EPISURF

EPISEALER® KNEE CLINICAL SUMMARY

AN OVERVIEW OF SCIENTIFIC PUBLICATIONS OF SPECIAL INTEREST IN THE FIELD OF EPISEALER® KNEE

PAGE 3	Preface
PAGE 4-5	No implant migration and good subjective outcome of a novel customized femoral resurfacing metal implant for focal chondral lesions
PAGE 6-7	Patient-specific metal implants for focal chondral and osteochondral lesions in the knee; excellent clinical results at 2 years
PAGE 8-9	Successful Treatment of Femoral Chondral Lesions with a Novel Customized Metal Implant at Midterm Follow-Up
PAGE 10-11	Patient-Specific Implants for Focal Cartilage Lesions in The Knee: Implant Survivorship Analysis up to Seven Years Post-Implantation
PAGE 12-13	Good subjective outcome and low risk of revision surgery with a novel customized metal implant for focal femoral chondral lesions at a follow-up after a minimum of 5 years
PAGE 14-15	Patient-specific resurfacing implant knee surgery in subjects with early osteoarthritis results in medial pivot and lateral femoral rollback during flexion: a retrospective pilot study

EPISURF MEDICAL

Episurf was founded in 2009 by Swedish orthopaedic surgeon Professor Leif Ryd. The company develops and commercializes patient-specific medical devices for the treatment of painful joint injuries. Episurf has an expanding product portfolio comprising the CE-marked joint implants Episealer® that aim to treat articular cartilage damage and underlying bone lesions. It enables orthopaedic surgeons to offer individualized solutions for patients suffering from articular lesions in the knee joint as well as in the ankle. By combining advanced 3D imaging technology with the latest manufacturing technology, we are able to adapt the Episealer® implant and surgical instruments to the patient's injury and anatomy.

Episealer® Knee is not available for sale in the United States.

Surgery should not be guesswork; that is what we have said from the first day we started developing the Episealer®

That is why every Episealer® starts with a Damage Marking Report where we show the condition of the patient's knee, focusing on our area of expertise, the cartilage, and the bone. We must ensure that the implant fits the knee and the defect perfectly every time we deliver an Episealer®.

We have also, from the very beginning, focused on research. As part of the development of the Episealer®, four pre-clinical studies were performed to ensure that our concept would work and that we were ready for clinical use.

The first patient to receive an Episealer® had his surgery in December 2012. He was one of ten patients included in our first clinical study, from which the publication "No implant migration and good subjective outcome of a novel customized femoral resurfacing metal implant for focal chondral lesions" was compiled. The study concludes good implant safety and patient satisfaction. The patients experienced reduced pain and significant improvement in knee function. Later on, when all patients in this study had had their implants for a minimum of 5 years, a continuation of the study was initiated, and the authors found that the good results shown at the 2 years' follow up remain at a mean follow up of 75 months – and there were still no implant revisions.

As it takes time to collect results, we are grateful that some of the very first Episealer® Knee implant users agreed to follow up on their patients and publish their results. This has resulted in the publication "Patient-specific metal implants for focal chondral and osteochondral lesions in the knee; excellent clinical results at 2 years", presenting the results from follow-up of 75 patients, from 9 clinics in 6 countries.

We know that our users, the orthopaedic specialists, make decisions based on evidence. Their daily work must never be guesswork. The treatment used for each patient must be the best treatment available.

To facilitate the decision whether an Episealer® would be the best treatment for your patient, we have compiled the studies above and other studies with Episealer® Knee implants in this Clinical Summary.

No implant migration and good subjective outcome of a novel customized femoral resurfacing metal implant for focal chondral lesions

Stålman A. et al., Knee Surg Sports Traumatol Arthrosc, 2018; 26(7): 2196-2204

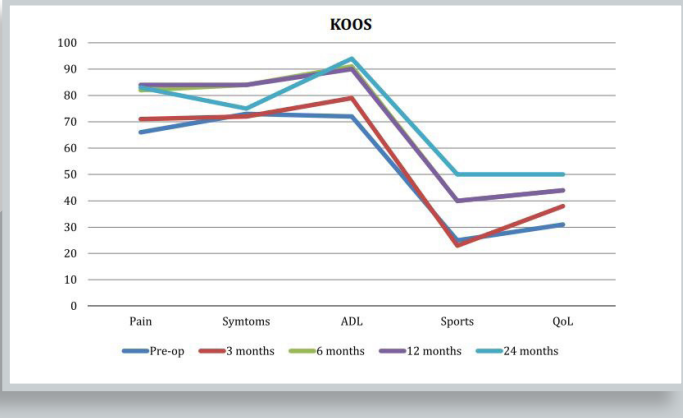
N = 10 patients
FU period = 24 months
Implant survival rate = 100%

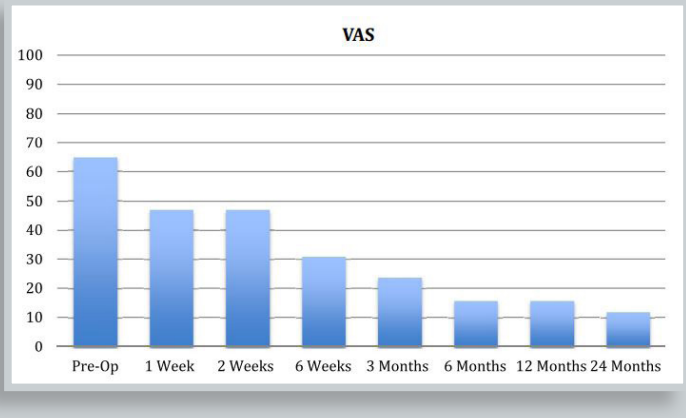
SUMMARY:

A prospective, consecutive, multicentre study with follow up of the first Swedish Episealer® Knee patients, with the primary objective to assess implant safety profile, surgical usability of the implant and instruments, and implant migration with radiostereometric analysis (RSA).

RESULTS:

- Significant improvements for VAS ($p \leq 0.001$), Tegner ($p = 0.034$) and the KOOS subscores ADL ($p = 0.0048$), sport and recreation ($p = 0.034$) and quality of life ($p = 0.037$). VAS and KOOS scores improved gradually at 3, 6 and 12 months.
- RSA did not show any implant migration.
- The short-term implant safety and patient-related outcome measures showed good-to-excellent results.





Knee Surgery, Sports Traumatology, Arthroscopy
https://doi.org/10.1007/s00167-017-4805-2

KNEE

No implant migration and good subjective outcome of a novel customized femoral resurfacing metal implant for focal chondral lesions

Anders Stålman[6] · Olof Sköldenberg[5] · Nicolas Martinez-Carranza[1] · David Roberts[2] · Magnus Högström[3] · Leif Ryd[4]

Received: 26 April 2017 / Accepted: 13 November 2017
© The Author(s) 2017. This article is an open access publication

Abstract

Purpose Managing focal cartilage injuries in the middle-aged patient poses a challenge. Focal prosthetic inlay resurfacing has been proposed to be a bridge between biologics and conventional joint arthroplasty. Patient selection and accurate implant positioning is crucial to avoid increased contact pressure to the opposite cartilage surface. A customized femoral condyle implant for focal cartilage injuries was designed to precisely fit each patient's individual size and location of damage. The primary objective was to assess implant safety profile, surgical usability of the implant and instruments, and implant migration with radiostereometric analysis (RSA).

Methods Ten patients 36–56 years with focal chondral defects, ICRS 3–4 of the femoral cartilage and failed earlier conservative or surgical interventions with VAS pain > 40. The patients were followed for 2 years with subjective outcome measures (VAS, EQ5D, KOOS) and RSA. The customized implant and guide instruments were manufactured by computer-aided design/computer-aided manufacturing (CAD/CAM) techniques using MRI data.

Results VAS, EQ5D and KOOS showed improvements that reached significance for VAS ($p \leq 0.001$), Tegner ($p = 0.034$) and the KOOS subscores ADL ($p = 0.0048$), sport and recreation ($p = 0.034$) and quality of life ($p = 0.037$). VAS and KOOS scores improved gradually at 3, 6 and 12 months. The improvements in EQ5D, KOOS pain and KOOS symptoms did not reach statistical significance. No infections, deep venous thrombosis or other complications occured in the postoperative period. No radiographic signs of damage to the opposing tibial cartilage was noted. The surgical usability of implants and instruments were good. RSA did not show any implant migration.

Conclusion This is the first clinical report of a new customized, focal knee resurfacing system. The short-term implant safety and patient-related outcome measures showed good-to-excellent results.

Level of evidence Prospective case series, Level 4.

Keywords Focal cartilage injuries · Prosthetic inlay resurfacing · Osteochondral injury

✉ Anders Stålman
anders.stalman@ki.se

[1] Department of Orthopaedics, Karolinska University Hospital, Stockholm, Sweden

[2] Department of Orthopaedics, Skane University Hospital, Malmö, Sweden

[3] Sports Medicine Umeå AB and Orthopedics, Department of Surgical and Perioperative Sciences, Umeå University, Umeå, Sweden

[4] LIME, Karolinska Institutet, Solna, Sweden

[5] Department of Orthopaedics, Danderyd Hospital, Stockholm, Sweden

[6] Stockholm Sports Trauma Research Center, Karolinska Institutet, Capio Artro Clinic, Sophiahemmet, Valhallavägen 91, 114 86 Stockholm, Sweden

Published online: 22 November 2017

Patient-specific metal implants for focal chondral and osteochondral lesions in the knee; excellent clinical results at 2 years

Holz, J., et al., Knee Surg Sports Traumatol Arthrosc, 2021; 29(9): 2899-2910

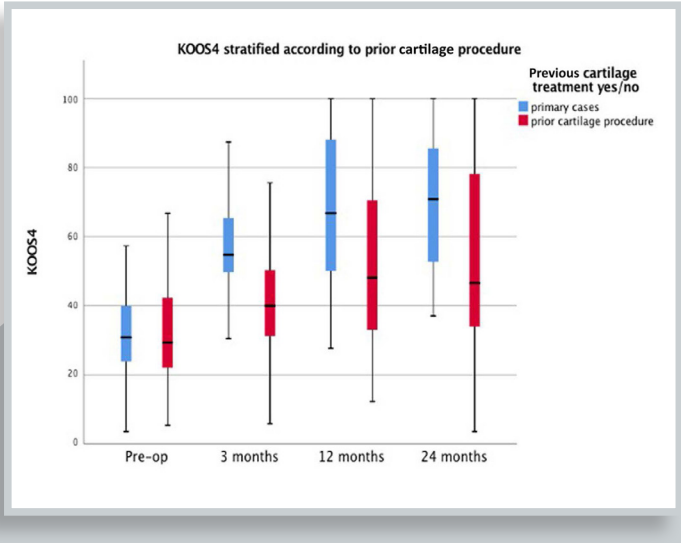
N = 80 patients
FU period = 24 months
Implant survival rate = 97,5%

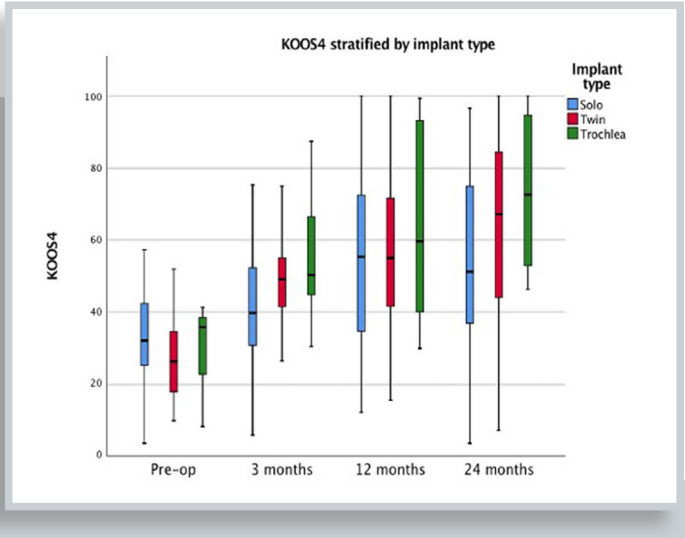
"This interim study indicates that there is a definitive place for this device in the management of a focal chondral or osteochondral defect affecting the distal femur."

SUMMARY:
A consecutive European multicenter study, performed by 11 surgeons at 9 clinics in 6 countries. The study aimed to report on clinical and functional outcomes and explore the effect of previous cartilage repair, site of the implant and implant type. This study shows the clinical outcome when Episealer® Knee implant is used in daily praxis, and not only by a few users with strictly limited inclusion criteria.

RESULTS:

- Low revision rate.
- VAS pain score and all subdomains of the KOOS scores significantly improved at 12 and 24 months.
- No significant differences in KOOS and VAS scores between groups according to implant type (solo, twin, trochlea), or lesion size (< 3 cm2, 3–4 cm2, > 4 cm2).
- No difference in clinical outcome between implantation on the femoral condyle and the trochlea, and whether treatment followed previous cartilage repair surgery.
- Articular surface reconstruction using an individualized mini-metal implant designed according to detailed MRI imaging, in combination with specific insertion guides, resulted in significant clinical and functional improvement at 2 years.





Knee Surgery, Sports Traumatology, Arthroscopy
https://doi.org/10.1007/s00167-020-06289-7

KNEE

Patient-specific metal implants for focal chondral and osteochondral lesions in the knee; excellent clinical results at 2 years

Johannes Holz[1] · Tim Spalding[2] · Tarek Boutefnouchet[2] · Pieter Emans[3] · Karl Eriksson[4] · Mats Brittberg[5] · Lars Konradsen[6] · Clemens Kösters[7] · Peter Verdonk[8] · Magnus Högström[9] · Martin Lind[10]

Received: 1 June 2020 / Accepted: 14 September 2020
© The Author(s) 2020

Abstract

Purpose Surgical treatment options for the management of focal chondral and osteochondral lesions in the knee include biological solutions and focal metal implants. A treatment gap exists for patients with lesions not suitable for arthroplasty or biologic repair or who have failed prior cartilage repair surgery. This study reports on the early clinical and functional outcomes in patients undergoing treatment with an individualised mini-metal implant for an isolated focal chondral defect in the knee.

Methods Open-label, multicentre, non-randomised, non-comparative retrospective observational analysis of prospectively collected clinical data in a consecutive series of 80 patients undergoing knee reconstruction with the Episealer® implant. Knee injury and Osteoarthritis Outcome Score (KOOS) and VAS scores, were recorded preoperatively and at 3 months, 1 year, and 2 years postoperatively.

Results Seventy-five patients were evaluated at a minimum 24 months following implantation. Two patients had undergone revision (2.5%), 1 declined participation, and 2 had not completed the full data requirements, leaving 75 of the 80 with complete data for analysis. All 5 KOOS domain mean scores were significantly improved at 1 and 2 years ($p < 0.001$–0.002). Mean preoperative aggregated KOOS4 of 35 (95% CI 33.5–37.5) improved to 57 (95% CI 54.5–60.2) and 59 (95% CI 55.7–61.6) at 12 and 24 months respectively ($p < 0.05$). Mean VAS score improved from 63 (95% CI 56.0–68.1) preoperatively to 32 (95% CI 24.4–38.3) at 24 months. The improvement exceeded the minimal clinically important difference (MCID) and this improvement was maintained over time. Location of defect and history of previous cartilage repair did not significantly affect the outcome ($p > 0.05$).

Conclusion The study suggests that at 2 years, Episealer® implants are safe with a low failure rate of 2.5% and result in clinically significant improvement. Individualised mini-metal implants with appropriate accurate guides for implantation appear to have a place in the management of focal femoral chondral and osteochondral defects in the knee.

Level of evidence IV.

Keywords Focal cartilage lesion · Focal knee resurfacing · Metal implants · Clinical outcomes · Customised · Personalized

Introduction

Focal chondral and osteochondral lesions are a significant cause of morbidity and can have a clinical impact similar to end-stage osteoarthritis, with an important socio–economic burden [15, 17]. Lesions are likely to progress to bifocal disease and pan-articular osteoarthritis [4, 7, 29].

Available methods for the management of focal chondral and osteochondral defects in the knee include cell-based regenerative procedures, bone marrow stimulation techniques including microfracture or scaffold augmented microfracture, and osteochondral grafting procedures which can be autograft or allograft [3]. Osteochondral allograft reconstruction (OCA) is highly cost-effective [30, 31] but the procedure is limited by the scarcity of fresh grafts and in some countries use is restricted by law [11, 46]. Patient age for all such options is a significant restrictive factor since transplanted cells and marrow cells tend to lose regenerative potential with increasing age [9, 21]. The outcome of

✉ Johannes Holz
dr.holz@oc-h.de

Extended author information available on the last page of the article

Published online: 06 October 2020

Successful Treatment of Femoral Chondral Lesions with a Novel Customized Metal Implant at Midterm Follow-Up

Martinez-Carranza N. et al., Cartilage, online 2020

N = 30 patients
FU period = Mean 55 months
Implant survival rate = 97%

SUMMARY:
A prospective consecutive cohort study with the 30 first patients from 9 Swedish clinics. The objective was to assess the subjective outcome in the short term and the risk of reoperation at midterm after surgery. PROMs KOOS and VAS available for 22 patients at 24 mth.

RESULTS:
- Good implant safety and improvement in patient outcome measurements.
- The risk of subsequent surgery during the follow-up period was in this study lower than previously described for other focal knee resurfacing systems.
- At 2 years, all the follow-up scores, the EQ5D VAS, VAS, and all the KOOS subscales, showed significant improvements compared to pre surgery.
- Considering the improvements in PROMs and the low risk of conversion to arthroplasty surgery, this implant could be an option for the challenging middle-aged patient with symptomatic cartilage injuries with failed biological treatment or lack of suitability for biological treatment.
- In the event of failure, the method does not seem to compromise potential future arthroplasty surgery.

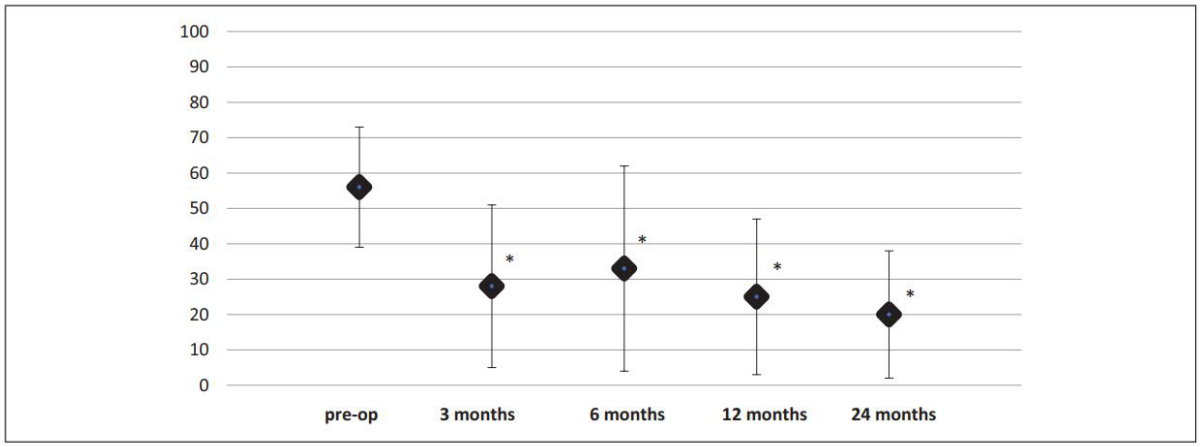


Figure 1. Visual Analogue Scale (VAS). VAS at preoperative, 3, 6, 12, and 24 months. VAS improved at 3 months and maintained significantly improved in comparison with preoperative over 24 months (3 months $P = <0.001$, 6 months $P = 0.006$, 12 months $P = <0.001$, 24 months $P = <0.001$).

Original Article

Successful Treatment of Femoral Chondral Lesions with a Novel Customized Metal Implant at Midterm Follow-Up

CARTILAGE
1–8
© The Author(s) 2020
Article reuse guidelines:
sagepub.com/journals-permissions
DOI: 10.1177/1947603520967064
journals.sagepub.com/home/CAR
SAGE

Nicolas Martinez-Carranza[1,2], Peter Rockborn[3], David Roberts[4], Magnus Högström[5,6], and Anders Stålman[7]

Abstract

Background. Full-depth cartilage lesions do not heal spontaneously and may progress to osteoarthritis (OA). Treatment for these lesions is warranted when symptomatic. At younger age, biological treatment remains the gold standard, but treatment in the middle-aged patient remains a clinical challenge and focal metal implants have been proposed. We aim to present the subjective outcome at 2 years and the risk of reoperation for any reason at midterm after surgery with a novel customized implant for focal femoral chondral lesions in the knee. *Methods*. In a prospective cohort study, 30 patients were included between January 2013 and December 2017 at 9 different clinics in Sweden. The primary outcome was subjective outcome measurements (Visual Analogue Scale [VAS], EuroQoL [EQ5D], Knee injury and Osteoarthritis Outcome Score [KOOS]) at a minimum of 2 years. The secondary outcome was reoperations for any reason during the follow-up period until December 2019 (mean of 55 months) studied retrospectively by analyzing medical records. *Results*. The VAS, EQ5D, and all the KOOS subscales showed significant improvements from preoperatively to the 2-year follow-up. The VAS showed the greatest improvement at the early (3 months) postoperative stage ($P < 0.001$). Five (7%) patients underwent reoperations and one of these was revised to hemiarthroplasty due to OA progression. No implant loosening was detected in any of the cases. *Conclusions*. This customized resurfacing metal implant showed good safety and patient satisfaction. The risk of OA progression and implant loosening is low. Subjective function and pain improved significantly.

Keywords

clinical trial, general, outcome measures, general, articular cartilage, tissue, knee, joint involved, resurfacing, procedures

Introduction

The main function of articular cartilage is to provide a bearing surface that permits almost frictionless movement.[1,2] Patients with focal cartilage defects often have functional impairments and pain that significantly affects their quality of life and socioeconomic situation.[3-5] Cartilage lesions constitute a pathology on the rise, due to the increased activity level in an aging population, as well as their association with sports injuries.[6]

Epidemiological studies show that chondral lesions, of any type, are present in about 60% of all knee arthroscopies.[3,7-9] Focal knee cartilage lesions, International Cartilage Research Society (ICRS) grades 1-2, are superficial and often do not require surgical treatment.[8] Deep knee cartilage lesions, ICRS grades 3-4, are thought to precede osteoarthritis (OA) and are therefore potential candidates for surgery. In patients over 40 years of age, full-depth single lesions with an area of 1 cm^2 or more are encountered in about 9% to 13% of all arthroscopies performed for any reason.[3,7-9]

For the last 30 years, biological treatment strategies have aimed to regenerate durable knee cartilage repair tissue.[10-12] Unfortunately, the healing power of articular cartilage is remarkably limited due to its avascular nature.[13] Nonetheless,

[1]Department of Orthopaedics, Institution of Clinical Sciences, Intervention and Technology (CLINTEC), Karolinska Institutet, Stockholm, Sweden
[2]Division of Orthopaedics, Karolinska University Hospital, Stockholm, Sweden
[3]Orthopedic Clinic, Vrinnevi Hospital, Norrköping, Sweden
[4]Ortho Center Skåne and Department of Orthopaedics, Skane University Hospital, Malmo, Sweden
[5]Sports Medicine Umeå and Orthopedics, Umeå, Sweden
[6]Department of Surgical and Perioperative Sciences, Umeå University, Umeå, Sweden
[7]Stockholm Sports Trauma Research Center, MMK, Karolinska Institutet, Stockholm, Sweden

Corresponding Author:
Nicolas Martinez-Carranza, Division of Orthopaedics, Karolinska University Hospital, Hälsovägen, SE-141 86 Stockholm, Sweden.
Email: nicolas.martinez-carranza@sll.se

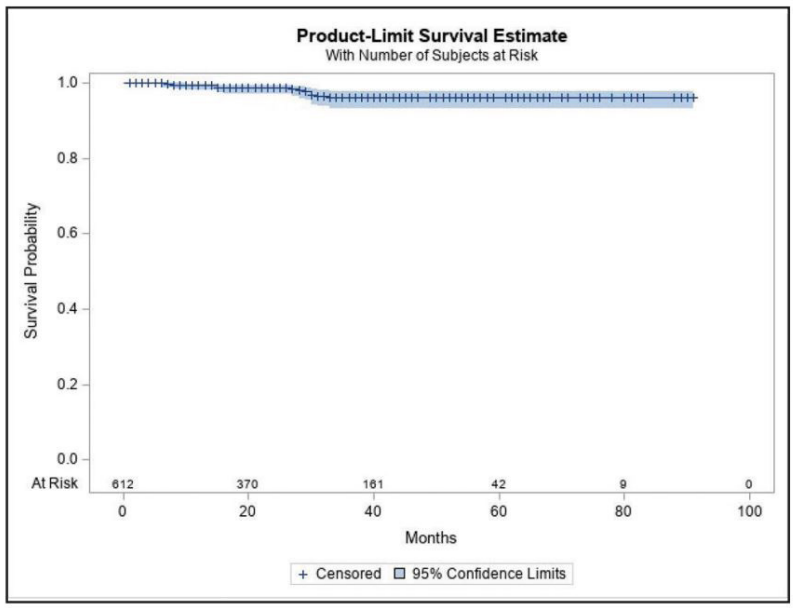
Patient-Specific Implants for Focal Cartilage Lesions in The Knee: Implant Survivorship Analysis up to Seven Years Post-Implantation

Ryd L. et al, Surg Technol Int, 2020; 38: 379-386

N = 612 patients
FU period = 7 years
Implant survival rate = 96%

SUMMARY:
A publication based on post market surveillance records, from a database held by the manufacturer, with all patients treated from December 2012 to June 2020. Revisions were tabulated and the reasons for revision were recorded in the adverse event analysis file. The cause of revision was analyzed for each case, and the original Damage Marking Report and treatment plan were reviewed.

RESULTS:
14 of the 612 operated knees had been revised (2.3%). A Kaplan-Meier survivorship analysis of the patients at risk at the beginning of each year of follow-up shows a survivorship at 7 years of follow-up of 96%.



Patient-Specific Implants for Focal Cartilage Lesions in The Knee: Implant Survivorship Analysis up to Seven Years Post-Implantation

Leif Ryd, MD
Senior Medical Consultant
Episurf Medical
Stockholm, Sweden

Katarina Flodström, PhD
Chief Scientific Officer
Episurf Medical
Stockholm, Sweden

Michael T. Manley, FRSA, PhD
Consultant in Orthopaedic Sciences
Michael T. Manley FRSA, PhD, LLC
Naples, FL, USA

ABSTRACT

In the quest for increased surgical precision and improved joint kinematics, Computer-Assisted Orthopedic Surgery (CAOS) shows promising results for both total and partial joint replacement. In the knee, computer-assisted joint design can now be applied to the treatment of younger patients suffering pain and restriction of activity due to focal defects in their femoral articular cartilage. By taking MRI scans of the affected knee and digitally segmenting these scans, we can identify and map focal defects in cartilage and bone. Metallic implants matched to the defect can be fabricated, and guide instrumentation to ensure proper implant alignment and depth of recession in the surrounding cartilage can be designed from segmented MRI scans.

Beginning in 2012, a series of 682 patient-specific implants were designed based on MRI analysis of femoral cartilage focal defects, and implanted in 612 knees. A Kaplan-Meier analysis found a cumulative survivorship of 96% at 7-year follow-up from the first implantation. Fourteen (2.3%) of these implants required revision due to disease progression, incorrect implant positioning, and inadequate lesion coverage at the time of surgery.

These survivorship data compare favorably with all other modes of treatment for femoral focal cartilage lesions and support the use of patient-specific implants designed from segmented MRI scans in these cases.

Copyright © 2020 Surgical Technology International™

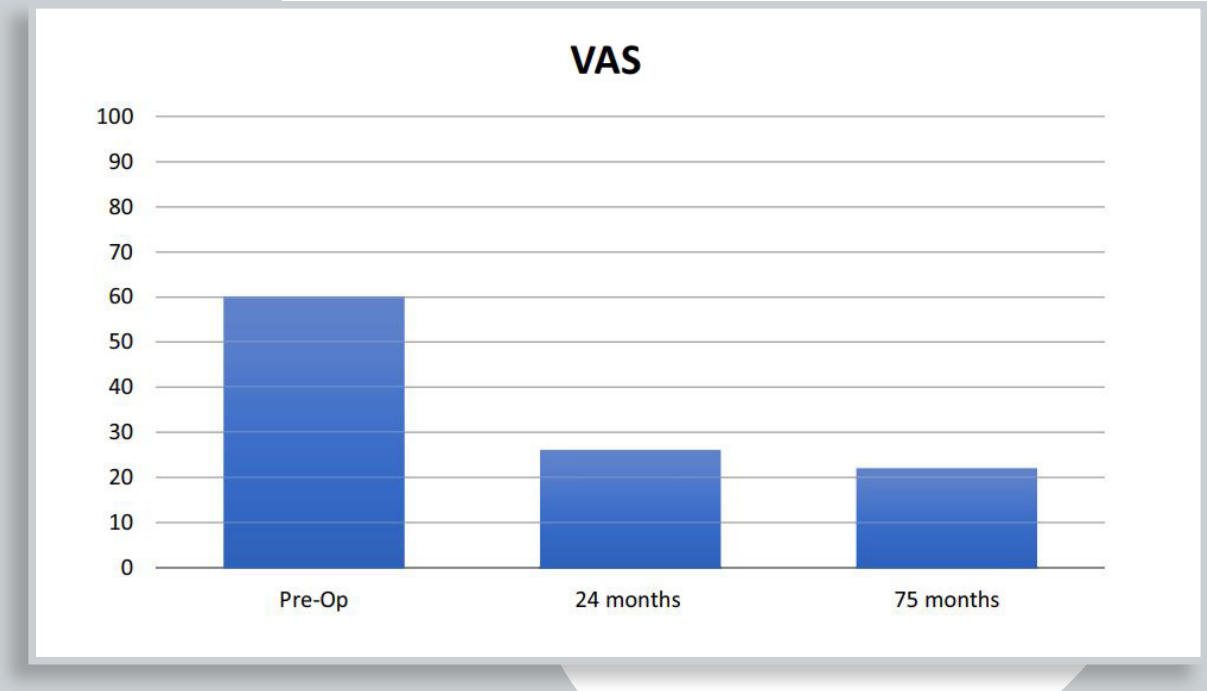
Good subjective outcome and low risk of revision surgery with a novel customized metal implant for focal femoral chondral lesions at a follow-up after a minimum of 5 years

Al-Bayati M. et al., Arch Orthop Trauma Surg, online 2021

N = 10 patients
FU period = 75 months
Implant survival rate = 100%

SUMMARY:
Follow up of the 10 first Swedish patients with the primary objective to assess subjective and objective function, and implant survival at a minimum of five years after surgery.

RESULTS:
- No revisions.
- The good improvements in subjective outcome measurements are maintained from 24 months to a follow-up after a minimum of 5 years (mean 75 months). The customized prosthesis system with patient-specific implants and surgical guide equipment improves the potential for adequate implant positioning, which may explain why the study reports a good result.
- The authors conclude that surgery has the potential to give patients significant pain relief, functional improvement and an increased perception of quality of life for several years after surgery.



Archives of Orthopaedic and Trauma Surgery
https://doi.org/10.1007/s00402-021-04160-z

KNEE ARTHROPLASTY

Good subjective outcome and low risk of revision surgery with a novel customized metal implant for focal femoral chondral lesions at a follow-up after a minimum of 5 years

Mohanad Al-Bayati[1,6] · Nicolas Martinez-Carranza[2,3] · David Roberts[4] · Magnus Högström[5] · Anders Stålman[6,7]

Received: 13 April 2021 / Accepted: 1 September 2021
© The Author(s) 2021

Abstract

Background and purpose Patients with focal cartilage lesions experience functional impairment. Results for biological treatments in the middle-aged patient is poor. Previous studies with focal prosthetic inlay resurfacing have shown a higher risk of conversion to total knee replacement at mid-term follow-up. A novel customized implant (Episealer, Episurf, Stockholm, Sweden) has been proposed to improve implant positioning and survival. The primary objective was to assess subjective-, objective function and implant survival at a minimum of five years after surgery.

Materials and methods The inclusion criteria were patients aged 30–65 years with symptomatic focal chondral defects in the medial femoral condyle, International Cartilage Research Society grade 3 or 4 and failed conservative or surgical treatment. Minimum follow-up of 5 years. Clinical and radiologic assessments were made. Patient-reported outcome measurements at the latest follow-up were compared with the baseline data for the Knee injury and Osteoarthritis Outcome Score (KOOS), the EuroQoL (EQ-5D), the Tegner Activity Scale and a Visual Analog Scale of pain (VAS 0–10).

Results Ten patients with the mean follow-up period of 75 months (60–86 months, SD 10) were included. Signs of osteoarthritis were seen in one patient (Ahlbäck 1). No cases with revision to knee replacement. VAS for pain and KOOS showed improvements that reached significance for VAS ($p \leq 0.001$) and the KOOS subscores Pain ($p = 0.01$), ADL ($p = 0.003$), Sport and Recreation ($p = 0.024$) and Quality of Life ($p = 0.003$).

Conclusion A good subjective outcome, a low risk of progression to degenerative changes and the need for subsequent surgery were seen at the mid-term follow-up with this customized focal knee-resurfacing implant.

Level of evidence Prospective case series, level 4.

Keywords Focal cartilage injuries · Prosthetic inlay resurfacing · Osteochondral injury · Knee

✉ Anders Stålman
anders.stalman@ki.se

1 Orthopedic Department, Skövde Hospital, Skövde, Sweden

2 Department of Orthopedics, Institution of Clinical Sciences, Intervention and Technology (CLINTEC), Karolinska Institutet, Stockholm, Sweden

3 Division of Orthopedics, Karolinska University Hospital, Stockholm, Sweden

4 Ortho Center Skåne and Department of Orthopedics, Skåne University Hospital, Malmö, Sweden

5 Department of Surgical and Perioperative Sciences, Sports Medicine Umeå and Orthopedics, Umeå University, Umeå, Sweden

6 MMK, Stockholm Sports Trauma Research Center, Karolinska Institutet, Solna, Sweden

7 Capio Artro Clinic, Sophiahemmet, Stockholm, Sweden

Introduction

Participation in sport as a competitive or recreational athlete is associated with a high incidence of cartilage injuries due to traumatic or chronic repetitive damage [1, 2]. Patients with focal cartilage lesions often experience significant functional impairment, impaired quality of life and pain to the same extent as patients with severe osteoarthritis [3]. The cartilage lacks innate abilities to mount a regenerative response to injury and even a small chondral lesion could induce unicompartmental osteoarthritis [4]. The natural history of the isolated chondral defect is not completely understood, but it is clear that patients with untreated focal cartilage injuries are more prone to experience a progression of cartilage damage, eventually leading to osteoarthritis [5]. Biological treatments, such as microfracture and autologous

Published online: 14 September 2021

Patient-specific resurfacing implant knee surgery in subjects with early osteoarthritis results in medial pivot and lateral femoral rollback during flexion: a retrospective pilot study

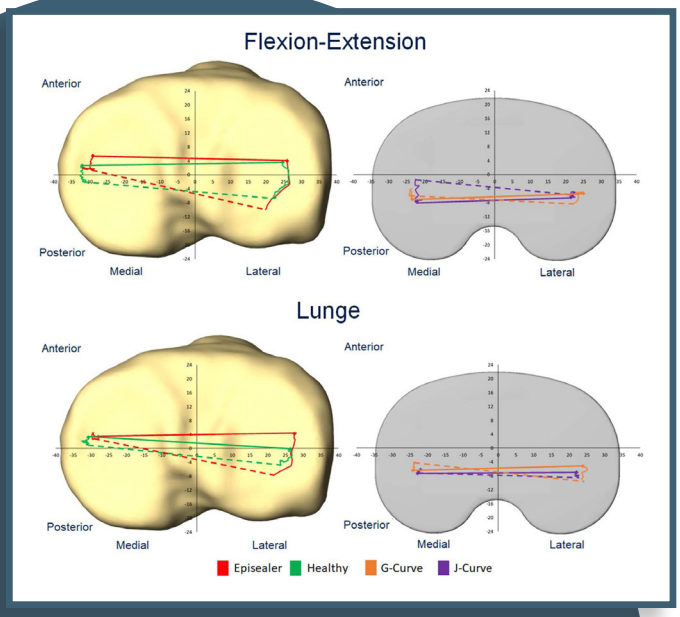
Moewis P. et al., Knee Surg Sports Traumatol Arthrosc, online 2021

N = 10 patients

SUMMARY:
The study aimed to analyze the knee kinematics in subjects with patient-specific Episealer® implants. Ten knees treated with an Episealer® underwent kinematic analysis. The result was compared with the result of ten healthy knees that were previously measured and analyzed under the same conditions. To provide a different point of comparison apart from the main aim of the study, the result was also compared with the result from previously tested TKA cases. The study hypothesized that the patient-specific Episealer® would lead to knee kinematics close to healthy knees, resulting in medial pivot and a high degree of femoral rollback during flexion.

RESULTS:

- Nearly physiological knee joint kinematics during flexion observed in vivo in the Episealer® knees.
- This was evidenced not only by the similar magnitude of movement at each compartment but also by the similar absolute condyle positions at extension and maximal flexion.



Left: absolute mean tibiofemoral kinematics during unloaded (flexion–extension) and loaded (lunge) activities during the main comparison between episealer and healthy knees.

Right: absolute mean tibiofemoral kinematics during unloaded (flexion–extension) and loaded (lunge) activities during the secondary analysis of J-Curve and G-Curve TKA knees. Solid lines indicate the position of the distal points during knee extension. Dashed lines indicate the position of the distal points during knee flexion.

Knee Surgery, Sports Traumatology, Arthroscopy
https://doi.org/10.1007/s00167-021-06749-8

KNEE

Patient-specific resurfacing implant knee surgery in subjects with early osteoarthritis results in medial pivot and lateral femoral rollback during flexion: a retrospective pilot study

Philippe Moewis[1] · René Kaiser[2] · Adam Trepczynski[1] · Christoph von Tycowicz[3] · Leonie Krahl[1] · Ansgar Ilg[2] · Johannes Holz[2] · Georg N. Duda[1]

Received: 31 March 2021 / Accepted: 9 September 2021
© The Author(s) 2021

Abstract

Purpose Metallic resurfacing implants have been developed for the treatment of early, small, condylar and trochlear osteoarthritis (OA) lesions. They represent an option for patients who do not fulfill the criteria for unicompartmental knee arthroplasty (UKA) or total knee arthroplasty (TKA) or are too old for biological treatment. Although clinical evidence has been collected for different resurfacing types, the in vivo post-operative knee kinematics remain unknown. The present study aims to analyze the knee kinematics in subjects with patient-specific episealer implants. This study hypothesized that patient-specific resurfacing implants would lead to knee kinematics close to healthy knees, resulting in medial pivot and a high degree of femoral rollback during flexion.

Methods Retrospective study design. Fluoroscopic analysis during unloaded flexion–extension and loaded lunge was conducted at > 12 months post-surgery in ten episealer knees, and compared to ten healthy knees. Pre- and post-operative clinical data of the episealer knees were collected using a visual analog scale (VAS), the EQ 5d Health, and the Knee Injury and Osteoarthritis Outcome Score (KOOS) questionnaires.

Results A consistent medial pivot was observed in both episealer and healthy knees. Non-significant differences were found in the unloaded ($p = 0.15$) and loaded ($p = 0.51$) activities. Although lateral rollback was observed in both groups, it was significantly higher for the episealer knees in both the unloaded ($p = 0.02$) and loaded ($p = 0.01$) activities. Coupled axial rotation was significantly higher in the unloaded ($p = 0.001$) but not in the loaded ($p = 0.06$) activity in the episealer knees. Improved scores were observed at 1-year post-surgery in the episealer subjects for the VAS ($p = 0.001$), KOOS ($p = 0.001$) and EQ Health ($p = 0.004$).

Conclusion At 12 month follow-up, a clear physiological knee kinematics pattern of medial pivot, lateral femoral rollback and coupled axial external femoral rotation during flexion was observed in patients treated with an episealer resurfacing procedure. However, higher femoral rollback and axial external rotation in comparison to healthy knees was observed, suggesting possible post-operative muscle weakness and consequent insufficient stabilization at high flexion.

Keywords Metallic resurfacing implants · Episealer implants · Osteoarthritis · Focal chondral lesions · Osteochondral lesions · UKA · TKA · Knee kinematics · Fluoroscopy

Johannes Holz and Georg N. Duda shared last authorship.

✉ Philippe Moewis
philippe.moewis@charite.de

[1] Berlin Institute of Health at Charité-Universitätsmedizin Berlin, Julius Wolff Institute, Augustenburger Platz 1, 13353 Berlin, Germany

[2] OrthoCentrum Hamburg, Hansastrasse 1-3, 20149 Hamburg, Germany

[3] Zuse Institute Berlin, Berlin, Germany

Abbreviations

OA	Osteoarthritis
UKA	Unicompartmental knee arthroplasty
TKA	Total knee arthroplasty
G-Curve	Gradually changing femoral radius
J-Curve	Conventional femoral multi-radius
VAS	Visual analog scale
KOOS	Knee Injury and Osteoarthritis Outcome Score
MRI	Magnetic resonance imaging
CR	Cruciate retaining
2D	Two-dimensional

Published online: 03 October 2021

Episurf Medical AB
Karlavägen 60
114 49 Stockholm
Sweden

info@episurf.com
+46 (0)8 612 00 20
www.episurf.com

© Episurf 2022

EPISURF

PMR_1004 v01