# A review on joint distraction including non-invasive alternatives for knee joint distraction

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# **Abstract**

Osteoarthritis is a joint disease common in middle-aged and elderly people and has a large impact on one's quality of life and wellbeing. Osteoarthritis is classified as a disease in which the cartilage of the joint degenerates with complications such as joint inflammation and swelling of the joint. This eventually can lead to severe pain and loss of function of the joint.

In this research study the causes, effects and treatments of osteoarthritis are described. A new option for the treatment of osteoarthritis is joint distraction, in which the joint is unloaded using invasive external distraction frames but at the same time joint movement and rotation are still allowed. The possible mechanism and effects of joint distraction in the ankle and the knee are described in this article followed by several possible non-invasive alternatives for the mechanical unloading of the knee joint. Finally the differences in the prevalence and progression of ankle and knee osteoarthritis are described to illustrate the need for a non-invasive knee joint distraction device. Today's options to achieve knee joint distraction in combination with joint movement and joint rotation including a non-invasive device are not sufficient and further research and development is required.

# Introduction

Osteoarthritis is a joint disease which affects a lot of people all over the world. This disease contributes on a large scale to the cause of disability of the human body. Epidemiological studies estimate around 15 % of the world population suffers from osteoarthritis, in the U.S. alone that is around 43 million people <sup>1</sup>. Due to these significantly high numbers osteoarthritis has a large effect on the modern day society; it is becoming a social, physiological and economic burden with high financial consequences. Also the percentage of patients suffering of osteoarthritis will increase as the population ages.

The disease is most common in middle-aged people aged between 30 and 60 years old, which represents 4 to 5% of disability-adjusted life-years in that age category <sup>2</sup>. The probability of encountering osteoarthritis increases with age and is harder to treat as the disease progresses. The joints most often affected by osteoarthritis are the hand, knee and hip. This often results in increased mechanical stress, ligament derangements, cartilage degradation, subchondral bone changes and muscular impairments. Also secondary inflammation of the synovium plays an important role in the progression of osteoarthritis <sup>1</sup>These factors lead to the symptoms of osteoarthritis, including joint pain, stiffness and eventually a non-optimal usage of the joint.

The mechanical stresses and loads which are experienced by a joint are one of the most important factors in the progression of osteoarthritis. Several studies support the concept that the mechanical demand of the joint often exceeds the tolerance of the joint and the different components such as the cartilage, bone and ligaments <sup>3</sup>. Next to increased mechanical stress other risk factors are defined, including age, genetic predisposition, joint congruency, increased bone density and obesity.

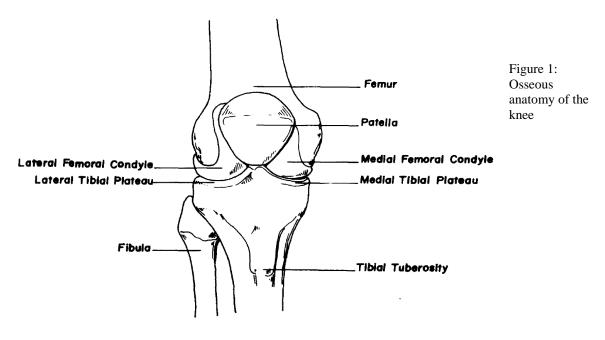
Available today for treatment include pharmacological (analgesics, corticosteroid injections), non-pharmacological (weight loss, bracing) and surgical (arthroscopic debridement, total knee arthroplasty) options. However, recent studies show that unloading a joint can reduce the rate in which osteoarthritis progresses or even reverse the effect in such a way that the joint can recover <sup>3-5</sup>.

This research study focusses on the recent developments of joint distraction, in this case the knee and the ankle, in order to treat osteoarthritis. Also non-invasive alternatives of joint distraction are discussed; these however are focussed on the knee due to recent developments of a device in development at the University Medical Center Groningen. First the anatomy of the knee is explained followed by an overview of osteoarthritis and all the contributing factors. Then the theory of joint distraction is reviewed followed by the difference between ankle and knee osteoarthritis.

# Anatomy of the knee

The knee is the joint connecting the bones of the lower limb, fibula and tibia, with the bones of the upper limb, the femur (fig.1 <sup>6</sup>). The proximal end of the tibia forms a plateau with a lateral and a medial section, divided by the tibial spine (fig.2 <sup>6</sup>). This plateau creates a 'seat' for the distal end of the femur, which consists of a lateral and a medial condyle <sup>6</sup>. The both menisci on medial and lateral side create an added depth of the seat which is very important for the stability of the joint <sup>6</sup>. The ends of the tibia and the femur consist of articular cartilage and are surrounded by a synovial membrane, creating the joint cavity which is filled with synovial fluid. Capsular ligaments are located on the medial and lateral side on the outer side of the synovial membrane for stability of the joint (fig.3 <sup>6</sup>). These ligaments are attached to the menisci in order to stabilize the knee and making sure the knee doesn't over rotate <sup>6</sup>.

The extensor mechanism of the knee is the quadriceps femoris, which is attached to the tibia through the patella (quadriceps tendon) and the patellar tendon (fig.4 <sup>6</sup>).



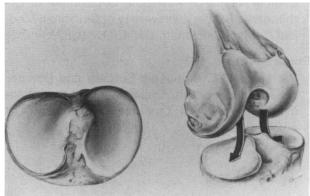


Figure 2: Tibial plateau with tibial spine

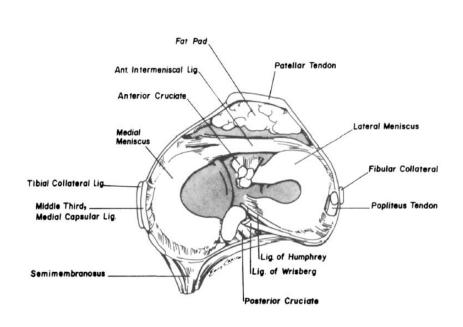


Figure 3: Superior view of the tibial plateau showing capsular ligaments

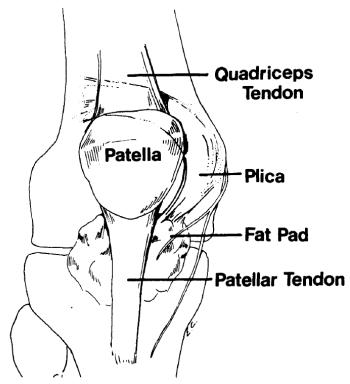


Figure 4: Components of extensor mechanism

# Osteoarthritis

# Cause

The degenerative changes to articular cartilage, which form the basis of all the symptoms concerning osteoarthritis, are very complex and involve biological, mechanical and structural pathways <sup>1,7</sup>. There is no main cause of osteoarthritis, a lot of factors influence the inducement and evolvement of the joint disease. Risk factors are defined over the last decades, including age, genetic predisposition, obesity, joint congruency, increased mechanical stress and greater bone density <sup>8</sup>. These factors however can never indicate whether or not a specific person will suffer from osteoarthritis in the future, therefore screening remains an essential part in the prevention of osteoarthritis. Often osteoarthritis will evolve as a consequence after a certain trauma; an antecedent incidence, this includes intraarticular fractures and ligament lesions. Also systemic diseases like rheumatoid arthritis, hemochromatosis, heamophilia, post infectious arthritis or osteochondrosis dissecans are identified as potential causes. Another cause may contribute to the evolvement of osteoarthritis; the result of a congenital or developmental anatomic abnormality <sup>1</sup>.

These diseases and traumas have a more of the same influence on cartilage on a cellular/tissue level. This means that the in vivo function is coupled to the structure and health of the particular joint. It is stated that cartilage adapts to mechanical stimuli and the maintenance of that mechanical stimulus is essential for normal tissue function. In abnormal tissue function (unhealthy cartilage), the equilibrium between degeneration and synthesis of cartilage constituents including collagen fibrils and proteoglycans is disrupted. This equilibrium is maintained by chondrocytes by controlling certain enzymatic processes. Studies show that high loads on an osteoarthritic knee results in a more rapid rate of cartilage breakdown, in contrast theoretical observations suggest that load can induce an positive adaptive response <sup>7,8</sup>. It may be so that the health of the cartilage determines the cartilage response to load.

Static and dynamic loading have a great impact on the way osteoarthritis originates and develops. In normal walking the peak tibio-femoral force in the knee is three times the bodyweight, however in extreme sports like alpine skiing the peak force may reach 24 times the bodyweight during drop landings <sup>8</sup>.

For examining the impact of a load on a joint a line is drawn from the hip to the ankle, specifically from the centre of the femoral head to the centre of the talus. This line has two axes at the knee joint, located at the top of the tibia and the bottom of the femur. The angle between these axes (HKA) should be 0° in a normal knee joint (fig.5, 9). A valgus moment arises when the knees are 'knocked', this is described as an positive deviation in the HKA. A varus moment arises when the knees are located more lateral than they should, also known as 'bow-legged'. This misalignment is described as a negative deviation in the HKA. Figure 5 illustrates this more clearly 9. The valgus or varus alignment have been known to influence the load distribution across the articular joint surface, especially a varus moment may be a factor to medial knee osteoarthritis 1.

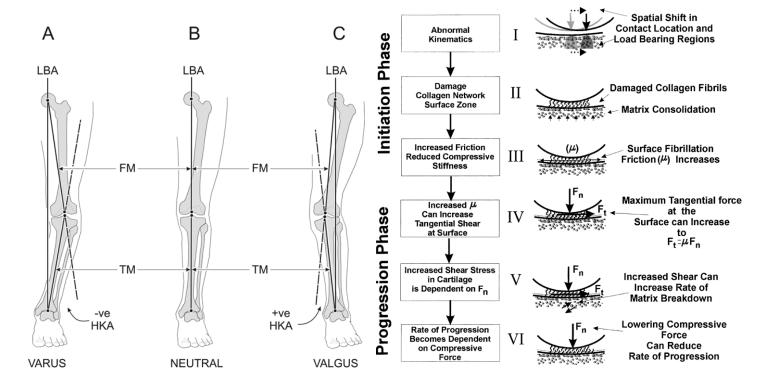


Figure 5: Common frontal plane lower limb alignment patterns

Figure 6: An illustration of a framework for the initiation and progression of osteoarthritis

Joint loading during activities which lead to excessive forces on the joint or misalignment of the knee joint may lead to changes of the alignment of articular surfaces due to ligament rupture, meniscal tearing or injury of the joint capsule <sup>1,10</sup>. These changes can lead to the initiation and faster rate of progression of osteoarthritis. The kinematic changes cause a shift in load bearing regions of the cartilage and further increased loading drives the progression of osteoarthritis. In the following figure the initiation and progression phase of osteoarthritis are shown and it is seen that during each phase the cartilage responds differently to mechanical stimuli (fig 6, <sup>7</sup>)

# **Effects**

The symptoms and effects of osteoarthritis are quite clear for the patient to recognize. The joint disease is characterized by deterioration and loss of articular cartilage, this is experienced by the patient by a large amount of pain, deformation of the joint and decreased and limited mobility of the joint <sup>8</sup>. Due to the misalignment of the mechanical axis further complications could be joint space narrowing, subchondral cyst formation, bone sclerosis and functional decline <sup>1,11</sup>.

The main effect and problem of osteoarthritis is the loss of cartilage, which can be induced by high levels of stress <sup>8</sup>. The loss of articular cartilage may destroy the normal mechanical stability of the tissue and change the mechanical properties, which then no longer are compatible with the high mechanical demands placed on the particular joint.

Experiments performed to identify the effects of osteoarthritis on a cellular and molecular level demonstrate that before the deterioration of the cartilage takes place, a lot of other actions occur, described in<sup>8</sup>. This includes a decrease of superficial proteoglycans concentration and separation and disorganization of the superficial collagen fibrils. Both of which appear to be intimately related to the local functional requirements of the joint. The loss of PGs (proteoglycans) and the loss and damage of type II collagen fibrils, both occur in advanced osteoarthritis, lead to a decrease of cartilage stiffness. The different zones of cartilage are illustrated in fig. 7(<sup>8</sup>). Once the structure of the superficial zone is compromised the underlying cartilage is exposed to abnormal levels of strain, this then leads to degenerative changes of the deeper zones of cartilage.

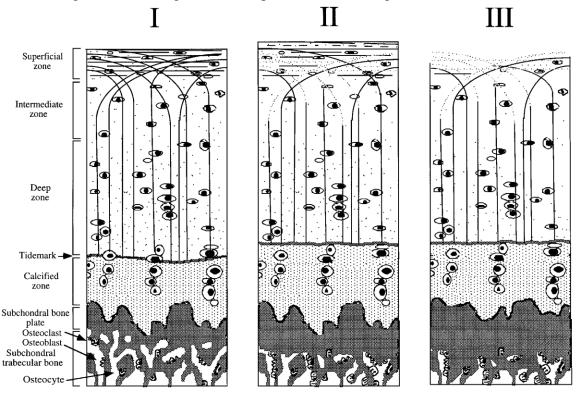


Figure 7: Hypothesis of the pathogenesis of osteoarthritis in the beagle dog model. Oval structures represent chondrocytes and the curved lines represent collagen fibrils. Normal cartilage is shown in I, progression of osteoarthritis is shown in II and III.

Osteoarthritis can also alter the way patients walk due to the decreased stability of the joint. This instability requires more muscle co-contraction to stabilize the joint, this however leads to further progression of osteoarthritis due to higher joint loads <sup>12</sup>. The progression of osteoarthritis is further accompanied by muscle weakness and atrophy, although it is not still clear whether it precedes it or it is caused by osteoarthritis. Joint inflammation is often accompanied with osteoarthritis, especially in the early stage. Inflammation can be triggered by malalignment, overuse, trauma and cystal formation <sup>1</sup>. In most of the cases inflammation of the synovium, synovitis, causes the pain well known to patients with osteoarthritis. Synovitis leads to the secretion of proinflammatory cytokines such as TNF-alpha, IL-1 or IL-6, which then can induce the induction of proteinases with cartilage degradation as a result <sup>1,7</sup>. However, movement of a joint

induces the expression of IL-10, a potent anti-inflammatory cytokine <sup>1</sup>. This may conclude that movement during the treatment of osteoarthritis will benefit the health of the joint.

### Common treatments

Until now a medical cure for osteoarthritis doesn't exist, treatments available today consist mainly of treating symptoms, for example relieving pain. Other objectives are providing joint stability and trying to postpone the end stage of osteoarthritis. In addition, when conservative treatments fail to relief symptoms, surgical interventions are an option for treatment. These surgical interventions aim for restoring ligament balancing, realigning the mechanical axes of the joint and re-establishing the natural biomechanics of the joint <sup>1,13</sup>.

The treatment options today are categorized as non-pharmacological (weight loss, bracing), pharmacological (nonsteroidal anti-inflammatory drugs, analgesics, opioids) and surgical (arthroscopic debridement, total knee arthroplasty). Most treatments consist of a combination of pharmacological and non-pharmacological modalities. These treatments however are classified as conservative and have major limitations because of the incapability of successfully correcting the underlying pathology  $^{2,11,14}$ . Conservative options are classified as orthotic joint unloading therapies, analgesics, antiinflammatories (NSAIDs), opioids, DMOADs (disease-modifying osteoarthritis drugs) and hyaluronic acid injections. These conservative treatments are used in the first stage of osteoarthritis, including joint unloading therapies such as weight loss, lateral wedge insoles and bracing. When the symptoms are not improved over 3-6 months, analgesics such as acetaminophen are recommended <sup>2,14</sup>. NSAIDs and capsaicin are often recommended as alternative or in combination with analgesics. If these oral analgesics fail, opioids may be used when severe pain is present. Intra-articular injections of hyaluronic acid may be considered as an alternative if these oral medications fail to achieve pain relief.

In most cases of mechanically induced osteoarthritis of the lower limb trauma is the predominant cause <sup>1</sup>. To treat the symptomatic stage of osteoarthritis in these patients, often a joint preserving surgery is chosen. For example, for unicompartimental knee osteoarthritis or for varus or valgus osteoarthritis, joint sparing osteotomies are used to unload the affected joint area as well as to improve joint congruency and coverage <sup>1</sup>. The orthopedic procedure includes a correction osteotomy which is done on the proximal tibia for knee osteoarthritis and on the distal tibia for ankle osteoarthritis. Either an open or a closing wedge is created followed by an arthroscopy for cartilage and meniscal surgery if needed, this will realign the mechanical axis in order to improve joint function and relieve pain. This technique however may benefit only young, active patients because of the ability of the body to restore joint function on itself.

Total joint replacement is used in cases of advanced osteoarthritis with totally destroyed articular surfaces, this group however is a minority of those with osteoarthritis<sup>2</sup>. In addition, the decision whether or not to operate should be based on the severity of pain, disability and distress, rather than on radiographical findings of the condition of the joint.

When all concerning parties agreed upon total joint replacement is ultimately the treatment of choice. Today's high quality and long durability of materials, anatomical modular systems and minimal invasive surgical procedures allows the patient to rehabilitate fast and efficient <sup>1</sup>. A large benefit of total joint replacements is that it may preserve the neighbouring joints from mechanical overload and wear <sup>1</sup>. Drawbacks might be a limitation of correction of deformity and adjusting of ligament balance, also infections, failure of prosthesis and loss of bone may compromise the treatment.

# Joint distraction

# **Background** information

Recent developments in treating knee and ankle osteoarthritis are unloading the joint in combination with joint movement in order to prevent and slow down progression of osteoarthritis, possibly reverse the structural damage and achieving symptom relief. Several studies show that unloading or off-loading the joint in combination with joint movement, in these studies achieved through joint distraction, has potential benefits for treating osteoarthritis <sup>3-5,15,16</sup>.

If loading is a major cause in development and progression of osteoarthritis, then unloading may be able to prevent and slow down progression of osteoarthritis <sup>3</sup>. When the damaged cartilage is mechanically unloaded, meaning no further wear and tear of the cartilage, the reparative activity of the cartilage may become effective. The unloading of the joint however needs to be accompanied by maintaining the intermittent synovial fluid pressure, which is essential for the nutrition of cartilage<sup>5</sup>. Movement of the joint, which occurs during walking, exercising and other daily activities, is essential for maintaining the pressure of the intermittent synovial fluid.

These studies remain non-conclusive about the clinical benefit of joint distraction. Actual repair of articular cartilage in the clinical situation, in vivo, is difficult to study. All evaluation methods such as histological evaluation of cartilage biopsies, evaluation of cartilage by X-ray, MRI or arthroscopy have their restrictions (not representative or too little material, no quantitative measures). Further research and more follow-up studies are required to fully understand the underlying mechanism and prove the clinical benefit of joint distraction.

# Distraction frames and possible mechanism

Joint distraction uses distraction frames to achieve a reduction of mechanical stresses in the concerning joint. These distraction frames are shown below in fig.8 (<sup>17</sup>) and fig.9 (<sup>3</sup>).

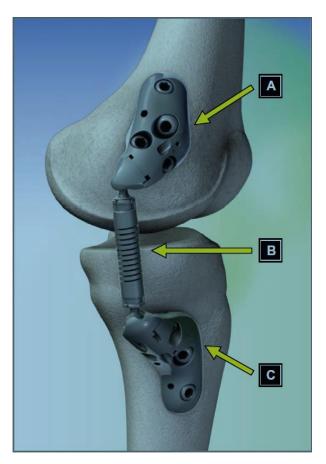


Fig.8: The KineSpring® knee implant system the(A)femoral base, (B)absorber unit, (C)tibial base

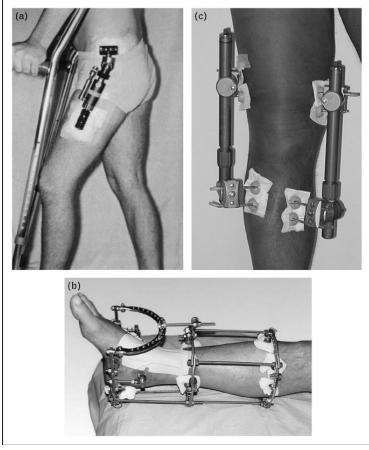


Fig.9: Different examples of joint distraction in treatment of osteoarthritis. (a) Hinged articulated hip distraction. (b) Ilizarov ankle distraction using thin wires. (c) Knee distraction using an Howmedica system with springs

These external distraction frames are surgically applied to completely unload a particular joint. These frames accomplish unloading by reducing mechanical stresses on the cartilage and preventing further wear and tear of the cartilage surfaces and allowing chondrocytes to initiate repair. By providing more joint space width using hinges, thin flexible wires and springs in the fixation frame, the distraction mechanism allows intermittent fluid pressure to be maintained. This pressure is essential for the nutrition of the chondrocytes <sup>3</sup>. The relief of mechanical loading of the peri-articular bone leads to temporary osteopenia within the distraction area. Growth factors known to be involved in cartilage growth and repair <sup>3</sup>, may provide support to the chondrocytes in a cartilage repair mode. The turnover of bone provides the storage for these growth factors leading to a possible structural repair of the cartilage. After distraction the less dense subchondral bone will absorb greater stress, resulting in lower stress on the overlaying cartilage.

# Effects

### Short term effects

Most of the studies describe only the short term effects, which include <sup>5,16,18</sup>. The short term effects consist for a large part in symptomatic relief, such as pain relief and a reduction in synovial inflammation<sup>3</sup>. In some studies more promising results were found, Waller et al. describes a pilot clinical study in nine joint arthroplasty candidates with severe knee osteoarthritis with a 2-month period of joint distraction. Results showed notable improvements in pain and function that have persisted for two years, as well as MRI evidence of 25% increase of cartilage thickness and 30% increase of cartilage volume. Another successful study is done by Intema et al., in which 20 patients with knee osteoarthritis are treated using joint distraction with a total distraction distance of 5 mm. Results showed an increase in joint space width and cartilage thickness and a decrease of denuded bone areas.

Lafeber et al. describes several studies including joint distraction performed on 11 patients with severe ankle osteoarthritis using an Ilizarov distraction for 15 weeks. Retrospective evaluation found that pain decreased in all patients, movement improved in 55% of patients and joint space widening was seen in 50% of patients after a follow-up period ranging from 9 to 60 months. Other studies in the review of Lafeber et al. describe more of the same results; on a short term pain relief, walking distance, joint movement and joint space width seem to increase, while in the long term subchondral bone density seems to increase.

In a canine model, Van Valburg et al. induced osteoarthritis in the knee joint in beagle dogs using anterior cruciate ligament transection. Results showed a reduction of inflammation as well as a change of cartilage PG metabolism towards values of control knees, which could depend on a functional change of the chondrocytes. Joint space width showed to persist over the entire period of treatment, however a significant difference in articular cartilage was not found, this could be due to a too short notice.

The clinical benefit of joint distraction of the ankle is described by Marijnissen et al.. Thirty-eight patients with severe ankle osteoarthritis were followed for up to a year. Results showed that average score for pain decreased by 38%, the average score for function increased by 69% and the average score for clinical condition increased by 120%. These improvements seemed to increase with time after treatment (5 years) <sup>5</sup>. Also the objective parameters such as subchondral bone density and joint space width tended to normalize in patients with severe ankle osteoarthritis <sup>5</sup>.

### Long term effects

Very few studies have a follow-up that reaches into the long term (>5 years). Lafeber et al. describes a study in which ankle distraction rendered good or excellent preliminary results in 18 of 20 joints with a follow-up ranging from 2 to 16 years. Ploegmakers et al. describe a follow-up study of  $10\pm2,5$  years of patients with severe ankle osteoarthritis treated with Ilizarov distraction. Distraction was carried out over a total distance of 5 mm. Results showed that clinical benefit was experienced by 73% of the patients and sustained on average for 10 years. Parameters such as function and clinical condition increased significantly and parameters such as pain and disability decreased significantly over time. Together with the results of Marijnissen et al. it can therefore be concluded

that joint distraction is very effective in the treatment of severe ankle osteoarthritis<sup>4</sup>. More prolonged follow-up studies and further research however are still necessary.

# Differences in progression of ankle and knee osteoarthritis

The prevalence of osteoarthritis in knee or ankle joint is very different. Studies show that approximately 10% of individuals over 65 years encounter osteoarthritis while only less than 1% will develop osteoarthritis in the ankle <sup>23</sup>. These differences in ankle and knee osteoarthritis are due to many different factors and properties, some of them are described below.

For a part the differences in biomechanics between the joints are a cause for the development of osteoarthritis. Muchleman et al. suggests that the ankle joint is generally not affected by progressive osteoarthritis. The relationship between the bone and cartilage responses of the knee and the ankle joint may be altered by the different biomechanics at the joint, caused by the different stresses placed upon the them <sup>24</sup>. However, also biochemical and biomechanical property differences of the joint play a role in the development of osteoarthritis. Aurich et al. describes in two studies the differences in ankle and knee joints with respect to several parameters, such as tissue composition and molecular interactions. Data from these parameters differ for the ankle from data for the knee. In lesional cartilage obtained from the knee, the expression of markers of collagen and proteoglycan synthesis was down-regulated and markers of degradation were upregulated <sup>23</sup>. In the ankle these markers of synthesis were up-regulated while markers of degradation were not. In Aurich et al. these markers for collagen and proteoglycan synthesis and degradation were both elevated in knee joints with more severe degeneration <sup>25</sup>. These data indicate that synthesis is increased in less severe lesions of the ankle, suggesting that the ankle is attempting repair. This may be the cause of the much lower incidence of full-depth osteoarthritic lesions in the ankle compared with the knee joint.

Results of the same study of the ankle joint show that metabolic reactions which are favourable for the damage repair caused by osteoarthritis, occur not only in the lesion site but also adjacent to and remote from the lesion <sup>25</sup>. This indicates a generalized reaction of articular cartilage within the ankle joint toward minor focal structural damage of the extracellular matrix. This is in contrast with what is seen in the knee joint <sup>25</sup>. Aurich et al shows a principal difference that distinguishes very early lesions in the ankle and the knee joint <sup>23</sup>. In the ankle an increase in collagen type II synthesis and aggrecan (cartilage-specific proteoglycan core protein) turnover is seen, which is not seen in the knee. More results show a net anabolic response in early ankle lesions and a net catabolic response in early knee lesions<sup>23</sup>. The results from these both studies point to differences in the responses of chondrocytes to early matrix damage and may account in part for the more frequent presence of osteoarthritis in the knee than in the ankle joint<sup>23</sup>.

With these differences of prevalence and progression of osteoarthritis in mind treating osteoarthritis by using knee joint distraction might be more difficult but at the same time the need for a non-invasive knee joint distraction device is greater. Therefore the non-invasive alternatives of joint distraction are focussed on the knee.

# Non-invasive alternatives for knee joint distraction

Surgical interventions for joint distraction are far from patient friendly, expensive and time intensive. Also the distraction device itself is not comfortable for the patient, therefore other solutions are needed to achieve joint unloading and joint distraction. Next to surgical approaches to unload joints and change the alignment of the knee also nonsurgical approaches such as footwear, bracing and orthoses are available, described further below.

The aim of joint distraction is to completely unload joints in combination with joint movement and joint rotation. However, unloading joints through joint distraction is not the only way. Unloading joints can also be achieved by footwear and bracing (nonsurgical), osteotomy (surgical) and life-style changes.

# Life-style changes

The easiest, cheapest and safest way for unloading joints is altering the life-style. Life-style changes do refer to weight loss. Studies show that weight loss lowers knee compressive forces, improves knee function and alleviates osteoarthritis knee pain <sup>15</sup>. Exercise and diet studies report that in older sedentary adults with an average BMI of 34 kg/m<sup>2</sup> 1 kg of weight loss resulted in a 4 kg reduction in knee compressive forces <sup>19</sup>. The risk of developing osteoarthritis can be reduced by 50% by a body weight loss of 5 kg (11 lbs) <sup>19</sup>. The hardest part of this therapy however is maintaining this weight loss. Losing excess body weight and maintaining a lower body weight can be extremely challenging and will be difficult for a lot of patients. Moreover, losing weight will only unload the particular joint for a small percentage and will only be effective in an early stage of osteoarthritis.

# Footwear and bracing

Lateral heel wedges or lateral-wedge insoles have been shown to effectively reduce the symptoms of medial compartment knee osteoarthritis <sup>20</sup>. Also knee braces proved to be successful in improving joint function by reducing the biomechanical load on the affected compartment of the knee, reducing the external varus or valgus moment and improving the patient's perception of instability <sup>20</sup>. A valgus-inducing knee brace described by Schmalz et al. proved to reduce the external varus moment for approximately 10%. Krohn describes a brace which reduces the varus moment with 20 to 25% and a joint space width of 1,2 mm. The biomechanical-model calculations suggest that the brace would result in a reduction of joint forces within the medial compartment of the knee in the order of 80 to 100 N<sup>21</sup>. A reduction of this magnitude could suggest that pain relief and functional improvements reported by the patients may be due to the result of the reduction in internal joint loading forces. This theory is supported by Brouwer et al. which concludes that pain relief of patients with a brace compared to a control group was significantly less over a 12 months follow-up. Also knee function in the brace group was better at each assessment point with the largest difference at 3 months follow-up <sup>22</sup>. At last the walking distances at 3 months were significantly longer in the brace group compared to the control group <sup>22</sup>.

However, results of unloading joints using braces and orthoses are very few in numbers, incomplete and few well-controlled clinical studies in this field have been done. Randomized clinical trials concerning bracing in knee osteoarthritis are still necessary.

Because of the nonsurgical procedure patients are interested in these approaches to theoretically affect disease progression. A lot of factors however are involved in a successful application of a brace or orthoses. This includes fitting of the brace, instruction of the brace to the patient, the familiarity of the orthotist with each brace's proper fitting and adjustment protocols, patient's motivation of wearing the brace and avoiding surgery, and finally the clinical trials with one brace may not be applicable to all knee braces. Considerable studies need to be done to further validate the effectiveness of braces and orthoses. Examples of braces and insoles are shown in fig.10 (15) and fig.11 (15).



Figure 10: Lateral wedge insoles



Figure 11: Knee unloader brace

In order to treat osteoarthritis braces and lateral wedge insoles are nowhere near the results joint distraction has achieved. Braces, orthoses and lateral wedge insoles can only reduce the load on the knee joint from 10 to 25%, which means the joint isn't completely unloaded. The results of studies such as Ploegmakers et al., Marijnissen et al. and Intema et al. are all acquired using distraction frames which completely unload the particular joint. Moreover, the distraction distance in knee braces proved to be 1,2 mm<sup>20</sup>, while in knee joint distraction the distraction distance is 5 mm<sup>16</sup>. With this in mind a knee brace or orthosis which completely unloads the knee joint, achieves joint distraction and preserves joint movement rotation is needed. Results in treating knee osteoarthritis achieved by joint distraction could then also be achieved by a knee brace or orthosis, which then rules out the need for surgical interventions. Such a device is now in development at the University Medical Center Groningen.

# Discussion

Joint distraction seems to be promising in the future treatment of osteoarthritis because of the possible capabilities to restore joint function and stimulate re-growth of cartilage. Conservative treatments such as analgesics and NSAIDS which only treat the symptoms of osteoarthritis will then possibly be used only in the early stage of osteoarthritis or in combination with joint distraction. However, the results available today for treating osteoarthritis using joint distraction, described earlier in this article, are not conclusive and still a lot of research needs to be done on joint distraction.

A major flaw in the treatment of osteoarthritis using joint distraction is the surgical intervention required. A lot of patients will not be willing to undergo such an intensive surgical intervention for treating osteoarthritis. Therefore non-invasive alternatives for treating knee joint osteoarthritis, which is a lot more common than ankle osteoarthritis, are available today. The differences in prevalence and progression of osteoarthritis in the knee and in the ankle are described earlier in this article, indicating the greater need for treating osteoarthritis in the knee.

These devices such as knee braces and lateral wedge soles available today are aimed only at treating the symptoms of osteoarthritis and don't accomplish distraction in the joint. The need for a non-invasive distraction device which in the end will at least achieve results close to the results achieved in invasive joint distraction still exists, more research and development is required for non-invasively achieve joint distraction. Such a device is now in development at the University Medical Center Groningen.

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