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Multicenter Study [Foot Ankle Int.](#) 2024 Nov;45(11):1258-1265.

doi: 10.1177/10711007241278947. Epub 2024 Oct 27.

Initial Safety of Total Talus Replacement Used to Treat Talar Avascular Necrosis

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PMID: 39462286 DOI: [10.1177/10711007241278947](#)

Abstract

Background: Total talus replacement (TTR) implants are designed to replace the diseased talar anatomy, reduce pain, maintain ankle range of motion, and restore ankle function after conservative treatments have failed. Currently TTR implants are produced by 3D printing a patient-specific implant designed from the patient's preoperative anatomy. TTR surgery using patient-specific implants is a relatively new technique that remains understudied in the literature. Therefore, the purpose of this investigation was to determine the early safety and potential benefit of the TTR implant in patients with talar avascular necrosis.

Methods: This retrospective, multicenter, cohort study evaluates the safety and potential benefits of TTR using 3D-printed patient-specific implants across 4 US centers. The primary outcome was the occurrence of early adverse events after TTR surgery. Secondary outcomes including, pain, and physical function were assessed using the pain visual analog scale (VAS), and Patient-Reported Outcomes Measurement Information System (PROMIS) physical function (PF), respectively.

Results: The study team analyzed 15 patients with more than 1 year of follow-up. The mean duration of follow-up was 25.9 months (range: 18.3-41 months). Although 33.3% (5 of 15) of patients experienced adverse events, primarily occurring within the initial 6 months postoperatively, 93% (14 of 15) of patients reported implant survivorship. Of the 5 cases (33.3%) resulting in an adverse event, 3 (60.0%) were determined to be unrelated to the subject device, 2 (40.0%) were determined to be possibly procedure-related, and none (0%) were determined to be device-related.

Conclusion: Although further studies are needed to compare TTR with the standard of care, the results of this study demonstrate the relative early safety of TTR surgery using a 3D-printed implant for the treatment of challenging talar pathologies. A larger and longer clinical study is required to see if the efficacy of this approach will be statistically and clinically meaningful.

Keywords: 3D printing; avascular necrosis; outcome studies; patient specific implant; safety; statistical analysis; total talus replacement; trauma.

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