Article

AO FAS AMERICAN ORTHOPAEDIC FOOT & ANKLE SOCIETY®

Foot & Ankle International®
2020, Vol. 41(9) 1092–1098

DOI: 10.1177/1071100720935034
journals.sagepub.com/home/fai

Outcomes of Polyvinyl Alcohol Hydrogel Implant of the Lesser Metatarsals

Bopha Chrea, MD[1], Jonathan Day, MS[1], Stephanie K. Eble, BA[1], Andrew Elliott, MD[1], Martin J. O'Malley, MD[1], Constantine Demetracopoulos, MD[1], Jonathan T. Deland, MD[1], and Mark C. Drakos, MD[1]

Abstract

Background: Lesser toe metatarsophalangeal (MTP) joint pathology presents a challenge for surgical treatment. At our institution, arthroplasty using a polyvinyl alcohol (PVA) hydrogel implant has been utilized in the second and third MTP joints for advanced arthritis, failed management of Freiberg's infraction, and osteochondral defects. We present a case series describing the clinical outcomes of 13 patients following PVA implantation of the second or third MTP.

Methods: We retrospectively identified 13 patients (14 joints) who underwent PVA hydrogel implantation of the second ($n = 12$) or third ($n = 2$) metatarsal between 2017 and 2019. The average age was 49 (range, 20-67) years, with 100% females. Patient-Reported Outcomes Measurement Information System (PROMIS) scores were collected preoperatively and at an average of 21.1 (range, 8.3-29.2) months postoperatively. Clinical outcomes were also evaluated. The average time to clinical follow-up was 24.7 (range, 7-35.8) months.

Results: On average, patients demonstrated pre- to postoperative improvement in all PROMIS domains, with significant improvements in Pain Intensity ($P = .01$) and Pain Interference ($P = .01$). Five postoperative complications were observed: 1 case of persistent avascular necrosis, 1 revision with implant removal and bone grafting, 1 periprosthetic fracture, and 2 recurrences of pain requiring ultrasound-guided injection.

Conclusion: This study represents the largest case series to date evaluating the use of PVA implant in the surgical correction of lesser toe MTP joint pathology. While the PVA implant presents a viable option in the setting of advanced arthritis, Freiberg's infraction, and certain osteochondral defects, it is not without complications. The specific indications for use of the PVA implant should be carefully considered.

Level of Evidence: Level IV, case series.

Keywords: arthritis, lesser metatarsals, Freiberg's infraction, polyvinyl alcohol implant

Introduction

Lesser toe metatarsophalangeal (MTP) joint pathology presents a surgical challenge when conservative therapy has failed. Freiberg's infraction, or avascular necrosis (AVN) of the metatarsal (MT) head, is one such pathology that typically affects the second MT and is characterized by degeneration and eventual arthritis.[5] Traditional operative treatment of Freiberg's infraction has focused primarily on joint preservation procedures. The dorsal closing wedge procedure was first described in 1979 by Gauthier and Elbaz and includes a dorsal closing wedge osteotomy through the involved MT head, allowing intact plantar cartilage to articulate with the proximal phalanx.[8] Despite good long-term results for operative treatment of most stages of Freiberg's disease, late-stage disease and failed primary procedures present a challenge.[5,7,8,12,14] Salvage options for failed osteotomies and advanced second MT head arthritis include resection arthroplasty, joint debridement, osteotomy, and osteochondral transplant.[4]

More recently, synthetic cartilage implants have been demonstrated in clinical trial to be safe and efficacious in treating advanced stage hallux rigidus, offering pain relief while preserving motion at the MTP joint.[2] In addition to its indication for use in the first MTP, our institution has utilized

[1]Hospital for Special Surgery, New York, NY, USA

Corresponding Author:
Bopha Chrea, MD, Hospital for Special Surgery, 523 East 72nd Street, 5th Floor, New York NY 10021, USA.
Email: bophachrea@gmail.com

the polyvinyl alcohol (PVA) hydrogel implant (Cartiva; Wright Medical, Memphis, TN) for the operative management of certain lesser toe MTP pathologies in the second and third MT heads. At the present time, the PVA implant is only approved by the Food and Drug Administration (FDA) for use in the first MT, and the implant is available only in 8-mm and 10-mm sizes in the United States. However, a previous cadaveric study from our institution demonstrated that the 8-mm implant can fit in approximately 80% of all second MTs and 60% of all third MTs, suggesting potential applications in the surgical treatment of lesser toe pathologies.[6]

We present a case series of 13 patients who underwent PVA implant of the second or third MT head and report their patient-reported outcomes as well as postoperative complications and reoperations.

Methods

Patient Cohort

Thirteen patients who underwent PVA hydrogel implantation of the second or third MT head between 2017 and 2019 at our institution were retrospectively identified. All procedures were performed by 1 of 5 foot and ankle fellowship-trained orthopedic surgeons. The study protocol was approved by the registry's research steering committee. Indications for PVA implant of the lesser MTs included failed conservative or operative treatment of Freiberg's infraction ($n = 5$), advanced MTP arthritis ($n = 6$), or osteochondral lesion (OCL) of the MT head ($n = 2$). Contraindications included active infection, uncontrolled diabetes mellitus, and insufficient cortical bone to contain the implant.

All patients in our study cohort were females, with an average age of 49 (range, 20-67) years and average BMI of 24.6 (range, 18.6-31.3) kg/m^2. Retrospective chart review was performed to determine concurrent procedures performed at the time of index surgery, as well as postoperative complications and reoperations. The average clinical follow-up time was 24.7 (range, 7-35.8) months.

Patient-Reported Outcomes Evaluation

Patient-reported functional outcomes were collected preoperatively and postoperatively using the Patient-Reported Outcomes Measurement Information System (PROMIS), which has been validated in foot and ankle surgeries.[1,10,11] PROMIS is a computer adaptive test (CAT) used to assess functional outcomes in multiple domains. The following PROMIS domains were evaluated: Physical Function, Pain Interference, Pain Intensity, Global Physical Health, Global Mental Health, and Depression. Scores have a standardized mean of 50, the reference population average, with a standard deviation (t score) of 10. Higher scores indicate greater physical function, severity of pain, global health, and depression. All 13 patients completed preoperative PROMIS, and 9 patients completed postoperative PROMIS with an average time to survey follow-up of 21.1 (range, 8.3-29.2) months.

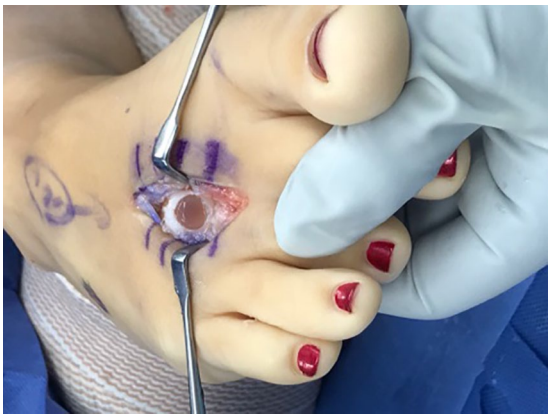

Figure 1. An 8-mm polyvinyl alcohol hydrogel implant is placed within the third metatarsal head in a patient with third metatarsophalangeal arthritis. Careful attention is given to ensure that only 2 mm of the implant is left protruding.

Operative Technique and Postoperative Management

A dorsal incision over the MTP joint was performed. The extensor tendons were identified and retracted out of the way while the joint was debrided, along with any loose bodies, synovitis, and osteophytes. The joint was then prepared for reaming, and a guide wire was placed in the center of the MT head into the shaft. The appropriate sizer was placed perpendicular and flush on the MT head. The MT head was then reamed flush to the articular surface and the guide wire was removed. An 8-mm PVA implant was then inserted with the delivery tube. A tamp was used to control for depth to ensure only 2 mm of the implant was protruding (Figure 1). The joint was then manipulated to ensure adequate range of motion.

Postoperatively, patients remained nonweightbearing in a splint for the first 2 weeks, followed by progressive weightbearing as tolerated in a postoperative shoe. Patients progressed into normal shoe wear as swelling allowed.

Statistical Analysis

Wilcoxon signed-rank tests were used to compare preoperative and postoperative PROMIS outcomes. Statistical significance was evaluated at an alpha level of 0.05.

Table 1. Patient Demographics, Prior Procedures, Surgical Procedures Performed, and Postoperative Events.

Patient	Sex	Diagnosis	Previous procedures	Concurrent procedures	Postoperative events
1	F	Freiberg	2nd MT debridement, closing wedge osteotomy (11 months prior)	2nd MT cheilectomy 2nd MT PVA implant Longus-to-brevis tendon transfer	
2	F	2nd MTP arthritis, 2nd hammertoe		2nd MT PVA implant 2nd PIP arthroplasty	
3	F	2nd MTP arthritis		2nd MT PVA implant	Persistent pain requiring ultrasound-guided injection (7 months postoperatively)
4	F	Freiberg		2nd MT PVA implant	Persistent pain
5	F	Hallux valgus, 2nd MTP arthritis, lesser toe contractures	1st MT osteotomy, Akin, 2nd Morton's neuroma resection, 2nd/3rd hammer toe correction (1 year prior)	HWR 2nd MT PVA implant 3rd MT PVA implant 2nd, 3rd, 5th MTP release	
6	F	2nd MT OCL	Subchondral drilling, 2nd MT Weil osteotomy (2 years prior)	HWR 2nd MTP release 2nd MT PVA implant	Periprosthetic fracture (4 months postoperatively), revision recommended
7	F	Freiberg		2nd MT PVA implant	
8	F	Hallux rigidus, Freiberg		1st MT PVA implant 2nd MT PVA implant	Postoperative imaging (2 years postoperatively) shows recurrent AVN but patient remains asymptomatic
9	F	2nd MTP arthritis	Hallux valgus diaphyseal osteotomy, 2nd MT Weil osteotomy (1 year prior)	HWR Lapidus 2nd MT PVA implant	
10	F	2nd MTP arthritis	2nd MT Weil osteotomy (2 years prior)	HWR 2nd PIP arthroplasty 2nd MT PVA implant	Persistent pain
11	F	2nd MT OCL		2nd MT PVA implant	Revision with implant removal and bone grafting of 2nd MT head (1 year postoperatively)
12	F	Freiberg		2nd MT PVA implant	Persistent pain requiring ultrasound-guided injection (7 months postoperatively)
13	F	3rd MTP arthritis	3rd MT shortening, rotational osteotomy (3.5 years prior)	HWR 3rd MT PVA implant	

Abbreviations: AVN, avascular necrosis; HWR, hardware removal; MT, metatarsal; MTP, metatarsophalangeal joint; OCL, osteochondral lesion; PIP, proximal interphalangeal; PVA, polyvinyl alcohol.

Results

Clinical Outcomes

Indications for PVA implantation and past surgical history varied across patients in the cohort (Table 1). Of the 5 patients who presented with Freiberg's infraction, PVA implantation was indicated in 1 patient after failed operative management with second MT debridement and closing wedge osteotomy performed 11 months prior, and in 4 patients after failed conservative management. Of the 6 patients who presented with advanced arthritis, 4 patients had previous procedures of the second and/or third MT, including second MT Weil osteotomy, second and third hammertoe corrections, and second MT shortening with rotational osteotomy. Of the 2 patients who presented with an OCL of the second MT, 1 patient had previous subchondral drilling with Weil osteotomy.

Five patients experienced a postoperative complication. One patient developed recurrent AVN following PVA implantation for Freiberg's disease but remained asymptomatic. One patient developed a symptomatic periprosthetic fracture and was indicated for a future revision. One patient developed persistent postoperative pain that required a revision surgery with implant removal and bone grafting of the second MT head. Two patients developed persistent pain requiring ultrasound-guided cortisone injections to the second MT. Two additional patients reported persistent pain at a minimum of 6 months postoperatively but were not indicated for additional treatment.

Figure 2. Postoperative radiograph demonstrating persistent avascular necrosis and collapse of the second metatarsal head. This patient remained asymptomatic at 2 years postoperatively.

Of the 5 patients who presented with Freiberg's infraction treated with PVA implant, 1 patient developed AVN following surgery (Figure 2). She remained asymptomatic at 2 years postoperatively and did not require any additional procedures. She requested the procedure for her fourth toe on the contralateral side. Two patients with Freiberg's infraction reported persistent pain postoperatively, one requiring ultrasound-guided injection, and the remaining 2 patients had no reported postoperative events.

Of the 6 patients who presented with second or third MTP arthritis treated with PVA implant, 2 patients reported persistent postoperative pain. One such patient required ultrasound-guided injection at 7 months postoperatively, with complete resolution of pain at 1 year postoperatively.

Of the 2 patients who presented with second MT OCL treated with a PVA implant, both patients experienced a postoperative complication. The first patient initially presented to our institution with a 4-mm second MT OCL with arthritis and contracture of the second MTP joint 2 years status post-microfracture of the second MT head and Weil osteotomy performed at an outside institution. This patient underwent hardware removal, second MTP joint release, and PVA implantation. While pain initially improved, she had recurrence of pain at 4 months postoperatively, with both magnetic resonance imaging (MRI) and computed tomography (CT) scans demonstrating a periprosthetic fracture around the base of the PVA implant (Figure 3). A revision was planned. The second patient initially presented with a 6-mm second MT OCL. She had failed nonoperative management and was treated with second MT PVA implantation. The patient had persistent pain with an MRI demonstrating substantial bone marrow edema in the second MT, and she subsequently underwent cortisone injection, 2 rounds of shockwave therapy, and ultimately a revision surgery at 1 year postoperatively requiring implant removal, interpositional arthroplasty, and bone grafting of the second MT. At the time of revision, it was noted that the implant was loose and mobile within the MT head. The patient recovered and has not had any postoperative complications in the first 2 months postoperatively.

Patient-Reported Outcomes

On average, there was significant improvement in PROMIS Pain Intensity and Pain Interference scores at an average of 21 months of follow-up. Average Pain Intensity improved by 11.5 points ($P = .01$) and average Pain Interference improved by 8.2 points ($P = .01$). Improvement was reported for all other PROMIS domains following surgery, but these did not reach statistical significance (Table 2).

Discussion

This is the largest case series to date evaluating clinical outcomes following PVA hydrogel implant in the lesser toes. All 13 patients in our study underwent off-label PVA implantation in the second or third MT head for lesser toe pathologies, including Freiberg's infraction, severe arthritis, and osteochondral defect of the MT head. Other surgical options for the treatment of these conditions have been described in the literature and include core decompression, open joint debridement, arthroscopic joint debridement, perichondral grafting, MT osteotomies, and excisional or interpositional arthroplasty.[4] However, to date there has been no consensus as to which operative treatment offers the best clinical outcomes. While long-term follow-up studies have recently begun to demonstrate the efficacy of dorsal wedge closing osteotomies for the treatment of Freiberg's disease, the best approach for failed operative management of the disease remains in question.[14] Five out of 13 patients in our cohort failed not only conservative management but also previous operative management for Freiberg's. Therefore, it is important to note that a common use of PVA implant in our study cohort was in the setting of a previously failed operative treatment.

Demographically, our cohort treated with PVA implant for lesser toe pathologies is consistent with the existing literature with regard to age, sex, and clinical follow-up times.[3,9] Our cohort was 100% female, and 5 of 13 patients presented with Freiberg's disease, which is consistent with the current literature suggesting the prevalence of Freiberg's disease predominantly in females.[4,5]

Figure 3. (A) Preoperative and (B) postoperative standing radiographs of the anteroposterior foot demonstrating the polyvinyl alcohol implant in the second metatarsal head. (C) Postoperative sagittal magnetic resonance imaging of the foot demonstrates increased signal intensity and a definitive periprosthetic fracture of the second metatarsal neck proximal to the implant.

Table 2. Mean Preoperative, Postoperative, and Pre- to Postoperative Change in PROMIS Scores.

PROMIS domain	Preoperative ($n = 13$)	Postoperative ($n = 9$)	Δ Pre- to postoperative ($n = 9$)	P[a]
Physical Function	39.6	41.9	2.3	.51
Pain Interference	63.4	56.3	−8.2	**.01**
Pain Intensity	54.9	45.1	−11.5	**.01**
Depression	50.2	50.3	−1.2	.96
Global Physical Health	42.7	48.5	9.7	.07
Global Mental Health	48.5	50.8	2.3	.46

Abbreviation: PROMIS, Patient-Reported Outcomes Measurement Information System.
[a]Boldface type indicates statistical significance.

Sizing of the implant remains an important consideration. A previous cadaveric study performed at our institution examined 10 cadaveric specimens and showed that the second MT could safely be reamed to accommodate an 8-mm synthetic cartilage implant while maintaining an intact cortical rim.[6] Previous study has also shown that 80%, 60%, and 50% of second, third, and fourth MT heads, respectively, could accommodate the 8-mm implant. In a recent study by Glazebrook and colleagues,[9] the authors presented a case series of 5 patients who underwent PVA implantation for Freiberg's infraction or arthritis of the second MT head and reported good clinical outcomes and no complications at an average of 25 months of follow-up. The authors utilized the 8-mm implant in all patients. In addition to Freiberg's infraction and second MT arthritis, 2 patients in our study cohort with osteochondral defects of the second MT were also indicated for PVA implantation. However, as previously mentioned, both patients developed postoperative complications, including 1 periprosthetic fracture, and both were indicated for revision. Although the number of cases is limited, these findings may discourage the use of PVA implantation in the treatment of OCLs of the lesser toes.

In a recent study, Brandao et al[3] evaluated the outcomes following second MT osteotomy compared with PVA hydrogel implantation for the operative management of second MT pathology. The authors compared clinical outcomes

between 6 patients who underwent PVA implant with a 6-mm prosthesis and 7 patients who underwent second MT osteotomy. They reported superior outcomes for the osteotomy patients compared with the PVA implant patients with regard to patient-reported pain and function, as well as higher failure rates for PVA implant patients, evaluated at an average clinical-follow up of 19 months. In their cohort, 4 out of 6 patients who underwent a PVA hydrogel implant, 3 indicated for Freiberg's infraction and 1 indicated for an osteochondral defect, had a revision Weil osteotomy at an average of 15 months following PVA implantation.[3]

As an alternative to synthetic cartilage implants, Miyamoto et al[13] published a case series of 4 patients who underwent osteochondral autograft plug transplantation for late-stage Freiberg's disease. MRI was performed for all patients prior to surgery, 6 months postoperatively, and 12 months postoperatively, at which time the patients underwent arthroscopic evaluation.[13] These authors reported an improvement in American Orthopaedic Foot & Ankle Society (AOFAS) scores from 70.8 preoperatively to 97.5 postoperatively, with an average follow-up of 52 months. At 12 months postoperatively, MRI scans demonstrated healing of the osteochondral plug and normal arthroscopic grading in 2 patients, with near-normal grading in the remaining 2, based on the International Cartilage Repair Society Cartilage Repair Assessment Score. The authors concluded that osteochondral autograft transplantation presents another potential surgical option for advanced degenerative arthritis, OCL, or Freiberg's infraction.

In light of the complications observed in our cohort, we recommend no more than 2 mm of protrusion above the cortical rim of the MT head in order to minimize overtensioning of the joint and erosion of the proximal phalanx. Patients should also be carefully evaluated with regard to MT head size. The 8-mm implant has been utilized at our institution for lesser MT pathology, but too great of a mismatch of implant to MT head may result in hoop stresses exceeding implant contaminant, resulting in periprosthetic fracture as corroborated in our previous cadaveric study and seen in 1 patient in this cohort.[8] It should be noted that at the time of this study, the 6-mm implant was not routinely available in the United States. In addition, the use of a PVA implant for the treatment of second MT OCLs should be carefully evaluated, as both patients in our cohort with a second MT OCL underwent revision surgery. We hypothesize that this may be due to inferior quality of the subchondral bone.

The primary limitation of this study is the small sample size and short-term follow-up. The majority of cited literature pertaining to the treatment of lesser toe pathology includes small case series and studies of limited power. Because the PVA implant has only been FDA approved in the United States for use in the first MT, its use in treating lesser toe pathology is relatively new. Nevertheless, we believe that even with a small sample, our results demonstrate that PVA hydrogel implantation of the second and third MT can result in improvements in clinical outcomes when used judiciously in a carefully selected patient population, usually in the setting of failed conservative or other operative management. In our cohort, persistent pain was more common for patients undergoing a primary procedure compared with a secondary procedure, but a future prospective study as well as longer-term follow-up in a larger cohort of patients would provide more insight in evaluating the proper indications, efficacy, and survivorship of the implant.

Conclusion

This study represents the largest case series to date evaluating the use of PVA hydrogel implant in the surgical treatment of second and third MTP pathology. While the implant presents a viable option in the setting of advanced lesser MTP pathology and failed conservative or operative management, it is not without complications. This study demonstrates the potential indications for successful treatment using this implant in the lesser toes and highlights the importance of proper patient selection. A larger prospective cohort study would provide valuable insight into the efficacy and safety of PVA hydrogel implantation for joint-destructive conditions of the lesser toes.

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: Constantine Demetracopoulos, MD, reports personal fees from Wright Medical, outside the submitted work. Jonathan T. Deland, MD, reports other from Wright Medical, outside the submitted work. ICMJE forms for all authors are available online.

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

ORCID iDs

Jonathan Day, MS, https://orcid.org/0000-0003-1106-3042
Stephanie K. Eble, BA, https://orcid.org/0000-0002-6425-5112

References

1. Anderson MR, Houck JR, Saltzman CL, et al. Validation and generalizability of preoperative PROMIS scores to predict postoperative success in foot and ankle patients. *Foot Ankle Int*. 2018;39(7):763-770.
2. Baumhauer J, Singh D, Glazebrook M, et al. Prospective, randomized, multi-centered clinical trial assessing safety and

efficacy of a synthetic cartilage implant versus first metatarsophalangeal arthrodesis in advanced hallux rigidus. *Foot Ankle Int*. 2016;37(5):457-469.
3. Brandao B, Fox A, Pillai A. Comparing the efficacy of Cartiva synthetic cartilage implant hemiarthroplasty vs osteotomy for the treatment of conditions affecting the second metatarsal head. *Foot Edinb Scotl*. 2019;41:30-33.
4. Carmont M, Rees R, Blundell C. Current concepts review: Freiberg's disease. *Foot Ankle Int*. 2009;30(2):167-176.
5. Cerrato RA. Freiberg's disease. *Foot Ankle Clin*. 2011;16(4):647-658.
6. de Cesar Netto C, Godoy-Santos A, Cabe T, et al. The use of polyvinyl alcohol hydrogel implants in the lesser metatarsal heads. Is it safely doable? A cadaveric study. *Foot Ankle Surg*. 2020;26(2):128-137.
7. Espinosa N, Maceira E, Myerson M. Current concept review: metatarsalgia. *Foot Ankle Int*. 2008;29(8):871-879.
8. Gauthier G, Elbaz R. Freiberg's infraction: a subchondral bone fatigue fracture. A new surgical treatment. *Clin Orthop*. 1979;142:93-95.
9. Glazebrook M, Morash J, Alhadhoud M, Daniels T. Preliminary experience with polyvinyl alcohol hydrogel implant for pathology of the second metatarsal head. *Foot Ankle Int*. 2019;40(11):1304-1308.
10. Ho B, Houck JR, Flemister AS, et al. Preoperative PROMIS scores predict postoperative success in foot and ankle patients. *Foot Ankle Int*. 2016;37(9):911-918.
11. Hung M, Baumhauer J, Latt L, et al. Validation of PROMIS® Physical Function computerized adaptive tests for orthopaedic foot and ankle outcome research. *Clin Orthop*. 2013;471(11):3466-3474.
12. Kinnard P, Lirette R. Freiberg's disease and dorsiflexion osteotomy. *J Bone Joint Surg Br*. 1991;73(5):864-865.
13. Miyamoto W, Takao M, Uchio Y, Kono T, Ochi M. Late-stage Freiberg disease treated by osteochondral plug transplantation: a case series. *Foot Ankle Int*. 2008;29(9):950-955.
14. Pereira B, Frada T, Freitas D, et al. Long-term follow-up of dorsal wedge osteotomy for pediatric Freiberg disease. *Foot Ankle Int*. 2016;37(1):90-95.