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Identifying the learning curve for total ankle replacement using a mobile bearing prosthesis

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ABSTRACT

Background: Total ankle arthroplasty remains a technically demanding surgery highly influenced by the operator experience. However, no consensus exists regarding the ideal number of cases that need to be performed before a surgeon is considered proficient. The aim of this study was to identify the learning curve of a specific replacement system with regards to intraoperative and postoperative outcomes. *Methods:* The first 31 patients undergoing total ankle arthroplasty were examined. No additional procedures were performed at the time of the TAA. Intraoperative characteristics, postoperative complications, as well as clinical and radiologic outcomes were assessed with 24-month follow-up. Learning curves, examining the relationship between surgeon experience and patient outcomes, were determined using the Moving Average Method.

Results: The operatory time, and the risk of intraoperative fractures decreased with increasing surgeon experience with the learning curve stabilizing after the 14th and 24th patient, respectively. Furthermore, there appeared to be a learning curve associated with most of the important clinical and radiological outcomes. The number of patients required to stabilize the learning curve for the VAS, ROM, and AOFAS was 11, 14 and 28, respectively. Radiographically, there appeared to be a learning curve of 22 patients required to stabilize the tibio-talar ratio. There was no learning curve associated with the SF-12 PCS and MCS as well as the α -, β -, and γ -angle.

Conclusion: This study demonstrates that a surgical learning curve does indeed exist when performing TAA. Most of the operative variables as well as clinical and radiological outcomes stabilize after a surgeon has performed 28 cases.

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1. Introduction

In patients with end-stage ankle arthritis, ankle arthrodesis has traditionally been the standard of care [1,36]. Ankle fusion effectively reduces the ankle pain by elimination the symptomatic motion of the affected joint. However, the loss of motion in addition to the risks of nonunion, malunion, and stress transfer to adjacent joints has led to the emergence of total ankle arthroplasty (TAA) as an alterative to ankle arthrodesis [11,14,15]. Importantly, TAA has demonstrated excellent clinical results, with functional

* Corresponding author at: IRCCS Istituto Ortopedico Galeazzi, Via Riccardo Galeazzi 4, 20161 Milan, Italy. Tel.: +39 3357351838. *E-mail address:* fusuelli@gmail.com (F.G. Usuelli). and quality of life improvements comparable to ankle fusion [18,26,31,41].

The majority of the available literature on TAA outcomes has been published by implant designers rather than general users of the prosthesis [4,6,20,21,29,30]. Therefore, the results from these studies may be biased and unreliable secondary to a greater familiarity with the prosthesis by the authors. Labek et al. reported that the revision rate found in studies from implant developers was nearly 50 percent less than rates found in national arthroplasty registry data [32].

The presence of a learning curve with TAA has been previously examined with variable findings. In most cases, increased experience and number of cases are associated with a decrease in perioperative and postoperative complications [9,16,28,29,34,39]. However, no consensus exists regarding the ideal number of cases that need to be performed before a surgeon is considered proficient.

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The purpose of this study is to determine if a learning curve can be established for a single, fellowship-trained foot and ankle surgeon, who is not an implant designer. We hypothesize that a learning curve not only exists, but more importantly, that there is a specific number of cases that need to be performed before the learning curve stabilizes.

2. Materials and methods

This retrospective study was approved by our institutional review board. A total of 46 patients underwent primary TAA from May 2011 to February 2013. In order to create a homogenous study population, patients were excluded if additional procedures were performed at the time of surgery. At least one additional procedure was performed in 15 patients (one procedure in 9/46, two in 5/46, and three in 1/46). The most frequent additional procedures included subtalar arthrodesis, Achilles lengthening, tibial osteotomy, and fibular osteotomy. The final study population included 31 patients.

All 31 patients had a preoperative diagnosis of ankle pain secondary to post-traumatic ankle osteoarthritis with a history of previous open reduction and internal fixation with subsequent hardware removal. All patients had radiographic evidence of endstage osteoarthritis (Grade 3 or 4, Kellgren-Lawrence scale) [27]. Each patient was offered both a total ankle arthroplasty and ankle arthrodesis. The risks, benefits, alternatives to, and complications associated with both of the procedures were discussed at length with each patient. All patients elected to proceed with ankle replacement surgery. Only after extensive discussion and counseling, especially in younger patients, were patients scheduled for total ankle arthroplasty.

All surgical procedures were performed by the senior author using the HINTEGRA total ankle prosthesis (Newdeal, Lyon, France; Integra, Plainsboro, NJ) using the standard surgical technique [3].

During the operative procedure, data collected included: operative side, implant sizes, intraoperative fractures and total surgical time.

2.1. Clinical and radiological evaluation

Patients were clinical evaluated preoperatively and postoperatively at 6, 12, and 24 months. Pain and function was assessed using the American Orthopedic Foot and Ankle Society (AOFAS) ankle and hindfoot score, Visual Analog Scale (VAS) pain score, and the 12-Item Short Form Health Survey (SF-12) – physical component summary (PCS) and mental component summary (MCS) [7,10,17,25,37]. Range of motion (ROM) was determined with the patient sitting by placing a goniometer on the lateral border of the foot and ankle along the length of the fibula [5]. Postoperative complications, if present, were also recorded.

Radiographic assessment included weight-bearing radiographs of the ankle (anteroposterior (AP), oblique, lateral, and hindfoot alignment views) preoperatively and postoperatively at 2, 6, 12, and 24 months. Radiological measurements were performed including the anatomic lateral distal tibial angle (ALDTA), anatomic anterior distal tibial angle (AADTA), tibio-talar ratio as well as the α , β and γ angles (Fig. 1A–C) [3,5,46]. All measurements were made using the standard tools in our Picture Archiving and Communication System (PACS) and evaluated by two orthopedic surgeons, who were not directly involved in the surgical procedure.

Preoperatively, the ALDTA (normal value 85–95 degrees) was measured on the AP view to assess the coronal alignment [5]. It is defined as the angle between the long axis of the tibia and the articular surface of the tibial plafond. On the lateral view, the AADTA (normal value 80–90 degrees) was measured to assess the preoperative sagittal alignment of the arthritic ankle [5]. It is the





angle between the anatomic axis of the tibia and the line connecting the distal points on the anterior and posterior tibial articular surface.

Postoperatively, the placement of the total ankle tibial implant was assessed by measuring the α -angle (normal value 90 \pm 2.0 degrees), which is the angle between the articulating surface of the tibial component and the longitudinal axis of the tibia on the AP view [3]. On the postoperative lateral view, the β -angle (angle between the longitudinal axis of the tibial component and the articular surface of the tibial component and the set of the articular surface).

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