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Treatment of Hallux Rigidus: Comparison of Hemiarthroplasty with Cartiva Implant, Allograft Interpositional Arthroplasty, and Arthrodesis

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Abstract

Background: A modern technique for the treatment of hallux rigidus (HR) is first metatarsophalangeal (MTP) hemiarthroplasty with the use of a Cartiva synthetic cartilage implant. Current scientific literature reporting early outcomes of the procedure is sparse and mixed, indicating the need for further analysis. The objective of this study was to compare improvement in visual analog scale (VAS) scores with first MTP hemiarthroplasty with Cartiva implant (HI), allograft interposition arthroplasty (IA), and arthrodesis (A) in patients who failed conservative management or cheilectomy.

Methods: A retrospective cohort study of 99 patients was performed. There were 49 patients in the HI group, 25 patients in the IA group, and 25 patients in the A group. A follow-up survey was administered from which updated VAS and updated American Orthopaedic Foot & Ankle Society scores were obtained.

Results: Mean VAS scores improved by 2.73 (SD ± 2.80) points in the HI group, 4.16 (SD ± 2.01) points in the IA group, and 4.36 (SD ± 3.67) points in the A group ($P = .035$). Mean AOFAS scores improved by 14.90 (SD ± 17.31) points in the HI group, 27.80 (SD ± 15.22) points in the IA group, and 27.88 (SD ± 25.34) points in the A group ($P = .005$). There were 3 (6.1%) revision surgeries in the HI group, 2 (8.0%) revision surgeries in the A group, and no revision surgeries in the IA group ($P = .59$). Within the HI group, all 3 revisions were due to pain associated with the implant and were revised to MTP arthrodesis. The A group had 1 revision due to broken hardware and 1 revision due to infection. In both cases, the patients were treated with hardware removal.

Conclusion: Pain and function may be slightly more improved with interpositional arthroplasty and arthrodesis for the treatment of HR, when compared to hemiarthroplasty with the Cartiva implant.

Level of Evidence: Level III, therapeutic studies; case-control study.

Keywords: hallux rigidus, arthroplasty, arthrodesis, implant

Introduction

Symptoms of hallux rigidus (HR) include pain with motion, swelling, and stiffness due to arthritis of the first metatarsophalangeal (MTP) joint, and can severely affect patients' quality of life.[9] HR is a common complaint, second only to hallux valgus in chief complaints of the great toe.[8] HR is the most common arthritis in the foot.[3] Etiologies include degenerative, posttraumatic, inflammatory, and idiopathic origins. HR also limits motion and patient activities, with deleterious effects on gait and footwear options.

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Surgical treatments for HR include cheilectomy, Keller osteotomy, arthrodesis, and implant- vs biologic-based arthroplasty. Cheilectomy has been shown to be beneficial for mild to moderate HR, whereas arthrodesis or arthroplasty is generally recommended in advanced HR stages.[18] Although arthrodesis has been shown to improve function per gait analysis,[6] many patients prefer other treatment modalities to preserve joint range of motion. Furthermore, first MTP arthrodesis has been shown to progress to nonunion in up to 13% of patients.[13]

Biologic interpositional MTP arthroplasty preserves bone, range of motion, and stability, which makes potential future revisions more feasible.[3] By using biologic tissue such as capsule or tendon rather than an implant, implant migration, wear, and reactions such as synovitis can be avoided.

Hallux MTP arthrodesis is the salvage procedure for failed arthroplasty and end-stage HR. Salvage arthrodesis is more technically difficult than a primary arthrodesis. A 2013 retrospective study by Gross et al[15] examined patients who underwent first-MTP arthrodesis after failure of an implant arthroplasty. Patients undergoing salvage arthrodesis for failed arthroplasty had higher reoperation rates and lower AOFAS scores compared to patients undergoing primary arthrodesis.

A novel technique for the treatment of HR is first MTP hemiarthroplasty with the use of a Cartiva synthetic cartilage implant. The Cartiva implant is designed to be elastic, compressible, and able to minimize friction in order to imitate natural cartilage. This allows patients to maintain motion at the first MTP joint. Current scientific literature reporting early outcomes of the procedure are mixed. In 2019, Glazebrook et al[14] prospectively assessed clinical and safety outcomes of hemiarthroplasty using the Cartiva implant for treatment of HR and reported a patient satisfaction of 93.6% at 5 years postoperatively. In the same year, a retrospective chart review of patients who underwent treatment for HR with the Cartiva implant conducted by Cassinelli et al[7] reported a patient satisfaction of 42.0% at an average of 18.5 months postoperatively. Additionally, a 2021 study by Akoh et al[1] analyzing United States Food and Drug Administration data from 2010 to 2018 found Cartiva implants to have the highest adverse event rate (24%) when compared to other MTP implants. This discrepancy of data indicates the need for further analysis.

We hypothesized that first MTP hemiarthroplasty with Cartiva implant would demonstrate comparable improvement in VAS scores while maintaining joint motion as compared to cases of first MTP allograft interpositional arthroplasty or first MTP arthrodesis. The objective of this study was to compare improvement in visual analog scale (VAS) with first MTP hemiarthroplasty with Cartiva implant, allograft interpositional arthroplasty, and arthrodesis in patients who have failed conservative management or cheilectomy.

Methods

A retrospective case-control study was performed on patient data collected from 2002 to 2020 at a single institution after approval by the institutional review board. Patients were identified using CPT and ICD codes. Cases were defined as patients who received hemiarthroplasty with implant (HI) for treatment of HR by the 4 foot and ankle surgeons at the institution from January 1, 2017, to April 30, 2020, with minimum of 1 year documented follow-up. Historical controls were defined as patients who received interpositional arthroplasty (IA) or arthrodesis (A) for treatment of HR by the 4 foot and ankle surgeons at the institution from January 1, 2008, to December 31, 2015, with a minimum of 1-year documented follow-up. Surgical technique used during this period varied depending on surgeon preference and individual patient characteristics. Similar selection criteria were used for all 4 surgeons across groups. Inclusion criteria included age $\geq$18 years, HR with pain, decreased first MTP motion, and radiographic findings of decreased joint space with evidence of osteophytes. Exclusion criteria were peripheral neuropathy in ipsilateral leg, previous MTP surgery (with the exception of failed cheilectomy), inflammatory arthritis, interphalangeal arthritis, prior ankle (tibiotalar), hindfoot, or midfoot fusion procedure: (subtalar, talonavicular, naviculocuneiform, calcaneocuboid), or prior ankle arthroplasty that would impact the patient's functional outcomes, and non-English-speaking subjects.

Basic demographic data, duration of symptoms, preoperative VAS score, and American Orthopaedic Foot & Ankle Society (AOFAS) scores were collected. The VAS score is a universal pain assessment tool in which patients rate pain on a scale of 0 to 10, with 0 being "no pain" and 10 being "pain as bad as it could possibly be." AOFAS scores are derived from multiple variables, including pain, activity limitations, support requirements, footwear requirements, maximum walking distance, difficulty with walking surfaces, gait abnormality, and alignment. Range of motion was not quantitatively documented in the electronic health records.

The decision to pursue one of the 3 treatments was based on both patient preference and shared decision making with their respective surgeon, because these operations were performed after failed conservative management or cheilectomy. A regenerative acellular allograft dermal matrix (GraftJacket Regenerative Tissue Matrix; Wright Medical, Memphis, TN) was used for patients undergoing interpositional arthroplasty. A synthetic cartilage implant (Cartiva Synthetic Cartilage Implant; Stryker Medical, Portage, MI) used for patients undergoing

hemiarthroplasty. The specific operative technique is described below. A modification to the study, approved by the Institutional Review Board, allowed the patients to be contacted via phone for follow-up VAS scores and AOFAS surveys. This was done to increase the follow-up time after surgery and determine how well patients were functioning years after their respective procedures.

A total of 99 patients met the inclusion criteria and were included in the retrospective chart review, with 49 patients in the hemiarthroplasty with implant (HI) group, 25 patients in the interpositional arthroplasty (IA) group, and 25 patients in the arthrodesis (A) group. A total of 34 patients in the HI group, 16 patients in the IA group, and 11 patients in the A group could be contacted and agreed to participate in the telephone survey. The rest of the patients could not be reached by telephone. Updated VAS and AOFAS scores were obtained through these calls. The mean total follow-up time after surgery was 36 months in the HI group, 43 months in the IA group, and 30 months in the A group. Symptom duration was collected for 49 patients in the HI group, 22 patients in the IA group, and 22 patients in the A group. Corresponding counts for symptom duration of each treatment group can be found in Figure 1.

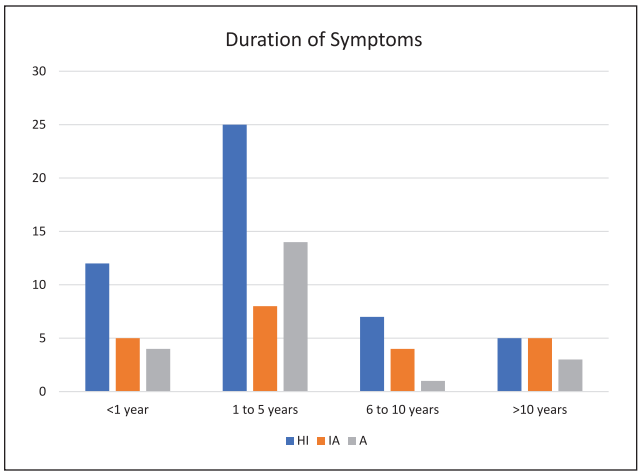

Figure 1. Symptom duration for each treatment group. HI, hemiarthroplasty with implant group; IA, interpositional arthroplasty group; A, arthrodesis group.

No significant differences were found in follow-up time, gender, mean age, BMI, smoking status, or duration of symptoms between treatment groups ($P > .05$). All demographic data is summarized in Table 1.

Surgical Techniques

Surgical techniques for MTP joint arthrodesis, hallux cheilectomy, and hallux interpositional arthroplasty have been previously described in Krumm et al.[17] A hallux cheilectomy was performed with all interpositional arthroplasties in order to ensure maintenance of MTP range of motion.

Hallux hemiarthroplasty with Cartiva implant: A cheilectomy was performed with all Cartiva implantations in order to ensure maintenance of MTP range of motion; however, special attention was paid in order to preserve adequate bone stock for the implant. After the cheilectomy was completed, the surgeon selected the appropriate size Cartiva implant, allowing for about a 2-mm rim of cartilage around the implant. The Cartiva implant comes in 2 sizes, 8 and 10 mm. The corresponding reamer was used to ream for the implant in the center of the metatarsal head and shaft. The implant was then inserted using the provided insertion tool, allowing for a press fit. This leaves the smooth, rounded head of the implant about 2 mm proud, allowing the base of the proximal phalanx to articulate with the implant rather than the degenerative metatarsal head.

Table 1. Demographic Data for Each Treatment Group.

Demographic Variable	HI Group	IA Group	A Group	*P* Value
Total follow-up, wk, mean ± SD	142.4 ± 77.32	170.2 ± 145.73	118.2 ± 122.35	.25
Gender, n (%)				
Male	12 (76)	8 (32)	3 (12)	
Female	37 (24)	17 (68)	22 (88)	.24
Mean age, y	57.5	56.2	57.9	.75
BMI, mean (range)	27.4 (20.8-37.1)	26.8 (19.5-41.1)	28.9 (22.9-36.0)	.26
Smoking status, n (%)				
Current	2 (4.1)	1 (4.0)	3 (12)	
Former	10 (20)	5 (20)	5 (20)	
Never	36 (73)	19 (76)	16 (64)	
Unknown	1 (2.0)	–[a]	1 (4.0)	.81
Duration of symptoms, mo, mean ± SD	56.5 ± 89.90	106.6 ± 170.32	49.6 ± 59.66	.15

Abbreviations: A, arthrodesis; BMI, body mass index; HI, hemiarthroplasty with implant; IA, interpositional arthroplasty.
[a]No value or not applicable.

Table 2. Mean Preoperative and Postoperative VAS and AOFAS Scores.

Treatment Group	VAS		AOFAS	
	Preoperative	Postoperative	Preoperative	Postoperative
HI	4.8	2.1	59.6	74.5
IA	5.6	1.4	47.7	75.5
A	5.2	0.8	49.0	76.9

Abbreviations: A, arthrodesis; AOFAS, American Orthopaedic Foot & Ankle Society score; HI, hemiarthroplasty with implant; IA, interpositional arthroplasty; VAS, visual analog scale.

Table 3. Mean VAS and AOFAS Improvement.

Score Variable	HI Group, Mean ± SD	IA Group, Mean ± SD	A Group, Mean ± SD	*P* Value
VAS	2.7 ± 2.80	4.2 ± 2.01	4.4 ± 3.67	.035*
AOFAS Improvement	14.9 ± 17.31	27.8 ± 15.22	27.9 ± 25.34	.005*

Abbreviations: A, arthrodesis; AOFAS, American Orthopaedic Foot & Ankle Society score; HI, hemiarthroplasty with implant; IA, interpositional arthroplasty; VAS, visual analog scale.
*Significant *P* value.

Statistical Analysis

Statisticians at the Michigan State University Center for Statistical Training and Consulting assisted with data analysis, including mean, SD, range, and analysis of variance tests to determine significance of changes in VAS and AOFAS scores. The data analysis was conducted using SPSS (IBM, Armonk, NY) to calculate statistics. Descriptive statistics were calculated with categorical data reported as counts with percentages and continuous data as mean ± SD. To evaluate categorical data, 2-group univariate comparisons were analyzed using χ^2 test for values greater than 5 and Fisher exact tests for values less than 5. One-way analysis of variance was used to compare the means between treatment groups. Missing data were removed from data analysis. Statistical significance for all analyses was set at $P < .05$.

Results

All treatment groups had a postoperative decrease in mean VAS scores and an increase in mean AOFAS scores. Preoperative and postoperative mean VAS and AOFAS scores for each treatment group are summarized in Table 2. Mean VAS scores improved by 2.7 (SD ± 2.80) points in the HI group, 4.2 (SD ± 2.01) points in the IA group, and 4.4 (SD ± 3.67) points in the A group ($P = .035$). Mean AOFAS scores improved by 14.9 (SD ± 17.31) points in the HI group, 27.8 (SD ± 15.22) points in the IA group, and 27.9 (SD ± 25.34) points in the A group ($P = .005$). Mean VAS and AOFAS improvement for each treatment group is summarized in Table 3.

There were 3 (6.1%) revision surgeries in the HI group, 2 (8.0%) revision surgeries in the A group, and no revision surgeries in the IA group ($P = .59$). Within the HI group, all 3 revisions were due to pain associated with the implant and were revised to MTP arthrodesis. The A group had 1 revision because of broken hardware and 1 revision because of infection. In both cases, the patients were treated with hardware removal. All treatment groups had a majority of positive responses to telephone survey questions asking if patients found the surgery beneficial, if they would have the procedure again, if they would recommend the procedure to a friend, if they were satisfied, and if they were happy with the appearance of the surgical site. There were no significant differences noted between groups via phone survey ($P > .05$). Revision rates and telephone survey responses for each treatment group are summarized in Table 4.

Discussion

The present retrospective case-control study of patients undergoing hemiarthroplasty with Cartiva implant, allograft interposition arthroplasty, and arthrodesis for the treatment of first MTP HR demonstrates postoperative improvement in VAS and AOFAS scores. Of note, postoperative VAS improvement was found to be significantly lower in the HI group (2.73, SD ± 2.80) when compared to the IA (4.16, SD ± 2.01) and A (4.36, SD ± 3.67) treatment groups ($P = .035$). Similarly, postoperative AOFAS improvement was also found to be significantly lower in the HI group (14.90, SD ± 17.31) when compared to the IA (27.80, SD ± 15.22) and A (27.88, SD ± 25.34) treatment groups ($P = .005$). However, there was no significant difference noted between revision rates and patient satisfaction noted between treatment groups.

To our knowledge, no study has previously compared these 3 treatments and reported on postoperative VAS and

Table 4. Revision Rate and Telephone Survey Responses.

Outcome Variable	HI Group, n (%)	IA Group, n (%)	A Group, n (%)	*P* Value
Revision surgery				
No	46 (94)	25 (100)	23 (92)	
Yes	3 (6.0)	–[a]	2 (8.0)	.59
Surgery beneficial?				
No	6 (18)	5 (31)	–[a]	
Yes	28 (82)	11 (69)	11 (100)	.11
Have procedure again?				
No	6 (18)	4 (25)	1 (9.0)	
Yes	28 (82)	12 (75)	10 (91)	.67
Recommend procedure?				
No	4 (12)	2 (12)	–[a]	
Yes	30 (88)	14 (88)	11 (100)	.71
Satisfied?				
No	6 (18)	5 (31)	–[a]	
Yes	28 (82)	11 (69)	11 (100)	.11
Happy with appearance?				
No	1 (3.0)	1 (6.0)	–[a]	
Yes	33 (97)	15 (94)	11 (100)	.69

Abbreviations: A, arthrodesis; HI, hemiarthroplasty with implant; IA, interpositional arthroplasty.
[a]No value or not applicable.

AOFAS improvement. A 2016 prospective, multicenter randomized controlled trial by Baumhauer et al[2] comparing the Cartiva implant to first MTP arthrodesis found both groups had significantly lower VAS scores (0-100) at 2 years postoperatively when compared to baseline, with a 63.4-point reduction observed in the arthrodesis group compared with a 53.5-point reduction in the implant group ($P = .002$). Brandao et al[5] performed a comparative study of patients who underwent Cartiva implant and cheilectomy for treatment of HR and found no significant difference between pain scores (27.52 vs 27.12, $P = .682$, respectively) using the Manchester Oxford Foot and Ankle questionnaire at a minimum of 1 year postoperatively. A more recent 2023 study by Hoskins et al[16] comparing Cartiva hemiarthroplasty to cheilectomy for treatment of HR found the Cartiva group had significantly higher mean postoperative AOFAS score when compared to the cheilectomy group: 89.7 and 85.3, respectively ($P = .045$). However, the cheilectomy group saw a greater increase in mean postoperative AOFAS score when compared to the preoperative baseline, with a 35.7-point increase in the cheilectomy group and 33.3-point increase in the Cartiva group.[16]

Surrogate outcomes for Cartiva implant failure have been reported as implant survival rates, secondary surgery rates, and revision/conversion surgery. A 2020 retrospective review by Eble et al[11] of 103 patients who underwent hemiarthroplasty with the Cartiva implant reported a revision surgery in 2 patients within the first 2 years postoperatively, for an overall rate of 1.90%. A recent case series evaluated the Cartiva implant in 55 patients with a minimum of 12 months' follow-up and reported a slightly higher revision rate of 3.64% (2 patients).[4] Similarly, a 2016 randomized clinical trial by Daniels et al[10] evaluating outcomes of hemiarthroplasty with Cartiva implant in 27 patients found only 1 revision at 5 years postoperatively, for a revision rate of 3.70%. Other studies have found significantly higher rates of failure. Baumhauer et al[2] reported a secondary surgery in 17 of 152 patients treated with Cartiva for HR, for an overall rate of 11.2%. This was lower than the 14% secondary surgery rate (7 of 50 patients) in the arthrodesis cohort; however, these rates were not found to be statistically significant between treatment groups. An even higher reoperation rate of 20% was observed in 13 of 64 patients who underwent treatment with synthetic cartilage implant, at an average follow-up of 18.5 months.[7] Given the discrepancy in published data, the 6.1% (3 patients) revision rate in the HI group observed in this study is reasonable and falls within normal limits of the published range. Additionally, there was no statistically significant difference noted between the revision rates between treatment groups ($P = .59$).

Although subjective and objective clinical outcomes are important metrics of how patients function postoperatively, perhaps an even more important metric is patient satisfaction. In the current study, the HI group had a satisfaction rate of 82%, compared with 69% in the IA group and 100% in the A group, with no statistically significant difference noted between groups ($P = .11$). Patient satisfaction rates in previously published studies solely examining outcomes of the Cartiva implant have ranged from 42% to 93.6%.[4,7,12,14] Studies comparing the Cartiva implant to other surgical treatments have not yet reported on patient satisfaction, making the results of the postoperative questionnaire in the current study the first of its kind.

The current study is not without limitations. Because of the retrospective nature of the study, it inherently involves selection bias. Additionally, the single-center design and smaller cohort sizes limits generalizability of these results to other patient populations. Another limitation is the exact radiographic criteria used by individual surgeons to determine treatment method, with a possibility that there was less radiographic severity in patients who were offered the Cartiva implant compared with the other treatment groups. Similarly, the degree of overall preoperative classification was never specified, resulting in a potential confounder. Further studies with larger patient cohorts, multicenter enrollment, and propensity matching would minimize selection bias and increase the external validity of our results. Although the study has limitations, it does provide insight into previously unexamined comparisons of subjective outcomes between surgical treatment options for HR.

Conclusions

Although drawing conclusions from a retrospective study of this nature and size is challenging, our data indicate that pain and function were significantly improved with interpositional arthroplasty and arthrodesis for the treatment of HR, when compared to hemiarthroplasty with the Cartiva implant. However, these improvements in pain and function may not be of consequence, given no significant difference was noted in patient satisfaction between treatment modalities.

Ethical Approval

The study was approved by the Mercy Health Institutional Review Board #22-0324-6.

Declaration of Conflicting Interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Daniel J. Patton, MD, reports general disclosures from Arthrex—fee paid for direct education hours—not related to a product named in the article nor in competition to a product named in this article. John G. Anderson, MD, John D. Maskill, MD, and Donald R. Bohay, MD, FACS, report disclosures relevant to manuscript from grant to help patients and physicians choose the appropriate surgery for end-stage hallux rigidus (award no. R01AR078487). Disclosure forms for all authors are available online.

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