STAR Design Evolution and Clinical History

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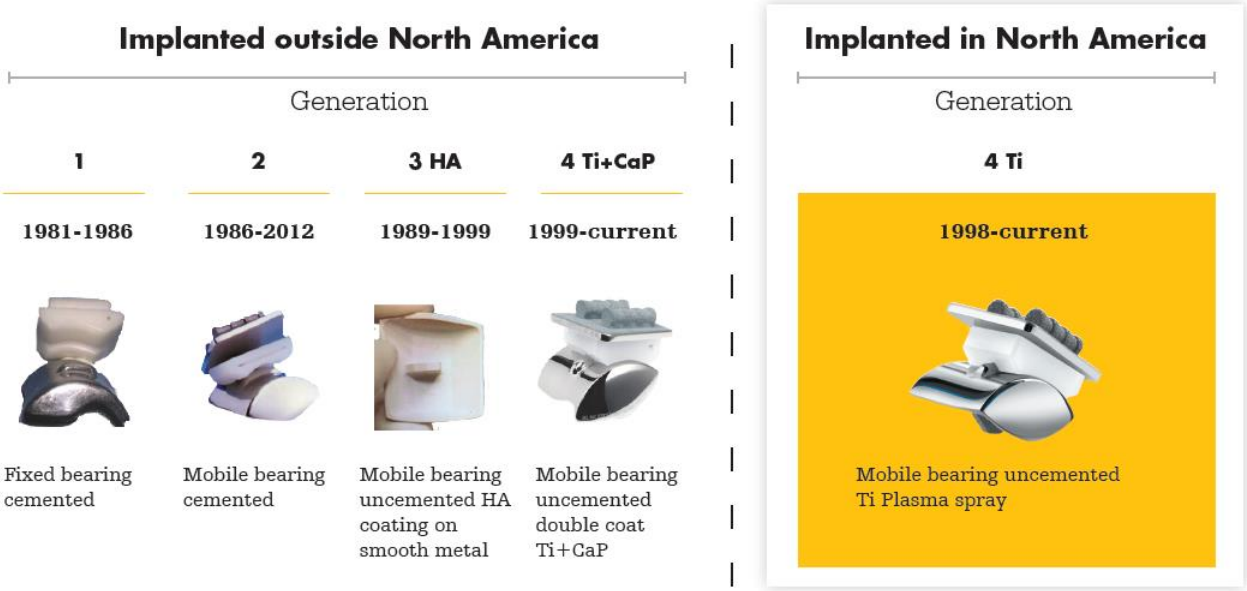
IMPLANT DESIGN HISTORY

When comparing clinical results of the STAR ankle implant, one must consider the generation of the design on which any report is based. There are 5 different versions of the STAR ankle which have been implanted since 1981.



First Generation

The Scandanavian Total Ankle Replacement (STAR) was designed by Hakon Kofoed, MD in collaboration with LINK AG, a German orthopedic implant manufacturer. The initial implant was a 2 piece cemented design consisting of a polyethylene tibial component and a cobalt chrome (CoCr) talar component (see Figure 1). This 1st generation STAR was only implanted from 1981-1986 using a cemented technique. The initial results reported by Kofoed showed a 70% survival rate at 12 years.[1]

Figure 1. First Generation STAR: Fixed Bearing Cemented(Outside North America)

Second Generation Outside North America

Kofoed wanted to improve his outcomes, so the STAR was changed from a 2 piece cemented to a Second Generation 3 piece cemented mobile bearing (see Figure 2). The main reasons for the change were to first 'minimize the rotational forces at the cement interface thereby reducing the loosening rate,' and second 'to allow for better ankle kinematics'.[2] The 2nd generation STAR was implanted in Europe from 1986 through 2012. Kofoed published his survivorship results with the 2nd generation cemented STAR achieving 70% survivorship at 12 years.[2]

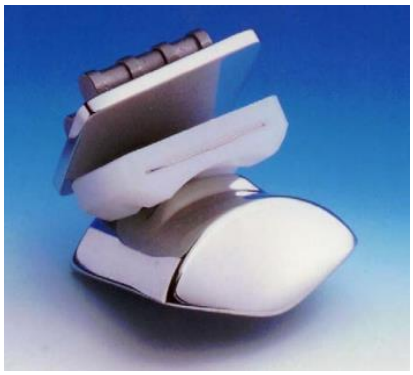


Figure 2. Second Generation STAR: Mobile Bearing Cemented (outside North America)

Third Generation

The 3rd generation was produced for ten years between 1989 and 1999. It was an uncemented 3 piece mobile bearing design with a HA coating over smooth CoCr (see Figure 3). Kofoed published the 12 year survivorship for his patients receiving the 3rd generation uncemented mobile bearing at 95.4%.[2]

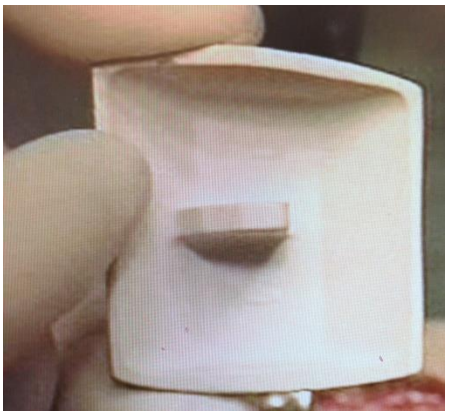


Figure 3. Third Generation STAR:
Three piece mobile bearing uncemented with HA over smooth CoCr(outside North America)

Kofoed explains that there are 3 reasons for the medial and lateral facets:[2]

- To cover the rough surfaces of the talar facets when the gutters require cleaning
- To preserve mobility as the facets are also involved in the degenerative processes of RA and OA
- To provide a broader surface area for talar component fixation. As the facets are covered in cartilage and normally articulate as part of the weight-bearing joint, this requires no vessel or ligament attachments to be sacrificed.

Fourth Generation

In 1998, the base coating of the STAR implant was changed to a rough Titanium plasma spray (see Figure 4). This is the design (Generation 4 Ti) which was used in the prospective clinical trials conducted in the US under the Investigational Device Exemption (IDE). A second version was introduced in 1999 by adding CaP (Generation 4 Ti + CaP) on top of the Titanium plasma spray (referred to as double coat) which is not available in the US(see figure 5).

Figure 4. Fourth Generation STAR: Mobile Bearing Uncemented Ti Plasma Spray (US Clinical IDE trials and Canada)

Figure 5. Fourth Generation STAR: Mobile Bearing Uncemented Ti Plasma Spray with CaP (referred to as double coat, implanted outside US and Canada)

INSTRUMENT DESIGN HISTORY

STAR Instruments (1978-2009)

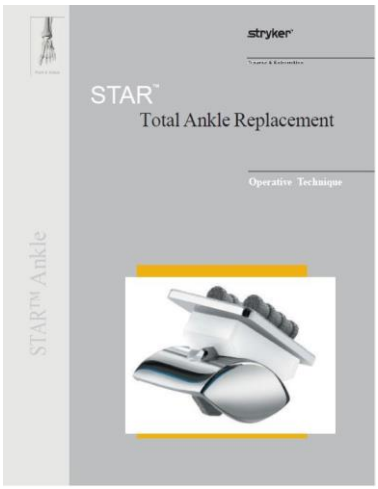
First Generation Instruments

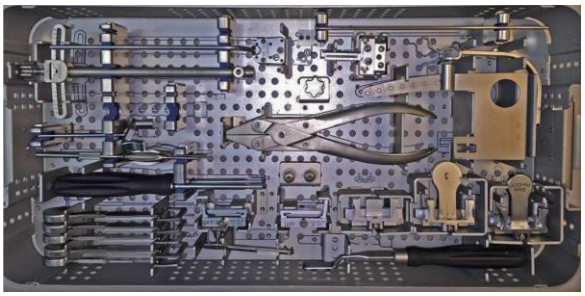
When LINK sold the STAR ankle in 2008, they stated that the instrumentation had not changed in 19 years which coincided with the release of the first cemented mobile bearing in 1986. "This surgical technique printed in 1993 and this Implant and Instrument brochure printed in 2001 show the surgical technique and instruments used prior to and up to the end of the clinical trials conducted in the US under the IDE" (see Figure 6).

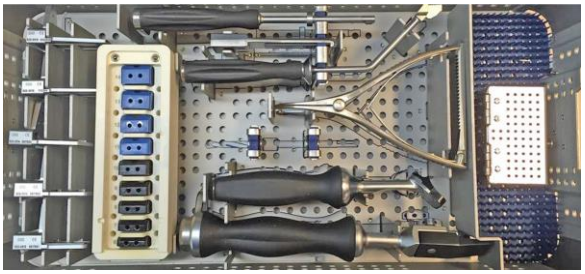
Figure 6. LINK Surgical Technique and implant and instrument brochure

Second Generation Instruments (2009-present)

The 2nd generation instruments were designed to coincide with the US market launch in 2009. The instruments were completely redesigned under the guidance of surgeons who participated in the clinical studies conducted under the IDE. The surgical technique was then re-written to incorporate the new instruments[17]. One of the conditions of FDA approval was to develop and implement a training program to ensure that surgeons were adequately trained on the surgical technique[16]. This training program was developed along with a new training video using the new instruments and technique. The courses were originally run by surgeons that participated in the IDE studies and subsequently expanded to additional Foot and Ankle surgeons experienced in Total Ankle Replacement. The goal in redesigning the instruments was to increase accuracy and repeatability by changing the cuts from open blocks to captured cutting guides used with key intra-operative C-arm images.







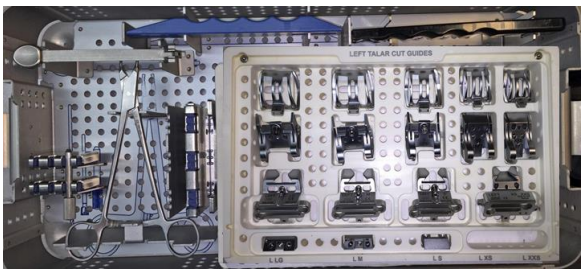


Figure 7. New STAR Surgical Technique and instrument sets

CLINICAL HISTORY

First and Second Generation

The clinical results for the 1st generation 2 piece and 2nd generation 3 piece STAR cemented implants both had 70% survivorship at 12 years previously described by Kofoed.[1,2]

Third and Fourth Generation

The clinical results for the 3rd generation STAR (smooth HA coating only) were reported by Kofoed to be 95.4% at 12 years.[2] Similar results (94%) were obtained by Carlsson[3] in which he compared the smooth single coat HA (3rd generation and rough double coat (4thgeneration Ti+CaP) at 5 years concluding that there did not appear to be a difference between single coat HA and double coat Ti+CaP during this time period. Wood[5] also found 93.3% survivorship at 5 years with the 3rd generation smooth single coat HA however these results decreased to 80.3% at 10 years. Wood[5] also conducted a prospective randomized study comparing two mobile bearing uncemented implants: STAR double coat Ti+CaP (4th generation outside North America) to Buechel Pappas. They reported 95% survivorship for STAR and 79% for Buechel Pappas at 6 years.[5] In a longer follow-up series Henricson et.al.[6] found that the smooth HA coat (3rd

generation) had lower survivorship scores than the rough double coat Ti+CaP (4th generation). Brunner et al published on smooth single coat HA (3rd generation) and showed a 70% implant survivorship at 11-15 years.[7] The most recent European study from Henricson and Carlsson[15] compares smooth single coat HA (3rd generation; referred to as STAR l) to 4th generation rough double coat Ti+CaP (referred to as STAR ll) reporting complications in the smooth single coat HA (3rd generation) group as 58/118 (49%) and the 4th generation rough double coat Ti+CaP as 67/206 (32%)[15]. However, if one excludes the complications due to infection and polyethylene breakage or wear, the complication rates drop to 44/118 (37%) for 3rd generation single coat HA and 48/206 (23%) for 4th generation double coat Ti+CaP. Note that none of the implants were done with the new instruments, as they were not released until 2009. The other interesting comment is that 4 surgeons performed 265 implantations (average 66 each) while 5 surgeons performed 59 surgeries (average 10 each).[15] Complications were found to be higher in the lower volume surgeon group.

The 4th generation Ti (rough Titanium plasma spray) was the version used in the US and Canadian long term studies. Mann et al found 91% metal component survivorship at 9.1 years, Haytmanek et al from Duke found 89.9% at 8 years and Coughlin et al found 94.4% at 12.6 year follow-up.[8,9,10] Finally, Daniels et al[11] from Canada showed 88% metal component survivorship at 9 years using the 4th generation single coat Ti. They considered revision as removal of one or both of the metal components as removal of only the bearing does not place the bone stock or total construct at risk[11].

Table 1. US and Canadian long term clinical results

Author	Type of implant	Average follow-up	Metal component survivorship
Daniels, Mayich, Penner[11]	Generation 4 Ti	9.0 years	88.0%
Haytmanek, Gross, Easley, Nunley[9]	Generation 4 Ti	8.0 years	89.9%
Mann, Mann, Horton[8]	Generation 4 Ti	9.1 years	91.0%
Jastifer, Coughlin[10]	Generation 4 Ti	12.6 years	94.4%

Table 2. European clinical results

Author	Type of implant	Average follow-up	Metal component survivorship
Wood et al[4]	Generation 3 HA	10 years	80.3%
Wood et al[5]	Generation 4 Ti+CaP	6 years	95%
Henricson, Nilsson, Carlsson[6]	Generation 4 Ti+CaP	10 years	76%
Brunner et al[7]	Generation 3 HA	10 years 14 years	70.7% 45.6%
Henricson and Carlsson[15]	Generation 4 Ti+CaP	12 years	64%
	Generation 3 HA	14 years	47%

LEARNING CURVE

As part of the U.S. PMA Approval of use of STAR in the U.S., the FDA required qualification and training of each new surgeon prior to shipping the STAR ankle to the hospital. The manufacturer complied with this and all new surgeons participated in a training program in order to be certified to insert the STAR.

The first publication addressing the learning curve using the STAR was reported by Haskell and Mann[12] where they reviewed the perioperative complications of the group of the initial surgeons that were carrying out the STAR prosthesis in the U.S.

Ten surgeons completed retrospective chart and radiographic reviews of their first 10 cases as well as 10 subsequent cases. This study showed that the overall incidence of adverse events was 3.1 times greater in the earlier 10 cases. In the early cases, wound complications accounted for the majority of the perioperative complications and were 3.2 times more prevalent in the first 10 cases. The wound complication rate dropped from 34% to 19%.

The initial report on the STAR U.S. IDE clinical trial was published by Saltzman, et al.[13], and this showed improvement from the initial 158 cases in the pivotal

cohort through the subsequent 448 cases in the continued access cohort. In the pivotal study of 158 cases, there were 14 major complications (8.9%). In the continued access group, there were 435 cases with 23 major complications, or a complication rate of 5.3%. Looking at the same figures with regard to interventions at 24 months, the pivotal group had revision or removal in 12 cases (7.6%) compared to the continued access group of 435 cases with 16 revisions or removals (3.7%).

Schimmel[14], et al. compared their first 50 STARs to the last 50 and this demonstrated a decrease in OR time and perioperative complications.

Daniels, et al.[11] reported a series of 111 cases between 2001 and 2005, and demonstrated an 18% revision rate of metal at 10 years in the first 40 ankles, while in the subsequent 71 ankles there was 8% metal revision at 8.4 years.

As in most technical orthopaedic procedures, there is a learning curve which needs to be considered when reviewing outcomes and results.

CONCLUSION

With time and experience, there has been evolution of the STAR prosthesis. The cemented versions all showed inferior results compared to the uncemented versions.[1] The uncemented 3rd generation single coat HA showed equivalent results compared to the uncemented 4th generation Ti+CaP at 5 years[4,] but went on to have inferior results at 10 years.[6,7,15] This may be due to the HA coating on the 3rd generation which gets resorbed with time leaving a smooth CoCr surface which is not ideal for bony ingrowth (see Table 2).

The best clinical results are seen with the uncemented 4th generation Ti from the U.S. and Canadian series. These results remain excellent at mid to long term follow-up.[8,9,10] The superiority and consistency of the results may be attributed to many factors, including strict inclusion-exclusion criteria, surgeon experience, and state of the bone-implant interface. Plasma sprayed Ti is one of the most common bone-implant interfaces in current day orthopedics, used on knee, hip as well as other prostheses. The US and Canadian studies show consistent results for the 4th generation Ti STAR. (see Table 1).

REFERENCES

1. Kofoed H: Cylindrical Cemented Ankle Arthroplasty. FAI 1995;16(8):474-479.
2. Kofoed, H, Scandanavian Total Ankle Replacement, CORR 2004;424:73-79.
3. Carlsson, A., Single and Double Coated star total ankle replacements: a clinical and radiographic follow-up study of 109 cases Orthopade 2006 May;35(5):527-32.
4. Wood, PL, Prem, H, Sutton, C., Total ankle replacement: medium-term results in 200 Scandinavian total ankle replacements. JBJS–Br 2008 May;90(5):605-9.
5. Wood PL, Sutton C, Mishra V, Suneja R. A randomized, controlled trial of two mobile bearing total ankle replacements. J Bone Joint Surg-Br 2009 Jan;91(1):69-74.
6. Henricson A, Nilsson JÅ, Carlsson A. 10-year survival of total ankle arthroplasties: a report on 780 cases from the Swedish Ankle Register. Acta Orthop. 2011;82(6):655-9.
7. Brunner, S, Barg, A, Knupp, M, Zwicky, L, Valderrabano, V, Hintermann, B, The Scandinavian total ankle replacement: long-term, eleven to fifteen-year, survivorship analysis of the prosthesis in seventy-two consecutive patients. JBJS-A 2013; 95(8):711-8.
8. Mann, JA., Mann, RA., Horton, E., STAR Ankle: Long-Term Results FAI 2011;32(5):473-484.
9. Haytmanek Jr, TC, Gross, C, Easley, ME, Nunley, JA Radiographic Outcomes of a Mobile-Bearing Total Ankle Replacement, FAI, 2015;36(9):1038-1044.
10. Jastifer, JR., Coughlin, MJ., Long-term follow-up of mobile bearing total ankle arthroplasty in the United States FAI, 2015;36(2):143-150.
11. Daniels, TR, Mayich, DJ, Penner, MJ Intermediate to Long-Term Outcomes of Total Ankle Replacement with the Scandinavian Total Ankle Replacement(STAR) JBJS-A 2015;97:895-903.

12. Haskell A., Mann, RA, Perioperative complication rate of total ankle replacement is reduced by surgeon experience. FAI 2004;25(5): 283-9.
13. Saltzman et al Prospective controlled trial of STAR total ankle replacement versus ankle fusion: initial results. FAI 2009;30(7):579-96.
14. Schimmel JJ1, Walschot LH, Louwerens JW. Comparison of the short-term results of the first and last 50 Scandinavian total ankle replacements: assessment of the learning curve in a consecutive series. FAI 2014;35(4):326-33.
15. Henricson A. and Carlsson A. Survival Analysis of the Singe- and Double-Coated STAR Ankle up to 20 years: Long-Term Follow-up of 324 cases From the Swedish Ankle Registry. FAI 2015;36(10):1156-1160.
16. PMA approval letter P050050 www.fda.com
17. STAR Total Ankle Replacement Operative Technique, VAX-ST-16, 02-2015.