Cartilage Reconstruction
using PIN-Implantation

An alternative method in arthrosis surgery
Evaluation of the Cartilage Repair Study 1999 – 2003

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with contributions of

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In Germany between 5 to 10 Million people suffer from mainly arthro­sis-related arthralgia, tendency increasing. In about 2.5 Million of these cases the pain is caused by chronic cartilage damages. Often this leads to total endoprosthesis as ultima ratio.

Due to severe degenerations caused by arthrosis manifesting themselves in corresponding symptoms, an annual total of app. 60,000 knee-TEP surgeries are conducted in Germany.

Within the last ten years several alternative methods of treating articular cartilage damages were developed, all of those are suitable for avoiding the complete manifestation of arthrosis.

If a complete manifestation of arthrosis has already occurred, most of the time only a TEP can lead to an improvement in symptoms.

Especially for the treatment of younger patients who show a complete manifestation of arthrosis, there is no validated surgical therapy available.

Besides, due to scientific ambition and the demand for the best arthrosis therapy as well as increasing financial bottle-necks, the search for alternative options for effective therapy with an optimized cost-performance-ratio has become top priority.

Within the last couple of years significant progress in the development of therapy approaches to avoid arthrosis has been made, especially in the treatment of joint cartilage damages.

Especially for isolated damages on the femur condyle new methods such as the osteochondral bone-cartilage transplantation and the autologous chondrocyts transplantation as well as the microfraction could establish themselves.
Restrictions

However, the situation for cartilage defects and arthritic degeneration of femur and tibia remains unsatisfactory.

Equally insufficient is the situation for elderly patients and especially for active employees, because the surgery methods mentioned above require intensive and long-term rehabilitation.

The by far biggest percentage of patients with knee arthrosis chooses symptomatic drug therapy with the related risks or put up with a significant reduction of their physical activity.

Another alternative is the endoprosthetical treatment, though this method is also related to considerable restrictions.

Thesis

It is inevitably important to develop alternatives to conventional therapy for genicular arthrosis. Accordingly, a valuable alternative for certain indications is the implantation of cartilage repair PINs, especially because it can be conducted under minimal invasive surgery (endoscopy).

Aim of study

The aim is to show - in the context of a retrospective outcome study - how patients themselves evaluate the success after the implantation of PINs into their knee-joints has been conducted. A randomized multicenter study will show objective results in the near future.
In between 1999 and 2002 the PIN implantation was conducted on 116 patients.

The average age of the patients was 60.7 years.

The average time period of follow-up accounted to 33.1 months.

47.8 % of the patients were male and 52.2 % were female.

In 52.6 % of the cases the right knee was treated, in 47.4 % the left knee was treated.

Altogether a total of 297 defects were treated using PIN surgery. The average size of the defect was about 8.1 cm².

In 34.7 % of the concerned cases the defect was located at the patella and the condyle. In 43.5 % of the cases the medial compartment was affected, in 21.8 % the lateral compartment.

Patients were interviewed for their subjective complaints according to the questionnaire by Flandry.

In addition, patients had to evaluate the over-all results of the surgery and were asked to indicate, in how far they felt better, the same or worse than before the treatment. Patients were asked to indicate the results on a 10-point-scale.
The use of cartilage repair implants has already a 20-year-long history. The implantation-PIN which is manufactured using a special weaving process, consists of pure carbon. This is the result of many years of research.

The pioneers of this process of renewing joint surfaces via cartilage reconstruction implants were R. J. Minns, J. A. Betts and D. S. Muckle in the early 1980s in Great Britain. Using the method developed by Minns, cartilage reconstruction PINs are implanted in order to stimulate the development of new cartilage issue.

Before the implantation of the PIN drilling of holes into the subchondral bone has to be done.

The PIN has a diameter of 2.95 mm and a length of 12.5 mm.

The drillings are conducted with a diameter of 3.2 mm. The drilling depth is 15 mm.

The bone marrow could be reached.

Afterwards, the cartilage reconstruction PIN was implanted using special instruments. Using the implantation of cartilage reconstruction PINs, which relies on the well-known technique of stimulating the bone marrow, fibro-cartilage substitute tissue is induced via pluripotent blasts, which reach the surface.

Hereby biologic resurfacing is expected. The material of the PINs has a high bio-tolerance, is non-toxic and does not induce cancer. The special construction of the PINs leads to a focussed and significantly increased growth in collagen tissue and fibre.
Surgery Method

In all cases of this study the minimal invasive surgery was conducted by the same surgeon. The surgery was conducted under blood blockage using a cuff pressure of 450 mmHg.

Initially arthroscopy of the knee-joint was done via the lateral standard access, then one, respectively two medial accesses were opened.

This was followed by a thorough inspection of the joint.

On 23% of the patients a partial resection of the lateral meniscus was conducted, on another 48% an additional partial resection of the medial meniscus was performed in the same session. This was just a parallel secondary therapy and not the actual target.

Within the implantation process of the cartilage reconstruction PIN firstly the free joint parts were removed, then the cartilage and especially cartilage edges were smoothed out thoroughly and thereby the defective arthritic areas were made visible and accessible.

Corresponding detritus was rinsed out. Finally the PINs were implanted.

One PIN per square centimetres of cartilage damage was implanted.

All patients were treated with Redon-drainage for one day.

The follow-up treatment was done using an average partial load of 10 to 15 kg for the treated leg within a period of six weeks.

Other elements of the therapy were lymph drainage as well as intensive physiotherapy in order to improve mobility, strength and coordination.

Besides, a passive "leg-mover" was recommended.
Results

99 patients replied to the study inquiry.

Altogether 450 PINs were implanted.

The observation time period was 33.1 months.

In 34.7 % cases of the participants in the study, patella or condyle were affected. In 43.5 % of the cases the medial compartment was affected, in 21.8 % the lateral compartment. Complications such as infection or delayed wound healing did not occur.

The total result of the surgery was evaluated as follows:

35 % (scale position 1 and 2) "very good", 28.3 % "good" (scale position 3 and 4), 15.3 % "satisfactory" (scale position 5 and 6), 9.2 % "sufficient" (scale position 7 and 8).

12.2 % "insufficient" (scale position 9 and 10).

Asked, if the patient significantly felt better or worse after the treatment in contrast to the initial state of health before the implantation,

63.3 % patients replied that they felt a significant improvement in their well-being after the surgery had been conducted (scale position 1 to 4).

For 24.5 % the situation was the same before and after the implantation (scale position 5 to 8) and 12.2 % of the patients indicated a worsening of their state of health (scale position 9 and 10).

Nevertheless, 74 % of all treated patients would again undergo surgery with cartilage repair PINs. Only 26 % would not like to have this method conducted on themselves again.
Discussion

90 out of 116 treated patients, this means 77% cases were completely documented and 101, meaning 87% could only be filed to some extend, because some points in the questionnaire were not filled in completely. This explains the fact, that the question regarding their post-surgical result was answered by 98 patients and the question, whether they felt better or worse, was answered correctly by 96 patients.

The average age of the patients was relative high, 60.7 years with a variance of +/- 8.6 years and can be related to the fact that an high percentage of the patients – whose only other option would have been TEP- wanted to avoid the very same or at least postpone it.

This relative old age should generally be seen as a disadvantage to this method which falls back on biological resources of bone marrow.

Therefore the good results of this study are even more surprising, because they might have been even better for younger patients!

The old age is also an explanation for the number of therapy resistant cases, which according to our impressions are usually found more often in older patients with less biological resources.

The relative long time period for follow-up examination for up to 44.5 months may lead to the assumption that good results may last stable for a long time period, if the biological resurfacing was enabled sufficiently enough. This proves the following hypothesis to be right:

Through the inert and biologically high tolerance of the PINs the supply of bone marrow to the bone surface via the drill channels can be maintained sufficiently.
This again enables the permanent transfer of blasts to the bone surface, which possibly is a big advantage to the Pridie-drilling or the microfrac-
tion, whereby the channels begin to disappear right after the recon-
struction of the bone lamellas and thereby the contact to the bone 
marrow is disconnected.

As a result, aging processes and signs of degeneration may occur in the 
new substitute tissue and these may reduce the life span of the issue.

After a certain period of time old symptoms may reoccur.

In order to gain an optimal biological resurfacing, we have followed the 
recommendations made by Minns and therefore we implanted the PINs 
leaving a space of 1 cm from one PIN to the next. Defects of patella 
were smoothed using arthroscopy (debridement) and were documented 
as such, but there was no PIN implanted in this area. The kneecap 
requires shorter PINs and therefore there is the need for an open sur-
gery method due to technical reasons. But our proclaimed aim was to 
keep the surgery as minimal invasive as possible.

The arising tendency, that the success rate was especially high in 
younger patients and smaller defects is logical and was expected.

Additional studies will have to work on a way to determine the indication 
regarding maximal size of the defect and maximum age. Alternative 
therapies for older patients may only be suitable as microfraction in 
order to treat minor defects. For the treatment of corresponding bigger 
defects there is no other suitable alternative than the total endopros-
thesis (TEP).

Three quarters of the patients would again choose to undergo surgery 
with implantation of carbon PINs.
This means that also patients, whose post-surgical results only were satisfactory or whose results were not clearly better than before the treatment, would again undergo the implantation.

The aim should be to further improve the already very good quota through an obvious indication, which surely should be possible thanks to the results and tendencies shown in this study.

Conclusion

A high patient satisfaction was proven. In the context of arthrosis therapy patients are offered an additional option with a high probability of success. The complication rate is very small. Even if the therapy isn’t a success, the implantation of a knee-TEP is not rendered more difficult.

In the context of further research the indication for implantation of PINs has to be further clarified. This especially relates to size and localization of the defects.

Cartilage reconstruction Pins offer patients affected by arthrosis the advantage of minimal invasive therapy with a very good outcome under a justifiable risk.
BIOMEDICAL IMPLANTS GmbH

Cartilage-Repair-Study

Data | Facts | Figures
1999 – 2003

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U. Guhlke-Steinwachs, MD, Ph. D.
<table>
<thead>
<tr>
<th>Description</th>
<th>Value</th>
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<tbody>
<tr>
<td>Surgery interval</td>
<td>1999 – 2002</td>
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<tr>
<td>Total number of patients</td>
<td>116</td>
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<tr>
<td>Completely documented</td>
<td>90 (77 %)</td>
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<tr>
<td>Partially documented</td>
<td>101 (87 %)</td>
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<td>Average Age</td>
<td>60,7 +/- 8,6 years</td>
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<td>Follow-Up</td>
<td>33,1 +/- 11,4 months</td>
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<tr>
<td>Gender</td>
<td>47,8 % male</td>
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<tr>
<td></td>
<td>52,2 % female</td>
</tr>
<tr>
<td>Side</td>
<td>52,6 % right side</td>
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<tr>
<td></td>
<td>47,4 % left side</td>
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<td>Therapie resistant cases (TEP)</td>
<td>12,9 %</td>
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<tr>
<td>Number of defects</td>
<td>297</td>
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<td>Average defect size</td>
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<td>Defect Localization I</td>
<td>Patella</td>
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<td></td>
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<tr>
<td>Medial Compartment 43.5 %</td>
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<td>Lateral Compartment 21.8 %</td>
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<p>| Defect Localization II                | Patella 14.8 %    |
|                                      |        | Size 2.11 +/- 1.0 cm²|
| Trochlea 17.9 %                      |        | Size 2.1 +/- 1.56 cm²|
| Med. FK 28.3 %                       |        | Size 4.2 +/- 2.5 cm² |
| Lat. FK 13.8 %                       |        | Size 2.0 +/- 1.4 cm² |
| Med. Tibia 17.5 %                    |        | Size 2.45 +/- 1.9 cm²|
| Lat. Tibia 7.7 %                     |        | Size 1.63 +/- 0.9 cm²|</p>
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<th>Total Result</th>
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**Average**

4.28 +/- 2.2

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<td>10</td>
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**Average**

4.07 +/- 2.3

**Would again undergo surgery with Repair PIN** 74.0 %

**Would not again undergo surgery with Repair-PIN** 26.0 %

Treatment of deep cartilage defects in the knee with autologous chondrocyte Implantation
N Eng Med 331: 889-895

Analysis of subjective knee complaints using visual analog scales.

Möglichkeiten der gelenkerhaltenden Gonarthrose-Therapie mittels Arthroskopie und ergänzender intraartikulärer Verfahren
Arthroskopie 12, 9-15

Clinical experience with the mosaic technique, Rev.-Osteal 4: 32-36


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Biological resurfacing of the knee, A review of surgical management, the knee Vol 1: 197-200

Improvement of the thickness chondral defect healing in the human knee after debridement and microfracture using continous passiv motion Am I knee Surg 7: 109-116
Klinische Ergebnisse nach Mikrofrakturierung bei der Behandlung
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Sportorthopädie – Sporttraumatologie 19 (291-294)

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