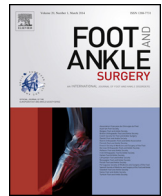




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## Are periprosthetic osteolytic lesions in ankle worth bone grafting?

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### ABSTRACT

**Background:** We retrospectively evaluated the medium-term follow-up of bone grafting due to periprosthetic osteolytic lesions in ankles.

**Methods:** 34 ankles (32 patients) with total ankle arthroplasty (TAA) underwent re operation. Indications were large periprosthetic osteolytic lesions or continuous growing of the lesions. The osteolytic lesions were imaged by CT before reoperation and once a year after that. The mean CT follow-up after re operation was 3.8 years (range, 2–6.2 years). Patient's clinical outcome was also monitored.

**Results:** Osteolysis continued to progress in 44 bone grafted lesions (68%) in CT follow-up. Pain ( $p=0.04$ ) and location of the lesion ( $p=0.03$ ) were associated with progression of osteolysis. In 18 bone grafted osteolytic lesions (28%) the radiological survival remained excellent. 25 out of 34 ankles showed improvement of the function after bone grafting.

**Conclusions:** There is no established treatment protocol for osteolysis around TAA. Bone grafting is one alternative in the treatment of osteolytic lesions.

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### 1. Introduction

Among the most important longer term complications after total ankle arthroplasty are periprosthetic osteolysis and aseptic loosening [1,2]. Osteolysis is common and well-recognized complication associated with many total ankle arthroplasty (TAA) implants. However, with the Ankle Evolutive System (AES) implant osteolysis has been shown to appear unacceptable frequent at very early phase in many cases [3–6].

Osteolysis has a multifactorial aetiology where both biological and mechanical factors contribute [7]. Wear debris is traditionally considered to have a central role in this complex biological cascade. However, in some studies, in spite of TAAs with large osteolytic lesions around the prosthesis components, the amount of wear debris has been low [4,8,9], and the polyethylene inlays have appeared intact in reoperation [4]. Recent studies have reported extensive tissue necrosis in failed TAAs [8,9]. Also, increased ligand (RANK-L), inflammatory cell and mediator expression in osteolytic

cavities around prosthesis components and nearby tissues has been found [8,10,11]. In addition to wear debris, the inflammatory pathway could be activated also by other factors, such as necrotic autogenous tissue or hydroxyapatite in TAAs with osteolysis [10,11].

Despite of osteolysis, TAA patients often remain asymptomatic for a long time [4,5,12]. There is no consensus of the best method to treat patients with well-functioning ankles having osteolysis around prosthesis components. Follow-up imaging is essential to timing of the reoperation [13,14]. Bone grafting with or without the use of longer stem prostheses or custom-designed components are the possible surgical alternatives besides arthrodesis [15–18]. We have added CT to our clinical follow-up protocol for patients with ankle TAA due to its superiority to radiographs in detecting osteolysis-related pathology [13], and routinely reoperated the ankles with large or continuously growing osteolytic lesions with debridement and bone grafting.

The purpose of the current study was to evaluate the medium-term follow-up of 34 ankle arthroplasties with bone grafting of osteolytic lesions. The lesions were evaluated by CT before and after bone grafting in order to follow the time course of the filled lesions; do they stabilize, or does the osteolytic process continue.

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Clinical outcome by means of pain and subjective function was also determined.

## 2. Methods

The first 3rd generation total ankle arthroplasty in our hospital was performed in 1997. First 34 implants used were Scandinavian Total Ankle Replacement (STAR; Waldemar Link, Hamburg, Germany) implants followed by Ankle Evolutive System (AES; Biomet, Warsaw, Indiana, USA) in 2002 due to more developed instrumentation. 130 AES prostheses were implanted before it was withdrawn from the market due to peri-implant osteolysis in 2008, giving the total amount of 164 prostheses. STAR consists of three components: tibial and talar components of cobalt-chrome (Co-Cr) and an ultra-high molecular weight polyethylene (UHMWPE) gliding core. A porous plasma spray of dual-coating (Ti-CaP) is applied to the STAR TAA. AES total ankle prosthesis is a 3-piece uncemented, unconstrained design with tibial and talar components of cobalt-chrome (Co-Cr) and UHMWPE between them. In 2004, the design was changed from Co-Cr components with a hydroxyapatite (HA) coating to a porous coating of pure titanium with an HA coating (dual-coated; Ti-HA). The tibial component was also changed from a modular stem to a monoblock.

46 of the 164 ankles (28%) ended up on reoperation due to periprosthetic osteolysis, the mean time-interval between the primary operation and reoperation was 4.5 years (range, 2.2–9.2 years). 12 patients were lost in CT follow-up, finally 32 patients with 34 ankle implants were included in this study. The demographic data of the patients is shown in Table 1. The patient selection for reoperation was done using CT: indications for reoperation were large, over 10 mm periprosthetic lesions or continuous growing lesions in follow-up. One to three osteolytic lesions in each ankle were grafted; there were altogether 65 bone grafted lesions in 34 ankles (32 patients). During the reoperation, the osteolytic cavities were curetted, debrided, and filled with either autologous or allogeneous bone graft, in some cases bone morphogenetic protein 7 (BMP-7) was also used. No exchange of the metal components was done. One to three orthopaedic surgeons participated in each reoperation. Postoperatively the ankle was immobilized in cast for 0–4 weeks depending of the size and location of the osteolytic lesion. The data of the reoperations is presented in Table 2, the table contains also patients' medication to osteolysis.

Postoperative result was controlled instantly after reoperation and postoperative course of the filled lesions was followed approximately once a year thereafter, both with CT. The mean CT follow-up after reoperation was 3.8 years (range, 2–6.2 years). A conversion to arthrodesis or repeated bone grafting was considered the end point of CT follow-up. Siemens Somatom Sensation 64-slice CT was used (Siemens AG Healthcare Sector, Erlangen, Germany). The protocol consisted of scanning at 120 kV with metal-artifact reduction algorithm. Also, automatic tube current modulation was used. The slice thickness was 0.6 mm and the reconstruction increment 0.4 mm. The scanned area included the whole implant and the peri-implant area. During scanning,

**Table 2**

Data of the reoperations (number of ankles, n = 34).

	Number	%
Bone graft	34	
Allograft	29	85
Autograft	4	12
Both	1	3
Polyethylene component changing	34	
Yes	24	71
No	10	29
BMP (bone morphogenetic protein) – 7	34	
Yes	5	15
No	29	85
Attendance in reoperation	34	
Orthopaedic surgeon no 1 (H.T)	21	68
Orthopaedic surgeon no 2	16	47
Orthopaedic surgeon no 3 (H.K)	6	18
Orthopaedic surgeon no 4	1	3
Orthopaedic surgeon no 5	5	15
Medical treatment	34	
Bisphosphonate (tsoledronic acid)	9	26
Denosumab	6	18
Both	16	47
No medical treatment	3	9

patients were supine on a table with straight knees. Coronal, sagittal and axial images (according to the tibial implant) were reformatted from the original data. Osteolytic lesions were defined as well-demarcated, periprosthetic lucencies without osseous trabeculae. The volume measurements of osteolytic lesions were done using Aycan Workstation Osirix<sup>Pro</sup> (version 1.04; Wurzburg, Germany). The streak artifacts caused by metallic ankle prosthesis were visually appraised. Volume measurements of the potential postoperative residual and recurrent osteolytic lesions after reoperation were done twice on CT images by one of the authors (I.K.) with 5 months between measurement sessions for evaluation of intraobserver reliability, and once by another author (J.K.) for interobserver reliability evaluation. Postoperative volume measurements were done at three different time points: instantly after operation, one year after operation and at the latest follow-up point available. Preoperative volume measurements of the osteolytic lesions on CT images were done once by the first author (I.K.).

During follow-up, an additional procedure was done in seven ankles: one triple arthrodesis and fusion of naviculo-cuneiform joint, one medial malleolar osteophyte resection, one lateral malleolar elongation and calcaneal osteotomy, one removal of fixation screws, one medial malleolar fracture fixation and removal of fixation material and two calcaneal osteotomies. The calcaneal osteotomies were performed at the same operation with bone grafting of osteolytic lesions. Pain before and after reoperation and postoperative subjective function were recorded. Interviewing after reoperation was done at the mean follow-up of 4.2 years (range, 1.1–6 years) by physiotherapists experienced in the treatment of TAA patients. The parameters used were modified from the Kofoed scale [19].

### Statistical analysis

The association of demographic parameters for appearing of osteolytic lesion compared to those with constant bone grafting during the follow-up period was analysed with binary logistic regression. Linear models were used to test the association of demographic parameters with progression of osteolysis in the follow-up period. Progression values were log-transformed due to positively skewed distribution. Generalised estimating equations

**Table 1**

Demographic data of the patients.

Sex	19 men, 13 women
Age at reoperation, mean	60.4 year (range, 36–78 year)
Age at primary operation, mean	55.7 year (range, 33–76 year)
BMI at primary operation, mean	29 kg/m <sup>2</sup> (range, 20–47 kg/m <sup>2</sup> )
Diagnosis	22 osteoarthritis, 10 rheumatoid arthritis
Prosthesis model	31 AES, 3 STAR
Side of the ankle	21 right, 13 left

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