

# The Vilex<sup>®</sup> Hemi-Implant: A Retrospective Analysis of 30 Patients in the Treatment of Hallux Rigidus

by David M. Davidson, DPM<sup>1</sup>✉, Kenneth T. Goldstein, DPM<sup>2</sup>, James D. Yakei, DPM<sup>3</sup>

The Foot and Ankle Online Journal 2 (10): 3

**Background:** Multiple surgical procedures have been described for the correction of hallux limitus deformity. A review of the Vilex<sup>®</sup> hemi-implant procedure for the surgical treatment of hallux limitus is presented. Clinical outcome and patient satisfaction in 30 patients is reviewed. In addition, a review of the pathophysiology and clinical evaluation of hallux limitus is also discussed.

**Methods:** The authors reviewed, retrospectively, 30 random cases of patients who failed conservative treatment and underwent a 1<sup>st</sup> metatarsophalangeal joint implant/arthroplasty using the Vilex<sup>®</sup> hemi-implant. This implant appears to limit some of the more common complications of implant arthroplasty including, but not limited to subluxation, pain and recurrence of deformity. Patients were chosen randomly after at least 12 months elapsed after surgery. Each patient was provided a questionnaire that asked why they chose to have the procedure and also if their symptoms were improved or eliminated after the procedure.

**Results:** The vast majority of patients were satisfied with the surgical results. Most were able to return to normal shoes and were able to return to activities with significantly less pain.

**Discussion:** This study represents a one-year clinical evaluation of patients who underwent surgery for symptomatic hallux rigidus using the Vilex<sup>®</sup> hemi implant technique. In this group of individuals, the outcome measures were good. The majority of patients reported they would undergo the procedure again.

**Key Words:** Hallux rigidus, hemi-implant, first metatarsophalangeal joint mobility, satisfaction

Accepted: August, 2009

Published: October, 2009

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In 1887, Davis-Colley<sup>1</sup> termed the phrase hallux limitus. Soon after, Cotterill<sup>2</sup> coined the term hallux rigidus.

Hallux rigidus, or degenerative joint disease of the first metatarsophalangeal joint (1<sup>st</sup> MPJ), is a deterioration of the joint<sup>3</sup> and subsequent ankylosis. This may cause absence of joint motion, resulting in pain and deformity. Numerous etiologies have been attributed to the degenerative process of hallux rigidus, which include elongated first metatarsal<sup>3,4</sup> first ray hypermobility<sup>5,6</sup> metatarsus primus elevatus<sup>7</sup>, osteochondritis dissecans<sup>8</sup>, and trauma.<sup>9</sup> Conservative techniques such as orthotics, shoe modifications, and steroid injections can be successful in eliminating some pain. If conservative treatment modalities fail, surgical intervention may be necessary.

**Address correspondence to:** David M. Davidson, DPM  
Email: [ddavidsonaapsm.org](mailto:ddavidsonaapsm.org)  
3980 Sheridan Drive, Amherst, NY 14226  
Phone (716) 839-3930, Fax: (716) 839-2667

<sup>1</sup> 3980 Sheridan Drive, Amherst, NY 14226

<sup>2</sup> 3980 Sheridan Drive, Amherst, NY 14226

Phone: (716) 839-3930, Fax: (716) 839-2667

<sup>3</sup> 36 S. 18th Ave., Ste. H, Brighton, CO 80601

Phone: (303) 659-5950, Fax: (303) 654-0948

**Interest Disclosure:** The authors have no financial relationship or conflicts of interest with Vilex<sup>®</sup>, Inc. other than occasional speaking engagements.

Multiple orthopedic and podiatric surgical procedures have been described in the literature to address hallux rigidus including joint preservation techniques<sup>10-14</sup>, and joint destructive procedures.<sup>15,16,17</sup> The choice of a procedure should be based on the degree of pain, range of motion, activity level of the patient, and surgeon's preference. Implant arthroplasty is one of many joint destructive techniques to address hallux rigidus. There are certainly many choices available to the surgeon when considering joint replacement. These include the total, hinged silastic implant with grommets, a hemi-silastic implant, a total, two-piece, cobalt chrome implant as well as many variations of a hemi-cobalt chrome implant.

Generally, FDA implanting protocol calls for "cementing" an implant into the phalanx. In over five years of experience and over 200 surgeries performed with the Vilex® CHI, the authors have not found a need for cementing nor have they encountered a dislocated or a loosening of the CHI implant.

## Materials and Methods

The authors reviewed, retrospectively, 30 random cases of patients who failed conservative treatment and underwent a 1<sup>st</sup> MPJ implant/arthroplasty using the Vilex® hemi-implant. Patients were chosen randomly after at least 12 months elapsed after surgery. Each patient was provided a questionnaire that asked why they chose to have the procedure and also if their symptoms were improved or eliminated after the procedure.

## Clinical Findings of Hallux Limitus

The most common finding is the gradual onset of pain and limitation of motion in the 1<sup>st</sup> MPJ. Clinical examination reveals an enlargement of the 1<sup>st</sup> MPJ dorsally and/or dorsomedially. Palpation of the joint may elicit pain. Early in the process, there may be muscle spasm of the extensor hallucis longus (EHL) tendon.<sup>18</sup> There is typically very limited range of motion (ROM), which may be painful, with or without crepitus.

Plantar flexion range of motion is usually normal. The hallux may be in a fixed plantarflexed position with the interphalangeal joint (IPJ) in a hyperextended position with keratoses. Soft tissue swelling may be present. If arthritic changes extend into the sesamoid apparatus, the sesamoids may also be tender.

## Radiographic Findings

Radiographic changes include first metatarsal head flattening, non-uniform joint space narrowing, osteophytic changes about the first metatarsal head and base of the proximal phalanx, subchondral cysts, and subchondral sclerosis. Metatarsus primus elevatus may be visualized and the proximal phalanx can be positioned plantar to the head of the 1<sup>st</sup> metatarsal. Regnaud<sup>19</sup> proposed a classification system from developing ankylosis to end stage joint disease:

### Grade I:

Functional limitation of first metatarsophalangeal joint dorsiflexion, hallux equinus/flexus, plantar subluxation of the proximal phalanx on the first metatarsal head, metatarsus primus elevatus, functional dorsiflexion of the first metatarsal with weight bearing, no radiographic degenerative changes, hyperextension of the hallux IPJ, or pronatory architecture.

### Grade II:

Flattening of the first metatarsal head, osteochondral defect of first metatarsal head, cartilage fibrillation and erosion, pain on end ROM, passive ROM may be limited, mild dorsal prominence, subchondral eburnation, peri-articular lipping of the proximal phalanx, first metatarsal head, and sesamoids.

### Grade III:

Severe flattening of first metatarsal head, osteophyte formation, especially dorsally; asymmetric narrowing of joint space, articular degeneration, erosions, crepitus, subchondral cyst formation, pain on full ROM, associated inflammatory flares.

**Grade IV:**

Obliteration of the joint space, exuberant osteophytosis with loose bodies, less than 10 degrees of ROM, deformity and/or mal-alignment; possible ankylosis and inflammatory flares, local pain as a result of skin irritation or bursitis secondary to underlying osteophytes. Coughlin and Shurnas<sup>20</sup> described a more complete classification system using the amount of dorsiflexion, radiographic changes, and clinical findings:

**Grade 0:**

Forty to 60 degrees of dorsiflexion and/or 10-20% loss compared to the normal side. No radiographic changes; no pain with only stiffness and loss of motion.

**Grade I:**

Thirty to 40 degrees of dorsiflexion and/or 20-50% loss compared to the normal side; dorsal osteophyte formation is the main finding with minimal joint space narrowing, peri-articular sclerosis, and minimal plantarflexion.

**Grade 2:**

Ten to 30 degrees of dorsiflexion and/or 50-75% loss compared to the normal side; diffuse osteophyte formation radiographically, with some flattening of the metatarsal head; with more narrowing and more than 1/4 of the dorsal joint space involved and with the sesamoids typically not involved. Clinically, moderate to severe pain and stiffness, and pain occurs just prior to maximum dorsiflexion and plantarflexion.

**Grade 3:**

Less than 10 degrees of dorsiflexion and/or 75-100% loss compared with the normal side, notable loss of metatarso-phalangeal plantarflexion; radiographic changes are the same as Grade 2 with more narrowing and more than 1/4 of the dorsal joint space involved. The sesamoids are either enlarged, cystic, irregular or a combination of all three. Clinically, the pain is more constant and there is significant stiffness at the extremes of range of motion.

**Grade 4:**

This is the same as Grade 3, from a dorsiflexion and radiographic standpoint. Clinically, there is definite pain at mid-range during passive motion.

**Surgical Procedure**

A curvo-linear incision is placed on the dorso-medial aspect of the 1<sup>st</sup> MPJ. Through the same incision, a linear, longitudinal capsulotomy is performed. The capsule is dissected from the head of the metatarsal and base of the proximal phalanx allowing adequate visualization of the MTP. The medial eminence, along with any hypertrophic bone growth and osteophytes, are resected. The base of the proximal phalanx is carefully freed of soft tissue attachments in order to protect the insertion of all intrinsic musculature. Approximately 4-5 mm of bone is then resected from the base, with an osteotomy performed perpendicular to the longitudinal axis of the shaft. The amount of bone removed is twice the thickness of the Vilex® implant to allow adequate decompression of the MPJ joint.

After placing an appropriate sizer over the new end of the proximal phalanx, a guide wire is inserted in the center hole and driven into the bone, making sure the wire is parallel to the long axis of the phalanx and centered therein. The desired implant size is determined by sliding a cannulated sizer over the guide wire. The sizer should sit flush with the resected surface, on the perimeter and not within it. The sizer is removed and the appropriate implant is *screwed* into the proximal phalanx and the guide wire is removed. (Fig. 1) The implant should be examined in order to ensure that it is flush with the bone. (Fig. 2)

The Vilex® hemi implant procedure allows the surgeon to assess the eventual position the implant before inserting the implant itself. In addition, the implant is screwed into the phalanx without drilling or broaching.



**Figure 1** Implant inserted into proximal phalanx over K-wire.

After a flush with a combination antibiotic/saline solution, the capsule is approximated with 3-0 Monocryl; the subcutaneous tissue is approximated with 4-0 Monocryl and the skin is closed to surgeon's preference. The surgical site is dressed with sterile compressive dressings.

Postoperatively, the patient is allowed to weight-bear immediately, in a typical, postoperative shoe. Sutures are removed in 10-14 days and most patients are referred to physical therapy for early, range of motion exercises. We have found that when patients ambulate to tolerance and motion exercises are instituted early in the postoperative period, patients respond more favorably.

## Results

The patients ranged in age between 40 – 78 years of age and all patients in this study were classified, based on their clinical history, having no major, systemic, medical problems (Table 1) Pre-operatively, 60% were performing moderate to significant exercise programs, 88% related moderate to severe pain that limited their activities, 80% were restricted in the types of shoes they could wear and only 39% did not like the way their foot looked. (Table 2)



**Figure 2** Implant correctly positioned into proximal phalanx.

Post-operatively, 80% related no or slight discomfort, 92% could participate in almost all activities without problems, 100% stated they could wear orthopedic, casual and/or any type of shoe, the majority of the time, only 22% did not like how their foot looked post-operatively, 80% felt they had more motion than pre-operatively and 77% of the patients were pleased with the outcome of the procedure. (Table 3) Of those not pleased, some were still having joint discomfort and some thought it took longer than they expected to recover.

## Discussion

This study represents a one year, clinical evaluation of patients who underwent surgery for symptomatic hallux rigidus using the Vilex® hemi implant technique. In this group of individuals, the outcome measures were good. The majority of patients reported they would undergo the procedure again.

There should be no question that with all patients who present with symptoms due to hallux limitus or hallux rigidus, all methods of conservative care should be exhausted before entertaining thoughts of surgical intervention. A joint destructive technique of any kind should never be presented to the patient as “*restoration of the original*” or “*as good as new*”.

Age	40-49	50-59	60-60	70+
Number of Patients	4	13	10	3
%	13%	43%	33%	10%
General Health	No Systemic Arthritic Conditions			

**Table 1** Hallux rigidus implant pre-operative evaluation.

Implant Results	Pre-Op	Post-Op
No Pain	0	11
Occasional Pain	3	15
Moderate/Severe Pain & Limited Activities	23	4
Acceptable appearance	16	26
Not Acceptable Appearance	10	2
Can Participate in All Activities	6	13
Can Participate in Most Activities	12	15
Limited/No Activity	8	2
Can Wear Any Shoe	5	28
Could Not Wear Dress Shoes	15	0
Moderate Pain/Limiting Activities	6	0
Only Athletic/Special Shoes	4	2

**Table 2** Implant results before and after surgery for patient group.

The goal should be limited to pain reduction and joint flexibility as opposed to arthrodesis. Steroid injection, anti-inflammatories, physical therapy and/or biomechanical (functional or accommodative) therapy are all possible choices of care. Once it is determined that a joint destructive technique would be beneficial, we have found that the Vilex® hemi-implant is a very useful procedure. The Vilex® Cannulated Hemi Implant (CHI) offers numerous advantages, some but not all are shared by others:

**Material** - With Vilex®, the surgeon has the option to use either titanium or cobalt-chrome with titanium backing. The titanium is lighter in weight than cobalt-chrome implants. In addition, titanium does not contain nickel, thereby avoiding the potential of allergic reaction to nickel present in cobalt-chrome. Also, the titanium is less likely to distort magnetic resonance imaging (MRI) should the patient need MRI scanning in the future.

Patient Response	Range of Motion	Overall Outcome
Improved/ Pleased	17	22
Unchanged/ Not Pleased	8	6
Less/Uncertain	5	2

**Table 3** Hallux rigidus implant postoperative evaluation.

**Low Profile** - The articular surface is elliptical in shape and its thickness ranges from 1.5 to 2.0 mm. In resecting the base of the proximal phalanx, the surgeon needs to remove between 3-4 mm of bone to provide room for the implant and to decompress the 1<sup>st</sup> MPJ. This is a major advantage to the patient because the minimal resection preserves the intrinsic structure of the joint and preserves the toe both functionally and cosmetically. In addition, it retains the option for the surgeon to perform arthrodesis or a Keller arthroplasty should the implant fail.

**Cannulation** - The fact that the implant is cannulated enables the implant to be placed optimally. After inserting a 1.6 mm guide wire, the surgeon can assess the position, orientation of the implant, and the accuracy of the cut. The surgeon can correct any error by simply relocating the guide wire. Once the wire is placed, the surgeon can visualize the final position of the implant through a simple test.

**Screw Shaft** - The implant shaft is essentially a cannulated screw with tight thread pitch and very generous major to minor diameter ratio. The three screw tips are hand-sharpened so that implanting the implant does not require drilling or tapping. The CHI is the only hemi-implant on the market with this type of shaft.

The majority of patients in this study did have significant improvement in symptoms. We have noted excellent results with substantial reduction in pain and an increase in the range of motion of the 1<sup>st</sup> MPJ.

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