Polyvinyl Alcohol Hydrogel Hemiarthroplasty of the Great Toe: Technique and Indications

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Abstract: Joint replacements of the first metatarsophalangeal (MTP) joint have traditionally had limited success. Joint replacements designed to date can be subdivided into hemiarthroplasties and total joint replacements. Despite ongoing requests from patients to have a joint replacement to preserve shoe wear options, many have failed to meet expectations because of loosening, implant wear, osteolysis, or loss of motion. Fusion has therefore remained the gold standard for treatment of end-stage MTP joint arthritis. A polyvinyl alcohol hydrogel implant shows promise. The Cartiva implant is a 8 or 10 mm disk of durable hydrogel material shown to resist compression and shear with exceptional wear characteristics. It is implanted with approximately 1 to 1.5 mm protrusion and acts as a spacer for the first MTP joint. This implant is commercially available in Europe and Canada. A prospective, randomized, multicenter clinical trial is underway in the United Kingdom and Canada to assess outcomes with this implant. This article outlines the indications for surgery, surgical technique, and potential complications for hemiarthroplasty of the great toe.

Key Words: great toe, metatarsophalangeal joint, first ray, joint replacement, hemiarthroplasty

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HISTORICAL PERSPECTIVE

Fusion has remained the gold standard for treatment of first metatarsophalangeal (MTP) joint arthritis. However, as with many joints, patient demand has resulted in the development of first MTP joint replacements. After the success seen in the hand, silastic implants were commonly used for the first MTP joint in the 1970s and 1980s.[1] However, a need to resect more bone makes salvage more difficult in the toe, and osteolysis, first reported in 1989, is common with silicone implants.[2–4] The silastic replacement may lack sufficient stiffness for the joint, and silicone fragmentation occurs over time. The fragments, observed in revision specimens using polarizing microscopy, are thought to be the cause of bone osteolysis around the components.[5] The use of metal supporting grommets may reduce the rate of osteolysis around the components.[6] The bone defect left secondary to the osteolysis can be difficult to revise and can require a segmental bone graft.[7,8] The silastic fragments may migrate to regional nodes.[9] As a result, most North American surgeons have abandoned silastic spacers in the foot due to concerns regarding osteolysis and fragmentation.

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Ceramic total MTP joint replacements have enjoyed short-term success, but on longer follow-up have been complicated by radiolucent lines and subsidence.[10] Should this joint replacement fail, a large deficit will exist.

Metal alloy total (phalanx and metatarsal head) MTP joint replacements have had problems with osteolysis and subsidence.[11–13] A randomized controlled trial of 39 metal alloy MTP joint replacements showed subsidence of the phalangeal component requiring revision in 6 toes and radiographic loosening in a further 8 toes for a loosening rate of 35% at 2 years.[14]

Hemiarthroplasties made from cobalt chrome or titanium are available. Complications of the titanium and cobalt chrome hemiarthroplasties include bone overgrowth[15] and subsidence,[16,17] resulting in ongoing pain. Some short-term uncontrolled case series have shown good outcomes.[18,19] One comparative study of 21 metallic hemiarthroplasties and 27 arthrodeses concluded that arthrodesis was a better procedure than hemiarthroplasty.[20]

First MTP joint deformity may cause failure of a joint replacement. Hallux rigidus is associated with vertical displacement of the first ray and may need to be corrected at the same time by osteotomy or first tarsometatarsal fusion to bring the first ray down if excessively elevated.[21] The role of sesamoid arthritis and pain should not be ignored in joint replacement.[18,22]

Because of the concerns regarding residual deformity, sesamoid arthritis, wear debridement with subsidence, and fragmentation associated with joint replacement, fusion has remained the gold standard for treatment of first MTP arthritis, with a nonunion rate of 5% in 1 meta-analysis[23] and good outcomes being reported in numerous studies.[24,25] Nevertheless, disadvantages remain for first MTP fusion, resulting in patients being potentially dissatisfied with the procedure. Patients less willing to accept first MTP joint fusion include those who require first MTP motion for work or recreational activities.[26] Shoe wear is also restricted in patients with an MTP fusion, and this might have work and social implications for some patients. The rehabilitation time for fusion may be longer, as the first ray has to be protected from load until the fusion is solid. Furthermore, adjacent joint arthritis may develop over time.[27]

THE POLYVINYL ALCOHOL (PVA) HYDROGEL IMPLANT

An implant comprised of a material with properties more similar to those of native cartilage would be more appealing to clinicians treating patients with advanced great toe joint osteoarthritis. The PVA hydrogel implant, Cartiva, (Alpharetta, GA) is softer than metal hemiarthroplasty spacers, has a water content similar to that of healthy cartilage,[28] and has a tensile strength of 17 Mpa, comparable with human normal articular cartilage.[29] The PVA hydrogel has shown good biocompatibility and biomechanical qualities in animal studies, preclinical tests, and surgical studies to treat chondral and osteochondral defects of the knee.[28]

The Cartiva synthetic cartilage implant was initially used in 2002 in Europe and later in Canada and Brazil to treat osteochondral defects in the knee,[30–33] talus, and first MTP joint.[34] It has been approved for use by Health Canada and has CE marking in Europe. The implant is available in 2 sizes suitable for the first MTP joint—an 8 and 10 mm diameter.

The PVA hydrogel demonstrates a considerably reduced friction in the knee under start-up conditions[35] and causes less inflammation compared with ultra–high-molecular weight polyethylene or polyurethane,[36] used in most conventional prostheses. The PVA hydrogel also produces less debris in articulation with cartilage compared with stainless steel.[28]

Outcomes with PVA hydrogel implants for treatment of knee chondral focal defects reported to date are promising. In the longest study to date,[30] at 4 to 8 years after surgical implantation of PVA hydrogel implants, 19 of 20 patients, mean age 54.4 years, were pain free and showed no signs of synovial joint reaction, osteolysis, or wear. One patient experienced implant dislocation at 1 year and underwent total knee replacement due to progressive arthritis. Maiotti et al[33] compared 18 patients, mean age 56 years, treated with hydrogel implantation for single traumatic knee chondral defects to 15 control patients matched for sex, age, and chondral damage treated by arthroscopic debridement. The implant group had significantly higher Lysholm II and Tegner scale scores at 24 months follow-up compared with controls. There was no evidence of mechanical loosening or adverse reactions around the implants by MRI, and implants were well integrated in 3 "second-look" arthroscopies to evaluate recurrent swelling of the knee. Other studies using the PVA hydrogel implant in the knee with shorter follow-up periods of 6 months[32] and 2.8 months[31] reported no loosening, dislocation, or synovitis.

INDICATIONS AND CONTRAINDICATIONS

The PVA implant is used for end-stage arthritis of the first MTP joint. Radiographic Coughlin grades 2, 3, and 4 arthritis can be treated using the implant, whereas grade 1 and less progressed grade 2 with preservation of the plantar cartilage are best treated by cheilectomy.

The skin envelope needs to be mobile and intact. The toe needs to be well aligned. The site should be free of infection, and there must be enough bone to support the prosthesis.

Contraindications include a poor soft-tissue envelope, poor bone stock, infection in the site, or malalignment needing osteotomy. Relative contraindications are hallux elevatus and sesamoid arthritis. Poorly controlled diabetes and charcot arthropathy are absolute contraindications. The flexor and extensor tendons must be intact, and the muscles of these tendons need to have appropriate power.

PREOPERATIVE PLANNING

Range of motion and the location of pain should be reviewed on clinical examination. Range of motion should include some dorsiflexion preoperatively. Pain should be located within the first MTP joint.

Preoperatively, standing anteroposterior and lateral radiographs of the foot should be obtained. Arthritis at the first MTP joint should be confirmed (Fig. 1). Hallux valgus and elevation of the first ray should be assessed on the radiographs and on clinical examination.

The skin should be intact with no evidence of ulceration or infection.

The pulses and capillary refill should be assessed and a vascular assessment performed if there is any concern.

If diabetes is present, a hemoglobin A1c test should be conducted. Poorly controlled diabetes is a contraindication for the procedure because of the risk of Charcot arthropathy and infection.

EQUIPMENT

The implant is separately wrapped and packaged. The implantation kit consists of an 8 and a 10 mm kit. Each kit contains a sizing device which is also used to place the guidewire, a reamer, and a delivery tube for compressing the implant and advancing it into the MTP cavity. The correct size is selected after the joint is exposed and the great toe joint assessed.

TECHNIQUE

The patient is placed on the operating room table with the foot in neutral position at the end of the table. A calf or thigh tourniquet can be used. The anesthetic can be regional, spinal, or general. Antibiotic prophylaxis is given before tourniquet inflation.

The first MTP joint is approached using a straight dorsal incision. The extensor tendon is retracted to the lateral side through incision of the capsule and dorsal medial tendon expansion. Care is taken to avoid injury to the dorsal medial digital nerve. The first MTP joint is exposed so that the osteophytes can be inspected on the medial, lateral, and dorsal sides. The joint needs to be mobilized so that exposure of the implant site can be easily achieved.

Dorsal, medial, and lateral osteophytes are removed (Fig. 2). Care is taken to avoid excessive dorsal resection and to leave a cortical rim of bone to support the prosthesis. Osteophytes should be removed to the point that the joint is congruent. If there is any concern, the sizer can be used to confirm that an adequate bone bridge remains to support the prosthesis. Osteophytes, if prominent, are also removed from the proximal phalanx on the dorsal side.

The metatarsal head needs to be exposed to the point that a direct approach can be made to the planned site of the implant. This may require release of the medial and lateral capsule and placement of retractors to maintain the proximal phalanx in flexion (Fig. 3).

The implant site is then sized for an 8 or 10 mm implant. A rim of 1 to 2 mm of bone needs to remain around the margin of the implant to support hoop stresses. If there is concern that a sufficient bone rim will be available for support, then downsizing to an 8 mm implant from a 10 mm implant may be required. The sizer is then held perpendicular to the joint surface while placing a K-wire centrally in the implant site. The wire should be advanced well beyond the implant bed into the proximal cortex of the metatarsal shaft.

The sizer is then removed and the position of the K-wire is reviewed. If satisfactory, then the reamer is placed over the K-wire with care to ensure that the wire is not displaced or bent by pressure from the proximal phalanx. As the rim of the reamer is larger than the sizer, more space is required around the edge of the proximal phalanx. Eccentric reaming may compromise the implant bed.

The step reamer is then advanced to the depth allowed (Fig. 4), and the implant site is inspected for eccentricity and depth (Fig. 5). The reamer is removed, as well as the K-wire, and bone reamings are saved. The bed is inspected for cysts and deficits (Fig. 6). If present, the bed should be grafted using

FIGURE 1. Preoperative standing radiographs of right foot: lateral view (A) and anteroposterior view (B). Note end-stage arthritis of the first metatarsophalangeal joint, minimal arthritis of the sesamoid to metatarsal head articulation, and a well-aligned first ray.

the saved reamings to ensure that the implant will protrude 1 to 1.5 mm.

It is important that the implant be appropriately placed. Before surgery, placement of the implant into the delivery tube should be practiced to ensure that the delivery is smooth. As a means for practice, an unsterile implant is placed into the delivery tube and advanced into a Perspex receiving hole. The implant is compressed by the delivery tube and expands as it comes out of the delivery tube. The surgeon must be able to deliver the implant in a single smooth action and ensure that the implant has been delivered to the bottom receiving hole, leaving the implant protruding 1 to 1.5 mm.

The sterile PVA implant is selected and placed flat side down and convex side up into the wide end of the delivery tube (Fig. 7). The tube is lubricated with the sterile storage saline to allow for smooth advancement of the implant. The implant is advanced at a second table using the sizer until the implant rests flush to the delivery end of the delivery tube. The tube has a shoulder to allow placement of the delivery tube over the reamed implant site at the first MTP joint.

The delivery tube is then held over the prepared implant site. Care is taken again to retract the proximal phalanx out of the way. Once correctly positioned, the sizer is pushed in a single smooth motion to deliver the implant into the reamed hole (Fig. 8). The implant is left protruding 1 to 1.5 mm (Fig. 9).

Once delivered, the implant is inspected. If <1 mm shoulder is protruding, then the implant has been placed too deep and should be removed using the sharp end of a K-wire and discarded. A new implant is opened. The implant bed is grafted with some reamings, and the reamings are compressed using the sizer. The new implant is delivered in a similar manner.

If the implant is protruding by >1.5 mm, then it will need to be placed deeper into the bed. The implant is removed using a K-wire and discarded. The K-wire is placed centrally back into the bed, and the bed is carefully reamed deeper. The bed is inspected for any defects and a new implant delivered.

To avoid having to revise the implant, the surgeon can check the depth of the reamed hole using the metal sizer and mark the depth after reaming and before placement of the graft. The bed should be gradually reamed and the depth checked on 2 or 3 occasions before removal of the guide rod and implant placement.

After delivery of an implant protruding by 1 to 1.5 mm, the joint is manipulated through the range of motion to ensure that an adequate range can be achieved. After irrigation, the capsule is sutured with absorbable stitches, and the skin is closed using interrupted nylon and steri-strips.

FIGURE 2. Removal of dorsal, medial, and lateral osteophytes. Care should be taken not to remove an excessive amount of dorsal osteophyte, as this may weaken the implant bed.

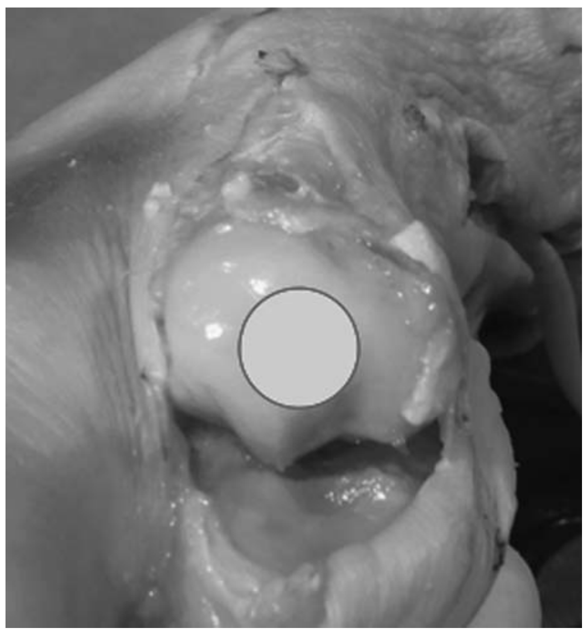

FIGURE 3. Exposure of the joint to allow approach and sizing of the joint. The prosthesis should be placed centrally in the metatarsal head.

FIGURE 4. Reaming over the K-wire. The reamer is placed down to the subchondral bone.

FIGURE 5. The bone bed shown with the K-wire in place.

FIGURE 6. Palpation of the base to ensure solid bone for the implant site. Weak bone and defects should be grafted using the bone from the reamer to ensure that the implant does not subside.

FIGURE 7. Placement of the implant in the delivery tube. The delivery tube is slightly cone shaped to allow compression of the implant. The tube is moistened to allow free movement of the implant.

FIGURE 8. Placement of the implant in the bone bed. The left hand stabilizes the tube and the right hand compresses the delivery plunger. The delivery tube is kept vertical and centralized over the bone bed site. The implant is delivered in 1 smooth motion.

FIGURE 9. Implant is in place. Note how the implant protrudes by 1 to 1.5 mm.

FIGURE 10. Postoperative radiographs of right foot of same patient as in Figure 1: lateral view (A) and anteroposterior view (B).

POSTOPERATIVE CARE

A soft dressing is placed. No plaster immobilization is required. The patient can perform touchdown weightbearing, progressing to full weightbearing when the wound has healed. Home physiotherapy can begin at 1 week. Follow-up with radiography is performed at 6 weeks (Fig. 10).

Dental prophylaxis is required for the first year after surgery.

COMPLICATIONS

Potential complications of surgery include wound healing problems, implant subsidence, metatarsal head fracture, dorsal medial great toe numbness, and persistent pain. Occasional irritation of the capsule area around the first MTP joint may be observed and is readily treated with anti-inflammatory medication.[34]

In the case of implant failure and persistent pain, the implant can be converted to a fusion with a dorsal plate and bone grafting of the defect. The reamed hole is 1 cm deep. The experience of revision is limited.[34] A dorsal plate is usually required, as there is insufficient bone to perform cross-screw fixation. The defect is a cavity, rather than structural, so the revision with a plate is similar to a primary fusion once the implant has been removed and the cancellous defect grafted. However, in some Cartiva revision cases, fusion with 2 annulated fixation screws was achieved without complication.

RESULTS

Results reported for other MTP joint implants demonstrate significant improvement in pain and range of motion of the first MTP joint after hemiarthroplasty.[37,38] Clinical results for implantation of the Cartiva synthetic cartilage implant PVA hydrogel in the first MTP joint in 175 patients, mean age 54.2 years (range, 27 to 72 y), were presented at the British Orthopaedic Foot & Ankle Society Meeting in 2008.[34] Preoperative inclusion criteria required the clinical presence of painful range of motion, 5-degree dorsiflexion, and 3-degree plantarflexion. Follow-up ranged from 2 to 64 months and was evaluated at 2, 4, 6, 12, 24, and 36 months postoperatively. American Orthopaedic Foot and Ankle Society scores improved from mean 28.4 points to mean 87.3 points. No patient reported postoperative infection. Clinical and radiologic examination found no evidence of mechanical loosening or failure of the implant in any patient. A total of 23 patients (13%) experienced irritations of the MTP joint capsule that were successfully treated with anti-inflammatory medication. One patient developed avascular necrosis of the medial metatarsal head not related to the implant 6 weeks post-implantation, but the implant was removed and an arthrodesis performed. Another patient with the longest follow-up was treated with arthrodesis due to hereditary, progressive osteoarthritis at 5.4 years after implantation.

The above study showed that the Cartiva implant performed as well as an MTP fusion for symptom relief while maintaining joint range of motion, justifying the need for a randomized controlled trial. The MOTION randomized controlled study of the Cartiva implant for first MTP hemiarthroplasty, underway in Canada and the United Kingdom, has completed enrollment, with 236 patients enrolled and 202 patients treated under the protocol (152 with Cartiva and 50 with fusion). These results will be available after completion of 2-year follow-up, expected sometime in 2014.

FUTURE OF THE TECHNIQUE

The Cartiva implant is currently used for isolated arthritis of the first MTP joint. The procedure preserves more bone, maintains motion in the joint, reduces rehabilitation time, and enables patients to return to normal activity sooner than with fusion. Although early results are promising, further studies currently underway are required to determine the factors associated with success of the implant. The MOTION study considered the hemiarthroplasty procedure in isolation, but there is potential to perform osteotomy or first tarsometatarsal fusion to stabilize and realign the first ray in hallux rigidus or hallux valgus, either as a staged or concomitant procedure. Further outcome series are required to delineate the outcome of the Cartiva implant.

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