Hintermann Series H3/Hintermann Series H3 Total Ankle Investigation

Note: This analysis compares the Hintermann Series H3/Hintermann Series H3 talar/tibial tray combination with all other total ankle prostheses.

This combination has been identified as having a significantly higher rate of revision. For a detailed explanation of the process used by the Registry that results in identification of prostheses that have a higher than anticipated rate of revision please refer to the Prostheses with Higher than Anticipated Rates of Revision chapter of the most recent AOANJRR Annual Report, https://aoanjrr.sahmri.com/annual-reports-2024.

Note: Procedures using prostheses with no recorded use in 2023 are excluded from the comparator.

TABLE 1

Revision Rate of Primary Total Ankle Replacement

The revision rate of the Hintermann Series H3/Hintermann Series H3 total ankle combination is compared to all other total ankle prostheses.

Table 1: Revision Rates of Primary Total Ankle Replacement

Component	N Revised	N Total	Obs. Years	Revisions/100 Obs. Yrs (95% CI)
Hintermann Series H3/Hintermann Series H3	99	558	4352	2.28 (1.85, 2.77)
Other Total Ankle	285	4055	20640	1.38 (1.23, 1.55)
TOTAL	**384**	**4613**	**24991**	**1.54 (1.39, 1.70)**

Note: Prostheses no longer used in 2023 are excluded from the comparator.

TABLE 2

Yearly Cumulative Percent Revision of Primary Total Ankle Replacement

The yearly cumulative percent revision of the Hintermann Series H3/Hintermann Series H3 total ankle combination is compared to all other total ankle prostheses.

Table 2: Yearly Cumulative Percent Revision of Primary Total Ankle Replacement

CPR	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs
Hintermann Series H3/Hintermann Series H3	4.0 (2.7, 6.0)	5.9 (4.2, 8.3)	8.4 (6.3, 11.1)	10.1 (7.8, 13.0)	11.4 (9.0, 14.6)	13.1 (10.4, 16.5)
Other Total Ankle	1.6 (1.3, 2.1)	3.5 (2.9, 4.2)	4.9 (4.2, 5.7)	6.0 (5.2, 6.9)	7.3 (6.4, 8.4)	8.1 (7.0, 9.2)

CPR	7 Yrs	8 Yrs	9 Yrs	10 Yrs	11 Yrs	12 Yrs
Hintermann Series H3/Hintermann Series H3	15.9 (12.9, 19.6)	17.9 (14.6, 21.8)	19.7 (16.2, 23.8)	20.4 (16.9, 24.6)	22.1 (18.3, 26.5)	22.6 (18.7, 27.1)
Other Total Ankle	8.8 (7.7, 10.0)	10.0 (8.8, 11.4)	11.6 (10.2, 13.2)	12.7 (11.2, 14.5)	13.5 (11.9, 15.3)	14.5 (12.7, 16.4)

CPR	13 Yrs	14 Yrs	15 Yrs	16 Yrs	17 Yrs
Hintermann Series H3/Hintermann Series H3	24.1 (19.8, 29.0)	25.4 (20.6, 31.1)			
Other Total Ankle	15.1 (13.2, 17.2)	15.7 (13.7, 18.1)	15.7 (13.7, 18.1)		

Note: Prostheses no longer used in 2023 are excluded from the comparator.

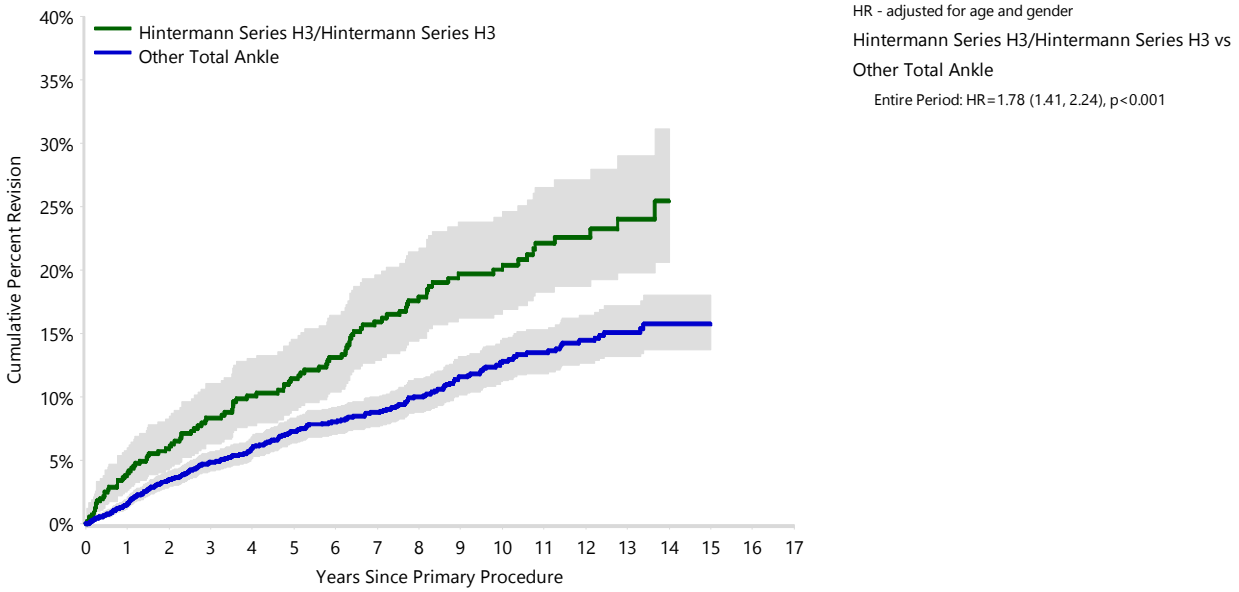
FIGURE 1

Yearly Cumulative Percent Revision of Primary Total Ankle Replacement

The yearly cumulative percent revision of the Hintermann Series H3/Hintermann Series H3 total ankle combination is compared to all other total ankle prostheses. In addition, hazard ratios are reported.

Hazard ratios are reported for specific time periods during which the hazard ratio is constant. This is done to enable more specific and valid comparisons of the risk of revision over time. The pattern of variation in risk has important implications with respect to the underlying reasons for any difference.

Figure 1: Cumulative Percent Revision of Primary Total Ankle Replacement



Number at Risk	0 Yr	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs	7 Yrs	8 Yrs
Hintermann Series H3/Hintermann Series H3	558	512	477	441	406	383	350	310	289
Other Total Ankle	4055	3362	2801	2289	1897	1592	1369	1174	997

Number at Risk	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs	16 Yrs	17 Yrs
Hintermann Series H3/Hintermann Series H3	252	213	168	122	84	44	23	5	0
Other Total Ankle	848	724	587	458	299	186	97	26	5

Note: Prostheses no longer used in 2023 are excluded from the comparator.

TABLE 3

Primary Diagnosis for Revised Primary Total Ankle Replacement

This table identifies the diagnosis of the primary procedure which was subsequently revised. This information is provided as there is a variation on outcome depending on the primary diagnosis. It is therefore important when considering the reasons for a higher than anticipated rate of revision that there is identification of the primary diagnosis. This information should be compared to the primary diagnosis for the revisions of all other total ankle prostheses.

Table 3: Primary Diagnosis for Revised Primary Total Ankle Replacement

	Hintermann Series H3/Hintermann Series H3		Other Total Ankle	
Primary Diagnosis	Number	Percent	Number	Percent
Osteoarthritis	96	97.0	266	93.3
Rheumatoid Arthritis	3	3.0	12	4.2
Instability			3	1.1
Other Inflammatory Arthritis			2	0.7
Osteonecrosis			1	0.4
Other			1	0.4
TOTAL	**99**	**100.0**	**285**	**100.0**

Note: Prostheses no longer used in 2023 are excluded from the comparator.

TABLE 4

Reasons for Revision

This is reported in two ways: a percentage of primary procedures revised and as a percentage of all revision procedures.

% Primaries Revised: This shows the proportional contribution of each revision diagnosis as a percentage of the total number of primary procedures. This percentage can be used to approximate the risk of being revised for that diagnosis. Differing percentages between groups, with the same distribution of follow up time, may identify problems of concern.

% Revisions: The number of revisions for each diagnosis is expressed as a percentage of the total number of revisions. This shows the distribution of reasons for revision within a group but cannot be used as a comparison between groups.

Table 4: Primary Total Ankle Replacement - Reason for Revision

Revision Diagnosis	Hintermann Series H3/Hintermann Series H3			Other Total Ankle		
	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Loosening	24	4.3	24.2	99	2.4	34.7
Infection	10	1.8	10.1	42	1.0	14.7
Lysis	6	1.1	6.1	27	0.7	9.5
Instability	11	2.0	11.1	23	0.6	8.1
Implant Breakage Ankle Insert	17	3.0	17.2	18	0.4	6.3
Impingement	5	0.9	5.1	15	0.4	5.3
Pain	9	1.6	9.1	13	0.3	4.6
Fracture	4	0.7	4.0	12	0.3	4.2
Arthrofibrosis	1	0.2	1.0	6	0.1	2.1
Heterotopic Bone				5	0.1	1.8
Prosthesis Dissociation	5	0.9	5.1	4	0.1	1.4
Malalignment	3	0.5	3.0	4	0.1	1.4
Wear Ankle Insert	2	0.4	2.0	4	0.1	1.4
Implant Breakage Tibial				2	0.0	0.7
Incorrect Sizing				2	0.0	0.7
Synovitis	1	0.2	1.0	2	0.0	0.7
Metal Related Pathology	1	0.2	1.0			
Osteonecrosis				1	0.0	0.4
Progression Of Disease				1	0.0	0.4
Tumour				1	0.0	0.4
Other				4	0.1	1.4
N Revision	**99**	**17.7**	**100.0**	**285**	**7.0**	**100.0**
N Primary	**558**			**4055**		

Note: Prostheses no longer used in 2023 are excluded from the comparator.

FIGURE 2

Cumulative Incidence Revision Diagnosis of Primary Total Ankle Replacement

This figure details the cumulative incidence of the most common reasons for revision. The five most common reasons for revision are included as long as each of these reasons account for more than 10 procedures or at least 5% of all revisions for the Hintermann Series H3/Hintermann Series H3 total ankle combination. A comparative graph is provided of the cumulative incidence for the same reasons for revisions for all other total ankle prostheses.

Figure 2: Cumulative Incidence Revision Diagnosis for Primary Total Ankle Replacement

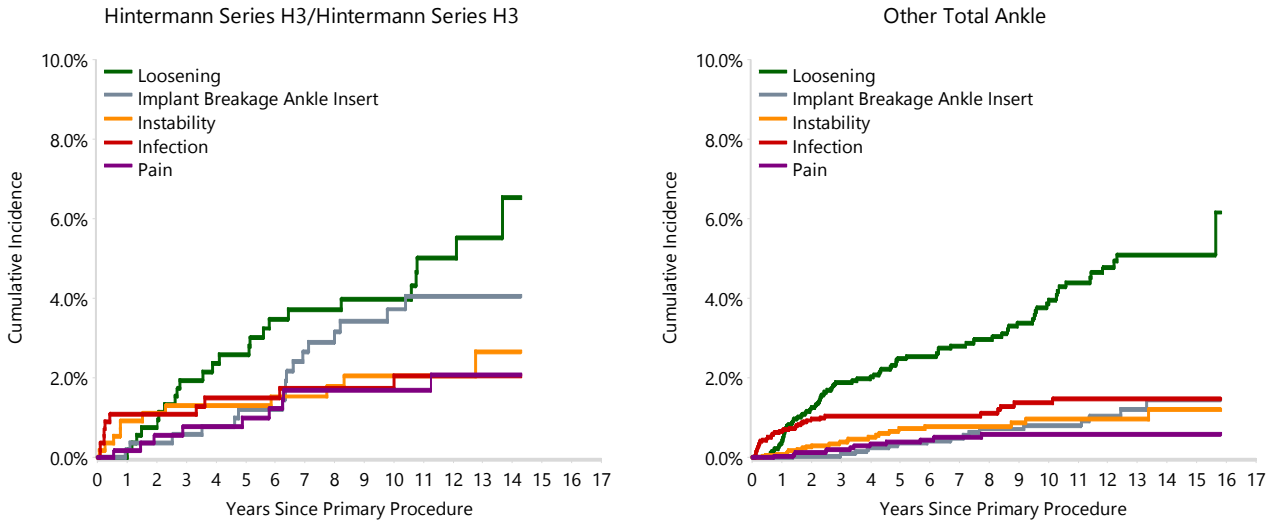


TABLE 5

Type of Revision Performed for Primary Total Ankle Replacement

This analysis identifies the components used in the revision of the Hintermann Series H3/Hintermann Series H3 total ankle combination and compares it to the components used in the revision of all other total ankle prostheses.

The reason this analysis is undertaken is to identify whether there is one or more components which are being replaced that differ from the components replaced for revisions of all other total ankle prostheses i.e. is there a difference in the type of revision undertaken for the Hintermann Series H3/Hintermann Series H3 total ankle combination compared to all other total ankle prostheses.

Table 5: Primary Total Ankle Replacement - Type of Revision

	Hintermann Series H3/Hintermann Series H3		Other Total Ankle	
Type of Revision	Number	Percent	Number	Percent
Tibial/Talar	18	18.2	52	18.2
Tibial Only	3	3.0	34	11.9
Talar Only	6	6.1	19	6.7
Cement Spacer	4	4.0	14	4.9
Removal of Prostheses	2	2.0	3	1.1
N Major	**33**	**33.3**	**122**	**42.8**
Insert Only	52	52.5	125	43.9
Arthrodesis	12	12.1	34	11.9
Minor Components	2	2.0	4	1.4
N Minor	**66**	**66.7**	**163**	**57.2**
TOTAL	**99**	**100.0**	**285**	**100.0**

Note: Prostheses no longer used in 2023 are excluded from the comparator.

TABLE 6

Revision Rates of Hintermann Series H3/Hintermann Series H3 Primary Total Ankle Replacement by Fixation

This analysis is provided as some prostheses have more than one fixation option. Additionally there are prostheses where an alternative to the recommended approach to fixation was used e.g. a cementless prosthesis that has been cemented or vice-versa.

Table 6: Revised Number of Hintermann Series H3/Hintermann Series H3 Primary Total Ankle Replacement by Fixation

Fixation	N Revised	N Total
Cementless	99	558
TOTAL	**99**	**558**

TABLE 7

Revision Rates of Primary Total Ankle Replacement by State

This enables a state by state variation to be identified for the Hintermann Series H3/Hintermann Series H3 total ankle combination and provides the comparative data for each of the states for all other total ankle prostheses.

The purpose of this analysis is to determine if the higher than anticipated rate of revision has widespread distribution between states. If there is widespread distribution then the reason for the higher than anticipated rate of revision is unlikely to be surgeon specific. If the prosthesis has been used in only a small number of states it is not possible to distinguish if the higher than anticipated rate of revision is related to the prosthesis, surgeon, technique or patient.

Table 7: Revised Number of Primary Total Ankle Replacement by State

Component	State	N Revised	N Total
Hintermann Series H3/Hintermann Series H3	NSW	41	247
	VIC	21	79
	QLD	0	63
	WA	15	67
	SA	5	14
	TAS	4	23
	ACT/NT	13	65
Other Total Ankle	NSW	62	1469
	VIC	113	1175
	QLD	14	320
	WA	64	491
	SA	25	371
	TAS	7	187
	ACT/NT	0	42
TOTAL		**384**	**4613**

Note: Prostheses no longer used in 2023 are excluded from the comparator.

TABLE 8

Number of Revisions of Hintermann Series H3/Hintermann Series H3 Primary Total Ankle Replacement by Year of Implant

This analysis details the number of prostheses reported each year to the Registry for the Hintermann Series H3/Hintermann Series H3 total ankle combination. It also provides the subsequent number of revisions of the primaries reported in that year.

Primary procedures performed in later years have had less follow up time therefore the number revised is expected to be less than the number revised in earlier years. For example, a primary procedure performed in 2023 has a maximum of one year to be revised, whereas a primary procedure performed in 2021 has a maximum of three years to be revised.

Table 8: Number of Revisions of Hintermann Series H3/Hintermann Series H3 Primary Total Ankle Replacement by Year of Implant

Year of Implant	Number Revised	Total Number
2007	1	6
2008	6	34
2009	11	45
2010	14	63
2011	13	56
2012	13	67
2013	8	48
2014	7	40
2015	9	34
2016	5	12
2017	2	25
2018	6	30
2019	1	13
2020	1	20
2021	2	24
2022	0	21
2023	0	20
TOTAL	**99**	**558**

TABLE 9

Revision Rates of Hintermann Series H3/Hintermann Series H3 Primary Total Ankle Replacement by Catalogue Number Range

Many prostheses have a number of catalogue ranges. The catalogue range is specific to particular design features; more than one catalogue range usually indicates a minor difference in design in a particular Hintermann Series H3/Hintermann Series H3 prosthesis.

This analysis has been undertaken to determine if the revision rate varies according to the catalogue number range.

Model	Catalogue Range	Catalogue Description	Cement	Material	Coating
Talar					
Hintermann Series H3	301110-302116	PRIMARY TALAR COMPONENT	NO	METAL	HA COATED
Hintermann Series H3	301121-302125	FLAT RESECTION TALAR COMPONENT	NO	METAL	HA COATED
Tibial Tray					
Hintermann Series H3	301200-302206	TIBIAL COMPONENT	NO	METAL	HA COATED

Table 9: Revised Number of Hintermann Series H3/Hintermann Series H3 Primary Total Ankle Replacement by Catalogue Number Range

Talar Range	Tibial Tray Range	N Revised	N Total
301110-302116	301200-302206	97	554
301121-302125	301200-302206	2	4
TOTAL		**99**	**558**