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# Clinical short-term analysis and effectiveness evaluation of optimally designed customized artificial talus implants

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Avascular necrosis (AVN) of the talus is a rare but debilitating condition that can lead to joint collapse and significant functional impairment. In advanced stages, joint-preserving surgical options are limited. This study aimed to develop a lightweight, patient-specific 3D-printed total talar implant and evaluate short-term clinical and radiographic outcomes in patients with idiopathic talar necrosis. A total of eight patients were approved for inclusion in this prospective clinical trial under the rare-disease framework established by the Ministry of Food and Drug Safety (MFDS) of Republic of Korea. Six patients underwent total talar arthroplasty starting in July 2023. As of this interim analysis, three patients had completed both the 6-week and 3-month postoperative follow-up assessments and were included in the analysis. The mean follow-up duration was 16 weeks. Radiographs were obtained at each follow-up visit to assess implant positioning and structural integrity. Clinical outcomes were evaluated using the visual analog scale (VAS), the Foot and Ankle Outcome Score (FAOS), and ankle range of motion (ROM). Preoperatively, all three patients reported VAS scores ranging from 7 to 10, which decreased by 3 to 7 points postoperatively. The median final FAOS improved from 48.0 [IQR: 17–76] to 61.0 [IQR: 48–72] at 3 months. Improvements were observed in pain and daily living function subscales, while lower gains were noted in sports and recreational activities. ROM was generally maintained or improved postoperatively, with plantarflexion increasing from a median of 40° [IQR: 0–45] to 40° [IQR: 35–55], and dorsiflexion maintained at a median of 10°. These preliminary findings suggest that total talar replacement using a patient-specific implant may preserve joint function and improve early clinical outcomes in selected patients with advanced talar AVN. Ongoing follow-up is required to assess mid- and long-term safety and implant durability.

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As of 2000, 21–58% of talus fractures led to avascular necrosis (AVN) of the talus<sup>1</sup>. The talus is unique, with blood supply from different internal arteries (Supplementary Information 1), making it susceptible to bone destruction due to ischemia, including AVN<sup>2–5</sup>. AVN of the talus usually occurs after a talus fracture due to trauma or other factors, disrupting the blood supply<sup>6,7</sup>. Thus, trauma accounts for 90% of talus AVN cases<sup>8</sup>. Talus fracture treatment is unrelated to AVN treatment. In the event of a road traffic accident or high fall, strong forces or impact through the sole (vertical forces) can act on the ankle to cause a talus fracture, leading to obstructed blood flow<sup>9–11</sup>. Alternatively, AVN of the talus can also be caused by alcohol poisoning, steroid use, dyslipidemia, or idiopathic factors<sup>12–15</sup>.

Approximately 60% of the talus surface consists of cartilage, which can also undergo AVN if the blood flow is restricted, impeding blood and oxygen supply. Cases can be categorized according to vascular impairment, compression, or extent of physical destruction<sup>16</sup>.

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Talus fracture is most closely related to the neck of the talus, followed by the part connecting the neck and body, and then the body<sup>17</sup>. The risk of traumatic osteonecrosis can be categorized based on the degree of injury using the Hawkins classification (Supplementary Information 2)<sup>18</sup>.

Hawkins class I fractures are vertical fractures of the talar neck with no subluxation, and the risk of developing AVN is < 15%. Class II involves mild posterior displacement of the distal neck fragment and subluxation of the subtalar joint, and the risk of developing AVN is 20–50%. Class III fractures involve dislocation or subluxation of both the subtalar and tibiotalar joints. These cases are always accompanied by AVN. Class IV fractures involve dislocation or incomplete dislocation of the subtalar, tibiotalar, talocalcaneal, and talonavicular joints. These fractures are also accompanied by AVN in 100% of cases. A partial Hawkins sign can also be a sign of osteonecrosis<sup>19</sup>. In addition to the Hawkins sign, the Ficat stage (Supplementary Information 3) can be used as revascularization of the necrotic bone is pathologically similar to osteonecrosis of the femoral head<sup>20</sup>.

Non-surgical approaches for the treatment of talus AVN include non-weight bearing or the use of a patellar tendon brace, as well as extracorporeal shockwave therapy. Surgical options can be broadly categorized as follows: first, joint-preserving techniques such as core decompression and bone grafting; second, procedures that sacrifice the ankle joint such as total/partial talar replacement; and finally, surgical methods aimed at preserving the ankle joint including talus excision, ankle arthrodesis (ankle fusion) connecting the ankle or talus with the surrounding bones, and total ankle replacement surgery<sup>21–26</sup>. Treatment approaches vary based on the Ficat stage and the underlying cause of talus AVN; detailed information can be found in the report by Dhillon et al.<sup>6</sup> (Fig. 1). Ankle fusion surgery, although considered a last resort, has disadvantages such as potential poor joint union and resultant leg length discrepancy<sup>27</sup>. Conversely, total ankle replacement surgery using artificial joints has shown a minimum success rate of 81.8% since 1974, with positive outcomes reported in range of motion (ROM), visual analog scale (VAS), and quality of life (QOL)<sup>28</sup>. It has emerged as a viable alternative, utilizing metal materials manufactured via 3D printing technology.

The aim of this study was to design and manufacture a 3D lightweight customized talar implant for patients with talar osteonecrosis and to examine patients' short-term clinical outcomes based on an analysis of postoperative pain, leg length, ankle ROM, and recovery period.

## Results

Of the eight patients approved for enrollment, six underwent implantation of the investigational device. Among these, three patients had completed the minimum required follow-up period at the time of analysis and were included in the present evaluation. The remaining three implanted patients are still undergoing follow-up, and two enrolled patients have not yet undergone surgery.

The mean postoperative follow-up duration was 16 weeks. Radiographic assessments, performed at each follow-up visit, confirmed appropriate implant positioning and the absence of gross complications (Fig. 2). Inter-observer agreement for radiographic interpretation was high, with a Cohen's kappa coefficient of 0.85, indicating strong agreement between the two independent evaluators.

Clinical outcomes were assessed using the visual analog scale (VAS), the Foot and Ankle Outcome Score (FAOS), and range of motion (ROM). Among these, the VAS score showed the greatest improvement. All patients reported preoperative VAS scores between 7 and 10, which decreased to between 3 and 7 at 3 months postoperatively. The mean VAS score improved from  $8.0 \pm 1.7$  preoperatively to  $3.3 \pm 0.6$  at 3 months (Fig. 3).

The median final FAOS increased from 48.0 (IQR: 17–76) at the preoperative screening to 61.0 (IQR: 48–72) at the 3-month follow-up (Table 1). Improvements were observed across all subscales, including symptoms and stiffness, pain, daily living function, sports and recreational activities, and quality of life (QOL). Notably, pain and daily living scores showed the most prominent changes, whereas sports-related function remained limited, with a median score of 35.0 (IQR: 20–45) at 3 months (Table 2).

Given the multidimensional nature of the FAOS, these findings indicate improvements in both physical function and patient-reported outcomes during the early postoperative period. However, some limitations persisted in high-demand activities involving repetitive or intense ankle motion.

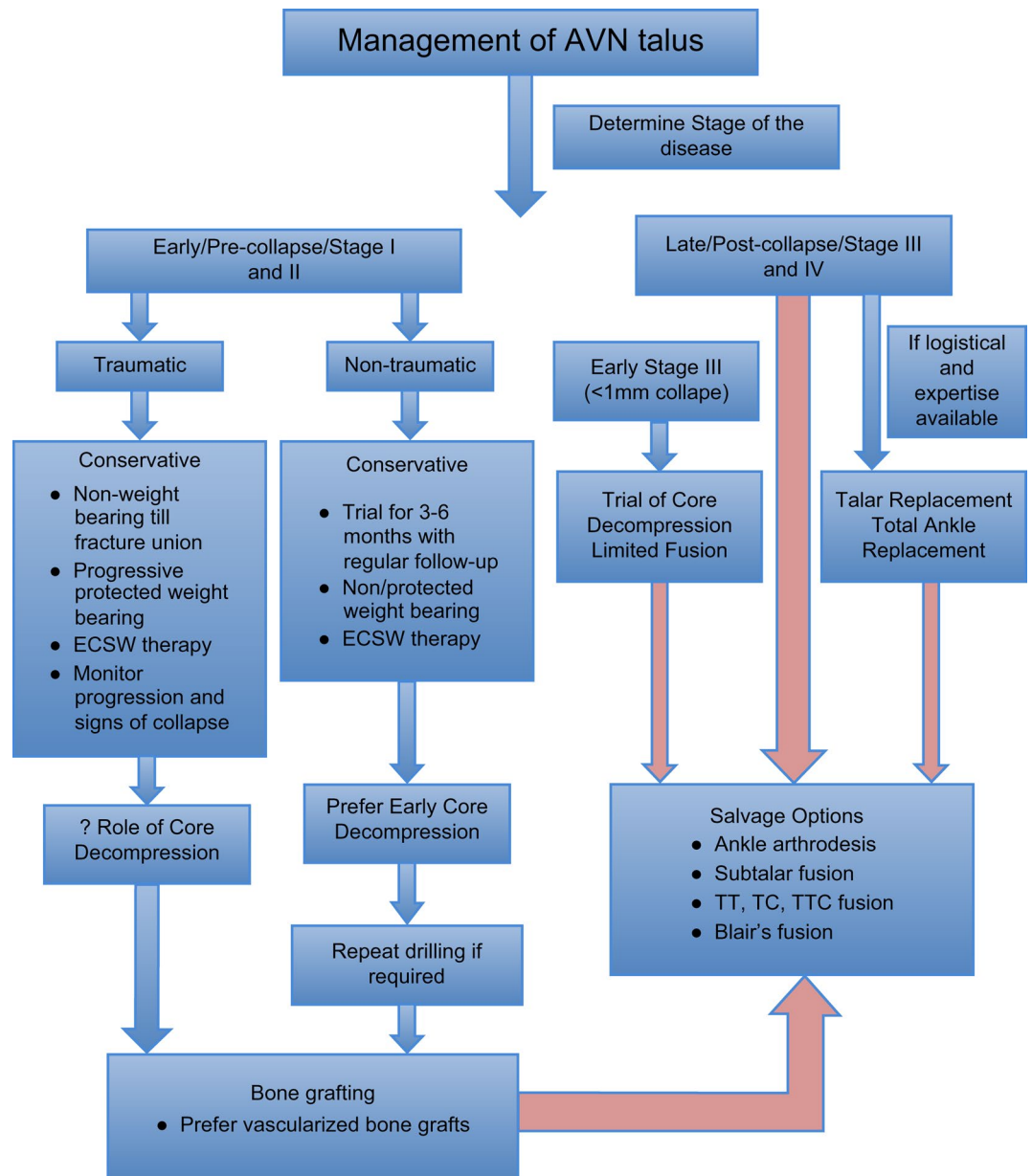
These results are based on short-term follow-up (6 weeks and 3 months) and represent interim findings. Longitudinal evaluation is ongoing, with follow-up assessments scheduled at 6 months and 12 months to further assess implant function, durability, and long-term clinical outcomes under weight-bearing conditions.

Range of motion (ROM) outcomes are presented in Table 3. At 3 months postoperatively, inversion decreased from a median of 20° (IQR: 20–30) to 15° (IQR: 15–25), and eversion decreased from 10° (IQR: 10–50) to 10° (IQR: 5–10). Plantarflexion increased from 40° (IQR: 0–45) to 40° (IQR: 35–55), while dorsiflexion remained unchanged at 10° across all timepoints.

Inversion and eversion were notably reduced at 6 weeks postoperatively but partially recovered by 3 months, with inversion approaching preoperative levels. Eversion remained lower than baseline. In contrast, plantarflexion and dorsiflexion showed early postoperative decline followed by improvement by 3 months, exceeding or returning to baseline values. These results suggest that sagittal-plane movements (plantarflexion and dorsiflexion) may recover earlier than frontal-plane motions (inversion and eversion), although further observation beyond 3 months is required.

## Discussion

In this clinical trial, we designed and manufactured a lightweight customized talar implant for patients with talar osteonecrosis and examined the patients' short-term clinical outcomes. We evaluated clinical efficacy based on the VAS, FAOS, and ROM. Of these, the VAS score, which measures the participants' subjective pain, improved the most at 3 months post-surgery.

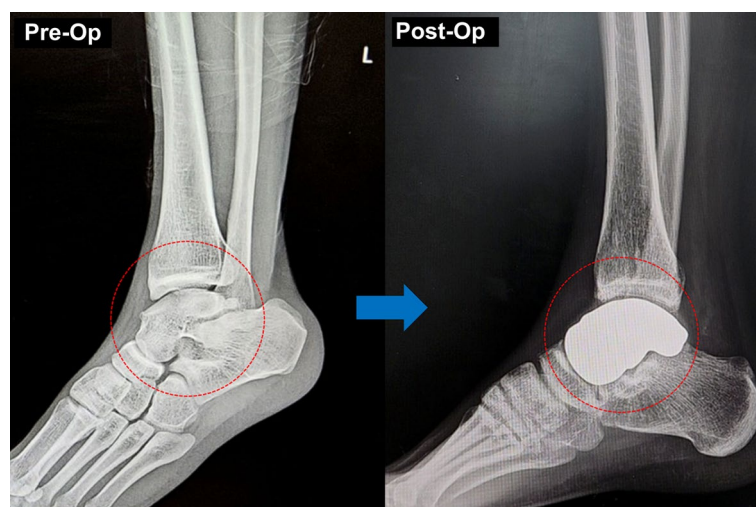


**Fig. 1.** Treatment of talus AVN according to the Ficat classification. AVN avascular necrosis.

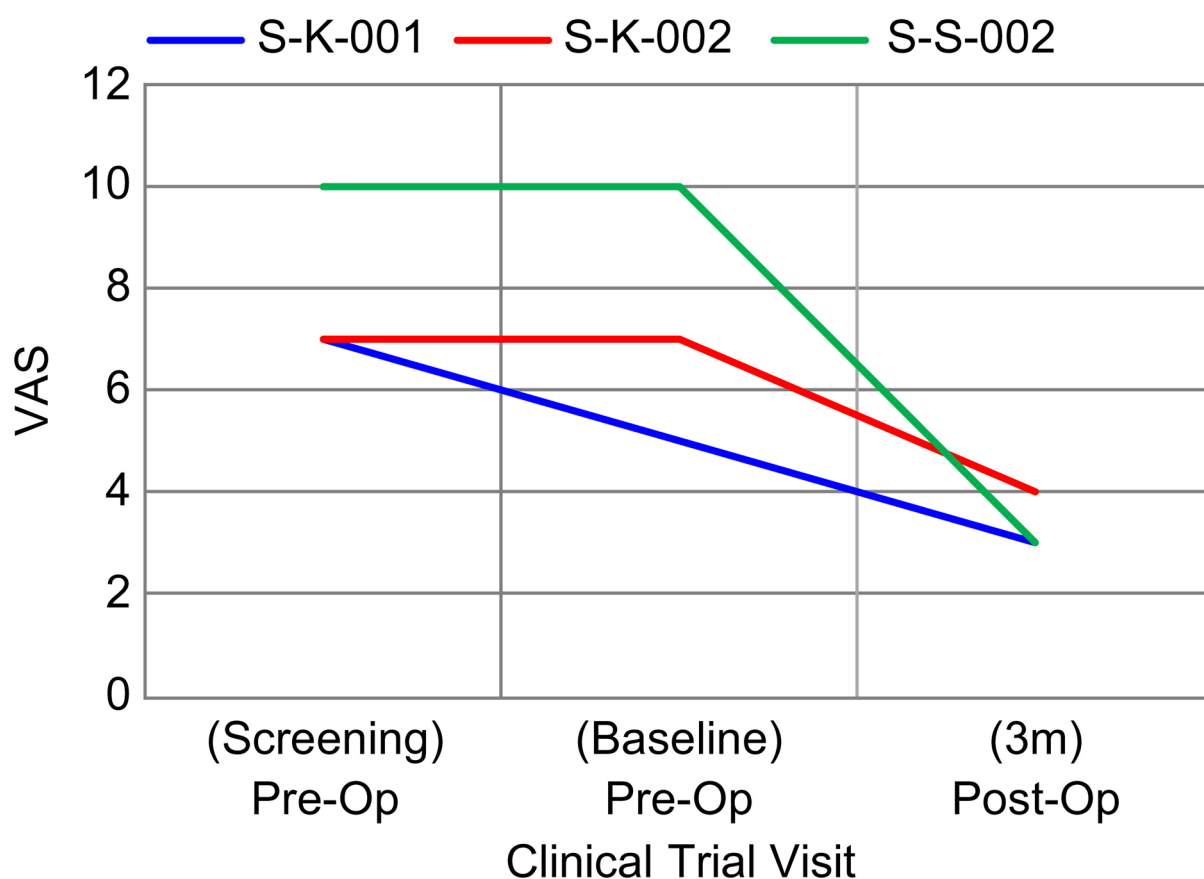
The talus bone is the third most common site of AVN<sup>29</sup>. Partial or total talar replacement has been performed since the 1980s, with high success rates to date<sup>30</sup>.

Prosthetic joints have been used to replace the talus since a report by Harnroongroj and Vanadurongwan in 1997<sup>31</sup>, and the materials used for prostheses have been changing. When the procedure was first performed in 1997, talar prostheses were talar domes made of stainless steel, but these implants collapsed into the talar neck. Thereafter, in a total talar replacement procedure performed by Taniguchi in 2015<sup>32</sup>, a ceramic talar prosthesis was used. About 54% of the patients showed obvious improvements in the American Orthopedic Foot Ankle Society scores. However, some patients (18.2%) developed complications as the parts connected to the talar neck and body became loose and eventually fractured. Metal talar prostheses were inserted in a small cohort of four patients by Anghong in 2014<sup>33</sup>, but there was a considerable increase in dorsiflexion ROM, from 0° preoperatively to 5° postoperatively, and plantarflexion ROM, from 20° preoperatively to 40° postoperatively. Furthermore, there was a substantial increase in inversion ROM, from 0° preoperatively to 10° postoperatively, and eversion ROM, from 0° preoperatively to 21° postoperatively.

In contrast, ankle arthrodesis, which is considered a last resort treatment for talus AVN, is a technique where the joint is aligned correctly to prevent damage. However, it can lead to problems such as gait abnormalities and secondary arthritis near the surgical site. The use of various types of ankle arthrodesis has generally yielded successful outcomes, but a systematic review by Gross et al.<sup>34</sup> showed that almost one in five patients experiences adverse effects, with failure of arthrodesis negatively affecting proper fusion of the ankle in 18% of cases. In a



**Fig. 2.** Comparison of preoperative X-ray of the talus and postoperative radiography after 6 weeks.



**Fig. 3.** VAS score decreased from 8 (7–10) preoperatively to 3.3 (3–4) postoperatively. VAS visual analog scale.

study by Dennison et al.<sup>35</sup>, delayed union was observed in all patients. Overall, considering the gait abnormalities and the fact that this is a last-line treatment, the high rate of adverse effects makes arthrodesis an unappealing choice for younger patients.

This clinical trial was designed based on the optimistic outcomes obtained using metal talar implants. Irrespective of age or sex, all patients in our trial were diagnosed with Ficat & Arlet stage III disease, even though

| FAOS subscale                                | Preoperative (Screening)     | Postoperative (6 Weeks)      | Postoperative (3 Months)     |
|----------------------------------------------|------------------------------|------------------------------|------------------------------|
| Symptoms and stiffness                       | 36 [7–61], Q1 = 7, Q3 = 61   | 57 [43–71], Q1 = 43, Q3 = 71 | 68 [61–82], Q1 = 61, Q3 = 82 |
| Pain                                         | 75 [14–78], Q1 = 14, Q3 = 78 | 67 [36–75], Q1 = 36, Q3 = 75 | 81 [44–86], Q1 = 44, Q3 = 86 |
| Function, daily living                       | 68 [18–93], Q1 = 18, Q3 = 93 | 74 [19–76], Q1 = 19, Q3 = 76 | 69 [53–74], Q1 = 53, Q3 = 74 |
| Function, sports and recreational activities | 0 [0–60], Q1 = 0, Q3 = 60    | 10 [5–45], Q1 = 5, Q3 = 45   | 35 [20–45], Q1 = 20, Q3 = 45 |
| Quality of life (QOL)                        | 31 [6–50], Q1 = 6, Q3 = 50   | 31 [6–50], Q1 = 6, Q3 = 50   | 50 [31–69], Q1 = 31, Q3 = 69 |
| Final FAOS score (Mean of 5 subscales)       | 48 [17–76], Q1 = 17, Q3 = 76 | 61 [24–79], Q1 = 24, Q3 = 79 | 61 [48–72], Q1 = 48, Q3 = 72 |

**Table 1.** FAOS subscale scores at preoperative screening, 6-week, and 3-month follow-up (Median [IQR], Q1–Q3) FAOS Foot and Ankle Outcome Score, QOL Quality of Life, IQR Interquartile Range, Q1 first quartile, Q3 third quartile.

| FAOS reference value |                                              | Preoperative (screening) | Postoperative (6 weeks) | Postoperative (3 months) |
|----------------------|----------------------------------------------|--------------------------|-------------------------|--------------------------|
| S-K-001              | Symptoms and stiffness                       | 61                       | 71                      | 61                       |
|                      | Pain                                         | 78                       | 67                      | 81                       |
|                      | Function, daily living                       | 93                       | 74                      | 74                       |
|                      | Function, sports and recreational activities | 60                       | 45                      | 35                       |
|                      | QOL                                          | 50                       | 50                      | 50                       |
|                      | FAOS score (final)                           | 76                       | 79                      | 61                       |
| S-K-002              | Symptoms and stiffness                       | 7                        | 57                      | 82                       |
|                      | Pain                                         | 75                       | 75                      | 86                       |
|                      | Function, daily living                       | 68                       | 76                      | 69                       |
|                      | Function, sports and recreational activities | 0                        | 10                      | 45                       |
|                      | QOL                                          | 31                       | 31                      | 69                       |
|                      | FAOS score (final)                           | 48                       | 61                      | 72                       |
| S-S-002              | Symptoms and stiffness                       | 36                       | 43                      | 68                       |
|                      | Pain                                         | 14                       | 36                      | 44                       |
|                      | Function, daily living                       | 18                       | 19                      | 53                       |
|                      | Function, sports and recreational activities | 0                        | 5                       | 20                       |
|                      | QOL                                          | 6                        | 6                       | 31                       |
|                      | FAOS score (final)                           | 17                       | 24                      | 48                       |

**Table 2.** FAOS reference value. FAOS Foot and Ankle Outcome Score, Pre-op pre-operation, Post-op post-operation, QOL quality of life.

| ROM (°)        | Preoperative (Screening)     | Postoperative (6 Weeks)      | Postoperative (3 Months)     |
|----------------|------------------------------|------------------------------|------------------------------|
| Inversion      | 20 [20–30], Q1 = 20, Q3 = 30 | 15 [15–20], Q1 = 15, Q3 = 20 | 15 [15–25], Q1 = 15, Q3 = 25 |
| Eversion       | 10 [10–50], Q1 = 10, Q3 = 50 | 10 [5–10], Q1 = 5, Q3 = 10   | 10 [5–10], Q1 = 5, Q3 = 10   |
| Plantarflexion | 40 [0–45], Q1 = 0, Q3 = 45   | 35 [20–45], Q1 = 20, Q3 = 45 | 40 [35–55], Q1 = 35, Q3 = 55 |
| Dorsiflexion   | 15 [10–40], Q1 = 10, Q3 = 40 | 10 [0–15], Q1 = 0, Q3 = 15   | 10 [5–15], Q1 = 5, Q3 = 15   |

**Table 3.** Ankle range of motion (ROM) at preoperative screening, 6-Week, and 3-Month Follow-up (Median [IQR], Q1–Q3) ROM Range of Motion, IQR Interquartile Range, Q1 first quartile, Q3 third quartile. All values are reported in degrees (°); n = 3.

the inclusion criteria permitted patients with stage I/II disease who showed no improvement after 3 months of conservative treatment or core decompression and were also unable to undergo total joint replacement, making ankle arthrodesis the last available treatment option. As the positive effects of metal talar prostheses have already been reported, we used prostheses made from cobalt-chrome alloy, which does not cause inflammation owing to its high biocompatibility. Although each implant was customized to fit the patients’ talus size, to account for potential differences between the implant and the actual talus size, implants of 2–3 different sizes were prepared for each patient. We designed a specific internal structure for the implants to prevent gait abnormalities due to the weight of metal implants.

As it has been less than 1 year since the trial began, it was not possible to observe significant preoperative/postoperative differences in the clinical efficacy endpoints, such as FAOS and ROM. The timepoint for data collection and statistical analysis was only 3 months postoperatively, which is a very short span of the total 5-year duration of this clinical trial. Nevertheless, there have been no reports of complications due to implant



placement or adverse reactions to medical devices. Furthermore, pain, which is a natural consequence of surgery, has gradually decreased in both frequency and intensity. All three patients who were followed up postoperatively have been capable of ambulation without crutches for 2 weeks after operation, and there was no change in leg length. We will continue to observe the clinical efficacy endpoints in these three patients and collect data on the clinical efficacy endpoints and date of first ambulation in the remaining three patients who are scheduled to undergo postoperative visits.

The inclusion of only three patients in the present analysis is not attributable to attrition or loss to follow-up, but rather reflects the timing of this interim evaluation. All patients approved for the study remain under active follow-up, and the trial is ongoing. Of the five patients not included in this interim analysis, some have not yet reached the predefined short-term follow-up milestones (6 weeks and 3 months), while others are awaiting surgery. This deliberate selection ensures that only complete and temporally appropriate data are analyzed, thereby maintaining data integrity and minimizing the risk of bias due to premature or incomplete outcome reporting.

In this interim analysis, improvements were observed across multiple domains of the Foot and Ankle Outcome Score (FAOS). Pain and daily living function showed the greatest gains, while recreational and sports-related activities remained limited. These results suggest early postoperative improvements in basic functional capacity and subjective well-being, although more demanding activities were still associated with residual limitations. Notably, the median final FAOS increased from 48.0 (IQR: 17–76) preoperatively to 61.0 (IQR: 48–72) at 3 months postoperatively, supporting the initial feasibility of the implant from the perspective of patient-reported outcomes.

Range of motion (ROM) results also reflected selective functional recovery. While inversion and eversion were initially reduced at 6 weeks, inversion showed partial recovery by 3 months, whereas eversion remained below baseline levels. Plantarflexion and dorsiflexion demonstrated recovery trajectories more consistent with preoperative function, with plantarflexion improving from a median of 40° (IQR: 0–45) preoperatively to 40° (IQR: 35–55) at 3 months. These findings suggest that sagittal plane motion may recover earlier, whereas frontal plane motion remains more susceptible to postoperative limitation, potentially due to discomfort during lateral stress.

Although the current follow-up completion rate (3 out of 8) may appear limited, it is important to emphasize that this manuscript is not intended to provide definitive conclusions regarding clinical effectiveness. Rather, it presents preliminary safety and feasibility data from a rare-disease population, with the understanding that comprehensive analyses will be conducted and reported as additional follow-up data become available over time.

In conclusion, the clinical endpoints evaluated in this interim report—including ROM and FAOS outcomes—suggest early recovery of basic ankle function and pain relief following total talar arthroplasty using a patient-specific implant. Patients were able to ambulate and demonstrated preserved or improved joint motion compared to preoperative assessments. Continued follow-up is necessary to assess the long-term durability of the implant and the risk of complications such as subsidence or adjacent-joint degeneration. Furthermore, while current results support the feasibility of this technique, ongoing research is warranted to improve implant design, particularly in reducing the weight of metallic components to better mimic the biomechanical properties of native bone.

## Methods

### Ethical approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the tenets of the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards. The study design was approved by the Ministry of Food and Drug Safety (approval number: 2023000218), the Institutional Review Boards of Yonsei University Health System, Severance Hospital (approval number: 1-2023-0034), and Yonsei University Gangnam Severance Hospital (approval number: 3-2023-0224). This clinical trial was conducted with the consent of the patients.

### Preliminary analysis

In this preliminary study, we constructed implants to be used in surgery and reduced their weight to prepare the final models. A rational scaffold model, where the internal scaffold shape is defined based on the size (minimum, medium, and maximum), can enable a superior design. Given that it is not practically feasible to optimize the topology for every implant manufactured, we based our approach on work efficiency.

The size specifications for the rational scaffold model were obtained based on topological optimization and scaffold simplification. The load conditions for selecting the worst-case scenario were based on the peak ground reaction force direction. The load directions were “plantar 10°” (P10), “dorsal 5°” (D5), and “dorsal 10°” (D10). Among the P10, D5, and D10 locations for the three sizes (nine locations in all), we selected the worst-case scenario. We performed finite element analysis reflecting a load of 5,340 N on each representative specifications-standard model, selected an arbitrary size among the small bone models as the worst-case scenario, and evaluated the validity of the standard model. To evaluate the validity, we applied the standard model to the rational structure and implemented a model that reflects the derived internal structure based on topological optimization of the arbitrary model (Supplementary Information 4).

For selecting the worst-case scenario, the highest peak von Mises stress (PVMS) was calculated from the minimum D5 model. Thereafter, finite element analysis showed PVMS of 218.01 and 565.35 MPa in the rational scaffold and topologically optimized models, respectively. This finding demonstrates that the rational scaffold model produced lower PVMS. Additionally, after reducing the weight via the rational scaffold model, the minimum model weight reduced from 1,106 to 965.4 g<sup>36</sup>.

| Parameter                               | Data                       |
|-----------------------------------------|----------------------------|
| Age (years), mean $\pm$ SD (range)      | 53.3 $\pm$ 17.1 (30–68)    |
| Body mass index, mean $\pm$ SD (range)  | 25.4 $\pm$ 2.6 (23.1–29.1) |
| Sex (male/female)                       | 4/2                        |
| Left/Right                              | 2/4                        |
| Follow-up, weeks, mean $\pm$ SD (range) | 14 (8–24)                  |
| Thyroid cancer, n (%)                   | 1 (16.67)                  |
| Prostatic hypertrophy, n (%)            | 1 (16.67)                  |
| Diabetes mellitus, n (%)                | 1 (16.67)                  |
| Hypertension, n (%)                     | 1 (16.67)                  |
| Hyperlipidemia, n (%)                   | 1 (16.67)                  |
| Smoker, n (%)                           | 2 (33.3)                   |
| Alcohol excess, n (%)                   | 0                          |
| Excessive steroid use, n (%)            | 0                          |

**Table 4.** Demographics of the patients ( $n=6$ ). SD standard deviation.

We confirmed that the rational scaffold design method was better than scaffold design by topological optimization of a general model and that the three types of rational scaffold for each size range included talus of all sizes within the range of anatomical variation. Thus, using the rational scaffold model, without the need to perform topological optimization, we designed superior talar implants that satisfied clinical requirements such as patient customization, weight reduction, and mechanical stability.

### Clinical trial

This multicenter, nonrandomized, prospective, noncontrolled clinical trial—designated as a confirmatory study by the Korean MFDS under its regulatory framework for rare conditions—was approved to enroll up to eight patients diagnosed with avascular necrosis (AVN) of the talus. These patients will undergo postoperative follow-up over a 5-year period beginning in July 2023. The inclusion criteria were as follows: adult patients who had received information regarding the study and voluntarily signed the informed consent form; patients diagnosed with Ficat classification stage I or II disease who did not improve with conservative treatment or core decompression and were unsuitable candidates for total ankle arthroplasty, leaving ankle arthrodesis as the only remaining option; or patients with Ficat stage III or IV disease with destruction of the talar body that similarly contraindicated total arthroplasty. Additional inclusion criteria included: a visual analog scale (VAS) pain score  $\geq 7$ ; no deformity in the contralateral talus; availability of imaging data for the healthy talus within 6 months prior to surgery for implant design; radiographic evidence of talar body necrosis with collapse or loss of congruent articulation; no destruction of adjacent bones (tibia, navicular, or calcaneus); and failure to respond to at least 6 months of conservative treatment.

The target sample size of eight patients was determined based on precedents established by regulatory-approved studies in comparable populations. In the United States, the Patient Specific Talus Spacer (Additive Orthopaedics, LLC) received Humanitarian Device Exemption (HDE) approval from the U.S. Food and Drug Administration (FDA) for use in rare diseases affecting fewer than 8,000 patients annually. The supporting clinical study for HDE approval involved 32 implanted cases in 31 patients at a single center, focusing on safety and probable benefit. Follow-up periods ranged from less than 1 year to up to 3 years. The study reported no device-related adverse events and demonstrated probable benefit through improved postoperative scores in pain (VAS), range of motion (ROM), and function (Foot and Ankle Outcome Score). These findings led to the conclusion that the benefits of using the device outweighed the potential risks<sup>37</sup>.

Considering the relative population scale of Republic of Korea compared to the United States, the present study adopted a target sample size of eight patients for confirmatory evaluation. This sample size was reviewed and approved by the Ministry of Food and Drug Safety (MFDS) of Republic of Korea. As of the current stage of the study, six patients have undergone the surgical procedure. However, among them, only three patients had reached a postoperative period suitable for short-term follow-up and analysis. Therefore, this interim report presents the clinical and radiological findings of those three eligible patients.

The exclusion criteria were as follows: patients with degenerative change or active infection of the tibiotalar, subtalar, or talonavicular joints; patients with severe deformity in the sagittal or coronal plane,  $\geq 15^\circ$  varus or coronal plane varus, or with  $\geq 50\%$  anterior or posterior subluxation in the sagittal plane; patients with necrosis in the calcaneus, distal tibia, or navicular; patients with an existing malignant tumor or systemic or local infection; and patients allergic to metal implants.

The mean age of the participants was  $53.3 \pm 17.1$  years (Table 4). Among the six patients currently enrolled in the study, two participants (33.3%) had underlying diseases: one with thyroid cancer and prostatic hypertrophy, and another with diabetes mellitus, hypertension, and hyperlipidemia. None of the participants reported excessive alcohol or steroid use. It should be noted that the total of six patients reflects those presently undergoing the study, and only three participants who reached the short-term follow-up were included in the outcome analysis.

We collected the following information: preoperative and postoperative VAS, FAOS, ROM, X-ray, and computed tomography data. We also recorded the time when participants started walking postoperatively. Visits

to the participants were scheduled for screening; baseline; 2 and 6 postoperative weeks; 3 and 6 postoperative months; and 1, 2, 3, 4, and 5 postoperative years. For ROM, we measured inversion, eversion, plantarflexion, and dorsiflexion. For postoperative management, the operated leg was fixed in a cast and subject to non-weight bearing. After 2 postoperative weeks, the stitches were removed, and some weight-bearing was allowed while wearing a tall walking boot. After 6 postoperative weeks, patients were instructed to wear regular shoes, and they started physiotherapy for ROM and strengthening. Computed tomography data from the healthy side were used to construct a cobalt-chrome alloy talar implant using 3D modeling (Corentec Co., Ltd., Seoul, Republic of Korea) (Supplementary Information 5).

## Data availability

The data that support the findings of this study are available from the corresponding author but restrictions apply to the availability of these data, which were used under license for the current study, and so are not publicly available. Data are however available from the authors upon reasonable request and with permission of the corresponding author.

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Conceptualization: Y.K. and K.H.P.; Methodology: Y.K., K.H.P., and E.J.; Investigation: Y.K., K.H.P., J.K., and S.H.H.; Formal analysis: Y.K., K.H.P., and J.W.L.; Writing – original draft: Y.K., K.H.P., J.W.L., and E.J.; Writing – review and editing: Y.K., K.H.P., J.K., and S.H.H.; Supervision: J.K. and S.H.H. Y.K. and K.H.P. are co-first authors who contributed equally to this work. All authors read and approved the final manuscript.

## Declarations

### Competing interests

The authors declare no competing interests.

### Additional information

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