

Evaluation of the Effect of the New Unloader Orthosis on Life Quality, Function and Pain in Patients with Knee Medial Compartment Osteoarthritis Using SF-36 and WOMAC: Case Report

Mehran Kazemi Meresht^a, Reza Razeghinezhad^{a*}, Maryam Ashkar^a, Hanieh Seyyedzadeh^b, Gholamreza Sheikh^c

^a Department of Orthotics and Prosthetics, School of Rehabilitation Sciences, Iran University of Medical Sciences, Tehran, Iran; ^b University of Social Welfare and Rehabilitation Science, Orthotics and Prosthetics, Tehran, Iran, Islamic Republic of Iran; ^c Department of Orthopedics, School of Medicine, Iran University of Medical Sciences, Tehran, Iran

*Corresponding Author: Reza Razeghinezhad, Department of Orthotics and Prosthetics, School of Rehabilitation Sciences, Iran University of Medical Sciences, Tehran, Iran; E-mail: reza.razeghinezhad@gmail.com

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Abstract

Introduction: Patients with Knee medial compartment osteoarthritis suffer from pain and stiffness. Pain reduces their function and life quality. One of the therapeutic methods is using unloader orthosis. This case report study aimed to evaluate effect of using a new unloader orthosis on score of pain, performance and life quality of patients with Knee medial compartment osteoarthritis. **Methods and Material:** Three women aged 60-70 years old and with moderate Knee medial compartment osteoarthritis were enrolled in the study based on Kellgren and Lawrence system for classification of osteoarthritis. The new unloader orthosis was produced in order to evaluate its efficacy on knee medial osteoarthritis based on the measurements of participants. The participants wore the new knee orthosis for six weeks. Before and after using the orthosis, the severity of pain was measured through visual analogue scale, and in order to measure life quality and assess physical activity, participants filled out the SF-36 and WOMAC osteoarthritis index, respectively. **Results:** The mean BMI of the participants was 28.9 kg/m². According to results in all the three participants, VAS score decreased after six weeks of using the new orthosis. WOMAC questionnaire score in first, second and the third participant also reduced respectively up to 35.5%, 7.3%, and 35.4%, and the SF-36 questionnaire score increased as 21.1%, 1.9%, and 18.6%, respectively. **Conclusions:** The new knee unloader orthosis reduced pain and improved performance of participants with knee medial osteoarthritis. Therefore, this orthosis can be appropriate for patients with knee osteoarthritis.

Keywords: knee osteoarthritis, pain, "knee unloader orthosis", quality of life

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Introduction

Knee osteoarthritis is one of the most prevalent musculo-skeletal disorders in old ages (1). In common, osteoarthritis is clinically identified by joint pain, stiffness, and motor limitation, and various degrees of inflammation, and the knee arthritis was recognized in the past as a diseases which involves just the cartilage, but nowadays the researchers found that arthritis is a disease which also involves all the joint-structures, the synovium, subchondral bones, and infrapatellar fat pad (2). 60-80% of the load on knee passes through medial compartment, and therefore, this compartment is mostly affected by osteoarthritis due to enduring the load during walking and activities (3).

The most important leading cause for medial compartmental osteoarthritis is larger adduction moment in "genu varum" or varus status, and it is probable that the load in these individuals reach to 100% of the all the loads during walking in the medial compartmental section which this can facilitate degenerative process of osteoarthritis (4). Therapeutic options for osteoarthritis include surgical and cautiously procedures (5, 6).

It is estimated that 25% of the patients with osteoarthritis are faced to challenges with their most activities such as walking, kneeling, climbing stairs, as well as activities at workplace (7, 8).

The previous studies showed that limitations in daily activities reduce quality of life (8-10). The aim of the clinical treatment is to improve health condition of the patients. Life quality is an important outcome in health condition and assessment of the treatment (11).

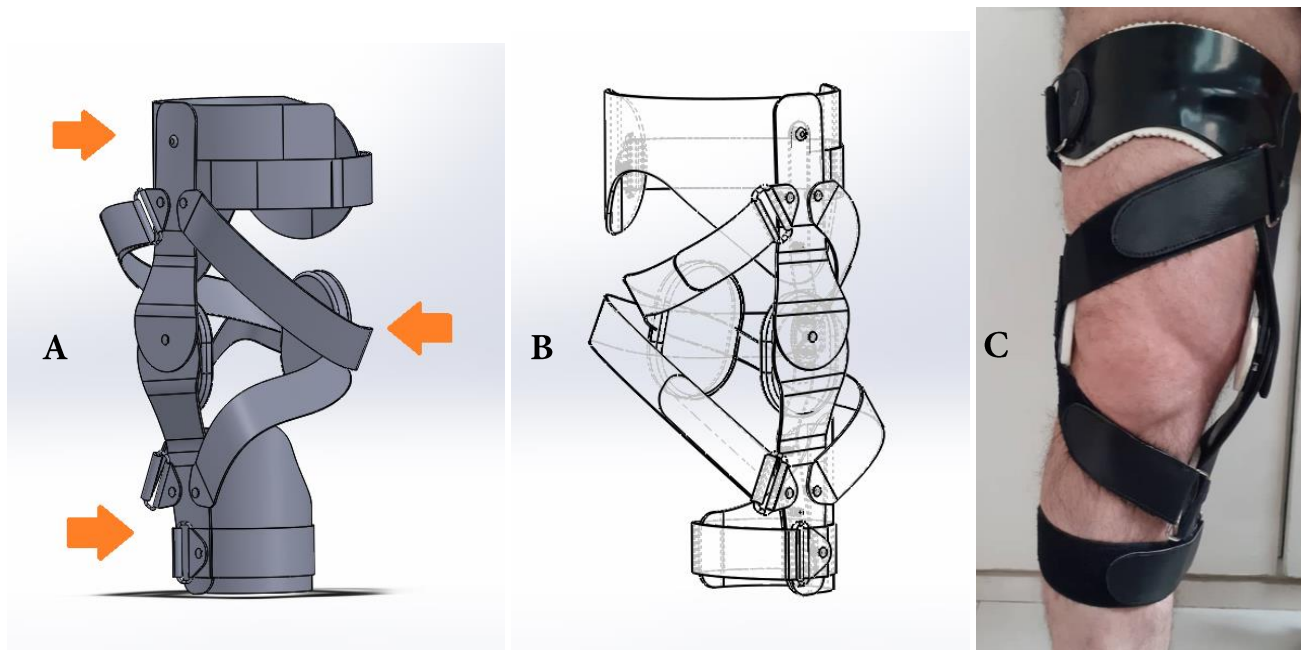


Figure 1. New unloader orthosis METOC. A) Shaded with edges view of the orthosis (along with area of three pressure points area); B) Hidden lines visible view of the orthosis; C) Real view of the orthosis on organ of the healthy individual

Prescription of orthosis in knee osteoarthritis is one of the common non-surgical or “conservative” treatments, and the main aim of the orthosis is reducing pain and improving the function, and produce a direct load on knee (12). “Valgus orthosis” produces an external moment through three points of pressure to reduce pressure and load on media compartment (12).

In general, the findings showed improvement of pain in patients who used unloader orthosis (13-16).

The studies showed that unloader orthosis transforms the knee to valgus status, and the patient experiences decline in pain and adductor moment (17-20).

Due to high prevalence of knee osteoarthritis and the vital role of knee in daily activities, decline in pain in patients are important (13), and decline in pain increases function and life quality (21).

In contrast, limitation in daily activities reduces life quality (9-11, 14). Aim of the clinical treatment of knee medial osteoarthritis is to improve health condition in patients including decline in pain and improvement of function which can promote life quality of these individuals.

Given that the role of orthosis in patients with osteoarthritis is challenging (22), therefore, the aim of this study is to investigate effect of using a new unloader orthosis on score of pain, function, and life quality in individuals with patients with knee medial compartmental osteoarthritis.

Methods and Materials

Orthosis design

The new knee unloader orthosis, Mehr Technical Orthopedics Clinic (METOC) consists of thigh basket, shank basket, aluminum two-axis uni-lateral joint, strap, and knee pad (Figure 1), and its intellectual property is registered (registry code “national patent”:100720).

The design of cutting baskets is so that it has greater touching surface in the thigh medial and shank medial and leads to improve hang. Thigh basket involves three-quarters of thigh and shank basket involves half of the shank circumference. This orthosis consists of “cross straps”. The elastic band was sewn to all the straps, and in other words, they are velcro-elastic band in knee movements, due to expansion and contraction of muscles, their volume is changed. Using elastic produces always a fitting and homogeny stability and provides the maximum compatibility with volumetric changes of the organ, and also produces more hang, and subsequently the knee orthosis remains stable in its place during various activities. METOC orthosis consists of a pressure pad which its locating area is settable.

METOC orthosis exerts three pressure points to the organ which includes:

The first force is from the superior medial part of thigh basket and the second force is from the lower medial part of shank basket which these two forces are exerted in one direction.

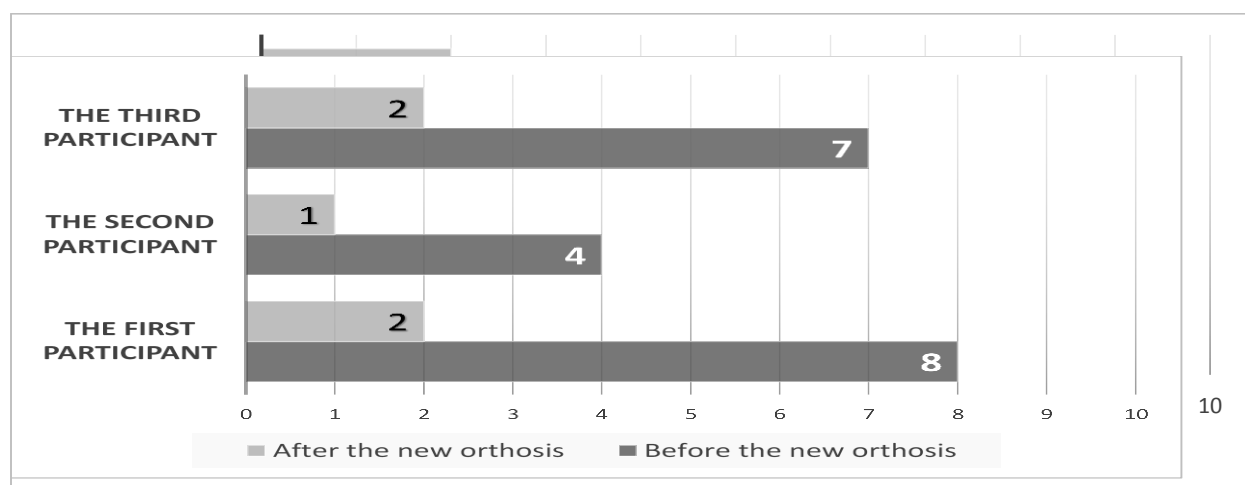


Figure 2. Assessment of pain in patients based on VAS before and after wearing new orthosis for six weeks

The third force is exerted opposite to kneecap joint through settable pressure pad in opposite direction of the first and second forces.

In biomechanics, if the couple forces are exerted as three pressure points, the third force should be as much as the other two forces but in opposite direction to be effective and confronting.

Therefore, the third force exerts greater pressure per unit area. The lower the third force, the lower the point pressure and leads the pain in the area.

Since pressure pad of this orthosis has greater width comparing to strap, therefore, exerts a force to the first and second forces however in a bigger unit area which is endurable for the patient.

Therefore, greater valgus force is implemented to the organ which this force has a better distribution due to pad shape and is more efficient.

In general, in the current project, due to novelty of cutting line of thigh basket and shank basket and velcro-elastic band of the straps, better hang and compatibility were obtained comparing to similar cases.

In addition, the most important part of this knee cap is the pressing pad which is settable in the area and helps better distribution of the force which is not present in the similar cases.

It should be noted that the baskets material is unbreakable and flexible poly propylene thermoplastic sheet with a thickness of 3 mm which leads to considerable decline in its weight.

Participants

The participants were selected from the patients referred to orthosis and prosthesis clinic in Tehran by orthopedist.

Diagnosis of osteoarthritis of knee medial compartment and the primary assessment of patients was performed by the specialist physician using radiography image in a supine status. Three women arbitrarily participated in the study according to

inclusion and exclusion criteria.

Inclusion criteria in the current study were as follow: patient with osteoarthritis of knee medial compartment, with grade of 1-4 based on "Kellgren and Lawrence system for classification" of the natural direction or knee varus (grade 0-10), lack of instability of ligament, diabetes mellitus, corticosteroids injection during past two months in the involved side and lack of injection during the study.

In addition, exclusion criteria include: history of surgery in knee medial compartment, lack of enduring weight thoroughly, lack of ability to use orthosis due to physical limitations, skin and vascular problems, the individual is not able to walk up to at least 10 m without any supporting equipments, diagnosis of arthritis in other joints of lower limbs and body mass index greater than 35 (obesity).

Orthotic Treatment

All the stages of the test were explained for the participants and they filled out the consent form, then the required measurements were done to make the METOC orthosis.

After preparation the mentioned orthosis, the patients were asked to wear it during daily activities and walking, and not to use it while sleeping, rest and duties without enduring weight, and they were also asked to inform the specialist physician and orthotist in case of any problem. The required information was gathered through face-to-face questions and questionnaire.

Firstly, for all the participants, the form related to baseline characteristics (gender, height, weight, and age) was filled out by the therapist, then prior to use the orthosis, the SF-36 questionnaire and WOMAC osteoarthritis index were filled out and they marked their pain score in VAS (23) (0 to 10), and they

referred after six weeks of using orthosis and filled out the mentioned questionnaires.

Table 1. Baseline characteristics of the participants

participant	Age (years)	Weight (kg)	Height (cm)	BMI
First	70	80.2	167	28.3
Second	60	79.5	164	29.5
Third	65	82.4	169	28.8

Table 2. Percentage of score for SF-36 before and after using METOC unloader orthosis

Items	Participants		First participant		Second participant		Third participant	
	Before	After	Before	After	Before	After	Before	After
Physical functioning (%)	20	65	85	90	20	45		
Role limitations due to physical health(%)	25	75	100	100	0	50		
Role limitations due to emotional problems(%)	100	100	100	100	66.7	66.7		
Energy/fatigue (%)	65	90	85	85	70	70		
Emotional well-being (%)	84	88	88	88	60	84		
Social functioning(%)	75	100	100	100	50	75		
Pain (%)	57.5	77.5	90	100	57.5	77.5		
General health(%)	50	50	55	55	30	35		
Mean percentage	59.56	80.68	87.87	89.75	44.27	62.9		

Table 3. Score of WOMAC questionnaire for knee osteoarthritis, before and after using METOC unloader orthosis

Items	Pain		Stiffness		Function		Total percentage	
	Before	After	Before	After	Before	After	Before	After
First	16	8	5	3	53	29	77.08	41.66
Second	5	2	2	2	16	9	23.95	16.66
Third	15	6	1	1	61	36	80.20	44.79

The translated version of SF-36 (24) and WOMAC (25) were used in the current study. Higher scores in WOMAC questionnaire present pain, stiffness, and more functional limitations, and in SF-36 present the optimum health condition of the patient.

Data analysis

Demographic data including age, height, and weight were computed and reported as mean and standard deviation. In order to achieve BMI of the participants, online England free health website (26) was used.

In addition, to score SF-36 questionnaire, online free OrthoToolKit website (27) was used, and scoring to WOMAC questionnaire was computed manually due to scoring system (0-4 for each question).

Results

Three women with mean age of 65 ± 5 year's old, mean height of 166.6 ± 2.5 cm, and mean weight of 80 ± 1.5 were entered into study. The three participants were with knee medial

osteoarthritis with grade 3 (moderate). Demographic information of the participants was reported in Table 1.

Pain score of the participants based on VAS (0-10), was 8 prior to use the new orthosis for the first participant, 4 for the second participant, and 7 for the third one.

After wearing orthosis for six weeks, VAS score reduced as 2, 1, and 2 units for the participants one to three, respectively (Figure 2).

Measurements of the WOMAC and SF-36 questionnaire for prior to use orthosis and six weeks after wearing orthosis were compared together which their results are reported in Table 2 and 3, respectively.

The findings showed that the designed orthosis reduces pain in participants, and were effective in improvement of life quality for the first and the third participants. Since life quality in the first and third participants increased as 21.1% and 18.6% and in the second participant was increased only 1.9%.

Discussion

Orthotic intervention in knee osteoarthritis is a non-surgical treatment and considered as a popular treatment (5, 18, 20).

Knee orthosis includes immobilizing orthosis, sleeves and unloader orthosis (28).

The main objective of the orthosis treatment is to reduce pain and improve function, and directly exerts valgus force on knee (12).

However, sleeves do not provide sufficient support for unstable joint (29). In the current study, the new unloader orthosis with settable pressure band was used to evaluate effect of it on pain, function, and life quality of three patients with osteoarthritis.

In order to evaluate participants, they filled out SF-36 and WOMAC questionnaires before and after using orthosis. The pain severity was also measured and recorded through VAS.

Patients with osteoarthritis have considerably lower quality of life (30). Studies indicate that using unloader orthosis in patients with knee osteoarthritis reduces pain and disability (12, 15-17, 20).

Results on wearing orthosis by the participants for six weeks showed that METOC orthosis reduces pain in individuals. This decline in pain was identified through VAS as well as WOMAC questionnaire.

Accordingly, the results of the current study were in line with the studies conducted regarding decline in pain by unloader orthosis (14, 17, 29) and decline in pain increases function and life quality.

The new orthosis also affects individuals' function and improves their performance. Some studies reported orthosis therapy as a positive effecting factor on life quality of individuals with osteoarthritis (11, 14, 31).

Given that findings of the study, despite short-term period of using the new orthosis, this orthosis also affects life quality of participants and improves life quality comparing to pre-using time. However this efficacy was greater in first and third patients.

As seen in the findings, the first and third participants reported greater pain prior to receive the new orthosis, and also they have greater limitations due to physical health comparing to the second participant. Pain and functional limitation are among factors effective in life quality, and based on the results of questionnaires of WOMAC and items of pain and physical function in SF-36 questionnaire, the new orthosis showed better efficacy in first and third participant, and thereby, the new orthosis was more effective in improving life quality of first and third participants. According to the findings of the current study, efficacy of the new orthosis in decreasing pain and improving personal function was greater than efficacy in life quality of participants and decrease in stiffness, and the underlying reason might be the short-term use of orthosis.

This study is a case report on three female participants, and

small sample size and lack of male participant were among limitations of this study, and thereby, the findings could not be generalized. The comfort of user in using the orthosis was not assessed in this study.

In addition, lack of assessment of the effect of the new orthosis on frontal angle and knee adduction force was among the limitations of the study.

Further studies through long-term assessment along with "Gait analysis" are warranted.

Conclusions

The current study showed that the METOC orthosis with settable pressure pad is able to decrease pain and improve function and promote life quality in short-term for the patient with knee medial compartment osteoarthritis.

However, it has no effect on improvement of knee stiffness. Performing numerous studies with larger sample size and gait analysis and the forces introduced to the organ while using orthosis are recommended.

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Conflict of interest:

None

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Authors' contributions:

Authors made substantial contributions to the conception, design, analysis, and interpretation of data.

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