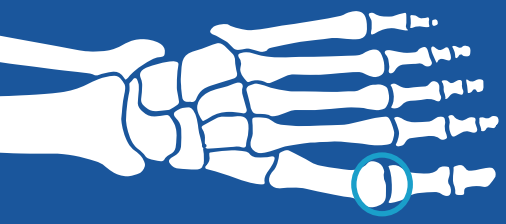
ANIKA

PATIENT GUIDE FOR THE TREATMENT OF TOE ARTHRITIS

A nationwide surgeon survey on over 2,000 HemiCAP toe procedures



Includes:

- Patient function and activity milestones
- Patient rehabilitation & physiotherapy information
- Treatment comparisons of joint replacement and fusion
- Surgeon satisfaction ratings and recommendations

Survey results are based on the experience of 35 foot & ankle surgeons, who together performed more than 2200 procedures with the Toe HemiCAP® and ToeMotion® Systems since 2005. Collectively, they have extensive experience with Anika toe implants and forefoot surgery. Their responses are based on long term observations and treatment of Hallux Rigidus. The purpose of this surgeon survey was to analyze their experience 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.

ANIKA arthrosurface

1st MTP Arthroplasty Surgeon Survey

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.

35 FOOT & ANKLE SURGEONS

2261 HEMICAP PROCEDURES

8 YEARS AVERAGE HEMICAP EXPERIENCE

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: *Metatarsophalangeal joint at the base of the toe*
Total Toe Arthroplasty: *Joint replacement on both sides of the joint*

Joint replacement features

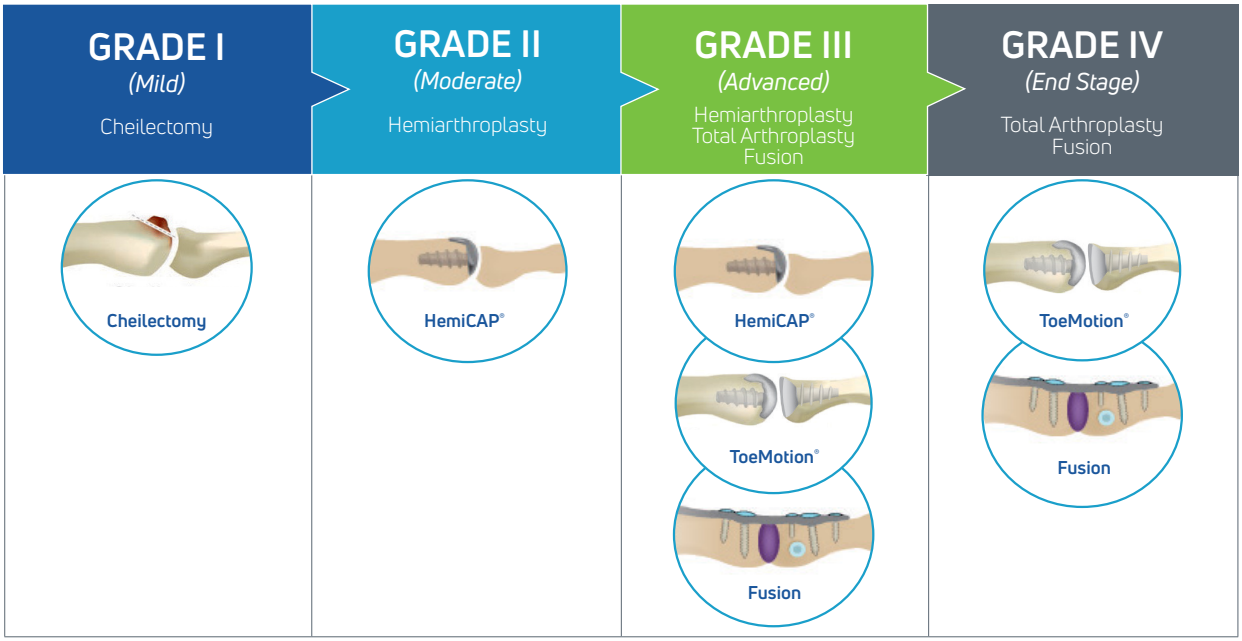
Based on their overall experience, surgeons were asked about the clinical benefits of the Toe HemiCAP® and ToeMotion® Systems. Results according to primary, secondary, and tertiary features are summarized in **Figure 1**.

Primary features	Secondary features	Tertiary features
• Motion preservation • Pain relief • Short procedure	• Fixation strength • Anatomical fit • Reproducible surgical technique • Revisability/ease of future surgery	• Fast recovery • Early weight bearing • Early motion • Patient specific sizing

Figure 1
Primary features: selected by 80% of the surgeons. **Secondary features:** selected by more than 50% 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. Based on survey results, the most popular (>50%) treatment choices per grade are shown below.



In forefoot surgery, a grading system is used that includes four 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 where 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, 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 hospital stay timelines

Based on surgeon experience, the typical duration of the Toe HemiCAP® and ToeMotion® joint replacement procedure was less than 60 minutes by 97% and of those, 34% indicated a procedure length of less than 30 minutes. 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

Surgery time is less than 1 hour

Hospital stay is less than 24 hours

1st MTP Arthroplasty Surgeon Survey

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

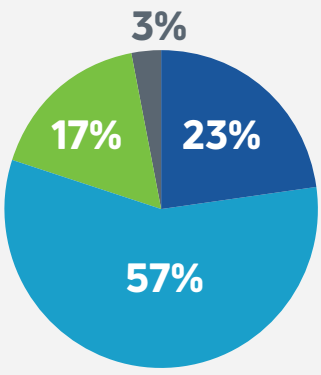
The typical pain relief following First Toe joint replacement procedures and fusion are summarized in **Figure 4**. The highest agreement for an excellent to very good rating was achieved by Total Toe Arthroplasty (94%), followed by HemiCAP DF (80%), and fusion (72%).

Figure 4: Postoperative Pain Relief Ratings

Surgeons were asked to rate postoperative pain relief 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.

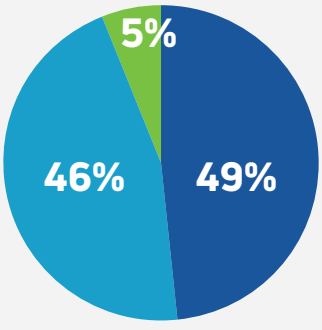
Postoperative pain relief ratings

Toe HemiCAP® Hemiarthroplasty



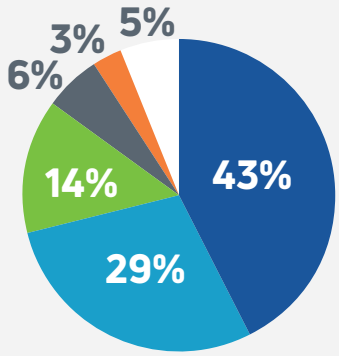
23%	Excellent
57%	Very Good
17%	Good
3%	Fair
0%	Poor

ToeMotion® Total Arthroplasty



49%	Excellent
46%	Very Good
5%	Good
0%	Fair
0%	Poor

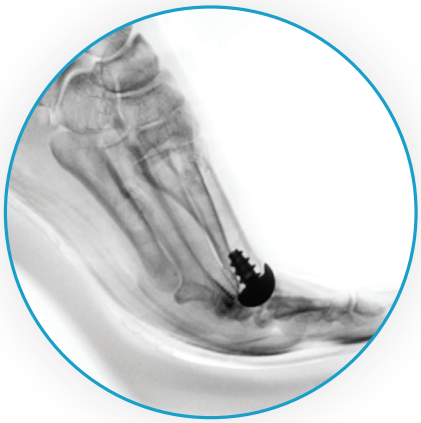
Fusion



43%	Excellent
29%	Very Good
14%	Good
6%	Fair
3%	Poor
5%	No Answer

Toe HemiCAP®

Hemiarthroplasty Implant System

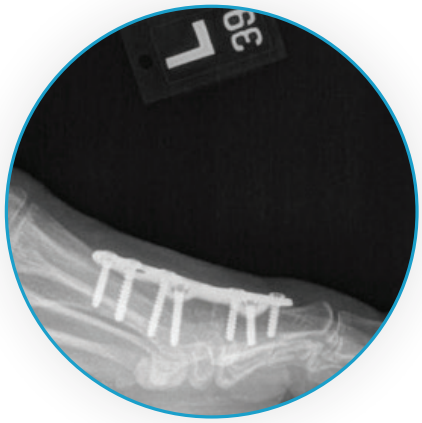


ToeMotion®

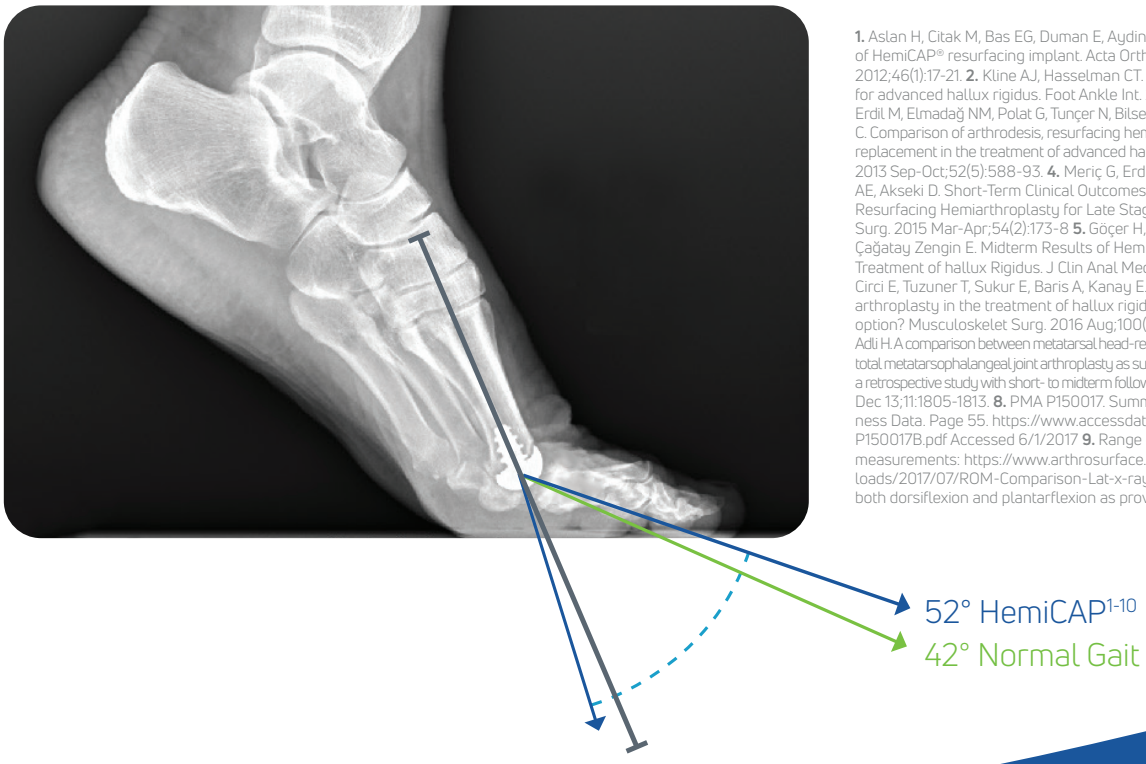
Total Toe Implant System

CheckMate®

Fusion Plate System



Range of Motion Results from Scientific Literature



1. Aslan H, Citak M, Bas EG, Duman E, Aydin E, Ates Y. Early results of HemiCAP® resurfacing implant. Acta Orthop Traumatol Turc. 2012;46(1):17-21. **2.** Kline AJ, Hasselman CT. Metatarsal head resurfacing for advanced hallux rigidus. Foot Ankle Int. 2013 May;34(5):716-25. **3.** Erdil M, Elmadağ NM, Polat G, Tunçer N, Bilsel K, Uçan V, Erkoçak OF, Sen C. Comparison of arthrodesis, resurfacing hemiarthroplasty, and total joint replacement in the treatment of advanced hallux rigidus. J Foot Ankle Surg. 2013 Sep-Oct;52(5):588-93. **4.** Meriç G, Erduran M, Atik A, Köse O, Ulusal AE, Akseki D. Short-Term Clinical Outcomes After First Metatarsal Head Resurfacing Hemiarthroplasty for Late Stage Hallux Rigidus. J Foot Ankle Surg. 2015 Mar-Apr;54(2):173-8 **5.** Göçer H, Çiraklı A, Köken M, Yazıcı AK, Çağatay Zengin E. Midterm Results of HemiCAP Operation in the Surgical Treatment of hallux Rigidus. J Clin Anal Med 2015;6(suppl 4): 431-3 **6.** Circi E, Tuzuner T, Sukur E, Baris A, Kanay E. Metatarsal head resurfacing arthroplasty in the treatment of hallux rigidus: is it reliable treatment option? Musculoskelet Surg. 2016 Aug;100(2):139-44. **7.** Mermerkaya MU, Adli H. A comparison between metatarsal head-resurfacing hemiarthroplasty and total metatarsophalangeal joint arthroplasty as surgical treatments for hallux rigidus: a retrospective study with short- to midterm follow-up. Clin Interv Aging. 2016 Dec 13;11:1805-1813. **8.** PMA P150017. Summary of Safety and Effectiveness Data. Page 55. https://www.accessdata.fda.gov/cdrh_docs/pdf15/P150017B.pdf Accessed 6/1/2017 **9.** Range of Motion literature summary measurements: https://www.arthrosurface.com/wp-content/uploads/2017/07/ROM-Comparison-Lat-x-ray-V2.jpg **10.** Average includes both dorsiflexion and plantarflexion as provided in reference 13

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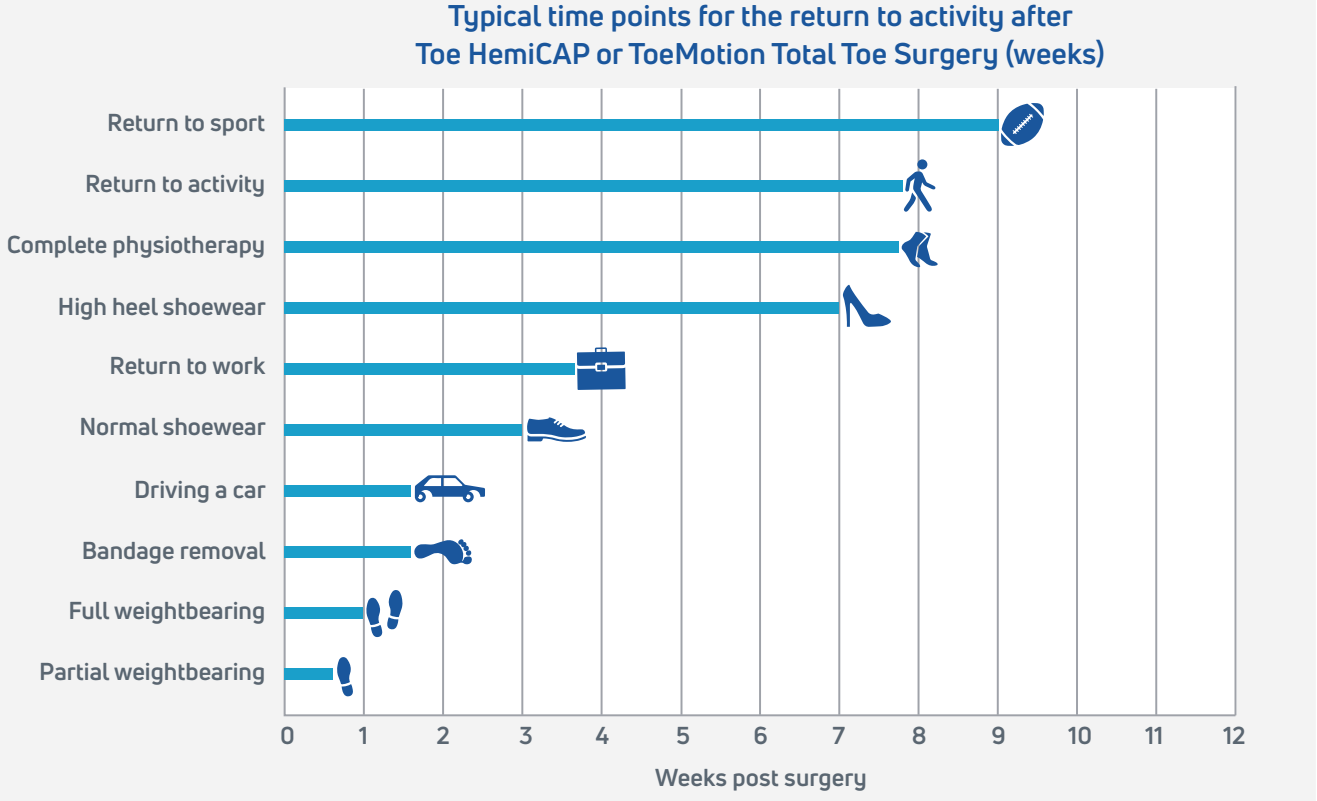
Typical patient function & activity milestones after hemiarthroplasty or total toe replacement

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. The majority of surgeons reported that their patients' return to activities of daily living, including return to work within 1 month 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 4 weeks after surgery (77%) or within a 15-30 day range (33.3%). The time to return to work was classified as equal or faster than cheilectomy and other implants and faster than fusion. Sports participation was started at a mean of 63 days and the satisfaction regarding the return to sport and an active lifestyle was rated as excellent to very good in 86% and good in 14%.

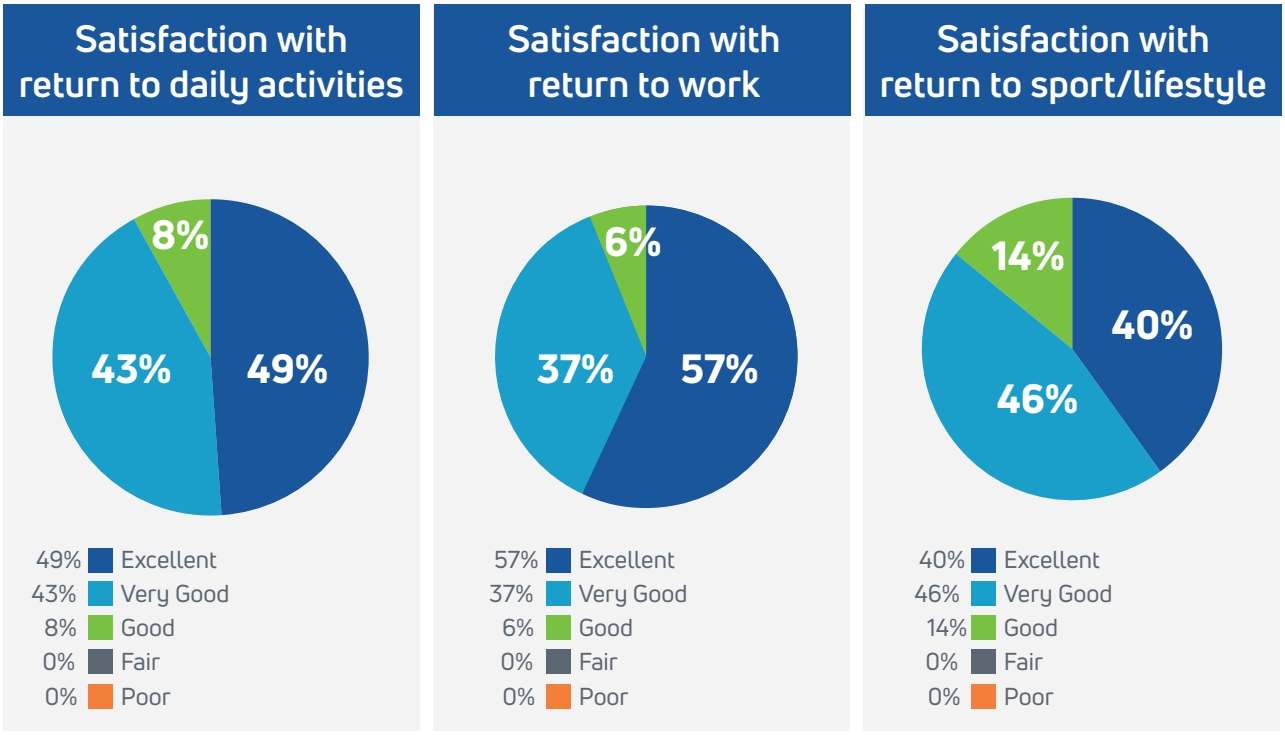
Figure 5: Time points for returning to various activity levels after surgery.



Satisfaction rating for Hemiarthroplasty and Total Toe Arthroplasty

Surgeons' overall satisfaction after Toe HemiCAP® or ToeMotion® Total Toe Replacement was rated Excellent to Very Good for Return to Activities of Daily Living (92%), Return to Work (94%), Return to Sports and Active Lifestyle (86%).

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

98%

of surgeons surveyed reported Very Good to Excellent Satisfaction ratings with the Toe HemiCAP & ToeMotion Implant systems.

Surgeons' choice

97%

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

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