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In-Patient Trends and Complications After Total Ankle Arthroplasty in the United States

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abstract

The number of total ankle arthroplasties (TAAs) performed annually in the United States has increased. The purpose of this study was to evaluate the in-patient demographics, complications, and readmission rates of patients after TAA at academic medical centers in the United States. The University HealthSystems Consortium administrative database was searched for patients who underwent TAA in 2007 to 2011. A descriptive analysis of demographics was performed, followed by a similar analysis of clinical benchmarks, including hospital length of stay, hospital direct cost, in-hospital mortality, and 30-day readmission rates. The study included 2340 adult patients with a mean age of 62 years (47% men and 53% women) who underwent TAA. The majority of patients were Caucasian (2073; 88.5%). Average hospital length of stay was 2.2 ± 1.26 days. Average total direct cost for the hospital was $\$16,212 \pm 7000$ per case, with 49.7% of patients having private insurance. In-hospital mortality was less than 1%, and overall complications were 1.4%. Complications after discharge included deep venous thrombosis (2.3%), reoperation (0.7%), and infection (3.2%). A readmission rate of 2.7% within the first 30 days from the time of discharge occurred. Total ankle arthroplasty in the United States is a relatively safe procedure with low overall complication rates. Patients who are male, have a history of community-acquired pneumonia, and have a larger number of preoperative comorbidities had a significant increased risk of developing 1 complication within 30 days of surgery. [*Orthopedics*]

tis has progressed slowly and hit several road bumps, despite the widespread acceptance of arthroplasty as the treatment of choice for end-stage arthritis of the hip and knee. First-generation TAA designs, released in the 1970s, had high complication and failure rates compared with arthrodesis, which remains the primary treatment for ankle osteoarthritis. However, arthrodesis has its own complications, such as pathology at adjacent joints including progressing arthrosis that may result in persistent pain and decreased range of motion.^{3,4}

More than 20 TAA systems have been developed worldwide, but between 1992 and 2005, the Food and Drug Adminis-

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Total ankle arthroplasty (TAA) has emerged as a viable alternative treatment for end-stage arthritis in the ankle, particularly in those patients

who are less active, non-obese, older than 50 years, and have adjacent joint arthritis.^{1,2} Documented success for TAA as a treatment for end-stage ankle arthri-

tration (FDA) had only approved 1 fixed-bearing system in the United States (Agility; DePuy Synthes, Raynham, Massachusetts). Between 2005 and 2006, the FDA granted approval to 3 additional fixed-bearing systems (IN-BONE, Wright Medical Technology, Inc, Memphis, Tennessee; Salto, Tornier, Inc, Bloomington, Minnesota; and Eclipse, Kinetikos Medical, Inc, Carlsbad, California) and the Agility system (DePuy, Warsaw, Indiana) released a major revision.

In 2009, the FDA approved its first and only mobile-bearing system (STAR; Small Bone Innovations, Morrisville, Pennsylvania). These later generation ankle designs seek to allow patients' lower extremity to follow a normal gait pattern with improved range of motion and, therefore, lower the incidence of adjacent joint arthritis. A recent meta-analysis shows an almost 90% survivorship at 10 years for the third-generation TAA implants.⁵ However, most studies purporting the effectiveness of these newer designs have used international registries (Norway, Finland, Sweden, New Zealand, and United Kingdom), which contain outcome data unavailable in the United States, as well as hardware that is not yet FDA approved.⁵⁻⁹

The authors isolated their study to TAA procedures performed at academic medical centers in United States from 2007 to 2011 to evaluate the in-patient demographics, complications, and readmission rates of approximately 2300 patients. Although the type of implant used in each case is unknown, the study date begins in 2007, when the later generation TAA designs approved in the United States were predominantly used. Although many international studies have used large patient registries, most US-focused studies have looked at relatively small sample sizes (<300 patients). The current study seeks to provide a more comprehensive overview of TAA trends, patient demographics, and complications in the United States using an in-patient database.

MATERIALS AND METHODS

A national administrative database of academic medical centers that tracks patients and hospital-specific outcomes was used to characterize patient trends. The University HealthSystems Consortium (UHC) is an alliance of the nation's leading nonprofit academic medical centers, with 116 academic medical centers and 261 affiliated hospital members. The UHC membership includes more than 90% of the nonprofit academic medical centers in the United States. It provides patient, hospital, and financial outcomes across different centers. The data in the UHC database are primarily acquired from submitted UB-04 billing forms, similar to the forms submitted by hospitals to receive reimbursement.

The UHC clinical data base resource manager (CDB/RM) provides the following information: synthetic hospital and surgeon identifiers, including specialty; unique patient visit identifiers; patient demographics; financials; procedural; and diagnostic information. Morbidity is defined using the UHC morbidity profiler. Both cost and charge information are reported in the CDB/RM. Charges are reported by each center and costs are calculated using institution-specific cost-to-charge ratios obtained from the department-level Medicare cost reports. Federally reported area wage indices are used to account for regional- and center-specific cost variations that are not directly attributable to a center.

The UHC has developed a severity of illness score for both risk adjustment and predicted resource allocation. This risk assessment method has been verified and validated by the UHC. Severity of illness takes into account several patient variables and weights them in the context of their illness, including other comorbid conditions, age, and diagnoses.¹⁰

The authors retrospectively queried the UHC administrative database from 2007 to 2011 for adult patients 18 years or older who underwent an elective TAA

procedure. Elective TAA was defined by the type of admission (elective) and the *International Classification of Diseases, Ninth Revision, Clinical Modification* (ICD-9-CM) procedural codes (81.56). A descriptive analysis of patient demographics was performed and included patients' age, sex, race, and insurance status (private, Medicaid, Medicare, government, and other). The outcomes of interest were perioperative morbidity, hospital length of stay¹¹ (defined as the interval from the date of procedure to the date of discharge), hospital direct cost, index hospitalization survival, complications, and 30-day readmission. Cost was defined as an expense that could be directly traced to the care of a patient, whether it was services or supplies rendered. In addition, a univariate analysis was performed to identify preoperative factors that would predict an increased risk of 30-day complications.

RESULTS

The authors identified 2340 TAA cases that were performed at associated institutions across the United States from 2007 to 2011. Of the 116 academic medical centers, TAA was performed in 95 academic centers (**Table**). The majority of centers (73 of 95) performed fewer than 10 TAAs. Four centers performed 50 to 100 cases and 6 centers performed 100+ cases during that same period. As suspected, most of the reported cases were done at a few institutions, and the highest total number of cases performed at one institution was 365. Although the majority of the institutions had a stable or increasing number of cases performed, there were 2 institutions that had a significant decrease.

Within this patient population, 53.1% were women and 46.9% men. Combined, the average age at which the cohort underwent surgery was 62.5 years. Of the 2340 patients, 2073 (88.6%) were white, 84 (3.6%) were African American, 23 (1%) were Hispanic, 18 (0.8%) were Asian, and

Table	
Total Number of Total Ankle Arthroplasties Performed From 2007 to 2011 in Academic Centers in the United States	
No. of Total Ankle Arthroplasty Cases	No. of US Academic Centers
0-10	73
11-50	12
51-100	4
>100	6

5 (0.2%) were Native Americans. The majority (67.1%) had a chronic medical condition. Average length of hospital stay was 2.2 days (Figure 1). The majority of patients (88.5%) were discharged home after their hospital stay, with a readmission rate of 2.7%. Average total direct cost was \$16,212 (range: \$1142 to \$94,827) (Figure 2). Medicare covered 48.5% of the patients, Medicaid covered 1.8% of patients, and policy or payment method other than Medicaid/Medicare covered 49.7% of the patients (Figure 3).

The overall complication rate for this procedure was 1.4% (Figure 4). Complications included 10 (0.4%) mechanical issues with the implant, 6 (0.3%) aspiration pneumonia, 1 (<0.01%) urinary tract infection, 1 (<0.01%) sepsis, and 14 (0.6%) miscellaneous complications. The majority of patients were discharged routinely (70.6%), whereas 17.9% were discharged to their home under the care of organized home health services, 8.5% were discharged to a nursing facility, 2.1% were discharged to a rehabilitation facility, and less than 1% were discharged elsewhere.

Univariate logistic regression analysis was also performed and found that patients who are male, who had history of community-acquired pneumonia, and

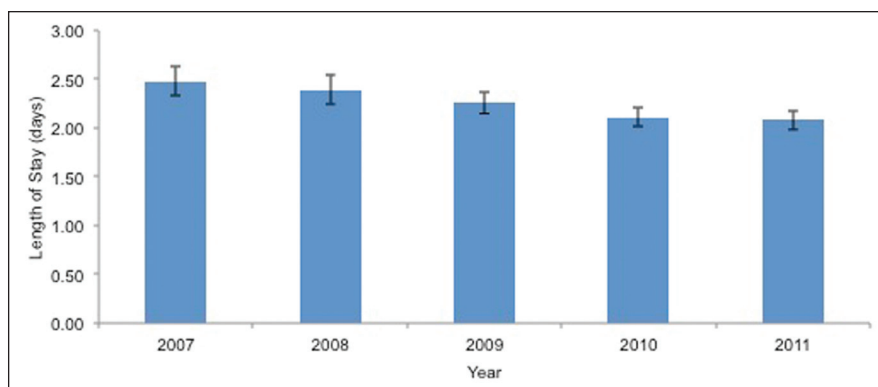


Figure 1: Bar graph showing the average length of stay for patients undergoing total ankle arthroplasty from 2007 to 2011.

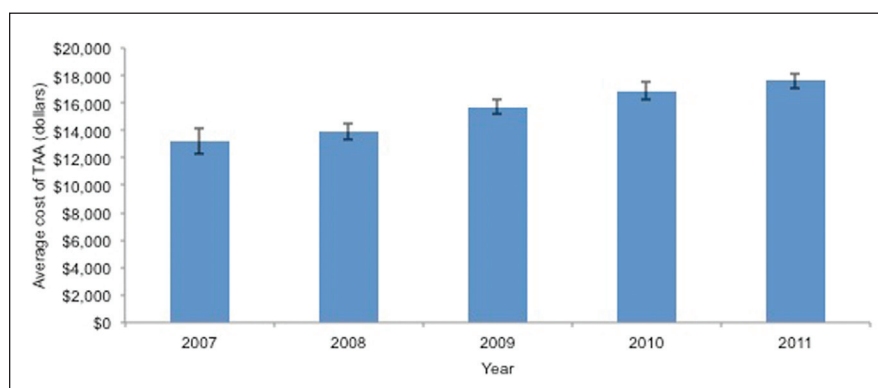


Figure 2: Bar graph showing the average cost of total ankle arthroplasty (TAA) per patient in the United States from 2007 to 2011.

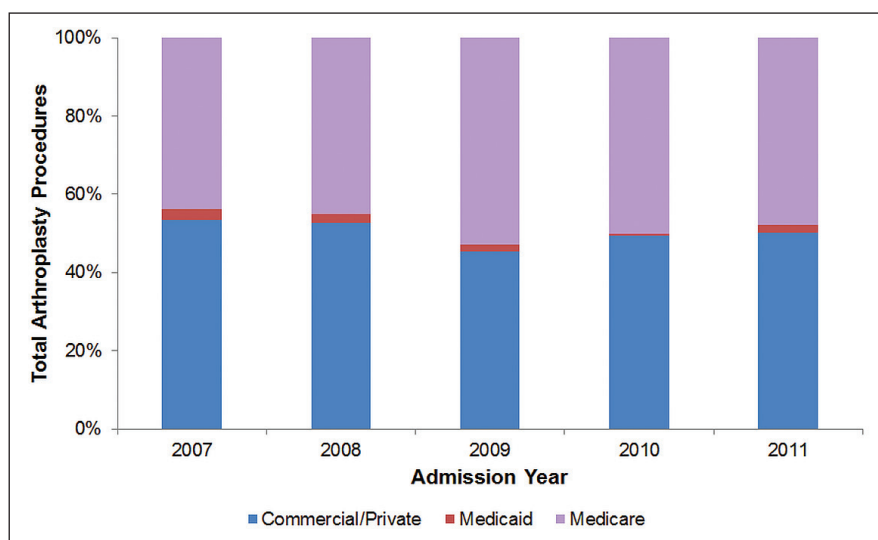


Figure 3: Bar graph showing the type of insurance for patients undergoing total ankle arthroplasty from 2007 to 2011.

those with an increasing number of pre-operative comorbidities had a statistically significant risk of developing 1 complication within 30 days of surgery.

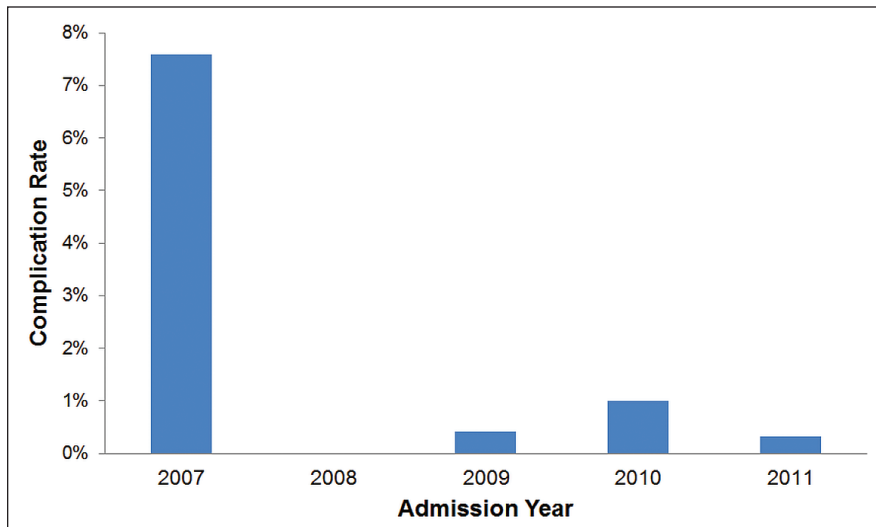


Figure 4: Bar graph showing the overall complication rate of patients after total ankle arthroplasty from 2007 to 2011.

DISCUSSION

The current study found that the incidence of TAA has increased in the United States annually. Although TAA was more likely to be performed on female patients in the past, the gender skew has equalized over time. With the approval of later generation TAA systems in the United States, hospital length of stay, complications, and readmission rates have decreased but the cost of treatment and payment by Medicare/Medicaid has increased.

Consistent with trends in other countries,⁶ the current study found that the incidence of TAA has increased in the United States, with the number of TAA procedures doubling from 290 in 2007 to 632 in 2011 as the procedure gained popularity among orthopedists. This increase in usage may also partially reflect the increasing incidence of traumatic ankle injuries and thus an increase in the incidence of osteoarthritis.¹² However, both Pugely et al¹³ and Terrel et al¹⁴ found that although volume and per-capita utilization of TAA has increased dramatically since 1991, per-capita utilization of ankle arthrodesis has remained nearly constant, suggesting that there is an increasing patient population who fit the criteria for the TAA pro-

cedure and more surgeons who are willing to offer this procedure to those patients.

Mounting evidence supporting the use of TAA as a safe and effective alternative treatment for ankle osteoarthritis has likely influenced the increase in the popularity of this procedure. Specifically, Haddid et al¹⁵ found that the mid-term functional outcome of TAA is similar to that of ankle arthrodesis.

The current registry did not record the cause of arthritis necessitating the TAA. Posttraumatic injury, such as ankle fractures or ligamentous injury, causes 70% of cases of osteoarthritis, whereas 12% of cases were from rheumatic disease and 7% of cases were from primary osteoarthritis.¹⁶ However, among TAA patients, posttraumatic injury osteoarthritis the primary indication for only 46% of cases, with 27% caused by primary osteoarthritis and 19% caused by rheumatoid arthritis.⁵

The current authors found the average age of patients undergoing TAA to be 62.5 years, which is slightly older than prior studies showing an average range of 50 to 60 years.^{6,7,9,17-20} Although the current study does not have survival data, an older average population age is often associated with a higher survival rate. Spirt et al²¹ found that a higher survival rate (89%)

in patients older than 54 years compared with patients younger than 54 years (74%). Henricson et al⁷ found that women with osteoarthritis who underwent TAA younger than 60 years had a statistically significant higher risk of revision compared with those that were older than 60 years. This finding maybe secondary to the increased activity level of younger patients when compared with the older patients after TAA.

In the current study, 53% of patients were women and the gender distribution has trended toward a 50/50 ratio in men/women over time. The percentage of female patients has decreased successively each year since 2007, when 56.2% of patients were women. In 2011, male patients (50.3%) outnumbered female patients (49.7%) for the first time, suggesting that TAA has gained in popularity as a treatment for men in the United States. Terrell et al¹⁴ reported even gender distribution in patients undergoing TAA; however, more male patients had arthroscopic or open fusion for ankle arthritis.

The trend toward roughly equal gender distribution for TAA in the United States stands in contrast with more skewed usage internationally. The majority of patients in Finland (63%) and Norway (71%) are women, whereas 60% of patients in New Zealand were male (40% female).^{6,8,9} The current study also challenges earlier studies, which suggested that TAA is more likely to be performed on older, female patients.¹⁴ The trend toward gender equality in TAA raises the question of whether the gender skew for ankle arthrodesis has changed. The majority of patients in the current study were white (88.6%). This number has actually trended higher over time, from 84.5% in 2007 to 91.9% in 2010 (but down to 89.9% in 2011). Only 3.6% of patients were Black and 1% Hispanic.

Although the average length of stay has decreased steadily since 2007, the average cost of TAA has increased steadily. In 2010, the average length of stay was only 2.08 days, down 16% from 2007 (an

average of 2.48 days). Over the same time period, the average cost of the procedure has increased 33% to \$17,614 (vs \$13,203 in 2007). This is likely due to the incorporation of the newer generation of more expensive implants into clinical practice. Despite the increase in cost of the implants, Courville et al²² found TAA to be a cost-effective alternative to ankle fusion in patients older than age 30 years based on quality-adjusted life scores and willingness to pay thresholds.

With a short-term postoperative complication rate of 1.4%, the current study further supports the use of TAA as a safe treatment plan. Data from 2007 actually skewed the study's complication rate upward because 22 of the 32 total complications during the current study occurred during that year. After 2007, the 30-day complication rate was less than 0.5%. This lower complication rate after 2007 possibly reflects the hardware design improvements of the new systems introduced in November 2006 (Salto, Eclipse, Agility Revision) or the surgeons' increasing familiarity with the new devices after an initial year of use. Of the 32 complications that did occur, miscellaneous complications contributed to 44% of complications, mechanical issues with the implant contributed to 32%, aspiration/nosocomial pneumonia contributed to 19%, urinary tract infection contributed to 3.1%, and sepsis contributed to 3.1%.

The overall complication rate is significantly lower than a recently reported meta-analysis that quoted an overall complication rate of 13.5%.⁵ However, the current complications were limited to short-term reporting of in-hospital and 30 days post-procedure. In addition, in 2008, there were no self-reported complications associated with TAA in this database, which can also provide bias to the overall complication rate of the current study. Mechanical complications occurred in only 0.4% of patients in the current study. Mechanical complications listed in other studies include

nontraumatic fractures of the tibia during implant insertion and fractured inserts at rates of 3.2% to 29% and less than 1%, respectively.^{24,25,31} Other common complications quoted in literature include infections (3.2% to 13%), wound healing issues (1.6% to 14%), and postsurgical pain (2% to 4%).^{6-9,23-31} Although these complications are not reflected in the current study, they are common reasons for readmission.

In addition, the current authors found that male patients, a medical history of pneumonia, and a higher number of preoperative comorbidities significantly increased the risk of having a postoperative complication within 30 days of surgery. The current study had an average readmission rate of 2.7%. However, the readmission rate decreased steadily between 2007 and 2011, with approximately half as many patients being readmitted in 2011 (2.2%) as in 2007 (4.1%). Discharge trends did not change significantly over time.

Payer mix was roughly evenly split between Medicare/Medicaid (50.3%) and commercial/private/other insurances (49.7%). This split had trended toward parity in 2011 compared with 2007, when only 46.6% of TAA patients were covered by Medicare/Medicaid and 53.4% were covered by commercial/private/other insurances.

Given that the current study used an in-patient multicenter database, the authors' conclusions were constrained by the available data and subject to several biases, particularly selection, detection, and reporting biases. Furthermore, UHC does not provide indications for surgery, reasons for readmission, outcomes, or long-term complications. The authors also do not know the type of device used in each case or the experience level of the surgeon performing the procedure. They also do not know whether the increasing incidence of TAA procedures is the result of more cases of end-stage arthritis of the ankle or an increase in favor among orthopedists.

CONCLUSION

In the United States, TAA is a relatively safe procedure with low overall complication rates (1.4%). Average hospital length of stay after the procedure is approximately 2 days; the average total direct hospital cost is \$16,000±\$7000; and there is a 2.7% readmission rate within 30 days. The majority of patients were white and payers were evenly split between private insurance and Medicare/Medicaid. Patients who are male, those with a history of community-acquired pneumonia, and those with increasing number of preoperative comorbidities had a significant increased risk of developing 1 complication within 30 days of surgery.

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