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First Metatarsophalangeal Joint Space Area Decreases Within 1 Month After Implantation of a Polyvinyl Alcohol Hydrogel Implant: A Retrospective Radiographic Case Series

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ABSTRACT

In 2016, the U.S. Food and Drug Administration approved the first and only polyvinyl alcohol hydrogel implant for the treatment of hallux rigidus. The implant functions as a bumper to maintain first metatarsophalangeal joint space to prevent contact of the phalangeal base with the first metatarsal head. Short-term and intermediate outcomes with this implant have reported positive outcomes with no radiographic outcomes of implant wear or subsidence. We performed a retrospective radiographic review of 27 consecutive patients who received the implant and measured preoperative and postoperative joint space area (JSA). We found a significant improvement in JSA ($p < .001$) between the preoperative JSA and JSA at the first postoperative visit at 1 to 2 weeks. We also found a significant decrease in JSA ($p < .001$) between the first postoperative visit and the second postoperative visit at 5 to 12 weeks. This information could have further implications for implant design as well as how we can better achieve functional improvements in the first metatarsophalangeal joint in patients with hallux rigidus.

Osteoarthritis of the first metatarsophalangeal joint (MTPJ), also known as hallux rigidus, is the most common arthritic condition in the foot (1). Treatments for hallux rigidus have evolved over the years. Classically, MTPJ fusion has been considered the gold standard for treatment of hallux rigidus (2). Implant arthroplasty, the alternative to fusion, has undergone numerous changes over the past few decades and involves either a partial or total joint replacement. Unfortunately, most implants have shown high rates of failures from implant fragmentation, implant loosening, and wear debris. Once the implant fails, revision surgery, usually an MTPJ fusion, has been shown to have more complications and worse functional results than a primary fusion (3,4).

In 2016, the U.S. Food and Drug Administration approved the first and only polyvinyl alcohol hydrogel implant for the treatment of hallux rigidus. There have been only 2 studies performed to date that look at outcomes of this implant (4,5). These studies were a part of a prospective multicenter randomized controlled trial performed by groups from the United Kingdom and Canada. The authors compared outcomes of the implant with the gold standard of MTPJ fusion. At 5 years of follow up, they found improvements in functional outcome, pain score, and implant survivorship to statistically significant levels. In addition, the study found no radiographic signs of movement, implant wear, or subsidence.

This polyvinyl alcohol hydrogel implant is designed to be performed in conjunction with a cheilectomy procedure. After performing a cheilectomy, the implant provide distraction and separation of the proximal phalanx from the first metatarsal head. The implant, a cylindrical device, acts like a bumper to prevent contact of the phalangeal base with the metatarsal head (7). The 2 studies to date on the polyvinyl alcohol hydrogel implant did not report on follow-up radiographic

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Fig. 1. Three patients with hallux rigidus who underwent polyvinyl alcohol hydrogel implant. (A) Preoperative radiograph joint space narrowing consistent with grade 2-3 hallux rigidus. (B) First postoperative radiograph at 2 weeks shows increased joint space after the implant was placed. (C) Second postoperative radiograph at 5 to 12 weeks shows subsidence of the implant.

findings or mention maintenance of MTPJ space area over time. The purpose of this study was to measure preoperative and postoperative radiographic joint space area (JSA) of the MTPJ. Our hypothesis was that the JSA increases immediately after the implant is placed but will decrease over time.

Case Series

We performed a retrospective radiographic and chart review of consecutive patients who underwent polyvinyl alcohol hydrogel implantation by multiple surgeons across 2 institutions between January 2017 and September 2018. Inclusion criteria were any patient who received the polyvinyl alcohol hydrogel implant (Cartiva® Synthetic Cartilage Implant; Cartiva®, Inc, Alpharetta, GA) for the treatment of hallux rigidus. Patients required 3-view weight-bearing radiograph from any preoperative visit as well as 2 postoperative visits with a minimum follow up of 5 weeks. The first postoperative visit occurred 1 to 2 weeks postoperatively, and the second visit occurred at 5 to 12 weeks postoperatively. A total of 27 consecutive patients met our inclusion criteria. Two surgeons (E.S., J.A.) measured preoperative and postoperative JSA on the anteroposterior weightbearing radiograph of the foot using a picture archiving and communication system (Phillips Medical Systems, Best, Netherlands) (Fig. 1). Using the region of interest function, the program allows the user to trace the borders of the MTPJ space in a freehand manner; as a result, the program generated a numeric value indicating the total area in centimeters squared. The implant was placed using standard technique as described by the manufacturer's guidelines (6). The decision to use an 8- versus a 10-mm implant size was determined by the surgeon based on the size of the metatarsal head. The implant was placed approximately 1 to 3 mm proud from the surface of the metatarsal head based on surgeon's preference (Fig. 2). Patient demographics collected were age and gender. Other outcomes measured included intermetatarsal angle, implant size, and any postoperative complications. Data analysis was performed using paired Student's *t* tests, and statistical significance was defined at the 5% ($p \leq 0.05$) level.

Results

A total of 27 patients were included in our study (Fig. 4). There were 17 (63%) females and 10 (37%) males, with a mean age of 60 ± 10.1 years (Table 1). Six (22.2%) patients had an 8-mm implant and 21 (77.8%%) had a 10-mm implant. One (3.7%) case underwent revision to arthrodesis at 5 months postoperatively because of persistent pain (Fig. 3). The mean preoperative JSA was 0.253 ± 0.10 cm^2. The mean first postoperative JSA increased to 0.443 ± 0.17 cm^2. This change between the preoperative JSA and the first postoperative JSA was statistically significant ($p < .001$). The JSA from the first postoperative visit decreased to 0.231 ± 0.13 cm^2 at the second postoperative visit. This change between the first and second postoperative visits was also statistically significant ($p < .001$). No statistically significant difference was observed between the preoperative JSA and the second postoperative JSA ($p = .398$). In other words, the increase in JSA provided by the implant as observed in the first postoperative visit was not preserved by the second postoperative visit (Table 2).

Table 1
Patient characteristics of polyvinyl alcohol hydrogel implant (N = 27 patients)

	Mean ± SD
Age, y	60 ± 10.1
Intermetatarsal angle, °	9 ± 2.6
Preoperative JSA, cm^2	0.25 ± 0.10
First postoperative JSA, cm^2	0.44 ± 0.17
Second postoperative JSA, cm^2	0.23 ± 0.13

Abbreviations: JSA, joint space area; SD, standard deviation.

Discussion

There does not appear to be a clear understanding if the implant functions as a spacer or a cartilage resurfacing procedure. According to the Cartiva® surgical implantation technique guide, the implant is designed to sit proud off the surface of the metatarsal head approximately 0.5 to 1.5 mm (6); however, because the implant mechanism is to function as a bumper to maintain interpositional space within the MTPJ, it has been emphasized to leave the implant proud with the metatarsal head so it can effectively provide a buffer between the 2 bones. Previous authors have even suggested the implant sit anywhere from 2 to 4 mm (7). There does not appear to be any consensus on the ideal amount the implant is designed to sit proud. Regardless, we believe the cylindric design of the implant makes it prone for the implant to subside into the soft medullary canal of the first metatarsal head.

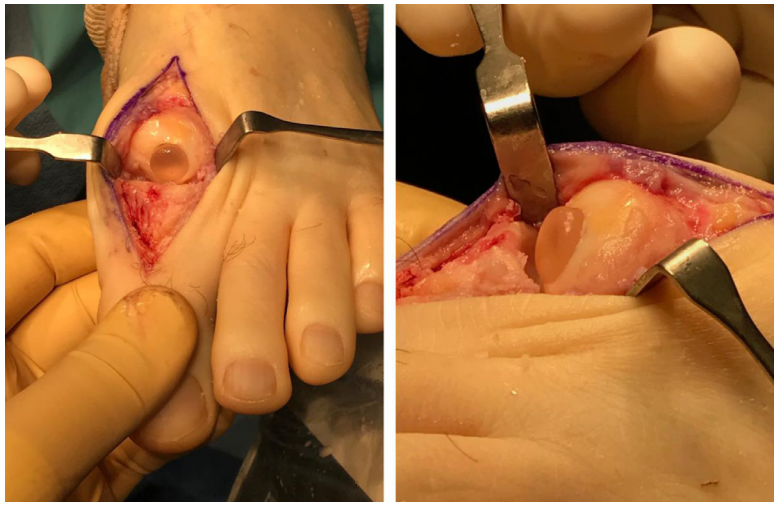

Fig. 2. Intraoperative photos of the implant left approximately 3 mm proud.

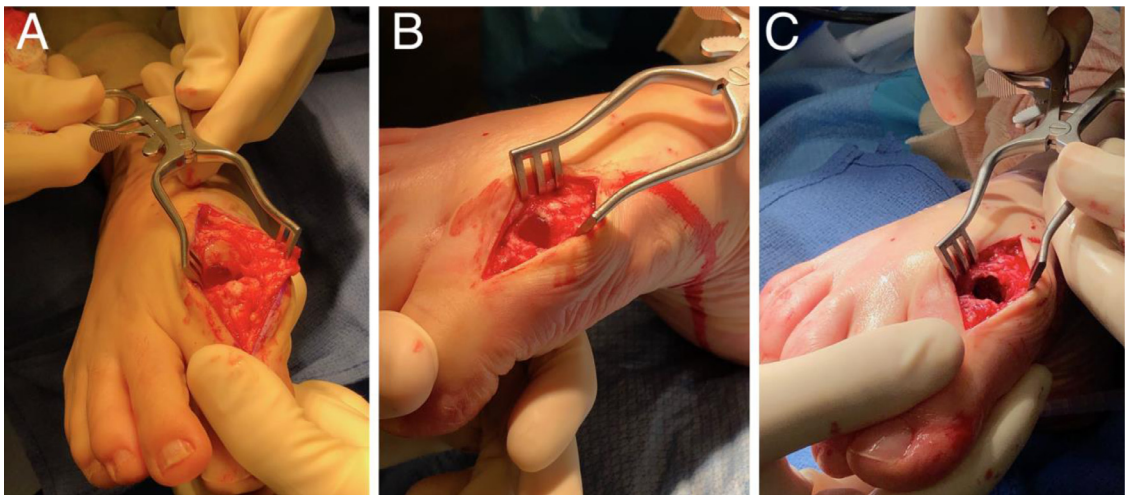

Fig. 3. Intraoperative photos of a revision case involving explant of the polyvinyl alcohol hydrogel implant and conversion to a first metatarsophalangeal joint fusion. (*A*) Subsidence of the implant, which was initially placed approximately 3 mm proud. (*B*) Side view showing subsidence of the implant. (*C*) Removal of the implant with an approximately 10-mm defect in the medullary canal of the first metatarsal head that had to be filled before fusion.

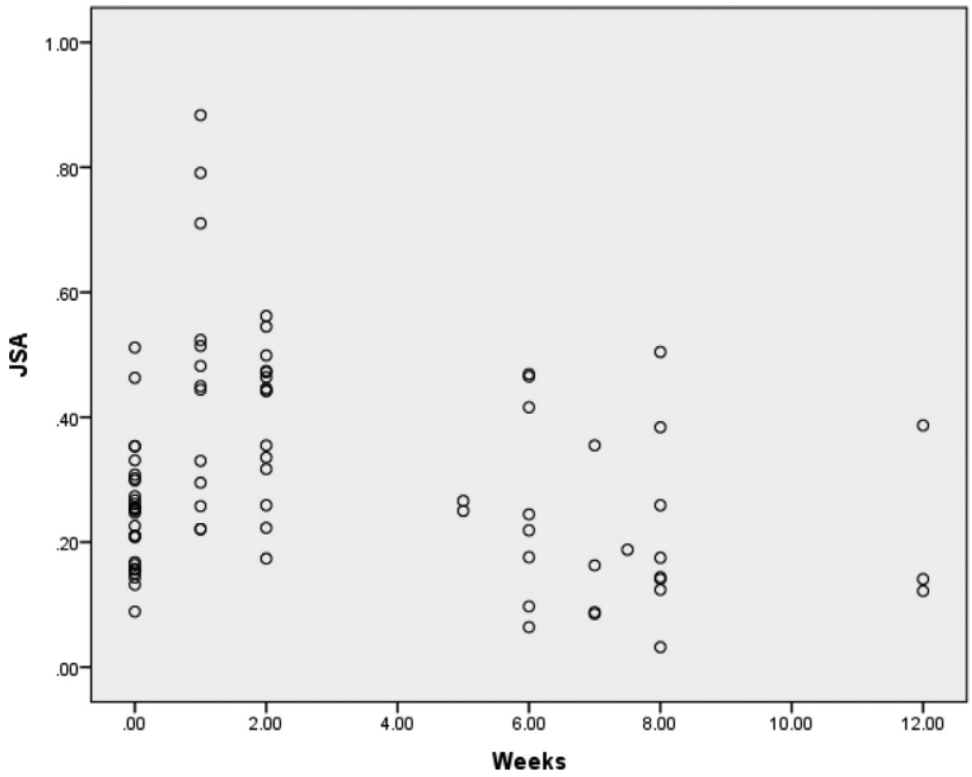

Fig. 4. Scatterplot of joint space area versus number of weeks of follow up. Data points at 0 weeks of follow up indicate preoperative joint space area.

There are several limitations to our study. The purely radiographic nature of this study does not include functional and subjective outcomes of patients. We understand that radiographs do not always correlate to clinical outcomes, but in performing our first step in evaluating a new surgical implant, we believed that the best objective measurement would be based off a radiographic measurement. Finally, our findings relied on measuring JSA, a 3-dimensional measurement, on a 2-dimensional image of an anteroposterior weight-bearing radiograph. These measurements could be affected by radiographic technique and the approximate angle by which the radiographs were taken. Moreover, there can be some measurement bias based on how the freehand lines were made on the radiographs, although the software is known to be sensitive to 0.001 millimeters squared, and

Table 2
Paired *t* test results (N = 27 patients)

	Mean ± SD	*p* Value
Preoperative JSA to first postoperative JSA	+0.19 ± 0.15 cm^2	<.001
First postoperative JSA to second postoperative JSA	−0.21 ± 0.12 cm^2	<.001
Preoperative JSA to second postoperative visit	−0.02 ± 0.13 cm^2	.398

Abbreviations: JSA, joint space area; SD, standard deviation.

the same investigators measured all of the images to minimize variation.

In conclusion, radiographic JSA of the MTPJ decreases significantly within 12 weeks after implantation of a polyvinyl alcohol hydrogel implant. This information could have further implications for implant design as well as how to better achieve functional improvements in the MTPJ in patients with hallux rigidus.

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