Tips & Tricks: The Scandinavian Total Ankle Replacement (STAR): Design Evolution and Clinical Results

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Introduction

Total ankle replacement (TAR) was introduced for end-stage arthritis of ankle in the 1970s. The Scandinavian Total Ankle Replacement (STAR, Waldemar Link, Germany) was originally designed in 1978 by Hakon Kofoed as a two-component, anatomic, fixed bearing, unconstrained resurfacing ankle prosthesis covering the medial and lateral facet joints. The 12-year survival rate for this prosthesis in terms of retention of both components was quoted at 70%[1, 2]. Most other first-generation ankle replacement designs had less successful outcomes[2-8]. Bolton-Maggs et al[6] reported at 5 year follow up of 41 ankle arthroplasties that 13 of them had been removed and converted to arthrodesis. Kitaoka et al[5] reported on the Mayo total ankle arthroplasty and observed a 42% survival rate at ten years. The first generation of TAR were a two-component design with a concave polyethylene tibial component and a convex metal talar component. Constrained and unconstrained designs were available, with constrained designs most often failing due to increased stress at the implant-bone interface leading to loosening. Unconstrained designs suffered instability due to increased stresses on the surrounding soft tissues[9]. The failure of some early prosthesis designs were also attributed to aggressive bony resections, improper balancing of the prosthesis and soft-tissue envelopes and non-congruent designs[10].

To aid in decreasing rotational stresses seen with a two-component design, the STAR was modified to a three-component design with a mobile-bearing polyethylene (PE) meniscus in the late 80's. The purpose of the PE meniscus between the tibial and talar components is to allow only compressive forces at the implant-bone interface and to avoid rotational stresses. This review will focus on the current implant design, fixation strategies and outcome data present in the literature.

Implant Design

The ankle joint is made up by the articulation of the tibia, talus and fibula. It is a highly congruent, reported as high as 96% during the arc of motion[2, 11], joint with nearly cylindrical motion between the talus and tibia[12]. The STAR prosthesis is a 3-part press-fit design. Notably, it is the only design which is approved for press-fit fixation by the FDA in the United States. The STAR incorporates a flat tibial component which is wider anteriorly. It carries two parallel bars on the superior surface which are inserted into solid subchondral bone during implant impaction. Holes for these bars are created with a drill and punch system[13]. Importantly, there is a stop on the drill system to prevent perforation of the posterior cortex of the distal tibia, therefore limiting communication between the ankle joint and distal tibia. This, along with proper sizing to match the tibial cortical surfaces, prevents joint fluid under high hydrostatic pressure from leeching into the distal tibia and causing cyst formation[14-16], leading to possible implant failure and need for revision[17-23]. Additionally, after impaction of the final tibial implant, the anterior drill holes are filled with bone graft to prevent this same complication.

The talus cap component is anatomically shaped with wings to replace the medial and lateral facets. A superior flat talar bony resection is made along with anterior and posterior chamfer resections with multiple cutting guides to accommodate the prosthesis. There is a crest along the dome of the prosthesis which corresponds to a groove on the PE insert. The talus component has a longitudinal stem on its undersurface for fixation into a groove created on the talus with a drill and punch[13].

The PE insert is square shaped and congruent with both the tibial and talar components. The groove on the undersurface limits rotation on the talus component, however it is free to rotate on the tibial component. The PE meniscus is made from ultra-high molecular weight PE and comes in different heights from 6-10 millimeters(mm).

The tibial and talus components are made of cobalt-chromium alloy and are available in different sizes (5 tibial sizes, 4 talar sizes), which are interchangeable. The talus component is available in right and left[13].

Evolution of STAR Implant Design

There have been four generations of the STAR to date. The first design by Kofoed was a two-component, fixed bearing cemented prosthesis (Figure 1). It consisted of a polyethylene tibial component and a cobalt chrome (CoCr) talar component. In 1986 the STAR was converted

Figure 1. First-generation fixed bearing cemented prosthesis. *Gilbert et al. 2016*[24]

from a two-component device to a Second Generation three-component mobile bearing device (Figure 2). This included CoCr tibial and talar components with a PE meniscus in between. Kofoed reported a 70% survival rate at 12 years with both of these devices[1, 2]. The Third Generation device was introduced in 1989 and implemented a hydroxyapatite (HA) coating over smooth CoCr and use cementless fixation. This is also referred to as the single-coated prosthesis. Kofoed reported a 95.4% survival rate 12-year survivorship of the third generation prosthesis. The base coating of the STAR was changed in 1998 to a rough Titanium (Fourth Generation Ti) plasma spray (Figure 3), and one year later a calcium phosphate coating was added on top of the titanium plasma spray (Fourth Generation Ti + CaP)[24]. The latter is also referred to as the double-coated prosthesis. It is important to note when reviewing the literature that only the Fourth Generation Ti is available in North America, while the Fourth Generation Ti + CaP is used in the European literature.

Clinical Outcomes

Early short-term outcome studies on total ankle arthroplasty showed encouraging results[25-28], however medium and long-

Figure 2. Second-generation mobile bearing cemented prosthesis. *Gilbert et al. 2016*[24]

Figure 3. Fourth-generation uncemented Ti plasma spray prosthesis. *Gilbert et al. 2016*[24]

term results revealed significant complications, including ankle pain, painful malleolar impingement, tibial component loosening and talar component subsidence[6, 8, 28-31]. The major factors implicated in loosening were highly constrained or incongruent designs, high soft tissue stress and aggressive bony resections with cement fixation[32]. The STAR implant was designed as a cementless, three component device that implements low constraint. Early medium term studies showed promising results, and more recently there has been 10-to-20-year data published.

European Data

Kofoed et al.[2] reported on 58 patients undergoing either cementless (HA coated) or cemented STAR with mean follow up 9.4 years. There were significantly higher failures in the cemented (9/33) over the cementless (1/25) group. Twelve-year survival rate for the cemented prosthesis was 70% while the cementless group showed a 95% survival rate.

Brunner et al.[22] reported on 77 third generation STAR with average follow up 12.4 years. The primary outcome was revision of one or both of the metallic components. They reported a survivorship of 70.7% at 10 years and 45.6% at 14 years. The main reasons for revision were aseptic loosening, subsidence of the talar component and progressive cyst formation. There were also 11 PE fractures.

Wood et al.[33] conducted a reported on 100 STAR Forth Generation Ti+CaP. At an average follow-up of 54 months there were only 4 failures; two patients required PE exchange due to PE fracture, one patient was converted to fusion due to early infection, and one patient was converted to fusion for aseptic loosening.

Henricson et al.[34] reported on 10-year follow up of uncemented 3-component TAR from the Swedish Ankle Register. In this study they analyzed data on both the third generation single-coat and fourth generation double-coat prosthesis. They found a lower rate of all-cause revision for the double-coat compared to the single-coat; 49 of 205 versus 56 of 117, respectively. Henricson and Carlsson[35] conducted a follow-up study of the Swedish Ankle Register. They reported a 53% revision rate at 14 years for the single-coated prosthesis

and a 36% revision rate at 12 years for the double-coated prosthesis.

More recently, Frigg et al.[36] reported on 50 STAR procedures over a ten year period by one surgeon. The primary endpoint was exchange of the whole prosthesis or conversion to arthrodesis. They reported a 94% survival rate at ten years and a 91% survival rate at nineteen years. There were both single and double-coated prostheses used in this study and they mentioned that the coating did not influence the outcomes, however they did not provide a breakdown of results by prosthesis.

North American Data

Daniels et al.[37] looked at 111 consecutive STAR over a four year period and reported a 29% revision rate at 9 years, although the survival rate of the metallic components was 88%. Twenty (18%) of the patients underwent PE bearing exchange, with the majority being for PE fracture. The combined rate of metal and PE bearing revision was greater for the first twenty ankles (38%) compared with the subsequent ankles (24%).

Haytmanek et al.[38] reported on 79 ankles undergoing TAR with fourth generation Ti done over a 9 year period. At average follow-up of 8 years they observed a metallic component survival of 89.9%. They reported that 27.8% of the patients required revision of at least one component, with 63.6% of them requiring PE exchange only.

Mann et al.[39] reported a 91% metallic component survival rate at 10 years of the fourth generation Ti component, and a follow-up study with 15 year follow up reported a 73% survival rate[40]. Jastifer and Coughlin[41] reported a 94.4% implant survival rate at 12.6 years in 18 patients.

Summary

End-stage ankle osteoarthritis is a debilitating condition with substantial impact on quality of life. Main surgical treatment options are arthrodesis or joint replacement. Total ankle replacement offers patients a motion sparing option, however its success has not been to the same level as total hip or total knee arthroplasty[36]. Early implant designs showed high rate of failure due to high constraint, creating increased rotation stresses at the impant-bone interface. The STAR implant is a three-component implant with a tibial and talar metal component with a PE bearing surface in between. This design allows a small degree of rotational freedom, thereby reducing the stress at the metal-bone interface. Overall, North American clinical results with the STAR show high intermediate and long-term survival rates, with ten-year survival rates as high as 95%, although other studies continue to show lower rates of survival . While the long term survival rate of the STAR prosthesis are reported as high, patients should be aware that their chance for reoperation is also high, most often due to aseptic loosening of the prosthesis.

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