

The HINTEGRA® Ankle Arthroplasty: Intermediate Term Results of 16 consecutive Ankles and a Review on the Current Literature

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Abstract

Purpose: Total ankle arthroplasty provides an alternative to arthrodesis for management of ankle osteoarthritis. The results of the third generation total ankle replacements have been promising. The purpose of the present study was to investigate the clinical and radiographical outcome and implant survival of 16 consecutive patients suffering from symptomatic ankle osteoarthritis treated with the HINTEGRA® (Newdeal SA, Lyon, France) prosthesis.

Methods: The first 16 implanted HINTEGRA® total ankle replacements (between 2001 and 2006) by a fellowship-trained foot and ankle surgeon were assessed clinically and radiographically after a mean of 61,8 months (range, 7–116). Eight female and eight male patients were operated at a mean age of 55 years (range, 34–77). Diagnosis was post-traumatic osteoarthritis in 10 (62,5%), primary osteoarthritis in 3 (18,7%) and arthritis secondary to infection in 3 (18,7%) patients.

Results: The mean AOFAS score at final follow-up was 77 (range, 49–91). Mean ankle ROM as determined clinically and fluoroscopically was 23,72 degrees (range, 12,0–47,5). Six patients required revisional surgery (37,5%). The mean follow up period until revisional surgery occurred was 50,6 months (range, 24–116). In total, implant survival in all followed ankles was 66,7%.

Discussion: Our study demonstrated that the functional results of the HINTEGRA® ankle were comparable to most high volume centres but the implant survival was lower. With regards to the steep learning curve of total ankle arthroplasty these results seem compatible.

Introduction

Approximately 15% of the world's adult population is affected by joint pain and disability resulting from osteoarthritis, and approximately 1% have osteoarthritis of the ankle [1]. As compared with hip and knee osteoarthritis, primary ankle osteoarthritis is rarely encountered [2].

Total ankle arthroplasty (TAA), which is an alternative to ankle arthrodesis for the treatment of end-stage ankle arthritis [3], has evolved over the past decade. TAA has been performed in selected patients with end-stage ankle idiopathic, post-traumatic osteoarthritis, and inflammatory arthritis since the 1970s [4].

The development of second generation TAA proceeded in two strategic directions. The first was the replacement of all three articulations (talofibular, tibiotalar, and medial malleolartalar) along with a fusion of the distal tibiofibular syndesmosis [5]. The second was replacement of the superior articulation with hemiarthroplasties of the medial and lateral malleolar articular surfaces [6]. Third generation TAA obtain three-components, two metal components (tibial and talar) and a mobile polyethylene bearing in between. Implants have a more anatomic design and require less bone resection than the two-component designs. Modern three-component TAA designs provide significantly better results than their predecessors due to the advantages conferred by a mobile-bearing, cementless fixation, and minimal bone resection, and offer a viable alternative to fusion for the treatment of ankle osteoarthritis [7,8]. Reported midterm results are optimistic but vary considerably between series, with reported survival rates varying between 70% and 95% [9-15].

Aim of this study was to evaluate the clinical and radiographical outcome and the implant survival of the first 16 patients treated with a third generation TAA prosthesis, the HINTEGRA® (Newdeal SA, Lyon, France) ankle.

Methods

We retrospectively reviewed the outcome of the first 16 HINTEGRA® total ankle replacements (Newdeal SA, Lyon, France) which were implanted between June 2001 and May 2006 by a fellowship trained foot and ankle surgeon (HJT). The study cohort consisted of 8 male and 8 female patients. Mean age at the time of surgery was 55 years (range, 34–77). The indication for surgery was debilitating ankle arthritis as a result of a post-traumatic condition in 10 (62,5%), primary osteoarthritis in 3 (18,7%) and arthritis secondary to infection in 3 (18,7%) ankles.

One patient died during the follow up. The remaining 15 patients were followed for a mean of 61,8 (range, 7 – 116) months.

Implant

The HINTEGRA® prosthesis (Newdeal SA, Lyon, France) was designed in 2000. It is a nonconstrained three-component system consisting of a tibial component, a talar component, and an ultra-high

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molecular weight polyethylene mobile bearing. Design changes have been made over three generations [16,17].

The tibial component is anatomically shaped and has a 4mm thick flat loading plate with six pyramidal peaks and an anterior shield that accommodates fixation with two screws through an oval hole. Anterior peaks are 6 mm in height, and the posterior peaks are 3 mm in height. The flat surface allows optimal contact with the subchondral bone of the entire resected area, including the cortical rim of the tibial metaphysis. This maximizes the load transfer area while limiting stress-shielding.

The talar component is conical like the native talus [18,19] and has a smaller radius of curvature on the medial side. It has a 2.5mm high rim on both sides to provide mediolateral stability to the polyethylene bearing and to serve as a guide for anteroposterior translation. The anterior shield, which is for the introduction of two screws, may increase support on the talar neck and increase the intrinsic stability in the sagittal plane while preventing adherence of scar tissue that may restrict range of motion. The talar and the tibial component are available in six sizes.

The ultra-high molecular weight polyethylene mobile bearing has a flat surface on the tibial side and a concave conical surface on the talar side. It has a minimum thickness of 5 mm and is also available in thicknesses of 6, 7, and 9 mm. There are six sizes, corresponding to the six possible talar components. The position and movement of the mobile bearing is restrained by the compressive action of the collateral ligaments and adjacent soft tissues. Therefore, when the bearing is properly positioned, dislocation is rare [20].

Surgical technique

Operations were performed through a 10 to 12 cm longitudinal anterior incision between the tibialis anterior and the extensor hallucis longus tendons. After removing capsular synovial tissue and osteophytes, the anterior rim of the distal tibia was resected to allow direct visualisation of the articular surface of the distal tibia. Tibial cutting was performed first using an extramedullary cutting block so as to spare as much subchondral bone as possible. The hindfoot was then corrected to neutral with the ankle held in a neutral position and the talus pressed against the tibial plane. The talar cut was made parallel to the tibial cut, and the spacer was then inserted into the joint space created to check hindfoot alignment and ligamentous stability of the ankle. An appropriate size for the talar component was determined, and then the medial and lateral cuts were done followed by the posterior cut. After trial components had been inserted, alignment, stability, and joint motion were checked clinically, and component position was checked fluoroscopically. The selected implants were then inserted. Two screws were used to fix the tibial component and the talar screws were optional because of the congruent shape of the talar component and the two fixation pegs. If the bone quality was poor, talar fixation screws were an option. Additionally, in patients with less than 5 degrees of dorsiflexion, percutaneous Achilles tendon lengthening was carried out to achieve at least 10 degrees of dorsiflexion. Finally, the wound was closed over one suction drain and covered with a compressive dressing.

After surgery, a well-padded short leg splint was used to keep the foot in a neutral position and to protect the ankle against plantarflexion movement for 6 weeks postoperatively, with non-weightbearing. Full weightbearing ambulation and a foot and ankle rehabilitation program, which included stretching of the triceps surae, intensive walking exercises and training regarding ankle motion and balance, were then started after 6 weeks.

Clinical evaluation

Clinical outcomes were evaluated by an independent orthopaedic surgeon using the American Orthopaedic Foot and Ankle Society (AOFAS) ankle-hindfoot scale [21]. Allocated scores are described as follows: above 90 points as 'excellent', 89 to 80 points as 'good', 79 to 70 points as 'fair', and 69 points or less as 'poor'. Ranges of ankle motion (ROM) were determined clinically using a goniometer along the lateral border of the leg and foot.

Radiographic evaluation

Radiographic examinations included anteroposterior and lateral radiographs of ankles taken preoperatively, immediately postoperatively, at 3 and 6 months postoperatively, and annually thereafter. Radiographic findings were reviewed by a single observer.

Loosening of the tibial component was defined as a change in position of the flat base of the component in relation to the long axis of the tibia of more than 2 degrees or a progressive radiolucency of more than 2 mm.

Statistical analysis

Descriptive statistics (arithmetic means, averages, and ranges) were calculated using standard formulas. The primary outcome was the implant survival. Kaplan-Meier survival analysis was performed with the following end points: revision by exchange or removal of the talar and/or tibial metallic component, or conversion to ankle fusion. The Student's t-test was used for statistical analysis, p values less than 0.05 were considered significant.

Results

Clinical results

The mean AOFAS score at final follow-up was 77 (range, 49–91). In terms of patient satisfaction a good or excellent result was achieved in 73% of TAA. Mean ankle ROM as determined clinically and fluoroscopically was 23,72 degrees (range, 12,0–47,5).

Radiographic results

Peri-prosthetic radiolucence was seen in six ankles (40,0%), six times in the tibia and one time in both, the talus and the tibia. From 15 ankle prosthesis loosening of the tibial component occurred in 4 ankles (26,6%) and of the talar component in 3 ankles (20,0 %), respectively. One patient with a post-traumatic osteoarthritis due to a talus fracture, suffered from an avascular necrosis of the talus.

Degenerative changes in the adjacent joints were detected in 8 ankles (53,3%). Six ankles had a subtalar joint arthritis (40,0%), one ankle (6,6%) had a subtalar joint arthritis combined with a talonavicular joint arthritis and one ankle (6,6%) developed a talar osteophyte. One patient underwent pan-arthrodesis of the hindfoot, because of an aseptic loosening of the prosthesis and adjacent joint degenerations.

Complications and implant survival

There occurred no perioperative complications. In total 6 patients required revisional surgery (37,5%). Three of them underwent a conversion to an ankle arthrodesis, two underwent a tibial component change and one patient underwent a change of the mobile bearing polyethylene inlay after 116 months. There was neither a deep infection, nor a complication that required below knee amputation.

Radiographically two patients had an aseptic loosening of the tibial

component, one patient suffered from an avascular necrosis of the talus and two patients had an aseptic loosening of both, the tibial and the talar component (Figure 1). Detailed description of complications during follow up is outlined in Table 1. The mean follow up period until revisional surgery was 50,6 months and ranged from 24 to 116 months. Implant survival in revised ankles was 37,6 months (range, 24 – 61). Overall implant survival in all followed ankles was 66,7%. (Figure 2).

Discussion

Several recent studies on three-component TAA have reported encouraging intermediate-term clinical results, and have shown that TAA is a viable option for the treatment of ankle osteoarthritis.

Aim of this study was to evaluate the clinical and radiographical outcome and the implant survival of the first 16 patients treated with the HINTEGRA® (Newdeal SA, Lyon, France) prosthesis operated by a fellowship trained foot and ankle surgeon.

Our clinical results with a good or excellent patient satisfactory rate of 73% coincide with a good ROM of 23.7 degrees and a mean

post operative AOFAS score of 77 points. One patient died during follow up (mean, 61.8 ; range, 7–116 months), therefore we followed 15 HINTEGRA ankles. Six patients underwent revisional surgery (37,5%) and the study cohort reached a five year implant survival rate of 66,7% (Table 1).

A shortcoming of our study besides its retrospective design, is the small cohort of 15 followed prosthesis. Nevertheless we think that it is important to publish results from low volume centers. Most reports on the outcome after total ankle replacements are from so called high volume centers. Low volume could probably be a risk factor for suboptimal clinical results. Reuver et al. showed that functional results in low volume centers were comparable to most high volume centres but implant survival was lower.²² This data corresponds well with our findings. Furthermore, the so called high volume centres are often closely involved in the development of the prosthesis used [10,11,13,14,16,17].

Several authors investigated short to midterm outcomes of the HINTEGRA® TAA. Their results revealed short term survival rates



Figure 1: 59 year old patient with an aseptic loosening of the tibial and talar component 41 months after TAA. After the explantation of the ankle prosthesis an arthrodesis with an iliac crest bone autograft was performed.

Patient	Age at Time of Taa (years)	Sex	Origin Of Oa	Radiographic Appearance	Revision	Fu until Revision (months)	Implant Survival (months)
G.J.	73	m	post traumatic OA	aseptic necrosis of the talus + loosening talar component	ankle arthrodesis	36	36
K.B.	55	f	OA secondary to infection	aseptic loosening of both components	ankle arthrodesis	41	41
K.M.	45	f	OA secondary to infection	aseptic loosening of both components + adjacent joint degeneration	Pan arthrodesis ankle and hindfoot	61	61
F.R.	59	m	OA secondary to infection	aseptic loosening tibial component	change of tibial component	24	24
F.J.	58	m	primary OA	aseptic loosening tibial component	change of tibial component	25	25
L.B.	47	f	post traumatic OA	polyethylen wear debris	change of mobile bearing inlay	116	
total revisions: 6	mean age: 56,1	f:m = 3:3	post-traumatic:secondary to infection:primary = 2:3:1	component loosening tibia:talus = 4:3	ankle arthrodesis: revision = 3:3	mean FU until revision: 50,6	implant survival revision: 37,6

Table 1: This table shows detailed information about revisional surgery which was performed during follow up.

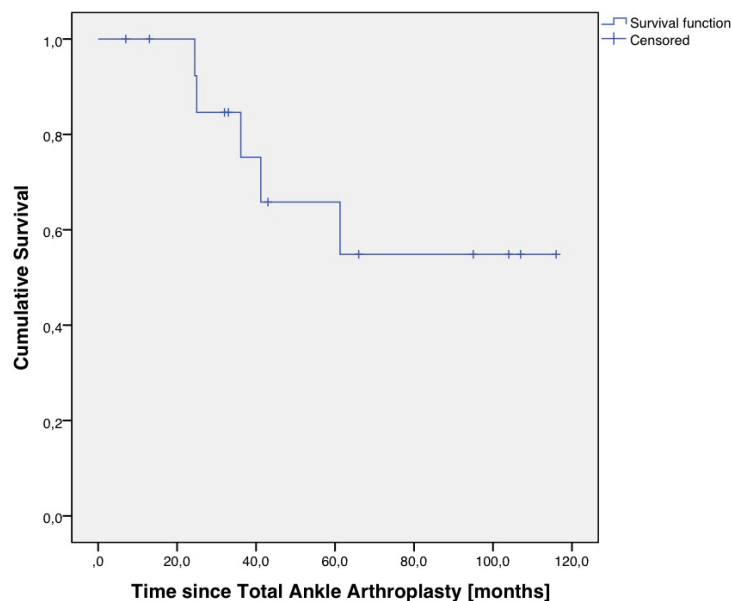


Figure 2: Kaplan-Meier survival curve, with revision (conversion to arthrodesis or tibial/talar implant exchange) as the end point, demonstrating the estimated overall implant survival.

Study	Year of publication	Mean Follow up (months)	Mean Age (years)	Number of Ankles	Number of Patients	AOFAS Score Post-op	Survival Rate Short Term	Survival Rate 5 years	Survival Rate 10 years
Hintermann et al.	2004	19	56	125	119	85	94%		
Hintermann et al.	2006	36	58	271	261	85	94%		
Valderrabano et al.	2006	34	60	152	147	84	94%		
Bai et al.	2010	38	56	67	65	86	97%		
Choi et al.	2013	53	63	32	32	82	87,5%		
Barg et al.	2013	76	61	722	684			94%	84%
Present study	2013	62	55	15	16	77		67%	

Table 2: This table lists published outcome and implant survival data concerning the HINTEGRA® total ankle arthroplasty.

ranging from 87,5% to 97%. Barg et al. reported a five year survival of 94% and a 10 year survival of 84% of implanted HINTERGA® TAAs [17].

A detailed description of HINTEGRA® survival outcomes are shown in Table 2.

In a systematic review, including thirteen Level-IV peer-reviewed studies with 1105 total ankle replacements, the overall survival rate at five years was approximately 90%, with a wide range between 68% and 100%. The authors reported that functional outcome improved in all studies. They included all modern mobile-bearing and fixed-bearing prostheses in their analysis. The superiority of one design over another was not supported by the data [4]. Another systematic review from Haddad et al. reported on studies between 1990 and 2005 using second generation prosthesis and found survival rates of 78% and 77% after five and ten years, respectively [3].

A systematic review of all three-component meniscal-bearing TAAs from Stengel et al. reported that the weighted five-year survival rate was about 90.6%. Most of the results were for one particular design (Scandinavian Total Ankle Replacement, Waldemar Link, Hamburg, Germany), and the authors did not identify differences in performance when comparing this design with the others that were considered [23].

A recent attempt to perform meta-analysis revealed that there exists no Level I study assessing the outcome of TAA. Outcomes might be related to the type of implant or surgical technique, although a lack of sufficient papers relating to certain TAAs made meta-analysis by type of implant impossible [24].

Choi et al. compared outcomes directly between two different TAAs performed by a single surgeon. Their rate of failure in the HINTEGRA® group was 12.5%, at a mean follow-up of 53 months [25] (Table 2).

Kim et al. evaluated the clinical outcome of the HINTEGRA® prosthesis performed in ankles with pre-operative varus alignment $\geq 10^\circ$ and came to the result, that TAA in varus ankles is comparable with that of neutrally aligned ankles when appropriate additional procedures to correct the deformity are carried out simultaneously with TAA. With one case of failure in both the varus and neutral groups, at a mean follow-up of 27 months (range, 12 to 47) the failure rates were 4.3% and 4.5%, respectively [26].

Publications by some research groups, particularly by implant inventors, show a deviation from the outcome published by other users and those shown in registry data. Labek et al. compared the outcome of specific implants in total ankle arthroplasty as reported in clinical studies and determined by national registries. He found that the

revision rates published in sample-based clinical studies were about half the value found in registries [27].

Total ankle replacement is a technically challenging procedure with a steep learning curve [28-31] Lee et al. reported on their 50 initial HINTEGRA® TAAs and compared the perioperative complications from the first 25 cases with the subsequent 25 cases. The rate of complications decreased by a factor of three and the proportion of secondary procedures by 38% [28]. In our series there occurred no malleolar fracture, nerve or tendon injuries or deep infections.

In conclusion, our study demonstrated that the functional results of the HINTEGRA® ankle were comparable to most high volume centers but survival was lower. More long-term results from non-implant developers will be needed to determine whether an implant survival rate of 84% [17] is reachable. Former studies regarding the first TAAs implanted by a foot and ankle surgeon mainly focused on perioperative complications. To the best of our knowledge this study is by now the only which evaluated the intermediate term outcome of the first HINTEGRA® ankles implanted by a single surgeon. With regards to the steep learning curve of total ankle arthroplasty these results seem compatible.

References

1. Valderrabano V, Horisberger M, Russell I, Dougall H, Hintermann B (2009) Etiology of ankle osteoarthritis. *Clin Orthop Relat Res* 467: 1800-1806.
2. Buckwalter JA, Saltzman C, Brown T (2004) The impact of osteoarthritis: implications for research. *Clin Orthop Relat Res* : S6-15.
3. Haddad SL, Coetzee JC, Estok R, Fahrback K, Banel D, et al. (2007) Intermediate and long-term outcomes of total ankle arthroplasty and ankle arthrodesis. A systematic review of the literature. *J Bone Joint Surg Am* 89: 1899-1905.
4. Gougoulias N, Khanna A, Maffulli N (2010) How successful are current ankle replacements?: a systematic review of the literature. *Clin Orthop Relat Res* 468: 199-208.
5. Pyevich MT, Saltzman CL, Callaghan JJ, Alvine FG (1998) Total ankle arthroplasty: a unique design. Two to twelve-year follow-up. *J Bone Joint Surg Am* 80: 1410-1420.
6. Kofoed H, Sørensen TS (1998) Ankle arthroplasty for rheumatoid arthritis and osteoarthritis: prospective long-term study of cemented replacements. *J Bone Joint Surg Br* 80: 328-332.
7. Deorio JK, Easley ME (2008) Total ankle arthroplasty. *Instr Course Lect* 57: 383-413.
8. Guyer AJ, Richardson G (2008) Current concepts review: total ankle arthroplasty. *Foot Ankle Int* 29: 256-264.
9. Anderson T, Montgomery F, Carlsson A (2003) Uncemented STAR total ankle prostheses. Three to eight-year follow-up of fifty-one consecutive ankles. *J Bone Joint Surg Am* 85-85A: 1321-9.
10. Bonnin M, Judet T, Colombier JA, Buscayret F, Graveleau N, et al. (2004) Midterm results of the Salto Total Ankle Prosthesis. *Clin Orthop Relat Res* : 6-18.
11. Buechel FF Sr, Buechel FF Jr, Pappas MJ (2004) Twenty-year evaluation of cementless mobile-bearing total ankle replacements. *Clin Orthop Relat Res* : 19-26.
12. Doets HC, Brand R, Nelissen RG (2006) Total ankle arthroplasty in inflammatory joint disease with use of two mobile-bearing designs. *J Bone Joint Surg Am* 88: 1272-1284.
13. Knecht SI, Estin M, Callaghan JJ, Zimmerman MB, Alliman KJ, et al. (2004) The Agility total ankle arthroplasty. Seven to sixteen-year follow-up. *J Bone Joint Surg Am* 86-86A: 1161-71.
14. Kofoed H (2004) Scandinavian Total Ankle Replacement (STAR). *Clin Orthop Relat Res* : 73-79.
15. Wood PL, Deakin S (2003) Total ankle replacement. The results in 200 ankles. *J Bone Joint Surg Br* 85: 334-341.
16. Hintermann B, Valderrabano V, Dereymaeker G, Dick W (2004) The HINTEGRA ankle: rationale and short-term results of 122 consecutive ankles. *Clin Orthop Relat Res* : 57-68.
17. Barg A, Zwicky L, Knupp M, Henninger HB, Hintermann B (2013) HINTEGRA total ankle replacement: survivorship analysis in 684 patients. *J Bone Joint Surg Am* 95: 1175-1183.
18. Hayes A, Tochigi Y, Saltzman CL (2006) Ankle morphometry on 3D-CT images. *Iowa Orthop J* 26: 1-4.
19. Inman VT. *The joints of the ankle*. Baltimore: Williams & Wilkins; 1976.
20. Barg A, Elsner A, Chuckpaiwong B, Hintermann B (2010) Insert position in three-component total ankle replacement. *Foot Ankle Int* 31: 754-759.
21. Kitaoka HB, Alexander IJ, Adelaar RS, Nunley JA, Myerson MS, et al. (1994) Clinical rating systems for the ankle-hindfoot, midfoot, hallux, and lesser toes. *Foot Ankle Int* 15: 349-353.
22. Reuver JM, Dayerzadeh N, Burger B, Elmans L, Hoelen M, et al. (2010) Total ankle replacement outcome in low volume centers: short-term followup. *Foot Ankle Int* 31: 1064-1068.
23. Stengel D, Bauwens K, Ekkernkamp A, Cramer J (2005) Efficacy of total ankle replacement with meniscal-bearing devices: a systematic review and meta-analysis. *Arch Orthop Trauma Surg* 125: 109-119.
24. Zaidi R, Cro S, Gurusamy K, Siva N, Macgregor A, et al. (2013) The outcome of total ankle replacement: a systematic review and meta-analysis. *Bone Joint J* 95-95B: 1500-7.
25. Choi GW, Kim HJ, Yeo ED, Song SY (2013) Comparison of the HINTEGRA and Mobility total ankle replacements. Short- to intermediate-term outcomes. *Bone Joint J* 95-95B: 1075-82.
26. Kim BS, Choi WJ, Kim YS, Lee JW (2009) Total ankle replacement in moderate to severe varus deformity of the ankle. *J Bone Joint Surg Br* 91: 1183-1190.
27. Labek G, Klaus H, Schlichtherle R, Williams A, Agreiter M (2011) Revision rates after total ankle arthroplasty in sample-based clinical studies and national registries. *Foot Ankle Int* 32: 740-745.
28. Lee KB, Cho SG, Hur CI, Yoon TR (2008) Perioperative complications of HINTEGRA total ankle replacement: our initial 50 cases. *Foot Ankle Int* 29: 978-984.
29. Myerson MS, Mroczek K (2003) Perioperative complications of total ankle arthroplasty. *Foot Ankle Int* 24: 17-21.
30. Saltzman CL, Amendola A, Anderson R, Coetzee JC, Gall RJ, et al. (2003) Surgeon training and complications in total ankle arthroplasty. *Foot Ankle Int* 24: 514-518.
31. Clement RC, Krynetskiy E, Parekh SG (2013) The total ankle arthroplasty learning curve with third-generation implants: a single surgeon's experience. *Foot Ankle Spec* 6: 263-270.