Patient-specific three-dimensional printed hemi talar prostheses for the treatment of talar osteonecrosis, case report and literature review

Jorge Javier Del Vecchio1,2, Lucas Nicolás Chemes1, Luciano Bertolotti3, Mauricio Esteban Ghioldi1, Eric Daniel Dealbera1, Marcos Galli Serra4 and Walter Parizzia4

Abstract
We present the case of a 43-year-old boy who presented with progressive pain as a result of history of lateral avascular necrosis of the talus secondary to traumatic open ankle luxation 20 years ago. Conservative treatment (12-month period) prior to surgery failed. It consisted of physiokinetic treatment, insoles and analgesic medication. A diagnostic injection was used in the ankle (positive) and subtalar joint (negative) in order to recognize origin of pain. Hemilateral avascular necrosis of the talus is rare. There are no prior reported cases of the use of hemi-implants. This case highlights the potential use of a patient-specific three-dimensional printed Ti6Al4V prosthesis presented in a complex scenario.

Keywords
Orthopaedics, rehabilitation, occupational therapy, talus, three-dimensional printing, hemi-prosthesis

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Introduction
Avascular necrosis (AVN) or osteonecrosis (ON) of the talus presents a treatment challenge to foot and ankle surgeons.1,2 Although ankle arthrodesis continues to be a valid procedure, it eliminates ankle motion and pseudarthrosis may happen.2–4 Reconstruction options that preserves motion has been described through a diversity of procedures counting core decompression,1,5,6 vascularized pedicle bone grafting from the cuboid,7 vascularized cuneiform bone flap and autograft,8 ankle cartilage allograft replacement,4,9–11 autograft bone cancellous grafting with/without tissue transfer12 and three-dimensional (3D) printed titanium cages.13 Also, in order to maintain mobility, some authors published their results using a total talar replacement such as alumina ceramic prosthesis,14 stainless-steel talar body prosthesis15 and nickel-plated cobalt implants.16

Fixation procedures may include utilization of fibula for tibiotalocalcaneal arthrodesis,17,18 tibiocalcaneal arthrodesis with a porous tantalum spacer19 and hindfoot fusion.20

The 3D printing – also called additive manufacturing – is the procedure of designing a preordained item or article via correct placement of materials in a layer-by-layer pattern. Additive manufacturing can build infinite structures with a multiplicity of materials, including plastics, metals, and living cells if necessary.21,22
This case report describes successful and rewarding reconstruction and consequent limb reconstruction procedure through the utilization of a patient-specific 3D printed Ti6Al4V ELI PER ASTM F3001 hemi-prosthesis to change a hemilateral AVN, thus preserving ankle joint.

Case report

Written informed consent was obtained from the patient for their anonymized information to be published in this article. Our institution does not require ethical approval for reporting individual cases. No permission was needed to reproduce any figures in this case report. A 43-year-old male patient presented with a talar AVN associated with progressive pain as a result of a traumatic open ankle dislocation 20 years earlier. The wound was laterally based and moderately contaminated. The patient initially underwent deep debridement and continuous irrigation of the open wound. Finally, he was stabilized with plaster and completed treatment with intravenous antibiotic for 2 weeks. The patient presented an AVN Irwin grade I4 (Chart 1): segmental articular deficit isolated to either a talar portion; subtype B: AVN deep to the articular segment (Figures 1 and 2). A percutaneous bone biopsy was made in order to confirm the AVN diagnosis (Figure 3). Conservative treatment (12-month period) prior to surgery failed. It consisted of physiokinetic treatment, insoles, and analgesic medication. A diagnostic injection was done in the ankle (Result positive 3/3) and subtalar joint (Result positive 2/3) to recognize origin of pain.

The use of patient-specific 3D printed Ti6Al4V ELI PER ASTM F3001 prosthesis with standard screws was deliberated with the patient. A computed tomography (CT) scan slices of 1 mm in all planes of the left ankle were collected and sent to medical application for processing and producing the implant. The manufacturer was Biotrom SA (Argentina);
3D printing vendor: Protolabs (Munich, Germany). The cost of the prosthesis was US$2498. The information was saved into a software (Mimics 11; Materialize®, Belgium) that allowed for 3D handling of the bones and articulations (Figure 4).

Then, fibular and tibial plafond osteotomy was made to allow correct visualization (not done to correct ankle malalignment) of the lateral region of the talus. When lateral portion of the talus was resected, it showed macroscopic signs of AVN (Figure 5). The Ti6Al4V prosthesis was implanted with a matching less than 1 mm (Figures 6 and 7) and subtal arthrodesis (evident subtal chondral lesion was seen under direct vision) was added to correct varus hindfoot.

Postoperatively, the patient continued non-weightbearing with a plaster for 8 weeks followed by 2 weeks of controlled weightbearing in a walker boot. He then changed to full weightbearing for 2 weeks. Weightbearing was allowed prior to full CT consolidation. By 4 months, CT showed complete bone integration. X-rays and CT scan showed successful bone integration (Figure 8).

At final follow-up (18 months), the patient showed improvement in different scores: foot and ankle ability measure (FAAM) activities of daily living (AVD) improved as 22.62 points (range: 38.09–60.71), FAMM sports enhanced as 35.71 points (range: 28.57–64.28), and the visual analogue scale (VAS) improved 6 points (range: 9–3).

**Discussion**

Treatment of AVN of talus has proven problematic for orthopaedic surgeons. According to some authors, a lengthy period of non-surgical treatment, including non-weightbearing combined with extracorporeal shock wave therapy (ESWT), followed by surgical treatment may be the best option.1,5 Gross et al. recommend – weak evidence – core decompression or bone grafting in patients with Ficat grades I to III, and arthrodesis may become an excellent revision procedure.1 According to some authors, core decompression continues to be a valid treatment for AVN at initial stages.

Although autografting may be a valid alternative for some authors,25 it has major inconveniences such as donor site morbidity and finite quantity,12 besides the difficulty to reproduce the anatomical structure in the receptor region. In the case presented this option was not viable because of the size needed.
Allografts are also likely limited in size and are less osteogenic with higher risk of malunion/non-union. Also, they may carry the abstract risk of infection transmission. Moreover, allograft has showed delayed failure leading to structural deterioration and can be limited by the ability to accurately arrive to the ideal configuration for limb salvage surgery. According to other authors, factors not found to be statistically different between the success group and the failure group were the time from death of the donor to transplantation, the donor’s age, the thickness of the both (ankle joint) allografts, and the postoperative alignment. Innovation technology, such as 3D printing, may arrange many of the problems of total or hemi allograft transplant.

Although ankle arthrodesis continues to be the gold standard, implicit long-term difficulties are related to this alternative. Recently, some authors showed the results of the utilization of fibula for tibio-talo-calcaneal (TTC) fusion (union rate near 85%) and tibiocalcaneal arthrodesis with a porous tantalum spacer. According to authors, this treatment offers a reliable option for complex salvage patients.

Fresh osteochondral allograft (OCA) can be used as a treatment option without excluding subsequent salvage surgeries such as repeat allograft transplantation, ankle arthrodesis or conversion to total ankle arthroplasty. The OCA viability must be defined and supported by the role of immunosuppression, thus confirmed by new studies. According to some authors, the high reoperation rate (2/17) and failure rate (5/17) must be taken into consideration and represent an option for young patients with advanced damage to the ankle. Post-implantation limb alignment, optimal host-graft size matching and fit, and meticulous transplantation technique.
have been shown to enhance results. Other factors such as the optimal graft thickness, duration of post-implantation non-weightbearing status, and histocompatibility matching are not clear enough, and this continues to explain the high complication rate shown in previous clinical studies.\textsuperscript{11,34,35} In a recent systematic review, Johnson and Lee showed a 13\%–42\% incidence of complications associated with cartilage allograft implantation. Although it persists as a good
treatment option, both authors showed that the overall quality of the existing studies is relatively insufficient and they recommend the design of randomized controlled trials (RCT) and prospective cohort studies in order to focus on better understanding indications and evolution of OCA.10

Nunley and Hamid showed their results during the treatment of 13 patients with talar ON and managed with vascularized pedicle bone grafting from the cuboid. The two patients who went on revision surgery with a total ankle arthroplasty were considered to have treatment failure and did not complete a postoperative questionnaire as it was non-contributory to an as-treated analysis.7

Recently, some authors published their results using different total talar replacement.14-16 The overall survival rate varies from 85% to 100%. Although this kind of procedures seems to be technically easy to perform, it does not allow too many options in case of revision surgery. The main indication would be a massive talar AVN, which was not the case presented.

The adaptability of 3D printing with regard to size, structure and biocompatible materials endures an interesting alternative for the treatment of segmental and cavitary defects in the distal tibia, ankle and foot as well.21

Conclusion
The adaption of a patient-specific 3D printed Ti6Al4V prosthesis contributed to a successful reconstructive procedure in a case of substantial hemilateral talar bone loss. Additive manufacturing prosthesis can evade the complications and disadvantages of autografts, allografts and arthrodesis procedures. Moreover, costs of 3D printers as well as implantable metallic biomaterials are decreasing their cost due to the demand of the health market and thus increase accessibility. New studies are needed to assess delayed complications such as implant failure and stress shielding, among others.

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ORCID iD
Jorge Javier Del Vecchio https://orcid.org/0000-0001-5263-7626

References
1. Gross CE, Haughom B, Chahal J, et al. Treatments for avascular necrosis of the talus: a systematic review. Foot Ankle Spec 2014; 7(5): 387–397
2. Tenenbaum S, Stockton KG, Bariteau JT, et al. Salvage of avascular necrosis of the talus by combined ankle and hindfoot arthrodesis without structural bone graft. Foot Ankle Int 2015; 36(3): 282–287
3. Dennison MG, Pool RD, Simonis RB, et al. Tibiocalcaneal fusion for avascular necrosis of the talus. J Bone Joint Surg Br 2001; 83(2): 199–203
4. Irwin TA, Kou JX and Fortin PT. Classification and treatment of severe ankle articular segment deficits: osteochondral allograft reconstruction. Foot Ankle Clin 2007; 12(1): 41–55
5. Dhillon MS, Rana B, Panda I, et al. Management options in avascular necrosis of talus. Indian J Orthop 2018; 52(3): 284–296.
6. Mont MA, Schon LC, Hungerford MW, et al. A vascular necrosis of the talus treated by core decompression. J Bone Joint Surg Br 1996; 78(5): 827–830
7. Nunley JA and Hamid KS. Vascularized pedicle bone-grafting from the cuboid for talar osteonecrosis: results of a novel salvage procedure. J Bone Joint Surg Am; 99(10): 848–854.
8. Yu XG, Zhao DW, Sun Q, et al. Treatment of non-traumatic avascular talar necrosis by transposition of vascularized cuneiform bone flap plus iliac cancellous bone grafting. Zhonghua Yi Xue Za Zhi 2010; 90(15): 1035–1038.
9. Haene R, Qamirani E, Story RA, et al. Intermediate outcomes of fresh talar osteochondral allografts for treatment of large osteochondral lesions of the talus. J Bone Joint Surg Am 2012; 94(12): 1105–1110
10. Johnson P and Lee DK. Evidence-based rationale for ankle cartilage allograft replacement: a systematic review of clinical outcomes. J Foot Ankle Surg 2015; 54(5): 940–943.
11. Winters BS and Raikin SM. The use of allograft in joint-preserving surgery for ankle osteochondral lesions and osteoarthritis. Foot Ankle Clin 2013; 18(3): 529–542
12. Boone DW. Complications of iliac crest graft and bone grafting alternatives in foot and ankle surgery. Foot Ankle Clin 2003; 8(1): 1–14.
13. Dekker TJ, Steele JR, Federer AE, et al. Use of patient-specific 3D-printed titanium implants for complex foot and ankle limb salvage, deformity correction, and arthrodesis procedures. Foot Ankle Int 2018; 39(8): 916–921
14. Taniguchi A, Takakura Y, Tanaka Y, et al. An alumina ceramic total talar prosthesis for osteonecrosis of the talus. J Bone Joint Surg Am 2015; 97(16): 1348–1353
15. Hamroongroj T and Hamroongroj T. The talar body prosthesis: results at ten to thirty-six years of follow-up. J Bone Joint Surg Am 2014; 96(14): 1211–1218.
16. Tracey J, Arora D, Gross CE, et al. Custom 3D-printed total talar prostheses restore normal joint anatomy throughout the hindfoot. *Foot Ankle Spec* 2018; 1: 1938640018762567.

17. Roukis TS and Kang RB. Vascularized pedicled fibula onlay bone graft augmentation for complicated tibiotalocalcaneal arthrodesis with retrograde intramedullary nail fixation: a case series. *J Foot Ankle Surg* 2016; 55(4): 857–867.

18. Watanabe K, Teramoto A, Kobayashi T, et al. Tibio-talo-calcaneal arthrodesis using a soft tissue-preserved fibular graft for treatment of large bone defects in the ankle. *Foot Ankle Int* 2017; 38(6): 671–676.

19. Cohen MM and Kazak M. Tibiocalcaneal arthrodesis with a porous tantalum spacer and locked intramedullary nail for post-traumatic global avascular necrosis of the talus. *J Foot Ankle Surg* 2015; 54: 1172–1177.

20. Urquhart MW, Mont MA, Michelson JD, et al. Osteonecrosis of the talus: treatment by hindfoot fusion. *Foot Ankle Int* 1996; 17(5): 275–282.

21. Hamid KS, Parekh SG and Adams SB. Salvage of severe foot and ankle trauma with a 3D printed scaffold. *Foot Ankle Int* 2016; 37(4): 433–439.

22. Michalski MH and Ross JS. The shape of things to come: 3D printing in medicine. *JAMA* 2014; 312(21): 2213–2214.

23. Martin RL, Irrgang JJ, Burdett RG, et al. Evidence of validity for the foot and ankle ability measure (FAAM). *Foot Ankle Int* 2005; 26(11): 968–983.

24. Arlet J and Ficat P. Non-traumatic avascular femur head necrosis. *Chir Narzadow Ruchu Ortop Pol* 1977; 42(3): 269–276.

25. DeOrio JK and Farber DC. Morbidity associated with anterior iliac crest bone grafting in foot and ankle surgery. *Foot Ankle Int* 2005; 26(2): 147–151.

26. Bouchard M, Barker LG and Claridge RJ. Technique tip: tantalum: a structural bone graft option for foot and ankle surgery. *Foot Ankle Int* 2004; 25(1): 39–42.

27. McGarvey WC and Braly WG. Bone graft in hindfoot arthrodesis: allograft vs autograft. *Orthopedics* 1996; 19(5): 389–394.

28. Conti SF and Wong YS. Osteolysis of structural autograft after calcaneocuboid distraction arthrodesis for stage II posterior tibial tendon dysfunction. *Foot Ankle Int* 2002; 23(6): 521–529.

29. Jeng CL and Myerson MS. Allograft total ankle replacement: a dead ringer to the natural joint. *Foot Ankle Clin* 2008; 13(3): 539–547.

30. Jeng CL, Kadakia A, White KL, et al. Fresh osteochondral total ankle allograft transplantation for the treatment of ankle arthritis. *Foot Ankle Int* 2008; 29(6): 554–560.

31. Devries JG, Philbin TM and Hyer CF. Retrograde intramedullary nail arthrodesis for avascular necrosis of the talus. *Foot Ankle Int* 2010; 31(11): 965–972.

32. Kitaoka HB and Patzer GL. Arthrodesis for the treatment of arthrosis of the ankle and osteonecrosis of the talus. *J Bone Joint Surg Am* 1998; 80: 370–379.

33. Adams SB Jr, Viens NA, Easley ME, et al. Midterm results of osteochondral lesions of the talar shoulder treated with fresh osteochondral allograft transplantation. *J Bone Joint Surg Am* 2011; 93(7): 648–654.

34. Bugbee WD, Khanna G, Cavallo M, et al. Bipolar fresh osteochondral allografting of the tibiotalar joint. *J Bone Joint Surg Am* 2013; 95(5): 426–432.

35. Gaul F, Barr CR, McCauley JC, et al. Outcomes of salvage arthrodesis and arthroplasty for failed osteochondral allograft transplantation of the ankle. *Foot Ankle Int* 2019; 40(5): 537–544.