Metatarsophalangeal prosthesis for hallux rigidus. Review of current models and Cartiva™ interposition endorthesis

Mariano Nuñez-Samper1, Ramon Viladot-Pericé (In Memoriam)2
1. Hospital Virgen del Mar, Madrid, Spain.
2. Orthopaedic Department, Clinica Tres Torres, Barcelona, Spain.

Abstract

Hallux rigidus of the first metatarsophalangeal joint affects between 35% and 60% of the population over 65 years of age and has multiple treatment options, among which we highlight metatarsophalangeal arthrodesis and prosthesis. Regarding the arthroplasty technique, we aim to provide information on the characteristics of the material, model, and design and on which one offers better results, relating it to the characteristics of the patient, such as age, presence of inflammatory joint diseases, and viability and durability of the implant. Some studies on the clinical and functional results with different prosthesis models are briefly exposed. According to the AOFAS criteria, prosthesis and arthrodesis present similar effectiveness values and the decision of which technique to use will be determined considering several factors and characteristics previously exposed. Cartiva™ is a synthetic polyvinyl alcohol hydrogel implant that has a water content with a compressive and tensile modulus similar to that of human articular cartilage. Thus, it is suitable for use in metatarsophalangeal hemiarthroplasties, and published studies in this regard report excellent short- and long-term clinical results.

Level of Evidence V; Therapeutic Studies; Expert Opinion.

Keywords: Arthroplasty; Hallux rigidus; Metatarsophalangeal joint; Prosthesis design; Prostheses and implants.

Introduction

Although arthrodesis is the treatment of choice for advanced hallux rigidus (HR), the greater patients’ demand and technical advances support the indication for implanting a prosthesis on the affected joint.

Many publications advocate for this indication; however, no prospective study assessed patient’s satisfaction and clinical results obtained with prosthesis implantation, despite the large body of critical literature on implants for HR, especially about those made of silicone, which present with many cases of reactive synovitis(1).

Metatarsophalangeal arthrodesis is still the safer and more predictable gold standard treatment to correct advanced HR, with acceptable functional results and lower rates of complications and reoperations compared with prosthesis(2).

In general, the following indications are established for the use of metatarsophalangeal prosthesis: HR with severe ankylosis, rescue of silicone implant, failed previous surgery, deforming rheumatoid arthritis, and young patients requiring mobility. Contraindications are the following: vascular failure, tendon failure, infection, and osteoporosis; the latter being a relative contraindication(3).

Characteristics and evolution of implants (Chart 1)

Prosthesis models

The first prosthesis used in the first metatarsophalangeal joint (MTPJ) of the foot was made of silastic and was widely used in the 1970s. However, due to prosthesis wear that caused reactive synovitis, the use of this type of prosthesis, as well as its subsequent modifications, was soon discontinued.

Subsequently, prostheses with two unconstrained, uncemented components were developed, as well as other two-piece ceramic models implanted by a press fit technique(4-6).
Currently, last-generation prostheses present the following characteristics:

- Three components.
- Limited bone resection.
- Unconstrained.
- Uncemented bone anchoring.
- Threaded phalangeal component with coating (Figure 1).

Characteristics of implantation

The choice for prosthesis implantation surgery involves a number of basic requirements that patients should comply with(7):

- Good bone quality to ensure accurate fixation of the two prosthetic components;
- Functional stabilizing structure of the joint;
- Proper metatarsophalangeal alignment;
- If the intermetatarsal angle is greater than 12 degrees, previous osteotomy should be performed;
- The rest of the phalanx should be of a sufficient size;
- Low functional demand;
- Absence of septic processes from previous interventions;

Results

In a study on the outcomes of patients with two-piece ceramic Moje implant, Fuhrmann and Martin(9) reported 12.5% of revision operations and only 63% of «much satisfactory» results, although postoperative mobility was much unsatisfactory in 4 patients, which was significantly associated with reduced American Orthopedics Foot and Ankle Society (AOFAS) scores (p=0.01).

Other study published by Dos Santos et al.(9) in Acta Ortopédica Brasileira in 2013 analyzes the outcomes of 11 patients treated through partial arthroplasty of the first MTPJ with Arthrosurface-HemiCAP™ technique from June 2008 to May 2009. All patients were initially treated with stretching of triceps surae muscles and footwear modification for 6 months without symptomatic improvement. After surgery, patients presented with a statistically significant improvement in AOFAS scores for hallux, visual analog scale for pain, and range of motion (in degrees) of the first MTPJ.

Small study sample and follow-up time shorter than 3 years do not allow for yielding robust results in favor of hemiarthroplasty for hallux rigidus.

In 2014, Duncan et al.(10) published the results of a retrospective review on the implantation of the ToeFit-Plus™ prosthesis, a modular, unconstrained, CoCr-polyethylene implant with titanium rods. HR was classified as stage III in 17 patients (65.4%) and stage IV in 9 (34.6%), with average follow-up time of 29.9 months. These patients had a remarkable increase in AOFAS and a decrease in pain that continued over time. Furthermore, there was an increase in dorsiflexion of hallux from 10 to 20 degrees.

Functional results, according to overall average AOFAS scores, were 77.5 points. Only 16 patients (15%) complained of pain in the hallux. Eight-two patients (78%) did not present with pain, and occasional pain was reported for 5 feet (4.8%). Average active range of motion was 36.8 degrees, and average passive range of motion was 46.82 degrees.

Another study published by Unger et al.(5) describes the results of 27 patients treated with 28 prostheses of the first MTPJ (Bio-Action Great Toe Implant, Osteo Med, Addison, TX). Average follow-up time was 8.8 years, and 53.6% of patients did not present with pain, which means that a little less than a half of the sample experienced postoperative pain.

---

**Chart 1. Characteristics and evolution of implants**

| PARTIAL TOTAL | MATERIAL | INTERFACE | GENERATION |
|---------------|----------|-----------|------------|
| PHALANGEAL HEMIARTHROPLASTY | POLYETHYLENE | SILICONE | CEMENTED | 1ST SILICONE |
| GRAFT | MOBILE MENISCUS | METALLIC | UN | 2ND WITH |
| | | | CEMENTED | RINGS |
| METATARSAL | CHROMIUM COBALCOBAL |
| HEMIARTHROPLASTY | THREE | COBALT | 3RD POLYETHYLENE | GRAFT |
| COMPONENTS | TITANIUM | 4TH METALLIC |
| CARTIVA | CERAMIC | MOBILE |
| | MENISCUS | |
| | HYDROGEL | THREADED |
| | PHALANX | |
with some degree of severity. Less than a half of patients remained with good range of motion. Overall, 85.7% of patients were satisfied, 3 (11%) of them presented with loosening of the phalangeal component, and 2 required revision operation.

In 2017, Kofoed et al.\(^{(1)}\) published a 15-year follow-up of 90 Rotoglide\(^{TM}\) third-generation implants placed on 80 patients (53 women and 27 men) with mean age of 58 years; they observed that median AOFAS scores increased significantly from 40 to 95 points after surgery. Four implants (4.4%) were extracted for other reasons than loosening. No aseptic loosening was reported. The survival rate at 15 years was 91.5% (83-100); thus, the authors concluded that this prosthesis has stood the test of time and observed that the results justify its further use.

An analysis of this retrospective study enables to infer that the last generations of metatarsophalangeal prosthesis of the hallux allow for patients with HR to reduce pain while maintaining, at least to some extent, previous articular movement.

**Cartiva\(^{TM}\) interposition endorthesis**

It is a synthetic polyvinyl alcohol hydrogel implant that has a water content with a compressive and tensile modulus similar to that of human articular cartilage\(^{(6)}\) (Figure 2), which makes it an ideal material for use in metatarsophalangeal hemiarthroplasties of the hallux\(^{(6,12)}\). A study conducted in 12 centers in Canada and in the United Kingdom with a 2-year follow-up showed improvement in pain and functional results equivalent to those of hemiarthroplasty and arthrodesis, with no cases of fragmentation or wear of the implant or bone loss. After 5 years, a new assessment was performed with 27 patients, showing an implant survival rate of 96% at 5.4 years.

**Conclusion**

In conclusion, this implant maintained function and dorsi-flexion after 5 years of follow-up, showing excellent survival and overall satisfaction of patients, who would be willing to undergo the same surgery.
References

1. Morgan S, Ng A, Clough T. The long-term outcome of silastic implant arthroplasty of the first metatarsophalangeal joint: a retrospective analysis of one hundred and eight feet. Int Orthop. 2012;36(9):1865-9.

2. Brewster M. Does total joint replacement or arthrodesis of the first metatarsophalangeal joint yield better functional results? A systematic review of the literature. J Foot Ankle Surg. 2010;49(6):546-52.

3. Sullivan MR. Hallux rigidus: MTP implant arthroplasty. Foot Ankle Clin. 2009;14(1):33-42.

4. Sorbie C, Saunders GA. Hemiarthroplasty in the treatment of hallux rigidus. Foot Ankle Int. 2008;29(3):273-81.

5. Unger AC, Stoica LA, Olms KH, Renken FG, Kasch R, Schulz AP. Eine retrospektive Analyse [Intermediate and long-term outcome after total joint replacement for hallux rigidus: a retrospective analysis]. Orthopade. 2013;42(7):561-8.

6. Grady JF, Axe TM, Zager EJ, Sheldon LA. A retrospective analysis of 772 patients with hallux limitus. J Am Podiatr Med Assoc. 2002;92(2):102-8.

7. Erkocak OF, Senaran H, Aytan E, Aydin BK, Acar MA. Short-term functional outcomes of first metatarsophalangeal total joint replacement for hallux rigidus. Foot Ankle Int. 2013;34(11):1569-79.

8. Fuhrmann RA, Martin X. Intrinsisches Implantatversagen der Moje-Prothese an den Zehengrundgelenken [Intrinsic failure of the Moje prosthesis at the metatarsophalangeal joint]. Fuß & Sprunggelenk 2009;7(1):31-8.

9. Dos Santos AL, Duarte FA, Seito CA, Ortiz RT, Sakaki MH, Fernandes TD. Hallux Rigidus: prospective study of joint replacement with hemiarthroplasty. Acta Ortop Bras. 2013;21(2):71-5.

10. Duncan NS, Farrar NG, Rajan RA. Early results of first metatarsophalangeal joint replacement using the ToeFit-Plus™ prosthesis. J Foot Ankle Surg. 2014;53(3):265-8.

11. Kofoed H, Danborg L, Grindsted J, Merser S. The Rotoglide™ total replacement of the first metatarso-phalangeal joint. A prospective series with 7-15 years clinico-radiological follow-up with survival analysis. Foot Ankle Surg. 2017;23(3):148-52.

12. Baker MI, Walsh SP, Schwartz Z, Boyan BD. A review of polyvinyl alcohol and its uses in cartilage and orthopedic applications. J Biomed Mater Res B Appl Biomater. 2012;100(5):1451-7.