



Equal rates of bone healing and reduced surgical time with iliac crest allograft compared to autograft in medial opening wedge high tibial osteotomy: a randomized controlled clinical trial

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Abstract

Introduction Iliac crest autograft is frequently used to fill in bone defects after osteotomies. Nonetheless, surgery for bone autograft procurement is associated with morbidity and pain at the donor site. Alternatives to it have been explored, but there is no consensus to guide their application as a routine practice in several orthopedic procedures. Thus, this study was designed to compare the efficacy and safety between iliac crest autograft and allograft in medial opening wedge high tibial osteotomy.

Materials and methods Forty-seven patients with a symptomatic unilateral genu varum and an indication for high tibial osteotomy were randomly assigned to receive either autograft or allograft to fill the osteotomy site. Operative time, bone healing, and complication rates (delayed union, nonunion, superficial and deep infection, loss of correction, and hardware failure) were recorded after a one-year follow-up. Data were expressed as Mean $\pm$ Standard Deviation and considered statistically significant when $p < 0.05$.

Results The time to radiologic union was similar between both groups (Allograft: 2.38 ± 0.97 months vs. Autograft: 2.45 ± 0.91 months; $p = 0.79$). Complication rates were also similar in both groups, with one infection in the allograft group and two in the autograft group, two delayed unions in the allograft group, and three in the autograft group. The operative time differed by 11 min between the groups, being lower in the allograft group (Allograft: 65.4 ± 15.1 min vs. Autograft: 76.3 ± 15.2 min; $p = 0.02$).

Conclusion Iliac crest allografts can be safely and effectively used in medial opening wedge high tibial osteotomy as it promotes the same rates of bone union as those achieved by autologous grafts, with the benefits of a shorter operative time.

Trial Registration Number U1111-1280-0637 1 December 2022, retrospectively registered.

Keywords Osteotomy · Bone healing · Allograft · Autograft · Genu varum

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Introduction

Symptomatic genu varum reduces individuals' quality of life when associated with pain and disability. Such a deformity can lead to premature degeneration of the knee medial tibiofemoral compartment. The medial opening wedge high tibial osteotomy (MOWHTO) has become the most popular surgical technique to correct this deviation [1]. However, it creates a bone defect in the tibia that can be filled in with a bone graft to enhance consolidation and reduce complications [2].

Iliac crest autograft is frequently used to fill bone gaps, but graft procurement has been associated with morbidity and pain at the donor site. A possible alternative is using an allograft, but concerns about increased complication rates have limited its widespread utilization. [3]. Previous studies do not allow for conclusions about the best option of bone graft for tibial osteotomies [4–6] as there are only a few randomized controlled trials comparing bone graft types [7, 8].

This randomized controlled clinical trial has been designed to compare autograft and allograft in MOWHTO, assessing and evaluating outcome variables such as bone healing time, operative time, and complication rates to gather information to assist surgeons in the decision process of this matter.

Methods

This study was performed in line with the principles of the Declaration of Helsinki. Brazilian Research Ethics Committee approved the study, which was retrospectively registered in the Brazilian Clinical Trials Registry with the protocol number U1111-1280-0637. Informed consent was obtained from all participants of the study.

The recruitment enrolled 60 patients with symptomatic varum deformity and osteotomy indication. Exclusion criteria included systemic inflammatory diseases; age over 60 years or under 20 years; corrections over 17° or with an opening wedge of less than 10 millimeters; previous surgeries on the affected knee; previous infections on the affected limb; pain at the lateral or anterior compartment of the affected knee; lateral meniscal injury; severe knee osteoarthritis (grades 4 and 5 of the Ahlbäck classification); range of motion with less than 90° flexion; and more than 10° flexion contracture. Then, 47 participants were selected and underwent MOWHTO between December 2020 and September 2021, with a minimum one-year follow-up, appropriate for the primary outcome analysis (bone healing) [9–11]. The osteotomy technique was the same in both groups, differing only whether an allograft or an autograft was used to fill in the osteotomy gap. Randomization was performed using a virtual tool available at (www.random.org), which allocated the patients into two groups: autograft or allograft. Participants were informed of group information after the surgery, while the surgeons were made aware of it before the procedure to enable adequate preparation for each graft type. All the surgeons performing the procedures had about ten years of experience with performing osteotomies.

Patients underwent preoperative radiographic evaluation with the knee weight-bearing AP view, the 30° flexion lateral view of each knee, the long hip-knee-ankle AP view, and the Merchant's patellar axial view. This enabled

limb misalignment calculations as well as planning for the needed correction to be done at surgery. A proximal, supratuberosity, uniplanar medial opening wedge tibial valgus osteotomy was performed about four centimeters distal and oblique to the joint line in a distal to proximal direction, with the aid of an oscillating saw and large osteotomes. A laminar spreader was placed posteriorly on the medial cortex of the tibia to create an opening for the desired correction. This technique maintains intact the lateral cortex at the fibular head apex.

The autograft was obtained from the iliac crest of the opposite limb undergoing the osteotomy by harvesting two tricortical bone wedges three centimeters in length and base size equivalent to the gap opening at the site of the osteotomy (Fig. 1). The graft procurement was accomplished by the same surgeon performing the osteotomy and not by another team as we so often observe as a routine. The reason behind that was to try to avoid compromise and bias in analyzing the operative time.

Iliac crest allografts from our Tissue Bank were processed by the deep-freezing method, without lyophilization or radiation, and then thawed in saline at room temperature at the time of surgery (Fig. 2). Two wedges three centimeters in length and base size equivalent to the gap opening, such as the autografts, were carved using a saw.

Both autograft and allograft followed the same standard steps for filling the osteotomy gap. Two fragments of corticocancellous bone were triangular wedges. They were carefully positioned at the osteotomy site so their cancellous bone surfaces could face tibial counterparts proximally and distally at the medial opening gap. After impacting the bone wedges using the press-fit technique, the osteotomy was fixed using a ten-hole locked tibial osteotomy plate without a shim (Neoortho[®], Curitiba, Paraná, Brazil). Three 5 mm-locked screws were used in the osteotomy's proximal segment; one 4.5 mm-cortical screw and three 5 mm-locked screws in the distal segment according to the manufacturer's technical recommendations.

The surgical time comprised the main duration of the procedure, excluding the incision closure period. Postoperative management was similar in all cases, and radiographic evaluation was performed monthly in the first semester and quarterly up to one-year follow-up. The postoperative image parameters were the same as the ones in the preoperative period. The ratio of the length of the osteotomy gap that was not visible to the measurements of the total osteotomy length at the AP radiographs view (Fig. 3) characterizes the Schröter index. Consolidation is considered when this score exceeds 0.75 [12].

The bone consolidation process was evaluated through the analysis of the AP radiographs view with the criteria described by van Hemert [13] and Staubli [14], where a

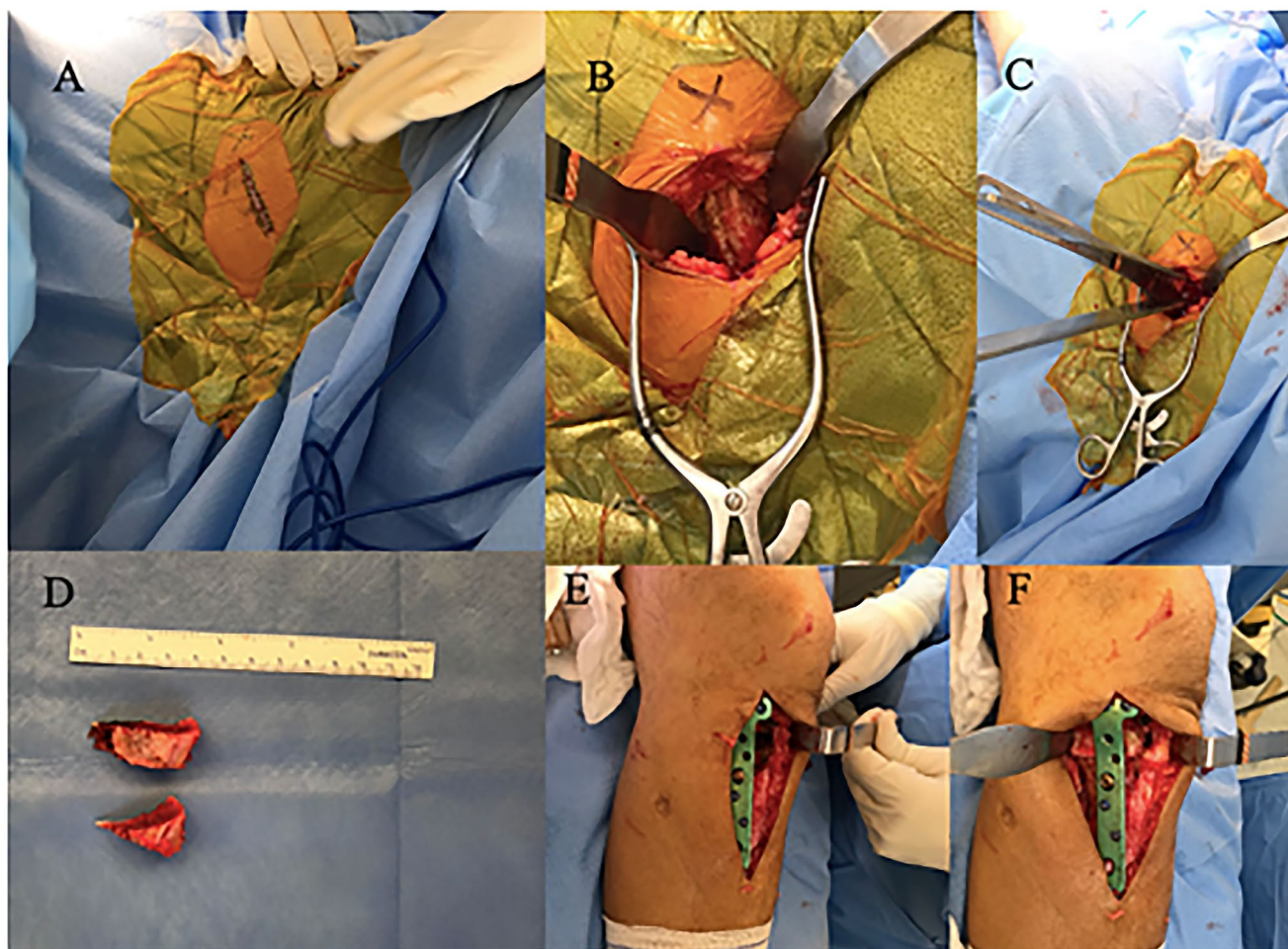


Fig. 1 Removal and impaction of the autologous graft. (A) Preparation of surgical fields to approach the iliac crest; (B) deep exposure of the iliac crest for graft removal; (C) introduction of osteotomes to remove the tricortical graft; (D) two fragments of tricortical graft removed

with equivalent size to the opening created; (E) osteotomy area with bone defect; (F) osteotomy filled in with bone graft. Source: Author's archive

score from 0 to 5 refers to gradual consolidation parameters and a score from 0 to 2 regarding gradual parameters of sclerosis and trabecular ossification, respectively. Non-unions, delayed unions, hardware failures, correction losses, superficial or deep infections, vascular injuries, tibial plateau fractures, compartment syndromes, wound healing problems, hematomas, neuromata formation, and arthrofibrosis were among the expected complications. Cases with bone consolidation between 4 and 6 months were considered delayed union.

Two orthopedic surgeons examined the radiographs and were blind regarding the participant's group. Divergences concerning bone consolidation parameters and complications were discussed between them, and whether they still disagreed, a third evaluator was called upon for a consensual final decision.

Data collection and tabulation were performed with Excel (Microsoft®) software. Data analysis involved comparisons of differences between categorical variables proportions (relative frequencies) with the chi-squared (χ^2) test or Fisher's exact test. Central tendency measures and their dispersion, such as mean and standard deviation (SD) and median and 25th–75th percentile (P25–P75), were calculated for numerical variables. However, median and P25–P75 were only shown for surgical duration. Student's t-test was applied when data distribution was parametric, and a Mann-Whitney test was used for non-parametric data distribution. All data analysis was performed using the SPSS 26.0 statistical software (Statistical Package for Science – Chicago, IL, 2019), and the significance level was $p < 0.05$.

Fig. 2 Preparation of the allograft in wedges. (A) Iliac crest fragment sent by the tissue bank for surgery; (B) planning to remove a bone fragment with equivalent size of the opening promoted in the osteotomy; (C) drawing of the bone fragment to be removed; (D) wedge removal using saw; (E) wedge fragment of molded graft, 3 cm deep and compatible with the opening of the osteotomy; (F) two tricortical iliac crest allografts for impaction. Source: Author's archive

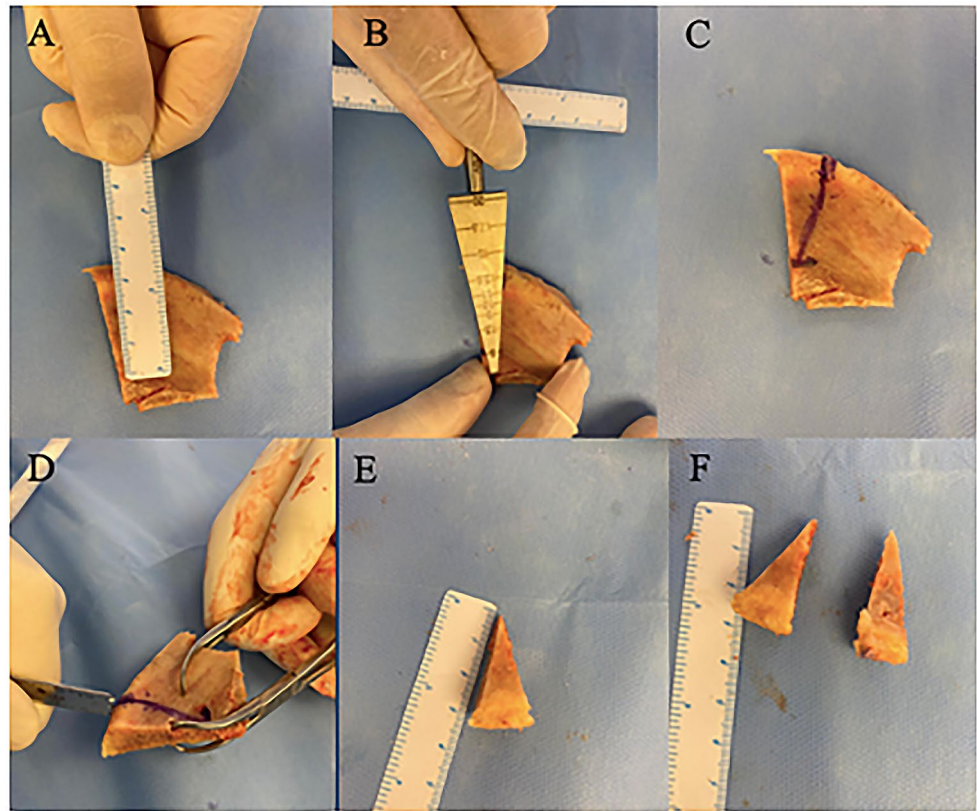
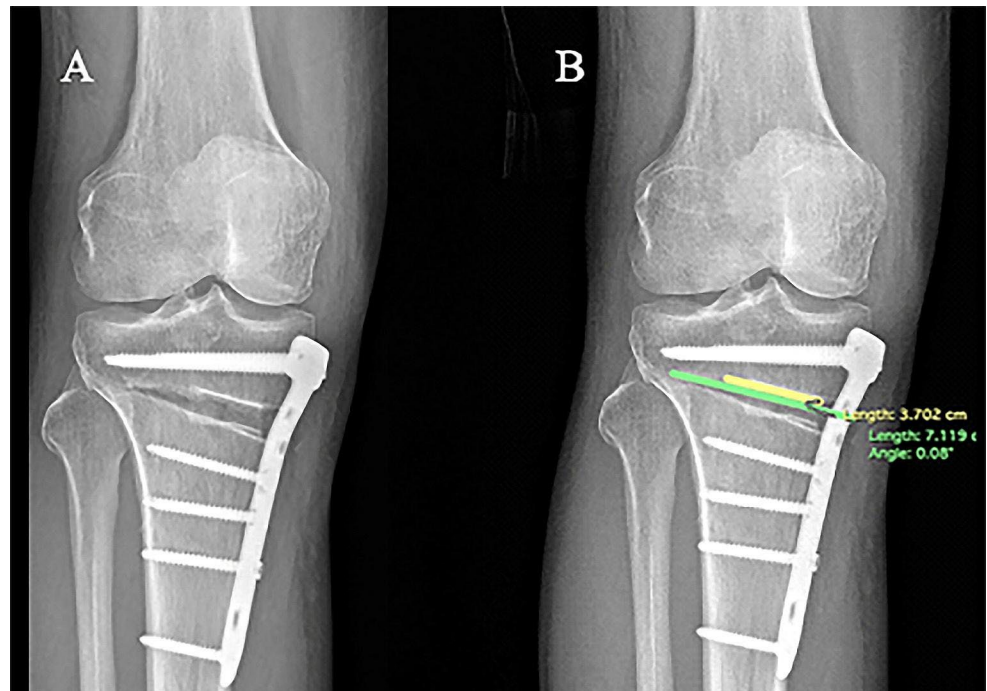


Fig. 3 Radiological evaluation of bone healing using the Schröter index. The ratio of the length of the osteotomy gap that was not visible to the measurements of the total osteotomy length, at the AP radiographs view, is considered. (A) Original image without bone consolidation markings; (B) marking referring to the area of the osteotomy with new bone (yellow) and marking referring to the total size of the osteotomy (green). An index measuring 0.52 is not yet compatible with consolidation. Source: Author's archive

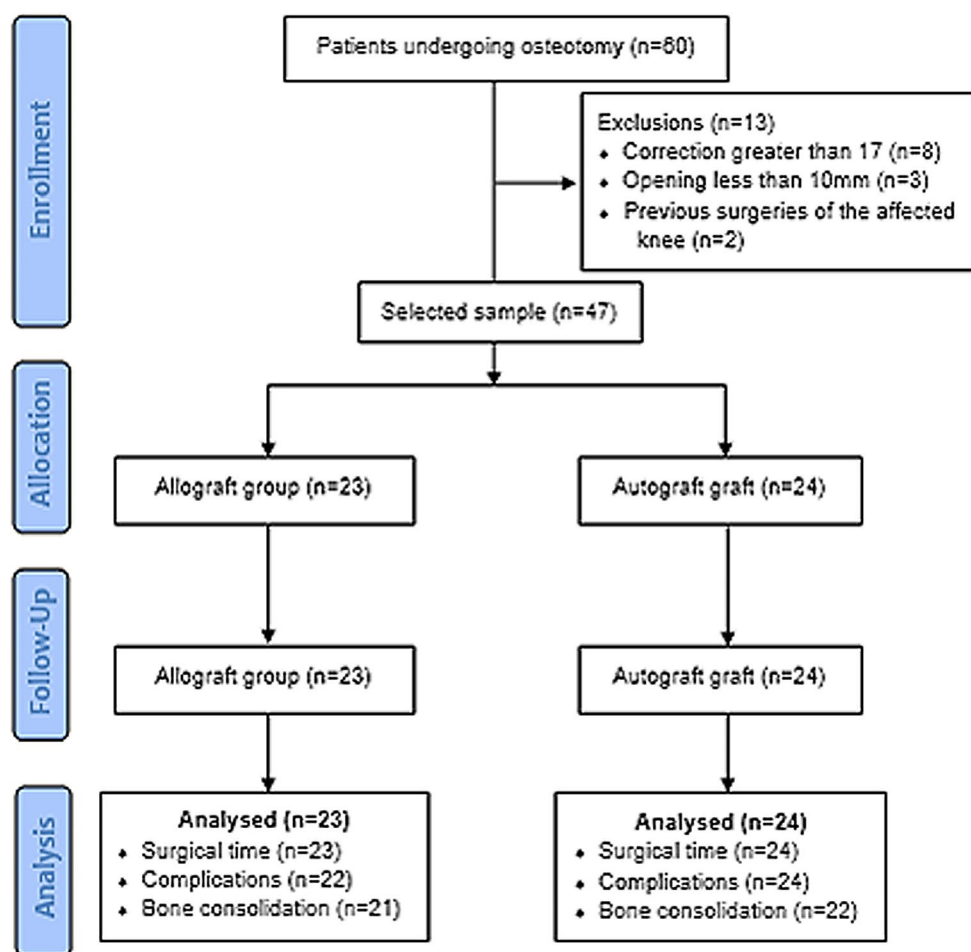


Results

Among the 47 participants of the study allocated into the allograft group ($n=23$) or the autograft group ($n=24$), one (4.3%) participant in the allograft group was lost to

follow-up, and so excluded from the final analysis. Additionally, two (8.3%) participants in the autograft group developed infection, one (4.2%) deep and the other (4.2%) superficial. In the allograft group, there was one (4.3%) case of deep infection (Fig. 4).

Fig. 4 Flowchart showing progress through the phases of this study: a Randomized Controlled Clinical Trial



Demographic characteristics showed no significant differences between the groups. The mean size of the osteotomy opening did not differ between the allograft and autograft groups, even though using two different forms of stratifying the osteotomy opening data (Table 1), considering 4-range split (10 or 12.5 or 15 or 17.5 millimeters) or 2-range split (<15 or ≥ 15 millimeters). However, the osteotomies with bone allograft presented a statistically significant shorter operative time than those with the autogenic bone graft (Table 1).

The time to radiologic union was similar between the groups (Schröter index: Mean $\pm$ Standard Deviation: Allograft -2.38 ± 0.97 months vs. Autograft -2.45 ± 0.91 months; $p=0.79$). No cases exceeding six-month consolidation time were observed, and no difference between the groups during the consolidation process using van Hemert or Staubli criteria. At the end of the surgery, all patients scored 0 on both scales, and after a month, they had evolved to some degree (Table 2).

At one-year follow-up, none presented a score of 5, which reflects complete bone healing with no distinction of the osteotomy opening. Four months after surgery, all the participants had evolved for van Hemert scores of 3–4,

which refers to an evident radiolucent or partially visible line on the proximal or distal surface but not on both. Furthermore, at that time, all patients already had a score of 2 on the Staubli scale regarding the presence of sclerosis in at least more than half of the thickness of the lateral cortex, as well as signs of trabecular ossification (Table 2).

Complication rates were also similar between the two groups (Table 3). Among the 24 participants of the autograft group, complications related to the graft harvest from the iliac crest were recorded. One (4.2%) permanent injury to the lateral femoral cutaneous nerve and two (8.3%) cases of persistent local pain were reported, with no other complications found.

Discussion

The most important finding of this study is that the iliac crest allograft bone wedge was shown to be equivalent to the iliac crest autograft bone wedge in MOWHTO regarding bone healing. Some case series have reported promising results with allogenic graft, including an average short recovery time of 12 weeks [10, 11]. In 2021, Haghpanah and

Table 1 Demographic characteristics of the participants and surgical parameters

Variable	Allograft <i>n</i> = 23 (<i>n</i> / %)	Autograft <i>n</i> = 24 (<i>n</i> / %)	<i>p</i> -value
Gender*			
Female	1 (4.3)	2 (8.3)	0.57
Male	22 (95.7)	22 (91.7)	
Age (years)			
Mean (SD)**	47.3 (6.1)	44.3 (11.6)	0.27
Height (m)			
Mean (SD)**	1.72 (0.07)	1.72 (0.06)	0.98
Weight (kg)			
Mean (SD)**	93.3 (16.8)	94.6 (14.9)	0.77
BMI (kg/m ²)			
Mean (SD)**	31.6 (5.6)	32.1 (4.9)	0.77
Tibiofemoral angle (degrees)			
Mean (SD)**	-1.9 (3.7)	-1.0 (3.6)	0.41
Osteotomy Opening (mm)#			
Stratifying form 1			
10	4 (17.4)	11 (45.8)	0.13
12.5	11 (47.8)	5 (20.8)	
15	5 (21.7)	5 (20.8)	
17.5	3 (13.0)	3 (12.5)	
Stratifying form 2			
< 15	15 (65.2)	16 (66.7)	0.94
≥ 15	8 (34.8)	8 (33.3)	
Surgical time (minutes)			
Mean (SD)**	65.4 (15.1)	76.3 (15.2)	0.02
Median (P25-P75) ***	66.0 (53.0–80.0)	77.5 (60.0–90.0)	0.01
Min – Max	36.0–90.0	60.0–90.0	-

Abbreviations: BMI – body mass index; SD – standard deviation; kg – kilogram; m – meter; mm – millimeter. * Chi-square test. **Student's *t* test # chi-square test. ***Wilcoxon test

colleagues conducted a clinical trial [7] comparing allograft and autograft in MOWHTO, and the consolidation time was approximately 11 weeks in both groups. Our study corroborates these results. Besides that, a systematic review pointed that all fillers had no effect on bone union time compared with unfilled group for MOWHTOs. However, it is essential to acknowledge that a certain mean range of correction angles (10.1°; IQR 8.1°–11.5°) and gap widths (10.9 mm; IQR 9.8–11.7 mm) were included in the study [15]. In 2010, Santic and colleagues reported that consolidation time was directly related to the tibial opening and varus deformities. Thus, Lobenhoffer et al. advocate for filling gaps exceeding 13 mm with autogenous cancellous bone, while El-Assal et al. recommend intervention for gaps surpassing 14 mm [16, 17]. The procedures that elicited more than 10 millimeters opening at the osteotomy site required consolidation time over 12 weeks [18]. In our study, all patients had corrections superior to 10 millimeters and, yet achieved bone healing before 12 weeks.

Table 2 Bone healing scales

	Radiological changes	Allograft <i>n</i> = 21 (<i>n</i> / %)	Autograft <i>n</i> = 22 (<i>n</i> / %)	<i>p</i> -value #
1st month	Van Hemert Scale			
	1–2	15 (71.4)	13 (59.1)	0.39
	3–4	6 (28.6)	9 (40.9)	
	Staubli Trabecular Structure			
	1	14 (66.7)	17 (77.3)	0.44
	2	7 (33.3)	5 (22.7)	
	Staubli Sclerosis			
	0	2 (9.5)	0 (0.0)	
	1	17 (81.0)	19 (86.4)	0.56
	2	2 (9.5)	3 (13.6)	
2nd month	Van Hemert Scale			
	1–2	4 (19.0)	2 (9.1)	0.63
	3–4	17 (81.0)	20 (90.9)	
	Staubli Trabecular Structure			
	1	5 (23.8)	6 (27.3)	0.74
	2	16 (76.2)	16 (72.7)	
	Staubli Sclerosis			
	1	5 (23.8)	5 (22.7)	0.92
	2	16 (76.2)	17 (77.3)	
3rd month	Van Hemert Scale			
	1–2	2 (9.5)	0 (0)	0.52
	3–4	19 (90.5)	22 (100.0)	
	Staubli Trabecular Structure			
	1	1 (4.8)	1 (4.5)	0.97
	2	20 (95.2)	21 (95.5)	
	Staubli Sclerosis			
	1	2 (9.5)	1 (4.5)	0.52
	2	19 (90.5)	21 (95.5)	
4th month	Van Hemert Scale			
	1–2	0 (0.0)	0 (0.0)	-
	3–4	21 (100.0)	22 (100.0)	
	Staubli Trabecular Structure			
	2	21 (100.0)	22 (100.0)	-
	Staubli Sclerosis			
	2	21 (100.0)	22 (100.0)	-

Chi-square test

Considering MOWHTO outcomes, the bone graft selection remains a subject of considerable scientific inquiry. A systematic review discussed that bone void filling materials had no superior effect on functional scores and radiological outcomes compared to no bone graft use [15], but the mean range correction was inferior to the one from this study. The investigation by Yazdi et al. (2022) undertook a retrospective cohort analysis encompassing 122 subjects undergoing MOWHTO with allogenic cancellous bone graft, elucidating robust gap healing dynamics and favorable clinical outcomes [19]. Conversely, Bodenbeck et al. (2023) delineated

Table 3 Postoperative complications

Complication	Allograft <i>n</i> = 22 (<i>n</i> / %)	Autograft <i>n</i> = 24 (<i>n</i> / %)	<i>p</i> -value
Deep infection	1 (4.5)	1 (4.2)	0.88
Superficial infection	0	1 (4.2)	0.72
Loss of angular correction	0	0	-
Delayed union	2 (9.1)	3 (12.5)	0.61
Nonunion	0	0	
Hardware failure	0	0	

Chi-square test

the advantages of autologous bone grafting, elucidating its pivotal role in expediting osseous consolidation and potentially ameliorating functional outcomes [20]. The present study concludes that, for corrections superior to 10 mm opening, the consolidation process is equivalent for autograft and allograft use.

In this study, there were no differences in complication rates between allograft and autograft groups. Similar results were described in case series reports [9–11, 21–23] and in a systematic review with meta-analysis [24]. Major and minor complications are rare in osteotomy around the knee (1.7% and 2.0%, respectively) [25]. Specifically, autogenic bone graft requires harvesting during the procedure. It is associated with a low risk of complications but not a complication-free procedure. It may be associated with local pain, hematoma formation, sensory disorders [24, 26], and, rarely, significant complications such as fractures and incisional hernias [27, 28]. The use of bone allografts is devoid of those additional removal procedures and their possible complications.

In 2009, Miller and colleagues analyzed bone grafting MOWHTO with iliac crest autograft and spongy allograft croutons. The complication rate was high (36.9%) but unrelated to the graft type [20]. Conversely, other reports pointed out that allografts had worse results than autografts. In 2010, Kuremsky and colleagues registered a high failure rate (30%), which was even higher associated with lateral cortical fracture (53%) [29]. A systematic review considering 56 articles on bone graft use in tibial osteotomies concluded that autograft was superior to allograft in terms of consolidation time and complications involving delayed union and pseudarthrosis [30]. Of the studies included in the review, 43 were case studies, and 13 were comparative cohort studies. Only one manuscript was a randomized controlled clinical trial, and most included studies had a low evidence level. In summary, the lack of standardization of the graft type, allograft-processing strategy, type of plate, and plate fixation technique make comparing data and inferences about the topic difficult.

This study certainly brings valuable contributions to the orthopedic community, considering that it has a

well-controlled design with solid points, such as randomization, standard protocols of graft procurement, preparation, setting, and fixation, as well as preoperative and postoperative patterns with a follow-up blinded analysis. The allograft type, its preparation, and sterilization methods may contribute to the excellent consolidation results observed in this report. The tricortical iliac crest fixation position provides an excellent structural effect, and the cancellous part of it acts as an osteoconductive substitute, enhancing bone healing. This characteristic is absent in other bone substitutes, such as hydroxyapatite, tricalcium phosphate, acrylic, and bone cement [11]. Besides, allograft preparation involves neither lyophilization nor sterilization through radiation, which would decrease its structural strength [31, 32].

Furthermore, we assume that the locked plate type and its fixation technique were important factors to avoid correction loss and hardware failure. On the other hand, high complication rates have been reported in other studies with non-locked plates [11, 22] and revision rate due to any reason was high [33].

Another advantage of the procedures with allografts was the shorter operative time compared to those with autografts. A systematic review and meta-analysis reported a mean difference of 13.95 min between the groups [24], and a clinical trial described a difference of approximately 13.7 min [11], similar to our study, whose difference averaged 10.9 min.

A systematic review reported good clinical outcomes and a high survivorship of 74.6% at ten year-follow up after high tibial osteotomy [34]. Beyond that, after one year-follow up, patient satisfaction was high and 78% of patients stated they would do the surgery again, especially the young ones [35]. Surgeons' choices concerning the procedure might influence patient outcomes, particularly whether graft use. In conclusion, the results of this study point out that using iliac crest allograft in MOWHTO is safe and comparable in efficacy to autograft, leading to a reduction in operative time. Therefore, whenever fits graft use indication, we encourage surgeons to include bone allografts as one more strategy in their routines to support healing for their osteotomies and possibly decrease patients' morbidity.

Supplementary Information The online version contains supplementary material available at <https://doi.org/10.1007/s00402-024-05410-6>.

Declarations

Statements & declarations The study was approved by the Brazilian Research Ethics Committee (CAAE 36297020.6.0000.5273, 20 September 2020), according to the 1964 Helsinki Declaration, and all patients gave their written consent to participate. Beyond that, the study was retrospectively registered at the Brazilian Clinical Trials Registry (UTN code: U1111-1280-0637, 1 December 2022). This study did not receive any funding, grants, or equipment. The authors do not have competing interests. The authors had no financial benefits to develop

this study. All authors contributed to the study's development. Rafael Erthal de Paula, Alan de Paula Mozella, and Aline Cordeiro performed study conception and planning. Rafael Erthal de Paula, Rodrigo Satamini Pires e Albuquerque, Ricardo Duran Sobral, Phelippe Augusto Valente Maia, Hugo Alexandre de Araujo Barros Cobra, and Eduardo Branco de Sousa performed surgeries execution and data collection. Rafael Augusto Dantas Prinz performed allograft protocol conception and preparation. Arnaldo César Couto performed statistical data analysis and contributed to data interpretation. Rafael Erthal de Paula, Alan de Paula Mozella, Idemar Monteiro da Palma, and Aline Cordeiro performed manuscript writing. All authors reviewed and approved the final manuscript.

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