Orthopaedics & Traumatology: Surgery & Research 109 (2023) 103700

Contents lists available at ScienceDirect

Orthopaedics & Traumatology: Surgery & Research

journal homepage: www.elsevier.com

Original article

Better clinical outcomes and faster weight bearing after medial opening-wedge high tibial osteotomy using allogeneic than synthetic graft: A secondary analysis of a Francophone Arthroscopy Society Symposium

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ARTICLE INFO

Article history:
Received 21 June 2023
Accepted 26 September 2023

Keywords:
Medial opening wedge high tibial osteotomy
Void
Allogenic graft
Synthetic graft
Osteoarthritis

ABSTRACT

Introduction: Although an autogenous graft has the highest rate of bone union to fill the void created in medial opening wedge high tibial osteotomy (MOWHTO), it also has some disadvantages, such as prolonged surgical time, donor site pain and morbidity. Two possible candidates for ideal grafts to replace autogenous grafts are allogeneic and synthetic graft, which are free from donor site pain and morbidity. However, previous reports comparing the clinical results of allogeneic to synthetic graft have been limited and controversial. The purpose of this study is to compare radiological findings and clinical outcomes of using synthetic versus allogenic graft to fill the void created in MOWHTO.
Hypothesis: The present clinical study hypothesized that allogenic graft to fill the void would allow the higher rate of bone union and better clinical outcomes.
Material and methods: This study compared the clinical and radiological outcomes of 95 patients who received MOWHTO to fill the void with either synthetic or allogenic graft (44 in Syn group, 51 in Allo group). Preoperatively and postoperatively, all patients were clinically evaluated; Return to work, Tegner activity score, and the Western Ontario and Macmaster University scores were reported. Radiographically, osteoarthritis grade and pre- and postoperative parameters were reported, including Hip-knee-ankle angle, mechanical lateral distal femoral angle, medial proximal tibial angle, joint line convergence angle, proximal posterior tibial angle, and limb length discrepancy. Perioperative details and complications were also reported.
Results: Mean follow-up (months) were 24.0 ± 1.3 in Syn group and 26.8 ± 1.2 in Allo group ($p = 0.13$). The postoperative improvement of pain and global WOMAC scores in Allo group were significantly better than in Syn group (ΔPain of WOMAC: Syn group 27.8 ± 4.4, Allo group 49.3 ± 3.8, p value < 0.001*) (ΔGlobal score of WOMAC: Syn group 16.7 ± 3.2, Allo group 37.4 ± 4.9, p value = 0.002*). The risk of hinge fracture in Syn group was significantly higher than in Allo group (Hinge fracture by Takeuchi grade (0/1/2/3): Syn group 37/3/3/1, Allo group 43/8/0/0, p value = 0.04*). The timing of full weight bearing in Allo group was significantly earlier than in Syn group (Weight Bearing (1 = FWB, 2 = PWB 3wk, 3 = PWB 6wk): Syn group 2.7 ± 0.1, Allo group 2.3 ± 0.1, p value = 0.01*).

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https://doi.org/10.1016/j.otsr.2023.103700

Discussion: The use of allogenic graft to fill the void in MOWHTO does not show superiority in bone union compared to synthetic graft, however it improves pain, function, decreases the risk of hinge fracture and allows faster weight bearing than synthetic graft.
Level of proof: III; Case-control study.

1. Introduction

Medial opening-wedge high tibial osteotomy (MOWHTO) is a well-established treatment for early and moderate medial unicompartmental knee osteoarthritis (UKOA) in constitutional varus malalignment in younger, active patients [1–7]. Recently, other indications of MOWHTO in the presence of varus knee were reported, such as meniscal transplantation after total medial meniscectomy [8,9], osteonecrosis or secondary degenerative arthritis with medial joint line pain [10–12], the combined correction of varus and posterior tibial slope malalignment [13] and ligamentous instability with varus thrust [14,15]. MOWHTO has been performed more frequently than lateral closing wedge HTO, since no fibular osteotomy is needed, correction is possible in both the frontal and sagittal plane, the correction can be adjusted during surgery [16], and there is limited bone loss and thus easier conversion to knee arthroplasty [17–20].

MOWHTO creates a distracting gap and nonunion or loss of correction are deemed as the major complications of this technique, which is increased for openings of more than 10 degrees [21,22]. So, various filling methods have been used to enhance stability and accelerate a healing of the gap. Three major methods have been reported: autogenous, allogenic and synthetic graft. Firstly, autogenous grafts, which are mainly harvested from tricortical iliac crest graft, have the most osteogenic, osteoinductive, and osteoconductive effects, as well its highest rate of bone union [23,24]. However, they also have some disadvantages, such as prolonged surgical time, donor site pain and morbidity [25–27]. Secondly, allogenic grafts are a good alternative option to autogenous grafts and would become the most frequently used material recently. Although they have the slight potential risk of an immune response, contamination, or disease transmission [28,29], they offer osteoconductive properties, faster operation and rehabilitation time, and structural support without harmful effects on the donor site [30–34]. Thirdly, Synthetic grafts, such as calcium phosphate cement, hydroxyapatite and tri-calcium phosphate, carries osteoconductive properties and initial high compressive strength [35–37]. Many basic science papers have supported that a synthetic graft carries osteoconductive properties utilized in both tibial plateau fracture treatment and supplementation to MOWHTO fixation [36,38,39]. Although autogenous graft has the most reliable results for bone union to fill the void created in MOWHTO [40–43], previous reports comparing the clinical results of allogenic to synthetic graft have been limited and controversial. Reliable evidence about an ideal graft substitute is necessary to offers better outcomes.

The purpose of this study is to compare radiological findings and clinical outcomes of using synthetic versus allogenic graft to fill the void created in MOWHTO. The present study hypothesized that allogenic graft would allow the higher rate of bone union and better clinical outcomes than synthetic graft.

2. Material & methods

2.1. Patients' enrollment

Between June 2017 and June 2018, a multicenter non-randomized prospective observational study was conducted for the arthroscopy symposia of French speaking society in 11 French centers specializing in knee surgery: Amiens, Caen, Echirolles, Gap, Grenoble, Lorient, Lyon Croix Rousse, Lyon Santy, Mérignac, Rennes, and Versailles. Informed consent was obtained, with approval from the CCPPRB review board (no ID-RCB 2018-A01353-52). From this multi-center database (including 126 patients), a secondary analysis was performed to identify 95 patients that met the following criteria (Fig. 1):

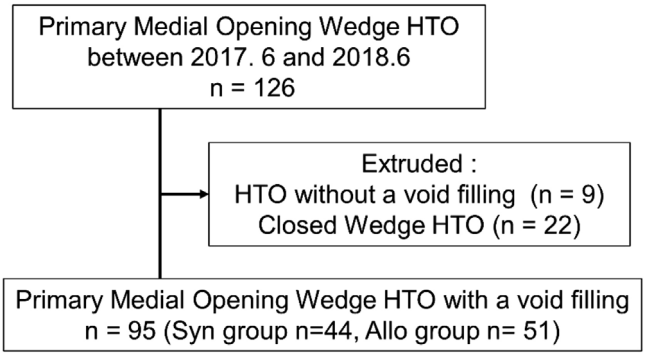

Fig. 1. Flowchart of inclusions. Syn: synthetic graft, Allo: allogenic graft.

- Medial OWHTO for knee varus. With substancial metaphysal (tibial) deformity (Mpta < 85);
- Osteotomy gap filling using either synthetic material (Syn Group (n = 44)) or allogenic graft (Allo group [n = 51]).

Exclusion criteria comprised history of fracture or periarticular osteotomy of the knee, stiff knee (flexion contracture > 5° and/or flexion < 120°), and operated or non-operated ligament injury.

2.2. Operative details

A conventional free-hand osteotomy technique was followed in 35% of the cases (n = 32) [20]. Patient-specific instrumentation was used in 40% (n = 38) [44], and navigation was used in the remainder of 26% of the patients (n = 25) [16]. A locking plate and screw system was used for all patients. Postoperatively, all patients are allowed to do full weight bearing. Postoperative complications and their management are reported in Table 1.

2.3. Radiological evaluation

All patients had a preoperative radiographic evaluation for the degree of osteoarthritic changes based on the Ahlbäck grade, and Kellgren Lawrence grade (Table 2). All patients had a postoperative radiographic evaluation at 3, 6 and 12 months after their surgery. The patients who would have a delayed union had more radiographic evaluation at the discretion of the doctor. Preoperative and postoperative radiological geometrical parameters were assessed including hip-knee-ankle angle, mechanical lateral distal femoral angle, medial proximal tibial angle and joint line convergence angle. The radiological characteristics and geometrical parameters are demonstrated in Table 3. Additionally, Delta values for the main geometrical parameters were calculated in Table 3; Δ Hip Knee Angle, Δ Joint Line Convergence Angle, Δ Medial Proximal

Table 1
Complications.

	None	Sensory Disturbance	Hematoma	Superficial Infection	Deep Infection	Deep Vein Thrombosis	Sciatic neuropathy	*p* value (* < 0.05)
Syn group (*n* = 44)	41	0	0	1	1	0	1	0.31
Allo group (*n* = 51)	46	1	1	0	2	1	0	

Syn: synthetic graft, Allo: allogenic graft.

Table 2
Patients demographics.

Total (*n* = 95)	Syn group (*n* = 44)	Allo group (*n* = 51)	*p* value (* < 0.05)
Sex (female/male)	5/39	12/39	0.11
Age (years)	51.2 ± 1.4 [47.9–54.6]	51.6 ± 1.3[49.1–54.2]	0.82
Body weight (kg)	81.7 ± 2.1 [77.4–85.9]	84.7 ± 1.9 [80.8–88.6]	0.29
Height (cm)	175.7 ± 0.01 [173.3–178.1]	172.9 ± 0.01 [170.7–175.2]	0.09
Body Mass Index (kg/m^2)	26.3 ± 0.5 [25.1–27.5]	28.2 ± 0.5 [27.2–29.3]	*0.01
Side of Ope (Right/Left)	19/25	28/23	0.25
Follow-up (months)	24.0 ± 1.3 [21.3–26.7]	26.8 ± 1.2 [24.3–29.3]	0.13
Ahlaback Grade (1/2/3)	8/31/5	10/31/10	0.49
Kellgren-Lawrence Grade (1/2/3/4)	3/11/17/13	4/17/25/5	0.10

Syn: synthetic graft, Allo: allogenic graft.

Table 3
Radiographic assessments at pre- and post-operation.

Pre-operation	Syn group (*n* = 44)	Allo group (*n* = 51)	*p* value (* < 0.05)
Hip Knee Angle (°)	173.2 ± 0.4 [172.3–174.2]	174.2 ± 0.4 [173.3–175.1]	0.14
Lateral Distal Femoral Angle (°)	89.9 ± 0.3 [88.2–90.3]	89.2 ± 0.2 [88.6–90.4]	0.43
Medial Proximal Tibia Angle (°)	84.3 ± 0.4 [83.3–85]	84.0 ± 0.4 [84.2–85]	0.44
Joint Line Convergency Angle (°)	2.7 ± 0.3 [2.0–3.3]	2.0 ± 0.2 [1.5–2.6]	0.13
Correction Angle (°)	8.8 ± 0.4 [7.9–9.7]	7.8 ± 0.4 [6.9–8.6]	0.10
Target Medial Proximal Tibia Angle (°)	89.1 ± 1.9 [85.2–92.9]	92.8 ± 1.7 [89.3–96.3]	0.15
Postoperation	**Syn group (*n* = 44)**	**Allo group (*n* = 51)**	***p* value (* < 0.05)**
Hip Knee Angle (°)	181.1 ± 0.4 [180.2–182.0]	181.0 ± 0.4 [180.2–181.9]	0.95
ΔHip Knee Angle (°)	7.8 ± 0.5 [6.8–8.8]	6.8 ± 0.4 [5.8–7.7]	0.15
Medial Proximal Tibia Angle (°)	91.6 ± 0.4 [90.7–92.5]	91.4 ± 0.4 [90.6–92.2]	0.74
ΔMedial Proximal Tibia Angle (°)	3.9 ± 0.4 [3.0–4.8]	3.8 ± 0.4 [3.0–4.6]	0.87
Joint Line Convergency Angle (°)	2.5 ± 0.3 [1.8–3.2]	1.8 ± 0.3 [1.2–2.5]	0.16
ΔJoint Line Convergency Angle (°)	2.4 ± 0.4 [1.6–3.2]	2.3 ± 0.4 [1.4–3.3]	0.95

Syn: Synthetic graft, Allo: Allogenic graft.

Table 4
Analysis of bone union, hinge fracture and weight bearing.

	Syn group (*n* = 44)	Allo group (*n* = 51)	*p* value (* < 0.05)
Time to bone union (weeks)	24.0 ± 1.3 [21.3–26.7]	26.8 ± 1.2 [24.3–29.3]	0.13
Delayed union (Yes/No)	4/40	6/45	0.67
Hinge fracture by Takeuchi grade (0/1/2/3)	37/3/3/1	43/8/0/0	0.04*
Weight Bearing(1 = FWB[a], 2 = PWB 3wk[b], 3 = PWB 6wk[c])	2.7 ± 0.1 [2.4–2.9]	2.3 ± 0.1 [2.1–2.5]	0.01*

Syn: synthetic graft, Allo: allogenic graft.
[a] FWB means that patients were started to do full weight bearing immediately after surgery.
[b] PWB 3wk means that patients started to do full weight bearing from 3 weeks after surgery.
[c] PWB 6wk means that patients started to do full weight bearing from 6 weeks after surgery.

Tibia Angle (Postop–Preop). Bone union confirmed the cortical continuity of medial, lateral and posterior cortex in AP and sagittal view [45] and time to bone union is demonstrated in Table 4. Delayed union confirmed not to unite posterior cortex at 8 months after surgery (Table 4).

2.4. Clinical evaluation

Preoperative and postoperative assessment of flexion range in degrees, and presence of flexion contracture in degrees were noted. Additionally, the preoperative and postoperative Tegner activity scores, and Western Ontario and Macmaster University scores (WOMAC) for stiffness, function as well as global WOMAC scores in Tables 5 and 6. The period during which the patient actually started the full weight bearing after surgery was recorded in three separate sections (FWB, PWB 3 and 6 wk) (Table 4): FWB means that patients were started to do full weight bearing immediately after surgery, and PWB 3 and 6 wk means that patients started to do full weight bearing from 3 and 6 weeks after surgery.

2.5. Statistical analysis

Data that are descriptive statistics are presented as mean ± SD. Statistical analysis was performed with SPSS™ 12.0 (IBM

Table 5
Western Ontario and McMaster Universities Arthritis Index (WOMAC).

Pre-operation	Syn group ($n = 44$)	Allo group ($n = 51$)	p value (* < 0.05)
Pain of WOMAC (0–100)	42.9 ± 3.2 [35.4–49.4]	36.7 ± 2.7 [31.2–42.3]	0.15
Stiffness of WOMAC (0–100)	47.6 ± 3.3 [40.9–54.4]	45.8 ± 3.4 [39.0–52.6]	0.70
Function of WOMAC (0–100)	59.8 ± 2.8 [54.1–65.5]	53.3 ± 2.6 [48.0–58.6]	0.09
Global score of WOMAC (0–100)	50.1 ± 3.1 [43.4–56.4]	45.2 ± 2.9 [39.4–51.1]	0.20
Post-operation	**Syn group ($n = 44$)**	**Allo group ($n = 51$)**	**p value (* < 0.05)**
Pain of WOMAC (0–100)	70.7 ± 3.9 [62.8–78.6]	86.1 ± 3.3 [79.4–92.9]	0.004*
ΔPain of WOMAC	27.8 ± 4.4 [18.9–36.7]	49.3 ± 3.8 [41.7–56.9]	< 0.001*
Stiffness of WOMAC (0–100)	70.6 ± 4.0 [62.5–78.6]	73.5 ± 3.4 [66.6–80.3]	0.58
ΔStiffness of WOMAC	22.6 ± 5.2 [12.2–33.0]	35.7 ± 4.4 [26.9–44.6]	0.05
Function of WOMAC (0–100)	79.3 ± 3.3 [72.7–85.9]	80.0 ± 2.8 [74.4 ± 85.6]	0.87
ΔFunction of WOMAC	19.3 ± 3.4 [12.3–26.2]	26.7 ± 2.9 [20.7–32.6]	0.11
Global score of WOMAC (0–100)	72.5 ± 3.9 [64.7–80.3]	76.8 ± 3.3 [70.1–83.5]	0.40
ΔGlobal score of WOMAC	16.7 ± 3.2 [10.0–23.3]	37.4 ± 4.9 [27.4–47.4]	0.002*

Syn: synthetic graft, Allo: allogenic graft.

Table 6
Tegner Activity Score, Return to Work and Satisfaction.

	Syn group ($n = 44$)	Allo group ($n = 51$)	p value (* < 0.05)
Preoperative Tegner Activity Score (0–10)	4.0 ± 0.2 [3.4–4.5]	3.7 ± 0.2 [3.1–4.2]	0.36
Postoperative Tegner Activity Score (0–10)	4.1 ± 2.0 [3.5–4.8]	3.6 ± 1.4 [3.2–4.0]	0.14
Δ Tegner Activity Score	0.1 ± 0.2 [−0.4–0.6]	−0.1 ± 0.2 [−0.6–0.3]	0.49
Return to work (months)	0.8 ± 0.06 [0.7–0.9]	0.7 ± 0.05 [0.6–0.8]	0.37
Satisfaction (disappointed/unsatisfied/satisfied/very satisfied)	1/4/18/20	1/11/21/17	0.34

Syn: synthetic graft, Allo: allogenic graft.

Corporation, Somers, NY, USA). Student's paired *t*-tests and Fisher tests were planned for intragroup comparison. Two-sample *t*-tests and Fisher tests were planned for intergroup comparisons. Non-parametric tests were used for parameters with non-gaussian distribution. Statistical significance was assumed at p values of < 0.05. A post hoc sample size analysis exhibited that our series allowed the comparison of lower-limb morphological parameters, clinical scores and demographic parameters with a statistical power > 80%.

3. Results

3.1. Patients demographics (Table 2)

Ninety-five patients (44 in Syn group, 51 in Allo group) were enrolled. Patients' demographics were not significantly different except for body mass index (Syn Group: 26.3 ± 0.5, Allo group: 28.2 ± 0.5, p value = 0.01*). Mean ages (years) were 51.2 ± 1.4 in Syn group and 51.6 ± 1.3 in Allo group ($p = 0.82$). Mean follow-up (months) were 24.0 ± 1.3 in Syn group and 26.8 ± 1.2 in Allo group ($p = 0.13$).

3.2. Radiographic assessments at pre- and post-operation (Table 3)

The radiographic assessments at pre- and post-operation were not significantly different. Mean correction angles were 8.8 ± 0.4 in Syn group and 7.8 ± 0.4 in Allo group ($p = 0.10$).

3.3. Clinical outcomes

All of WOMAC score in pre-operation were not significantly different (Table 5). The postoperative improvement of pain and global WOMAC scores in Allo group were significantly better than in Syn group (Table 5) (ΔPain of WOMAC: Syn group 27.8 ± 4.4 [18.9-36.7], Allo group 49.3 ± 3.8 [41.7-56.9], p value <0.001*) (ΔGlobal score of WOMAC: Syn group 16.7 ± 3.2 [10.0-23.3], Allo group 37.4 ± 4.9 [27.4-47.4], p value = 0.002*). The risk of hinge fracture in Syn group was significantly higher than in Allo group (Table 4) (Hinge fracture by Takeuchi grade (0/1/2/3): Syn group 37/3/3/1, Allo group 43/8/0/0, p value = 0.04*). The timing of full weight bearing in Allo group was significantly earlier than in Syn group (Table 4) (Weight Bearing (1 = FWB, 2 = PWB 3wk, 3 = PWB 6wk): Syn group 2.7 ± 0.1 [2.4-2.9], Allo group 2.3 ± 0.1 [2.1-2.5], p value = 0.01*).

3.4. Complications (Table 1)

Complications in both groups were not significantly different. Sciatic neuropathy in the Syn group was caused from anesthesiologic problem. All these complications were solved at final follow-up and did not have any influence on the bone union.

4. Discussion

The most important findings in the presented study are demonstrating better clinical outcomes in Allo group than in Syn group. Allo group showed the better improvement of pain and global WOMAC scores and the lower risk of hinge fracture after MOWHTO than Syn group. The timing of full weight bearing in Allo group was significantly earlier than in Syn group and so postoperative recovery would be better in Allo group.

Different methods to deal with the opening gap in MOWHTO such as autologous bone graft, allogenic graft, synthetic bone substitute and no graft were previously reported [33,46–48]. The development of a locking plate enabled the maintenance of enough stability of the osteotomy, the possibility of early weight-bearing,

and various graft choices [5]. Although autologous bone graft is the most effective graft material for bone union due to its osteoconductive and osteoinductive properties, the donor site morbidity has led to a demand for alternatives [49]. Allogenic and synthetic graft have the advantages of short surgical time and no donor site morbidity and have thus been used more and more in recent years. However, there are controversial results of the union rate after MOWHTO between using synthetic and allogenic graft to fill the gap in MOWHTO. The systematic review of 3033 open wedge osteotomies by Lash et al. indicated that the synthetic bone substitute group resulted in the highest rate of delayed union or non-union (4.5%) [43]. On the other hand, other systematic reviews showed that no clinically significant difference was found for the union rate between groups using allogenic and synthetics graft [41,50]. A meta-analysis by Han et al. investigated the radiological outcomes of medial OWHTO using different graft types (autologous, allogenic and synthetic graft) in 1841 patients and similar non-union and delayed union rates were reported regarding the different graft types [51]. In the current study, the rate of delayed union also did not indicate any difference between Syn and Allo group.

Although some systematic review and meta-analysis reported that there were no significant differences of functional scores, lateral hinge fracture, VAS scores and complication rates between using synthetic, autologous and allogenic graft in OWHTO [40,52,53], the current study showed the better improvement of pain and global WOMAC scores and the lower risk of hinge fracture in Allo group. This is the first study to compare the bone union progression and clinical outcomes in MOWHTO between the use of synthetic and allogenic graft. In terms of allogenic graft, Haghpanah et al. in their randomized controlled study showed that iliac allogenic graft to fill the gap in OWHTO was useful and safe with comparable radiologic union and WOMAC score to iliac crest autologous graft [33]. In terms of synthetic graft, basic science or biomechanical study about stability of synthetic graft in relation to OWHTO has been validated [36,37], but clinical outcomes are lacking. The randomized controlled study by Lind-Hansen et al. investigated the influence of three different bone graft (calcium phosphate cement, local bone autologous graft and iliac crest autologous graft) on stability and clinical outcome in OWHTO, and indicated that calcium phosphate cement had lower quality of life KOOS sub score at 2 years follow-up [42].

Initiation of weight-bearing after OWHTO could possibly depend on the surgical technique, including fixation material, and patient's confidence and conditions [54]. Many contemporary rehabilitation protocols allow partial weight-bearing until 4–6 weeks after OWHTO, with permission of full weight bearing at 6–10 weeks [55,56]. Van et al. reported that applying structural triangular allogenic graft in OWHTO led to early ambulation [32]. The accelerated rehabilitation was demonstrated by the fraction of their patients (50%) able to walk without support or by the use of only one crutch (21% of right and 29% of left, respectively) after 4 weeks [32]. In our study, patients from the Allo group showed significantly earlier full weight bearing after OWHTO than Syn group patients.

There were several limitations to the current study. Firstly, the retrospective nature of this study yielded low statistical power. Secondly, the surgeries in the current study were conducted in multiple centers. So, various synthetic and allogenic graft, and various plates and techniques were included. All above the things have created some heterogeneity in our postoperative analysis and thus decrease the clinical significance of our results. Thirdly, the follow up period was only around 2 years. Therefore, long-term clinical results are unknown. Fourthly, we did not exclude the patients requiring small amount of correction in whom the gap would probably heal even when no grafts used. Several studies suggested that bone grafts are less recommended if the opening gap is less than 10 mm [23,57]. Santic et al. reported that within 12 weeks, cancellous bone allogenic grafts $\leq$ 9 mm healed in 90% of cases, while 10 mm bone allografts healed in 47% and 11–16 mm allograft healed only in 6% [57]. In the current study, the means of correction angle were around 8 degrees in both groups. So, correction angle may have potentially had bigger influence on bone union than the type of bone graft. Fifthly, smoking history was not included in the current study. Several reports have shown that smoking history has had a negative effect on bone union in high tibial osteotomy [58,59]. It may be potentially occurred that smoking history had an influence on the results of this study. Finally, a hinge fracture could be related to both of procedures during surgery and a postoperative mechanical stress (ex: an early weight bearing, a wrong position of plate and screws etc.). It would be difficult to define the causes of a hinge fracture in this current study.

Based on these results, the use of allogenic graft can be recommended except in cases where autograft is recommended, such as large corrections, heavy smokers and excessive BMI. It seems that allogenic graft has enough efficacy to promote bone healing of the osteotomy site, reduce pain and allow faster rehabilitation, thus eliminating the need for autograft harvest.

5. Conclusion

The use of allogenic graft to fill the void in MOWHTO does not show a superiority in bone union compared to synthetic graft, however it does show a better improvement in pain and allows faster weight bearing than synthetic graft.

Disclosure of interest

Matthieu Ollivier, Jean-Marie Frayard: Newclip consultant.

Matthieu Ollivier: education consultant and royalties from Stryker.

The authors (Jae-Sung An, Nicolas Bouguennec, Cécile Batailler, Nicolas Tardy, Goulven Rochcongar) have not supplied their declaration of competing interest.

Funding

The symposium was partially funded by the SFA (Société Francophone d'Arthroscopie).

Author contribution

All authors participate in the SFA symposium article.

AI statement

No artificial intelligence was used for the writing of the submitted work.

Ethical approval

CCPPRB review board (no. ID-RCB 2018-A01353-52).

Informed consent

N/A.

Authors' contributions

JA, MO drafted the manuscript and completed the necessary revisions.

JMF GR edited the paper extensively.

JMF GR CB NT NB created initial dataset.
All the authors have reviewed and edited the manuscript.

Acknowledgements

N/A.

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