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The influence of a novel ankle-foot orthosis on biomechanical parameters and its clinical outcome for patients with medial knee osteoarthritis

Dissertation
zum Erwerb des Doktorgrades der Medizin an
der Medizinischen Fakultät der
Ludwig-Maximilians-Universität zu München

vorgelegt von

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aus
München

Jahr

2022

Mit Genehmigung der Medizinischen Fakultät der

Ludwig-Maximilians-Universität zu München

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Tag der mündlichen Prüfung:	23.06.2022

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AFO	Ankle-foot orthosis
ADL	Activity of daily living
APP	Anterior/posterior position
BMI	Body mass index
COP	Center of pressure
FTA	Femorotibial angle
GRF	Ground reaction force
KAM	Knee adduction moment
KR	Mean force hindfoot
KV	Mean force forefoot
K&L	Kellgren and Lawrence classification
KOA	Knee osteoarthritis
KOOS	Knee Injury and Osteoarthritis Outcome score
MFL	Maximum force heel lateral
MFM	Maximum force heel medial
MM	Maximum force midfoot
MVI	Maximum force forefoot internal
MVL	Maximum force forefoot lateral
MVM	Maximum force forefoot medial
MZ	Maximum force toes
NASAID	Non-steroidal anti-inflammatory drugs
NRS	Numeric rating scale
OA	Osteoarthritis
PRM	Physical and Rehabilitation Medicine
QOL	Quality of life
SV	Lateral shift
T0	Recruitment
T1	Before intervention
T2	After intervention
VAS	Visual analogue scale

1 Zusammenfassung

Die Auswirkung einer neuartigen Fuß-Knöchel-Orthese auf biomechanische Parameter und deren Effekt auf die Funktionalität und Schmerzintensität bei Patienten mit medialer Gonarthrose.

Ziel: Untersuchung der Wirksamkeit einer neuartigen Fuß-Knöchel-Orthese (AFO) in Bezug auf die Verschiebung der Kraftwirkungslinie im Knie nach lateral und die Kraftverteilung im Fuß während des Gehens als Hauptzielparameter, sowie deren Auswirkungen auf die Schmerzintensität und Funktionalität im alltäglichen Leben als Nebenzielparameter.

Design: Monozentrische, prospektive, interventionelle Kohortenstudie mit Vorher/Nachher-Design kombiniert mit einem Querschnittstudiendesign.

Einrichtung: Klinik und Poliklinik für Orthopädie, Physikalische Medizin und Rehabilitation, Klinikum der Universität München (LMU).

Patienten: 24 Patient*innen mit medialer Gonarthrose, welche die Einschlusskriterien erfüllten. Rekrutierung über Datenbanken der Arthrose-Tageskliniken der Klinik sowie aus der wöchentlichen Kniesprechstunde der Poliklinik.

Intervention: Behandlung mit einer neuartigen Fuß-Knöchel-Orthese über 4 Wochen bei Patienten mit diagnostizierter medialer Gonarthrose.

Ergebnismessungen und Analysen: Die Studie beinhaltet zwei verschiedene Zeitpunkte der Messungen: Vor der Intervention (T1) und nach der Intervention (T2). Die Hauptzielparameter „Position der Kraftwirkungslinie am Kniegelenk“ und die Kraftverteilung während des Gehens an der Fußsohle wurden im Design einer Querschnittsstudie an einem Zeitpunkt (T1) von April bis Mai 2018 ermittelt. Die Differenz des Kraftwirkungslinienversatzes am Kniegelenk mit und ohne Orthese wurde mittels einer Laservermessung (L.A.S.A.R. Posture® System) erhoben. Eine Ganganalyse (Zebris®) wurde einmalig (T1) in drei verschieden Bedingungen (2km/h, 4km/h und selbst gewählte Wohlfühlgeschwindigkeit) mit und ohne Verwendung der Orthese durchgeführt. Die Lage des Belastungsschwerpunktes (center of pressure, COP) wurde durch die Parameter

„Seitliche Verlagerung“ und „Anterior/posterior Position“ ermittelt. Die Kraftverteilung an der Fußsohle wurde mittels einer Messung von sieben verschiedenen Kraftzonen erhoben.

Die Datenerhebung der Nebenzielparameter wurde in Form einer longitudinalen Studie durchgeführt. Der kniespezifische Fragebogen Knee Injury and Osteoarthritis Outcome score (KOOS) mit den Subskalen Symptome, Schmerz, Aktivität des alltäglichen Lebens (ADL), sportliche Aktivität und Lebensqualität wurde an zwei verschiedenen Zeitpunkten, vor der Intervention (T1) und nach der Intervention (T2) erhoben. Der Parameter „Schmerz“ wurde zudem durch zwei Schmerztagbücher mit morgendlichen und abendlichen Schmerzverlauf jeweils über die 4 Wochen vor Verwendung der Orthese und für 4 Wochen mit der Verwendung der Orthese ermittelt. Mit einem selbst erstellten Fragebogen wurde die Zufriedenheit der Patienten im August 2018 evaluiert. Die Überprüfung auf signifikante Unterschiede der Messungen erfolgte mit nicht-parametrischen Tests. Die longitudinale Schmerzmessung wurde mittels randomisierten mixed-effect Modellen statistisch ausgewertet.

Ergebnisse: Die Daten von 24 Patient*innen wurden analysiert. Es konnte bei allen Patient*innen eine Verschiebung der Kraftwirkungslinie am Kniegelenk bei einem Mittelwert von 16,03 mm (±5,22; $p<0,001$) nach lateral beobachtet werden. Die Messungen der Kraftverteilung innerhalb der sieben Zonen der Fußsohle während des Gehens zeigten in der Ganganalyse eine deutliche Verschiebung nach lateral. Bis auf eine Messreihe (Maximalkraft Vorfuß medial bei Wohlfühlgeschwindigkeit) waren die Unterschiede in allen Konditionen stets signifikant ($p<0,05$). Durch Verwendung der Fuß-Knöchel-Orthese konnte eine Verschiebung des COPs nach lateral in allen Konditionen von 0,31 mm bei 2 km/h, 2,43 mm bei 4 km/h und 1,69 mm bei Wohlfühlgeschwindigkeit beobachtet werden. Statistische Signifikanz der Unterschiede mit und ohne Orthese konnten nur in der Messreihe von 4 km/h gezeigt werden ($p=0,02$).

Die ermittelten Werte des KOOS-Fragebogens zeigten in allen Bereichen im Mittel eine numerische Verbesserung. Einen statistisch signifikanten Unterschied konnte nur in der Unterkategorie „Aktivität im täglichen Leben“ (ADL) beobachtet werden ($p=0,013$).

Der longitudinale Schmerzverlauf zeigte eine höchst signifikante Schmerzreduktion ($p<0,001$) durch die Verwendung der Orthese.

Schlussfolgerung: Es konnte eine klare Verlagerung der Kraftwirkungslinie im Knie nach lateral hin zur gesunden Seite durch die Fuß-Knöchel-Orthese beobachtet werden. Weiterhin konnte eine Verbesserung des Schmerzverhaltens festgestellt werden, sowie eine Zunahme an Aktivität. Die Ergebnisse dieser Studie deuten darauf hin, dass die Verwendung der

Orthese positive Auswirkungen auf die Aktivität und Schmerzen bei Patienten mit medialer Gonarthrose haben könnte. Der enge und alleinige Zusammenhang zwischen Verschiebung der Lastlinie durch die Orthese und der aufgetretenen Schmerzreduktion kann durch dieses Studiendesign nicht gänzlich geklärt werden.

2 Abstract

The influence of a novel ankle-foot orthosis on biomechanical parameters and its clinical outcome for patients with medial knee osteoarthritis.

Objective: Investigation of the effectiveness of a novel ankle-foot orthosis (AFO) for the knee regarding biomechanical parameters including shift of the load bearing axis and dynamic force distribution at the sole as primary outcome. The effects on pain progression and functionality of the knee in daily living for patients with medial knee osteoarthritis (KOA) were investigated as secondary outcome.

Design: Monocentric prospective interventional cohort study with pre/post design and cross-sectional study.

Setting: Department of Orthopaedics, Physical Medicine and Rehabilitation, University Hospital, LMU München, Germany.

Patients: 24 patients with medial knee osteoarthritis fulfilling the inclusion criteria. The patients were recruited from a database of an osteoarthritis day hospital program and from the outpatient consultations.

Intervention: Treatment with a novel ankle-foot orthosis (AFO) over 4 weeks in patients with diagnosed medial knee osteoarthritis (KOA).

Outcome measures and analysis: The study contains two points of assessment: before intervention (T1) and at the end of the intervention (T2). The primary outcome parameters including the shift of the load bearing axis in the knee and force distribution during walking at the foot sole were determined in the design of a cross-sectional study at a time point (T1) from April to May 2018. A laser measurement (L.A.S.A.R. Posture System®) was performed once at T1 to assess the shift of the load bearing axis throughout the use of the AFO. A gait analysis (Zebris®) was conducted in three different conditions (2 km/h, 4 km/h and blinded self-selected speed) with and without orthosis at T1. For the force distribution over the foot sole seven force-zones were measured. The center of pressure (COP) was determined by the parameters “lateral shift” and “anterior/posterior position”.

Data collection of the secondary outcome parameters were collected in the form of a longitudinal study. The Knee Injury and Osteoarthritis Outcome Score (KOOS) containing the subscales symptoms, pain, activities of daily living (ADL), sports and quality of life was performed before (T1) and after intervention (T2). Furthermore, a pain diary was kept for longitudinal pain measurement (including morning and evening pain) for 28 days before intervention and for 28 days with the use of the AFO. A self-made questionnaire on patients´ satisfaction was performed at the end of the study in August 2018. The effects were analyzed by means of nonparametric tests. The longitudinal pain-measurement was tested using a randomized mixed-effect model.

Results: A significant lateralization of the load line with a mean value of 16.03 mm (±5.22) in the knee joint was observed ($p<0.001$). The measurements of the force distribution of the foot sole during walking also showed an obvious lateralization in all conditions. A reduction in the measured force in all medial zones and an increase in the lateral zones were observed. Except for one measurement (maximum force forefoot medial at self-selected speed), all measurements showed significant differences in all conditions ($p<0.05$). A lateral shift of the COP of 0.31 mm at 2 km/h, 2.43 mm at 4 km/h and 1.69 mm at self-selected speed in the mean value could be observed. Only the difference in the condition of 4 km/h had statistical significance ($p=0.02$).

A highly significant reduction of pain could be observed over the course of the intervention ($p<0.001$). The KOOS showed an improvement in all areas. However, only the differences in the subscale ADL were statistically significant ($p=0.013$).

Conclusion: A lateral shift of the load line towards the unaffected compartment could be observed by using the AFO. Furthermore, improved activity and reduced pain could be shown. The use of the AFO seems to have positive effects in patients with medial KOA.
The close and sole connection between shifting the load line through the orthosis and the measured pain reduction cannot be fully clarified by this study design.

3 Introduction

This work concerns the investigation of the effectiveness of a novel ankle-foot orthosis (AFO) for the knee regarding biomechanical parameters and the load bearing axis of the knee joint. The effects on pain progression and functionality of the knee for patients with medial knee osteoarthritis (KOA) were investigated. Parts of this dissertation have already been published as a research article (Ranker & Friedl, 2019).

The musculoskeletal system represents the essence of the special fields of "Orthopedic surgery" and "Physical and Rehabilitation Medicine" (PRM). Diseases of the musculoskeletal system play an outstanding role in terms of their socio-economic impact. Even in the early years of the history of medicine, orthopedic devices were used in conservative medicine. The modification of these orthopedic devices is an ongoing process. One of the important functions of the orthopedic devices is to relieve pain in the affected joints in the human body from pain and to gain more participation in daily living.

The most common pathologies of joints with increasing age are degenerative changes in the context of osteoarthritis (OA). The knee joint and the hip joint are the most frequently affected joints and assume top priority in daily life. KOA is a very common disease with a lifetime prevalence of 45% (Murphy et al., 2008). KOA causes high costs and presents a growing problem in the health system due to the aging population (Ong et al., 2019).

There are different points of reference with respective advantages and disadvantages in the treatment of KOA. In the treatment of KOA, the focus is on improving mobility and pain and can be successfully treated even in advanced disease. The use of medication, such as non-steroidal anti-inflammatory drugs (NASAIDs), contributes to reduction in pain, increased quality of life and an increase in activity levels. However, the use of medical drugs offers no improvement of the underlying biomechanical causes and may cause side effects. Side effects of NASAIDs include renal, cardiovascular and gastrointestinal problems (Diehl et al., 2013). Surgery involves risks such as thrombosis, embolism and infection. Even after surgery, some patients report persistent pain in the affected knee.

Exercise therapy with muscle strengthening and endurance training as well as weight reduction in overweight persons improve pain and physical functioning. They are an indispensable part of conservative therapy and show the highest level of evidence of effectiveness in KOA treatment (Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften (AWMF), 2018; Bannuru et al., 2019). However, the effect is often small and for some patients not sufficient. Accordingly, additional components of conservative treatment would be helpful. A reasonable further option for conservative KOA treatment is orthotic supply. Unloader braces are seen as a substantial part of therapy for KOA. The use of an unloader brace in combination with exercise therapy could reduce the rate of surgery and the associated risk for the patients and costs for the healthcare system. The effect of orthopedic devices, such as unloader braces, in relieving pain and reducing the load in the knee has been well established (Gok et al., 2002; Self et al., 2000).

The benefit of such conventional unloader braces is limited by the loss of patients´ compliance due to skin irritation, discomfort (T. B. Schmalz, S.; Drewitz, H., 2011) and cosmetic reasons (Moyer et al., 2015). A notable alternative to the unloader braces placed on the knee is a novel AFO. The AFO applies a force on the lateral shank and aims to reduce the load in the affected compartment of the knee.

The use of this orthosis as a conservative treatment could decrease pain and in consequence improve activity and participation in daily living. Most studies have based the positive effect of the orthosis on a biomechanical conclusion by reducing the knee adduction moment (KAM). This present study also investigates pain, symptoms, physical function and activities of daily living.

We hypothesized that the AFO changes the load bearing axis and thereby improves pain, knee specific physical functioning, activities in daily living and health-related quality of life.

The introduction to this work intends to illustrate the underlying knowledge of the subject area and concentrates on the most relevant fields.

3.1 Knee joint

3.1.1 Anatomy

The knee joint represents the largest and even one of the most complex joints in the human body. Due to its complex structure, the knee is vulnerable to injuries and degenerative processes. The associated bones of articulation include the femur, tibia and patella. The fibula plays a subordinate role in the articulation of the knee joint. The distal end of the femur forms the condyles (Condylus femoralis medialis et lateralis). The condyles articulate with the pair of tibia condyles and the patella as a separate articular body in itself. The surface of the articular body is covered by the cartilage, which ensures a supple knee movement. The knee consists of two functional parts: The patellofemoral joint, which includes the dorsal side of the patella and distal femur and the femorotibial joint, which is composed of the medial and the lateral condyle of the femur and the antagonists of the tibia (Flandry & Hommel, 2011).

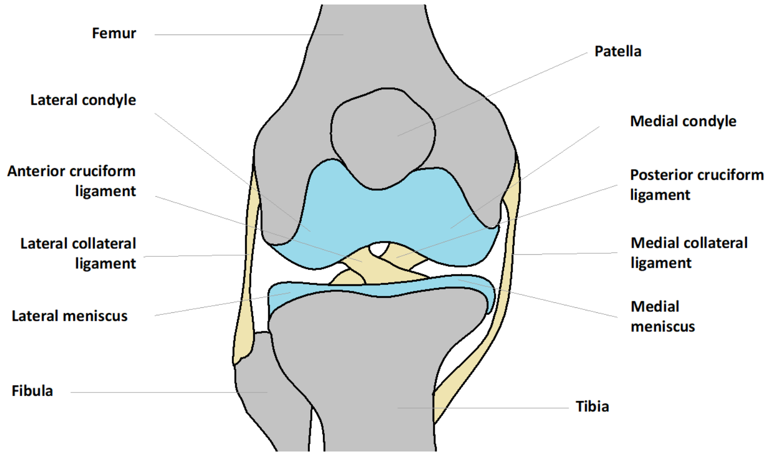


Figure 1: Anatomy of the knee, ventral view.
Own modified diagram based on (Flandry & Hommel, 2011).

The femorotibial joint transfers the body weight from the femur to the tibia.

The menisci lie on the surface of the tibia plateau and serve the purpose of shock absorption and load distribution by enlarging the joint surface. The medial meniscus is shaped in a c-form and is fixed with its front and back horn to the anterior and posterior area intercondylaris. At the same time, it grows together with the inner ligament and therefore tends to be injured. The lateral meniscus is more mobile due to its lower integration in the joint. During gait, the menisci are dragged toward the dorsal side of the knee (Makris et al., 2011).

The pair of cruciate ligaments are located intracapsular and ensure joint stability. In every position, certain parts of the cruciate ligaments are tensed and hold the knee in a correct position. The extracapsular structures, such as ligaments and muscles, are also decisively responsible for stability. The extracapsular ligaments include the medial and the lateral collateral ligament, thus preventing a varus or valgus position of the knee (Flandry & Hommel, 2011).

The knee is generally divided into a medial and a lateral compartment, which is important for the distribution of the load in the joint.

3.1.2 Biomechanics

The knee is a very complex joint with a combination of a hinge joint and a pivot joint. This type of joint is called trochoginglymus. It enables the movement of a hinge and a rotation in the knee. The respective movements are defined as a function of their axis as described below (Woo et al., 1999):

- Transverse axis: flection/extension
- Sagittal axis: abduction/adduction (varus/valgus)
- Longitudinal axis: internal rotation/external rotation
- Sagittal axis: anterior-/posterior translating
- Transverse axis: medial-/lateral translating
- Longitudinal axis: distracting/interpenetrating

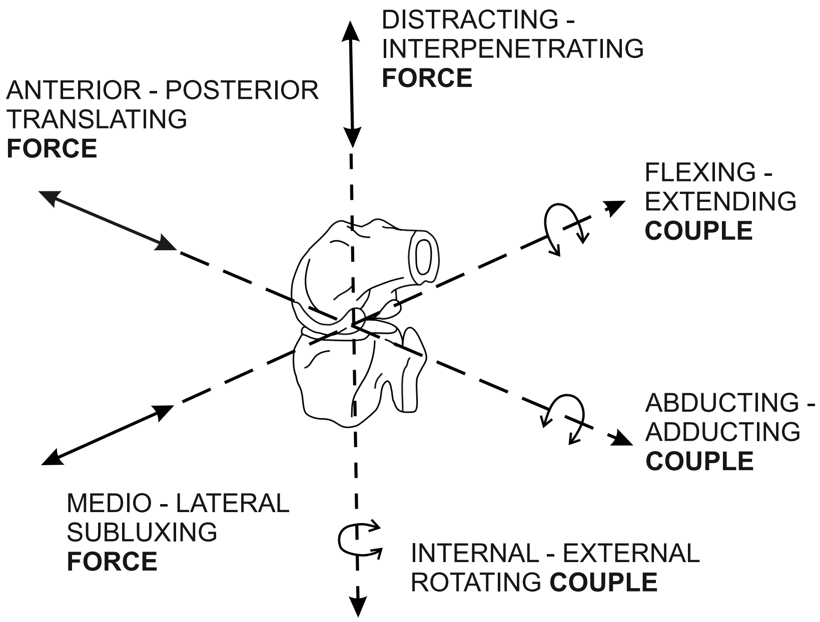


Figure 2: Simplified representation of the directions of movement.
Own modified diagram based on (Goodfellow & O'Connor, 1978).

Of great importance for load distribution in the knee is the geometric position of the structures involved in the lower limb. With normal mechanical axes, all large joints of the lower extremity lie in a straight line. This line is called the Mikulicz Line and is defined as a line from the center of the femoral head to the center of the ankle (Waldt, 2017). The Mikulicz Line provides insights into the load distribution in the knee and is also described as the load bearing axis of the knee (Lahm, 2018). In contrast to the tibia, the mechanical axis in the femur is not congruent with the anatomical line. The angle between the mechanical axis and the anatomical line of the femur is normally between 5 and 9 degrees. The angle between the femur and the tibia is called the femorotibial angle (FTA) and is on average 174 degrees (Yang et al., 2010). The malalignments of the lower limbs include the genu varum and genu valgum. The load bearing axis gives information about a malposition of the leg axis in relation to a varus or valgus position. In a varus deformity, the load bearing axis passes medially through the center of the knee joint. In contrast, the load bearing axis passes the center of the knee laterally for valgus malalignment. Figure 3 shows the course of the mechanical axes in relation to the deformity of lower limb.

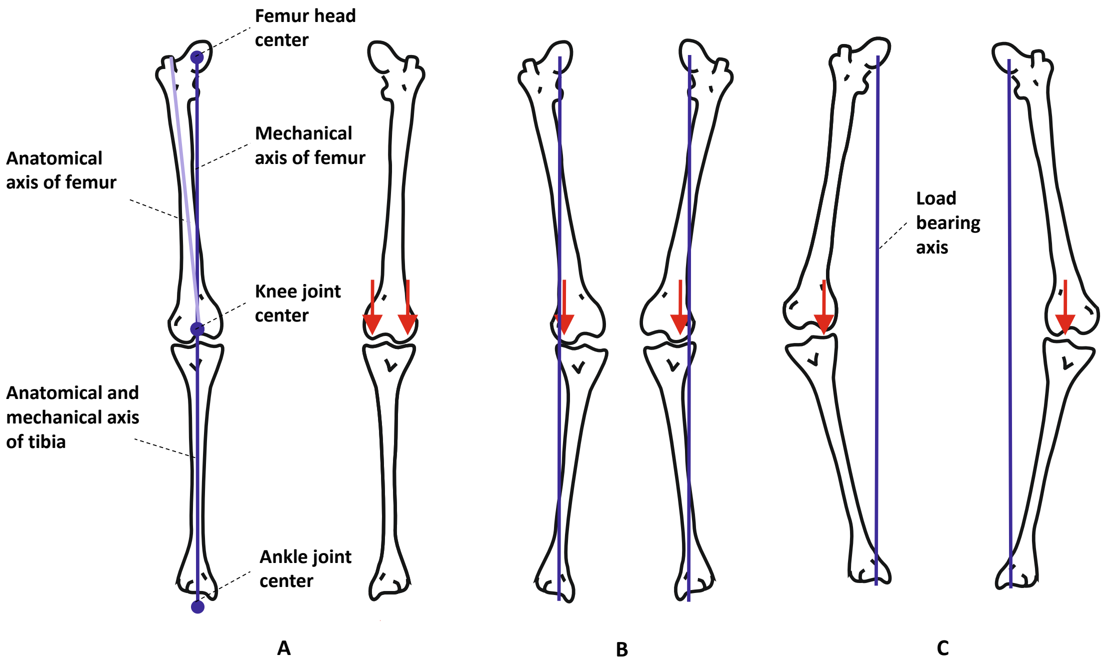


Figure 3: Load bearing axis of lower limb. (a) Normal alignment, (b) varus malalignment and (c) valgus malalignment. The red arrows illustrate the load distribution. Own modified diagram based on (Monk et al., 2016).

The Mikulicz Line implicates the load bearing axis in the knee, which shows the load distribution between the medial and lateral compartments. Figure 3 makes it clear that a shift in the load bearing axis leads to unequal distribution of the acting force on the knee. A varus angle forces the legs into a bowlegged position that overloads the medial compartment. In consequence, a varus malalignment increases the load in the medial compartment (Sharma et al., 2001). In a neutral position, the load in the knee is not evenly distributed. It could be shown that 60-80% of the load passes through the medial compartment (Andriacchi, 1994).

The forces and moments acting on the knee are essential for understanding the use of orthopedic aids. An increased load in the knee joint is noticeable on every contact with the ground and the resulting forces. The force that is transferred to the body with every ground contact is called ground reaction force (GRF). The position and the magnitude of the vertical vector of the GFR is decisive for the load in the joints of the lower limb (Duivenvoorden et al., 2015).

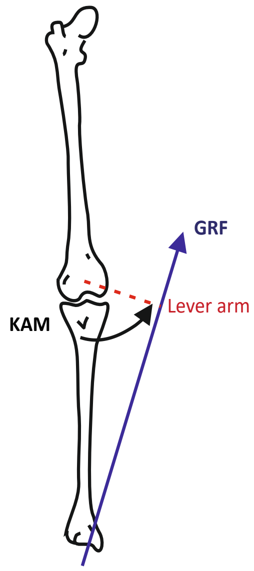


Figure 4: Vector of ground reaction force of lower limb.
Own modified diagram based on (Duivenvoorden et al., 2015).
Legend to figure 4: GRF = ground reaction force; KAM = knee adduction moment.

The point where the total sum of a pressure field acts on the foot is called the center of pressure (COP). Through that point runs the vertical vector of the GRF (B. J. Benda, 1994). The COP is a common parameter, which is measured by many instrumental devices (Lugade & Kaufman, 2014).

Since the vertical vector of the GRF does not pass through the center of the joints, the so-called pivot point, it produces a moment (Hunt et al., 2006). A moment is defined as the product of the force and the perpendicular distance to the pivot point. As a consequence, the vertical vector of the GRF and the perpendicular distance to the center of the knee produce a moment acting on the knee. This moment is called knee adduction moment (KAM) or varus moment (Ramsey & Russell, 2009). Obviously, an enlargement of the lever arm, i.e. the perpendicular distance between the vector and the pivot point, leads to an increase in the KAM. The load on the affected compartment in the knee depends on the length of the lever arm. There are various reasons for altering the length of the lever arm and hence the KAM. These possibilities include the inclination of the vector of the ground reaction force, the position of the COP and the varus angle in the knee. Furthermore, the magnitude of the ground reaction force influences the KAM (Fantini Pagani et al., 2014). Figure 5 illustrates the different reasons for changing the lever arm in the frontal plane.

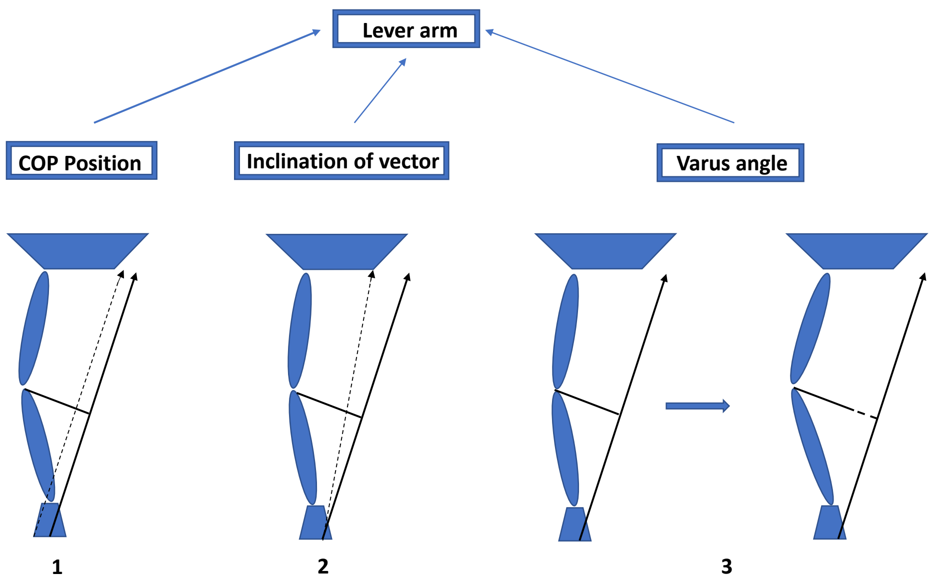


Figure 5: Reasons for changing lever arm. (1) Position of the COP (center of pressure), (2) inclination of the vector of ground reaction force, (3) varus angle in the knee.
Own modified diagram based on (Fantini Pagani et al, 2014).

The knee is subjected to a varus moment, except for a short valgus moment after initial heel contact, during normal gait (Winter & Robertson, 1978). The magnitude of the KAM is contingent on the biomechanical alignment and the vertical vector of the GRF (Menger et al., 2016).

3.2 Knee osteoarthritis

OA generally describes a wear and tear that exceeds the usual age-related physical decline. KOA describes the degenerative destruction of the knee including joint structures such as ligaments, bones, synovial and fibrous joint capsule and periarticular musculature (Madry & Kohn, 2004).

3.2.1 Epidemiology

KOA is a common cause of disability and pain. In general, OA is the most common joint disease (Woolf et al., 2012). More than 10 % of the population over 55 years of age suffer from OA symptoms (Peat et al., 2001). KOA is the most common joint disease within a prevalence of 6% (Felson et al., 2000) and the second most musculoskeletal disease worldwide (Neogi, 2013). In total, more than 250 million people suffer from OA (Vos et al., 2012). According to a study dating from 2012, the overall prevalence of KOA is 23.8% in Germany (Koch-Institut, 2012). However, the prevalence of clinical symptoms relating to radiological KOA is lower at 10 to 15 % (Hannan et al., 2000).

Among the elderly population, KOA presents one of the most common reasons for disability (Guccione et al., 1994). In respect of the increasing prevalence, caused by the aging population, KOA is considered to be a big burden on the public health system. KOA gives rise to direct costs for the public health system amounting to 27 billion dollars in the USA annually (Ong et al., 2019). In addition, the indirect costs of OA such as work-loss days are also considered a heavy burden.

KOA can affect one compartment of the knee, referred to as unicompartmental KOA, or both compartments. Due to the unequal distribution of the load in the knee, the medial compartment is approximately ten times more affected than the lateral compartment (Felson et al., 2000; Schipplein & Andriacchi, 1991). These facts demonstrate the huge importance of treatment and further research into the disease.

3.2.2 Aetiology and pathogeneses

OA is a multifactorial, degenerative disease of the joints that leads to the progressive restructuring of joint structures. The destruction of the joint can cause functional limitations up to complete loss of function (Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften (AWMF), 2018).

Even if OA affects all structures of the joint, the hyaline cartilage plays a key role in the aetiology of KOA (Diehl et al., 2013). 95% of joint cartilage consists of extracellular matrix containing collagen and proteoglycans. These are responsible for the resilient property of the cartilage.

The chondrocytes, constituting a 5 % share, ensure anabolic and catabolic metabolism of extracellular matrix. An unbalanced metabolism of the chondrocytes due to mechanical or biological stress leads to a changed composition of the matrix. This can lead to a continuous loss of cartilage if the regeneration capacity of the cartilage is reduced (Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften (AWMF), 2018). The fissures of the cartilage can extend to the bone and promote the ossification, such as osteophytes and subchondral ossification. Osteophytes describe the exostoses, which emerge at the joint margin. The osteophytes can cause pain and limitation of movement. The destruction of the cartilage matrix leads to the detachment of cartilage parts, which can manifest itself as a reactive inflammation of the synovial membrane (Diehl et al., 2013). The course of OA can develop in a circulus vitiosus when the inflammation promotes the degenerative metabolism in the cartilage (Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften (AWMF), 2018).

The major risk factors of KOA are increasing age, female sex, obesity and prior knee injuries (Neogi & Zhang, 2011). Furthermore, the genetic component, biomechanical changes and metabolic influence are also risk factors of KOA. Obesity can increase the lifetime risk up to 60% and a prior knee surgery up to 57% (Murphy et al., 2008).

The malalignment of the lower limb is seen as a very important factor for progression of KOA (Andriacchi et al., 2004; Birmingham et al., 2001). The load on the affected compartment is influenced by malalignment (Heidari, 2011). Due to a varus malalignment, the load bearing axis is shifted to the medial side. Thus, the vertical vector of the GFR passes medially from the knee center and results in increased load on the medial compartment (Tetsworth & Paley, 1994). It has been shown that an increased varus angle of 4 – 6 degrees can enhance the load on the medial compartment by up to 70 – 90 % (Fitzgerald, 2005). As a consequence of the medially shifted vertical vector of the GRF there is an enlargement of the lever arm and therefore also an increase in the KAM. Figure 6 illustrates the shift of the GRF through a varus malalignment. Through the medial shift of the vertical vector of the GRF the length of the lever arm increases.

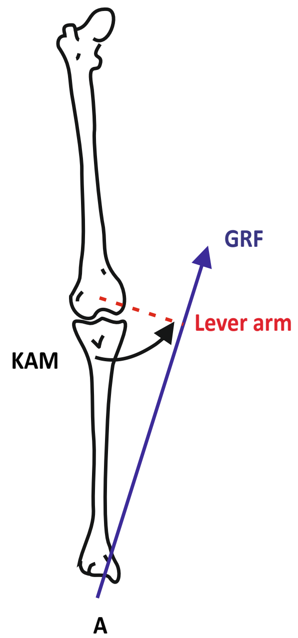


Figure 6: Ground reaction force and varus malalignment. (a) Normal alignment and (b) varus malalignment. Own modified diagram based on (Duivenvoorden et al., 2015). Legend to figure 6: GRF = ground reaction force; KAM = knee adduction moment.

Several studies have suggested that the KAM is the most important biomechanical indicator for the load distribution in the knee (Baliunas et al., 2002; Gok et al., 2002; Hurwitz et al., 2002; Weidenhielm et al., 1994). A high value of the KAM has also been reported in patients with medial KOA (Miyazaki et al., 2002). Therefore, medialization of the load bearing axis causes a high KAM, whereby the force and the compression in the medial compartment increases (Draper et al., 2000). The high load in the medial compartment facilitates the progress of cartilage destruction, thereby causing the joint space to narrow. Through the loss of cartilage in the medial compartment, the biomechanics in the lower limb change, producing a varus deformity (Andriacchi et al., 2009). Thus, the load on the affected compartment in the knee increases. Consequently, a circulus vitiosus develops, whereby the increased load in the medial compartment promotes the narrowing of the joint gap and the resulting varus angle in turn progressively increases the load in the medial compartment. As a result, the laxity in the frontal plane is increased (Iorio & Healy, 2003). Moreover, studies have shown that the KAM correlates with joint space narrowing (Miyazaki et al., 2002; Sharma et al., 1998).

3.2.3 Symptoms and diagnosis

In the anamnesis, first symptoms of KOA are pain during activity, after long activity or after resting and joint stiffness in the morning (Andriacchi et al., 2004). The typical pain course shows an increase in intensity over the day. In addition, overheating, swelling, instability, pinching, crepitation and morning stiffness can occur. Pain and instability constrain functional performance (Fitzgerald et al., 2002) and limit daily life activities and mobility (Andriacchi et al., 2004).

The diagnosis of KOA is made clinically and radiologically. The Kellgren and Lawrence classification (K&L) is a common method for classifying radiological severity. This classification is divided into four stages (Kellgren & Lawrence, 1957): (1) Low subchondral sclerosing, no osteophytes, no joint space narrowing. (2) Beginning osteophyte formation, low joint space narrowing. (3) Pronounced osteophyte formation, joint space narrowing, irregularity of the joint surface. (4) Distinctive narrowing of the joint space up to complete destruction, deformation of joint partners.

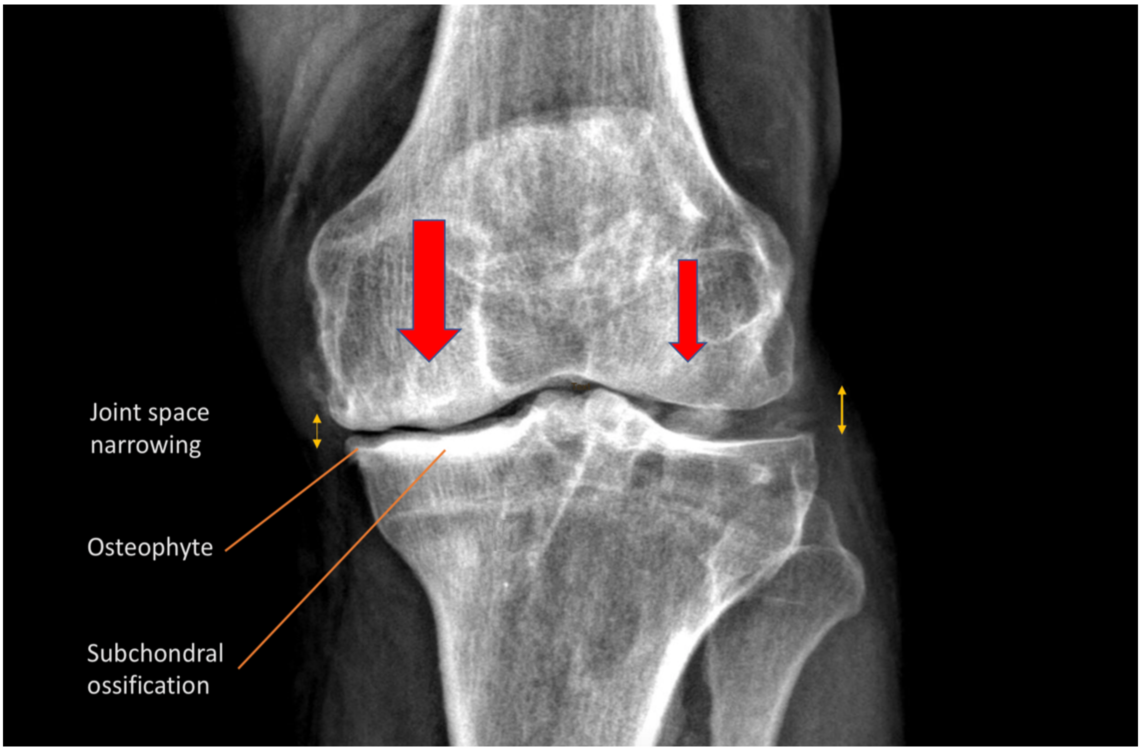


Figure 7: Medial knee osteoarthritis, X-ray picture with K&L Score II. The red arrows illustrate the magnitude of the load in the compartment. The yellow arrows show the different joint space. Adapted from database of participants.

The X-ray (Fig. 7) shows a typical radiographic appearance of KOA. A clear narrowing of the joint and a subchondral ossification in the medial compartment can be detected.

3.2.4 Therapy

The chronic course of the disease without any prospect of complete cure poses a major challenge both for the patient and for medical care. The primary objectives of KOA management are the reduction of pain and maintaining mobility of the patients. Further goals are to decelerate progress of KOA, reduce disability and inflammation and improve function (Sarzi-Puttini et al., 2005).

The conservative therapy is of paramount importance to the treatment of mild KOA. Sensible handling of the joints is vital for preventing the provocation of pain. However, the activity of the patient is an indispensable part of the conservative therapy. In particular, steady and controlled movements, such as swimming or cycling, are conducive to controlling the course of the disease (Kuster et al., 2000). The greatest evidence of reduction of pain and improvement of activity in patients with KOA has been achieved with strengthening exercises of the involved muscles. Furthermore, aerobic exercises, stretching and balance exercises are recommended (Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften (AWMF), 2018) (Bannuru et al., 2019). In addition to exercise therapy, patient education plays an important role. In this context, special emphasis should also be placed on weight reduction for overweight patients.

Pharmacological medication, such as NASAIDs, can be administered at any stage (Bannuru et al., 2019). When using NASAIDs, the side effects such as renal, gastrointestinal and cardiovascular problems must always be considered. In advanced stages, injections of local anesthetics and cortisone can also be used. Physiotherapy and physical medicine represent a central pillar of the conservative therapy.

Over the last few years, orthopedic devices have become more important in the therapy of KOA. A distinction is made between inlays, shoe finishes and orthoses. The German guidelines of KOA recommend the use of orthoses to adjust to the degree of complaint. Orthoses are effective in pain relief and functional improvement (Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften (AWMF), 2018).

In therapy, a distinction is made between conservative and surgical therapy. The decision has to be made individually, depending on the symptoms and physical limitations. Surgical intervention should always be performed only after failed conservative therapy. Recent recommendations emphasize sharing the decision-making process with the patient (Lützner

J, 2018). Surgical intervention includes (amongst others) the total joint replacement, the unicompartmental joint replacement and the high tibia osteotomy for correction of the axis. The following main criteria should be fulfilled for the indication of a joint replacement: knee pain lasting longer than 3-6 months, evidence of structural damage to the knee, failure of conservative therapy and limited quality of life due to knee pain. Secondary criteria include limited walking distance, malalignment of the leg axis, instability of the knee and limitation of mobility and strength of the knee (Lützner J, 2018).

The high tibia osteotomy represents a permanent solution for a malalignment of the knee as surgical intervention (Petersen & Metzlaff, 2016). The objective of osteotomy is realignment, whereby the load is shifted away from the affected compartment and can delay the need for a joint replacement (Brouwer et al., 2006).

In general, the treatment of unicompartmental KOA aims at reducing the load in the affected compartment to prevent disease progression (Walter et al., 2010).

3.3 Ankle-foot orthosis

3.3.1 History and classification

The history of orthotics can be traced back to antiquity, where the use of orthoses is first described (Nerlich, 2002). For a long time, deviations of the normal body were considered to be God-given and did not need treatment. But with the enlightenment of the 18th century, doctors began to correct deformities of the body (Wellmann-Stühring, 2014). Since then, the development of orthosis has been progressing continuously and in the meantime, there is a variety of different orthoses. Orthoses are recognized orthopedic aids which serve to stabilize, immobilize and relieve various musculoskeletal disorders. According to the American Academy of Orthopaedic Surgeons, knee orthoses are divided into four subgroups (Paluska & McKeag, 2000). Table 1 shows the subgroups of different orthoses.

Table 1: Classification of knee braces

Type	Function
Prophylactic	Prevent severity of knee injury
Functional	Provide stability and protection for ligaments deficiency or after repair
Rehabilitative	Allow protected motion of injured knees
Unloader/offloader	Provide pain relief in arthritic knees

3.3.2 Unloading mechanism

The unloader braces have attracted much attention in the therapy of unicompartmental KOA in recent years. Unloader braces are designed to modify the distribution of the load in the knee by shifting the load away from the affected and degenerative compartment. The goal of the unloader braces is to reduce the KAM in the knee by exerting a valgus force. Several studies have shown a reduction of the KAM by between 5 – 20 % by using an unloader brace (Gok et al., 2002; T. Schmalz et al., 2010; Self et al., 2000). This has also been confirmed by a positive effect on the clinical outcome, such as reduced pain and increased activity in daily living (Hewett et al., 1998). In the course of developments in orthotics, the AFO has appeared in recent years, with a view to improving the compliance of patients with orthopedic treatment. The AFO offers a new concept of the load-relieving mechanism in unicompartmental KOA (Fig. 8). The ulterior motive of this new orthosis was to develop an uncomplicated brace for lower limb only, which relieves the affected compartment in the knee with a similar effect to the conventional unloader braces. In order to achieve this effect, the orthosis exerts a targeted force on the lower leg at every contact with the ground in order to counteract malalignment.

The mechanism of the unloading effect on the affected compartment is explained below. By applying an external valgus force on the subject´s leg, the load shifts away from the affected compartment. This force is transmitted via the unilateral frame of the AFO to the lateral proximal shank. By moving the vertical vector of the GRF laterally, the knee lever arm, defined as the distance between the center of the knee joint and the vector of the GRF, is reduced. As a result of the reduced knee lever arm, the external KAM decreases (T. Schmalz et al., 2006). Thus, the provocative mechanical stress on the knee is reduced (Gross &

Hillstrom, 2008). Several previous studies have shown a reduction of the KAM by this kind of orthosis (Fantini Pagani et al., 2014; Mauricio et al., 2018; T. B. Schmalz, S.; Drewitz, H., 2011). Figure 8 illustrates the load-relieving mechanism of the AFO.

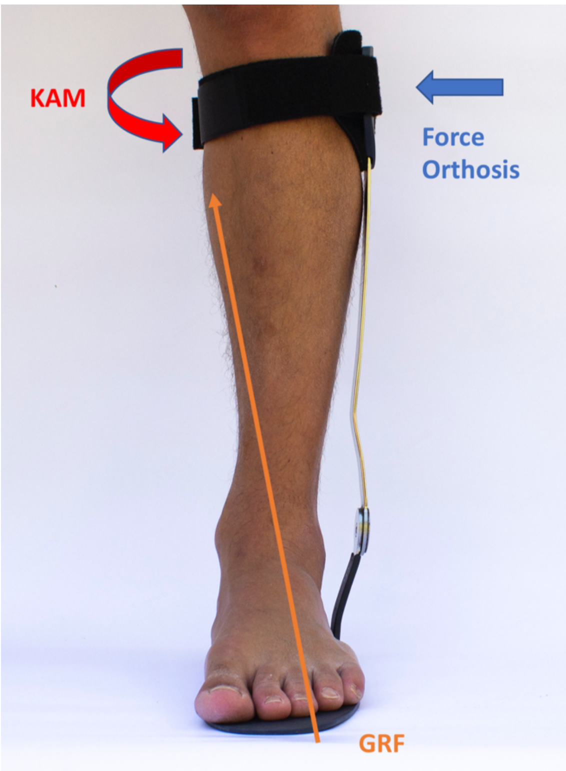


Figure 8: Mechanism of the AFO.
Legend to figure 8: KAM=knee adduction moment, GRF=ground reaction force.

The orthosis restricts the subtalar joint in the frontal plane to avoid a lateral rotation of the tibia in the frontal plane (Fantini Pagani et al., 2014). Free mobility in the sagittal plane makes plantar and dorsal flexion possible and therefore does not restrict the patient's gait pattern. The lateral shift of the load bearing axis and the reduction of the KAM offers proper transmission in the knee joint (T. B. Schmalz, S.; Drewitz, H., 2011).

3.4 Gait analysis

3.4.1 Gait cycle

Walking is the most important form of locomotion for humans and even the smallest of pathologies can severely restrict the quality of life. Deviations in the gait pattern can affect the entire musculoskeletal system and lead to irreversible damage as the disease progresses. Therefore, the unmasking of pathologies in the gait pattern is of great importance. The gait analysis is a common tool for analyzing the gait pattern of patients. The goal of gait analysis is to gain insights into the movement of the gait pattern and to be able to draw conclusions about pathologies.

The gait cycle is described as a cyclic process that begins with the first ground contact of one foot and ends with the following ground contact of the same foot. In general, the gait pattern of a human being consists of a swing phase and a stance phase. The phase between the first contact with the ground and the separation of the toes from the opposite side is referred to as the loading response (double limb stance) (Jacquelin Perry, 1992). This phase is regarded as the decisive phase for the load in the knee, which contains the first KAM peak (Chehab et al., 2014; Jones et al., 2013). This is directly followed by the single limb stance. By placing weight on the opposite foot, the swing phase is initiated (pre-swing phase) and begins with the lifting of the toes of the leg being observed (Jacquelin Perry, 1992). The distribution of the phases of the gait pattern is given as a percentage, with the stance phase representing 62% (12% loading response, 38% single limb stance and 12% pre-swing) and the swing phase 38% (Kramers-de Quervain, 2008). Figure 9 illustrates the different phases of a gait pattern.

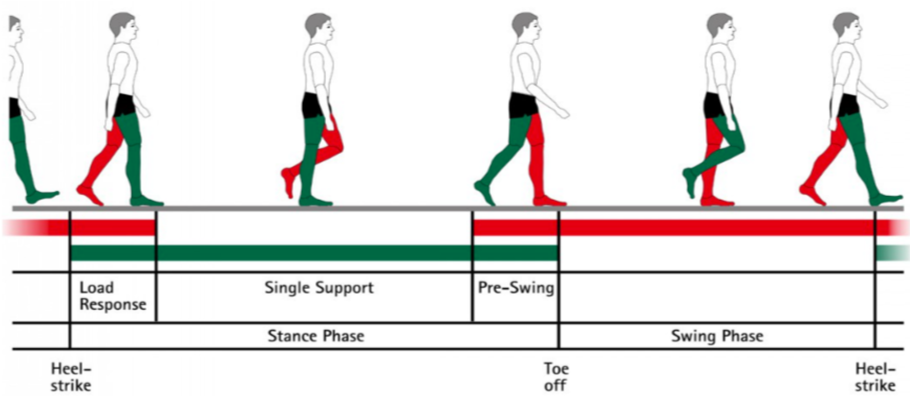


Figure 9: Gait cycle. Adapted from (Zebris FDM gait analysis report).

The data acquisition of a meaningful gait analysis includes the gait velocity measurements, foot pressure recordings and ground reaction forces (Kramers-de Quervain, 2008).

3.4.2 Pedobarography

Pedographic examinations serve to determine the pressure distribution over the foot sole during walking. The pressure image (Fig. 10) shows the maximum pressure values of a complete roll-off pattern. The legend shows the different pressure intensities by means of color coding. The line of black points in the pressure image represents the so-called progression line, which indicates the change in the center of gravity of pressure during walking. The progression line should extend from the heel over the metatarsus and metatarsal heads II/III to the big toe. Figure 10 reflects a regular pressure distribution with high values above the heel, metatarsal heads II/III and the big toe. Above the middle foot, a low pressure ratio should prevail (C.Fritsch, 2004).

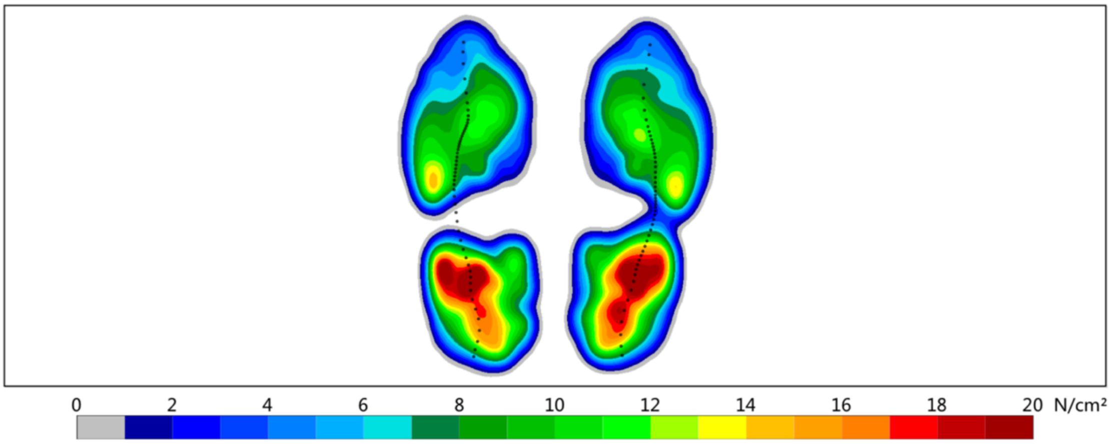


Figure 10: Pedobarography. Maximum pressure picture showing the distribution over foot sole. Measurement of one participant as an example. Adapted from (Zebris FDM gait analysis report).

3.4.3 Cyclogram

The cyclogram (Fig. 11), which represents the continuous trajectory of the COP during walking, serves to illustrate the position of the COP (Kalron & Frid, 2015). Taking into account the double limb stance phase with a load transfer to the other foot, the typical butterfly image of the cyclogram (Fig. 11) is obtained.

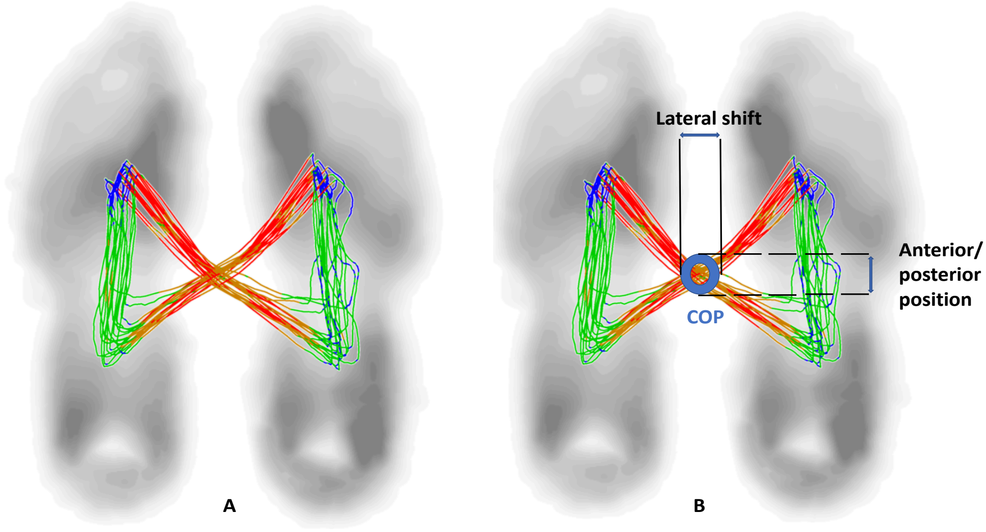


Figure 11: Cyclogram. (a) Normal cyclogram, colors corresponding to different levels of speed: red = fast, green = intermediate, blue = slow. (b) Describing the position of the COP (center of pressure). Modified and adapted from (Zebris FDM gait analysis report).

The "lateral shift" and "anterior/posterior position" parameters are essential for describing the position of the COP. To determine the COP, all pressures of the foot are measured during walking.

3.5 Objectives of the study

The objective of this study was to evaluate the biomechanical and clinical effects of a novel AFO.

The primary aim was to evaluate the AFO with regard to its influence on the shift of the load bearing axis by a static load posture measuring system and focusing on potential changes of biomechanical parameters on the foot sole during gait by a force sensitive treadmill.

The secondary aims were to assess effectiveness of the AFO on pain reduction measured by a patient pain diary. Moreover, the changes in self-reported pain, symptoms, activities of daily living, sport activities and knee-joint specific quality of life measured by the Knee Injury and Osteoarthritis Outcome score (KOOS) before wearing the AFO and after 4 weeks wearing the AFO and to compare self-selected "feel good" walking speed on the treadmill with and without the AFO were evaluated.

Further secondary aims were to describe satisfaction and compliance of the patients with evaluating the AFO by a specific self-made questionnaire.

The hypothesis was that the AFO can significantly shift the load bearing axis laterally in patients with medial KOA and thereby improves the pain relief, knee specific physical functioning, activities in daily living and health related quality of life and walking speed.

4 Methods

4.1 Design

This is a monocentric prospective interventional cohort study with pre/post design combined with a cross-sectional study design. The study contains two points of assessment: before intervention (T1) and at the end of the intervention (T2). Figure 12 shows an overview of the study design.

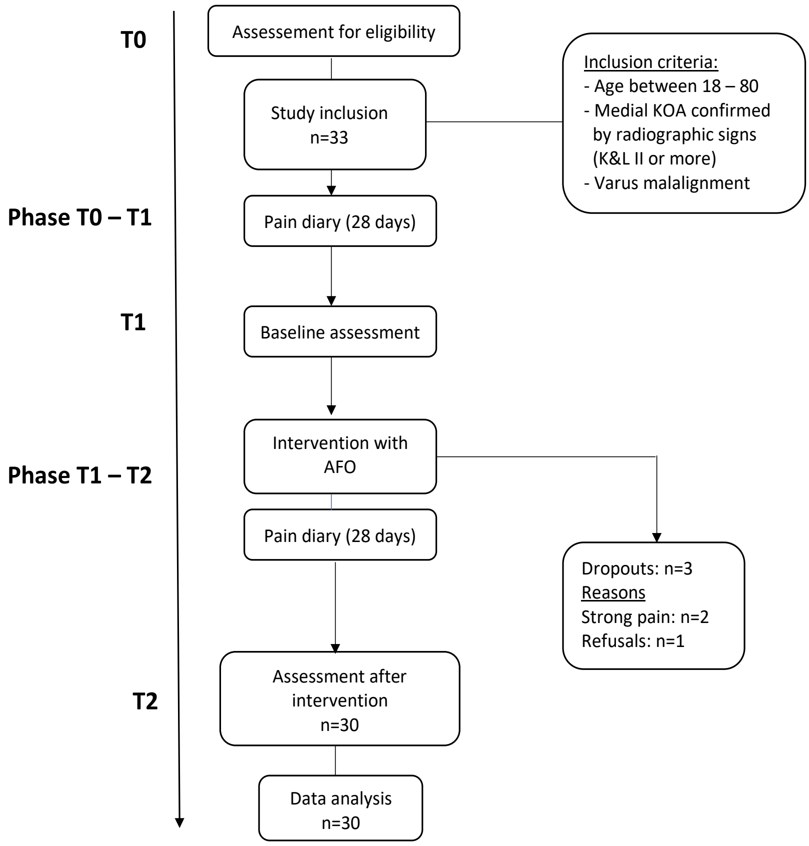


Figure 12: Flow diagram.

Legend to figure 12: T0 = recruitment and assessment of eligibility, T1 = assessment before intervention, T2 = assessment after intervention; n = number of investigated knees (the number of investigated knees deviates from the number of included patients, as 6 patients were provided with an orthosis on both knees). 27 patients were included with a total of 33 study knees (n=33) at T0. After dropout (n=3), 24 patients with 30 study knees were investigated at T2 (n=30).

The study design was essentially divided into two periods, before intervention and after intervention for longitudinal assessment (Fig. 12). The assessment at T1 was performed as a cross-sectional study to compare primary outcome parameters at one point in time. At T0 inclusion criteria were checked, demographic data was collected and baseline data was taken. The assessments at T1 and T2 included clinical tests and the patient reported outcome measures. The AFOs were issued at T1 and worn in the phase T1 – T2.

4.2 Ethical approval

The study design was approved by the ethical committee of the medical faculty of the Ludwig-Maximilians-Universität München (Project-Number 18-072, accepted 20th March 2018, Chairman Prof. Dr. W. Eisenmenger)

4.3 Setting

The study was conducted at the outpatient clinic of the Department of Orthopaedics, Physical Medicine and Rehabilitation, University Hospital, Ludwig-Maximilians-Universität München, Germany.

4.4 Study participants

The patients of this study were recruited between March and April 2018 (T0) from a list taken from the osteoarthritis day hospital program of the Department of Orthopaedics, Physical Medicine and Rehabilitation, University Hospital, Ludwig-Maximilians-Universität München, Germany. Furthermore, patients were recruited from the outpatient clinic (special consultations for knee-specific issues, once a week). The recruitment started with an invitation to patients for a physical examination including weight, body height, intercondylar distance and a specific examination of the knees. The examination of the knee included inspection of the menisci, cruciate ligaments and collateral ligaments, as well as varus and valgus stress examinations. Furthermore, a detailed anamnesis was performed with the focus on former knee surgeries, current therapy and location of pain. The examination was carried out by the supervisor of the study.

In this context, patients were finally enrolled, provided they met the following inclusion criteria:

1) Between 18 and 80 years of age
2) Medial KOA confirmed by radiographic signs (K&L II or more)

3) Cognitive ability and German language skills
4) Varus malalignment
5) Signed informed consent

The varus alignment was assessed by using the intercondylar distance measured with a straight edge (more than 2cm), as a high correlation is reported between the mechanical axes and the intercondylar distance (Navali et al., 2012).

Patients were excluded from the study if one or more of the following exclusion criteria applied:

1) Lateral KOA
2) Valgus malalignment
3) Former high tibia osteotomy
4) Former knee replacement
5) Underlying malign disease

When patients qualified for participation based on the inclusion/exclusion criteria, they were informed by the supervisor of the study and received information about the study. After examination of the knee and the patient's agreement to participate in the study, they were finally enrolled. All patients signed an informed document before enrollment in the study.

4.5 Data collection

The measurements of this study were performed from March to August 2018. Table 2 gives an overview of the time points of the different measurements.

Table 2: Dates of measurements:

	Assessments		
T0	Recruitment		
Phase T0 – T1	Pain diary without AFO (28 days)		
T1	Load line measurement	Gait analysis	KOOS-Questionnaire
Phase T1 – T2	Intervention with AFO and pain diary (28 days)		
T2	KOOS-Questionnaire	Satisfaction Questionnaire	

The assessment before intervention (T1) includes the load line measurement and the gait analysis as primary outcome. The measurement of the load line was performed at the medical facility (Sanitätshaus Kurtze, Seidlstrasse 23, München) from April to May 2018. Furthermore, a gait analysis was performed at T1 in the laboratory of the Department of Orthopaedics, Physical Medicine and Rehabilitation, University Hospital, Ludwig-Maximilians-Universität München, Germany. The gait analysis was performed once at T1 with the use of the orthosis and without testing the difference.

The secondary outcomes including the pain diary and KOOS were used to measure the outcome from the patient's perspective before and after intervention. The KOOS was completed at T1 and T2. The patient´s pain diary was kept daily between T0 and T1 (without AFO) and a modified version between T1 and T2 (with AFO).

Patients were informed about the contents of the questionnaires and attention was drawn to the importance of truthfully completing the questionnaire.

4.6 Intervention

As intervention, the AFO was applied on all patients. If possible, the AFO should be worn at least 6 hours every day, especially when walking. All patients were asked to note the daily time of application in the modified pain dairy. During pain measurement the patients should not alter their daily living patterns and current therapy, such as medical treatment and physiotherapy.

The orthosis was individually adjusted by a technician at the medical facility (Sanitätshaus Kurtze, Seidlstrasse 23, München) from May to June 2018.

4.6.1 Ankle-foot orthosis

We investigated the effect of an AFO on the mechanical axes and its clinical outcome. In this study the KNEO (KNEO, Fa. Sporlastics, Nürtingen, Germany) was used. The AFO aims to reduce the load on the affected compartment in the knee joint, resulting from malalignment of the lower limb. Therefore, the orthosis induces a force on the lateral, proximal side of the shank. The direction of the vector and the severity of this force is adjustable and depends on the malalignment. For a varus malalignment, the orthosis applies a lateral force on the shank to laterally shift the load bearing axis in the knee. Conversely, the orthosis can apply a medial force for a valgus malalignment. In this study, only the orthosis for varus malalignment was used.

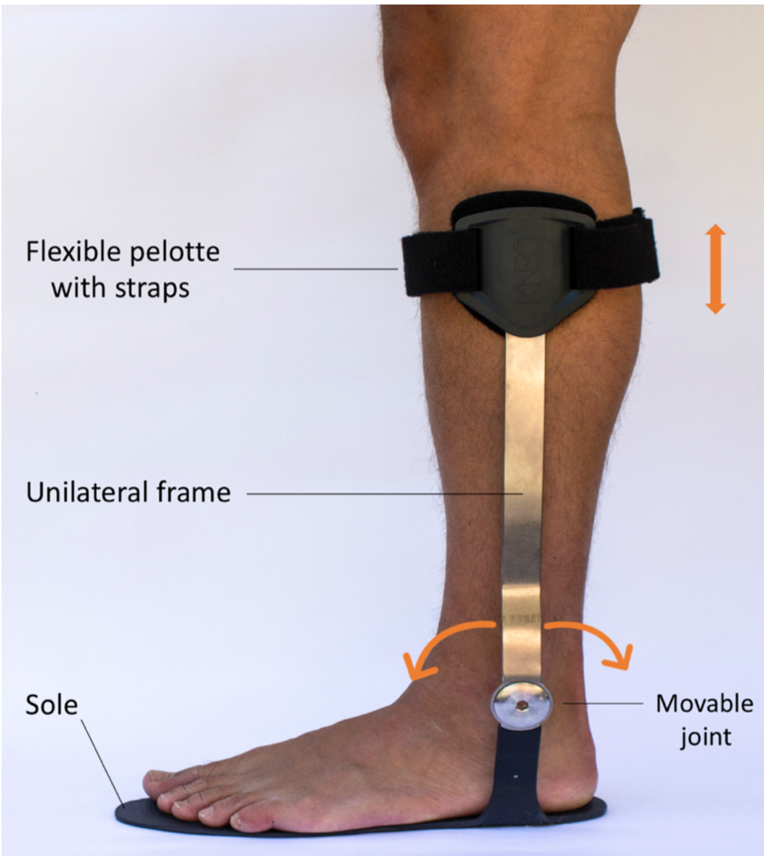


Figure 13: Construction of the AFO.

The orthosis consists of a sole, a unilateral frame and a pelotte with fastening straps (Fig.13). The sole is placed in the patient´s shoe and connected by a movable joint to the unilateral frame. The sole of the AFO is cut by the technician to fit the patient´s shoe size. The hinge joint of the orthosis provides free movement in the sagittal plane. The pelotte is attached to the distal end of the unilateral frame. The top of the pelotte is articulated and thus optimally adapts to walking. The pelotte is attached to the subject´s shank with a semi-flexible fastening device that transfers the valgus force of the orthosis to the patient´s leg. Above the ankle, the angle of varus or valgus can be adjusted with special devices. To enhance wearing comfort, the orthosis is fitted with soft pads on the pelotte and at the ankle.

The orthosis is available in different sizes depending on the size of the patient's shank. In order to choose the right size, two leg lengths are measured: the distance from the ground to the ankle and to the head of the fibula. With the help of these measurements, the appropriate orthosis can be selected. The AFO is available in 6 different combinations of the two measurements. Table 3 shows the different sizes of the AFO.

Table 3: Different sizes of the AFO

Size	Ankle height in cm	Head of fibula height in cm
1	6.5 – 7.5	35 – 38
2	6.5 – 7.5	38.5 – 41.5
3	6.5 – 7.5	42 – 45
4	7.5 – 8.5	39.5 – 42.5
5	7.5 – 8.5	43 – 46
6	8.5 – 9.5	44 - 47

In order to prevent an imbalance in the leg lengths caused by the inlaying sole of the AFO and the resulting pelvic obliquity with sequelae, the opposite side is provided with a raised inlay in the shoe.

4.7 Measurements

4.7.1 Measurement of the load line

As primary outcome the load bearing axis of the knee can be visualized by means of the load line measured with a static laser measuring device. The Laser Assisted Static Alignment Reference (L.A.S.A.R.) Posture® (Otto Bock, Duderstadt, Germany) System was used for this measurement, as it is considered to be a sensitive way of determining the load bearing axis in the knee (T. Schmalz et al., 2006). The L.A.S.A.R. Posture® system consists of a force plate, a projection system, a stepper motor and a service and display unit. Figure 14 shows the structure of the L.A.S.A.R. Posture® system. The force plate of the system contains four force-sensitive receptors, one in each corner of the plate. The force plates determine the center of pressure (T. Schmalz et al., 2006). The optics of the system convert the laser into a bright line. The stepper motor moves the laser line sideways and facilitates the exact localization of the laser on the leg under examination.

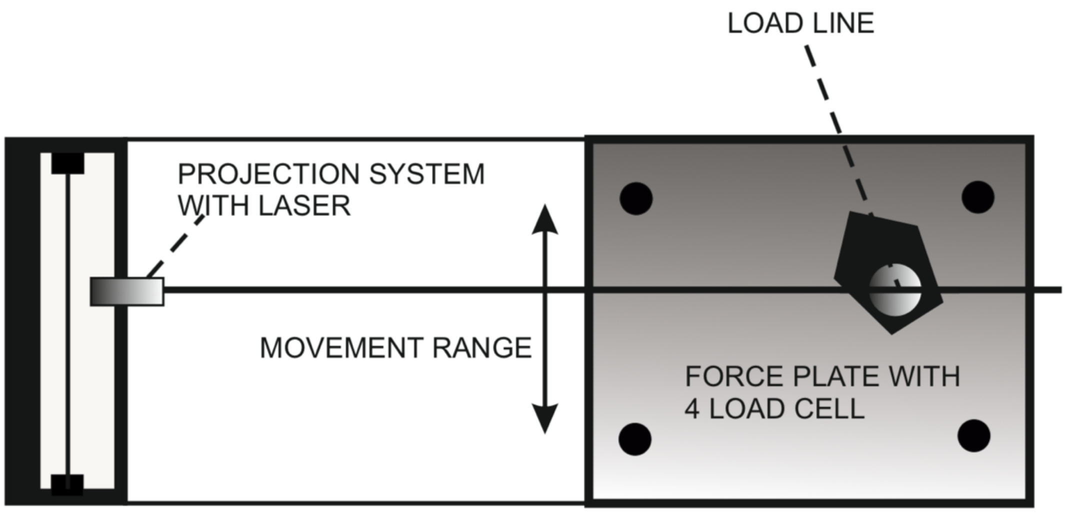
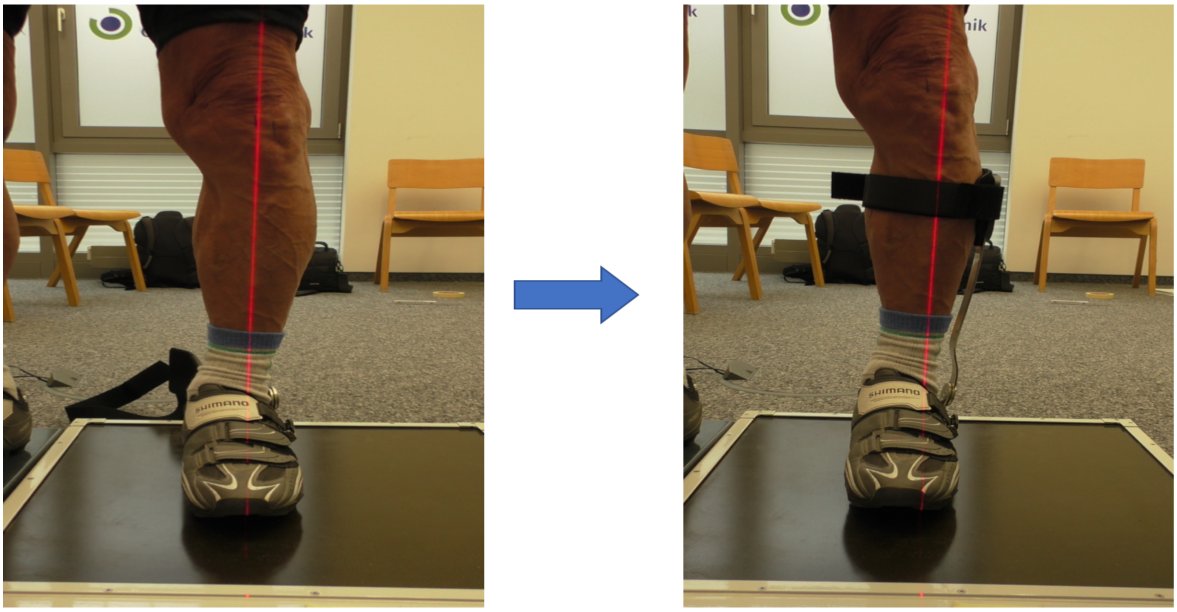


Figure 14: Schematic representation of the L.A.S.A.R. Posture® system.
Own modified diagram based on (T. Schmalz et al., 2006).

Figure 15: Design of the L.A.S.A.R. Posture® system.

Figure 15 illustrates the design of the L.A.S.A.R. Posture® system. The system illustrates the position of the load line through the force distributions in the foot of the leg being examined. While the force distribution is being measured, the patient stands with one foot on the force plate and the other on the plate beside. When the patient's weight is equally distributed, the laser line indicates the load line on the patient's leg in the frontal plane. The same horizontal position of both feet and the distance between the medial edge of the feet is important for an accurate measurement. As soon as the patients had been informed, the measurement began without orthosis to determine the load line of the knee joint. The patients were asked to stand in an upright position with their arms hanging downwards. The patients´ eyes should focus on a point on the wall, in order not to influence the laser line by shifting their weight. The load line visualized by the laser line was marked with a pencil on the knee, when the weight was equally distributed, and the laser line appeared. The height of the mark is set to the same level for all measurements. The medial joint space was set as an orientation for the level of the markings.

The second measurement was carried out with the orthosis fitted. To enhance the accuracy of the measurement, the orthosis was put on with the unilateral frame already folded back for the first measurement. Then the unilateral frame was folded up to apply the lateral force on the leg for the second measurement. The patients were asked to stand on the force plate without moving at all during the fitting of the lateral frame. As with the first measurement, the marking was set at the same level to visualize the load line of the knee with the orthosis.



A B

Figure 16: Load line measured by the L.A.S.A.R. Posture System®. (a) Measurement without AFO (folded back) and (b) measurement with AFO at T1.

Figure 16 shows the measurement of the load line on the patient´s leg (a) without and (b) with the applied force of the AFO. The red laser line indicates the load line of the knee.

Then the distance between the two markers was measured (Fig. 17) and entered in a logbook. The measured distance with lateralization of the load line received a positive value, while with medialization it in contrast received a negative value.

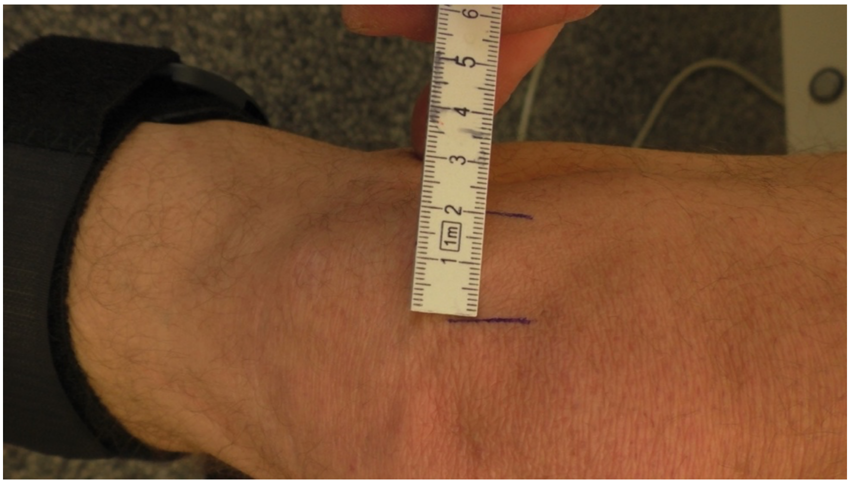


Figure 17: Measurement of the distance between the marks with and without the application of the AFO in mm at T1.

The measurements of all patients were performed by the same orthopedic technician. The technician was introduced to the measurement by the supervisor of the study.

The L.A.S.A.R. Posture® system was also used for the individual adaptation of the orthosis. The magnitude of the lateral force of the orthosis was determined by the lateral shift of the load line and the patients´ convenience. The varus angle (AFO angle) of the orthosis was adjusted with special forceps by the orthopedic technician; the more the AFO angle was modified, the stronger the lateral force acting on the lower leg. Figure 18 shows the magnitude of the lateral force as a function of the AFO angle.

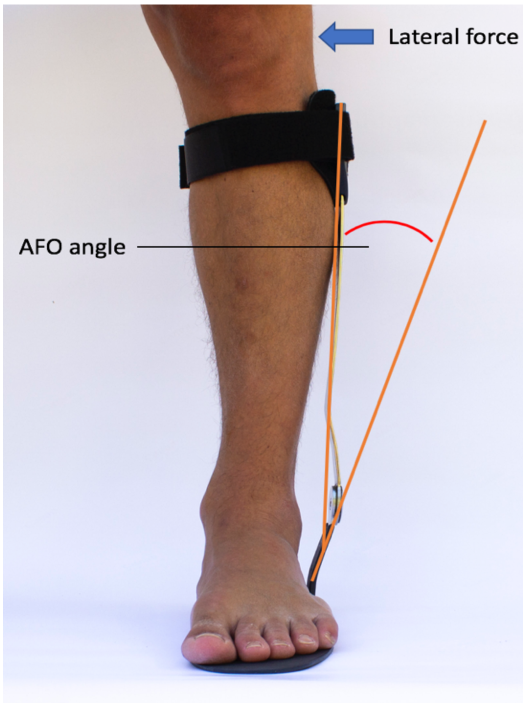


Figure 18: Angle of the lateral frame.

4.7.2 Gait analysis

A pressure-sensitive treadmill (Zebris FDM-T Treadmillsystem ®, Isny, Germany) was used for the gait analysis. The Zebris FDM-T® was combined with a camera (SyncLightCam®) for synchronous video analysis. The Zebris FDM-T® system contains a pressure-sensitive treadmill with an integrated, calibrated measuring sensor. By means of compensated movement of the treadmill it is possible to analyze a stable gait and roll-off pattern. The walking area of the treadmill contains 5378 pressure/force sensors over a surface of 150 x 50 cm and with a frequency of 300 H (Granacher et al., 2011).

Figure 19: Zebris® treadmill at the physical medicine laboratory.

Figure 19 shows the Zebris® treadmill surrounded by the safety rack. If patients had a very unsafe gait, they could be secured to the rack to avoid possible falls.

The pressure sensors and the camera send the data to an external computer. On the desktop of the computer the different forces and pressures relating to the gait cycle are displayed. Figure 20 shows a screenshot of the desktop during a gait analysis.

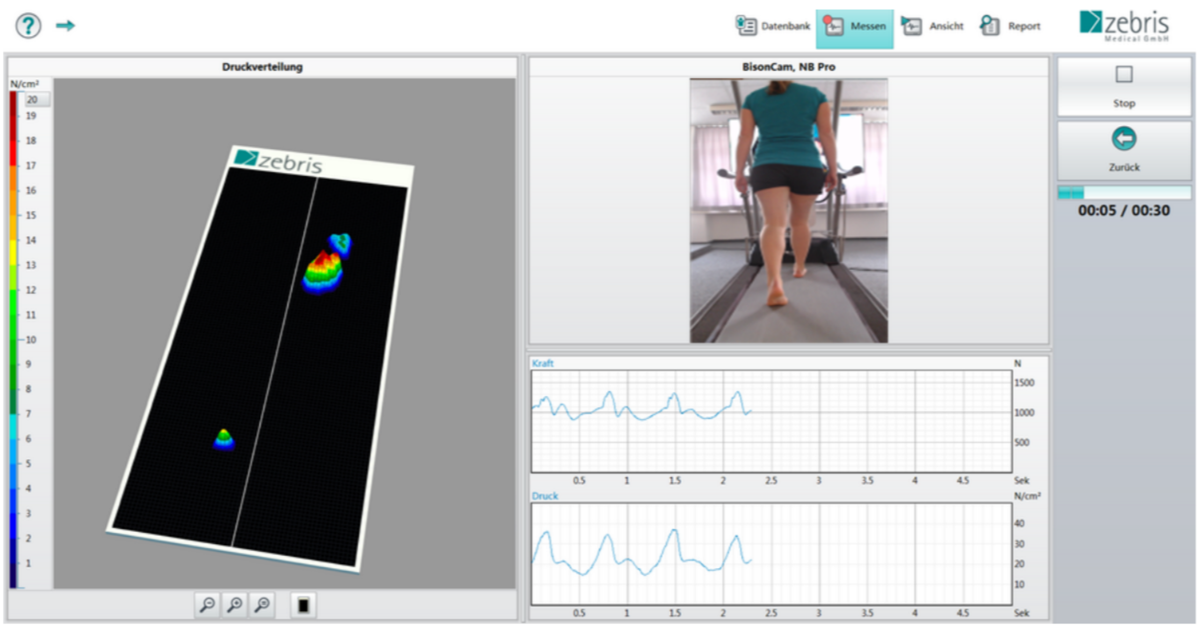


Figure 20: Screenshot of the Zerbis® program on the computer.
Adapted from (Zebris FDM gait analysis report).

The different colors indicate the variation of density according to the legend on the left-hand side. After 30 seconds of gait analysis the program delivers a detailed report on the selected gait parameters. In this study the COP descriptive parameters and the distribution of forces over the foot sole were analyzed. The parameter describing the COP includes the lateral shift (SV) and the anterior/posterior position (APP). The deviation of the starting position is given in millimeters. The zero position of the APP is set as the rearmost point of the heel. For the lateral shift, the zero position is described as the intersection point of the cyclogram. A negative value for the lateral shift indicates a shift to the left-hand side and a positive value a shift to the right-hand side.

The distribution of the force over the foot sole was analyzed by the mean force forefoot (KV) and mean force hindfoot (KR). For a more precise representation of the force distribution over the foot, the seven foot-zones analysis is used with the following seven foot-zones: maximum force toes (MZ), maximum force forefoot medial (MVM), maximum force forefoot lateral (MVL), maximum force forefoot internal (MVI), maximum force midfoot (MM), maximum force heel medial (MFM), maximum force heel lateral (MFL). Figure 21 shows the picture of the seven foot-zones analysis.

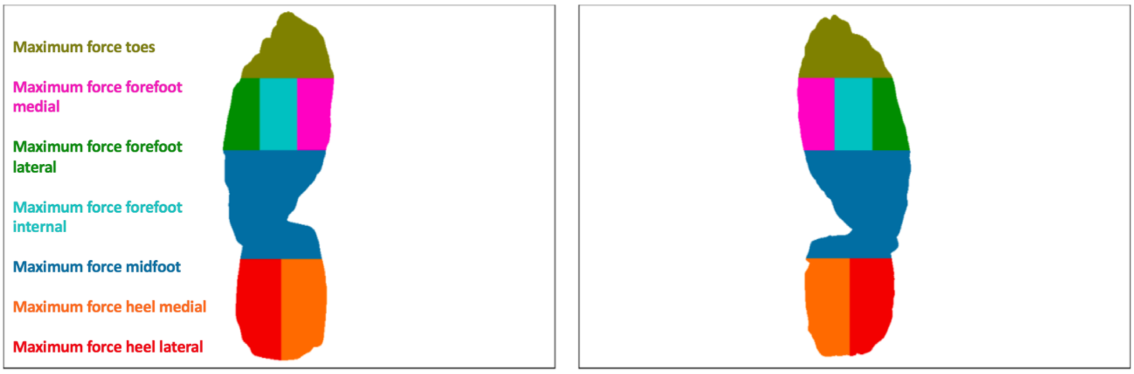


Figure 21: Seven foot-zones analysis.

3.6.4.1 Randomization of the gait analysis

Before each measurement the treadmill was calibrated automatically. The gait analysis was performed under three different conditions: 2km/h, 4km/h and a self-selected speed (speed of convenience). All measurements were performed under all three conditions with and without the orthosis. However, to avoid systematic bias and achieve high accuracy, the order of the gait analysis was randomized by a highly valid model. All patients were pseudonymized and registered in a chronologically ordered list from 1 to 30. All odd numbers (starting with 1) received an envelope containing either the letter "A" or "B". The letter "A" stood for "starting the measurement without AFO following by all measurements with AFO and "B" for the other way around. The even numbers (starting with 2) were consequently always starting in the opposite manner, without choosing an envelope. The envelopes were prepared by an independent person with the randomize function in Microsoft Excel 2010 and opened just before the gait analysis.

To determine the self-selected comfortable speed, the speed was increased until a convenient speed for the patient was reached. The patients were asked to increase the speed until the patient found their speed of convenience, which they would choose in daily living. After the patient has adjusted the speed to his personal "hiking-speed", the parameters were recorded and the treadmill was switched off.

To increase reliability, the speed level normally displayed on the treadmill was blinded. This procedure was performed for every patient with and without AFO. The self-selected speed was noted in an Excel chart.

Figure 22: Display of the Zebris® treadmill.

The display is attached to the treadmill and, among other parameters, shows the participants the current speed, time and distance. The display is equipped with an emergency switch, which can be actuated to immediately stop the treadmill. Furthermore, it is fitted with a handrail to ensure the patients´ safety. All patients were advised on how to stop the measurements immediately if necessary.

The pedobarography-measurement circle always started with the self-selected speed followed by all measurements with 2 km/h and finally 4 km/h. The measurement time on the treadmill was defined as 30 seconds (international standard). Immediately before measuring, all patients had a bit of time to accustom themselves to the speed.

The data from the treadmill were calculated by the FDM-T® system of the external computer, which provided an extensive report of the gait pattern. A subgroup in the report presents the pedobarography, which provides data on distribution of the forces acting on the foot sole during walking. After the gait analysis, the orthosis was issued to the patients.

4.7.3 Knee Injury and Osteoarthritis Outcome Score (KOOS)

The validated German version of the KOOS was used (Kessler et al., 2003). As a patient-reported outcome measure, the KOOS reflects the patients´ perspective of the health status (Collins et al., 2016). It represents a valid questionnaire for patients with KOA. The KOOS can be used to evaluate the progress of the disease and outcomes referring to surgical, pharmacological and other interventions (Roos et al., 1998). The questionnaire consists of five different subscales:

1. Pain (9 items)
2. Other symptoms (7 items)
3. Activities of daily living (17 items)
4. Sport and recreation (5 items)
5. Knee-related quality of life (4 items)

Each subscale contains different items, which can be answered on a five-point scale of severity: (0) none (1) mild (2) moderate (3) severe (4) extreme.

The six patients with an AFO on both knees performed a separate questionnaire for each knee. Completion of the KOOS questionnaire takes about 10 minutes.

4.7.4 Pain measurement by a patient diary

A further outcome of this study was the effect of the AFO on pain reduction. Patients reported their pain twice a day in a pain diary.

The VAS (visual analogue scale) describes a unidimensional measure of pain intensity, which is a frequently used instrument for measuring pain (McCormack et al., 1988). In this study a numeric rating scale (NRS), which is a segmented numeric version of the VAS scale, was used. The scale is anchored by “no pain” (score of 0) and “extreme pain” (score of 10). The pain intensity is represented on a scale ranging from 0 to 10 points. The numbers describing the severity of pain are arranged in a horizontal bar. The participants mark a number that best reflects their pain (Rodriguez, 2001). The patients were asked to use the scale to record their current pain on a daily basis once in the morning and once in the evening. The specific pain on the scale referred only to the knee affected by OA. The second pain diary was kept with the AFO being used. This pain dairy was modified by adding the number of hours per day that the AFO was worn and the need for medication. The pain diaries represent both the morning and the evening pain. All patients were asked to complete the pain diary conscientiously and with care. All patients provided with an AFO on both knees performed a separate pain diary for each knee.

4.7.5 Comfort and compliance

In order to analyze the compliance and comfort of the AFO, specific questionnaires were created. The daily wearing time was recorded in conjunction with the pain diary, whereby the wearing time was recorded each day by the patient.

The satisfaction and comfort of the AFO was covered by a questionnaire containing the following subgroups:

(1) Handling
(2) Comfort
(3) Relief
(4) Improvement of complaints
(5) Overall impression
(6) Continuation with treatment

The subgroups were answered by ticking the answer options. The answer options were divided into the following four descending severity levels: *excellent, good, fair, poor* for handling, comfort and overall impression as well as *significant, mild, hardly any and no improvement* for relief and improvement of complaints. A further goal of the questionnaire was to detect the damage of the AFO to the footwear. The answer options were divided into *serve damage, slight damage, hardly any damage and no damage* to the footwear. The options of answers to the question as to whether patients wanted to continue wearing the AFO were limited to *yes* or *no*.

4.7.6 Data analysis

The statistical analysis was performed with SPSS Statistics 24 (SPSS, Inc., IBM, Chicago, IL). The data were collected from March to September in 2018. The data analysis was performed in December 2018 in the Department of Orthopaedics, Physical Medicine and Rehabilitation, University Hospital, Ludwig-Maximilians-Universität München, Germany.

Before the data were evaluated, all data were entered twice in two separate files for control purposes and to avoid errors. Afterwards a check for consistency was performed to detect transmission errors. This double check was carried out by two different examiners to ensure the accuracy of the data.

The following statistical analysis was performed under the observation of a statistician (Dr. Alexander Crispin) of the Institute for Medical Information Procession, Biometry and Epidemiology (IBE) and the co-supervisor of this thesis (Dr. med. Alexander Ranker).

In order to examine statistical significance between baseline (before intervention) and after intervention, all data were previously tested for normality. The Kolmogorov-Smirnov test and the Shapiro-Wilk test can be used to analyze normal distribution, among others. Because of the small number of the sample size, the Shapiro-Wilk test was performed. As a general rule, the informative value of a normal distribution test is low, as the standard error rate is high. The Shapiro-Wilk test has a relatively high informative value for small sample sizes. The alpha level for this test was set at $\alpha = 0.05$. The null hypothesis of the Shapiro-Wilk test states that the population is normally distributed. Therefore, the null hypothesis is not rejected if the p value is greater than the alpha level and the population is considered to be normally distributed.

The statistical analysis of the lateral shift of the load line by using the AFO was performed using the Wilcoxon signed-rank test. This test was used to determine whether there was a significant difference in the position of the load line due to the application of the AFO. The Wilcoxon signed-rank test is a non-parametric test to assess whether the mean ranks differ in the repeated measurement on a single sample. In this test, ranks are formed from the differences. The paired-sample signed-rank test uses the magnitude and the sign of the paired difference ranks. The lateral displacement was measured in millimeters and the difference to the starting point of the measurement (load line without AFO) was calculated. In order to establish the differences, the starting points (measurement without AFO) were set at zero. Thus, the distance between both visualized load lines describes the difference. These differences were used to calculate the significance.

The parameters of the gait analysis between the intraindividual differences with AFO and without AFO were examined for significance. The Wilcoxon test was used for this examination. All parameters were examined for significance at three different speed levels (self-selected speed, 2 km/h, 4 km/h) of the gait analysis. Since a negative value for the "lateral shift" parameter describes a shift of the COP to the left and a positive value a shift to the right, the differences were multiplied by a factor of -1 for measurements of left-sided AFO in order to be able to compare all values, regardless the side.

The outcome of the KOOS subscales (symptoms, pain, activity, sports and quality of life) were described by means of quantitative parameters. Each subscale score is calculated independently. The formula for the calculation of the subscale scores is presented below. The score of 0 points indicates a serious problem and 100 points indicates no complaints. The subscales were calculated by Excel® using specific formula:

Pain: $$100 - \frac{Meanscore(Subscale\ pain)\ x\ 100}{4} = KOOS\ Pain$$

Symptoms: $$100 - \frac{Meanscore(Subscale\ symptoms)\ x\ 100}{4} = KOOS\ Symptoms$$

ADL: $$100 - \frac{Meanscore(Subscale\ ADL)\ x\ 100}{4} = KOOS\ ADL$$

Sport: $$100 - \frac{Meanscore(Subscale\ sport)\ x\ 100}{4} = KOOS\ Sport$$

QOL: $$100 - \frac{Meanscore(Subscale\ QOL)\ x\ 100}{4} = KOOS\ QOL$$

The mean, and standard deviation, as well as minimum and maximum, were determined to test for a significant difference between the KOOS outcome at T1 and T2. The quartiles, such as median, were analyzed. For this statistical analysis, the Wilcoxon test was used.

The difference between the longitudinal pain-measurement without AFO (Phase T0 – T1) and using the AFO (Phase T1 – T2) on the NRS scale was tested using a randomized mixed-effect model. For this analysis, the GLIMMIX procedure of the SAS Statistical Analysis System® version 9.4 for Windows (SAS Institute, Cary, NC) was used.

The randomized mixed-effect model was compared across four groups (morning pain, evening pain, with AFO and without AFO) by modeling individual trends using random intercept models. Afterwards, separate models for morning pain and evening pain were adapted. Group, time and the interaction of time and group were regarded as fixed factors. An individual random intercept model was adapted for each patient. Then a first order autoregressive correlation matrix was used.

The percentage distribution of answers was taken into account and evaluated in the contentment questionnaire.

5 Results

5.1 Patients

Initially, a sample of 27 patients with 33 study knees was included in this study, as 6 patients had been provided with an orthosis on both knees (Figure 12). Three patients (each provided with single orthosis = 3 study knees) dropped out of the study prematurely. Two of them broke off the study due to severe pain in the affected knee. One other patient did not feel comfortable with the orthosis and left the study. All the remaining 24 patients (30 study knees) finished the study. The mean age was 61.43 (± 7.85) (12 female, 12 male). A total of 30 knees were examined in this study (n=30, 18 patients with single knee, 6 patients with both knees). The mean body mass index (BMI) was 29.01 kg/m^2 (± 4.2) (23.5 min; 39.04 max). The mean K&L Score was 2.23 (± 0.43). Table 4 shows the patients´ data.

Table 4: Baseline characteristics of all patients.

Participants characteristics	Mean (SD)	Range
Socio-demographics		
Age (years)	61.43 (±7.85)	44.00-79.00
Gender (female/male)	12/12	
Health factors		
Body height [m]	1.71 (±0.08)	1.59-1.91
Body weight [kg]	84.50 (±14.51)	65.00-138.00
BMI [kg/m²]	29.01 (±4.20)	23.50-39.04
Kellgren-Lawrence Score	2.33 (±0.43)	2.00-3.00
Mean pain at beginning (VAS-scale)	3.20 (±1.47)	1.00-7.00

Legend to table 4: BMI = Body Mass Index, VAS = Visual Analogue Scale; all values given in mean and standard deviation (written in parenthesis). Number of participants: 24 (30 study knees)

5.2 Displacement of the load line

A considerable lateralization of the load line on the affected knee through the applied force of the AFO was observed in all patients by taking measurements with the L.A.S.A.R. Posture® system. The mean of the lateral shift of the load line by the application of the AFO was 16.03 mm (± 5.22) (9.00 mm min; 31.00 mm max). The median of lateralization was 15.50 mm. These differences were highly significant ($p<0.001$). Figure 23 shows the lateral displacement of the load line using the AFO in millimeters [mm] of each measurement.

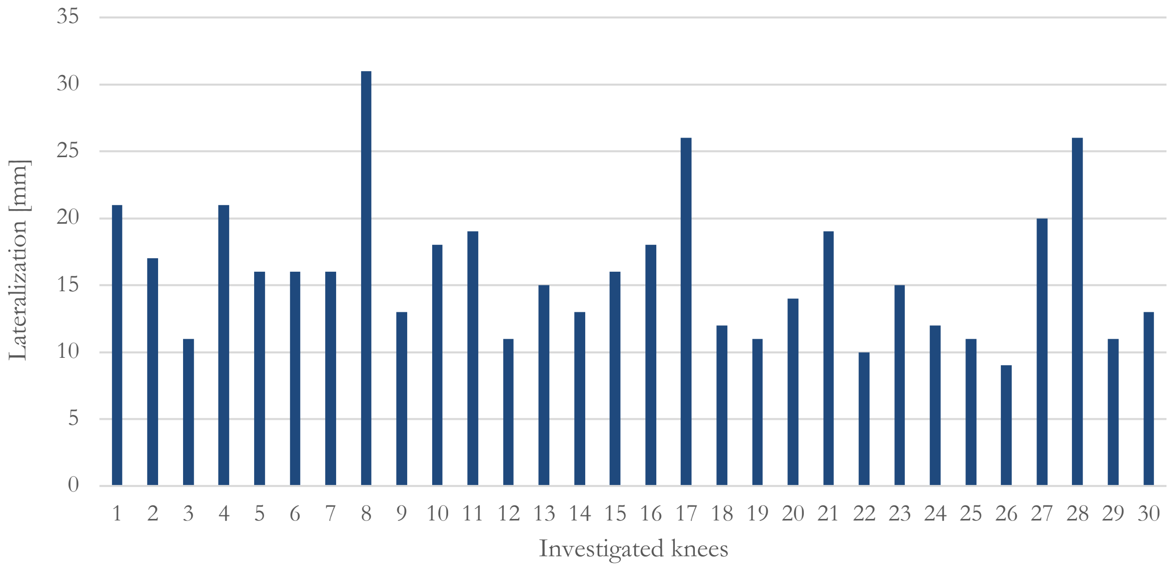


Figure 23: Lateralization of the load line in [mm] of the investigated knees (n=30) by using the AFO. Measured with L.A.S.A.R. Posture® at T1.

Figure 24 shows that there was a lateralization of the load line in all measurements and illustrates the lateral shift on a schematic sketch of the knee.

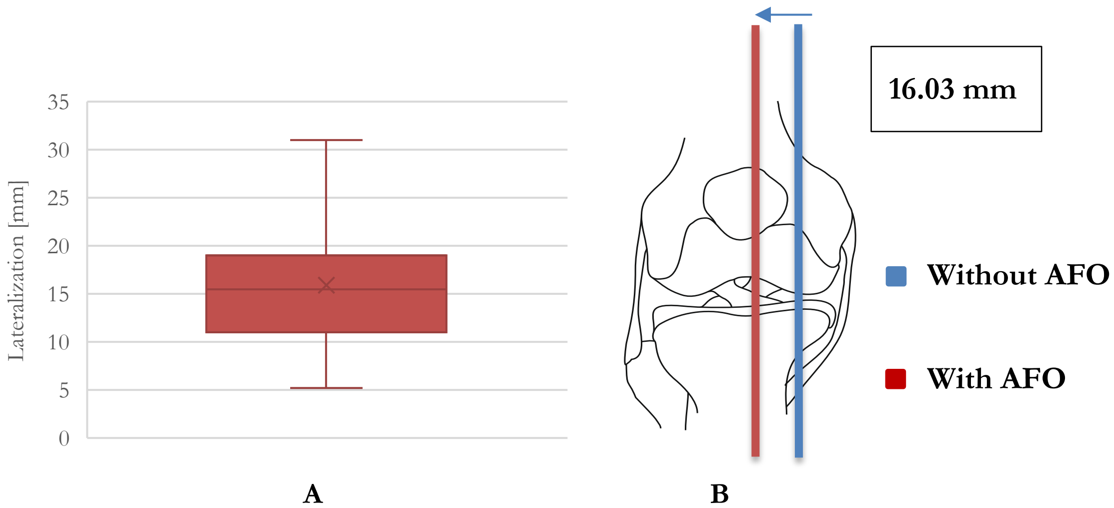


Figure 24: Lateralization of the load line. (a) Boxplot showing the distribution of lateralization of the load line in [mm]. (b) Schematic illustration of the load line shift with mean value by using the AFO. Measured with L.A.S.A.R. Posture® at T1; n = 30.

In all measurements the orthosis had a clear effect on the position of the load line. From the boxplot (Fig. 24) the range of the lower and upper quartile and the median value (15.50 mm) can be seen.

5.3 Gait analysis

The precision distribution of the force distribution over the sole of the foot was carried out with the seven foot-zones analysis. This measurement showed a significant lateralization of the force distribution by using the AFO. With the exception of the maximum force forefoot medial at self-selected speed, all differences showed statistical significance. The force measured at the lateral edge of the foot sole increased significantly in all conditions during intervention with the orthosis. At the same time, the force on the medial side of the foot-sole decreased significantly under all conditions. In addition, an increase in the forces over the toes were observed. The maximum force toes (MZ) increased to a statistically significant extent under all conditions.

Table 5 shows the observed results of the seven foot-zones analysis with different walking speed.

Table 5: Force distribution over the foot sole measured by the seven foot-zones analysis at 2 km/h, 4 km/h and self-selected speed at T1. All values in Newton (N).

Seven foot-zones analysis	Mean (SD)			
	Without AFO	With AFO	Delta (Δ)	Significance
2 km/h				
Maximum force toes	118.02 (±45.94)	133.01 (±51.61)	14.99	p=0.001
Maximum force forefoot medial	162.60 (±46.95)	143.46 (±39.80)	19.14	p<0.001
Maximum force internal	254.99 (±3.84)	253.65 (±46.81)	1.34	p=0.58
Maximum force lateral	118.78 (±22.63)	134.67 (±27.03)	15.89	p<0.001
Maximum force midfoot	347.19 (±120.91)	323.42 (±114.6)	23.76	p=0.001
Maximum force heel medial	179.02 (±42.42)	123.65 (±40.25)	55.37	p<0.001
Maximum force heel lateral	191.62 (57.45)	259.6 (70.85)	67.98	p<0.001
4 km/h				
Maximum force toes	156.52 (±70.95)	185.91 (±68.20)	29.38	p<0.001
Maximum force forefoot medial	182.22 (±42.50)	164.76 (±38.30)	17.46	p=0.001
Maximum force internal	302.48 (±58.81)	302.59 (±57.78)	0.11	p=0.68
Maximum force lateral	128.59 (±27.67)	146.83 (±30.060)	18.24	p<0.001
Maximum force midfoot	375.20 (±139.61)	352.90 (±134.60)	22.30	p=0.01
Maximum force heel medial	240.42 (±48.99)	159.42 (±42.74)	81.01	p<0.001
Maximum force heel lateral	241.49 (±68.23)	321.07 (±84.16)	79.58	p<0.001
Self-selected speed				
Maximum force toes	125.13 (±57.64)	150.58 (±53.83)	25.44	p=0.002
Maximum force forefoot medial	160.61 (±44.56)	154.01 (±39.64)	6.59	p=0.11
Maximum force internal	255.32 (±61.66)	262.12 (±42.28)	6.807	p=0.36
Maximum force lateral	114.56 (±21.57)	135.62 (±24.55)	21.06	p<0.001
Maximum force midfoot	351.55 (±116.20)	323.01 (±114.20)	28.53	p=0.005
Maximum force heel medial	189.97 (±42.54)	124.66 (±36.25)	65.30	p<0.001
Maximum force heel lateral	199.11 (±65.18)	265.54 (±68.95)	57.42	p<0.001

Legend to table 5: All values given in mean and standard deviation (written in parenthesis).

Figures 25 - 27 show all differences of the seven zones analysis with and without the application of the AFO in three conditions (2km/h, 4kmh/h and self-selected speed).

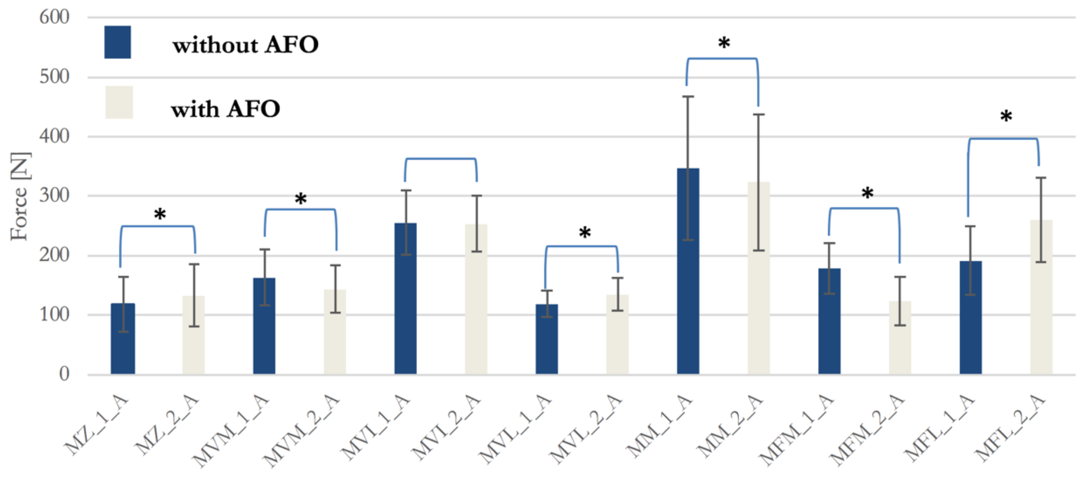


Figure 25: Comparison of the force distribution through the application of the AFO over the foot sole in [N] at T1. Seven foot-zones at 2 km/h; n = 30.

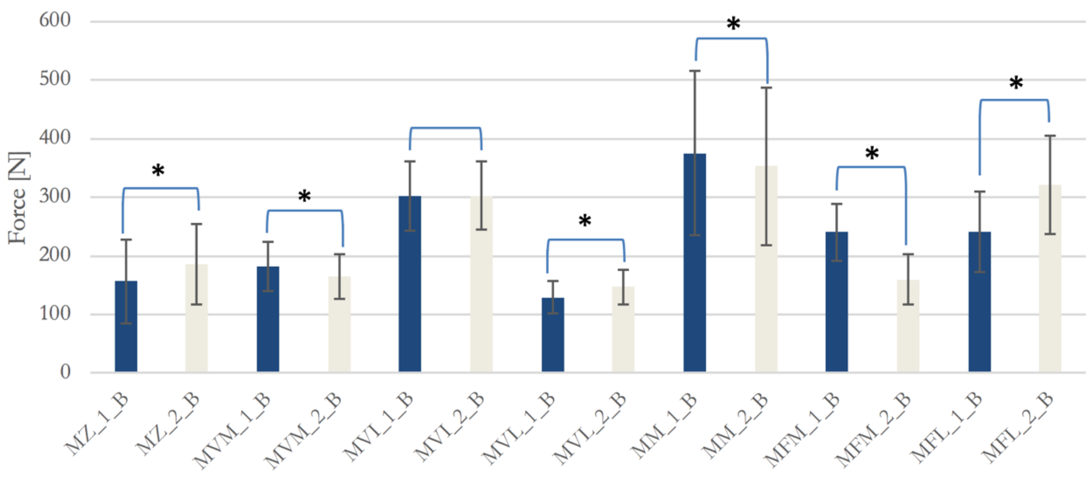


Figure 26: Comparison of the force distribution through the application of the AFO over the foot sole in [N] at T1. Seven foot-zones at 4 km/h, n = 30.

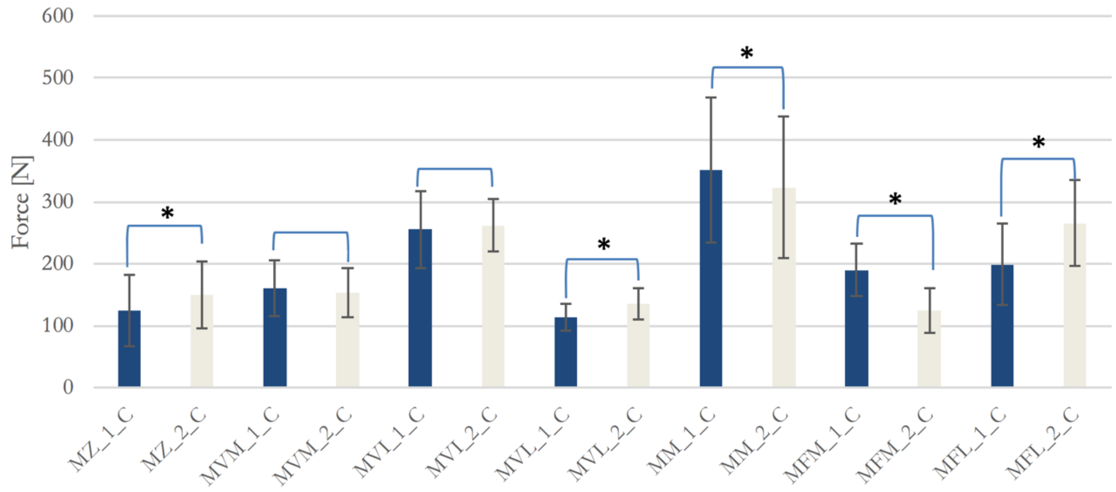


Figure 27: Comparison of the force distribution through the application of the AFO over the foot sole in [N] at T1. Seven foot-zones at self-selected speed, n = 30.

Legend to Figures 25-27: MZ = Maximum force toes; MVM = Maximum force forefoot medial; MVI = Maximum force forefoot internal; MVL = Maximum force forefoot lateral; MM = Maximum force midfoot; MFM = Maximum force heel medial; MFL = Maximum force heel lateral; (1) = without AFO; (2) = with AFO; A = 2km/h; B = 4km/h; C = self-selected speed; AFO = ankle-foot orthosis; ***** =significance.

A clear difference can be observed in the lateral and medial areas of the foot sole. All forces of the medial areas of the seven foot-zones are reduced by the influence of the AFO. Consequently, a significant increase in maximum force can be observed in all lateral areas.

Figure 28 shows a direct comparison of the medial and lateral zones as influenced by the AFO.

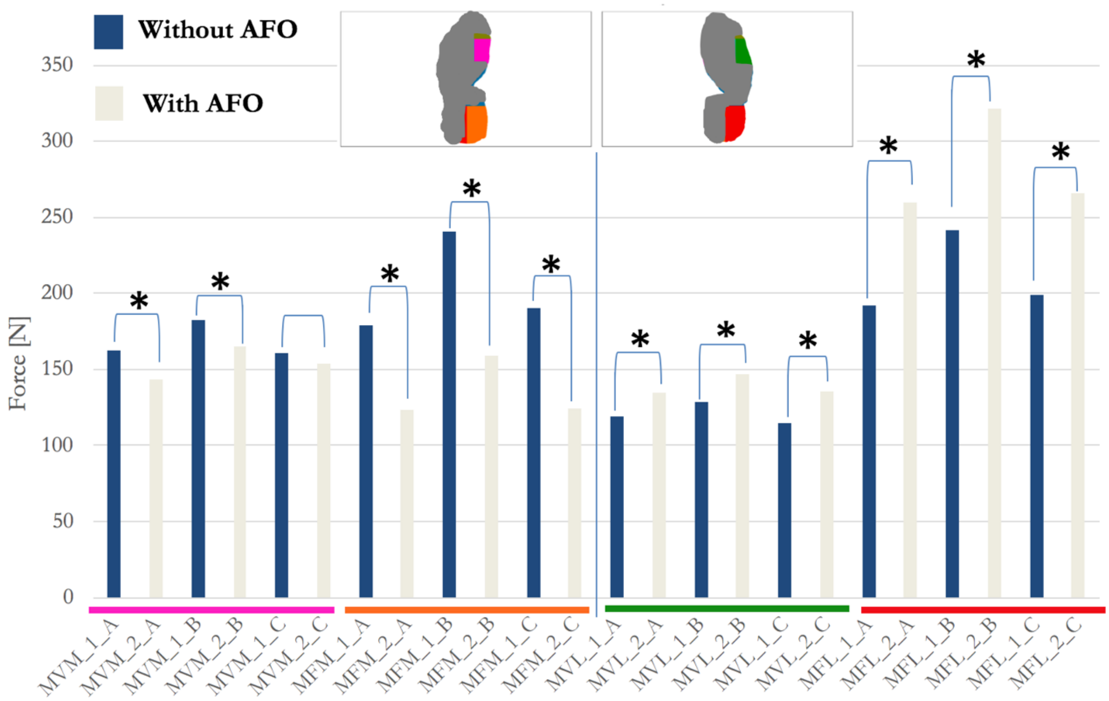


Figure 28: Comparison of the force distribution through the application of the AFO over the foot sole in [N] at T1, showing the lateral increase and medial decrease of the force over the foot sole, n = 30.

Legend to Figure 28: MZ = Maximum force toes; MVM = Maximum force forefoot medial; MVI = Maximum force forefoot internal; MVL = Maximum force forefoot lateral; MM = Maximum force midfoot; MFM = Maximum force heel medial; MFL = Maximum force heel lateral; (1) = without AFO; (2) = with AFO; A = 2 km/h; B = 4 km/h; C = self-selected speed AFO = ankle-foot orthosis; * = significance.

Figure 28 illustrates the clearly larger measured differences over the heel compared with the forefoot. In particular, a clear difference could be observed over the lateral heel. When measuring with the AFO, significantly higher values could be measured over the lateral heel.

This direct comparison can be used to infer a significant lateral shift in forces.

The pressure mapping images, which are composed of the average value for the stance phase, show a clear distribution of forces in terms of lateralization (Fig. 29). Figure 29 is taken from an example of the gait analysis at 2 km/h measurement.

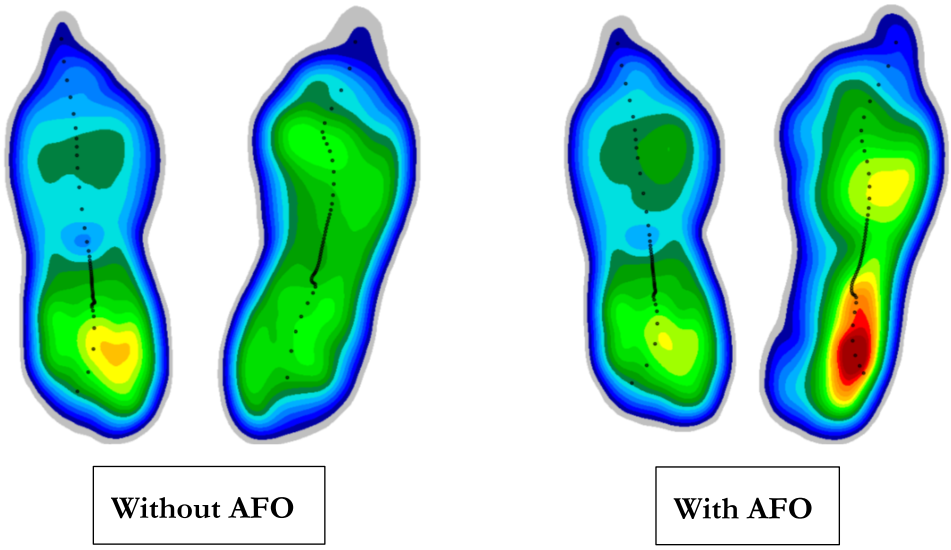


Figure 29: Comparison of maximum pressure picture of the foot without AFO and with AFO on the right foot. Measurement of one participant as an example. Adapted from (Zebris FDM gait analysis report).

The analysis of the force distribution showed alteration under all conditions. The mean force forefoot (KV) decreased from 706.53 N (±125.56 N) to 681.23 N (±109.81 N) in the condition of 2 km/h. This result was statistically significant (p=0.008). The measurements of the forefoot force (KV) were not statistically significant at 4 km/h and self-selected speed. The mean values changed from 753.37 N (±108.47 N) to 750.68 N (±104.47 N) at 4 km/h and from 703.30 N (±117.85 N) to 715.63 N (±104.88 N) at self-selected speed. The mean values of force measured on the hindfoot showed the following changes during intervention with the orthosis: from 510.23 N (±122.01 N) to 523.00 N (±139.67 N) at 2 km/h, from 613.27 N (±136.60 N) to 611.80 N (±128.71 N) at 4 km/h and 529.66 N (±121.57 N) to 514.53 N (±122.81 N) at self-selected speed. Figure 30 shows the distribution of the force over the foot sole between hindfoot and forefoot by the means of an example.

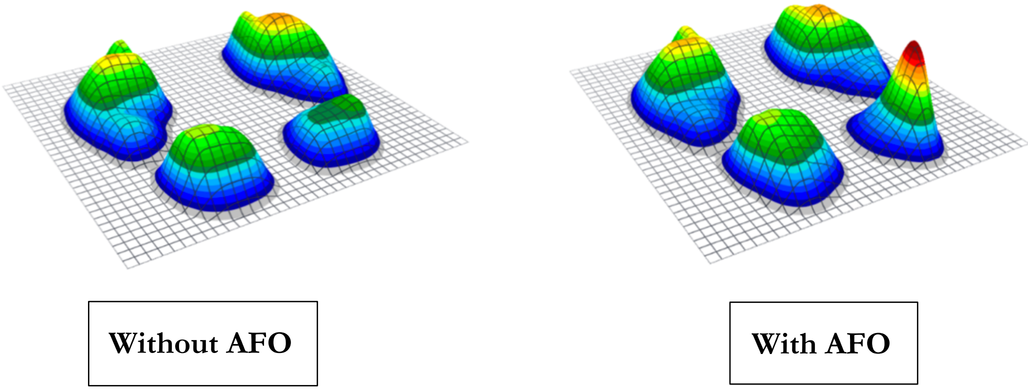


Figure 30: Distribution of force over the foot sole between hindfoot and forefoot by the use of the AFO on the right foot. Measurement of one participant as an example. Adapted from (Zebris FDM gait analysis report).

The gait analysis showed an acceleration of the self-selected speed. The self-selected speed increased from the mean of 2.21 (±0.53) km/h to 2.38 (±0.54) km/h. This result was statistically significant (p=0.001). Figure 31 visualizes the difference between the gait speed with and without intervention.

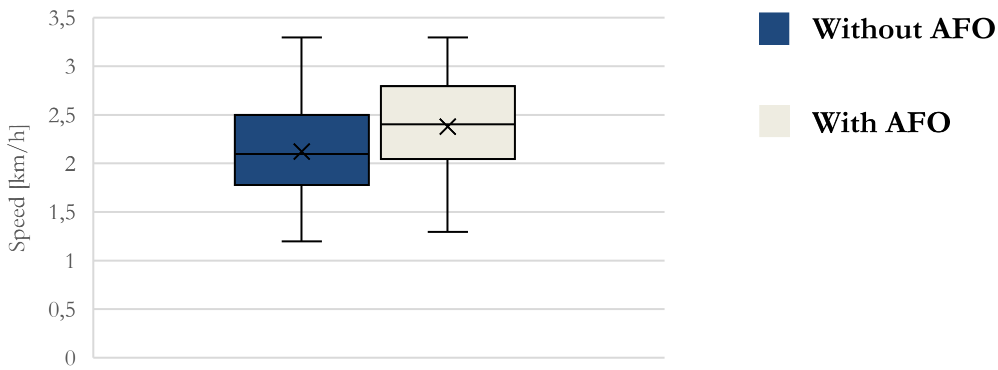


Figure 31: Patients´ comfortable self-selected speed with and without AFO at T1. Boxplot showing the increase of the self-selected speed by the use of the AFO, n = 30.

The mean value of the step length increased numerically with the AFO in all three conditions: at 2 km/h from 42.46 cm (±5.17 cm) to 42.93 cm (±5.38 cm), at 4 km/h from 58.07 cm (±5.96 cm) to 59.10 cm (±5.69 cm) and at the self-selected speed from 41.53 cm (±10.19 cm) to 41.73 cm (±9.21 cm). These differences showed no statistical significance.

The anterior/posterior position parameter represents a longitudinal shift in the position of the COP. The anterior/posterior position showed a ventral shift of the COP at 2 km/h and 4 km/h by using the AFO. At self-selected speed the anterior/posterior position showed a slight shift towards dorsal. The anterior/posterior position was only statistically significant in the condition of 4 km/h (p=0.02). Furthermore, the "lateral shift" parameter showed an alteration under all conditions. A shift of the COP to the side provided with the orthosis could be observed.

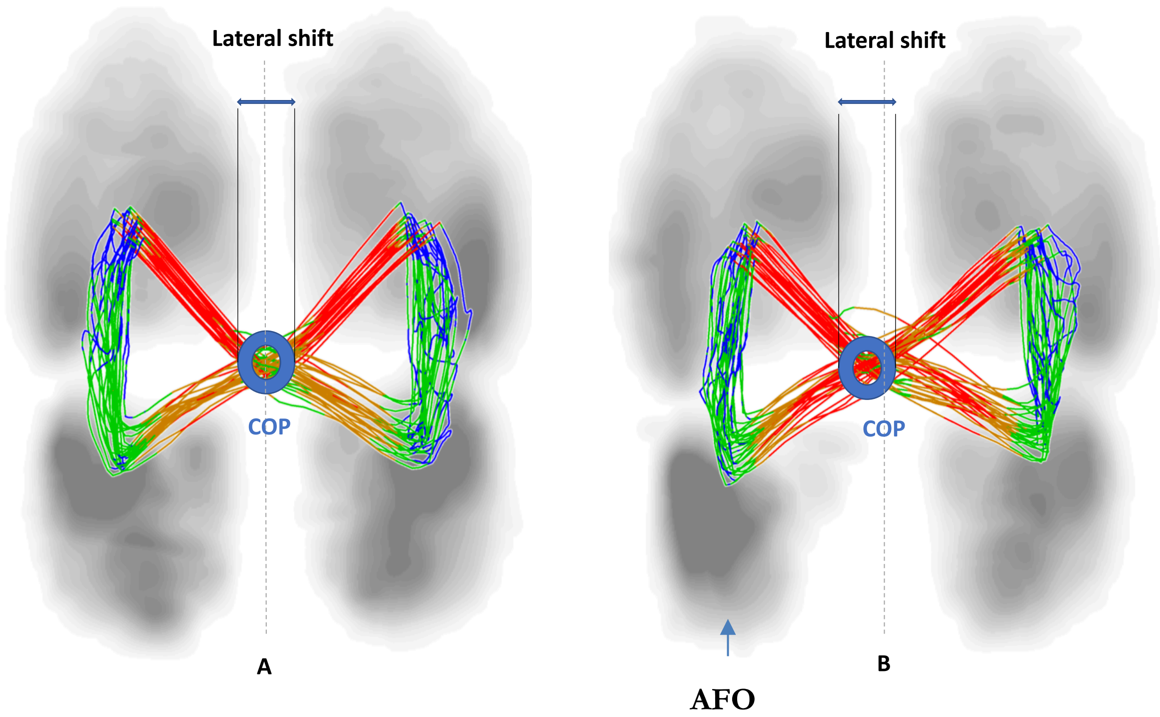


Figure 32: Lateral shift of the COP position in a cyclogram. (a) Without AFO and (b) with AFO fitted on the left foot at self-selected speed. Measurement of one participant as an example at T1. Modified diagram based on (Zebris FDM gait analysis report).

Figure 32 shows the lateral shift of the COP on an example of the gait analysis of a participant with an AFO on the left side. A shift of the COP towards the side with AFO could be observed in the condition of 4 km/h and self-selected speed. The displacement of the COP was negligible under the condition of 2 km/h. In the mean, a shift of the COP of 0.31mm at 2 km/h, 2.43 mm at 4 km/h and 1.69 mm at self-selected speed could be observed. The statistical analysis showed significance only for the condition of 4 km/h (p=0.02). Table 6 shows the parameter describing the COP.

Table 6: Displacement of the Center of pressure (COP) by the use of the AFO. The table shows the parameters Lateral shift und Anterior/posterior position at 2 km/h, 4 km/h and self-selected speed.

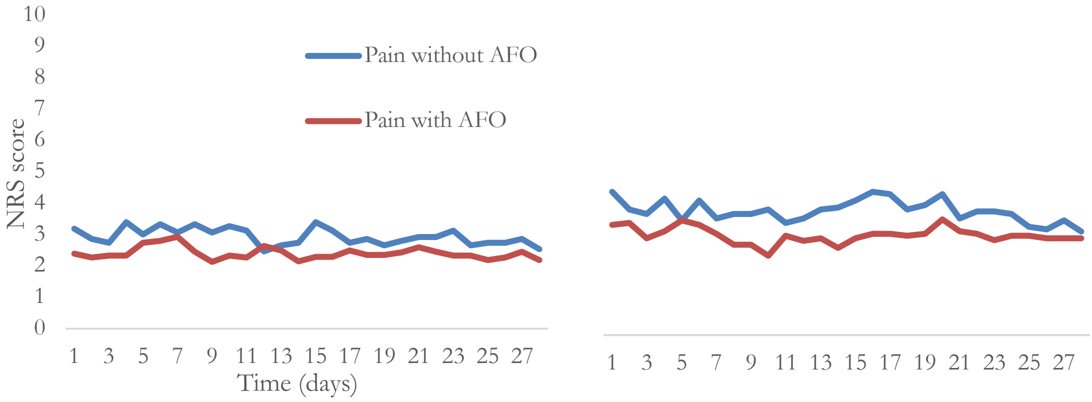
COP parameters in [mm]	Without AFO	With AFO	Delta (Δ)	Significance
2 km/h				
Anterior/posterior position	161.32 (±14.15)	163.21 (±14.09)	1.89	p=0.67
Lateral shift	-6.34 (±15.61)	-6.65 (±17.72)	-0.31	p=0.70
4 km/h				
Anterior/Posterior position	158.89 (±12.59)	165.97 (±17.26)	7.08	p=0.02
Lateral shift	-4.55 (±12.11)	-2.12 (±13.17)	2.43	p=0.02
Self-selected speed				
Anterior/Posterior position	165.07 (±25.38)	163.48 (±13.25)	-1.59	p=0.10
Lateral shift	-6.68 (±14.46)	-4.98 (±15.39)	1.69	p=0.22

Legend to table 6: All values given in mean and standard deviation (written in parenthesis).

5.4 Pain reduction

The longitudinal pain measurement showed a steady reduction of the mean pain levels during the 28-day period wearing the AFO compared to the period before intervention. These differences were highly significant throughout the whole survey period by calculating it with a randomized mixed effect model ($p<0.001$). The longitudinal pain measurement was divided into the pain reported in the morning, and the pain reported in the evening.

A direct comparison of the pain course with and without the use of the AFO is shown in Figure 33. A significant reduction in pain can be observed over the entire period, both in the morning and in the evening. In general, the mean pain values measured in the evening were higher than in the morning. Furthermore, a higher reduction of the longitudinal pain measurement was observed in the evening.



(a) Morning pain **(b) Evening pain**

Figure 33: Comparison of mean longitudinal pain with AFO (phase T1 – T2) and without (phase T0 – T1) AFO in the morning (a) and evening (b), n = 30.

The distribution of the mean values over the 28-day period of pain measurement is depicted in Figure 34. A significant reduction of the mean values can be observed. The mean value for evening pain over the 28-day period decreased from 3.75 (±0.33) to 3.01 (±0.24) points on the NRS scale. There was a smaller decrease observed in the morning from 2.94 (±0.26) to 2.41 (±0.19).

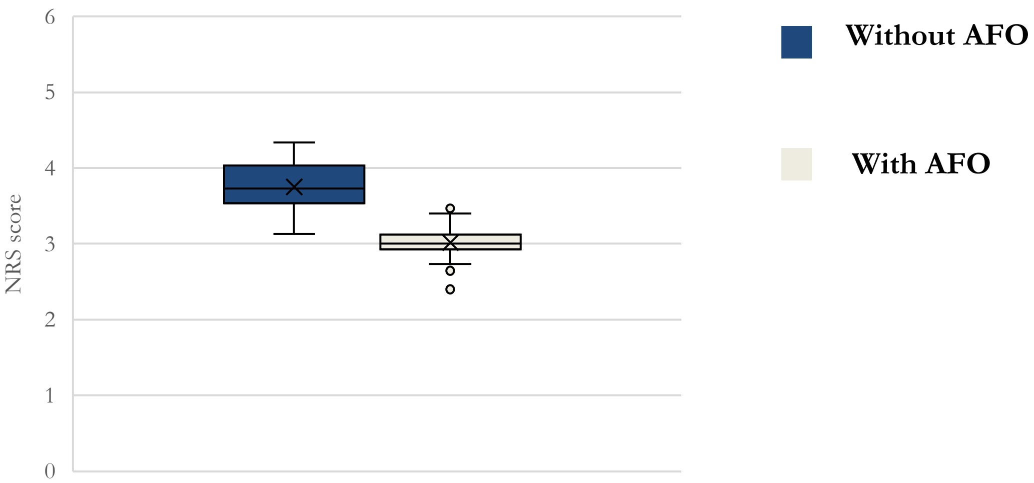


Figure 34: Pain reduction (evening pain) on numeric rating scale (NRS) through the application of the AFO. Boxplot showing the distribution of the mean values, n = 30.

5.5 Knee Injury and Osteoarthritis Outcome score

Increases in the KOOS questionnaire were observed in every subscale. The pain subscale increased from 54.4 (±16.14) to 59.3 (±17.01). The difference showed no statistical significance (p=0.08). There was a significant improvement from 60.87 (±16.53) to 67.57 (±16.13) in the activities of daily living under observation (p=0.01). The sport subscale increased insignificantly from 29.83 (±19.67) to 30.33 (±20.48) (p=0.16). There was an increase of 34.17 (±14.97) to 34.57 (±12.91) in the quality of life subscale (p=0.85). The mean of the subscale symptoms was almost unchanged from 60.33 (±16.67) to 60.37 (±18.46) (p=0.68). Table 7 shows the results of the KOOS questionnaire subdivided into the subscales.

Table 7: Knee Injury and Osteoarthritis Outcome score at baseline (T1) and after intervention (T2), n=30.

Knee Injury and Osteoarthritis Outcome Score (max. 100 points)				
Subscales	Baseline (T1)	After intervention (T2)	Delta(Δ)	Significance
Pain	54.40 (±16.14)	59.30 (±17.01)	4.9	p=0.08
Symptoms	60.33 (±16.67)	60.37 (±18.46)	0.04	p=0.68
Activities of daily living	60.87 (±16.53)	67.57(±16.13)	6.7	p=0.01
Sports	29.83 (±19.67)	33.33 (±20.48)	3.5	p=0.16
Quality of life	34.17 (±14.97)	34.57 (±12.91)	0.4	p=0.85

Legend to table 7: All values given in mean and standard deviation (written in parenthesis). KOOS scales: 0 = extreme symptoms, 100 = no symptoms

The statistical analysis showed significance in the difference before and after intervention only for the ADL subscale (p=0.01). The results of the KOOS questionnaire are visualized in Figure 35.

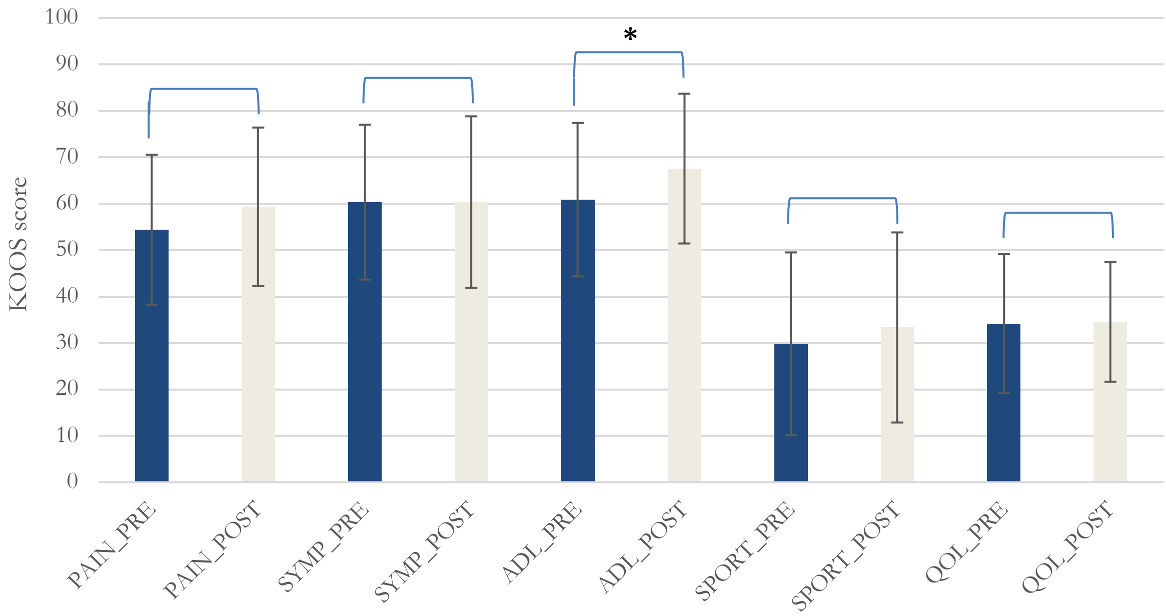


Figure 35: Knee Injury and Osteoarthritis Outcome score at baseline (T1) and after intervention (T2), n = 30.

Legend to Figure 35: PRE = before intervention (T1), POST = after intervention (T2); * = significance; Subscales: SYMP = symptoms, ADL = activity of daily living, QOL = quality of life, KOOS = Knee Injury and Osteoarthritis Outcome score.

The spider net diagram (Fig. 36) shows the change in the KOOS subscales between baseline (T1) and after intervention (T2) and compares the participants with the healthy population. The values of the healthy population refer to the age group from 55 to 74 years and are therefore compare well with the age group of this study (Paradowski et al., 2006). Figure 36 also illustrates the differences between the individual subscales of the patients and the normal population, as reflected in particular in the sport and quality of life subscales.

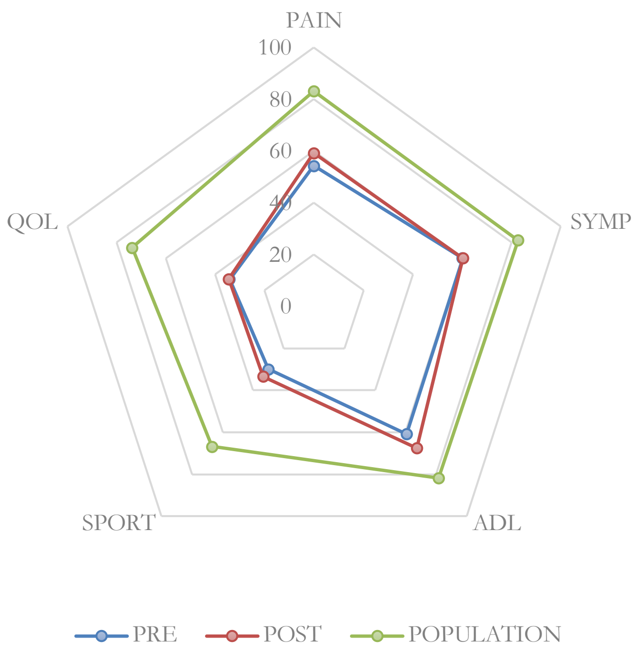


Figure 36: Knee Injury and Osteoarthritis Outcome score subscales of healthy population and participants at baseline (PRE) and after intervention (POST), n=30.

Legend to Figure 36: PRE = before intervention (T1), POST = after intervention (T2); a larger spider figure represents less symptoms. Subscales: SYMP = symptoms, ADL = activity of daily living, QOL = quality of life.

5.6 Patients´ satisfaction and compliance

An analysis of the average wearing time of the AFO from the diaries completed by the patients shows a mean value of 4.54 (±1.89) hours per day. The handling of the AFO was rated with a mean value of 1.875 (±0.33) points, which would indicate easy handling. Five patients answered the question as to whether the complaints had shown any improvement with "significant", ten patients with "mild", four patients with "hardly any" and three patients with "no improvement". The chart (Fig. 37) shows the distribution of the answered questions.

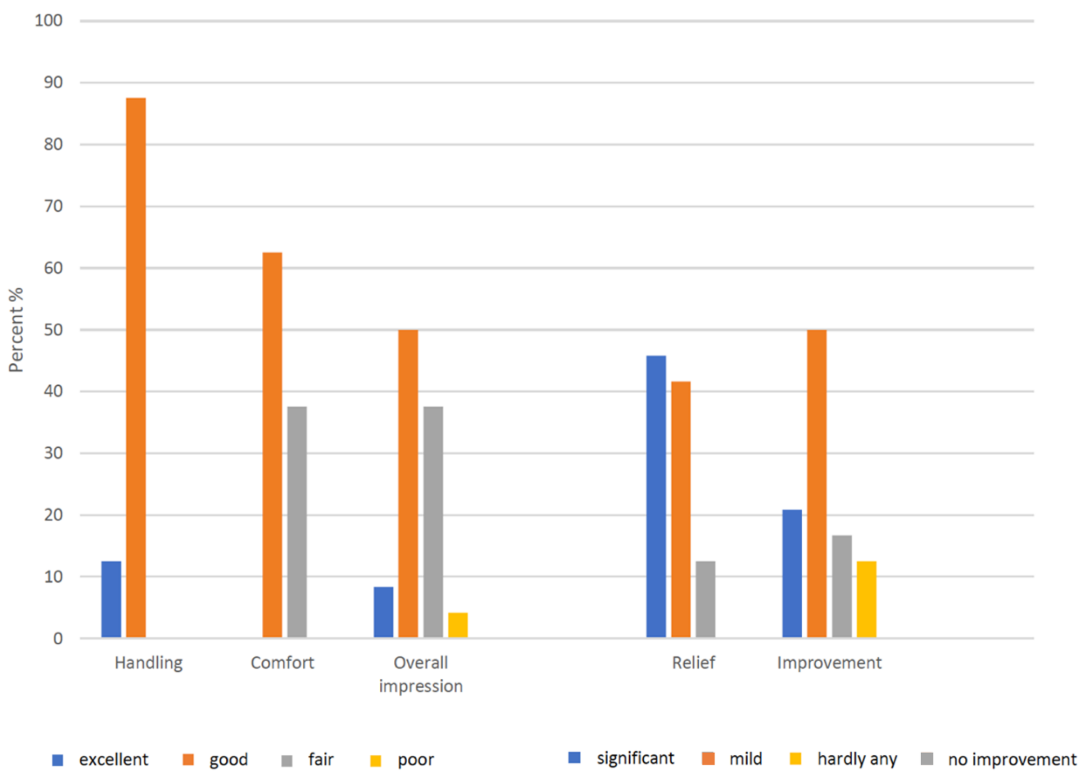


Figure 37: Comfort and handling of the AFO, n=24.

Legend to figure 37: Relief = Relief of the affected compartment; Improvement = Improvement of the complaints.

Damage by the AFO to footwear was rated with a mean value of 2.29 (±0.91) points, which would indicates slight damage. 12.5% of the participants reported no damage, 50% reported slight damage and 20.8% hardly any damage to footwear. 16.6% of the participants answered the question with severe damage to their footwear.

In total, 66.67 % wanted to continue wearing the orthosis.

6 Discussion

6.1 Load distribution

In this study, the focus was placed on the investigation of the effectiveness of a novel orthosis. The hypothesis of the functional principle of the present AFO was that the AFO lateralizes the position of the load bearing axis and therefore relieves the affected (medial) compartment. As a result of the reduced load in the medial compartment, a reduction in pain was suspected. Through the lateral frame of the orthosis a force applied on the knee should shift the load bearing axis towards lateral. The valgus degree of the orthosis should change the tibial orientation in the frontal plane producing a verticalization of the tibia (Fantini Pagani et al., 2014). In order to evaluate the effectiveness of the orthosis, the main outcome focused on the changes in the load line achieved by the orthosis. Furthermore, the pain was measured over a period of 28 days both before intervention and with the use of the AFO and a knee-specific questionnaire was completed.

The most important finding of this study was the statistically high significant lateral shift of the load line on the affected knee through the use of the AFO. The lateralization of the load line could be shown by taking measurements with the L.A.S.A.R. Posture® system. The mean of the lateralization of the load line was 16.03 mm (±5.22 mm). In consequence, the results show a change in the knee alignment depending on the leg axis. Similar results were shown in other external postural measurements (Fantini Pagani et al., 2014; Menger et al., 2016; T. Schmalz et al., 2006). Schmalz et al. showed a lateralization with a sample of 12 patients with medial KOA using the same system in the frontal plane with a mean value of 11 mm. An orthosis with the same operating principle was used. In addition, Schmalz et al. showed a correlation between the static and the dynamic measurements and their equivalent attitude (T. B. Schmalz, S.; Drewitz, H., 2011). In the biomechanical model it could be shown that a displacement of 10 mm involves a reduction of the moment by 5-7 Nm resulting in a reduction of the acting force on the medial compartment of approximately 100 N (Pollo et al., 2002). The mean lateralization of 16.03mm from this study could therefore result in force reduction up to 160 N in the medial compartment.

A further gait parameter is the KAM, which is also associated with lateralization and a reduction of the lever arm. In this study the KAM was not part of the assessment and was not calculated. As there is a high correlation between the KAM and the lateralization of the load line, results of other studies calculating the KAM are well comparable.

Other authors have examined this type of orthosis with a view to reducing the KAM. By changing the GRF and its lever arm, the KAM becomes smaller with a lateralization of the load line (Fantini Pagani et al., 2012). Fantini Pagani et al. could show a reduction of the KAM by 11.9% and a significant decrease in the knee angle in the frontal plane in a sample of 14 patients (Fantini Pagani et al., 2014). The study analyzed the effectiveness of an AFO compared to lateral wedges for the lever arm and the KAM. Significant decreases of the KAM and the lever arm could only be shown with the use of the AFO. Mauricio et al. even showed a KAM reduction of 21% (Mauricio et al., 2018). A total of 52 patients were examined in this study. A gait analysis in different condition (normal shoe, AFO, lateral wedge and unloader brace) was performed. The greatest reduction of KAM could be achieved by the application of an AFO. Greater benefit of the orthosis was observed when the KAM was relatively high in baseline measurements (Mauricio et al., 2018). With regard to the equivalence of the dynamic and static measurements and the change of the KAM depending on the direction of GRF and consequently on the load bearing axis, the present results can be well compared with this study.

The magnitude of the OA can result in a loss of cartilage. Through the loss of cartilage in the medial compartment, the biomechanics in the lower limb change, producing a varus deformity (Andriacchi et al., 2009). Thus, the load on the affected compartment in the knee increases. It is assumed that by relieving the affected compartment, the orthosis counteracts the process of joint space narrowing. This process could be confirmed by studies which showed a correlation between increased KAM values and narrowing of the joint gap (Sharma et al., 1998; Wada et al., 2001). However, the KAM should not be considered as the only indicator responsible for the development of pain in the knee. Even if the KAM is significantly reduced, it can be limited by a form of compensated function. These compensating functions include the passive structures of the knee. For this reason, each knee can respond differently to the same applied lateral force of the orthosis. As a consequence, the laxity and instability of the knee in the passive frontal plane can determine the progression of the disease (Lewek et al., 2004). By applying this fact to the effectiveness of the AFO it can be stated that it depends on the individual force of the passive structures around the knee and the ankle.

Another decisive factor for instability in the knee is proprioception. Several studies have shown reduced proprioception in patients with KOA (Barrack et al., 1983; Barrett et al., 1991). As a result of a reduced proprioception capability, abnormal kinetics may occur in the knee (de Oliveira et al., 2014). Reduced proprioception compounded with an increased varus moment, which shifts the load to the affected compartment, may promote degeneration of the knee in patients with OA. It has been shown that knee braces or bandages can improve proprioception in the knee (Birmingham et al., 2001). Presumably, the AFO may also increase proprioception through its stabilizing character and may result in higher stability and therefore in pain relief.

The stiffness of the knee, which occurs in connection with the external moment and changes in the angle in the frontal plane (Fantini Pagani et al., 2014), is affected by passive joint structures and neuromuscular aspects (Butler et al., 2003). Thus, the movement of the knee is determined by the passive structures of the knee. In another study, a relatively small reduction of the KAM (11%) was found, while a significant improvement in pain and activity level was observed (Pollo et al., 2002). This result could mean that the KAM is not the only important indicator of progression of the disease. Therefore, passive joint structures should also be taken into consideration and can falsify the results of load parameter measurements.

Limiting the static measurement could account for the measurement being inaccurate. Even if patients had to keep rigidly still during the measurement, errors may occur due to the variability of the patients´ posture. This could explain the comparatively high values measured compared to the results of Schmalz et al. (T. B. Schmalz, S.; Drewitz, H., 2011).

6.2 Gait analysis

The clear change in the load distribution by the AFO is a very important result. Both the L.A.S.A.R. Posture® values and essential gait parameters showed a clear lateralization of the load distribution. To represent the GRF acting on the knee, the force distribution in the foot during a dynamic gait analysis was investigated. The system used in this study for investigating the gait is a valid and reliable system for measuring gait performance (Reed et al., 2013; Wearing et al., 2013). A clear lateralization of the force distribution was observed. A high increase in the force over all lateral areas and a decrease over all medial areas of the foot sole were observed. However, the altered biomechanics in the lower leg due to the orthosis also leads to a change in the force applied to the ankle joint. Toda Y et al. showed a significant increase in the eversion angle in the subtalar joint by the use of lateral wedges. However, the forces could be better transferred to the knee by stabilizing the ankle joint (Toda & Tsukimura, 2004). A changed force in the ankle joint could result in OA over a long period of time. In 2006 Schmalz et al. has already demonstrated the importance of the rigid bridging of the subtalar joint by investigating the KAM as a function of compensating moments of the subtalar joint. Examination of the KAM showed hardly any change when using only lateral wedges, but a significant reduction in the KAM of 30% could be observed with simultaneous use of the rigid orthosis (T. Schmalz et al., 2006).

The rigid lateral frame of the orthosis used in this study restricts the subtalar joint in the frontal plane. But it is doubtful whether the ankle joint is fully restricted by the orthosis. Due to a compensatory function of the subtalar joint, the force acting on the subtalar joint could change anyway. Furthermore, a general increase in the load was observed, which could have amplified the progression of the ankle joint destruction. Both the maximum force in the forefoot and the maximum force in the hindfoot increased. Although no pain or problems in the ankle joint were reported over prolonged follow-up of one year with a sample of 23 patients using an AFO (Menger et al., 2016), the specific damage to the joint caused by a biomechanical deformity could emerge over a period of longer than one year. Longer follow-up investigations on this type of orthosis do not exist. Therefore, further attention should be paid to long-term examination of the ankle joint in future studies.

Through the lateralization of the vertical component of the GRF, the lever arm in the knee becomes smaller. Hinmann et al. showed a significant correlation between the changes in the COP and the GRF with the changes of the KAM (Hinman et al., 2012). On the other hand, Fantini et al. found no significant changes in the position of the COP as the lever arm in the knee was reduced (Fantini Pagani et al., 2014). In the present study, the lateral shift of the COP in the cyclogram showed a lateralization toward the side fitted with the orthosis. As mentioned above, the changed position of the COP is one of the decisive factors influencing the KAM. The lateralization of the COP, which is described by the "lateral shift" parameter, confirms the assumption of a relieving effect of the orthosis on the affected compartment. However, although a trend was clearly visible, statistical significance was shown only for the condition of 4 km/h, probably due to the small sample size.

6.3 Cause of pain

It can be assumed that pain does not depend only on biomechanical parameters, such as the KAM and the COP. The reasons for pain in unicompartmental KOA are discussed at length in literature. What causes the actual pain in the medial compartment has still not been clarified yet. The investigation into the relationship between the magnitude of radiographic signs and the severity of pain showed no correlation (Dieppe et al., 1997; Haviv et al., 2013). Other structures in the knee such as the joint capsula, infrapatellar fat or periosteum can cause pain in the knee (Kidd, 2006). It could be shown that tension caused by local pressure or irritation by inflammatory mediators can result in pain in the knee (Zimmermann, 1989).

The laxity of the knee represents another important factor in the cause of pain. Lewek et al. showed that even laxity in the passive frontal plane can determine disease progression (Lewek et al., 2004). Given the fact that pain and stiffness depend not only on disease progression, further studies should investigate the passive structures of the knee, as they also influence gait parameters. In the present study, the role of the passive structures was perhaps underrated, as no specific tests or measurements were performed and evaluated. This is certainly a limitation of the present study.

Since the affected area is subjected to repetitive stress, which can cause initial pain during movement, it is conceivable that only a slight lateralization of the load line could reduce the pain. Lateralization of the load distribution is a generally accepted method for treating unicompartmental KOA (Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften (AWMF), 2018).

The present study shows highly significant pain reduction during the 4 weeks of treatment compared to 4 weeks without AFO. It is a well-known fact that patients with KOA experience pain in variable intensities fluctuating over time (Allen et al., 2009). Activities carried out prior to the measurement can play a major role here. To avoid a measuring bias by taking only baseline and follow-up measurements, longitudinal pain measurement was performed. In order to enhance the accuracy of longitudinal pain measurement, the pain was measured at two different times of day. A significant reduction was observed not only a few days after the AFO was first worn, but throughout the whole period. The morning pain was on average less than the evening pain. Although, less pain was measured in the morning, a clearly higher reduction of pain could be observed in the evening after using the AFO during the day. Thus, the mean pain could be reduced from 3.75 (±0.33) to 3.01 (±0.24) points in the evening and from only 2.94 (±0.26) to 2.41 (0.19) points on the NRS scale in the morning. The difference between the morning and evening pain levels could indicate the relieving effect of the orthosis in the affected compartment. Menger et al. reported results from a one-year follow-up pain measurement with 23 patients by using an AFO. The pain level improved significantly over the entire follow-up period from 4.9 (±1.6) at baseline to 3.7 (±2.3) after six months and 3.4 (±2.8) after one year (Menger et al., 2016). These results are similar to the pain reduction in this study, although they are not longitudinally measured. Schmalz et. al. observed the character of pain during walking and showed an even higher reduction of pain from 7.7 to 3.8 on the NRS scale (T. B. Schmalz, S.; Drewitz, H., 2011). In this study a sample of 12 patients was examined.

In the pain subscale of the KOOS questionnaire, a reduction in pain was also observed. The median of the pain subscale increased with a difference of 7.5 points (from 53 to 60.5 points). Although the result did not show any statistical significance, the results suggest a trend towards improvement of the pain.

This result is in line with the results of a study by Petersen et al. in which an AFO is compared with an unloader brace in terms of pain behavior over a total period of 6 months. In that study, a total of 160 patients were included and randomly allocated to treatment with an AFO or treatment with an unloader brace. It showed an improvement of 11.1 points in the KOOS pain subscale by the use of the AFO and an improvement of 8.3 points through the unloader brace (Petersen et al., 2019).

However, it is interesting to note that the pain intensity decreased immediately after usage of the AFO. Both the morning and the evening pain reduced noticeably from the first day. A placebo effect cannot be totally excluded by the present study design and should be included in the interpretation of the results.

6.4 Activity of daily living

Due to the reduction of pain, an increase in activity in daily life is possible. This assumption could be confirmed by a significant increase in the "activity of daily living" subscale. The patients´ activity is one of the important parts of the therapy for KOA (Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften (AWMF), 2018). It has been shown that in particular moderate activity such as Nordic walking or swimming has positive influence on pain and activity in daily life (Bannuru et al., 2019). Thus, the AFO could in the long term become an important part of non-surgical treatment for KOA. The increase from 27.5 to 35 points on the "sport" subscale supports the benefit of the AFO. Despite not showing significance (p=0.16), the results show a clear trend toward improvement. An increase in the quality of life subscale was also observed. Peterson et al. even showed a twofold increase in quality of life with the AFO compared to a conventional unloader brace (Petersen et al., 2019). As all the subscales of the KOOS questionnaire showed an improvement, it could be assumed that the AFO brings clear benefits.

An increase in activity could also be shown in the gait velocity. The gait velocity was measured to detect a difference when walking with the AFO and without the AFO. The gait velocity of an individual is associated with the lowest energy expenditure and can represent a visible measure of general functionality in the case of acceleration or deceleration (Kramers-de Quervain, 2008). An increase in the mean gait velocity from 2.21 km/h (±0.53 km/h) to

2.38 km/h (±0.54 km/h) through the use of the AFO could be observed. This result was statistically significant (p=0.001). The reference values for gait velocity in the literature are given between 4.3 km/h and 5.4 km/h (Kramers-de Quervain, 2008). Despite an increase in the gait velocity, the values are far below the norm. The increased gait speed generally suggests an improved gait pattern and could promote the activity of the patient. However, six patients showed a deceleration of the self-selected speed when wearing the AFO. Other authors found no significant improvement in the gait velocity (Mauricio et al., 2018; T. Schmalz et al., 2006). The increase in gait velocity may have been due to the patients' desire for the orthosis to bring improvements in the sense of an expectation bias. Because the goal of the study was already known to the patients in advance, it could have falsified the result. An expected outcome can influence the result regardless of the underlying biomechanical effect (Moerman & Jonas, 2002). However, to ensure the best possible outcome, the order of the measurements (with and without AFO) was randomized and in order to become accustomed to the orthosis before the gait analysis, all the patients were asked to walk for 10 minutes with the orthosis before measuring.

Furthermore, it could be observed that the effect of the orthosis was higher at 4 km/h and the self-selected speed. Presumably, the orthosis achieves a more pronounced effect at a higher gait speed. Chung et al. showed that the gait velocity has an influence on the gait parameters, especially the GRF. Thus, the GRF increased with higher gait velocity (Chung & Wang, 2010). The clinical outcome of this study is well comparable with the observed altered biomechanics in the lower leg of the orthosis.

6.5 Patients´ compliance

On average, the AFO was worn for 4.56 (±1.89) hours per day. According to a study, the optimal wearing time of an orthosis is estimated at 6 hours (van Raaij et al., 2010). A comparable result was reported by Peterson et al. with 57.5 % of the patients wearing the AFO for more than 6 hours a day. A reduction in the wearing time from 57.5% to 44.8% (more than 6 hours a day) over the period covered has also been observed after 6 months (Petersen et al., 2019).

Another very important factor is the comfort of the orthosis. As the orthosis only changes the biomechanics of the knee during walking and standing, the orthosis is not to be used as a cure. This underlines the importance of compliance of the patients, in order to ensure the orthosis is used. Compliance with using the orthosis depends strongly on the comfort of the orthosis. In this study, 60.9 % rated the wearing of the orthosis as pleasant. A similar AFO was rated in a study as the most comfortable compared with a conventional unloading brace and lateral wedges (Mauricio et al., 2018). This could lead to increased compliance with the novel AFO. A long-term follow-up of the unloader brace showed poor results in terms of compliance. After 2.7 years only 41% were still using the brace and after 11.2 years none of the patients were using the unloading brace (Wilson et al., 2011).

Skin irritation has been identified in several studies as a common reason for loss of compliance (Squyer et al., 2013; van Raaij et al., 2010). Skin irritation is caused by the brace pads on the lateral femoral condyle. For cosmetic reasons and due to the discomfort of the unloader braces, poor compliance is observed (Moyer et al., 2015). In view of these facts, the longtime effectiveness of the unloader braces is affected by the loss of compliance (Giori, 2004). Understandably, an unloading brace presents a cosmetic disadvantage and is therefore often not the first choice of patients. The AFO is worn under the trousers and this could therefore improve compliance. Furthermore, the AFO does not cover the knee, which allows unrestricted movement in the knee joint. These facts could considerably improve the compliance of patients. However, in this study 37.5 % rated the comfort of the orthosis as hard. One reason for the discomfort of the AFO was the great distance between the ankle and the lateral frame of the orthosis. In some cases, the distance between the lateral frame and the ankle joint caused severe damage to footwear. In this study, 50 % claimed that the orthosis caused slight damage to footwear and as many as 12.5 % claimed severe damage. These facts could strongly influence the patients´ compliance. Most of the patients gave the AFO a rating of *good* for the overall impression. However, only 66.69 % of patients would continue to use the AFO.

6.6 Limitations of the study

Certainly, the present study has its limitations, such as the small number of participants. The number of participants is, however, comparable to other studies investigating an AFO with the same underlying biomechanical principle (T. Schmalz et al., 2006; T. B. Schmalz, S.; Drewitz, H., 2011).

The small number assumed less importance through the fact that every individual was tested in both situations intraindividually. This improved the accuracy and comparability of the results, as attention was paid to individual anatomical particularities.

Another limitation was that all patients were recruited by clinical diagnoses without knowing the exact varus degree. Despite the high reliability of the method used, the variability of the varus deformity could falsify the result (Navali et al., 2012). However, as the main goal was to measure the effectiveness and the improvement in clinical symptoms, the latter was the main factor for the recruitment. It is well known that the degree of varus malalignment does not correlate with symptoms. Furthermore, intraindividual differences were measured as mentioned above.

Moreover, due to the lack of a control group, it is not possible to detect placebo effects. The comparability of the course of pain without intervention could not be demonstrated either. However, a study design without a control group also has its advantages. As only a small portion of patients can be enrolled in a randomized clinical trial, there is a lack of generalizability (Petersen et al., 2015). Because of the need for high comparability between the groups, strict enrollment is necessary for a randomized trial. Due to lack of time and capacity it was not possible to conduct the study as a randomized trial. In order to demonstrate the benefit of this type of orthosis, further study designs should be conducted on a long-term follow-up basis in a randomized trial.

7 Conclusion

This study aimed to evaluate the efficacy of a novel ankle-foot orthosis on the change of load bearing axis in the knee joint and its clinical outcome in terms of pain reduction and improved functionality in daily life.

The results of this study indicate a clear benefit of the AFO for patients with medial KOA and provide new insights into the non-surgical treatment of unicompartmental KOA. A substantial displacement of the load bearing axis away from the affected compartment could be shown. The displacement of the load bearing axis in the lower extremity, however, raises the issue of a changed load in the ankle joint and its potential risk of degenerative changes. Further research is needed with particular attention to ankle joint changes in a long-term investigation.

Moreover, a significant reduction in pain and improved functionality of the affected knee could be observed. In particular, the increased activity through the usage of the AFO represents an important pillar in the therapy of KOA. The results of this study also showed a more pronounced effect at a higher gait speed. Therefore, the AFO could be used not only in daily life but also during training episodes to make it more effective.

The sole relationship between shifting the load line through the orthosis and the measured pain reduction cannot be fully clarified by this study design. Further studies on pain behavior regarding leg axis in patients with KAO are needed.

The patients' compliance with this AFO was relatively high and their overall comfort was also well evaluated. However, further studies should investigate the AFO over a longer period with randomized controlled design.

Overall, the AFO seems to have positive effects on patients with unicompartmental KOA and could make a decisive contribution to delaying an upcoming surgical intervention in the context of a joint replacement.

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9 Attachment

9.1 Knee injury and osteoarthritis outcome score (KOOS)

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Probanden-ID:

K O O S

Knee injury outcome Score

Deutsche Version (Kessler et.al. 2003)

Dieser Ankreuzbogen befragt Sie, welchen Eindruck Sie von Ihrem Knie haben. Die dadurch gewonnenen Informationen werden uns helfen zu überwachen, wie es Ihnen mit Ihrem Knie geht und wie gut Sie in der Lage sind, Ihre üblichen Aktivitäten zu verrichten.

Welches Knie tut Ihnen besonders weh? ______________

Dann beziehen sich diese Fragen auf ihr _____________ Kniegelenk.

Beantworten Sie bitte jede Frage durch ankreuzen des zugehörigen Kästchens.

Bitte **nur ein Kästchen pro Frage ankreuzen**.

Beispiel:

1. Subskala Schmerz				
1. Wie oft tut Ihnen das Knie weh?				
niemals	monatlich	wöchentlich	täglich	immer
	X			

Wenn Sie sich unsicher sind, wie Sie die Frage beantworten sollen, wählen Sie die Antwort aus, die Ihnen am zutreffendsten erscheint.

Diese Fragen beziehen sich auf Beschwerden von Seiten Ihres Kniegelenkes in der **vergangenen Woche.**

Vielen Dank!

Direktor der Klinik: Prof. Dr. med. Dipl.-Ing. Volkmar Jansson
Das Klinikum der Universität München ist eine Anstalt des öffentlichen Rechts.
Vorstand: Ärztlicher Direktor: Prof. Dr. Karl-Walter Jauch (Vorsitz), Kaufmännischer Direktor: Gerd Koslowski,
Pflegedirektorin: Helle Dokken, Vertreter der Medizinischen Fakultät: Prof. Prof. Dr. med. dent. Reinhard Hickel (Dekan)
Institutionskennzeichen: 260 914 050, Umsatzsteuer-Identifikationsnummer gemäß §27a Umsatzsteuergesetz: DE 813 536 017

In dem ersten Frageblock geht es um Beschwerden von Seiten Ihres Kniegelenkes in der **vergangenen Woche.**

1. Subskala Symptome				
S1. Haben Sie Schwellungen an Ihrem Knie?				
niemals	selten	manchmal	oft	immer
S2. Fühlen Sie manchmal ein Mahlen, hören Sie manchmal ein Klicken oder irgend ein Geräusch, wenn Sie Ihr Knie bewegen?				
niemals	selten	manchmal	oft	immer
S3. Bleibt Ihr Knie manchmal hängen, oder blockiert es, wenn Sie es bewegen?				
niemals	selten	manchmal	oft	immer
S4. Können Sie Ihr Knie ganz ausstrecken?				
immer	oft	manchmal	selten	niemals
S5. Können Sie Ihr Knie ganz beugen?				
immer	oft	manchmal	selten	niemals
Steifigkeit Die nachfolgenden zwei Fragen betreffen die Steifigkeit Ihres Kniegelenkes während der letzten Woche. Unter „Steifigkeit“ versteht man ein Gefühl der Einschränkung oder Verlangsamung der Fähigkeit Ihr Kniegelenk zu bewegen. Für jede der nachfolgenden Aktivitäten sollen Sie das Ausmaß der Schwierigkeiten angeben, welche Sie durch Ihr Kniegelenk innerhalb der letzten Woche erfahren haben				
S6. Wie stark ist Ihre Kniesteifigkeit morgens direkt nach dem Aufstehen?				
keine	schwach	mäßig	stark	sehr stark
S7. Wie stark ist Ihre Kniesteifigkeit nach dem Sie saßen, lagen oder sich ausruhten **im Verlauf des Tages**?				
keine	schwach	mäßig	stark	sehr stark
Gesamtpunktezahl Subskala Symptome				

In dem zweiten Frageblock geht es um Beschwerden von Seiten Ihres Kniegelenkes in der **vergangenen Woche**

2. Subskala Schmerz				
P1. Wie oft tut Ihnen das Knie weh?				
niemals	monatlich	wöchentlich	täglich	immer
P2. Wie ausgeprägt waren Ihre Schmerzen in der vergangenen Woche als Sie sich im Knie drehten?				
keine	schwach	mäßig	stark	sehr stark
P3. Wie ausgeprägt waren Ihre Schmerzen in der vergangenen Woche als Sie ihr Knie ganz ausstreckten?				
keine	schwach	mäßig	stark	sehr stark
P4. Wie ausgeprägt waren Ihre Schmerzen in der vergangenen Woche als Sie ihr Knie ganz beugten?				
keine	schwach	mäßig	stark	sehr stark
P5. Wie ausgeprägt waren Ihre Schmerzen in der vergangenen Woche als Sie auf ebenem Boden gingen?				
keine	schwach	mäßig	stark	sehr stark
P6. Wie ausgeprägt waren Ihre Schmerzen in der vergangenen Woche als Sie Treppen herauf oder herunter gingen?				
keine	schwach	mäßig	stark	sehr stark
P7. Wie ausgeprägt waren Ihre Schmerzen in der vergangenen Woche als Sie Nachts im Bett lagen?				
keine	schwach	mäßig	stark	sehr stark
P8. Wie ausgeprägt waren Ihre Schmerzen in der vergangenen Woche als Sie saßen oder lagen (z.B. auf der Couch)?				
keine	schwach	mäßig	stark	sehr stark
P9. Wie ausgeprägt waren Ihre Schmerzen in der vergangenen Woche als Sie aufrecht standen?				
keine	schwach	mäßig	stark	sehr stark
Gesamtpunktezahl Subskala Schmerz				

In dem dritten Frageblock geht es um Ihre körperliche Leistungsfähigkeit. Hierunter verstehen wir Ihre Fähigkeit sich selbstständig zu bewegen bzw. sich selbst zu versorgen.
Für jede der nachfolgenden Aktivitäten sollen Sie das Ausmaß der Schwierigkeiten angeben, welche Sie durch Ihr Kniegelenk innerhalb der **letzten Woche** erfahren haben.

3. Subskala Aktivität des täglichen Lebens				
A1. Welche Schwierigkeiten hatten Sie letzte Woche als Sie Treppen herunterstiegen?				
keine	wenig	einige	große	sehr große
A2. Welche Schwierigkeiten hatten Sie letzte Woche als Sie Treppen heraufstiegen?				
keine	wenig	einige	große	sehr große
A3. Welche Schwierigkeiten hatten Sie letzte Woche als Sie vom Sitzen aufstanden?				
keine	wenig	einige	große	sehr große
A4. Welche Schwierigkeiten hatten Sie letzte Woche als Sie standen?				
keine	wenig	einige	große	sehr große
A5. Welche Schwierigkeiten hatten Sie letzte Woche als Sie sich bückten um z.B. etwas vom Boden aufzuheben?				
keine	wenig	einige	große	sehr große
A6. Welche Schwierigkeiten hatten Sie letzte Woche als Sie auf ebenem Boden gingen?				
keine	wenig	einige	große	sehr große
A7. Welche Schwierigkeiten hatten Sie letzte Woche als Sie ins Auto ein- oder ausstiegen?				
keine	wenig	einige	große	sehr große
A8. Welche Schwierigkeiten hatten Sie letzte Woche als Sie einkaufen gingen?				
keine	wenig	einige	große	sehr große
A9. Welche Schwierigkeiten hatten Sie letzte Woche als Sie Strümpfe oder Socken anzogen?				
keine	wenig	einige	große	sehr große

A10. Welche Schwierigkeiten hatten Sie letzte Woche als Sie vom Bett aufstanden?				
keine	wenig	einige	große	sehr große
A11. Welche Schwierigkeiten hatten Sie letzte Woche als Sie Strümpfe oder Socken auszogen?				
keine	wenig	einige	große	sehr große
A12. Welche Schwierigkeiten hatten Sie letzte Woche als Sie im Bett lagen und sich drehten, ohne dabei das Knie zu beugen?				
keine	wenig	einige	große	sehr große
A13. Welche Schwierigkeiten hatten Sie letzte Woche als sie in die Badewanne/aus der Badewanne stiegen?				
keine	wenig	einige	große	sehr große
A14. Welche Schwierigkeiten hatten Sie letzte Woche als Sie saßen?				
keine	wenig	einige	große	sehr große
A15. Welche Schwierigkeiten hatten Sie letzte Woche als Sie sich auf die Toilette setzten oder aufstanden?				
Keine	wenig	einige	große	sehr große
A16. Welche Schwierigkeiten hatten Sie letzte Woche als Sie schwere Hausarbeit verrichteten (schrubben, Garten umgraben,...)				
keine	wenig	einige	große	sehr große
A17.Welche Schwierigkeiten hatten Sie letzte Woche als Sie leichte Hausarbeit verrichteten (Staub wischen...)?				
keine	wenig	einige	große	sehr große

Gesamtpunktezahl Subskala Aktivitäten des täglichen Lebens	

In dem vierten Frageblock geht es um Ihre körperliche Belastbarkeit im Rahmen eher sportlicher Aktivitäten. Für jede der nachfolgenden Aktivitäten sollen Sie das Ausmaß der Schwierigkeiten angeben, welche Sie durch Ihr Kniegelenk innerhalb der **letzten Woche** erfahren haben.

4. Subskala sportliche Aktivitäten / Freizeit				
SP1. Welche Schwierigkeiten hatten Sie letzte Woche als Sie z.B.: in die Hocke gingen?				
Keine	wenig	einige	große	sehr große
SP2. Welche Schwierigkeiten hatten Sie letzte Woche als Sie z.B.: rannten?				
keine	wenig	einige	große	sehr große
SP3. Welche Schwierigkeiten hatten Sie letzte Woche als Sie z.B.: hüpften?				
keine	wenig	einige	große	sehr große
SP4. Welche Schwierigkeiten hatten Sie letzte Woche als Sie z.B.: sich auf ihrem kranken Knie umdrehten?				
keine	schwach	mäßig	stark	sehr stark
SP5. Welche Schwierigkeiten hatten Sie letzte Woche als Sie z.B.: sich hinknieten?				
keine	wenig	einige	große	sehr große
Gesamtpunktezahl Subskala sportliche Aktivitäten / Freizeit				

In dem fünften Frageblock geht es um die Gesamtheit der Einschränkung an der Lebensqualität, verursacht durch die Beschwerden am Kniegelenk.

5. Subskala Lebensqualität				
Q1. Wie oft spüren Sie Ihr erkranktes Knie?				
nie	monatlich	wöchentlich	täglich	immer
Q2. Haben Sie Ihre Lebensweise verändert um eventuell Ihrem Knie schadende Tätigkeiten zu vermeiden?				
gar nicht	wenig	etwas	stark	vollständig
Q3. Wie sehr macht es Ihnen zu schaffen, dass Ihr Knie nicht stabil ist?				
gar nicht	wenig	etwas	stark	vollständig
Q4. Wie würden Sie insgesamt die Schwierigkeiten bewerten die Sie durch das Knie haben?				
keine	wenig	einige	große	sehr große
Gesamtpunktezahl Subskala Lebensqualität				

Bitte überprüfen Sie noch einmal ob Sie bei jeder Frage ein Kreuz gemacht haben. Sie sollten pro Frage nur 1 Kreuz machen.

Vielen Dank.

Der Fragebogen ist hier zu Ende

9.2 Pain diary

9.2.1 Pain diary without AFO

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Das Eintragen erfolgt nach dem Prinzip der numerischen Schmerzskala.
Das bedeutet, Sie haben für jeden Tag eine Skala von 0 bis 10.
Dabei bedeutet 0 kein Schmerz und 10 der für Sie vorstellbare maximale Schmerz.
Bezogen sind die Schmerzen in diesem Falle auf ihr ________________ Kniegelenk!

Im Folgenden noch ein Beispiel der Skala:

Kein Schmerz **0** **1** **2** **3** **4** **5** **6** **7** **8** **9** **10** Maximaler Schmerz

Bitte füllen Sie jeden Tag am Morgen **unmittelbar nach dem Aufstehen** sowie **am Abend** Ihre Schmerzen ein.
Außerdem immer vor und nach der Behandlung bei uns.

Vielen Dank

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Institutionskennzeichen: 260 914 050, Umsatzsteuer-Identifikationsnummer gemäß §27a Umsatzsteuergesetz: DE 813 536 017

Datum														
	Morgens	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
	Abends	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
	Morgens	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
	Abends	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
	Morgens	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
	Abends	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
	Morgens	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
	Abends	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
	Morgens	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
	Abends	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
	Morgens	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
	Abends	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
	Morgens	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
	Abends	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
	Morgens	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
	Abends	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
	Morgens	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
	Abends	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
	Morgens	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
	Abends	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
	Morgens	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
	Abends	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
	Morgens	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
	Abends	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
	Morgens	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
	Abends	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
	Morgens	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
	Abends	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz

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Morgens	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
Abends	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
Morgens	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
Abends	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
Morgens	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
Abends	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
Morgens	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
Abends	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
Morgens	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
Abends	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
Morgens	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
Abends	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
Morgens	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
Abends	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
Morgens	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
Abends	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
Morgens	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
Abends	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
Morgens	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
Abends	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
Morgens	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
Abends	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
Morgens	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
Abends	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
Morgens	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
Abends	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
Morgens	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
Abends	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz

Unterschrift Proband.____

9.2.2 Pain diary with AFO

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Datum				
	Morgens	Kein Schmerz	**0 1 2 3 4 5 6 7 8 9 10**	Maximaler Schmerz
	Abends	Kein Schmerz	**0 1 2 3 4 5 6 7 8 9 10**	Maximaler Schmerz
		Medikation:		Tragedauer:
	Morgens	Kein Schmerz	**0 1 2 3 4 5 6 7 8 9 10**	Maximaler Schmerz
	Abends	Kein Schmerz	**0 1 2 3 4 5 6 7 8 9 10**	Maximaler Schmerz
		Medikation:		Tragedauer:
	Morgens	Kein Schmerz	**0 1 2 3 4 5 6 7 8 9 10**	Maximaler Schmerz
	Abends	Kein Schmerz	**0 1 2 3 4 5 6 7 8 9 10**	Maximaler Schmerz
		Medikation:		Tragedauer:
	Morgens	Kein Schmerz	**0 1 2 3 4 5 6 7 8 9 10**	Maximaler Schmerz
	Abends	Kein Schmerz	**0 1 2 3 4 5 6 7 8 9 10**	Maximaler Schmerz
		Medikation:		Tragedauer:
	Morgens	Kein Schmerz	**0 1 2 3 4 5 6 7 8 9 10**	Maximaler Schmerz
	Abends	Kein Schmerz	**0 1 2 3 4 5 6 7 8 9 10**	Maximaler Schmerz
		Medikation:		Tragedauer:
	Morgens	Kein Schmerz	**0 1 2 3 4 5 6 7 8 9 10**	Maximaler Schmerz
	Abends	Kein Schmerz	**0 1 2 3 4 5 6 7 8 9 10**	Maximaler Schmerz
		Medikation:		Tragedauer:
	Morgens	Kein Schmerz	**0 1 2 3 4 5 6 7 8 9 10**	Maximaler Schmerz
	Abends	Kein Schmerz	**0 1 2 3 4 5 6 7 8 9 10**	Maximaler Schmerz
		Medikation:		Tragedauer:
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		Medikation:		Tragedauer:
	Morgens	Kein Schmerz	**0 1 2 3 4 5 6 7 8 9 10**	Maximaler Schmerz
	Abends	Kein Schmerz	**0 1 2 3 4 5 6 7 8 9 10**	Maximaler Schmerz
		Medikation:		Tragedauer:

Morgens	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
Abends	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
	Medikation:									Tragedauer:			
Morgens	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
Abends	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
	Medikation:									Tragedauer:			
Morgens	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
Abends	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
	Medikation:									Tragedauer:			
Morgens	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
Abends	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
	Medikation:									Tragedauer:			
Morgens	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
Abends	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
	Medikation:									Tragedauer:			
Morgens	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
Abends	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
	Medikation:									Tragedauer:			
Morgens	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
Abends	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
	Medikation:									Tragedauer:			
Morgens	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
Abends	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
	Medikation:									Tragedauer:			
Morgens	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
Abends	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
	Medikation:									Tragedauer:			
Morgens	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
Abends	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
	Medikation:									Tragedauer:			

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Morgens	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
Abends	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
	Medikation:									Tragedauer:			
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Abends	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
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Morgens	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
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Morgens	Kein Schmerz	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Maximaler Schmerz
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	Medikation:									Tragedauer:			

Unterschrift Proband.____

9.3 Contentment questionnaire

Patientenbefragung zur KNEO Orthese

(vom /von Patienten/tin zum Ende des Beobachtungszeitraums auszufüllen und an den behandelnden Arzt auszuhändigen)

Name: ___________________________

Tragedauer pro Tag: ______ Stunden (durchschnittlich)

1. Wie lässt sich die KNEO Schiene anlegen?

- o sehr einfach
- o einfach
- o schwer
- o sehr schwer

Bemerkung: ____

____

2. Haben sich Ihre Beschwerden durch das Tragen der KNEO Schiene verbessert?

- o deutlich
- o leicht
- o kaum
- o nein

3. Spüren Sie beim Tragen der KNEO Schiene eine Entlastung des Kniegelenks?

- o deutlich
- o leicht
- o kaum
- o nein

4. Wie kommen Sie mit der KNEO Schiene im Alltag zurecht?

____

____

____

5. Wie ist der Tragekomfort?

- o sehr angenehm
- o angenehm
- o schwer
- o sehr schwer

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6. Wie ist Ihr Gesamteindruck?

- o sehr gut
- o gut
- o befriedigend
- o ausreichend
- o mangelhaft

7. Möchten Sie die KNEO Schiene weiterhin tragen?

- o ja
- o nein

8. Bei welchen Aktivitäten wurde die KNEO Schiene getragen?

____

____

9. Haben Sie Probleme mit Ihrem Schuhwerk beim Tragen der KNEO Schiene?

- o stark beschädigtes Schuhwerk
- o leicht beschädigtes Schuhwerk
- o kaum beschädigtes Schuhwerk
- o keine Beschädigung

10. Sind durch das Tragen der KNEO Schiene Probleme aufgetreten?

- o nein
- o ja ______________________________________

____

11. Bemerkung:

____

____

____

____

____

____

____

10 Danksagung

An dieser Stelle möchte ich allen an dieser Dissertation beteiligten Personen meinen Dank aussprechen.

Herrn PD Dr. Martin Weigl danke ich für die Überlassung des Themas und die kompetente Unterstützung.

Besonderer Dank gilt Herrn Dr. Alex Ranker für die ausgezeichnete Betreuung während der gesamten Promotionszeit.

Ich danke dem Institut der Orthopädie, Physikalischen Medizin und Rehabilitation der Ludwig-Maximilians-Universität München für die Bereitstellung der Räumlichkeiten und dessen Ausstattungen.

Außerdem möchte ich mich bei allen Probanden und Mitarbeiten bedanken, die diese Studie mit ihrer Teilnahme ermöglicht haben.

Besonderer Dank gilt meinen Eltern für die kompromisslose Unterstützung während des Studiums und der Promotionszeit.

11 Eidesstattliche Versicherung

Hiermit erkläre ich Felix Tino Friedl an Eides statt, dass ich die vorliegende Dissertation mit dem Thema „The influence of a novel ankle-foot orthosis on biomechanical parameters and its clinical outcome for patients with medial knee osteoarthritis" selbstständig verfasst, mich außer der angegebenen keiner weiteren Hilfsmittel bedient und alle Erkenntnisse, die aus dem Schrifttum ganz oder annähernd übernommen sind, als solche kenntlich gemacht und nach ihrer Herkunft unter Bezeichnung der Fundstelle einzeln nachgewiesen habe.

Ich erkläre des Weiteren, dass die hier vorgelegten Dissertation nicht in gleicher oder ähnlicher Form bei einer anderen Stelle zur Erlangung eines akademischen Grades eingereicht wurde.

München, 28.06.2022	Felix Friedl
Ort, Datum	Unterschrift Doktorand