

Two-Year Revision Rates in Total Ankle Replacement Versus Ankle Arthrodesis

A Population-Based Propensity-Score-Matched Comparison from New York State and California

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Background: The aim of this study was to compare outcomes between total ankle replacement (TAR) and ankle arthrodesis (AA) for ankle osteoarthritis using real-world data.

Methods: We used longitudinal claims data from New York State from October 2015 to December 2018, and from California from October 2015 to December 2017. The primary outcome was revision. Secondary outcomes were in-hospital complications and below-the-knee amputation. Propensity-score matching adjusted for differences in baseline characteristics. To determine predictors of the main outcome, each group was analyzed using multivariable Cox regressions.

Results: There were 1,477 TAR procedures (50.2%) and 1,468 AA procedures (49.8%). Patients undergoing TAR were less likely to belong to a minority group and had fewer comorbidities compared with those undergoing AA. Crude analyses indicated that the TAR group had a lower risk of revision (5.4% versus 9.1%), in-hospital complications (<1% versus 1.8%), and below-the-knee amputation (<1% versus 4.9%) (p < 0.001 for all). However, in the propensity-score-matched analysis, the risk of revision was no longer significantly lower (TAR, 5.6% versus AA, 7.6%; p = 0.16). In the multivariable analyses, older age was predictive of a lower risk of revision after TAR (hazard ratio [HR], 0.96 [95% confidence interval (CI), 0.93 to 1.00]), but age was not predictive of revision after AA (HR, 0.99 [95% CI, 0.97 to 1.01]). Female patients were less likely to undergo revision after AA (HR, 0.61 [95% CI, 0.39 to 0.96]), but sex was not predictive of revision after TAR (HR, 0.90 [95% CI, 0.51 to 1.60]).

Conclusions: The 2-year adjusted revision risk was 5.6% after TAR and 7.6% after AA. This difference did not reach significance. Older age was a predictor of lower revision risk after TAR. Men had a higher risk of revision than women after AA. The number of TAR procedures has now caught up with the number of AA procedures.

Level of Evidence: Therapeutic Level III. See Instructions for Authors for a complete description of levels of evidence.

H nd-stage osteoarthritis of the ankle can be devastating, causing great pain and discomfort^{1,2}. Ankle arthrodesis (AA) is considered the gold standard of surgical treatment of end-stage ankle OA³⁻⁵. Total ankle replacement (TAR) was introduced in the 1970s as an alternative to AA to allow range of motion of the ankle joint. The first-generation TARs failed early, but TAR design has evolved, as has surgeons' understanding of indications for use^{6,7}. Still, in recent series⁸⁻¹⁰,

5-year revision rates were >15%, which is much higher than revision rates for hip and knee replacements, but possibly comparable with reoperation rates after AA. Regardless, TAR is gaining popularity among patients and surgeons, with a steady increase in procedures performed^{4,11,12}. The reasons for the increase in TAR procedures are likely related to functional limitations of AA associated with lack of ankle motion^{12,13}. Despite the increased interest in TAR, there is currently no

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Fig. 1

Flowchart of included patients. TAR = total ankle replacement, and NYS = New York State.

consensus on which intervention is superior, or which patients would benefit from TAR rather than AA.

The aim of this study was to compare risks and determine predictors of early revision (within 2 years) after primary TAR and AA using propensity-score matching.

Materials and Methods

This study was approved by the Weill Cornell Medicine institutional review board.

We used data from the New York State Department of Health Statewide Planning and Research Cooperative System (SPARCS) from October 2015 to December 2018, and data from the California Office of Statewide Health Planning and Development (OSHPD) from October 2015 to December 2017. SPARCS is an all-payer reporting system for all inpatient, emergency department, and outpatient visits within New York State, collecting patient characteristics, diagnoses, and procedures. The OSHPD administrative database contains similar patient data from all licensed health-care facilities in California.

Study Population

We identified patients who had undergone primary TAR or AA in New York State and California using the International Classification of Diseases, Tenth Revision, Procedure Coding System (ICD-10-PCS). We started from October 2015 because the ICD-10 became effective at that time and records laterality of the procedure. We excluded patients who, at the time of the procedure, were <22 years of age (i.e., pediatric patients per Section 520m(6)E of the Federal Food, Drug, and Cosmetic

TABLE I Number of Procedures*								
	TAR			AA			All Cases	
	Uncemented	Cemented	Unspecified	Total	Open	Arthroscopic	Total	Total
NYS	342	69	205	616	591	33	624	1,240
CA	323	155	383	861	793	51	844	1,705
Total	665	224	588	1,477	1,384	84	1,468	2,945

*TAR = total ankle replacement, AA = ankle arthrodesis, NYS = New York State, and CA = California.

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	TAR (N = 1,477)	AA (N = 1,468)	P Value
Age (yr)			
Mean (SD)	65.5 (9.7)	58.3 (13.6)	<0.001
Median (range)	66 (23-91)	60 (22-94)	
Sex (no. [%])			0.82
Male	827 (56.0%)	828 (56.4%)	
Female	650 (44.0%)	640 (43.6%)	
Race/ethnicity (no. [%])			<0.001
White	1.273 (86.2%)	952 (64.9%)	
Black	36 (2.4%)	132 (9.0%)	
Hispanic	88 (6.0%)	235 (16.0%)	
Other/unknown	80 (5.4%)	149 (10.1%)	
Insurance (no. [%])			<0.001
Medicare	782 (52.9%)	617 (42.0%)	
Medicaid	67 (4.5%)	228 (15.5%)	
Commercial	564 (38.2%)	486 (33.1%)	
Other	64 (4.3%)	137 (9.3%)	
State (no. [%])			0.66
New York	616 (41.7%)	624 (42.5%)	
California	861 (58.3%)	844 (57.5%)	
Indications (no. [%])			<0.001
Rheumatoid arthritis	67 (4.5%)	62 (4.2%)	
Traumatic arthritis	454 (30.7%)	327 (22.3%)	
Osteoarthritis	956 (64.7%)	527 (35.9%)	
Neuropathic/diabetic arthritis		187 (12.7%)	
Other	_	365 (24.9%)	
Comorbidities (no. [%])			
Osteoporosis	69 (4.7%)	91 (6.2%)	0.07
Morbid obesity	293 (19.8%)	446 (30.4%)	< 0.001
Peripheral vascular disease	68 (4.6%)	141 (9.6%)	<0.001
Coronary artery disease	155 (10.5%)	232 (15.8%)	<0.001
Hypertension	882 (59.7%)	943 (64.2%)	0.01
Congestive heart failure	40 (2.7%)	149 (10.1%)	<0.001
Diabetes	217 (14.7%)	511 (34.8%)	<0.001
Chronic pulmonary disease	251 (17.0%)	311 (21.2%)	0.004
Chronic kidney disease	85 (5.8%)	249 (17.0%)	< 0.001

Act), which is consistent with on-label use of TAR designs approved by the U.S. Food and Drug Administration (FDA) (Fig. 1).

Outcome Definition

The primary outcome was revision after the index TAR and AA procedures (see Appendix Table A). Revision was defined as the addition or removal of any component, a replacement of the implant, or an arthrodesis following the index TAR or AA. Patients were censored based on above-the-knee amputation, death, or the

end of the study, whichever came earlier. We recorded the reason for revision, including mechanical complications, infection, and nonunion after AA. Secondary outcomes were in-hospital complications (neurovascular injury, wound complications, postoperative infection, deep venous thrombosis, and pulmonary embolism) and below-the-knee amputations.

Covariates

Covariates examined were patients' age at the time of the index procedure, sex, race and ethnicity (non-Hispanic White, non-

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Fig. 2

Kaplan-Meier curve for implant survival, unadjusted analysis. Hall-Wellner bands indicate the 95% confidence interval for revision risk. TAR = total ankle replacement.

Hispanic Black, Hispanic, and other), insurance (Medicare, Medicaid, commercial, and other), state, indication (rheumatoid arthritis, traumatic arthritis, osteoarthritis, neuropathic or diabetic arthritis, and other), comorbidities, and type of TAR (cemented, uncemented, and unspecified) and AA (open and arthroscopic).

Statistical Methods

Groups were compared using chi-square tests for categorical variables and a Student t test for age. We examined below-theknee amputation and revision as time-to-event variables and derived the estimated risks of amputation and revision at 2 years following the index procedure using Kaplan-Meier analyses.

We performed propensity-score matching to account for differences in TAR and AA patients' baseline characteristics. The AA cohort was therefore limited to patients with rheumatoid arthritis, traumatic arthritis, or osteoarthritis. Propensity-score matching adjusts for baseline confounding by creating a matched cohort of patients with similar probabilities of receiving a TAR. We used multivariable logistic regression to obtain the propensity scores for each individual (the probability of receiving a TAR). Potential baseline confounder variables were age, sex, race/ethnicity, insurance, state, indications for the procedure, and comorbidities. We performed nearest-neighbor matching of the 2 groups at a 1:1 fixed ratio, using a caliper width of 0.2 of the standard deviation of the logit of the propensity score. The caliper width was set to minimize differences in the probability of receiving a TAR between the matched pairs. We examined the balance in baseline covariates in the matched cohort using standardized mean differences and Cochran-Mantel-Haenszel and paired t tests. A covariate is considered balanced between groups when the absolute value of the standardized mean difference is <0.1. There was some difference in age between groups after matching, and we therefore adjusted for age in the subsequent Cox proportionalhazard models to compare the groups with respect to revision and below-the-knee amputation and in logistic-regression models to compare the groups with respect to in-hospital complications. A robust sandwich variance estimator was used in the Cox and logistic-regression models to account for the paired data structure.

To examine independent predictors of revision, we used multivariable Cox regressions among the TAR and AA patients separately. We performed a sensitivity analysis to examine the association between TAR and revision in hypothetical cases of all unspecified TARs having been cemented and all unspecified TARs having been uncemented. All analyses were performed using SAS 9.4 (SAS Institute).

TABLE III Crude Outcomes and Analysis*							
	TAR (N = 1,477)	AA (N = 1,468)	P Value				
In-hospital complications† (no. [%])	<15 (<1%)	27 (1.8%)	<0.001				
Median follow-up (IQR) (mo)	15 (8-23)	16 (8-24)					
Below-the-knee amputation							
No. (%)	<15 (<1%)	53 (3.6%)					
Estimated risk at 24 mo (95% CI)	<1%	4.9% (3.6%-6.7%)	<0.001				
Revision/fusion							
No. (%)	52 (3.5%)	99 (6.7%)					
Estimated risk at 24 mo (95% CI)	5.4% (3.6%-8.1%)	9.1% (6.9%-11.9%)	<0.001				
Diagnosis associated with first revision							
Device mechanical complication	16 (30.8%)	22 (22.2%)					
Device infection	<15 (<28.8%)	32 (32.3%)					
Nonunion	—	21 (21.2%)					

*TAR = total ankle replacement, AA = ankle arthrodesis, IQR = interquartile range, and CI = confidence interval. Rare incidents (fewer than 15) are indicated by <15, as per the data-use agreement. †In-hospital complications were nerve injury, wound complications, infection, vascular injury, pulmonary embolism, and deep venous thrombosis.

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Fig. 3

Propensity density before and after propensity-score matching. TAR = total ankle replacement.

TABLE IV Comparison of Patient Characteristics After Propensity-Score Matching*				
	TAR (N = 753)	AA (N = 753)	P Value	SMD
Age (yr)			<0.001	0.14
Mean (SD)	63.5 (10.6)	61.9 (11.6)		
Median (range)	64 (23-91)	63 (22-91)		
Sex (no. [%])			0.47	-0.038
Male	428 (56.8%)	414 (55.0%)		
Female	325 (43.2%)	339 (45.0%)		
Race/ethnicity (no. [%])			0.15	0.075
White	601 (79.8%)	578 (76.8%)		
Black	33 (4.4%)	40 (5.3%)		
Hispanic	67 (8.9%)	76 (10.1%)		
Other/unknown	52 (6.9%)	59 (7.8%)		
Insurance (no. [%])			0.94	0.043
Medicare	346 (45.9%)	342 (45.4%)		
Medicaid	58 (7.7%)	66 (8.8%)		
Commercial	299 (39.7%)	292 (38.8%)		
Other	50 (6.6%)	53 (7.0%)		
State (no. [%])			0.56	0.030
New York	325 (43.2%)	314 (41.7%)		
California	428 (56.8%)	439 (58.3%)		
Indication (no. [%])			0.60	0.046
Rheumatoid arthritis	50 (6.6%)	48 (6.4%)		
Traumatic arthritis	233 (30.9%)	249 (33.1%)		
Osteoarthritis	470 (62.4%)	456 (60.6%)		
Comorbidities (no. [%])				
Osteoporosis	42 (5.6%)	42 (5.6%)	1	0
Morbid obesity	185 (24.6%)	194 (25.8%)	0.59	-0.028
Peripheral vascular disease	35 (4.6%)	46 (6.1%)	0.20	-0.065
Coronary artery disease	77 (10.2%)	81 (10.8%)	0.74	-0.017
Hypertension	437 (58.0%)	467 (62.0%)	0.11	-0.081
Congestive heart failure	30 (4.0%)	31 (4.1%)	0.90	-0.007
Diabetes	139 (18.5%)	157 (20.8%)	0.20	-0.060
Chronic pulmonary disease	152 (20.2%)	144 (19.1%)	0.59	0.027
Chronic kidney disease	49 (6.5%)	60 (8.0%)	0.24	-0.056

*TAR = total ankle replacement, AA = ankle arthrodesis, SD = standard deviation, and SMD = standardized mean difference. (An absolute value of the SMD of <0.1 indicates good balance after matching.)

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Fig. 4

Kaplan-Meier curve for implant survival, after propensity-score matching. Hall-Wellner bands indicate the 95% confidence interval for revision risk. TAR = total ankle replacement.

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Results

uring the study period, 2,945 patients who were \geq 22 years of age underwent a primary TAR (n = 1,477, 50.2%) or AA procedure (n = 1,468, 49.8%) in New York State and California (Fig. 1, Table I). The patients in the TAR group were older than the patients in the AA group (mean age of 65.5 versus 58.3 years; p < 0.001). There was no difference in distribution by sex between the groups, although there were more men (56%) than women (44%) overall. Patients treated with TAR were less likely to belong to a minority race and ethnic group or be Medicaid recipients and presented with fewer comorbidities than patients treated with AA (Table II). Unadjusted analyses indicated that TAR recipients had a significantly lower risk of revision (5.4% versus 9.1%; p < 0.001), in-hospital complications (<1% versus 1.8%; p < 0.001), and below-the-knee amputation (<1% versus 4.9%; p < 0.001) compared with AA patients (Fig. 2, Table III).

After limiting the analyses to patients with osteoarthritis, rheumatoid arthritis, and traumatic arthritis (i.e., to match TAR patients), 753 patients in each group were matched (Fig. 3). A comparison of patient characteristics after matching revealed good balance of all variables, except for age, which was adjusted for in further analysis (Table IV). After propensity-score matching, the risk of revision was lower, but no longer significantly so, in the TAR cohort compared with the AA cohort (5.6% versus 7.6%; hazard ratio [HR], 0.70 [95% confidence interval (CI), 0.43 to 1.15]; p = 0.16) (Fig. 4). The risk of below-the-knee amputation was lower for the TAR group than for the AA group (HR, 0.12 [95% CI, 0.02 to 0.98]; p = 0.048). There was no significant difference in in-hospital complications between the TAR and AA cohorts (HR, 0.50 [95% CI, 0.12 to 2.00]; p = 0.33).

Age and sex were predictive of revision risk for TAR and AA, respectively (Table V). Older age was a predictor of lower revision risk in the TAR group (HR for 1-year increase in age, 0.96 [95% CI, 0.93 to 1.00]; p = 0.04), but age was not predictive of revision after AA (HR, 0.99 [95% CI, 0.97 to 1.01]; p = 0.4). Women were less likely to have revision after AA (HR, 0.61 [95% CI, 0.39 to 0.96]; p = 0.03), but sex was not predictive of revision after TAR (HR, 0.90 [95% CI, 0.51 to 1.60]; p = 0.71). We did not find any differences in revision risk between cemented and uncemented TARs (Fig. 5). The fixation method was not specified in 588 (40%) of the TAR procedures. Therefore, we performed a sensitivity analysis, which demonstrated that fixation would not have influenced revision risk if all of the unspecified cases had been either cemented or uncemented (Table VI).

Discussion

The main finding of this study was that there was no significant difference in 2-year revision risk between TAR and AA after propensity-score matching. We did not identify any risk factors for revision after TAR other than younger age, while women had a lower risk of revision after AA. This information is useful for clinicians when considering surgical treatment for end-stage arthritis of the ankle.

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	TAR	TAR		AA	
	HR (95% CI)	P Value	HR (95% CI)	P Value	
TAR type					
Cemented	Ref.		_	_	
Uncemented	0.97 (0.44-2.12)	0.94	_	_	
Unspecified	0.68 (0.30-1.58)	0.37	_	_	
Age (for 1-yr increase)	0.96 (0.93-1.00)	0.04	0.99 (0.97-1.01)	0.4	
Sex					
Male	Ref.		Ref.		
Female	0.90 (0.51-1.60)	0.71	0.61 (0.39-0.96)	0.03	
Race/ethnicity					
White	Ref.		Ref.		
Black	0.96 (0.34-2.74)†	0.94	0.95 (0.47-1.93)	0.89	
Hispanic	, ,, †		0.72 (0.39-1.33)	0.29	
Other/unknown	1.32 (0.45-3.82)	0.61	0.59 (0.27-1.30)	0.19	
Insurance					
Medicare	Ref.		Ref.		
Medicaid	0.45 (0.10-2.16)	0.32	1.08 (0.57-2.05)	0.82	
Commercial	0.46 (0.22-0.98)	0.04	0.53 (0.29-0.96)	0.03	
Other	1.35 (0.48-3.75)	0.57	1.21 (0.58-2.52)	0.62	
Indication					
Rheumatoid arthritis	2.01 (0.77-5.23)	0.15	0.75 (0.18-3.17)	0.69	
Traumatic arthritis	1.00 (0.54-1.85)	0.99	0.91 (0.50-1.65)	0.75	
Osteoarthritis	Ref.		Ref.		
Neuropathic/diabetic arthritis	_	_	1.81 (0.95-3.45)	0.07	
Other	_	—	0.96 (0.56-1.67)	0.9	
Comorbidities					
Osteoporosis	2.18 (0.80-5.94)	0.13	0.76 (0.27-2.17)	0.61	
Morbid obesity	0.67 (0.29-1.53)	0.34	0.99 (0.62-1.57)	0.97	
Peripheral vascular disease	0.38 (0.05-2.88)	0.35	1.34 (0.74-2.42)	0.34	
Coronary artery disease	0.50 (0.15-1.67)	0.26	1.26 (0.72-2.20)	0.43	
Hypertension	1.08 (0.59-1.95)	0.81	1.05 (0.62-1.79)	0.86	
Congestive heart failure	†		1.50 (0.78-2.90)	0.23	
Diabetes	1.02 (0.44-2.33)	0.97	1.11 (0.66-1.87)	0.7	
Chronic pulmonary disease	1.59 (0.82-3.08)	0.17	1.10 (0.67-1.80)	0.7	
Chronic kidney disease	0.93 (0.22-3.99)	0.93	1.10 (0.61-1.95)	0.76	

*Significant results shown in bold. CI = confidence interval. †Because of sample-size restrictions, Black and Hispanic are combined and congestive heart failure is not included in the model of TAR patients.

AA has broader indications than TAR, but the indications for TAR are increasing and approaching those of AA¹⁴. The number of TAR procedures in California and New York State is now equal to that of AA. Previous studies have found that AA is the preferred surgical treatment for ankle osteoarthritis, with 2 to 6 times as many AA procedures performed compared with TAR procedures^{12,13,15}. Initially, TAR was mainly recommended for older patients with low physical demands. However, new data indicate that younger age (<50 years) should no longer be considered a contraindication for TAR¹⁶. Furthermore, patients with gross deformities were initially advised

against TAR, but recent studies indicate that these patients can also benefit from TAR¹⁷⁻¹⁹. Increased patient demand to retain ankle movement and expanding indications can explain why the number of TAR procedures in California and New York State has equaled that of AA. The only absolute contraindication to TAR is infection of the ankle joint, where AA may provide a definite solution.

Patients in the TAR group were less likely to have comorbidities, such as morbid obesity, peripheral vascular disease, and diabetes. This is in line with a study by Vakhshori et al. that found that surgeons perform TAR in patients who are healthier than

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Kaplan-Meier curve for implant survival, after propensity-score matching, according to subgroups for total ankle replacement (TAR). Hall-Wellner bands indicate the 95% confidence interval for revision risk.

those who undergo AA¹². Surgeons may be reluctant to offer arthroplasty to patients with comorbidities because of fear of severe complications^{14,20}. However, AA is also a major intervention with potential disastrous complications, including limb amputation and death. Whether patients with comorbidities are less likely to experience detrimental outcomes following AA than TAR needs further investigation²¹. Furthermore, we found that minority patients (Black and Hispanic) and Medicaid insurance holders were more likely to be treated with AA than TAR, also after controlling for comorbidities. This is consistent with reported social discrepancy in treatment options that merits further scrutiny²².

The complication and revision rates after TAR and AA were compared in 2 recent meta-analyses^{3,23}. Interestingly, the 2 reviews had no overlap of included articles and came to opposite con-

TABLE VI Sensitivity Analysis for Unspecified TAR Procedures*							
	HR (95% CI)	P Value					
If all unspecified are cemented							
Cemented	Ref.						
Uncemented	1.26 (0.71-2.20)	0.43					
If all unspecified are uncemented							
Cemented	Ref.						
Uncemented	0.83 (0.40-1.75)	0.63					
*TAR = total ankle replacement, HR = hazard ratio, and CI = con- fidence interval.							

clusions. Kim et al. included 10 studies published between 2007 and 2015, and found that outcomes were similar but the incidence of reoperations and major surgical complications was higher after TAR²³. Lawton et al. included 11 studies, also published between 2007 and 2015, and reported a lower complication rate following TAR than following AA, which is more aligned with our results³. We found no difference between the groups after propensity-score matching, while the crude analysis demonstrated fewer revisions in the TAR group, although this was confounded by differences in patient characteristics. Patients receiving TAR and AA are different in age and have different comorbidities, and therefore, a comparison of patient cohorts without matching is subject to selection bias²⁴. Furthermore, changes in indications have altered patient characteristics so that the older case series included in the 2 metaanalyses might not be relevant to today's practice.

The first-generation TARs were all cemented implants. High failure rates led to an interest in cementless fixation, but little data exist in the literature to support one method over the other. There was no significant difference in revision risk between cemented and uncemented TAR designs in our study. This is reassuring considering the concerns regarding the Scandinavian Total Ankle Replacement (STAR) Ankle device (Stryker) issued by the FDA²⁵, but there is a high degree of variability in clinical practice, and our follow-up was short (2 years). Further comprehensive studies with longer follow-up are needed to determine any potential differences in revision risk between cemented and uncemented TAR designs. Furthermore, the fixation method was not specified in 40% of the cases (588 of 1,477). A sensitivity analysis showed that, if all of these were either cemented or uncemented, it would not affect early

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revision risk. However, some of these procedures might have been hybrid fixations (i.e., 1 of the components was cemented), but the lack of information impeded further analysis. It is not uncommon for surgeons to use a negligible amount of cement to comply with on-label use, and thus it is unclear whether cemented implants in our included cases can truly be considered cemented. It should be mentioned that no TAR implant is designed for hybrid fixation, and certain TAR implants are marketed in the U.S. for cemented use only, so any such procedure would be an "off-label" use.

Arthroscopic AA has been proposed as a procedure with fewer complications and quicker recovery compared with open AA⁴. Proponents argue that arthroscopic AA is associated with a shorter hospital stay, speedier recovery, and improved outcome²⁶⁻²⁸, although it is arguably more technically demanding. Our data indicate that arthroscopic AA has not been widely adopted in New York State and California, with <6% of AA procedures (84 of 1,468) being reported as arthroscopic, which is somewhat lower than the 9% reported by Lawton et al.³. In their analysis, Lawton et al. included studies performed in larger specialized centers, which may be more likely to perform arthroscopic AA, while we also included comprehensive claims data from smaller community hospitals, which may be less likely to offer arthroscopic AA. Our study did not find any difference in revision risk between the 2 methods, but the arthroscopic AA group was small (n = 84).

One challenge in comparing TAR and AA is that they have different advantages and types of complications²⁹. TAR has the benefits of improved gait and protection of adjacent joints but may lead to implant loosening, polyethylene breakage, and persistent pain^{3,4,6,8}. In contrast, because AA eliminates movement from the arthritic joint, pain associated with motion of the joint is eliminated. However, loss of motion results in a shift of forces to adjacent joints and changes biomechanics⁵.

Limitations

We had a short follow-up of 2 years, while other studies have indicated that the revision rates of TAR are twice that of AA after 5 years²³. Many surgical complications after TAR, such as loosening or breakage of the plastic insert, occur beyond 2 years^{6,25,30}, while many complications following AA, such as wound problems, infection, and nonunion, occur within the first 2 years^{29,31}. Additional studies with follow-up beyond 5 years are needed to advance our understanding of the benefits and limitations of TAR and AA^{21,30}.

Our results are based on administrative databases from 2 states with 2 years of follow-up, and so may have reduced generalizability, although the results from studies using comprehensive statewide claims data may be more generalizable than those from single-center studies. However, these databases are subject to coding errors and a lack of device details, which may lead to some misclassification of outcomes. Nevertheless, our previous study of algorithm-based linkage between registry and claims data showed that procedure variables were mostly accurately captured³². Data reporting was insufficient to calculate risk estimates for certain subgroups and device designs.

Another limitation of the administrative database is the lack of patient-reported outcomes. We were therefore unable to compare differences in function, pain, quality of life, and other relevant outcomes that could influence the preference for one treatment over the other. Prospective comparative studies that include the patient perspective are therefore needed.

Although every effort was made to conduct comprehensive propensity-score matching, the patients receiving TAR and AA may exhibit fundamentally different characteristics that are not accounted for. Propensity-score matching could only account for known confounding variables. Some differences in patient characteristics may not be captured by claims data and cannot be adjusted for, leaving unmeasured confounding.

Conclusions

The 2-year adjusted revision risk was 5.6% after TAR and 7.6% after AA. This difference did not reach significance. Older age was a predictor of lower risk of revision after TAR, but the effect size was small. Men had a higher risk of revision than women after AA. This information can improve shared clinical decision-making when choosing operative treatment for arthritis of the ankle. The number of TAR procedures has now caught up with the number of AA procedures.

Appendix

eA Supporting material provided by the authors is posted with the online version of this article as a data supplement at jbjs.org (http://links.lww.com/JBJSOA/A375). ■

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References

^{1.} Saltzman CL, Zimmerman MB, O'Rourke M, Brown TD, Buckwalter JA, Johnston R. Impact of comorbidities on the measurement of health in patients with ankle osteoarthritis. J Bone Joint Surg Am. 2006 Nov;88(11):2366-72.

^{2.} Glazebrook M, Daniels T, Younger A, Foote CJ, Penner M, Wing K, Lau J, Leighton R, Dunbar M. Comparison of health-related quality of life between patients with endstage ankle and hip arthrosis. J Bone Joint Surg Am. 2008 Mar;90(3):499-505.

openaccess.jbjs.org

3. Lawton CD, Butler BA, Dekker RG 2nd, Prescott A, Kadakia AR. Total ankle arthroplasty versus ankle arthrodesis-a comparison of outcomes over the last decade. J Orthop Surg Res. 2017 May 18;12(1):76.

4. Veljkovic AN, Daniels TR, Glazebrook MA, Dryden PJ, Penner MJ, Wing KJ, Younger ASE. Outcomes of Total Ankle Replacement, Arthroscopic Ankle Arthrodesis, and Open Ankle Arthrodesis for Isolated Non-Deformed End-Stage Ankle Arthritis. J Bone Joint Surg Am. 2019 Sep 4;101(17):1523-9.

Fuchs S, Sandmann C, Skwara A, Chylarecki C. Quality of life 20 years after arthrodesis of the ankle. A study of adjacent joints. J Bone Joint Surg Br. 2003 Sep;85(7):994-8.
Haddad SL, Coetzee JC, Estok R, Fahrbach K, Banel D, Nalysnyk L. Intermediate

and long-term outcomes of total ankle arthroplasty and ankle arthrodesis. A systematic review of the literature. J Bone Joint Surg Am. 2007 Sep;89(9):1899-905. 7. Gougoulias NE, Khanna A, Maffulli N. History and evolution in total ankle

arthroplasty. Br Med Bull. 2009;89:111-51.

8. Daniels TR, Younger AS, Penner M, Wing K, Dryden PJ, Wong H, Glazebrook M. Intermediate-term results of total ankle replacement and ankle arthrodesis: a COFAS multicenter study. J Bone Joint Surg Am. 2014 Jan 15;96(2):135-42.

9. Skyttä ET, Koivu H, Eskelinen A, Ikävalko M, Paavolainen P, Remes V. Total ankle replacement: a population-based study of 515 cases from the Finnish Arthroplasty Register. Acta Orthop. 2010 Feb;81(1):114-8.

10. Labek G, Klaus H, Schlichtherle R, Williams A, Agreiter M. Revision rates after total ankle arthroplasty in sample-based clinical studies and national registries. Foot Ankle Int. 2011 Aug;32(8):740-5.

11. Singh JA, Ramachandran R. Time trends in total ankle arthroplasty in the USA: a study of the National Inpatient Sample. Clin Rheumatol. 2016 Jan; 35(1):239-45.

12. Vakhshori V, Sabour AF, Alluri RK, Hatch GF 3rd, Tan EW. Patient and Practice Trends in Total Ankle Replacement and Tibiotalar Arthrodesis in the United States From 2007 to 2013. J Am Acad Orthop Surg. 2019 Jan 15;27(2):e77-84.

13. Raikin SM, Rasouli MR, Espandar R, Maltenfort MG. Trends in treatment of advanced ankle arthropathy by total ankle replacement or ankle fusion. Foot Ankle Int. 2014 Mar;35(3):216-24.

14. van der Plaat LW, Haverkamp D. Patient selection for total ankle arthroplasty. Orthop Res Rev. 2017 Jul 31;9:63-73.

15. Pugely AJ, Lu X, Amendola A, Callaghan JJ, Martin CT, Cram P. Trends in the use of total ankle replacement and ankle arthrodesis in the United States Medicare population. Foot Ankle Int. 2014 Mar;35(3):207-15.

16. Samaila EM, Bissoli A, Argentini E, Negri S, Colò G, Magnan B. Total ankle replacement in young patients. Acta Biomed. 2020 May 30;91(4-S):31-5.

17. Demetracopoulos CA, Cody EA, Adams SB Jr, DeOrio JK, Nunley JA 2nd, Easley ME. Outcomes of Total Ankle Arthroplasty in Moderate and Severe Valgus Deformity. Foot Ankle Spec. 2019 Jun;12(3):238-45.

18. Lee GW, Lee KB. Outcomes of Total Ankle Arthroplasty in Ankles with >20° of Coronal Plane Deformity. J Bone Joint Surg Am. 2019 Dec 18; 101(24):2203-11.

 Day J, Principe PS, Caolo KC, Fragomen AT, Rozbruch SR, Ellis SJ. A Staged Approach to Combined Extra-articular Limb Deformity Correction and Total Ankle Arthroplasty for End-Stage Ankle Arthritis. Foot Ankle Int. 2021 Mar;42(3):257-67.
Tai K, Vannabouathong C, Mulla SM, Goldstein CL, Smith C, Sales B, Yeardley D, Bhandari M, Petrisor BA. A Survey for End-Stage Ankle Arthritis Treatment: Ankle Arthrodesis Versus Ankle Arthroplasty. J Foot Ankle Surg. 2020 Mar - Apr;59(2): 330-6.

21. Goldberg AJ, Zaidi R, Thomson C, Doré CJ, Skene SS, Cro S, Round J, Molloy A, Davies M, Karski M, Kim L, Cooke P; TARVA study group. Total ankle replacement versus arthrodesis (TARVA): protocol for a multicentre randomised controlled trial. BMJ Open. 2016 Sep 6;6(9):e012716.

22. Baciu A. The State of Health Disparities in the United States. In: Weinstein JN, Geller A, Negussie Y, Baciu A, editors. Communities in Action: Pathways to Health Equity. The National Academies Press; 2017.

23. Kim HJ, Suh DH, Yang JH, Lee JW, Kim HJ, Ahn HS, Han SW, Choi GW. Total ankle arthroplasty versus ankle arthrodesis for the treatment of end-stage ankle arthritis: a meta-analysis of comparative studies. Int Orthop. 2017 Jan;41(1): 101-9.

24. Odum SM, Van Doren BA, Anderson RB, Davis WH. In-Hospital Complications Following Ankle Arthrodesis Versus Ankle Arthroplasty: A Matched Cohort Study. J Bone Joint Surg Am. 2017 Sep 6;99(17):1469-75.

25. U.S. Food & Drug Administration. Risk of Device Component Breaking in Patients with Stryker's STAR Ankle: FDA Safety Communication. 2021 Oct 1. https://www.fda.gov/medical-devices/safety-communications/risk-device-component-breaking-patients-strykers-star-ankle-fda-safety-communication

26. Townshend D, Di Silvestro M, Krause F, Penner M, Younger A, Glazebrook M, Wing K. Arthroscopic versus open ankle arthrodesis: a multicenter comparative case series. J Bone Joint Surg Am. 2013 Jan 16;95(2):98-102.

27. Mok TN, He Q, Panneerselavam S, Wang H, Hou H, Zheng X, Pan J, Li J. Open versus arthroscopic ankle arthrodesis: a systematic review and meta-analysis. J Orthop Surg Res. 2020 May 24;15(1):187.

28. Bai Z, Yang Y, Chen S, Dong Y, Cao X, Qin W, Sun W. Clinical effectiveness of arthroscopic vs open ankle arthrodesis for advanced ankle arthritis: A systematic review and meta-analysis. Medicine (Baltimore). 2021 Mar 12;100(10):e24998.

29. Ross BJ, Savage-Elliott I, Wu VJ, Rodriguez RF. Complications Following Total Ankle Arthroplasty Versus Ankle Arthrodesis for Primary Ankle Osteoarthritis. Foot Ankle Spec. 2021 Jan 20:1938640020987741.

30. Glazebrook M, Burgesson BN, Younger AS, Daniels TR. Clinical outcome results of total ankle replacement and ankle arthrodesis: a pilot randomised controlled trial. Foot Ankle Surg. 2021 Apr;27(3):326-31.

31. Frey C, Halikus NM, Vu-Rose T, Ebramzadeh E. A review of ankle arthrodesis: predisposing factors to nonunion. Foot Ankle Int. 1994 Nov;15(11):581-4.

32. Mao J, Etkin CD, Lewallen DG, Sedrakyan A. Creation and Validation of Linkage Between Orthopedic Registry and Administrative Data Using Indirect Identifiers. J Arthroplasty. 2019 Jun;34(6):1076-1081.e0.