Patient selection for total ankle arthroplasty

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Abstract: Total ankle arthroplasty is a treatment option for end-stage osteoarthritis of the ankle, as is ankle arthrodesis. Many variables, including patient characteristics, are thought to influence clinical outcome and survival. As with any surgery, but especially with total ankle replacement (TAR), patient selection is considered critical for good (long-term) outcome. In this review, we summarize the available scientific evidence regarding patient characteristics and its influence on the results of TAR.

Keywords: total ankle arthroplasty, ankle prosthesis, ankle arthrodesis, patient characteristics, contraindications

Introduction

The number of total ankle replacements (TARs) performed is ever increasing,¹⁻⁸ and indications are expanding⁴ due to improvements in design and outcome. Historically, osteonecrosis/loss of bone stock,⁵⁻¹⁴ neuroarthropathy,⁶⁻¹¹,¹³,¹⁴ (diabetic) neuropathy,¹² diabetes,¹⁵ peripheral vascular disease,⁶⁻¹⁵ smoking,¹⁵ poor skin integrity/envelope,⁹⁻¹¹ osteoporosis,⁹⁻¹³ (gross) deformity,⁹⁻¹³ noncompliance,¹² high physical demand/body mass index (BMI),⁹⁻¹³,¹⁵,¹⁶ marked ankle instability⁹⁻¹³,¹⁶ and (a history of) joint infection⁹⁻¹⁴ are considered (relative) contraindications to modern total ankle arthroplasty, but the scientific basis for these recommendations is scarce.

It remains difficult to choose between TAR and ankle arthrodesis (AA) as they are both viable options for the surgical treatment of end-stage ankle osteoarthritis (OA). Despite many attempts to compare outcomes, clear-cut guidelines to choose between the two are lacking. A critical review of the available evidence with regard to patient characteristics might help guide the choice between TAR and AA.

The optimal patient for TAR is said to be physically low-demanding,¹³,¹⁴ non-obese,¹³,¹⁵ older,¹³,¹⁵,¹⁷ with end-stage non-traumatic primary ankle arthrosis¹⁷ or multiple joint arthritis¹⁵ with minimal deformity,¹³⁻¹⁵ good bone stock,¹⁴ no neurovascular leg impairment¹³,¹⁵ and excellent/more than two-thirds of normal range of motion.¹³,¹⁷ Unfortunately, the majority of our patients do not meet these requirements,¹³ and scientific evidence for these recommendations is unavailable.¹⁰

The goal of this review is therefore to summarize the current evidence on patient characteristics with regard to selection for TAR.
General patient characteristics

Gender

To our knowledge, the possible influence of gender on patient satisfaction and/or revisions has not been studied explicitly. In register studies, no influence of gender on TAR survival was found.1,5,18–20 This is in accordance with results from other studies.21,22 Female gender was found to be a significant risk factor for wound-healing problems, but after correcting for confounding variables, it was no longer a predictor for disturbed wound healing.23 In a national database study, male gender was found to be a statistically significant risk factor for the occurrence of one or more complications within 30 days after surgery.8

Considering all evidence, we think gender should play no role when considering a patient for TAR.

Age

Younger age at implantation might influence longevity of the implant in two ways. The TAR will need to function longer due to a higher life expectancy of the patient. Additionally, younger patients tend to be more active, which has been proven to be associated with polyethylene wear of hip prostheses.24 Special consideration should be given to patients with inflammatory joint disease (IJD), as they are younger at implantation in general25 but less active due to the fact that multiple joints are often affected.

Influence of age on results of TAR has been explicitly investigated by a few authors. In 1999, Kofoed and Lundberg-Jensen published their results of 100 (un)cemented Star prostheses. Thirty were implanted in patients aged <50 years, with a survival of 75% at 6.8 years. Seventy in patients aged ≥50 years, with a survival of 81% at 6.0 years, with no statistically significant difference between the groups.26 Others have also found lower age at implantation not to be a significant risk factor for revision.22,25,27

A review of 103 Salto prostheses (n=31 <50 years; n=72 ≥50 years) at an average 41 months’ follow-up revealed no statistically significant differences with regard to major complications and survival between groups.28

In a cohort of 395 primary Inbone, Salto Talaris and Star prostheses wound complications, reoperations and revisions were similar in three age groups (<55, 55–70 and >70 years) at an average 3.5 years of follow-up.29

Barg et al30 found age under 70 years to be an independent predictor of failure of the Hintegra ankle prosthesis at an average follow-up of 6.3 years. Others have also found lower age at implantation to be a risk factor for revision.21,31

Spirt et al reported that each 1-year increase in age at implantation of the Agility prosthesis resulted in a 3.5% decrease in failure hazard, with patients aged ≤54 years at implantation having a 2.65 times greater risk of failure compared to patients aged ≥55 years at implantation. The estimated survival rate at 61 months with failure as the end point was 0.74 (0.60–0.91) for the younger group, compared to a survival rate at 47 months of 0.89 (0.80–0.99) for the older group.32

A report from 780 TARs from the Swedish Ankle Register showed patients with primary or posttraumatic osteoarthritis (PTA) under 60 years of age to have a 1.8 higher chance of revision compared to older patients. This relationship was not found for patients with rheumatoid arthritis and only statistically significant in women.3 No relation between age and survival was found in the Norwegian, Finnish and New Zealand Ankle Register.1,19,20 Influence of age on wound-healing problems was not observed by Raikin et al.23 In an epidemiological study by Seaworth et al,4 younger age at implantation was found to be a risk factor for failure.

Possibly, activity level, with its influence on polyethylene wear, is a confounding factor,24 explaining the conflicting evidence on the influence of age on survival of TAR. Younger age at implantation leads to more load cycles, which in itself is expected to lead to revision down the line. With an average follow-up of 4–7 years in the studies explicitly comparing age groups, evidence on the long-term survival of TARs is still lacking, and we therefore feel younger age should remain a contraindication for TAR (especially in non-IJD patients), not through an absolute age limit, but by taking into consideration the aspired activity level of the patient. When considering a younger patient for TAR, the distinct possibility of future revisions (either through revision arthroplasty and/or salvage fusion) should be discussed.

Activity level

As stated earlier, activity level might be an important factor influencing TAR survival. Nevertheless, research into this relationship is seldomly performed. Valderrabano et al33 found no harmful influence of increased activity level on the revision rate at an average 2.8 years of follow-up of 152 Hintegra TARs. In accordance with these results at 3.7 years of follow-up, no relationship between physical activity level and the incidence of periprosthetic lucencies in 101 TARs (Buechel-Pappas and Mobility) was found.34 Bonnin et al35 also found no relationship between activity level and adverse effects with the Salto prosthesis.
Unfortunately, due to short follow-up, the relationship between activity level and revision rate remains unclear. Despite the absence of a scientific basis, guidelines for sports activities after TAR have been proposed. These correlate closely with the results of a recent survey among foot and ankle surgeons regarding sports activities after TAR. When counseling a patient for TAR, the patients’ aspired activity level and types of physical activity should be taken into account, and the patient should be counseled with regard to future sports.

**BMI**

Historically, obesity (defined as BMI ≥30) was considered a (relative) contraindication for TAR, and since then, a few studies have evaluated this relationship. BMI of obese patients does not decrease after successful TAR, but does obesity decrease survival of TAR?

Barg et al reported a survival rate of 93% at 6 years follow-up of 123 Hintegra prostheses in a group of obese patients, comparable to the results of regular cohorts. These findings were confirmed in their total cohort of 722 Hintegra prostheses, where obesity was not associated with failure of TAR.

When comparing the results of TARs (Mobility, Hintegra and Star) in obese and non-obese patients, Bouchard et al found that, at an average of 3.8 years of follow-up, both groups showed significantly improved scores on the Ankle Osteoarthritis Scale and the Short Form-36 (SF-36). Furthermore, there were no significant differences with regard to complications and revisions. These findings were in accordance with those of others.

High BMI was not found to be a risk factor for infection in a combined primary and revision TAR cohort and also not for wound-healing problems. With longer follow-up (8 years) of the Agility prosthesis, however, Schipper et al found obese patients to have a 2.8 times higher chance of revision compared to non-obese patients. Especially, obese patients with idiopathic OA were at risk.

In a Medicare database study, obese patients had a significantly higher chance of complications including revision within 90 days compared to the non-obese group. However, the cohorts differed significantly with regard to age, tobacco use and comorbidities (including diabetes and peripheral vascular disease), all in favor of the non-obese group, and therefore, these results should be interpreted with care. However, obese patients with comorbidities clearly are not ideal candidates for TAR.

The majority of studies into the subject have not found a relation between BMI and results of TAR. Perhaps, the relationship between BMI and survival is also influenced by activity level or the cumulative load exerted on the prosthesis, with sedentary overweight patients showing similar survival to active non-overweight patients. We therefore think high BMI in itself (within reasonable limits) should not be considered a contraindication for TAR.

**Smoking**

Even though smoking has been deemed a contraindication for TAR, to our knowledge, there is only one study investigating the relationship between smoking and TAR. In a retrospective review of 642 Inbone, Salto-Talaris and Star TARs, smoking was shown to significantly increase wound breakdown. Infections and (non)-revision surgery were not significantly different between groups.

In other studies, <12 pack years of smoking was not found to be a significant risk factor for wound-healing problems or infection in a combined cohort of primary and revision TARs. This is in accordance with results from others. With the current knowledge of the alarming effects of smoking on bone and soft tissue healing and the benefits of (temporary) perioperative cessation, requiring patients to abstain from smoking before high-risk surgery as TAR seems reasonable.

**Comorbidities**

**Diabetes**

At an average 5 years of follow-up of 173 Hintegra TARs, clinical failure defined as an American Orthopaedic Foot & Ankle Society (AOFAS) hindfoot score of 79 or less was significantly higher in the diabetic group (21%), compared to the nondiabetic group (15%). However, the number of revisions did not differ between groups. The rate of delayed wound healing was not significantly different between groups, except when comparing uncontrolled diabetics to nondiabetics. Raikin et al also found diabetes to be a risk factor for minor wound-healing problems (solvable with local wound care and/or oral antibiotics) although in well-controlled diabetics. A relationship with major wound-healing problems (requiring surgery) was not observed. Whalen et al did not find a relation between diabetes and wound breakdown. Delayed wound healing and diabetes were found to be risk factors for infection in a retrospective review of a cohort of primary and revision TARs by Patton et al.

Gross et al compared the results of Star, Salto-Talaris and Inbone TARs in 50 diabetic patients to those of 55 controls from a total cohort of 813 primary TARs. The number of
secondary surgeries, infections and revisions was not statistically different between groups at 2–3 years of follow-up, even though the American Society of Anesthesiologists (ASA) score, BMI, age and smoking history were significantly higher in the diabetic group. This is in accordance with the findings from others. However, in a national database study, after correcting for confounding variables, diabetes was found to be independently associated with in-hospital (general) complications (relative risk 4.1) but not with surgical debridement. No subgroup analysis for controlled and uncontrolled diabetes was performed.

Current literature does not unequivocally support the notion of diabetes being a contraindication for primary TAR, possibly with the exception of uncontrolled diabetes. We advise to have every diabetic counseled preoperatively to optimize their diabetic control before performing surgery.

**Neuro(arthro)pathy and vascular insufficiency**

We were unable to find literature regarding the influence of neuro(arthro)pathy and vascular insufficiency on results of TAR, probably because these conditions are still considered absolute contraindications for TAR. Whalen et al reported on a consecutive series of 57 TARs; 16 had wound breakdown, with 4 progressing to deep infection. Three of these were later shown to have an occluded or absent anterior tibial artery, leading the authors to recommend preoperative vascular studies in patients with known (risk factors for) cardiovascular disease. A simple and useful algorithm for preoperative vascular workup, which we recommend following, was described by Sorg et al:

1. Check pulses of dorsal foot artery and posterior tibial artery
2. If absent, perform an ankle-brachial index
3. If the results are <0.9 or >1.2, then perform angiography
4. If a stenosis or complete obstruction is found, then perform vascular surgery before TAR

**Other**

**Bilateral OA**

Bilateral ankle fusion (AA) is said to greatly impair gait and function, and therefore, patients with bilateral ankle OA should be especially considered for TAR. However, Vaughan et al reported good results of eight patients with bilateral AA at 6 years of follow-up, with seven of eight (88%) patients being satisfied and an AOFAS score of 79.5. This is in accordance with results from others. In a series of 16 patients with a TAR and a contralateral TAR, patients were equally satisfied with each ankle. The sparse literature covering this topic does not support the notion that end-stage bilateral OA should be treated with at least unilateral TAR.

**Factors related to the ankle joint**

**Etiology of arthritis**

Of all factors potentially influencing TAR survival, etiology of arthritis has received the most attention. But surprisingly little studies have explicitly addressed the subject (Table 1). Most cohort studies on TAR divide etiology in PTA, idiopathic OA, OA due to IJD and “other”. More recently, bleeding disorders, gout and instability have been studied as separate entities.

None of the studies in Table 1 found etiology to significantly influence survival. Not surprisingly, patients with IJD had significantly worse scores on the physical component scale of the Short Form Health Survey, the Kofoed score and the disability scale of the Ankle Osteoarthritis Scale compared to patients with non-IJD.

Survival of Star and Norwegian TPR TARs was not influenced by the etiology of arthritis in the Norwegian Arthroplasty Register. This is in accordance with the results from the New Zealand Ankle Registry, the Finnish Arthroplasty Register and others. Contrary to these findings, the Swedish register estimated that survival at 10 years of follow-up was 0.72 for patients with RA, 0.68 in primary OA and 0.66 in PTA. Barg et al also found lower survival in patients with primary OA (0.71) and PTA (0.84), compared to other etiologies (0.94) at >10 years of follow-up.

Perhaps, the relationship between etiology and survival of TAR is confounded by activity level, with, for instance, patients suffering from IJD being less active due to the nature of their disease with multiple joints affected. This might explain the absence of differences in survival between varying etiologies at shorter follow-up, whereas with longer follow-up survival in IJD patients might be better. This would be in accordance with the findings of Hurowitz et al, who found patients with IJD being younger at implantation, but with better survival.

**Deformity**

The majority (55%) of osteoarthritic ankles have a varus deformity (when defined as the angle between the tibial shaft and the talar dome <90°), while only 8% will present with a valgus deformity (when defined as the angle between the tibial shaft and the talar dome >90°). The importance of deformity correction before or during TAR has been recog-
Differentiating between symmetrical and asymmetrical deformities appears to be of paramount importance. From the senior authors' (DH) experience, generally speaking, varus ankles can be reliably corrected through a medial malleolar osteotomy as described by Doets et al. However, valgus ankles pose a more difficult problem, especially when the deep deltoid ligament (the prime stabilizer of the ankle joint) has become insufficient. These ankles have a tendency to relapse into valgus with maltracking and loosening as a consequence.

Results of studies comparing results of TAR with preoperative coronal plane deformities to non-deformed ankles are summarized in Table 2. With the exception of the study by Doets et al, no differences in survival were found. No concomitant procedures to correct these deformities during TAR placement were described by Doets et al. Their paper should be viewed as descriptive in this regard, highlighting the fact that preoperative deformities could negatively influence TAR results.

Only Hobson et al found a significant difference in postoperative AOFAS scores between groups. A higher score was obtained by the patients with deformity. The authors hypothesized that the deformed group had more to gain. Their results could not be replicated by later studies.

Considering the scientific evidence, it seems safe to assume that deformity is no longer a contraindication for TAR, as long as stepwise realignment procedures are meticulously followed.

Prior procedures

From a cohort of 619 primary and 347 revision TARs, 29 (15 primary, 14 revision) were diagnosed with deep infection. The number of prior surgeries in the infected group was 2.3, compared to 1.1 in the matched control group. These results are in accordance with the findings from other authors. Hurowitz et al and Whalen et al, on the other hand, found no significant influence of previous surgery on survival and wound breakdown, respectively.

Other

Bone defects

The development of bone cysts, with possible talar collapse after TAR, has been recognized as threat to long-term survival. The etiology of these cysts has not fully been...
elucidated.\textsuperscript{91–95} Sometimes, these cases are revised with total talar prostheses,\textsuperscript{96} but this falls outside the scope of this review.

Results of primary TAR with total talar replacement have been reported in a few case series/reports. The first year after implantation, these patients seem to function well.\textsuperscript{97} Isolated talar body replacement (without replacing the distal tibia) with a metal component has been very successful at 10–36 years follow-up. Twenty-eight of 33 were still in place at latest follow-up, with an average AOFAS score of 75.\textsuperscript{98} At 53 months follow-up of 55 ceramic total talar replacements, 0 needed revision, and scores on foot and ankle questionnaires significantly improved.\textsuperscript{99}

Currently, scientific evidence for TAR for end-stage ankle arthritis with substantial bone loss is lacking, but isolated total talar replacement seems promising.

Tumors
Shekkeris et al reported results of six patients treated by a custom-made distal tibia and ankle prosthesis. Due to persistent infection, two were converted to below-knee amputation, with the remaining four being able to comfortably perform most activities of daily living (ADL) at 9.6 years of follow-up. One patient required talar revision for aseptic loosening.\textsuperscript{100} In six patients treated with a customized hinged ankle prosthesis after 5.3 years of follow-up, pain was minimal during ADL. One required revision because of talar collapse.\textsuperscript{101} At 40 months follow-up of six comparable patients, three were converted to amputation (two local recurrence, one deep infection), with the remaining three able to function pain free with a stable prosthesis.\textsuperscript{102}

OA of neighboring joints
AA is said to increase OA in neighboring joints, and therefore, TAR should be considered in patients with concomitant ankle and sub/midtalar OA.\textsuperscript{103} A causal relationship, however, has not been definitively established.\textsuperscript{104,105} Treatment options for combined ankle and subtalar OA are TAR with subtalar arthrodesis (either as staged procedures or simultaneously) or tibiotalocalcaneal (TTC) fusion.\textsuperscript{106}

TTC fusion can be performed in multiple ways,\textsuperscript{107} which is beyond the scope of this review. In a cohort of 41 patients with TTC fusion, 80% had successfully fused at 45 months’ follow-up, with a complication rate of 41%. Patient-reported outcomes were not described.\textsuperscript{108} Rammelt et al reported on 38 patients with TTC fusions with an average follow-up of 2 years. Fusion rate was 84% with a complication rate of 24% and SF-36 physical health score of 41 and SF-36 mental
health score of 53 with 61% reporting minimal or no pain (average numeric rating scale 2).109

In a consecutive series of 1001 TARs, 26 patients subsequently required a hind- or midfoot fusion. The fusion rate was 93%, and the complication rate was 12%. SF-36 score was 56 at an average 71 months of follow-up.110 This fusion rate is similar to the 92% reported by Usuelli et al in 25 patients undergoing simultaneous TAR with subtalar fusion. No further major complications were reported. At 12 months of follow-up, the average SF-12 physical health score was 44, the mental health component 51 and the visual analog pain scale 2.111

Kim et al112 compared the results of 60 patients with TAR and pre-, per- or postoperative hindfoot fusions to those of a control group with isolated TAR consisting of the remainder of the same cohort. Patient satisfaction, complication and survival rate were not different between groups.

The cohorts with TTC fusion do not solely consist of patients with combined ankle and subtalar OA, and therefore, comparison to results of TAR with subtalar fusion is difficult. Based on the current evidence, TAR combined with subtalar fusion does not seem to be strictly superior to TTC fusion with regard to functional results but might result in slightly higher fusion rates and lower complication rates.

Post-infectious OA
Implantation of 22 TARs in patients who were symptom free for an average 9 years after prior septic arthritis or osteomyelitis of the ankle was not complicated by deep infection. However, 14% required reoperation (two subtalar AA, one cyst grafting). AOFAS, SF-36 and VAS scores all improved significantly.113 The sparse literature regarding this topic does not support the notion of post-infectious OA being a contraindication for TAR.

Avascular talar necrosis
Evidence-based treatment of avascular necrosis (AVN) of the talus is lacking.114 It appears to be a contraindication for TAR when reading the summary of previous literature (nine cases) by Lee et al.115 Of these nine cases reported, five had collapsed at 2–5 years of follow-up and three more had complications. Lee et al reported two cases of their own. A Hintegra TAR was implanted in two patients for AVN after establishing talar revascularization with magnetic resonance imaging and radionuclide bone scanning. These two patients had AOFAS scores of 91 and 85 at 30 and 24 months’ follow-up, respectively.115

Devalia et al reported results of seven patients treated with a two-stage procedure, consisting of subtalar arthrodesis for revascularization of the talus, followed by TAR on average 10 months later. At 3 years of follow-up, the AOFAS score was 78. However, radiological signs of talar subsidence were noted at 1 year follow-up without progression or deterioration of clinical scores at 3 years in two patients.116

At this time, we consider treatment of AVN of the talus with TAR experimental due to lacking sufficient scientific evidence.

Discussion
Over time, the results of more and more TAR cohorts have been published. Most authors provided information on the cohort (gender, etiology of arthritis, etc.). 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. We propose that future studies on this subject include all characteristics of the patients with failed TARs discussed in this review.

In addition to patient characteristics, other factors, such as the type or version of prosthesis used,1,2,9 duration of surgery,20,89 surgeon volume117,118 and surgeon experience,119–124 might influence the number of complications and TAR survival although conflicting evidence exists. These factors are not within the scope of this review.

One of the strengths of our study is the extent of literature review as we are certain that the vast majority of relevant data have been included in this review due to our comprehensive knowledge of literature pertaining to TAR. Another strength is the scope of patient characteristics discussed, with all current and historical factors considered to be of influence on TAR analyzed. A third strength is our clear recommendation for future TAR cohort studies, specifically regarding characteristics of patients with failed TARs.

Our study is not without limitations. As it was written as an editorial, the PRISMA guidelines125,126 for a systematic review, with subsequent high level of evidence, were not followed. The available scientific evidence was therefore not graded, and no meta-analysis was performed. Furthermore, our conclusions are partially based on the results of TARs no longer available on the market for various reasons. Due to paucity of available evidence, this is inescapable. However, as we have focused on patient characteristics, we do not think this invalidates our results; we expect similar results with currently available implants.
Conclusion

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 interlinked (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.

Disclosure

The authors report no conflicts of interest in this work.

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