

A New Design 1st MTP Hemi Implant for the Treatment of Hallux Limitus/Rigidus

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Background

Hallux limitus, hallux rigidus, arthritic changes, and post traumatic 1st MTP injuries are a common problem. Journal articles regarding this pathology are ongoing, encompassing statistics, varied treatment plans, and outcomes. This paper will present a newly designed 1st MTP hemi implant for the treatment of stages 2, 3, and in some cases stage 4 hallux limitus/rigidus and how it can reduce potential malformations with current market implants.



Figure: Hallux limitus/rigidus stages

There are a variety of surgical options for this pathology with the two most popular being 1st MTP implant surgery and arthrodesis. Each may work well in a particular surgeon's hands and both can present complications. The primary goal of both procedures is relief of pain. There are also two schools of surgical philosophies. Those who are satisfied with absence of joint motion, i.e. fusion, and those who desire to maintain joint motion, i.e. implant surgery. There is a great deal of literature describing possible complications with all surgical choices.

This paper will center on current hemi implants with possible complications versus the new BioPro HemiEdge® 1st MTP Implant and how these issues can be reduced or eliminated.

Hemi implant surgery is a relatively easy procedure (may be combined with adjunctive procedures if required) but variable outcomes differ with different surgeons along with patients follow up and adherence to post-operative protocols. The basic design of phalangeal based hemi implants has not changed in over 60 years. The articulating surfaces are basically the same in all implants with variances in stem design, thickness, and angulation. Potential issues may be related to surgical technique (different surgeons achieve different results), implant sizing and/or placement, implant deviation or telescoping, and bone overgrowth reducing the functionality of the joint.



Figure: various complications with current implants

Objective

The BioPro HemiEdge® 1st MTP Implant was designed to address these potential issues and help afford the patient a longer functional joint life.



The HemiEdge® implant has been in use during the trial phase since 2011. From 2011 to 2014, nine implants have been inserted.

The first three patients received the initial design with modifications in technique and instrumentation. The technique and design were subsequently changed and the remaining six patients present with the current BioPro HemiEdge® design.

Method

As an initial study and review, there are a limited number of patients, however much greater numbers and in depth reviews and analysis will be forthcoming proportional to the amount of implants used and length of time. For this paper, basic information was gathered and is presented. Of the six patients with the current BioPro HemiEdge®, four accepted the invitation for the review and analysis. All of the patients were 2 ½ - 3 years post-surgery. This survey included simple subjective questions, review of pre-op and current x-rays, objective x-ray parameters, and 1st MTP functionality.

Results

A modified version of ACFAS Universal Evaluation questionnaire was used. Results of four patients:

Subjective Findings: all patients were asked:

1. Over the past month, how much has your foot pain limited your daily activities? All answered, "I have no pain with normal activities."
2. How would you rate the appearance of your big toe joint? All answered, "I like it very much."
3. How frequently do you have pain while wearing shoes? All answered, "I am able to continuously wear any type of shoe."

Objective Findings:

1. All patients had HAA of 0-20°
2. All patients had an IMA of 0-10°
3. Three patients had a normal declination angle, one abnormal
4. One patient had an elevatus which required a Youngswick procedure

Functionality: Hallux Purchase (Paper Pullout Test)

1. Three of the four patients scored, "Non-moveable." One patient scored, "Easy." It should be noted that this patient stated he did not follow the required post-op protocol.

Range of Motion:



1. Patient #1 - 45-59°
2. Patient #2 - 45-59°
3. Patient #3 - 45-59°
4. Patient #4 - < 36°

The patients were then asked:

1. Would you have the surgery again? All responded yes.
2. Would you refer a friend for the surgery? All responded yes.

The BioPro HemiEdge® 1st MTP Implant maintains the successful long standing articulation and stem design. The design change incorporates an “edge” extending dorsally, medially, and laterally around 60% of the implant with no change plantarly to allow for the FHB pathway. The dorsal edge incorporates two windows or portals to view proper implant seating at the bone/implant interface. With this unique design, the BioPro HemiEdge® 1st MTP Implant helps reduce or eliminate the following potential complications:

1. Abnormal placement or insertion. The Edge on the implant ensures it can only be inserted in the proper orientation, avoiding angled insertions.
2. Abnormal implant size selection. Improperly sized implants will not fit properly.
3. Elimination of shift or deviation. The Edge assists in maintaining proper position and stabilizing the implant.

4. Compression or telescoping of the implant into the phalanx. The implant is larger than the peripheral cortices to maintain implant stability.
5. Abnormal bone overgrowth or impingement. The BioPro HemiEdge® encompasses the dorsal, medial, and lateral sides of the proximal phalanx assisting in reducing or eliminating bone overgrowth.



HemiEdge®



HemiEdge® with Youngswick Procedure

Summary

In summary, the BioPro HemiEdge® 1st MTP Implant is a design update to an implant design used for over 60 years. The implant is designed to address potential problems while maintaining the current instrumentation and implantation techniques. One more procedural step is required with the addition of the HemiEdge® sizers. 1st MTP implant surgery for hallux limitus/rigidus is an easy surgical procedure with quick healing (absence of adjunctive procedures). It provides a great

choice for all patients wishing to maintain joint motion. The implant is recommended for patients 50 years and older as clinical literature has shown higher success rates in patients above 50 years. However, the study author has successfully used the implant on patients 35 years and older and recommends surgeon discretion for implant use in younger patients. All patients should follow recommended post-operative protocol per their physician or recommendations as written in BioPro pamphlets.

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