Patient information brochure

Healing cartilage injuries biologically

Autologous chondrocyte transplantation

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Information for patients

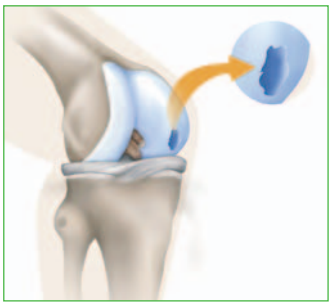
Dear patient,

Every day you put strain on your joints in many different ways – and they do extremely heavy work. For example, each step you take puts a load 5½ times your body weight on your knee (if you weigh 70 kg, that means 385 kg), and when you jump, it's even more. With your knee under such pressure it's no wonder that just one false move can result in injury to the ligaments and cartilage in the joint. You can feel the effects of this for yourself: pain, swelling, discharge or blocking in the joint reduce your ability to perform precisely when you are at your most active. Nowadays there are many forms of treatment available for cartilage regeneration and symptom relief. This patient information brochure describes in more detail one of the most modern and effective methods, autologous chondrocyte transplantation (ACT) with NOVOCART® 3D.

Information for patients

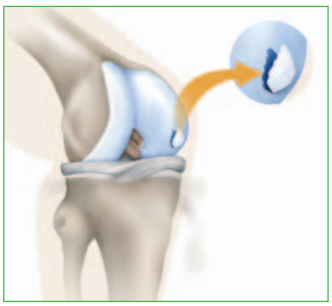
Cartilage injuries have various causes

Traumatic cartilage injuries



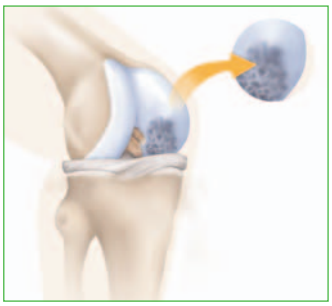
are caused by a short, intensive, non-physiological strain on the joint, as a result pieces of cartilage become detached from the joint surface. The depth of these lesions can vary, and not everyone affected complains of pain, although the cartilage is already damaged. This condition often affects young, active people who can subject their joints to non-physiological strain either during sport or in normal daily activity.

Osteochondrosis dissecans (OD)



is the name of a bone disease that occurs most frequently in youths and young adults. When individual areas of the bone are affected, the cartilage covering these areas can also become diseased. This results in the affected section of cartilage becoming detached and forming a free body within the joint, leaving a lesion that reaches down into the bone.

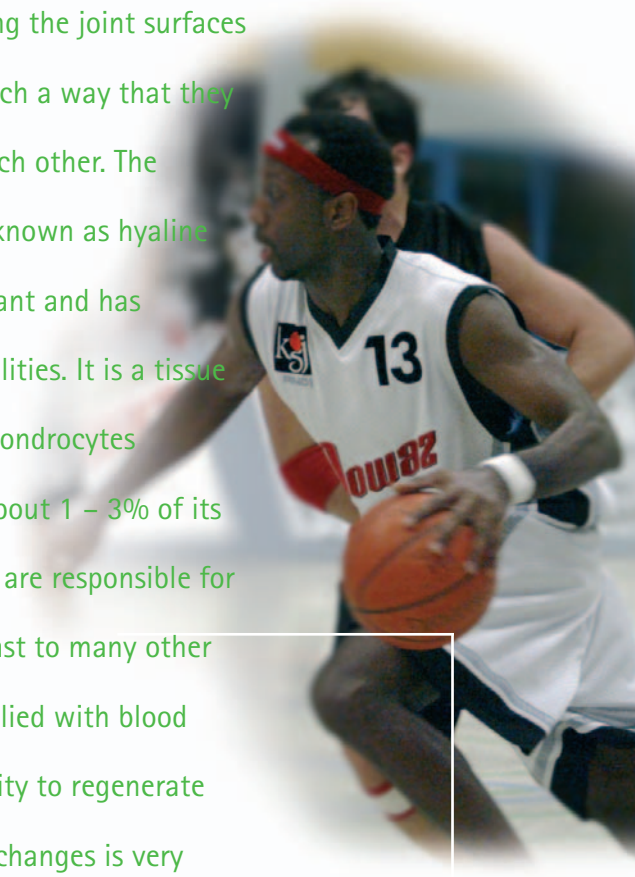
Degenerative cartilage defects



known as arthrosis, normally develops from wear and tear of the cartilage surface as part of the ageing process. The cartilage surface gradually becomes rough and is then slowly worn away over a long period of time, until finally bone is rubbing against bone. At this point, the only possible treatment is to replace the joint with an artificial knee; the biological methods described in this brochure can only be used to treat arthrosis in exceptional cases. If traumatic cartilage injuries or osteochondrosis dissecans are left untreated, they lead in most cases to the premature development of arthrosis.

Why does cartilage not heal by itself?

If we cut our finger, the wound heals within a few days or weeks – skin can regenerate itself. It is different with cartilage. Joint cartilage is a pressure resistant supportive tissue covering the joint surfaces of bones that are connected in such a way that they are able to move in relation to each other. The cartilage in a healthy knee joint, known as hyaline cartilage, is highly pressure resistant and has enormous shock absorbing capabilities. It is a tissue containing very few cells, with chondrocytes (cartilage cells) making up only about 1 – 3% of its total volume. These chondrocytes are responsible for forming cartilage tissue. In contrast to many other body tissues, cartilage is not supplied with blood vessels, which means that its ability to regenerate itself after injury or pathological changes is very limited. The repair tissue that does form in some cases cannot cope with the strains imposed on the joint in the long term, since it possesses neither the low friction surface nor the shock absorbing and pressure resistant qualities of healthy joint cartilage.



Information for patients

Various forms of treatment are available

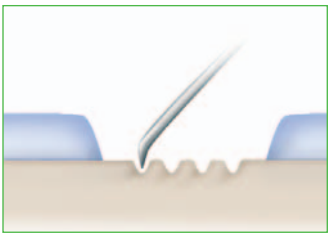
If the cartilage injuries are large, this greatly increases the risk of arthrosis, independent of the patient's age. If they are accompanied by damage to the meniscus or ligaments, the risk of developing arthrosis is increased still further. As cartilage tissue cannot regenerate itself, cartilage defects in the knee joint must be treated surgically in most cases.

Conservative treatment

Physiotherapy, pain killers or treatments with hyaluronic acid, for example, relieve the symptoms, but cannot heal the damage to the cartilage. However, these forms of treatment offer good temporary pain relief in order to bridge the period before surgery.

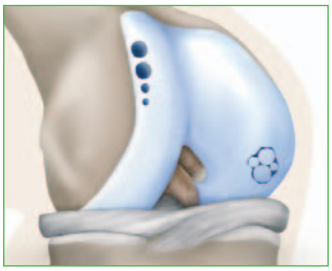
Microfracture

During an arthroscopic procedure, the bone lamella beneath the cartilage lesion is pierced with drills or chisels. This causes blood to flow out, infiltrating the defect area with regenerative cells (stem cells). Over the next few months, these cells fill the defect area with scar tissue. The biomechanical properties of this scar tissue are substantially different from those of normal hyaline cartilage: it is soft and considerably less shock absorbing. Nevertheless, this treatment can be very successful for small cartilage lesions up to 2 cm^2, in low loadbearing areas of the joint, and particularly in youthful patients.



Autologous osteochondral cylinder transplantation (OCT)

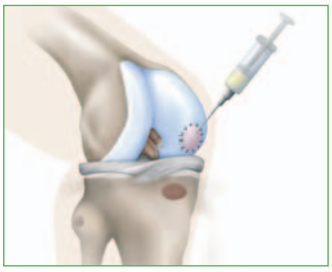
In OCT, also known as osteochondral transplantation, osteochondral (bone and cartilage) cylinders or plugs are harvested from a low loadbearing surface of the joint and transplanted into the defect area, that has been prepared to the appropriate size. This procedure fills a large proportion of the defect surface with high quality hyaline cartilage. The remaining gaps between the osteochondral plugs are covered with low quality scar tissue. The results of this technique are good, but it does destroy areas of healthy joint surface, and this can lead to similar symptoms in the harvest site to those experienced in the original defect area. In order to limit these harvesting symptoms, OCT can only be successfully applied for cartilage lesions up to approximately 3 cm^2.



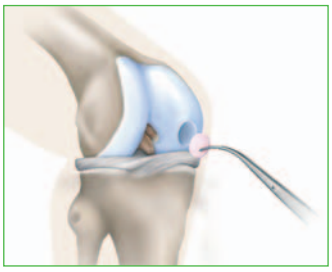
Autologous chrondocyte transplantation (ACT)

For more than 15 years, transplantation of the patient's own cartilage cells (autologous chondrocyte transplantation) has been successfully used for cartilage reconstruction, primarily in traumatic injuries or in osteochondrosis dissecans. This procedure is superior to those already described particularly where the defect area measures more than 4 cm^2. There are two different techniques:

1. In classical ACT, chondrocytes are harvested from a non loadbearing area of the knee, cultivated in a laboratory and delivered back to the surgeon in a nutrient solution. During transplantation, a suitably sized periosteal flap is removed from the shin bone and sewn over the defect area. The cells in the nutrient solution are then injected into this impermeable chamber.



2. The new generation of ACT uses a carrier material or matrix for the cartilage cells, which can be more quickly and easily transplanted and causes less tissue damage during the operation. The exact procedure for matrix-based ACT transplantation is described below, using the NOVOCART® 3D method as an example.



Treatment with ACT is particularly suitable for patients between 18 and 50 years of age.

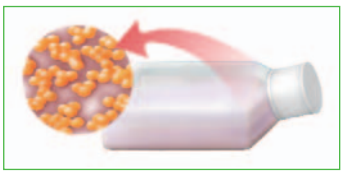
Information for patients

NOVOCART® 3D – the new generation autologous chondrocyte transplantation

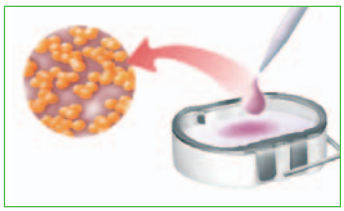
Producing the transplant

For NOVOCART® 3D, a small amount of cartilage is harvested from a non loadbearing area of the patient's knee during arthroscopy. A certain amount of blood is also taken from the patient. The chondrocytes are extracted from the cartilage tissue in the laboratory clean room and cultivated using the patient's blood. After the required number of cells has been cultivated, the chondrocytes are sown into a special three dimensional collagen matrix, which to a great extent matches the original biological cell environment in the cartilage, and here the cells already begin to produce new cartilage ground substance. Before NOVOCART® 3D is delivered to the hospital for transplantation, exactly three weeks later, the most up to date analysis techniques are used to check the vitality and sterility of the chondrocytes, as well as their ability to form hyaline cartilage.

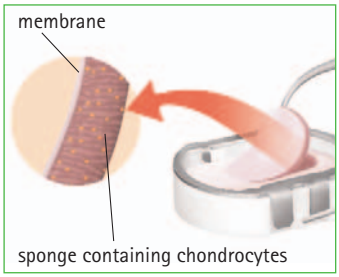
A small amount of cartilage is harvested from a non loadbearing area of the knee.



The chondrocytes are extracted and cultivated using the patient's blood.



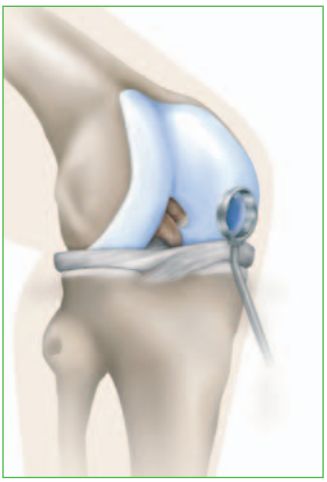
The chondrocytes are sown into a special three dimensional collagen matrix.



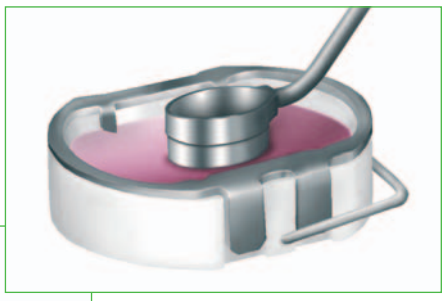
The matrix consists of an impermeable membrane and a sponge.

Transplantation

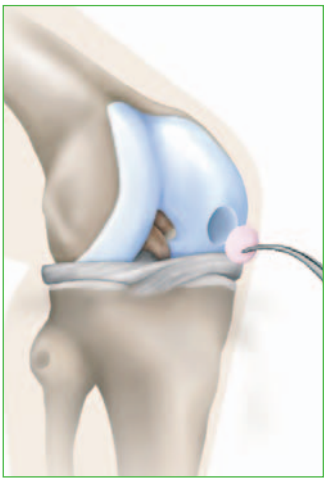
Three weeks after the harvest arthroscopy, NOVOCART® 3D is transplanted into the patient. This is performed in a minimally invasive, tissue preserving operation that takes just under 45 minutes. A small skin incision approx. 5 cm long is made to provide access to the damaged cartilage. The transplant is cut to match the defect area exactly and is inserted into the lesion. Now the special feature of the NOVOCART® 3D matrix comes into play – the chondrocytes are introduced into the lesion inside the sponge-like matrix, and the firmly attached covering membrane holds them in place in the defect area and protects them from the rest of the joint. The matrix is fixed with absorbable sutures, biodegradable pins or fibrin adhesive, and the operation wound is closed.



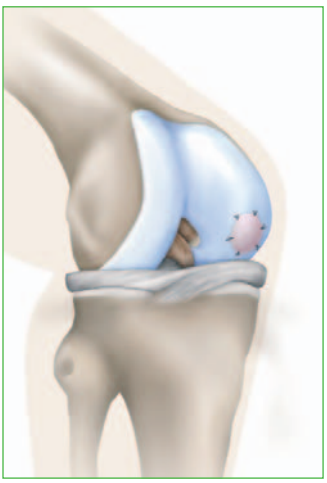
The damaged cartilage area is prepared with a punch.



The transplant is cut to fit exactly into the lesion.



The chondrocytes in the matrix are introduced into the defect area.



The matrix is fixed into place with absorbable sutures.

Information for patients

What is the postoperative treatment following chondrocyte transplantation?

The postoperative treatment depends primarily on the anatomical position of the cartilage injury in the joint. There are basically two different possibilities: lesions in the main loadbearing area of the joint and lesions on the knee cap or its corresponding gliding surface on the main joint.

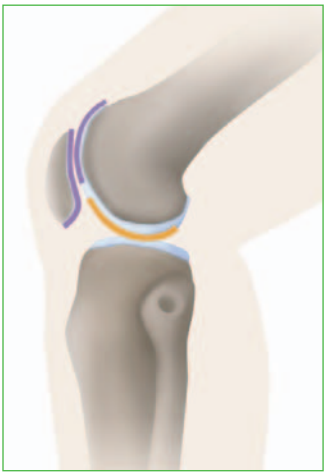
Lesions in the main loadbearing area

immediately postoperative
- 48 hours bed rest
- the joint should not be moved

48 hours postoperative
- drainage tubes are removed
- the joint is mobilized

for 6 weeks
- crutches are used for support
- partial loading of the joint with 10 – 20 kg body weight
- free mobilization of the joint
- accompanying physiotherapy

after 6 weeks
- gradual increase in joint loading by 30 kg increments every two weeks up to full body weight



Main loadbearing area
Knee cap and gliding surface

Lesions on the knee cap or on the gliding surface

immediately postoperative
- 48 hours bed rest
- the joint should not be moved
- IROM splint with flexion limit at 30°

48 hours postoperative
- drainage tubes are removed
- the joint is mobilized

for 6 weeks
- full loadbearing permitted
- flexion limited to 30°

after 6 weeks
- gradual increase in flexion by 30° every two weeks
- IROM splint removed when 90° flexion has been achieved

In the first few months after full loadbearing or full flexion capability has been achieved, you should only undertake types of sport that place little or no strain on the joint. After one year the cartilage has healed sufficiently so that contact sports and sports which impose strain on the joints can also be resumed. The postoperative treatment described above is only a recommendation. Your doctor will discuss this matter with you and put together the best postoperative treatment programme for your particular case. In order to make your treatment as successful as possible, you should follow your doctor's or therapist's instructions exactly. This is the only way to ensure that you will be able to put your full weight back on your knee at the end of your postoperative treatment.

We wish you a rapid return to active daily life free from pain – with your own cartilage.

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