Total ankle replacement (TAR)

Indications and Contraindications for TAR

Indications

Total ankle replacement (TAR) is an alternative to ankle arthrodesis for the treatment of end-stage ankle osteoarthritis (OA) in select patients with advanced painful arthropathy of all three main etiologies: primary, post-traumatic, and secondary. One of the main advantages of TAR compared with ankle arthrodesis is preservation of functional range of motion (ROM) which is sacrificed in ankle fusion. Improved ROM allows patients to better perform activities of daily living and possibly regain athletic activities.

The ideal candidate for TAR is an older (middle- to old-aged), reasonably mobile patient with no significant co-morbidities, a normal or low body mass index, adequate bone stock, a well-aligned and stable hindfoot, good soft tissues conditions, and no neurovascular impairment of the lower extremity.

Another indication for TAR is bilateral end-stage ankle OA. Bilateral ankle fusion may not be the most appropriate treatment option given its significant detrimental effects on gait and functional status of patients. Furthermore, in patients with previously performed subtalar, triple, and/or midfoot fusion the tibiotalar fusion would completely "stiffen" the hindfoot, while the TAR may preserve functional motion. It has been shown that the clinical outcome of TAR when combined with hindfoot fusion is comparable to that of ankle replacement alone.

Contraindications
The relative contraindications for TAR are severe osteoporosis, history of osteomyelitis, diffuse osteonecrosis, or significant bone defect on the tibial and/or talar site. Previous long-term therapy with steroids or immunosuppressive substances may also reduce bone quality, resulting in compromised osteointegration of prosthesis components. Further relative contraindications for TAR include heavy physical work, medium level of sports activities (eg, tennis, jogging, and downhill ski), high body mass index, diabetes, and smoking.

Significant preoperative varus or valgus deformity (>10°) has also been seen as a contraindication for TAR. Doets et al found that preoperative deformity in the frontal plane is difficult to correct, causing instability and subluxation of the bearing, which may result in the prosthesis failure. Wood and Deakin observed in their study including 200 STAR implants that preoperative varus or valgus deformity >15° may cause edge loading of the mobile bearing. Therefore, they stated that this may be a relative contraindication for TAR.

However, the preoperative hindfoot deformity should not be an absolute contraindication, as long as additional realignment procedures (supramalleolar and/or calcaneal osteotomies, ligament reconstruction, subtalar fusion) may correct the deformity. Karantana et al did not observe any differences in functional outcome and prosthesis component survivorship between patients with and without preoperative deformities as long the deformity was addressed at the time of prosthesis implantation. Daniels et al demonstrated that correction of moderate to severe varus deformities is possible and results in good functional outcome and stability of prosthesis components. Kim et al reported that the clinical outcome of TAR performed in ankles with preoperative varus deformity >10° is comparable with that of neutrally aligned ankles. However, the simultaneous surgical procedures addressing the preoperative deformity are necessary to achieve good results.

The absolute contraindications for TAR include:

- Neuroarthropathy (Charcot foot)
- Non-manageable hindfoot malalignment
- Massive joint laxity (eg, patients with Marfan disease)
- Highly compromised periarticular soft tissues (eg, in patients with posttraumatic OA who underwent several previous surgeries)
- Severe sensomotoric dysfunction of foot/ankle
- Active soft-tissue or bony infection

Additionally, TAR should not be considered as the first-choice therapy in patients with a high level of functional demand (eg, contact sports).

While many authors suggest that previous ankle infection is an absolute contraindication for TAR, we do not confirm this idea. In a series of 17 consecutive patients who underwent HINTEGRA TAR, we achieved good functional results and did not observe any recurrence of infection (unpublished data). Eichinger et al and Espinosa and Klammer also recommend TAR in patients with ankle OA due to previous infection.

In several studies, avascular necrosis of the talus has been identified as an absolute contraindication for TAR. However, it should be considered that some prosthesis designs offer the possibility to use the revision talar component. Also custom made components may be used replacing the whole body of talus.

**66.2 First-Generation Total Ankle Replacements**
Since the 1970s, ankle arthrodesis has been recognized as having limitations regarding complication rate and functional outcome. In most articles addressing TAR history, the study by Lord and Marotte is described as the first clinical study with TAR patients. However, Muir et al described in 2002 outcome results in a 71-year-old male who underwent talar dome resurfacing with a custom Vitallium implant for post-traumatic OA in 1962. The clinical examination at 40-year follow up showed mild hindfoot malalignment with slightly decreased ROM (25° plantar flexion), AOFAS score of 85, no pain, and no activity limitation.

In their study, Lord and Marotte used an inverted hip stem, which was implanted into the tibia. After the talus had been completely removed, they implanted a cemented acetabular cup in the calcaneus. This procedure was performed in 25 consecutive patients and only seven patients reported satisfaction postoperatively. Twelve of the 25 arthroplasties failed, and therefore the authors did not recommend the further use of this prosthesis design. At the time, the authors recognized the complexity of ankle biomechanics and concluded that a simple hinge prosthesis system with plantar flexion and dorsiflexion would be insufficient to mimic the normal ankle joint. Overall, the majority of first-generation prostheses were eventually withdrawn from the market because of high failure rates with subsidence, continued patient pain, or progressive alignment deformities.

The research published by these original investigators led to the development of the first-generation of TARs. These included:

- **St. Georg-Buchholz ankle prosthesis**, a semi-constrained prosthesis type introduced in 1973
- **Imperial College of London Hospital prosthesis**, a two-component, constrained implant with a polyethylene tibial component
- **Irvine Ankle TAR** (Howmedica prosthesis), one of the first early ankle prostheses where a special talus anatomy was regarded, with the prosthesis designers performed anatomical measurements of 32 tali to establish the morphology of talus
- **Richard Smith TAR**, a non-constrained so-called “ball-and-socket” (spherocentric) prosthesis that was introduced in 1975
- **Conaxial Beck-Steffee ankle prosthesis**, a very constrained prosthesis type
- **Newton ankle implant**, a non-constrained cemented prosthesis including the high density polyethylene tibial and Vitallium talar components
- **Bath-Wessex TAR**, an unconstrained, two-component total ankle design.
- **Mayo TAR**, a highly congruent two-component design including a polyethylene tibial component with cement fixation
- **Oregon ankle prosthesis**, a single-axis, two-component TAR design
- **Thompson-Richard prosthesis**, a two-component semi-constrained cemented implant that included a polyethylene tibial component with a concave articular surface and a lip on each side
- **New Jersey or Cylindrical TAR**, developed by a bioengineer and an orthopaedic surgeon

### 66.3 Second-Generation of Total Ankle Replacements

Based on research demonstrating the high complication and failure rates and lack of patient satisfaction with the first-generation of TARs, a second-generation was developed, including:
The Agility ankle prosthesis (Depuy), the first of a new generation of ankle prostheses, has been used since 1984.\(^1\) The Agility has been approved by the FDA and is currently the most widely used ankle prosthesis in the United States, and with more than 20 years of implantations, it has the longest follow up of any fixed-bearing TAR.\(^2\) The Agility ankle prosthesis is a semi-constrained, two-component prosthesis consisting of a titanium tibial and cobalt-chromium talar component. For improved osseous integration, both components have a sintered titanium bead surface. As this prosthesis is a two-component system, a modular polyethylene insert is locked into the tibial component. In 2007, the Agility LP Total Ankle System was introduced with some modification of its design.\(^2\) All improvements were designed after careful analysis of published data to improve the outcome and avoid mid- and long-term complications. The new prosthesis features include: a redesigned broad-based talar component (to avoid subsidence of the tibial component, especially in patients with nonunion of tibiofibular syndesmosis), the ability to mix and match component sizes to match native anatomy, and a front-loading polyethylene (easier surgical technique for exchange of insert).\(^2\)

The Buechel-Pappas ankle prosthesis is the first reported three-component prosthesis with a mobile bearing. It is the evolution of the first-generation New Jersey ankle prosthesis.\(^3,5\) In the first Buechel-Pappas design (Mark I), the anterior-posterior constraint between the tibial and mobile bearing components was removed. This shallow sulcus design allowed more ROM without compromising the intrinsic sagittal stability of the ankle replacement. Postoperative complications included delayed wound healing, reflex sympathetic dystrophy, deep infection, mobile bearing subluxation, talar component subsidence, severe bearing wear, malleolar fracture, and osteolysis. Analysis of complications from using this prosthesis led to modifications resulting in the Mark II Buechel-Pappas prosthesis. This new design (also known as the deep sulcus design) included two fins, a thicker meniscal component, and deeper sulcus with a gap in the plastic.

The Scandinavian Total Ankle Replacement (STAR) was developed as a two-component, anatomic, unconstrained resurfacing ankle prosthesis with congruent parts covering the medial and lateral facet joints.\(^5\) Since 1986, the tibial part of the STAR prosthesis has included a polyethylene component.\(^5\) This modification was performed to minimize rotational stress at the implant-bone interface. The current design of the STAR prosthesis is a congruent, cylindrical, three-component prosthesis. Initial osseous integration of the prosthesis is secured by a single fin on the talar side and by two cylindrical fins on the tibial side. Both metallic components have hydroxyapatite coated surfaces. The STAR prosthesis, one of the most popular TARs used in Europe, has one of the longest histories in ankle replacement surgery, with several modifications made during its clinical use.\(^5\)

### 66.4 Results of First- and Second-Generation TARs

The majority of first-generation TAR designs were two-component prostheses that used cement fixation on both the talar and tibial sides. The reason for cement fixation was simple: in the 1970s cementless fixation had not been widely used in knee and hip prostheses and cement fixation led to acceptable early component stability. However, an extremely high complication rate was observed with increased incidence of loosening, wide osteolysis, subsidence, and mechanical failure of prosthesis components.
Cement fixation required a larger bone resection. Therefore, bone quality at the cement-bone interface was not optimal, as the main load transfer occurred on the weaker metaphyseal bone. Most TARs included a polyethylene concave tibial and a metal convex component for the talus, usually made using cobalt chrome alloy. Both types of prostheses – constrained and unconstrained – were available at that time. One design feature of most first-generation TAR designs was a tibial component that was significantly larger than the talar. The idea was to allow physiological dorsi-/plantar flexion ROM as well as axial rotation. However, due to low intrinsic stability, significant increases in shear forces occurred. This was especially true in patients with chronic ligamental instability which resulted in prosthesis loosening early on.

Most clinical studies addressing outcomes in patients who underwent first-generation TAR were case reports or studies including between 20 to 40 patients. Another critical factor was the short follow-up periods reported (mostly 5 years or less). Patient satisfaction with first generation TAR was reciprocally proportional to the length of follow-up and varied between 19% and 81%.

Generally, the clinical results of first-generation TAR were highly discouraging. The alarmingly high prosthesis component failure rate along with other complications like wound healing and unacceptable functional results were the reasons that foot and ankle surgeons were advised to use ankle fusion as the primary treatment option for ankle OA. Failure analysis of first generation TARs showed that only significant improvements in prosthetic design, change of fixation (elimination of use of cement), and improved anatomical access would change arthroplasty outcomes.

An analysis of the main failure reasons of the first-generation TAR designs was crucial for the development of the second-generation ankle prostheses. More conservative and sparing bone cuts and the elimination of bone cement have significantly improved problems with component loosening. New biologic interfaces with special porous coatings for bony ingrowth and/or adding of hydroxyapatite were investigated as another possible method to ensure the primary prosthesis fixation. To reduce subsidence, second-generation ankle prostheses were designed to increase the surface area of the metallic components. Increased surface area sought to decrease the average local contact pressure and pressure peaks during gait.

The three main second generation TAR designs – Agility, Buechel-Pappas, and STAR prostheses – have been implanted with encouraging mid- and long-term results. Positive clinical results, high patient satisfaction, and acceptable survivorship of prosthesis components presented at national meetings and published in orthopaedic literature led to rethinking that ankle fusion may not be the only one reasonable treatment option for patients with severe ankle OA. The continued critical review of second-generation implant failures and biomechanical studies provided important data that led to the development of modern TAR designs.

66.5 Modern TAR Designs (Third-Generation TARs)
• The **Salto Total Ankle** was developed between 1994 and 1996 by Michel Bonnin. This TAR represents the third-generation of cementless meniscal-bearing designs. The tibial component has a flat surface toward the mobile bearing, allowing its free translation and rotation. The 3-mm medial rim is designed to avoid insert impingement against the medial malleolus. For osseous integration, the component has a keel and a fixation peg. The specific shape of the talar component mimics the natural talar geometry with the anterior width being wider than the posterior, and the lateral flange having a larger curvature radius than the medial. The mobile bearing is manufactured from ultra-high-molecular-weight polyethylene (UHMWPE) and has full congruency with the talar component in flexion and extension. All components are available in three sizes.

• The **HINTEGRA TAR** is an unconstrained, three-component system that provides inversion-eversion stability and was designed in 2000 by Beat Hintermann, Greta Dereymaeker, Ramon Viladot, and Patrice Diebold. The mobile bearing provides axial rotation and normal flexion-extension mobility. The HINTEGRA TAR includes two metallic components and an ultrahigh-density polyethylene mobile bearing. The non-articulating surfaces have a porous coating with 20% porosity and are covered by titanium fluid and hydroxyapatite. The tibial component has a flat, 4-mm thick loading plate with pyramidal peaks against the tibia. Additional stability may be achieved by fixation with two screws. The talar component is conically shaped with a smaller radius medially than laterally, mimicking the normal anatomy of talus. It has 2.5-mm high rims on each side that ensure stable positioning and guide the anteroposterior translation of the mobile bearing. The anterior shield of this component increases primary bone support, especially in cases with weaker bone, and may prevent the adherence of scar tissue and avoid restriction of ROM in cases with arthrofibrosis.

• The **Mobility Ankle System** was developed by Pascal Rippstein, Peter Wood, and Chris Coetzee. This is a three-component Buechel-Pappas type prosthesis with a short, conical tibial stem. The talar component of the Mobility implant resurfaces the superior dome of the talus, while the medial and lateral aspects of the talus remain untreated (unlike the Buechel-Pappas prosthesis). The talar component has a central, longitudinal sulcus and two fins, enhancing its intrinsic stability. The non-articulating surfaces are porous coated with a titanium spray.

• The **Ramses TAR** was developed in 1987 and first implanted in 1989 by a French design group. The Ramses TAR is a three-component, semi-constrained prosthesis with the high-density mobile bearing. Initially, a cemented fixation of prosthesis was used between 1980 and 2000. Since its introduction in 1975, the **TNK total ankle replacement** has undergone many modifications to address the material of the components (stainless steel, polyethylene, alumina ceramic), coating (without/with hydroxyapatite), and fixation (cement/cementless fixation). Currently, this is the only TAR design containing alumina ceramic components. While the studies by the designer reported favorable results using the third-generation TNK prosthesis, independent studies addressing TAR results in patients with rheumatoid OA show less promising results.
The **Ankle Evolutive System (AES) TAR** is a further development of the Buechel-Pappas-type prosthesis. This design has a modular stem and allows hemi-replacement of the medial tibiotalar and talofibular joints.\(^75\) This prosthesis has been widely used in England and France,\(^76,77\) and has also been introduced in Norway.\(^78\) Recent studies of the AES TAR reported a high rate of osteolytic lesions.\(^79-82\) It is still unclear whether the osteolysis process is a result of failure of the hydroxyapatite coating of the metal components or failure of the mobile bearing. As a result of independently published results showing high osteolysis rate, the AES prosthesis has been withdrawn from the market.\(^83\)

The **BOX TAR** was developed in the late 1990s by Leardini et al. This prosthesis is a three-component implant with metal components fixed to the proximal talus and the distal tibia and interposed UHMWPE meniscal bearing. The biomechanical development of this prosthesis type has been well documented in the literature by its designers.\(^84-86\)

The **ESKA ankle** is a two-component prosthesis designed for cementless implantation between 1985 and 1989.\(^87,88\) The following features were included to improve biomechanics of the replaced ankle: cementless implantation and porous-structured implant surface for faster osteointegration, shear force reduction by shape design of both metallic components, and easy replacement of the polyethylene without disturbing prosthesis anchoring.\(^87,88\) Because of the ridge-like shaping and its transverse anchoring peg in both metallic components, a lateral or in special cases, medial malleolar approach has to be used for implantation.\(^87\)

Other modern TAR designs include:
- **German Ankle System**, a three-component prosthesis allowing rotation around each of the three possible movement axes
- **Alphanorm Total Ankle Replacement**, a non-constrained Buechel-Pappas type design with a 90° tibial stem without inclination
- **TARIC Total Ankle Replacement**, which has a titanium coating and is optionally available with an additional hydroxyapatite coating
- **INBONE TAR**, a fixed-bearing, two-component total ankle system with a modular stem system for both metallic components

### 66.6 The TAR Learning Curve

It has been shown that there is a steep learning curve associated with performing TAR. The following intraoperative complications have been commonly reported:

- Medial and/or lateral malleolar fractures
- Laceration to the tendons (posterior tibial tendon, flexor digitorum/hallucis longus)
- Nerve injuries (deep/superficial peroneal nerve)\(^89-92\)

The influence of surgeon experience on complication rates in patient receiving the Agility prosthesis was examined by Saltzman et al.\(^91\) The perioperative records of the first 10 cases of nine surgeons with different training levels were recorded. The authors did not identify any specific training method that significantly decreased complication rates.\(^91\)
Myerson and Mocked performed a retrospective radiographic and chart review of 50 arthroplasties performed by the same surgeon using the Agility prosthesis.\textsuperscript{90} Patients were divided into two groups due to surgeon’s experience, each including 25 patients. The number of minor wound complications decreased from six in the first group to two in the second group. Also, the number of intraoperative fractures was different in favor of the second group (five vs. two fractures). The nerve or tendon lacerations (n=4) all occurred in the first group. Regarding the overall decreased complication rate in the second group of 25 patients, the authors stated that there was a notable learning curve in TAR performance.\textsuperscript{90}

A similar study with 50 patients who underwent Agility TAR was performed by Schuberth et al.\textsuperscript{93} In this study, patients were also divided into two 25-patient groups. There was a significantly decreased rate of the following complications with increased surgeon experience: medial and lateral fractures, major revisions, and malpositioning of prosthesis components.\textsuperscript{93} Schutte and Louwerens reported their initial results obtained in 49 patients who received a STAR prosthesis.\textsuperscript{92} The following intraoperative complications were detected: six fractures of the medial and two of the lateral malleolus, three fractures of the distal tibia, one injury of the peroneal nerve, and two malpositions of the tibial and two of talar components. Based on these numbers, the authors concluded that TAR should be performed only by an experienced orthopaedic foot and ankle surgeon.\textsuperscript{92}

The aforementioned studies addressed intraoperative complications in patients receiving second-generation TARs.\textsuperscript{89-92} Similar studies have been conducted for patient groups receiving third-generation TARs.\textsuperscript{89,94} Lee et al addressed the perioperative complications in the 25 initial patients to receive the HINTEGRA prosthesis and compared these results with those from a subsequent 25 cases.\textsuperscript{89} In the first group, perioperative complications occurred in 60\% of all cases, while in the second group, only five complications (20\%) were observed. All major complications (deep infection and aseptic loosening) occurred in the first group. The rate of minor complications (fractures, minor wound problem, nerve/tendon injuries, and heterotopic ossifications) significantly decreased in the second group. However, the authors were unable to show a decrease in the number of malpositioning of prosthesis components as a result of increased surgeon experience.\textsuperscript{89} The same working group compared the perioperative complication of the HINTEGRA total ankle system with the MOBILITY total ankle system.\textsuperscript{94} The authors did not find any differences in perioperative complications between the two total ankle systems, but medial malleolar fractures did occur more frequently when using the MOBILITY prosthesis.\textsuperscript{94}

Recently, Reuver et al addressed short-term results of TARs performed in low-volume arthroplasty centers.\textsuperscript{95} In total, 64 TARs were performed using Salto implants between 2003 and 2007 at four low-volume centers. Fifty-five patients (59 ankles) were reviewed at a mean follow up of 36 months. Seven ankles had to undergo revision surgery – two revision arthroplasties and five fusions – because of loosening, and two cases of deep infection resulting in a survivorship of 86\% at final follow up. Significant pain relief and functional improvement were observed in this review, as assessed using VAS and AOFAS score. The authors felt confident that results of TAR performed in low-volume centers are comparable to most high-volume centers. However, the survival of implanted components was significantly lower, especially regarding the relatively short follow up.\textsuperscript{95}

In summary, despite the encouraging results reported by studies using modern third-generation TAR, we believe, that TAR should be limited to foot and ankle orthopaedic surgeons with special training and adequate experience in arthroplasty techniques.
See Special Situations for Total Ankle Replacement for more on the use of TAR in painful ankle arthrodesis and simultaneous bilateral TAR.

66.7 Modern TAR Designs: Promising Results

Stengel et al performed a systematic review and meta-analysis to address the efficacy of TAR with meniscal-bearing implants. The following inclusion criteria were defined for this study: a minimum sample size of 20 subjects, at least 1 year of follow up, and a clinically relevant study endpoint. In total, 18 studies with 1,086 patients were included in the review. Most patients experienced significant functional improvement (average 45.2 points using standardized 100-point ankle and hindfoot scores) and a mild increase of ROM (mean increase = 6.3%, 95% CI, 2.2% - 10.5%). Weighted complication rates ranged from 1.6% (deep infection) to 14.7% (impingement). Secondary surgeries were necessary in 12.5% of all patients. Ankle fusions were required in 6.3% of patients due to implant failure, resulting in 1- and 5-year survivorship of 96.9% (95% CI, 94.9% - 98.8%) and 90.6% (95% CI, 84.1% - 97.1%), respectively. The data of this meta-analysis showed that TARs using current three-component designs provide an acceptable benefit-risk ratio. However, the results should be interpreted with caution due to non-optimal methodological quality, sample sizes, and short follow ups.

SooHoo et al compared reoperation rates following ankle fusion and TAR using California’s hospital discharge database. A total of 4,705 ankle fusions and 480 TARs were included in the review during the 10-year study period (1995 through 2004). It was shown that patients who underwent TAR had an increased risk of periprosthetic infection. The rates of major revision surgery after TAR were 9% at 1 year and 23% at 5 years compared with 5% and 11% following ankle fusion. However, TAR was shown to have advantages in terms of functional results.

In another study from 2004, SooHoo and Kominski performed cost analyses of TAR compared to ankle fusion. The authors performed a thorough literature review to identify possible outcomes and their probabilities following ankle fusion versus TAR. They found that TAR generated total expected lifetime treatment costs of $16,568, which is $6,990 more than costs following ankle fusion. Furthermore, TAR had an incremental cost-effectiveness ratio in the reference case of $18,419 for each quality-adjusted life year gained.

In 2007, Haddad et al performed a systematic literature review addressing the outcome of TAR implants currently in use. In total, 13 Level IV peer-reviewed studies were included, reporting the outcome of 1,105 TARs:
Postoperatively, a remarkable portion of patients still had residual pain (range, 27% - 60%). Also, superficial wound complications and deep infection were often reported, with rates up to 14.7% and 4.6%, respectively. Overall failure rate at 5 years had a wide range, 0% and 32%. In general, most patients experienced significant functional improvement as assessed by the AOFAS score. However, the postoperative improvement of ROM was relatively small (0° - 14°). Therefore, the patients should be informed that significantly improved ROM is not one of the postoperatively expected benefits of TAR.

Recently, Slobogean et al compared preference-based quality of life in patients with end-stage ankle OA treated with TAR or ankle fusion. The quality of life of 107 subjects was assessed using health state values derived from SF-36 (SF-6D transformation). The mean baseline SF-6D health state value in the TAR group was 0.67 (95% CI, 0.64 – 0.69) and in the ankle fusion group 0.66 (95% CI, 0.63 – 0.68). At 1 year follow up, both groups had significant and comparable improvements with 0.73 for the TAR group (95% CI, 0.71 – 0.76) and 0.73 for the ankle fusion group (95% CI, 0.70 – 0.76).

To date, there has been no clear evidence in the literature that three-component TAR designs are superior compared with two-component designs. Also, the high-quality comparative studies addressing postoperative outcomes in patients who underwent TAR vs. ankle fusion are rare. There has been only one prospective, controlled, comparative surgical trial performed including both patient cohorts. Future high-quality prospective, randomized, controlled studies would significantly help to establish the clinical practice guidelines needed for surgeons to make a correct decision about treatment choice.

### 66.8 Future Insights

TAR is increasingly gaining acceptance as a valuable option for treating patients with end-stage ankle OA. Current reports of this procedure show consistently good to excellent mid-term results with significant pain relief, good functional outcomes, and high patient satisfaction. The high failure rate of the first-generation ankle prostheses has been thoroughly analyzed and the TAR designs have been significantly improved. Current fixation techniques without cement have become the gold standard using “biological surfaces” (eg, introduction of hydroxyapatite in the 1990s) for better osseous integration of metallic prosthesis components.
One of the main principles of TAR surgical technique is preserving adequate bone stock.\textsuperscript{111} It has been widely recognized, with regard to bone resection, that less is more. An extensive bone resection may drastically limit the revision surgery in case of failure of the TAR, especially on the talar side. Also, the bone resection for implantation of prosthesis components should consider the anatomical inner structure of bone and especially trabecular microarchitecture for optimal load transfer.\textsuperscript{111} The optimal load transfer is very important because this would avoid pathologically increased pressure peaks, which may cause loosening and subsidence of components. Therefore, the load transfer on a tibial component that incorporates circumferential bony support may be superior to that of a stemmed component in the long term.\textsuperscript{110} Furthermore, the natural articular geometry of the ankle should be considered during the design of any ankle prostheses.

Modern implants try to retain the radius of the curvature of the talus, resulting in improved and a more natural ROM.\textsuperscript{111} The modern TAR is not only a resurfacing procedure of the osteoarthritic ankle but also a restoration of normal biomechanics of the entire hindfoot.\textsuperscript{110} If necessary, additional surgeries should be performed to achieve the appropriate ligamental and osseous balancing of the hindfoot.\textsuperscript{8-10,110} Failure to correct hindfoot alignment or undercorrection of hindfoot deformity can cause a significant increase of translation forces and movements during gait. Especially in patients with remaining valgus misalignment, this may lead to prosthesis failure because valgus misalignment is tolerated more poorly than varus.\textsuperscript{110}

In conclusion, TAR with current devices, equipment, and techniques has improved considerably over the past several decades to show that the ankle fusion is no longer the “gold standard” treatment for all patients with severe end-stage ankle OA. Future biomechanical and clinical studies addressing the outcomes and biomechanical properties of TAR should be continued with the aim of improving current TAR designs.

66.9 References


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66.10 AES Total Ankle Replacement

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Learn about the AOFAS

The Ankle Evolutive System (AES) TAR is a further development of the Buechel-Pappas-type prosthesis. This design has a modular stem and allows hemi-replacement of the medial tibiotalar and talofibular joints.1 This prosthesis type has been widely used in England and France2,3 and has also been introduced in Norway.4 While some studies show promising functional results, this prosthesis has experienced significant problems relating to osteolysis and has been withdrawn from the market.17
One of the first reports addressing the outcome in patients who underwent AES TAR is a study by Patsalis. This study included 15 AES TAR patients with an average short-term follow up of 8.5 months. Three malleolar fractures were observed intraoperatively. Two replaced ankles had to be revised, while the remaining 13 patients showed significant functional improvement as assessed by the AOFAS score.

In 2005, a short-term study by the designers of the AES prosthesis outlined the suggested surgical technique and reported good preliminary results.

Henricson and Ågren addressed the influence of preoperative hindfoot alignment on secondary surgery after TAR. The patient cohort included 109 STAR, 62 Buechel-Pappas, and 22 AES TARs. The mean follow-up time in the whole patient group was 4.2 years. Two cases with instability requiring additional surgery (one case with preoperative varus and one case with preoperative valgus deformity) were observed in the AES TAR group. No revision surgeries addressing prosthesis loosening were necessary.

Brooke et al presented two cases with valgus malalignment following TAR using an AES prosthesis. They performed a fibula lengthening osteotomy to regain the anatomical alignment and to avoid pathological increases in wear. In both cases, good clinical and radiographic results were achieved. Kharwadkar and Harris published a report of two cases using the AES tibial component as a revision component in patients with failed STAR prostheses. The hybrid AES-STAR revision procedures were performed at 4 and 7 years following the primary STAR prosthesis implantation. The mid-term results were satisfactory, with no restriction of daily activities.

Dahabreh et al published a case report with a patient having revision surgery due to extrusion of a metal radiological marker. The exchange of polyethylene insert was performed 9 months after the initial TAR using an AES implant. During revision surgery, the insert was found to be intact without fracture. Morgan et al presented 2.5 years’ follow-up results in a female patient who had poliomyelitis as a child and had been treated with the AES prosthesis because of a painful, degenerate ankle with preoperatively significant varus deformity. The patient showed a satisfactory functional outcome with a well-aligned replacement ankle and no evidence of loosening or osteolysis around prosthesis components.

Anders et al reported their mid-term results in 94 patients who underwent AES TAR between 2002 and 2007. One patient was deceased, leaving 93 ankles for evaluation at a mean follow up of 3.5 years. There were five intraoperative malleolar fractures, which were all secured with screws. One patient was revised after 5.5 years due to loosening of both metallic components, and two patients with loosening of the tibial component were pending revisions. In an additional three cases osteolysis, around the component was seen. Two ankles were revised due to fixed varus or valgus deformity. In one patient, an ankle fusion was performed because of a fracture of the distal tibia. Two patients were revised for deep infection. Overall, the cumulative 5-year survivorship with revision for any reason was 90%. In summary, the authors stated that mid-term results in their patient cohort were promising.

Morgan et al presented the outcomes of 38 consecutive patients who were treated with AES TAR between 2002 and 2004. All patients were reviewed clinically and radiographically at a minimum follow up of 4 years. Most patients presented with significantly improved function and pain relief. Two replaced ankles were converted to ankle fusion resulting in a cumulative 6-year survivorship of 94.7% (95% CI, 80.3% - 98.7%). Ten patients presented with edge-loading, of whom nine had corrective surgery. In nine patients significant osteolysis around the prosthesis components was seen. Because of non-progressive symptoms no further revision surgeries were suggested.
Despite high patient satisfaction, the authors reported some concerns about an observed high rate of osteolysis.\textsuperscript{13} The reported high rate of osteolysis in patients who underwent AES TAR has been confirmed by other studies. Besse et al reported mid-term results of their prospective study including 51 AES implants performed from 2003 to 2006.\textsuperscript{14} All patients were reviewed at a mean follow-up of 40 months. Eighty-two percent of all patients had good functional outcome showing a significant postoperative improvement of AOFAS score. In two patients, replaced ankles were converted to ankle fusion because of talar component subsidence and mechanical dislocation. Although the functional outcome and patient satisfaction were comparable to other results published in studies using other third generation prostheses, significant osteolysis with the AES TAR was more frequent with risk of subsidence. As a consequence, the authors stopped implantation of this prosthesis type and recommended a preventive grafting for severe osteolysis.\textsuperscript{14}

The comparably high osteolysis rate was also seen in a study by Koivu et al reviewing 130 consecutive AES implants performed between 2002 and 2008.\textsuperscript{15} Radiolucent lines or osteolytic lesions were seen on plain radiographs in 48 ankles (37%). Marked osteolytic lesions were found in 27 ankles (21%). The talar component migrated in nine ankles, in an additional two ankles, a shift of the tibial component was observed. Of the 27 ankles with marked osteolysis, 16 underwent revision surgery resulting in a revision rate of 15.5%. The contents of the osteolysis cavities were used for microbiological and histological analysis. The histological findings were interpreted as a foreign-body reaction. The authors concluded that the use of AES implants should be avoided until the reason and extent for the problem of osteolysis has been solved.\textsuperscript{15} Rodriguez et al observed a high frequency of delayed appearance of osteolysis (77%) in 18 ankles replaced with AES prosthesis at the mean follow-up of 39.4 months.\textsuperscript{16}

In summary, recent studies of the AES TAR reported a high rate of osteolytic lesions.\textsuperscript{13-16} It is still unclear whether the osteolysis process is a result of failure of the hydroxyapatite coating of the metal components or failure of the mobile bearing. As a result of independently published results showing high osteolysis rate, the AES prosthesis has been withdrawn from the market.\textsuperscript{17}

\section*{66.10.1 References}


66.11 Alphanorm Total Ankle Replacement

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Learn about the AOFAS

The Alphanorm TAR was developed by Professor Tilmann in Germany and has been used since 1996. The Alphanorm prosthesis is a non-constrained Buechel-Pappas type design with a 90° tibial stem without inclination. The prosthesis is made out of cobalt chrome alloy with a titanium coating. The medial and lateral talar surfaces are not replaced during component implantation, thus preventing inversion and eversion. Before developing the Alphanorm TAR for use, the designer had experience with the TRP prosthesis, New Jersey prosthesis, and STAR prosthesis between 1976 and 1998.
To date, there are no published studies available from Professor Tilmann or others addressing clinical outcomes or surgical technique of the Alphanorm TAR.

66.11.1 References


66.12 BOX Total Ankle Replacement

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Learn about the AOFAS

The BOX TAR was developed from a collaborative effort of the Rizzoli Orthopaedic Institute (Drs. Giannini, Catani, Leardini) in Italy and Oxford University (Dr. O’Connor) in England in the late 1990s. This non-constrained, mobile-bearing prosthesis is a three-component implant with metal components fixed to the proximal talus and the distal tibia and interposed UHMWPE meniscal bearing. The upper UHMWPE surface is concave, not flat is in previous designs. The biomechanical development of this prosthesis type has been well documented in the literature by its designers.1-3 Original research studies by the designers of this prosthesis focused on movement and stability of the ankle and sought to provide detailed understanding of the role of the ligaments in controlling and limiting joint movement.
In 2001 Leardini developed a geometrical model of the intact human ankle complex that established the basic principles for design of a new total ankle prostheses.\(^1\) Seven lower leg specimens were prepared for passive flexion analysis using a stereophotogrammetric system. It was shown that the geometry of the articular surface of the ankle is strictly related to that of the ligaments. Therefore, the author stated that the ideal TAR design should be based on ligament compatibility and the careful reconstruction of ligaments should be performed in any foot and ankle surgery to recreate the normal kinematics and mechanics of the ankle.\(^1\) A four-bar linkage model was developed from this initial study that also showed that both rolling and sliding motions take place at the talocrural joint.

In 2004 Leardini et al described the BOX TAR design and rationale, including compatibility to the physiological function of surrounding ligaments.\(^2\) The designers aimed to reproduce physiological ankle mobility with the following design features:

- Spherical convex tibial component
- Talar component with radius of curvature in the sagittal plane longer than that of the natural talus
- Fully conforming meniscal bearing.

Preliminary results from their study of two female patients demonstrated the feasibility of their surgical technique.\(^2\) Reggiani et al developed a finite element model to address the BOX TAR analysis during the stance phase of gait.\(^3\) Overall kinematics, contact pressures, and ligament forces were analyzed during both, passive (eg, virtually unloaded) and active (eg,stance phase of gait) conditions. The authors showed that this prosthesis design could allow the necessary ROM and constrain the motion of the prosthetic components, especially the mobile bearing.\(^3\)

Affatato et al have used a four-station knee joint simulator to address meniscal wear of the BOX TAR mobile bearing.\(^4\) The knee wear simulator was able to reproduce load-motion patterns comparable to those of a replaced ankle. Tests of three specimens showed a linear penetration of 0.0178, 0.0081, and 0.0339 mm per million-cycle. The linear penetration observed in this study was comparable to that found in ceramic-to-polyethylene or metal-to-polyethylene couplings.\(^4\)

Two years later, Affatato et al performed a comparative study of wear behavior in the BOX TAR between an in vitro simulation and retrieved prostheses.\(^5\) Three retrieved mobile bearings were available from revision surgeries performed 24, 24, and 9 months after the initial TAR surgery. Visual and microscopic observations, analyses, and Raman crystallinity-based measurements showed similarity between the patterns generated experimentally using a four-station knee joint simulator and those seen in retrievals with similar wear duration.\(^5\)

Ingrosso et al performed gait analysis in BOX TAR patients by a stereophotogrammetric system with eight M2-cameras.\(^6\) The study included 10 patients with a follow-up of 6 and 12 months after the surgery. Normal patterns and ROMs were observed in all 10 patients at both follow-ups.\(^6\)

Giannini et al presented short-term results in 51 patients who were treated with a BOX TAR.\(^7\) The minimum follow-up in this study was 24 months. All patients showed significant functional improvement as assessed by the AOFAS score. A revision arthroplasty had to be performed in one patient because of lateral impingement, resulting in a 3-year cumulative survivorship of 97%.\(^7\) The main indication for this procedure was stage III ankle OA (with subtotal or total disappearance or deformation of joint space) with preserved or restored ankle anatomy.\(^8\)
In summary, the design process and biomechanical properties of the BOX TAR have been documented in detail.\textsuperscript{1-3} The designers claim that it maintains complete congruency during the entire arc of motion and closely resembles normal ankle biomechanics. Studies addressing the wear behavior in this prosthesis design have significantly contributed to the understanding of modern three-part prostheses.\textsuperscript{4,5} The short-term results are promising, with high satisfaction among treated patients, good functional results, and a low revision rate.\textsuperscript{7} However, all aforementioned studies were performed by one of designers of this prosthesis; therefore, further study by independent groups should be performed. Long-term results have to provide evidence on their clinical success.

### 66.12.1 References


### 66.13 ESKA Ankle Prosthesis

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Learn about the AOFAS

The ESKA TAR is a non-constrained, fixed-bearing, two-component prosthesis that was designed in Germany for cementless implantation between 1985 and 1989. It has a shallow groove on the talar component that is congruous to the ultra-high-molecular-weight polyethylene (UHMWPE) bearing fixed to the tibial prosthesis. The following features were included to improve the biomechanics of the ankle replacement:

- Cementless implantation and porous-structured implant surface for faster osteointegration
- Shear force reduction and rotational force control by shape design of both metallic components
- Easy replacement of the polyethylene without disturbing prosthesis anchoring

Because of the ridge-like shaping and its transverse anchoring peg in both metallic components, a lateral approach with fibular osteotomy or in special cases, a medial malleolar approach is used for component implantation.

In 2001, the prosthesis designer, Dr. Rudigier, published short-term results of 56 patients treated with the ESKA prosthesis since 1990. Forty of 56 patients were reviewed at a minimum follow up of 1 year. All patients experienced significant pain relief, improved ankle ROM and ability to walk, and showed functional improvement as assessed by the Kofoed ankle score. In two cases, deep infection led to prosthesis removal and conversion to ankle fusion. Another patient showed painful progressive ossification of the joint capsule resulting in ankle fusion. The same patient cohort was again reviewed at a longer follow up and the results were published in another two studies. The authors reported a significant improvement of the Kofoed ankle score from 37.6 points preoperatively to 90.4 points postoperatively. Of 12 TARs performed 10-15 years before, 8 (67%) remained in situ (2 early deep infections, 2 aseptic loosenings). In 20 implants inserted 5-10 years before, 3 were revised, leaving 17 (85%) in situ functioning well. None of the implants with a follow-up of 1-5 years failed. No results from independent authors have been published.

In summary, the limited studies performed by ESKA prosthesis designers reported favorable mid-term results with improved ankle ROM, pain relief, and ability to walk long distances postoperatively. However, the authors conceded that this surgery should be limited to only highly experienced foot and ankle surgeons due to the demanding lateral approach with fibular osteotomy. As with the BOX TAR, published results have come from only the prosthesis designers. Thus, additional, independent analyses of ESKA efficacy are needed.

66.13.1 References


66.14 German Ankle System

The German Ankle System is a three-component prosthesis allowing rotation around each of the three possible movement axes.¹ The talar component of this prosthesis includes side borders to keep the mobile bearing in position, which may prevent inlay dislocation. Both metallic components have BONIT© coating (porous coating with titanium plasma sprayed surface and an additional layer of calcium phosphate) to ensure the proper osteointegration. The system includes an option for computer-assisted implantation surgery.

Richter et al performed the robotic-guided surgical approach on a cadaver and compared the results with those obtained using a HINTEGRA prosthesis.¹ The authors found that the German Ankle Prosthesis had smaller effect on resulting forces and torques during partial weight-bearing passive ankle motion than the HINTEGRA prosthesis.¹ However, to date no clinical results from patients treated with this prosthesis type are available, raising some concern regarding the interpretation of obtained data in the study by the designer.

66.14.1 Reference

The HINTEGRA Total Ankle Replacement (TAR) is an unconstrained, three-component system that provides inversion-eversion stability and was designed in 2000 by Beat Hintermann, Greta Dereymaeker, Ramon Viladot, and Patrice Diebold. The mobile bearing provides axial rotation and normal flexion-extension mobility. The HINTEGRA TAR includes two metallic components and an ultrahigh-density polyethylene mobile bearing. The non-articulating surfaces have a porous coating with 20% porosity and are covered by titanium fluid and hydroxyapatite.

The tibial component has a flat, 4-mm thick loading plate with pyramidal peaks against the tibia. Additional stability may be achieved by fixation with two screws. The talar component is conically shaped with a smaller radius medially than laterally, mimicking the normal anatomy of talus. It has 2.5-mm high rims on each side that ensure stable positioning and guide the anteroposterior translation of the mobile bearing. The anterior shield of this component increases primary bone support, especially in cases with weaker bone, and may prevent the adherence of scar tissue and avoid restriction of ROM in cases with arthrofibrosis.

The HINTEGRA TAR has been used since 2000 in Europe, since 2004 in Canada and Korea, and since 2005 in Brazil. The use of this prosthesis is also documented in National Arthroplasty Registers of Finland, Sweden, Norway, and New Zealand.

In the current literature there are numerous studies addressing clinical outcome and biomechanical properties of the HINTEGRA TAR, published by the designer. In 2004, Hintermann et al published the first study reporting HINTEGRA design rationale, surgical technique, and short-term results of the first consecutive 122 ankles in 166 patients. All patients were reviewed at a mean follow up of 19 months. Eight ankles had to undergo revision surgery, four because of loosening of at least one component, one because of dislocation of the mobile bearing, and three for other reasons. All revisions were successful. Most patients experienced significant functional improvement postoperatively, as assessed by the AOFAS score; 68% were pain free at latest follow up. The clinically and radiographically measured ROM was 39° and 37°, respectively. Tibial components were stable in all reviewed ankles; in two ankles a slight migration of the talar component was observed. Similar results were published in a study by Valderrabano and Hintermann, including 125 HINTEGRA implants.
In 2006, Hintermann et al presented mid-term results of 271 HINTEGRA TARs performed in 261 patients between 2000 and 2004. The mean follow-up was 36 months with a range between 12 and 64 months. Intraoperatively, four malleolar fractures occurred, which all healed within 6 weeks. Five ankles (1.8%) had to be converted to ankle fusion. Thirteen talar and two tibial components were later revised. In total, 39 revision surgeries (e.g., open arthrolysis, lengthening of Achilles tendon, ligament reconstruction) were necessary to address late postoperative complications.

Kim et al compared the outcome and complications of HINTEGRA TAR with and without hindfoot fusion. In total 60 ankles with HINTEGRA implants and subtalar or triple fusion were compared to a control group of 288 ankles treated with TAR alone. The mean follow up was 39.5 months. The authors found that the clinical outcome of TAR when combined with hindfoot fusion (subtalar or triple fusion) is comparable to that of ankle replacement alone. Therefore, the authors recommended that hindfoot fusion should be performed simultaneously with TAR in cases when indicated.

Recently, Barg et al published clinical observation studies addressing clinical and radiological outcomes in patients who underwent HINTEGRA TAR because of end-stage osteoarthritis (OA) due to hemophilia or hemochromatosis. In both patient cohorts, favorable outcomes with significant pain relief and functional improvement were observed, demonstrating TAR as a reliable option treatment.

Valderrabano et al addressed the sporting and recreational activity of patients with end-stage ankle arthritis before and ankle TAR. The authors recommended specific Sports Frequency Score. A clinical evaluation was performed preoperatively and at a mean follow up of 2.8 years in 147 patients (152 ankles). All patients experienced significant functional improvement as assessed by the AOFAS score. After TAR, patients with sports activities had a higher AOFAS score. The three most frequent sports activities after TAR were hiking, biking, and swimming.

Daniels et al published their results for 32 TARs in patients with significant preoperative varus talar deformities. In all patients, cementless, mobile-bearing, three-part component prostheses had been used: 26 HINTEGRA, four Mobility, and two STAR implants. A satisfactory radiographic correction was obtained in the most cases (30 ankles) at a mean follow up of 17 months. In 24 ankles, additional procedures after TAR were required to obtained a plantigrade foot.

Lee et al addressed perioperative complications of HINTEGRA TAR in their 50 initial cases. The same author presented two case reports addressing HINTEGRA TAR in patients following revascularization of avascular necrosis of the talar body. The authors stated that in patients with avascular necrosis of the talus, healing of necrotic bone by creeping substitution TAR is a valuable option.

Kim et al described clinical outcome of TAR in 23 patients with moderate to severe varus deformity and compared results to those in 22 patients with neutral alignment. All patients were reviewed at a mean follow-up of 27 months and showed substantial pain relief and functional improvement in both groups as assessed by VAS and AOFAS score, respectively. Failure of the implant with conversion to ankle fusion occurred in one case in each group. The authors stated that the TAR is a valuable treatment for severe ankle OA, including patients with hindfoot misalignment. However, the appropriate additional procedures to address the deformity are necessary to obtain good clinical results including prosthesis stability and ROM.
Recently, Bai et al compared clinical outcome and revision rate after TAR between patients with posttraumatic and primary OA.\(^{23}\) Sixty-seven consecutive TARs were performed using HINTEGRA prosthesis in 65 patients between 2005 and 2007. All patients were divided into two groups: posttraumatic OA group (37 ankles) and primary OA group (30 ankles). At a mean follow-up of 38 months the clinical (AOFAS score, ROM) and radiographic outcome were comparable. However, the incidence of postoperative complications was significantly higher in the posttraumatic OA group.\(^{23}\)

Valderrabano et al published a series of studies addressing muscle biomechanics and muscle rehabilitation in patients with severe ankle OA who underwent TAR.\(^{24-27}\) A prospective study performed including 15 patients who were reviewed preoperatively and postoperatively in 3-month intervals up to 1 year showed that TAR surgery may improve muscle biomechanics as assessed by torque measurement and EMG intensity.\(^{24}\) However, in most patients the muscle rehabilitation was not complete at a follow up of 1 year.\(^{24}\)

Müller et al used a Heidelberger foot and ankle analysis model to address the 3D kinematics and foot and ankle shape in 12 patients who underwent HINTEGRA TAR.\(^{28}\) The authors detected some decreased ROM after ankle replacement compared with contralateral ankles free of degenerative changes. However, these differences did not affect the gait kinematics, showing TAR may be able to preserve ROM which, in turn, may avoid or at least decelerate the degenerative changes in adjacent joints.\(^{28}\)

Lee et al investigated static and dynamic postural balance after TAR using HINTEGRA in 30 patients and compared the results to an age- and sex-matched control group.\(^{29}\) The authors showed that patients who underwent TAR have a higher degree of dynamic postural imbalance. Some motor control deficits were also detected in the TAR group. The authors stated that more intensive postoperative balance training may decrease the observed deficits.\(^{29}\)

In conclusion, the mid-term results in patients with HINTEGRA TAR are favorable.\(^{12,14}\) However, most clinical studies have been published by the designer. Comparable studies by independent authors and studies with longer follow-ups should be performed.

### 66.15.1 References


### 66.16 INBONE Total Ankle Replacement

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Learn about the AOFAS

The INBONE TAR is a fixed-bearing, two-component total ankle system. A special feature of this ankle design is a modular stem system for both metallic components. The tibial stem has the ability to be extended by adding more modular segments. The stem of the talar component may be short and limited to the talar body. However, in cases where subtalar fusion has to be performed or for greater stability, the talar stem may be extended across the subtalar joint.

To date, there are limited reports in the literature on clinical and radiographic outcomes in patients who received INBONE TARs. The designer of the prosthesis has performed more than 240 INBONE TARs and data have been collected in preparation for publication. There are also no biomechanical studies available that address the kinematics and biomechanical properties of this prosthesis design.

### 66.16.1 References

66.17 Mobility Ankle System

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The Mobility Ankle System, developed by Pascal Rippstein, Peter Wood, and Chris Coetzee, is a three-component Buechel-Pappas type prosthesis with a short, conical tibial stem. The talar component of the Mobility implant resurfaces the superior dome of the talus, while the medial and lateral aspects of the talus remain untreated (unlike the Buechel-Pappas prosthesis). The talar component has a central, longitudinal sulcus and two fins, enhancing its intrinsic stability. The nonarticulating surfaces are porous coated with a titanium spray.

Goldberg et al reported results of their questionnaire-based survey sent to all Consultant members of the British Orthopaedic Foot & Ankle Society. The Mobility prosthesis was the most commonly used prosthesis among 62% of all surgeons in the United Kingdom. The use of this prosthesis has also been documented in the Swedish Ankle Arthroplasty Register and New Zealand Ankle Arthroplasty Register. The Swedish Ankle Arthroplasty Register included a total of 531 total ankle replacements (TARs) with 23 Mobility prostheses implanted since 2005. No peri- or postoperative complications with the Mobility prosthesis were observed in the Swedish cohort. The New Zealand Ankle Arthroplasty Register included a total of 202 TAR with a mean follow-up of 6 years. Twenty-nine patients in this registry underwent Mobility prosthesis; no failures were observed in this study.

Recently, Wood et al published early results from their prospective study that included 100 Mobility implants performed in 96 patients between 2003 and 2005. At a minimum follow up of 5 years, a total of five ankles (5%) had to undergo revision surgery -- two ankle fusions and three revision arthroplasties -- resulting in 3- and 4-year survivorship of 97% (95%CI, 91% -- 99%) and 93.6% (95%CI, 84.7% -- 97.4%), respectively. In 14 ankles a radiolucent line or osteolytic cavity was observed. However, only in five ankles was it more than 10 mm in width. The authors presented encouraging short-term results which are comparable to those obtained using other modern three-component prostheses.
Naal et al addressed habitual physical activity and sports participation before and after TAR in 137 consecutive patients with 155 implants. One hundred one ankles were available for the review at a mean follow up of 44 months, 54 of them were Mobility implants. The percentage of patients who were active in sports did not change after the TAR (62.4% preoperatively and 66.3% postoperatively). The most common sports activities after TAR were swimming, cycling, and fitness/weight training. The authors registered high functional improvement in their patient cohort as assessed by AOFAS scores. No association was found between sports participation, increased physical activity level, and the appearance of periprosthetic radiolucencies.

Thermann et al reported a single case of a 58-year-old patient who underwent Mobility TAR and tibialis posterior tendon transfer for ankle osteoarthritis (OA) and drop foot deformity. Postoperative radiographs showed a medial malleolus fracture despite intraoperative pinning with the Kirschner wires. However, the fracture completely healed after 8 weeks. Three years after the primary procedure, the patient was asymptomatic and had a stable ankle joint with 5° dorsiflexion and 20° plantar flexion.

Goldberg et al reported two cases of early failure in patients who underwent Mobility TAR due to component malposition. In both cases, the talar component was inserted back to front, as was the polyethylene insert, requiring ankle fusion in the first case and revision arthroplasty in the second case. The authors emphasized the need for adequate training of foot and ankle surgeons for performing TARs. They also suggested that designers have a responsibility to improve marketing and education for surgeons using their products to minimize incidents of incorrect use.

Espinosa et al generated two finite element models of TAR prostheses (Agility and Mobility) to investigate the misalignment of prosthesis components on joint contact pressures. The authors have shown that the highly congruent mobile-bearing design of Mobility prosthesis may result in more evenly distributed contact pressures than the less congruent two-component Agility prosthesis. However, in both design the misalignment of prosthesis components may lead to pathologically increased contact stresses.

Bell and Fisher investigated polyethylene wear in Mobility and Buechel-Pappas prostheses using a modified knee prosthesis simulator. The authors showed that wear in the two models was comparable and that the wear rate for both designs significantly increases with the inclusion of an anterior/posterior displacement in the kinematic inputs, simulating malalignment of prosthesis components.

In conclusion, the Mobility TAR has been in general use since 2003 in Europe, Australia, New Zealand, South Africa, and Canada. In the United States a multicenter FDA trial including this prosthesis type is running.

66.17.1 References


66.18 Ramses Total Ankle Replacement

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Learn about the AOFAS

The Ramses TAR was developed in 1987 and first implanted in 1989 by a French designer group. The Ramses TAR is a three-component, semi-constrained prosthesis with a high-density mobile bearing. Initially, cemented fixation of the prosthesis was used between 1980 and 2000.

A total of approximately 350 TARs using the Ramses TAR have been performed by the inventing group. Mendolia et al reported long-term results in 69 patients who underwent Ramses TAR between 1989 and 1993. In seven cases, the replaced ankle had to be converted to an ankle arthrodesis (four ankles for pain without loosening and three ankles for clinical and radiographic loosening). In an additional five cases, a second surgery was performed (two cases with mobile bearing ankle replacement and three cases with revision arthroplasties).
Delagoutte performed a retrospective analysis of 110 TARs between 1991 and 1998. This was a multicenter study including 22 hospitals. Three different TAR types were used in this study: Ramses (n=66, 60%), LCS (n=36, 33%), and STAR (n=8, 7%) prosthesis. The follow up varied in this study between 3 and 37 months. In general, the postoperative functional results were less favorable, with no postoperative improvement in dorsiflexion. In two patients with Ramses prostheses, revision surgery was necessary to address prosthesis loosening.

Use of the Ramses prosthesis has been listed in 11 of 202 TARs mentioned in the New Zealand national joint registry. Two failures in this patient cohort were reported.

In conclusion, the mid- and long-term results in patients who underwent Ramses TAR are not satisfactory due to high revision rates of 18% and 34% at 2 and 10 years, respectively. The number of pain free patients also has equaled the number of patients with remaining pain.

66.18.1 References


66.19 Salto Total Ankle Prosthesis

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The Salto Total Ankle Prosthesis was developed between 1994 and 1996 by Michel Bonnin. This total ankle replacement (TAR) is the third generation of cementless meniscal-bearing designs. The tibial component has a flat surface that faces the mobile bearing, allowing free translation and rotation. The 3 mm medial rim is designed to avoid insert impingement against the medial malleolus. For osseous integration, the component has a keel and a fixation peg. The specific shape of the talar component mimics the natural talar geometry - the anterior width is wider than the posterior width and the lateral flange has a larger curvature radius than the medial. The mobile bearing is manufactured from UHMWPE and has full congruency with the talar component in flexion and extension. All components are available in three different sizes.

In 2008, Leszko et al performed an in vivo kinematics study of the Salto TAR in 20 patients using fluoroscopy and a 3D-to-2D registration technique. The motion of the prosthesis was described in terms of clinical rotations and as rotation about the helical axis. Among the clinical rotations, the dorsi-/plantarflexion was the most dominant with a mean ROM of 9.2 degrees. The anterior-posterior translation of the mobile bearing was measured at 1.5 mm and 2.3 mm for gait and step-up, respectively.

The first clinical study on the Salto prosthesis was published in 2004 by the prosthesis designer. Bonnin et al implanted 98 consecutive Salto prostheses between 1997 and 2000. Ninety-three implants in 91 patients were reviewed clinically and radiographically at a mean follow-up of 35 months. Most patients were pain free and showed a significant functional improvement as assessed by AOFAS score (from 32.2 to 83.1 points). Two prostheses had to be converted to ankle fusion, resulting in survivorship of over 95% at 68 months. In the following 2 years, 22 additional Salto implants were performed, as published by Weber et al, who included a total of 115 implants in their study. At a mean follow up of 22 months, four ankles had to undergo revision surgery.

Recently, Bonnin et al presented survivorship at 7 to 11 years in a retrospective review of 98 TARs performed between 1997 and 2000. Six replaced ankles had to be converted to ankle fusion and an additional 18 ankles underwent reoperation without ankle fusion (10-year survivorship 65% with 95% CI of 50% to 80%). The most common complications requiring additional surgery were bone cysts (11 ankles), fracture of polyethylene (5 ankles), and unexplained pain (3 ankles).

Furthermore, Bonnin et al addressed the sports activity level of 145 patients who underwent Salto TAR between 1997 and 2005. Ankle function was assessed using the Foot Function Index and Foot and Ankle Ability Measurement. In most cases, replaced ankles were reported to have normal (15.2%) or nearly normal (60.7%) function. Participation in sports and recreational activities was analyzed only in the osteoarthritis (OA) group (100 patients), but not in patients with rheumatoid arthritis. While most patients participated in some sport activities, a return to impact sports was rarely possible.

In conclusion, the mid-term results of the Salto TAR are promising. However, the only clinical reports come from the prosthesis designer. In the United States, a modified design of the Salto TAR is approved for use in patients with ankle OA. This fixed-bearing design includes a titanium tibial component with a highly conforming polyethylene articulating insert. However, to date no clinical studies reporting results of this prosthesis are available.

### References
66.20 Special Situations for Total Ankle Replacement

Takedown of Painful Ankle Fusion and Total Ankle Replacement

Simultaneous Bilateral Total Ankle Replacement

66.20.1 Simultaneous Bilateral Total Ankle Replacement

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Learn about the AOFAS

Some patients may present degenerative changes on both ankles concurrently. In such patients, an appropriate treatment may be bilateral total ankle replacement (TAR).
There is limited information in the current literature about the outcome of simultaneous bilateral TAR. Karantana et al published a case series including five consecutive simultaneous bilateral TARs performed between 2002 and 2006 using the STAR prosthesis. The mean follow-up in this patient cohort was 46 months, with a range between 26 and 65 months. Two patients had delayed wound healing. In one patient, a stress fracture of medial malleolus was seen 10 weeks postoperatively and treated nonoperatively in an Aircast splint for 6 weeks. At the latest follow-up, all patients experienced significant pain relief and presented with good functional outcome and reported excellent satisfaction relating to their experience.

Barg et al recently compared pain relief, quality of life, and functional outcome of 23 simultaneous bilateral TARs with that of 46 matched unilateral TARs. After 4 months, patients with simultaneous bilateral TAR had a higher pain level and worse functional outcome and quality of life as assessed by using AOFAS and SF-36 scores, respectively. However, the observed differences disappeared at the 1- and 2-year follow-up.

In summary, the two available clinical studies suggest that simultaneous bilateral TAR under one anesthetic can be offered to patients with bilateral severe ankle OA. However, further studies including more patients with clinical and radiographic review at longer follow-up should be performed to prove the safety and efficacy of this procedure.

References


66.20.2 Takedown of Painful Ankle Fusion and Total Ankle Replacement

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Ankle fusion as a treatment option for end-stage ankle osteoarthritis (OA) has been reported as the “gold standard”.\(^1\) Most patients who undergo ankle fusion experience significant early pain relief postoperatively.\(^1\) However, many patients with an ankle fusion develop long-term degenerative changes in adjacent joints.\(^2,4\) This progressive development of degenerative changes may require addition fusion surgery, eg, subtalar fusion.\(^5\)

A nonunion or malunion of an ankle fusion is an uncommon but severe post-surgical complication.\(^1\) In patients with painful nonunited or malunited ankle arthrodesis, takedown of the arthrodesis and subsequent implantation of a total ankle prosthesis may be a treatment option.

Newton performed three total ankle replacements (TARs) using the Newton Ankle Implant in patients with nonunion of a prior ankle fusion.\(^6,7\) The initial ankle fusion was performed because of avascular necrosis of the talus. In one patient, four unsuccessful fusion attempts were performed. All three implants failed, requiring one prosthesis revision and two lower leg amputations. Therefore, the author stated that TAR should not be performed in patients with a previously failed ankle fusion.\(^6,7\)

In 2004, Greisberg et al published a retrospective study of 23 procedures in 22 patients to review takedown of ankle fusion and conversion to TAR using the Agility prosthesis.\(^8\) At a mean follow-up of 30 months, 18 patients (19 ankles) were available for clinical and radiological review. In three patients, a lower leg amputation was performed because of significant residual pain. In the remaining 16 ankles, a significant functional improvement was detected as assessed by the AOFAS score. Thus, in this study a remarkable rate of postoperative complications with a failure rate of 42.1% was reported. However, the authors suggested that this procedure is a viable alternative to amputation, primarily in patients with a definable source of pain and who have not had previous malleolar resection during the initial ankle fusion.\(^8\)

Between 1999 and 2004, Hintermann et al performed 29 conversions of painful ankle fusion to TAR in 27 patients using the HINTEGRA TAR.\(^9,10\) At a mean follow up of 56 months, most patients (82.7%) were satisfied with results and showed significant pain relief and functional improvement as assessed using VAS and AOFAS scores, respectively. One ankle had to be revised because of persistent pain and significant loosening of the talar component. All but one tibial component were stable; the talar component was found to have migrated in four ankles but was asymptomatic in two of them.\(^9,10\)

Atkinson et al published a case report addressing clinical outcome and gait analysis following conversion of tibiotalocalcaneal fusion to TAR using HINTEGRA implants.\(^11\) Two years after the conversion to TAR, the patient was subjectively delighted with her increased mobility and functional improvement. The objective results of her gait analysis, which included comfortable walking pace, stride length, and cadence, showed a trend toward normalization of gait mechanics.\(^11\)

In 2010, Barg and Hintermann published the detailed technique of this procedure.\(^12\) The absolute contraindications for the procedure include:
Clubfoot deformity
* Non-manageable hindfoot deformity
* Highly comprised soft tissues and large scars on the medial side
* Severe vascular and/or neurological deficiency
* Active osteomyelitis and/or deep infection
* Chronic pain syndrome existing over years
* Neuropathic disorders (Charcot arthropathy).  

This procedure may be used with some restrictions (relative contraindications) in the following cases:
* Previous fibulectomy
* Long-standing immobilization
* More than 3 cm shortening of the affected leg
* High demands for physical and sports activities
* Diabetic syndrome without polyneuropathy.  

In conclusion, current studies show favorable mid-term results after conversion to TAR in patients with painful ankle arthrodesis. However, this procedure is technically more demanding that primary TAR and should be limited to foot and ankle surgeons with adequate experience in primary TAR. Additionally, careful preoperative planning and selection of patients are very important factors in achieving a good clinical outcome.

References


66.21 TARIC Total Ankle Replacement

The TARIC TAR was developed by Schill in Germany and has been used since 2006.¹ The TARIC prosthesis has a titanium coating and is optionally available with an additional hydroxyapatite coating. The tibial component has two fixation pegs.² Before creating the TARIC TAR, the designer had experience with the TRP and STAR prostheses.³

Currently, there are no studies available addressing clinical outcomes or surgical technique of the TARIC TAR.

66.21.1 References


66.22 TNK Total Ankle Replacement
The TNK prosthesis was developed by Dr. Takakura in Japan in 1975. It is currently the only total ankle prosthesis with alumina ceramic components. The third generation of this device has shown promising results in reports by the designer, but these have not been results have not been duplicated by others.

In 1988, Takakura et al reported a comparative study of cemented metal and uncemented ceramic TNK ankle prostheses. Both types were two-component prostheses with high-density polyethylene fixed to the tibial component. Before 1980, the authors implanted 30 cemented stainless steel prostheses (first generation); after 1980 they used 9 cemented and 30 uncemented ceramic prostheses (second generation). The mean follow-up time for cemented and uncemented total ankle replacements (TARs) was 8.1 and 4.1 years, respectively.

Patients who underwent TAR with an uncemented prosthesis were 67% more satisfied than those who underwent the procedure with a cemented prosthesis (27%). Five metal TARs and one ceramic TAR had to be revised (five arthrodeses and one revision arthroplasty).

The initial encouraging results were not maintained in another study by the same working group, published in 2004. Significant loosening and subsidence of the prosthesis were observed in most patients with the first-generation TAR (stainless steel prosthesis). The second-generation TAR (ceramic prosthesis) was implanted in 60 ankles between 1980 and 1991 (in 12 ankles, cement fixation was used). However, loosening and significant subsidence occurred in most patients within 5 years after the surgery.

In 1991, the ceramic prosthesis (second generation) was modified by adding bead-formed alumina coated with hydroxyapatite (third generation). Between 1991 and 2001, this prosthesis type was used in 70 ankles. The mean follow up in this patient group was 5 years. In three patients, the replaced ankle had to be fused (one case with deep infection, two cases with severe subsidence of talar component). Overall results were excellent or good in the most patients (52 ankles). The patient satisfaction rate was higher in patients with osteoarthritis (OA) compared with patients with rheumatoid OA.
The TNK prosthesis has been used for treatment of rheumatoid OA with poor clinical and radiographic outcomes, as shown in two studies.\textsuperscript{4,5} Nishikawa et al reviewed 26 patients (six patients received bilateral TAR) with rheumatoid OA who were treated with a TNK prosthesis between 1984 and 2000. At a mean follow up of 72 months 27 ankles in 21 patients were reviewed. Three ankles had to undergo revision surgery. Nine patients reported their outcome as excellent or good, but patients complained about residual pain in 13 ankles. A high rate of radioluency was observed in this patient cohort: migration of the tibial component in 13 ankles and collapse of the talus in nine.\textsuperscript{4}

Nagashima et al reported results of 21 TARs performed in 19 patients between 1998 and 2002 using the TNK prosthesis.\textsuperscript{5} Hybrid-type fixation (talus component cemented, tibial component not cemented) was used in 15 of 21 cases, while both components were cemented in the remaining cases. Early postoperative complications included two patients with delayed wound healing and one patient with deep infection. In 11 of 21 ankles, significant radioluency lines were observed. Most patients experienced pain relief and functional improvement; however, postoperative improvement of ROM directly correlated with preoperative ROM.\textsuperscript{5}

Shinomiya et al performed 20 TARs using TNK prosthesis in 18 selected patients with rheumatoid OA between 1988 and 1996.\textsuperscript{6} All patients were reviewed at a mean follow up of 8 years, with a range of 5 to 12 years. All patients experienced substantial pain relief and showed functional improvement superior to those who underwent ankle arthrodesis in the same period. No conversions to ankle fusion or revision arthroplasties were necessary in this cohort. However, a radiolucent line was observed in all replaced ankles at the final follow up. The authors stated that TAR may be useful in young patients with rheumatoid OA, considering their better postoperative quality of life.\textsuperscript{6}

Shi et al developed a special hydroxyapatite augmentation for bone atrophy in TAR for rheumatoid patients receiving a TNK prosthesis.\textsuperscript{7} This specially designed hydroxyapatite coating was used in 16 ankles (14 patients) and results were reviewed at a mean follow up of 23 months. More than half of all ankles showed a radioluency zone between hydroxyapatite and the tibial component on radiographs at the final follow up. However, no significant changes of coating position were registered; also, no significant subsidence was noted. The authors suggested that this new technique using hydroxyapatite may increase the primary implant fixation to the bone, especially in patients with rheumatoid OA and showing significant bone atrophy.\textsuperscript{7}

Recently, Tsukamoto et al reported a case using a custom-made alumina ceramic total talar component for treatment of collapse of the talar body in one patient who received a TNK prosthesis.\textsuperscript{8} The revision surgery was performed in a 56-year-old female patient 4 years after the initial TAR. The authors achieved substantial pain relief and functional improvement especially regarding walking ability. This case report demonstrated a feasible revision treatment in patients with failed TAR.\textsuperscript{8}

In summary, since its introduction in 1975, the TNK prosthesis has undergone many modifications to address the material of the components (stainless steel, polyethylene, alumina ceramic), coating (without/with hydroxyapatite), and fixation (cement/cementless fixation). Currently, this is the only TAR design with alumina ceramic components. While the studies by the designer reported favorable results using the third-generation TNK prosthesis,\textsuperscript{2,3} independent studies addressing TAR results in patients with rheumatoid OA show less-promising results.\textsuperscript{4,5}

66.22.1 References


