AMERICAN ORTHOPAEDIC FOOT & ANKLE SOCIETY

Foot & Ankle International®
1–10

DOI: 10.1177/1071100715609719
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Inconsistency in the Reporting of Adverse Events in Total Ankle Arthroplasty: A Systematic Review of the Literature

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Abstract

Background: Systems for classifying complications have been proposed for many surgical subspecialties. The goal of this systematic review was to analyze the number and frequency of different terms used to identify complications in total ankle arthroplasty. We hypothesized that this terminology would be highly variable, supporting a need for a standardized system of reporting.

Methods: Studies that met predefined inclusion/exclusion criteria were analyzed to identify terminology used to describe adverse events. All terms were then tabulated and quantified with regard to diversity and frequency of use across all included studies. Terms were also grouped into 10 categories, and the number of reported occurrences of each adverse event was calculated. A reporting tool was then developed.

Results: Of 572 unique terms used to describe adverse outcomes in 117 studies, 55.9% (320/572) were used in only a single study. The category that was most frequently reported was revision surgery, with 86% of papers reporting on this event using 115 different terms. Other categories included "additional non-revision surgeries" (74% of papers, 93 terms), "loosening/osteolysis" (63% of papers, 86 terms), "fractures" (60% of papers, 53 terms), "wound problems" (52% of papers, 27 terms), "infection" (52% of papers, 27 terms), "implant problems" (50% of papers, 57 terms), "soft tissue injuries" (31% of papers, 30 terms), "heterotopic ossification" (22% of papers, 17 terms), and "pain" (18% of papers, 11 terms).

Conclusion: The reporting of complications and adverse outcomes for total ankle arthroplasty was highly variable. This lack of consistency impedes the accurate reporting and interpretation of data required for the development of cohesive, evidence-based treatment guidelines for end-stage ankle arthritis. Standardized reporting tools are urgently needed. This study presents a prototype worksheet for the standardized assessment and reporting of adverse events.

Level of Evidence: Level-III, decision analyses, systematic review of Level III studies and above.

Keywords: complications, ankle arthroplasty, ankle replacement, outcomes research, ankle surgery, ankle arthritis

Introduction

Evidence indicates that end-stage ankle arthritis is as debilitating as end-stage hip arthritis.[31] Accepted surgical treatments include total ankle arthroplasty and ankle arthrodesis. However, the relative merits of these 2 procedures continue to provoke considerable debate in the orthopedic community. Although the benefits and disadvantages of each have been extensively documented in the literature,[*] only a few recent studies have directly compared these procedures in terms of clinical outcomes and complications.[20,34,55,57,72,73,79]

If surgeons are to make educated treatment decisions, it is imperative that they have access to consistent, reliable reporting of both favorable and adverse outcomes. Only then can the benefits and potential disadvantages of all treatment options be weighed against the goals of the individual patient.

The reported complication rates for both total ankle arthroplasty and ankle arthrodesis have been extremely variable, ranging from 7% to 60%.[†] Likewise, the rate of

*References 10, 16, 17, 20, 21, 23, 26, 27, 29, 30, 32, 34, 48, 54, 55, 57, 67, 68, 72, 73-75, 78, 79, 82, 85, 89.

[†]References 1-3, 16, 20, 21, 24, 30, 51, 55, 68, 69, 81, 89.

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implant failure has ranged from 1.3% to 32.3%.[30] These wide variations indicate a lack of consistency either in technique or in the reporting of complications.

One solution to this problem lies in the development and validation of a classification system for complications. The Clavien-Dindo system was developed for use in general surgery.[15] While such standardization has generally been lacking in orthopedic surgery,[33] the Knee Society recently developed a standardized list of complications and adverse outcomes for accurate reporting of total knee arthroplasty outcomes.[37] Sink et al[77] have modified and validated the Clavien-Dindo complication classification system for hip surgery. Iorio et al[42] then further stratified these standardized complications and adverse events according to severity.

Despite a proposal by Glazebrook et al,[32] no standardized classification system has yet been adopted for total ankle arthroplasty surgery. The purpose of the present systematic review of the literature, therefore, was to investigate the types of peri- and postoperative complications that have been most frequently reported for total ankle arthroplasty, and to evaluate the terminology used for the reporting of these adverse outcomes. We hypothesized that this terminology would be highly variable, suggesting a pressing need for a standardized system of reporting.

Methods

Data Collection

Standard systematic review methods were used.[19,53] Initially, a prospective protocol was written to describe the objectives, search criteria, study selection criteria, predefined exclusion criteria, variables of interest, and plans for analysis. According to this protocol, a broad search of the literature spanning almost 16 years, from January 1998 until September 2013, was conducted. MEDLINE was searched via PubMed using the following search algorithm: [“ankle replacement” OR “ankle arthroplasty”]. All clinical study designs were eligible for inclusion.

Exclusion criteria were as follows: meta-analyses, review articles, technique guides, not directly related to ankle arthroplasty, written in a non-English language, lacking an available abstract, fewer than 10 arthroplasties reported, or limited to radiographic outcomes or gait analysis. Outcome studies published prior to 1998 were also excluded, as these were assumed to involve earlier implant designs not directly relevant to current practice.

In the initial analysis of terminology, publications that involved the same patient population (ie, kinship studies) were included in the data set as separate studies, based on the hypothesis that each study in a kinship group may report different complications or use different terms. However, each group of kinship studies was then combined as a single cohort, in order to minimize double counting of patients while tabulating the number of reported occurrences for each adverse event. The number of occurrences of a specific adverse event was taken from the study that reported the greatest number of events within the kinship group.

All terms describing complications, adverse events, or adverse outcomes and the frequency of said event from each eligible publication were then tabulated into a data-extraction database (Excel; Microsoft, Redmond, WA) by one fellowship-trained reviewer familiar with total ankle arthroplasty and the literature involved. These terms were then confirmed by a nonblinded second fellowship-trained researcher. If a discrepancy was found, the paper and terms in question were discussed until a consensus decision was reached. If multiple descriptors were used throughout a study, the most specific term was used to reduce the incidence of event reporting duplication.

Outcome Measures

The primary outcome measure for this study was the number of unique terms extracted from all included studies, as described above. The secondary outcome measure was the number of reported occurrences for each adverse event in the reviewed literature.

Construction of Standardized Reporting Tool

A worksheet was developed listing the most commonly reported adverse events, identified using a limited number of standardized terms. The list of adverse events and surgical interventions represented on the worksheet were based on the frequency of reporting within the generated categories, as well as the number of occurrences reported in the literature.

Statistical Analysis

The total number of unique terms used throughout the literature was calculated using the final data set compiled from the database of terms. The frequency of use for each unique term was calculated by dividing the number of studies that included a specific term by the total number of studies analyzed. The number of reported occurrences for specific adverse events was calculated by summing the reported frequency of each unique term across all studies reviewed. The reviewers were then able to sort the reported complications into 10 categories of adverse events. This information was then used to guide development of a standardized reporting tool in the form of a simple worksheet.

Results

The initial search algorithm identified 1588 potentially eligible studies, which were retrieved for further review. A total

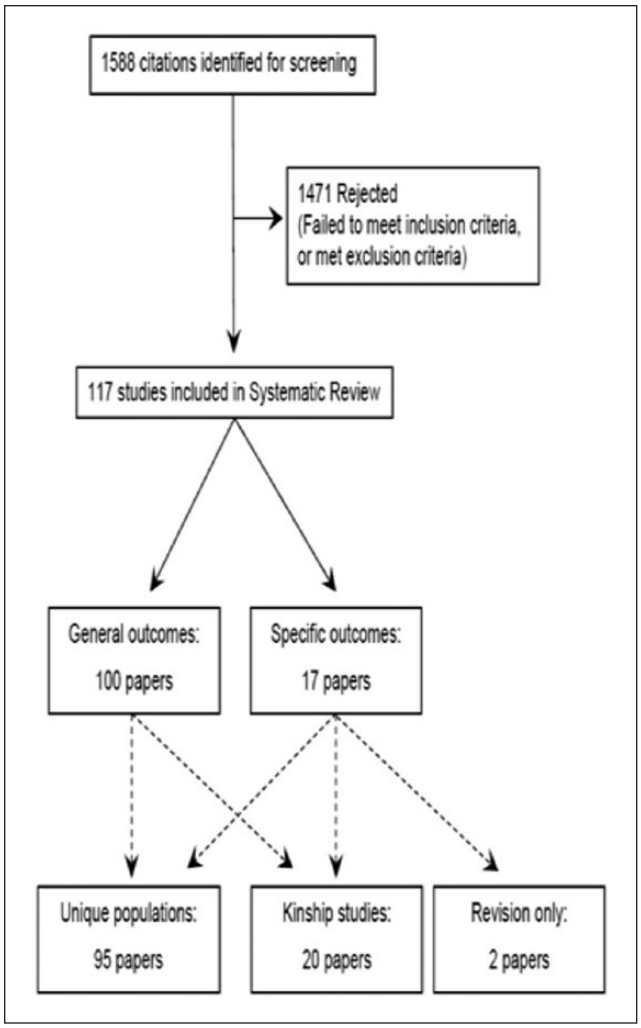


Figure 1. Study attrition diagram. This algorithm outlines the filtration of studies from inception to conclusion of the project. Note the substantial number of studies that were rejected on the basis of rigid inclusion and exclusion criteria.

of 117 studies (Appendix A, available online at http://fai.sagepub.com/supplemental) met all eligibility criteria for inclusion and exclusion and were included in the database. Study attrition is outlined in the flow diagram in Figure 1. A total of 10 261 ankle arthroplasties were included in these 117 studies. Ninety-five studies had unique cohort populations, whereas 20 were identified as kinship studies in which 2 or more papers reported on the same cohort of patients, and 2 papers focused on revision arthroplasty. One hundred studies reported on general outcomes (ie, all events related to the treatment of patients with total ankle arthroplasty), whereas 17 examined specific outcomes and adverse events (ie, limited-focus papers analyzing a particular event, such as heterotopic ossification[14,50] or osteolysis[52]). The mean follow-up was 44.1 months (range: 10 days to 296 months).

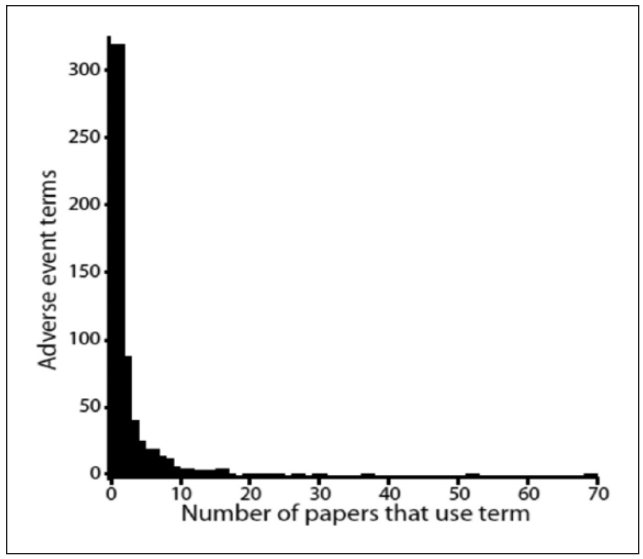


Figure 2. Histogram showing incidence of use of unique terms for adverse events found in citations analyzed in the present systematic review of the literature. The x-axis indicates the number of studies that used a particular term to describe an adverse event (ie, the incidence of use of that term in the reviewed studies); the y-axis indicates the number of unique terms with a particular incidence of use (eg, 320 terms were used in a single study, 90 terms were used in 2 studies, etc).

Quantitation of Term Usage

In the 117 studies analyzed, 572 unique terms were used to describe adverse events during or following total ankle arthroplasty (Appendix B, available online at http://fai.sagepub.com/supplemental). More than half of these terms (55.9%, 320/572) were used in only a single study and did not occur elsewhere in the literature on ankle arthroplasty. Only 4.9% of terms (28/572) were used in 10 or more studies (Figure 2).

The most frequently reported terms used to describe adverse events were "revision to fusion," used in 59% of studies (69/117), and "revision to total ankle replacement/arthroplasty," which was noted in 44% (51/117) of studies. Of the 28 terms that were reported in 10 or more studies, 64% (18/28) referred to nonrevision additional surgeries. Other commonly reported events were related to fractures, wound healing, infection issues, subsidence, heterotopic ossification, and failure (Appendix B, available online at http://fai.sagepub.com/supplemental).

Frequency of Reporting of Adverse Events

The 100 studies that investigated general outcomes for total ankle arthroplasty reported a mean of 15.6 ± 9.2 different types of adverse event per study. The 17 studies that investigated specific outcomes reported a mean of 8.1 ± 9.8 different types of adverse event per study.

Table 1. Categories and Rates of Occurrence of Terms Used to Describe Adverse Events.

Category	Unique Terms[a]	Number of Studies[b]	Reporting Rate[c]	Reported Occurrences[d]
Revision surgery	115	97	82.9%	1021
Additional non-revision surgery	93	80	68.4%	1385
Loosening/osteolysis	86	72	61.5%	1616
Fractures	53	63	53.8%	693
Wound-healing problems	27	58	49.6%	500
Implant-related problems	57	56	47.9%	489
Infection	27	55	47.0%	262
Soft tissue injuries	30	32	27.4%	239
Heterotopic ossification	17	27	23.1%	546
Pain	11	21	17.9%	288
Other	56	65	55.6%	734

[a]Number of unique terms identified within each category.
[b]Number of studies reporting adverse events within each category (out of a total of 117 studies).
[c]Percentage of all studies analyzed that reported adverse events within each category.
[d]Number of occurrences of adverse events within each category, among all studies analyzed.

A total of 7831 adverse events were reported among 10 261 ankle arthroplasties performed on 9878 patients in the 95 unique populations. The most commonly used complication terms could be classified into 10 main categories, as shown in Table 1. These categories were "revision surgery," "additional non-revision surgery," "loosening/osteolysis," "fractures," "wound-healing problems," "implant-related problems," "infection," "soft-tissue injuries," "heterotopic ossification," "pain," and "other." These 10 categories (not including "other") encompassed 89.9% (7039/7831) of all reported adverse events and 90.2% of terms used (517/572). (Please refer to Appendix A, available online at http://fai.sagepub.com/supplemental, for the complete list of terms within these designated categories.)

Revision surgery was the most frequently mentioned category of adverse events, reported in 82.9% (97/117) of papers. Additional surgery (68.4%, 80/117), loosening and osteolysis (61.5%, 72/117), and fractures (53.8%, 63/117) were also commonly reported. There were 115 unique terms within the "revision" category and 93 unique terms in the "additional non-revision surgery" category, mostly referring to complications that would lead to surgery. The complete breakdown of terms can be seen in Table 1.

Occurrence Reporting of Adverse Events

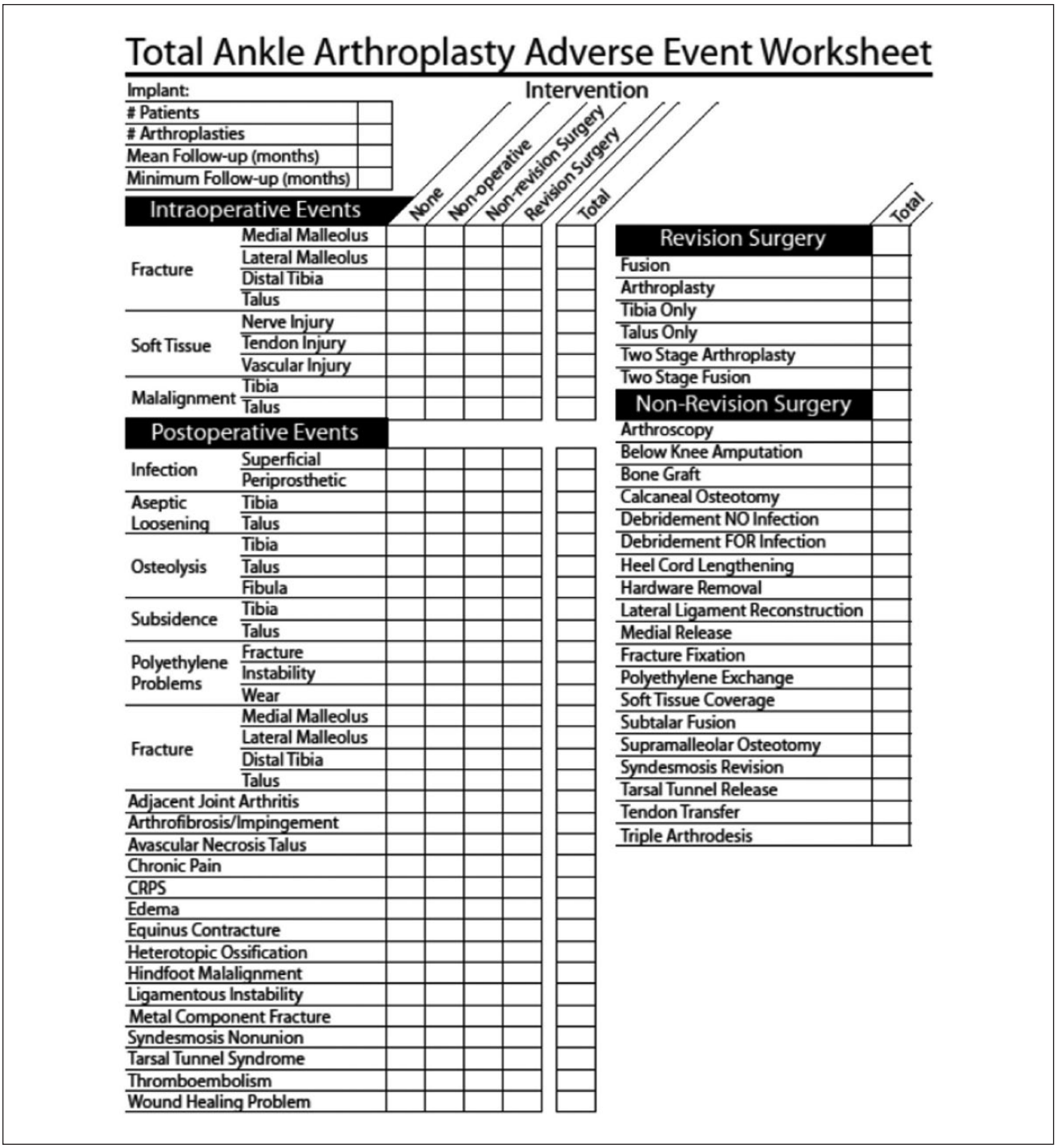
The most commonly reported adverse events were related to loosening or osteolysis, with 1616 reported cases in the 95 unique cohorts. Requirement for additional nonrevision surgery after the index procedure was also reported frequently, with 1385 nonrevision surgeries performed after the index total ankle arthroplasty in 68.4% (80/117) of papers. Revision surgery occurred 1021 times and was reported in 82.9% of papers (97/117). Of the 20 studies that did not report revisions, 6 were designed to analyze specific outcomes,[6,14,50,56,63,66] 4 had an average follow-up shorter than 2 years,[7,45,61,62] and 3 studied fewer than 20 arthroplasties.[5,25,35]

Construction of Standardized Reporting Worksheet

All adverse events having 5 or more occurrences among the 10 261 ankle arthroplasties reviewed in the present study were captured in the list of possible events, which was then used to construct the worksheet for use in outcomes reporting (Figure 3). Some events (eg, non-union of intraoperative fracture, metal allergy, peroneal tendon dislocation) did not occur frequently enough (<0.05% of arthroplasties) to merit inclusion on the worksheet. The list of 572 unique terms that were initially identified in the present study (Appendix B, available online at http://fai.sagepub.com/supplemental) was reduced to 39 standardized terms for adverse events and 25 terms for surgical interventions. The severity of the events was then further divided, according to the intervention required to treat the adverse event. The 4 categories were "no intervention," "non-surgical intervention," "non-revision surgery," and "revision surgery." Adverse events such as nerve injuries and radiographic observations of osteolysis that neither required extra treatment nor lead to deviation from the standard postoperative protocol fell into the "no intervention" category. Adverse events that required interventions such as extra clinic visits for closer monitoring of wounds, antibiotic treatment for infections, and prolonged weight-bearing restrictions for intraoperative fractures qualified as "non-surgical intervention" events.

Discussion

This systematic review of the literature analyzed the variability of terms used to report complications in total ankle



Total Ankle Arthroplasty Adverse Event Worksheet

Implant:	
# Patients	
# Arthroplasties	
Mean Follow-up (months)	
Minimum Follow-up (months)	

		Intervention				
		None	Non-operative	Non-revision Surgery	Revision Surgery	Total
Intraoperative Events						
Fracture	Medial Malleolus					
	Lateral Malleolus					
	Distal Tibia					
	Talus					
Soft Tissue	Nerve Injury					
	Tendon Injury					
	Vascular Injury					
Malalignment	Tibia					
	Talus					
Postoperative Events						
Infection	Superficial					
	Periprosthetic					
Aseptic Loosening	Tibia					
	Talus					
Osteolysis	Tibia					
	Talus					
	Fibula					
Subsidence	Tibia					
	Talus					
Polyethylene Problems	Fracture					
	Instability					
	Wear					
Fracture	Medial Malleolus					
	Lateral Malleolus					
	Distal Tibia					
	Talus					
Adjacent Joint Arthritis						
Arthrofibrosis/Impingement						
Avascular Necrosis Talus						
Chronic Pain						
CRPS						
Edema						
Equinus Contracture						
Heterotopic Ossification						
Hindfoot Malalignment						
Ligamentous Instability						
Metal Component Fracture						
Syndesmosis Nonunion						
Tarsal Tunnel Syndrome						
Thromboembolism						
Wound Healing Problem						

	Total
Revision Surgery	
Fusion	
Arthroplasty	
Tibia Only	
Talus Only	
Two Stage Arthroplasty	
Two Stage Fusion	
Non-Revision Surgery	
Arthroscopy	
Below Knee Amputation	
Bone Graft	
Calcaneal Osteotomy	
Debridement NO Infection	
Debridement FOR Infection	
Heel Cord Lengthening	
Hardware Removal	
Lateral Ligament Reconstruction	
Medial Release	
Fracture Fixation	
Polyethylene Exchange	
Soft Tissue Coverage	
Subtalar Fusion	
Supramalleolar Osteotomy	
Syndesmosis Revision	
Tarsal Tunnel Release	
Tendon Transfer	
Triple Arthrodesis	

Figure 3. Worksheet for the tracking and reporting of adverse events related to total ankle arthroplasty. We propose that researchers would complete this worksheet and provide it with submission of total ankle arthroplasty outcomes research. If more than 1 adverse event were to occur, each would be marked on the same worksheet. Categories are the same as those outlined in Table 1. The adverse events and types of interventions necessary are defined in Appendix C , available online at http://fai.sagepub.com/supplemental. (Note: "Intervention" refers to a change in postoperative protocol, ie, additional weight-bearing restrictions, additional clinic visits, antibioitics, etc. "None" indicates that no intervention was required, ie, no change in standard operative or postoperative protocol. "Non-revision surgery" and "revision surgery" indicate that adverse event necessitated return to operating room for additional surgery. "Subsidence" indicates loose component collapse into region of osteolysis. If this option applies, only "subsidence," not "loosening" or "osteolysis," should be checked. For "osteolysis" to apply, the area should be >2 mm.)

arthroplasty. Among the 117 clinical studies selected for inclusion, no consistent standard of terminology or reporting was observed. More than half of the terms analyzed were used in only a single study, and only a small minority was used in 10 or more studies.

Evidence-based treatment guidelines or consensus statements require that outcomes be accurately compared from one study to another, particularly as surgical techniques and implant designs continue to evolve. However, imprecise or inadequate data undermine the value of this research. Consistent reporting of complications is therefore crucial for the evaluation of different techniques or types of implants. Unfortunately, the variability of terms identified in the present study makes both a direct comparison of outcomes, and accurate determination of the true incidence of adverse events, extremely problematic.

There are a number of likely explanations for the wide variations observed in this study. Term definitions and usage have routinely been determined by individual authors, rather than based on consensus guidelines or a validated classification system, and may thus be arbitrary and inconsistent even among papers by the same authors.

While one research group may report a particular adverse event, another group may disregard the same event. For example, 3 studies[14,50,59] included in the present analysis were focused on the radiographic finding of postoperative heterotopic ossification (HO) and reported incidences of 25%, 34.4% and 86%, respectively. In the remaining 114 studies analyzed, however, HO was mentioned in only 27,* with a compiled occurrence rate of 5.3%. Meanwhile, among all 546 cases of HO that were reported, only 14 were reported to be symptomatic, 13 of which were reported by only 2 authors.[5,59] The study by Choi et al[14] concluded that HO development rarely correlates with symptoms, suggesting that symptomatic HO is an uncommon adverse event and that radiographic identification may not warrant reporting. Similarly, lucency due to osteolysis was commonly reported (61.5% of papers reported some form of the term, with a total of 1616 cases), yet only 25% of those cases required treatment. This again suggests that a radiographic finding is not necessarily an adverse event, unless it correlates with symptoms that necessitate an intervention. Thus, it is difficult to determine whether certain adverse events are infrequently reported because they are rarely observed, or simply because authors feel that they do not merit discussion because of minimal impact on outcome.

Although some studies have focused specifically on complications,† others refer to adverse events only in vague or general terms. Some studies exclude certain adverse events altogether. For example, Kim et al[46] and Lee et al[60] included neither "failures" nor "revisions" in their analysis. Such omissions may easily be overlooked if the study methods are not carefully scrutinized.

In addition, the inclusion criteria for this study contributed to the variability of terminology identified, as papers from 20 different countries were included. While this likely increased the number of unique terms, a subgroup analysis of US-based orthopedic practices showed a similar amount of variability in terminology usage. Within the 27 studies conducted by US-based orthopedic groups, there were a total of 231 terms, with 146 of them being unique to a single paper. Likewise, inclusion of 5 podiatric-authored papers could increase the variability, but there were only 10 unique terms seen within this group, which is on par with the variability seen across the entire population of papers.

Outcomes research should enable both surgeon and patient to understand the inherent risks of all treatment options, in order to weigh those risks against the potential benefits. Moreover, studies have found that when patients are well informed regarding the inherent risks of a procedure prior to surgery, they are more likely to accept those adverse events that do occur[41,49] Providing surgeons with the best information available will enable them to provide better informed consent and allow the patient to make a better decision regarding the best treatment for their ankle arthritis.

Another advantage to the use of standardized terminology and reporting is that it may allow the surgeon to anticipate potential complications, and perhaps to avoid them altogether (or at least to ameliorate their impact).[18,64,84] Accurate reporting of complications can also have a direct impact on routine surgical practice. For example, wound complications following surgical repair of Achilles tendon rupture has led to a resurgence in nonsurgical "functional rehabilitation."[8,43,80,88]

With these factors in mind, we have developed a list of standardized definitions (Appendix C, available online at http://fai.sagepub.com/supplemental) and a worksheet (Figure 3) that could be incorporated into the submission process for outcomes research on total ankle arthroplasty. We propose that researchers could standardize and improve their reporting of adverse events by adhering to these definitions and completing the worksheet for all patients.

The present study has several strengths, including a clear definition of the research question in order to eliminate bias in the selection of studies for inclusion, adherence to an explicit research protocol developed prior to the analysis, a comprehensive literature search, and consensus between 2 reviewers with regard to all data elements prior to completion of the database.

There are also several limitations to this study. The interpretation of text may be somewhat subjective. Although we attempted to mitigate this factor by including the confirmation of all terms and consensus between 2 reviewers, the analysis may nonetheless have been subject to some degree

*References 4-6, 9, 11-14, 22, 28, 38-40, 44, 47, 48, 50, 58-60, 65, 70, 71, 76, 83, 86, 87.

†References 10, 29, 32, 36, 48, 55, 61, 62.

of confirmation bias based on the fact that the second reviewer was confirming data extracted by the first reviewer.

The standard protocol for a systematic review usually requires independent assessment of all studies by 2 researchers in order to ensure consistency. However, because the goal of the present review was not to compile precise statistics regarding the incidence of specific events, but rather to highlight the *inconsistency* of terminology in the literature, this redundancy was deemed to be unnecessary. In addition, papers were not blinded prior to review, because both reviewers were so familiar with the literature that blinding would serve little purpose, as noted by Kranke et al.[53]

It should be noted that the worksheet developed from the present analysis (Figure 3) has not been validated in an external analysis. Further development should incorporate input from leaders in the field of total ankle arthroplasty, in order to ensure that all adverse events are well defined prior to implementation. In addition, the present classification system could be further stratified in order to provide an estimate of the severity or likelihood that each complication will lead to arthroplasty failure (defined as an adverse event necessitating removal of metal implants), as originally suggested by Glazebrook et al.[32] This would provide the added benefit of enabling a direct comparison of the actual resources required for each option (eg, the frequency of reoperation).

In their analysis of the general orthopedics literature, Goldhahn et al[33] concluded that clinical trials in orthopedics must undergo substantial improvements in complication assessment and reporting (particularly in comparison with trials in other medical specialties such as rheumatology), and that a universal classification system for complications should be developed as an outcome tool. The results of this present study clearly indicate that this recommendation is equally relevant to studies of total ankle-arthroplasty.

In conclusion, the reporting of complications and adverse outcomes for total ankle arthroplasty was highly variable. We assert that this lack of consistency impedes the accurate reporting and interpretation of data required for the development of cohesive, evidence-based treatment guidelines for end-stage ankle arthritis. Standardized reporting tools are urgently needed. The present study presents a prototype worksheet for the assessment and reporting of adverse events, and we propose that it serve as a template for the development and validation of a standardized reporting protocol.

Acknowledgments

The authors wish to thank Katherine Austin, PhC, for editorial assistance in the preparation of this manuscript, and to acknowledge the contributions of the Orthopaedic Research Office at St. Paul's Hospital in Vancouver.

Supplemental Material

Supplemental material for this article is available on the *Foot & Ankle International* website at http://fai.sagepub.com/supplemental.

Declaration of Conflicting Interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Alastair S.E. Younger, MB ChB, ChM, FRCSC, has a patent Fastening device for ankle joint replacement issued.

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

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