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Mini-Review on Mini-Metal Implants for Focal Cartilage Lesions

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Mini Review

Recently, two studies have been published on a patient specific metal implant for focal chondral lesions in the knee where clinical results as well as revision data were quite favorable [1,2]. In the quest for an acceptable mode of treatment for the so-called GAP-patient [3], i.e. patients that are too old for biologic treatment and too young for joint replacements, these reports might indicate a new level of success and possibly an increasing interest for such mini-metal implants.

Focal lesions of cartilage in the knee is generally viewed as a common precursor of osteoarthritis (OA) [4,5] and in view of the current epidemic of knee OA [6], any attempt at reducing the need for TKA would appear warranted. Moreover, with increasing demands on functionality, up to 20% of patients receiving a TKA express discontent with the procedure [7,8]. In the last 25 years, intensive research has been carried out on biologic methods of transplantation of chondrocytes into these focal defects [9-11]. These attempts have been successful to an extent but are generally limited to younger patients, under 30 to 35 years of age. Also, biologic methods are plagued with long rehab periods of 12 to 18 months [12] and have been subject to regulatory constraints. Therefore, the various alternatives to chondrocyte transplantation have not met the success that was originally anticipated.

A hard resurfacing implant, where the rehab period is limited to soft-tissue healing time, may appear beneficial. Such hard implants have appeared during the last decade [13] and have shown promising results [14-17]. They all consist of round or elongated hats with one or two fixation peg(s) of some particular design. They are all aiming at the distal femur and are of the uni-polar design, i.e. the implant material articulates directly against normal hyaline cartilage on the tibia or patella (although the HemiCap can be used with a patellar implant). This is a short review of relevant issues regarding these implants to preserve the knee joint from knee replacements in the middle-aged population.

A first-generation implant (the HemiCAP family, Arthrosurface, US) appeared in the mid 2000s and consists of a CoCr metal alloy hat connected to a titanium fixation screw, joined by a Morse-taper. The articulating hat comes in an off-the-shelf library with a number of different shapes where the best is fitted to the particular joint using so called sizing cards. The system uses a guide to fit a Kirschner wire perpendicular to all tangents of the cartilage surface to be replaced as the base for implantation. A number of reports have shown good clinical results [14,18,19]. Indeed, a case-report on 2 cases after 12 years showed good clinical results and no deterioration of the opposing cartilage [20]. However, a number of studies show disconcerting revision figures in the order of 25% after 5 years [21,22].

Somewhat later, another hard-material implant, the BioPoly (BioPoly, US) [16], appeared. This is a one-piece titanium implant with a polyethylene cap towards the joint cavity. The polyethylene is enhanced ("micro-composite") with hyaluronic acid in order to be gentler to the opposing cartilage. There is one published report on 40 patients of which 12 were followed over the full 2-years FU-period [16]. Initial results were reported to be good with clinical improvement of the same order of magnitude as other treatment modalities and only one case had been revised within this short period of time.

At about the same time, a third metal implant for focal chondral lesions appeared, the Episealer implant (Episurf Medical, Sweden). This technology is based on three fundamentals; a MRI-based Damage Marking Report (DMR), individualized guide instruments based on the MRIs and an individualized implant again from the MRIs [23]. The implant itself is a one-piece CoCr alloy hat with one or two fixation peg(s). Surfaces meeting bone/cartilage are coated with a double coating of

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titanium and hydroxyapatite for osteo- and chondrointegration [24]. Recent published papers report good clinical results [1] and favorable revision figures in mid-term FU [2].

Opposing Cartilage

Arguably the most important issue with these uni-polar implants is how the opposing cartilage reacts to the artificial material. Here, this natural tissue will meet artificial metal/polymers under the extremely harsh mechanical conditions that prevail in the human knee where compressive forces of 4x to 6x body weight occur. There are some previous experiences. Normal joint cartilage articulates with patellar cartilage in TKA where the patella is not resurfaced and this appears to go well [25]. However, uni-polar hip replacement has a mixed track record [26,27]. These focal implants also show mixed records. The first-generation implant has shown conspicuous signs of wear of the opposing cartilage in some studies [21,28] while the very same implant explicitly has shown little problem of this kind with a unchanged medial joint space after 5 years [14]. Again, after as long as 12 years, the opposing cartilage was reported to hold up nicely. This may suggest that it is not the material itself but rather the precision of insertion and preoperative indications that are crucial. Obviously, a metal implant must not sit proud or it will harvest the opposing cartilage [29,30]. Therefore, precise guide instruments may be of decisive importance. The Episealer MRI-based individualized guides allow for incremental fine-tuning of insertion depth in steps of 200 µm to consistently position the implant about 0.5 mm below the surrounding cartilage and this position is checked with a "dummy", an exact replica of the implant. Human cartilage asymptotically compresses by about 20% [31] and 0.5 mm, corresponds to 20% of the cartilage thickness (one-sided) in a normal knee [32].

Surrounding Cartilage

The surrounding cartilage must accept and preferably integrate with the artificial material. From hip- and knee replacements, it is well-known how wear products from joint replacements can invade the peri-prosthetic space and create osteolysis [33]. It is improbable that the materials in these focal implants should wear into malignant particles but even joint fluid itself is aggressive and could cause osteolysis [34,35]. For this reason, bonding of cartilage to implant suggests a feasible construct. Of the three focal implants, only the Episealer features a provision for bonding to cartilage. The HA-coating of the periphery of the hat facing cartilage has been shown to produce so called chondrointegration, i.e. a bond between implant and cartilage effectively sealing the cartilage defect [24].

Moreover, and contrary to any other mode of treatment, these mini-metal implants immediately support the surrounding cartilage. Edge loading of the cartilage rim surrounding the lesion is subject to excessive stress on normal locomotion. This creates a progressive increase in size of the lesion, the so-called "pot hole" effect [36,37] whereby the focal lesion deteriorates into a progressively larger one, eventually leading to full-blown OA. With physical support of the cartilage rim, excessive stress/strain is counteracted and may well be a decisive factor for better longevity.

Bonding

All three focal implants are inserted without bone cement but rely on direct bonding to bone. The HemiCAP and the BioPoly implants bond to bone by osseointegration to titanium [38,39], a time-honored, consistent and well documented mode of fixation. Despite this, the Australian registry reports a substantial number of loosening for the HemiCAP, presumably being caused by failure of the Morse taper. Technically, the insertion of the titanium screw is an exacting procedure, not too deep or the Morse taper will not catch and not too shallow or the hat will protrude. The Episealer bonds by way of a double coating, hydroxyapatite superficially for fast bonding [40,41] and titanium underneath for consolidation of the fixation should there be hydrolysis of the hydroxyapatite [40]. No loosening has been reported for the Episealer device.

Patient Selection

As with any kind of surgical procedure, patient selection is crucial. For these patients, the problem often starts with a traumatic incident [42,43] that hits the cartilage often close to the apex of the femoral condyle. Sometimes this leads to an osteochondral fracture and a loose piece of cartilage in the knee. More often, however, the mechanical trauma is smaller having only a crushing effect of the intact cartilage at the apex. This may alter the metabolism of the chondrocytes into a more destructive pathway and the scene is set for a slow, continuous process towards OA [44]. Somewhere along this continuum, there is a window of opportunity for focal implants, when the lesion is not too large, when the opposing cartilage is not yet too damaged and when there is still a possibility to regain joint homeostasis [45]. This window can be sought by MRI that can delineate the extent of the lesion and the status of the subchondral bone as well as the status of opposing cartilage. For this reason, MRI is an integral part of the Episealer system and the DMR allows a careful selection of patient that is fit for the procedure. Possibly, too wide indications explain the untoward revision statistics for the HemiCAP [21,28].

MRI also allows examination of possible Bone Marrow Lesions (BML). Cartilage does not carry nerves, but subchondral bone does. Pain sits in the bone and large BMLs, or bony defects too, can be addressed by a thicker Episealer implant.

Conclusion

Small, metallic implants have the advantage of immediate function once soft-tissue healing after surgery has taken place. Post-operative rehabilitation is short. Recently published results indicate good clinical effects in terms of well-being and, provided correct patient selection and precise surgery, longevity appears to be consistent and of promising magnitude.

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