Salto Talaris Fixed-Bearing Total Ankle Replacement System

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KEYWORDS

• Arthroplasty • Salto • Joint pain • Joint replacement • Tibio-talar joint

KEY POINTS

- Apart from being only 1 of 4 Food and Drug Administration–approved ankle implants in the United States, the Salto Talaris total ankle system has moved the mobile-bearing concept from the implant to the instrumentation at the time of tibial trial.
- This was because of in situ motion analysis determination that very little movement (universally, <1 mm) occurred between the ultra-high molecular weight polyethylene insert and the tibial tray in the mobile-bearing Salto design used outside the United States.
- Additional design improvements include varying radii of the talar component to allow for physiologic tensioning of the medial and lateral collateral ligament complexes.
- Liberal use of image intensification, adherence to a perioperative protocol, and strict adherence to surgical technique, indications, and contraindications are essential for a quality outcome.

INTRODUCTION

Total ankle replacement has become a reliable and valuable procedure for patients who suffer from degenerative arthritis of the ankle joint. Historically, the only definitive option for treatment of end-stage degenerative arthritis was arthrodesis. Total ankle replacement has become a predictable alternative to arthrodesis that is credited to improving surgical technique, understanding surgical biomechanics of total ankle replacement, improved prosthesis design, and precision instrumentation.[1] Furthermore, total ankle replacement seems to have a preserving affect on the subtalar joint that are subject to further degenerative changes after ankle arthrodesis.[1–3] In addition, it seems that ankle arthrodesis leads to less favorable functional results and diminishing patient satisfaction.

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The Salto total ankle prothesis was designed in 1994 and was first used clinically in Europe in 1997.[4] The name Salto is derived from the Italian word for "jump." The design rationale was to construct a meniscal-bearing, cementless implant. The initial Salto prosthesis had remarkable clinical success.[5] It was further studied and revised after numerous cadaveric and retrospective evaluations.

SALTO TALARIS DESIGN

The Salto Talaris (Talaris is derived from the Italian word for "sandal") prosthesis received clearance for use with polymethylmethacrylate cement fixation in the United States by the Food and Drug Administration in 2006 (see http://www.accessdata.fda.gov/cdrh_docs/pdf9/K090076.pdf) (**Fig. 1**). The design was based on the initial successful experiences of the Salto mobile-bearing total ankle prosthesis in Europe. The mobile-bearing prosthesis showed 93% survivorship at a mean of 6.4 years.[5] Results of the Salto total ankle prosthesis were promising, yet designers decided to develop a fixed-bearing ankle prosthesis. The decision for transition to a fixed-bearing prosthesis was based on clinical and radiographic evaluation of 20 patients who received total ankle replacement. The mobile-bearing prosthesis experience showed that there was very little motion between the tibial component and the mobile-bearing ultra-high molecular weight polyethylene (UHMWPE) insert (Amy Ables, PhD, personal communication, July 2, 2012). Seventeen of the patients showed no anterior-to-posterior motion between the inferior surface of the tibial component and the superior surface of the UHMWPE insert. In the remaining 3 patients, there was less than 1 mm of motion. This demonstration essentially showed that the UHMWPE insert was not functioning as a mobile-bearing 3-component system and instead remained essentially fixed to the tibial prosthesis like a 2-component fixed-bearing system.[4]

Fig. 1. The Salto Talaris total ankle replacement is a fixed-bearing prosthesis with anatomic design features. The talar component has varying radii of curvature that simulate the mechanical frustrum of the ankle with motion. The plasma titanium spray on the surface promotes ingrowth of bone and stable biologic fixation. The keel increases osseous contact.

Three-dimensional studies on 50 cadaveric studies helped redesign the tibial and talar components. The talar component was redesigned to a conical surface, with 2 radii of curvature. The differing radii allowed for equal tensioning of the collateral ligaments that provides mechanical stability for the prosthesis (**Fig. 2**). This is a critical adaptation for an anatomic designed prosthesis. There is often asymmetric laxity within the medial and lateral collateral ligament complexes. The varying radii of the talar component allow for physiologic tensioning throughout the total ankle range of motion. The redesigned talar component is designed with a sagittal groove, which directs transverse plane motion with dorsiflexion of the ankle. Moreover, the converging radii define a frustum that recreates the important triplanar motion of the ankle.

Another key design change is that the mobile-bearing concept was shifted from the implant to the instrumentation at the stage of tibial trial reduction. The instrumentation allows for a precise amount of bone resection from the tibia and talus that is equal to the overall thickness of the prosthesis (**Fig. 3**). The trial tibial base is placed with the talus and UHMWPE insert. The tibial base is smooth and is allowed to rotate with ankle motion. This rotation sets the proper axis for the prosthesis. Once the proper axis is set, the tibial keel is created. Before final placement of the tibial prosthesis, the UHMWPE insert is fixed to the tibial tray.

PREOPERATIVE CONSIDERATIONS

Imaging of the total ankle replacement candidate must evaluate several criteria: (1) the presence of degenerative change to the ankle and the subtalar and talonavicular joints; (2) limb and articular alignment on standing films (hindfoot alignment views are also important to evaluate if frontal plane deformity exists); (3) joint subluxation or incongruent articular deformity; (4) computed tomography (CT) scans are indicated for evaluate periarticular cysts and to further delineate degenerative changes in the subtalar and talonavicular joints; and (5) magnetic resonance (MR) imaging is used by the authors if avascular necrosis is suspected in the talus or distal tibial in cases of posttraumatic arthritis. Small amounts of avascular necrosis that can be resected
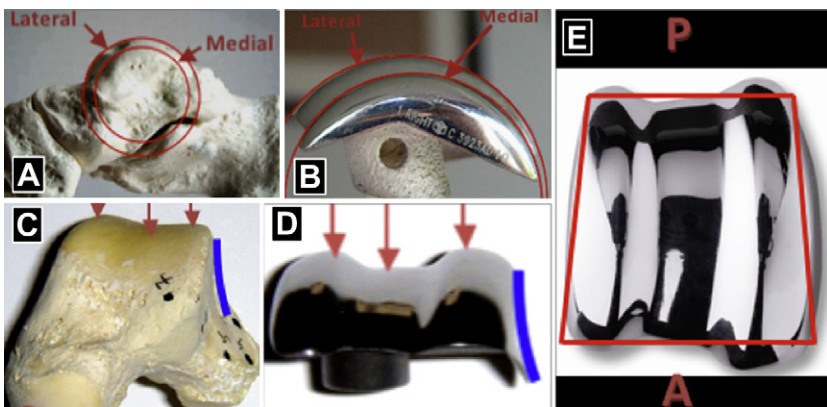

Fig. 2. Medial view of a cadaveric osseous model (*A*) and Salto Talaris talar component (*B*) and anterior view of a cadaveric osseous model (*C*) and Salto Talaris talar component (*D*) demonstrating the differing radii for the medial and lateral surfaces as is anatomically present in the human talus. Superior view of the Salto Talaris talar component (*E*) demonstrating the curvature to the differing radii and the wider aspect of the component being anterior as is anatomically present in the human talus (A, anterior; P, posterior).
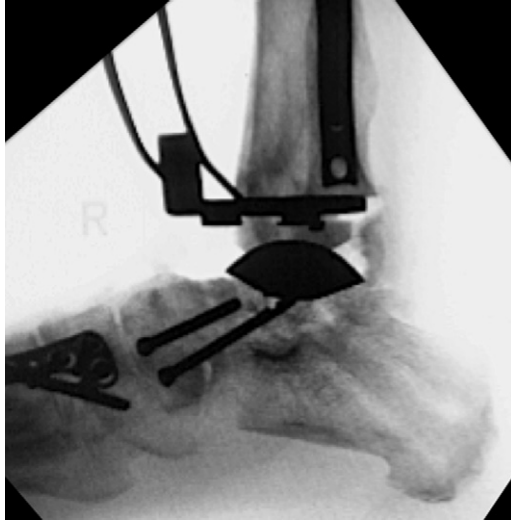
Fig. 3. Trial stage with talus and tibial tray in place. The tibial tray is allowed to rotate and translate with ankle motion. This is directed by the talus through the poly insert. The tibial tray must be seated properly before the keel is fashioned. The lateral C-arm view verifies proper posterior contact of the trial. Note the anterior slope has been reduced.

are of minimal consequence. Significant amounts of avascular necrosis may contraindicate a total ankle replacement.

Surgical Approach

The senior author (S.M.R.) has developed a perioperative protocol that is reproducible for all surgeons performing ankle replacement. All patients undergo a regional popliteal nerve block with catheter preoperatively in addition to general anesthesia. This has greatly improved pain control after the procedure and has also dramatically reduced the duration of hospital stays. A tourniquet is used for hemostasis to minimize blood loss. Generally, the procedure can be completed with less than 90 minutes of tourniquet time. After the prosthesis is placed, the tourniquet is released and hemostasis is assessed after irrigation before closure. Closure is performed over a reinfusion drain.

The procedure is performed with the patient in the supine position with a bump under the ipsilateral hip. The surgical incision is the standard approach for a total ankle procedure (interval between the extensor hallucis longus and the anterior tibial tendon). Throughout the procedure, proper handling of the anterior soft tissues is of upmost importance; wounds of the anterior compartment can be disastrous to manage. To minimize soft tissue damage, the author has adopted deep retraction with Gelphi retractors instead of skin-edge manual retraction to prevent necrosis. The periarticular osteophytes from the anterior distal aspect of the tibia and dorsal talar neck are removed. Resection of the anterior plafond must expose the apex of the plafond for accurate placement of the tibial alignment guide.[6]

Anterior Alignment Guide and Tibial Resection

The tibial alignment guide is zeroed and a pin is placed into the proximal tibia perpendicular to the anterior tibial tubercle (**Fig. 4**). The guide will then be aligned
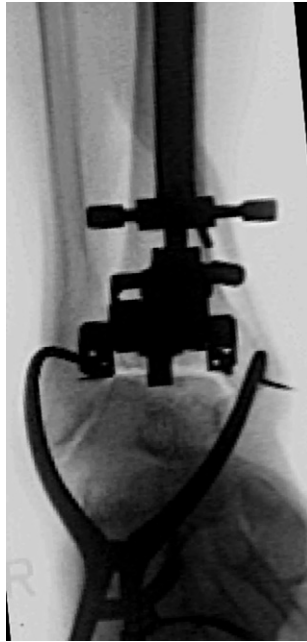
Fig. 4. Anterior alignment jig in place with talar alignment block. Note the coaxial alignment of the anatomic axis of the tibia and alignment guide. Deep retraction avoids skin edge necrosis. The talar alignment block is attached to align the prosthesis and talus.

to the tibial shaft (ie, anatomic axis) and secured distally with a medial pin. The guide and position relative to the tibial axis should be assessed with an intraoperative image intensification C-arm at this time. A useful modification at this step is to angle the proximal tibial pin inferior in the sagittal plane, removing the anterior slope of the tibial resection (**Fig. 5**). Removal of the anterior slope can improve motion postoperatively and protect from anterior subluxation in patients who have anterior talar listhesis (**Fig. 6**).

After the axial alignment has been confirmed, the distal alignment and proper size implant can be determined. Rotational alignment is set to the alignment of the talar body. Care must be taken with deformity that influences talar rotation. Varus hindfoot deformity will create external positioning of the talus. Internal malpositioning of the talar component will occur if the talar deformity is not recognized. Medial and lateral translation is used to fine-tune the tibial resection. The goal is to not resect the fibula and to leave enough medial isthmus on the malleolus to prevent iatrogenic fracture when placing the prosthesis. Medial and lateral positioning is adjusted to allow for the largest prosthesis without compromising the malleoli.

Initial tibial resection is no more than 9 mm from the roof of the plafond.

The tibial resection block is secured with medial and lateral shoulder pins and the plafond cut is made. The shoulder pins protect the malleoli during the tibial cut. Close clinical assessment must be taken at this step, because there may be rotational malalignment in the foot and tibia. Failure to recognize this malalignment will result in resecting too much posteromedial tibia or posterolateral fibula. The resected tibial bone is carefully removed to prevent malleolar fracture. The posterior malleolar fragment is safely left for removal after the posterior talar chamfer cut.
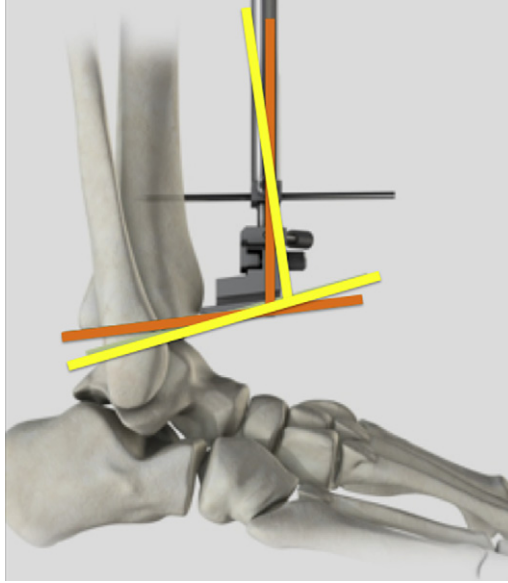
Fig. 5. Lateral view of illustrated osseous model demonstrating the traditional resection angle of the distal tibial plafond (*yellow line*) and the modification used to remove the anterior slope of the distal tibia (*orange line*).

Talar Bone Resection

The talar pin is set with the guide based off the tibial alignment guide and resection. The foot is held in a neutral position to accept the talar pin in the talus with the ankle in the functional neutral position. At this point, the tibial alignment guide can be

Fig. 6. Preoperative anteroposterior (*A*) and lateral (*B*) radiographs demonstrating anterior subluxation (listhesis) of the talus is associated with post-traumatic recurvatum articular deformity and chronic ankle instability. The talus must be repositioned beneath the tibial axis when the prosthesis is placed. Meticulous deltoid release and lateral ligament repair is often necessary to reestablish ligament stability. Postoperative anteroposterior (*C*) and lateral (*D*) radiographs following total ankle replacement. Note the anterior slope has been taken out to prevent anterior motion of the talus.

removed. The surgeon should leave the pins in place on the tibia. If additional bone is required, the cutting block can be replaced and additional resection preformed. With the talar pin in place, the posterior talar resection guide is placed with the paddles flush on the articular surface of the talus. The posterior talar chamfer cut is done carefully with care taken to protect the malleoli. With removal of the posterior talar dome, one can remove the remaining posterior distal aspect of the tibia.

Once the bone has been evacuated from the posterior tibia and the posterior chamfer resection is determined to be optimal, the remaining preparation can proceed. The anterior chamfer guide and resection is based off an accurate and precise posterior chamfer resection. The resection guide uses the anterior tibial plafond as a reference to ensure proper anterior to posterior positioning.

Trial Size Evaluation and Implant Selection

After bone resection, a thorough irrigation is helpful to remove debris and assess all resected surfaces for accuracy and completeness. The trial talus and tibia are placed. UHMWPE insert trials can be placed starting with 8-mm thickness to appropriately tension the collateral ligaments. In this important step, the surgeon must optimize conformity of the UHMWPE insert fit without binding motion in the prosthesis. Optimal motion may require lengthening of the posterior calf musculature during this step. At the same time as the proper size UHMWPE insert is chosen, the surgeon is performing a "dynamic flexion and extension" test. This allows the tibial tray to rotate and translate on the resected tibia. This motion is directed through the talus and UHMWPE insert. The author performs this sequence with lateral image intensification C-arm guidance. Proper seating of the tibial tray is critical at this step. Visual assessment of the tibial tray anteriorly and image intensification C-arm assessment of the posterior aspect of the tibial tray ensure proper position of the tibial tray on the resected tibial surface.

Once the proper size prosthesis and UHMWPE insert have been determined, and the functional axis of the prosthesis has been determined by dynamic motion, the keel can be prepared. Drilling of the keel sets the final position of the tibial component. Axial retrograde pressure on the foot is applied at this step. Once the keel is drilled and prepared, the trials are removed. The final UHMWPE is fixed to the tibial tray. The joint is irrigated of bone debris and the final prosthesis is inserted.

Several assessments must be determined at this time: (1) The implant must have uniform contact with the resected osseous surfaces. (2) The UHMWPE insert has optimal conformity without binding the ankle motion. Conversely, an undersized insert may inadequately tension the collateral ligaments that leads to unnecessary "slop" between the UHMWPE insert and talar component. (3) Make liberal use of intraoperative image intensification to evaluate the presence of malleolar fracture during implantation. (4) Hindfoot alignment should also be evaluated. Excessive varus of valgus mal-alignment will result in excessive eccentric loading and potential early prosthesis failure. (5) Bone grafting is performed of any cysts that were not included during osseous resection.

Deformity Evaluation and Surgical Considerations

The steps for bone resection are uniform for each individual procedure, although there are some key considerations to each deformity that must be evaluated and corrected with the surgical technique. Failure to evaluate and address intrinsic deformity will result in the prosthesis being placed without proper alignment, which can significantly alter the long-term prognosis of the prosthesis and UHMWPE insert.[7] Espinosa and colleagues[7] demonstrated that malalignment (>5°) of the prosthesis created UHMWPE contact pressures that exceeded the yield point in both fixed-bearing

and mobile-bearing designs. This is an important concept, reinforcing that proper prosthesis alignment is critical regardless of whether a fixed or mobile-bearing device is used.

Bone loss or periarticular deformity can create deformity in any plane and presents with several considerations in ankle prosthesis. Careful preoperative planning will determine if the deformity can be corrected at the time of bone resection or if ancillary osteotomy is required. Often, asymmetric frontal plane bone loss can be corrected with simple bone resection. In general, the bone resection from the distal tibial plafond will correct intrinsic frontal plane bone loss. The proper bone resection is reliant on the anterior alignment jig being properly aligned in the frontal and sagittal plane.

Another consideration is periarticular bone cysts.[8] These are often identified radiographically and can be further delineated using preoperative CT scans (**Fig. 7**). Distal bone resection from the plafond usually eliminates any cyst formation. When the tibial bone resection does not remove periarticular cysts, grafting of the cyst becomes necessary.

There are instances when mechanical axis of the tibia is deviated in varus or, less often, valgus malalignment. The tibial alignment jig is designed to be placed parallel to the anatomic axis of the tibia. In these instances, the cutting jig should be aligned with the mechanical axis of the leg. This is defined as the center of the acetabulum to the center of the ankle joint.

Asymmetric bone loss from the talus results from various causes. The bone loss is usually associated with intrinsic varus or valgus malalignment. It is important to account for bone loss when making the talar cuts. This is done at the step of the posterior chamfer resection. Sheaths or "paddles" of various thicknesses can be placed over the posterior talar resection guide to account for this bone loss. Doing this ensures the plane of the posterior chamfer cut is parallel to the plafond resection in the frontal plane. Failure to do so will result in frontal plane malalignment of the talar prosthesis. This can potentially result in asymmetric tensioning of the collateral ligaments and frontal plane mal-alignment of the ankle and hindfoot.

Talar coverage is also important to achieve the best cortical overlap and fit of the prosthesis. The dimensions of the talar components are variable. The distance
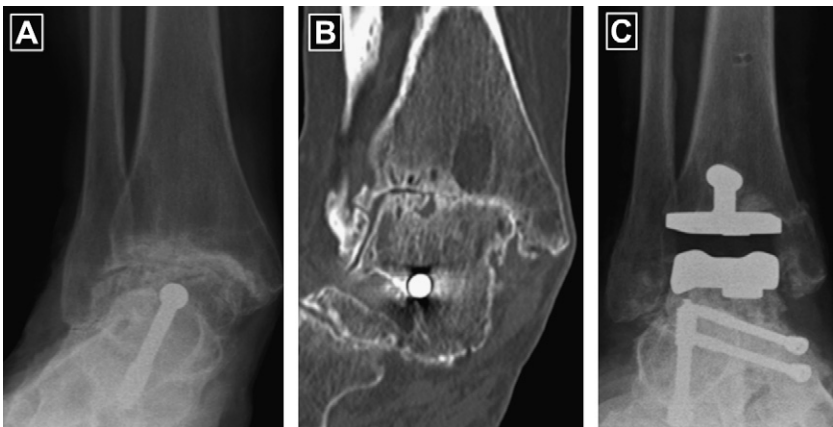
Fig. 7. Anteroposterior plain film (*A*) and coronal CT scan image (*B*) of 60-year-old woman with rheumatoid arthritis. Note the large plafond cyst, which was not resected with instrumentation during implantation of her Salto Talaris total ankle replacement (*C*). These bone defects must be grafted after placement of the final prosthesis.

between the center of the implant to the lateral flare of the talar component is fixed along all sizes. The medial width of the prosthesis is variable and can be sized up to appropriately cover the medial side of the talus. Further, the lateral chamfer cuts can be adjusted medially with small amounts for better medial bone coverage before performing the bell cut.

In instances with post-traumatic arthritis secondary to chronic ankle instability, the foot will drift anterior with respect to the mechanical axis of the tibia. The talus has been extruded anteriorly (talar listhesis). This lateral collateral ligament instability should be carefully evaluated in conjunction with varus malalignment. Reconstruction of the varus ankle has been well described by Schuberth and colleagues[9] to rebalance the intrinsically varus unstable ankle with arthroplasty. Deltoid sleeve release may be required in an effort to properly seat the talus posterior beneath the mechanical axis of the leg. In instances when the talus has been extruded forward, attempts at repositioning the talus back beneath the mechanical axis can result in fracture of the medial malleolus if appropriate soft tissue release has not been performed.

Clinical Results in the Salto Prosthesis

The Salto Talaris ankle implant has shown that patients have had success returning to activities without major complications. Bonnin and colleagues[5] in a prospective study evaluated 98 consecutive implants in 96 patients between 1997 and 2000. Ninety-three implants in 91 patients were available for review. Sixty-two women and 36 men with a mean age of 56 years were reported with a mean follow-up of 35 months. The overall survivorship of the Salto prosthesis at 68 months when using surgical revision or radiographic loosening as the end point was reported to be 93.8% in the favorable scenario and 91.8% in the unfavorable scenario, and using implant removal as the endpoint, the rates were 98% and 94.9%, respectively. In addition, mean American Orthopedic Foot and Ankle Society scores improved significantly from 32.3 points preoperatively to 83.1 points postoperatively. Dynamic range of motion radiographs also showed significant improvement from 15.2° preoperatively to 28.3° at follow-up. The authors concluded that these results were encouraging and supported the concept of anatomic replacement to improve functional outcomes but recognized the need for longer follow-up for further validation.

Bonnin and colleagues[8] followed their original study with a survivorship analysis (7–11 years). They found that survival at 10 years without any reoperation was 65%. Six implants had to be converted to ankle arthrodesis. Other reasons for reoperation included UHMWPE insert exchange, symptomatic osteolytic cysts, and osteolysis. The authors concluded that there were 3 main reasons for reoperation: (1) bone cysts, (2) UHMWPE insert fracture, and (3) unexplained pain.

It should be noted that in all of these reports, and in the authors' practice, the Salto Talaris total ankle replacement is implanted without antibiotic polymethylmethacrylate cement fixation. The effect on implant longevity and patient outcomes with cement fixation is therefore unknown.

Range of Motion

Schuberth and colleagues[9] studied range of motion of the Salto Talaris during the first year of placement. Ninety-seven cases were examined at regular intervals at 6 weeks (11°) and at the 3-month (14°), 6-month (18°), and 12-month (20°) follow-ups. They demonstrated that motion increased the most between the 6-week and 6-month marks. The results of the study demonstrated that at least 20° of ankle motion can be expected after Salto Talaris implant arthroplasty at 1 year postoperatively.[9]

Leszko and colleagues[10] used fluoroscopy and 3 dimensional–to–2-dimensional registration techniques to determine the in vivo kinematics for 20 total ankle replacement subjects in performing 2 activities: gait and step-up. They witnessed translation of the mobile-bearing 1.5-mm and 2.3-mm devices for the 2 activities, respectively. From this data the authors concluded the dominant motion must be rotation.[10]

POSTOPERATIVE PROTOCOL

After implantation, the patient remains in the hospital for an average of 2 days. The drain is removed on postoperative day 2. Venous thromboembolism prophylaxis is initiated on postoperative day 1 and continued for 21 days. The patient is seen at 10 days; the sutures are removed, and the patient is placed in a below-the-knee non–weight-bearing cast. In general, the patient is non–weight bearing for 5 weeks, after which graduated weight bearing and physical therapy begin. In isolated cases, the patient is allowed early weight bearing in a cast at 3 weeks to assist is seating the prosthesis.

COMPLICATIONS

The general complications associated with the Salto Talaris ankle replacement prosthesis are the same as with other replacement systems. They can be categorized into soft tissue and prosthesis-related complications. Complications involved in the soft tissue are centered on wound healing and infection. Taking meticulous care of the anterior soft tissues during the surgery and avoiding skin edge retraction with manual retractors are critical in minimizing wound edge necrosis. Prevention of infection should be of primary importance to all surgeons performing total ankle replacement. The authors use a 3-day preoperative preparation with 4% weight/volume chlorhexidine gluconate scrub of the operated extremity before surgery. Preoperative antibiotics are indicated in all cases. Close attention should be paid to when the antibiotics are given; they should be given at least 1 hour before the operation to maximize soft tissue penetration. Maintenance of hemostasis and avoidance of undermining of the subcutaneous flaps are critical and maintaining the health and viability of the anterior soft tissue envelope. Skin closure should be performed in layers over a closed suction drain.

Prosthesis-related complications are highly variable. The most common reasons for implant revision and failure reported in the literature are the results of implant loosening, infection, and malalignment.[4,11] These complications will never be absolutely avoided, although close attention to surgical technique can mitigate avoidable errors. Close attention to proper size and fit of the prosthesis minimizes binding of the prosthesis and gutter impingement. Optimizing cortical overlap is critical to the long-term stability of the prosthesis (Fig. 8). Removal of osteophytes from the medial and lateral gutters also reduces the risk of impingement. Ensuring the prosthesis is properly seated on the tibia and talus is critical to the osseous on-growth of the implant. All bone cysts that are not resected must be grafted to ensure the best substrate for the prosthesis. Aseptic loosening and osteolysis have been reported and are difficult to predict. In general, it is agreed that this is caused by poor osseous ingrowth or UHMWPE insert particulate wear debris reactions. Mechanical factors also come in to play, such as poor alignment and eccentric loading of the implant, which can cause the implant to wear abnormally and eventually fail. Alignment is also critical to UHMWPE insert wear. Eccentric loading of the UHMWPE insert can cause early wear patterns and fracture (see Fig. 8).
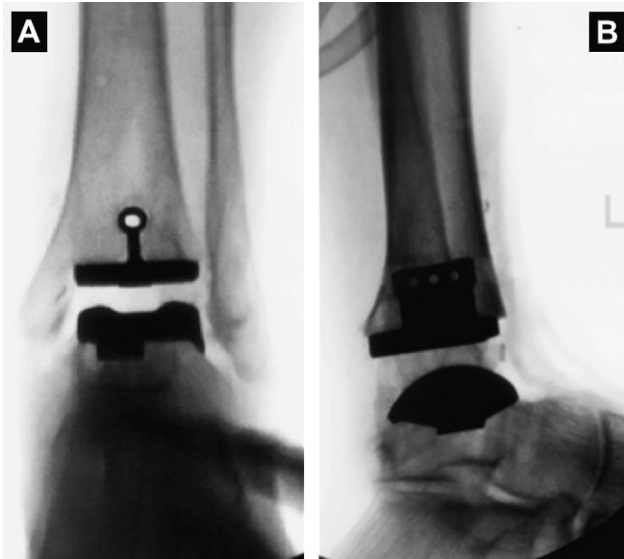
Fig. 8. Proper alignment of the total ankle replacement minimizes eccentric loading of the prosthesis. Optimizing cortical overlap and UHMWPE insert conformity with motion minimize edge loading of the insert.

SUMMARY

Total ankle replacement remains an evolving procedure to treat in stage ankle arthritis. The unique anatomy associated with the ankle, post-traumatic deformity, ligamentous instability, and variable bone quality makes ankle joint replacement a challenging endeavor. Close attention to the surgical technique and patient selection is critical to the ultimate success of the procedure. Further, understanding the surgical biomechanics associated with total ankle replacement and realignment of the foot is critical to the long-term success of the prosthesis. Recent results showing high clinical success and functional outcomes with total ankle replacement ensure that the new-generation prostheses will continue to be a valuable and predictable option for patients with end-stage ankle arthritis. The true role of polymethylmethacrylate cement fixation remains unknown, as no data exist comparing this with the off-label use of an uncemented Salto Talaris total ankle replacement in the United States.

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