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RESEARCH

Two-stage replacement of total and subtotal foot bone defects in Charcot neuroosteoarthropathy using personalised allogenic 3D bone bioimplant

Stanislav Osnach[1] · Victor Protsko[1] · Vladimir Obolenskiy[2] · Larisa Volova[3] · Aikush Nazaryan[3] · Vadim Bregovsky[4] et al. ***[full author details at the end of the article]***

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Abstract

Introduction Charcot diabetic arthropathy is one of the most serious complications in patients with diabetes mellitus with sensorimotor neuropathy of the lower extremities, accompanied by metabolic disturbances and subsequent destruction of bones and joints. There are many methods of surgical treatment of diabetic charcot's foot described in the literature. A review of the literature found no publications describing the surgical treatment of Charcot arthropathy patients using the method of two-stage replacement of total and subtotal foot bone defects with heterotopic allografts using 3D modelling.

Purpose The aim of the study is to determine the clinical efficacy of surgical treatment of patients with diabetic Charcot foot with destruction of the middle and hindfoot in remission (without active infectious process) and with active purulent infection by two-stage replacement of total and subtotal bone defects of the foot with heterotopic allografts using 3D modeling.

Materials and methods This study analysed the treatment outcomes of 40 patients with bone defects due to Charcot neuroosteoarthropathy who were treated at the Centre for Foot and Diabetic Foot Surgery, Yudin City Clinical Hospital in 2022 to 2023. The localisation of the pathological process was diagnosed in the bones of the midfoot in seven patients (type 2 to 3, Sanders & Frykberg classification), of the hindfoot in 30 patients (type 4 to 5, Sanders & Frykberg classification) and of the combined midfoot and hindfoot in three patients (type 3 to 4 to 5, Sanders & Frykberg classification). There were 12 men and 23 women. The mean age was 51.1 ± 2.1 M ± σ (24 to 71) years. The average body mass index was 30.0 ± 1.2 M ± σ (18 to 46.9). Type 1 diabetes mellitus was present in 9 patients and type 2 diabetes mellitus was present in 31 patients.

Results The mean volume of the simulated allografts for the midfoot was 22.7 ± 6.2 cm3 M ± σ, 37.8 ± 2.9 cm3 for the hindfoot and 41.2 ± 7.6 cm3 for combined defects of the hindfoot and midfoot. The duration of follow-up after the end of treatment ranged from 12 to 36 months. Good results were obtained in all patients with midfoot damage and with combined midfoot and hindfoot damage. In isolated hindfoot lesions, a good result was seen in 19 of 30 patients, or 60.7%. In six patients with hindfoot damage (21.4%), crushing of the allograft was observed with the neoarthrosis formation in supporting region with relative limb shortening, which was considered a satisfactory outcome. Non-union or recurrent osteomyelitis was noted in five patients with hindfoot lesions (17.9%), requiring allograft removal and arthrodesis in an external fixation device (EFD) with intraoperative segment shortening. These results were considered unsatisfactory despite the preservation of the limb. Overall, for the entire cohort of patients, 29 of 40 (72.5 per cent) had a good outcome, six (15 per cent) had a satisfactory outcome and five (12.5 per cent) had an unsatisfactory outcome.

Conclusion The utilisation of 3D allografts provides a solution to the issue of restoration total bone defects in Charcot osteoarthropathy, not only at the level of individual bones, but also across the entire segments of the foot while enabling the precise replication of the intricate contours of a complex geometry. The proposed method of restoration bone defects in Charcot arthropathy has been demonstrated to be sustainable and enabling the successful filling of extensive bone defects without complications and the staged compression throughout the entire fixation period, while minimising the risk of implant damage.

Keywords Arthropathy · Allografts · Congenital foot deformities

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Introduction

Charcot diabetic arthropathy is one of the most serious complications in patients with diabetes mellitus with sensorimotor neuropathy of the lower extremities, accompanied by metabolic disturbances and subsequent destruction of bones and joints [1–3]. The subsequent development of total and subtotal defects of the foot bones leads to a disruption of the supporting function, and the secondary infection poses a threat to the limb and even life. The unstable nature of the deformity, especially when complicated by ulceration and infection (stages 1 to 3 according to Wagner's classification), makes it difficult to successfully practice conservative treatment (orthoses, therapeutic footwear, etc.), and therefore reconstructive surgery is one of the ways, and in some cases the only way, to avoid limb amputation [4–7]. Radical removal of the bone tissue destruction foci with subsequent restoration of the functional capabilities of the foot through reconstruction of its anatomical structure, segment length and biomechanics is the main goal of surgical treatment of patients with complicated diabetic neuro-osteoarthropathy.

In reconstructive surgery for Charcot foot with ankle and subtalar joint damage, calcaneotibial arthrodesis is becoming an increasingly popular surgical procedure [8]. For the defects of the mid- and hindfoot in Charcot arthropathy, that correspond to types III, IV, V according to Sanders & Frykberg anatomical classification, methods of resection arthrodesis with internal fixators are known, but some authors have noted a high rate of complications—formation of non-unions, migration of fixators, loss of correction, recurrence of ulcers, etc [9, 10]. There are controversial reports in the literature on the technique and methods of foot fixation, and therefore the surgeon's preferences may be influenced by many factors, taking into account the advantages and disadvantages of each method [11–13]. A number of researchers have noted the benefits of using metallic internal fixation devices in the treatment of Charcot osteoarthropathy patients [14–18]. At the same time, it has been revealed that in cases corresponding to stage 2 according to the Eichenholtz radiological classification, resection arthrodesis with internal fixators increases the likelihood of non-union, bone loss and subsequent secondary fragment displacement, as well as the incidence of secondary amputation. Advocates of external fixation have also rejected the use of internal fixators in favour of transosseous osteosynthesis, preferring to treat patients with Charcot osteoarthropathy using the Ilizarov external fixator for for the ankle arthrodesis in the presence of purulent complications, soft tissue defects, severe osteoporosis, osteomyelitis [19–26].

The described methods of single-stage arthrodesis with internal and external fixators shows a number of disadvantages: the need for bone resection with consequent segment shortening that results in a forced foot position and the subsequent need for manufacture and unvarying use of individual orthopaedic footwear. It is not always possible to achieve bone ankylosis due to the lack of sufficient contact area and congruence between the arthrodesed fragments.

There are many clinical studies on the two-stage method of restoration extensive defects in long tubular bones using the Masquelet technique and Ilizarov non-free bone grafting, as well as their combined use. The further complete reconstruction of the implanted material is ensured by the formation of an osteoinductive membrane in the area of the bone defect, with priority given to external fixation using transosseous osteosynthesis [27–29]. The experience of restoration partial midfoot defects in Charcot arthropathy in two stages has also been demonstrated [30]. To replace extensive bone defects with autogenous bone material, the material is taken from the iliac crests, whose anatomy limits the harvesting of a large volumes of cancellous bone, so this manipulation is associated with massive trauma to the cortical bone layer over a large area and the risk of damage to the femoral cutaneous nerve and the parietal peritoneum [31]. The experience of performing a two-stage calcaneotibial arthrodesis using the Synthes Reamer Irrigator Aspirator in patients with large bone defects of the Charcot foot has been described in the national and international literature [32].

Foreign authors also propose a method that is based on the creation of a template from the results of 3D reconstruction of CT scans, to give bone cement a shape corresponding to the bone defect of the calcaneus. In the second stage, following the Masquelet technique the cement spacer was removed and autogenous bone was implanted to restore the bone defect [33]. In addition, a study by national authors demonstrated the experience of using a custom-made graft of allogeneic lyophilised bone in maxillofacial surgery. The patient underwent CT of the affected segment, then followed computer modelling to obtain digital 3D models of the bone defect and milling of the bone implant on a CNC machine, with sterilisation by irradiation afterwards. The resulting bone implant was then inserted in a single step. This technique allows to solve the problem of bone implant personalisation and reduce the patient rehabilitation period [34].

A review of the literature found no publications describing the surgical treatment of Charcot arthropathy patients using the method of two-stage replacement of total and subtotal foot bone defects with heterotopic allografts using 3D modelling.

The aim of the study is to determine the clinical efficacy of surgical treatment of patients with diabetic Charcot foot with destruction of the middle and hindfoot in remission (without active infectious process) and with active purulent infection by two-stage replacement of total and subtotal

bone defects of the foot with heterotopic allografts using 3D modeling.

Materials and methods

This study analysed the treatment outcomes of 40 patients with bone defects due to Charcot neuro-osteoarthropathy who were treated at the Centre for Foot and Diabetic Foot Surgery, Yudin City Clinical Hospital in 2022 to 2023. The localisation of the pathological process was diagnosed in the bones of the midfoot in seven patients (type 2 to 3, Sanders & Frykberg classification), of the hindfoot in 30 patients (type 4 to 5, Sanders & Frykberg classification) and of the combined midfoot and hindfoot in three patients (type 3 to 4 to 5, Sanders & Frykberg classification). There were 12 men and 23 women. The mean age was 51.1 ± 2.1 M ± σ (24 to 71) years. The average body mass index was 30.0 ± 1.2 M ± σ (18 to 46.9). Type 1 diabetes mellitus was present in nine patients and type 2 diabetes mellitus was present in 31 patients.

Due to the impossibility to objectively describe the processes occurring at the lytic lesion in this cohort of patients, and also taking into account the preservation of main or modified main peripheral blood flow in all patients (according to ultrasound angiography and/or CT angiography), the Chantelau & Grützner and WiFi classifications as proposed by the Russian and IWGDF recommendations were not used [35–37].

Glycaemic control and correction and, if indicated, systemic antibacterial therapy and limb unloading were performed in all patients.

The first stage of the proposed two-stage procedure involved the removal and resection of destructively altered bone fragments to contain resection bonesaw-lines of the preserved bone ends within the boundaries of visually healthy tissue. In case of purulent process, after osteonecrectomy, hydrosurgical treatment of the diastasis zone was performed using the Pulse Lavage system (rinsing the wound with six litres of saline + polyhexanide at a rate of 1 mL per litre of solution). Diafixation pins were used to secure the foot in a functionally correct position. Taking into account the fact that patients frequently come to the Centre for Foot and Diabetic Foot Surgery not immediately but after three to six months or even more from the moment of the disease manifestation, a reduction of soft tissues was observed in the area of the affected part of the foot, which prevented a single-step complete intraoperative restoration of the segment length without the risk of skin tension and possible necrosis formation in the postoperative period, therefore the restoration of length was always performed taking into account this clinical factor. Extra-focal osteosynthesis was then performed using an external fixation device consisting of two rings attached to the mid-lower third of the leg and two half rings on the foot: in the heel area and in the forefoot. In the projection of the rings and half-rings, the pins were drawn in an oblique frontal plane, fixed and stretched in the plane of the rings using a standard technique, the rings were connected to each other with threaded rods at the tibia and with single or double plane hinges to connect the rings at the tibia and half-rings at the foot. A polymethylmethacrylate cement spacer with gentamicin was then implanted into the defect area, with the addition of two to four doses of vancomycin as indicated (if the microbiological test results revealed methicillin-resistant Staphylococcus or resistant Enterococcus). During the placement process, the complete distribution of cement in the defect area and preventing its release into the soft tissue was controlled using Image Intensifier. The wounds were tightly sutured without drainage.

In the post-operative period, all patients underwent a CT scan of the operated segment, based on the results of which methods were developed to obtain a 3D model taking into account the presence of metal structures; according to individual parameters, the milling methods and fixation devices necessary to obtain a large-block bone bioimplant were selected.

Digital modelling of a bio-implant with specified parameters, suitable for the size of a particular patient's orbit, was carried out in a CAD/CAM system on the basis of the individual 3D model of the orbits obtained, after which a computer 3D model was formed and subsequent polygonal digital modelling of the parameters of the reconstructive bone implant was done out depending on individual characteristics and size ratios, taking into account the specifics of further implantation. This was how the final digital model was obtained (Fig. 1).

The 3D model was then sliced into layers and loaded into the milling machine's control programme to produce a customised bio-implant from the allogeneic Lioplast® bone block. Bone blocks were obtained from heterotopic sources of cadaveric bone tissue for the reconstruction of the diabetic foot, taking into account the biomechanical and bioplastic properties. The bone implant model was prepared using external customisable tools for layer-by-layer model segmentation and then sent to a Roland MDX 40a CNC machine for milling the individual reconstructive bone implant (Fig. 2).

Standard gamma irradiation was used to sterilise this graft.

In the second stage, following the Masquelet technique [38], the cement spacer was removed after six to eight weeks without damaging the formed inductive membrane and the diastasis defect was filled with a prepared 3D custom bone alloblock. The wound was also tightly sutured

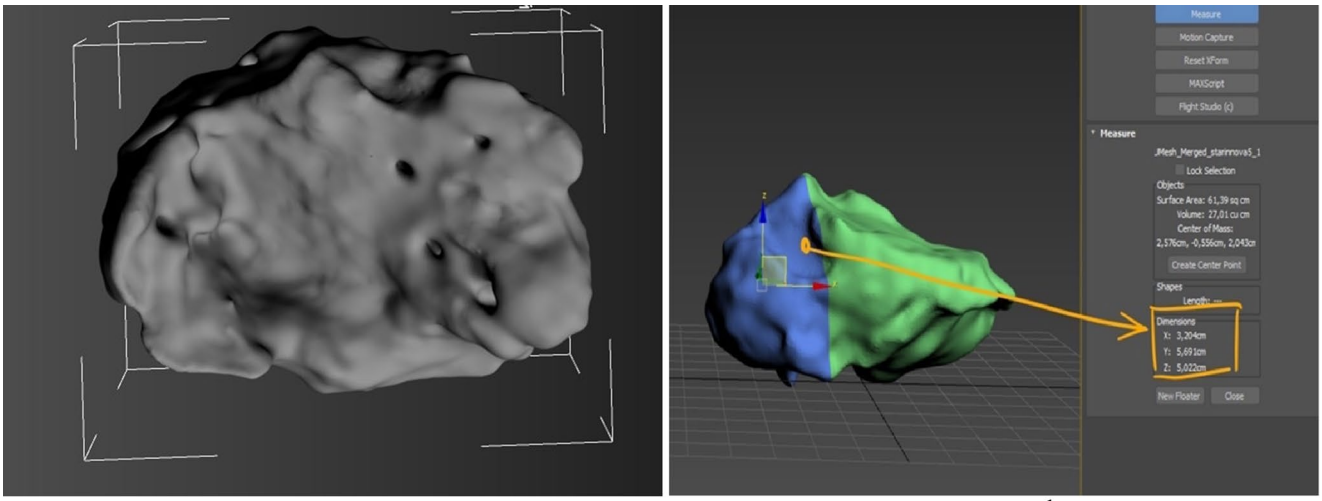

Fig. 1 Initial view of the modelled implants (**a**, **b**)

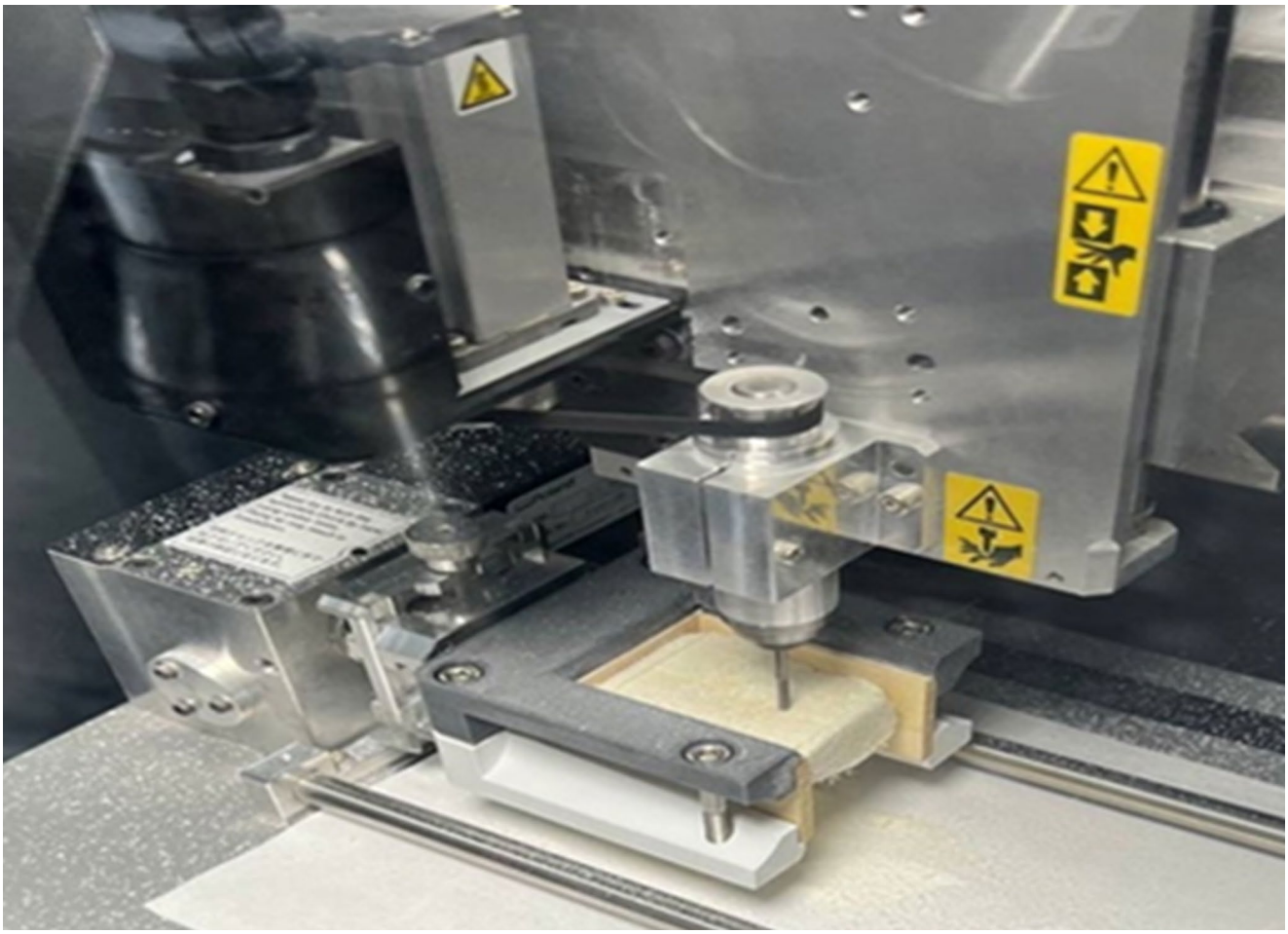

Fig. 2 A machine that performs 3D milling of an implant from an alloblocks

Table 1 Mean volume of 3D allografts used to replace different parts of the foot

	Midfoot, $n = 7$	Hindfoot, $n = 30$	Mid- and hindfoot, $n = 3$
Mean allograft volume, cm^3	22.7 ± 6.2	37.8 ± 2.9	41.2 ± 7.6

Table 2 Treatment outcomes

Result	Midfoot, $n = 7$	Hindfoot, $n = 30$	Mid- and hindfoot, $n = 3$
Good	7 (100 per cent)	19 (60.7 per cent)	3 (100 per cent)
Satisfactory	0	6 (21.4 per cent)	0
Unsatisfactory	0	5 (17.9 per cent)	0

without drainage. External fixation device was used to stabilise the fragments afterwards. The sutures were removed four to six weeks following the operation. Staged X-ray control was performed every one to 1.5 months. If there were clear radiological signs of consolidation and after clinical examination, the external fixation device was removed and fixation with a posterior splint for two to three weeks was done until the wounds in the sites of the removed fixation elements had healed, and the patient then started using individual orthopaedic footwear. The results of the study were evaluated using descriptive statistics.

The patients signed an informed consent for the surgical procedure and for the publication of the data obtained without any personal identification.

Results

The mean volume of the simulated allografts for the midfoot was 22.7±6.2 cm^3 M±σ, 37.8±2.9 cm^3 for the hindfoot and 41.2±7.6 cm^3 for combined defects of the hindfoot and midfoot (Table 1).

The duration of follow-up after the end of treatment ranged from 12 to 36 months (the mean period was 21 months).

Good results (radiological signs of bone ankylosis, absence of pathological mobility) were obtained in all patients with midfoot damage and with combined midfoot and hindfoot damage. In isolated hindfoot lesions, a good result was seen in 19 of 30 patients, or 60.7 per cent.

In 6 patients with hindfoot damage (21.4 per cent), crushing of the allograft was observed with the neoarthrosis formation in supporting region with relative limb shortening, which was considered a satisfactory outcome.

Non-union or recurrent osteomyelitis was noted in five patients with hindfoot lesions (17.9 per cent), requiring allograft removal and arthrodesis in an external fixation device (EFD) with intraoperative segment shortening. These results were considered unsatisfactory despite the preservation of the limb (Table 2).

Overall, for the entire cohort of patients, 29 of 40 (72.5 per cent) had a good outcome, six (15 per cent) had a satisfactory outcome and five (12.5 per cent) had an unsatisfactory outcome.

Table 3 Comparison of mean BMIs in three groups of patients with hindfoot defects

Result	Good	Satisfactory	Unsatisfactory
Mean BMI	27.9 ± 1.64	29.3 ± 2.6	31.7 ± 3.6

Considering the presence of satisfactory and unsatisfactory results in the group of patients with hindfoot bone defects, a comparative retrospective analysis of the BMI of each group was carried out (Table 3).

Case report 1

Patient M., 59 years old, height 192 cm, weight 150 kg, BMI 40.69 kg/m^2. Five years prior to hospitalisation, type 2 diabetes mellitus was diagnosed. In June 2022, following a minor injury, they began to notice a foot swelling, walked with a limp and denied the existence of a pain syndrome. Over the course of one month, they observed an increase in the deformation of their left foot; over the course of six-months, they were treated conservatively according to the place of residence with negative trends noted during this period which manifested as an increase in the varus deformity of the ankle joint and a lameness increase. In December 2022, the patient sought consultation at our centre; following the control radiographs, a patient was a diagnosed with Charcot diabetic arthropathy, categorised as 2 to 3 according to the Sanders classification and stage 2 according to the Eichenholtz classification. During the surgical procedure, evidence of damage to the talus and marginal damage to the tibia and calcaneus was observed. In the initial stage of the procedure, an external fixation device was employed for osteosynthesis, with plastic surgery subsequently performed on the resulting defect utilising a spacer. In the postoperative period, a 3D allograft was created using the aforementioned methodology and was subsequently installed two months later. The device was fixed in place for six months. Following the dismantling of the device, the patient could move using TCCs with the provision of supplementary support measures and a limited load on the left lower limb. Three

months following the device dismantling, the production of individual orthopaedic shoes commenced (Fig. 3).

Case report 2

Patient K. 49 years old, type 2 diabetes mellitus. BMI 32. From the anamnesis, it became known that 1.5 years prior to the presentation the patient had noted a foot swelling, which they denied was due to an injury. Over time, the patient observed the foot deformity and was monitored on an outpatient basis. A dissection of the foot phlegmon was conducted on two occasions at medical institutions according to the place of residence. The patient was observed on an outpatient basis and noted that an ulcerative defect had formed on the plantar surface. Following an examination, the diagnosis was diabetic Charcot neuroosteoarthropathy of the right foot, classified as type 3 to 4 to 5 according to the Sanders classification, stage 2 according to Eichenholtz classification, and a stage 2 trophic ulcer according to Wagner. In the initial stage of the procedure, the EFD was secured with the right foot in the standard correction position; subsequently, destructive tissue excision was performed, and the bone defect was filled with an antibacterial spacer. In the postoperative period, a 3D allograft was created using the aforementioned methodology and was subsequently installed two months later. The device was fixed in place for six months. Following the dismantling of the device, the patient could move using TCCs with the provision of supplementary support measures and a limited load on the right lower limb. However, as the load increased, the patient began to observe alterations in the ankle joint shape; radiographic images revealed a reduction in the transplant height up to its complete crushing. In the absence of angular foot deformities and threats of ulceration, the patient was instructed to continue loading using orthosis; the staged radiographs demonstrated the neoarthrosis formation in supporting region. The patient was provided with customised orthopaedic footwear (Fig. 4).

In one instance of non-union, the allograft was subjected to removal of fragments, which were subsequently subjected to histological examination with the use of haematoxylin and eosin staining (Fig. 5).

The histological examination of the removed allograft yielded intriguing findings: the bone structure exhibited Haversian canals, the intertrabecular space was filled with reticular stroma and separate blood vessels, and there were no indications of inflammation.

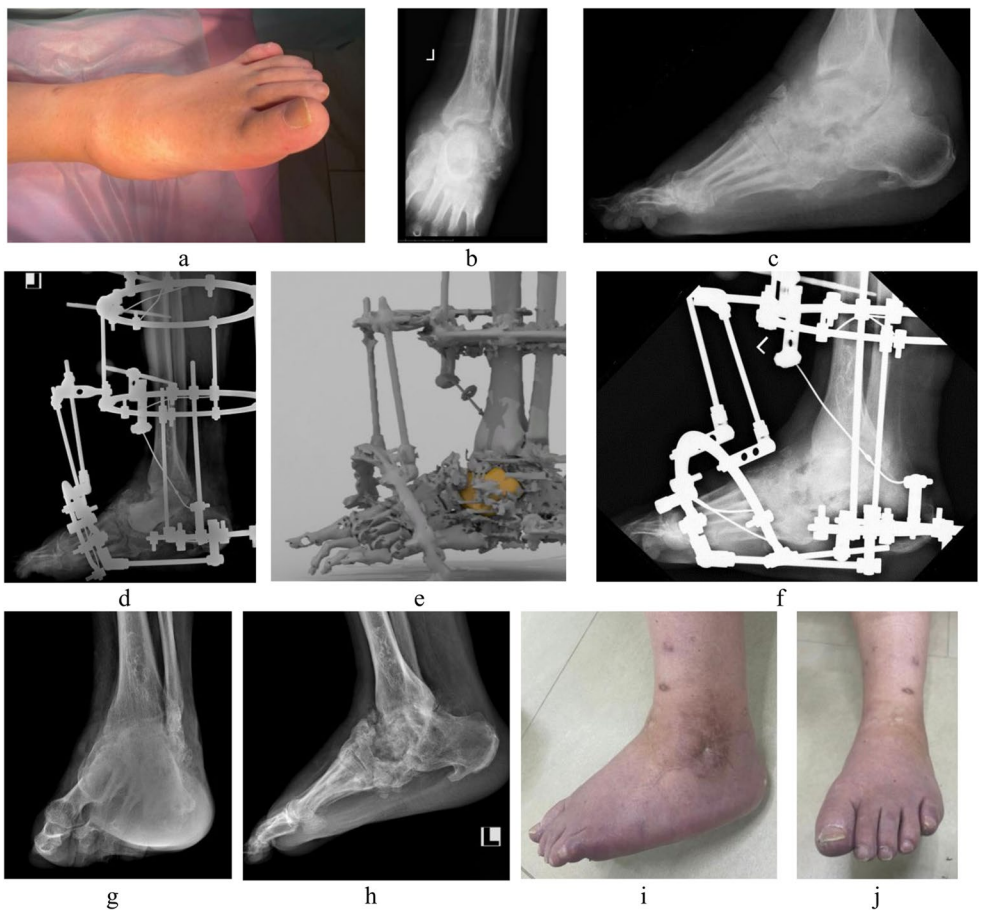

Fig. 3 The images presented herewith include photographs (**a**) and radiographs of the foot and ankle joint (**b**, **c**), a lateral foot projection radiograph after the spacer installation (**d**), a 3D model of the foot with the spacer installed (**e**), a lateral foot projection radiograph after the implant installation (**f**), and a radiograph of the foot and ankle joint in direct and lateral projections 1 year after the device was dismantled (**i**, **j**)

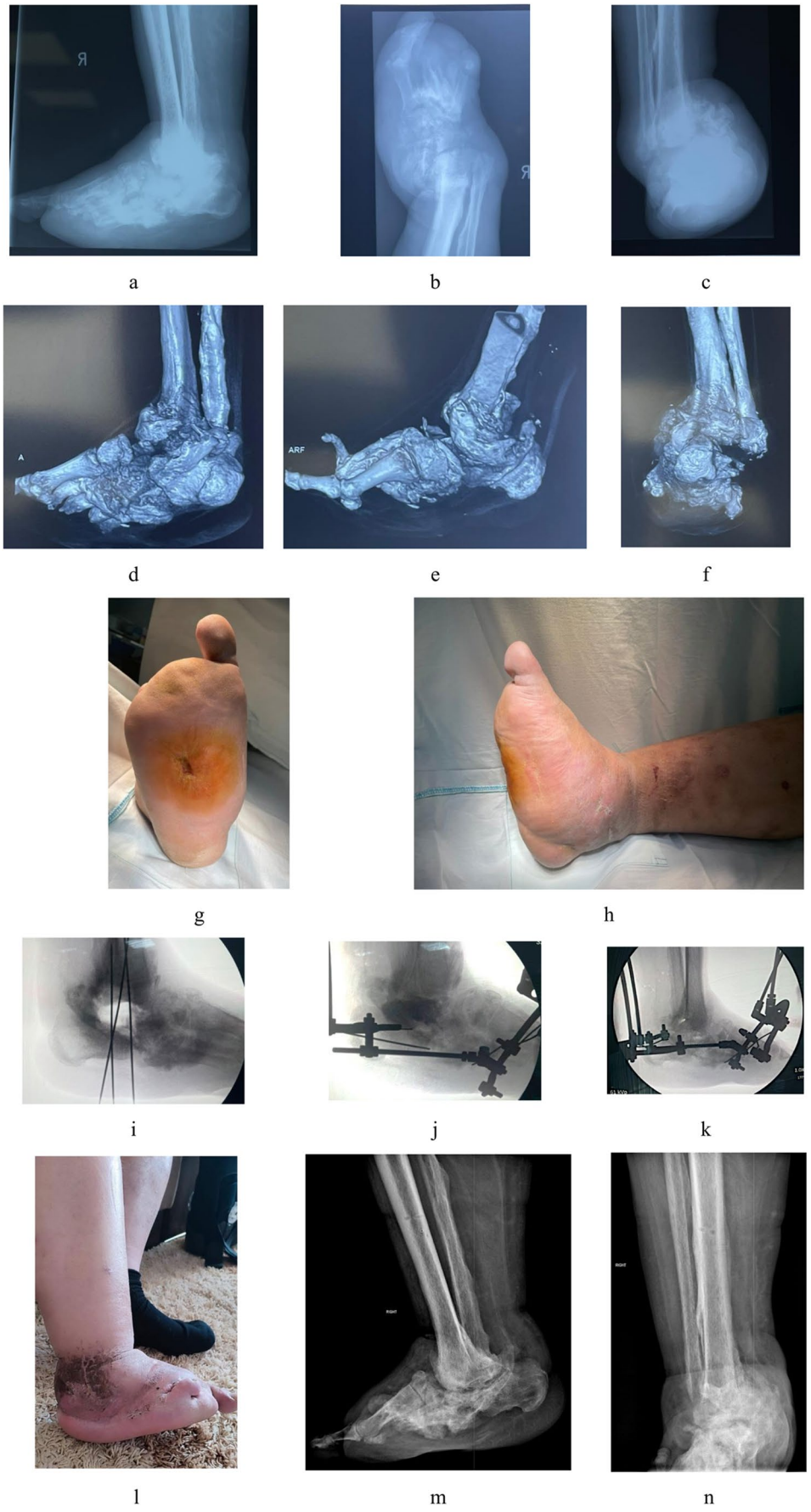

Fig. 4 The radiographs of the foot and ankle joint (**a, b, c**); CT-based 3D models (**d, e, f**); photograph of the foot upon admission (**g, h**); the Image Intensifier control after the fixation of the foot with the formed bone defect (**i**) and after filling the defect with a spacer (**j**); Image Intensifier scan of the foot lateral projection following the spacer removal and a 3D allograft installation; photograph of the foot taken 6 months after the commencement of loading on the leg (**l**); radiographs of the foot in 2 projections taken 6 months after the start of loading on the foot (**m, n**)

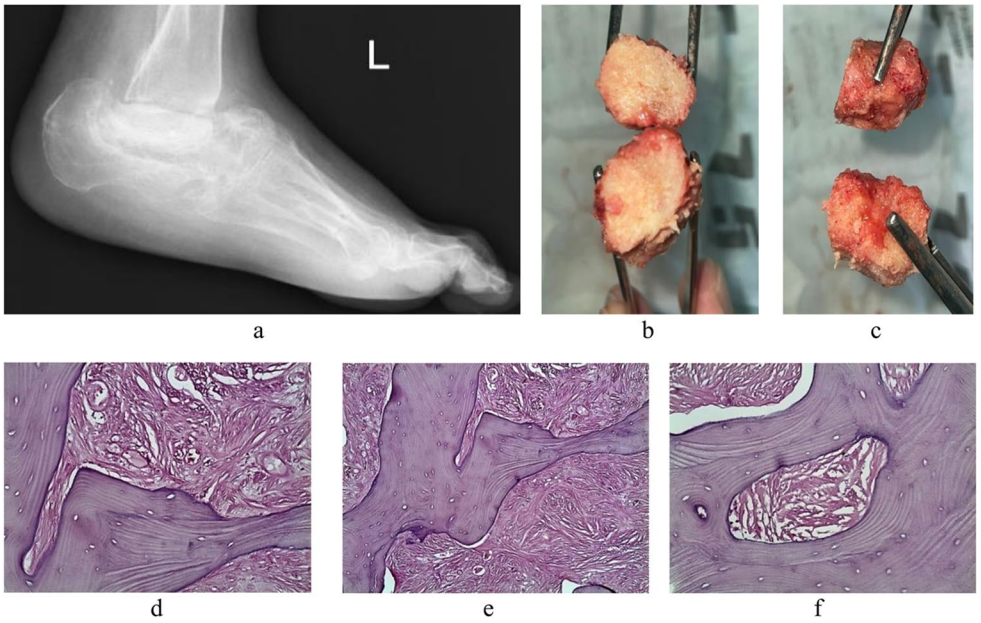

Fig. 5 The X-ray of the foot with an implant installed in the lateral projection (**a**); a photograph of the extracted allograft (**b, c**); histological sections of the transplant (**d, e, f**)

Discussion

The admission of patients with Charcot foot with extensive bone defects requiring replacement precluded the use of exclusively autografts due to the large volume of autograft required and the process of collecting donor material associated with high trauma incidence. It was therefore concluded that allograft bone represented the optimal solution, given the considerable volume of defects resulting from the removal of non-viable bone. Nevertheless, the utilisation of orthotopic transplants was not feasible due to the technical challenges associated with the production of 3D models, given the size and shape of the defects. The anticipated 10 per cent lysis rate of demineralised bone graft led us to refrain from using such bone material in the fabrication of 3D implants, despite the better re-modelling prognosis. The CT results indicate that native bone exhibits greater strength during the installation and a lower risk of lysis, however, it also demonstrates a reduced capacity for re-modelling.

Although autograft represents the "gold standard" for repairing bone defects, in clinical practice encountered are bone defects that exceed 30 to 40 cm^3 and are regarded unsuitable for autografting due to the potential trauma to the donor area in this category of patients. Furthermore, patients with type 2 diabetes mellitus as a rule exhibit an elevated BMI, which mainstreams the strength of bone tissue in general and the implants used in particular.

In cases of extensive defects of the hindfoot bones, the use of bilocal replacement according to Ilizarov represents a potential solution, However, the midfoot defects still pose a challenge for orthopaedic practitioners. This prompts to seek out novel methods of replacement. It is our contention that the utilisation of allografts represents a methodology of choice, and as it is evidenced by the histological examination, the replacement of allograft bone with bone tissue and the subsequent growth of vessels into the implanted fragment signifies the potential for further research and the sustained implementation of this method.

In spite of the good results in the replacement of bone defects of the midfoot, the authors associate the percentage of unsatisfactory results in patients with hindfoot lesions with high axial loads on the implant in patients with increased BMI, which, in conditions of incomplete fusion and reconstruction of the implant, leads to its crushing and deformation recurrence. Further study is required regarding this situation in order to address the lack of established protocols for increasing the load on the operated limb and to investigate the risk factors for implant destruction in patients with Charcot arthropathy.

Conclusion

The utilisation of 3D allografts provides a solution to the issue of restoration total bone defects in Charcot osteoarthropathy, not only at the level of individual bones, but also across the entire segments of the foot while enabling the precise replication of the intricate contours of a complex geometry. The proposed method of restoration bone defects in Charcot arthropathy has been demonstrated to be sustainable and enabling the successful filling of extensive bone defects without complications and the staged compression throughout the entire fixation period, while minimising the risk of implant damage.

The positive outcomes yielded by the substitution of the midfoot and hindfoot substantiate the viability of the proposed methodology. The percentage of unsatisfactory outcomes in patients with hindfoot defects and elevated BMI calls for a caution in the application of this technique in addressing total bone defects and strikes the necessity for a comprehensive investigation into the risk factors associated with the failure of this approach and the formulation of rehabilitation protocols.

Author contributions L.V., A.N. and S.O. conceived the study. S.T. and V.P. developed the theoretical framework. S.O. and V.O. performed the surgical procedures. V.V. aided in the analysis. V.K. supervised the project. All authors discussed the results and contributed to the final manuscript.S.T. and G.Z. contributed to the final version of the manuscript and supervised the project. V.B. and E.K. contributed to the interpretation of the results. V.V. and V.K. planned the follow-up and carried out the follow-up. D.B. took the lead in writing the manuscript. All authors provided critical feedback and helped shape the research, analysis and manuscript.

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Data availability No datasets were generated or analysed during the current study.

Declarations

Consent to participate Written informed consent was obtained from patients for their participation in the study.

Consent for publication Written informed consent was obtained from patients for their anonymized data to be published in this article.

Competing interests The authors declare no competing interests.

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Authors and Affiliations

Stanislav Osnach[1] · Victor Protsko[1] · Vladimir Obolenskiy[2] · Larisa Volova[3] · Aikush Nazaryan[3] · Vadim Bregovsky[4] · Elena Komelyagina[5] · Vladimir Vinogradov[6] · Vasiliy Kuznetsov[1] · Georgy Zayratiants[1] · Sargon Tamoev[1] · Dmitrii Bobrov[7]

✉ Dmitrii Bobrov
dr.bobroff@gmail.com

Stanislav Osnach
stas-osnach@yandex.ru

Victor Protsko
89035586679@mail.ru

Vladimir Obolenskiy
gkb13@mail.ru

Larisa Volova
csrl.sam@mail.ru

Aikush Nazaryan
a.k.nazaryan@samsmu.ru

Vadim Bregovsky
dfoot.tdc@gmail.com

Elena Komelyagina
komelelena@yandex.ru

Vladimir Vinogradov
vovavin15@gmail.com

Vasiliy Kuznetsov
vkuznecovniito@gmail.com

Georgy Zayratiants
goshaz@mail.ru

Sargon Tamoev
sargonik@mail.ru

1 S.S. Yudin City Clinical Hospital of the Moscow City Health Department, Moscow, Russian Federation

2 City Clinical Hospital No. 13 of Moscow, Moscow, Russian Federation

3 Samara State Medical University, Samara, Russian Federation

4 City Consultative and Diagnostic Centre No. 1, Saint-Petersburg, Russian Federation

5 State Budgetary Healthcare Institution “Endocrinological dispensary”, Moscow, Russian Federation

6 Peoples’ Friendship University of Russia, Moscow, Russian Federation

7 Sechenov University, Moscow, Russian Federation