

# A Comparison of PROMIS Scores of Metatarsophalangeal Joint Arthrodesis and Polyvinyl Alcohol Hydrogel Implant Hemiarthroplasty for Hallux Rigidus

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**Background:** The current literature shows similar clinical outcomes between first metatarsophalangeal (MTP) joint arthrodesis and synthetic cartilage implant (SCI) hemiarthroplasty in the treatment of hallux rigidus; however, prior studies have not reported validated patient-reported outcome measures (PROMs). To our knowledge, this is the first study to compare PROMs using 6 domains of the validated Patient-Reported Outcomes Measurement Information System (PROMIS) in patients treated for hallux rigidus with MTP joint arthrodesis and with SCI hemiarthroplasty. In addition, this novel study provides comparative data on the complication and revision rates for each procedure.

**Methods:** A single-center, retrospective registry search identified all patients with preoperative PROMIS scores who underwent MTP joint arthrodesis or SCI hemiarthroplasty for hallux rigidus between February 2016 and June 2021. The study aimed to determine if the 2 procedures showed statistically or clinically equivalent PROMIS scores in 6 domains: physical function, pain interference, pain intensity, global physical health, global mental health, and depression. A multivariable linear regression analysis was performed to compare adjusted 1-year postoperative PROMIS scores between the 2 cohorts. Complication and revision rates were also compared.

**Results:** The study included 82 patients who underwent SCI hemiarthroplasty and 101 who underwent MTP joint arthrodesis. Demographic data and preoperative hallux rigidus severity showed no significant differences between the cohorts. PROMIS scores were mostly comparable between the 2 groups, except for the pain intensity domain. The patients who underwent MTP joint arthrodesis exhibited significantly better pain relief at 1 and 2 years postoperatively, which was supported by adjusted postoperative PROMIS scores. At 2 years, the SCI group had worse pain intensity scores and lower global physical health scores. There were no differences between the cohorts in additional PROMIS scores or complication data.

**Conclusions:** While outcomes in most of the domains were similar, MTP joint arthrodesis was more effective at mitigating pain intensity compared with SCI hemiarthroplasty. This information can guide patient counseling and decision-making when considering surgical intervention for hallux rigidus.

Level of Evidence: Therapeutic Level III. See Instructions for Authors for a complete description of levels of evidence.

H allux rigidus, or first metatarsophalangeal (MTP) joint arthritis, is a common condition that affects 2.5% of adults who are older than 50 years of age<sup>1</sup>. Radiographically, it is characterized by dorsal osteophytes, narrowing of the joint space, and flattening of the metatarsal head, and it ultimately leads to the insidious onset of pain and joint

\*A list of the HSS Orthopaedic Foot and Ankle Surgery Group members is included as a note at the end of the article.

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stiffness<sup>1-3</sup>. Like many orthopaedic conditions, when nonoperative treatment fails, operative intervention is indicated. There are a multitude of surgical options to treat hallux rigidus, including arthrodesis, arthroplasty, and cheilectomy<sup>4</sup>. The gold-standard treatment is first MTP joint arthrodesis; however, this is a motionsacrificing procedure that has been shown, in some studies, to impact gait, impact the ability to resume certain physical activity, and restrict footwear selection<sup>5-7</sup>.

In an effort to conserve joint motion, motion-sparing procedures have evolved over the years. Implantation of a synthetic cartilage implant (SCI) is one such procedure that addresses MTP joint arthritis but maintains motion postoperatively. The polyvinyl alcohol hydrogel implant replicates cartilage on the damaged bone's surface, with properties of low protein adsorption, biocompatibility, high water content, and chemical resistance<sup>8</sup>. Prior studies investigating the outcomes of SCI arthroplasty have had variable results. Some studies have shown that the SCI procedure provides significant improvement in Foot and Ankle Ability Measure (FAAM) scores, with patients reporting a 40% increase in functionality during activities of daily living, and improvements in all domains of the Manchester-Oxford Foot Questionnaire at the 1-year followup9. However, other studies have reported "neutral" satisfaction, mild increases in postoperative pain interference and physical dysfunction, and a continued need for corticosteroid injections for pain management<sup>10</sup>. An industry-sponsored multisite randomized prospective study, the CARTIVA Motion trial, found outcomes of the SCI to be noninferior to those of MTP joint arthrodesis in all aspects<sup>11</sup>. A follow-up of that study cohort was done at 5 years and demonstrated that the pain visual analog scale (VAS), the Short Form-36 (SF-36), and the FAAM activities of daily living and sports subscales remained improved and closely resembled the scores of the first study<sup>12</sup>. The initial CARTIVA Motion trial was a licensing randomized controlled trial required by the U.S. Food and Drug Administration (FDA) that provided Level-I evidence. However, there is literature that questions the validity of the findings<sup>13</sup>. Additionally, there have been a few subsequent studies that have directly compared the use of SCI to MTP joint arthrodesis; however, to our knowledge, no subsequent study has utilized 6 domains of a validated metric such as the Patient-Reported Outcomes Measurement Information System (PROMIS). The mixed results in the literature regarding the use of an SCI highlight the need for further investigation into long-term outcomes.

Given the paucity of long-term postoperative patientreported outcome measures (PROMs) and the lack of studies using validated PROMs, the efficacy and benefits of SCI versus MTP joint arthrodesis remain uncertain. This study aimed to bridge this knowledge gap by comparing preoperative and postoperative PROM scores between MTP joint arthrodesis and SCI hemiarthroplasty using the validated PROMIS metric. Additionally, this study aimed to provide comparative data on complication and revision rates associated with each procedure. We hypothesized that patients undergoing SCI hemiarthroplasty would exhibit largely equivalent PROMIS scores across all domains when compared with those undergoing MTP joint arthrodesis. Nonetheless, given the precedent set by the existing literature, we anticipated a more modest improvement in the physical function domain among patients undergoing arthrodesis, owing to the joint-sacrificing nature of this procedure. Furthermore, we postulated that both procedures would have similar postoperative complication and revision rates.

## **Materials and Methods**

## **Patient Selection**

F ollowing institutional review board approval, a retrospective review of prospectively collected data was performed. This single-center study investigated patients who underwent MTP joint arthrodesis or polyvinyl alcohol hydrogel implant hemiarthroplasty by 1 of 11 fellowship-trained foot and ankle orthopaedic surgeons between February 2016 and June 2021. All surgeons, except 1 who only performed arthrodesis, performed both types of procedures during this time period. Patients were allocated to MTP joint arthroplasty or to SCI hemiarthroplasty through a shared decision-making process based on both surgeon and patient preference. Inclusion criteria included (1) patient age of  $\geq 18$  years, (2) performance of MTP joint arthrodesis or SCI hemiarthroplasty (Stryker) for a primary diagnosis of hallux rigidus, and (3) availability of preoperative and 1-year postoperative PROMIS scores. Patients were excluded if they (1) had a history of previous ipsilateral first-ray surgeries, (2) had a diagnosis of rheumatoid arthritis or gout, or (3) were undergoing revision surgery. Figure 1 summarizes the patient selection and exclusion processes for this study.

#### Clinical Data

Patient charts were reviewed to obtain demographic data, including patient age, weight, and height to calculate body mass index (BMI), and to verify operative information, including which procedure(s) had been performed. Postoperative clinical notes were reviewed to identify all subsequent ipsilateral first-ray surgeries, revisions, infections, persistent pain, and other complications.

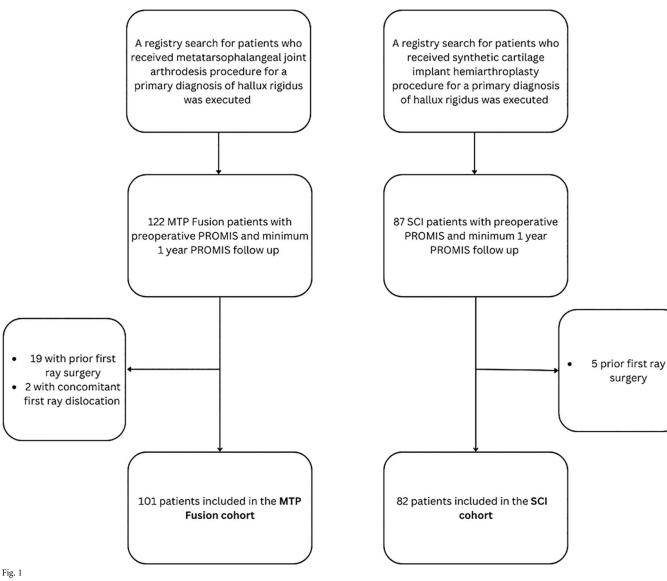
## Radiographic Data

Preoperative anteroposterior and lateral foot radiographs were reviewed with the IDS7 PACS system (Sectra) to determine the severity of each patient's hallux rigidus using the method outlined by Coughlin and Shurnas<sup>3,14</sup> (Table I).

## **PROMs**

PROMs were evaluated utilizing PROMIS questionnaires. These questionnaires employ computerized adaptive testing (CAT) that is grounded on item response theory and has been validated for use in foot and ankle research<sup>15,16</sup>. PROMIS scores were collected preoperatively and at 1 and 2 years postoperatively. The PROMIS domains of physical function, pain interference, pain intensity, global physical health, global mental health, and depression were collected. Scores from these surveys were recorded in the registry database as t-scores with a mean of 50 and a standard deviation [SD] of 10, representing the U.S. population. For each distinct PROMIS domain, it is crucial to note that a higher score connotes a more pronounced

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Patient selection and exclusion process.

presence of the domain that is being assessed. For example, elevated scores in the physical function domain signify superior physical functionality. Conversely, higher scores in the pain interference, pain intensity, and depression domains are indicative of less favorable outcomes, and are characterized by heightened pain and increased depressive symptoms.

## Statistical Analysis

Descriptive statistics were presented as the mean, SD, median, and range for continuous variables, and as the count and percentage for categorical variables. First, differences in patient characteristics (e.g., age, sex, BMI, and arthritis grade) between the cohorts were calculated using the independent-samples t test or the Pearson chi-square test. Second, to determine if PROMIS scores were equivalent between the 2 cohorts at the preoperative, 1-year, and 2-year time points, two one-sided t

tests (TOSTs) were conducted. A ±5-unit margin of difference was set as the clinically meaningful difference between the cohorts, similar to previously published literature on minimal clinically important differences (MCIDs) for PROMIS scores in patients with foot and ankle issues<sup>17</sup>. It is important to note that when equivalence testing is done, a p value of <0.05 indicates that the 2 cohorts are statistically equivalent. Therefore, when testing for equivalence of the PROMIS scores between the patients who underwent MTP joint arthrodesis and SCI hemiarthroplasty, a p value of >0.05 was indicative of statistically inequivalent means between the treatment groups. In order to determine if a difference in 1-year PROMIS scores between the cohorts existed after adjusting for age, sex, BMI, and preoperative PROMIS scores, contrast estimates were derived from linear regression models using restricted cubic splines with 3 knots for age, BMI, and preoperative score to relax

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| TABLE I Hallux Rigidus Radiographic Grading System <sup>14</sup> |                                                 |  |  |
|------------------------------------------------------------------|-------------------------------------------------|--|--|
| Grade                                                            | Criteria                                        |  |  |
| 1                                                                | Minimal or no dorsal<br>osteophytes             |  |  |
|                                                                  | Minimal flattening of the first metatarsal head |  |  |
| 2                                                                | Moderate dorsal osteophytes                     |  |  |
|                                                                  | Minimal joint-space narrowing                   |  |  |
| 3                                                                | Several dorsal osteophytes                      |  |  |
|                                                                  | Irregular joint-space narrowing                 |  |  |
|                                                                  | Subchondral cyst formation                      |  |  |
| 4                                                                | Severe dorsal osteophytes                       |  |  |
|                                                                  | Absent joint space                              |  |  |

the linearity assumption. Significance was defined as an alpha value of 0.05. Clinical importance was defined as a difference whose 95% confidence interval (CI) extended beyond the  $\pm 5$  margin around 0, which was based on our predetermined MCID for PROMIS scores in patients who had been treated for foot and ankle issues. The analysis was conducted in R (R Core Team 2023) with the TOSTER and rms packages.

## Results

# Demographics and Preoperative Hallux Rigidus Severity

**P** atient demographic information can be found in Table II. There were 82 patients who underwent SCI hemiarthroplasty and 101 who underwent MTP joint arthrodesis; they were identified on the basis of the diagnosis code and date of surgery. Of the SCI group, 64 (78%) had 2-year PROMIS scores, and among the MTP joint arthrodesis group, 60 (59%) had 2-year PROMIS scores; thus, 64 patients in the SCI group and 60 patients in the MTP joint arthrodesis group were included in the 2-year follow-up analysis. There were no significant differences in age, BMI, or sex distribution between the 2 cohorts. Additionally, there were no significant differences in the distribution of preoperative hallux rigidus grades (p = 0.378) or preoperative range of motion.

## PROMs

Preoperative, 1-year postoperative, and 2-year postoperative PROMIS scores are shown in Table III. In our sample, there were no significant differences in physical function, pain interference, global physical health, global mental health, or depression scores between the SCI and MTP joint arthrodesis cohorts at any of the time points that were evaluated. Additionally, there were no significant differences between the cohorts in the changes in these scores between the preoperative and postoperative time points. However, the equivalence comparison of PROMIS scores showed that the SCI cohort had significantly worse pain intensity scores at 2 years (42.0 versus 38.9, p = 0.105) and significantly less improvement in pain intensity scores from the preoperative to the 1-year postoperative period (-6.3 versus -9.4, p = 0.096). Moreover, in addition to the increase in pain intensity experienced by those in the SCI cohort at the 2-year time point, these patients also had significantly lower global physical health scores (51.1 versus 53.8, p = 0.081).

When adjusting for age, sex, BMI, and preoperative PROMIS scores, multivariable linear regression models revealed score changes (contrast values) for physical function, pain interference, and pain intensity that were all statistically different from 0 (p < 0.05). However, similar to the results stated above, only the pain intensity subscale had a significant value that also had a 95% CI extending beyond the  $\pm 5$  margin of difference, thus indicating clinical importance as well (3.07, 95% CI = 0.52 to 5.62, p = 0.019). The differences in the remainder of the subscales were neither significant nor clinically important (Table IV).

## **Complications and Subsequent Surgeries**

There were no intraoperative or postoperative wound complications in the SCI cohort, but there was 1 patient in the MTP

|                               | SCI (N = 82) | (N = 101)    | P Value |
|-------------------------------|--------------|--------------|---------|
| Mean age (SD) (yr)            | 58.8 (11.98) | 63.1 (12.86) |         |
| Mean BMI (SD) (kg/m²)         | 25.3 (4.57)  | 25.8 (4.47)  | 0.427   |
| Female sex (no. [%])          | 56 (68.3%)   | 72 (71.3%)   | 0.782   |
| Radiographic grade† (no. [%]) |              |              | 0.378   |
| 1                             | O (O%)       | O (O%)       |         |
| 2                             | 5 (7.1%)     | 7 (7.6%)     |         |
| 3                             | 27 (38.6%)   | 26 (28.3%)   |         |
| 4                             | 38 (54.3%)   | 59 (64.1%)   |         |

\*SCI = synthetic cartilage implant, MTP = metatarsophalangeal, SD = standard deviation, and BMI = body mass index. Significance was defined as p < 0.05. †Some radiographs were not available for grading in each cohort. The severity of each patient's hallux rigidus was determined by the method of Coughlin and Shurnas (see Table I)<sup>14</sup>.

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| PROMIS Domain          | Procedure             | Preop.      | 1-Year Postop. | 2-Year Postop. | Change from Preop.<br>to 1-Year Postop. |
|------------------------|-----------------------|-------------|----------------|----------------|-----------------------------------------|
| Physical function      | MTP joint arthrodesis | 45 (6.69)   | 49.7 (8.89)    | 49.8 (8.29)    | 4.7 (8.57)                              |
|                        | SCI hemiarthroplasty  | 44.6 (6.35) | 48.1 (7.53)    | 48.3 (7.35)    | 3.6 (6.54)                              |
|                        | P value               | <0.001      | 0.003          | 0.006          | <0.001                                  |
| Pain interference      | MTP joint arthrodesis | 58.1 (5.52) | 50.2 (8.98)    | 49.2 (9.26)    | -7.9 (8.73)                             |
|                        | SCI hemiarthroplasty  | 57.7 (5.87) | 52.5 (8.06)    | 51.5 (8.24)    | -5.3 (7.2)                              |
|                        | P value               | <0.001      | 0.016          | 0.044          | 0.025                                   |
| Pain intensity         | MTP joint arthrodesis | 49.9 (5.85) | 40.4 (8.85)    | 38.9 (8.94)    | -9.4 (9.26)                             |
|                        | SCI hemiarthroplasty  | 49.5 (6.62) | 43.2 (8.19)    | 42 (7.94)      | -6.3 (7.87)                             |
|                        | P value               | <0.001      | 0.041          | 0.105†         | 0.096†                                  |
| Global physical health | MTP joint arthrodesis | 46.8 (7.18) | 51.9 (9.48)    | 53.8 (8.44)    | 5.2 (7.63)                              |
|                        | SCI hemiarthroplasty  | 46.8 (7.27) | 51.5 (9.25)    | 51.1 (8.24)    | 4.7 (7.09)                              |
|                        | P value               | <0.001      | <0.001         | 0.081†         | <0.001                                  |
| Global mental health   | MTP joint arthrodesis | 54.5 (8.4)  | 53.7 (9.15)    | 55.6 (9.27)    | -0.8 (6.5)                              |
|                        | SCI hemiarthroplasty  | 55.1 (7.64) | 54.5 (8.98)    | 55.2 (8.68)    | -0.6 (6.97)                             |
|                        | P value               | <0.001      | 0.001          | 0.003          | <0.001                                  |
| Depression             | MTP joint arthrodesis | 46.4 (7.95) | 46.9 (8.17)    | 45.8 (8.31)    | 0 (5.25)                                |
|                        | SCI hemiarthroplasty  | 47.1 (6.23) | 47 (7.15)      | 46.8 (7.57)    | -0.2 (6.46)                             |
|                        | P value               | <0.001      | <0.001         | 0.004          | <0.001                                  |

\*Data are presented as the mean (standard deviation). Significance was defined as p < 0.05. Significant p values indicate evidence of equivalence within a margin of difference of 5 PROMIS points. PROMIS = Patient-Reported Outcomes Measurement Information System, MTP = metatarso-phalangeal, and SCI = synthetic cartilage implant. †P > 0.05, indicating a significant difference between the 2 cohorts.

joint arthrodesis group who developed a superficial wound infection, although it did not require repeat operative intervention. Six patients (7.3%) in the SCI group underwent revision to MTP joint arthrodesis within 3 years due to continued pain and/or subsidence of the implant. Three patients (3%) in the MTP joint arthrodesis group underwent revision due to nonunion, and 13 patients (12.9%) in the MTP joint arthrodesis group had symptomatic hardware that required removal (Fig. 2, Table V).

## **Discussion**

T o our knowledge, this study represents the most extensive comparative analysis (other than the CARTIVA Motion trial)<sup>11</sup> to date between hemiarthroplasty with an SCI and MTP joint

| PROMIS Domain     | SCI                    | MTP Joint Arthrodesis  | Contrast†              | Contrast P Value |
|-------------------|------------------------|------------------------|------------------------|------------------|
| Physical function | 49.00 (46.81 to 51.18) | 51.14 (48.99 to 53.29) | -2.14 (-4.24 to -0.04) | 0.045            |
| Pain interference | 52.43 (49.79 to 55.06) | 49.94 (47.48 to 52.40) | 2.49 (0.03 to 4.95)    | 0.047            |
| Pain intensity    | 44.35 (41.78 to 46.92) | 41.28 (38.89 to 43.68) | 3.07 (0.52 to 5.62)    | <b>0.019</b> †   |
| Global physical   | 53.53 (51.04 to 56.01) | 54.27 (51.92 to 56.61) | -0.74 (-3.03 to 1.55)  | 0.524            |
| Global mental     | 55.91 (53.68 to 58.14) | 55.61 (53.45 to 57.78) | 0.30 (1.79 to 2.39)    | 0.778            |
| Depression        | 47.64 (45.79 to 49.48) | 47.66 (45.79 to 49.54) | -0.03 (-1.83 to 1.78)  | 0.976            |

\*Adjusted by preoperative PROMIS score, age, sex, and BMI. Data are presented as the mean (95% confidence interval [CI]); significance was defined as p < 0.05. Significant contrast values indicate a PROMIS difference that is statistically different from 0. PROMIS = Patient-Reported Outcomes Measurement Information System, SCI = synthetic cartilage implant, and MTP = metatarsophalangeal. †The difference in adjusted values between the cohorts is presented as SCI hemiarthroplasty minus MTP joint arthrodesis. †The contrast value is statistically different from 0, and the 95% CI also extends beyond the  $\pm 5$  margin of difference (the predefined minimal clinically important difference [MCID]), indicating a difference that is clinically important according to this MCID.

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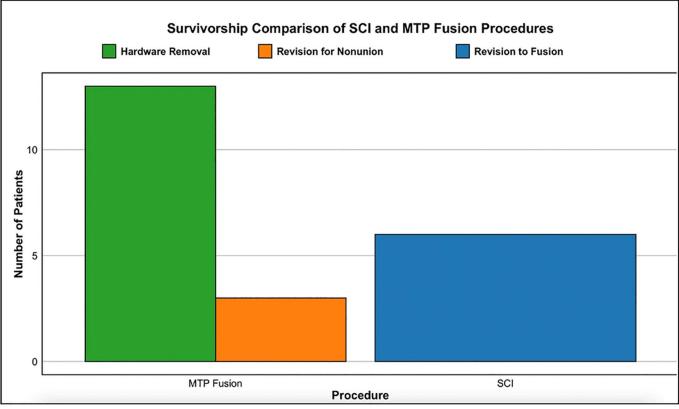


Fig. 2

Survivorship comparison of SCI and MTP joint arthrodesis procedures.

arthrodesis for the management of hallux rigidus. Furthermore, we believe that this is the first study that directly compares the 2 operative interventions using 6 domains of the PROMIS, a metric validated in the foot and ankle literature<sup>16,18-26</sup>. The inclusion of validated preoperative, 1-year, and 2-year PROMIS data spanning 6 domains facilitates a nuanced assessment of outcome disparities and enhances the comprehension of hallux rigidus management.

In general, a comprehensive analysis of PROMIS scores between the SCI cohort and the MTP joint arthrodesis cohort revealed predominantly comparable results. Contrary to our ini-

| TABLE V Revision and Complication Data*                            |                                      |                                       |  |  |
|--------------------------------------------------------------------|--------------------------------------|---------------------------------------|--|--|
|                                                                    | SCI<br>Hemiarthroplasty<br>(no. [%]) | MTP Joint<br>Arthrodesis<br>(no. [%]) |  |  |
| Subsequent procedure                                               | 6 (7.3%)                             | 16 (16%)                              |  |  |
| Removal of hardware                                                | 0 (0%)                               | 13 (13%)                              |  |  |
| Revision                                                           | 6 (7.3%)                             | 3 (3%)                                |  |  |
| Conversion to<br>arthrodesis                                       | 6 (7.3%)                             | 0 (0%)                                |  |  |
| Infection                                                          | 0 (0%)                               | 1 (1%)                                |  |  |
| *SCI = synthetic cartilage implant, and MTP = metatarsophalangeal. |                                      |                                       |  |  |

tial hypothesis, there was not a significant difference noted in physical function between the cohorts, despite the motion preservation that had been achieved with the SCI. In fact, although not reaching significance, patients in the MTP joint arthrodesis cohort displayed a more substantial improvement in average physical function from the preoperative state to 1 year postoperatively.

The most noteworthy significant difference between the cohorts was in the domain of pain intensity: patients who underwent MTP joint arthrodesis had more pain relief postoperatively. At 1 year after surgery, the MTP joint arthrodesis cohort demonstrated an average pain reduction of 9.4 points, while the SCI cohort exhibited a 6.1-point reduction in pain (p = 0.096), a significant change based on our criteria. This disparity is consistently supported by analysis of the adjusted postoperative PROMIS scores, with pain intensity emerging as the sole subscale to demonstrate both significance and a 95% CI extending beyond the  $\pm 5$  margin, indicating clinical importance based on the MCID criterion (p = 0.019). Additionally, at 2 years after surgery, the patients who underwent MTP joint arthrodesis had significantly lower pain scores (mean, 38.9; SD, 8.94) compared with those who underwent SCI (mean, 42; SD, 7.94; p = 0.105), which further supports the existence of a difference in pain.

The SCI cohort displayed notably lower average scores in the global physical health domain compared with their MTP joint arthrodesis counterparts (51.1 versus 53.8, p = 0.081). Unlike the pain intensity domain, changes in the global physical health scores

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from the preoperative baseline to the 1-year postoperative assessment did not achieve significance when accounting for demographic variables; however, the divergence in the global physical health scores merits attention, with a plausible explanation stemming from the heightened pain experienced by these patients in the context of their clinical condition.

With regard to subsequent procedures that were performed and complications, 6 patients (7.3%) in the SCI group needed to undergo revision, compared with only 3 patients (3%) in the MTP joint arthrodesis group. All 6 patients in the SCI group underwent revision to MTP joint arthrodesis. However, despite the higher overall number of subsequent surgeries in the MTP joint arthrodesis cohort, it is important to note that hardware removal is relatively straightforward for both the surgeon and the patient. These removal procedures do not require prolonged patient recovery periods, unlike the more complex and extensive conversion to an arthrodesis.

Direct comparisons between MTP joint arthrodesis and implantation of an SCI in the literature are scarce. The CAR-TIVA Motion Study Group completed a noninferiority-based randomized controlled clinical trial that compared MTP joint arthrodesis with an SCI procedure using the VAS pain scale and the FAAM sports subscale, and reported the number of subsequent surgeries that were required<sup>11</sup>. That was a Level-I study, which inherently is superior with regard to methodology when compared with our present study. However, while those authors concluded that there were equivalent pain relief and functional outcomes between the 2 cohorts, these results have been challenged. In fact, Guyton reanalyzed the data from the trial and noted that varying the assumptions impacted the ability to prove noninferiority<sup>13</sup>. Specifically, he noted that a direct comparison of pain outcomes showed that MTP joint arthrodesis resulted in a better mean result for VAS pain than use of an SCI did, which is consistent with our findings of improved pain intensity PROMIS scores in the arthrodesis group. Of note, Guyton's reanalysis represents a single-author study with Level-V evidence.

Similar to our study, Joo et al. compared SCI hemiarthroplasty with MTP joint arthrodesis using PROMIS scores, although they only reported the physical function and pain interference domains<sup>27</sup>. In contrast to our study's findings, Joo et al. concluded that patients who underwent SCI hemiarthroplasty exhibited marginally superior improvements in physical function scores at all follow-up intervals relative to the arthrodesis cohort; however, the study had significant preoperative disparities in PROMIS physical function scores between the 2 groups, which potentially influenced postoperative physical function outcomes. Aside from having equivalent preoperative cohorts, we controlled for various demographic variables, including preoperative PROMIS scores, when evaluating changes in PROMIS scores in an effort to avoid selection bias and decrease confounding variables. Unfortunately, the study by Joo et al. did not report PROMIS scores within the domains of pain intensity or global physical health, which represented our most notable differences.

Although the outcomes in our study appear predominantly comparable between the 2 techniques, MTP joint arthrodesis was noted to be the more efficacious intervention in mitigating pain. With these results, patients should be counseled that while hemiarthroplasty preserves MTP joint motion, it may not relieve pain intensity to the same extent as arthrodesis. This critical consideration should help inform the decision-making process for patients seeking operative intervention for hallux rigidus. In patients in whom preserved motion is important, SCI hemiarthroplasty remains a viable and acceptable option, particularly when preoperative pain intensity scores remain relatively low. However, patients with higher preoperative pain intensity scores may be better advised to pursue arthrodesis.

The relatively large sample size and use of PROMIS scores are 2 strengths of this study. However, of note, this was a Level-III retrospective study, which by definition will have lower scientific validity than higher-quality Level-II and I studies. Furthermore, this study does have several limitations that impact its generalizability. First, this study was performed at only a single institution. Nevertheless, the large number of surgeons (11) should improve its generalizability. Second, there is potential bias in the present results since the patients in the analysis were required to have follow-up data. Patients may or may not have filled out follow-up PROMIS surveys for various reasons, which may have influenced our results. Third, factors that can potentially influence hallux rigidus development or surgical outcomes, such as radiographic arch parameters, foot morphology (hallux valgus), or first-ray instability or hypermobility, were not investigated, thereby decreasing the generalizability of the findings of our study. Finally, future studies should systematically investigate the long-term disparities in outcomes between these 2 surgical groups. Extended follow-up studies spanning 5 to 10 years would be invaluable in providing a comprehensive comparative assessment of these procedures.

#### Conclusions

Treatment of hallux rigidus by polyvinyl alcohol hydrogel implant hemiarthroplasty and by MTP joint arthrodesis had equivalent outcomes for all PROMIS domains except the pain intensity domain. While patients in both cohorts had improvement in pain from the preoperative to postoperative time points, SCI hemiarthroplasty was not as effective as MTP joint arthrodesis at relieving pain intensity at a follow-up of 1 year. While SCI hemiarthroplasty is a motion-sparing procedure that allows for more variety in shoe wear, patients with a primary goal of improving pain may be better suited for MTP joint arthrodesis.

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#### References

 Ho B, Baumhauer J. Hallux rigidus. EFORT Open Rev. 2017 Mar 13;2(1):13-20.
Patel HA, Kalra R, Johnson JL, Huntley SR, Lehtonen EJ, McGwin G, Naranje S, Shah A. Is interposition arthroplasty a viable option for treatment of moderate to severe hallux rigidus? - A systematic review and meta-analysis. Foot Ankle Surg. 2019 Oct;25(5):571-9.

**3.** Kim J, Rajan L, Fuller RM, Mizher R, Cororaton AD, Kumar P, An TW, Deland JT, Ellis SJ. A Patient-Reported Outcome-Based Comparison of Cheilectomy With and Without Proximal Phalangeal Dorsiflexion Osteotomy for Hallux Rigidus. Foot Ankle Spec. 2024 Feb;17(1):67-77.

4. Brage ME, Ball ST. Surgical options for salvage of end-stage hallux rigidus. Foot Ankle Clin. 2002 Mar;7(1):49-73.

**5.** Raikin SM, Ahmad J, Pour AE, Abidi N. Comparison of arthrodesis and metallic hemiarthroplasty of the hallux metatarsophalangeal joint. J Bone Joint Surg Am. 2007 Sep;89(9):1979-85.

6. Da Cunha RJ, MacMahon A, Jones MT, Savenkov A, Deland J, Roberts M, Levine D, Elliot A, Kennedy J, Drakos M, Ellis SJ. Return to Sports and Physical Activities After First Metatarsophalangeal Joint Arthrodesis in Young Patients. Foot Ankle Int. 2019 Jul;40(7):745-52.

**7.** DeFrino PF, Brodsky JW, Pollo FE, Crenshaw SJ, Beischer AD. First metatarsophalangeal arthrodesis: a clinical, pedobarographic and gait analysis study. Foot Ankle Int. 2002 Jun;23(6):496-502.

 Baker MI, Walsh SP, Schwartz Z, Boyan BD. A review of polyvinyl alcohol and its uses in cartilage and orthopedic applications. J Biomed Mater Res B Appl Biomater. 2012 Jul;100(5):1451-7.

9. Brandao B, Aljawadi A, Hall A, Fox A, Pillai A. Cartiva case series: The efficacy of the Cartiva synthetic cartilage implant interpositional arthroplasty at one year. J Orthop. 2020 Jun 30;20:338-41.

**10.** Cassinelli SJ, Chen S, Charlton TP, Thordarson DB. Early Outcomes and Complications of Synthetic Cartilage Implant for Treatment of Hallux Rigidus in the United States. Foot Ankle Int. 2019 Oct;40(10):1140-8.

**11.** Baumhauer JF, Singh D, Glazebrook M, Blundell C, De Vries G, Le IL, Nielsen D, Pedersen ME, Sakellariou A, Solan M, Wansbrough G, Younger AS, Daniels T; for and on behalf of the CARTIVA Motion Study Group. Prospective, Randomized, Multicentered Clinical Trial Assessing Safety and Efficacy of a Synthetic Cartilage Implant Versus First Metatarsophalangeal Arthrodesis in Advanced Hallux Rigidus. Foot Ankle Int. 2016 May;37(5):457-69.

**12.** Daniels TR, Younger ASE, Penner MJ, Wing KJ, Miniaci-Coxhead SL, Pinsker E, Glazebrook M. Midterm Outcomes of Polyvinyl Alcohol Hydrogel Hemiarthroplasty of the First Metatarsophalangeal Joint in Advanced Hallux Rigidus. Foot Ankle Int. 2017 Mar;38(3):243-7.

**13.** Guyton GP. Philosophies of Surgical Care Are Embedded in Outcome Studies: An Illustrative Reanalysis of the Cartiva MOTION Trial. Foot Ankle Int. 2022 Oct; 43(10):1364-9.

**14.** Coughlin MJ, Shurnas PS. Hallux rigidus: demographics, etiology, and radiographic assessment. Foot Ankle Int. 2003 Oct;24(10):731-43.

**15.** Anderson MR, Houck JR, Saltzman CL, Hung M, Nickisch F, Barg A, Beals T, Baumhauer JF. Validation and Generalizability of Preoperative PROMIS Scores to

Predict Postoperative Success in Foot and Ankle Patients. Foot Ankle Int. 2018 Jul; 39(7):763-70.

 Hung M, Baumhauer JF, Latt LD, Saltzman CL, Soohoo NF, Hunt KJ. Validation of PROMIS® physical function computerized adaptive tests for orthopaedic foot and ankle outcome research. Clin Orthop Relat Res. 2013 Nov;471(11):3466-74.
Hung M, Baumhauer JF, Licari FW, Voss MW, Bounsanga J, Saltzman CL.

PROMIS and FAAM Minimal Clinically Important Differences in Foot and Ankle Orthopedics. Foot Ankle Int. 2019 Jan;40(1):65-73.

**18.** Brodke DJ, Saltzman CL, Brodke DS. PROMIS for Orthopaedic Outcomes Measurement. J Am Acad Orthop Surg. 2016 Nov;24(11):744-9.

 Cheung JTM, Zhang M, An KN. Effect of Achilles tendon loading on plantar fascia tension in the standing foot. Clin Biomech (Bristol, Avon). 2006 Feb;21(2):194-203.
Cella D, Riley W, Stone A, Rothrock N, Reeve B, Yount S, Amtmann D, Bode R, Buysse D, Choi S, Cook K, Devellis R, DeWalt D, Fries JF, Gershon R, Hahn EA, Lai JS, Pilkonis P, Revicki D, Rose M, Weinfurt K, Hays R; PROMIS Cooperative Group. The Patient-Reported Outcomes Measurement Information System (PROMIS) developed and tested its first wave of adult self-reported health outcome item banks: 2005-2008. J Clin Epidemiol. 2010 Nov;63(11):1179-94.

**21.** Hung M, Baumhauer JF, Brodsky JW, Cheng C, Ellis SJ, Franklin JD, Hon SD, Ishikawa SN, Latt LD, Phisitkul P, Saltzman CL, SooHoo NF, Hunt KJ; Orthopaedic Foot & Ankle Outcomes Research (OFAR) of the American Orthopaedic Foot & Ankle Society (AOFAS). Psychometric comparison of the PROMIS physical function CAT with the FAAM and FFI for measuring patient-reported outcomes. Foot Ankle Int. 2014 Jun;35(6):592-9.

22. Ziedas AC, Abed V, Swantek AJ, Rahman TM, Cross A, Thomashow K, Makhni EC. Patient-Reported Outcomes Measurement Information System (PROMIS) Physical Function Instruments Compare Favorably With Legacy Patient-Reported Outcome Measures in Upper- and Lower-Extremity Orthopaedic Patients: A Systematic Review of the Literature. Arthroscopy. 2022 Feb; 38(2):609-31.

**23.** Hung M, Nickisch F, Beals TC, Greene T, Clegg DO, Saltzman CL. New paradigm for patient-reported outcomes assessment in foot & ankle research: computerized adaptive testing. Foot Ankle Int. 2012 Aug;33(8):621-6.

**24.** Hung M, Franklin JD, Hon SD, Cheng C, Conrad J, Saltzman CL. Time for a paradigm shift with computerized adaptive testing of general physical function outcomes measurements. Foot Ankle Int. 2014 Jan;35(1):1-7.

**25.** Sanchez T, Sankey T, Schick S, Arthur R, Young M, Underwood M, Harrelson W, Shah A. PROMIS Scores for Plantar Fasciitis Before and After Gastrocnemius Recession. Foot Ankle Int. 2023 May;44(5):459-68.

**26.** Koltsov JCB, Greenfield ST, Soukup D, Do HT, Ellis SJ. Validation of Patient-Reported Outcomes Measurement Information System Computerized Adaptive Tests Against the Foot and Ankle Outcome Score for 6 Common Foot and Ankle Pathologies. Foot Ankle Int. 2017 Aug;38(8):870-8.

**27.** Joo PY, Baumhauer JF, Waldman O, Hoffman S, Houck J, Kohring JM, Flemister AS, Ketz JP, DiGiovanni BF, Oh I. Physical Function and Pain Interference Levels of Hallux Rigidus Patients Before and After Synthetic Cartilage Implant vs Arthrodesis Surgery. Foot Ankle Int. 2021 Oct;42(10):1277-86.

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