restor3d

TOTAL TALUS REPLACEMENT IMPLANT AND INSTRUMENTATION SYSTEM

INSTRUCTIONS FOR USE

DEVICE DESCRIPTION

The restor3d Total Talus Replacement Implant and Instrumentation System is designed to replace a native talus bone that has been affected by a disease state or injury. The implant is an additively manufactured Cobalt Chromium alloy construct produced by laser powder bed fusion. The data driven design of the implant enables the patient to maintain ankle range of motion, reduce pain and improve physical function.

The implant is patient specific and made available in multiple sizes to facilitate intraoperative flexibility. Non-sterile single-use disposable instrumentation including size trials and impactors are provided to assist in the surgical placement of the implant. It is important that the provided trials and impactors are used to ensure accurate implantation of the device.

SYSTEM COMPONENTS

The restor3d Total Talus Replacement Implant is manufactured from a medical grade of Cobalt-28 Chrome-6 Molybdenum alloy (meeting the requirements of ASTM F3213). The implant is available in up to five sizes. The Impactors and Size Trials are manufactured from a biocompatible polymer. Impactors are provided in two configurations: flat and contoured. Size Trials are provided to match implant sizes.

INDICATIONS FOR USE

The restor3d Total Talus Replacement Implant is indicated for:

- avascular necrosis of the talus
- avascular necrosis of the talus in addition to talar collapse, cysts or non-union
- large, uncontained, unstable, or cystic talar osteochondral defects with risk of collapse or talar osteochondral defects not responsive to traditional treatments
- non-union following talar fracture or talar extrusion, unresponsive to more conservative treatments

The implant is patient specific and is designed from computed tomography (CT) scan. The anatomical landmarks necessary for the design and creation of the restor3d Total Talus Replacement implant must be present and identifiable on CT scan.

CONTRAINDICATIONS

- Surgical procedures other than those listed in the indications for use.
- Use of implant greater than 6 months from date of patient's preoperative CT scan.
- Degenerative changes in the tibiotalar, subtalar or talonavicular joints.
- Gross deformity in sagittal or coronal planes. More than 15 degrees of varus or valgus deformity in the coronal plane, or more than 50% subluxation anteriorly or posteriorly of the talus in the sagittal plane
- Patients with an active local or systemic infection.
- Osteonecrosis of the calcaneus, distal tibia or navicular.
- Known history of existing malignancy, or any systemic infection, local infection, or skin compromise at the surgical site.
- Blood supply limitations and previous infections that may prevent healing.
- Physical conditions that would eliminate adequate implant support or prevent healing, including inadequate soft tissue coverage.
- Conditions which may limit the patient's ability or willingness to restrict activities or follow directions postoperatively during the healing period.
- Presence of neurological deficit which would prevent patient postoperative compliance.
- Patients with foreign body sensitivity, suspected or documented material allergy or intolerance. Where material sensitivity is suspected, appropriate tests

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should be conducted, and sensitivity ruled out prior to implantation.

POTENTIAL ADVERSE EFFECTS

Potential adverse effects resulting from use of the restor3d Total Talus Replacement Implant include, but are not limited to, the following:

- Infection, deep and superficial
- Loosening or migration of the implant
- Nerve damage due to surgical trauma
- Inadequate healing
- Increased pain, soft tissue discomfort or abnormal sensation due to the presence of the device
- Allergies or other reactions to implant materials
- Loss of anatomic position with rotation or angulation
- Bone resorption or over-production
- Untoward histological responses possibly involving macrophages and/or fibroblasts
- Embolism
- Migration of particle wear debris possibly resulting in a bodily response

WARNINGS

- The Total Talus Replacement System provided by restor3d is NONSTERILE. In-hospitalization sterilization is required before implantation.
- It is recommended that the surgeon evaluate the patient's contralateral side in addition to the affected talus, to determine if the patient is a candidate for a restor3d Total Talus Replacement Implant.
- If the surgeon believes there are significant deformities on the affected side and/or the contralateral side, then the patient may not be a suitable candidate for a patient specific restor3d Total Talus Replacement Implant.
- The implant must be used within 6 months from the date of the CT scan. If the patient's anatomy has changed significantly since the time of the CT scan, the implant should not be used, even if the time period of 6 months has not expired.
- It is mandatory that the user, surgeon and surgery personnel are acquainted with the respective-surgical technique and implants used.
- The surgeon or surgical staff is obligated to examine the surgical implant and its packaging for damages prior to each application (i.e. use). If the implant or its packaging is damaged or deformed, it is not to be used.
- Improper selection, placement, positioning, alignment and fixation of the implant may result in unusual stress conditions and a subsequent reduction in the service life of the prosthetic implant.
- Malalignment or inaccurate implantation can lead to excessive wear and/or failure of the implant or procedure.
- Inadequate preclosure cleaning (removal of surgical debris) can lead to excessive wear.
- Improper preoperative or intraoperative implant handling or damage (scratches, dents, etc.) can lead to crevice corrosion, fretting, fatigue, fracture and/or excessive wear.
- The surgeon is to be thoroughly familiar with the implant and surgical procedure prior to performing surgery. For further information, contact restor3d and consult the Surgical Technique Guide.
- The restor3d Total Talus Replacement System is patient specific and for single use only.
- Do not reuse the restor3d Total Talus Replacement System. Reuse of this product may result in infection or other systemic complications that may affect the patient's overall health. Additionally, the reuse of this product could adversely affect the function of the device. Any implant that has been damaged, mishandled, or removed from the sterile field may have surface damage that could result in implant fracture and/or particulate and should be discarded.
- This is a patient specific implant, do not use in a patient other than the one listed in the product labeling and/or the physician order form.
- The restor3d Total Talus Replacement Implant and Instrumentation System is provided in its final and complete form. Do not modify the Implant or System.

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Modified devices may not perform as intended and could result in patient injury.

PRECAUTIONS

- Surgical implants may only be used in surgeries, for which the designated application of the implant is explicitly necessary and defined.
- Correct selection of the implant is extremely important. Carefully select the appropriate device size based on the needs of each individual patient.
- Following surgery, the patient should employ adequate external support and restrict physical activities which would place stress upon the implant or allow movement of the implant and delay healing.
- Postoperative care is extremely important. The patient must be advised that noncompliance with postoperative instructions could lead to adverse effects. The risk of device failure may increase due to patient-related factors including activity level, weight, or noncompliance due to psychological conditions.
- Patient specific Total Talus Replacement Implants are designed from patient data acquired from Computed Tomography (CT) scan. Over time, a patient's anatomy can change. If a significant amount of time has elapsed from the time of collection of the patient data (date of scan) to the time of surgery utilizing a Patient Specific Total Talus Replacement Implant, the implant may not fit the patient's anatomy correctly.
- Never attempt to reuse. Once the restor3d Total Talus Replacement Implant has been removed from the packaging, the device should be either used, discarded, or returned to restor3d. Never attempt to reuse the implant, even though it may appear undamaged.
- Use only restor3d instruments when handling and implanting the restor3d device.

HOW SUPPLIED

A) NON-STERILE IMPLANTS

restor3d Total Talus Replacement Implants are provided to the hospital in a clean, but not sterile packaging. Only sterile devices should be used in surgery. Unless otherwise indicated, these devices are NOT STERILE and MUST be sterilized prior to use. For sterilization, remove all packaging material prior to sterilization. See part C below for the recommended steam autoclave cycle. No further cleaning other than sterilization is required.

B) NON-STERILE DISPOSABLE INSTRUMENTS

restor3d non-sterile disposable instruments are provided CLEAN but NOT STERILE. No further cleaning other than sterilization is required. For sterilization, remove all packaging material prior to sterilization. See part C below for the recommended steam autoclave cycle. Only sterile implants and instruments should be used in surgery.

C) NON-STERILE IMPLANT AND DISPOSABLE INSTRUMENT STEAM STERILIZATION CONDITIONS

- The following steam autoclave cycle is validated for the non-sterile Total Talus Replacement implants and associated disposable instruments.
- Prior to sterilization, implants and instruments should be double wrapped in 1-ply FDA-cleared sterilization wrap, placed in a stainless steel mesh sterilization basket and sterilized prior to surgical use.
    - Parts should be placed inside the basket in a single layer.
    - Do not stack more than two baskets.
    - Ensure the basket is thoroughly cleaned before placing the parts to be sterilized. If baskets are not visually cleaned, repeat cleaning and inspect again.
- Implants and instruments must be steam autoclaved using a full cycle, and repeated autoclaving will not adversely affect them, unless otherwise noted on the label. Detailed below is the cycle for steam sterilization of wrapped goods:

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- Use a validated, properly maintained, and calibrated steam sterilizer following the manufacturer's recommendations to ensure that the maximum load is not exceeded.
- Effective steam sterilization can be achieved using the following protocol in accordance with our validated results:
    - Sterilizer type: prevacuum
    - Preconditioning pulses: 4
    - Temperature: 132°C
    - Full cycle time: 4 minutes
    - Dry time: 60 minutes
    - Open door time: 30 mins
    - Cool-down time: 30 minutes
    - Cool down phase should be completed outside of the chamber on a wire-rack
    - Do not rapidly cool polymeric instruments.
- Store sterile packaged instruments in a manner that provides protection from dust, moisture, insects, vermin and extremes of temperature and humidity.

RESPONSIBILITIES OF THE USER

General: Health care personnel bear the ultimate responsibility for ensuring that any packaging method or material is suitable for use in sterilization processing and sterility maintenance. DO NOT ATTEMPT TO STERILIZE THE DEVICE IN THE PACKAGING MATERIALS SUPPLIED.

Sterility: The healthcare facility should conduct testing to ensure that the conditions essential to sterilization can be achieved and are acceptable for the steam sterilization process. ANSI/AAMI ST46 Steam Sterilization and Sterility Assurance in Health Care Facilities provides guidelines for design and personnel considerations, processing recommendations, care of sterilizers, quality control, and quality process improvement.

DIRECTIONS FOR USE

This outlines the basic procedure for device implantation, which is described more fully in the Surgical Technique Guide. It is the responsibility of the surgeon to be familiar with the procedure before use of the products. Each surgeon must evaluate the appropriateness of the surgical technique used based on personal medical training and experience. As the manufacturer of this device, restor3d does not practice medicine and does not recommend this or any other surgical technique for use on any specific patient.

1. Prepare the insertion site using standard surgical techniques. A straight skin incision is made over the anterior ankle, similar to the anterior approach used for a total ankle replacement.
2. The anterior capsule of the tibiotalar joint is then opened, and the talus divided into sections using a chisel. Once divided, the talus is then resected.
3. Assess articulations through dorsiflexion and plantarflexion of the ankle as well as inversion and eversion. Flexibility at the midfoot is also demonstrated through multiple planes of movement.
4. Utilize the provided size trials to determine preferred size. Once the proper size is determined insert the corresponding patient specific Total Talus Replacement Implant and ensure the fit using the impactors provided.
5. It is recommended to confirm the fit of the implant using fluoroscopy.
6. Optionally, the anterior talofibular, deltoid or the talonavicular ligament may be repaired using the soft tissue attachments sites on the Total Talus Replacement Implant, if present. Soft tissue attachment sites should be utilized if additional stability in the ankle is needed post implantation of the Total Talus Replacement implant.
7. To use the attachment sites, pass a size 2 suture tape or braided suture, using a CT2/T5 or common surgical needle, through one of the eyelets of the device and then through the ligament (2 passes in

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total through the lateral soft tissues). Then pass the suture through the other eyelet of the implant and tie the suture ends. Ensure the suture does not contact the porous area of the suture attachment feature.

CLINICAL DATA

Data from 27 adult patients (≥22 years of age) who underwent foot or ankle deformity correction at with a patient-specific, 3D-printed Total Talus Replacement (TTR) implant device manufactured by restor3d were analyzed for safety and probable benefit endpoints. The data collection was approved by two local Institutional Review Boards (IRBs), and a centralized IRB (WCG IRB). Data was collected across four sites.

The study enrolled patients from a diverse group of sites and surgeons. Each site enrolled between 4 to 12 patients who met the inclusion criteria, and each site had between 1 and 5 participating surgeons. These real-world data contribute to the development of the safety profile and understanding of the probable benefits of the TTR device.

The co-primary safety endpoints were: 1) the rate of adverse events (AEs), device- or procedure-related AEs, and serious AEs, 2) the rate of subsequent surgical intervention (SSI), defined as any surgical procedure or service required after the initial implant of the TTR device, and 3) the rate of implant survivorship.

The primary probable benefit endpoint was improvement in pain, as measured by the Pain Numerical Rating Scale (NRS) and PROMIS 1.0 – Pain Interference scale, at last follow-up from baseline. The secondary probable benefit endpoints included physical function, as measured by the PROMIS 1.0 – Physical Function scale, and ankle range of motion (ROM).

Patient Demographics

A summary of the patient demographics is provided below in Table 1. Twenty-seven (27) patients were treated with 27 implants. None of the enrolled patients had bilateral procedures (i.e., a TTR implanted in both the left and right ankles).

Table 1. *Patient Demographics.*

Age at Surgery (in years) (n=27)	
Mean ± SD	49.9 ± 15.0
Range	22-69
Race (n=27)	
Black/African American, n (%)	1 (3.70%)
White/Caucasian, n (%)	25 (92.6%)
Other, n (%)	1 (3.70%)
Ethnicity (n=27)	
Hispanic or Latino, n (%)	1 (3.70%)
Not Hispanic or Latino, n (%)	22 (81.5%)
Unknown, n (%)	4 (14.8%)
Education Level (n=27)	
12th grade or less, n (%)	1 (3.70%)
Graduated high school or equivalent, n (%)	6 (22.2%)
Some college, no degree, n (%)	1 (3.70%)
Bachelor's Degree, n (%)	2 (7.41%)
Unknown/Not Reported, n (%)	17 (63.0%)
BMI (n=27)	
Mean ± SD	32.6 ± 6.80
Range	21.2-51.2
Smoking Status (n=27)	
Current, n (%)	6 (22.2%)
Former, n (%)	10 (37.0%)
Never, n (%)	11 (40.7%)
Alcohol Use Status (n=27)	
Current, n (%)	15 (55.6%)
Former, n (%)	7 (25.9%)
Never Used, n (%)	5 (18.5%)
Laterality (n=27)	
Left, n (%)	12 (44.4%)
Right, n (%)	15 (55.6%)
Comorbid Conditions (n=27)	
Yes, n (%)	13 (48.1%)
No, n (%)	14 (51.9%)
Surgical History (n=27)	
Yes, n (%)	20 (74.1%)
No, n (%)	7 (25.9%)

Safety Results

There was a total of ten (10) safety events reported in five (n=5, 18.5%) patients. The safety events include nine (9) subsequent surgical interventions (SSIs) across four (n=4, 14.8%) patients and one adverse event in one (n=1, 3.70%) patient that did not have an SSI. The nine (9) SSIs included one patient who had four (4) SSIs, one patient who had three (3) SSIs, and two patients who had one (1) SSI following the index surgery. The initial safety event for each patient (e.g., four initial SSIs to address wound dehiscence, osteochondral defect and tibial AVN, contracture of the flexor hallucis longus and plantar fasciitis, and one AE where the patient developed compartment syndrome) were categorized for their relatedness to the device (see Table 2 below). The initial safety event for three (3, 11.1%) patients was

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determined to be unrelated to the subject device, and for two (2, 7.40%) patients was determined to be possibly procedure-related. None (0, 0%) were determined to be device-related. The one (1) adverse event without an SSI was also determined to be unrelated to the device.

Importantly, to date, the study team has not received any reports of below the knee amputation (BKA), and all patients (27/27, 100%) were successfully able to salvage their limbs with the TTR device. See Table 2 for an overview of initial reported safety events.

Table 2. *Categorization of Initial Reported Safety Events.*

	Possibly Device-Related	Possibly Procedure-Related	Unrelated
Serious Adverse Events (n=4)	0	2	2
Subsequent Surgical Interventions	0	2	2
Adverse Events (n=1)	0	0	1
Total (n=5)	**0**	**2**	**3**

Only one (1/27, 3.70%) adverse event (excluding SSIs) was reported and was determined by the surgeon to not be related to the subject device. This patient developed chronic compartment syndrome of the lower extremity approximately 1.5 years after TTR device implantation. The patient was offered a subsequent surgical intervention but opted not to have surgery.

At the request of the surgeon, eight implanted (8/27, 29.6%) devices had soft tissue attachment sites for optional intraoperative use. In two (2/8, 25%) of these implants, attachment sites were used to attach patients' ligaments during device implantation and were not associated with any SAEs, SSIs or AEs. For the six implanted devices where the attachment sites were not used, one patient (RECLAIM-1-019) reported four (4) subsequent surgical interventions. This rate of patients with SSIs (1/8, 12.5%) for devices with attachment sites is equivalent to the rate of patients reporting SSIs across the entire study population (4/27, 14.8%), thereby not only demonstrating safety but also confirming that the inclusion of soft tissue attachment sites on the TTR implant does not place the patient at additional risk for SAEs, SSIs, or other AEs.

Implants remained in place for 26/27 (96.3%) patients, demonstrating a high rate of implant survivorship. To date, no additional implants have been removed in the study population.

Probable Benefit Results

Pain scores were assessed preoperatively, and then at the most recent follow-up time point, grouped by the duration of time to last follow-up (e.g., <1 year, or >1 year). At baseline, the mean pain score was 4.50 ± 2.39; and at last follow-up, the mean pain score was 2.75 ± 2.38, indicating a 1.75-point mean improvement in scores on the Pain NRS (see Figure 1 and Table 3). Of note, the improvement in pain scores was sustained over time.

Figure 1. *Pain NRS – mean baseline and last follow-up by duration of follow-up. Bars represent standard deviations.*

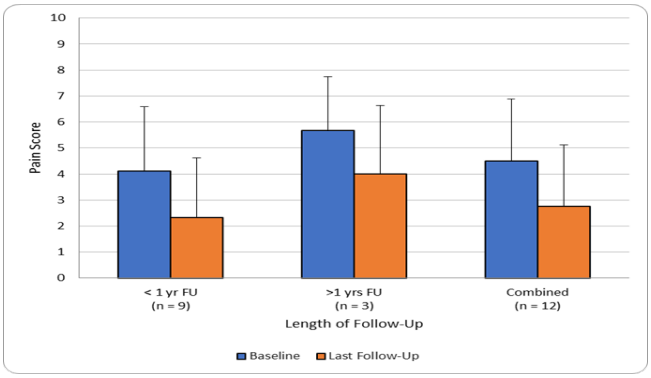

Table 3. *Pain NRS –baseline, last follow-up, and change from baseline scores by duration of follow-up.*

Cohort	Assessment	Mean	SD	Range	95% CI
<1 Year (n=9)	Baseline Last Follow-up Change from Baseline	4.11 2.33 1.78	2.47 2.29 3.31	1 - 8 1 - 8 -3 - 7	2.49, 5.73 0.83, 3.83 -0.38, 3.94
>1 Year (n=3)	Baseline Last Follow-up Change from Baseline	5.67 4.00 1.67	2.08 2.65 1.53	4 - 8 1 - 6 0 - 3	3.31, 8.03 1.01, 6.99 -0.06, 3.40
Combined (n=12)	Baseline Last Follow-up Change from Baseline	4.50 2.75 1.75	2.39 2.38 2.90	1 - 8 1 - 8 -3 - 7	3.15, 5.85 1.40, 4.10 0.11, 3.39

PROMIS-Pain Interference scores were reported for 40.9% (9/22) of the analysis-eligible population. In each follow-up group, PROMIS-Pain Interference T-scores improved from baseline to last follow-up (see Figure 2

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and Table 4). Across all cohorts, the mean baseline T-score was 63.8 ± 6.51 points, and at last follow-up, the mean T-score was 58.8 ± 5.91 points, indicating a 5.00-point mean improvement in T-scores, and well exceeding the MID noted in the literature. Importantly, last follow-up pain T-scores continued to improve as the follow-up period increased past the 1-year post operation time point (T-score = 56 points). Given that a T-score of 55 points is within normal limits, these patients returned to pain levels similar to the general U.S. population.

Figure 2. *PROMIS-Pain Interference – mean baseline and last follow-up scores by duration of follow-up. Bars represent standard deviations.*

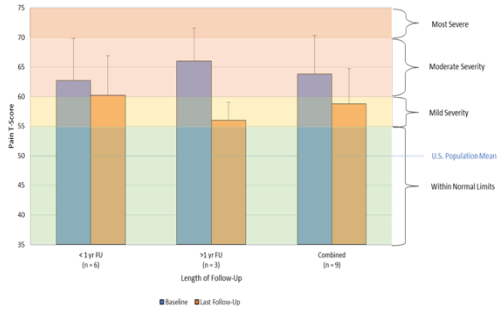


Table 4. *PROMIS-Pain Interference – baseline, last follow-up, and change from baseline scores by duration of follow-up.*

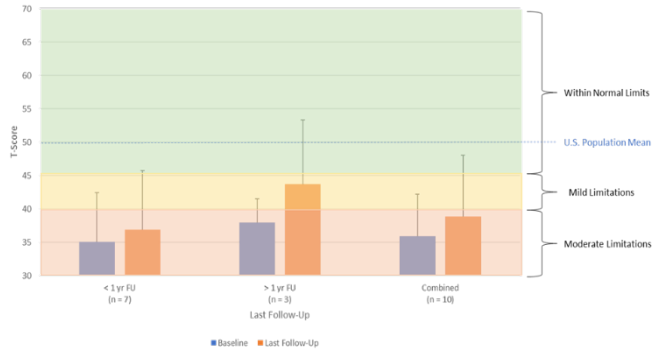
Cohort	Assessment	Mean	SD	Range	95% CI
<1 Year (n=6)	Baseline Last Follow-up Change from Baseline	62.7 60.2 2.50	7.15 6.74 10.5	50 - 70 50 - 67 -17 - 12	57.0, 68.4 54.8, 65.6 -5.89, 10.9
>1 Year (n=3)	Baseline Last Follow-up Change from Baseline	66.0 56.0 10.0	5.57 3.00 2.65	60 – 71 53 – 59 7 – 12	59.7, 72.3 52.6, 59.4 7.01, 13.0
Combined (n=9)	Baseline Last Follow-up Change from Baseline	63.8 58.8 5.00	6.51 5.91 9.19	50 - 71 50 - 67 -17 - 12	59.5, 68.1 54.9, 62.7 -1.01, 11.0

Secondary Probable Benefit Endpoints Results

Physical Function

Across all patients, irrespective of follow-up duration, the mean baseline PROMIS-Physical Function T-score was 35.9 ± 6.33 points, and at last follow-up was 38.9 ± 9.15 points, indicating a 3.00-point improvement in T-scores. When compared to the less than 1 year of follow-up, the patients who had more than 1 year of follow-up and consequently had more time elapse from surgery experienced greater improved physical functioning, and mean T-scores at last follow-up after 1 year were 43.7 ± 9.61 points. A T-score between 40 and 45 points represents mild physical limitations and the mean T-score of 43.7 points at last follow-up in the greater than 1 year cohort is within 1.5 points of normal (see Figure 3).

Figure 3. *Mean PROMIS-Physical Function scores by follow-up duration. Bars represent standard deviations.*



Range of Motion

Ankle plantarflexion and dorsiflexion were reviewed. The postoperative goal for ankle ROM in this study is return to preoperative ROM. Sagittal plane ROM was measured pre and postoperatively. See Figure 4 for plantarflexion scores, and Figure 5 for dorsiflexion scores. Eight (8/22, 36.4%) patients had preoperative and postoperative plantarflexion scores available. Similar to published reports, in the greater than 1-year postoperative cohort, there was no identified difference in pre and postoperative plantarflexion with a mean ROM of 30±10 degrees at last follow-up, signifying that these patients returned to their preoperative ROM after a year from surgery has elapsed. Patients in the less than 1 year follow-up cohort demonstrated an 11-degree reduction in postoperative ROM, which likely contributed to the -6.9 ± 15.1-degree reduction in plantarflexion across all cohorts. One patient in the less than 1 year group had a 30-degree reduction (50 degrees to 20

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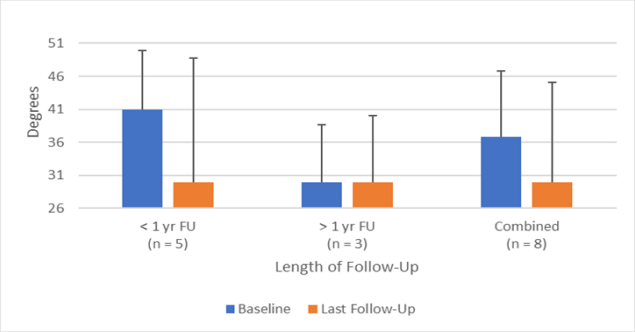
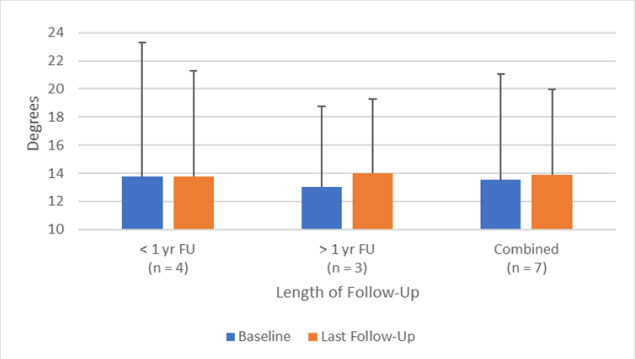
degrees) in ROM from preoperative to postoperative timepoints, and because of the low sample size, these data points impacted the overall means in the <1 year and combined cohorts. When reviewing data summarized in the >1 year cohort, the results of this study demonstrate that ROM is restored to baseline over time.

Figure 4. *Mean degrees of plantarflexion by follow-up duration. Bars represent standard deviations.*



Seven (7/22, 31.8%) patients had preoperative and postoperative dorsiflexion measures available (see Figure 5) . Similar to published reports and across all cohorts, there was no notable difference in degrees of dorsiflexion from preoperative to postoperative visits. Across all follow-up periods, mean dorsiflexion at last follow-up was 13.9 ± 6.12 degrees.

Figure 5. *Mean degrees of dorsiflexion by follow-up duration. Bars represent standard deviations.*



Conclusion

Across the enrolled participants in the clinical study, the restor3d patient specific TTR implant was demonstrated to provide a limb and joint sparing solution, as well as improvement in patient quality of life through reduction of pain, maintenance of range of motion and improved physical functioning. These positive impacts afford patients the ability to return to work, maintain a healthy lifestyle through physical activity, and engage with friends and family.

The restor3d Total Talus Replacement device was able to restore motion to a degenerated joint that was plagued with risk of fusion or amputation. Patients reported an improvement in perceived pain from baseline to last follow-up on the Pain NRS and PROMIS-Pain Interference scales. There was improved physical function as more postoperative time elapsed. Importantly, patients who had more than 1 year of follow-up reported a 6.00-point improvement in PROMIS-Physical Function T-scores, nearly meeting the within normal limits cutoff value. By the 1-year postoperative time point, degrees of plantarflexion returned to baseline. Similarly, degrees of dorsiflexion returned to baseline, irrespective of follow-up duration.

No (0, 0%) surgical interventions were attributed to the subject device and only two patients (2/27, 7.41%) reported SSIs that were potentially attributed to the procedure. No (0, 0%) adverse events were attributed to the subject device. No (0, 0%) SAEs, SSIs or AEs were reported in patients where the soft tissue attachment sites were used, and the rate of patients with SSIs among the patients who had devices implanted with soft tissue attachment sites (1/8, 12.5%) was equivalent to the rate of patients with SSIs reported across the entire study population (4/27, 14.8%). More importantly, 26 (26/27, 96.3%) participants retained their devices, suggesting strong implant survivorship. No (0, 0%) patients reportedly received a below the knee amputation and all patients were successfully able to salvage their limbs.

MR SAFETY INFORMATION

The restor3d Total Talus Replacement System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety

Humanitarian Device: Authorized by Federal law for use in the treatment of avascular necrosis of the talus with or without talar collapse, cysts or non-union, large, uncontained, unstable, or cystic talar osteochondral defects with risk of collapse or talar osteochondral defects not responsive to traditional treatments, and non-union following talar fracture or talar extrusion unresponsive to more conservative treatments in adult patients, in adult patients. The effectiveness of this device for this use has not been demonstrated. Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

of the Total Talus Replacement System in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

TRAINING

Surgeons may obtain training from a qualified instructor prior to implantation of this device to ensure thorough understanding of instrumentation, implantation, and removal techniques. Please contact restor3d Customer Service toll-free in the U.S. at 984-888-0593 or email customerservice@restor3d.com to arrange training with a qualified instructor.

CAUTION

U.S federal law restricts this device to sale by or on the order of a physician.

Rx Only NON STERILE

For symbols glossary, please refer to:
https://www.restor3d.com/resources/instruction

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Durham, NC 27709
Phone: (984) 888-0593
Email: customerservice@restor3d.com
www.restor3d.com

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