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Horizon Scanning Technology Prioritising Summary

Total ankle replacement with uncemented prostheses

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**Australian
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and Efficacy
Register
of New
Interventional
Procedures -
Surgical**



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PRIORITISING SUMMARY

REGISTER ID S000108

NAME OF TECHNOLOGY UNCEMENTED SCANDINAVIAN TOTAL ANKLE REPLACEMENT (STAR) SYSTEM

PURPOSE AND TARGET GROUP PATIENTS WITH PAINFUL ARTHRITIC ANKLE JOINTS DUE TO OSTEOARTHRITIS, POST-TRAUMATIC ARTHRITIS OR RHEUMATOID ARTHRITIS

STAGE OF DEVELOPMENT (IN AUSTRALIA)

- | | |
|--|---|
| <input type="checkbox"/> Yet to emerge | <input type="checkbox"/> Established |
| <input type="checkbox"/> Experimental | <input type="checkbox"/> Established <i>but</i> changed indication or modification of technique |
| <input type="checkbox"/> Investigational | <input type="checkbox"/> Should be taken out of use |
| <input checked="" type="checkbox"/> Nearly established | |

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- Yes
- No
- Not applicable

INTERNATIONAL UTILISATION

| COUNTRY | LEVEL OF USE | | |
|---------|------------------------------|-------------|-----------------|
| | Trials Underway or Completed | Limited Use | Widely Diffused |
| Europe* | | | ✓ |

*over 10,000 implantations per year in countries including Sweden, Demark, and England (ScoutNews 2009).

IMPACT SUMMARY

The Scandinavian Total Ankle Replacement system (Waldemar Link GmbH & Co., Germany) provides patients with painful arthritic ankle joints with uncemented ankle replacement when conventional treatment has failed, as a realistic alternative to arthrodesis, with the aim of providing pain relief and improved mobilisation.

BACKGROUND

The ankle is a complex weight-bearing structure made up of four distinct bones and three separate joint systems. The four bones that make up the ankle include the tibia (larger of

the lower leg bones), fibula (smaller of the lower leg bones), talus, and calcaneus (heel bone) (Sports Injury Clinic 2009). The three joints include:

1. the talocrural joint, which is a hinge joint that is formed at the distal ends of the fibula and tibia and encloses the upper surface of the talus. This joint allows the increase (plantarflexion) and decrease (dorsiflexion) of the angle between the foot and the shin,
2. the inferior tibiofibular joint, which is a strong joint between the lower surfaces of the fibula and tibia, reinforced by ligament, and
3. the subtalar joint, which is made up of the articulating surfaces of the talus and calcaneus. This joint provides shock absorption and allows inward (inversion) and outward (eversion) ankle movements (Sports Injury Clinic 2009).

Ankle pain may occur as a result of arthritis or trauma. The first line of action for ankle pain is conservative treatment which may include rest, elevation and taping of the ankle, anti-inflammatory medications, orthotic devices, and operative debridement (SooHoo and Kominski 2004). Surgery is considered when conservative treatment has failed to provide sufficient relief and traditionally involves ankle arthrodesis (fusion). Total ankle replacement is a less common technique used to overcome some of the limitations of ankle fusion.

Specific indications for ankle replacement include rheumatoid arthritis, inflammatory arthritis of another origin (for example psoriatic arthritis or gout), hemochromatosis, primary osteoarthritis, and post-traumatic osteoarthritis (Anderson et al 2004).

Since the 1970s many total ankle prostheses have been trialled, many of which disappeared from the market due to unsatisfactory results, including failure of the prostheses (Anderson et al 2003). The first-generation Scandinavian Total Ankle Replacement (STAR) system (Waldemar Link GmbH & Co., Germany) was designed in 1978 as a two-component anatomic unconstrained resurfacing ankle prosthesis with congruent parts covering the medial and lateral facet joints (Kofoed 2004). From 1986, the tibial component of the STAR system included a polyethylene meniscus, which was intended to minimise rotational stress forces on the implant-bone interface (Kofoed 2004). Later in 1990 the device was further improved so that the prosthesis was used with a bioactive surface for uncemented implantation (Kofoed 2004). These two changes gave rise to the second-generation STAR system prosthesis.

The metallic components of the second-generation STAR system prosthesis are made of cobalt-chromium alloy (Anderson et al 2004). These metal components are coated with a thin layer of titanium (approximately 300µm thick), with a pore size of 75-200µm and a porosity of 25-35%, and a hydroxyapatite layer (approximately 25µm thick, porosity 60%) (Anderson et al 2004). The prosthesis comprises of a tibial component, talar component, and meniscal components (Anderson et al 2004).

The STAR procedure is carried out in patients in the supine position, generally under spinal anaesthesia (Anderson et al 2004). Prophylactic antibiotics are administered

intraoperatively (Anderson et al 2004). The ankle joint is exposed, using a straight anterior incision, and cleaned before the insertion of the prosthesis takes place.

The potential benefit of the STAR system over existing treatments for patients with arthritic or deformed ankles may include the ability to preserve some range of motion in the foot by closely imitating the function of the natural ankle.

CLINICAL NEED AND BURDEN OF DISEASE

Ankle arthritis may occur as a result of wear and tear, injury, or as a part of a systemic arthritis (rheumatoid arthritis) (Sangeorzan 2009). Specific data relating to arthritis of the ankle joint alone was not available.

In general, approximately 6 million Australians experience long-term pain and disability from arthritis and musculoskeletal conditions (Australian Institute of Health and Welfare 2010). Hospital-admitted patient services and prescription pharmaceuticals are the main sources of expenditure used to manage arthritis (Australian Institute of Health and Welfare 2010). From 2004 to 2005, arthritis and musculoskeletal conditions were the fourth largest overall contributor to direct health expenditure in Australia, at \$4 billion (Australian Institute of Health and Welfare 2010). Arthritis also accounted for more expenditure on out-of-hospital medical services (general practitioner and/or medical specialist care) than any other disease (Australian Institute of Health and Welfare 2010).

According to the Australian Orthopaedic Association National Joint Replacement Registry (AOA NJRR) the number of ankle procedures recorded per year has increased from 2006 to 2009. In 2006 only 5 procedures were reported, which increased to 59 in 2007, 178 in 2008, and 204 in 2009 (AOA NJRR 2010). Ankle arthrodesis was carried out in 899 individuals from 2006 to 2007, and in 883 individuals from 2007 to 2008 (Australian Institute of Health and Welfare – data cubes 2010).

DIFFUSION

The STAR system is widely used throughout Europe, with approximately 10,000 implantations per year already taking place (ScoutNews 2009). The majority of studies retrieved that reported the use of the device for ankle replacement were produced in Denmark, Sweden and England.

The United States Food and Drug Administration (FDA) approved the STAR system for general use on May 27th 2009 (FDA 2010). Literature regarding the STAR systems CE approval was not available; however, in order to be used throughout Europe the device must have the CE mark.

There are three similar total ankle replacement devices currently listed on the Australian Register of Therapeutic Goods (Australian Register of Therapeutic Goods and Medicines 2010). They include the Buechel-Pappas Total Ankle Replacement System (Endotec P/L, United States), the Salto ankle prosthesis (Tornier P/L, France), and another device produced by Depuy P/L, United States.

COMPARATORS

The STAR system is proposed as an alternative to ankle arthrodesis (Anderson et al 2003). Arthrodesis involves the removal of the damaged portion of the tibiotalar joint followed by fusion of the ankle joint in a solid, optimum position (Goddard and Choudhury 2008). Successful ankle arthrodesis relieves pain but reduces the range of motion in the ankle, alters gait kinematics, and may increase the risk of arthritis in adjacent joints (SooHoo and Kominski 2004).

In regards to ankle replacement, three ankle prosthesis designs without bone cement (including the STAR system) currently dominate the market (Anderson et al 2003). These designs include the Buechel-Pappas (BP) prosthesis and the Agility prosthesis. The BP device has a meniscus and is implanted without bone cement, and the Agility prosthesis lacks a meniscus and was first implanted in 1984 (Anderson et al 2003).

SAFETY AND EFFECTIVENESS ISSUES

Four comparative studies were identified as relevant for inclusion in this summary (Saltzman et al 2010; Wood et al 2009; Kofoed 2004; Wood et al 2000). Three studies compared the STAR system with another ankle replacement system (Wood et al 2009; Kofoed 2004; Wood et al 2000), one of which was randomised (Wood et al 2009), and the remaining study compared the STAR system with the current gold standard, ankle arthrodesis (Saltzman et al 2010).

Study description

Saltzman et al (2010) compared the clinical and radiographic outcomes and early perioperative complications associated with the STAR prosthesis and ankle arthrodesis. Seventy-one patients with noninflammatory arthritis who underwent treatment with the STAR device (n=42) or ankle fusion (n=29) using cannulated screws (n=14), plates and screws (n=10), or external fixators (n=3) were retrospectively reviewed. Complete follow-up was achieved in 88% (37/42) of the STAR group and 79% (23/29) of the fusion group. The STAR group had significantly older patients (mean 64 years) than the fusion group (56.2 years) (P=0.034), and had a higher proportion of females and lesser percentage of those with post-traumatic osteoarthritis (P values not given). Mean follow-up for patients in the STAR group was 3.8 years (range, 2.2-4.3 years) and mean follow-up for patients in the fusion group was 4.8 years (range, 2.2-5.9 years); there was no significant difference between the groups in terms of follow-up (P=0.874). Foot function was evaluated using the Ankle Osteoarthritis Scale¹ (AOS) for pain and disability, along with measures of mental and physical health using the short form health survey (SF-36). Radiographic outcomes were assessed using the Kellgren/Lawrence (K/L) arthritis scale².

Between March 2000 and July 2003, 200 patients requiring primary total ankle replacement were randomised to receive either the STAR prosthesis (n=100) or the BP

¹ Ankle Osteoarthritis Scale (AOS): measures the pain/disability associated with osteoarthritis, where a score of 100 points reflects the worst imaginable pain with all activities or at all times of day, and a score of 0 points indicates absolutely no pain with any activities at any time of day.

² Kellgren/Lawrence (K/L) arthritis scale: a 5-point grading system used to classify the radiographic signs of arthritis, where 0 = normal, 1 = minimal, 2 = mild, 3 = moderate, 4 = severe.

prosthesis (n=100) (Wood et al 2009). The randomisation method used was the closed envelope technique, which took place the day prior to surgery. Forty-eight male and 52 female patients in the STAR group had a mean age of 65 years (range, 23-83 years), and 58 male and 42 female patients in the BP group had a mean age of 64 years (range, 29-84 years). The two groups were similar in terms of age, gender, and the proportion of patients with osteoarthritis and rheumatoid. During the study period the composition of the tibial and talar components of the BP implant was changed from nitrided titanium (first 50 procedures) to cobalt chrome. Both designs were intended for uncemented implantation with a porous coating on the components to promote osseointegration. All patients had a minimum of three years follow-up, with the primary outcome being failure (defined as the need for fusion or revision surgery). The mean follow-up for surviving patients in the STAR group was 54 months (range, 36-85 months), and in the BP group it was 54 months (range, 36-75 months).

Wood et al (2000) aimed to assess the clinical and radiological outcomes of two biomechanically different ankle prostheses, the cemented Thompson Parkridge Richards (TPR) and the cementless STAR system, in two demographically similar groups of patients with rheumatoid arthritis. A single surgeon carried out primary total ankle replacements in 7 patients using the STAR prosthesis and compared the findings with 7 patients undergoing primary TPR replacements. One patient in each group underwent bilateral (non-simultaneous) ankle replacement; therefore the total number of consecutive procedures was 14. The mean age of the 1 male and 6 female patients in the STAR group was 62.9 years (range, 36-76 years), and the mean age of the 1 male and 5 female patients in the TPR group was 60.7 years (range, 44-71 years). Although both groups had statistically different age and sex ratios, they had comparable overall disability caused by rheumatoid arthritis and no difference in preoperative morbidity status (measured using the Health Assessment Questionnaire [HAQ] score). Mean follow-up for the STAR and TPR groups were 5.4 years (range, 5-6 years) and 7.2 years (range 6.8-7.8 years), respectively.

Kofoed (2004) carried out ankle replacements using the STAR system in a total of 58 patients with rheumatoid arthritis or osteoarthritis. From 1986 to 1989, 33 patients were implanted with cemented STAR, and from 1990 to 1995, 25 patients were treated with the uncemented version. The mean age of the 14 male and 19 female patients in the cemented group was 60 years (range, 31-78 years), and the mean age of the 16 male and nine female patients in the uncemented group was 58 years (range, 29-81). Mean follow-up in each group was 9.3 ± 2.7 years and 9.5 ± 1.7 years, respectively. To make the two groups comparable, patients in the cemented group were only followed up until 1997 and patients in the uncemented group were only followed up until 2002. There was no difference between the groups in terms of age, gender, follow-up duration, or preoperative scoring; however, there were significantly fewer patients with rheumatoid arthritis in the uncemented group.

Safety

In the study by Saltzman et al (2010) additional (postoperative) procedures were carried out in 41% (15/37) of patients in the STAR group and 22% (5/23) of patients in the

fusion group (P value not reported). Reoperation in the STAR group occurred for indications including lateral or posterior impingement (n=7, treated with debridement plus bony resection), exostosis (n=2, treated with debridement), osteolysis (n=3, treated with poly exchange and bone grafting including revision of the tibial component with calcaneal realignment [n=1] and revision closure for wound dehiscence [n=2]), and non-union (n=1, treated with medial malleolar osteotomy revision fixation). Also in the STAR group there were 5 intraoperative medial or posterior malleolar fractures that were fixed internally at the index operation. Two patients developed deep vein thrombosis that was treated with anticoagulation, and another patient developed superficial wound dehiscence which healed uneventfully. Of the patients undergoing ankle fusion, indications for reoperation included non-union (n=2, requiring revision arthrodesis), hardware pain (n=2, requiring hardware removal), and naviculocuneiform joint arthritis progression (n=1, requiring fusion). Other complications in patients in the fusion group that were successfully treated without the need for surgical intervention included leg length discrepancy (n=1), delayed union (n=1), tibia stress fracture (n=1), hardware pain and wound dehiscence (n=1), and impingement (n=1).

In the randomised controlled trial by Wood et al (2009) complications that did not require further surgery included aseptic loosening in one patient (with severe systemic complications of rheumatoid arthritis), and osteolytic cavities in the tibia in 8 cementless STAR patients and 3 cementless BP patients.

Wood et al (2000) reported delayed wound healing in one patient in the cemented TPR group, which is a known risk for patients with rheumatoid arthritis as the disease may affect all connective tissue not just the joints and ligaments (Wood et al 2000). Another patient, in the cementless STAR group, suffered an intraoperative medial malleolar fracture, which was treated with a below-knee cast for 3 weeks and healed with no adverse effect on clinical results.

Complications that occurred in the study by Kofoed (2003) included aseptic loosening of the tibial component, in both the cemented STAR (n=6) and uncemented STAR group (n=1), and unexplainable pain in one patient in the cemented STAR group. There were no cases of meniscal breakage and either patient group throughout the study period.

Effectiveness

Saltzman et al (2010) reported a significant difference in postoperative SF-36 (mental component summary) score between patients in the STAR and fusion groups, with a higher score (better mental function) achieved in STAR patients (45.9 versus 40.4) (P=0.011). AOS-pain scores were also significantly different between the groups, with less pain experienced in STAR patients (26.0) compared with fusion patients (51.2) (P=0.001). Other clinical outcomes measures, including SF-36 physical component summary score and AOS-disability score were not significantly different for patients undergoing STAR or ankle fusion (P=0.131 and P=0.105, respectively). K/L arthritis grade was recorded at the subtalar, talonavicular, calcaneocuboid and midfoot for both pre- and post-operative radiographic assessment. Wilcoxon tank tests found no significant difference in preoperative or postoperative osteoarthritis between the STAR and fusion

groups at any joint evaluated. There was also no significant difference in the change in osteoarthritis (pre- to post- operative) between the two groups.

In the RCT by Wood et al (2009), 21 patients had died by the final follow-up (mean 18 months [range, 1-50 months]). Overall 8% (16/200) of ankles failed, 4% (4/100) in the cementless STAR group and 12% (12/100) in the cementless BP group. In the cementless STAR group removal of all components and fusion was carried out as a result of early infection (n=1), aseptic loosening (n=1), and replacement of a broken polyethylene insert (n=2). Additional surgery that did not fall into the fusion/revision category was required by one ankle in the cementless STAR group, this procedure involved debridement of the medial side of the joint for persistent pain at 20 months postoperative. Fusion was carried out for similar indications in the cementless BP group, including aseptic loosening (n=5), recurrent deformity (n=4), and broken titanium tibial implant (n=1). Revision surgery was required in two cementless BP patients for recurrent deformity, and additional surgery (neither fusion nor revision) was carried out in three ankles. These procedures included autologous bone grafting at 63 months for osteolytic cavities beneath the tibial and talar components, re-impaction of the tibial components three days after surgery as a result of technical error during the original procedure, and washout three weeks postoperative for infection.

At the last review all of the ankle replacements had satisfactory radiological appearance and all patients were satisfied with their outcomes. The American Orthopaedic Foot and Ankle Surgeon's (AOFAS) ankle and hind foot score for pain and function improved to a similar extent in both the cementless STAR and cementless BP groups. All patients had severe pain as the indication for surgery; therefore, their AOFAS score preoperatively was 0. This improved to a mean of 34 (range, 20-40) in the cementless STAR group and to a mean of 37 (range, 30-40) in the cementless BP group. The mean AOFAS function score improved from 31 (range, 10-44) and 33 (range, 12-51) preoperatively, respectively, to 45 (range, 21-58) and 46 (range, 29-58) postoperatively. The range of ankle movement overall did not deteriorate after surgery in either group. Specifically, the range of dorsiflexion improved by $\geq 10^\circ$ in 18% (16/88) of cementless STAR ankles and 19% (14/75) of cementless BP ankles, and the plantarflexion also improved by $\geq 10^\circ$ in 17% (15/88) of cementless STAR ankles and 8% (6/75) of cementless BP ankles.

The change in tibiotalar ratio in osteoarthritic ankles with preoperative anterior subluxation was not significant postoperatively, in either group. Edge loading of the ultra-high-molecular-weight polyethylene bearing was observed in 6 cementless STAR prostheses and 12 cementless BP prostheses. Sixteen percent (1/6) of edge loading STAR components were revised, and 50% (6/12) of edge loading BP components were revised. Preoperative varus/valgus alignment ($>15^\circ$) resulted in edge loading in 20% (4/20) of cementless STAR ankles and 33% (7/21) of cementless BP ankles. There was no significant difference between the prosthesis designs; however, in patients with a varus/valgus deformity of 15° preoperatively there was a 6.52 greater likelihood of developing edge loading than in patients with well aligned ankles.

There was also a trend seen towards a lower failure rate in patients receiving the cementless STAR prosthesis compared with the cementless BP prosthesis; however, this did not reach statistical significance ($P=0.09$). The presence of valgus and varus deformity preoperatively had a significant effect on survivorship in both groups ($P=0.02$). This meant for a patient presenting with varus/valgus deformity of the ankle of 15° the predicted six-year survival for the STAR would be 89.9% and for the BP it would be 73.6%, whereas for ankles in the neutral position preoperatively the predicted survival rate would be 97.1% and 91.9%, respectively.

Wood et al (2000) reported death in one patient in the cemented TPR group at 12 months postoperative from an unrelated cause. In the remaining 6 patients, radiographic loosening was apparent in 67% ($n=4$). Two of these patients went on to have their procedures fail at 22 and 26 months postoperative, respectively. Revision surgery (ankle arthrodeses) was required in both cases. Conversely there were no cases of radiographic loosening or revision in the uncemented STAR group. Only one patient in the cemented TPR group had a satisfactorily functioning ankle at the end of follow-up compared with 100% of patients in the uncemented STAR group. Pain was experienced by 75% (3/4 patients that had not failed) of patients in the cemented TPR group upon commencement of walking (characteristic of component loosening) compared with the uncemented STAR group patients who did not experience any pain. Mean Kofoed score³ in the uncemented STAR group was 74, compared with 52 in the cemented TPR group. The mean range of motion from maximum dorsiflexion to maximum plantarflexion for the uncemented STAR group was 30° compared with 22° .

In the study by Kofoed 2004, mean postoperative Kofoed score for the cemented and uncemented STAR prostheses respectively were 74.2 ± 19.3 and 91.8 ± 7.4 ($P>0.0001$). Bone-prosthesis radiolucency was observed in six patients in the cemented group and in one patient in the uncemented group. The need for revision or fusion surgery was considered a treatment failure. In the cemented group 9 patients' procedures failed and in the uncemented group 1 patient's procedure failed. Reasons for failure in the cemented group included tibial component subsidence after trauma ($n=1$), aseptic tibial component loosening ($n=6$), varus malalignment after a severe ankle distortion and lateral ligament ruptures ($n=1$), and unexplainable pain ($n=1$). Mean time to failure was 5 years (range, 2-11 years). The reason for failure in the uncemented group was painful loosening of the tibial component.

Twelve year survival rate was 70% (95% confidence interval, 60.3-78.5%) in the cemented STAR group and 95.4% (95% confidence interval, 91.0-99.9%) in the uncemented STAR group. There was a significant difference in the confidence intervals between the groups, indicating that outcomes for uncemented patients were superior.

³ Kofoed (2004) gave each ankle a clinical score out of 100, where 100 points were awarded to a normal ankle. Fifty points were given for no pain, 30 points were given for the patient's ability to participate in activities of daily living, and 20 points were given for normal mobility and no deformity.

COST IMPACT

The cost of the STAR system device alone is \$9,850 (ScoutNews 2009).

A cost-effectiveness analysis of total ankle arthroplasty was published in 2004 (US clinical context) (SooHoo and Kominski 2004). The purpose of the study was to evaluate whether available evidence at the time of the analysis justifies the emerging use of total ankle arthroplasty (device not specified). A decision model was created for the treatment of ankle arthritis with ankle arthrodesis and ankle arthroplasty. The literature was reviewed to identify possible outcomes and their probabilities. Gross costs were estimated from United States Medicare charge and reimbursement data. Assuming 10 year survival of the prosthesis, an incremental cost-effectiveness ratio for ankle arthroplasty of \$18,419 per quality-adjusted life year gained resulted. This reflects a 0.52 quality-adjusted life year at cost \$9575 gain when ankle arthroplasty was chosen over ankle arthrodesis. Because literature at the time of the analysis could not illustrate the predictable durability and function of arthroplasty it was not possible to show the cost-effectiveness of ankle arthroplasty. Given long-term clinical trials, provided they can support 10 year survival of the prosthesis, total ankle arthroplasty may prove to be a cost-effective alternative to ankle arthrodesis.

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were identified from the retrieved material.

OTHER ISSUES

One concern with total ankle replacement using uncemented prostheses is that many surgeons are performing the procedure with limited experience (Personal communication 2010).

SUMMARY OF FINDINGS

Total ankle replacement using the STAR system did not appear to be associated with major complications. In terms of effectiveness, the use of the STAR system generally reduced pain and improved function in patients suffering from painful arthritic ankle joints. Failure (defined as the need for revision surgery or arthrodesis) was less common in patients receiving the STAR system than other ankle replacement systems or the cemented version of the STAR system. Compared with fusion, pain and mental functioning outcomes were better following STAR; however, there was no significant difference seen in disability and physical functioning outcomes, or in radiographic outcomes between the groups.

HEALTHPACT ACTION

Given the increasing debate regarding the use of uncemented or cemented joint replacement procedures, it is recommended that a Horizon Scanning Report be written to explore these procedures in greater detail.

NUMBER OF STUDIES INCLUDED

| | |
|-------------------------|---|
| Total number of studies | 4 |
| Level III-1 evidence | 1 |
| Level III-2 evidence | 1 |
| Level III-3 evidence | 2 |

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SEARCH CRITERIA TO BE USED

Scandinavian total ankle replacement

Scandinavian total ankle replacement system

STAR system

Uncemented ankle replacement