Autograft versus sterilized allograft for lateral calcaneal lengthening osteotomies

Comparison of 50 patients

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Abstract
Sterilized allografts may be less resistant to collapse and prone to nonunion leading to loss of correction in open wedge osteotomies. These adverse events usually occur at early time points (i.e., < 9 months postoperatively). The goal of this study was to compare sterilized allografts to autologous grafts in respect to secondary loss of hindfoot alignment and graft incorporation after lateral calcaneal lengthening osteotomies.

Fifty patients (22F/28M, age: 16–69 years) who had undergone 50 lateral calcaneal lengthening osteotomies for adult flatfoot deformity were included in this retrospective study. Cortical sterilized allografts were used in 25 patients, autologous grafts in the remaining 25. Patients’ preoperative, 6 and 12 weeks, and 6 to 9 months follow-up weight-bearing radiographs of the affected foot were analyzed by 2 blinded radiologists: on each radiograph, graft incorporation, the talo-first metatarsal angle (TFMA), the talonavicular coverage angle (TNCA), and the calcaneal pitch angle (CPA) were assessed. Loss of hindfoot alignment was defined as an increase of the TFMA or the TNCA or a decrease of the CPA, each by 5°.

Inter- and intraclass correlation coefficients for TFMA, TNCA, and CPA measurements ranged from 0.93 to 0.99. At all follow-up visits, the ratio of patients with loss of hindfoot alignment and graft incorporation was not significantly different between the allograft and autograft group. However, loss of correction was associated with failure of graft incorporation.

Compared with autografts, sterilized allografts do not increase the risk for loss of hindfoot alignment in lateral column lengthening of the calcaneus. With respect to mechanical resistance, allografts thus mean an equal and valid alternative without risk of donor site morbidities.

Abbreviations: BMI = body mass index, CI = confidence interval, CPA = calcaneal pitch angle, DP = dorso-plantar, FU = follow up, ICC = intraclass correlation coefficients, TFMA = talo-first metatarsal angle, TNCA = talo-navicular coverage angle.

Keywords: allograft, autograft, calcaneus, lateral column lengthening, loss of hindfoot alignment

1. Introduction
Lateral calcaneal lengthening is commonly performed to correct hindfoot malalignment in adult and pediatric flatfoot deformity resulting from stage II tibial tendon insufficiency.[1–3] In this procedure, a structural bone graft is placed into an open wedge osteotomy within the anterior calcaneal process. Autologous cortical bone grafts may be considered the preferred graft type for this procedure: They incorporate quickly due to favorable osteoinductivity and osteoconductivity.[6–9] Moreover, they show remarkable biomechanical resistance.[10] All these characteristics may prevent graft collapse and nonunion with subsequent loss of correction. Nonetheless, the use of autologous graft is associated with donor site morbidity and increased operating time.[11–14] Sterilized allografts can be used as an alternative to autologous grafts. Ethylendioxide irrigation[15] or gamma irradiation[16] is commonly applied as a final step of the sterilization process. However, these processes may affect the mechanical strength[17–19] and the osteoconductive properties of these grafts.[20] Yet, to date, it is unclear whether the use of sterilized allografts in adult lateral calcaneal lengthening osteotomies gives rise to graft collapse and/or nonunion and thus recurrence of flatfoot deformity. Previous studies[3,6,21] were either performed in pediatric patient populations and/or showed major limitations due to small sample sizes, multiple confounders, and most importantly due to late (>12 months) follow-up evaluations.[22] Graft-specific loss of flatfoot correction is rather observed in the early postoperative period, that is, from the onset of full weight bearing to a time point where the graft is integrated, but not fully replaced by local bone. This time period usually spans from 6 weeks to 6 months postoperatively.[23] Any loss of hindfoot correction beyond this time period may rather result from continued tendon and ligament degeneration than from graft collapse.
Here, we aimed to compare sterilized allografts with autologous grafts in lateral calcaneal lengthening osteotomies in respect to (i) early radiographic loss of hindfoot alignment and (ii) rates of nonunion. We hypothesized that the use of sterilized allografts is associated with an increased risk of graft collapse and nonunion.

2. Patients and methods

2.1. Study design

This study was designed as a retrospective comparative study; Level of evidence: III.

2.2. Patient demographics

This retrospective cohort study included 50 patients (50 ankles). All surgical procedures were performed between January 2006 and December 2011 at the University Hospital of Basel, Switzerland. Only patients with unilateral osteotomies and without any additional hind- and/or midfoot osteotomies and/or arthrodesis were included. The study was conducted in accordance with the Declaration of Helsinki and the Guidelines on Good Clinical Practice. The study protocol was approved by the local Ethics Committee (106/11; March 7, 2011). Prior to surgery, all participants provided written informed consent to have their data used for clinical studies. The preoperative diagnosis was acquired based on preoperative dorso-plantar (DP) and lateral weight-bearing radiographs. The lateral calcaneus lengthening procedure was planned on the basis of preoperative DP and lateral weight-bearing radiographs of the affected foot and performed as described elsewhere. A 4 cm skin incision was made from the tip of the fibula to the base of the fifth metatarsal. The peroneal tendons were dissected and retracted to expose the lateral side of the anterior process of the calcaneus. The sinus tarsi fat pad was dissected and lifted cranially. Using an oscillating saw, an osteotomy was made at the base of the anterior calcaneal process. The osteotomy was then distracted using a lamina spreader until any forefoot abduction was fully reduced and the talus head was completely covered by the navicular bone as assessed under fluoroscopic control. The length and width of the osteotomy gap was measured. Either an autologous bone graft harvested from the iliac crest or an acellular allograft (Tutoplast; Tutogen Medical GmbH, Neunkirchen am Brand, Germany) was shaped to fully fill in the osteotomy gap and impacted into the osteotomy. The graft was secured using a 3.5 cortical screw, from distal to proximal through the osteotomy in a lateral medial and cranio-caudal direction.

Additional surgical procedures such as ankle ligament reconstructions, posterior tibial tendon transfers, and hallux valgus corrections were then performed without any adaptations.

2.3. Operative technique

The lateral calcaneus lengthening procedure was planned on the basis of preoperative dorso-plantar (DP) and lateral weight-bearing radiographs of the affected foot and performed as described elsewhere. A 4 cm skin incision was made from the tip of the fibula to the base of the fifth metatarsal. The peroneal tendons were dissected and retracted to expose the lateral side of the anterior process of the calcaneus. The sinus tarsi fat pad was dissected and lifted cranially. Using an oscillating saw, an osteotomy was made at the base of the anterior calcaneal process. The osteotomy was then distracted using a lamina spreader until any forefoot abduction was fully reduced and the talus head was completely covered by the navicular bone as assessed under fluoroscopic control. The length and width of the osteotomy gap was measured. Either an autologous bone graft harvested from the iliac crest or an acellular allograft (Tutoplast; Tutogen Medical GmbH, Neunkirchen am Brand, Germany) was shaped to fully fill in the osteotomy gap and impacted into the osteotomy. The graft was secured using a 3.5 cortical screw, from distal to proximal through the osteotomy in a lateral medial and cranio-caudal direction.

Additional surgical procedures such as ankle ligament reconstructions, posterior tibial tendon transfers, and hallux valgus corrections were then performed without any adaptations.

2.4. Postoperative management

After complete wound healing, patients were discharged from the hospital wearing a below-knee, removable, fixed ankle walker boot with weight-bearing restriction to 15 kg for 6 weeks postoperatively. Patients were followed up at 6 (follow-up 1 = FU1), 12 weeks (follow-up 2 = FU2), and 6 to 9 months (follow-up 3 = FU3) postoperatively. At each FU visit, the presence of wound healing and any signs of infection at the osteotomy site were evaluated. In addition, weight-bearing DP and lateral radiographs of the foot were taken to assess bone healing (=bridging trabeculation across the osteotomy gap) and the correction of the flatfoot deformity as described below. As soon as bone healing was evident, patients were permitted to bear weight as tolerated.

2.5. Follow-up assessment

2.5.1. Clinical follow-up. The records of the follow-up consultations were reviewed for time until full weight-bearing permission and appearance of complications, particularly surgical site infection as defined by Mangram et al.[24] with possible revision surgery or treatment with antibiotic alone.

2.5.2. Radiographic follow-up. For each patient, weight-bearing DP and lateral radiographs taken preoperatively and at 6 and 12 weeks as well as 6 to 9 months postoperatively were retrieved. Digital radiographs were exported to Matlab (Mathworks, version 13) and analyzed by 2 blinded board-certified radiologists. On each radiograph, the talo-first metatarsal angle (TFMA), the talo-navicular coverage angle (TNCA), and the calcaneal pitch angle (CPA) were measured as follows: the TFMA corresponded to the angle between the longitudinal axis (midline) of the talus and the first metatarsal bone on a lateral full weight-bearing radiograph of the foot. The TNCA was defined by a line connecting the edges of the articular surface of the talar head and another line connecting the edges of the articular surface of the navicular on the DP weight-bearing radiograph. The CPA was measured between 2 lines both originating at the most plantar surface of the calcaneus and connecting the inferior border of the calcaneal-cuboid joint and the plantar aspect of the fifth metatarsal, respectively (Fig. 1).

All measurements were performed using Matlab. Radiologists had to digitally mark the above-mentioned anatomical landmarks. The corresponding angles were automatically projected, calculated, and exported to Microsoft Excel by the software. In addition to joint angle measurements, radiologists had to assess the presence of graft integration as evidenced by bridging trabecular lines through the osteotomy gap on both the DP and lateral view.

Any disagreement between the 2 radiologists regarding the designation of an anatomical landmark was solved by consensus. To determine the inter- and intraobserver reliability of the digital angle determination used in this study, 22 DP and lateral weight-bearing feet radiographs were randomly selected and analyzed twice by each radiologist in a blinded and independent manner with a time span of at least 7 days between the 2 readings.

2.6. Statistical analysis

A Kolmogorov–Smirnov test was performed to verify whether the data were normally distributed. Independent-samples t test and Mann–Whitney rank sum test were used for comparison of continuous data with normal and not normal distribution, respectively. Fisher exact test was used for comparison of 2 unmatched categorical data. The intraclass correlation coefficients (ICC) and their 95% confidence intervals (CI) were used to summarize the inter- and intraobserver reliability of measurement of continuous data. The kappa statistics was used as the chance-corrected measurement of agreement in measurement of categorical data. The reliability values were interpreted according to the definitions of Landis and Koch.[25]
Initial correction was compared across groups using t tests for the 3 endpoints TNFA, TNCA, and CPA. Loss of correction was assessed by regressing the change in correction on graft type and time. We included patient age and the amount of initial correction as potential confounders. Since changes in angles were potentially two-directional (increase or decrease), all angles were assessed using the root of mean sum of squares to account for negative or positive signs.

An univariate Cox regression test was performed to identify risk factors associated with an increased incidence of loss of hindfoot valgus correction over time, that is, a decrease of ≥5° of the TFMA or CPA or an increase of ≥5° of the TNCA between the 6 weeks and subsequent follow-up visits. A post hoc power calculation for loss of correction ≥5° within FU1 and FU2 follow-up visits was performed. The power to detect significant differences between the allograft and autograft group was 99.9% for TFMA, 69.0% for TNCA, and 43.1% for CPA. An univariate Cox regression test was also performed to identify risk factors with an increased incidence of osseous nonunion observed at last follow-up. Evaluated risk factors included age ≥50 years, gender, body mass index (BMI) between 25 and 30 kg/m², type of graft, diabetes, former and current tobacco use.

Factors associated with an increased incidence were considered for inclusion in a logistic multiple-regression model with stepwise forward and backward variable selection. Those statistically significant (P ≤ 0.05) factors that remained in the model were considered to be independent predictors. The calibration of the model was assessed by comparing the observed and expected risk outcome using a Hosmer-Lemeshow goodness-of-fit test.[26]

3. Results

3.1. Clinical follow-up

3.1.1. Time to full weight bearing. Patient started full weight bearing at average 8 (±3.5) weeks in the allograft group and at average 7 (±2) weeks in the autograft group. In 47 of the

| Table 1 | Patient demographics and clinical data. |
|---------|----------------------------------------|
| Parameter | All patients | Allograft | Autograft | P value |
| Number of patients (ankles) | 50 (50) | 25 (25) | 25 (25) | — |
| Mean age (range) (y) | 46.2 (16.1–69.3) | 48.7 (16.1–69.3) | 43.8 (21.0–63.9) | 0.14* |
| Gender ♂:♀ | 28:22 | 14:11 | 14:11 | 0.69† |
| Side right:left (ankles) | 21:29 | 11:14 | 10:15 | 0.24† |
| Mean BMI (range) (kg/m²) | 25.4 (16.7–39.4) | 23.9 (16.7–32.0) | 26.8 (19.5–39.4) | 0.03‡ |
| Diabetes yes:no | 4:46 | 1:24 | 3:22 | — |
| Tobacco use yes:no | 14:36 | 10:15 | 4:21 | 0.13† |
| Current tobacco use yes:no | 11:39 | 8:17 | 3:22 | 0.53† |

BMI = body mass index.
* Using Mann–Whitney rank sum test.
† Using Fisher exact test.
‡ Using Student t test.
included 50 cases, patients started full weight bearing between FU1 and FU2. In 3 cases (1/25 in the allograft group and 2/25 in the autograft group), full weight bearing was initiated at FU2. Patient demographics are summarized in Table 1.

### 3.1.2. Postoperative complications.
There was 1 superficial infection at the calcaneal osteotony in the autograft group, which healed after the administration of oral antibiotics. Two cases in the autograft group showed clinical signs of reflex sympathetic dystrophy syndrome at 6 weeks postoperatively which entirely resolved after the nasal administration of calcitonin for 4 weeks.

### 3.2. Radiographic follow-up

#### 3.2.1. Intra- and interobserver reliability of hindfoot angle measurements.
The intra- and interobserver reliability for all measurements was perfect according to the benchmark definitions of Landis and Koch [25] (Tables 2 and 3).

#### 3.2.2. Hindfoot alignment.
Table 4 lists the TFMA, TNCA, and CPA, which were measured in the allograft and autograft group preoperatively and at all follow-up time points. At all time points, there was no significant difference between the groups. A change of ≥5° of the TFMA, TNCA, or CPA was defined as substantial (Table 5). In univariate analysis, age, gender, and tobacco use were not independent risk factors for a radiographic change of the TFMA, TNCA, or CPA ≥5°.

#### 3.2.3. Nonunion.
At final follow-up, there were 5 nonunions in the autograft group and 1 nonunion in the allograft group, as judged by the blinded radiologists. However, in only 1 case (allograft group) the absence of union was clinically symptomatic beyond FU2 and prompted clinicians to defer weight bearing beyond this time point. Patient demographics, clinical data, and radiographic findings in both groups—with respect to osseous consolidation and nonunion—are shown in Tables 6 and 7. The regression model showed that changes of ≥5° in talo-first metatarsal angle and in talo-navicular coverage angle at FU3 were independently associated with an increased risk of osseous consolidation.

### Table 2
Intraobserver reliability (intraclass correlation coefficient; ICC—95% confidence interval: 95% CI).

| Parameter       | ICC   | ICC 95% CI | Kappa value | P value |
|-----------------|-------|------------|-------------|---------|
| TFMA            | >0.99 | >0.99–>0.99| —           | <0.001  |
| TNCA            | >0.99 | >0.99–>0.99| —           | <0.001  |
| CPA             | >0.99 | >0.99–>0.99| —           | <0.001  |
| Union           | —     | —          | 0.81        | <0.001  |
| Screw breakage  | —     | —          | 1.0         | <0.001  |

Cl = confidence interval, CPA = calcaneal pitch angle, TFMA = tali-first metatarsal angle, TNCA = talo-navicular coverage angle.

### Table 3
Interobserver reliability (intraclass correlation coefficient; ICC—95% confidence interval: 95% CI).

| Parameter       | ICC   | ICC 95% CI | Kappa value | P value |
|-----------------|-------|------------|-------------|---------|
| TFMA            | 0.97  | 0.93–0.99  | —           | <0.001  |
| TNCA            | 0.97  | 0.93–0.99  | —           | <0.001  |
| CPA             | 0.99  | 0.96–>0.99 | —           | <0.001  |
| Union           | —     | —          | 0.83        | <0.001  |
| Screw breakage  | —     | —          | 1.0         | <0.001  |

### Table 4
Radiographic findings.

| Parameter       | Preoperative values | 1st follow-up | 2nd follow-up | 3rd follow-up |
|-----------------|---------------------|---------------|---------------|---------------|
| TFMA (°)        | 20.0 (–9.8 to 16.4) | –4.8 (–20.2 to 14.8) | 25.0 (15.2–32.7) | 30.2 (20.7–49.9) |
| TNCA (°)        | 8.6 (–24.6 to 31.7) | –0.3 (–30.9 to 25.0) | 14.2 (11.7–18.9) | 2.3 (–23.4 to 16.2) |
| CPA (°)         | 16.4 (–25.8 to 28.7) | 14.8 (–25.8 to 26.7) | 25.2 (16.0–31.9) | 20.9 (–27.2 to 30.0) |

### Table 5
Change of radiologic parameters at the 2nd and 3rd follow-ups.

| Parameter       | Change ≥5° | Change <5° |
|-----------------|------------|------------|
| TFMA            | n = 14 (28%) | n = 36 (72%) |
| TNCA            | n = 25 (50%) | n = 25 (50%) |
| CPA             | n = 7 (14%) | n = 43 (86%) |

3rd follow-up (mean 30.2 (SD 5.7) wk, range: 20.7–49.9 wk)

TFMA  n = 6 (12%)  n = 44 (88%)

TNCA  n = 10 (20%)  n = 40 (80%)

CPA  n = 1 (2%)  n = 49 (88%)

* Using Mann–Whitney rank sum test.
† Using Student’s t-test.
The goal of this study was to compare acellular allografts to autografts in respect to early loss of hindfoot alignment after lateral calcaneal lengthening osteotomies as assessed on consecutive weight-bearing radiographs. The analysis was restricted from 6 weeks up to 9 months after surgery, a time span in which the graft is continuously invaded, however not fully replaced by surrounding bone\(^27,28\) and at the same time exposed to mechanical loads (i.e., weight bearing). Animal studies have suggested that the biomechanical competence of autologous and autogenous bone transplants substantially decreases at 6 to 8 weeks,\(^10,29\) and then rises to 70% of that of intact bone at 4 months\(^29\) and to 100% at 6 to 12 months postoperatively.\(^10,28,30\) Therefore, loss of hindfoot alignment in the early postoperative period may be strongly related to graft collapse, rather than to secondary degeneration of supporting tendons and ligaments.

The results of our study suggest no significant difference between autograft and allograft mediated adult lateral column lengthening osteotomies in respect to early loss of radiographic hindfoot alignment. There was 99% power to detect differences regarding the loss of TFMA $\geq 5^\circ$ between FU1 and FU2. Previous studies have shown strongest correlation between the TFMA and plantar pressure distributions under dynamic loads as compared with other radiographic hindfoot measures.\(^4,11\) As outlined above, the transplanted grafts may also be most susceptible to collapse between FU1 and FU2.\(^11,10\) Therefore, our study may have been sufficiently powered to detect any clinically relevant and significant hindfoot collapse related to type of the implanted graft.

The biomechanical equivalence of both graft types observed in this study is contradictory to basic science studies, which have suggested inferior mechanical resistance of sterilized allografts as compared with autografts as a result of sterilization procedures\(^20,32\) and led to the hypothesis of this study. On the other hand, our results corroborate the findings by Kwak et al\(^8\) which did not detect any difference in loss of hindfoot alignment between structural autografts and allografts in Evans osteotomies. In contrast to our investigation, this study was performed in a pediatric patient population and based their analysis on radiographs taken at late time points (13–31 months).

Our analysis did also not show any difference regarding graft incorporation between the allograft and autograft group which corroborates the findings of a recent systematic review.\(^22\) However, the rate of union at 12 weeks was lower in both the allograft and autograft group than in previous reports: There was even absence of complete radiographic union in 5 patients in the autograft and 1 patient in the allograft group at final follow-up. In contrast, Dolan et al\(^33\) reported full graft incorporation at 12 weeks for both allograft and autograft-mediated adult lateral column lengthening procedures. Yet, in this study, union was not only defined radiographically, but also clinically as absence of pain upon full weight bearing. In our study, clinicians deferred weight bearing in only 1 patient after FU2, which highlights that most radiographic nonunions were asymptomatic. The clinical relevance of radiographic nonunion may therefore be questionable.

However, a loss of equal to or more than 5 degrees of the TFMA and/or the TNCA was an independent predictor of nonunion. For bony healing, the graft needs to be incorporated and subsequently remodeled by the host.\(^27\) In the absence of graft remodeling by viable cells, the graft will be subjected to fatigue failure under repetitive loading. This may result in graft collapse and consecutive loss of hindfoot alignment.

We observed high inter- and intraobserver reliabilities for all hindfoot angle measurements which were generally consistent with previous reports\(^34\) although we noted slightly higher inter- and intraclass correlation coefficients for the measurements of the TFMA. In the study by Sensiba et al\(^34\) TFMA measurements showed an intra- and interclass correlation coefficient of 0.78 and 0.83 respectively, as opposed to $>0.99$ and 0.97 in our study. In our study a semiautomated algorithm to measure hindfoot angles was used to improve the reliability of our measurements. Prior to our study, radiologists were also trained extensively in the recognition of relevant anatomical landmarks and use of the software, which might have also improved precision of our measurements.

We acknowledge some limitations of our study. The retrospective, nonrandomized study design may introduce several biases. Nonetheless, both groups were balanced for comorbidities that affect bone healing (Table 1) and for any additional procedure that may influence hindfoot alignment. Radiographic assessments of hindfoot alignment and nonunion were also not correlated with clinical outcome measurements. While radiographic and clinical outcomes may not be the same, significant correlations were found between the TFMA and the arch index, the ratio of the midfoot which is dynamically loaded in gait in proportion to the total foot length.\(^5\) All hindfoot angles used in this study have also shown significant correlations with static

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**Table 6**

| Parameter         | OR (95% CI) | P value |
|-------------------|-------------|---------|
| Age $\geq 50$ y   | 0.48 (0.05–4.8) | 0.53    |
| Age $\geq 60$ y   | 1.33 (0.07–2.4) | 0.85    |
| Male gender       | 1.67 (0.28–10.06) | 0.58    |
| BMI $\geq 25$ kg/m$^2$ | 0.32 (0.03–3.17) | 0.33    |
| BMI $\geq 30$ kg/m$^2$ | 3.40 (0.18–64.68) | 0.42    |
| Allograft use     | 6.00 (0.65–55.67) | 0.12    |
| Diabetes          | —           | —       |
| Tobacco use       | 3.50 (0.26–48.03) | 0.35    |
| Current tobacco use | 0.20 (0.01–4.72) | 0.32    |
| Change $\geq 5^\circ$ at FU2 | — | —       |
| TFMA              | 10.57 (0.89–126.74) | 0.06    |
| TNCA              | 0.13 (0.01–1.56) | 0.11    |
| CPA               | —           | —       |
| Change $\geq 5^\circ$ at FU3 | 5.90 (0.63–55.27) | 0.1    |
| TFMA              | 6.92 (0.85–56.30) | 0.07    |
| TNCA              | —           | —       |
| CPA               | —           | —       |

**Table 7**

| Parameter | OR (95% CI) | P value |
|-----------|-------------|---------|
| Change $\geq 5^\circ$ at FU3 | 5.95 (0.63–56.03) | 0.05    |
| TFMA      | 7.06 (0.87–57.55) | 0.049   |
| TNCA      | —           | —       |
| CPA       | —           | —       |
measurements of hindfoot alignment used in clinical examina-
tions[1–3] and with clinical rating systems of clubfoot surgery.[4–5]
Nevertheless, the primary goal of this study was to compare the
biomechanical resistance of sterilized allografts to that
of autografts upon exposure to significant loads in human
subjects and not to specifically study clinical outcomes.
In conclusion, this retrospective study demonstrated that
sterilized allografts do not increase the risk for loss of hindfoot
alignment after lateral calcaneal lengthening osteotomies. Thus,
allografts represent a valid alternative for lateral calcaneal
lengthening osteotomies without the disadvantages of donor site
morbidty due to harvesting of the autograft. Loss of hindfoot
alignment of equal to or more than 5 degrees of the TFMA and/or
the TNCA at 6 months may indicate nonunion of transplanted
bone grafts. More studies, preferably prospective randomized
control trials are desired to prove the suitability of allografts
for other osteotomies of the lower extremities.

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