S.T.A.R/S.T.A.R Total Ankle Investigation

Note: This analysis compares the S.T.A.R/S.T.A.R 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-2022.

TABLE 1

Revision Rate of Primary Total Ankle Replacement

The revision rate of the S.T.A.R/S.T.A.R 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)
S.T.A.R/S.T.A.R	11	49	324	3.40 (1.70, 6.08)
Other Total Ankle	301	3399	18096	1.66 (1.48, 1.86)
TOTAL	**312**	**3448**	**18419**	**1.69 (1.51, 1.89)**

TABLE 2

Yearly Cumulative Percent Revision of Primary Total Ankle Replacement

The yearly cumulative percent revision of the S.T.A.R/S.T.A.R 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
S.T.A.R/S.T.A.R	4.1 (1.0, 15.5)	8.3 (3.2, 20.6)	12.6 (5.8, 25.8)	14.7 (7.3, 28.4)	14.7 (7.3, 28.4)
Other Total Ankle	2.2 (1.8, 2.8)	4.1 (3.4, 4.8)	5.8 (5.0, 6.7)	7.2 (6.3, 8.3)	8.8 (7.8, 10.1)

CPR	6 Yrs	7 Yrs	8 Yrs	9 Yrs	10 Yrs
S.T.A.R/S.T.A.R	17.1 (8.9, 31.4)	22.3 (12.6, 37.8)	22.3 (12.6, 37.8)		
Other Total Ankle	9.9 (8.7, 11.2)	10.9 (9.7, 12.4)	12.3 (10.9, 13.9)	14.0 (12.5, 15.8)	15.2 (13.6, 17.1)

CPR	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs
S.T.A.R/S.T.A.R					
Other Total Ankle	15.7 (13.9, 17.6)	16.1 (14.3, 18.1)	16.1 (14.3, 18.1)		

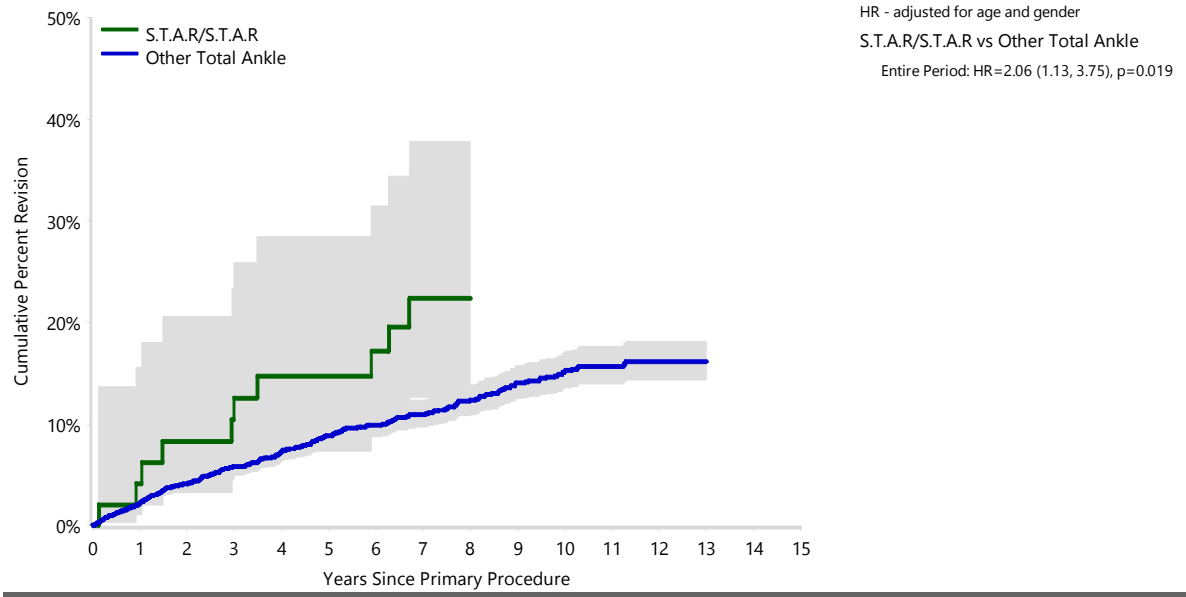
FIGURE 1

Yearly Cumulative Percent Revision of Primary Total Ankle Replacement

The yearly cumulative percent revision of the S.T.A.R/S.T.A.R 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
S.T.A.R/S.T.A.R	49	46	44	41	39	39	34	28
Other Total Ankle	3399	2826	2382	2049	1779	1543	1356	1179

Number at Risk	8 Yrs	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs
S.T.A.R/S.T.A.R	17	5	3	2	2	0	0	0
Other Total Ankle	1018	832	636	421	253	136	35	5

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

	S.T.A.R/S.T.A.R		Other Total Ankle	
Primary Diagnosis	Number	Percent	Number	Percent
Osteoarthritis	11	100.0	283	94.0
Rheumatoid Arthritis			14	4.7
Instability			3	1.0
Other Inflammatory Arthritis			1	0.3
TOTAL	**11**	**100.0**	**301**	**100.0**

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 (Follow-up Limited to 12.6 Years)

	S.T.A.R/S.T.A.R			Other Total Ankle		
Revision Diagnosis	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Loosening	3	6.1	27.3	85	2.5	28.3
Infection	1	2.0	9.1	39	1.1	13.0
Lysis				32	0.9	10.7
Instability	1	2.0	9.1	27	0.8	9.0
Implant Breakage Ankle Insert	4	8.2	36.4	23	0.7	7.7
Pain				21	0.6	7.0
Impingement				17	0.5	5.7
Fracture	1	2.0	9.1	14	0.4	4.7
Prosthesis Dissociation				8	0.2	2.7
Malalignment				6	0.2	2.0
Wear Ankle Insert				6	0.2	2.0
Arthrofibrosis				5	0.1	1.7
Heterotopic Bone				5	0.1	1.7
Implant Breakage Tibial				2	0.1	0.7
Incorrect Sizing				2	0.1	0.7
Synovitis	1	2.0	9.1	2	0.1	0.7
Metal Related Pathology				1	0.0	0.3
Osteonecrosis				1	0.0	0.3
Tumour				1	0.0	0.3
Other				3	0.1	1.0
N Revision	**11**	**22.4**	**100.0**	**300**	**8.8**	**100.0**
N Primary	**49**			**3399**		

Note: This table is restricted to revisions within 12.6 years for all groups to allow a time-matched comparison of revisions.

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 S.T.A.R/S.T.A.R 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

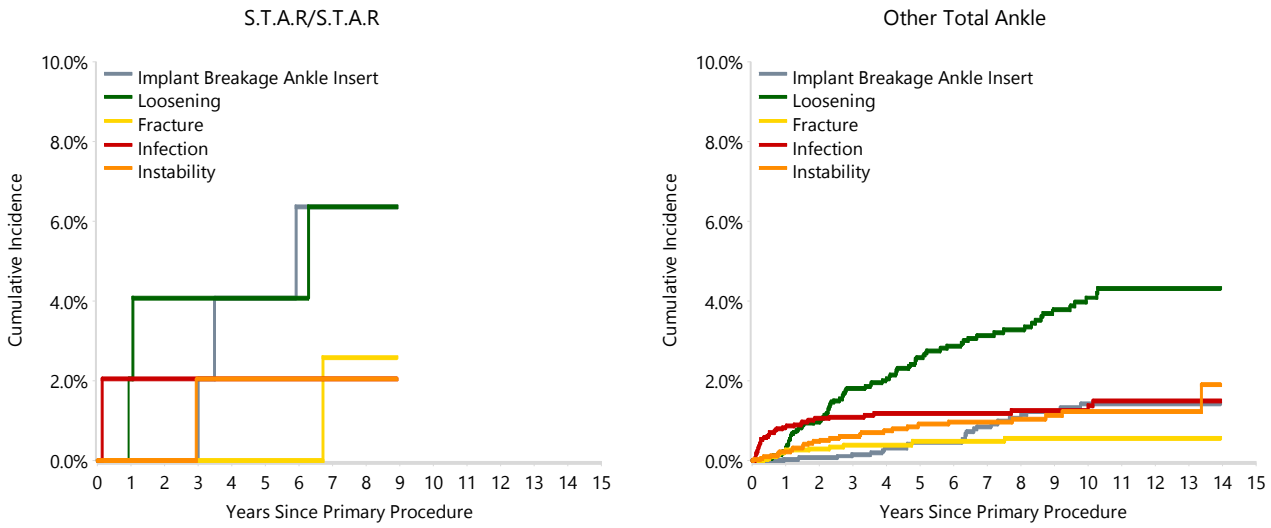


TABLE 5

Type of Revision Performed for Primary Total Ankle Replacement

This analysis identifies the components used in the revision of the S.T.A.R/S.T.A.R 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 S.T.A.R/S.T.A.R total ankle combination compared to all other total ankle prostheses.

Table 5: Primary Total Ankle Replacement - Type of Revision (Follow-up Limited to 12.6 Years)

	S.T.A.R/S.T.A.R		Other Total Ankle	
Type of Revision	Number	Percent	Number	Percent
Tibial/Talar	3	27.3	36	12.0
Tibial Only	1	9.1	32	10.7
Talar Only	1	9.1	17	5.7
Cement Spacer			12	4.0
Removal of Prostheses	1	9.1	5	1.7
Reinsertion of Components			1	0.3
N Major	**6**	**54.5**	**103**	**34.3**
Insert Only	4	36.4	148	49.3
Arthrodesis	1	9.1	37	12.3
Minor Components			11	3.7
Cement Only			1	0.3
N Minor	**5**	**45.5**	**197**	**65.7**
TOTAL	**11**	**100.0**	**300**	**100.0**

Note: This table is restricted to revisions within 12.6 years for all groups to allow a time-matched comparison of revisions.

TABLE 6

Revision Rates of S.T.A.R/S.T.A.R 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 S.T.A.R/S.T.A.R Primary Total Ankle Replacement by Fixation

Fixation	N Revised	N Total
Cementless	11	47
Hybrid (Tibial Cemented)	0	2
TOTAL	**11**	**49**

TABLE 7

Revision Rates of Primary Total Ankle Replacement by State

This enables a state by state variation to be identified for the S.T.A.R/S.T.A.R 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
S.T.A.R/S.T.A.R	NSW	4	6
	VIC	2	10
	WA	5	33
Other Total Ankle	NSW	76	1195
	VIC	101	969
	QLD	10	273
	WA	62	434
	SA	29	320
	TAS	10	122
	ACT/NT	13	86
TOTAL		**312**	**3448**

TABLE 8

Number of Revisions of S.T.A.R/S.T.A.R Primary Total Ankle Replacement by Year of Implant

This analysis details the number of prostheses reported each year to the Registry for the S.T.A.R/S.T.A.R 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 2021 has a maximum of one year to be revised, whereas a primary procedure performed in 2019 has a maximum of three years to be revised.

Table 8: Number of Revisions of S.T.A.R/S.T.A.R Primary Total Ankle Replacement by Year of Implant

Year of Implant	Number Revised	Total Number
2007	1	1
2009	2	3
2010	2	3
2011	1	4
2012	0	2
2013	3	15
2014	2	12
2015	0	4
2016	0	4
2018	0	1
TOTAL	**11**	**49**

TABLE 9

Revision Rates of S.T.A.R/S.T.A.R 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 S.T.A.R/S.T.A.R 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
Talar				
S.T.A.R	400211-400220	TALAR COMPONENT	NO	METAL
S.T.A.R	400250-400259	ANKLE TALAR COMPONENT COCRMO	NO	METAL
Tibial Tray				
S.T.A.R	400230-400234	ANKLE TIBIAL COMPONENT	NO	METAL
S.T.A.R	400260-400264	ANKLE TIBIAL COMPONENT - SINGLE COATED	NO	METAL

Table 9: Revised Number of S.T.A.R/S.T.A.R Primary Total Ankle Replacement by Catalogue Number Range

Talar Range	Tibial Tray Range	N Revised	N Total
400211-400220	400230-400234	11	47
	400260-400264	0	1
400250-400259	400230-400234	0	1
TOTAL		**11**	**49**