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The ceramic coated implant (CCI). Evolution total ankle replacements: a retrospective analysis of 40 ankles with 8 years follow-up

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Diminutive data is available on the outcome of several previously used total ankle replacement implants. The purpose of this study was to investigate the medium-term functional and radiological outcome and implant survival of the CCI Evolution implant. Consecutive series of 40 ankles operated in our hospital with primary TAR using the CCI Evolution implant in 2010-2013 were available for follow-up. The prospective clinical and radiographic data including the Kofoed score, subjective satisfaction and standard radiographs were collected preoperatively and at fixed time-points postoperatively. A CT was obtained in cases where osteolysis or loosening were suspected. The improvement of the Kofoed score and subjective satisfaction were statistically significant (p<0.0001). The implant survival was 97% (95% confidence interval (CI) 81%-100 %) at 5 years, and 81 % (95% confidence interval (CI) 60 %-92%) at 8 years. There were altogether 25 (64%) complications. Overall revision rate was 28% and failure rate 13%. The CCI implant outcome was not acceptable. The malposition of prosthetic components, subsidence, and peri-implant osteolysis were recorded often. Although the patient reported outcome measures improved, mostly due to positive changes in pain severity, overall revision and failure rates were high and comparable with previous findings of the CCI implant.

Keywords: ceramic coated implant (CCI); total ankle replacement, survival, complications.

INTRODUCTION

Despite of the improvement of the outcome, total ankle replacement (TAR) still has high complication and reoperation rates, mainly due to aseptic loosening, technical error, and subsidence[1-4]. Several modern TAR implants have been used, and some of them withdrawn from the market due to marked complications and inferior survival[5,6]. At least the postoperative alignment, implant design, and surgeons experience have been shown to influence the results[3,7,8]. The outcome is proposed to improve along with the evolvement of the material technology and implant design, refined patient selection, and improvement of surgical techniques, which was already noted by better survival of modern implants in the recent analysis from the Swedish Ankle Registry[2]. To further enhance the longevity of TAR it is essential to report the results of series of the previously used implants. Although important information of these abandoned implants is provided by the registries, many of them are recently established and some do not specify data between different implants. Previous series addressing the survival and outcome solely of the CCI Evolution implant (Ceramic Coated Implant; Wright Medical Technology, Arlington, TN, USA) showed inferior results compared to other third-generation mobile-bearing ankle implants[9]. Based on these previous results and our clinical experience we hypothesized that the outcome of the CCI Evolution implant would be inferior also in our series. The purpose of this study was to investigate the medium term functional and radiological outcome and implant survival of the CCI Evolution implant performed in an independent specialized center.

MATERIALS AND METHODS

Between November 2010 and March 2013, 39 consecutive patients (40 ankles) underwent primary

Table I. — Baseline characteristics.

Variable	Estimate
Age, years	65 (SD 12)
Gender	
Men	18 (46%)
Women	21 (54%)
Larsen	
2	10 (26%)
3	10 (26%)
4	9 (23%)
5	10 (26%)
Diagnosis	
Rheumatoid arthritis	14 (35%)
Posttraumatic osteoarthritis	25 (63%)
Idiopathic osteoarthritis	1 (2%)

TAR using CCI implant. The prospective clinical and radiographic data were collected and analyzed retrospectively. All the operative procedures were performed in Turku University Hospital by 4 experienced surgeons, one senior author participating nearly all operations. The indication was post-traumatic osteoarthritis in 25 (63%), idiopathic osteoarthritis in 1 (2%) and rheumatoid arthritis in 14 (35%) of the patients. The study was conducted by the Helsinki Declaration ethical principles and the institutional approval was obtained from the University Hospital.

The baseline characteristics are presented in Table I. The average age of 39 patients was 65 (SD 12, range 40-84) years and there were 18 (46%) male and 21 (54%) female patients.

Implant characteristics

The CCI implant was a three-piece uncemented, unconstrained design with tibial and talar components of titanium nitride (TiN) coated cobalt-chromium (Co-Cr) and a mobile-bearing polyethylene insert. The TiN is an ultra-hard technical ceramic providing supremely smooth surface on the articulating surface of the components to decrease wear. The components had a titanium plasma spray and calcium phosphate (CaP) dual-coating. The tibial component was trapezoidal design being wider anteriorly than posteriorly and it has a keel-type fixation fin, and the talar component had a V-shaped design. The implant was made obsolete in 2016.

Operative technique and postoperative management

Operations were performed from an anterior midline incision. The Modular Resection Guide utilizing the tibial tuberosity as reference point combined with the Tibial Resection Block was used for tibia resection aiming for a 0-degree slope, and the V-shaped resection of the talus was made by using the Free-Hand Talar Resection Guide. Postoperatively, patients were immobilized with a short leg cast for six weeks, with first nonweightbearing, partial weightbearing from two weeks, and full weightbearing from four weeks postoperatively. Rehabilitation program was initiated at six weeks when the cast was removed.

A clinical evaluation was performed preoperatively and at 3 months, 6 months and 1 year after the operation, and every 2 years after that. Clinical outcome was measured using the Kofoed scale (Supplement Material)[10], in which the points for pain were analyzed separately. The subjective outcome was assessed using an inhouse questionnaire for improvement in function and for overall satisfaction with scale from 1 (worse) to 4 (markedly better/very satisfied) (Supplement Material) The clinical range of motion (ROM) was determined measuring the maximum dorsiflexion and plantarflexion of the ankle nonweightbearing subtalar joint at a neutral position measured by experienced physiotherapist using a goniometer. The duration of follow-up lasted until 2020 and was defined in full months.

The radiographic evaluation included anteroposterior (AP) and lateral views of the ankle at baseline, on the first postoperative day and at the latest clinical control. The radiographic changes were defined according to the Larsen scale. The tibiotalar angle was measured as the angle between the longitudinal axis of the tibia and a parallel line to the superior articular surface of the talus[11]. The tibiotalar ratio (tt-ratio) was calculated as described by Tochigi et al.[12]. The malposition was recorded when tibial and talar component were not congruent to each other. Subsidence was defined as a change in vertical position of prosthesis component ≥ 5 mm. Radiolucency, defined as complete radiolucent line < 2 mm in width, and osteolysis, defined as discrete, well-circumscribed areas of lucency ≥ 2 mm in width in the periprosthetic bone, were recorded and divided into zones on anteroposterior and lateral radiographs (Fig. 1).

A helical CT was undertaken when osteolysis or loosening were suspected at follow-up. The scanned area included the whole implant and the peri-implant area. During scanning, patients were lying supine on the

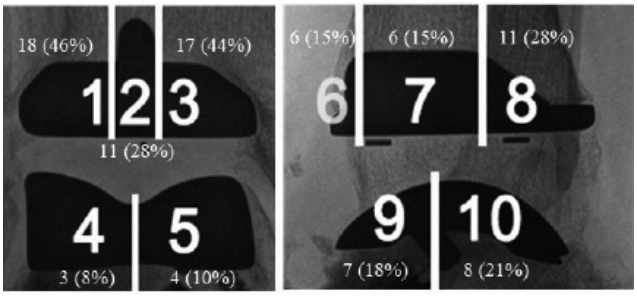

Figure 1 — Number of patients with radiolucent lines (%) shown located in the radiographic zones. Zones 1-5 in AP-view; Zones 6-10 in lateral view.

table knees straight and ankle at 90 degrees of flexion, which has been shown to minimize the metal artifacts produced by the implant[13]. 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 containing no osseus trabeculae. The CT was analyzed by an experienced musculoskeletal radiologist (IK).

The estimates were presented as absolute numbers and percentage. When appropriate, normally distributed estimates were presented as means and standard deviations (SD), and abnormally distributed estimates were presented as medians, ranges, and interquartile ranges (IQRs). Due to abnormal distribution, the Kofoed scores were transformed into their normal logarithms, and further multinomial (quadratic) regression analysis was performed on lognormal scale. As a sensitivity test, cubic regression was tested and found to not improve the model compared to a quadratic one. The results of regression analysis were evaluated graphically. Due to small n-numbers at the end of follow-up, the estimates obtained after 5 (6 to 9 years) years were combined as ">6 years". The analyses were performed using Stata/IC Statistical Software: Release 16. College Station (StataCorp LP, TX, USA).

RESULTS

1 patient was lost in follow up at 12 months post-operatively leaving 39 ankles in 38 patients for final evaluation. The average follow-up time was 70 months (5.8 years), with range of 6 to 108 months. 6 patients died during follow-up to causes not related to ankle replacement. The average Kofoed score was 40,6 points (SD 12,6) at baseline and 67,2 points (SD 21,1) at the end of follow-up (p=0.0001) (Fig. 2 and Supplementary Material). At the end of follow-up 6 patients had fair, 6 patients good, and 8 patients excellent result, but in 19 patients, the score was defined as not acceptable. Preoperatively, all but one patient (98%) reported pain at rest or always when walking. At the end of follow-up 15 patients (38%) did not report any pain, and only seven patients (18%) experienced pain at rest or always when walking. In subjective questioning 32 patients (82%) reported improved ankle function, 24 (62%) were very satisfied, and 12 (31%) were satisfied with the ankle (p<0.001) at the latest follow-up. The mean total ankle motion was 35 degrees (SD 6.4; range 5-40) preoperatively, and 35 degrees (SD 5.3; range 15-40) at the latest follow up.

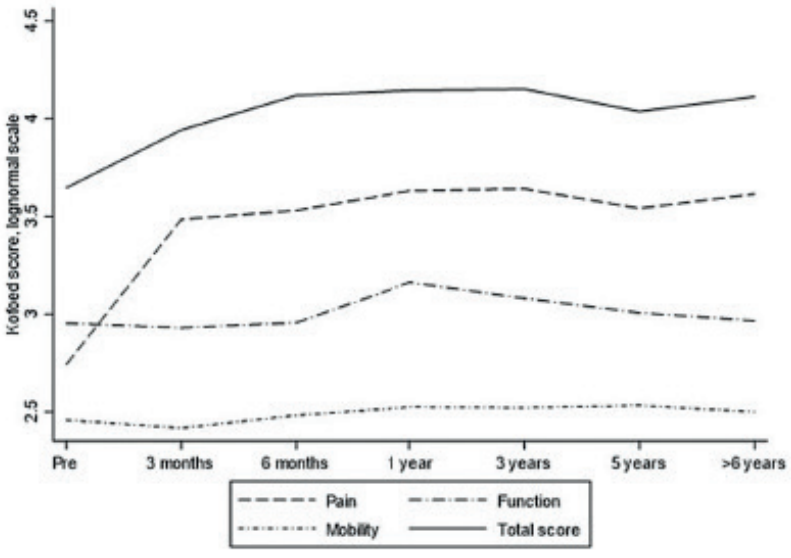

Figure 2 — Development of Kofoed score over time of follow-up (lognormal scale).

Supplementary Table I. — Kofoed ankle scale

Kofoed scale					
Pain (max. 50 points)					
No pain **50**	Starting pain **40**	Pain walking levels **35**	Loading pain occasionally **30**	Loading pain always **15**	Pain during test or spontaneously **0**
Function (max. 30 points)					
Toe walking **3**	Heal walking **3**	Normal cadence walking stairs **6**	One-leg standing **6**	No walking aids **6**	No orthopedic foot wear **6**
Mobility (max. 20 points)					
Extension	> 10 degrees **5**	5-9 degrees **3**	< 5 degrees **1**		
Flexion	> 30 degrees **5**	15-29 degrees **3**	< 15 degrees **1**		
Supinaion	> 30 degrees **3**	15-29 degrees **2**	< 15 degrees **1**		
Pronation	> 20 degrees **3**	10-19 degrees **2**	< 10 degrees **1**		
Valgus	< 5 degrees **2**	5-10 degrees **1**	> 10 degrees **0**		
Varus	< 3 degrees **2**	4-7 degrees **1**	> 7 degrees **0**		
85-100 Excellent; 75-84 Good; 70-74 Fair; < 70 Not acceptable.					

Supplementary Table II. — Questionnaire for assessment of subjective outcomes for patients

	1	2	3	4
Improvement in function	Worse	No change	Better	Markedly better
Satisfaction	Worse	Cannot say	Satisfied	Very satisfied

Supplementary Table III. — Main outcome measures at baseline and follow-up

Estimate	Min	Max	Median	IQR		N
				25%	75%	
Pain						
Pre	0	30	15	0	15	39
3 months	0	50	30	0	30	31
6 months	0	50	30	15	50	33
1 year	0	50	30	30	50	38
3 years	0	50	50	30	50	30
5 years	0	50	30	7.5	40	20
>6 years	0	50	35	30	50	25
Function						
Pre	0	30	21	15	27	39
3 months	6	30	21	15	27	31
6 months	6	30	21	18	27	33
1 year	0	30	24	18	30	38
3 years	0	30	24	18	30	31
5 years	0	30	22.5	16.5	30	20
>6 years	0	30	24	12	30	25
Mobility						
Pre	2	18	12	10	15	39

3 months	6	18	12	10	13	31
6 months	6	20	12	10	14	33
1 year	6	20	13	11	14	38
3 years	6	19	12	11	15	31
5 years	7	18	12.5	10.5	16	20
>6 years	7	18	12	10	14	25
Total score						
Pre	14	77	42	33	49	39
3 months	17	91	58	34	75	31
6 months	14	96	70	49	85	33
1 year	8	99	72.5	57	90	38
3 years	12	99	78	57	89	31
5 years	21	98	65	43.5	76.5	20
>6 years	14	98	68	58	82	25

Supplementary Table IV. — The location (according to zones presented in Figure 1.), measurements (mm), and volume (mm^3) of the cysts detected in CT (n=20); MM=medial malleolus

Patient	Location	Size (mm)	Volume (mm^3)
1	4,9	6x5x11	173
2	1,8	8x8x10	335
	4-5,9	5x7x9	165
	MM	6x6x6	113
3	1,6-7	11x13x13	973
	3,6-7	5x9x7	165
	5,9	4x5x8	84
4	4,10	5x4x5	52
	4,10	7x6x5	110
5	3,8	7x8x9	264
	5,9	7x8x13	381
6	3,6-7	6x12x15	471
	MM	11x9x9	467
	MM	8x6x5	126
7	3,6	8x14x8	469
	2-3,6-7	35x19x14	4875
8	1-2,7-8	8x18x34	2564
	4,10	12x8x14	704
9	3,6-7	20x13x16	2178
	1,6-8	15x12x28	2639
10	3,6-7	14x11x11	887
	1,6-7	11x10x9	518
	3,8	8x12x11	553
	1,8	4x10x15	314
	4-5,9-10	23x28x27	9104
11	5,9	14x14x17	1745
12	4-5,9	7x20x11	806
13	2,6	14x11x8	645
	1,6-7	13x10x10	681
	5,9	14x14x14	1437
	4,9-10	12x15x21	1963
14	1,6-7	19x14x23	3203
	3,6-8	9x33x10	1542
	4-5,9	7x3x4	44
15	MM	23x1x4x15	2529
16	3,8	8x7x6	176
	1,6-7	10x9x16	754
17	MM	35x15x25	6872
	2-3,8	12x15x16	1508
	5,9	6x9x13	368
	4-5,10	3x9x7	99
18	1-3,6	4x28x10	586
	4-5,9	8x22x12	1106
	MM	9x6x12	339
19	3,6-7	7x11x24	968
	4-5,9-10	6x12x18	679
20	1-2,6-8	17x22x32	6266
	3,7	15x13x10	1021
	4,9	27x25x28	9896
	MM	17x13x10	1148
	MM	12x10x13	817

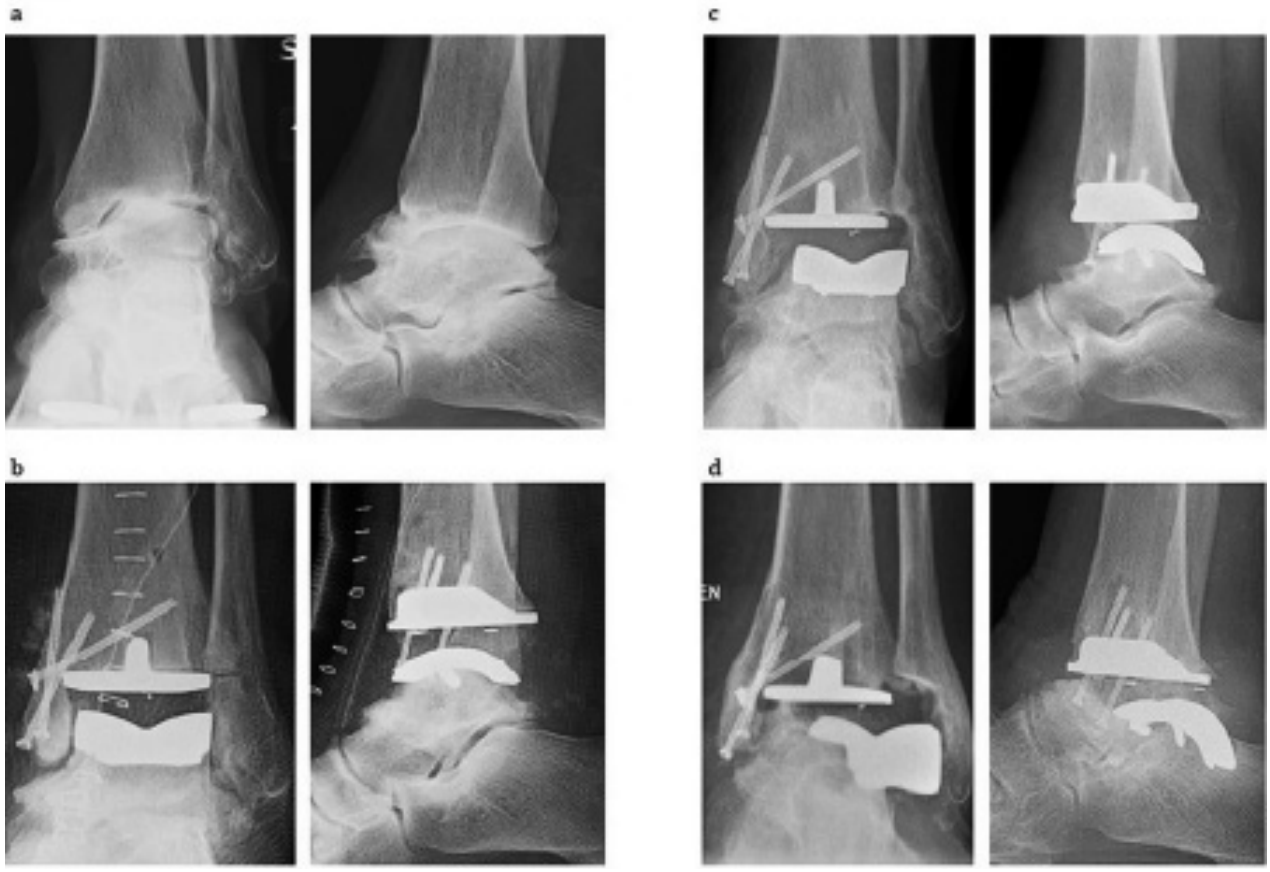

Figure 3 — Example of subsidence of talar component. 63 years old female patient with varus ankle, CCI implant operated in June 2012. Postoperative radiographs immediately postoperative, at 27 months, and at 84 months postoperative, respectively.

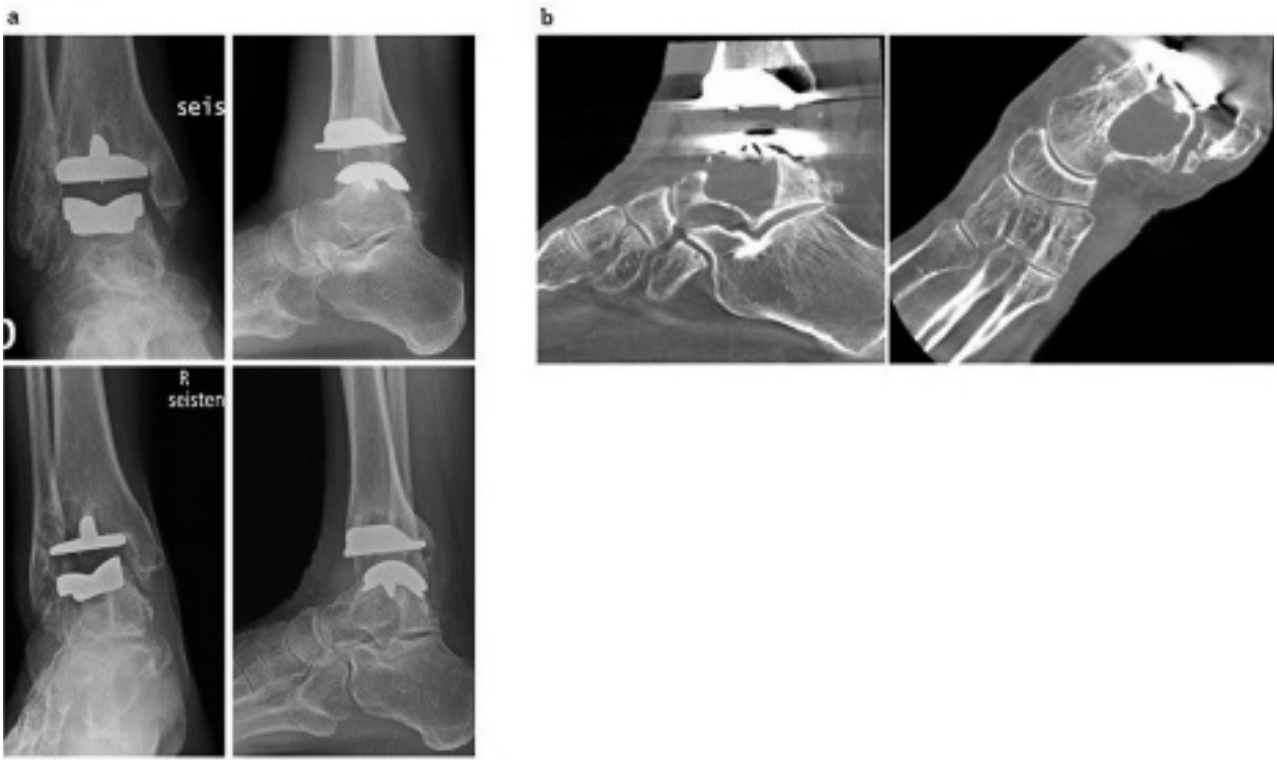

Figure 4 — Kaplan-Meier survival estimate. 95% confidence interval shown in grey color.

Table II. — Complications and additional procedures. If there were several operations on one ankle, it appears only in the column of the last operation, but the same case may appear on several rows.

	No further surgery	Intra-operative corrective surgery	Further corrective surgery	Revised by fusion	Revised by exchange	Revised with debridement and filling
Major delay of wound healing			1			
Deep infection				1		
Intraoperative fracture of medial malleolus		3				
Intraoperative fracture of lateral malleolus		2				
Stress fracture of medial malleolus	5					
Osteolysis	12		6	2	1	3
Aseptic loosening	1					
Component migration	13			1	1	
Varus malalignment (> 10º)	3		2			
Valgus malalignment (> 10º)	1					

Average preoperative varus alignment was 7.4 (range 2-20; SD 5.4) degrees in 19 ankles and valgus alignment 6.3 (range 0-16; SD 5.4) degrees in 20 ankles. Average varus alignment at the end of follow-up was 4.7 (range 1-15; SD 4.2) degrees in 23 ankles and valgus alignment 2.2 (range, 0-5; SD 1.9) degrees in 16 ankles.

The average preoperative TT-ratio was 38% (range 31-60%) and the average postoperative TT-ratio was 37% (range 20-65%) at the latest visit. The malposition of prosthetic components was seen in 12 (31%) ankles. Talar component migration was found in 10 (26%) and tibial component migration in 3 (8%) ankles during follow-up (Fig. 3.).Radiolucent lines or osteolytic lesions were found on radiographs after 1 year postoperatively in 6 (15%) ankles and at the end of follow-up in 22 (56%) ankles at least in 1 zone. Of those 22 ankles, half had radiolucent lines in more than 3 zones and 2 in all 10 zones. Most of the radiolucency was seen on tibial side. Osteolysis was detected in 12 (31%) ankles at the end of the follow-up on radiographs. The distribution of the radiolucency is shown in Fig. 1 and example of osteolysis in Fig. 4. Postoperative CT was available in 29 ankles within 2 to 7 years postoperatively of which 9 had no osteolysis. The amount and locations of the lesions are shown in Supplementary Material.

There were 6 perioperative fractures, which were fixed perioperatively. 2 fractures were in lateral malleolus, 3 in medial malleolus, and 1 in talus. All healed without complications. Postoperatively, there were 5 stress fractures of the medial malleolus, which all healed conservatively. 1 lesion of the flexor hallucis longus (FHL) tendon was sutured without further problems. 2 nerve injuries involved the tibial nerve, one was both on lateral and medial and the other on medial plantar nerve. There was 1 wound complication requiring operative treatment with skin transfer, which healed. 2 ankles with varus malalignment were re-operated, one with subtalar arthrodesis and calcaneal osteotomy and the other with medial malleolar lengthening and calcaneal osteotomies. There were 3 revisions due to osteolysis, all in the talus. 1 was done by curettage and bone grafting with good result. In the other 2 the cavities were filled with Cerament resorbable bone cement (Bonesupport AB, Lund, Sweden), which dissolved during follow-up from both ankles. There was 1 component revision with Hintegra revision components (Newdeal SA, Lyon, France) at 71 months postoperatively due to large osteolysis under talar component causing migration with good result so far. 4 ankles (10%) were converted to arthrodesis by intramedullary nailing at average of 74 months (range 50-98) postoperatively. 2 were due to marked osteolysis, 1 due to migration, and 1 due to deep infection. Of these ankles 1 healed well, 1 required a revision nailing, 1 has suboptimal union and pain, but patient refused further surgery, and 1 ended up in amputation due to deep infection at 17 months after the nailing. There were no hardware removals, debridement or insert fractures. The complications are shown on Table II.

There were 5 (13%) failures defined as a need for revision by exchange of metal components or conversion to arthrodesis. The implant survival was 97% (95% confidence interval (CI) 81%-100%)

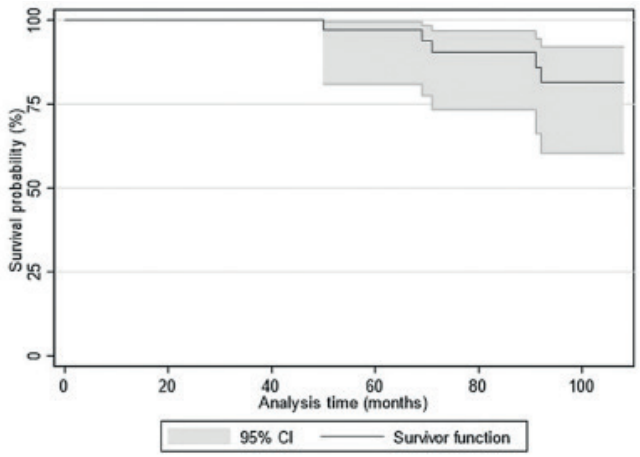

Figure 5 — Example of osteolysis. a, Radiographs of CCI implant at one year and four years after implantation. Note visible osteolysis around talar and tibial components. b. CT scan two years after the operation with large osteolytic cyst under the talar component.

at 5 years, and 81% (95% confidence interval (CI) 60%-92%) at 8 years (Fig. 5). Besides the cases of failure there were 20 (51%) complications including perioperative fractures. The overall revision rate was 28% (11/39) including all postoperative revisions for wound healing problems, malalignments, osteolysis, component exchanges, and conversions to arthrodesis.

DISCUSSION

In this medium-term study of the CCI implant, we found an overall revision rate of 28% and a failure rate of 13% defined as a need for revision by exchange of metal components or conversion to arthrodesis. In addition, complications were recorded often, 64%. In a resent systematic review the mean complication rate after total ankle arthroplasty was 23.7% (range 2.4-52%)[4]. The improvement of the Kofoed score was statistically significant, mostly due to the positive changes in pain severity, while function and mobility sub-scores remained essentially unchanged. Despite that, 82% of the patients reported improved ankle function and 92% were very satisfied or satisfied with their ankle. The functional subdomain of Kofoed score is probably not optimal, especially for rheumatoid patients, and the contradictory clinical results emphasize the importance of PROMs in the follow-up of orthopedic surgery in general as well as the importance of pain reduction in patient´s perspective.

The latest analysis from the Swedish Ankle Register included 151 CCI implants with 28 revisions (19%) in approximately eight-year follow-up, the most common reason for revision being loosening, followed by pain[2]. The specific reasons for loosening were not reported in that study[2]. Voesenek et al.[14] presented an abstract of 58 CCI implants with radiological and clinical outcome in a mean follow-up of 21.6 months (range 1.45-66.0) with relatively high incidence of complications and re-operations and concluded that clinical outcome can be predicted by radiographic migration characteristics and pain. For a short-term study a relatively high number of patients (33%) underwent one or more re-operations, including component revision, exchange of PE inserts or conversion to arthrodesis. In accordance with our findings, Voesenek et al.[14] found that migration in the frontal and sagittal plane was common with the CCI implant.

The largest study of 254 CCI implants with long-term results was published recently by van Es with 10-year follow-up[9]. They reported a 67.5% 10-year survival rate for all cause revision with a median follow-up of 6.9 (range 0.04-13.9) years with a mean time to revision of 4.5 (range 0.04-12.2) years. The 10-year survival rate for aseptic loosening was 70.0% (95% CI 61.-78.6). Although the survival rates are not directly proportional to our study because of differences in presenting the revisions, and number of revisions for implant failure was higher compared to our findings, it is likely that the survival rate will decrease over time due to high number of problems encountered also in our series.

The number of complications seems to be high in all the CCI series. Voesenek et al.[14] reported 37% postoperative complications including impingement, deep infection, delayed wound healing, and minor nerve injuries in short-term. Altogether, complications including all re-operations were recorded in 64% of ankles in our study and in 45% of the ankles in the study by van Es et al.[9]. However, not all complications are the same in terms of the risk for implant failure, and only one-fifth of the complications in our study feasible to be defined by classification system developed based on the severity were high-grade[15]. Nevertheless, the reoperation rates were still high, 37% in the study by van Es et al.[9] and 28% in our series. Besides longer follow-up time and larger number of patients, the differences in numbers between studies may be explained by slightly different patient populations, for example, the share of rheumatoid patients was slightly bigger in our series.

The surgical technique influences the implant survival due to steep learning curve[8]. Although several surgeons participated the operations, our results are not entirely explained by the surgical skills, as over 160 total ankle replacements were operated before the CCI TARs in

this center by these surgeons most with over 10 years of experience of TAR. Updated instrumentation has been shown to decrease malalignment by increasing the precision in centering the talar component relative to tibial component[8] and the talar component malposition is significantly associated with the postoperative pain level, functional outcome, and the ankle motion[16]. It is challenging to accurately determine the ideal positioning and standardize the rotation of the implants due to wide variation of tibial torsion between patients, especially with instrumentations using the tibial tuberosity for referencing[17]. Like van ES et al.[9], we also found the talar instrumentation to be inadequate to securely place the talar cuts. Also, the design of the talar component with short and thin pegs to secure the initial fixation to the bone might explain the high amount of postoperative talar component malalignment. However, the malalignment developed mostly during follow-up to the primary well-aligned ankles, or the components migrated due to osteolysis, so the association between the primary component seating and outcome remains unclear.

Osteolysis has been one of the major problems of TAR potentially leading to massive bone loss and loosening, and the treatment of progressive osteolytic cysts is contradictory[18-22]. The incidence of osteolysis has been high with many third-generation implants, up to 70%[5,6]. In this series the incidence of osteolysis was quite high, 31% in radiographs, and 69% in those ankles which were imaged by CT scanning, and over half of the revisions were performed due to osteolysis. This is consisted by previous findings related to the CCI implant[14]. The etiology of osteolysis is multifactorial, principal cause being local immune response of the host tissue cells initiated by the biological or mechanical factors[22,23]. A significant association was found between presence of cysts and non-anatomic design, HA-coating, mobile-bearing, and non-tibial-stemmed implants[24], and the coronal alignment was shown to have significant influence on the amount and location of cysts[25]. The implant design, coating, alignment, incomplete seating, and geometry of the components may influence the amount of micromotion at bone-implant interface and the initial stability[22,26-28]. The highest micromotion was found in stem-type implants, followed by keel-type and bar-type, and lowest in peg-type geometries, and the initial stability of an ankle implant was proposed to be optimized by decreasing fixation size[28]. The CCI tibial component is a keel-type design, whereas most of the more recent TAR tibial components are nowadays peg- or bar-type designs. The dual-coating with titanium and calcium phosphate of CCI implant resembles many other designs at that time, which might have had an effect to the problems observed.

At present CT is recommended for the radiological follow-up of TAR due to its better ability to detect osteolytic lesions compared to radiographs[29]. The cone-beam (CBCT) technology enabling the weight-bearing CT imaging (WBCT) is nowadays emerging in evaluating the foot and ankle patients[30]. Although conventional helical-CT and CBCT are both relevant in detecting peri-implant osteolysis, WBCT allows more accurate imaging of the ankle due to possibility of alignment measurements and more precise joint pathology imaging. The weight bearing images can be utilized both in preoperative planning as well as follow-up of TAR[25,30].

There are several limitations of this study. The main weaknesses are the retrospective design, small number of ankles, and medium-term follow-up time. The associations between patient related factors or ankle alignment with the outcome were not possible to conduct. As the CT scanning was scheduled only when there was a suspicion of osteolysis or loosening, not as a routine clinical follow-up, there is variation of the time between the operation and CT scanning. Despite the limitations we believe that consecutive series with definite follow-up scheme of previously commonly used implants provides necessary information both for future implant development as well as for TAR surgeons and patients having those implants.

CONCLUSIONS

The CCI implant outcome was not acceptable as malposition, subsidence, and peri-implant osteolysis were recorded often. Although most of the patients were satisfied with their ankle, we discontinued the use of the implant already after two years because of unsatisfactory experience. The overall revision and failure rates were consistent with previous findings reported from the CCI implant. Patients with these implants should be monitored carefully and more research is needed to investigate the reasons for causing these implants to fail.

Declaration of conflicts of interest: The authors declare that this manuscript is original, has not been published before, and is not currently being considered for publication.

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