The use of biodegradable fixation devices in the treatment of osteochondritis dissecans and osteochondral fractures

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Summary
Knee joint disorders in man may always have existed. The first known description of the removal of loose bodies from the knee joint was made by Ambroise Paré in 1558. In the following centuries, the origin of osteochondritis dissecans (OCD) is still not elucidated. The treatment evolved from only removing the fragment to removing and abrasion of the dissecat bed and, finally, to fixation of the fragment after consolidation promoting procedures, like debriding and drilling of the bottom of the crater and cancellous bone transplantation. In the treatment algorithm, a differentiation should be made between adolescents and adults.

In adolescents, the course of the disease is milder and, if the fragment is still in place, only drilling and fixation is sufficient to lead to consolidation of the fragment in the majority of the cases, if conservative treatment fails. If the fragment is partly or totally detached, but still intact, fixation should follow after debridement of the dissecat bed. Cancellous bone transplantation is then optional.

In adults, however, the OCD should be considered as a fully developed pseudarthrosis and the treatment should be like the appropriate established pathways for pseudarthrosis therapy, i.e. debridement, cancellous bone transplantation and a compressive, stable fixation. If the dissecat is fragmented or the cartilage is heavily damaged, cartilage restoring procedures, instead of fragment replacement should follow, like Matrix induced Autologous Cartilage Introduction (MACI) or, in first instance, micro fracture chondroplasty. Research is continuing to evaluate which one of those two procedures will be to be preferred in future.

Pins and K-wires are used as fixation devices. However, regarding at OCD as a pseudarthrosis, compressive fixation devices such as screws or staples should be applied to fix the fragments. Metallic devices have to be removed in most cases during a second procedure before loading the limb to prevent damage to the opposite cartilage. Even embedded under the surface in an effort to prevent this cartilage damage, protrusion can occur. An additional long term disadvantage of the permanent implantation of metallic devices is scattering during CT or MRI scanning and some metals, such as chromium, nickel and cobalt can evoke local allergic reactions like eczema. Chromium, nickel and cobalt are also potent carcinogens in animals.

Several research groups have explored the use of autologous cartilage bone plugs as fixation devices. However, donor site morbidity, the absence of producing substantial compression and failure of the re-integration process at the interface of donor and recipient cartilage make this procedure less than optimal.

The use of biodegradable fixation devices would prevent radiological scattering, lacking the other, previously mentioned, disadvantages and renders a removal operation unnecessary.

In chapter 2, the consolidation is described of five intact and still attached fragments after trans-fragmental drilling and fixation with biodegradable pins. Two patients with detached lesions were successfully treated by fixation with one, centrally placed, metallic screw, providing compression, combined with three biodegradable pins of polydioxanone to obtain rotational stability, whereas
two detached fragments, fixed with only biodegradable pins, failed to consolidate.

However, the screw still had to be removed before loading the leg during a second surgical procedure, to prevent damage of the opposite cartilage.

This was the motive for the in vivo research project in goat knees, described in chapter 3. A standardized created cartilage bone fragment was fixed with one centrally placed biodegradable screw, 20mm in length and 2.7mm in diameter (Ø), and two pins, 20mm long and 1.5mm in Ø, composed of the same material. As biodegradable polymers, commercially available materials were used: a random copolymer composed of 82% poly-L-lactic acid (PLLA) and 18% poly-glycolic acid (PGA) copolymer (PGA/PLA) and the as-polymerized poly(96L-D-lactide) (PLA96) polymer. The results were compared to those when devices of surgical steel were inserted. A sham operation served as a control.

Around all eight screws in the PGA/PLA group, starting at twelve weeks post operatively, osteolytic defects were found, which is in contrast to only once at eighteen weeks after implantation around a screw of PLA96. This is a significant difference (p < 0.001). The screws of PLA96 were found to show degenerative changes at forty-six weeks, comparable with the PGA/PLA screws at twelve weeks, and some damage of the opposite cartilage was observed. One time a cavity was seen around a pin of PGA/PLA. This was never found around the other fifteen pins of this polymer and also never around the sixteen pins of PLA96. This is not significant and the conclusion was made that pins of the selected two polymers can safely be used, regarding the tissue reaction, but not the screws. Either, it is likely that cavities develop, or that the degradation is so slow, that undesirable damage of the opposite cartilage is caused. This phenomenon is found in the literature as well.

Meniscus Arrows® (MAs) were designed and introduced several years ago (1994) and are already in current use for arthroscopic mending of ruptures in the vascularised part of menisci. They consist also of poly-L-DL lactide and have a smaller Ø (1.1mm) than the smallest biodegradable screws (2.0mm), barbed nails (Smart Nails® (SNs) 1.5mm) or cannulated metallic screws (2.4mm).

In chapter 4 is the outcome of pull-out tests in axial direction described, comparing the hold in bone of three times a single Arrow versus a single 2.0mm in Ø metallic screw. Bone blocks, fixed with three MAs were pulled-off in axial- and tangential direction, the last mentioned in order to mimic shear forces. Average forces of more than 60Newton (N) were noted for the single Arrows and of more than 120N for the bone blocks in both directions.

The screws performed higher, but the results of the Arrows were appreciated to be enough for clinical application.

The impetus for the tests, described in chapter 5 was that swelling or distension, due to the uptake of water, has been equated in literature with an increase of weight of the material. In fact, only a few authors measure the increase of the dimensions in some way and term this swelling. However,
a substantial swelling, or distension, could increase the hold of the MAs in solid materials like bone like expanding bolts.

During the tests, six MAs, directly retrieved from the package, were weighed. Reweighing was repeated after 2, 4, 6, 8, 24, 28, 32, 48, 60 hours and 7, 10, 14, 18, 28 days during submersion in a sterile, phosphate buffered saline solution at 36ºC, refreshed twice a week under sterile circumstances. This period of 28 days is the time after which the first consolidation of the fragments can be expected. Parallel to this series the core diameter and the distance between the tips of the barbs of a second series of six new MAs were measured in a field-emission scanning electron microscope, also starting at t=0 (t1) and at 2, 4, 6, 24 hours and 3, 4, 5, 7, 11 and 18 days afterwards, being submerged as well. This experiment was finished after 18 days, achieving, statistically, sufficient results.

The weight of the MAs increased during the first two hours from an average of 0.0227 gram to an average of 0.0248 gram or 9.16%. This is significant (p = 0.027). However, after two hours the weight remained more or less stable at an average total weight gain after 28 days of 0.0017 gram or 7.18 %. The average weight variation was not significant.

During the swelling or distension experiment a subtle increase of the average core diameter of the arrows with 0.01 mm, or 1.01%, from 1.22 mm to 1.23 mm was noted. This is significant (p = 0.031). The barb-barb diameter decreased, unexpected and significantly (p = 0.031) in time with 0.15 mm, or 8.6%, from an average of 1.74 mm to 1.59 mm.

In conclusion, the maximum change of weight occurred in the first two hours, staying stable afterwards and no correlation was found with a theoretical swelling or distension of the devices. Indeed, only the core diameter increased negligible, regarding the mechanical properties. In contrast, the significant decrease of the barb-barb diameter could have consequences for the anchoring capacity in bone.

The effect of decrease of the barb-barb diameter of the MA’s during the degradation on the hold in bone was evaluated during an experiment, described in chapter 6. Eight new MAs were pulled out of a thawed fresh frozen human femoral condyle, in comparison with six MAs, after being submerged during thirty-one days in a sterile phosphate buffered saline solution at 37º Celsius. The average extraction force of the new, non-degraded MAs and the degraded MAs did not differ significantly (t-test: p = 0.23). Also the spreading of the results did not differ significantly according to the Mann-Whitney test (p= 0.28). In the two-way ANOVA test no significant interaction between degradation and location on the condyle (p= 0.7), no difference between degraded or non-degraded MAs (p= 0.15) or location on the lateral- or medial condyle (p=0.14) was noted.

The conclusion can be made, that, although the inward curling of the barbs after a degradation period of thirty-one days suggests that this could lead to a decrease of the hold in a solid material like bone, this is not confirmed in our study and that this phenomenon does not interfere with the successful application of MAs to fix small bony fragments in fracture surgery and in OCD disease.
Finally, after evaluating the previously mentioned data, pull-out tests were performed with MAs and SNs to choose between both devices for the application of fixing the fragments in the treatment of Osteochondritis Dissecans and Osteochondral fractures in patients (chapter 7). In two recent papers the successful clinical application of SNs as fixation devices in the treatment of OCD is described in, respectively, 30 and 11 patients without negative side effects. However, the smaller diameter of the MAs, compared to the SNs, respectively 1.1mm and 1.5mm, would cause less damage to the fragments and would permit the use of more devices, spreading the compression, with equivalent or less damage, which could be advantageous. The composition of current MAs and SNs is equivalent; both are manufactured from the same self reinforced poly-L-DL (80-20) Lactide copolymer. So, in view of the successful use of the SNs for this indication, no negative side effects are to be expected from the smaller MAs as well.

First, three MAs and three SNs were, successively, pulled out of a thawed, fresh frozen, human condyle. Second, three bone blocks, each with either three MAs or three SNs were fixed at the condyle and pulled off as well, in axial and tangential direction, the latter mimicking one cycle of shear forces. The pull out tests showed for the single MA’s an average value of 68 N. The single SNs required an average pull-out force of 61N. The required forces in the bone blocks group to distract the blocks with the three MAs from the condyle showed an average force of 122N, and shear force testing showed an average force of 121N. The blocks with three SNs as fixation devices needed an average force of 88N to be pulled off. The Levene’s test showed no significant difference in the variances of the transformed variable (P = 0.454). Based on the outcome of these tests, we chose to employ the smaller MAs for the clinical application.

In two patients, group 1, an OCD dissecat, once attached and once detached, was fixed with, respectively, three and five MAs. During surgery on the first patient, arthroscopic drilling was followed by fixation with three MAs. In the second patient the procedure started arthroscopically but was converted due to the size of the fragment and the necessity to drill and insert the MAs from diverse angles. In this patient, after debridement, drilling of the bottom of the defect and cancellous bone transplantation, the dissecat was fixed with five MAs and Tissuecoll® was applied on the cartilage margins of the dissecat.

In group 2, an osteochondral fracture in three patients was fixed within two weeks after the initial trauma with, respectively, twice two MAs and one time with five MAs. All procedures started arthroscopically and were continued through a small arthrotomy, due to the size of the fragment. Tissuecoll® was put on the cartilage edges of the fragment before fixation. A second look arthroscopy, six weeks after the first surgery, showed a congruent interface between the fragmental and recipient cartilage and a stable fragment. After an average follow-up period of five years, varying between two and nine years, all patients were free of complaints, although the patients in group 1 spontaneously avoided peak force inducing sports as a precaution.
**Conclusion 1:** based on the results from in vitro pull-out tests and available clinical studies, biodegradable devices like Meniscus Arrows® and Smart Nails® are likely to perform adequately as fixation devices for small fragments in the treatment of Osteochondritis Dissecans disease and osteochondral fractures in the knee. They both provide the advantage of one stage surgery without the need for subsequent surgery to remove the implants. The smaller diameter of the Meniscus Arrows® suggests that this device should be preferred for this indication. In this study, MAs allowed undisturbed healing of osteochondral lesions of the knee in five patients after reduction and fixation without complications.

According to the state of the fragment the proposed OCD treatment algorithm is as follows:

<table>
<thead>
<tr>
<th>state of the osteochondral fragment (according to Bots, 1983)</th>
<th>stage</th>
<th>fragment stability</th>
<th>cartilage</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1a</td>
<td>stable</td>
<td>intact cartilage</td>
</tr>
<tr>
<td></td>
<td>1b</td>
<td>stable</td>
<td>fissure at the margins of the fragment</td>
</tr>
<tr>
<td></td>
<td>2a</td>
<td>mobile, but attached</td>
<td>fraying at the edges and mild degenerative changes</td>
</tr>
<tr>
<td></td>
<td>2b</td>
<td>loose body</td>
<td>still vital with minimal degenerative changes</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>loose body or fragmented</td>
<td>seriously damaged</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>proposed OCD treatment algorithm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stage</td>
</tr>
<tr>
<td>adolescent</td>
</tr>
<tr>
<td>adult</td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

**Conclusion 2:** The aforementioned properties of the MAs indicate, that biodegradable devices like MAs could also serve as fixation devices for several other indications, where the use of small and good in bone anchoring biodegradable devices is advantageous, especially, if they can be inserted arthroscopically.

Some examples:
- displaced tibial spine fractures in children and adolescents
- displaced radial head fractures
- Mallet fractures of the distal phalanges of the hand
- avulsion fractures at the base of the first phalanx of the thumb (the so-called ski thumb)
- humeral epicondyle fractures in children

Further research should be performed to explore the potential benefit of these applications.