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Research Paper

A quantitative CT analysis of fibula inlayed in a massive allograft for femoral diaphysis reconstruction

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HIGHLIGHTS

- In diaphyseal reconstructions for bone tumor resection, massive bone allografts (MBA) the gold standard.
- However, they present an elevated risk of infection, nonunion and structural failure.
- A viable fibula enhances incorporation of the allograft and decreases the risk for both structural failure and infection.
- Consecutive CT scans proved to be a reliable method for assessing fibular vitality.

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ABSTRACT

Introduction: In diaphyseal reconstructions for bone tumor resection, massive bone allografts (MBA) are historically regarded as the gold standard. However, these are not without complications, and they present an elevated risk of infection, nonunion and structural failure that increases over time as the graft remains largely avascular. To counteract this disadvantage, a combination of allograft with a vascularized fibula has been proposed. The aim of our study was to objectively review the results of combined vascularized fibula-allograft constructs compared to plain allograft reconstruction for bone defects in tumor patients and to assess fibular vitality predictive factors from imaging studies.

Materials and methods: Our data was retrospectively reviewed for patients with femoral diaphysis reconstructions in the past ten years. Ten patients (six males and four females) with a mean average follow-up time of 43.80 months (range 20–83, SD 18.17) with combined graft (Group A) were included in the study. As a control group 11 patients (six males and five females) with a mean average follow-up of 56.91 months (range 7–118, SD 41.33) with a simple allograft reconstruction were analyzed (Group B). Demographic and surgical data, adjuvant therapy as well as complications were analyzed in both groups. Both groups were assessed with plain radiographs for bony fusion at the osteotomy sites. Patients in "Group A" had consecutive CT scans at 6 months and then annually to check for potential bone stock and bone density changes. We analyzed total bone density as well as incremental changes in three different areas of the reconstruction. This was done at two defined levels for each patient. Only patients with at least two consecutive CT scans were included in the study.

Results: There were no statistical differences between the groups in terms of demographics, diagnosis or adjuvant therapy ($p = 1.0$). The mean average surgical time (599.44 vs 229.09) and mean average blood loss (1855.56 ml vs. 804.55 ml) were significantly higher in the combined graft group A ($p < 0.001$ and $p = 0.01$, respectively). The mean average length of resection (19.95 cm vs. 15.50 cm) was higher in the combined graft group ($p = 0.04$). The risk for non-union and infectious complication was higher in the allograft group, however, the difference was not significant ($p = 0.09$ and $p = 0.66$, respectively). The mean average time to union at junction sites was 4.71 months (range 2.5–6.0, SD 1.19) for cases of successful fibula transfer, 19.50 months (range 5.5–29.5, SD 12.49) for the three cases where we presumed the fibula was not viable and 18.85 months (range 9–60, SD 11.99) for the allograft group. The difference in healing time was statistically significant ($p = 0.009$). There were four cases of non-union in the allograft group.

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Seven out of ten patients in Group A exhibited incremental changes in all CT scan measured values. This difference was statistically significant already at 18 months from the index surgery ($p = 0.008$). The patients with a non-viable fibula had a smaller increase in the percentage of total bone density area measured in the CT scan compared to those patients with a successful fibula transfer (4.33, SD 2.52 vs. 52.29, SD 22.74, $p = 0.008$). The average bone density incremental increase in-between the fibula and allograft was different among patients with an unsuccessful fibula transfer (32.22, SD 10.41) and the ones with a viable fibula (288.00, SD123.74, $p = 0.009$). Bony bridges were observed in six cases of viable fibula and in none of the tree presumably dead fibulas ($p = 0.03$). The mean average MSTS score was higher for the subgroup of successful fibular transfer (26.7/30, SD 2.87) when compared to the group of non-viable fibular graft (17.00/30, SD 6.08) and this was also statistically significant ($p = 0–007$).

Conclusion: A viable fibula enhances incorporation of the allograft and decreases the risk for both structural failure as well as infectious complications. Viable fibula also contributes to better functional status of the recipient. Consecutive CT scans proved to be a reliable method for assessing fibular vitality. When no measurable changes are present at 18-month follow-up, we can declare the transfer unsuccessful with a good amount of certainty. These reconstructions behave as simple allograft reconstructions with analogue risk factors. The presence of either axial bridges between the fibula and allograft or newly formed bone on the inner surface of the allograft is indicative of a successful fibular transfer. The success rate of fibular transfer in our study was only 70% and skeletally mature and taller patients seem to be at increased risk for failure. The longer surgical times and donor site morbidity therefore warrant stricter indications for this procedure.

1. Introduction

Primary bone tumors are rare compared to other malignancies; however, they are the third most frequently occurring oncologic diagnosis in the population aged between 10 and 24 years [1]. Given the current interdisciplinary approach, the 10-year survival rate for localized disease is close to 70% and limb-salvage techniques are performed in 90% of the cases [2]. Since the introduction of limb salvage surgery at the end of 20th century, this is the first generation of oncological orthopedists who can critically review the long-term survivors in regard to the quality of the reconstructions [3]. The main goal being a durable reconstruction alternative, that would allow patients a close to normal function and quality of life.

In periarticular locations, the most frequent reconstruction option is the megaprosthesis. In diaphyseal reconstructions, however, metallic implants are not that prevalent due to the risk of loosening and mechanical failure [4–6]. Reinforced acrylic cement spacers have a low risk of infection but are a rather temporary solution not suitable for young active patients [7,8]. Massive bone allografts (MBA) are historically regarded as the gold standard. However, they present risk of infection as well as nonunion and structural failure that increases over time as the graft remains largely avascular [9–11]. To counteract this disadvantage, a combination of allograft with a vascularized fibula has been proposed [12,13]. The vascularized fibula has the biologic potential for remodeling and the capability to actively react to mechanical stresses. Therefore, the fibula strengthens the reconstruction over time, where the allograft provides the initial strength and protection to the fibula in the early stages. This allows the patient to resume early full weight-bearing and rehabilitation without the risk of reconstruction failure [14]. The fibula also induces osteo-integration of the allograft to the native remaining bone, decreasing the rate of non-union [15–17]. The vascularized fibula enhanced allograft technique, however, can be time consuming and skill demanding, which hinders its aspirations to become the main reconstruction choice for many surgeons. Furthermore, dispute exists over whether the additional surgical time and potential risks are truly translated to measurably better long-term outcomes [18].

For the success of this technique, the vitality of the fibula after the transfer is paramount. The survivorship of the fibula allows for predictions on the future of the construction and will also dictate the management recommendations of any potential complications. The alive fibula can promote spontaneous healing of a fractured reconstruction without the need of a surgical intervention [16]. Therefore, accurate information regarding fibular vitality is critical for future management and recommendations.

Assessing the fibular vitality using the SPECT/CT imaging modality is oftentimes neither practical nor reliable [17]. In 2004 Manfrini et al. described structural changes observed on consecutive CT-scans of patients with a vascularized fibula-allograft construct [19]. The author describes three different patterns of remodeling, where two of these are associated with allograft fracture. In the case of a non-fractured allograft, the density and diameter changes of the fibula, assessed subjectively and visible four to seven years after the surgery, were used as a proxy to predict the success of the construct.

The aim of our study was to objectively review the results of combined vascularized fibula-allograft constructs compared to plain allograft reconstruction for bone defects in tumor patients. Moreover, potential fibular vitality predictive factors from imaging studies were assessed.

Our study objectives were to offer answers for these questions:

1) Does the addition of a vascularized fibula decrease the risk of nonunion and increase incorporation of the allograft at the osteotomy sites? Is there a clinical benefit?
2) How do the complication rates of these two methods compare?
3) Can we reliably assess fibular vitality based on early follow-up consecutive CT scans?
4) What is the success rate of combined graft reconstruction and are there any risk factors for failure?

2. Materials and methods

Our data was retrospectively reviewed for patients with femoral diaphysis reconstructions in the last ten years. A total of 46 patients were identified; 14 patients had a simple allograft reconstruction, 15 patients had a combined graft reconstruction, 5 patients had a prosthetic intercalary spacer, 5 patients had a simple cement spacer reconstruction, 4 patients had variable forms of reconstruction (e.g., non-vascularized fibula combined with autologous spongioplasty), and 3 patients had a solitary fibular reconstruction with vascular anastomosis and dual osteosynthesis (plate and nail).

We included only patients with either combined graft or simple massive allograft reconstruction. For patients with combined graft, only those with at least two consecutive CT scans of the reconstruction were included for analysis. Patients with simple allograft reconstruction were assessed as the control group. Exclusion criteria were lack of adherence to the protocol (e.g.: missing CT scans and radiographs) or incomplete data for analysis.

Demographic data (age at the time of surgery, gender, height, diagnosis, tumor staging according to Enneking criteria, surgical time, estimated blood loss, length of reconstruction, surgical team, surgery

indication (primary reconstruction vs. revision surgery) and adjuvant therapy (chemotherapy, external radiation) were recorded and analyzed. All complications were documented, including the donor site morbidity in the combined graft group. Revision surgeries including simple supplementary bone grafting of the osteotomy sites were recorded. Failure of the reconstruction was defined as removal of the reconstruction or amputation.

After exclusion criteria ten patients with combined graft (Group A) and eleven patients with simple allograft (Group B) were included in the study. In the "Group A" there were six males and four females with mean average age at the time of surgery of 25.20 years (range 11–52, SD 13.63). The mean average follow-up time was 43.80 months (range 20–83, SD 18.17). Four patients had a diagnosis of high-grade osteosarcoma, three patients had a diagnosis of Ewing's sarcoma, and three patients had a chondrosarcoma. Seven patients had a localized disease (IIA and IIB according to Enneking's classification) and three patients had known oligo-metastatic disease of the lungs (stage III). Seven patients received chemotherapy, two of them received also adjuvant external radiation therapy. Three patients with chondrosarcoma had no adjuvant therapy.

In the "Group B" there were six males and five females of average age at the time of surgery 33.82 years (range 12–66, SD 20.88). The mean average follow-up was 56.91 months (range 7–118, SD 41.33). Five patients had a diagnosis of high-grade osteosarcoma, two patients had a diagnosis of low grade parosteal osteosarcoma, two patients had a chondrosarcoma, one patient had a diagnosis of Ewing's sarcoma, and one patient had a high-grade soft tissue synovial sarcoma invading the bone. Seven patients had a localized disease (IIA and IIB according to Enneking) and four patients had known distant metastatic disease (stage III). Seven patients received adjuvant chemotherapy, three of them also adjuvant external radiotherapy. Four patients received no adjuvant treatment.

The surgical technique and reconstruction strategy was consistent throughout the patient group. All patients had a fibula placed inside of an oversized allograft with an oval opening at the site of the vascular stump. The fibula was always harvested longer than the anticipated resection length. This allowed for overlap within the host bone and osteosynthesis with a large locking plate bridging both osteotomy sites which was used to secure the reconstruction (Picture 1). The ipsilateral fibula was used in all cases. The decision whether to use a simple allograft or combined graft was dependent on the surgeons and patients' preference case by case.

All patients in the combined graft group had CT scans performed at the same institution, using the same CT scan machine and imaging protocol (Somatom Definition EDGE, Slice 1 mm – tra, cor, sag, IMAR – metal artifact reduction, native examination). All patients had a CT scan scheduled at six months after surgery and then annually. For two patients in only the first two CT scans were available, four patients had three CT scans and only four had four or more (up to six) consecutive CT scans. To achieve better homogeneity with focus on early stages of demodulation, we analyzed only the first three CT scans (when available), that amounted to 30 months of follow-up. The measurement design was conceived in concordance with the chief radiologist, who performed the measurements. Changes in bone stock and bone density were assessed analyzing two different levels in the graft - always half the distance between the "pedicle window" and the osteotomy site (Picture 1). The density was measured in standard Hounsfield units. The initial CT scan six months from the initial surgery served as the baseline to which the consecutive measurements were related and noted as a percentile change. The total average density of the cross-section, with the exception of the outer allograft cortex, was measured and calculated (Picture 2). The density was also measured in three constant areas, that were defined on the initial postoperative CT scan. These were area from the center of the fibula to the outer edge of fibular cortex (defined by a sudden drop in density), the space between the fibula and the allograft (defined by sudden increase in density) and area across the allograft (end defined by sudden drop in the density). For these measurements two directions opposite to the plate at 120 degrees and 240 degrees were chosen to minimize metal artifacts. Mean and maximal bone density was recorded in all three areas (Picture 3). Changes visible to the naked eye such as new bone formation on the inner surface of the allograft and bony "bridges" extending from fibula to the allograft, were also documented. For these changes, all levels of the reconstruction were assessed by both the radiologist and the orthopedic oncologist and recorded positive only if both of them concurrently labeled them as positive. If the noted changes were not supported by measurable density gradient change (Picture 4), they were labeled as false positives.

Consecutive radiographs were analyzed for bony fusion at the osteotomy sites. Radiographs were obtained more frequently than CT scans at each outpatient visit using plain antero-posterior and lateral views, and these were done in the same comparable fashion in both groups. Bony fusion was considered successful when visible calcified callus bridging the osteotomy was present on at least one radiographic projection or the junction line was hazy and diminished (Picture 6). The radiographs were assessed by both the radiologist and the surgeon. The time of fusion was noted as average in case opinions differed.

Patients' functional status was assessed at each outpatient visit using the MSTS scoring system. Statistical analysis was performed using IBM SPSS Statistics for Windows, version 28.0 (IBM Corp., Armonk, N.Y., USA). All tests were deemed significant if p was < 0.05.

3. Results

The average surgical time of a combined graft (Group A) was 594.44 min (range 405–740, SD 104.63) and the mean average estimated blood loss (EBL) was 1855.56 ml (range 500–4000 ml, SD 1208.42 ml). The mean average length of reconstruction was 19.95 cm (range 12.50–26.00, SD 5.73). The mean average height of patients in this group was 164.5 cm (range 120–180, SD 19.03).

In the allograft group (Group B), the mean average surgical time was little under four hours (229.09 min, Range 100–360, SD 83.24) and the mean average EBL was 804.55 ml (Range 200–1500 ml, SD 498.22). The mean average length of reconstruction was 15.50 cm (Range 10–20 cm, SD 3.35).

There was no statistical difference between the two groups in terms of receiving adjuvant chemotherapy or radiotherapy ($p = 1.00$). The group with combined graft had a younger mean age (25.20 vs. 33.82), however, this difference was not significant ($p = 0.28$). The length of the reconstruction in "Group A" had a mean average longer length (A:19.95 vs. B:15.50, $p = 0.04$). The mean average surgical time (A: 599.44 min vs B: 229.09 min) as well as the mean average estimated blood loss (A: 1855.56 ml vs. B: 804.55 ml) were significantly higher in the combined graft group ($p < 0.001$ and $p = 0.01$, respectively). The risk for non-union and infectious complication was higher in the allograft group, however, the difference was not significant ($p = 0.09$ and $p = 0.66$, respectively).

Only seven patients in Group A exhibited incremental changes in all measured values and we believe these are cases of successful fibular transfer (Fig. 1,2). In the remaining three cases, the density values remained virtually unchanged ($p = 0.008$) (Picture 5). Moreover, this difference was statistically significant already at 18 months from the index surgery. The average bone density incremental increase in-between the fibula and allograft was also different among patients with an unsuccessful fibula transfer (32.22, SD 10.41) and the ones with a viable fibula (288.00, SD123.74), this was statistically significant ($p = 0.009$) (Fig. 1). There was a tendency for maximal fibular density as well as allograft density to decline, but this was not statistically significant ($p = 0.06$, $p = 0.26$, respectively) (Fig. 2).Fig. 3.Fig. 4.Fig. 5.Fig. 6.Fig. 7. Fig. 8.

Bony bridges were observed in six cases of viable fibula and in none of the three presumably dead fibulas; this difference was statistically significant ($p = 0.03$). New bone formation on inner site of the allograft

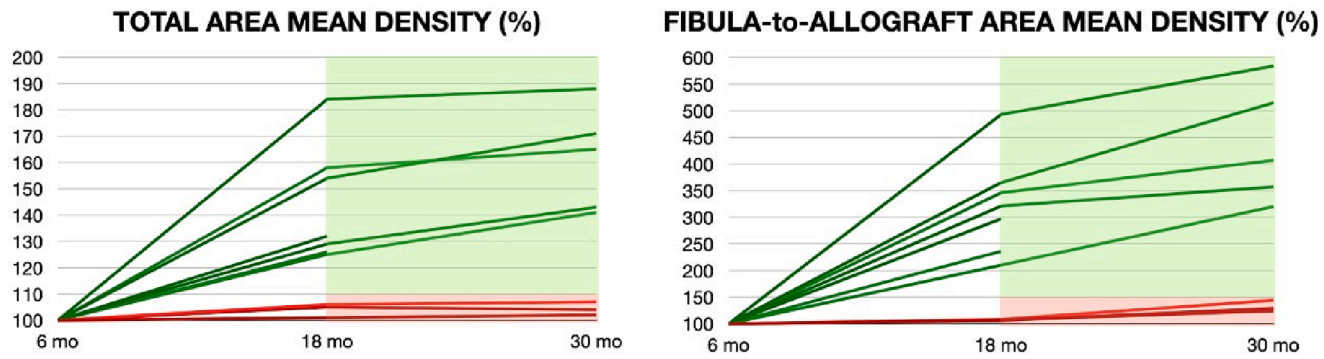

Fig. 1. A graph depicting the percentage change in total area bone density (A) and mean bone density in-between fibula and inner edge of the allograft (B). Green field accounts for vital fibulas and red for failed fibular transfer. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

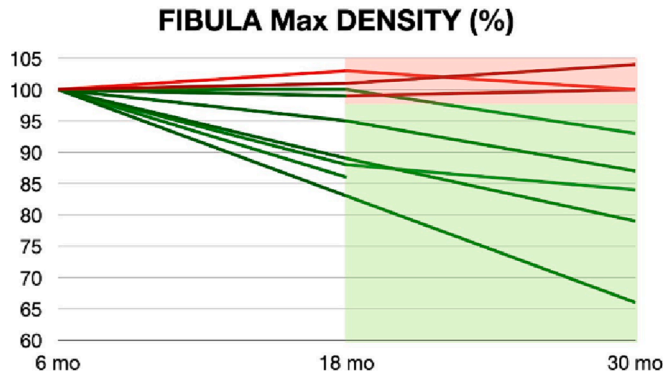

Fig. 2. A graph showing an incremental decrease in peak fibular density. Green field accounts for vital fibulas and red for failed fibular transfer. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

was present in four cases of the viable fibula and in none of the non-viable fibula cases, however, this difference did not achieve statistical significance. There were no false positives.

Bony fusion was achieved in all patients in "Group A". The mean average time to union at junction sites was 4.71 months (range 2.5–6.0, SD 1.19) for cases of successful fibula transfer and 19.50 months (range 5.5–29.5, SD 12.49) for the three cases where we presumed the fibula was not viable. This difference was significant ($p = 0.009$). Two patients received additional autologous bone grafting of the osteotomy sites (one in each subgroup). The patient in viable fibula subgroup had a revision surgery at 5 months due to plate breakage. There were no infectious complications and no allograft fractures in this group. Three patients (33%) had minor complications at the donor site. Two of them developed contracture of the long flexor of the hallux and one patient complains of ankle pain upon load that is addressed with ankle orthosis. We observed no cases of peroneal palsy after the fibular harvest. One patient in the non-viable subgroup was converted to a megaprosthesis at 83 months due to hip pain and femoral head necrosis.

The risk factor analysis of the different variables did not achieve any significance, although, all the patients with a failed transfer were skeletally mature (100% vs. 42.9%) and were taller than those with a viable fibula (174.67 cm, SD 2.52 vs. 160.29, SD 21.65). However, this difference was not significant ($p = 0.30$).

The mean average MSTS score was higher for the group of successful transfer subgroup (26.7/30, SD 2.87) when compared to the group of non-viable fibular graft (17.00/30, SD 6.08). The difference was statistically significant ($p = 0–007$). The reason for this difference is the ability to fully weight bear without pain, when actively remodeling reconstruction was in place. In the subgroup of failed fibula one patient developed painful hip necrosis and the other had a prolonged healing (42 months to fusion) of one of the osteotomy sites, which caused discomfort upon loading. Patients also complained of pain in the ankle at the donor site.

There were four cases of non-union in Group B. Two of these patients had the allograft removed due to infection at 7 and 15 months post-surgery, one patient died of disease at 25 months and one patient is still alive at 31 months of follow-up with no signs of bone fusion. He received adjuvant radiation therapy and had not yet had a revision surgery for failure of the reconstruction. The mean average time to union in the remaining seven cases was 18.85 months (range 9–60, SD 11.99). Four of these patients had a total of seven revision surgeries with autologous bone grafting of the osteotomy sites. When comparing the simple allograft group time to union with the viable fibula cases from group A (18.85 vs, 4.71 months) the difference was significant ($p = 0.009$).

Both groups showed a mean average shorter union time for the metaphyseal osteotomy site compared to the diaphyseal site (Group A: 4.70 vs 13.60, Group B: 14.14 vs 23.57), however, this only achieved significance in Group B ($p = 0.03$).

4. Discussion

Our study reinforces the existing literature suggesting that massive allografts are prone to infectious complications and non-union at the junction sites [3]. Other alternatives, such as distraction osteogenesis have also been proposed, however, this technique is also associated with complications as well as a longer surgical time and extended recovery [20]. The addition of a vascularized fibula to the reconstruction decreases the likelihood of both threaded complications, however, it prolongs the surgical time significantly. Moreover, this study has also shown a only 70% success rate of the fibular transfer. This warrants further analysis to assess whether the additional risk associated with a longer anesthesia time and greater blood loss justifies the benefits of this surgical alternative. Li et al. reported surgical times of approximately 6 h for the combined procedure; a period not much longer than that of our allograft sample, nonetheless, this seems to be a shorter surgical length than what is usually reported [17,18,21]. Italian groups who historically report the highest numbers of patients with this procedure, report similar surgical times of approximately 9 h. However, they also report considerably lower failure rates of 9–15% [13,15,18,19]. This can potentially be explained by either the lengthy experience of Italian authors with this infrequent procedure or by different group demographic characteristics among the studies. The average age in our sample was 25 years of age, as opposed to 14–16 years of age reported by Capanna and Manfrini [18,19]. Therefore, the hypothesis that in older and skeletally mature patients this technique is less successful due to lower periosteal activity as well as difficulty in finding a suitable oversized graft, that

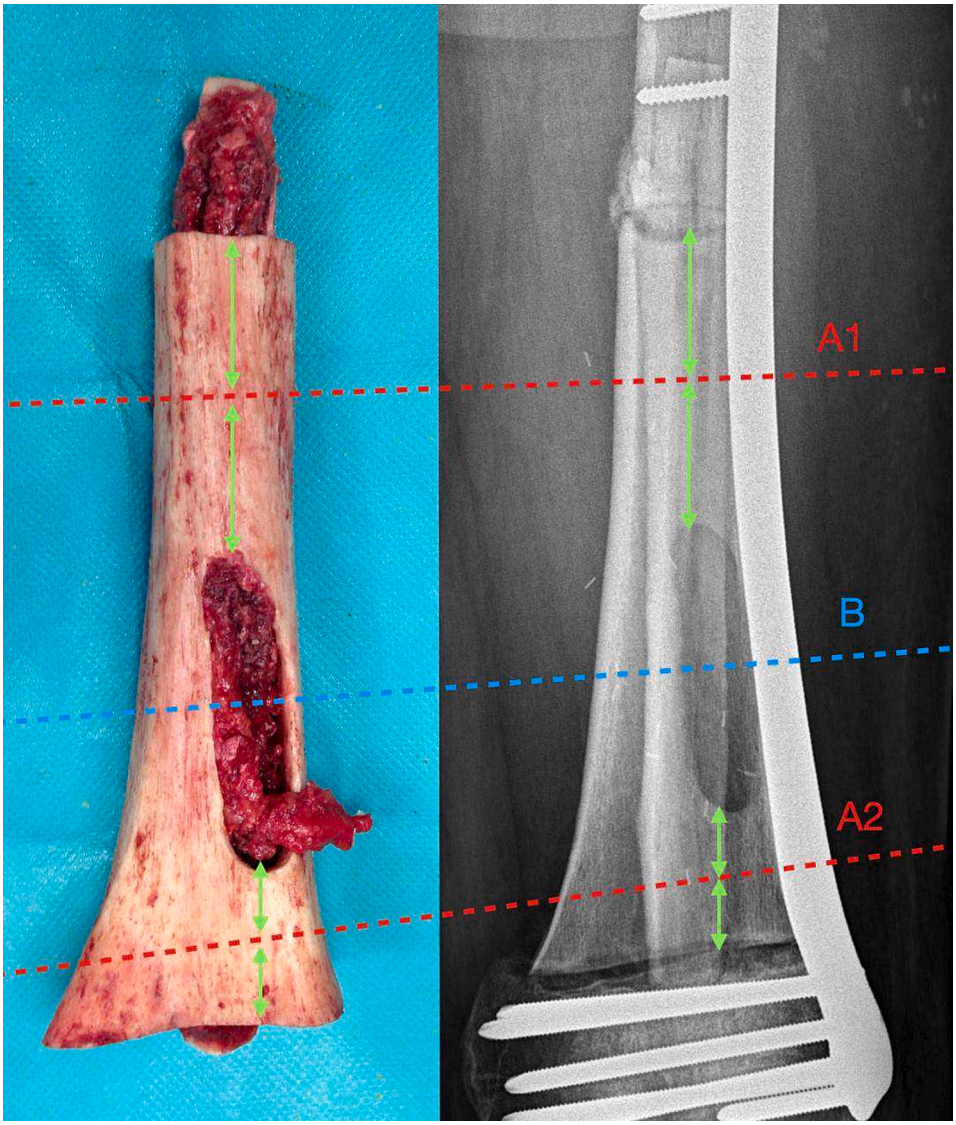

Fig. 3. A) Picture showing the used surgical technique and oval opening in the massive allograft for fibular stump. Red dotted lines correspond to two levels of measurement. B) Postoperative X-ray showing technique of bridging LCP plate osteosynthesis used in all cases. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

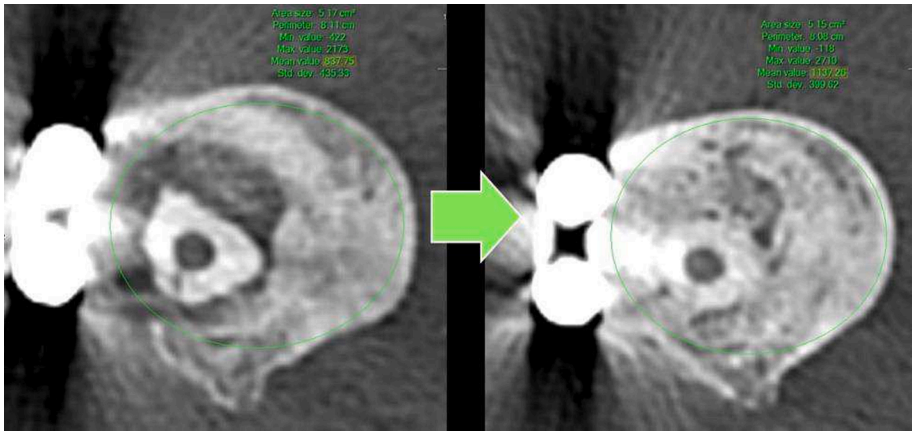

Fig. 4. Two consecutive CT scans at 6mo and 18mo showing the method used to measure whole area bone density and both visible and measurable increase in a case of successful fibular transfer.

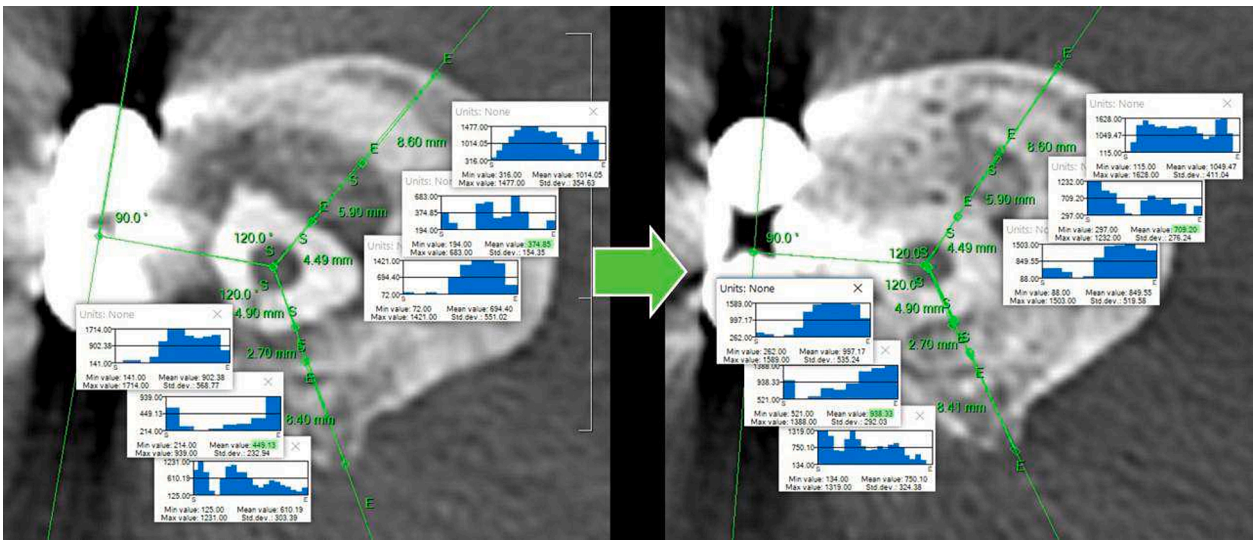

Fig. 5. Two consecutive CT scans at 6mo and 18mo showing the method used to define the three measured areas using the densitogram (twice for each level) and its application for the following scans where the changes on densitogram are less abrupt in case of successful transfer.

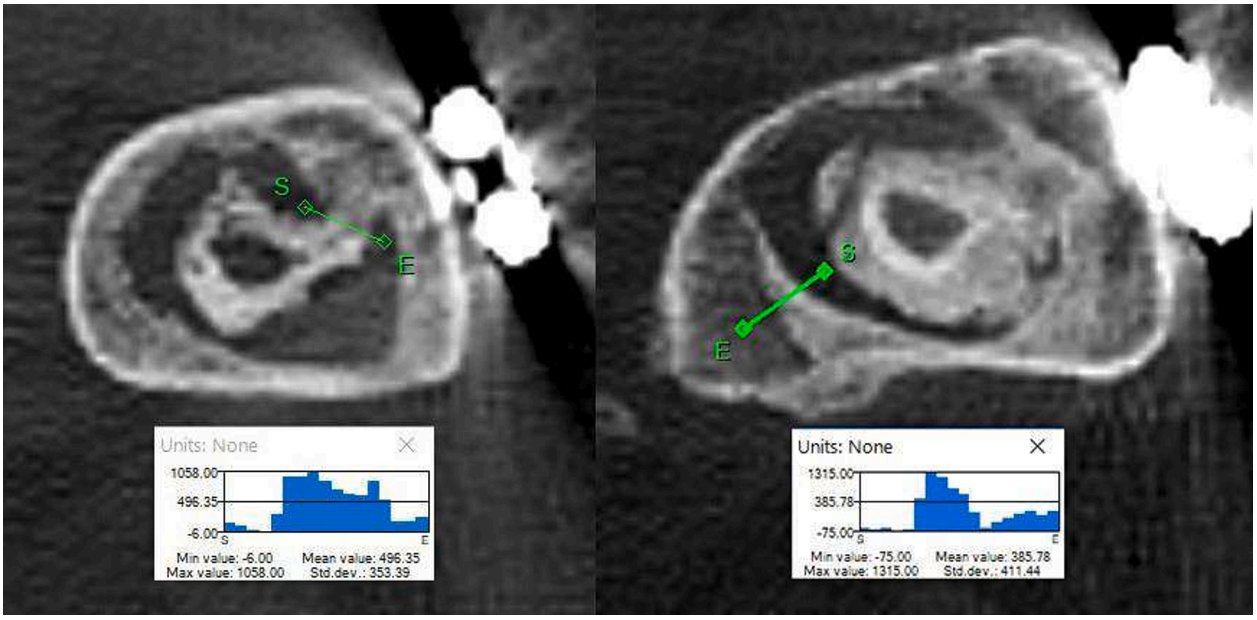

Fig. 6. CT scans demonstrating densitometrically confirmed bony bridges (A) and new bone formation on the inner site of the allograft (B).

would not impinge on fibular vessels, should be considered. This is supported by our data, where all the patients with a failed transfer were skeletally mature and rather tall. Based on this analysis we decided to change our surgical technique to opening the allograft shell throughout its entire length as described by Capanna [13]. Patients operated in this fashion were however not included in this study. There were no non-unions in the combined graft group, even if the fibular transfer was not successful. This may be attributed to the fact that there is always a fibular overlap at the junction providing double the surface area of contact with the host bone stump.

Consecutive CT scans proved to be a reliable method of assessing the fibular vitality, that correlates well with the radiographic signs of early bony fusion at the osteotomy sites. To our knowledge this is the first study to focus on exact quantitative measurements of bone density changes following fibular transfer inlaid in a massive allograft. Manfrini [4] and Ceruso [8] published two papers focusing on CT scan related changes. These papers present an overlapping group of patients and focus mainly on qualitative changes that can be observed with a naked eye without a densitometric analysis. Furthermore, the most dramatic changes are described in patients with fractures of either the allograft or the fibula. In cases of non-fractured reconstructions, the described changes can only be reliably assessed after several years and are rather subjective. This reduces the clinical usefulness of such observations and does not give any guidance on how to proceed in the case of early complications. The quantitative analysis of consecutive CT scans proposed by our study is a reproducible method that gives valuable information regarding the construct prognosis as early as 18 months after the initial surgery. Additionally, a simple CT scan is a cheap and fast examination [17], that is readily available at most centers.

This is a retrospective single institution study of a relatively small number of patients and as such is subjected to certain levels of selection bias and small number bias. In addition, our study analyses only the biologic aspects of these reconstructions, not taking into consideration other techniques.

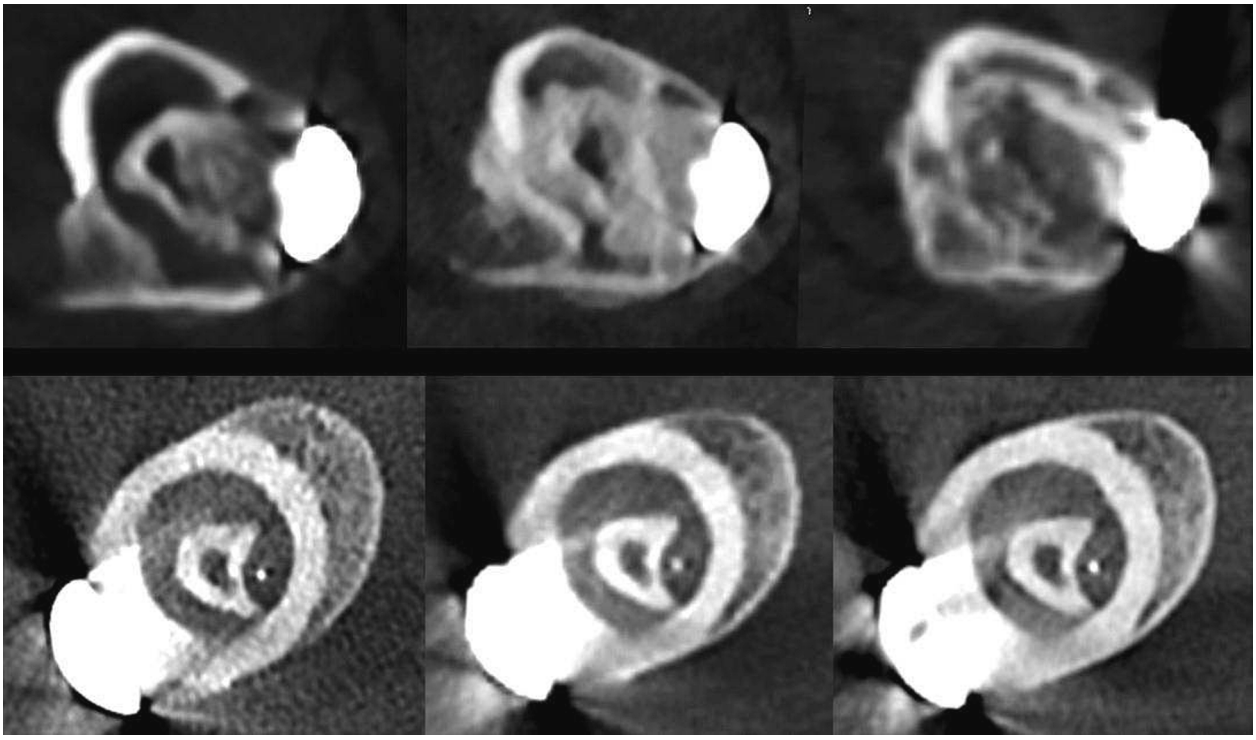

Fig. 7. Consecutive CT scans at 18, 30 and 42 months showing progressive remodeling in case of a successful transfer (above) and the lack of such in a case of unsuccessful transfer (below).

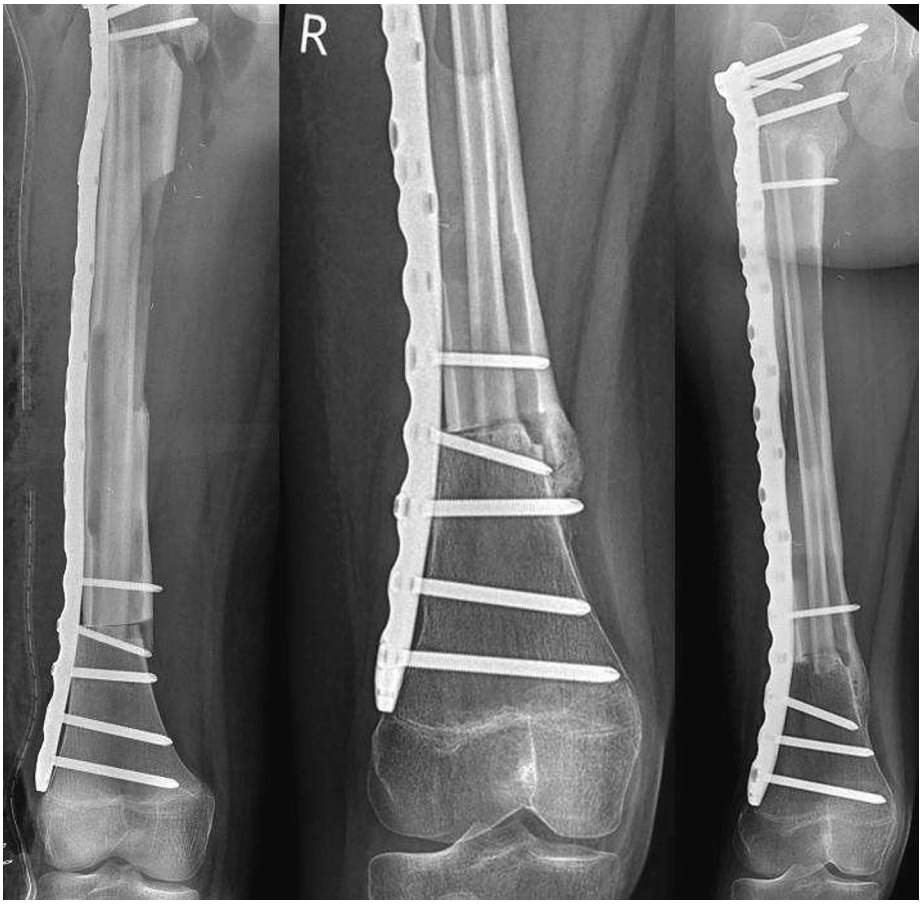

Fig. 8. Radiographic signs of healing through bridging callus distally at 3mo post surgery and through diminished osteotomy line proximally at 8mo. This patient had a revision surgery at 5 months due to plate breakage at the level of proximal osteotomy.

5. Conclusion

1) A viable fibula contributes to healing of the osteotomy sites decreasing the risk for non-union and greatly shortening the time to fusion. Remodeling reconstruction and promptly healed osteotomies provide a better functional status for the patient.
2) Adding a fibula to the reconstruction significantly increases the surgical time and blood loss and also has additional risk for complications at the donor site. However, the risk for structural as well as infectious failure is decreased.
3) Consecutive CT scans proved to be a reliable and reproducible method of assessing the vitality of fibular graft. When no quantitative changes to a bone density are measurable at 18-month follow-up, we can declare the transfer unsuccessful with a good amount of certainty. These reconstructions behave as simple allograft reconstructions with analogue risk factors. The presence of either axial bridges between the fibula and allograft or newly formed bone on the inner surface of the allograft is indicative of a successful fibular transfer.
4) The success rate of fibular transfer in our study was only 70% warranting more cautious indications of these lengthy and risky surgeries. Skeletally mature and taller patients seem to be at higher risk of failure.

Source of Founding

No funding was received for this project.

Institutional Review Board Statement

The study was approved by the Faculty and Hospital ethical committee.

Informed Consent Statement

Not applicable.

Availability of data and materials

Further case information is available from the corresponding author on reasonable request.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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