

3-Year Clinical Result of a Customized Metal Mini-Prosthesis for Focal Chondral Lesion in The Knee Of A Formerly Active 31-Year-Old Man.

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Objective

The treatment of (osteo) Chondral lesions remains a clinical challenge. [1-3,6,7,8,16] A “gap” has been identified (9), where some patients with focal knee-lesions are considered too old for biological treatment or failed treatment, but too young for uni- or total arthroplasty (UKA/TKA). In order to fill this gap, an innovative, patient-specific metal implant (Episealer) has been designed from MRI-images and the lesion-size, and ongoing CPL (Controlled Product Launch) is taking Place, with almost 2-year follow-up. [11-14,15,17,18] the aim of this study is to present a case report of the first “Danish patient” with 3 year clinical and radiographic follow-up of this new resurfacing mini-prosthesis [18].

Methods

An innovative MR examination including a 3D-sequence and diagnostic sequences was obtained and analyzed into a “damage report” specifying the cartilage damage and bone marrow lesions (Fig. 1). Subsequently, individualized implants and guide instruments were manufactured. The mini-prostheses were inserted recessed 0.5 – 1 mm below the surrounding cartilage.

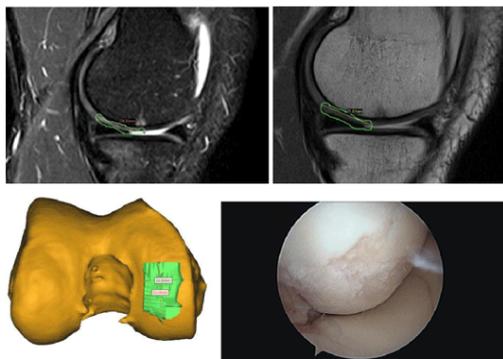


Figure 1: MRI scans of the lesion and 3-D marking – and orthoscopic verification.

Detail of the prosthesis

The mini-prosthesis (Episurf Medical) was manufactured from cobalt-chrome alloy. The articulating surfaces were individualized to the curvature of the affected condyle. (Fig.2&3) The bone facing part had an undercut peripheral edge and a flat underside designed to rest on the subchondral bone. Surfaces facing bone/cartilage were double coated with a layer of hydroxyapatite on top of a layer of titanium, both 60 µm thick. There was a 3 mm wide, 15 mm long peg inserted in an undersized drill hole to provide immediate interference fixation. Clinical results (VAS and KOOS scores), were obtained preoperatively and at 3 and 12 months and annually.



Figure 2: Episealer 20 mm femoral condyle.



Figure 3: Episealer in place postoperatively.

Patient case

31 year-old former fulltime carpenter, very active football- and handball-player. Knee injury in 2011 in handball with ACL – lesion and cartilage lesion on medial femur-condyle. Arthroscopic ACL-reconstruction and micro-fracturing of the 2 cm², ICRS grade-3 cartilage lesion on the medial condyle. No effect on the medial knee-pain, and new arthroscopy 6 months later revealed a then grade-4 cartilage lesion. A new micro-fracturing procedure was carried out, but without effect. He had daily pain (VAS 7-8) in the knee – taking painkillers, paracetamol and NSAID regularly, and had been unable to work for almost 2 years. Two years after the index injury, he was operated with this new resurfacing mini-prosthesis (Episealer) (Fig. 2&5). He has not used any painkillers since the operation, followed according to the CLP – protocol with 3 months, 1, 2 and now 3-year clinical control. VAS declining from initial 7 – 8 until now, at 3 year control, at 2 (active) and KOOS rising from 40 until now 90. He returned to fulltime work as a carpenter 3 months after the operation, is still going strong without problems in his daily work, and has now

even returned to playing soccer and handball. He was followed with radiographic controls at follow-up times. (Fig. 4) showing only slightly narrowing of the joint space - KL-grade [4] from 0 to 1 - and with fine cartilage on the tibial side adjacent to the mini-prosthesis.



Figure 4:3 years control – note no progression in cartilage wear.



Figure 5:Operating tools and operation

Conclusion

The early follow-up results after treatment with a customized metal mini-prosthesis in a challenging “older” patient with focal (osteo) Chondral lesions and a history of failed previous cartilage surgery demonstrated significant pain and subjective outcome improvements at 3 years. The patient had been out of work as a carpenter for almost 2 years and was at risk of losing his ability to work completely and becoming a heavy financial burden on society. We know from other studies [6,7,8,10] – that the loss of working ability can be fatal for such patients, who are

still of working age, and the economic costs for society enormous, especially for these patients in the “Treatment Gap”. In the US, 3.6 million patients with symptomatic knee-pain fall into this group [10].

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