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

Wouters, Diederick Bernard
Pull-out tests, comparing Meniscus Arrows® and Smart Nails®, followed by a prospective series of five clinical cases applying Meniscus Arrows® as fixation devices of osteochondral fragments in the human knee.

D.B. Wouters¹,²
J.G.M. Burgerhof²
J.Th.M. de Hosson³
R.R.M. Bos⁴

¹ Department of General-, Arthroscopic Surgery and Traumatology, TweeSteden Hospital, Tilburg, the Netherlands,
² Department of epidemiology, University Medical Centre Groningen, Groningen, the Netherlands,
³ Department of Applied Physics, University of Groningen, Groningen, the Netherlands,
⁴ Department of Oral and Maxillofacial Surgery, University Medical Centre Groningen, Groningen, the Netherlands.
ABSTRACT

The aim of this study was to compare the hold in bone of Meniscus Arrows® and Smart Nails®. After in vitro tests the clinical application of the selected device was performed. Straight pull-out tests were performed to analyse the hold in bone of single Meniscus Arrows® and Smart Nails® and, tangentially, to assess the fixation capacity of three devices of each kind in bone blocks. The results were statistically analyzed using the Student T- and the Mann-Whitney test, the Anova two-way test and the Levene test. Because no significant difference was noted between the hold of both nails, we choose the thinner Meniscus Arrow® as fixation device in a prospective, consecutive patient series of two patients with a symptomatic osteochondritis dissecans fragment and three patients with an osteochondral fracture of a femur condyle, fixed twice with two Meniscus Arrows®, one time with three and twice with five, according to the size of the fragment. All procedures started arthroscopically, four times conversion followed into an arthrotomy, due to the size of the fragment. The cartilage margins were glued with Tissuecoll®.

Results: all five fragments consolidated and at an average follow-up period of five years (ranging from two to nine years) no pain, effusion, locking, restricted range of motion or signs of arthrosis were reported.

We conclude, that based on the results from in vitro pull-out tests and available clinical studies, Meniscus Arrows® and Smart Nails® are likely to perform adequately in the treatment of Osteochondritis Dissecans disease and osteochondral fractures in the knee. They both provide the advantage of one stage surgery. However, the smaller diameter of the Meniscus Arrows® suggests it should be preferred for this indication. In this study, MA’s allowed undisturbed healing of osteochondral lesions of the knee in five patients without complications.

Key Words: biodegradable – fixation devices – Meniscus Arrows® - osteochondral fragments – osteochondritis dissecans
INTRODUCTION

Compressive metallic fixation devices such as screws, non compressive pins or Kirschner wires, or staples are used to fix the fragments in the treatment of Osteochondritis Dissecans (OCD). However, in most cases, they have to be removed during a second procedure to prevent damage to the opposite cartilage.

Devices have been developed to be inserted and embedded under the cartilage surface in an effort to prevent cartilage damage, but they can cause damage as well, if protrusion occurs after all. 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, gold, platinum, and cobalt can evoke local allergic reactions like eczema. Chromium, nickel and cobalt are also potent carcinogens in animals.

Several 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.

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

During the last four decades, intensive research has been conducted to develop an appropriate material and device. Biodegradable pins and screws of polydioxonan, polyglycolic acid and polylactic acid, their copolymers, combinations or blends are now in use for small fragment fixation in fracture or OCD treatment.

Each of these materials and devices, while useful, has significant shortcomings. Biodegradable screws produce the required compression, but their current minimal head diameter (Ø) of 3mm, in combination with the necessity to insert at least two devices to obtain rotational stability cause a considerable damage of the fragile fragments. Furthermore, during the degradation process, wear of the opposite cartilage still occurs. In an attempt to address this problem, more rapidly degrading materials were created. Unfortunately, though, sinus formation is observed when screws of these materials are used. Biodegradable pins share this disadvantage to a smaller extent, but cannot give adequate compression. This compression is generally considered as a necessity for healing.

Biodegradable barbed nails such as Smart Nails® (SN’s, ConMed Linvatec Ltd Tampere, Finland), 1.5mm in Ø, have currently been used for fragment fixation in patients with OCD fragments and, according to these papers, perform better than pins.

The composition of Meniscus Arrows® (MA’s, ConMed Linvatec Ltd Tampere, Finland) and SN’s is equivalent; both are manufactured from the same self reinforced poly-L-DL (80-20) lactide copolymer.

MA’s with their tiny head and an even smaller core Ø of 1.1mm combined with a length of 16mm could potentially act as small fragment fixation devices as well. The hold in bone was evaluated...
during in-vitro research, showing a considerable force, more than 60 Newton (N), which was required to pull the MA's out of a human femoral condyle.\textsuperscript{10}

The smaller diameter of the MA's, compared to the SN's would cause less damage to the fragments, or would permit the use of more devices with equivalent or less damage.

The purpose of this study was to perform in vitro pull out tests comparing the hold in bone of single MA's and SN's and of bone blocks, fixed with three devices of each kind.

Second, to conduct a clinical prospective study on patients with intact osteochondritis dissecans fragments and osteochondral fractures of femoral condyles, using these devices, showed to be the most adequate for this indication, according to the results of these tests.

**SUBJECTS AND METHODS**

To compare the hold in bone of MA's and SN's, the experiment was divided in two parts.

First, three MA's with a length of 16mm and three SN's with a length of 20mm were successively pulled out of a thawed, fresh frozen human condyle, clamped in an Instron 1195 draw bench. The scale was set at 0 –200N, the time 0 – 300 sec. The extraction speed was 5mm / min. The standard hand instruments were used to create the holes and to insert the devices (Figure 1a,b). Subsequently they were pulled out (Figure 1c).

Second, three bone blocks, each with three MA's or SN's were fixed at the condyle and were pulled out as well (Figure 1d), mimicking the situation in vivo. The results are depicted in table 1.

The Student T-test and the Mann-Whitney test were used for the single MA's and SN's. For both groups the Anova two way tests after the logarithmic transformation and the Levene test of equality

<table>
<thead>
<tr>
<th>Table 1: results</th>
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<tbody>
<tr>
<td><strong>Meniscus Arrow</strong></td>
</tr>
<tr>
<td>no.</td>
</tr>
<tr>
<td>1</td>
</tr>
<tr>
<td>2</td>
</tr>
<tr>
<td>3</td>
</tr>
<tr>
<td>Average:</td>
</tr>
<tr>
<td>st. dev.:</td>
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</table>

<table>
<thead>
<tr>
<th><strong>bone block + 3 Arrows</strong></th>
<th><strong>bone block + 3 nails</strong></th>
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</thead>
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<td>result*</td>
</tr>
<tr>
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</tr>
<tr>
<td>2</td>
<td>148</td>
</tr>
<tr>
<td>3</td>
<td>108</td>
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<tr>
<td>Average:</td>
<td>122</td>
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<tr>
<td>st. dev.:</td>
<td>22,5</td>
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</tbody>
</table>

*data in Newtons
Pull out tests, comparing Meniscus Arrows® and Smart Nails®, followed by a clinical series of error variances was applied. Based on the outcome of these tests, we chose to utilize the smaller MA’s (Figure 6) for the clinical study.

In the OCD group, two women, 20 years (patient #1, right knee) and 38 years old (patient #2, left knee) with a symptomatic intact OCD fragment of the medial condyle were operated between 1999 and 2001, with a follow-up period of 9 and 7 years. The size of the fragment varied from 20x25mm in diameter in patient #1 to 30x30mm in patient #2 (table 2). Surgery was initiated arthroscopically in both cases. For patient #1, a fully arthroscopic procedure was performed. A central drill hole was made in the still attached fragment with intact covering cartilage (Figure 2a). Pressure on the

Figure 1:  
- a: Meniscus Arrow® handset  
- b: Smart Nail® handset  
- c: extraction of the first Meniscus Arrow®, note the drill hole indicating wires for the next extractions  
- d: the bone block with 3 MA’s fixed before being pulled off, mimicking shear forces

of error variances was applied.
Table 2: the patient group

<table>
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<tr>
<th>patient nr.</th>
<th>diagnosis</th>
<th>age</th>
<th>side, condyle</th>
<th>number of M.A.’s</th>
<th>f.u. (years)</th>
<th>fragment size*</th>
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<tr>
<td>3</td>
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<td>right, lateral</td>
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<td>2</td>
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<tr>
<td>4</td>
<td>osteochondral #</td>
<td>15</td>
<td>right, lateral</td>
<td>2</td>
<td>2</td>
<td>25 x 30</td>
</tr>
<tr>
<td>5</td>
<td>osteochondral #</td>
<td>20</td>
<td>left, lateral</td>
<td>5</td>
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<td>25 x 30</td>
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<tr>
<td>average</td>
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<td>20.8</td>
<td></td>
<td>3</td>
<td>5</td>
<td>24 x 29</td>
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</tbody>
</table>

* size in mm.

Figure 2: patient #1: a: central drilling;
          b: after fixation with 3 Meniscus Arrows® and release of the tourniquet, note the bleeding from a drill hole;
          patient #2: c: insertion of a Meniscus Arrow® from the lateral portal in the fragment after debridement and a spongyous bone transplantation;
          d: the final situation

Fragment did not reveal debris, indicating the presence of underlying necrosis, emanating from the drill hole. It was therefore concluded, that no significant necrosis was present in the sub-fragmental space. A compressive fixation with three MA’s, 16mm in length, was performed after three additional drill holes were made to allow introduction of locally bone marrow cells to promote healing. After releasing the tourniquet, bleeding was observed from the drill holes (Figure 2b).

In patient #2, the arthroscopy was converted into a small arthrotomy, due to fragment size, the
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presence of infra-fragmental necrosis (the fragment was already partially loose at first sight and necrosis and fibrosis was observed in the dissecat bed) and the necessity for spongious bone transplantation in this case. Also proper reduction and the orientation, required to insert the devices (Figure 2c) necessitated the conversion. After debridement of the bottom of the crater, spongious bone was harvested with a punch from the ileac crest, and placed between the fragment and the recipient bone. The fragment was reduced and temporarily fixed with two K-wires, 1mm in Ø, inserted from different angulations, perpendicular to the cartilage surface. They were subsequently exchanged by two MA’s with a length of 16mm, followed by the drilling and insertion of an additional three MA’s, to provide a spread adequate compression (Figure 2d).

The second group of patients (# 3,4,5) consisted of two children of 11 and 15 years old and one adult of 20 years old with a traumatic osteochondral fracture, one time sized 20x30mm and twice 25mm x 30mm in Ø (table 2). The operation was performed within two weeks after the trauma. Tissuecoll® (Baxter–Immuno, Vienna, Austria) was applied in the defect to glue the cartilage borders. The bony fixation was performed using two MA’s (Figures 3 a-e, 4a - d) in patients # 3 and # 4 and five MA’s in patient # 5 (Figure 5a - e). Both the arthrotomy as the arthroscopy portals were closed in layers in all patients.

Postoperatively a plaster splint was applied for two weeks, followed by a hinged brace for four weeks. A second look arthroscopy was carried out in this group six weeks postoperatively to assess the reliability of the fixation.

Gradual progressive weight bearing was allowed in the next four weeks.

Figure 3: patient # 3: a: arthroscopical view of the fragment, b: aspect of the defect in the lateral femur condyle, c: the fragment, d: fixation with the first Meniscus Arrow®, e: the final situation

(see for color image: page 143)
RESULTS (table 1)

The in vitro tests The pull-out tests showed values of the single MA’s varying between 59 Newton (N) and 78N with an average of 68 N. The single SN’s required a value between 53N and 66N, the average was 61N. The required forces in the bone blocks group to distract the blocks with the MA’s from the condyle varied from 108N to 148N with an average of 122N, the blocks with SN’s fixation needed 55N to 115N, with an average of 88N.

All information was combined into one statistical analysis. A two-way ANOVA was performed with the type of nail (SN vs. MA) and condition (single nail or bone block) as fixed factors. A logarithmic transformation of the required force was used to equalize variances. Levene’s test showed no significant difference in the variances of the transformed variable (P = 0.454). As expected, the bone blocks, fixed with 3 devices, required significantly more force to be distracted than the single devices (P = 0.007), but no significant difference is found between the MA’s and the SN’s (P = 0.108).

The clinical application After the initial healing period of three months, no effusions, locking, or pain occurred in the two OCD patients during a follow-up period of seven and nine years respectively. The patients did not experience restrictions in daily life or sports activities, although they spontaneously avoided high impact sports as a precaution.

All three osteochondral fractures healed without sequelae. Within three months both children returned to their previous activities. The adult patient (# 5) returned to previous activities in six

Figure 4: patient # 3: a,b,c: removal of the heads of the Meniscus Arrows® at 6 weeks after insertion. Note the smooth cartilage of the tibia plateau (a). d: patient # 4, 6 weeks after insertion
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months. During a second look arthroscopy at six weeks postoperatively, consolidation of the fragment was found in all cases, with anatomical alignment of the cartilage. In patient # 3 (Figure 4a), the heads of the MA's were visible and came incidentally loose at the junction between the head and the first barb, after some traction was applied with an arthroscopic forceps, while evaluating the devices. The heads were removed from the joint (Figure 4b-c).

In patient # 4 the heads of the MA's were still embedded under the cartilage surface and were stable (Figure 4d).

No MA heads were seen in patient # 5 at arthroscopy (Figure 5e).

No wear or damage was observed in the cartilage of the opposite tibia plateau of any of these three patients (Figures 4,5).

![Figure 5: Patient # 5: a: the loose fragment b: the defect c: measuring 25mm x 35mm d: fixation with Issuecoll® and five Meniscus Arrows® e: the result at six weeks postoperative](see for color image: page 144)
DISCUSSION

In the last five decades, reduction of OCD fragments and osteochondral fractures, if remaining intact, followed by rotation stable fixation with compression, has been generally accepted as optimal treatment. A spongeous bone transplantation and debridement of the dissecat bed, if necrosis is found, should also be considered in case of osteochondritis dissecans.\textsuperscript{1-6,13-20}

Use of biodegradable devices provides the possibility to repair these conditions with a single procedure, avoiding the need of a removal operation. On the other hand, the application of biodegradable screws has potential disadvantages such as damage to the opposite cartilage from exposed screw heads and, if rapidly degrading material has been used, sinus formation.\textsuperscript{13-17}

Small barbed pins such as MA's or SN's have been shown to fix compressive as well as, and perform better than smooth pins to fix the bony part of the fragment without causing sinus formation.\textsuperscript{19,20,21}

In this study no statistical difference between the required pull out forces of either the single MA's and SN's, or the bone blocks fixed with three of each type of device, was demonstrated. Though there may be a trend in favour of the MA's, this is not significant (p = 0.108 at \( \alpha = 0.05 \)), according to the corrected Anova test.

Given their equal mechanical behaviour, combined with reduced tissue damage and increased options for number and arrangement of MA's, permitted by their smaller diameter, we choose for the MA's for clinical application (Figure 6).

\textbf{Figure 6:} a: a Smart Nail\textsuperscript{®}  
b,c: two Meniscus Arrows\textsuperscript{®} in different directions to show the head and barbs
During the second look arthroscopy no signs of chondral damage was noted, either at control arthroscopy or during the follow-up period. This is consistent with the findings of Weckström et al\textsuperscript{19} and Dines et al.\textsuperscript{21}

They did not mention chondral damage in their series with SN’s as fixation devices as well. The number of reports of chondral damage while using MA’s in meniscal surgery is limited to only a few case reports, despite their frequent and worldwide numerous application in these orthopaedic procedures.\textsuperscript{22,23} Case reports of chondral damage are also found in relation to other devices, so this phenomenon is not restricted to MA’s.\textsuperscript{24,25}

The MA heads were incidentally removed in patient # 3 during the second look arthroscopy, while testing their stability with a forceps. In patient # 4, the heads were stable. In patient # 5 no heads were found at all.

We have no explanation for these different findings, performed at the same postoperative interval at six weeks. The clinical course, however, was equivalent for all three patients.

The chondral part of the fragment in our three patients with osteochondral fractures was fixed with Tissuecoll\textsuperscript{\textregistered}, according to recommendations in the literature\textsuperscript{26,27} to promote cartilage healing. Good and stable congruency was found during second look arthroscopy.

The OCD disease is a rare condition. Lindën\textsuperscript{28} found an average incidence of one out of 10,000 patients under the age of 50 years in Malmö during a follow-up period of 10 years, with a maximum incidence between the ages of 10 years and 20 years. Widuchowski et al.\textsuperscript{29} reported a prevalence of two percent in a sample of 25124 arthroscopies. Given the low prevalence of OCD in the population, our series of patients is small as well.

However, the clinical outcome in our series with MA’s combined with the results in the clinical series using the larger SN’s\textsuperscript{19,21} supports the application of both type of device.

The diameter of the MA’s is 26% smaller, compared to the SN’s (1.1mm versus 1.5mm, Figure 6). The surface of the defect in the fragment for each MA is 0.79mm, compared to 1.77mm for each SN. For three devices, a potential average for fixation, the total damage to the fragment is 2.4mm vs. 5.3mm.

This combined with their frequent availability in hospitals for already established indications and their excellent hold in bone, at least equal to that of the SN’s as demonstrated during our pull out tests, makes the MA’s arguably the more advantageous device for the fixation of OCD fragments and osteochondral fractures.

**CONCLUSION**

Based on the results from in vitro pull-out tests and available clinical studies, Meniscus Arrows\textsuperscript{\textregistered} and Smart Nails\textsuperscript{\textregistered} are likely to perform adequately in the treatment of Osteochondritis Dissecans disease and osteochondral fractures in the knee. They both provide the advantage of one stage surgery. The smaller diameter of the Meniscus Arrows\textsuperscript{\textregistered} suggests it should be preferred for this indication. In
this study, MA’s allowed undisturbed healing of osteochondral lesions of the knee in five patients without complications. For the benefit of the one stage operation, applying MA’s for this indication, second look arthroscopy should only be performed if indicated.
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References

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