Total Ankle Replacement Survival Rates Based on Kaplan-Meier Survival Analysis of National Joint Registry Data

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KEYWORDS

- Ankle evolutive system • Kaplan-Meier estimator • Prosthesis survival
- Scandinavian total ankle replacement • Total ankle arthroplasty

KEY POINTS

- National joint registries provide (1) timely feedback to surgeons and industry, (2) a sentinel for complications, (3) a reduction in patient morbidity, (4) the monitoring of new surgical techniques and implant technology, and (5) indications of poor implant design.
- The Kaplan-Meier estimator forecasts the probability of an event occurring over time with graphic representation of the resultant survival probability curve. The resultant survival curves based on the Kaplan-Meier estimator can be digitized and re-created to determine trends between registries.
- The survival rates of the 5152 primary total ankle replacements included over a 2- to 13-year period for all national joint registries were 0.94 (95% CI, 0.90–0.97) at 2 years, 0.87 (95% CI, 0.82–0.91) at 5 years, and 0.81 (95% CI, 0.74–0.88) at 10 years.
- National joint registries that included the Ankle Evolutive System (AES), Buechel-Pappas (BP), or Scandinavian Total Ankle Replacement (STAR) as greater than or equal to 35% of total prostheses implanted had survival rates between 0.78 and 0.89 at 5 years compared with registries with less than 35% of these implants, which were between 0.90 and 0.93 at 5 years.
- The STAR system should be implanted with caution until a dedicated revision system is developed and more robust long-term data are available supporting its continued use as a primary total ankle replacement (TAR).

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INTRODUCTION

TAR has experienced clinical failure in early generations and accordingly was rendered nearly extinct. Dissatisfaction with ankle arthrodesis and the success of hip and knee arthroplasty, however, have renewed interest in TAR. Furthermore, the current growth of TAR can be credited to innovative surgeons and industry learning from the initial generations and modifying concepts to create a more biomechanically sound prostheses that can be inserted more reliably.[1]

The evolution of TAR is historically categorized into 3 generations based predominantly on (1) the number of components used, (2) the fixation method of the components to bone, and (3) the decades in use. Specifically, first-generation TARs (1960s through 1980s) consisted of a metallic component fixated to the tibia and polyethylene (PE) component fixated to the talus and vice versa that obtained bone fixation purely with polymethylmethacrylate (PMMA) cement. Limited dedicated instrumentation for prosthetic component implantation existed. Second-generation TARs (1980s through 2000s) consisted of 2 metallic or ceramic components, 1 affixed to the tibia and the other to the talus, secured to bone predominantly with PMMA cement, but some were fixated with metallic or biological porous coating. The PE insert was predominantly immobile and affixed to the undersurface of the tibial component, but some involved a partially mobile PE insert. Rudimentary instrumentation for prosthetic component implantation existed. Third-generation TARs (2000s to present day) consist of 2 metallic components, 1 affixed to the tibia and the other to the talus, secured to bone predominantly with metallic or biological porous coating and rarely PMMA cement. The PE insert predominantly involves a partially mobile design or, in a few designs, is immobile and affixed to the undersurface of the tibial component. Robust instrumentation for prosthetic component implantation exists, including intra- and extramedullary referencing, computer-assisted bone preparation, and CT scan–derived patient-specific guides.

It is generally believed that the first-generation TAR prostheses were far inferior to the second-generation prostheses, which in turn were inferior to the current third-generation prostheses.[1] Accordingly, TAR prosthesis longevity continues to be questioned and poorly understood, especially the effect, if any, the various design characteristics have had on prosthesis survival. It becomes more difficult to assess the effect of design characteristics because most TAR publications involve the prosthesis inventor, design team members, or paid company consultants. Therefore, strong potential for selection (inventor) and/or publication (conflict of interest) bias exists. For example, Labek and colleagues[2] studied the outcomes of second-generation TARs reported in clinical studies and national joint registries and identified significant selection (inventor) bias in approximately 50% of clinical studies. This effect was especially strong for the BP (Endotec, South Orange, New Jersey) and STAR (Waldemar Link, Hamburg, Germany/Small Bone Innovations, Morrisville, Pennsylvania/Stryker Orthopaedics, Mahwah, New Jersey) compared with national joint registry data. Additionally, a systematic review of primary implantation of the Agility Total Ankle Replacement System (DePuy Orthopaedics, Warsaw, Indiana) demonstrated that excluding the inventor increased the incidence of complications approximately 2-fold, from 6.6% (68/1033) to 12.2% (156/1279), implicating selection (inventor) bias.[3] Similarly, a systematic review of primary implantation of the STAR demonstrated that excluding the inventor or faculty consultants increased the incidence of complications more than 2-fold, from 5.6% (45/807) to 13.2% (224/1700), implicating selection (inventor) and publication (conflict of interest) bias.[4]

The implementation of national joint replacement registries worldwide would limit bias by providing large-scale prospective data collection and analysis of

patient-related data and prosthetic component data and by including revision with explanation for failure as the primary outcome.[5] Currently, 33 national joint registries exist for all major orthopedic joints amenable to prosthetic implantation (http://www.arthroplastywatch.com/?page_id=5; last accessed August 23, 2014).

The Kaplan-Meier estimator is commonly used in orthopedic joint implant survival analysis in peer-reviewed articles and in worldwide joint registries.[6,7] The Kaplan-Meier estimator forecasts the probability of an event occurring over time, with graphic representation of the resultant survival probability curve. The survival probability of each time interval is calculated as a product of the conditional properties of surviving time until a chosen time. The survival times are censored when a patient is lost to follow-up, experiences death, or does not experience the event, such as a revision. Dobbs[8] first used this estimate for implant revision in 1980, reporting on 400 Stanmore total hip arthroplasties (Centre for Biomedical Engineering, Royal National Orthopaedic Hospital, Middlesex, England). Although the Kaplan-Meier estimator has become a more common reporting statistic in orthopedic literature, it is not consistently reported for direct comparison of implant survival and trends at any point in time, such as 1 year, 5 years, or 10 years.

To date, no study has been performed that specifically compares TAR prosthesis survival between national joint registries. Therefore, this article re-creates primary TAR survival curves among published national joint registry data sets using the Kaplan-Meier estimator to determine the survival rates between registries at 1-year intervals. The number and type of TAR prosthesis implanted also were recorded and reported.

METHODS

The 33 listed joint registries identified worldwide were searched in detail (http://www.arthroplastywatch.com/?page_id=5; last accessed August 23, 2014). Additionally, 2 general Internet-based search engines, Google and Google Scholar, were used to search for additional national joint registry publications involving TAR based on a prior publication of this topic.[5]

TAR survival was defined as retention of the prosthesis without revision, removal, or exchange of part of or the entire prosthesis. The national joint registries' specific definitions of revision were noted and are described in **Table 1** for consistency, although slight variations were apparent between registries.

Next, each national joint registry was evaluated for the presence of a Kaplan-Meier TAR survival curve and values reported. The Kaplan-Meier data points were extracted from the included articles as a portable document format (PDF) and imported into the software DigitizeIt (http://www.digitizeit.de/; last accessed August 23, 2014) (DigitizeIt, Braunschweig, Germany) for hand digitization.[9] Censored events were excluded from digitization due to poor resolution quality to differentiate the number of events. The digitized coordinates of time (X axis) and survival probability (Y axis) were exported into Microsoft Excel 2010 (Microsoft, Redmond, Washington) for further analysis. Time increments of 1 year each were defined and extracted from each data set to re-create the Kaplan-Meier curve. If a Kaplan-Meier curve was not provided, the reported values were recorded according to 1-year increments.

RESULTS

Australia[10]; England, Wales, and Northern Ireland[11]; Finland[12]; New Zealand[13–15]; Norway[16,17]; and Sweden[18–20] had data available from their national joint registry data sets that involved TAR and had enough information to generate Kaplan-Meier

Table 1
Definitions of failure of a total ankle replacement as reported in national joint registries

National Joint Registry	Definition of Total Ankle Replacement Failure
New Zealand Joint Registry[13–15]	New operation in previously operated ankle joint with 1 or more components exchanged, added, removed or manipulated
Norwegian Arthroplasty Register[16,17]	Removal or exchange of a part of implant or the whole implant
Swedish Ankle Registry[18–20]	Exchange or extraction of 1 or more of the 3 prosthetic components with the exception of incidental exchange of the PE insert
AOA National Joint Replacement Registry[10]	Revision procedures are reoperations of previous ankle replacements where 1 or more of the prosthetic components are replaced or removed or another component is added. Revisions include reoperations of primary partial, primary total, or previous revision procedures.
National Joint Registry for England, Wales and Northern Ireland[11]	None provided
Finnish Arthroplasty Register[12]	One component or the whole implant removed or exchanged

survival curves. Among the included registries, 5152 primary and 591 TAR revisions were reported over a 2- to 13-year period. Primary TAR survival rates from all national joint registries were 0.94 (95% CI, 0.90–0.97) at 2 years, 0.87 (95% CI, 0.82–0.91) at 5 years, and 0.81 (95% CI, 0.74–0.88) at 10 years.

The authors determined that Kaplan-Meier estimator curves could be reliably reproduced to plot survival trends for evaluation and determine the Kaplan-Meier estimator at any point of time (**Fig. 1**). The Finnish Arthroplasty Register[12] had no difference between re-created value of 0.83 and 0.83 (95% CI, 0.81–0.86) reported at 5 years. The New Zealand Joint Registry[13–15] had no discrepancy of values between stated and re-created plots (0.99 at 1 year, 0.93 at 5 years, and 0.90 at 7 years, with reported values censoring deceased patients at time of death). The Norwegian Arthroplasty Register[16,17] had no difference in stated and re-created values at 5 years of 0.89 (stated 95% CI, 0.84–0.93). The Swedish Ankle Registry[18–20] demonstrated minor differences between stated and re-created plots of 0.92 re-created and 0.94 (95% CI, 0.93–0.95) reported at 1 year, 0.78 re-created and 0.81 (95% CI, 0.79–0.83) reported at 5 years, and 0.66 re-created and 0.69 (95% CI, 0.67–0.71) reported at 10 years. The Australian Orthopaedic Association (AOA) National Joint Replacement Registry[10] and National Joint Registry for England, Wales and Northern Ireland[11] provided reported data without supporting survival curves and accordingly these could not be evaluated.

The New Zealand Joint Registry[13–15] reports a 13-year analysis on 944 primary TARs performed (**Table 2**); 53 revisions and 6 re-revisions were performed out of the primary TAR group. The most common prosthesis implanted was the Mobility Total Ankle System (DePuy, Leeds, England) (n = 443, 47%) followed by the Salto Mobile version ankle prosthesis (Tornier, Saint-Martin, France) (n = 316, 33%). The calculated Kaplan-Meier estimator was 0.98 at 2 years, 0.93 at 5 years, and 0.86 at 10 years.

The Norwegian Arthroplasty Register[16,17] reports a 13-year analysis on 720 primary TARs performed (see **Table 2**); 216 revisions were reported. The most common
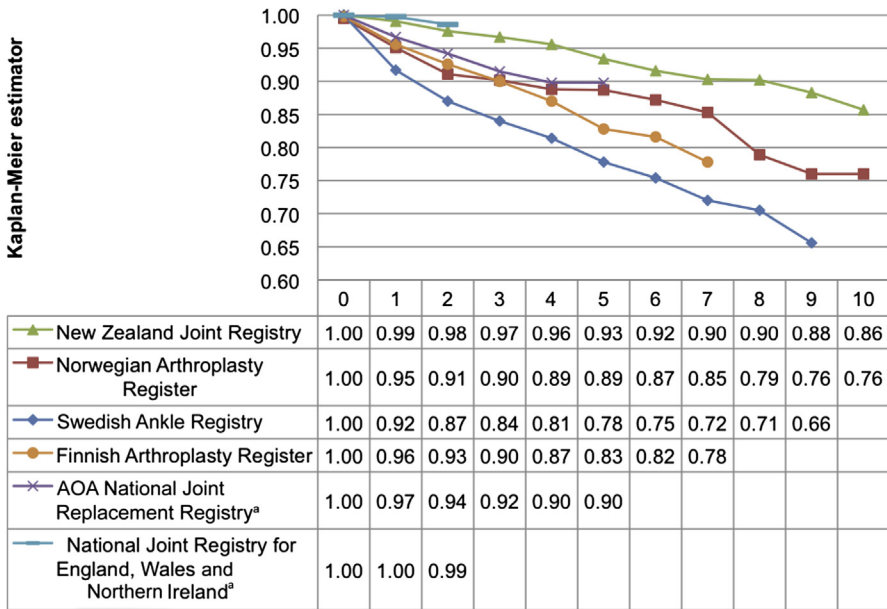
Fig. 1. Survival of TARs based on registry data of re-created Kaplan-Meier estimators. [a]Kaplan-Meier estimators as reported without a survival curve re-created. (*Data from* New Zealand Joint Registry,[13–15] Norwegian Arthroplasty Register,[16,17] Swedish Ankle Registry,[18–20] Finnish Arthroplasty Register,[12] AOA National Joint Replacement Registry,[10] and National Joint Registry for England, Wales and Northern Ireland.[11])

prosthesis implanted was the STAR (n = 537, 75%). The calculated Kaplan-Meier estimator was 0.91 at 2 years, 0.89, at 5 years, and 0.76 at 10 years.

The Swedish Ankle Registry[18–20] reports a 12-year analysis on 871 primary TARs performed (see **Table 2**); 208 revisions were reported. A wide variety of prosthesis

Table 2
National joint registries evaluated, including total ankle replacement prostheses studies, implantation start, final study year, and reported revisions

Registry	Publication Year	Study Start Year	Study Final Year	Total Ankle Replacements (n)	Revisions Reported
New Zealand Joint Registry[13–15]	2013	2000	2012	944	59
Norwegian Arthroplasty Register[16,17]	2013	2000	2012	720	216
Swedish Ankle Registry[18–20]	2013	2000	2012	871	208
AOA National Joint Replacement Registry[10]	2013	2007	2012	1127	72
National Joint Registry for England, Wales and Northern Ireland[11]	2012	2010	2012	999	9
Finnish Arthroplasty Register[12]	2010	2000	2010	491	27
Total	—	—	—	5152	591

were implanted, including the Mobility (n = 234, 27%), STAR (n = 194, 22%), BP (n = 154, 18%), CCI Evolution (Implantcast, Buxtehude, Germany) (n = 128, 15%), and AES (Transysteme-JMT Implants, Nimes, France) (n = 117, 13%). The calculated Kaplan-Meier estimator was 0.87 at 2 years, 0.78 at 5 years, and 0.66 at 9 years.

The AOA National Joint Replacement Registry[10] reports a 6-year analysis on 1127 primary TARs performed (see **Table 2**); 72 revisions were reported. The 2 most common prosthesis implanted were the Mobility (n = 494, 44%), Hintegra total ankle prosthesis (Integra, Saint Priest, France) (n = 256, 23%), and Salto Mobile (n = 198, 18%). The reported Kaplan-Meier estimator was 0.94 at 2 years and 0.90 at 5 years.

The National Joint Registry for England, Wales and Northern Ireland[11] reports a 5-year analysis on 999 primary TARs performed (see **Table 2**); 9 revisions were reported. The 2 most common prosthesis implanted were the Mobility (n = 539, 54%) and Zenith total ankle replacement (Corin Group, Cirencester, England) (n = 210, 21%). The reported Kaplan-Meier estimator was 0.99 at 2 years.

The Finnish Arthroplasty Register[12] reports a 7-year analysis on 491 primary TARs performed (see **Table 2**); 27 revisions were reported. The 2 most common prostheses implanted were the AES (n = 298, 61%) and STAR (n = 181, 37%). The calculated Kaplan-Meier estimator was 0.87 at 2 years, 0.78 at 5 years, and 0.66 at 9 years.

The number of TAR prostheses available within a national joint registry may allow for more versatility of choosing an implant specific for each patient (**Table 3**). The Australian[10]; England, Wales, and Northern Ireland[11]; New Zealand[13–15]; and Norwegian[16,17] registries included greater than or equal to 7 TAR designs and the cumulative Kaplan-Meier estimator ranged from 0.89 to 0.93 when 5-year survival data were provided. When the AES and STAR were greater than or equal to 35% of the TAR prosthesis included within the registry,[12,16–20] the Kaplan-Meier was 0.78 to 0.89 at 5 years, whereas for registries with less than 35% of these prostheses included, the Kaplan-Meier was 0.90 to 0.93 at 5 years.[10,11,13–15]

DISCUSSION

The purpose of this study was to re-create primary TAR survival curves among available national joint registry data sets using the Kaplan-Meier estimator to determine the survival rates between registries at 1-year intervals. A total of 6 national joint registry data sets were identified that included TAR prostheses.

A review of the data allow for some generalized observations. First, the definitions of TAR failure as stated in the included registries were similar and consisted of removal or exchange of a part of or the whole prosthesis, excluding incidental exchange of the PE insert (see **Table 1**). The National Joint Registry of England, Wales and Northern Ireland[11] did not provide a definition of revision within their registry data. These definitions should continue to be monitored for consistency when included in future implants survival analysis to predictably exclude secondary procedures or PE insert exchanges as revisions.[21]

Second, the included studies spanned 2 to 13 years of national joint registry data evaluating 5152 primary and 591 TAR revisions recorded, demonstrating a lengthy follow-up period with robust patient population for evaluation. A lengthy follow-up and patient population demonstrate the generational trends apparent within the evolving TAR industry and surgeon learning curve during both primary and revision TAR.[1] For example, a systematic review of TAR prosthesis use in national joint registries was able to identify 3 general patterns of prosthesis use over a 10-year period: (1) minimal use, (2) initial embracement followed by abrupt disuse, and (3) embracement with sustained growth. Further analysis of national joint registries for those TAR prostheses

Table 3
Number of total ankle replacements implanted per prosthesis type and national joint registry

Total Ankle Replacement System/Prosthesis Type	AES[a]	Agility[b]	BOX[c]	BP[d]	CCI[e]	ESKA[f]	Hintegra[g]	Inbone II[h]	Mobility[i]	Ramses[j]	Rebalance[k]	Salto Mobile[l]	STAR[m]	Taric[n]	Zenith[o]	Total
New Zealand Joint Registry[13–15]	—	119	4	—	—	—	5	—	443	11	—	316	46	—	—	944
Norwegian Arthroplasty Register[16,17]	3	—	—	—	58	—	11	—	85	—	15	11	537	—	—	720
Swedish Ankle Registry[18–20]	117	—	—	154	128	—	—	—	234	—	44	—	194	—	—	871
AOA National Joint Replacement Registry[10]	—	2	93	59	4	1	256	—	494	—	—	198	13	—	7	1127
National Joint Registry for England, Wales and Northern Ireland[11]	—	—	72	—	—	—	43	2	539	—	15	63	54	1	210	999
Finnish Arthroplasty Register[12]	298	—	—	—	—	—	12	—	—	—	—	—	181	—	—	491

^a AES (Transysteme-JMT Implants, Nimes, France).
^b Agility (DePuy Orthopaedics, Inc, Warsaw, IN).
^c Bologna-Oxford (Finsbury, Leatherhead, United Kingdom).
^d BP (Endotec, South Orange, NJ).
^e CCI Evolution (Implantcast GMBH Lüneburger Schanze Buxtehude, Germany).
^f ESKA (GmbH & Co, Lübeck, Germany).
^g Hintegra (Integra, Saint Priest, France).
^h Inbone II (Wright Medical Technology, Memphis, TN).
ⁱ Mobility (DePuy UK, Leeds, England).
^j Ramses (Laboratoire Fournitures Hospitalières Industrie, Heimsbrunn, France).
^k Rebalance (Biomet UK Ltd, Bridgend, South Wales, England).
^l Salto Mobile Version (Tornier, Saint-Martin, France).
^m STAR (Waldemar Link, Hamburg, Germany/Small Bone Innovations, Inc, Morrisville, PA/Stryker Orthopaedics, Mahwah, NJ).
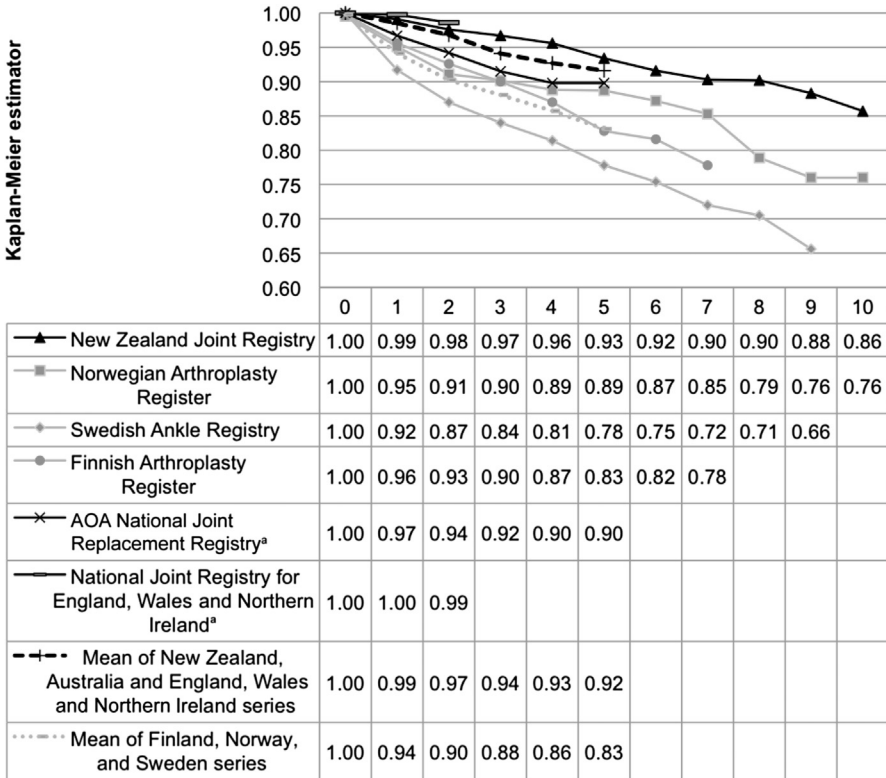ⁿ Taric (Implantcast GmbH, Buxtehude, Germany).
^o Zenith (Corin Group PLC, Cirencester, England).

that were initially embraced only to abruptly fall into disuse may help warn surgeons, industry, and the public about prosthesis design flaws or specific surgeon concerns that led to the abrupt disuse. A prime example of the initial embracement followed by abrupt disuse trend is the withdrawal of the AES prosthesis after identification of a higher than expected complication rate. Ultimately it was determined that the use of hydroxyapatite coating was the major cause of the severe aseptic osteolysis seen with the AES prosthesis (http://webarchive.nationalarchives.gov.uk/20141205150130/http://www.mhra.gov.uk/home/groups/dts-bs/documents/medicaldevicealert/con174792.pdf; last accessed August 23, 2014), and industries producing TAR systems with this coating should take heed to avoiding repeating the past. Furthermore, current TAR prostheses that are in a sustained growth period should be carefully evaluated to identify any trends in use that may be a cause for concern prior to widespread abrupt disuse. For example, analysis of the Salto Mobile prosthesis across national joint registries up to 2011 indicates it is has been embraced and is undergoing sustained growth.[5] The Salto Mobile prosthesis first appeared in the Norwegian Arthroplasty Register[16] in 2012, however, and was abruptly replaced by the fixed-bearing Salto Talaris and Salto Talaris XT total ankle prostheses (Tornier, Bloomington, Minnesota) in 2013.[22] The rationale for this abrupt conversion from the mobile to PE fixed-bearing version of the same TAR system, especially when the other TAR systems included in the registry have relatively consistent use over a much longer time period, is intriguing but unknown. Analysis over time within this and other registries may clarify the reason for this trend and herald the importance of scrutiny of primary TAR implantation trends in national joint registries.

Third, for national joint registries that included the AES, BP, or STAR as greater than or equal to 35% of total primary TARs implanted, the survival rate was 0.78 to 0.89 at 5 years compared with registries with less than 35% of these prostheses, where the survival rate was 0.90 to 0.93 at 5 years (Fig. 2). The BP was withdrawn from use in 2009 and the AES in 2010 for the reasons discussed previously.[5] The version of the STAR available for use in the United States is a single-coated titanium plasma spray on the metallic components.[4] This is an important consideration because the Norwegian Arthroplasty Register demonstrated a difference in survival between the hydroxyapatite single-coated and partially titanium–calcium phosphate double-coated version compared with the double-coated design that demonstrated better results specific to incidence of prosthetic loosening.[16,17] This same study found no difference in revision incidence between both versions of the uncemented STAR and the cemented Thompson Parkridge Richards ankle prosthesis, which was a first-generation prosthesis removed from use in 1997.[16,17] Furthermore, the Finnish Arthroplasty Register[12] demonstrated a parallel and steep incidence of revision between the double-coated version of the STAR and the AES, which, as noted, has been withdrawn from use due to higher than expected frequency of osteolytic lesions and component failure.[23] Finally, the second generation of the STAR has been demonstrated to have a similar survival rate as the first-generation version of the STAR that involved an all-PE tibial component secured with PMMA cement and a stainless steel metallic talar component[24] irrespective of age at time of implantation[25] or etiology.[26,27] This is concerning because there has been apparent widespread adoption of the porous titanium single-coated STAR in the United States (http://www.businesswire.com/news/home/20120411006339/en/Independent-Survey-U.S.-Foot-Ankle-Surgeons-Affirms; last accessed August 23, 2014). Unfortunately, multiple studies have demonstrated that the complication rate and incidence of revision are even higher than previously reported for the STAR prosthesis. Brunner and colleagues[28] presented 10.8- to 14.9-year results for 77 primary STAR prosthesis with a single coating of hydroxyapatite;

Kaplan-Meier estimator	0	1	2	3	4	5	6	7	8	9	10
New Zealand Joint Registry	1.00	0.99	0.98	0.97	0.96	0.93	0.92	0.90	0.90	0.88	0.86
Norwegian Arthroplasty Register	1.00	0.95	0.91	0.90	0.89	0.89	0.87	0.85	0.79	0.76	0.76
Swedish Ankle Registry	1.00	0.92	0.87	0.84	0.81	0.78	0.75	0.72	0.71	0.66	
Finnish Arthroplasty Register	1.00	0.96	0.93	0.90	0.87	0.83	0.82	0.78			
AOA National Joint Replacement Registry[a]	1.00	0.97	0.94	0.92	0.90	0.90					
National Joint Registry for England, Wales and Northern Ireland[a]	1.00	1.00	0.99								
Mean of New Zealand, Australia and England, Wales and Northern Ireland series	1.00	0.99	0.97	0.94	0.93	0.92					
Mean of Finland, Norway, and Sweden series	1.00	0.94	0.90	0.88	0.86	0.83					

Fig. 2. Survival of TARs based on registry data of re-created Kaplan-Meier estimators separating registries that included greater than or equal to 35% of total implants as AES and/or STAR prostheses (*black lines*) and registries that included less than 35% of total implants as AES and/or STAR prostheses (*gray lines*). [a]Kaplan-Meier estimators as reported without a survival curve re-created. (*Data from* New Zealand Joint Registry,[13–15] Norwegian Arthroplasty Register,[16,17] Swedish Ankle Registry,[18–20] Finnish Arthroplasty Register,[12] AOA National Joint Replacement Registry,[10] and National Joint Registry for England, Wales and Northern Ireland.[11])

29 (38%) of the 77 prostheses had a revision and the survival rates were 0.71 at 10 years and 0.46 at 14 years. Similarly, Clough and colleagues[29] presented 13- to 19-year results of 200 consecutive primary STAR prostheses and reported a survival rate of 0.77 (95% CI, 66.4–87.3) at 15 years. Furthermore, the complete abandonment of the STAR prosthesis in the New Zealand Joint Registry[13–15] and near-complete disuse evident in the Finnish Arthroplasty Register[12] should be carefully considered. These findings support the critical evaluation of prosthesis implantation and revision trends through national joint registries with expansion to include modes of failure as an understanding of the actual incidence of revision, the most common etiology leading to failure, and the revision options for each prosthesis system is critical to optimizing patient outcome.

Fourth, survival curves of re-created Kaplan-Meier estimators can be reliably reconstructed as demonstrated (see **Fig. 1**) and matched to the reported estimators. All values re-created are exact, as demonstrated by Finish,[12] New Zealand,[13–15] and Norwegian[16,17] registries or within the stated 95% CI, as demonstrated by the Swedish[18–20] registry data. When the survival curve is included in the registry data

and re-created in a reproducible standard method,[9] further data points can be inferred to compare time intervals that may not be clearly stated. The number and reasons of specific implant failure are lacking, which allows for re-creation of the TAR prosthesis survival curves and the ability to infer trends, such as minimal use, disuse, or sustained use, that may be related to failure rates per implant design and collectively per generation.[5,30,31]

LIMITATIONS

Kaplan-Meier survival curves are commonly used in orthopedic literature for implant survival data but are not without limitation. The Kaplan-Meier estimator is designed to estimate the probability of an event to eventually occur for all patients, such as death. This assumption does not hold true for those with a prosthetic joint replacement where component loosening or failure may occur before death. The estimator has the ability to overestimate probability of an event occurring with time in the presence of competing risks, such as revision, long-term component loosening, or failure in general as an endpoint[6,7]

The authors recommend that future peer-reviewed studies and national joint registry data include a Kaplan-Meier survival curve with the numbers at risk for complete parallel of survival outcomes. Revision rates by specific TAR prosthesis were not always reported, leading to uncertainty of prosthesis longevity based on individual design, PE insert characteristics, or other features. Future inclusion of revision rates specific to prosthesis type would lead to further understanding of TAR survival or failure trends, thereby benefiting patients, surgeons, and industry because changes could be made to the specific TAR that may ultimately improve prosthesis survival.

Reconstruction of Kaplan-Meier curves can provide further information about TAR survival but not without limitations.[8] First, a Kaplan-Meier curve does not separate information about various subgroups but, instead, pools data together over differing covariants that may affect survival, leading to aggregation bias. Second, reliability of the reconstructed data relies on the quality of initial input of information and the level of information provided by the publication. Low-quality PDF images can lead to difficulty extracting accurate data via digitization and were the result of not digitizing censored events. Future publications and national joint registry data should strive to include time-to-event outcomes, Kaplan-Meier curves with numbers at risk, and total number of events to be transparent in data re-creation or worldwide trends.

Limited peer-reviewed publications are available for prosthesis survival analysis and are often accompanied with significant selection (inventor) bias and must be interpreted with caution. The use of national joint registry data is not without error but is reported prospectively for the participating countries in a similar process involved with the peer-review process leading to publication.

SUMMARY

National joint registry data collectively provide unique information about primary TAR and subsequent revision to collectively analyze prosthesis survival. When provided, survival curves based on the Kaplan-Meier estimator can be digitized and re-created with accuracy. Overall, 5152 primary and 591 TAR revisions were included over a 2- to 13-year period, with prosthesis survival rates for all national joint registries of 0.94 (95% CI, 0.90–0.97) at 2 years, 0.87 (95% CI, 0.82–0.91) at 5 years, and 0.81 (95% CI, 0.74–0.88) at 10 years. For national joint registries that included the AES, BP, and/or STAR as greater than or equal to 35% of total prostheses implanted, the survival rate was 0.78 to 0.89 at 5 years compared with registries with less than 35% of

these prostheses at 0.90 to 0.93 at 5 years. Both the AES and BP have been withdrawn from the market and, based on available national registry data, the STAR has fallen into worldwide disuse. This finding supports the critical evaluation of primary TAR implantation and revision trends through national joint registries with expansion to include modes of prosthesis failure. The STAR system should be implanted with caution until a dedicated revision system is developed and more robust long-term data are available supporting its continued use as a primary TAR. Future studies and national joint registry data sets should continue to strive for completion of data presentation to include revision definitions, modes of failure, time of failure, and patients lost to follow-up or death for complete accuracy of the Kaplan-Meier estimator.

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