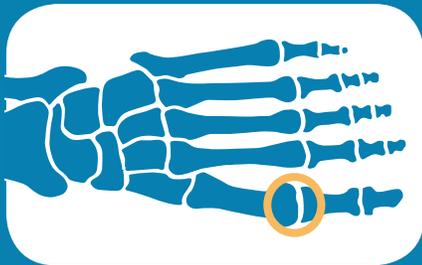


SURGEON SURVEY ON THE TREATMENT OF FIRST TOE ARTHRITIS

A Patient Guide to Surgeons' Experiences



INCLUDES:

- Patient Function and Activity Milestones
- Patient Rehabilitation & Physiotherapy Information
- Treatment Comparisons between Implants and Fusion
- Surgeon Satisfaction Ratings and Recommendations

The survey was sent to a limited number of high volume surgeons, who together had performed more than 1000 procedures with the Toe HemiCAP® and ToeMotion® Systems since 2005. Collectively, they have extensive experience with the ArthroSurface toe products and forefoot surgery. Their responses are based on the surgeons' long term observations and treatment of Hallux Rigidus using the Toe HemiCAP® and ToeMotion® implant systems. The purpose of this surgeon survey was to analyze their experience with ArthroSurface® implants in comparison to fusion procedures and share the results with patients and doctors. Survey participants were compensated for their time to complete the survey and to provide feedback on their experiences.

Combined, Surgeons
Performed
More Than
1000
CASES

.....
An Average Of
10.5 YEARS
Experience
With The HemiCAP®
System

Introduction to Hallux Rigidus

Arthritis at the base of the first toe is the most common form of arthritis in the foot and many patients have symptoms in both toes. This condition is also called Hallux Rigidus or Hallux Limitus. Early stage management consists of non-operative treatments using shoe modifications, pain medication and other modalities or surgery using a cheilectomy procedure which removes the bony bump on the top of the toe. (See Figure 2). Treatment options for later stages are divided into two categories: joint replacement, to maintain toe motion and treat arthritic pain and joint fusion, to remove any motion in the arthritic joint by making it permanently stiff to treat arthritic pain. When the bones in the joint no longer move against each other the motion that caused pain is gone and so is the pain. Both have been extensively described in the scientific literature. Over the last decade, new implant designs have been introduced providing new motion preserving alternatives to fusion.

Keywords

Arthrodesis: Surgical technique to produce permanent stiffness of the joint
Arthroplasty: Joint Replacement
Fusion (same as Arthrodesis): Surgical technique to produce permanent stiffness of the joint
Hallux Rigidus/Hallux Limitus: Joint arthritis at the base of the first toe
Hemiarthroplasty: Joint replacement on one side of the joint
MTP: Metatarso-Phalangeal Joint at the base of the toe
Total Toe Arthroplasty: Joint replacement on both sides of the joint

Joint Replacement Features

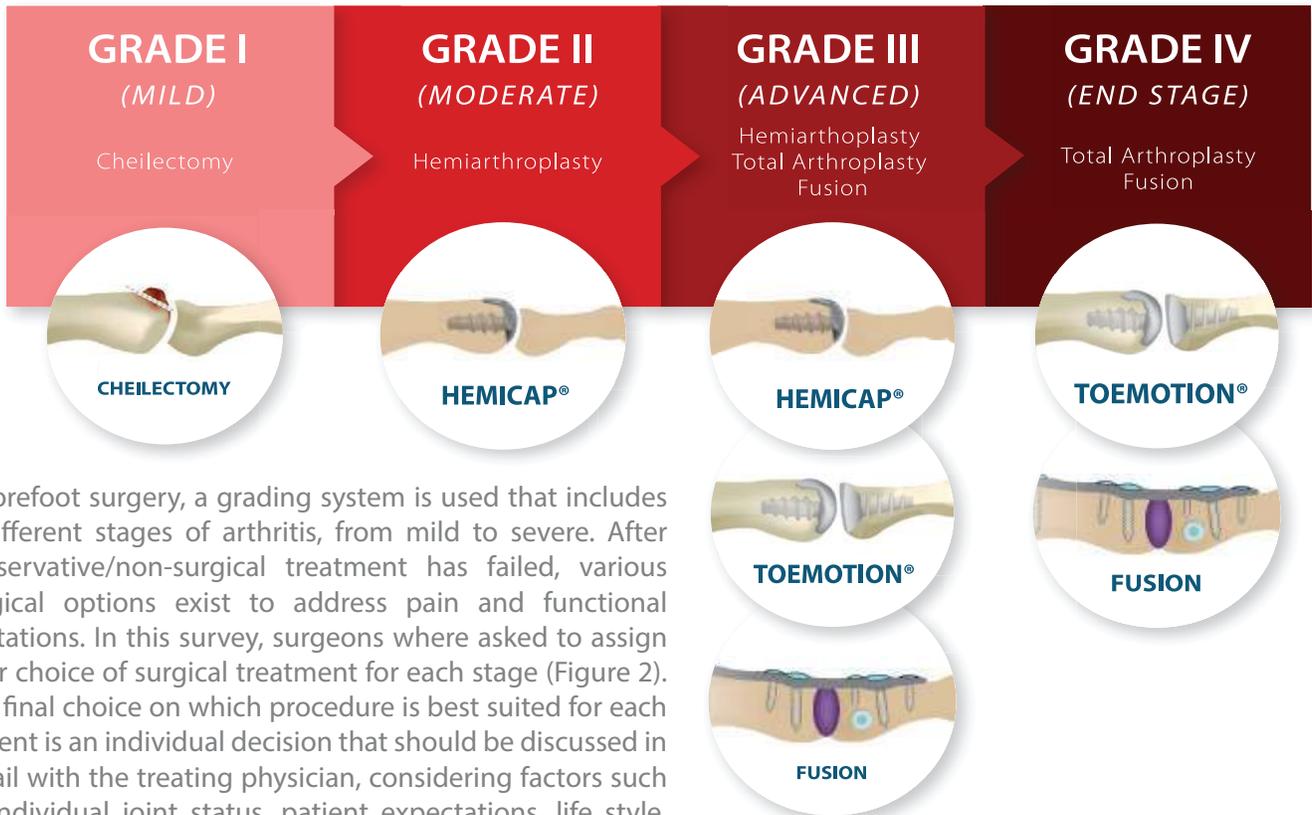
Based on their overall experience, surgeons were asked about the clinical benefits of the Toe HemiCAP® and ToeMotion® Systems. Results according to primary, secondary, and tertiary features are summarized in Figure 1.

Figure 1: Primary Features—selected by 100% of the surgeons.
Secondary Features - selected by the majority of surgeons.
Tertiary Features – mentioned as additional benefits.



Treatment Options for First Toe Arthritis

Figure 2: Stages and Treatment Options for First Toe Arthritis. Early stage, mild arthritis includes non-surgical management or surgical cheilectomy with removal of the bony bump on the top of the toe. More advanced stages are typically treated with joint replacement or fusion procedures.



In forefoot surgery, a grading system is used that includes 4 different stages of arthritis, from mild to severe. After conservative/non-surgical treatment has failed, various surgical options exist to address pain and functional limitations. In this survey, surgeons were asked to assign their choice of surgical treatment for each stage (Figure 2). The final choice on which procedure is best suited for each patient is an individual decision that should be discussed in detail with the treating physician, considering factors such as individual joint status, patient expectations, life style, body habitus, age, surgical history, physical examination, the ability to heal an arthrodesis, or the willingness to undergo a procedure where future surgery might be required.

Procedure and Hospitalization Timelines

Based on their experience, the typical duration of the Toe HemiCAP® and ToeMotion® joint replacement procedure was reported as less than 30 minutes by 50% of the responders or 30-60 minutes by the other half. All surgeons indicated that the procedure is performed on an outpatient basis with a hospital stay for less than 24 hours.

Figure 3: Procedure and Hospital Stay Timelines after Toe HemiCAP® and ToeMotion® joint replacement procedures



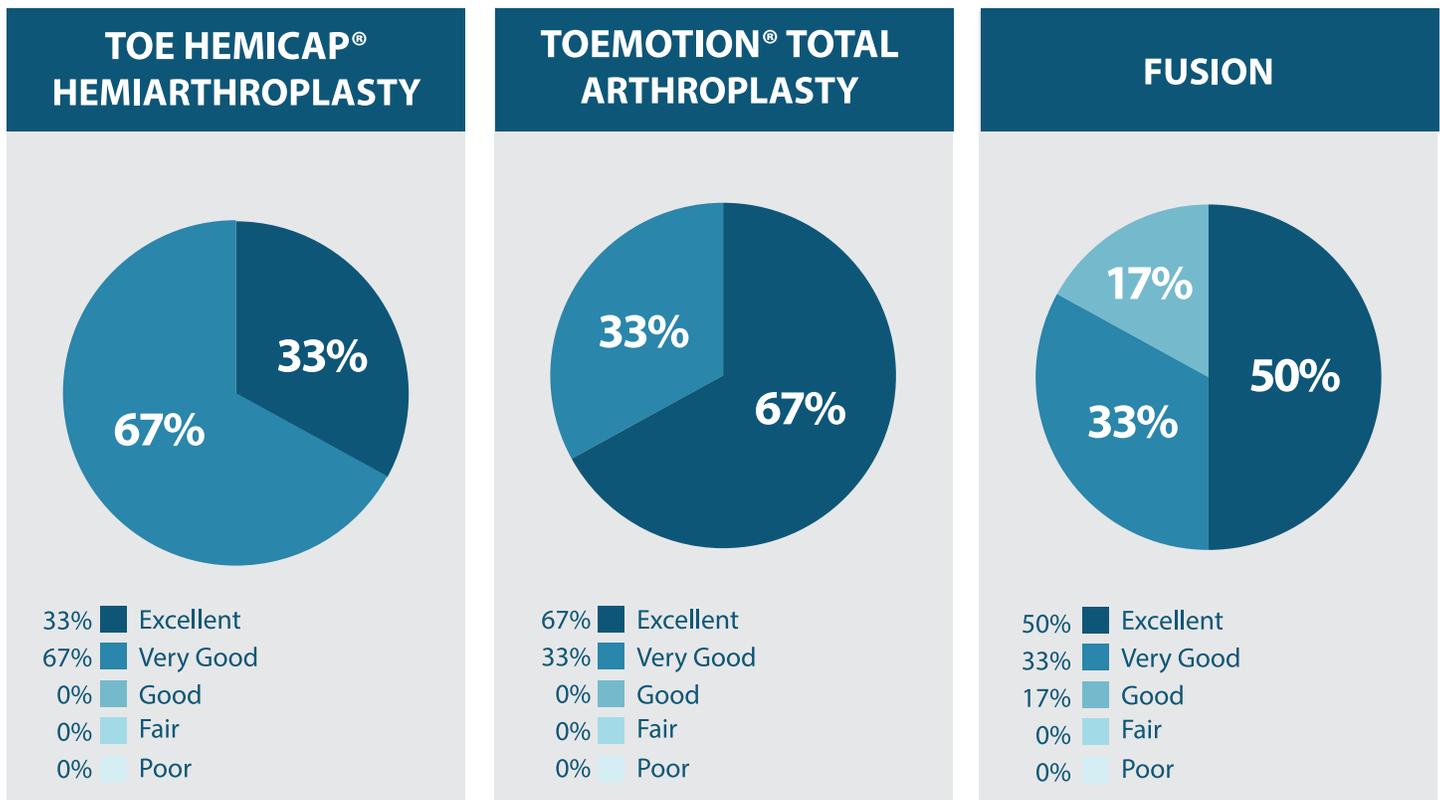
Pain Relief Comparison of Hemiarthroplasty, Total Toe Replacement, and Joint Fusion

Based on the surgeons response, typical pain relief following First Toe joint replacement procedures and fusion are summarized in Figure 4. The highest agreement for an excellent rating was achieved by Total Toe Arthroplasty (67%), followed by fusion (50%). The overall pain relief after Toe HemiCAP® or ToeMotion® total toe arthroplasty was rated from very good to excellent, whereas fusion was rated from good to excellent.

Figure 4: Post Operative Pain Relief Ratings

Surgeons were asked to rate pain relief in the first 6-12 months after surgery for three different procedures including hemiarthroplasty, total toe replacement and joint fusion. Answers for joint replacement procedures were specific to the Toe HemiCAP® System, whereas fusion ratings were non-specific and based on various fusion techniques.

Post Operative Pain Relief Ratings



Toe HemiCAP®
Hemiarthroplasty
Implant System



ToeMotion®
Total Toe
Implant System



CheckMATE®
Fusion Plate
System



CheckMATE®
Fusion Plate
System



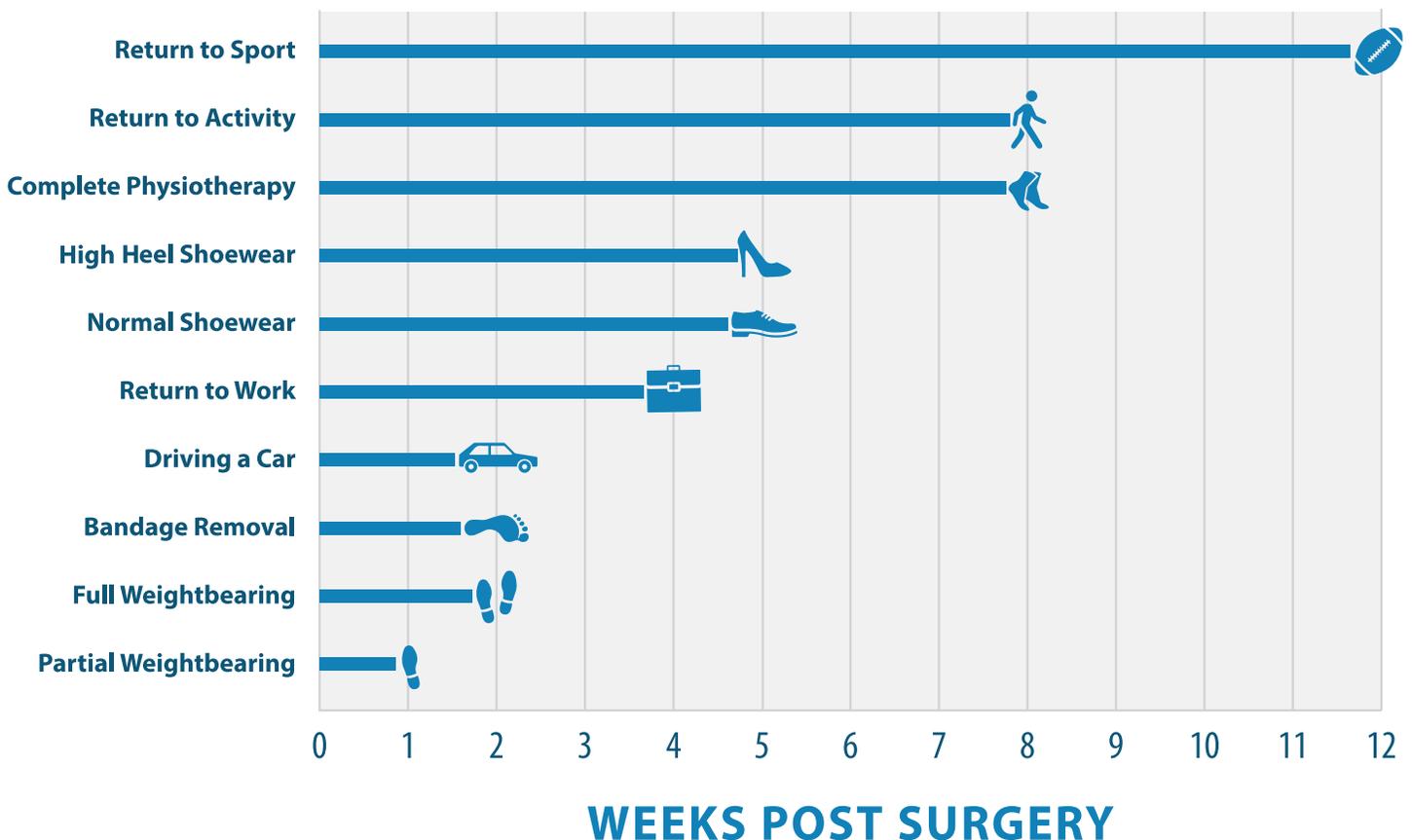
Typical Patient Function & Activity Milestones after Hemiarthroplasty or Total Toe Replacement

Based on their experience, surgeons rated the time it took for patients to achieve certain milestones after surgery such as driving a car, walking in shoes and returning to work, activity or sport. Typically, patients are able to perform the activities of daily life, including returning to work, 2-6 weeks after surgery.

Following Toe HemiCAP[®] hemiarthroplasty, or ToeMotion[®] Total Toe replacement, all surgeons stated that patients are expected to return to work with maintenance of their job levels. No job, sports or activity restrictions were recommended. Following these procedures, most patients are expected to return to work within 2 weeks after surgery (66.7%) or within a 15-30 day range (33.3%). The time to return to work was classified as equal or faster than cheilectomy, faster than other implants and faster than fusion. Sports participation was started at a mean of 49.3 days and the satisfaction regarding the return to sport and an active lifestyle was rated as Excellent (66.7%), Very good (33.3%) or Good (16.7%).

Figure 5: Time Points for Returning to Various Activity levels After Surgery.

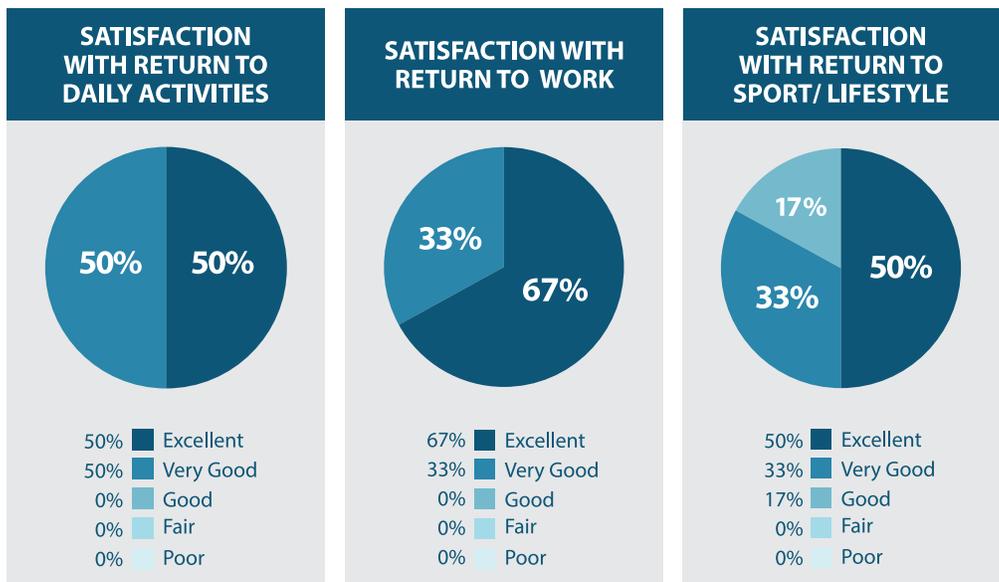
Typical Timepoints for the Resumption of Activity After Toe HemiCAP[®] or ToeMotion[®] Total Toe Surgery (Weeks)



Satisfaction Rating For Hemiarthroplasty and Total Toe Anthroplasty

The surgeons' overall satisfaction after Toe HemiCAP® or ToeMotion® Total Toe Replacement for the resumption of the Activities of Daily Living and Return to Work were all rated as Very Good or Excellent. Return to Sport or Active Lifestyle were rated as Very Good to Excellent in 83% of the time.

Figure 6: Satisfaction Rating after Toe HemiCAP® or ToeMotion® Total Toe Replacement for Return to Activities of Daily Living, Return to Work, and Return to Sport and Active Lifestyle.



Overall Satisfaction

83% of surgeons surveyed reported Excellent Satisfaction ratings with the Toe HemiCAP® & ToeMotion® Implant systems.

Surgeons' Choice

All surgeons indicated that they would undergo a Toe HemiCAP® Arthroplasty themselves and that they would recommend the procedure to their friends and family.





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