A perspective on MTPJ implant arthroplasty

The BioPro® MTPJ Hemi Implant System: 65 years of successful clinical use
The following analysis was designed for medical professionals to reiterate treatment options and rationale for hallux limitus/rigidus and DJD of the MTPJ. BioPro has compiled practical experience from medical professionals as well as clinical research to shed light on the controversy surrounding implant arthroplasty. The BioPro hemi implant has been successfully implanted since 1952, allowing us to gain statistically significant knowledge about why some implants work and others fail. BioPro wants to share this information with the medical community to promote evidence-based research and analysis, thus improving patient outcomes.
The BioPro MTPJ Hemi Implant System

Scientific Findings

Similar re-operation rates with a higher patient satisfaction compared to arthrodesis. [1]

95% good or excellent results on 279 implants with an 8-month to 33-year follow-up. [10]

90%+ patient satisfaction and significant improvement in FFI scores in patients with 50% or more of metatarsal head cartilage missing. [5]

468 joints, ranging from 2 months to 38 years post-op, showed a 97.2% implant survivorship. [7]

Of the 103 operations performed at our center since 2000, no failures requiring implant removal have occurred. There have been no deep infections requiring excision. Because the implant acts as a spacer, no problems with loosening or implant dislocation have been encountered. [3]

Despite the presence of first metatarsal head cartilage degeneration, the ACFAS outcome score and the range of motion improved following implant arthroplasty, and these findings support the use of this procedure as a useful salvage intervention even in patients with pre-existing double-sided first metatarsophalangeal joint disease. [8]

Dorsiflexion improved from an average of 36 degrees preoperatively to 56 degrees postoperatively. [11]

The BioPro implant offers good short- to mid-term functional outcomes and is a cost-effective intervention. [4]

91% (20 of 22) of implants survived at two years post-op with average AOFAS scores improving from 61 preoperatively to 86 postoperatively. [12]

Hemiarthroplasty patients demonstrated high satisfaction (81.6%) and a low failure rate (5.6%) at an average 38 months follow up, compared with 77.4% satisfaction and a 11% failure rate in the arthrodesis group. [2]

*see clinical data section to find study information
Choosing the right patient

When used on the right patient, the BioPro First MTPJ Hemi Implant offers many advantages over other treatment options; including restoration of normal joint biomechanics and pain relief. While the implant has been successfully used on a wide variety of patients, we recommend all factors be considered prior to surgery including stage of disease, patient age, patient activity level, any comorbidities, and patient expectations.

BioPro recommends the First MTPJ Hemi Implant for Stage II and III Hallux Limitus/Rigidus patients. The implant has been successfully used on Stage IV patients[^13^], however we recommend this at the surgeon's discretion only. Additionally, the implant can be easily combined with distal metatarsal osteotomies for treating comorbidities such as Hallux Valgus, Elevatus, DMAA/PASA, or a long first metatarsal.

While each surgeon's ideal patient will vary, we recommend the implant for low to moderate demand stage II/III patients, 50+ years of age[^14^], who wish to maintain motion in their first MTP joint. The implant is particularly popular amongst women wishing to retain the ability to wear shoes with heels.

When evaluating joint condition, note it is not necessary to maintain metatarsal head cartilage as the implant is shown to still provide pain relief and motion with most to all of the metatarsal head cartilage missing[^13^]. Although it is necessary to remodel the head to provide a smooth, round articulating surface for the implant to glide against.

Pay particular attention to the sesamoid complex, both pre-operatively and intra-operatively. It is typically necessary to “free up” the sesamoids during surgery to regain near-normal joint motion as they are typically stiff and fibroed from years of limited motion. However, if there is radiographic evidence that the sesamoid complex is arthritic during pre-op review, this is a contraindication. While the implant will provide pain relief in the MTP joint, the sesamoids will still be painful.
Keller Resection

The Keller Resection is one of the oldest treatments for hallux limitus/rigidus. It involves removal of 1/3 to 1/2 of the base of the proximal phalanx, reducing joint tension and bone on bone contact. While it may offer some pain relief, it typically results in detachment of the flexor hallucis brevis leading to lack of toe purchase and in some cases, transfer metatarsalgia.[3,15,19]

What advantage does the BioPro First MTPJ Hemi Implant offer? While utilizing a similar technique to the Keller Resection, the BioPro implant removes considerably less bone, leaving the brevis intact for normal joint function. The implant resurfaces the base of the phalanx with a highly polished surface for smooth motion and pain relief.

Cheilectomy

The Cheilectomy is a popular conservative option for early stage disease, removing a portion of the metatarsal head. The diseased portion of the head is remodeled to remove painful osteophytes while a portion of the dorsal aspect is removed to decompress the joint. While it is a predictable procedure for pain relief and restored motion, pain often returns years later as there is still bone on bone contact in many cases.[3]

What advantage does the BioPro First MTPJ Hemi Implant offer? When used in conjunction with either a full or partial Cheilectomy, the implant allows the same head remodeling and joint decompression, but adds in the highly polished implant to remove the bone on bone contact, offering years of pain relief and motion.

Arthrodesis

Arthrodesis is often viewed as the “gold standard” for hallux limitus/rigidus treatment, offering predictable pain relief and for stage IV patients or those with arthritic sesamoids, it is typically the best option. However, complete loss of motion at the MTP joint is unacceptable to many patients and can lead to degenerative joint disease in adjacent joints. This can negatively affect the patients gait and other major joints within the body. [16,17,19]

What advantage does the BioPro First MTPJ Hemi Implant offer? For earlier stage patients, especially those wishing to maintain some joint motion, the BioPro implant offers a conservative alternative for pain relief that restores or maintains motion. Due to the minimal bone resection technique, the implant maintains normal joint anatomy with sufficient bone stock in the event that a revision to arthrodesis is required in the future.
Total MTPJ Implant

Total implants are typically offered in two main styles, one-piece silastic implants and multi component metallic implants. Both styles replace the base of the proximal phalanx and the metatarsal head, typically removing significant bone and the flexor brevis attachment. When required, revision surgery to arthrodesis can be difficult due to lack of bone stock, and often require bone grafting to maintain proper length on the first ray. Additionally, the metatarsal component of some implants may cause sesamoiditis.\textsuperscript{18}

What advantage does the BioPro First MTPJ Hemi Implant offer? The conservative approach of the BioPro implant allows for pain relief and restored range of motion without the invasive bone removal techniques necessary for many total joint implants. Normal joint anatomy is maintained providing improved function while preserving bone stock in the event an arthrodesis is required in the future. Also, the implant does not interact with the sesamoids, which avoids any irritation or cartilage degradation.

Metatarsal Head Implants

Implants placed on the metatarsal head versus the base of the phalanx claim to treat the point of the disease when arthritic changes are present on the metatarsal head. Potential issues include placing the implant on the main weight bearing surface of the joint\textsuperscript{21} and the inability to combine these implants with distal metatarsal osteotomies to address comorbidities. Additionally, if placed too far plantar, these implants can irritate the sesamoid complex, leading to cartilage degradation and sesamoiditis.\textsuperscript{23}

What advantage does the BioPro First MTPJ Hemi Implant offer? While resurfacing the phalanx to treat a defect on the head may seem counterintuitive, clinical literature shows that the BioPro implant offers pain relief with little to no met head cartilage\textsuperscript{13}. This allows the implant to sit on the non-weightbearing side of the joint, for combination with distal metatarsal osteotomies to address comorbidities and avoids the sesamoid complex.
Applied Forces During Weightbearing

Following his principle beliefs, Dr. Townley focused on developing an implant for the base of the proximal phalanx as opposed to the metatarsal head due to the applied forces each joint surface is exposed to. Studies show during normal weight bearing, the first metatarsal head is subject to forces up to 119% of patient body weight\(^{[20]}\), compared to relatively minimal forces on the proximal phalanx. Clinical studies have shown in more than 50% of patients with metatarsal head implants, subsidence is seen.\(^{[21]}\) Furthermore, no long term clinical data has been presented involving metatarsal head implants that is equivalent to the long term data available on the BioPro implant. We believe implant subsidence will ultimately prevent metatarsal head implants from providing implant survivorship of 20+ years as the BioPro phalanx based implant has shown.\(^{[22]}\)
**Distal Metatarsal Osteotomies**

The BioPro First MTPJ Hemi Implant surgical procedure can be easily combined with a distal metatarsal osteotomy for correction of any accompanied pathologies. It is widely accepted that distal metatarsal osteotomies, such as the Chevron procedure, are some of the most stable and effective solutions for correction of Hallux Valgus. Additionally, related pathologies such as elevatus, long first metatarsal, and distal metatarsal articular angle can easily be addressed with a distal metatarsal osteotomy, allowing for stable fixation and early patient ambulation. When placing an implant in the metatarsal head, any accompanying osteotomies would need to be performed on the proximal metatarsal, requiring significant non-weight bearing time for the patient.

**Sesamoid Complex**

During normal range of motion, the metatarsal head articulates over the medial and lateral sesamoid. Both sesamoids are embedded within the flexor hallucis brevis, therefore unrestricted motion is necessary for maintenance of normal First MTP Joint motion. Placing an implant on the base of the phalanx leaves the sesamoid complex undisturbed. However, placing an implant on the metatarsal head may result in implant contact with the sesamoids during dorsiflexion. Over time, repeated transitioning between an implant surface and the plantar surface of the metatarsal can lead to cartilage degradation and inflammation, typically referred to as sesamoiditis.[23] This can cause metatarsalgia, pain, reduced function and loss of range of motion.[18,21]
Design Rationale

Dr Townley believed an "implant must simulate the anatomical and functional modalities inherent in a subject joint". When designing the BioPro First MTPJ Hemi Implant, he stayed true to these beliefs. Since he first designed and implanted it in 1952, the BioPro First MTPJ Hemi Implant design has changed very little, though the last 20+ years have been spent expanding the product line and perfecting the design. The articular surface of the implant is oval shaped and slightly concave, similar to the natural anatomy of the First MTP joint. Additionally, the implant is extremely thin, allowing for minimal bone resection from the base of the proximal phalanx, to preserve the natural anatomy. The implant stem includes angled barbs for intramedullary fixation while the diamond shape prevents rotation.

Low Profile Stem

The diamond shaped stem on the First MTPJ Hemi Implant is less than 3mm thick in the center and includes serrated teeth to provide intramedullary stability. This low profile stem, combined with our compression broaching technique assists in bone preservation. The broaching procedure does not remove any intramedullary bone, only compresses it to accommodate the implant stem, again maintaining maximum natural bone stock.
Minimal Bone Resection Design

The BioPro First MTPJ Hemi Implant is a low profile implant, approximately 2mm thick. This allows for a minimal bone removal technique that helps preserve the maximum amount of the patient’s natural bone stock. Additionally, this minimal resection technique helps preserve the attachment of the flexor hallucis brevis, which typically attaches to the base of the proximal phalanx approximately 6 to 8mm from the base. Preservation of the flexor brevis is extremely important for normal foot function, essential for plantar flexion and toe off. BioPro's recommended technique suggests resecting approximately double the thickness of the implant (4mm) for decompression. This leaves the brevis attachment undisturbed. Thicker implant designs may require resection beyond the brevis attachment, affecting the patient’s ability to stabilize the hallux.
Porous Coated and Non-Porous Coated Implants

Townley’s original design was a non-porous coated press fit implant which proved extremely successful in multiple clinical studies. We still offer this same design, along with a version that incorporates porous coating on the back of the implant surface and a portion of the stem. The non-porous coated implant maintains its successful track record and is recommended for patients with solid, supportive bone stock. For patients with soft or suspect bone stock, the porous coated implant offers more stability along with an ingrowth surface for the phalanx to integrate into the implant.

Implant Sizing

The original implant, first used in 1952, was only available in three sizes. To assist in accommodating a wider variety of patient anatomy while ensuring proper phalanx coverage, the BioPro First MTPJ Hemi Implant is now provided in five standard sizes. These range from a small implant that is 17mm wide to a large that is 23mm wide. The implant thickness is consistent between all sizes while the stem width and length increases incrementally with implant size.
Cobalt Chrome vs Titanium

Dr. Townley used cobalt chrome as his material of choice for the BioPro First MTPJ Hemi Implant for multiple reasons. First, cobalt chrome has a proven record of excellent biocompatibility. Second, it is an extremely hard alloy, allowing it to be polished to a very smooth final surface for excellent articulation against the metatarsal head. BioPro currently uses the same cobalt chrome alloy today, however cobalt does contain a small amount of nickel. Though rare, a small segment of patients have a nickel allergy. For those patients we offer the implant in titanium, which is nickel free.

If you’re unsure about a patient’s potential metal allergy, BioPro recommends the MELISA blood test, one of the few accurate methods to determine a metal allergy. For more information visit www.melisatest.com.
HemiEDGE™ Design

Adding to the extensive options within the successful BioPro First MTPJ Hemi Implant family comes a whole new approach to implants. The HemiEDGE™ implant incorporates an overlapping edge, which extends around the medial, lateral, and dorsal aspects of the implant. Partially encompassing the cortex of the phalanx ensures more accurate replication of natural joint surface sizing, improves implant stability and reduces the potential of bony overgrowth. Like the standard implant, it is available in 5 sizes. Refer to the BioPro surgical technique for proper procedure instructions.

Lesser MTPJ Hemi Implant

Rounding out the BioPro Hemi Implant System is a product offering for the Lesser MTP Joints. The Lesser MTPJ Hemi Implant is based on the clinically successful design of the First MTPJ Hemi Implant, but designed to accommodate the anatomy of the smaller joints in digits two through five. Available in nine standard sizes, the Lesser MTPJ Implant has a round profile and a narrower, shorter stem. A cannulated version is also available for use in conjunction with hammertoe corrections. Applications for the implant include osteoarthritis and Frieberg’s Infraction.
The BioPro Hemi Implant product offering gives surgeons a total of 43 different Hemi Implant options, allowing the flexibility to fit their patient with the perfect implant for their condition.

Our Hemi Toe Implants are simple to implant, remove the minimum amount of bone possible, and preserve the natural anatomy of the First MTP joint. For many patients, they are an excellent alternative to fusion, offering pain relief and restored range of motion.
BioPro Hemi Implant Studies


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3. Giza E, Sullivan MR. First Metatarsophalangeal Hemiarthroplasty for Grade III and IV Hallux Rigidus Techniques in Foot and Ankle Surgery 4(1):10-17,2005


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