intra-operative and post-operative complications were recorded.

Results The mean patient age was 44.17 ± 6.77 years; no patient was lost to follow-up at a mean of two years. The mean Δ HKA was $1 \pm 0.95^\circ$, the mean Δ MPTA was $0.54 \pm 0.63^\circ$, and the mean Δ PPTA was $0.43 \pm 0.8^\circ$. No significant differences (all p values > 0.05) were observed between the desired correction defined pre-operatively and the correction obtained post-operatively (Δ HKA, Δ MPTA, Δ PPTA). An improvement of 27 ± 25 for the KOOS Pain, 28 ± 26 for the KOOS symptoms, 27 ± 28 for the KOOS ADL, 26 ± 33 for the KOOS sport/rec, 28 ± 38 for the KOOS QOL, and 2.6 ± 2.4 for the UCLA was obtained as compared with the pre-operative values (all $p < 0.0001$). No procedures observed were abandoned, and the PSCG was well positioned in all cases. The overall complication rate was 32% up to two years post-operatively, most of them being classed as minor events (28%).

Conclusion Performing an OW-HTO with PSCG produces an accurate correction with good functional outcomes at a mean of two years. Furthermore, there is no increase in the rate of specific or non-specific complications. A study to assess the reproducibility of this technique, regardless of the surgical level, is needed.

Keywords Open-wedge tibial osteotomy · Patient-specific cutting guides · Osteotomy

This work was performed at the Institute for Locomotion, Aix-Marseille University, Marseille, France.

✉ Matthieu Ollivier
matthieu.ollivier@ap-hm.fr

¹ Department of Orthopedics and Traumatology, Institute of Movement and Locomotion, St. Marguerite Hospital, 270 Boulevard Sainte Marguerite, BP 29 13274, Marseille, France

² Aix Marseille University, APHM, CNRS, ISM, Marseille, France

Introduction

The aim of medial opening-wedge and lateral closing tibial osteotomies is to correct varus alignment in the lower limb in order to treat overload in the medial compartment of the knee joint [1].

In the last decade, medial opening-wedge high tibial osteotomy (OW-HTO) has gained increasing popularity, as more and more studies continue to report respectable post-operative outcomes with fewer complications [2, 3]. Accurate

correction in all three spatial planes is a pivotal factor to obtain good clinical outcomes [4]. To achieve the ideal planned correction, various planning methods, surgical techniques, and differing instrumentations have been developed: examples of this would include conventional methods (with various intra-operative techniques to assess lower-limb alignment), computer-assisted surgery, and recently the use of patient-specific cutting guides (PSCG) [5, 6]. Several recent studies have reported reliable and accurate correction with the use of PSCG for OW-HTO, but the reports are either small case series [7–9] or ex vivo studies [10]. The objectives of this study were (1) to evaluate the accuracy of post-operative lower limb alignment, by comparing the achieved correction to the planned correction, (2) to evaluate the functional outcomes through the KOOS and UCLA activity scale, and (3) to evaluate the number of specific and non-specific complications found in the first 100 patients treated using PSCG in a single surgical centre. The hypothesis of this study was that performing an OW-HTO with PSCG results in a reliable and accurate correction with good or satisfactory patient-reported functional outcomes at a mean of two years. We also hypothesized that the use of PSCG would not increase the rate of specific or non-specific complications.

Methods

Patients

In this single-centre, prospective, observational study, 100 patients undergoing OW-HTO using PSCG, by three senior surgeons, from February 2014 to November 2017 were assessed. Inclusion criteria were patients < 60 years with isolated medial knee osteoarthritis (Ahlbäck ≤ 2 /Kellgren and Lawrence < 4) [11] and significant metaphyseal tibial vara (medial plateau tibial angle (MPTA) < 85°). Exclusion criteria were patients with advanced osteoarthritis (Ahlbäck > 2), evidence of symptomatic patellofemoral or lateral knee osteoarthritis, previous surgery, and hardware or bony abnormalities that would interfere with obtaining a high-quality CT scan. Patient consent was collected pre-operatively after they were informed of the procedure in accordance with the principles of the Helsinki declaration. A local ethics committee approved our study protocol prior to the investigation.

In the pre-operative planning stage, the planned correction was first calculated by the surgeon using conventional radiographs (weight-bearing long-leg, A/P, and lateral views). Subsequently, all patients underwent a CT scan. The surgeon took measurements and filled out an order form for the engineer which specified the correction objectives in the frontal and sagittal planes through variations in the hip-knee-ankle (HKA) angle, medial proximal tibia angle (MPTA), and posterior proximal tibia angle (PPTA).

The CT scan protocol consisted of acquiring images centered on the femoral head, the knee (allowing the distal femur and 15 cm of the proximal tibia to be captured), and one centered over the ankle. The slice thickness was 0.625 mm for the knee and 2 mm for the hip and ankle (GE Light Speed VCT 64).

An OW-HTO model was used to virtually position the Activmotion HTO plate (Newclip Technics®, Haute-Goulaine, France) on the tibia following the manufacturer's recommendations for "ideal" positioning. The PSCG design takes into account the resection plane and the position of the screw tunnels relative to the virtual positioning of the plate. The objective behind the PSCG is to define the optimal plate position after tibial osteotomy correction, and then to report this anatomical position to the pre-osteotomy guide position. When the plate's position fits the drill holes using the PSCG, the osteotomy is created, and subsequent opening wedge of the tibia allows optimal correction of the MPTA and PPTA.

The PSCG was secured to the bone with two pins, and then fluoroscopy was used to confirm the orientation of the osteotomy cut. The eight holes needed for the plate were pre-drilled prior to performing the osteotomy. The osteotomy was then performed with the PSCG in place. The saw blade was guided by a specific slotted capture of the PSCG, after which the proximal portion of the modular cutting guide was removed to finish the osteotomy in a single plane or two planes. This step was dependent on the planned correction and the position of the patellar tendon.

The osteotomy was then gradually opened/distracted with a lamina-spreader until the pre-drilled screw holes were aligned with the holes in the plate. The plate was secured using eight screws, the sizes of which were pre-determined during the pre-operative planning (Fig. 1a–f). The bone defect was left empty or filled with a femoral head wedge allograft or injectable phosphocalcic cement (QuickSet, Graftys®, Aix-en-Provence, France).

Grafted material was decided upon the surgeon's preference. Post-operative management included partial to full-weight bearing as tolerated at day 1 aided if needed with the use of crutches.

All patients were reviewed one month post operatively to evaluate potential early complications and to undergo a CT scan in order to evaluate the accuracy of post-operative alignment and hinge evaluation (fractures were classified according to Takeuchi [12]). The patients were then re-reviewed every three months for regular follow-up with radiographs (long-leg standing, A/P, and lateral). Bone union and hinge stability were systematically assessed.

Patients were reviewed at one, three, 12, 18, and 24 months then every year to ensure there were no delayed complications.

At each appointment, an independent observer assessed the following:

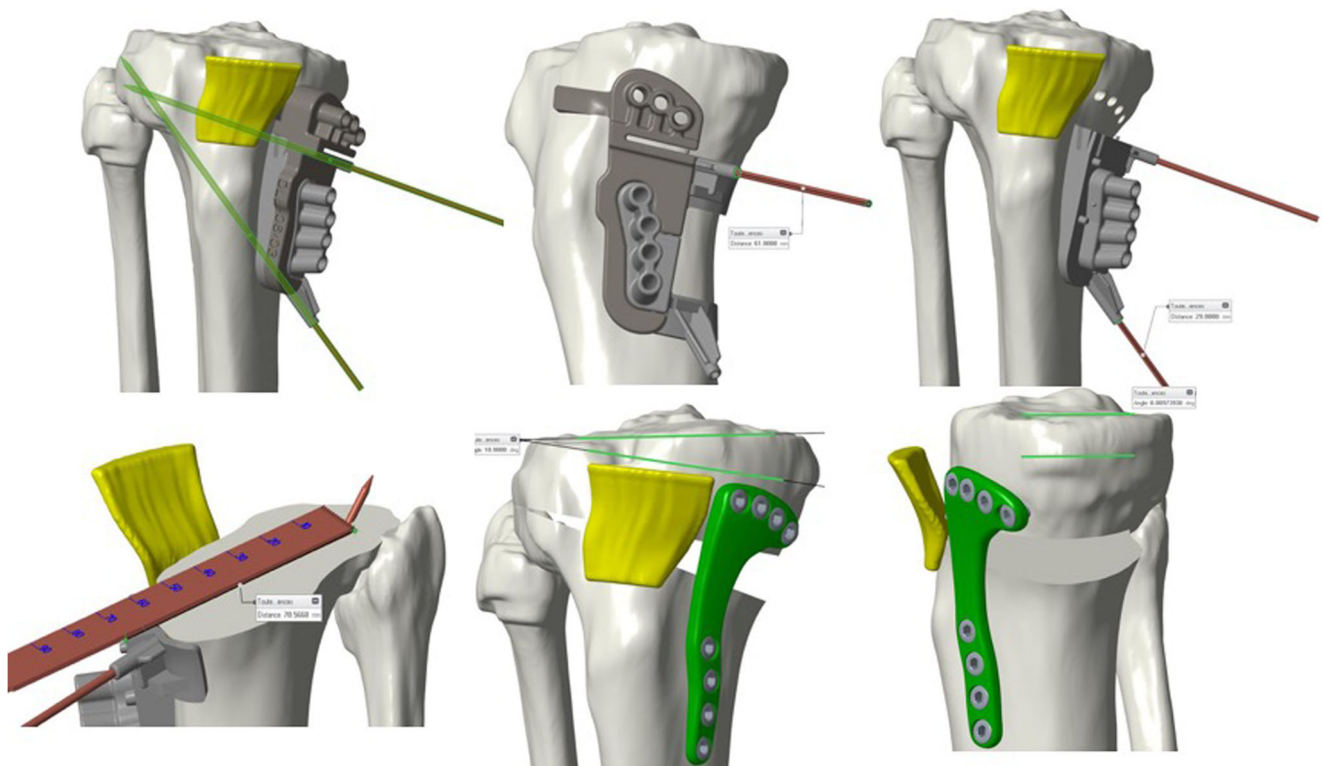


Fig. 1 Pre-operative 3D templating illustrating the operative technique of patient-specific cutting guides. **a, b** Optimal positioning of the cutting guide with two pins (one to protect the lateral hinge during the osteotomy and one to guide the saw). **c** Pre-drilling the 8 holes of the plate with the

guide. **d** Illustration of lateral hinge protection by pin. **e, f** Opening of the osteotomy with definitive positioning of the plate and screws on the pre-drilled holes

- Accuracy of the correction (post-operative alignment) is defined as the difference between the desired correction (defined pre-operatively) and the correction obtained post-operatively measured on CT scan (Δ HKA, Δ MPTA, Δ PPTA) at one month.
- KOOS scoring system [13] and the UCLA activity scale [14] were recorded before the surgery and at one and two years.

Changes in the KOOS sub-scores were estimated comparing pre-operative to final follow-up assessment: Δ KOOS Pain, Δ KOOS Symptoms, Δ KOOS ADL, Δ KOOS Sport/Rec, and Δ KOOS QOL were defined this way.

The UCLA activity scale evaluates the patient physical activity. The scale has ten descriptive activity levels ranging from wholly inactive and dependent on others (level 1) to regular participation in impact sports such as running, skiing, or playing tennis (level 10).

UCLA scores were recorded both pre-operatively (Po) and before the onset of symptoms (BS) as estimated by patients. Subsequently, two values compared to their last follow-up assessment of sport activities, Δ UCLA-Po and Δ UCLA-BS, were defined this way.

To estimate socio-professional improvement, ability to return to work and sport were also recorded.

Intra-operative and post-operative complications were recorded with a specific focus on the number of cases in which the PSCG procedure was abandoned, difficulties with wound and bone healing, hinge fracture, delayed or absent graft integration, and the number of cases requiring hardware removal (Fig. 2).

Population

One hundred patients (59 men and 41 women) were included; no patients were lost to follow-up at a mean of two years. The mean patient age was 44.2 ± 6.8 . Pre-operatively, the mean HKA angle was $171.6 \pm 2.8^\circ$, the mean MPTA was $79.8 \pm 3.1^\circ$, and the mean PPTA was $9.2 \pm 3^\circ$ (Table 1).

Statistical analysis

The descriptive statistic was present as mean \pm standard deviation for quantitative variables. The Mann-Whitney *U* test for two independent samples with 95% confidence interval (95% CI) was used to evaluate the differences between two variables, one-way ANOVA between more than two variables, and multiple linear regressions for relationships. The paired Student *t* test was used to estimate evolution of functional outcomes during follow-up. The differences in proportions between two samples were estimated with the *z* test with

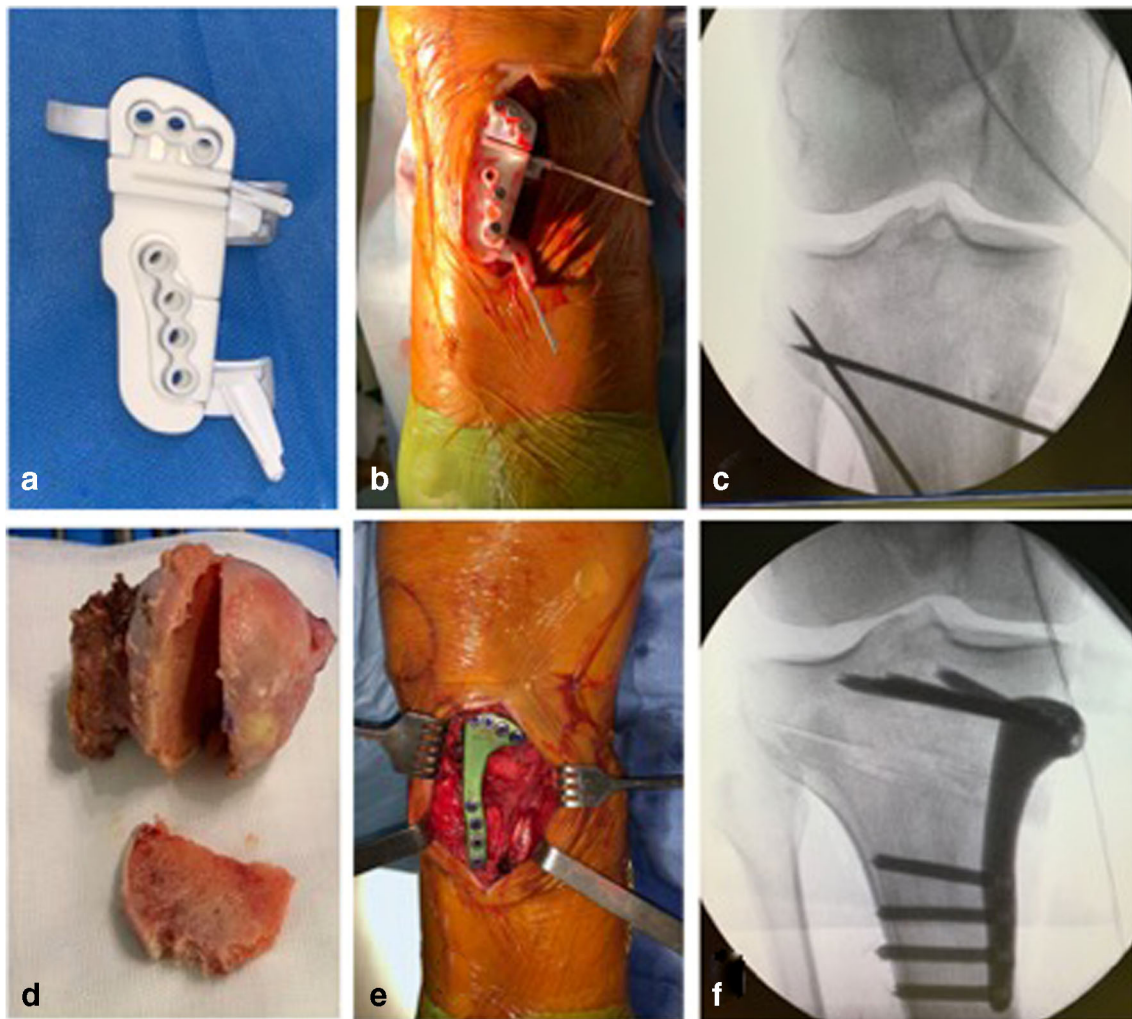


Fig. 2 Intra-operative pictures of a 54-year-old patient undergoing HTO using a PSCG. **a–c** The PSCG is secured onto the tibia; two k-wires help to guide the saw blade and to protect the lateral hinge. **d** A wedge is

sculpted in a femoral head allograft. **e, f** Final plate and screws' positions verified on a fluoroscopic image

95% CI. Finally, a multivariate analysis evaluating factors related to accuracy, clinical outcomes, and complications rate was performed.

Results

Accuracy of post-operative alignment (Tables 2 and 3)

The mean Δ HKA was $1 \pm 0.9^\circ$, the mean Δ MPTA was $0.5 \pm 0.6^\circ$, and the mean Δ PPTA was $0.4 \pm 0.8^\circ$. No significant differences (all p values > 0.05) were observed between the desired correction defined pre-operatively and the correction obtained post-operatively (Δ HKA, Δ MPTA, Δ PPTA). Inter-observer correlation coefficients (CCIs) were found to be 0.67, 0.88, and 0.89 regarding the capability of the PSI system to reproduce planned correction for HKA, gender, age, physical lifestyle at work (sedentary vs active), HKA pre-op,

MPTA pre-op, PPTA pre-op, and graft material which did not correlate with significant accuracy differences in both univariate and multivariate analyses. A significant association was found between Δ HKA, Δ PPTA, and the occurrence of a hinge fracture (respectively $p = 0.04$ and $p < 0.0001$).

Functional outcomes (Tables 4 and 5)

At a mean of two years, an improvement of 27 ± 25 for the KOOS Pain, 28 ± 26 for the KOOS symptoms, 27 ± 28 for the KOOS ADL, 26 ± 33 for the KOOS sport/rec, 28 ± 38 for the KOOS QOL, and 1.6 ± 2.4 for the UCLA was obtained as compared to the pre-operative values (all $p < 0.0001$).

Gender, HKA pre-op, MPTA pre-op, PPTA pre-op, Δ HKA, Δ MPTA, and hardware removal did not correlate with significant difference in terms of functional outcomes in the univariate or multivariate analysis. A significant correlation was found between age, Δ PPTA, time to bone healing,

Table 1 Global series’ pre-operative demographic, radiographic, and functional outcomes of our series

	Patients series (<i>n</i> = 100)	IC 95%
Age (years)	44.2 ± 6.8	(32–59)
Male gender (%)	59	–
HKA (°)	171.6 ± 2.8	(169–175)
MPTA (°)	79.8 ± 3.1	(76.2–83.5)
PPTA (°)	9.2 ± 3	(5.6–12.8)
KOOS pain (/100)	56 ± 15	(43–65)
KOOS symptoms (/100)	53 ± 17	(40–62)
KOOS ADL (/100)	53 ± 16	(49–66)
KOOS sport/rec (/100)	40 ± 21	(32–51)
KOOS QOL (/100)	47 ± 23	(39–62)
UCLA-Po (/10)	6 ± 2.1	(5.6–6.4)
UCLA-BS (/10)	8.7 ± 1.9	(8.3–9.1)

HKA hip-knee-ankle angle, *MPTA* medial proximal tibial angle, *PPTA* posterior plateau tibial angle, *KOOS* Knee injury and Osteoarthritis Outcome Score, *UCLA* University of California Los Angeles activity scale

the occurrence of a hinge fracture or post-operative complications, and KOOS sub-score improvement (all *p* < 0.05). The mean time to return to work and sports were 2.7 ± 2.1 and 5.4 ± 4.3 months, respectively.

Complications (Table 6)

No abandonment of the PSCG procedure was observed.

Minor complications included benign lateral hinge fractures Takeuchi type 1 (18%), postoperative haematoma (9%), graft osteolysis (2%), and persistent phosphocalcic cement graft at the last follow-up (7%). Major complications (10%) included Takeuchi type 2 and 3 fractures (6%), deep wound infections (3%), and non-union of the osteotomy (1%). Hardware removal was required (medical reason, e.g., local pain related to hardware) in three patients at the last-follow-up.

The mean time to bone healing was 4.6 ± 2.1 months.

Table 2 Accuracy of postoperative alignment

	Pre-op	Post-op	Delta Δ	IC 95%	<i>p</i>
HKA (°)	171.6 ± 2.8	182.1 ± 1.3*	1 ± 0.9	(0.8–1.2)	<i>p</i> = 0.5
MPTA (°)	79.8 ± 3.1	90.6 ± 1.8*	0.5 ± 0.6	(0.4–0.7)	<i>p</i> = 0.3
PPTA (°)	9.2 ± 3	7.6 ± 2*	0.4 ± 0.8	(0.3–0.6)	<i>p</i> = 0.8

The accuracy of the post-operative alignment correction was defined by the difference between the desired correction defined pre-operatively and the correction obtained post-operatively measured on Ct scan (ΔHKA, ΔMPTA, ΔPPTA)

HKA hip-knee-ankle angle, *MPTA* medial proximal tibial angle, *PPTA* posterior plateau tibial angle

*All *p* < 0.0001 regarding the difference between the pre-op and post-op values

Table 3 Results of our multivariate analysis of factors influencing the accuracy of post-operative alignment correction; all *p* values calculated using multiple analysis of variance (ANOVA) tests

Confounding factors for accuracy of post-operative alignment correction	Δ HKA	Δ MPTA	Δ PPTA
Age	<i>p</i> = 0.39	<i>p</i> = 0.07	<i>p</i> = 0.57
Gender	<i>p</i> = 0.83	<i>p</i> = 0.06	<i>p</i> = 0.51
Difficulty of the job	<i>p</i> = 0.33	<i>p</i> = 0.35	<i>p</i> = 0.51
HKA pre-op	<i>p</i> = 0.26	<i>p</i> = 0.8	<i>p</i> = 0.88
MPTA pre-op	<i>p</i> = 0.15	<i>p</i> = 0.63	<i>p</i> = 0.41
PPTA pre-op	<i>p</i> = 0.48	<i>p</i> = 0.4	<i>p</i> = 0.38
Grafted material	<i>p</i> = 0.07	<i>p</i> = 0.17	<i>p</i> = 0.51
Hinge fracture	<i>p</i> = 0.04 <i>R</i> ² = 0.13	<i>p</i> = 0.6	<i>p</i> = 0.0001 <i>R</i> ² = 0.22

The accuracy of the post-operative alignment correction was defined by the difference between the desired correction defined pre-operatively and the correction obtained post-operatively measured on Ct scan (ΔHKA, ΔMPTA, ΔPPTA)

*R*² correlation coefficient, *HKA* hip-knee-ankle angle, *MPTA* medial proximal tibial angle, *PPTA* posterior plateau tibial angle

Discussion

The main finding of this study is as follows: performing an OW-HTO with PSCG is a reliable and accurate procedure. It also allows good functional outcomes to be observed at a mean of two years without increasing the rate of specific or non-specific complications.

The first objective of this study was to analyze the reliability of this technique by comparing the accuracy of the achieved correction (measured on CT scan) relative to the planned correction (defined pre-operatively) in both the coronal and sagittal planes (HKA, MPTA, and PPTA). Importantly, varying intra-operative methods have been described to control and instrument the osteotomy; however, these techniques seem to limit the accuracy that can be obtained from osteotomy surgery and only focus on coronal plane

Table 4 Post-operative data in patients undergoing HTO with PSCG

	Pre-op	Post-op	Delta Δ	IC 95%	<i>p</i>
KOOS pain	56 ± 15	83 ± 19	27 ± 25	(22–32)	<i>p</i> < 0.0001
KOOS symptoms	53 ± 17	81 ± 19	28 ± 26	(22–33)	<i>p</i> < 0.0001
KOOS ADL	53 ± 16	80 ± 20	27 ± 28	(22–32)	<i>p</i> < 0.0001
KOOS sport/rec	40 ± 21	66 ± 25	26 ± 33	(20–33)	<i>p</i> < 0.0001
KOOS QOL	47 ± 23	75 ± 26	28 ± 38	(20–35)	<i>p</i> < 0.0001
UCLA	6 ± 2.1	7.6 ± 1.5	1.6 ± 2.4	(1.1–3)	<i>p</i> < 0.0001

ΔKOOS pain, ΔKOOS symptoms, ΔKOOS ADL, ΔKOOS sport/rec, ΔKOOS QOL, ΔUCLA-Po, and ΔUCLA-BS: difference between the value obtained in the pre-operative questionnaire and that obtained at the last follow-up (mean 2 years)

Table 5 Results of our multivariate analysis of factors influencing the functional outcomes; all *p* values calculated using multiple analysis of variance (ANOVA) tests

Confounding factors for functional outcomes improvement	Δ KOOS pain	Δ KOOS symptoms	Δ KOOS ADL	Δ KOOS sport/rec	Δ KOOS QOL	Δ UCLA-Po	Δ UCLA-BS
Age	$p = 0.02$ $R^2 = -0.14$	$p = 0.02$ $R^2 = -0.16$	$p = 0.09$	$p = 0.09$	$p < 0.0001$ $R^2 = -0.28$	$p = 0.7$	$p = 0.6$
Gender	$p = 0.2$	$p = 0.5$	$p = 0.7$	$p = 0.7$	$p = 0.3$	$p = 0.3$	$p = 0.6$
Job	$p = 0.2$	$p = 0.5$	$p = 0.6$	$p = 0.5$	$p = 0.4$	$p = 0.5$	$p = 0.7$
HKA pre-op	$p = 0.8$	$p = 0.8$	$p = 0.6$	$p = 0.7$	$p = 0.1$	$p = 0.6$	$p = 0.07$
MPTA pre-op	$p = 0.9$	$p = 0.6$	$p = 0.8$	$p = 0.8$	$p = 0.1$	$p = 0.9$	$p = 0.07$
PPTA pre-op	$p = 0.7$	$p = 0.6$	$p = 0.9$	$p = 0.7$	$p = 0.7$	$p = 0.5$	$p = 0.1$
Δ HKA	$p = 0.4$	$p = 0.2$	$p = 0.3$	$p = 0.1$	$p = 0.9$	$p = 0.3$	$p = 0.9$
Δ MPTA	$p = 0.6$	$p = 0.9$	$p = 0.51$	$p = 0.2$	$p = 0.9$	$p = 0.7$	$p = 0.08$
Δ PPTA	$p = 0.1$	$p = 0.048$ $R^2 = 0.13$	$p = 0.008$ $R^2 = 0.16$	$p = 0.1$	$p = 0.07$	$p = 0.2$	$p = 0.2$
Grafted material	$p = 0.7$	$p = 0.8$	$p = 0.3$	$p = 0.7$	$p = 0.4$	$p = 0.03$ $R^2 = 0.15^*$	$p = 0.003$ $R^2 = 0.14$
Hinge fracture	$p = 0.1$	$p = 0.2$	$p = 0.1$	$p = 0.4$	$p = 0.02$ $R^2 = -0.19$	$p = 0.04$ $R^2 = -0.11$	$p = 0.9$
Time to bone healing	$p < 0.0001$ $R^2 = -0.34$	$p = 0.01$ $R^2 = -0.26$	$p = 0.008$ $R^2 = -0.16$	$p = 0.08$	$p = 0.02$ $R^2 = -0.17$	$p = 0.09$	$p = 0.03$ $R^2 = -0.14$

Δ KOOS pain, Δ KOOS symptoms, Δ KOOS ADL, Δ KOOS sport/rec, Δ KOOS QOL, Δ UCLA-Po, and Δ UCLA-BS: difference between the value obtained in the pre-operative questionnaire and that obtained at the last follow-up (mean 2 years). The accuracy of the post-operative alignment correction was defined by the difference between the desired correction defined pre-operatively and the correction obtained post-operatively measured on Ct-scan (Δ HKA, Δ MPTA, Δ PPTA)

R^2 correlation coefficient, HKA hip-knee-ankle angle, MPTA medial proximal tibial angle, PPTA posterior plateau tibial angle

* Better UCLA scores were found in patients receiving a femoral head allograft as compared to phosphocalcic cement

correction. In a review of the literature by Van Den Bempt et al., they report a wide range of deviation away from the ideal coronal plane correction being attempted [15]. The mean accuracy was 5.6° (from 4° to 8°) for conventional methods, and it was 5.5° (from 4° to 7°) using the computer-assisted surgery.

Furthermore, previous series have observed a 30 to 50% accuracy of correction after conventional OW-HTO [16]. Other groups that have published work focusing on computer-assisted surgery have also failed to demonstrate optimal correction in more than 20% of their patients undergoing OW-HTO [10]. This is contrary to the results of this study, where the post-operative correction was reproducible and accurate to the pre-planned correction using PSCG technology.

The results of this study compare favorably to those of Saragaglia et al. who reported a 96% accuracy for a planned HKA angle of $184^\circ \pm 2^\circ$ using computer-assisted surgery [17].

Several recent studies have published accurate and reliable corrections in OW-HTO surgery with the use of PSCG. Victor et al. [8] reported an accuracy of 1° in the coronal plane and 2° in the sagittal plane, except that the study was performed with radiographic analysis only. Perez-Mananes et al. [9] had similar results and reported an accuracy of 2° in the coronal plane; however, in their series the tibial slope was not measured and

neither was CT analysis performed. Munier et al. [7] in their pilot study observed an accuracy measured on a CT scan of less than 2° in the coronal and sagittal planes. In terms of achieving an accurate correction, the results demonstrated in this study are similar to these three published series.

It is well documented that correcting the sagittal plane is essential in preserving knee biomechanics [8, 18]. An OW-HTO is known to modify the sagittal plane by increasing the tibial slope [19–21]. Findings of this study suggest that changes within the tibial slope (PTTA) are predictably accurate, which in turn is essential for managing cruciate ligament balance within the knee and trying to maintain the native biomechanics.

Another objective of this study was to evaluate the functional outcomes through the KOOS and UCLA activity scale, at a mean of two years of follow-up. In contrast to this study, other series using PSCG for OW-HTO demonstrate little or no clinical follow-up of patients. All sub-scores of the KOOS in this study showed an improvement of approximately 25 points between the value obtained in the pre-operative questionnaire and that obtained at the last follow-up (mean 2 years). This study was consistent and parallel with other published studies demonstrating that functional scores improved after HTO [22–24]. Several studies have published results on return to

Table 6 Post-operative data in patients undergoing HTO with PSCG

	Patients series (n = 100)	IC 95%
Grafted material (%):		
Left empty	21	
Injectable phosphocalcic cement	38	–
Femoral head wedge allograft	41	
Hinge fracture on CT evaluation (%):		
Takeuchi 1	18	
Takeuchi 2	3	–
Takeuchi 3	3	
Intra-op: PSCG abandonment (%)	0	–
Post-operative complications (%):		
Delayed wound healing	0	
Superficial wound infection	0	
Haematoma	9	–
Graft's osteolysis	2	
Cement persistence	7	
Deep wound infection	3	
Non-union	1	
Early conversion to arthroplasty	0	
Hardware failure with correction loss	0	
Hardware removal (%):		
For medical indications (sepsis, failure)	3	
Time to bone healing (month)	4.6 ± 2.1	(4.2–5.1)

sports after HTO [25–27] and concluded that return to sports was possible at the same or a higher functioning level; the findings in this present study reinforce these conclusions (gain of 1.6 ± 2.4 for the UCLA was obtained, at a mean of 2 years). The use of PSCG for OW-HTO allows good socio-professional outcomes with early return to work and sport (2.7 ± 2.1 months and 5.4 ± 3.3 months, respectively).

The last objective was to evaluate the occurrence of specific and non-specific complications occurring in the first 100 patients treated using PSCG for OW-HTO in this series.

Several recent studies have reported that the complication rate following medial OW-HTO ranged from 1.9 to 55% [28]. The overall complication rate was 32% up to two years post-operatively, and the majority of the complications were classed as minor (28%). Major complications requiring procedure modification or additional surgery were found in 10% of patients in this series.

Recently in 2019, Han et al. [29] reported a 29.7% complication rate after medial OW-HTO using locking plates; most of their complications were minor (21.1%). The most reported complication was an un-displaced lateral hinge fracture, while major complications requiring additional surgical treatment were found in 8.6% of their treated patient population.

In this series, the incidence of lateral hinge fractures detected on CT scan was 24%. This is similar to recent reports with incidence rates ranging from 15.6 to 25.4% [28, 30].

This study bears several limitations; firstly, this is a non-comparative study and although data exists on the safety and accuracy of conventional or computer-assisted surgeries, a control group of conventional HTO would have been valuable to draw direct comparison. The early results of this study and experience with PSCG have made the authors stop and transition from the use of conventional HTO procedure completely.

Secondly, OW-HTO using PSCG requires a pre-operative CT scan, which subsequently increases the radiation exposure and is not necessary in conventional or computer-assisted surgeries. Nevertheless, Perez-Mananes et al. [9] published that PSCG reduced the use of intraoperative fluoroscopy (average of 55 in conventional procedure) and required less surgical time. Moreover, CT scanning and 3D modeling have shown to have a number of advantages over using standard radiographs; it improves the visualization and thus understanding of the procedure, defines the required correction during pre-operative planning, and importantly improves the reliability of measuring the post-operative correction to the pre-operative planned correction and any potential complication such as hinge fractures [31, 32].

Thirdly, the mean follow-up time was two years following surgery, which may be sufficient to assess the complication rate. However, longer follow-up will be necessary to estimate clinical benefits and TKA-free survivorship.

Finally, many factors might have influenced postoperative outcomes; upon those, the type of graft used to fill the osteotomy gap seems to be detrimental. Better functional outcomes (UCLA score) were found in patients operated on using femoral head allograft, as compared to phosphocalcic cement (Table 5). Those results corroborate with recent literature in both translational [33] and clinical sciences [34] underlining the need for more research in this peculiar area.

Despite these limitations, this is the largest reported series to date (100 cases as compared to 14 [8] and 8 for [9]). The use of PSCG in OW-HTO surgery was observed to be safe and accurate, and allows significant improvement in commonly used functional outcome scores two years after the procedure.

Conclusion

In the largest series to date, PSCG technology used for OW-HTO was safe and allows accurate achievement of the desired correction in the coronal and sagittal planes without increasing the rate of specific or non-specific complications.

PSCG and OW-HTO provide satisfactory and favourable functional outcomes at two years of follow-up.

Compliance with ethical standards

Patient consent was collected pre-operatively after they were informed of the procedure in accordance with the principles of the Helsinki declaration. A local ethics committee approved our study protocol prior to the investigation.

Conflict of interest Matthieu Ollivier is an educational consultant for New-Clip, Stryker, and Arthrex.

Sebastien Parratte is an educational consultant for New-Clip, Zimmer, and Arthrex.

Jean-Noël Argenson receives royalties from Zimmer.

Samir Chaouche, Maxime Fabre, Akash Sharma, and Christophe Jacquet have nothing to disclose.

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