Knee Orthosis for Cartilage Repair

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1 Background

Damage of joint tissues usually starts with damage to articular cartilage. The ultimate result, degenerative joint disease or osteoarthritis, is frequently occurring: approximately 80% of people over 60 years of age have osteoarthritis features in X-rays of their knee and hip joints. The ultimate treatment is inevitably a total joint prosthesis.

Since several years a new, successful treatment exists: joint distraction (1). Key elements are unloading the joint and preservation of motion. Unloading prevents further cartilage damage and creates favourable restoration conditions. Motion of the joint enables transportation of nutrition to the damaged area and removal of waste products. It has been proven that restoration of the cartilage can be obtained in 2-3 months (2).

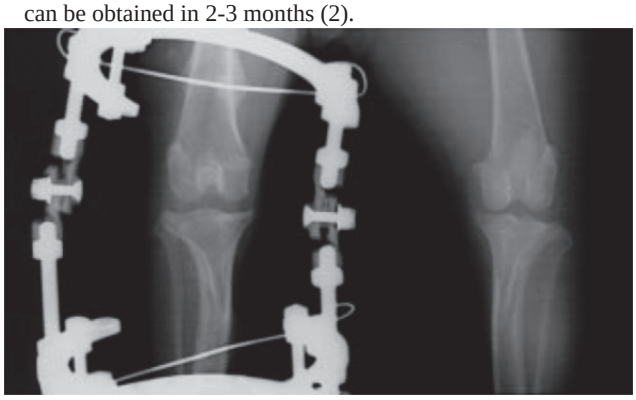

Figure 1: Knee distraction using an external frame with hinges

Currently only one surgical method of joint distraction is known with an application in the knee, see figure 1. Pins are inserted into the bone proximally and distally to the joint. The pins are connected by a hinged frame that distracts and unloads the joint. The hinge allows the patient to walk with a fully functional knee joint without mechanically loading the cartilage. One drawback of this method is the invasive character of it. Pins are penetrating the skin, thus infection is likely to occur. Not many people take this risk. Also, wearing the external frame poses a social burden (e.g. patient cannot wear normal clothes) as well as a psychological burden on the patient.

Orthoses exist which can to some extent unload a joint, but which do not allow functional use of the joint. An example is the Thomas Splint, which is a leg brace intended to unload the hip joint. Ideally it would fully remove the weight on one leg. Literature reports, however, that it removes at the most 50% of the body weight from the hip. It does not remove any of the muscle forces on the hip joint. It also does not provide distraction of either the hip or the knee joint, nor does it allow motion of the knee joint.

Our newly designed and fabricated orthosis combines the best of both worlds. It can unload the knee joint, like the distraction frame, at the same time allowing full ROM of the joint. And, as being an orthosis it does not require transcutaneous connections to the bone. The movement should be sufficient for efficient distribution of nutrients and removal of waste products such that the joint tissue can regenerate. The unloading should be enough to start regeneration of cartilage. A first clinical trial has been performed. Results are presented in this paper.

2 Methods

The orthosis (fig. 1) is derived from an upper leg prosthesis. The bottom of the socket is removed to allow the leg to be present. The lower leg is forced to have a slight angle with the upper leg. In this way the loading of the knee is decreased. In a fully extended position the femoral condyles and the tibia plateau are in close contact to realize sufficient stability for the leg to land on the ground and to bear load. In a more flexed position the contact is less severe and thus the loading on the cartilage limited. The orthosis will support the body via an adapted upper leg socket. Forces between socket and body are transferred via a tuberosity support. The weight is transferred directly to the floor by the orthosis, bypassing the knee and the ankle. That is, the patient stands on the orthosis, not on his foot. The orthosis contains a lower leg part connected to the upper leg part by a hinge. The lower leg part is also connected to the lower limb. The hinge is aligned with the anatomical knee joint. To make up for the leg length difference, the shoe on the contralateral side is provide with a thicker sole and heel.

Traction can be applied on the lower limb by the orthosis, causing unloading of the joint even under muscle activity. Several types of hinges are applicable, such as the automatically locking Basko SPL-joint. Using an automatically locking joint will reduce muscle activity around the knee as the patient does not need to stabilize the knee. For the first clinical trial, a traditional hinge mechanism without locking mechanism was applied.

The first patient was a female with severe cartilage damage according to the X-rays. She walked for two months with the knee orthosis and used crutches all the time. The orthosis was always applied when walking. To improve the flow in the joint each day exercises on a home trainer bicycle was done at the lowest possible resistance.

After two months the orthosis was removed. X-rays were taken to register the amount of knee cartilage recovery. Gradual loading was prescribed over a period of 6 weeks.

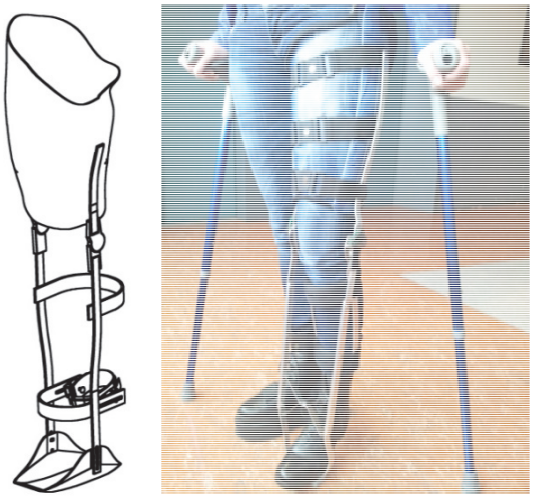

Figure 1: Knee orthosis, schematic vies (left) and tested prototype (right)

3 Results

Recruting a patient for this trial was rather difficult. In spite of the prospect of possible cartilage regeneration without the need for percutaneous pins, several prospective users were reluctant to agree to wearing an orthosis.

The orthosis was comfortable enough to use it for a period of 2 months in every walking or standing situation. Although it should be possible to use it without crutches, this patient felt too unsecure to do so. Her motivation was high enough to use the orthosis all the time.

Detailed results about cartilage repair are not available yet, but will be presented during the congress.

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4 Interpretation

Spontaneous cartilage repair was found to be impossible until some 15 years ago. Animal experiments showed that joint distraction with preservation of motion could start a healing process of damaged joint cartilage. After 2 months repair was visible. And when after 2 months knee loading was brought back to normal, the repair process continued. Cartilage apparently needs a period of rest to allow the repair process to start.

However, this treatment is very uncomfortable and risky for patients. Due to the percutaneous pins there is a high risk of infection, with the risk of the infection spreading to the bone. The pins that are present could cause damage to the skin or clothing of the other leg.

As a more patient-friendly alternatve a knee orthosis was developed. The orthosis proved to be comfortable enough for this single patient to be used for a period of 2 months.

Results are not present yet, but will be discussed during the congress.

References

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