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Incidence of Revision After Primary Implantation of the Salto® Mobile Version and Salto Talaris™ Total Ankle Prostheses: A Systematic Review

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A B S T R A C T

The incidence of revision of total ankle replacement prostheses remains unclear. We undertook a systematic review to identify the material relating to the incidence of revision after implantation of the Salto® mobile version and Salto Talaris™ total ankle prostheses. Studies were eligible for inclusion only if they had involved primary total ankle replacement with these prostheses and had included the incidence of revision. Eight studies involving 1,209 Salto® mobile version prostheses, with a weighted mean follow-up period of 55.2 months, and 5 studies involving 212 Salto Talaris™ total ankle prostheses, with a weighted mean follow-up period of 34.9 months, were included. Forty-eight patients with Salto® mobile version prostheses (4%) underwent revision, of whom 24 (70.5%) underwent ankle arthrodesis, 9 (26.5%) metallic component replacement, and 1 (3%) below-the-knee amputation. Five (2.4%) Salto Talaris™ total ankle prostheses underwent revision (3 metallic component replacement and 2 ankle arthrodeses). Restricting the data to the inventor, design team, or disclosed consultants, the incidence of revision was 5.2% for the Salto® mobile version and 2.6% for the Salto Talaris™ total ankle prostheses. In contrast, data that excluded these individuals had an incidence of revision of 2.8% for the Salto® mobile version and 2.0% for the Salto Talaris™ total ankle prostheses. We could not identify any obvious difference in the etiology responsible for the incidence of revision between these mobile- and fixed-bearing prostheses. The incidence of revision for the Salto® mobile version and Salto Talaris™ total ankle prostheses was lower than those reported through systematic review for the Agility™ and Scandinavian Total Ankle Replacement™ systems without obvious selection (inventor) or publication (conflict of interest) bias.

Contemporary total ankle replacement systems, compared with those available decades ago, have demonstrated promise because they include improved materials, a more precise surgical technique, and a focus on maintaining the normal anatomy and function of the ankle joint (1–10). Mobile-bearing technology has allowed for increased implant conformity, with a reduction of implant constraint. This theoretically reduces wear and loosening (8,11,12), at the expense of increased potential for ultra-high-molecular-weight polyethylene (UHMWPE)-bearing fracture, dislocation, and malleolar impingement (13–15). Nevertheless, even with advancements in technology and implant engineering, total ankle replacement has continued to have unpredictable long-term survivorship (1–9,16).

One third-generation total ankle implant is the Salto® mobile version prosthesis (Tornier NV, Amsterdam, The Netherlands), which was invented by Michael Bonnin, MD, Jean-Alain Colombier, MD, Thierry Judet, MD, and Alain Tornier between 1994 and 1996 using anatomic studies of the ankle joint. The device was first implanted in January 1997 and was limited to these surgeon inventors from 1997 to 1999 (17). The first clinical results were published in 2000 (18,19).

The Salto® mobile version prosthesis is a 3-component, cementless, mobile-bearing anatomic resurfacing prosthesis and was initially available in 3 sizes (i.e., 1, 2, 3) until 2009, when a fourth size (i.e., 0) was added. Each tibial component initially had a flat 2-mm-thick surface intended to accommodate the superior surface of the UHMWPE mobile-bearing insert and a 3-mm medial rim intended to prevent the insert from impinging the medial malleolus. In 2013, the tibial component was redesigned to add 1 mm to the width and 2 mm to the length to improve tibial

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coverage, in addition to rounding off the anteromedial and anterolateral surfaces to reduce overhang. Tibial component fixation is achieved primarily with anterior cortical contact of the flat surface and a 12-mm-long central keel attached to a hollow tapered anteroposterior conical fixation plug that is impacted into the tibial metaphysis. The tibial component is designed for insertion with a 7° posterior slope relative to the long axis of the tibia. The tibial base can be the same or 1 size larger than the talar component, allowing for mismatching of the tibial and talar components, depending on the patient's anatomy. The tibial components are interchangeable, but the talar components have dedicated left and right sides owing to the double radii (i.e., medial radius smaller than lateral radius) and biconvex articular surface, resembling the native morphology of the talar dome. The undersurface of the talar component matches 3 sharply angulated bone cuts about the posterior, anterior, and lateral talar body, affording primary stability in the anteroposterior and medial–lateral planes. Secondary talar component fixation for component sizes 1, 2, and 3 includes a posterior angled 11.6-mm-deep, 12.7-mm outer diameter medially offset hollow fixation plug, and size 0 has a 10.4-mm-deep, 8-mm outer diameter solid fixation plug. The center of the fixation plug is a constant distance from the concave lateral facet for each talar component. Talar component sizes 1, 2, and 3 remove 7 mm of talar bone height and size 0 removes 5.5 mm. Both the tibial and the talar components are made of cobalt-chromium and are dual-coated with 200-μm plasma-sprayed titanium (T40). Before being discontinued in 2012, an additional external coating of hydroxyapatite was used to promote osseous integration. The UHMWPE inserts were originally available in 3, 4, 5, 6, and 7 mm thicknesses. However, owing to fractures of the 3-mm-thick UHMWPE insert, this thickness is no longer available for use, and, in 2009, an 8-mm-thick insert was added. The UHMWPE inserts' articular surface is size matched to the talar component and have dedicated left and right sides. The contact area between the UHMWPE insert and talar component allows for 3° of freedom of motion between these components, with full congruency in dorsiflexion to plantarflexion. An optional cemented UHMWPE lateral malleolar resurfacing component was created by the surgeon design team to reduce fibular impingement; however, it was abandoned after 20 cases because no clear benefit was appreciated (20). Dedicated instrumentation, including an external alignment jig with tibial and pedal referencing, is used to resect the distal tibia and talus and insert the trial and final prosthesis components (http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0CCQQFjAA&url=http%3A%2F%2Fwww.rpa.spot.pt%2Fgetdoc%2F6065d9a6-dd01-46cf-b5f9-f6f73ed785d5%2FSalto-II-%281%29.aspx&ei=zsXlUpHpBsbsqAG_5IHoCg&usg=AFQjCNGVxwT-iGV-bGerfA6_-lWddjBKaQ&bvme=bv.59930103,d.aWM&cad=rja).

The in vivo kinematics of the Salto® mobile version was investigated in 20 patients using fluoroscopy with a 2-dimensional to 3-dimensional registration technique. In that study, translation between the UHMWPE mobile-bearing insert and tibial base plate averaged 1.5 mm during gait, and the insert remained in internal rotation throughout the arc of motion (21). In another study of stress lateral radiographs from 20 patients, variation of the anteroposterior translation of the UHMWPE mobile-bearing insert relative to the tibial base was not noticeable in 17 patients and was only 1 mm in 3 patients (22,23). These studies have indicated that the UHMWPE insert did not function as a mobile-bearing system but rather remained essentially fixed to the tibial component. With this realization, in conjunction with the problems associated with malleolar impingement and UHMWPE wear debris-induced osteolysis (24), the fixed-bearing Salto Talaris™ total ankle prosthesis (Tornier, Inc, Bloomington, MN/Wright Medical Technology, Inc., Arlington, TN) was developed.

The Salto Talaris™ total ankle prosthesis was trademarked in April 2006 (http://trademarks.justia.com/789/26/salto-talaris-78926758.html). In that same year, it was first implanted by the each of the original French inventors in June (http://www.healio.com/orthopedics/foot-ankle/news/print/orthopedics-today/%7B8c89d9dd-1a2a-4aa1-98c7-9372f3d05f9b%7D/results-by-design-researchers-look-to-future-tar-developments) received U.S. Food and Drug Administration (FDA) 510(k) clearance for use in November (http://www.accessdata.fda.gov/cdrh_docs/pdf6/k060544.pdf) and was first implanted in the United States in December (http://www.thefreelibrary.com/TornierþReceivesþFDAþClearanceþforþtheþSaltoþTalaris%28TM%29 þ Anatomic...-a0155628807). It has been cleared by the FDA only for use with polymethylmethacrylate cement fixation, which has been demonstrated in the technique guide (http://www.tornierdx.info/pdf/SALTO_SXT_INST2_UJAT092-1oct09-a.pdf). Compared with the Salto® mobile version, the Salto Talaris™ total ankle prosthesis' tibial component base is 3 mm thick, does not have a medial rim because the UHMWPE insert is fixed to the tibial base, and the UHMWPE inserts are available in thicknesses of 5, 6, 7, and 8 mm (http://www.tornierdx.info/pdf/SALTO_SXT_INST2_UJAT092-1oct09-a.pdf). Both the tibial and the talar components are made of cobalt-chromium and are single-coated with 200-μm plasma-sprayed titanium (T40) to promote osseous integration. The talar component has been redesigned with deeper biconvex medial and lateral articular surfaces with a concave trochlear groove and a 12° apex medial frontal plane axis to allow for external rotation of the foot with dorsiflexion and internal rotation during plantarflexion. Furthermore, the mobile-bearing concept has been moved from the implant design to the instrumentation at the stage of the trial reduction. According to the surgical technique guide (http://www.tornierdx.com/pdf/SALTO_SXT_INST2_UJAT092-1oct09-a.pdf), accurate and reproducible tibial and talar component alignment are possible by first performing a measured resection with equal implant replacement for the distal tibia and talus. Next, the trial tibial base, featuring a highly polished surface that remains mobile against the resected distal tibia, is allowed to rotate into proper position during ankle range of motion and tracking of the talar component through a securely fixed, highly conforming, articulating trial fixed-bearing insert. Only after this intrinsic ankle alignment has been achieved are the final bone cuts for the tibial keel and plug completed, fixing the tibial base and insert assembly into the optimized position. The instrumentation ensures proper positioning of the tibial implant and UHMWPE insert in relation to the talar implant. The same dedicated instrumentation, including an external alignment jig with tibial and pedal referencing, is used to resect the distal tibia and talus and insert the trial and final prosthesis components. The accuracy of tibial component alignment using this extramedullary referencing guide was tested in 83 ankles and determined to be within a mean of 1.5° and 4.1° in the coronal and sagittal planes, respectively, from the surgeon's intended position (25). The anatomic design of the talar component is intended to reproduce normal ankle kinematics without overstressing the deltoid ligament complex. The method of fixation for the tibial base and talar implant was not altered from that used with the Salto® mobile version design. The contact area between the UHMWPE insert and talar component allows ±2-mm varus and valgus motion, 5° of internal and external rotation, 2 mm of anterior-to-posterior translation, and a sagittal plane arc of motion from 20° dorsiflexion to 25° plantar flexion.

Total ankle replacement is a demanding procedure that can ultimately fail for a variety of reasons and require revision. As proposed by Henricson et al (26), the specific definitions for secondary procedures include revision, defined as any removal or exchange of 1 or more of the implant components, except for incidental exchange of the UHMWPE insert (i.e., metallic component replacement, custom implant usage, ankle arthrodesis, or below-the-knee amputation);