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Total Talus Replacements

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Abstract

Background: Total talus replacements are a surgical treatment for talar avascular necrosis (AVN) replacing the entire talus. The potential for total talus replacements has increased with the advent of patient-specific implants using 3D printing based on computed tomographic scanning of the ipsilateral or contralateral talus. The primary aim of this review is to summarize the literature on total talus replacements, providing a historical survey, indications, controversies, complications, survival, and functional outcomes.

Methods: A systematic review was performed. Articles with survival of total talus replacements were included. Basic percentages and a critical review of the literature was performed.

Results: Nine articles with 115 patients were included. The mean age ranged from 27.6 to 72 years, but with 5 studies having a mean age of <50 years. Mean follow-up ranged from 12.8 to 152 months. The most common indication was avascular necrosis in 67 patients (58%). Five studies used customized implants and 4 studies used 3D printing. Four studies used ceramic prostheses, 3 cobalt chromium, 1 stainless steel, and 1 titanium with ceramic surface. Three studies involved a talus replacement in conjunction with an ankle replacement. Postoperative complications ranged from 0% to 33%. Of 24 functional outcomes scores, 66.7% demonstrated significant improvement.

Conclusion: Total talus replacements are a promising alternative to tibiotalocalcaneal fusion for patients with avascular necrosis of the talus; however, further studies are required to ensure reliable outcomes prior to widespread adoption of this technology.

Level of Evidence: Level IV, review of case series.

Keywords: total talus replacement, talus avascular necrosis, osteonecrosis, tibiotalocalcaneal

Introduction

Replacing part or all of the talus with a customized prosthesis has been developed for the treatment of a range of pathologies affecting the talus, but principally avascular necrosis (AVN) or osteonecrosis following trauma, medications, autoimmune conditions, and tumors.[12,18]

The talus is a complex bone with a unique shape and blood supply. The surface of the talus is composed of more than 60% cartilage and has minimal soft tissue attachments for arterial supply. This combination of factors leads to the risk of AVN from several pathologies including fractures of the talar neck.[4,7]

Nonoperative treatment options for talar AVN are limited. These include activity modification, protected weightbearing and bracing, potential pharmacologic treatments, and even shockwave therapy has been proposed for earlier stages of the disease process.[4] Historically, the mainstay of surgery for talar AVN has been either a tibiotalocalcaneal

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(TTC) fusion using bulk allograft or tibiocalcaneal fusion with talar excision, often in conjunction with a limb-lengthening procedure. Although there are studies that report TTC fusion as having an improvement in functional scores,[4,15] these procedures can be surgically challenging, with varied functional outcomes and high rates of reported nonunion and reoperation.[4,14,15]

The first talar replacement prostheses were implanted in 1974 in Thailand.[6] Harnroongroj designed a partial replacement of the body of the talus using slit scanogram measurements from plain radiographs and manufactured with 316L stainless steel. A last was created and fashioned to replace the body of the talus that was fixed to the neck of the talus with a tapered peg with or without bone cement, through a transmalleolar approach. Sixteen patients, 12 with AVN and 4 following crush fractures to the body, were followed up for a mean of nearly 9 years. Two were revised and the remainder reported satisfactory outcomes. The same author modified the peg and reported on a larger series of 34 implants, including 2 tumors, in 2014. Fifteen percent of these prostheses were revised for failure (nonunion, collapse, tumor recurrence, or infection), a further prosthesis, or a transtibial amputation.[5,6] They later reported good AOFAS ankle-hindfoot scores up to 36 years.[5] Tanaka's group in Japan developed an alumina ceramic talar body replacement from computed tomographic (CT) images.[18] In the first generation, they included a peg to fix into the neck of the talus, but this was subsequently removed after all of the first-generation prostheses loosened and the remaining talus necrosed. The second generation fared little better, and in 2012, they concluded that those patients who had been converted to a total talus replacement (TTR) appeared to fare best.[18]

The proposed advantages of talar replacement over fusion include preservation of joint mobility, limb length, and a shorter period of weightbearing restrictions, and the potential to delay the need for fusion surgery.[11,20] However, the outcomes of talar replacements are still in their infancy and quite heterogeneous with partial and total talar replacements, and those linked to an ankle replacement above, which makes a systematic review very challenging. In this article, we attempt to consolidate the literature and provide a contemporaneous review focusing on TTRs. Although partial talar replacements are an important subject, they will not form part of this review.

Methods

A systematic review was undertaken using all levels of evidence and following PRISMA guidelines. PubMed, Embase, CINAHL, and Cochrane reviews were searched for relevant studies. The search terms used were a combination of (total talus) and (talus arthroplasty). All were cross-referenced for additional citations. This resulted in 556 articles whose titles were reviewed. Following this, 200 relevant abstracts were reviewed, which resulted in 135 full articles being reviewed by 2 authors independently. Articles published by the same author were reviewed to ensure that there was no overlap between study participants. Nine articles met the inclusion criteria to be included in the final analysis (Figure 1). Because of the heterogeneity of the articles selected, it was inappropriate to consider performing a meta-analysis.

Eligibility Criteria

The inclusion criteria were (1) TTR, (2) at least 3 patients, (3) a mean follow-up of >1 year, and (4) English language. The exclusion criterion was partial talar prosthesis.

Data Extraction

Two reviewers independently reviewed all articles. Data were extracted and recorded on Microsoft Excel using a standardized proforma. If there were any disagreements, then the senior author reviewed the data and came to a final decision. Data collected included demographic data, surgical technique, technique for producing the implant, postoperation complications, functional outcomes, and survival.

Statistical Analysis

Statistical analysis was undertaken using Stata, version 15. Basic percentages were calculated. Study bias was assessed using the MINORS criteria.[17] This is designed with 8 points that are scored as 2 for reported or adequate, 1 reported but inadequate, 0 not reported. This gives a total score of 16 for noncomparative studies.

Results

In total, 115 patients from 9 studies were included that analyzed TTRs (Figure 1). Six studies with 80 patients used a TTR alone and 3 studies with 35 patients combined TTRs with a tibial prosthesis of an ankle replacement above. All but 1 of the studies was a case series, and the majority lacked long-term follow-up.

There was a high risk of bias using the MINORS criteria.[17] Only 4 studies clearly documented that the study involved consecutive patients, only 2 studies were prospective, 3 recorded losses to follow-up, and no studies calculated a sample size. The articles were found to have a high degree of variability in indications, implants, techniques, follow-up, and outcomes. Therefore, it was decided that pooling the data would lead to incorrect conclusions, and therefore no further statistical analysis was performed.

Four studies were published from Japan, 3 from the USA, 1 from Thailand, and 1 from South Africa. Three of

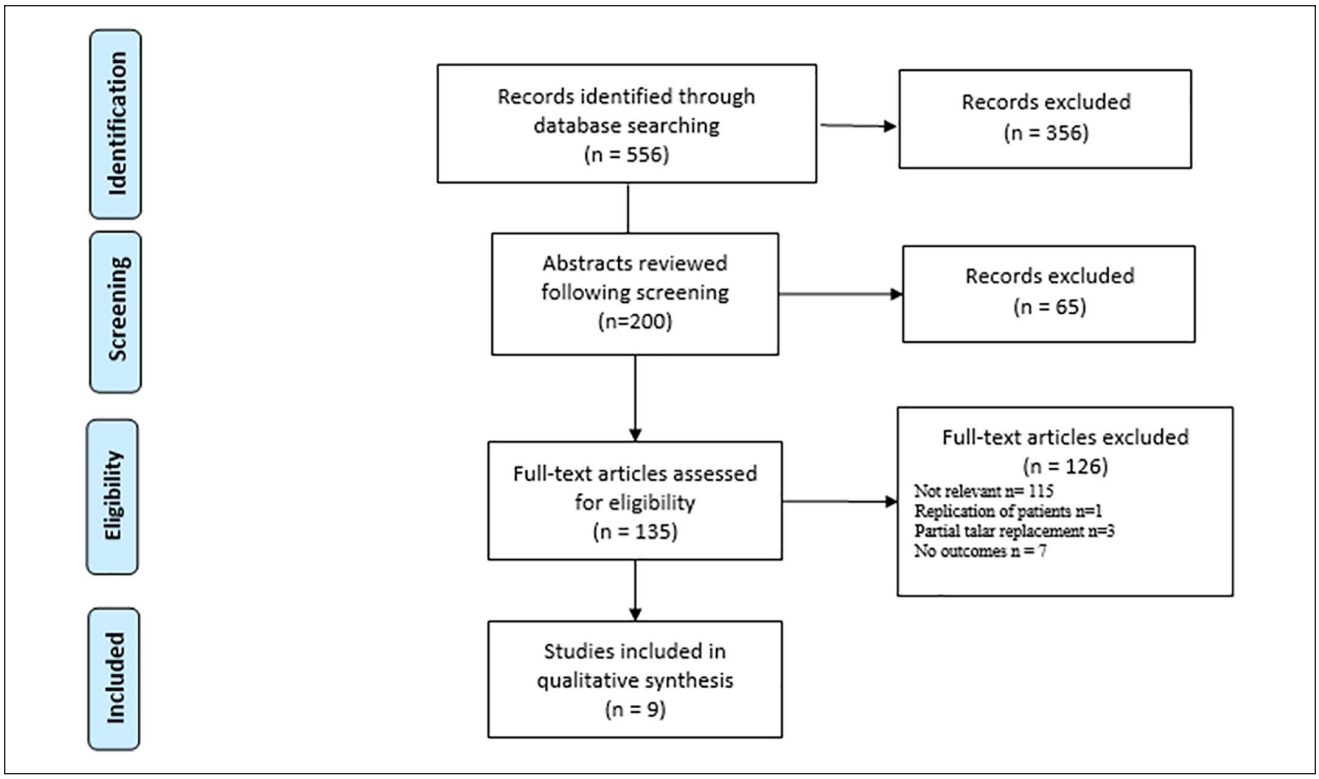

Figure 1. PRISMA diagram for literature search.

Table 1. Included Studies and Demographics.

Author	Country	Number	Age, y, Mean (Range)	Sex, Female (%)	Follow-up, mo, Mean (Range)	Tibial Component of TAR
Morita et al[13]	Japan	19	63	94.4	152 (138-160)	No
Angthong and Rajbhandari[2]	Thailand	5	27.6 (18-49)	Unknown	17.8	No
Kadakia et al[9]	USA	27	44 (20-69)	21 (77.8)	22.2	No
Abramson et al[1]	South Africa	8	46 (23-71)	4 (50)	23.1	No
Katsui et al[11]	Japan	6	40.3 (19-59)	1 (16.7)	46.8	No
Scott et al[16]	USA	15	45 (20-69)	9 (60)	12.8	No
West[23]	USA	3	69.2	1 (33)	13.7	STAR
Kanzaki et al[10]	Japan	22	72 (62-80)	15 (68.2)	34.9	TNK ankle
Kurokawa et al[12]	Japan	10	71 (61-82)	8 (80)	58	TNK ankle

Abbreviation: TAR, total ankle replacement.

the studies from Japan came from the same institute. The mean age in the studies ranged from 27.6 to 72, with 5 of the 9 studies having a mean age of less than 50 years. Mean follow-up ranged from 12.8 to 152 months (Table 1).

Surgical Implants and Technique

The indication for surgery was avascular necrosis in 67 (58%) patients, due to osteoarthritis in 29 (25%), 10 (9%) due to trauma, 3 (<3%) due to tumors, and 3 (<3%) rheumatoid arthritis. In 3 (<3%) patients, the indication was unknown. All studies used an anterior surgical approach. Four studies used 3D printing and 5 used customized implants. Three studies reported on TTR linked to an ankle replacement.

There was variation in the prosthetic materials used. Four studies used ceramic prostheses and 3 cobalt chromium—of which 1 had a titanium nitride coating, 1 used stainless steel, and 1 used titanium with a ceramic surface. Only 3 studies clearly recorded concomitant procedures at the time of surgery (Table 2). We have separated our review into TTR only and TTR linked to a TAR.

Table 2. Surgical Technique and Adjuvant Procedures.

Author	N	Indication	Implant	Material	Ankle replacement	Approach	Adjuvant procedures
Morita et al[13]	19	Idiopathic osteonecrosis	Custom-made prosthesis	Alumina ceramic	No	Anterior	
Angthong and Rajbhandari[2]	5	2 total talar loss due injury, 1 AVN, 2 giant cell tumor	Customized based on CT of contralateral talus	Stainless steel 4, titanium 1	No	Anterior	2 lateral ligament reconstruction and 1 tibialis anterior transfer/deltoid repair
Kadakia et al[9]	27	AVN	Customized 3D-printed CT (ipsilateral if no collapse or contralateral)	Cobalt chromium ± titanium nitride coating	No	Anterior	Not documented
Abramson et al[1]	8	2 trauma, 4 posttrauma AVN, 2 tumors	Customized 3D-printed (contralateral talus)	Titanium with ceramic surface treatment for a titanium oxide surface layer	No	Anterior approach for trauma and AVN. Dual approach for tumors	Not documented
West and Rush[23]	3	AVN	Custom 3D printed from CT scan of contralateral talus	Cobalt chromium	Yes	Anterior	All subtalar arthrodesis 1 lateral ligament stabilization + first MT osteotomy
Katsui et al[11]	6	Trauma	Custom-made prosthesis	Ceramic	No	Anterior	Not documented
Scott et al[16]	15	AVN (5 trauma, 2 chemotherapy, 1 stress fracture, 7 idiopathic)	Custom 3D printed from CT scan of contralateral talus	Cobalt chromium	No	Anterior	3 patients with TA lengthening, 1 with FDL transfer, and 1 with a tibial nail
Kanzaki et al[10]	22	19 OA (14 with subtalar OA, 2 with talar cyst, 9 with flatter talus, 1 with talar osteonecrosis), 3 RA	Custom-made prosthesis based on CT scan of contralateral talus	Alumina ceramic	TNK ankle	Anterior	Not documented
Kurokawa et al[12]	10	End-stage ankle arthritis, severe collapse, or with a large cyst in the talus	Custom-made prosthesis based on CT scan	Alumina ceramic	TNK ankle	Anterior	Not documented

Abbreviations: AVN, avascular necrosis; CT, computed tomography; FDT, flexor digitorum longus; MT, metatarsal; OA, osteoarthritis; RA, rheumatoid arthritis; TA, Achilles tendon.

Table 3. Functional Scores in Total Talus Replacements.

Author	Number	Functional Score	Preoperation	Postoperation	Significance
Morita et al[13]	19	JSSF total score	58	97	Significant
		JSSF pain	20	40	Significant
		JSSF function	28	47	Significant
		JSSF alignment	10	10	Not significant
		AOS pain	6.0	0.3	Significant
		AOS function	6.3	0.4	Significant
Angthong and Rajbhandari[2]	5	VAS	42.83	82.37	Not significant
		SF-36	69.95	83.38	Not significant
Kadakia et al[9]	15	VAS	7.1	3.9	Significant
		FAOS pain	47.7	78.2	Significant
		FAOS symptoms	47.7	71.3	Significant
		FAOS ADLs	56.3	87.6	Significant
		FAOS QoL	11.7	51.9	Significant
		FAOS sports	26	42.6	Significant
Abramson et al[1]	8	AOFAS		79.25	Not calculated
		SF-36		83.25	Not calculated
Katsui et al[11]	6	AOFAS		78.8	Not calculated
Scott et al[16]	15 (9)	VAS	7	3.6	Significant
		FAOS pain	43	60	Not significant
		FAOS ADLs	48.4	68.5	Not significant
		FAOS sport/recreation	20	33	Not significant
		FAOS QoL	2.38	31.2	Significant
Kanzaki et al[10]	22	JSSF	50.5	91.5	Significant
		JSSF pain	17.5	35.7	Significant
		JSSF function	28	46	Significant
		JSSF alignment	5	9.7	Significant
Kurokawa et al[12]	10	AOS pain	5.8	2.5	Not calculated
		AOS function	5.5	2.2	Not calculated
		JSSF	44	89	Not calculated
		SAFE-Q	Yes	Yes	All not significant

Abbreviations: ADLs, activities of daily life; AOFAS, American Orthopaedic Foot & Ankle Society ankle-hindfoot scale; AOS, Ankle Osteoarthritis Scale; FAOS, Foot and Ankle Outcome Score; JSSF, Japanese Society for Surgery of the Foot; QoL, quality of life; SAFE-Q, Self-Administered Foot Evaluation Questionnaire; SF-36, 36-Item Short Form Health Survey; VAS, visual analog scale.

TTR

Six studies and 80 patients were reported for TTR alone. Twenty-two different functional scores and subscores were reported, of which 3 did not calculate significance. Thirteen (68.4%) of these showed significant improvement from pre- to postoperation. All the other scores demonstrated a nonsignificant improvement (Table 3).

Morita reported the results of 19 ceramic TTR in 18 patients with a median follow-up of 152 months and showed improved clinical scores from baseline. They reported no failures.[13] The mean BMI of patients in this series, however, was 22.9, and hence the authors were quick to point out that the results in an obese population are unknown. As 4 articles were all from the same group reported at various time points, a decision was taken to use only the data from the most up-to-date article.[11,12,13,19]

Two studies reported pre- and postoperative range of motion (ROM). The study by Kadakia et al[9] found no significant differences in pre- and postoperative dorsiflexion, plantarflexion, and total ROM. Morita et al[13] found an improvement in ROM from 25 to 45 degrees. Three studies analyzed gait. One patient of 5 in the study by Angthong and Rajbhandari[2] had stiffness in the subtalar joint and 1 had limited weightbearing due to pain. Abramson et al[1] found 7 of 8 patients had decreased subtalar ROM and minor gait abnormalities, with 3 also suffering fixed hindfoot varus and 3 discomfort on ankle movement. Katsui et al[11] found 2 of the 6 patients had limited ROM.

Studies reported varied radiologic outcomes. Kadakia et al[9] reported 1 patient with distal tibial AVN and Abramson et al[1] reported 1 of 8 patients with minor tibial wear. Angthong and Rajbhandari[2] did not find any radiologic signs of loosening. Morita et al reported tibiotalar osteophyte

changes in 47% preoperatively and in 90% postoperatively. There was also an increase in periarticular osteophytes affecting the talonavicular joint (63%), but the authors stated that the presence of worsening degenerative changes did not seem to affect their clinical scores.[13]

All studies with TTRs reported low rates of complications. Kadakia et al[9] noted 1 case of distal tibial AVN, 1 superficial infection, and 1 superficial peroneal nerve neuroma. In other studies, only 2 patients underwent nonrevision reoperations, and 4 TTR failed, with 2 requiring a tibial component of an ankle replacement, 1 undergoing revision surgery, and 1 amputation. One patient in the study by Scott et al[16] required an incision and drainage of a wound dehiscence postoperatively. Katsui et al[11] reported that 2 patients required further surgery. One patient developed restricted dorsiflexion and required a posterior release 3 months after surgery followed by Achilles tendon lengthening at 10 months. Arthritis of the tibia progressed and then a tibial replacement was performed. A second patient also developed arthritic changes and required a tibial replacement.[11] A patient in the study by Kadakia developed a superficial personal neuroma that required surgical excision 31 months postoperatively. Additionally, 2 implants failed in this study. One was converted to an intramedullary combination tibial component with a revision total talus. One patient underwent corrective surgery for a cavus deformity 24 months after surgery. Because of persistent pain and deformity following this surgery, the patient underwent a below-knee amputation 31 months after the initial surgery.[9]

The materials and manufacturing of TTR have advanced, and now patient-specific implants are available. Several studies produced TTR using 3D printing based on CT images of the contralateral talus, which has been shown to be an almost exact match.[8,10,20,21] This has the advantage of creating exact joint congruence to distribute joint forces in the same way as the native ankle.[20] The most commonly used total talar implants are alumina ceramic, stainless steel, and cobalt chrome, but more recent trends have turned to titanium nitride as a preferable material to articulate against native articular cartilage[22] (Figure 2).

Figure 2. Total talus replacement implant coated in titanium nitride (image courtesy of Meshworks, Alloyed, Oxford, United Kingdom).

Combined TTR Linked to Ankle Replacement

A further consideration is whether to use the talar implant as an isolated implant or as part of a total ankle replacement (TAR) whereby a tibial tray and polyethylene insert are used to articulate against the TTR in cases where the ankle joint is arthritic. Creating such an articulation clearly introduces the risks of wear and related complications associated with TAR.[3,10,19,23]

Three studies analyzed combined TTR and ankle replacement including 35 patients. Kanzaki et al[10] analyzed 22 patients with a mean follow-up of 34.9 months. The total talus was made from CT images producing a stereolithographic model and an alumina ceramic prosthesis. This was combined with a TNK tibial component (Kyocera, Osaka, Japan). Their indications for surgery were ankle OA with severe talar osteonecrosis or patients with ankle OA with subtalar OA or large talar cyst or flat-top talus, and rheumatoid arthritis with subtalar destructive changes. There was an improvement in dorsiflexion and total ROM, but concerns were raised about less improvement in plantar flexion following surgery.[10] All components of the Japanese Society for Surgery of the Foot (JSSF) score improved following surgery. There were 3 cases of delayed wound healing and 3 medial malleolar fractures, of which 1 occurred intraoperatively. None of these required revision surgery.[10]

Kurokawa et al[12] compared 10 patients with a TTR combined with an ankle replacement against 12 patients with a standard ankle replacement for end-stage arthritis. A TNK tibial component (Kyocera) was used combined with alumina ceramic artificial talus (Kyocera), designed using individualized CT data. The JSSF and Ankle Osteoarthritis Scale scores improved from pre- to postoperative, but significance was not calculated. It was demonstrated that the mean postoperative JSSF score of the TTR and ankle replacement group were significantly higher than the ankle replacement alone group, but there were no differences in Ankle Osteoarthritis Scale scores or SAFE-Q scores. Further surgeries or revisions were not reported.[12]

West and Rush reported on 3 consecutive TTR combined with a tibial component. The TTR was a custom 3D-printed implant based on a CT scan of the contralateral talus. In all cases, the TTR was fused to the calcaneum. Two patients' radiographs did not demonstrate any cystic changes or collapse. One patient who underwent concomitant lateral ankle stabilization, peroneus longus to brevis transfer, plantar release of contracted soft tissue, and dorsal closing-wedge arthrodesis at the first tarsometatarsal joint developed

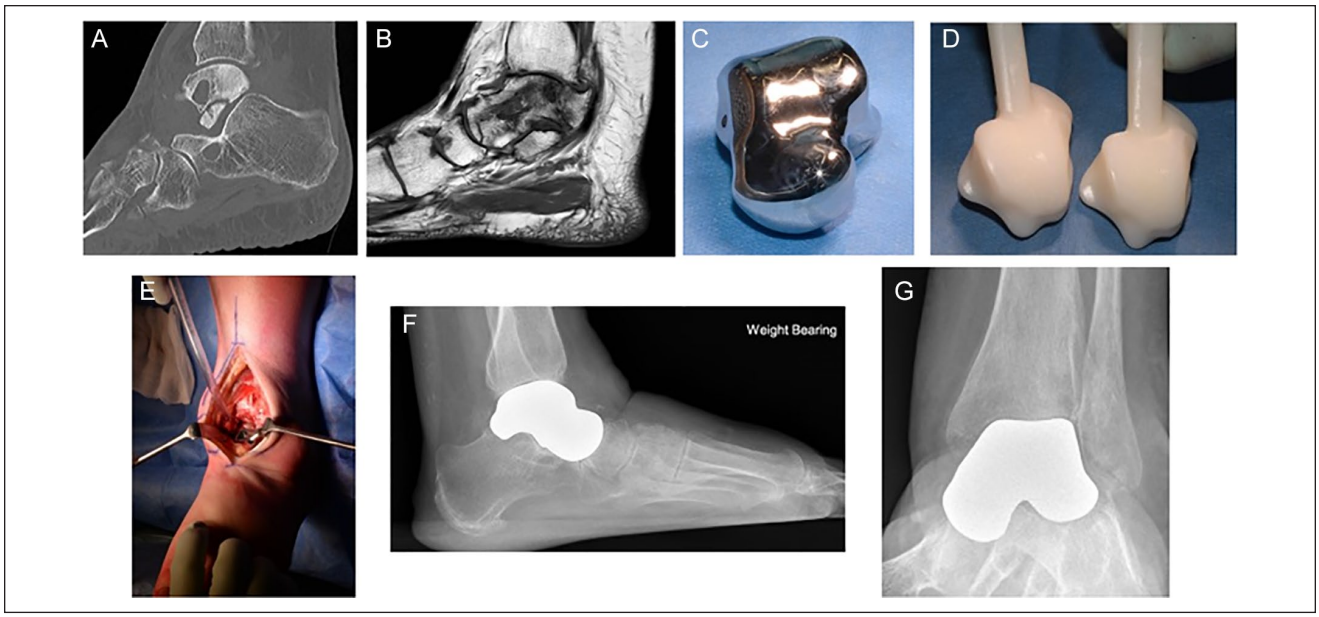

Figure 3. Preoperative (A) computed tomographic scan and (B) magnetic resonance imaging scan demonstrating talar AVN with fragmentation but reasonably preserved articular surfaces. (C) TTR modeled on the contralateral normal talus. (D) TTR trial manufactured from medical-grade plastic. (E) Intraoperative photograph demonstrating anterior approach to the talus and insertion of the TTR. (F) Lateral postoperative radiograph at 3 years. (G) Anteroposterior postoperative radiograph at 3 years. AVN, avascular necrosis; TTR, total talar replacement.

aseptic loosening of the tibial component 1 year postoperatively and required a revision tibial component.[23]

Authors' Preferred Technique

Although Harnroongroj originally used a transmalleolar approach, we favor an anterior approach to the ankle by making an anterior incision and accessing the ankle in the interval between the tendons of extensor hallucis longus and tibialis anterior but extending the incision distally to access the talonavicular joint. In certain circumstances, for example, where there are previous anteromedial incisions, the approach has to be modified. The capsule to both the ankle and the talonavicular joint is divided longitudinally in line with the skin incision. It is crucial not to resect any joint capsule so that the prosthesis is as stable as possible when a sound repair is made of the joint capsule. In order to reset the talus, a saw and osteotomes are used to osteotomize the neck of the talus. Then, much like performing a trapeziectomy, the talus can be resected in a piecemeal manner taking care to sharply dissect all ligaments from their attachments to the talus. The most difficult part of the talus to resect is the ligamentous complex at the sustentaculum tali owing to the scale of ligamentous attachment. Following implantation of the talar prosthesis, areas of impingement in the medial or lateral gutter can be addressed, and possible Achilles tendon lengthening or gastrocnemius recession to address equinus contracture.

Figure 3 illustrates a case of a 55-year-old woman with idiopathic AVN of the entire talus in which, following appropriate informed consent, a TTR was performed. Her quality of life and function were improved and she returned to manual work.

Stability of the implants is often of concern—as the majority of implants do not reattach ligaments. However, in our review of the literature, there were no cases of instability, dislocations, or displacement and similarly in our own experience we have had no cases of instability following TTR. The reason for the lack of instability is uncertain but may relate to the bony congruence of the implant and adjacent joints, as well as scar tissue formed from the pathologic process and the surgery.

In circumstances where the ankle joint is severely arthritic or in cases of a failed TAR where the talus is destroyed, an option to use a TTR in conjunction with a tibial implant of a TAR is available. Because no manufacturers have off-the-shelf solutions for this problem, the solution has to be custom, and this in itself presents significant challenges. In particular, matching the articular surface of the tibial component with the upper surface of the TTR requires matching both in coronal alignment and in axial rotation. In our experience, the custom TTR manufacturers do not have access to the blueprints of the tibial components of the TAR manufacturers, and hence many assumptions need to be made and the surgeon is required to make some "off-label" decisions. In our cases, we

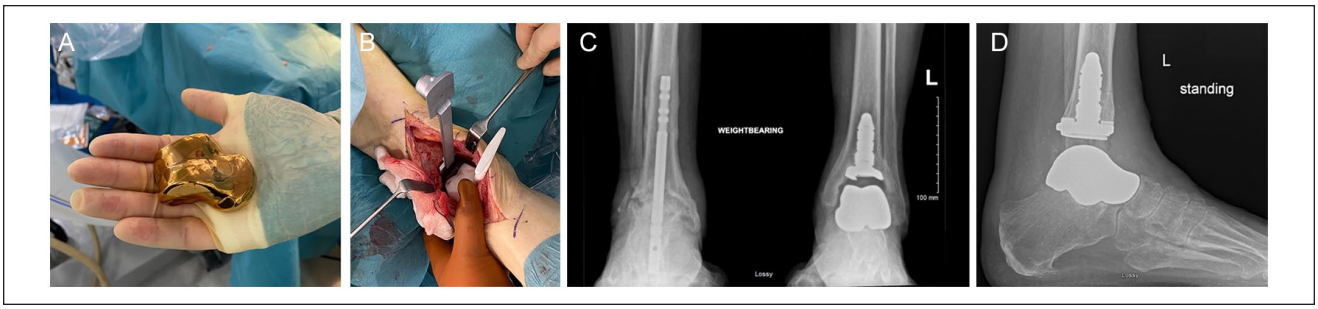

Figure 4. (A) A TTR (Ti6Al4V with TiN coating and mirrored polish finish (Additive Orthopaedics–Paragon 28; Little Silver, NJ) with matched articulation on the upper surface to an INBONE poly insert. (B) Intraoperative photograph, showing nylon TTC trials to match to the INBONE tibial trial. (C) A postoperative anteroposterior radiograph of the patient that has undergone revisions of 2 failed TARs, on the right to a TTC (3 years prior), and on the left to a TTR matched to the INBONE TAR (2 years prior). (D) A lateral radiograph of the TTR implanted in panel C. TAR, total ankle replacement; TTC, tibiotalocalcaneal; TTR, total talar replacement.

decided to match the upper surface of the TTR to the INBONE (Stryker Inc, Portage, MI) tibial component and hence we had to 3D print several tali articular surfaces in neutral and in 5 and 10 degrees of external rotation, each with a trial made out of nylon, so that the best-fit TTR could be used in the patient matched to the INBONE articulation, inserted using PSI (Prophecy; Stryker Inc). As salvage cases, these can do exceptionally well; for example, in an 86-year-old man who had bilateral failed TARs with massive osteolysis, a decision was made to revise the right side to a TTC, but because of severe metal debris and osteolysis, despite a femoral head allograft and a compressed TTC nail, the subtalar joint never united even after dynamization and he was left with a limp. When deciding to revise his left failed TAR, he was offered a TTR linked to a TAR. At short-term follow-up (2 years), he was walking pain free and very happy on the left side but remained disappointed with the pain and a limp on his right-sided TTC (Figure 4).

A further note must be made that surgical treatment for a failed TTR is challenging. The surgery would potentially require a plantar arthrodesis and the management of a large bone void.

Conclusion

AVN of the talus causes considerable morbidity, and the treatment options are limited. Currently the accepted gold standard is a TTC fusion, but this is not without its limitations and has limited long-term outcome data. This review has demonstrated that TTR could offer an alternative treatment option and can be combined with a TAR, but much research still needs to be done to assess optimal matching of implants, optimal materials for articulation against articular cartilage, and obtain longer-term outcomes in particular in comparison to TTC fusion, before widespread adoption is recommended.

Ethical Approval

Ethical approval was not sought for the present study as it was a contemporary review

Declaration of Conflicting Interests

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