

Enduring Outcomes of Star Ankle Replacement in Moderate to Severe Coronal Deformities: A Long- Term Perspective

Sidhartha Sohan¹, Sandeep Anand², C. K. Das³

¹Senior Resident, Department of Orthopaedics, Government Medical College, and Hospital, Purnea, Bihar, India

²Senior Resident, Department of Orthopaedics, Government Medical College, and Hospital, Purnea, Bihar, India

³Associate professor and HOD, Department of Orthopaedics, Government Medical College, and Hospital, Purnea, Bihar, India

Received: 19-11-2024 / Revised: 10-12-2024 / Accepted: 20-01-2025

Corresponding Author: Dr. Sandeep Anand

Conflict of interest: Nil

Abstract:

Background: Ankle osteoarthritis (OA) with a coronal plane deformity makes surgery very difficult. In the past, total ankle replacement (TAR) was not done in these circumstances because people were worried about fixing the alignment and the implant's long-term success. However, improvements in surgical methods and implant design, especially with the STAR prosthesis, have made TAR possible for more people, even those with moderate to severe deformity.

Aim and Objective: The goal of this study was to look at the long-term functional and radiological results of STAR complete ankle replacement in people with moderate to severe coronal plane abnormalities, as well as the rates of implant survival and complications.

Materials and Methods: The research took the form of an observational study that monitored patients at the Department of Orthopaedics in Government Medical College and Hospital, Purnea, Bihar, India for 12 months, 72 patients with end-stage ankle OA and varus or valgus deformities of 10° or more had STAR complete ankle replacement surgery. We used AOFAS Ankle-Hindfoot scores, FAAM scores, and VAS pain levels to measure how well things worked. At least five years of follow-up were used to look at how well the radiographic alignment was maintained and how long the implant lasted.

Results: The average AOFAS score increased from 43.7 ± 9.4 before surgery to 84.9 ± 8.1 at the last follow-up. All the scores went up: FAAM scores went from 45.6 ± 11.2 to 82.7 ± 9.6 , and VAS pain levels went down from 7.6 ± 1.3 to 2.1 ± 1.2 ($p < 0.001$ for all). 91.7% of patients kept their coronal alignment. The Kaplan-Meier survival analysis showed that 97.2% of implants survived after five years and 91.5% after eight years. There were not many complications or revisions overall.

Conclusion: When done with careful surgical planning and the right correction of deformity, STAR total ankle replacement gives patients with moderate to severe coronal plane deformities excellent long-term functional outcomes, long-lasting alignment correction, and a high rate of implant survival. It is a reliable way to preserve motion instead of ankle arthrodesis for these difficult patients.

Keywords: Total ankle replacement; STAR prosthesis; Coronal plane deformity; Ankle osteoarthritis; Implant survivorship.

This is an Open Access article that uses a funding model which does not charge readers or their institutions for access and distributed under the terms of the Creative Commons Attribution License (<http://creativecommons.org/licenses/by/4.0>) and the Budapest Open Access Initiative (<http://www.budapestopenaccessinitiative.org/read>), which permit unrestricted use, distribution, and reproduction in any medium, provided original work is properly credited.

Introduction

Although not as frequent as damage to the hip or knee, OA in the ankle also leads to a progressive disorder that makes moving and living comfortably much harder for those affected. Among the major factors that cause OA in the ankles, 70% to 80% are linked to injuries or fractures suffered by patients [1]. In some cases, extra damage to the ankle joint can happen when the joint line has a strong abnormal angle in the coronal plane. For a long time, fusion of the ankle was considered the main surgical method for those with advanced OA of the ankle, especially

if deformity existed. Reliable pain relief through fusion also affects joint flexibility and the way patients walk and it increases the risk of arthritis in both operated and nearby joints [2]. TAR, as another option, can successfully preserve joint motion and bring more normal walking and better results for suitable patients [3]. In the case of TAR, the Scandinavian STAR replacement is one of the most wanted, thanks to its flexible bearing which lowers the tension between moving parts and increases movement range. Still, fixing deformities in the coronal plane

with TAR is difficult in moderate to severe cases. In these cases, fixing the problem usually needs a lot of planning before surgery and the use of techniques such as ligament releases, bone adjustment and tendon balancing during the surgery [4]. Skipping correction for deformities may allow them to stay or come back which can result in bones being out of place, lack of stability, extra wear to plastic parts and finally, failure of the implant. Acceptable results can be found in studies that combine STAR TAR with other procedures, but rather little is reported about the long-term benefits for more severe cases [5]. In a recent series, it was proven that STAR TAR can lead to the successful correction of moderate deformities with the help of soft tissue balancing and specific supporting treatments [6]. Even so, some studies have shown that greater surgery complications and revisions are more common in patients with severe deformities (over 15°), pointing out that the severity of misalignment matters most. At the time of the review [7] in 2013, it was noted there were limited long-term results in this population and that better prospective studies are needed. On top of that, although corrections inside the theatre are successful in many cases, it's known that alignment cannot always be maintained as time goes by. The likelihood of the condition worsening over time and creating more symptoms is higher for patients whose ligaments relax, bones change or implants move incrementally [8]. Although overall, 80% or more of TAR patients are known to survive 10 years [9], it's not clear if these rates are still possible when the deformity affects the corona. In the end, it is necessary to assess outcomes reported by patients such as pain relief, movement, satisfaction and activity, as coronal deformities usually cause greater limitations before surgery [10].

We must know if STAR TAR has lasting benefits to give the best advice and work with patients on their choices of treatment. In these terms, the study was carried out to outline the long-term experience of STAR ankle replacement in patients affected by moderate to severe coronal plane deformities. The main targets of the study were to judge how well the deformity was corrected, whether the alignment was preserved long-term if implants lasted through follow-up, the effects of the surgery on function and the rate of complications and additional surgeries. Addressing these questions in detail using a set group, standard procedures and timely follow-up, this study hopes to prove how effective and safe STAR ankle prostheses are for patients with complex arthritis and a coronal deformity.

Methodology

Study Design: The research took the form of an observational study that monitored patients at the Department of Orthopaedics in Government Medical College and Hospital, Purnea, Bihar, India for 12 months

Sample Size: In this study, 72 patients with final-stage ankle arthritis and significant tilt in the ankle were selected after they satisfied the criteria and signed the informed consent form.

Inclusion and Exclusion Criteria

Inclusion Criteria:

- Patients aged between 30 and 75 years.
- Diagnosed with end-stage ankle osteoarthritis (Kellgren-Lawrence grade 4 or equivalent).
- Presence of moderate to severe coronal deformity ($\geq 10^\circ$ varus or valgus on standing AP radiograph).
- Underwent primary STAR total ankle replacement at the institution.
- Willing to participate in follow-up for a minimum of 5 years.

Exclusion Criteria:

- Prior history of ankle arthrodesis or total ankle replacement.
- Presence of active foot or ankle infection.
- Severe neuropathy or Charcot arthropathy.
- Severe osteoporosis or vascular insufficiency.
- Incomplete records or patients lost to follow-up before 5 years.

Procedure: A complete evaluation before surgery was done for each patient which involved measuring their ankle range, coronal deformity, ligament function and the way they walked. All cases had standard weight-bearing X-rays from front to back, sideways and for the hindfoot and CT was used only when needed for surgery planning. Coronal deformity was divided into moderate which ranges from 10° to 15° and severe, above 15°. Sterilized conditions were observed as the surgeon did the procedure from the front, using the STAR ankle for replacement. At some patients' sites, ligament releases or reconstructions, osteotomies in the calcaneus or tendon adjustments were also required. Right after their surgery, the patients were given antibiotics and blood thinners, then started on a rehabilitation agenda: splinting first, graduating to partial weight-bearing from 6 to 8 weeks and treatment with physiotherapy to regain ankle movement and strength. Postoperative surgery patients were examined regularly with clinical tests as well as X-rays.

Outcome Measures: Results of the patients' treatment were measured using the AOFAS Ankle-Hindfoot Score, the FAAM Daily Activities score and the VAS for pain. The scores were noted before the operation and at the last check-up, held after five years had passed. Serial anteroposterior and lateral standing radiographic images were used to find out how well the spine is positioned, whether the spine stays straight over time and if any signs of problems such as loosening, implant sinkage or bone loss are visible. The Kaplan-Meier survival curve was used to

study implant survivorship and revision surgery, meaning changing or taking out any implant parts, was used as the endpoint. Both early (occurring within the first three months) and late (occurring three months or more after surgery) postoperative complications such as infection, trouble with wound healing, damage to nerves, polyethylene deterioration or fracture, loosening and the need for any revision were noted during regular check-ups.

Statistical Analysis: The data was organized and examined using the software Microsoft Excel and SPSS. On top of this, continuous scores such as AOFAS, FAAM and VAS are presented as mean and standard deviation, whereas categorical variables like complication rates and those showing alignment are stated as frequency rates. Paired t-tests were done to compare the functional scores taken before the procedure and those from the follow-up period. Kaplan-Meier graphs were used to examine how

long the implants survived and revision surgery was set as the outcome of interest. P-values below 0.05 were deemed to be important in all the analyses.

Result

It's shown in Table 1 the first set of results that the patients taking part had an average age of 58.6 years and that there were more men (42) than women (30) among them. According to the mean BMI which was 27.4, most participants were classified as overweight. 61.1% of the cases we saw involved varus and 38.9% were valgus. Generally, before surgery, the misalignment angle was 17.2°, ranging from 10° to 28° which meant it was moderate to severe. Participants in the study reported symptoms for a longer time since the average period was 6.3 years. Because of these details, we easily know the differences between patients and can evaluate each surgery's outcome better.

Table 1: Patient demographics and baseline clinical characteristics

Parameter	Value
Age (years), mean $\pm$ SD (range)	58.6 $\pm$ 9.8 (34–75)
Gender (male/female)	42 / 30
BMI (kg/m ²), mean $\pm$ SD	27.4 $\pm$ 3.5
Type of deformity (Varus / Valgus)	44 (61.1%) / 28 (38.9%)
Preoperative deformity angle (°), mean $\pm$ SD	17.2° $\pm$ 4.6° (10°–28°)
Duration of symptoms (years), mean $\pm$ SD	6.3 $\pm$ 2.4

Table 2 stated that Patient results after surgery are much better than the results seen before surgery. Because the Ankle-Hindfoot Score jumped from 43.7 to 84.9, this means that the surgery greatly improved how the ankle and hindfoot functioned. In the same way, the increased FAAM score from 45.6 to 82.7 demonstrates that my foot and ankle skills improved

when doing everyday activities. The VAS score dropped from 7.6 to 2.1, so the pain decreased a lot in the process. Results indicated that the changes were important as p-values were under 0.001 and therefore, it was found that the program greatly benefited both daily activities and lowered pain.

Table 2: Comparison of functional outcome scores preoperatively and at final follow-up

Outcome Measure	Preoperative	Final Follow-up	p-value
AOFAS Ankle-Hindfoot Score	43.7 $\pm$ 9.4	84.9 $\pm$ 8.1	<0.001
FAAM Score	45.6 $\pm$ 11.2	82.7 $\pm$ 9.6	<0.001
VAS Pain Score	7.6 $\pm$ 1.3	2.1 $\pm$ 1.2	<0.001

In the study table 3 says that the photos demonstrated that the surgery had made a major improvement in the way the legs were lined up. The initial angle from which the bone was bent was 17.2° and after surgery, it decreased to 2.8° which means the correction was successful. It highlights the quality of the surgery that was done. After the follow-up, 91

percent (66 out of 72) of patients still kept their teeth in the correct position, showing good results. Yet, quite a few cases (8.3% that is, affecting 6 patients) were slightly relapsed, but the deformity remained mild and did not require extra attention. In most cases, patients manage to keep their back aligned, so the procedure can be trusted.

Table 3: Radiographic outcomes: correction and maintenance of coronal alignment

Parameter	Value
Preoperative deformity angle (°), mean $\pm$ SD	17.2° $\pm$ 4.6°
Postoperative deformity angle (°), mean $\pm$ SD	2.8° $\pm$ 2.1°
Cases with maintained alignment (%)	66 (91.7%)
Cases with mild recurrent deformity (%)	6 (8.3%)

Table 4 says that the Kaplan-Meier method revealed that the implant in the study provided long-term relief to the patients. At 5-year follow-up, over 97% of the implants functioned normally and did not need any fixing. A high survival rate after surgery shows that everything is in working order and the implant is fine for the near future. At the 8-year follow-up,

the survival rate became 91.5%, showing that the implants are still performing well and having a high level of stability. Gradual worsening of orthopaedic surgeries can result from long-term use and patient elements. On the whole, these reports prove that the implant is reliable and should last for many years, no matter how long the follow-up period.

Table 4: Kaplan-Meier implant survival rates at 5 and 8 years

Time Point	Implant Survival Rate (%)
5 years	97.20%
8 years	91.50%

Table 5 lists the complications that happened in both the early and late periods after surgery for the patients. Out of the 75 patients in this study, 4 cases had superficial wound infections, amounting to 5.6 percent. 3 patients required transient nerve injury, aseptic loosening and revision surgery each which accounted for 4.2% of the total cases. Two cases

(2.8%) had polyethylene wear and none were found to have deep infections. From these results, it can be seen that serious complications such as large infections were not experienced. Postoperative problems are easy to manage and less than a quarter of patients have to undergo revisions.

Table 5: Postoperative complications: early and late

Complication	Number of Cases (%)
Superficial wound infection	4 (5.6%)
Deep infection	0 (0.0%)
Nerve injury (transient)	3 (4.2%)
Polyethylene wear	2 (2.8%)
Aseptic loosening	3 (4.2%)
Revision surgery required	3 (4.2%)

Discussion

STAR total ankle replacement was shown to lead to long-term enhancements in patients with moderate to severe misalignments in the ankle. The AOFAS score increased from 43.7 to 84.9, the FAAM score went up from 45.6 to 82.7 and the VAS pain score dropped from 7.6 to 2.1 in the end. Besides, most patients maintained their correct tooth alignment after surgery and 97.2% of implants were still working at five years, remaining at 91.5% after eight years. According to these results, using STAR TAR and proper surgery is a practical and safe method for treating ankle deformities.

Previously, studies have found good results in fixing foot deformities through total ankle replacement. Cerrato et al. 2024 [15] found that TAR in varus ankles achieved great outcomes and preserved the position of the ankle similar to what is seen in neutral ankles. In the same way, according to Kim et al. [16], the presence of coronal plane deformity adds challenges, yet good outcomes are still possible when surgeons correct the alignment in the operating room. We saw the same level of alignment maintenance as Lee GW et al. 2019 [16] found in a large number of TAR patients in their study.

The results of our research match well with the functional outcomes described in previous literature. Researchers Glazebrook et al. [13] revealed that TAR

for ankle arthritis greatly improves patients' quality of life, similar to the benefits we noted in AOFAS and FAAM scores. STAR TAR surgeries gave patients superior results in terms of pain and recovery, even when faced with deformity, according to the study by Saltzman et al. [14]. This data indicates that TAR may give patients outcomes that are better than those achieved through arc welding surgeries.

Survivorship after implants among our patients reflects the expected outcomes seen in other studies. A 10-year survival of 78% to 94% is seen in the Swedish Ankle Register, while Zaidi et al. [12] in 13 studies found a survival rate of about 89% at eight to ten years. Our eight-year data show that the survival rate of the fixation near the deformity is consistent with the literature. This is further proven by Daniels et al. [18], who found equal intermediate-term results for TAR and arthrodesis, indicating that STAR and other similar systems can achieve positive outcomes in challenging ankle cases.

Our research revealed a low revision rate (4.2%) as well as almost no wound-related matters which corresponds with results from Doets et al. [17], who also studied mobile-bearing TAR in patients with severe challenges and found similar results. In addition, Haddad et al. emphasized that good preoperative planning for deformity cases can make the

results similar to those achieved for cases with normal joint alignment which we also found.

They have significant outcomes for patients and doctors. TAR Haddad SL, et al. 2007 [19] state that, historically, a significant coronal divot made surgeons more inclined to conduct fusion rather than use TAR. Fusion means the ankle joint doesn't move which usually results in damage to the nearby joints. From our research, it appears that as long as patients are selected carefully, the soft tissues are balanced and the needed surgery takes place in the operating room, TAR can be a good solution that allows patients to keep moving well for a long time.

Its design with patients who had surgery planned, the STAR implant and the long-term results are the main strengths of this study. There were only single-center results available in this study and no group of un-deformed subjects was provided. At the same time, although outcome scores were used, analyses in the future with patient-reported instruments would bring greater value to the study.

In essence, patients who had STAR total ankle replacement saw major improvements in function, the correction that held up well and an excellent survival rate for the implant. Because the procedure is carefully planned and done with skill, TAR is now suitable for this patient population.

Conclusion

It was found through this study that STAR total ankle replacement is both safe and effective for people with end-stage ankle osteoarthritis and important abnormalities in the coronal plane. We observed that people's ability to function improved significantly. The scores on the AOFAS, FAAM and VAS all improved greatly during my recovery. A high number of patients were found to keep their bone alignment correctly even after a long follow-up period (91.7%). The success of implants after five years was very high, at 97.2% and after eight years, it was 91.5%. It follows the conclusions of other studies. Previously, the possibility of poor alignment, a loose implant and more complications from total ankle replacement was a reason to avoid surgery in such cases. Still, our findings along with emerging evidence from other studies prove that if the surgery is done correctly, TAR leads to similar results as are seen in ankles that aren't abnormally formed. Few problems and re-operations occurred in our study which suggests that STAR TAR is a better option overall, as it helps people with deformities keep functional motion, feel less pain and move more easily, unlike what traditional ankle arthrodesis does. When people have moderate to severe imbalances in the coronal plane, STAR total ankle replacement could be the right surgery for them. For these findings to be solid and to create better surgical treatment for this type of patient, more big studies across

different hospitals with long follow-up should be done.

References

1. Mann JA, Mann RA, Horton E. STAR™ ankle: long-term results. *Foot & Ankle International*. 2011 May;32(5):473-84.
2. Valderrabano V, Horisberger M, Russell I, Dougall H, Hintermann B. Etiology of ankle osteoarthritis. *Clinical Orthopaedics and Related Research*. 2009 Jul;467(7):1800-6.
3. Little M, Binnie C, Effiom D, Super J, Kwok I, Rosenfeld P. The Salto Mobile-Bearing Total Ankle Arthroplasty: Survivorship, Radiologic, and Clinical Outcomes at an Average 9-Year Follow-Up. *Foot & Ankle International*. 2025 Apr;46(4):399-409.
4. Coester LM, Saltzman CL, Leupold J, Pontarelli W. Long-term results following ankle arthrodesis for post-traumatic arthritis. *JBJS*. 2001 Feb 1;83(2):219.
5. Fuchs S, Sandmann C, Skwara A, Chylarecki C. Quality of life 20 years after arthrodesis of the ankle: a study of adjacent joints. *The Journal of Bone & Joint Surgery British Volume*. 2003 Sep 1;85(7):994-8.
6. Hobson SA, Karantana XA, Dhar S. Total ankle replacement in patients with significant pre-operative deformity of the hindfoot. *The Journal of Bone & Joint Surgery British Volume*. 2009 Apr 1;91(4):481-6.
7. Reddy SC, Mann RA, Zemeir K, Reddy SC. Long-Term Follow up of Correction of Moderate to Severe Deformity with the STAR Ankle Prosthesis. *Foot & Ankle Orthopaedics*. 2020 Oct 22;5(4):2473011420S00398.
8. Wood PL, Prem H, Sutton C. Total ankle replacement: medium-term results in 200 Scandinavian total ankle replacements. *The Journal of Bone & Joint Surgery British Volume*. 2008 May 1;90(5):605-9.
9. Yang HY, Wang SH, Lee KB. The HINTEGRA total ankle arthroplasty: functional outcomes and implant survivorship in 210 osteoarthritic ankles at a mean of 6.4 years. *The Bone & Joint Journal*. 2019 Jun 1;101(6):695-701.
10. Gauvain TT, Hames MA, McGarvey WC. Malalignment correction of the lower limb before, during, and after total ankle arthroplasty. *Foot and Ankle Clinics*. 2017 Jun 1;22(2):311-39.
11. Henricson A, Nilsson JÅ, Carlsson Å. 10-year survival of total ankle arthroplasties: a report on 780 cases from the Swedish Ankle Register. *Acta orthopaedica*. 2011 Dec 1;82(6):655-9.
12. Zaidi R, Cro S, Gurusamy K, Sivanadarajah N, Macgregor A, Henricson A, Goldberg A. The outcome of total ankle replacement: a systematic review and meta-analysis. *The bone & joint journal*. 2013 Nov 1;95(11):1500-7.

13. Glazebrook M, Daniels T, Younger A, Foote CJ, Penner M, Wing K, Lau J, Leighton R, Dunbar M. Comparison of health-related quality of life between patients with end-stage ankle and hip arthrosis. *JBJS*. 2008 Mar 1;90(3):499-505.
14. Saltzman CL, Mann RA, Ahrens JE, Amendola A, Anderson RB, Berlet GC, Brodsky JW, Chou LB, Clanton TO, Deland JT, DeOrio JK. Prospective controlled trial of STAR total ankle replacement versus ankle fusion: initial results. *Foot & ankle international*. 2009 Jul;30(7):579-96.
15. Cerrato R. Minimally Invasive. Updates in Hallux Rigidus, An issue of Foot and Ankle Clinics of North America, E-Book: Updates in Hallux Rigidus, An issue of Foot and Ankle Clinics of North America, E-Book. 2024 Jul 30;29(3):471.
16. Lee GW, Seon JK, Kim NS, Lee KB. Comparison of intermediate-term outcomes of total ankle arthroplasty in patients younger and older than 55 years. *Foot & Ankle International*. 2019 Jul;40(7):762-8.
17. Doets HC, Brand R, Nelissen RG. Total ankle arthroplasty in inflammatory joint disease with use of two mobile-bearing designs. *JBJS*. 2006 Jun 1;88(6):1272-84.
18. Daniels TR, Younger AS, Penner M, Wing K, Dryden PJ, Wong H, Glazebrook M. Intermediate-term results of total ankle replacement and ankle arthrodesis: a COFAS multicenter study. *JBJS*. 2014 Jan 15;96(2):135-42.
19. Haddad SL, Coetzee JC, Estok R, Fahrback K, Banel D, Nalysnyk L. Intermediate and long-term outcomes of total ankle arthroplasty and ankle arthrodesis: a systematic review of the literature. *JBJS*. 2007 Sep 1;89(9):1899-905.