THE MINI-METAL CONCEPT FOR TREATING FOCAL CHONDRA L LESIONS AND ITS POSSIBLE APPLICATION IN ATHLETES

- Written by Leif Ryd, Sweden

The focal chondral lesion may have many aetiologies. Traumatic (osteo-) chondral defects are relatively common in the knee and ankle. Osteochondritis dissecans and osteonecrosis occur in the hip and the knee. There are also indications that repeated minor trauma could cause degenerative focal lesions. All of these conditions may, in the long term, progress to osteoarthritis (OA). Considering the enormous increase in the number of total knee arthroplasty procedures required in the future, treatment of these conditions becomes a matter of necessity not only for patients, but also in terms of healthcare economics.

Contained focal chondral lesions have been the focus of intensive research over the last 20 years. Great advances have been made, but there is presently no universally accepted ‘cure’. Hence, this clinical entity is becoming somewhat of an enigma. Despite lesions usually developing in younger and middle-aged individuals, total knee arthroplasty procedures are not available until late in life, when the lesion has progressed into full-blown OA. While often considerably symptomatic in early life, various biologic treatment methods for patients under the age of 35 years, while often helpful, are seldom curative. In the middle-aged, results after biologic treatment are worse. Hence, a gap in available treatment methods has been acknowledged, the middle-aged patient may be too old for biological treatment and too young for a knee prosthesis.

MINI METAL IMPLANTS

An alternative method of treatment which has generated some interest in recent years is the use of small metal implants, which act much like a dental filling. These implants are inserted to replace the missing cartilage tissue in the defect, usually on a femoral condyle in the knee. This approach brings hard biomaterial into articulation with opposing cartilage. There are different
experiences with such an articulating couple in orthopaedics. While unipolar prostheses in the hip are aggressive to the cartilage in the acetabulum, total knee arthroplasty without a patellar button is the norm in many countries and has functioned for decades. There are a few clinical reports on a first generation of such an implant (HemiCap device, Arthrosurface, Arthrosurface Franklin, MA, USA) and the mid-term (5 year) results are tentatively positive.

A hard material implant poses special requirements on the instruments, on the surgeon and on the implant itself. The operation has to be performed with the utmost precision, so that no part of the implant protrudes above the surrounding cartilage, thereby acting as a plough to the opposing articulating surface.

In an attempt to address the requirements for precision, a second generation of focal resurfacing has been developed and launched as Episealer (Episurf Medical). Here, MR images are used to assess the lesion and inform the surgeon and implants and guide instruments are manufactured through CAD/CAM (computer aided design and manufacturing) processing. This paper will describe the principles, studies and published illustrations) in animal studies.

- **Bonding to bone:** the first generation implant has a titanium screw for fixation. This screw bonds well to bone. On to this screw a hat is attached by a morse taper, which appears to have caused some problems. In the second generation implant, the base substrate is prosthetic grade CrCo-alloy. The surfaces facing bone and surrounding cartilage are coated with a layer of commercially pure titanium, approximately 60 µm thick, on top of which sits a layer of hydroxyapatite (HA), approximately 60 µm thick. HA is well-known in orthopaedics and is routinely used to bond hip and knee implants to bone. The Ti-coating underneath corresponds to titanium dental implants, which have been used successfully for more than 40 years.

When dental implants are inserted unloaded, it takes about 2 months for them to become osseo-integrated, after which they can carry the load of a subsequent dental crown. Knee implants cannot be inserted unloaded. Instead the HA-coating acts as an ‘absorber’ of micromotions, as has been shown in previous studies. Söballe et al. were able to show that HA can accommodate motions as much as 0.5 mm and still result in bony bonding. The Episealer has been inserted in sheep and followed for 12 months. During this time period bone-to-implant contact increased and reached a mean 92.3%. These studies also showed that, at rare places where cancellous bone marrow voids reached the HA, the HA tended to dissolve. In those instances, the titanium stabilised the bonding and no osteolysis or inflammation developed. Hence, this double coating has performed exactly as intended and it is concluded that this mode of fixation should show satisfactory longevity.

- **Opposing cartilage:** in animals, Custers et al showed unfavourable results in the rabbit knee. Metal implants, placed flush with the surrounding cartilage damaged the opposing cartilage less than micro-fracturing did in the goat knee. The HemiCap device inserted in 6 goat knees showed promising results with only minor cartilage changes, despite a rather small implant curvature radius (as assessed from published illustrations). Correctly implanted, somewhat recessed below the surrounding cartilage, damage caused by the Episealer to the opposing cartilage was quite negligible.

**Positioning of the mini-metal implants**

The importance of positioning the implants at an appropriate level, not too deep and not proud, has been studied by finite element-simulation. The authors concluded if the implant is positioned too deep, its edges can become over-burdened, resulting in a progressive degeneration or so-called ‘pot-hole’ effect.

Clinically, cartilage has proven to be able to articulate well against CrCo alloy. In Sweden, a vast majority (95%) of all total knee arthroplasties are inserted without

1. The implant must bond to the living tissue and become securely fixed.
2. The tribological situation must be accepted by the opposing cartilage.
3. The surrounding cartilage must accept the implant.

These three issues have been addressed in animal studies.

**Preclinical studies**

When a hard material is implanted in a cartilage lesion, there are three fundamental challenges that must be met:
a patella button, with the cartilage on the backside of the patella articulating against the femoral flange. This will work well for decades. A first generation of a focal metal implant showed a decrease of the joint space of just 0.1 mm after 5 years. Hence it appears that a metal implant, inserted slightly recessed below the surrounding cartilage and at a correct angle, will have only minimal effect on the opposing cartilage.

- **Cartilage injury:** the majority of cartilage lesions are caused by trauma, resulting in immediate rupture of the cartilage as in (osteo-) chondral fractures or, as a result of minor but more iterative trauma, in slowly developing lesions. There is currently some scientific consensus that cartilage breakdown and eventual development of OA is caused by the chondrocytes starting to produce metalloproteases and collagenases – enzymes that break down cartilage matrix. It is reasonable to assume that, as with osteochondral fractures, this often occurs at the apex of the medial femoral condyle.

- **Focal lesions:** here it is reasonable to assume that this action (the production of metalloproteases and collagenases) is at play and will be perpetuated until complete cartilage breakdown. The process here has been likened to that of a road pothole where the edges slowly fold into the defect, which spreads peripherally, thereby sequentially affecting more and more chondrocytes. For this reason, the reaction of the cartilage in and surrounding the focal lesion may be the very linchpin of success, irrespective of what treatment is given.

**Why use a metal implant for a focal cartilage lesion?**

As discussed above, the hard metal implant may be uniquely suited to the lesion. Unlike any other treatment mode, such as autologous chondrocyte implantation, microfracture and even osteochondral autograft, the metal will instantaneously support the surrounding cartilage, thereby stopping the ‘pot-hole’ development. Hence, conceivably, the surrounding chondrocytes stay healthy and will not be recruited to the process of degradation, through which the disease propagates. This would appear speculative at this point in time, but recent studies have lent some support.

In a controlled study, uncoated implants were compared with two types of HA-coated implants (n=3 x 8 animals). The implants were inserted in sheep and followed for 3 months. Histology showed close adherence to the HA by both the calcified and the hyaline cartilage (chondro-integration) which was totally absent in uncoated devices. This sealing effect may be a decisive part of success, where joint fluid is kept out of the bonding interfaces and chondrocytes are supported in a healthy state.

**Important design criteria**

As found in animal studies, a meticulous fit of the implant to each individual knee is mandatory. Hence, one device uses a library of different shapes and the most appropriate one is chosen during surgery. Alternatively, a better fit can be achieved by customising the implants and guides. To do this, data is obtained from MR images, which are segmented to delineate bone and cartilage and subsequently fed through a CAD/CAM process. This way implants are manufactured with an articulating surface exactly corresponding to that of the affected condyle prior to damage and guide instruments are made to enable exact positioning of that same implant, both factors being a prerequisite for a ‘perfect fit’.

While instrumentation in the first generation implant consists of a tray of instruments and implants with 16 different curvatures to achieve a ‘close fit’, the second generation device uses seven instruments, delivered together with the implant. These instruments consist of a flange corresponding to the cartilage surface. A tube is fitted onto this flange, through which all tissue is handled. The tube ensures perfect angulation of the implant and, by sequential drilling and testing, precise depth of implantation is achieved. This guide principle proved satisfactory in a previous animal study.
The clinical setting

An integral part of the procedure is assessment of the cartilage lesion. Typically, this is done via arthroscopic evaluation of the lesion or by MR investigations. When using dedicated MR settings, a web-based platform, µFidelity, is used for communication. The MR files are used to create a three-dimensional model of the knee allowing the cartilage lesion to be assessed (Figure 2). By communication with the surgeon over the web, the appropriate treatment can be decided on. The surgeon will then accept, discard or suggest an alternative size/position for the implant. In case of approval, the surgical kit is delivered within 4 weeks.

Indications

Focal resurfacing implants fill the gap. For young patients, various modalities of ‘cell transplantation’ are currently preferred. By the age of 30 to 35, however, results of cell therapy deteriorate® and alternative methods, like resurfacing, may be indicated as primary procedures. Further, autologous chondrocyte implantation has been reported to give inferior results following previous biologic treatment® and therefore resurfacing would serve well as a salvage procedure in such cases. Finally, cases where the subchondral bone is also affected, such as osteonecrosis and osteochondritis dissecans represent situations in which cell therapy is less effective. Focal resurfacing appears particularly appealing in such cases and a customised implant can be designed to also replace the bone defect.

Clinical results

Currently, 5-year results of the first generation of resurfacing have been reported. The clinical results appear good, with considerable improvement in patient well-being®. The revision rate, however, has been reported to be around 25% at 5 years®. The customised second-generation implant has been inserted in approximately 100 cases over a 3-year period. There has not been a single revision so far and a first short-term follow-up shows excellent patient well-being with a mean knee injury and osteoarthritis outcome score (KOOS) in excess of 80®.

Resurfacing and the athlete

Bone marrow stimulation such as microfracture, osteoarticular transfer system and cell-based therapies – such as the various generations of autologous chondrocyte implantation – are usually considered for the young adult up to approximately 35 years of age, after which results have been reported to deteriorate®. For this reason, mini-metal prostheses have been reserved for the somewhat elderly and less than athletic patients® and this has also been the initial approach for the use of the second generation customised implant, the Episealer. Has this approach been overly prudent? Probably not, considering the novel principal of function of these mini-metal prostheses. The novel approach of letting cartilage articulate against metal is not intuitively adopted. In previously treated patients, however, wear of the opposing cartilage has been reported to be as little as 0.1 mm over 5 years®. Among the different reasons for choosing one treatment over another, there is one factor that stands out as distinctly in favour of a mini-prosthesis – postoperative rehabilitation. Although a somewhat earlier full weight-bearing (8 weeks vs 12 weeks) is beneficial®, it is accepted knowledge that the neo-tissue after any type of biological treatment demands 12 to 24 months of maturation until heavy loading should be permitted®. For an athlete this is a considerable time. Resurfacing implants bond to bone in a matter of weeks. At approximately this time, the wound healing is also well advanced and no further limitations of physical exercise need to be imposed.

CONCLUSIONS

Resurfacing mini-metal prosthesis harmonise well with the articulating surfaces and the surrounding ligaments, thus securing a good patient outcome. A customised implant in combination with individually adapted guide instruments for implantation should allow perfect restoration of the cartilage surface and, hence, excellent patient well-being. This is in opposition to, for example, knee prostheses where a considerable portion of patients are dissatisfied®. Perfect articulating surface restoration should benefit good long-term survival, including in the physically active patient.

These anticipated good results are also now emerging. The number of patients are still small and the length of follow-up still too short for a definite statement, but both parameters are rapidly improving as time passes.

While it is, perhaps, too early to recommend mini-metal prostheses as a first-line treatment for athletes, the shorter return to full activity postoperatively compared to cell-based therapies presents a distinct advantage in this population. Resurfacing by metal implants could be a salvage procedure in athletes after all biologic alternatives have been exhausted. As effective as treatments for focal chondral lesions are still sought, the mini-metal concept presents one possible option to be further investigated.

References

Available at www.aspetar.com/journal

Leif Ryd
Professor, Orthopaedics Department (Retired)
Department of Learning, Informatics, Management and Ethics (LIME)
Karolinska Institute
Stockholm
Sweden

Contact: leif.ryd@episurf.com

CARTILAGE – SURGICAL OPTIONS TARGETED TOPIC | 295