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Comparison Between Polyvinyl Alcohol Implant and Cheilectomy With Moberg Osteotomy for Hallux Rigidus

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Abstract

Background: In 2016, the US Food and Drug Administration (FDA) approved the use of a polyvinyl alcohol (PVA) hydrogel implant for the surgical management of hallux rigidus. Though recent studies have evaluated the safety and efficacy of the implant, no study has compared outcomes following PVA implantation with those following traditional joint-preserving procedures for hallux rigidus, such as cheilectomy with Moberg osteotomy. The purpose of this study was to compare clinical and patient-reported outcomes for patients undergoing cheilectomy and Moberg osteotomy, with or without PVA implant, at a single multisurgeon academic center. Our hypothesis was that the addition of the PVA implant would result in superior clinical and patient-reported outcomes.

Methods: In total, 166 patients were identified who underwent cheilectomy and Moberg osteotomy with (PVACM; $n = 72$) or without (CM; $n = 94$) a PVA implant between January 2016 and December 2018 by 1 of 8 foot and ankle fellowship-trained orthopedic surgeons at our institution. Of these patients, 60 PVACM and 73 CM patients had both baseline and minimum 1-year postoperative Patient-Reported Outcomes Measurement Information System (PROMIS) scores. The average time to survey follow-up was 14.5 months for PVACM patients and 15.6 months for CM patients. Retrospective chart review was performed to assess the incidence of postoperative complications and reoperations, with an average clinical follow-up of 27.7 (range, 16.0-46.4) months for PVACM patients and 36.6 (range, 18.6-47.8) months for CM patients.

Results: Both PVACM and CM cohorts demonstrated significant improvement in the PROMIS Physical Function, Pain Interference, Pain Intensity, and Global Physical Health domains when comparing preoperative and postoperative scores within each group ($P < .01$). When comparing scores between the PVACM and CM cohorts, preoperative scores were similar, while CM patients demonstrated significantly higher postoperative Physical Function (51.8 $\pm$ 8.7 vs 48.8 $\pm$ 8.0; $P = .04$) and significantly lower Pain Intensity (39.9 $\pm$ 8.3 vs 43.4 $\pm$ 8.7; $P = .02$) scores. The pre- to postoperative change in Physical Function was also significantly greater for CM patients (7.1 $\pm$ 8.5 vs 3.6 $\pm$ 6.2; $P = .011$). In the PVACM group, there were 3 revisions (5%), 1 reimplantation, 1 conversion to arthrodesis, and 1 revision to correct hyperdorsiflexion. In the CM group, there was 1 revision (1.4%), a conversion to arthrodesis ($P = .21$). Other postoperative complications included persistent pain (7 out of 60 PVACM patients [11.7%] and 8 out of 73 CM patients [11.0%]; $P = .90$) and infection in 3 PVACM patients (5%) and no CM patients ($P = .05$).

Conclusion: Though our results generally support the safety and utility of the PVA implant as previously established by the clinical trial, at 1 to 2 years of follow-up, CM without a PVA implant may provide equivalent or better relief compared with a PVACM procedure, while avoiding potential risks associated with the implant.

Level of Evidence: Level III, retrospective comparative study.

Keywords: hallux rigidus, polyvinyl alcohol implant, Cartiva, cheilectomy, Moberg osteotomy

Introduction

Hallux rigidus, or degenerative arthritis of the first metatarsophalangeal (MTP) joint, is one of the most common arthritic conditions in the foot and ankle. Biomechanically, the first MTP plays an important role in maintaining physiologic gait and weightbearing.[17] Arthritis of the first MTP is characterized by dorsal cartilage loss, which extends to the entire first MTP joint and results in pain, stiffness, difficulty with shoe wear, and limitations in physical activities. While degenerative arthritis is commonly associated with a more senior population, hallux rigidus is reported in 2.5% of patients at a mean age of 50 years.[9-11,20]

Historically, initial surgical options for symptomatic hallux rigidus have focused on joint-preserving procedures, including first metatarsal cheilectomy and phalangeal osteotomies, as opposed to joint-sacrificing procedures such as excisional or interpositional arthroplasty, or arthrodesis. Patients with more advanced hallux rigidus presenting with pain in the midrange of motion have had poor results following cheilectomy alone, with failure rates as high as 37.5% reported for Coughlin grade III hallux rigidus patients.[6,13] For these more advanced cases, first MTP arthrodesis has shown reliable improvements in functional outcomes and high union rates, approaching 77% to 100%, though decreased range of motion remains a limitation of arthrodesis.[8,21,22]

Recently, a synthetic cartilage implant has been shown in clinical trials to be safe and effective in the treatment of advanced stage hallux ridigus.[4] This polyvinyl alcohol (PVA) hydrogel implant (Cartiva; Wright Medical, Memphis, TN) represents an alternative to fusion, allowing for treatment of symptomatic first MTP arthritis with preservation of motion at the joint. While initial prospective randomized clinical trials demonstrated promising early results for patients treated with the PVA implant, other authors have reported less positive results.[1,4,5,12] Cassinelli et al[5] reported neutral patient satisfaction, mild pain and physical dysfunction postoperatively, and a relatively high conversion rate to arthrodesis (8%) at the early (1- to 2-year) follow-up. Additionally, in their cohort, 33 out of 64 implants (52%) were treated with corticosteroid injection for persistent pain, and 9 of 64 (14%) required additional dynamic splinting for functional range of motion limitations.

At our institution, we utilize a surgical technique in which we perform a combined limited cheilectomy with extension osteotomy of the great toe proximal phalanx (Moberg) for advanced arthritis.[19] The Moberg osteotomy is added theoretically to increase dorsiflexion and shift pressures across the MTP joint more plantar. It is routinely added to a standard cheilectomy for the surgical management of hallux rigidus.[18,19] When the PVA implant became available, we utilized a limited cheilectomy and Moberg osteotomy in conjunction with the implant to address the articular cartilage loss that is routinely seen in advanced hallux rigidus cases. The concept stemmed from the inability of a standard CM procedure to address cartilage defects in the plantar 50% of the metatarsal head, as well as the proximal phalanx articulation, which in theory could lead to persistent symptoms despite a technically well-performed operation. This technique represents a deviation from the technique described by the manufacturers of the implant. The purpose of this study was to compare clinical and patient-reported functional outcomes for patients who underwent cheilectomy and Moberg osteotomy (CM) with those who underwent cheilectomy and Moberg with PVA implant (PVACM) for moderate to advanced hallux rigidus. Our hypothesis was that the addition of the PVA implant to the metatarsal and proximal phalanx osteotomies would result in greater improvements in clinical and patient-reported functional outcomes and lower rates of revision surgery.

Methods

This is a retrospective study evaluating patients with moderate to advanced hallux rigidus who received a joint-preserving procedure between January 2016 and December 2018. The study protocol was approved by our institution's Foot and Ankle Registry research steering committee. Retrospective review of the registry was performed, and 262 patients were identified and screened for inclusion. Patients were excluded if they had prior surgical treatment for their condition (33 patients) or if they underwent cheilectomy alone (41 patients), with or without PVA hydrogel implant. Twenty-two patients were excluded who underwent PVA implantation alone. Patients with little to no motion at the first MTP joint and with advanced arthritis on plain film radiographs underwent MTP fusion and as such were not included. Thirty-three patients were also excluded who had insufficient follow-up and/or were missing baseline functional outcome scores. In total, 133 patients were included, 60 patients treated with PVACM and 73 patients treated with CM. All procedures were performed by 1 of 8

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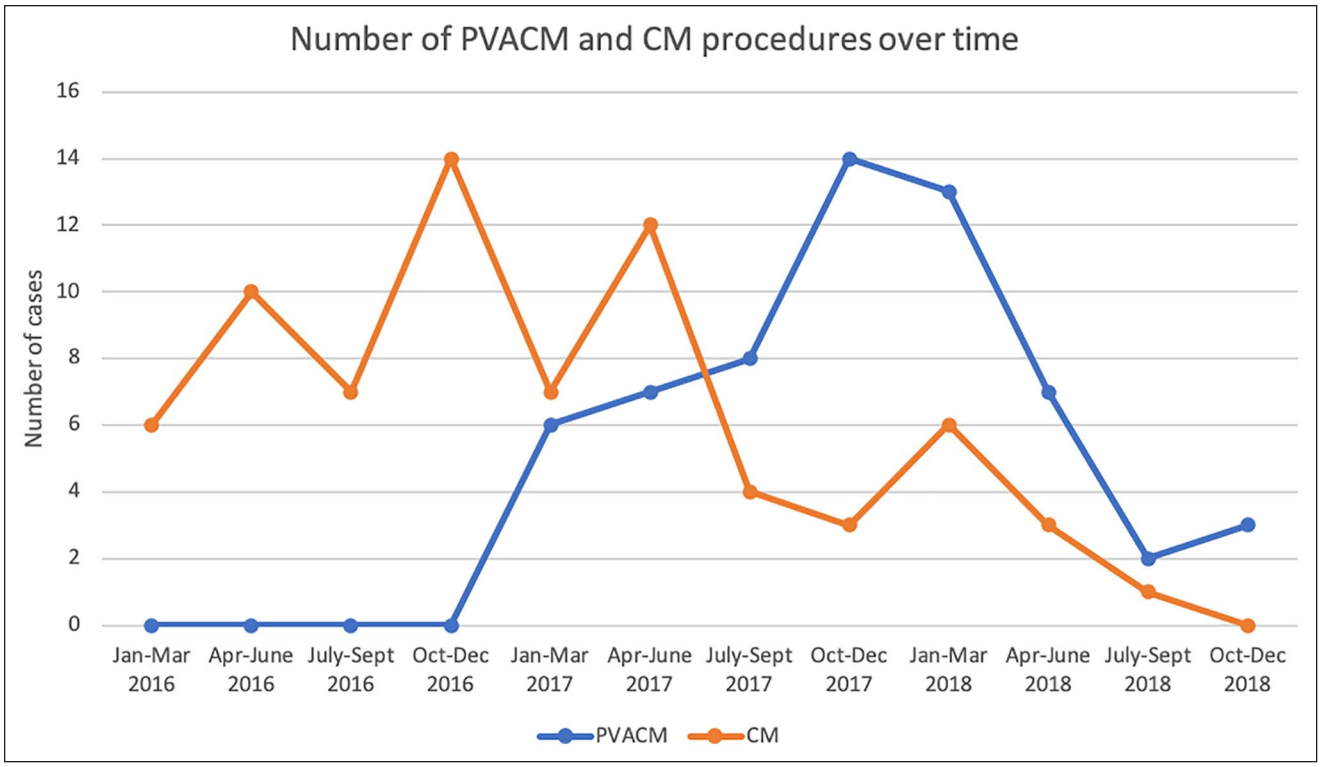

Figure 1. Graph demonstrating the number of cheilectomy and Moberg with (PVACM) and without (CM) a polyvinyl alcohol implant cases over the course of the study collection period.

orthopedic foot and ankle fellowship-trained surgeons. Each represented surgeon performed a statistically similar proportion of PVACM and CM cases, with the exception of 1 surgeon, who performed significantly more CM procedures (29%) than PVACM procedures (12%; $P = .018$). No surgeon performed more than 50% of cases in either group.

Study Population

Preoperatively, each patient underwent standing anteroposterior (AP), oblique, and lateral plain radiographs as well as clinical evaluation. The severity of hallux rigidus was assessed using the Coughlin and Shurnas[6] classification system. Our cohort consisted of patients with severity of grade II, III, or IV based on combined radiologic and clinical examination. Many of these patients were candidates for first MTP arthrodesis but desired preservation of joint motion and had at least 20 degrees of first MTP joint dorsiflexion preoperatively.

Chart review was performed to collect demographic information and to record any postoperative complications. The average age for all patients was 56 (range, 25-75) years, with an average of 57 (range, 26-75) years for the PVACM group and 54 (range, 25-73) years for the CM group ($P = .10$). The average body mass index (BMI) for all patients was 25.7 (range, 18.2-42.3) kg/m^2, with an average of 26.6 (range, 18.2-42.3) kg/m^2 for the PVACM group and 24.9 (range, 18.2-35.4) kg/m^2 for the CM group ($P = .05$). Ninety-seven out of 133 total patients (72.9%) were female, 44 of 60 patients (73.3%) in the PVACM group and 53 of 73 patients (72.6%) in the CM group ($P = .91$). The average time from surgery to clinical follow-up was 27.7 (range, 16.0-46.4) months for PVACM patients and 36.6 (range, 18.6-47.8) months for CM patients. The CM group has had a longer follow-up period as we have been performing this procedure for a longer period of time compared with the PVACM procedure, which was introduced with the more recent Food and Drug Administration (FDA) approval of the PVA implant. A graph showing the number of PVACM and CM cases performed over the course of the study collection period is provided (Figure 1).

Survey Outcomes

Patient-reported outcomes were assessed using Patient-Reported Outcomes Measurement Information System (PROMIS) scores, which has been validated in various foot and ankle surgeries.[2,14,15] PROMIS is a computerized 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, pain interference, pain intensity, global health, and depression. In our cohort, PROMIS scores were collected preoperatively and at a minimum of 1 year postoperatively. All patients received PROMIS surveys at 1 and 2 years postoperatively through the foot and ankle registry at our institution, and for the purposes of this study, an attempt was made to collect the most recent PROMIS scores for all patients. In total, 60 PVACM patients and 73 CM patients had both preoperative and minimum 1-year postoperative PROMIS scores. The average time from surgery to survey follow-up was 14.5 (range, 12-25) months for PVACM patients and 15.6 (range, 12-25) months for CM patients.

Surgical Technique and Postoperative Protocol

Cheilectomy-Moberg Procedure (CM Group). At our institution, we utilize a surgical technique in which we perform a combined cheilectomy with extension osteotomy of the great toe proximal phalanx (Moberg) for advanced arthritis.[19] This procedure was performed with the addition of a PVA implant in 60 study patients but modified to include a limited cheilectomy.

Patients were positioned supine on the table. Regional anesthesia and/or a spinal block were utilized along with a thigh or ankle tourniquet for hemostasis. A straight dorsal incision positioned over the medial aspect of the extensor hallucis longus was made to access the first MTP joint. Dorsal osteophytes were removed with a rongeur or a saw blade. When a PVA implant was not planned, up to 30% of the dorsal metatarsal head was excised. A Moberg osteotomy was then performed removing a 2- to 3-mm wedge of dorsal bone of the proximal phalanx and secured with a 7 × 9–mm staple or 2-mm screw based on the surgeon's preference. The metatarsal head and the proximal phalanx were contoured using an oscillating rasp, ensuring that no sharp edges remained. Positioning of hardware was confirmed on fluoroscopy. A layered closure was then completed beginning with the capsule. A soft dressing with postoperative shoe or splint was applied. Patients were allowed to bear weight immediately or were limited for the first 2 weeks to allow the incision to heal. Sutures were removed 2 to 3 weeks postoperatively and patients were transitioned into regular shoe wear.

Cheilectomy-Moberg-PVA Procedure (PVACM Group). A straight dorsal incision positioned over the medial aspect of the extensor hallucis longus was made to access the first MTP joint. Dorsal osteophytes were removed with a rongeur or a saw blade. A limited cheilectomy was performed involving approximately 10% of the metatarsal head. This was performed ensuring that a sufficient amount of intact cortical rim remained. A central guide was placed in the metatarsal head extending into the shaft, with positioning confirmed on fluoroscopy. The sizer was then placed over the guidewire, often requiring plantarflexion of the proximal phalanx to clear enough room for the sizer and subsequent reamer. The appropriately sized reamer was selected. Of the 60 PVACM patients, 3 received an 8-mm implant and 57 received a 10-mm implant. Reaming was completed until flush with the metatarsal head (Figure 2A). The PVA implant was then loaded into the delivery system and placed in the metatarsal head 2 mm beyond the margin of the metatarsal head (Figure 2B). The stability of the implant and range of motion of the MTP joint were then assessed. A Moberg osteotomy as described above was then performed. The metatarsal head and the proximal phalanx were contoured using an oscillating rasp, ensuring that no sharp edges remained. A layered closure was then completed beginning with the capsule. The postoperative protocol as outlined above was performed.

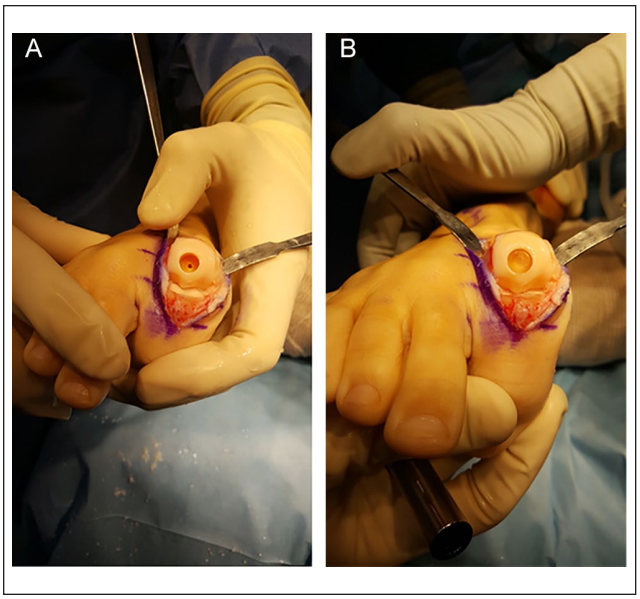

Figure 2. Intraoperative images showing (A) reaming and (B) placement of a polyvinyl alcohol implant in the first metatarsal head.

Statistical Analysis

Paired *t* tests were used to compare preoperative and postoperative PROMIS scores within each group after assessing for normality with the Shapiro Wilk's test. Student's 2-group *t* tests were used to compare preoperative, postoperative, and change in pre- to postoperative PROMIS scores between the PVACM and CM groups. Chi-square tests were used to compare frequencies, including rates of revision and other postoperative complications. Statistical significance was determined with an alpha of 0.05.

Table 1. Comparison of PROMIS Scores Between PVACM ($n = 60$) and CM ($n = 73$) Patients.[a]

	Preoperative score (± SD)	Postoperative score[b] (± SD)	*P* value	Score change (± SD)
Physical Function				
PVACM	44.6 (± 8.2)	48.8 (± 8.0)	**<.01**	+3.6 (± 6.2)
CM	45.0 (± 6.3)	51.8 (± 8.7)	**<.01**	+7.1 (± 8.5)
P value	.763	**.043**		**.011**
Pain Interference				
PVACM	58.9 (± 6.5)	51.2 (± 8.4)	**<.01**	–7.2 (± 8.6)
CM	58.1 (± 5.7)	49.4 (± 9.6)	**<.01**	–9.1 (± 9.2)
P value	.466	.248		.268
Pain Intensity				
PVACM	51.6 (± 6.1)	43.4 (± 8.7)	**<.01**	–7.5 (± 7.7)
CM	49.9 (± 6.7)	39.9 (± 8.3)	**<.01**	–10.2 (± 8.6)
P value	.139	**.019**		.086
Global Physical Health				
PVACM	46.9 (± 7.5)	51.9 (± 8.7)	**<.01**	+5.1 (± 7.2)
CM	47.3 (± 7.4)	53.8 (± 8.2)	**<.01**	+6.7 (± 7.2)
P value	.765	.216		.229
Global Mental Health				
PVACM	53.1 (± 8.1)	54.0 (± 8.8)	.245	+1.1 (± 5.3)
CM	54.1 (± 8.9)	55.5 (± 8.8)	.074	+1.0 (± 6.9)
P value	.507	.352		.948
Depression				
PVACM	46.9 (± 7.7)	47.6 (± 6.4)	.509	+0.4 (± 5.9)
CM	47.4 (± 8.5)	46.9 (± 8.3)	.611	–1.9 (± 10.0)
P value	.750	.606		.148

Abbreviations: CM, cheilectomy and Moberg without PVA implant; PROMIS, Patient-Reported Outcomes Measurement Information System; PVA, polyvinyl alcohol; PVACM, cheilectomy and Moberg with PVA implant.

[a]Boldface type indicates statistical significance.

[b]Postoperative scores represent the latest available survey follow-up scores. The average time to survey follow-up was 14.5 (range, 12-25) months for PVACM patients and 15.6 (range, 12-25) months for CM patients.

Results

Clinical Outcomes

Both the PVACM and CM cohorts demonstrated significant improvement in Physical Function, Pain Interference, Pain Intensity, and Global Physical Health ($P < .01$) (Table 1). Preoperatively, there were no significant differences in PROMIS domains between the PVACM and CM cohorts. Postoperatively, the CM group demonstrated significantly greater Physical Function (51.8 ± 8.7 vs 48.8 ± 8.0; $P = .043$) with a significantly greater improvement pre- to postoperatively (7.1 ± 8.5 vs 3.6 ± 6.2; $P = .011$) compared with the PVACM group. In addition, the CM group demonstrated significantly lower Pain Intensity (39.9 ± 8.3 vs 43.4 ± 8.7; $P = .019$) compared with the PVACM group (Figure 3).

A total of 7 PVACM (11.7%) and 8 CM (11.0%) patients reported persistent pain postoperatively. These patients were subsequently treated with a combination of steroid injections, orthotics, and/or shockwave therapy. The rates of persistent pain requiring additional intervention were not significantly different between groups ($P = .90$).

Three PVACM patients (5%) had a documented postoperative infection requiring antibiotics. No patient who underwent CM had a documented postoperative infection ($P = .05$). No other major postoperative events were reported in either group. There were no significant differences in complication rates across the surgeons represented.

Revisions

The rate of revision between the PVACM and CM groups was not significantly different ($P = .21$). Three out of 60 PVACM patients (5%) required revision surgeries at 14, 22, and 33 months, respectively, following the index surgery. One revision included a patient who developed inflammation and fibrous tissue at the MTP joint with loosening of the PVA implant 14 months postoperatively; this patient underwent removal of the PVA implant with conversion to MTP arthrodesis and bone grafting. A second patient presented with first MTP pain and was noted to have wearing of the medial aspect of the implant; this patient underwent removal of the implant and revision hemiarthroplasty at 22 months postoperatively. A third patient presented with

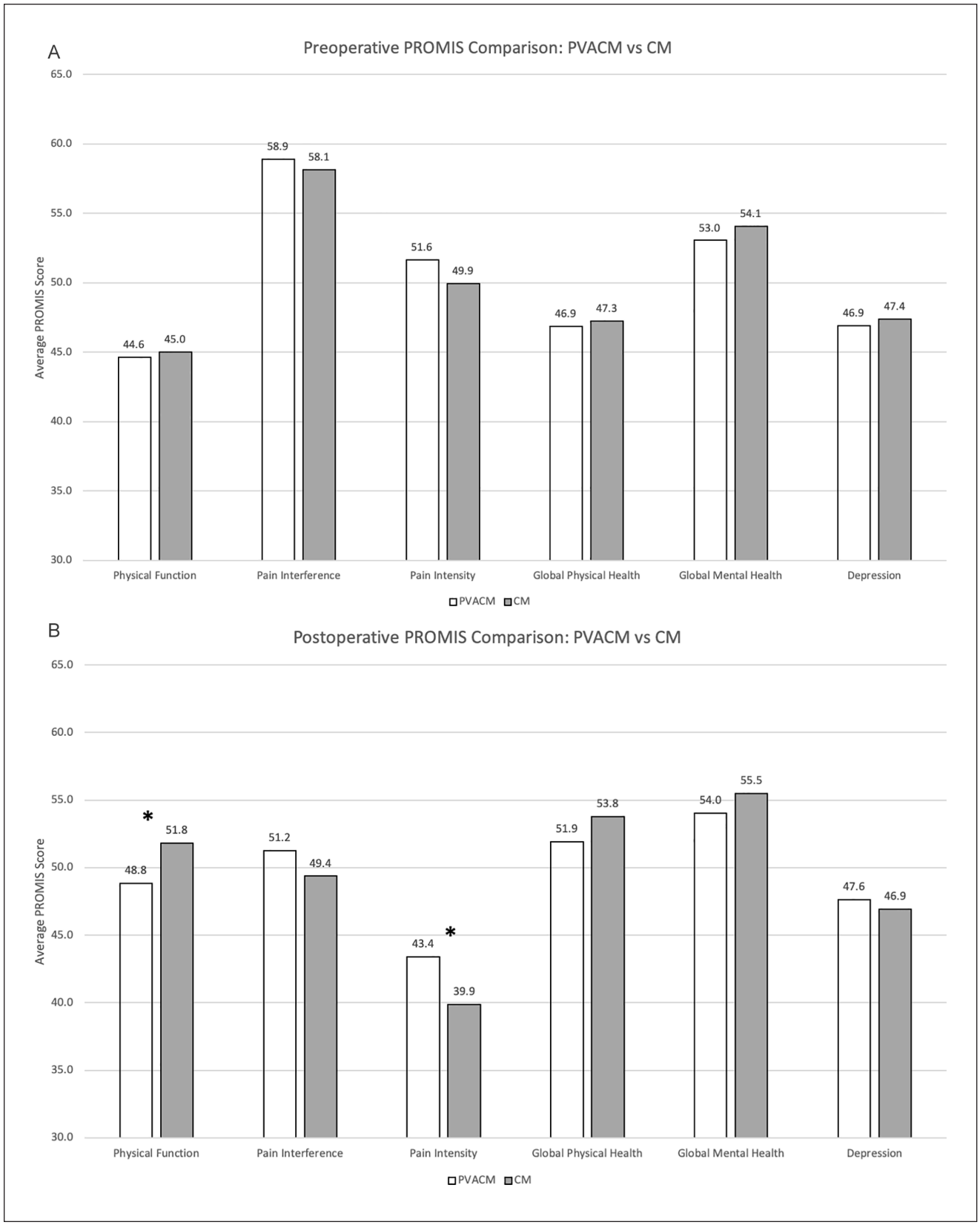

Figure 3. Bar graphs comparing (A) preoperative and (B) postoperative Patient-Reported Outcomes Measurement Information System (PROMIS) scores between the cheilectomy and Moberg with (PVACM) and without (CM) a polyvinyl alcohol implant cohorts.

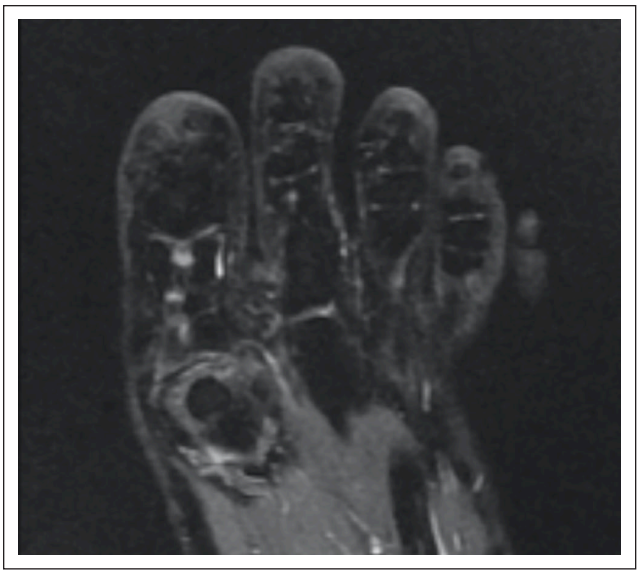

Figure 4. A 44-year-old female underwent an initial cheilectomy and Moberg (CM) revised with a polyvinyl alcohol (PVA) implant 21 months after the initial procedure. Magnetic resonance imaging at 8 months following the PVA implant procedure shows persistent edema surrounding the implant.

persistent pain and a hyperdorsiflexed hallux at 33 months postoperatively; this patient underwent revision to correct the hyperdorsiflexion.

One out of 73 CM patients (1.4%) required revision at 21 months postoperatively. This patient was diagnosed with a metabolic bone disorder concurrently managed by a metabolic bone specialist and rheumatologist. She underwent revision cheilectomy with PVA implantation at 21 months following the index procedure. The patient subsequently developed persistent pain with a magnetic resonance imaging (MRI) scan showing a stable PVA implant with significant edema (Figure 4) 8 months following the revision procedure. She underwent 2 rounds of shockwave therapy as well as ultrasound-guided injection of the first MTP.

Discussion

This study sought to evaluate the potential benefit of adding a PVA implant to a procedure that historically has produced good outcomes. The genesis of the PVACM procedure was based on the inability of the standard CM procedure to address cartilage defects in the plantar 50% of the metatarsal head as well as the proximal phalanx articulation, which in theory could lead to persistent symptoms despite a technically well-performed operation. To our knowledge, this study represents the first to compare the addition of a PVA implant in the setting of a limited cheilectomy and Moberg osteotomy with a traditional joint-preserving procedure for hallux rigidus without the use of a PVA implant. Demographic variables were generally similar between the groups, and although the BMI was found to be statistically different between groups ($P = .05$), from a clinical standpoint, we do not believe that this difference in BMI drastically affected our results.

In our study, both PVACM and CM cohorts demonstrated significant improvement in PROMIS Physical Function, Pain Interference, Pain Intensity, and Global Physical Health domains ($P < .01$). The CM patients, however, demonstrated significantly higher postoperative Physical Function, significantly lower Pain Intensity, and greater pre- to postoperative improvement in Physical Function, despite statistically similar preoperative scores. Hung et al[16] have reported the minimal clinically important difference (MCID) for PROMIS Physical Function to be as high as 11.3 using anchor-based methods, though the same authors report an MCID of 4.5 to 4.7 using a one-half standard deviation method. It is interesting to note that our pre- to postoperative change in PROMIS Physical Function of 3.6 for the PVACM group is below the MCID of 4.5, while the change of 7.1 for the CM group is above that threshold. For Pain Interference, Hung et al[16] report the MCID to be 4.1 to 4.3 using the one-half standard deviation method, and both the PVACM (7.2) and CM (9.1) cohorts in this study reached that MCID threshold. Though our results generally support the safety and utility of the PVA implant as previously established by the clinical trial, comparison to our control group at 1- to 2-year follow-up demonstrates that CM without the PVA implant may provide equivalent or better relief compared with a PVACM procedure. In addition, the CM procedure avoids the potential risks associated with the implant, including subsidence, loosening, and edema.

Historically, surgical treatment for patients with advanced hallux rigidus has been a first MTP arthrodesis. While arthrodesis presents a viable option with regard to pain relief,[6] decreased range of motion remains a major limitation with arthrodesis, particularly for younger and more active populations. For advanced hallux rigidus, performing an isolated cheilectomy alone has been associated with failure rates as high as 37.5%, with failure defined by persistent pain in the toe and limitations to activities of daily living.[6,13] The addition of an extension Moberg osteotomy to standard cheilectomy in the surgical management of advanced hallux rigidus has been described with good to excellent outcomes.[19] The Moberg osteotomy has been shown clinically and biomechanically to increase dorsiflexion and shift pressures more plantarly. O'Malley et al[19] previously demonstrated improved dorsiflexion and American Orthopaedic Foot & Ankle Society (AOFAS) scores and an 85% satisfaction rate in their cohort of 81 patients with a minimum 2-year follow-up following cheilectomy and Moberg osteotomy for grade III hallux rigidus.

Baumhauer et al[4] presented the first study evaluating the PVA hydrogel implant following a prospective, randomized, noninferiority study comparing the implant with first MTP arthrodesis. These authors reported significant but similar improvements in Foot and Ankle Ability Measure (FAAM) Sports and Activities of Daily Living scores, as well as the visual analog scale (VAS) between the two cohorts at 12 and 24 months of follow-up. Recent studies have presented less promising results with regard to the PVA implant at short-term follow-up.[1,5]

Cassinelli et al[5] presented the first study evaluating the PVA implant following FDA clinical trials, reporting Physical Function and Pain Interference PROMIS outcomes as well as patient satisfaction measures in a cohort of 60 patients (64 implants). These authors did not include baseline patient-reported outcomes assessment or comparison with a control group. The authors reported an average postoperative Physical Function score of 42 ($n = 42$) and Pain Interference score of 60 ($n = 40$).[5] The higher Physical Function and lower Pain Interference scores observed in our PVA cohort may reflect the differences in surgical technique, as patients in our study underwent additional concurrent limited cheilectomy and Moberg osteotomy.

For patients undergoing PVA implantation in the initial clinical trial, Baumhauer et al[4] reported that 14 out of 152 PVA implant patients (9.2%) required a subsequent conversion to arthrodesis at an average of 1 year postoperatively. Cassinelli et al[5] reported a higher incidence of PVA implant revision, with 13 out of 64 patients (20%) in their cohort undergoing revision surgery at an average of 12.6 months postoperatively, though they report a comparable rate of conversion to arthrodesis (5 of 64 implants [8%]) at an average of 16.4 months. In their cohort of CM patients, O'Malley et al[19] reported that 4 out of 81 patients (4.9%) required conversion to arthrodesis, 1 at 1 year, 2 at 3 years, and 1 at 7 years postoperatively. In the first 1 to 2 years postoperatively, we observed only 4 total revisions, 3 out of 60 (5%) in the PVACM group and 1 out of 73 (1.4%) in the CM group. At 1- to 2-year follow-up, these rates of revision are substantially lower than those that have been reported previously following PVA implantation or cheilectomy with Moberg alone. Despite relatively low rates of revision in our cohort, about 10% to 15% of patients reported persistent postoperative pain, though a majority of these cases resolved over time or with conservative management, including injection, orthotics, and shockwave therapy. Several PVACM patients presenting with persistent postoperative pain underwent MRI, which demonstrated persistent edema in the first metatarsal head. The patterns of edema observed were consistent with those described in a recent study evaluating symptomatic PVA implants on MRI.[1]

There are several limitations of the present study. Though previous studies have evaluated outcomes with respect to severity or grade of hallux rigidus, we did not stratify our cohorts based on preoperative grade, though the indication for operative management with a joint-preserving procedure at our institution typically includes grade II or III hallux rigidus based on the Coughlin scale.[6] Further, Baumhauer et al[3] have previously shown that active dorsiflexion range of motion and baseline VAS pain scores did not correlate with the Coughlin hallux rigidus grade and did not predict the success or failure of either PVA hydrogel implantation or first MTP arthrodesis. Their results suggest that clinical symptoms should be used to guide treatment as opposed to grading systems that have not been validated.

The primary difference between our PVA implant cohort and those described in the existing literature is that we routinely added a cheilectomy and Moberg osteotomy in conjunction with PVA implantation in our study cohort. The present study included all patients undergoing cheilectomy with Moberg at our institution, with or without use of the PVA implant. Therefore, this criterion for inclusion in our study may not allow for direct comparisons to be made with results from other PVA implant cohorts represented in the existing literature due to the difference in surgical technique. Nonetheless, our study represents the first to compare outcomes for patients undergoing PVA implantation with limited cheilectomy and Moberg osteotomy versus a standard joint-preserving procedure for hallux rigidus.

Because cheilectomy with Moberg osteotomy was the primary procedure performed at our institution to address hallux rigidus before the PVA implant was FDA approved, CM has been performed for a longer duration of time, and therefore clinical follow-up for the CM group is significantly longer, 36.6 months on average compared with 27.7 months for the PVACM group. While there is a significant difference in follow-up times, we believe a meaningful comparison can be made, as both cohorts had a minimum of 2 years of clinical follow-up on average. A longer follow-up in both cohorts would be optimal, as 1 study evaluating midterm outcomes using the PVA implant reported that pain and symptom relief observed in the first 2 years postoperatively was maintained at 5 years, though 9 out of 119 patients (7.6%) underwent conversion to arthrodesis between 2 and 5 years.[7]

In order to better distinguish the impact of the PVA implant, we excluded patients who underwent cheilectomy only with PVA implant or first MTP resurfacing with PVA implant alone, allowing for comparison of patients treated only with cheilectomy and Moberg, with or without the PVA implant. In order to ensure that sufficient intact cortical rim remained for the implant in PVACM procedures, we performed a limited cheilectomy involving approximately 10% of the metatarsal head for PVACM cases, compared with up to 30% in the CM group, which is a limitation of our comparison. As previously mentioned, we acknowledge that our

use of the PVA implant with concurrent cheilectomy and Moberg osteotomy is not consistent with the technique described by the manufacturer.[23] We also acknowledge that our use of the CM technique prior to the introduction of the PVA implant and subsequent shift to the PVACM technique introduces a potential bias based on technical familiarity with the CM procedure. The nature of this multisurgeon study also introduces the potential for variations in surgical technique, though the fact that 8 orthopedic surgeons are represented may allow for more generalizable conclusions to be drawn with regard to outcomes for hallux rigidus patients undergoing PVACM or CM.

Since this review of our outcomes, a number of attending surgeons in our group no longer have any indications for PVA implantation and utilize cheilectomy with Moberg osteotomy alone when a patient is indicated to avoid arthrodesis, otherwise electing to perform an arthrodesis if the condition is advanced. These members of our group have shifted away from utilizing the PVA implant in light of patients whose postoperative imaging showed bone marrow edema such that the implant appears unable to transmit loads to the bone appropriately in some cases. However, some surgeons are still using the implant in a limited capacity when the disease is not as advanced and the patient has maintained motion.

Conclusion

PVA hydrogel implantation in combination with cheilectomy and Moberg osteotomy presents a viable option in the operative management of moderate to advanced hallux rigidus. However, our data demonstrate that patients in both the CM and PVACM groups achieved improvements in pain relief and physical function postoperatively, with greater improvement for patients who did not undergo the addition of the PVA implant. A longer follow-up is needed to evaluate long-term functional and clinical outcomes, including survivorship of the implant and need for revision.

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