# Pain Relief and Functional Improvement With Metatarsal Resurfacing In Hallux Rigidus

## Preliminary Results In a Multicenter Case Series With A Surgical Alternative To Joint Fusion

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## Abstract

**Background:** First metatarsophalangeal joint degeneration is a common problem leading to esthetical shortcomings, functional limitations, and severe pain in many patients. Surgical treatment options, in particular in the late stage disease process, have been limited and provided mixed results. A novel, anatomic, metatarsal sided resurfacing technology has been recently introduced to the market that allows for intraoperative 3-dimensional mapping of the joint surface geometry and placement of a matching implant. The objective of this investigation is to quantify the effectiveness of the HemiCAP® contoured articular prosthesis in the management of pain and restoration of joint function.

**Materials and Methods:** Between February 2005 and November 2006, 86 patients with 97 implants underwent metatarsal head resurfacing at four participating institutions. Eleven patients had bilateral implants. Twenty-one patients were male, sixty-five female. The mean age at the time of surgery was 57 years (range 30-74). The mean follow-up was eight months (range 1-20). A population subset allowed for pain and AOFAS scores calculation at baseline and last follow-up. 90% (n=87) had a 15mm diameter implant and 10% (n=10) a 12mm implant.

**Results:** The mean preoperative AOFAS score improved by 64% from 49.1 (range 27-69) to 80.4 (range 44-95, n=35) at last follow-up; the average baseline pain score improved by 83% from 7.5 (range 2-10) to 1.3 (range 0-7, n=81); passive dorsiflexion improved by 104% from 26 degrees (range: 0-60) before surgery to 53 degrees (range: 25-90, n=97) at the most recent follow-up. The average duration of device implantation (excluding cases with concurrent procedures) was 40 minutes. The most frequent concomitant procedure was correctional proximal phalangeal osteotomy in more than half of the cases. Ninety-four percent of the patients reported very good to excellent results at last follow-up. No device revisions have been performed to date.

**Conclusion:** Intraoperative mapping of the joint surface geometry permits an anatomic restoration of the metatarsal head. The HemiCAP® system is a joint preserving procedure with minimal removal of bone stock and preservation of healthy cartilage. The surgical technique is reproducible and has a short learning curve. Preliminary results demonstrate excellent pain relief and functional improvement while avoiding end stage joint fusion.

**Level of Evidence:** Therapeutic study, Level IV (case series).

*No significant payments have been made to investigators or institutions in support of this study.*

## Introduction

As part of a novel clinical treatment strategy in the management of pain, preservation of motion and functional improvement of the first metatarsophalangeal (MTP) joint, a new metatarsal (MT) sided resurfacing system has been introduced to the market in February 2005: The HemiCAP® contoured articular prosthesis and instrumentation set (Arthrosurface®, Franklin, MA), allows for joint reconstruction in advanced degenerative disease (Hallux Rigidus/Limitus), posttraumatic arthritis, or angular deformities in the forefoot which result in first MTP joint degeneration. Primary indication for metatarsal HemiCAP® resurfacing is Hallux Rigidus, a diagnostic term used to describe degenerative arthritis of the first metatarsophalangeal joint. Early stage symptoms are amenable to conservative measures; however, surgical intervention becomes necessary as articular cartilage loss progresses, loss of joint space and periarticular osteophytes develop, negatively impacting an increasingly painful range of motion.

## Treatment Options

Cheilectomy, interpositional arthroplasty, exisional arthroplasty, phalangeal and first metatarsal osteotomies, conventional implant arthroplasty and arthrodesis have been described with varying success rates. Cheilectomy is typically utilized in the earlier spectrum of the disease process, versus conventional arthroplasty and arthrodesis which are employed in late stage and salvage procedures. The HemiCAP® technology provides instrumentation that allows for real-time, intra-operative 3-dimensional mapping of the surface joint geometry providing curvature offsets in both the dorsal/plantar and medial/lateral planes under direct visualization. This facilitates anatomic reconstruction of a smooth and congruent articular joint surface using a series of asymmetrical off-the-shelf articular components.

## Material And Methods

### *Study Design*

This clinical investigation is a multicenter case series to evaluate initial outcomes of HemiCAP® resurfacing at four participating institutions.

### *Patient Population*

Between February 2005 and November 2006, 86 patients (24% male, 76% female) underwent HemiCAP® resurfacing at four participating institutions. Eleven patients underwent bilateral implantation providing a total of 97 cases. The average age at the time of surgery was 57 years (range: 30-74). The mean follow-up was 8 months (range: 1-20). No patients were lost to follow-up (Table 1).

Indication for all operations was intractable pain in the first MTP joint, most frequently combined with limited to lost mobility, that negatively impacted activities of daily living. Patients had previously not responded to conservative measures such as shoe modifications, rigid inserts, non-steroidal anti-inflammatory medications, hyaluronic acid injections or activity modification. Most patients were treated for Hallux Rigidus (91%). 15/97 cases had a previous procedures performed to the first metatarsophalangeal joint (Table 1).

**Table 1: Patient Profile**

| | | |
|---|---|---|
| N: | 86 patients | 97 implants |
| Gender: | 24% male | 76% female |
| Average Age: | 57 years | (range: 30-74) |
| **Indications:** | | |
| Hallux Rigidus/Limitus: | | 91% (n= 88 cases) |
| Hallux Valgus Arthrosis: | | 8 % (n= 6 cases) |
| OCD/Subchondral Cysts: | | 4 % (n= 3 cases) |
| **Surgical History:** | | |
| Cheilectomy: | | 10 % (n= 8 cases) |
| Bunion Surgery: | | 5 % (n= 4 cases) |
| Resection Arthroplasty: | | 4 % (n= 3 cases) |

### *Device Description*

The HemiCAP® contoured articular toe prosthesis consists of two components: a fixation component and a modular articular component, which are connected via a morse taper interlock (Figure 1). The fixation component is a titanium cancellous screw with full-length cannulation. The cobalt chrome articular component is available in 12mm and 15mm diameter sizes for the first MTP joint. Each diameter comes in a variety of incremental offset sizes which correspond to the dorsal/plantar and medial/lateral radius of curvatures at the implant site.

**Figure 1:** HemiCAP® device: Fixation and articular component.

## *Operative Technique*

The review of preoperative radiographs helps to determine the method of individual joint space decompression (Figure 2). In patients with normal or short metatarsal bone length and normal phalangeal angulation, intra-articular joint decompression can be achieved by slightly advancing (2mm) the fixation component beyond the normal joint height reference line, while allowing surface reamers to perform the additional resection; it is important to avoid any interference with the sesamoid function. In patients with long MT bones, or phalangeal mal-positioning, an extra-articular metatarsal or phalangeal osteotomy can also achieve the desired decompressing effect.

The procedure is typically performed under a regional block or general anesthesia. In most cases, a standard dorsal longitudinal incision is utilized which is centered over the MTP joint, medial to the extensor hallucis longus tendon, which is retracted to the lateral side. As an alternative, a medial incision over the joint capsule can be used, which might aid in the prevention of possible postoperative extensor tendon adhesions and might help with lateral collateral tendon stability. Following the capsulotomy, the MTP joint is exposed and the articular surfaces are examined (Figure 3).

Debridement of hypertrophic synovial tissue and loose bodies, soft tissue releases, removal of periarticular osteophytes (in particular dorsal bone spurs) and assessment of sesamoid mobility (including release and mobilization to allow for free sesamoid gliding over the prosthesis and improved fulcrum function for flexor tendons), all greatly influence the postoperative outcome and provide utmost benefit to the resurfacing procedure.

Utilizing the drill guide, maximum coverage of the defect is verified and a guide pin is placed perpendicular to the joint surface into the center of the defect under fluoroscopic visualization. Pin placement should be slightly favored towards the dorsal aspect and verified in the lateral fluoroscopic view in order to provide improved coverage on the superior border of the metatarsal head (Figure 4); however, attention has to be paid to avoid pin penetration through the plantar cortex.

The cannulated instrumentation set supports a perpendicular working axis to the joint surface. Great care has to be given to maintain this axis throughout the procedure, due to the long lever-arm of the instrumentation set to prevent exaggerated pin end forces in the metatarsal head and implant bed widening, particularly in the elderly female patient population. After drilling a pilot hole, the fixation component is screwed into place. A high pitched tapered titanium screw provides solid fixation in the majority of cases. Cement can be used in the bone tunnel, if fixation is deemed to be insufficient. A contact probe determines the curvature offsets in two planes (Figure 5). In particular, the largest curvature offset (typically in the dorsal/plantar plane) provides the number for the corresponding reamer used for implant bed preparation. If mapping results in sizes that fall in between available offsets, the smaller (=flatter) reamer should be utilized first. Increased edge recession of the implant is achieved through stepwise use of higher offset reamers, which are available in increments of 0.5mm to prepare for a precise inlay placement into the metatarsal head. The anatomic fit, provided by matching the curves of the HemiCAP® implant to the patient's metatarsal head, facilitates a smooth transition from articular component to the surrounding native tissue during range of motion. A diameter specific sizing trial with corresponding offsets, allows for final verification of proper joint surface/implant fit. As a final step before HemiCAP® device implantation, dorsal osteophyte removal is performed using a rongeur or motorized saw blade. It is important to perform the dorsal osteophyte removal towards the end of the procedure so as to avoid distorting the initial mapping of the joint surface. The final articular component is then properly aligned and impacted to lock the morse taper. Concurrent treatment options, such as correctional osteotomies, are carried out at this point with final verification of range of motion before closing.

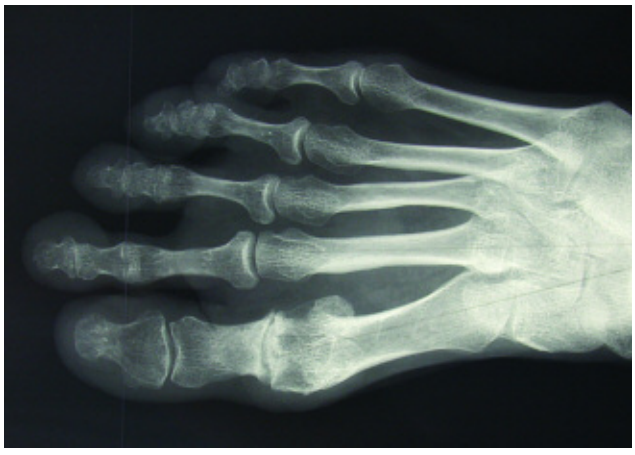


**Figure 2:** Preoperative AP radiograph (patient MC)

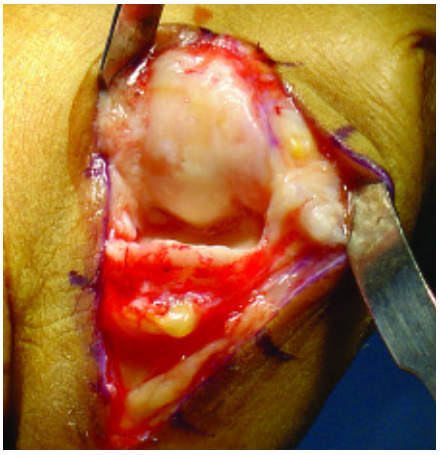


**Figure 3:** Intraoperative view of the first metatarsal head

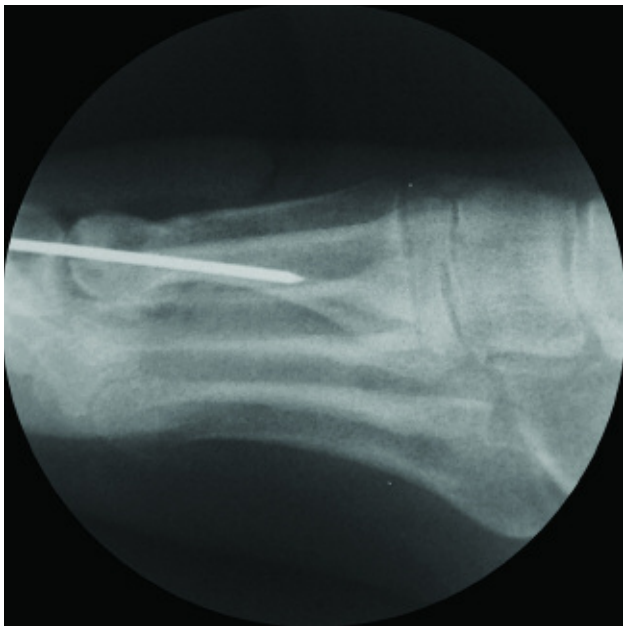


**Figure 4:** Pin placement under fluoroscopic control – lateral view

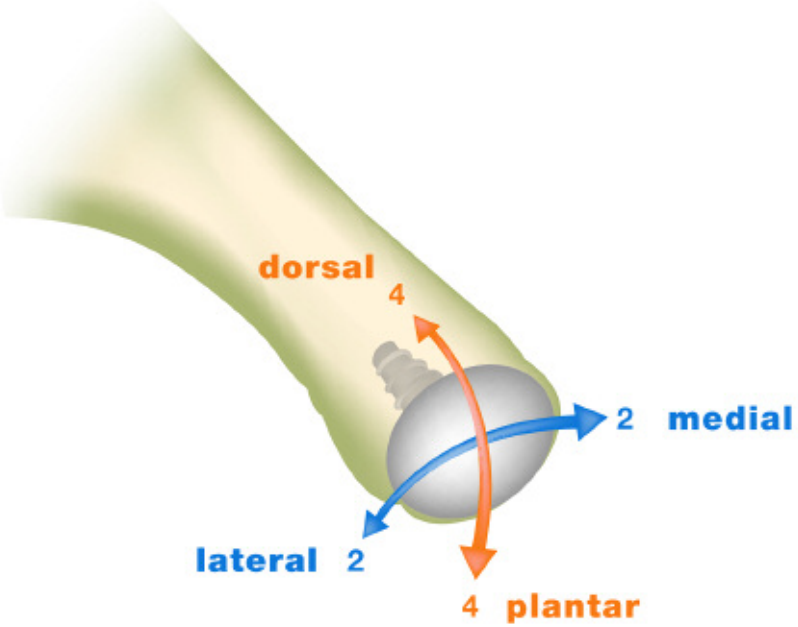



**Figure 5:** Intraoperative 3-dimensional mapping of the surface curvature in dorsal/plantar and medial/lateral planes

**Figure 6:** One year postoperative AP radiograph (patient MC)

## *Radiographic Findings*

Routine radiographs (anteroposterior and lateral views) were performed at all follow-up visits. Postoperative x-rays were reviewed for evidence of radiographic loosening, including radiolucent lines around the fixation component, osteolysis and device migration (Figure 6).

## *Postoperative Care*

Immediate postoperative wound care follows standard procedure. RICE (rest, ice, compression, elevation) instructions are helpful in decreasing postoperative swelling during the first two weeks. Preliminary results have been encouraging for both accelerated and delayed weight-bearing range of motion. Early toe touch weight-bearing followed by progressive full weight-bearing as indicated by symptoms versus delayed weight-bearing motion with four weeks of protected walking boot-orthosis. The walking boot orthosis prevents dorsi- and plantar flexion, however allows for weight-bearing starting at 24 hours after the procedure. Both groups achieved pain free full weight-bearing toe stand three months after surgery in most cases. Early results indicate that accelerated motion may prevent the build up of scar tissue and adhesions which can reduce the amount of functional improvement in some patients. Further studies are required to identify long term benefits of either rehabilitation approach. Normal shoe wear can be typically used within three to four weeks postoperatively.

## Results

### *Intraoperative Review*

In order to effectively cover metatarsal lesions, 90% (n=87) of HemiCAP® implants used in this study had a 15mm diameter and 10% a 12mm (n=10). The average length of operation in cases without any concurrent procedures was 40 minutes. The most frequent concomitant procedure was a correctional proximal phalangeal osteotomy in 67% (n=65), followed by an adjuvant interpositional graft in 17% (n=17) as performed on a more routine basis at one institution. Rare concurrent procedures included Extensor Hallux Longus tendon split and transfer (n=4), metatarsal osteotomy (n=2), excision of a Morton neuroma (n=1), and interphalangeal joint arthrodesis (n=1). Debridement, loose body removal, soft tissue releases, sesamoid mobilization and exostectomies/cheilotomies were performed as indicated in order to maximize the intraoperative gain in range of motion in the first metatarsophalangeal joint.

### *Outcomes Measures*

To date, 35 cases are available with baseline and last follow-up AOFAS scores (0=lowest score, 100=best score): The mean preoperative score improved by 64% from 49.1 (range: 27-69) to 80.4 (range 44-95) at an average follow-up of 12 months (range: 2-20). Assessment of pain (n=81 cases), (0=no pain, 10=extreme pain) revealed an improvement by 83% from 7.5 (range: 2-10) at baseline to 1.3 (range: 0-7) with an average follow-up of 8 months (range: 1-20). Passive dorsiflexion (n=97) improved by 104% from 26 degrees (range: 0-60) at baseline to 53 degrees (Range: 25-90) at last follow-up. Results were rated as “excellent” with none to mild pain and dorsiflexion greater than 50 degrees; as “very good” with none to mild pain and dorsiflexion of 30 to 45 degrees; as “good” with mild to moderate pain and dorsiflexion greater than 45 degrees; as “fair” with moderate to severe pain and dorsiflexion less than 45 degrees. 94% of the results were rated as “very good” to “excellent” (n=77/82 cases); one patient at one month after surgery was rated as “fair” (Table 2).

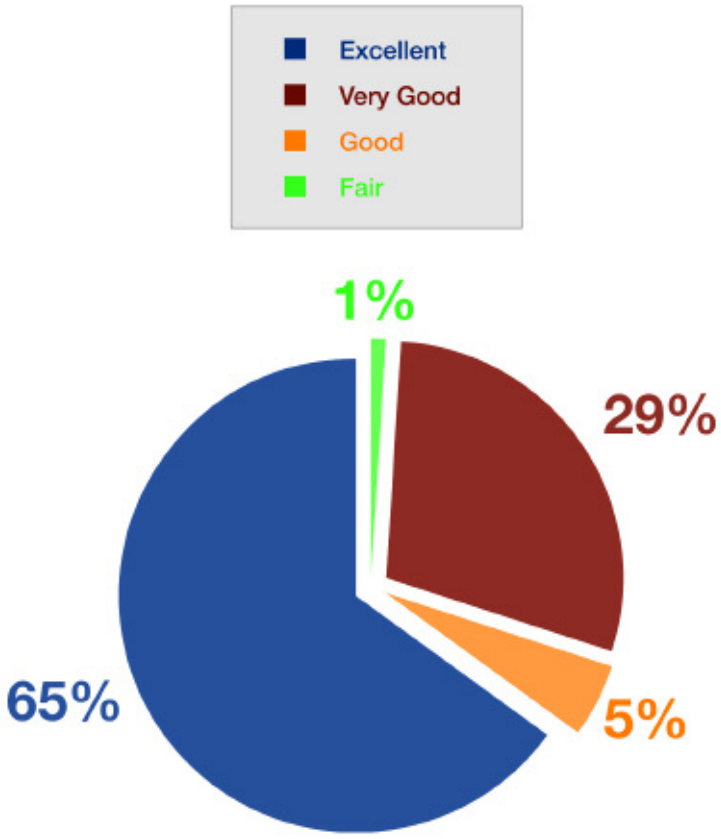
### *Radiographic Review*

Standard anteroposterior and lateral postoperative radiographs have been reviewed for signs of device disengagement, progressive periprosthetic radiolucency and device migration. To date, all x-rays demonstrated solid fixation of both device components.

### *Complications*

No patients had any intraoperative complications. Postoperatively, there were no wound infections, dislocations, or neurological complications. Two patients developed a transient sesamoiditis which later resolved in both cases. One patient

**Table 2: Outcomes Ratings at a Mean Follow-up of 8 Months (n=81 cases)**



developed a late Hallux Valgus deformity which was treated with a phalangeal osteotomy and one patient underwent a secondary procedure for removal of osteotomy hardware. All HemiCAP® implantations performed at participating institutions were free of prosthetic revisions, or device related procedures to date.

## Discussion

Many studies report favorable results with arthrodesis, in particular for patients with end stage Hallux Rigidus with less than 50% of the articular surface remaining. Coughlin et al. describe the procedure with hallux placement in neutral rotation, 15 degrees of valgus, and 20 degrees of dorsiflexion to allow for ambulation in a flat shoe. Nevertheless, these results have to be seen against the background of a salvage treatment option offered to patients in whom surgical intervention was delayed until advanced joint destruction had occurred, clinical symptoms were incapacitating and activities of daily living severely compromised. At this stage, patient concerns were more concentrated on pain relief and expectations could be met with joint fusion especially in light of the limited surgical alternatives. Today, with the option of HemiCAP® resurfacing, many patients find joint fusion with the associated loss of joint mobility unacceptable to gain pain relief and are willing to undergo this new treatment option despite the lack of long term clinical experience.

Surgical alternatives for varying degrees of MTP joint degeneration include cheilectomy, osteotomy, excision arthroplasty, conventional replacement arthroplasty, interposition arthroplasty, and arthrodesis; however, these procedures have limitations, in particular for the more active patients with advanced stage disease: Transfer metatarsalgia, malposition deformity, weakness, non-union, joint shortening and particle wear/synovitis suggest a wide array of potential shortcomings.

HemiCAP® resurfacing of the metatarsal head allows for anatomic reconstruction of the first metatarsal head with an inlay prosthetic device that matches the individual native joint surface geometry. It provides functional improvement and pain relief as a primary indication in degenerative Hallux Rigidus, post-traumatic arthritis, angular deformity based degeneration of the first MTP joint, or as a revision option for failed previous cheilectomies, resection arthroplasties, interpositional arthroplasty and other etiologies and procedures resulting in first MTP arthrosis. Soft tissue contractions must be freed up during the procedure, angular deformities addressed and range of motion must be provided for in the postoperative rehabilitation program. Earlier surgical intervention may offer a successful benefit to avoid soft tissue contractures and allow for faster postoperative mobilization. Effects of technical differences related to the extent of exostectomies, joint decompression, the use of adjuvant interpositional grafting, and postoperative rehabilitation require further investigation to detect differences in postoperative pain relief and functional improvement. Nevertheless, as a group, this HemiCAP® multicenter patient population has demonstrated substantial post-implantation benefits to date. The procedure has become a patient-driven treatment option in a short period of time since it allows for effective pain relief and the avoidance of joint fusion. Furthermore, functional improvement with a significant increase in range of motion has achieved a high level of patient satisfaction. Longer-term follow-up is required in order to establish the effectiveness of the device in the treatment of first metatarsophalangeal joint arthrosis.

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