



Intraoperative Radiation Exposure During Revision Total Ankle Replacement

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ABSTRACT

Intraoperative C-arm image intensification is required for primary total ankle replacement implantation. Significant radiation exposure has been linked to these procedures; however, the radiation exposure during revision total ankle replacement remains unknown. Therefore, we sought to evaluate the radiation exposure encountered during revision total ankle replacement. The data from 41 patients were retrospectively analyzed from a prospective database: 19 AgilityTM to AgilityTM; 4 AgilityTM to Custom AgilityTM; 9 AgilityTM to INBONE[®] II; 5 AgilityTM to Salto Talaris[®] XT; 2 Scandinavian Total Ankle Replacement Prosthesis to Salto Talaris[®] XT; and 2 INBONE[®] I to INBONE[®] II revision total ankle replacements were performed. Two broad categories were identified: partial revision (AgilityTM to AgilityTM, AgilityTM to Custom AgilityTM, INBONE[®] I to INBONE[®] II) and complete conversion (AgilityTM to INBONE[®] II, AgilityTM to Salto Talaris[®] XT, Scandinavian Total Ankle Replacement Prosthesis to Salto Talaris[®] XT). The mean radiation exposure per case was significant at 3.49 ± 2.21 mGy. Complete conversions, specifically AgilityTM to INBONE[®] II, exhibited the greatest radiation exposure and C-arm time. Revision implant selection and revision type (complete or partial) directly contributed to radiation exposure. Accordingly, revision systems requiring less radiation exposure are preferable. Surgeons should strive to minimize intraoperative complications and limit additional procedures to those necessary, because both lead to additional radiation exposure.

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Exposure to ionizing radiation is associated with myriad adverse health-related issues (1–3). Intraoperative C-arm image intensification exposes patients, surgeons, and operating room personnel to significantly greater ionizing radiation than conventional radiography (1,3,4). Efforts to reduce radiation by embracing the As-Low-As-Reasonably-Achievable philosophy (5) are dependent on the established reference levels for intraoperative C-arm image intensification-guided procedures. Total ankle replacement has a greater radiation burden relative to other prosthetic joint replacements owing to the obligatory requirement for serial intraoperative C-arm image intensification to accurately insert the prosthesis (6–10).

The radiation exposure during primary total ankle replacement for 3 commonly used prostheses within the United States was shown to be 1.15 ± 0.84 mGy and 77 ± 34 seconds per case (11). Because the distance from the anode to the patient's ankle is relatively fixed,

the radiation exposure received is directly related to the duration of the intraoperative C-arm image intensification used. The International Commission on Radiological Protection has recommended a limit of 20 mSv of occupational radiation exposure averaged over 5 years, with a maximum of 50 mSv in any individual year (12); 1 mGy (unit of physical quantity of absorbed exposure) and 1 mSv (unit of equivalent dose to tissue) are considered equivalent (13). Angthong et al (11) determined the effective radiation exposure for 3 commonly used total ankle replacement systems in the United States to be approximately one fifth of the established annual radiation limits for an unprotected patient (12,13). Although typical operating room personnel radiation exposure is lower than the patient's by a factor of 1000 at 1 m, it is proportional. Scattered radiation from the patient is the main source of radiation exposure to operating room personnel. This is because fluoroscopy radiation is scattered ≤ 1.8 m from the surface of the patient where the x-ray beam is collimated. Consequently, higher patient radiation exposure corresponds to higher operating room personnel radiation exposure.

It has been demonstrated that the intensity and duration of C-arm image intensification varies among prosthetic systems and reference guide designs (11). Specifically, the INBONE[®] I total ankle replacement system (Wright Medical Technologies, Inc., Arlington, TN) with an

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intramedullary reference guide used more intraoperative radiation ($n = 20$; 1.59 ± 1.11 mGy; 97 ± 47 seconds) than did the Salto Talaris® anatomic ankle prosthesis (Integra Life Sciences, Plainsboro, NJ; $n = 17$; 0.87 ± 0.51 mGy; 79 ± 32 seconds) or the Scandinavian Total Ankle Replacement Prosthesis (STAR™; Stryker Orthopaedics, Inc., Mahwah, NJ; $n = 19$; 1.04 ± 0.58 mGy; 72 ± 22 seconds) using extramedullary referencing guides (11). Therefore, the patient received approximately 50% more ionizing radiation exposure with the INBONE® I total ankle replacement system than with the Salto Talaris® anatomic ankle prosthesis or STAR™ prosthesis (11). Although not statistically significant, this same group of prostheses demonstrated greater absorbed radiation exposure with ≥ 2 additional procedures requiring imaging assistance (1.96 ± 1.55 mGy) than those that did not require additional procedures (1.15 ± 0.79 mGy) (11).

Because the frequency at which foot and ankle surgeons are performing primary total ankle replacements continues to build, it is intuitive that revision total ankle replacement will become more common. This pattern has been demonstrated over time in the Norwegian Arthroplasty Register (<http://nrlweb.ihelse.net/Rapporter/Rapport2015.pdf>). Owing to the complexity involved in partially or completely explanting the original total ankle prosthesis, correcting any deformity present, and subsequently implanting new prosthetic components, high radiation exposure from intraoperative C-arm image intensification can be expected when performing revision total ankle replacement. No published data are available on the radiation exposure associated with revision total ankle replacement. Therefore, we evaluated the radiation exposure encountered during a series of revision total ankle replacements. Additionally, we sought to investigate any correlations among the implant designs, revision total ankle replacement types, and the radiation exposure encountered.

Patients and Methods

An observational case series was performed involving a retrospective review of prospectively collected data from 41 consecutive revision total ankle replacements. These were performed by the senior author (T.S.R.) for the management of failed primary Agility™ or Agility™ LP total ankle replacement (DePuy Synthes Joint Reconstruction, Warsaw, IN), INBONE® I total ankle replacement, and STAR™ prosthesis systems at our facility from October 2010 to May 2015. All but one of the primary Agility™ total ankle replacements in our series were performed by a single surgeon at our facility before retiring, and the lone remaining replacement was performed by a different surgeon at an outside health care center. All the STAR™ prostheses were performed by a different surgeon at our facility before referral to the senior author (T.S.R.) for revision. Both INBONE® I total ankle replacements were performed at outside health care centers. It should be noted that none of the primary Agility™ and Agility™ LP total ankle replacement or INBONE® I total ankle replacement systems had polymethylmethacrylate cement fixation, although it is included in the surgeon technique guides for these prostheses. Each patient, regardless of prosthesis type, demonstrated a varied severity of pathology and/or persistent pain indicative of implant failure. All were deemed to be at significant risk of impending catastrophic consequences had they not elected to undergo revision total ankle replacement.

At the preoperative evaluation of the Agility™ and Agility™ LP total ankle replacement systems, based on a comparison of serial weightbearing radiographs over time, 25 of the 37 patients (67.6%) demonstrated progressive aseptic osteolysis ≥ 5 mm of the tibia (about the medial malleolus or syndesmosis), fibula (about the vertical lateral tibial component side wall), and/or talus (predominantly within the neck region adjacent to the half pin used during external fixation application). Ten of these were considered massive osteolysis ≥ 15 mm and involved a cortical breach of the adjacent bone (13,14). Nine exhibited $\geq 5^\circ$ progressive varus or valgus and/or ≥ 5 -mm anteroposterior or lateral malalignment (13,14). Five had clinically significant lateral ankle instability uncontrolled by prescription brace therapy. Three had obvious syndesmosis nonunion. Two had confirmed deep periprosthetic infection. Finally, one presented with multiple periprosthetic midfoot fractures secondary to a traumatic injury. At revision, 34 patients (91.9%) had documented talar component loosening, with 9 (24.3%) of these also exhibiting tibial component loosening. Nineteen of these patients (51.4%) underwent partial component revision in which the original, revision, or LP talar component and corresponding ultra-high-molecular-weight polyethylene (UHMWPE) insert were replaced with revision or LP talar components and the best UHMWPE insert to achieve ligamentous tensioning (15–18) (i.e., Agility™ to Agility™). Nine of these patients (24.3%) underwent explantation of the Agility™ or Agility™ LP total ankle replacement system and conversion to an INBONE® II total ankle replacement system (Wright Medical

Technologies; i.e., Agility™ to INBONE® II) (17,19–22). Five of these patients (13.5%) underwent explantation of the Agility™ or Agility™ LP total ankle replacement system and conversion to a Salto Talaris® XT revision ankle prosthesis system (Integra Life Sciences) (i.e., Agility™ to Salto Talaris® XT) (17,22). Four of these patients (10.8%) underwent partial component revision in which the original, revision, or LP talar component and corresponding UHMWPE insert were replaced with a custom-designed long-stemmed augmented Agility™ LP talar component and an UHMWPE insert to achieve appropriate ligamentous tensioning (i.e., Agility™ to custom-designed long-stem Agility™ LP) (17,23,24).

Specific to the STAR™ prostheses, based on a comparison of serial weightbearing radiographs over time, both patients demonstrated progressive aseptic loosening of the tibial and talar components and periprosthetic aseptic osteolysis (13,14,25). At revision, both patients had documented tibial and talar component loosening. Both patients underwent explantation of the STAR™ ankle prosthesis and conversion to Salto Talaris® XT revision ankle prosthesis (i.e., STAR™ to Salto Talaris® XT) (17).

Specific to the INBONE® I total ankle replacement systems, from a comparison of serial weightbearing radiographs over time, both patients demonstrated progressive aseptic osteolysis of the talus predominantly within the contact zone between the talar component and talar body and the talar stem (26–28). At revision, both patients had documented talar component loosening. Both patients underwent partial component revision in which the original saddle-shaped talar component and corresponding UHMWPE insert were replaced with sulcus-shaped talar components and UHMWPE inserts to achieve appropriate ligamentous tensioning (i.e., INBONE® I to INBONE® II).

Whenever present, retained deep metallic fixation was removed to facilitate revision total ankle replacement and minimize future surgery complexity if tibiotalo-calcaneal arthrodesis with a bulk structural allograft was required. Each revision total ankle replacement was performed with free hand osteotomy, except for the Agility™ to INBONE® II conversions. These procedures used the extramedullary alignment guide in accordance with the manufacturer's described surgical technique (29–31).

For each revision, when good osseous apposition was possible, we chose to use a thin layer of antibiotic-impregnated polymethylmethacrylate cement (Simplex P with tobramycin; Stryker Orthopaedics, Mahwah, NJ) about the perimeter of the replaced metallic components. In situations involving advanced aseptic osteolysis and resultant contained extensive osseous defects from cyst formation, we used metal-reinforced polymethylmethacrylate cement to backfill the osseous defect and secondarily provide some early stability to the metallic components (32,33). Cancellous allograft chips impregnated with concentrated calcaneal bone marrow aspirate was impaction bone grafted into smaller contained tibial and talar cysts.

When varus deformities persisted after osseous preparation of the talus to correct the malalignment, a posterior tibial tendon recession was performed at the musculotendinous junction (34). Furthermore, a deep deltoid release off the talus was performed if additional correction was required (35–37). If the varus ankle was coupled with lateral ankle instability, this was corrected with an extra-anatomic autogenous peroneus brevis tendon transfer to the distal-lateral tibia (38,39) or a modified Bröström lateral ligament reconstruction (40,41). Similarly, when valgus deformities were encountered, osseous preparation of the talus to correct any malalignment was performed (16,18,22,24). If the valgus ankle was coupled with medial ankle instability, this was corrected with an extra-anatomic autogenous peroneus brevis tendon severed proximally, redirected through the talar neck, and secured to the distal medial tibia for deltoid reconstruction (42). Other than these, we did not encounter the need to perform other osseous osteotomies, arthrodeses, or tendon-balancing procedures to achieve a balanced ankle. Intraoperative fractures, when encountered, were stabilized with compression screw and/or plate and screw fixation to achieve stability and anatomic alignment.

Intraoperative C-Arm Image Intensification Use

Intraoperative C-arm image intensification was used at each major step of the revision total ankle replacement and as appropriate for any additional procedures required. The General Electric OEC 9900 Elite digital mobile C-arm (GE Healthcare, Salt Lake City, UT) with the low-exposure option, and an exposure time of 0.2 second per image was used. Regardless of the specific side undergoing surgery, the image intensification unit was positioned to the right of the surgeon (patients' left side). The imaging was posterior-to-anterior, with the X-ray source tube placed below the operating table and lateral with the X-ray source tube placed furthest from the limb (the image intensifier was closest to the limb). The cumulative absorbed exposure for each case was calculated by the C-arm image intensification system's software. The exposure and total image intensification time for each case were recorded in the standard picture archiving and communication system. As noted previously, for the diagnostic energies used, 1 mGy (unit of physical quantity absorbed dose) and 1 mSv (unit of equivalent dose to tissue) were considered equivalent (12).

Statistical Analysis

The variables measured included subject gender, subject age, intraoperative C-arm image intensification time (seconds), absorbed radiation exposure (milliGray), number of intraoperative images, additional total ankle replacement-specific procedures and intraoperative complications encountered. The revision total ankle replacements were

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