

# Total ankle replacement with INBONE-II prosthesis: A short-to-medium-term follow-up study in China

Yong Wu<sup>1</sup>, Hanyuan Yang<sup>1</sup>, Xiangbin Guo<sup>2</sup>, Hui Du<sup>1</sup>, Xiaofeng Gong<sup>1</sup>

<sup>1</sup>Department of Foot and Ankle Surgery, Beijing Jishuitan Hospital, Beijing 100035, China;

<sup>2</sup>Department of Foot and Ankle Surgery, Beijing Chaoyang Emergency Medical Center, Beijing 100021, China.

## Abstract

**Background:** Total ankle replacement (TAR) is a viable option for the treatment of end-stage ankle arthritis. In China, the INBONE-II implant is the only total ankle prosthesis approved since 2016. The purpose of this study is to report a large sample of findings for the TAR with INBONE-II prosthesis.

**Methods:** A total of 64 patients with end-stage ankle arthritis, who underwent primary TAR using INBONE-II by the same surgeon from 2016 to 2019, at a single institution were included in this retrospective, single-center study. Clinical data, radiographic findings, survival rate, and complications were recorded and assessed pre-operatively and at the most recent follow-up.

**Results:** A total of 64 patients were available for follow-up at least 2 years after surgery; the mean follow-up duration for clinical outcomes was 37.9 months (24–59 months), and for radiographic findings was 22.8 months (12–59 months). There were significant improvements ( $P < 0.01$ ) in the American Orthopedic Foot and Ankle Society hindfoot scale, the visual analog scale for pain, and the Short Form-36. There were statistically significant differences between pre-operative and post-operative comparisons of the talar tilt angle (TT) and the tibial lateral surface angle (TLS) in the radiographic findings (TT from  $4.7 \pm 4.3^\circ$  to  $1.3 \pm 1.3^\circ$ , TLS from  $80.4 \pm 7.7^\circ$  to  $87.4 \pm 2.3^\circ$ ,  $P < 0.01$ ). There was no statistically significant difference in improvement of the tibial anterior surface angle ( $P = 0.14$ ). Ten complications (all low grade) were recorded according to the Glazebrook classification system. The survivorship of the prosthesis was 100% (64/64).

**Conclusion:** Patients who underwent TAR with INBONE-II prosthesis demonstrated significant improvements in all measures of pain and function as well as in radiographic findings. High survival and a low incidence of complications were observed in this study.

**Keywords:** Total ankle replacement; Total ankle arthroplasty; Outcomes; Complications; INBONE-II

## Introduction

Ankle osteoarthritis (OA) is a chronic disease.<sup>[1]</sup> The causes include trauma, degenerative changes, rheumatic diseases, hemophilia, hemochromatosis, gout, avascular necrosis, and post-infectious states. End-stage ankle arthritis often manifests as severe weight-bearing pain, dysfunction, and impaired mobility.<sup>[1]</sup> Currently, common surgical procedures for the treatment of end-stage ankle arthritis include ankle arthrodesis (AA) and total ankle replacement (TAR). Previous studies have confirmed that AA can effectively relieve pain and restore limited function, but this operation sacrifices ankle joint mobility and may cause or aggravate arthritis in adjacent joints.<sup>[2]</sup> TAR can relieve pain and improve function while preserving the range of motion of the ankle joint, and its clinical outcome has gradually been confirmed.<sup>[2-9]</sup> It

has been considered that AA is the gold standard for the treatment of end-stage ankle arthritis before TAR. In recent years, with the continuous improvement of surgical techniques and prosthetic products, the application of TAR has become more common, and it has become a common treatment for end-stage ankle OA.<sup>[2-6]</sup>

There have been many reports of the use of different types of TAR prostheses for the treatment of end-stage ankle OA, and the satisfaction rate, function, and pain improvement are significant.<sup>[7-9]</sup> However, the clinical and radiographic results of using INBONE-II (Wright Medical Technology, Arlington, TN, USA), prosthesis were rarely reported. INBONE-II is a third-generation, 2-component TAR prosthesis, which allows for improved biomechanical stability over the previous design, particularly in the coronal plane.<sup>[10]</sup> In 2016, the INBONE-II

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**Correspondence to:** Xiaofeng Gong, Department of Foot and Ankle Surgery, Beijing Jishuitan Hospital, 31 Xinjiekou East Street, Xicheng District, Beijing 100035, China  
E-Mail: gregorygong@126.com

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prosthesis was put into the market in China. It is the only TAR prosthesis on the market in our country for a period of time, but there is still a lack of relevant large-sample clinical studies of whether it is suitable for ankle OA caused by common domestic causes and its clinical efficacy. Therefore, this study aimed to explore the medium-term and short-term clinical outcomes, radiographic findings, complications, and prosthetic survival of single-center, large-sample TAR surgery using INBONE-II prosthesis.

## Methods

### Ethical approval

This study was approved by the Ethics Committee of Beijing Jishuitan Hospital (No. 202204-16-01). In this retrospective study, informed written consent was obtained from all patients before their enrollment in this study. All patients allowed researchers to analyze their data and produce academic results.

### Inclusion and exclusion criteria

Inclusion criteria: (1) INBONE-II prosthesis use for TAR; (2) Age  $\geq 18$  years; (3) Patient informed consent obtained; (4) Negative past history of TAR or AA surgery; and (5) Post-operative follow-up time  $\geq 2$  years.

Exclusion criteria: (1) Active infection or previous infection in the foot and ankle; (2) Neurogenic arthropathy (Charcot joint); (3) Severe benign joint hypermobility syndrome; (4) Full-length non-digital lower limb x-rays with abnormal alignment in knee joints or hip joints; (5) Uncontrolled diabetes; (6) Tumors, peripheral neurovascular diseases, etc.; and (7) Incomplete medical records.

### Observation indicators

From August 1, 2016 to June 31, 2019, a total of 69 patients underwent TAR surgery using the INBONE-II prosthesis, all of which were performed by the same surgeon. According to the above inclusion and exclusion criteria, a total of 64 patients were included in the study.

We recorded various demographic data from the hospital medical record system, including age, gender, height, weight, etiology, history of smoking, history of diabetes, and history of previous ankle surgery. We also recorded surgery-related information, including the amount of bleeding, the length of the operation, etc. According to the medical record system and post-operative follow-up, the types and numbers of intra-operative and post-operative complications were recorded. The grade of complications was classified according to the Glazebrook classification system.<sup>[11]</sup>

We used the American Orthopedic Foot and Ankle Society (AOFAS) ankle hindfoot scale, visual analog scale (VAS), and the Short Form-36 (SF-36) to evaluate patients pre-operatively and at the final follow-up. Using the hospital imaging system, on the weight-bearing X-ray images, we

used the tibial anterior surface angle (TAS), tibial lateral surface angle (TLS), and talar tilt angle (TT) to measure the radiographs of patients with pre-operative and follow-up time of  $>1$  year after surgery [Figure 1]. TAS is defined as the angle between the articular surface of the distal tibia and the axis of the tibia on the anterior-posterior view, TT is defined as the angle between the articular surface of the distal tibia and the articular surface of the talus, TLS is defined as the angle between the articular surface of the distal tibia and the axis of the tibia on the lateral view. The range of motion of the patient's ankle dorsiflexion and plantar flexion was recorded before the operation and at the final follow-up.

### Surgical methods

The patient was brought into the operating room and was placed in a supine position with a thigh tourniquet applied to the operative lower extremity. An ipsilateral hip bump was placed to internally rotate the leg. The foot and ankle were prepped to the level of the knee in the standard fashion by pre-operative fluoroscopy. A central anterior incision or arc incision of the ankle joint was made to expose the joints from the interval of tibialis anterior and the extensor hallucis longus. The osteophytes and hyperplastic synovium were resected, and the soft tissue released. After reducing the ankle to the anatomically corrected position, K-wire was used to cross fix the tibiotalar joint. The lower extremity was then placed into the external fixation jig with the help of manufacturer's guidelines and technique for the INBONE-II TAR. Intraoperative fluoroscopy was used for the alignment of our extra-medullary alignment and sizing for our tibial and talar cuts under standard manufacturer's guidelines and techniques. A 6 mm drill bit was used to drill through the calcaneus into the talus, about 5 to 6 cm deep into the medullary cavity of the tibia. An appropriate size osteotomy guide was selected, and fixed to the front of the fixator, after making sure the size of the osteotomy guide was appropriate (just within the ankle joint). Using a pendulum saw to cut the bone, the front guide plate was removed, the bone block taken out and rinsed with the flushing gun, and finally the anteroposterior size of the tibial tray was tested. The tibial stem and tibial tray were installed, and fluoroscopy was performed. The talus stem and talus dome were then installed, and the lateral view checked through fluoroscopy. Finally, the polyethylene component was inserted and the position of the prosthesis

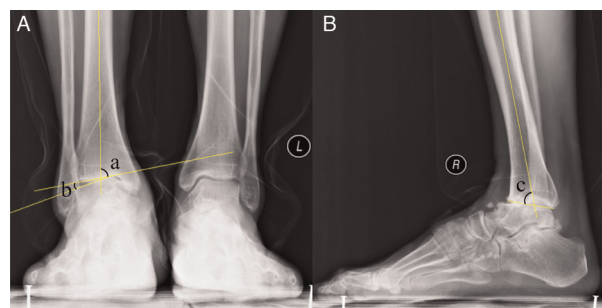
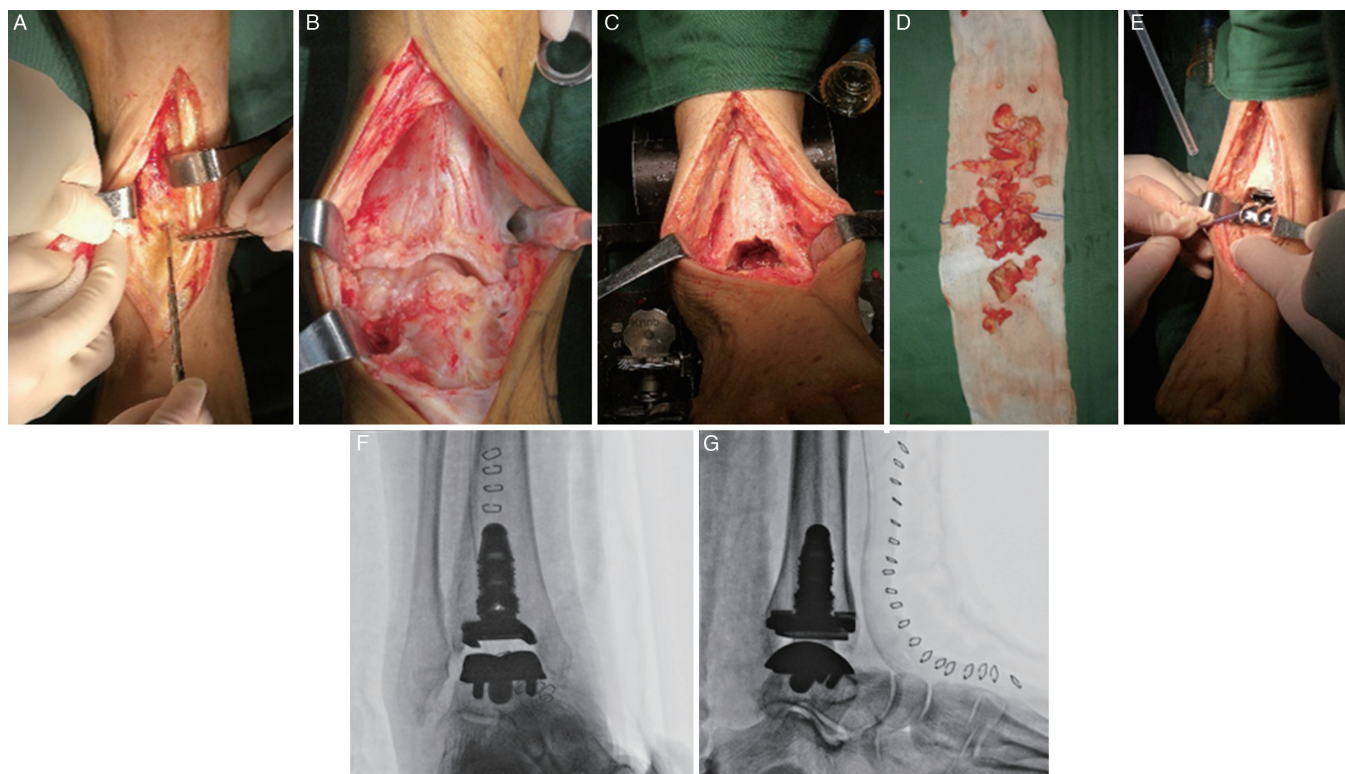


Figure 1: Measurement of tibial anterior surface angle (TAS), talar tilt (TT) on anterior-posterior view (A), and tibial lateral surface angle (TLS) on lateral view (B). a: TAS; b: TT; c: TLS.



**Figure 2:** Intra-operative photographs (A–E) of the ankle joint and immediate post-operative X-rays (F,G). (A) Shows the interval between the tibialis anterior and the extensor hallucis longus; (B) shows the joint capsule is opened, and osteophyte proliferation is obvious, the articular surface is severely worn, and the cartilage damage area exceeds 2/3; (C) shows the osteotomy after removing the osteophyte and synovium; (D) shows the removed osteophytes and bone obtained from osteotomy; (E) shows the implantation of the prosthesis; (F) and (G) show the X-ray on AP and lateral view immediately after the operation, when the prosthesis is in a good position.

was checked through fluoroscopy. The mobility of the ankle joint was also checked [Figure 2]. Achilles lengthening was also performed as needed. In this study, one patient underwent additional Achilles tendon lengthening.

### Statistical methods

IBM SPSS 25.0 (SPSS Inc., Chicago, IL, USA) software was used for statistical analysis. For continuous variables, Shapiro–Wilk’s test for normality detection was first used, then mean  $\pm$  standard deviation (SD) for normal distribution. Two independent sample *t* test was used for independent sample comparison between the two groups, and paired sample *t* test was used for pre-operative and post-operative sample comparison. Those that did not conform to the normal distribution were expressed by median (P25, P75), and the Wilcoxon signed-rank test was used for comparison between the two groups. The difference was considered to be statistically significant when  $P < 0.05$ .

### Results

A total of 64 patients (33 males, 31 females) were available for the final follow-up in this study, with an average age of  $59.9 \pm 10.5$  years (39–79 years) at the time of surgery. In terms of etiology, traumatic arthritis, primary arthritis, and arthritis due to other causes (all rheumatic) accounted for 47, 14, and 3 cases of arthritis, respectively. Among all

64 patients, twenty of them had a history of smoking, nine had type 2 diabetes, and 19 patients had a history of ankle surgery. The operating time was  $164.2 \pm 33.4$  minutes, and the amount of bleeding was  $186.3 \pm 90.9$  ml.

The average follow-up time was 37.9 months (24.0–59.0 months). During this time, the post-operative AOFAS score increased from 5.0 to 83.6, the VAS score decreased from 94.0 to 127.4. The differences of pre-operative and post-operative clinical results were statistically significant ( $P < 0.01$ ); the ankle dorsiflexion range increased from  $7.6^\circ$  to  $13.2^\circ$ ; and the plantar flexion range was restored from  $15.1^\circ$  to  $22.2^\circ$ . These were statistically significant differences ( $P < 0.01$ ). The average follow-up time of the patient’s imaging results was 22.8 months (12.0–59.0 months), the last follow-up TAS was  $87.8 \pm 2.4^\circ$ , TLS was  $87.4 \pm 2.3^\circ$ , and TT was  $1.3 \pm 1.3^\circ$ . There were significant differences of TLS and TT before and after surgery ( $P < 0.01$ ) [Table 1]. At the last follow-up, none of the patients had any failure of the prosthesis, and the survival rate of the prosthesis was 100% (64/64).

A total of 10 patients had surgery-related complications, and the complication rate was 15.6%. Among the 64 patients, three cases (4.7%) had medial malleolus fractures during operation, 4 (6.3%) had wound healing problems after operation, two (3.1%) had toe numbness, and one (1.6%) had wound infection, all of which were mildly complicated. The symptoms were detected on time and

**Table 1: Pre-operative and final follow-up clinical outcomes and radiographic findings.**

Items	Pre-operative	Post-operative	Statistics	P value
AOFAS	47.1 ± 14.9	83.6 ± 10.8	16.14*	<0.01
VAS	5.0 (4.0, 6.0)	1.0 (0.0, 2.0)	270.00†	<0.01
SF-36	94.0 ± 11.7	127.4 ± 9.5	9.56*	<0.01
Ankle range of motion (°)	22.8 ± 7.5	35.2 ± 10.9	8.01*	<0.01
Ankle dorsiflexion range (°)	7.6 ± 4.8	13.2 ± 5.0	6.32*	<0.01
Ankle plantar flexion range (°)	15.1 ± 4.6	22.2 ± 7.4	7.38*	<0.01
TAS (°)	84.9 ± 12.8	87.8 ± 2.4	1.52*	0.14
TLS (°)	80.4 ± 7.7	87.4 ± 2.3	5.94*	<0.01
TT (°)	4.7 ± 4.3	1.3 ± 1.3	8.16*	<0.01

Values are presented as mean ± standard deviation or median (P25, P75). AOFAS: American Orthopedic Foot and Ankle Society; SF-36: Short Form-36; TAS: Tibial anterior surface angle; TLS: Tibial lateral surface angle; TT: Talar tilt; VAS: Visual analog scale. \* Paired *t* test. † Wilcoxon signed-rank test.

**Table 2: Treatment and outcome of 10 complications.**

Patient No.	Complication	Time of occurrence	Treatment	Outcome
1	Numbness of the toes	Post-operation	Neurotrophic drug therapy	Got better, still a little numb
2	Medial malleolus fracture	During operation	Intra-operative reduction, fixation with one screw	Healed
3	Medial malleolus fracture	During operation	Intra-operative reduction, fixation with one screw	Healed
4	Medial malleolus fracture	During operation	Intra-operative reduction, fixation with two screws	Healed
5	Delayed wound healing	Post-operation	Change the dressing regularly	Healed 12 weeks after surgery
6	Wound dehiscence	Post-operation	Rehospitalized at 1 month after surgery for local flap transfer	Healed 4 months after surgery
7	Delayed wound healing	Post-operation	Change the dressing regularly	Healed 12 weeks after surgery
8	Delayed wound healing	Post-operation	Change the dressing regularly	Healed 4 months after surgery
9	Numbness of the toes	Post-operation	Neurotrophic drug therapy	Got better, still a little numb
10	Wound infection	Post-operation	Rehospitalized at 1 month after surgery for debridement	Healed 2 months after surgery

treated accordingly, and all the cases turned out to be good [Table 2]. No serious complications occurred in all patients.

Among all the patients, 47 patients (73.4%) were very satisfied with the operation, 11 (17.2%) were relatively satisfied, and four (6.3%) considered they only got little effect. The overall satisfaction rate reached 90.6%. There were two patients (3.1%) who were not satisfied with the operation due to persistent pain in the ankle joint and persistent numbness in the toes [Table 3]. Figure 3 shows a typical case of TAR using INBONE-II prosthesis.

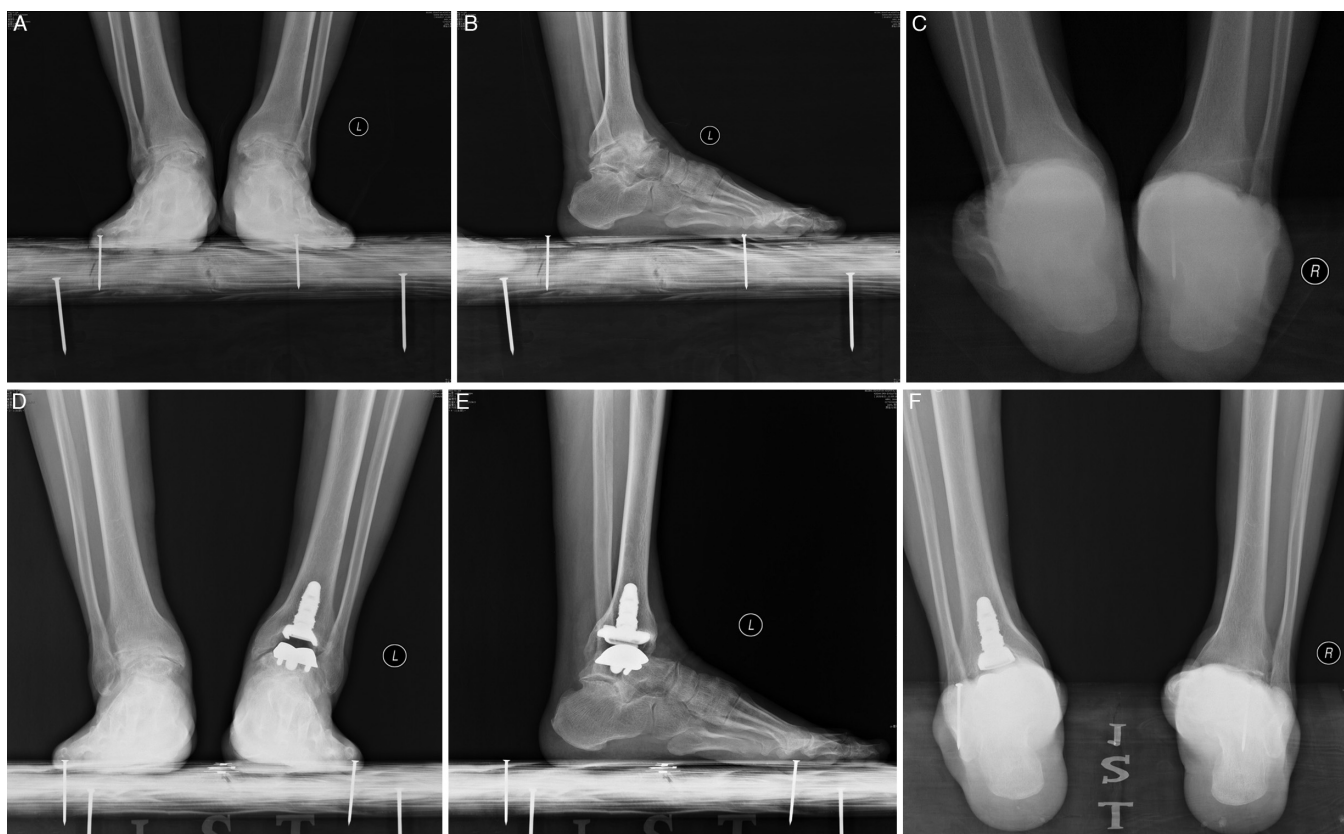
**Discussion**

In this study, we performed TAR using INBONE-II prosthesis. The post-operative clinical results, radiographic findings, and ankle range of motion were significantly improved. The incidence of complications was low (15.6%, 10/64), and there was no case need revision. Only 3.1% (2/64) were not satisfied with the operation. It is proved that the use of INBONE-II prosthesis in the treatment of end-stage ankle arthritis can significantly release pain, improve function, and bring good imaging performance.

There have been literature reports on the post-operative efficacy and imaging of other prostheses for TAR surgery, most of which shown that they produce reliable and significant improvement, and that their imaging performance is good.<sup>[7-10]</sup> However, there are still a few clinical research reports on the use of INBONE-II prosthesis for TAR [Table 4]. Adams *et al*<sup>[12]</sup> first published the early results of 194 cases of INBONE-II prosthesis for initial replacement in 2014, and the results showed that the clinical score had significantly improved 3.7 years after surgery (*P* < 0.003). A retrospective study of 59 cases of INBONE type I and type II prostheses showed that at a follow-up time of 2 years, the AOFAS score in the INBONE-II group averaged 90.1 points, the average VAS score was 1.3 points, and the average ankle joint range of motion was 39.7°.<sup>[13]</sup> Another study showed that 56 cases of INBONE-II prosthesis replacement had a good clinical outcome 2 years after surgery; the proportion of post-operative prostheses in a neutral position in the coronal position was 96.4%, and this proved that the use of INBONE-II prosthesis replacement has a good corrective effect on the TT.<sup>[14]</sup> Research by Rushing *et al*<sup>[15]</sup> showed that 6 weeks after INBONE-II prosthesis replacement, the coronal and sagittal alignments were satisfactory, and it was observed that the alignment

**Table 3: Six patients evaluated as not ideal or unsatisfied.**

Patient No.	Evaluation	Reasons for dissatisfaction	Treatment	Outcome
1	Not ideal	Numbness of the toes	Neurotrophic drug therapy	Got better, still a little numb
2	Not ideal	Ankle pain	Drug therapy, rehabilitation exercise	Improved, still pain when walking with weight-bearing
3	Not ideal	Ankle pain and swelling	Drug therapy, rehabilitation exercise	The swelling is gone, still pain when walking with weight-bearing
4	Not ideal	Limping, difficult to turn when walking	Drug therapy, rehabilitation exercise	Got better
5	Unsatisfied	Ankle pain	Drug therapy, rehabilitation exercise	Got better, still having resting pain
6	Unsatisfied	Numbness of the toes	Neurotrophic drug therapy	Got better, still a little numb



**Figure 3:** The male patient, 47 years old, with traumatic ankle arthritis. (A-C) The pre-operative X-ray showed that the ankle joint was seriously damaged, osteophyte hyperplasia is obvious, the joint space disappeared, and the distal tibia and the top of the talus had sclerosis; (D-F) 2 years after TAR, X-ray showed that the position of the prosthesis was good, the alignment was neutral, and there was no obvious prosthesis displacement and heterotopic ossification. TAR: Total ankle replacement.

remained good at the 7-year follow-up ( $P=0.684$ ,  $P=0.837$ ). Our study showed that the post-operative AOFAS score, VAS score, SF-36 score, and ankle range of motion significantly improved compared to their pre-operative values; TAS, TLS, and TT showed that the alignment of post-operative ankle joints can be improved (Table 1). Therefore, we believe that the use of INBONE-II prosthesis for TAR has a reliable, obvious therapeutic effect, and satisfactory radiographic performance. In addition, the pre-operative TT of the patients in this study was  $4.7 \pm 4.3^\circ$ , and eight patients had  $TT \geq 10^\circ$ . Previous studies have shown that excessive pre-operative coronal deformity may be a risk factor for early failure of TAR. As the degree of deformity increases, it becomes

difficult to restore the neutral position of the ankle joint alignment. Poor alignment is likely to be left behind in the ankle joint after surgery, which may lead to prosthesis wear, joint instability and dislocation, and lead to failure of the operation.<sup>[16,17]</sup> However, recent studies have shown that if the ankle joint is stable and in a neutral position after TAR, the pre-operative deformity will not reduce the clinical outcome.<sup>[17-23]</sup> In our study, all the patients were satisfied with post-operative TT correction ( $TT = 1.3 \pm 1.3^\circ$ ), and the clinical effect was good, indicating that the use of INBONE-II prosthesis for TAR can also make patients with severe ankle coronal deformity obtain good clinical results and imaging performance.

**Table 4: Relevant literature on the use of INBONE-II prosthesis for total ankle arthroplasty.**

Article	Type of study	No.	Follow-up time (years)	Clinical outcomes	Radiographic findings	Implant survival rate (%)	Complications (%)
Hsu and Haddad <sup>[13]</sup>	Retrospective study	31	2.9	AOFAS: 90.1 ± 11.9 VAS: 1.3 ± 2.1 Ankle range of motion: 39.7 ± 10.4°	–	100	25.8
Lewis <i>et al</i> <sup>[14]</sup>	Single-center prospective controlled study	56	2.1	SF-36 averaged: 78.7 VAS averaged: 0.9 AOFAS averaged: 82.5	Neutral alignment: 96.4% TT: 1.6° (preoperative varus deformity) TT: –1.0° (preoperative valgus deformity)	97.4	8.9
Rushing <i>et al</i> <sup>[15]</sup>	Case series study	15	7.1	–	TT: 2.6 ± 2.2° Tibial axis–talar ratio (TTR) averaged: 36% Rate of heterotopic ossification: 66.7%	93.7	33.3
Berlet <i>et al</i> <sup>[24]</sup>	Case series study	121	2.4	–	–	95.0	24.8

AOFAS: American Orthopedic Foot and Ankle Society; SF-36: Short Form-36; TT: Talar tilt; VAS: Visual analog scale; –: Not applicable.

The complication rate in this study was low (15.6%, 10/64) compared to previous studies, of which three cases (4.7%) had medial malleolus fractures during operation, four of 64 (6.3%) had wound healing problems after operation, 2 (3.1%) had toe numbness, and one had (1.6%) wound infection, but all were mild complications. They were promptly detected and treated accordingly, and they all recovered well. No serious complications occurred in our cohort group, and this result is close to previous studies<sup>[13-15,24]</sup>. Among them, three patients with medial malleolus fractures all had osteoporosis, two were post-menopausal women, and one was a man with traumatic arthritis and had disuse osteoporosis due to long-term crutches. Therefore, for patients with osteoporosis, intra-operative manipulation should be carried out more carefully to avoid fracture. There were four patients had wound healing problems, and three of them had diabetes. This reminds us that for patients with diabetes, special attention should be paid to peri-operative blood glucose control. In this study, the survival rate of the prosthesis was 100%. In the previous literature on the use of INBONE-II prosthesis for total ankle arthroplasty, the study by Hsu and Haddad<sup>[13]</sup> showed that the survival rate of INBONE-II prosthesis was 100% at a follow-up time of 2 years. Research by Lewis *et al*<sup>[14]</sup> showed that the reoperation rate of 56 cases of INBONE-II prosthesis after 2 years was 15.9%, and the failure rate was 2.6%. Research by Rushing *et al*<sup>[15]</sup> showed that 7 years after INBONE-II prosthesis replacement, the prosthesis survival rate reached 93.7%, and the complication rate was 33.3%. The case series of Berlet *et al*<sup>[24]</sup> showed that the 2.4-year implant survival rate after INBONE-II prosthesis replacement was 95.0%, and the complication rate was 24.8%. Therefore, we believe that the short-term complication rate of TAR with INBONE-II prosthesis is relatively low, and the survival rate of the prosthesis is relatively high. On the one hand, the surgeons in this study have expertise in using other TAR prostheses; but the medium-term and long-term complication rate and revision rate of the TAR using INBONE-II prosthesis need further follow-up.

In this study, the satisfaction rate of patients who underwent TAR using INBONE-II was 90.6%, which is similar to the results of previous literature<sup>[7-15,24]</sup>. Dissatisfaction in this group of cases mainly manifested as numbness around the wound and distal toes, difficulty in wound healing, and pain around the ankle joint. The operation of TAR surgery cannot dislocate and fully expose the joints like knee and hip replacements. Instead, the prosthesis needs to be implanted in a relatively small space. In patients with varus deformity, it is necessary to perform a thorough soft tissue release on the medial ankle, and special attention should be paid to the protection of soft tissues during the operation. Excessive peeling and stretching will affect the blood supply of the skin and damage the cutaneous nerves, resulting in difficulty in wound healing, swelling, and numbness around the wound. Post-operative pain around the ankle joint is relatively common and can occur in the early post-operative period, such as within 3 months. This may be related to insufficient clearance of the abnormal synovial membrane during the operation and soft tissue swelling and compression. The pain in the later stage may be caused by inadequate osteotomy, heterotopic ossification, and slight changes in the position of the prosthesis. This requires the operation to carefully clean up the osteophytes formed by long-term deformities after osteotomy according to the osteotomy guide plate, especially in the areas where post-operative impact may occur, such as the posterior medial ankle point and the posterior malleolus. The bone debris should be rinsed from multiple osteotomies in the wound promptly to prevent premature heterotopic ossification. After the operation, a brace should be used to restrict activities or walking boots be worn to control weight-bearing for a month; these measures are conducive for soft tissue recovery and reduce heterotopic ossification.

The limitations of this study are that, first, the follow-up time of patients is relatively short (24–59 months), and a small number of patients do not have imaging follow-up data for >2 years, which may affect the results. Second,

the imaging findings of this study mainly focused on the observation of the angles on the coronal and sagittal planes of the ankle. In fact, the post-operative anteroposterior position of the talus prosthesis relative to the tibia may have an impact on the clinical efficacy which has been obtained, and clinical biomechanical experiments of Barg *et al*<sup>[25]</sup>, Wood *et al*,<sup>[26]</sup> and Tochigi *et al*<sup>[27]</sup> had confirmed that. Thus, we need to accumulate cases for risk factor analysis in future research.

In summary, the short-term and medium-term clinical results, imaging findings, complications and prosthetic survival rate after TAR with INBONE-II prosthesis is good. It is a good choice for the treatment of end-stage ankle OA.

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### Conflicts of interest

None.

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