



Medical Coverage Policy

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Total Ankle Arthroplasty/Replacement

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Related Coverage Resources

- [Hip Replacement/Arthroplasty \(CMM 313\)](#)
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- [Physical Therapy - \(CPG 135\)](#)
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Overview

This Coverage Policy addresses total ankle arthroplasty/replacement.

Coverage Policy

Total ankle arthroplasty/replacement for a skeletally mature individual with a FDA-approved device is considered medically necessary for the treatment of severe inflammatory arthritis (e.g., rheumatoid arthritis), severe osteoarthritis, or post-traumatic arthritis of the ankle, as an alternative to ankle arthrodesis, when ALL of the following criteria have been met:

- moderate to severe ankle pain that:
 - is function-limiting at short distances (e.g., walking less than ¼ mile, limiting activity to two city blocks, the equivalent to walking the length of a shopping mall) for at least three (3) months duration
 - interferes with the ability to carry out age appropriate activities of daily living and/or demands of employment
- failure of at least six months of conservative therapy (i.e., anti-inflammatory medications, orthotic devices, activity modification, physical therapy)

- any **ONE** of the following:
 - arthritis in adjacent joints of the involved extremity (i.e., subtalar, midfoot)
 - severe arthritis of the contralateral ankle
 - previous arthrodesis of the contralateral ankle

- absence of **ALL** the following:
 - active infection
 - insufficient bone/osteonecrosis
 - loss of musculature in the affected limb/insufficient ligament support
 - vascular insufficiency in the affected limb
 - Charcot's or other peripheral neuropathy
 - neurological impairment
 - severe ankle deformity precluding proper alignment
 - malalignment or severe deformity of involved or adjacent anatomic structures (e.g. hindfoot, forefoot, knee)
 - absence of medial or lateral malleolus, or both
 - poor skin conditions secondary to surgical scars or trauma

Revision total ankle arthroplasty is considered medically necessary for moderate to severe ankle pain secondary to failure of an implanted device (e.g., implant loosening, malpositioning, periprosthetic infection, periprosthetic fracture).

Total ankle arthroplasty/replacement for any other indication including combined with total talar prosthesis is considered experimental, investigational or unproven.

General Background

Total ankle arthroplasty (TAA) also known as total ankle replacement (TAR) is the process of replacing a diseased ankle with a prosthetic ankle. The procedure has been proposed as an alternative to ankle arthrodesis (i.e., ankle fusion) for non-inflammatory arthritic conditions such as severe osteoarthritis (OA) or post-traumatic arthritis, or inflammatory arthritic conditions, such as rheumatoid arthritis (RA) of the ankle. Arthritic ankle joints frequently result in decreased range of motion, swelling, joint stiffness, pain with weight-bearing activity, instability secondary to pain, and, in some cases, visible joint deformity. Conservative management typically consists of medications for pain control, limiting activity, the use of ankle braces to stabilize the joint, shoe modifications, heat, and physical therapy to control the pain associated with ankle arthrosis.

When conservative management fails, ankle arthrodesis (AA) has been the standard surgical treatment of choice to control the pain of severe ankle arthritis. During an ankle arthrodesis, the joint is fused together, limiting up-and-down movement. While pain may be relieved with ankle arthrodesis, the main drawback is the later development of arthrosis in the adjacent joints, particularly fusion of the subtalar joint.

Total ankle replacement (TAR) has reemerged as a viable and often preferable option to ankle arthrodesis for patients with end-stage ankle disease. The decision between ankle arthroplasty and arthrodesis should be made on a case-by-case basis. There are no consensus guidelines. Since introduction in the 1970s, three generations of implants have been developed, with several total ankle arthroplasty systems approved for use in the United States by the US Food and Drug Administration (FDA) since 2005.

U.S. Food and Drug Administration (FDA)

First generation TARs (in the 1970s and 1980s) were constrained and cemented in design, and had a very high rate of aseptic loosening. Second-generation TARs employed bone conserving surgery without cementation and with less constraint between components. They have demonstrated upwards of 89% survival at 10 years, were developed to more closely mimic physiologic movement and stability, and avoid the osteolytic issues of the early designs. Newer, third generation implants feature a metallic baseplate fixed to the tibia and a domed component resurfacing the talus, with ultra-high molecular weight polyethylene (UHMWPE) bearings to avoid the stability

issues of previous implants due to increased polyethylene wear. There have been several recall notices for various implants / implant components.

Mobile-bearing total ankle replacement (Class III devices, Product code NTG)

- Scandinavian Total Ankle Replacement (STAR®) system (Small Bone Innovations Inc., Morrisville, PA) Received FDA premarket approval on May 27, 2009, for use as a non-cemented implant to replace a painful arthritic ankle joint due to osteoarthritis, posttraumatic arthritis, or rheumatoid arthritis (P050050). As a condition of FDA approval, the company will evaluate the safety and effectiveness of the device during the next 8 years. There are several supplements.
- Note: Hintermann Series H3™ mobile-bearing Total Ankle Replacement prosthesis is not FDA-approved at this time. It is a non-constrained, three-component total ankle replacement system (formerly known as HINTEGRA TAR prosthesis) (DT MedTech LLC., Towson MD)

Fixed-component total ankle replacement (Class II devices, product code HSN)

Examples include but are not limited to:

- Agility™ LP Total Ankle (Alvine Ankle) (DePuy Orthopaedics Inc., Jacksonville, FL)
- Eclipse Total Ankle Implant (Kinetikos Medical Inc.; Integra Lifesciences Corporation, Plainsboro, NJ)
- Hintermann Series H2™ Total Ankle System (DT MedTech LLC.)
- Inbone™ Total Ankle (including I and II) (Wright Medical Technology Inc., Memphis, TN)
- Infinity™ Total Ankle System (Wright Medical Technology Inc.)
- Integra® Cadence™ Total Ankle Replacement System (Ascension Orthopedics) (Integra Lifesciences Corp.)
- Invision™ Total Ankle Revision System (Wright Medical Technology Inc.,
- Salto XT, Salto Talaris® (Tornier SAS, France; Integra Lifesciences Corp.)
- Topez Total Ankle Replacement (Topez Orthopedics Inc.)
- Vantage® Total Ankle System (Exactech Inc. Gainesville, FL)

FDA-approved indications vary depending on device type: fixed-bearing or mobile-bearing. In general these devices are intended for adult patients with reduced activity levels, who have severe rheumatoid arthritis, post-traumatic arthritis or osteoarthritis of the ankle. Contraindications also vary depending on device type, but may include the following:

- active infection
 - insufficient bone/osteonecrosis
 - loss of musculature in the affected limb/insufficient ligament support
 - vascular insufficiency in the affected limb
 - Charcot's or other peripheral neuropathy
 - neurological impairment
 - severe ankle deformity precluding proper alignment
 - malalignment or severe deformity of involved or adjacent anatomic structures (e.g. hindfoot, forefoot, knee)
 - absence of medial or lateral malleolus, or both
 - poor skin conditions secondary to surgical scars or trauma
 - patient age, weight or activity levels that introduces unnecessary risk of failure
 - skeletal immaturity
- (FDA; Hayes, 2017).

Revision surgery

Revision surgery may be necessary in the presence of failed arthroplasty. Failed arthroplasty is typically suspected when pain occurs progressively over time and is persistent, indicating implant loosening and subsidence. Periprosthetic infection should be ruled out early. Bone scans or computerized tomography (CT) scans may be performed to evaluate the implant with some individuals requiring surgical evaluation. Surgical

management of failed TAR may include ankle arthrodesis, revision arthroplasty, or amputation. Contraindications to revision TAR are similar to those for initial procedure and include deep infection, neuropathic joint, insufficient bone stock, soft-tissue breakdown, absence of the distal part of the femur, instability resulting from incompetent ligaments, severe malalignment, peripheral vascular disease, significant bone loss, and morbid obesity (Murphy, 2017).

Total Talar Prosthesis

Combined TAR with implantation of a three-dimensional (3D) printed total talar prosthesis (TTP) has been proposed for degenerative joint disease of the ankle, avascular osteonecrosis, and osteomyelitis. See Literature Review section below.

Literature Review

A review of the current published peer-reviewed literature includes prospective and retrospective studies that compare TAR to ankle arthrodesis (Norvell, et al., 2019; Merrill, et al., 2019; Veljkovic, et al., 2019; Wasik, et al., 2019; Veljkovic, et al., 2019; Segal, et al., 2018; Mehdi, et al., 2018), compare TAR devices (Nunley, et al., 2019; King, et al., 2019), compare patient subpopulations undergoing TAR (e.g., degree of deformity, age of patient, etiology of osteoarthritis) (Lee, et al., 2019; Usuelli, et al., 2019; Demetracopoulos, et al., 2018), compare primary TAR versus revision TAR (Lai, et al., 2019) and evaluate survivorship of the TAR implant (Palanca, et al., 2018, 15.7 years; Lee, et al., 2019, 6.2 years; Koo et al., 2018, 5 years; Marks, et al., 2019, 4.9 years).

Hayes, Inc. published a Comparative Effectiveness Review on Total Ankle Replacement (TAR) (December 28, 2017). Hayes Rating = C for use of TAR as an alternative to conventional ankle arthrodesis (AA) for treating adult patients with end-stage ankle arthritis without contraindications to TAR. This Rating reflects an overall low-quality body of evidence that suggests that the effectiveness of TAR is at least comparable with AA for the treatment of adult patients with end-stage ankle arthritis. This Rating also reflects some uncertainties about rates of reoperation and complications due to inconsistencies in the evidence, the small number of studies reporting certain outcome measures, and questions regarding the long-term durability of TAR. Hayes (2017) states that although patient selection for type of treatment may somewhat be based upon surgeon preference, there are no recognized differences in the literature regarding candidacy for TAR versus AA. According to narrative reviews of TAR, the ideal candidate for TAR is more than 50 years old with end-stage ankle arthritis, no significant comorbidities, good bone quality, neutral alignment, good stability, and preserved mobility of the ankle. In addition, TAR may be more beneficial for patients with bilateral osteoarthritis of the ankle or prior subtalar, triple, and/or midfoot fusion, since the tibiotalar fusion would arrest functional motion. Hayes annual update (March 26, 2019) notes no change in current Rating of C. Evaluation of the literature indicates that evidence on patient selection criteria is unchanged since publication of the 2017 Directory Report.

Lawton et al. (2017) conducted a systematic literature review to assess outcomes and complications following AA and TAR treatment of symptomatic tibiotalar arthritis. A total of six studies reporting on outcomes following TAR and five studies reporting on outcomes following AA met inclusion criteria and were included for pooled data analysis.

- TAR studies: Only studies including modern third-generation TAR implants approved for use in the USA (HINTEGRA, STAR, Salto, INBONE) were included. Five of the studies were prospective and one was retrospective. The studies report on a total of 2239 ankles operated on from 1993 to 2013. INBONE was used in 682 ankles, STAR in 455 ankles, Salto in 380 ankles, and HINTEGRA in 722 ankles. The adjusted mean follow-up was 4.8 years.
- AA studies: All studies were retrospective in nature. The studies report on a total of 635 ankles operated on from 1993 to 2013. Arthrodesis was performed through an open approach in 577 ankles and through an arthroscopic approach in 58 ankles. Three of the studies reported mean follow-up with an adjusted mean follow-up of 4.3 years.

The adjusted overall complication rate was higher for AA (26.9%) compared to TAR (19.7%), with similar findings in the non-revision reoperation rate (12.9% for AA compared to 9.5% for TAR). The adjusted revision reoperation rate for TAR (7.9%) was higher than AA (5.4%). Analysis of results from ten studies directly comparing TAR to AA suggests a more symmetric gait and less impairment on uneven surfaces after TAR. The authors stated that pooled data analysis demonstrated a higher overall complication rate after AA, but a higher reoperation rate for revision after TAR. Based on the existing literature, the decision to proceed with TAR or AA for end-stage ankle arthritis should be made on an individual patient basis.

Kim et al. (2017) conducted a meta-analysis including comparative studies that assessed TAR versus AA for the treatment of end-stage ankle arthritis. The primary outcomes were clinical scores and patient satisfaction and secondary outcomes were the prevalence of complications and the re-operation rate. Ten comparative studies were included (four prospective and six retrospective studies). There were no significant differences between the two procedures in the American Orthopaedic Foot and Ankle Society ankle-hindfoot score, Short Form-36 physical component summary and mental component summary scores, visual analogue scale for pain, and patient satisfaction rate. The risk of re-operation and major surgical complications were significantly increased in the TAR group. A limitation of this meta-analysis is the majority of included studies were retrospective design. The authors stated that further studies of high methodological quality with long-term follow-up are needed.

van der Plaat, et al. (2017) conducted a literature review and concluded:

- The optimal patient for TAR is said to be physically low-demanding, nonobese, older, with end-stage non-traumatic primary ankle arthrosis or multiple joint arthritis with minimal deformity, good bone stock, no neurovascular leg impairment and excellent/more than two-thirds of normal range of motion.
- Unfortunately, the majority of our patients do not meet these requirements, and scientific evidence for these recommendations is unavailable.
- Unfortunately, the characteristics of patients with failed TARs are rarely specified (except incidentally etiology of arthritis), which makes it difficult to determine the risk factors for failure.
- Many factors historically considered to be contraindications for TAR should no longer be considered contraindications based on scientific evidence. Some of these factors are probably interconnected (for instance, BMI, activity level, diabetes and vascular disease). Instead of considering each of these factors in isolation, the surgeon should try to judge the patient as a whole when choosing between TAR and AA.

Maffulli et al. (2017) performed a systematic literature review, including 21 prospective and retrospective studies, reporting a total of 32,422 procedures for the management of end stage ankle arthritis. A total of 26,175 (80.7%) AA and 6247 (19.3%) TAR procedures were performed. Seven studies, reporting 647 TAR procedures, also reported the type of prosthesis of choice. TAR was performed using two- or three-component designs. These were also classified as fixed or mobile-bearing. Average follow-up was 73.1 months (76.2 months for AA group, and 61.3 months for the TAR group). The authors noted that there is some evidence to support TAR to conserve ankle motion and offer improved function and decreased pain with high satisfaction rates. Revision rates for TAR are significantly higher than revision rates for AA. They concluded proper patient selection should be better addressed in future studies for successful treatment of end-stage ankle OA.

Total Talar Prosthesis: Combined TAR with implantation of a total talar prosthesis (TTP) has been proposed for some patients including younger patients, patients with stage 3 and 4 osteonecrosis, and patients with talar collapse. An artificial talar prostheses is proposed to prevent leg length discrepancy, preserve the joint function, and allow early weight bearing. There is a lack of large, well-designed prospective trials evaluating the long term outcomes of total talar prosthesis (Kanzaki, et al., 2019; Kurokawa, et al., 2019; Shnol, et al., 2018; Taniguchi, et al., 2015).

Professional Societies/Organizations

American College of Foot and Ankle Surgeons (ACFAS): The ACFAS Position Statement on Total Ankle Replacement Surgery (Approved 2016) notes that not every patient with end-stage arthritis of the ankle is a sound candidate for ankle replacement. A surgeon experienced in total ankle surgery can make this determination through careful history and physical evaluation. In the United States, total ankle replacement surgery is currently a safe and effective treatment option for select patients with end stage ankle arthritis. Studies have shown total ankle replacement surgery improves patient function, reduces pain, and promotes improved quality of life.

American Orthopaedic Foot & Ankle Society (AOFAS): The AOFAS Position Statement on The Use of Total Ankle Replacement for the Treatment of Arthritic Conditions of the Ankle (approved April 2018) concludes “Ankle arthritis is a condition that can result in substantial pain and dysfunction. The American Orthopaedic Foot & Ankle Society supports the use of total ankle replacement as an option for the treatment of ankle arthritis that has failed conservative management in select patients due to its demonstrated improved outcomes in multiple peer reviewed publications.”

The American Board of Internal Medicine's (ABIM) Foundation Choosing Wisely® Initiative
No relevant information.

Centers for Medicare & Medicaid Services (CMS)

- National Coverage Determinations (NCDs): None.
- Local Coverage Determinations (LCDs): None

Use Outside of the US

No relevant information.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
27702 [†]	Arthroplasty, ankle; with implant (total ankle)
27703 [†]	Arthroplasty, ankle; revision, total ankle
27704	Removal of ankle implant

HCPCS Codes	Description
C1776 [†]	Joint device (implantable)
L8699	Prosthetic implant, not otherwise specified

†Note: Experimental/investigational/unproven when used to report total ankle arthroplasty/replacement when combined with total talar prosthesis

***Current Procedural Terminology (CPT®) ©2019 American Medical Association: Chicago, IL.**

References

1. Abicht BP, Roukis TS. The INBONE II Total Ankle System. Clin Podiatr Med Surg. 2013 Jan;30(1):47-68.
2. American College of Foot and Ankle Surgeons (ACFAS). Position Statement on Total Ankle Replacement Surgery. July 2016. Accessed Jan 2020. Available at URL address: <https://www.acfas.org/Health-Policy-and-Advocacy/Policy-Statements/Position-Statements/>
3. American Orthopaedic Foot & Ankle Society (AOFAS). Position Statement: The Use of Total Ankle Replacement for the Treatment of Arthritic Conditions of the Ankle. Approved April 12, 2018. Accessed Jan 2020. <https://www.aofas.org/research-policy/health-policy>
4. Angthong C, Chumchuen S, Khadsongkram A. A systematic review of intermediate-term outcomes and failure rates for total ankle replacements: An Asian perspective. Foot Ankle Surg. 2013;19(3):148-154.
5. Barg A, Zwicky L, Knupp M, Henninger HB, Hintermann B. HINTEGRA total ankle replacement: survivorship analysis in 684 patients. J Bone Joint Surg Am. 2013;95:1175-83.
6. Braito M, Dammerer D, Kaufmann G, Fischler S, Carollo J, et al. Are our expectations bigger than the results we achieve? a comparative study analysing potential advantages of ankle arthroplasty over arthrodesis. Int Orthop. 2014 Aug;38(8):1647-53.

7. Clough T, Bodo K, Majeed H, Davenport J, Karski M. Survivorship and long-term outcome of a consecutive series of 200 Scandinavian Total Ankle Replacement (STAR) implants. *Bone Joint J.* 2019 Jan;101-B(1):47-54 (Abstract only).
8. Daniels TR, Younger AS, Penner M, et al. Intermediate-term results of total ankle replacement and ankle arthrodesis: A COFAS multicenter study. *J Bone Joint Surg Am.* 2014;96(2):135-142.
9. Demetracopoulos CA, Adams Jr SB, Queen RM, DeOrio JK, Nunley 2nd JA, Easley ME. Effect of age on outcomes in total ankle arthroplasty. *Foot Ankle Int.* 2015;36:871-80.
10. Demetracopoulos CA, Cody EA, Adams SB Jr, DeOrio JK, Nunley JA et al. Outcomes of Total Ankle Arthroplasty in Moderate and Severe Valgus Deformity. *Foot Ankle Spec.* 2019 Jun;12(3):238-245.
11. DT MedTech, LLC. 2018. Hintermann Series H3™ Total Ankle Replacement (TAR) Prosthesis. Accessed December 2019. Available at URL address: <https://www.dtmedtech.com/products/united-states-us/h3-ankle-us/>
12. Ewalefo SO, Dombrowski M, Hirase T, Rocha JL, Weaver M, et al. Management of Posttraumatic Ankle Arthritis: Literature Review. *Curr Rev Musculoskelet Med.* 2018 Dec;11(4):546-557.
13. Ferguson Z, Anugraha A, Janghir N, Pillai A. Ankle arthrodesis: A long term review of the literature. *J Orthop.* 2019 Aug 13;16(5):430-433. eCollection 2019 Sep-Oct.
14. Gaudot F, Colombier JA, Bonnin M, Judet T. A controlled, comparative study of a fixed-bearing versus mobile-bearing ankle arthroplasty. *Foot Ankle Int.* 2014;35(2):131-140.
15. Gougoulas N, Khanna A, Maffulli N. How successful are current ankle replacements?: a systematic review of the literature. *Clin Orthop Relat Res.* 2010 Jan;468(1):199-208.
16. Gross C, Erickson BJ, Adams SB, Parekh SG. Ankle arthrodesis after failed total ankle replacement: a systematic review of the literature. *Foot Ankle Spec.* 2015 Apr;8(2):143-51
17. Haddad SL, Coetzee JC, Estok R, Fahrbach K, Banel D, Nalysnyk L. Intermediate and long-term outcomes of total ankle arthroplasty and ankle arthrodesis. A systematic review of the literature. *J Bone Joint Surg Am.* 2007 Sep;89(9):1899-905.
18. Hahn ME, Wright ES, Segal AD, Orendurff MS, Ledoux WR, Sangeorzan BJ. Comparative gait analysis of ankle arthrodesis and arthroplasty: initial findings of a prospective study. *Foot Ankle Int.* 2012 Apr;33(4):282-9.
19. Hayes, Inc. Medical Technology Directory. Comparative Effectiveness Review. Total Ankle Replacement: A Review of Reviews. Lansdale, PA; Hayes, Inc. Published December 28, 2017. Annual review March 26, 2019.
20. Hsu AR, Davis WH, Cohen BE, Jones CP, Ellington JK, Anderson RB. Radiographic Outcomes of Preoperative CT Scan-Derived Patient-Specific Total Ankle Arthroplasty. *Foot Ank Int.* 2015 Oct, 36(10):1163-9.
21. Jeyaseelan L, Si-Hyeong Park S, Al-Rumaih H, Veljkovic A, Penner MJ, et al. Outcomes Following Total Ankle Arthroplasty: A Review of the Registry Data and Current Literature. *Orthop Clin North Am.* 2019 Oct;50(4):539-548
22. Kanzaki N, Chinzei N, Yamamoto T, Yamashita T, Ibaraki K, Kuroda R. Clinical Outcomes of Total Ankle Arthroplasty With Total Talar Prosthesis. *Foot Ankle Int.* 2019 Aug;40(8):948-954.

23. Kim HJ, Suh DH, Yang JH, Lee JW, Kim HJ, et al. Total ankle arthroplasty versus ankle arthrodesis for the treatment of end-stage ankle arthritis: a meta-analysis of comparative studies. *Int Orthop*. 2017 Jan;41(1):101-109.
24. King A, Bali N, Kassam AA, Hughes A, Talbot N, Sharpe I. Early outcomes and radiographic alignment of the Infinity total ankle replacement with a minimum of two year follow-up data. *Foot Ankle Surg*. 2019 Dec;25(6):826-833.
25. Koo K, Liddle AD, Pastides PS, Rosenfeld PF. The Salto total ankle arthroplasty - Clinical and radiological outcomes at five years. *Foot Ankle Surg*. 2019 Aug;25(4):523-528.
26. Kraal T, van der Heide HJ, van Poppel BJ, Fiocco M, Nelissen RG, Doets HC. Long-term follow-up of mobile-bearing total ankle replacement in patients with inflammatory joint disease. *Bone Joint J*. 2013 Dec 1;95-B(12):1656-61.
27. Krause FG1, Schmid T. Ankle arthrodesis versus total ankle replacement: how do I decide? *Foot Ankle Clin*. 2012 Dec;17(4):529-43.
28. Kurokawa H, Taniguchi A, Morita S, Takakura Y, Tanaka Y. Total ankle arthroplasty incorporating a total talar prosthesis: a comparative study against the standard total ankle arthroplasty. *Bone Joint J*. 2019 Apr;101-B(4):443-446.
29. Lai WC, Arshi A, Ghorbanifarajzadeh A, Williams JR, Soohoo NF. Incidence and predictors of early complications following primary and revision total ankle arthroplasty. *Foot Ankle Surg*. 2019 Dec;25(6):785-789.
30. Lawton CD, Butler BA, Dekker RG, Prescott A, Kadakia AR. Total ankle arthroplasty versus ankle arthrodesis-a comparison of outcomes over the last decade. *J Orthop Surg Res*. 2017 May 18;12(1):76.
31. Lee KT, Lee YK, Young KW, Kim HJ, Park SY, et al. Perioperative complications of the MOBILITY total ankle system: comparison with the HINTEGRA total ankle system. *J Orthop Sci*. 2010 May;15(3):317-22.
32. Lee GW, Lee KB. Outcomes of Total Ankle Arthroplasty in Ankles with >20° of Coronal Plane Deformity. *J Bone Joint Surg Am*. 2019 Dec 18;101(24):2203-2211.
33. Lee GW, Santoso A, Lee KB. Comparison of Intermediate-term Outcomes of Total Ankle Arthroplasty in Primary and Ligamentous Post-traumatic Osteoarthritis. *Foot Ankle Int*. 2019 Nov;40(11):1273-1281.
34. Lee GW, Seon JK, Kim NS, Lee KB. Comparison of Intermediate-Term Outcomes of Total Ankle Arthroplasty in Patients Younger and Older Than 55 Years. *Foot Ankle Int*. 2019 Jul;40(7):762-768
35. Lefrancois T, Younger A, Wing K, Penner MJ, Dryden P, et al. A Prospective Study of Four Total Ankle Arthroplasty Implants by Non-Designer Investigators. *J Bone Joint Surg Am*. 2017 Feb 15;99(4):342-348.
36. Lewis Jr JS, Green CL, Adams Jr SB, Easley ME, DeOrio JK, Nunley JA. Comparison of first- and second-generation fixed-bearing total ankle arthroplasty using a modular intramedullary tibial component. *Foot Ankle Int*. 2015;36:881-90.
37. Maffulli N, Longo UG, Locher J, Romeo G, Salvatore G, Denaro V. Outcome of ankle arthrodesis and ankle prosthesis: a review of the current status. *Br Med Bull*. 2017 Dec 1;124(1):91-112.
38. Mann JA, Mann RA, Horton E. STAR™ ankle: long-term results. *Foot Ankle Int*. 2011 May;32(5):S473-84.

39. Marks RM. Mid-Term Prospective Clinical and Radiographic Outcomes of a Modern Fixed-Bearing Total Ankle Arthroplasty. *J Foot Ankle Surg.* 2019 Nov;58(6):1163-1170.
40. Mehdi N, Bernasconi A, Laborde J, Lintz F. Comparison of 25 ankle arthrodeses and 25 replacements at 67 months' follow-up. *Orthop Traumatol Surg Res.* 2019 Feb;105(1):139-144.
41. Merrill RK, Ferrandino RM, Hoffman R, Ndu A, Shaffer GW. Comparing 30-day all-cause readmission rates between tibiotalar fusion and total ankle replacement. *Foot Ankle Surg.* 2019 Jun;25(3):327-331.
42. Morash J, Walton DM, Glazebrook M. Ankle Arthrodesis Versus Total Ankle Arthroplasty. *Foot Ankle Clin.* 2017 Jun;22(2):251-266.
43. Murphy GA. Total Ankle Arthroplasty. In: *Campbell's Operative Orthopedics*. Ch 11, 535-568, e3. Copyright © 2017 by Elsevier.
44. Nelissen RG, Doets HC, Valstar ER. Early migration of the tibial component of the buchel-pappas total ankle prosthesis. *Clin Orthop Relat Res.* 2006 Jul;448:146-51.
45. Nodzo SR, Miladore MP, Kaplan NB, Ritter CA. Short to Midterm Clinical and Radiographic Outcomes of the Salto Total Ankle Prosthesis. *Foot Ankle Int.* 2013 Oct 24.
46. Norvell DC, Ledoux WR, Shofer JB, Hansen ST, Davitt J, et al. Effectiveness and Safety of Ankle Arthrodesis Versus Arthroplasty: A Prospective Multicenter Study. *J Bone Joint Surg Am.* 2019 Aug 21;101(16):1485-1494
47. Nunley JA, Caputo AM, Easley ME, Cook C. Intermediate to long-term outcomes of the STAR Total Ankle Replacement: the patient perspective. *J Bone Joint Surg Am.* 2012 Jan 4;94(1):43-8.
48. Nunley JA, Adams SB, Easley ME, DeOrio JK. Prospective Randomized Trial Comparing Mobile-Bearing and Fixed-Bearing Total Ankle Replacement. *Foot Ankle Int.* 2019 Nov;40(11):1239-1248.
49. Onggo JR, Nambiar M, Phan K, Hickey B, Galvin M, Bedi H. Outcome after total ankle arthroplasty with a minimum of five years follow-up: A systematic review and meta-analysis. *Foot Ankle Surg.* 2019 Jul 25. pii: S1268-7731(19)30111-0. [Epub ahead of print]
50. Palanca A, Mann RA, Mann JA, Haskell A. Scandinavian Total Ankle Replacement: 15-Year Follow-up. *Foot Ankle Int.* 2018 Feb;39(2):135-142.
51. Pedersen E, Pinsker E, Younger AS, Penner MJ, Wing KJ, Dryden PJ, Glazebrook M, Daniels TR. Outcome of total ankle arthroplasty in patients with rheumatoid arthritis and noninflammatory arthritis: a multicenter cohort study comparing clinical outcome and safety. *J Bone Joint Surg Am.* 2014 Nov 5;96(21):1768-75.
52. Pedowitz DI, Kane JM, Smith GM, Saffel HL, Comer C, Raikin SM. Total ankle arthroplasty versus ankle arthrodesis: a comparative analysis of arc of movement and functional outcomes. *Bone Joint J.* 2016 May;98-B(5):634-40
53. Pinar N, Vernet E, Bizot P, Brilhault J. Total ankle arthroplasty - total ankle arthroplasty in Western France: influence of volume on complications and clinical outcome. *Orthop Traumatol Surg Res.* 2012 Jun;98(4 Suppl):S26-30.
54. Queen RM, Franck CT, Schmitt D, Adams SB. Are There Differences in Gait Mechanics in Patients With A Fixed Versus Mobile Bearing Total Ankle Arthroplasty? A Randomized Trial. *Clin Orthop Relat Res.* 2017 Oct;475(10):2599-2606.

55. Queen RM, Sparling TL, Butler RJ, Adams SB Jr, DeOrto JK, et al. Patient-Reported Outcomes, Function, and Gait Mechanics After Fixed and Mobile-Bearing Total Ankle Replacement. *J Bone Joint Surg Am*. 2014 Jun 18;96(12):987-993.
56. Roukis TS, Elliott AD. Incidence of revision after primary implantation of the Salto® mobile version and Salto Talaris™ total ankle prostheses: a systematic review. *J Foot Ankle Surg*. 2015 May-Jun;54(3):311-9.
57. Roukis TS. Incidence of revision after primary implantation of the Agility™ total ankle replacement system: a systematic review. *Foot Ankle Surg*. 2012 Mar-Apr;51(2):198-204.
58. Saltzman CL, Mann RA, Ahrens JE, Amendola A, Anderson RB, Berlet GC, et al. Prospective controlled trial of STAR total ankle replacement versus ankle fusion: initial results. *Foot Ankle Int*. 2009 Jul;30(7):579-96.
59. Santana DC, Anis HK, Mont MA, Higuera CA, Piuze NS. What is the Likelihood of Subsequent Arthroplasties after Primary TKA or THA? Data from the Osteoarthritis Initiative. *Clin Orthop Relat Res*. 2020 Jan;478(1):34-41.
60. Schenk K, Lieske S, John M, Franke K, Mouly S, Lizee E, Neumann W. Prospective study of a cementless, mobile-bearing, third generation total ankle prosthesis. *Foot Ankle Int*. 2011;32:755–63
61. Schuh R, Hofstaetter J, Krismer M, Bevoni R, Windhager R, Trnka HJ. Total ankle arthroplasty versus ankle arthrodesis. Comparison of sports, recreational activities and functional outcome. *Int Orthop*. 2012 Jun;36(6):1207-14.
62. Segal AD, Cyr KM, Stender CJ, Whittaker EC, Hahn ME, et al. A three-year prospective comparative gait study between patients with ankle arthrodesis and arthroplasty. *Clin Biomech (Bristol, Avon)*. 2018 May;54:42-53.
63. Shane A, Sahli H. Total Ankle Replacement Options. *Clin Podiatr Med Surg*. 2019 Oct;36(4):597-607.
64. Shnol H, LaPorta GA. 3D Printed Total Talar Replacement: A Promising Treatment Option for Advanced Arthritis, Avascular Osteonecrosis, and Osteomyelitis of the Ankle. *Clin Podiatr Med Surg*. 2018 Oct;35(4):403-422.
65. Stengel D, Bauwens K, Ekkernkamp, Cramer J. Efficacy of total ankle replacement with meniscal-bearing devices: a systematic review and meta-analysis. *Arch Orthop Trauma Surg*. 2005 Mar; 125(2):109-19.
66. Taniguchi A, Takakura Y, Tanaka Y, Kurokawa H, Tomiwa K, et al. An Alumina Ceramic Total Talar Prosthesis for Osteonecrosis of the Talus. *J Bone Joint Surg Am*. 2015 Aug 19;97(16):1348-53.
67. Taniguchi A, Tanaka Y. An Alumina Ceramic Total Talar Prosthesis for Avascular Necrosis of the Talus. *Foot Ankle Clin*. 2019 Mar;24(1):163-171.
68. U.S. Food and Drug Administration (FDA). Scandinavian Total Ankle Replacement System (STAR Ankle). Premarket approval. P050050. Accessed Jan 2020. Available at URL address: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm?id=P050050>
69. Usuelli FG, Di Silvestri CA, D'Ambrosi R, Orenti A, Randelli F. Total ankle replacement: is pre-operative varus deformity a predictor of poor survival rate and clinical and radiological outcomes? *Int Orthop*. 2019 Jan;43(1):243-249.
70. van der Plaats LW, Haverkamp D. Patient selection for total ankle arthroplasty. *Orthop Res Rev*. 2017 Jul 31;9:63-73.

71. van Heiningen J, Vliet Vlieland TP, van der Heide HJ. The mid-term outcome of total ankle arthroplasty and ankle fusion in rheumatoid arthritis: a systematic review. *BMC Musculoskelet Disord*. 2013 Oct 26;14:306.
72. Veljkovic AN, Daniels TR, Glazebrook MA, Dryden PJ, Penner MJ, et al. Outcomes of Total Ankle Replacement, Arthroscopic Ankle Arthrodesis, and Open Ankle Arthrodesis for Isolated Non-Deformed End-Stage Ankle Arthritis. *J Bone Joint Surg Am*. 2019 Sep 4;101(17):1523-1529.
73. Rinaldi RZ. Total joint replacement for severe rheumatoid arthritis. In: UpToDate, Romain PL (Ed), UpToDate, Waltham, MA. Literature review current through Dec 2019. Topic last updated Jul 18, 2019.
74. Wasik J, Stołtny T, Pasek J, Szyluk K, Pyda M, et al. Effect of Total Ankle Arthroplasty and Ankle Arthrodesis for Ankle Osteoarthritis: A Comparative Study. *Med Sci Monit*. 2019 Sep 10;25:6797-6804.
75. Weme RA, van Solinge G, N Doornberg J, Sierevelt I, Haverkamp D, Doets HC. Total ankle replacement for posttraumatic arthritis. Similar outcome in postfracture and instability arthritis: a comparison of 90 ankles. *Acta Orthop*. 2015;86(4):401-6.
76. Wright Medical Group N.V. Wright Foot and Ankle. Preoperative Navigation Guides. Accessed Jan 2020. Available at URL address: <http://www.wright.com/healthcare-professionals/foot-ankle>
77. Wood PL, Sutton C, Mishra V, Suneja R. A randomised, controlled trial of two mobile-bearing total ankle replacements. *J Bone Joint Surg Br*. 2009 Jan;91(1):69-74.
78. Zaidi R, Cro S, Gurusamy K, et al. The outcome of total ankle replacement: a systematic review and meta-analysis. *Bone Joint J*. 2013; 95-B(11):1500-1507.
79. Zaidi R, Macgregor AJ, Goldberg A. Quality measures for total ankle replacement, 30-day readmission and reoperation rates within 1 year of surgery: a data linkage study using the NJR data set. *BMJ Open*. 2016 May 23;6(5):e011332.
80. Zhao H, Yang Y, Yu G, Zhou J. A systematic review of outcome and failure rate of uncemented Scandinavian total ankle replacement. *Int Orthop*. 2011 Dec;35(12):1751-8.

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