Incidence of Complications During Initial Experience with Revision of the Agility and Agility LP Total Ankle Replacement Systems

A Single Surgeon's Learning Curve Experience

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KEYWORDS

• Complications • INBONE Total Ankle Replacement System
• Salto Talaris Total Ankle Replacement System • Salvage • Total ankle arthroplasty

KEY POINTS

- The Agility and Agility LP Total Ankle Replacement Systems were the primary prosthesis systems available for use in the United States for more than a decade, spanning 1998 to 2010.
- Surgeons unfamiliar with the primary implantation of the Agility and Agility LP Total Ankle Replacement Systems will likely encounter patients with failure of these prostheses that require revision. Revision of the failed Agility and Agility LP Total Ankle Replacement Systems is challenging with little published guidance available.
- Exchange of the Agility and Agility LP Total Ankle Replacement System components to Revision or LP talar components and ultrahigh-molecular-weight polyethylene (UHMWPE) insert with, in select instances, additional metal-reinforced polymethylmethacrylate cement augmentation; conversion to custom-designed stemmed components; or explantation and conversion to another total ankle replacement system are considerations.
- Custom-designed stemmed Agility LP Total Ankle Replacement is unfortunately no longer available because of US Food and Drug Administration regulation. Explantation with conversion to alternative total ankle replacement systems is a high-risk surgery with strong potential for complications to occur.
- Whenever feasible, exchange with Revision or LP talar components and UHMWPE insert with, in select instances, additional metal-reinforced polymethylmethacrylate cement augmentation remains a simple, low-cost, and viable option with limited occurrence of complications.

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INTRODUCTION

Despite early generation failures, total ankle replacement (TAR) is now an established alternative to ankle arthrodesis for the treatment of end-stage ankle arthritis.[1–8] With the advent of third-generation TAR systems, foot and ankle surgeons competent in primary TAR have achieved clinical outcomes comparable to if not superior to ankle arthrodesis.[1–13] As the frequency in which foot and ankle surgeons are performing primary TAR continues to build, revision TAR will likely become more commonplace. This pattern has in fact been clearly demonstrated over time in the Norwegian Arthroplasty Register (http://nrlweb.ihelse.net/Rapporter/Rapport2014.pdf; Accessed July 18, 2015). Accordingly, there will be a need for an established benchmark by which to evaluate the safety of revision TAR as determined by the incidence of complications encountered. It seems intuitive that most complications occurring during primary TAR that lead to revision will occur during the surgeons' learning curve period. Although many reports exist suggesting the presence of a learning curve, there has been no large-scale published analysis of the exact incidence of complications encountered during the surgeon learning curve period for the primary TAR prosthesis systems available for current use.

At present, the US public can receive only 1 of 9 metal-backed fixed-bearing cemented TAR devices that are 510(k) cleared and one 3-component mobile-bearing uncemented device approved by the US Food and Drug Administration (FDA) for general use. The 9 metal-backed fixed-bearing cemented TAR devices that have been FDA cleared for use are (1) Agility and Agility LP Total Ankle Replacement Systems (DePuy Synthes Joint Reconstruction, Warsaw, IN, USA); (2) INBONE I, INBONE II, and INFINITY Total Ankle Replacement Systems (Wright Medical Technology, Inc, Arlington, TN, USA); (3) Eclipse (Integra LifeSciences, Plainsboro, NJ, USA); (4) Salto Talaris Anatomic Ankle Prosthesis and Salto Talaris XT Revision Ankle Prosthesis (Tornier, Bloomington, MN, USA); and (5) Zimmer Trabecular Metal Total Ankle (Zimmer, Inc, Warsaw, IN, USA). In addition, one 3-component mobile-bearing uncemented TAR has received FDA premarket conditional approval for use: the Scandinavian Total Ankle Replacement system (S.T.A.R. System, Small Bone Innovations, Inc, Morrisville, PA, USA/Stryker Orthopedics, Mahwah, NJ, USA).

The Agility Total Ankle Replacement System was the only US FDA–cleared ankle replacement readily available in the United States until 2007 (http://fda.gov/cdrh/panel/summary/ortho-04207.html; Accessed July 18, 2015). As a result, the Agility Total Ankle Replacement System was the most widely implanted ankle replacement in the United States for over a decade. It is well established that the Agility Total Ankle Replacement System was unforgiving as a primary prosthesis. A review of publications specific to the complication rate associated with primary implantation of the Agility Total Ankle Replacement System during the surgeon learning curve period reveals an incidence of complications of 60.8% (141/232).[4,7,14,15] The authors were able to further categorically divide these complications based on both the classification system proposed by Glazebrook and colleagues[16] and the simplified system proposed by Gadd and colleagues.[17] Under the classification system of Glazebrook and colleagues,[16] 14.2% of the complications were considered high grade, 29.1% were medium grade, and 50.3% were low grade. Under the classification system of Gadd and colleagues,[17] 43.3% were considered high grade, whereas 50.3% were low grade. According to each classification system, 6.4% of complications were unclassified, and these consisted of nerve and tendon injuries.

Although highly dependent on the specific TAR prosthesis system used, debate remains as to whether patients with failed primary TAR are best served with revision