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Registry Data Trends of Total Ankle Replacement Use

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ABSTRACT

Joint arthroplasty registry data are meaningful when evaluating the outcomes of total joint replacement, because they provide unbiased objective information regarding survivorship and incidence of use. Critical evaluation of the registry data information will benefit the surgeon, patient, and industry. However, the implementation and acceptance of registry data for total ankle replacement has lagged behind that of hip and knee implant arthroplasty. Currently, several countries have national joint arthroplasty registries, with only some procuring information for total ankle replacement. We performed an electronic search to identify publications and worldwide registry databanks with pertinent information specific to total ankle replacement to determine the type of prostheses used and usage trends over time. We identified worldwide registry data from 33 countries, with details pertinent to total ankle replacement identified in only 6 countries. The obtained information was arbitrarily stratified into 3 distinct periods: 2000 to 2006, 2007 to 2010, and 2011. Within these study periods, the data from 13 total ankle replacement systems involving 3,980 ankles were identified. The vast majority (97%) of the reported ankle replacements were 3-component, mobile-bearing, uncemented prostheses. Three usage trends were identified: initial robust embracement followed by abrupt disuse, minimal use, and initial embracement followed by sustained growth in implantation. Before the widespread acceptance of new total ankle replacements, the United States should scrutinize and learn from the international registry data and develop its own national joint registry that would include total ankle replacement. Caution against the adoption of newly released prostheses, especially those without readily available revision components, is recommended.

The early history of total ankle replacement arthroplasty consisted of uninterrupted clinical failure and, accordingly, was rendered nearly extinct (1–8). However, dissatisfaction with ankle joint arthrodesis (9–11) and the success of total hip and knee implant arthroplasty (12), combined with the efforts of innovative surgeons and industry working together to address the problems associated with the early generation implant designs, have resulted in renewed interest in total ankle replacement. Thus, newer generation total ankle replacement designs are considered more biomechanically rational to mimic the motion of the native ankle joint, with better balance mobility and constraint and appreciation of the soft tissue ligament contribution to ankle and hindfoot function (1–10). Additionally, these implants are capable of more accurate insertion, with improved instrumentation, and allow for biologic on-growth to promote long-term fixation (1–10). However, total ankle replacement, regardless of the design, has continued to have unpredictable long-term survivorship (1–15). Recent systematic reviews of the Agility® (DePuy Orthopaedics, Warsaw, IN) (16) and Scandinavian Total Ankle Replacement® (STAR, Waldemar Link, Hamburg, Germany/Small Bone Innovations, Morrisville, PA) (17) systems revealed a markedly greater incidence of revision using noninventor, non–paid-consultant data. However, these potentially biased studies account for most of the implant-specific data available for review and highlights the importance of nonindustry-based data collection and analysis.

The use of joint replacement registries would be one such tool because they allow for large-scale prospective data collection and analysis of patient-related and prosthetic component data and universally include revision as the primary outcome (18,19). A movement has begun to include universally accepted and validated patient-derived outcomes data along with specific radiographic data to improve the sensitivity of the assessment. In general, registries provide the following information:

1. Timely feedback to surgeons and industry
2. A sentinel for complications
3. A reduction in patient morbidity

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4. The monitoring of new surgical techniques and implant technology
5. Indications of poor implant design (20)

One example of all 5 benefits is the response to lipid contamination associated with the Sulzer total hip arthroplasty components (Centerpulse Orthopedics, Austin, TX) identified in 2000. At that time, 17,500 contaminated components had been implanted in the United States, and 3,000 were later revised (21). In contrast, Swedish surgeons were notified by analysis of their registry data of the unacceptably high failure rate at nearly the same time, and the implants were discontinued after only 30 had been used, with 5 later revised (22). A more recent example includes the recall of more than 7,700 ADEPT® 12/14 Modular Head (DePuy Orthopaedics) implants used in total hip replacement from 21 countries after a review of registry data regarding its revision rate. The implant was determined to have a cumulative revision rate of 12.1% at 7 years, according to the results analyzed from the U.K. National Joint Registry Supplier Feedback data and a cumulative revision rate of 7.1% at 3 years in the Australian Orthopaedic Association National Joint Replacement Registry (available at: www.mhra.gov.uk/home/groups/fsn/documents/fieldsafetynotice/con222579.pdf; accessed June 10, 2013).

However, despite the development of the first total joint registry by Mayo Clinic physician Mark B. Coventry, MD, in 1969 (available at: http://orthodoc.aaos.org/ajrr/Revolutionizing%20Joint%20Replacement%20Research-Gioe.pdf; accessed June 10, 2013) and with significant effort to encourage participation (23), the United States does not have a formal national joint replacement registry (24). The 3 U.S.-based registries that exist do not include total ankle replacement (American Joint Replacement Registry, available at: http://teamwork.aaos.org/ajrr/default.aspx; Kaiser Permanente National Implant Registries, available at: http://www.kpimplantregistries.org/Registries/Total_Joint.htm; and U.S. Health East Joint Replacement Registry, available at: http://www.healtheast.org/orthopaedic-care; accessed June 10, 2013). One registry system in the United States that does include ankle replacement is the proprietary EVEREST Lower Extremity Registry, which tracks the INBONE® systems (Wright Medical Technology, Arlington, TN). However, the data ares protected and only available to corporate-selected surgeons (25,26). Although analysis of worldwide registry data involving total ankle replacement has been limited, the available data raise concerns about the incidence of revision. One publication determined that the revision rate after primary total ankle replacement was more than 20% at 5 years and more than 40% at 10 years, much greater than the that from the total knee and hip replacement data for the same periods (12). Similarly, another review of registry data demonstrated a nearly threefold increase in the 10-year revision rate of total ankle replacement compared with total knee and hip replacement (13).

We were able to identify 57 total ankle replacement implants developed for clinical use (Fig. 1) involving 10 different design criteria (Fig. 2). Despite no definitive evidence to support mobile-bearing device superiority compared with fixed-bearing devices regarding the incidence of revision and patient-related satisfaction data (27), the worldwide use of mobile-bearing devices has clearly eclipsed that of fixed-bearing devices. However, currently, the U.S. public can receive only 1 of 5 metal-backed, fixed-bearing, cemented total ankle replacement devices that have been cleared according to the 510(k) rules and one 3-component, mobile-bearing, uncemented device approved by the Food and Drug Administration (FDA) for general use. The fixed-bearing, cemented total ankle replacement devices can be cleared for use in the United States under the Medical Device Amendments of 1976 without premarket clinical data, but any new mobile-bearing, uncemented device requires full FDA approval. Perhaps because of this difference in entry to the U.S. market, 1 company converted their successful 3-component, mobile-bearing, uncemented total ankle replacement system (Salto Mobile Prosthesis, Tornier SA, Saint Ismier, France) to a fixed-bearing cemented design (Salto Talaris Anatomic Ankle, Tornier, Bloomington, MN; available at: http://www.accessdata.fda.gov/cdrh_docs/pdf9/K090076.pdf; accessed June 10, 2013). Searching the U.S. National Institutes of Health for studies involving total ankle replacements failed to yield any trials involving implants not currently available for general use in the United States (available at: http://www.clinicaltrials.gov/ct2/results?term=ankle+replacement&Search=Search; accessed June 10, 2013). However, since the United States has limited access to 3-component, mobile-bearing, uncemented total ankle replacements, it would seem prudent to understand the trends in specific implant use and disuse in other countries. An analysis of the worldwide registry data collected during a sufficient period could help with this determination. Because no such study exists, we undertook a detailed observational analysis of the available worldwide registry data involving specific total ankle replacement use in an effort to determine any trends in usage of newly released designs and those that have fallen into disuse.

Materials and Methods

An electronic database, OvidSP-Medline (available at: http://ovidsp.tx.ovid.com/; last accessed June 10, 2013) was searched from October 2012 to June 2013, with no restriction regarding date or language of publication, using an inclusive text word query for "ankle arthroplasty" OR "ankle implant" OR "ankle replacement" AND "database" OR "registry" OR "revision surgery," in which the capitalized words represent the Boolean operators used. The references from the identified studies were manually searched for additional potentially pertinent published works, which were then secured for review. Additionally, the 33 listed joint registries identified worldwide were seached in detail (available at: www.arthroplastywatch.com/?page_id=5; last accessed June 10, 2013). Also, the specific guardians of the registry data were electronically contacted in an effort to secure relevant data regarding total ankle replacement. Finally, 2 Internet-based search engines, Google (http://www.google.com; last accessed June 10, 2013) and Google Scholar (http://scholar.google.com; last accessed June 10, 2013), were used to identify the available sources that could potentially provide useful information, using combinations of the text words listed.

If a reference could not be obtained through purchase, librarian assistance, or electronic mail contact with the author, it was excluded from consideration. If the reference was not written in English, the entire content of the reference was translated from its native language of Danish, German, or Romanian to English using an Internet-based translator (Google Translate; available at: http://translate.google.com/#; last accessed June 10, 2013).

Results

The search for potentially eligible information for inclusion yielded 5 publications and 5 online Internet-based updates involving total ankle replacements. Australia (28), England/Wales (29), Finland (30), New Zealand (31–33), Norway (34,35), and Sweden (36,37) had data available from their registry data sets that involved total ankle replacements. Using the release into, or withdrawal from, the market for the specific total ankle replacements included in the various registry data systems, we arbitrarily stratified the data into 3 study periods: 2000 to 2006, 2007 to 2010, and 2011. The data from 13 total ankle replacement systems involving 3,980 ankles was collected worldwide from 2000 to 2011 (Table 1). The most frequently implanted prosthesis was the Mobility™ (n = 1,307, 33%; DePuy UK, Leeds, United Kingdom).

A review of the data presented in Table 1 revealed that the disuse of certain total ankle replacement systems within the countries that included total ankle replacement in their national joint registry system was obvious. Specifically, the Agility® has not been implanted since 2007 and only 3 times from 2006 to 2007. The Ankle Evolutive System (Transysteme-JMT Implants, Nimes, France) has not been implanted since 2008 and was withdrawn from use in 2012 (available at: http://www.mhra.gov.uk/home/groups/dts-bs/