

TABLE E-1 Clinical Outcome in Patients Who Underwent Total Ankle Replacement with Use of the HINTEGRA Prosthesis*

Study	Type	Number of Ankles	Follow-up (Years)	Functional Outcome	Revisions	Specific Comments
Álvarez-Goenaga ²¹	RS, SC	25	2.5	AOFAS score = 80; ROM = 26°	2 (aseptic loosening)	NA
Bai et al. ²²	RS, SC	67	3.2	AOFAS score = 87 (range, 70 to 100), ROM = 37° (range, 10° to 60°)	1 (deep infection)	The clinical and radiographic outcomes for posttraumatic and primary osteoarthritis were comparable
Besse et al. ²³	RS, MC	22	3.1	AOFAS score = 82 (range, 43 to 98), ROM = 33° (range, 0° to 75°)	NA	Multicenter French study with 892 ankles
Daniels et al. ²⁵	RS, SC	26	1.4	Satisfactory radiographic results in 94%	NA	All patients had preoperative varus deformity of >15°
Diel et al. ²⁶	PS, MC	55	1.0	AOFAS score = 76 (range, 42 to 93)	2 (aseptic loosening)	NA
Fevang et al. ³⁰	PS, MC	6	up to 10	NA	NA	Norwegian Arthroplasty Register with 257 ankles
Frigg et al. ²⁷	RS, SC	28	4.1	AOFAS score = 73	NA	Inframalleolar alignment, as assessed by hindfoot alignment view, influenced clinical outcome
Henricson et al. ³¹	PS, MC	29	up to 5	NA	2 (aseptic loosening), 1 (technical error), and 1 (instability)	Swedish Ankle Register with 531 ankles
Henricson et al. ³³	PS, MC	36	up to 10	NA	3 (aseptic loosening), 2 (technical error), 1 (instability), 1 (infection), and 1 (painful varus)	Swedish Ankle Register with 780 ankles
Kim et al. ¹⁹	RS, SC	45	2.3	VAS = 3.1, AOFAS score = 79.5, ROM = 39.8°	1 (aseptic loosening) and 1 (deep infection)	23 of 45 ankles had a varus deformity of ≥10°, clinical outcome in those ankles was comparable with that of neutrally aligned ankles

*RS = retrospective; SC = single center; MC = multicenter; PS = prospective; AOFAS = American Orthopaedic Foot & Ankle Society hindfoot score; ROM = range of motion; VAS = visual analog scale, and NA = information not applicable or not given.

TABLE E-2 Design Rationale for Three Generations of the HINTEGRA Prosthesis

Design Rationale	1st Generation	2nd Generation	3rd Generation
In use	May 2000-April 2001	May 2001-May 2003	Since June 2003
Talar component			
Shape	Anatomic, conical	Anatomic, conical	Anatomic, conical
Rim	2.5 mm	2.5 mm	2.5 mm
Wings			
Lateral	Yes	Yes	Yes
Medial	Yes	Yes	Yes
Pegs	No	No	Yes
Available sizes	1 to 5	1 to 5	1 to 6
Tibial component			
Shape	Anatomic, trapezoid	Anatomic, trapezoid	Anatomic, trapezoid
Peaks			
Number	6: 3 anterior, 3 posterior	6: 3 anterior, 3 posterior	6: 3 anterior, 3 posterior
Height	2/4 mm	2/4 mm	3/6 mm
Form	Flat	Flat	Sharp
Shield	Yes	Yes	Yes
Medial coating	No	No	Yes
Available sizes	1 to 5	1 to 5	1 to 6
Polyethylene inlay			
High density	Yes	Yes	Yes
Available sizes	1 to 5	1 to 5	1 to 6
Available thicknesses	5, 7, and 9 mm	5, 7, and 9 mm	5, 6, 7, and 9 mm
Coating			
Hydroxyapatite	Yes	Yes	Yes
Porous coating (200 μ m)	No	Cobalt-chromium	Titanium
Screw fixation	Yes	Yes	No (optional)

TABLE E-3 Procedures Performed in Addition to Primary Total Ankle Replacement					
Additional Procedures	All Ankles	1st Generation	2nd Generation	3rd Generation	P Value*
Osteotomies	104 (14.4%)	6 (14.6%)	18 (15.4%)	80 (14.2%)	0.944
Supramalleolar osteotomy	21 (2.9%)	0 (0.0%)	1 (0.9%)	20 (3.5%)	0.150
Calcaneal osteotomy†	46 (6.4%)	4 (9.8%)	7 (6.0%)	35 (6.2%)	0.656
Fibular osteotomy	17 (2.4%)	0 (0.0%)	3 (2.6%)	14 (2.5%)	0.591
Medial malleolus osteotomy	25 (3.5%)	1 (2.4%)	5 (4.3%)	19 (3.4%)	0.830
Medial cuneiform osteotomy	7 (1.0%)	0 (0.0%)	3 (2.6%)	4 (0.7%)	0.142
Dorsiflexion first metatarsal osteotomy	20 (2.8%)	1 (2.4%)	3 (2.6%)	16 (2.8%)	0.978
Arthrodeses	104 (14.4%)	5 (12.2%)	13 (11.1%)	86 (15.2%)	0.694
Double-hindfoot arthrodesis‡	42 (5.8%)	2 (4.9%)	5 (4.3%)	35 (6.2%)	0.694
Subtalar arthrodesis	42 (5.8%)	2 (4.9%)	5 (4.3%)	35 (6.2%)	0.694
Talonavicular arthrodesis	20 (2.8%)	1 (2.4%)	3 (2.6%)	16 (2.8%)	0.978
Ligament and/or tendon procedures	228 (31.6%)	14 (34.1%)	26 (22.2%)	188 (33.3%)	0.059
Collateral ligament reconstruction§	97 (13.4%)	10 (24.4%)	5 (4.3%)	82 (14.5%)	0.001
Peroneus longus transfer	34 (4.7%)	5 (12.2%)	0 (0.0%)	29 (5.1%)	0.004
Posterior tibial tendon reconstruction	24 (3.3%)	0 (0.0%)	2 (1.7%)	22 (3.9%)	0.230
Tendo-Achilles lengthening	125 (17.3%)	4 (9.8%)	20 (17.1%)	101 (17.9%)	0.411

*With use of chi-square test. †Including medial displacement calcaneal osteotomy, Dwyer calcaneal osteotomy, and z-shaped calcaneal osteotomy. ‡Double-hindfoot arthrodesis = subtalar and talonavicular arthrodesis. §Including lateral and/or medial ligament augmentation.

TABLE E-4 Survival Data for 722 Consecutive Ankles				
Interval (yr)	Number of Ankles Entering the Interval	Number of Events	Cumulative Proportion Surviving at the End of the Interval	95% Confidence Interval
0 to 1	722	6	0.99	0.99 to 0.99
1 to 2	716	13	0.97	0.96 to 0.98
2 to 3	697	6	0.96	0.95 to 0.97
3 to 4	595	6	0.95	0.94 to 0.96
4 to 5	501	7	0.94	0.93 to 0.95
5 to 6	392	5	0.93	0.92 to 0.94
6 to 7	307	6	0.91	0.90 to 0.92
7 to 8	252	6	0.88	0.80 to 0.90
8 to 9	188	3	0.87	0.85 to 0.89
9 to 10	123	3	0.84	0.82 to 0.86
10 to 11	62	0	0.84	0.82 to 0.86
11 to 12	33	0	0.84	0.82 to 0.86

TABLE E-5 Survival Data for Three Generations of the HINTEGRA Prosthesis*

Interval (yr)	Number of Ankles Entering the Interval			Number of Events			Cumulative Proportion Surviving at the End of the Interval		
	1st Gen	2nd Gen	3rd Gen	1st Gen	2nd Gen	3rd Gen	1st Gen	2nd Gen	3rd Gen
0 to 1	41	117	564	1	1	4	0.98	0.99	0.99
1 to 2	40	116	560	5	2	6	0.85	0.97	0.98
2 to 3	35	114	548	3	1	2	0.78	0.97	0.98
3 to 4	32	113	450	2	2	2	0.73	0.95	0.97
4 to 5	30	111	360	0	3	4	0.73	0.92	0.96
5 to 6	30	108	254	0	3	2	0.73	0.90	0.95
6 to 7	30	105	172	2	4	0	0.68	0.86	0.95
7 to 8	28	101	123	2	2	2	0.63	0.85	0.93
8 to 9	26	99	63	1	1	1	0.61	0.84	0.90
9 to 10	25	94	4	0	3	0	0.61	0.80	0.90
10 to 11	25	37	NA	0	0	NA	0.61	0.80	NA
11 to 12	25	8	NA	0	0	NA	0.61	0.80	NA

*NA = information not available.

TABLE E-6 Survival Data Based on Underlying Ankle Osteoarthritis Etiology*

Interval (yr)	No. Entering the Interval			No. of Events			Cumulative Proportion Surviving at the End of the Interval		
	Prim.	Postt.	Sec.	Prim.	Postt.	Sec.	Prim.	Postt.	Sec.
0 to 1	69	571	82	0	5	1	1.00	0.99	0.99
1 to 2	69	566	81	0	13	0	1.00	0.97	0.99
2 to 3	68	548	81	0	6	0	1.00	0.96	0.99
3 to 4	60	466	69	0	6	0	1.00	0.94	0.99
4 to 5	47	395	59	3	4	0	0.93	0.93	0.99
5 to 6	33	307	52	0	5	0	0.93	0.92	0.99
6 to 7	28	236	43	2	4	0	0.86	0.90	0.99
7 to 8	24	191	37	2	4	0	0.78	0.88	0.99
8 to 9	16	138	34	0	3	0	0.78	0.85	0.99
9 to 10	13	84	26	1	1	1	0.71	0.84	0.94
10 to 11	8	38	16	0	0	0	0.71	0.84	0.94
11 to 12	7	17	9	0	0	0	0.71	0.84	0.94

*Prim. = primary ankle osteoarthritis, Postt. = posttraumatic ankle osteoarthritis, and Sec. = secondary ankle osteoarthritis.

TABLE E-7 Univariate Analysis of Risk Factors*

Parameter	Ankles Needing Revision (%)	Ankles with No Revision (%)	OR (95% CI)	P Value
Sex				
Male (387 ankles)	29 (7.5%)	358 (92.5%)	1.30 (0.77 to 2.21)	0.322
Age				
≤30 years (14 ankles)	1 (7.1%)	13 (92.9%)	0.83 (0.11 to 6.46)	0.831
≤40 years (47 ankles)	3 (6.4%)	44 (93.6%)	0.73 (0.22 to 2.41)	0.725
≤50 years (139 ankles)	9 (6.5%)	130 (93.5%)	0.71 (0.34 to 1.47)	0.354
≤70 years (178 ankles)	5 (2.8%)	173 (97.2%)	0.25 (0.10 to 0.64)	0.004
Weight				
≥90 kg (169 ankles)	12 (7.1%)	157 (92.9%)	0.79 (0.41 to 1.52)	0.472
≥100 kg (58 ankles)	2 (3.4%)	56 (96.6%)	0.37 (0.09 to 1.54)	0.170
Body mass index				
≥25 kg/m ² (468 ankles)	40 (8.5%)	428 (91.5%)	1.04 (0.60 to 1.80)	0.897
≥30 kg/m ² (158 ankles)	10 (6.3%)	148 (93.7%)	0.68 (0.34 to 1.37)	0.281
Cause of ankle osteoarthritis				
Primary (69 ankles)	8 (11.6%)	61 (88.4%)	5.25 (1.08 to 25.59)	0.040
Posttraumatic (571 ankles)	51 (8.9%)	520 (91.1%)	3.92 (1.04 to 16.43)	0.045
Secondary (82 ankles)	2 (2.4%)	80 (97.6%)	0.25 (0.06 to 1.03)	0.054
Prosthesis generation				
1st (41 ankles)	16 (39.0%)	25 (61.0%)	9.05 (4.51 to 18.15)	0.001
2nd (117 ankles)	22 (18.8%)	95 (81.2%)	3.36 (1.91 to 5.92)	<0.001
3rd (564 ankles)	23 (4.1%)	541 (95.9%)	0.13 (0.08 to 0.23)	<0.001
Additional surgical procedures				
Arthrodeses (104 ankles)	7 (6.7%)	97 (93.3%)	0.75 (0.33 to 1.71)	0.497
Osteotomies (104 ankles)	4 (3.8%)	100 (96.2%)	0.39 (0.14 to 1.11)	0.078
Learning curve				
≤25 arthroplasties (113 ankles)	17 (15.0%)	96 (85.0%)	2.15 (0.65 to 7.08)	0.209
≤50 arthroplasties (163 ankles)	26 (16.0%)	137 (84.0%)	1.68 (0.56 to 5.02)	0.351
Senior resident (63 ankles)	4 (6.3%)	59 (93.7%)	0.30 (0.07 to 1.27)	0.102
*Odds ratio (OR) are expressed with 95% confidence intervals (CI) for prosthesis failure: revision meant exchange or removal of the talar and/or tibial components or conversion to ankle fusion.				