Physical Medicine & Rehabilitation Journal

SCIENTIFIC LITERATURE

Special Issue Article "Prosthetics and Orthotics"

Research Article

A New Ankle-Foot-Orthosis Alters Radiographic Parameters of the Lower Limb on Micro-Dose Full-Length Standing Radiographs in Patients with Medial Knee Osteoarthritis

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ARTICLE INFO

Received Date: August 23, 2019
Accepted Date: September 24, 2019
Published Date: September 30, 2019

KEYWORDS

Knee osteoarthritis (KOA)
Ankle-foot orthosis (AFO)
Hip-knee-angle (HKA)
Tibiotalar angle (TTA)
Lateral distance to mikulicz-line (LDML)
Knee osteoarthritis outcome score (KOOS)

Citation for this article: Ranker A, Friedl F, Baur-Melnyk A and Winkelmann A. A New Ankle-Foot-Orthosis Alters Radiographic Parameters of the Lower Limb on Micro-Dose Full-Length Standing Radiographs in Patients with Medial Knee Osteoarthritis. Physical Medicine & Rehabilitation Journal. 2019; 2(2):121

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ABSTRACT

Background: Knee Osteoarthritis (KOA) is a very common cause of disability, pain and stiffness. An important role in the treatment of KOA is played by the use of orthoses. A novel Ankle-Foot Orthosis (AFO) should alter the lower limb biomechanics and change the loading on the knee compartiments. The goal of this study is to examine the effects of these load-changing ankle-foot orthoses on full-length standing radiographs on patients with KOA.

Material and Methods: 13 patients with a secured diagnosed medial KOA (mean age 63, 2 y± 5,84, BMI 29,57kg/m^2±4,79) were recruited for this study. Micro-dose full-length standing radiographs were used for analyzing the acute effect on radiographic parameters of the leg axes with and without AFO. The calculated parameters were: Hip-Knee-Angle (HKA), Tibiotalar Angle (TTA), Tilt Angle of the Ankle (TAA) and the Lateral Distance to Mikulicz-Line (LDML). Secondary outcome measurements were evaluated by the Knee Osteoarthritis Outcome Score (KOOS) at baseline and after 4 weeks of AFO-treatment and longitudinal pain measurement via pain diary for 28 days.

Results: All radiographic parameters alter by using the AFO. A significant decrease of the Hip-Knee Angle (HKA) and the lateral distance from the lateral tibial condyle to the mikulicz-line (LDML) was found (HKA pre/post p= 0.016; LDML pre/post p=0.005).The median of HKA was 3.02° (0.52°/10.71°) without AFO and 1.79° (-1.35°/9.71°) with AFO. The mean LDML was 56.41mm without AFO and 54.81mm with AFO. The statistical analysis of the TAA-differences showed no significance (p=0.433). The TTA was reduced 1.16° in the mean (0.79°/3.83°) with statistical significance (p=0.004).The longitudinal pain decreased significantly (p<0,001). All KOOS subscales improved. However only the ADL-subscale showed significant differences (p=0,013).

Conclusion: This AFO alters radiographic parameters in full-length standing radiographs. The pain was reduced over a midterm period. No conclusions can be drawn towards a possible dependency between axes-alteration and pain-reduction with this study.

INTRODUCTION

KOA is common cause of disability and pain. More than 10 % of the population over the age of 55 suffers from these symptoms [1]. KOA is the most common joint disease with a prevalence of 6% [2] and the second most common musculoskeletal disease worldwide [3]. In respect to the increasing prevalence, caused by the aging population, OA is considered to be a big burden to the public health system [4]. The primary symptoms of KOA are pain and stiffness [5]. Those symptoms can heavily affect the functional performance, activities of daily living and in consequence quality of life [6]. It should be noted, that pain in KOA is showing a typical undulation over the time.

An important risk factor for the progression of KOA is increased joint loading [5,7]. Due to the physiological mechanical axes, the medial compartiment is affected approximately ten times more than the lateral compartiment [2,8]. A varus malalignment shifts the load line towards medial, thus causing high load in the medial compartment [9]. As a result of the medial shift of the weight bearing line the load in the medial compartment increases [10]. During normal gait the knee is, except after initial heel contact, subjected to an external adduction moment [11,12]. The perpendicular distance between the vector of the GFR and the rotation point in the knee produces the external adduction moment (KAM) [13]. Several studies considered the KAM as the most important biomechanical indicator for the load in the knee [14-18]. Moreover, studies have shown that the KAM correlates with joint space narrowing [19,20]. Therefore therapies and solutions are contemplated to reduce the varus malalignment in order to reduce joint loading on the medial compartment. A common procedure in daily practice is the use of wedged insoles. However, detailed reviews show no significant benefit in studies with control groups with plane insoles [21]. Another interesting approach is the use of unloader braces. It has been shown that unloader braces reduce the KAM between 5-20% [14,22,23]. Nevertheless, the benefit of conventional unloader braces is strongly dependent on patients' compliance. Non-compliance causes are skin irritation, discomfort and cosmetic reasons [24]. A remarkable alternative for the unloader braces is a novel Ankle-Foot-Orthosis (AFO) with a lateral lever arm [25]. These AFOs are designed to modify the distribution of the load line in the knee. They consist of an insole placed in the shoe. This sole is connected to the unilateral frame (Figure1). The frame is attached on the lateral, proximal shank approximately above the fibular head with straps. By restricting the subtalar joint in the frontal plane, the AFO avoids compensating movements in the sagittal plane [26].

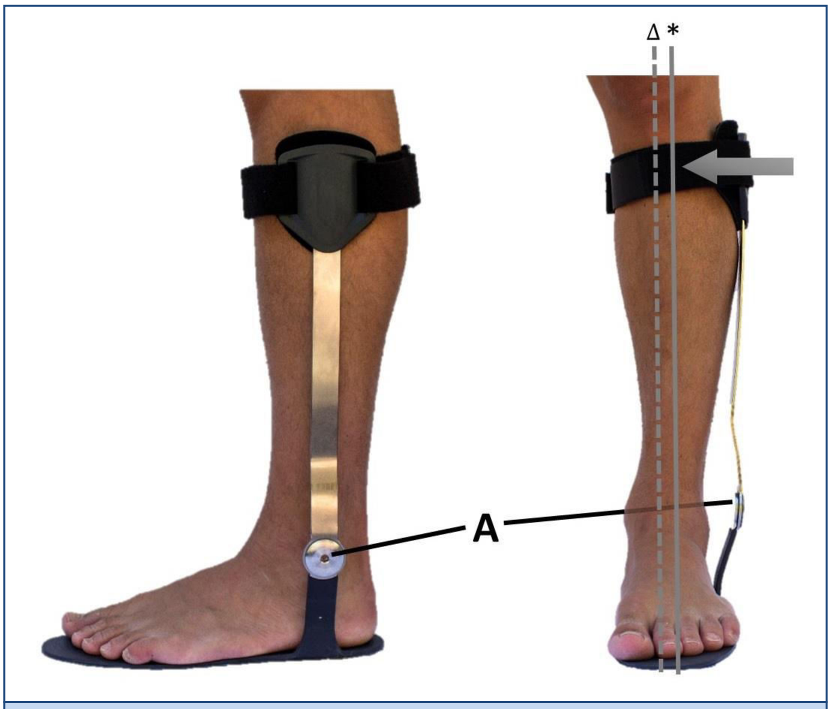

Figure 1: Ankle-Foot-Orthosis and theory of the operating principle.

The flexible insole is worn inside the shoe. The lever arm has a hinge at the level of the ankle (A) that allows normal gait. The top of the lever arm is positioned a little bit distal to the lateral joint-line of the knee. The mechanism should push the tibia medially, reduce the varus-angle and is thus shifting the weight-bearing line towards lateral (Δ without AFO, * with AFO).

Previous studies investigated the kinematics of the AFO and showed significantly reductions of the KAM [21,27]. Furthermore, pain reduction and increasing quality of life has been shown by using this type of AFOs [28]. Irrespective of the good clinical outcome the effect on altering leg axes and reducing varus malalignment has only been shown indirectly by gait measurements or through external postural measurements with laser and line optics [25,29]. A radiographic evaluation of potential alteration of the relation of femur to tibia has not been done before. Therefore, this study aimed to investigate the acute effect of the AFO on the mechanical axes by using full-length standing anteroposterior micro-dose-radiographs. A second goal of this study was to measure longitudinal pain-levels. Because of the typical undulation in pain intensity in KOA, it is known that single pain-intensity measurements can lead to biased results. Affected by the good clinical outcomes in previous studies we hypothesized, that radiographic parameters on full-length standing anterior-posterior radiographs can be altered by applying this type of AFO. In consequence we hypothesized that pain reduction will be present over the whole period of wearing the AFO.

MATERIAL AND METHODS

Study design and ethical approval

This prospective clinical trial observed the intraindividually effects on radiographic parameters of full-length standing anteroposterior radiographs of the lower limbs with and without interventions. The study was carried out in compliance with the Helsinki Declaration. It was approved by the ethical committee at the medical faculty of the Ludwig Maximilian University Munich (Project-Number 18-072, accepted 20th March 2018, Chairman Prof. Dr. W. Eisenmenger).

The study-design was essentially divided in two periods (Figure 2). In the first 4 weeks baseline-data was collected and pain measurement was performed by pain diaries over 28 days. In the meantime, the orthosis was adjusted. After 4 weeks, the AFOs were handed out to the participants and primary outcome measurements were performed. Afterwards the participants wore the AFO for 4 weeks and filled out secondary outcome measurements at 4 weeks follow-up.

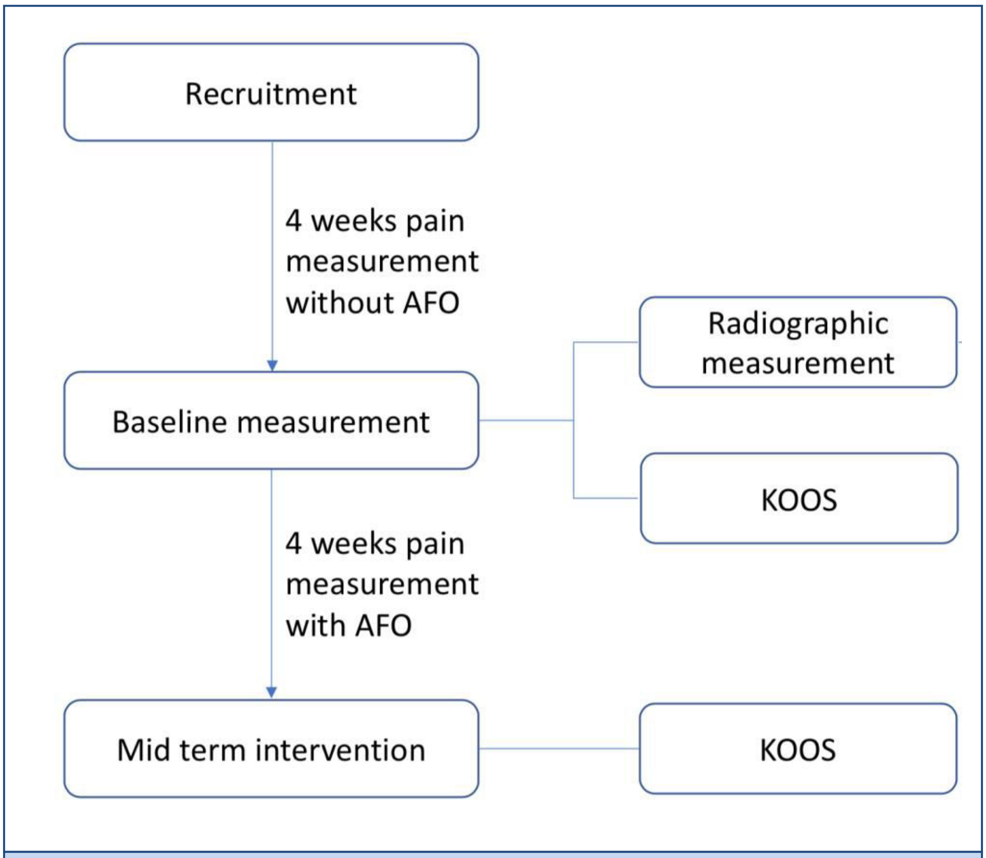

Figure 2: Flow-chart of the Study design.

Participants

Recruitment and inclusion criteria: The patients were recruited between April and July 2018 from the clinical outpatient consultation at hospital (Table 1). Defined inclusion criteria required that patients had diagnosed medial knee osteoarthritis, as according to the American colleagues of Rheumatology [30] with a Kellgren and Lawrence Score II or III. All patients had to present persistent pain located at the medial joint space, as well as having typical symptoms for varus malalignment. The pain intensity had to reach more than 3/10 on the Numeric Rating Scale (NRS). Further inclusion criteria were defined as failed conservative therapy (including multimodal pain treatment), age over 18 years, knowledge of the German language and normal cognitive ability. The exclusion criteria were added by former knee surgery such as knee replacement, or presence of malign disease. Patients that required knee osteotomy surgery were offered the alternative to participate in the study first instead of having the operation.

Table 1: Baseline-Characteristics and comparability of the participants.

Participant characteristics (n=13)			
Characteristics	Mean (SD)	Range	Significance within the group
Socio-demographics			
Age (years)	63.2 (5.8)	54-71	n.s.
Gender (male/female)	7/6		
Health factors			
Body height (m)	1.73 (0.1)	1.6-1.91	n.s.
Body weight (kg)	87.9 (15.6)	68-138	n.s.
BMI (kg/m^2)	29.6 (4.8)	23.5-39	n.s.
Kellgren-Lawrence-Score	2.3 (0.48)	2-3	n.s.
Mean pain at beginning (NRS-scale)	4.3 (1.34)	2-6	n.s.
Abbreviations: BMI = Body Mass Index			

Ankle-foot-orthosis

In this study an AFO (KNEO, Fa. Sporlastic, Nürtingen, Germany) was used (Figure 1), which is regularly on the market and can be prescribed through physicians. This AFO is a medical device for unicompartmental knee OA with a CE-certification. The orthosis is composed of a sole, connected by a hinge to a unilateral frame placed on the lateral side of the shank. The hinge allows free range of motion in the sagittal plane and locks the subtalar joint in the frontal plane. By restricting the subtalar joint in the frontal plane, the orthosis ensures a proper force transmission in the knee joint [28]. The angle of the frame and its resulting force on the lateral shank can be adjusted for a neutral varus or valgus degree. The degree of the varus/valgus variation depends on the patient´s requirement. The AFO implicates a lateral shift of the weight bearing line, and thus a reduction of its lever arm [25]. As a result, the acting varus moment on the knee is reduced. The AFO acts according to the three-point bending mechanism by applying a valgus moment on the knee.

Primary and secondary outcome measurements

Primary outcome measurements were evaluated through the calculated means of radiographic parameters. Secondary outcome parameters were defined as longitudinal pain measurement with and without intervention over 28 days, as well as KOOS at baseline and after 4 weeks follow-up.

Micro-dose full-length standing radiographs of the lower limb: The alignment of the knee was measured by using a Micro-dose full-length standing radiograph. The micro-dose imaging (EOS, Biospace med, France) had a reduction of 94% of exposed radiation in contrast to the conventional X-ray on a spinal imaging [31]. It is expected to have similar dose reduction on full-length standing radiographs. For the medical imaging, the patients were well positioned according to standard position [32]. All patients were already equipped with the AFO.

For determining the effect of the AFO on the mechanical axes, two radiographic images were taken. The first without the lateral force of the AFO through the lever arm and another with the lateral force of the AFO. To enhance the accuracy of the imaging, the first image was taken with the sole of the AFO inserted in the shoe. By tilting the unilateral frame forward on the first image, the effect of the AFO was disabled. For the second image, the patients were asked to stand without any movements and the lateral frame was attached by a medical technical assistant. All images were evaluated digitally with Picture Archiving and Communication System (PACS, Carestream Health. Inc., Canada).

Measuring of radiographic parameters: The main authors (RA and FF) independently measured the selected angles by using the same method for all radiographs (Figure 3). They were previously trained by a very experienced senior of the Institute of Radiology of the clinic (BMA), who also checked all measurements afterwards in order to assure high measurement accuracy. Because of the fact that both radiographs (without and with AFO) were taken immediately in succession, the comparability was increased. Angles of the Hip-Knee Angle (HKA) were measured to see the effects on the mechanical axis. For potential effects on ankle-position the Tibiotalar Angle (TTA) and the Tilt Angle of the Ankle (TAA) were calculated as well. Although measuring the HKA is a common procedure in practice, literature about reliability and reproducibility shows variations in HKA up to 2° [33]. As bigger effects than 2° have not been assumed, and the main aim was to measure relations from tibia to femur, the parameter of lateral distance from the lateral tibial condyle to the mikulicz-line (LDML) was added.

The whole measurement was strictly standardized and divided in steps (Figure 3). The first step was to draw the Miculicz-Line (ML), which is the connection of the center of the femoral head and the midpoint of the talus joint surface. For the center of the femoral head, moses circles were used [34]. The second step was to define the midpoint of the knee, which was found at the level of the top of the intercondylar notch. The center of the femoral condyles was detected and marked. The third step was to measure the HKA, which is formed by a line from the mid of the talus joint surface to the center of the knee, and a second line from the center of the femoral head to the center of the knee. The fourth step was to measure the TAA and the TTA. Therefore, the ankle was zoomed in. The TAA is formed by two intersecting lines that are drawn through the joint surface of the Talus. The TAA can have both, positive (supination) or negative (pronation) values. The TTA is the angle between the anatomical axis of the Tibia and the joint surface of the Talus. On the last step the lateral distance to the mikulicz-line was measured by using a crosshair with a vertical line and a horizontal line. The Knee was zoomed in and the contrast was increased. The first osseous contact on the lateral epicondyle from the tibia served as anchor point for the vertical line. The horizontal line was then shifted continuously downwards until it reached osseous contact with any structure of the lateral epicondyle of the tibia. At this point, the distance between the intersection of the crosshair and the mikulicz-line was measured in millimeters (Figure 3).

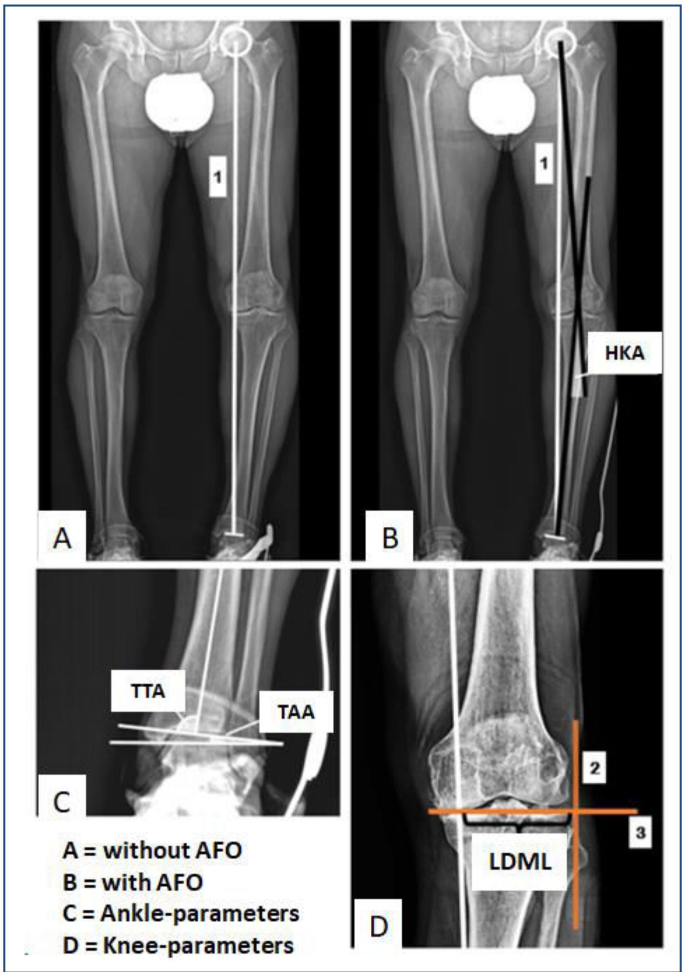

Figure 3: Radiographic measurement.

All parameters were measured without AFO and with AFO. The lever arm of the AFO is clearly visible on the X-ray (A vs. B). Picture D is showing the measurement of the Lateral Distance to Mikulicz-Line (LDML) by using a crosshair.

Knee osteoarthritis outcome score (KOOS): The KOOS is a knee specific questionnaire. It represents a valid questionnaire for patients with knee OA. The KOOS can be used to evaluate the progress of the disease and outcomes in regard to surgical, pharmacological and other interventions [35]. 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). All subscales are rated with a scale from 0 – 100 points. 100 points on this scale indicates no problem and on the other side 0 points indicates severe problems.

Longitudinal pain measurement: The pain was measured by using a Numeric Rating Scale (NRS) from 0-10. The patients were asked to record their current pain based on the scale every evening at the same time. The specific pain on the scale referred only to the investigated knee affected by osteoarthritis. Two pain diaries were performed over a four-week period, one with and one without using the AFO. The first pain diary was accomplished without the AFO. The second pain diary was performed with the use of the AFO.

Statistical analysis

The statistical analysis was performed with SPSS Statistics 24 (SPSS, Inc., IBM Company, Chicago, IL). For the changes in radiographic measurements the Wilcoxon-test was performed as well as descriptive analysis. For graphic interpretation the mean changes from baseline were converted into percentage values.

The secondary outcome pain and the KOOS subscales (symptoms, pain, activity, sports and quality of life) were described through quantitative parameters. It includes the mean, and standard deviation, as well as minimum and maximum. The quartiles, such as median, were analyzed. Because of the small number of participants, the Shapiro-Wilk test was used to test for normal distribution. For the statistical analysis, the Wilcoxon test was used. The secondary outcome pain on the NRS scale was tested by using a randomized mixed effect model for longitudinal pain measurement. For this analysis, the GLIMMIX procedure of the Statistical Analysis System SAS version 9.4 for Windows (SAS Institute, Cary, NC) was used.

RESULTS

15 Knees were included in the study (n=15; 13 patients with single Knee, 1 patients with both knees, female=7, male=6). All patients finished the study. The Mean age was 63.2 years (±5.84). The Mean BMI was 29.57 kg/m² ± 4.79 (mn.23.52kg/m²min/ max.39.04 kg/m²). The measurements for the patient with both knees were done separately.

5.1. Radiographic parameters

The HKA and the LDML decreased in all patients. The median of HKA was 3.02° (0.52°/10.71°) without AFO and 1.79° (-1.35°/9.71°) with AFO. The mean LDML was 56.41mm (±1.51) without AFO and 54.81mm (±1.72) with AFO. These differences were statistically significant (HKA pre/post p= 0.016; LDML pre/post p=0.005).

The Ankle parameters showed also alteration. TAA showed a mean difference of 1.15°. However, in 4 cases an increased supination had been detected through the AFO, whereas all other cases showed a pronation-tendency through the AFO. The statistical analysis of the TAA-differences showed no significance (p=0.433). The TTA was reduced 1.16° in the mean (0.79°/3.83°). These differences were statistically significant (p=0.004). Overall all parameters changed in a range from 1.4% to 7.9% when compared to baseline (Figure 6).

KOOS and longitudinal pain measurement

Increases in the KOOS questionnaire were observed in every subscale, except symptoms (Figure 4). The pain subscale increased from 48.3 (SD 14.39) to 55.9, the activities of daily living increase from 56.2 (SD 15.5) to 65.7 (SD16.2) in activities of daily living. (p=0.011).There was an increase of 28.9 (SD 10.9) to 31.1 (SD 14.6) in the subscale quality of life (Table 2). The means of the subscale symptoms decreases of 55.8 (SD 13.8) to 53,3 (SD 16.2) (Figure 4) but without statistical significance. The statistical analysis showed significance only for the subscale ADL (p=0.011).

The longitudinal pain measurement showed a constant reduction of the mean pain levels through wearing the AFO (Figure 5). The mean pain level was NRS 3.69/10 (±2.56) without AFO and NRS 2.91/10 (±2.72) with AFO during the 28 days period. To calculate the longitudinal effect the differences of single day were calculated with a randomized mixed effect models and show highly significant differences throughout the whole survey period (p< 0.001), (Figure 5,6).

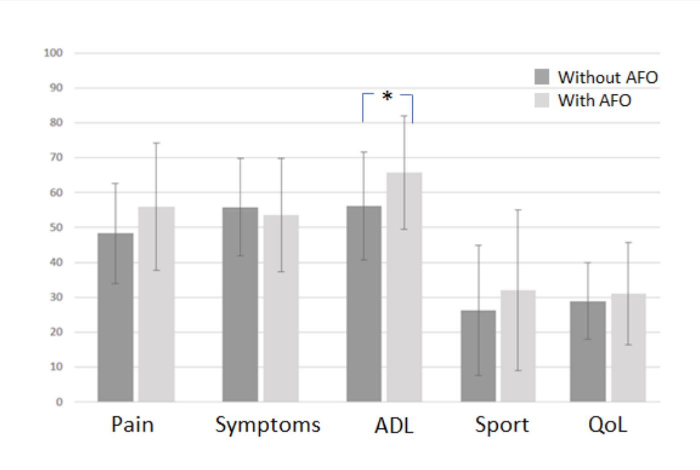

Figure 4: KOOS-Outcome.

Presented are mean-values of the subscores. The error-bars are showing the stand error of the mean, * = stat. significant ($p<0.05$).

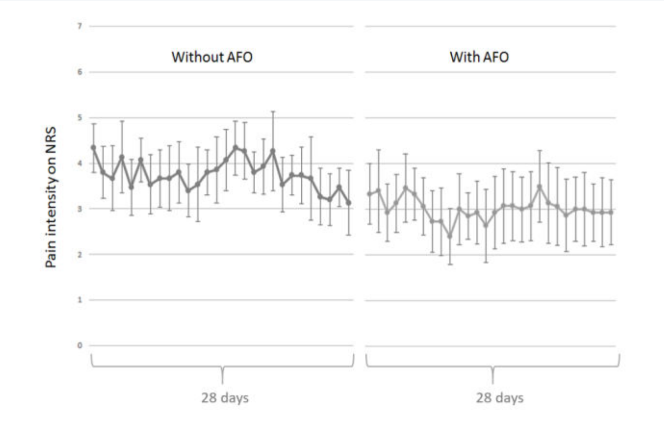

Figure 5: Longitudinal pain-measurement.

Presented are mean-values for every day (28 days) without AFO and with AFO. The error-bars are showing the standard deviation.

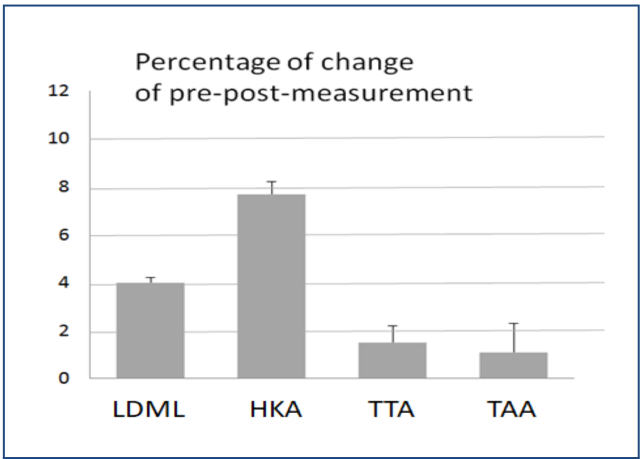

Figure 6: Percentage of changes of pre to post measurements of the X-ray parameters.

Mean Pre to post changes of the calculated X-ray-parameters presented in percentages.

The inter-individuality baseline values were defined as 100%. The changes were then calculated and the difference to baseline is presented. Error bars showing positive SD.

Table 2: KOOS Scoring.

Knee Osteoarthritis Outcome Score (max. 100 points)				
Subscales	**Baseline**	**After intervention**	**Delta(Δ)**	**Significance**
Pain	48.3 (14.39)	55.9 (18.2)	7.6	n.s
Symptoms	55.8 (13.9)	53.3 (16.2)	2.5	n.s
Activities of daily living	56.2 (15.5)	65.7 (16.2)	9.5	0.011
Sports	26.3 (18.6)	32 (23.1)	5.7	n.s
Quality of life	28.9 (10.9)	31.1 (14.6)	2.2	n.s
All values in mean and (standard deviation)				

DISCUSSION

The most important findings are that the used AFO alters tibio-femoral and tibiotalar ratios on radiographic assessment. HKA, TTA and LDML showed significant differences with and without orthosis. In consequence, the results show a changing in Knee alignment according to the leg axis. Similar results were already shown by external postural measurement [21,28,29].

However, these presented differences in the literature are much higher than on the present radiographic measurements of this study. Schmalz et al., showed changes of the weight-bearing line to the lateral compartiment up to 13mm [25]. Sliepen et al., showed a significant decrease of 14% of the angle in the frontal plane resulting in a reduced varus moment [36]. In the present study the differences were much smaller. The HKA showed a pre/post mean difference of 1.23° and the LDML 1.6mm. Although these results are showing obvious alterations through the use of the AFO in all patients without exceptions, it still has to be emphasized that the differences are small. Taking into account that the reproducibility of HKA on full lengths lower limb X-rays with an accuracy up to 2° are reported [33] it has to be questioned if these significant results can really justify the obvious improvements in pain and activities of daily living.

In literature the reasons for pain in KOA are highly discussed. The question what actually causes the pain in the medial compartiment in medial KOA is still not clear. It is known that the pain is not only depending on the affected knee and the degree of KOA. It has been shown that there is no correlation between magnitude of radiographic signs and the severity of pain [37]. Other structures in the knee such as the joint capsula, infrapatellar fat or periosteum can turn out in pain [38]. Zimmermann et al., shows that tension by local pressure or irritation by inflammatory mediators manifest oneself as pain in the knee [39].

A further important component of the cause of pain is the laxity of the knee. It has been shown that even the laxity in the passive frontal plane determines disease progression [40]. Due to the fact that the pain and the stiffness is not only depending on disease progression, the passive structures of the knee should earn more attention, as they also influence gait parameters such as the knee adduction moment [21]. It has been shown that the KAM is a very high indicator for the load in the knee [14-16]. Several studies are showing significant changes in the KAM through the use of AFOs [21,27]. Therefore, the passive joint structures should also be taken into consideration and can falsify the results of pain and load parameters measurements and decrease the level of activity in daily life.

This Activity in Daily Life (ADL) plays an important role in the process of pain and disease progression [41]. It is well known that increasing the level of activity can lead to pain reduction [41,42]. Therefore it is a major approach in the therapy of KOA to try to increase the level of activity. But because the affected area is subjected of repetitive stress and can cause initial pain during movements, especially in the beginning of loading the compartiments, it could be quite possible that only a slight shift of the load line can improve the pain because of its load relief.

The present study shows high significant pain reduction over the whole measuring period, which was a daily measurement over 4 weeks. It is well known, that pain in KOA shows variable intensities and undulations over the time and is highly suggestible according to the activities prior to the measurement [43]. To prevent from measuring bias by measuring only at baseline and follow-up, a longitudinal pain-measurement was performed and analyzed by complex statistical tests with randomized mixed effect models. A significant reduction was not only seen after the first days the AFO was worn, but throughout the whole period. In addition, the KOOS-subscale pain showed a clear tendency towards an improvement especially in pain and activity of daily living. The latter show statistical significance. However, due to the low number of participants the improvements in the other subscales showed no significance. Overall, the present results allow the conclusion that a pain reduction and an increasing of the activity level might be possible by using this AFO. This can confirm existing results from other studies [25,27,28,44].

However, it is still not known, if shifting the mechanical axis produces side-effects on other weight bearing joints, like the ankle, in the long-term view. The radiographs in this study showed alterations in the ankle-joint in both directions, either towards a greater supination (n=4) or an increased pronation (n=11). As it is well known that punctual weight bearing on the talus surface can increase the risk of cartilage damage [45], these alterations should be evaluated in further studies and in long term results. It is self-evident, that no recommendations in terms of wearing time of the AFO or adjustments can be given by the present radiographic results, but the changes in the tibiotalar relations attracted attention by the authors. Interestingly a biomechanical study from Fantini et al., with this AFO shows not only a reduction of the KAM in their gait analysis on 14 healthy subjects, but also a higher eversion of the ankle, which can result in an external rotation of the shank [21]. This can be confirmed by the present radiographic results as the TTA was reduced significantly (p=0.004) with a dominance of pronation.

Nevertheless, the AFO has already shown good clinical outcomes in pain and posture-changing and no complications in other weight bearing joints have been reported to the author's knowledge. Menger et al., showed results of a one year follow-up pain measurement [28]. The pain significant improved over the entire follow up from 4,9±1,6 at base line to 3,7±2,3 after six month and 3,4±2,8 after one year. These results are similar to the pain reduction in this study. Certainly, the present study has limitations, such as the small number of participants. Compared to other studies investigating the effects of the AFO the number is comparable [25,29]. Furthermore it is a pilot-study that presents radiographic measurements with this AFO, which was never published before. Therefore sample-size calculation was not performed. To ensure high accuracy and comparability the participants were tested intra-individually, with regards to individual anatomical circumstances.

CONCLUSION

This study shows significant alterations in radiographic parameters of the lower limb full-length standing radiographs in patients with medial knee osteoarthritis through the use of an AFO. Especially the Tibia-femoral and the tibia-talar relation is changing and the tibia is shifting medially towards the mikulicz-line. Pain reduction and improvement of activities in daily living can be achieved by the use of this AFO.

ACKNOWLEDGEMENT

We thank Dipl. Ing. Helmut Wagner and Dr. Timo Schmeltz pfenning for supporting us in this study. Furthermore we have to thank the Biomechanics Laboratory of the Department of Orthopaedics, Physical Medicine and Rehabilitation University Hospital, LMU Munich

And Conny Kugler and Gerhard Kurlitsch from Fa. Kurtze, who have done the adjustments of the AFOs.

CONFLICT OF INTEREST

All authors claim to have no conflict of interest. The Sporlastic Company (Nurtingen, Germany) provided the used orthoses in this study. They had no influence in the study design nor in the presented results or the choice of the journal.

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