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The effect of new unloader knee orthosis on walking in subjects with medial compartment knee osteoarthritis

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Abstract

Background: Current knee braces are not being used for extended periods by knee OA patients due interface problems; so compliance is an issue. The aim of this study was to design a new orthosis which could be providing the required correction to reduce medial compartment loading.

Case Description and Methods: A new knee orthosis was initially evaluated on walking in two volunteer subjects with grade 2 medial compartment knee OA.

Findings and Outcomes: The knee adduction angle was significantly reduced, and the speed of walking significantly increased when wearing the orthosis. An increase the knee range of motion, in step length was also observed with the orthosis.

Conclusion: The orthosis provided frontal plane correction of the knee during walking. It could therefore prove to be suitable for use by knee OA patients.

Keywords: Knee osteoarthritis, knee brace, gait, kinematic

Introduction

Any conservative treatment should demonstrate a positive effect on external knee adduction angle (1). Unloader knee orthoses are an alternative conservative method of treating knee osteoarthritis using direct application of forces to alter frontal plane knee alignment whilst simultaneously reducing the external knee adduction angle (2-15). They have also been shown to improve confidence, function, stiffness and varus rotation during walking (16). Draper et al. demonstrated that valgus braces immediately improved the function of patients with uni-compartmental osteoarthritis of the knee(17). Kirkley et al also demonstrated that such orthoses were effective in improving quality of life , function and pain in knee OA patients(18).

However, brace compliance is a problem (19). In this paper it was demonstrated that the use of the knee brace was less than 3 hours per day compared to insoles. This is likely to be due to the uncomfortable superstructure and non user-friendly designs and why these devices are not being used for extended periods by knee OA patients (20). Existing knee OA braces have mostly been adapted from designs, technology and materials previously used for braces designed to protect anterior cruciate-deficient knees, Current corrective knee orthoses, both bespoke and off the shelf (OTS), are fabricated from metal, thermoplastic or composite materials, and provide corrective forces via straps, adjustable superstructures or inflatable bladders on either the lateral or medial superstructure, which translate and rotate the proximal and distal segments of the knee towards corrective alignment. The clinical effect of using these systems over long periods may cause skin irritation (18, 21). This would indicate the need for a new design of bespoke orthosis to be developed based on providing both comfort and an adequate valgus/varus correction to reduce

medial knee loading. Therefore, the design and construction of a new design of knee orthosis that resolves these limitations along with proof of clinical efficacy is required. The aim of this study was therefore to develop a user-friendly OA knee orthosis incorporating a dynamic system and a superstructure specifically-aligned in a comfortable and corrected position for the knee, and to determine its effect on two subjects with knee osteoarthritis.

Method

Subjects

Two volunteer subjects (table 1) participated in this study. Subjects were referred

to the Orthotics & Prosthetics clinic of the University of Social Welfare and Rehabilitation

Sciences.

Referred subjects were assigned to participate in this study according to the following inclusion and exclusion criteria. pain in one or both knees, with grade 1 or 2 knee medial compartment osteoarthritis according to the Kellgren/Lawrence (KL) Scale which ranges from severity 0-4, with zero being the lowest rating(22) considered as inclusion criteria in this study. Subjects who had received any injury, or invasive treatment including injection therapy for the knee during the past 6 months, neurological disease, a symptomatic spine, hip, ankle or foot disease, skin problems, or any disease which made it difficult to apply a brace (e.g. due to arthritis in the hand or difficulty in bending) were excluded from study. Subjects wore a knee orthoses on the affected side. The ethical committee of University of Social Welfare and Rehabilitation Sciences approved the performance of this study and the subjects signed an informed consent form.

subject	Gender	Age(years)	Weight(kg)	Height(cm)	BMI(kg/m2)
1	female	61	69	154	29.01
2	female	56	86	171	29.41

Table1-descriptive characteristics of two subjects

Description of knee unloader orthoses

Subjects used a new design of knee unloader orthosis, which comprised of a lateral side bar design (Figure 1). The knee unloader orthoses were custom moulded and individually constructed from a cast of each subject's lower extremity. Valgus correction was performed manually during

the casting process by an experienced orthotist. The knee was corrected in the frontal plane to a less-varus position whilst the patient was sat down with the knee extended. It was corrected to the maximal corrected position which was still comfortable for the patient.

All orthoses construction was also performed by an experienced orthotist.

Design of the new knee orthosis was based on the convert knee flexion to abduction to prevent of knee joint varus in gait cycle. In end of the swing, needed varus position provided for positioning of knee joint in normal position in frontal plane in stance phase. Other purpose in new knee joint design was preparing compliance in subjects when knee joint have flexion position. Consequently convert of flexion to abduction must be active one sided. One pivot of translation and two pivot of rotation were considered in design of new knee orthosis to providing normal knee joint pattern when new knee orthosis was used. Figure 1 shows the new orthosis which used in this study.

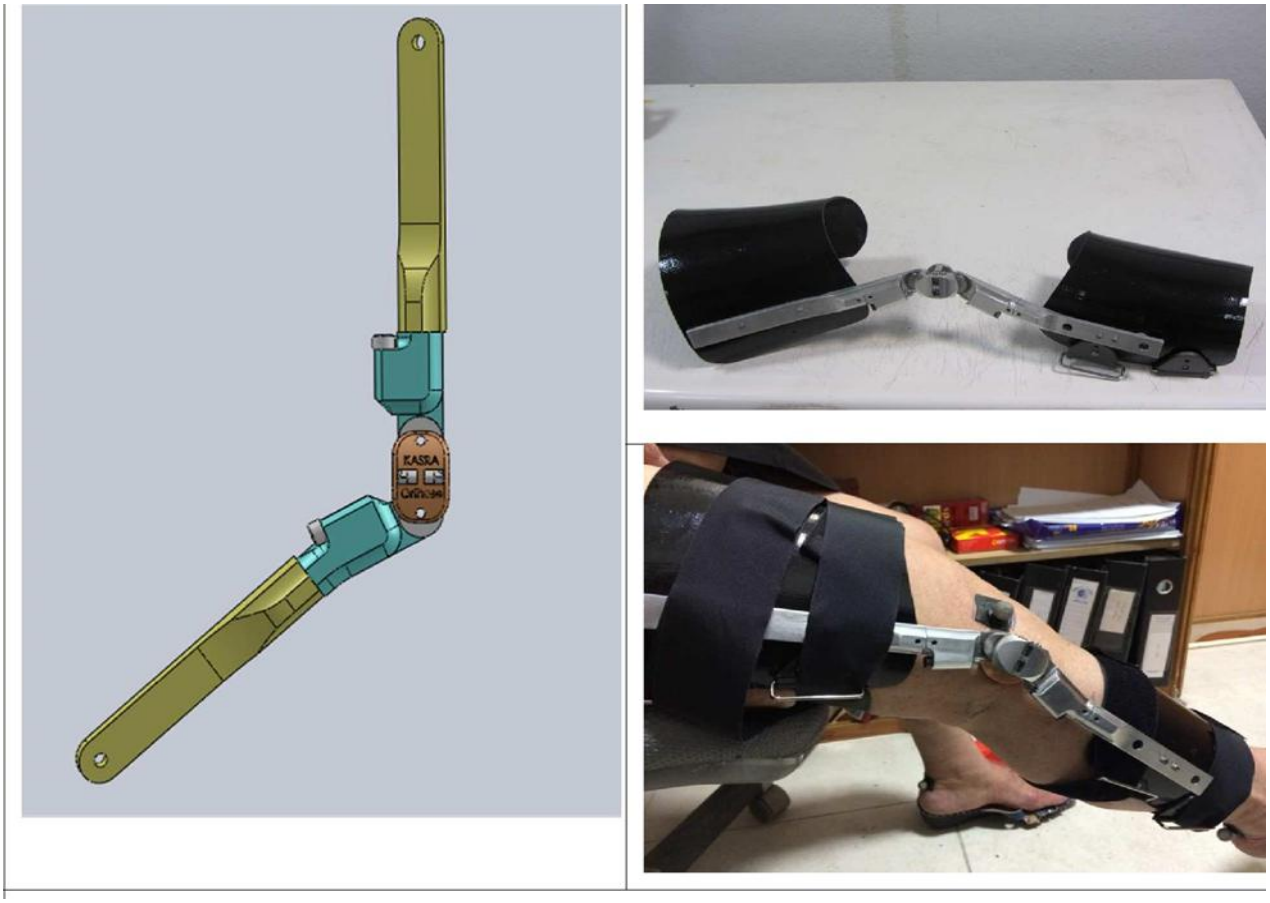

Figure 1: the new orthosis which used in this study.

Gait analysis

The gait of two patients was assessed in two conditions and in a random order (i.e. with and without the orthosis in situ). The subjects wore identically-styled lightweight, comfortable footwear for each gait analysis session. The shoe was selected to reflect a typical heel height and pitch which could be worn by subjects. They eventually walked along the walk way of the gait laboratory at their comfortable self-selected speed in each test condition in order to collect five data sets. Kinematics and kinetics data were gathered by a Vicon digital motion capture system (Oxford Metrics, UK), using six cameras (Vicon, Infrared model number 460) at a frequency of 100 HZ and two force platforms set apart and positioned to capture a left and right heel strike (Kistler 9286BA, Switzerland). The marker placements were based on those utilised in a previous paper (23). The knee range of motion maximum, externally applied knee adduction angle, walking speed, cadence and step length were analysed in this study. The two stance – phase variables of interest were peak adduction angle , mean adduction angle .these variables were extracted and averaged from five individual trials for each subject(24).

Results

Tables 2 and3 show the overall results of use of the new knee orthosis in this study. The external knee adduction angle was significantly reduced (figure2 and table2), and the speed of walking significantly increased when wearing the orthosis. An increase in the knee range of motion, step length was also observed with the orthosis (Table 2and

subject	Knee flexion stance maximum(Degree)		Knee flexion swing maximum(Degree)		Maximum knee adduction angle in stance phase(degree)		Maximum knee adduction angle in swing phase(degree)	
	with brace	without brace	with brace	without brace	with brace	without brace	with brace	without brace
1	24.46	25.51	46.19	44.728	2.3	4.25	11.78	11.76
2	44.94	46.13	56.04	54.386	2.34	5.3	1.71	1.75

Table2- flexion/extension angle (°) of the knee and maximum knee adduction angle in stance and swing phase on the affected side with and without orthosis

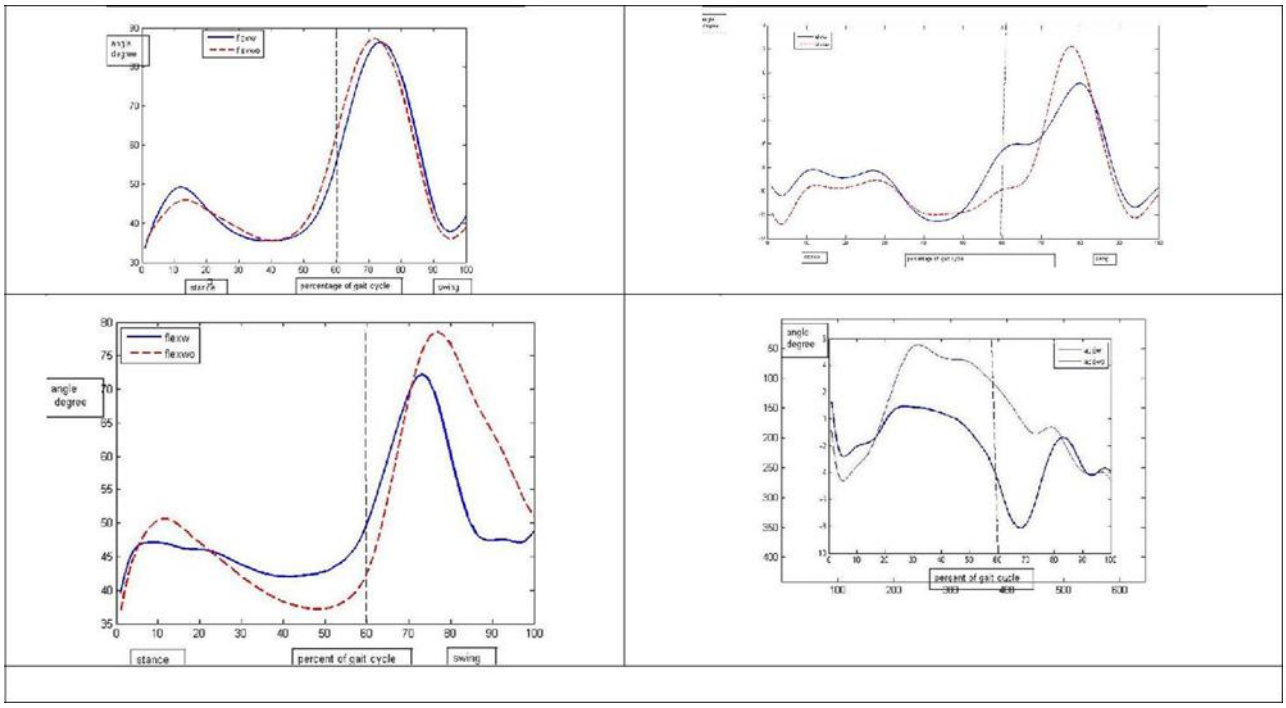

Figure2:graph

subject	Speed (m/s)		cadence (steps/min)		Stance phase (% of cycle)		Stride length (m)		Stride time (sec)		Double limb Support time (Sec)	
	with brace	without brace	with brace	without brace	with brace	without brace	with brace	without brace	with brace	without brace	with brace	without brace
1	0.93	0.88	91.24	89.60	62.68	63.53	1.145	1.125	1.24	1.32	0.16	0.164
2	0.748	0.684	68.965	62.50	61.05	63.37	1.45	1.142	1.66	1.815	0.21	0.434

Table3- temporal –spatial parameters of walking on the affected side with and without orthosis

DISCUTION:

This study sought to investigate if a new orthosis would influence walking in patients with mild or moderate knee OA. The findings of this present study showed significant decrease in the applied maximum external knee adduction angle and increased speed of walking as compared to without the orthosis when using the knee orthosis.

The knee orthoses used in this study applied a corrective force to the knee joint and reduced the external knee adduction angle in these patients. Schmalz et al(25) and Harrington et al(26) demonstrated that valgus-inducing knee brace can reduce approximately 10 percent of the produced external genu varus moment in the knee joint. This reduction in the external knee adduction moment is thought to be the main biomechanical mechanism in reducing knee pain, providing functional improvement and a more symmetrical gait pattern in knee osteoarthritis patients at early and middle stages of osteoarthritis. Although the external knee adduction moment was significantly reduced in this present study, the percentage reduction found in this study appears to be lower (3%) compared to previous studies and the reduction of 0.02 Nm/kg in this parameter may not be clinically relevant. The low (but significant) reduction in adduction moment may have been due to the volunteer subjects having KL1 and KL2 grade OA. Previous studies have involved subjects with these lower grades of OA classification (27). A larger study is therefore planned to include all grades of OA severity.

Using this new orthosis increased the immediate speed of walking in patients with medial compartment knee OA. Although the mean of this parameter was greater as compared to the

without-orthosis condition, this mean is still low as compared to healthy subjects of similar age.

An increase in step length linked with no significant difference in cadence when walking with the orthosis improved the speed of walking in these subjects. Factors such as an increased confidence in walking caused by a more stable knee joint when wearing an orthosis can cause this result.

Despite the knee ROM was same with the brace compared to the without brace condition, but the step length was longer with the brace. Patients with knee osteoarthritis have pain, instability of knee joint in stance and less ROM of hip joint (28, 29) during walking. According to these points can expect that improvement of pain and stability of knee joint and increase ROM of hip joint during walking with orthosis may be affected increased step length, although the structure of

orthosis may be influenced ROM of the knee joint in this study. The kinematics of hip and ankle joint was not analysed in this study, and further study will be beneficial in this field.

The new orthosis was designed to decrease the interface limitations demonstrated from wearing previous orthoses evidenced in the literature by providing frontal plane correction via close fitting custom made shells which would re-distribute load and providing the corrected form of knee frontal position in swing phase during ambulation. The reduction in knee adduction angle was still relatively small in value. The efficacy of the brace in unloading the medial compartment and therefore reducing pain levels is as yet not ascertained in a large population of people with medial compartment knee OA. This study was designed to give initial findings and therefore the results cannot be generalized to a large population.

The valgus/varus orientations of the uprights of the brace were positioned as dictated by the orthotist, and because this was the first clinical trial of the orthosis, caution was observed. It is the intention in a larger study to apply maximal corrective angulation via the brace in a larger study subject whilst still being comfortable for the participants.

The immediate effects of walking with the knee orthosis were assessed in this study. This point is one of the main limitations of this study. In addition the patients analysed as their own controls, therefore this study did not have a placebo control group. The small sample size and the lack of subjects with KL 3 and KL4 grade of OA were also limitations.

Conclusion

This case study illustrated the potential of a new knee orthosis as a conservative treatment approach for patients with mild medial compartment OA. A new knee orthosis has been constructed and is shown have immediate benefits in improvement of walking parameters and knee adduction angle in patients with mild medial knee OA.

References:

[1] Arazpour M, Bani MA, Hutchins SW, Jones RK, Babadi MH. Frontal plane corrective ability of a new unloader orthosis for medial compartment of the knee. Prosthetics and orthotics international. 2013;37(6):481-8.

[2] Arazpour M, Bani MA, Maleki M, Ghomshe FT, Kashani RV, Hutchins SW. Comparison of the efficacy of laterally wedged insoles and bespoke unloader knee orthoses in treating medial compartment knee osteoarthritis. Prosthetics and Orthotics International. 2012.

[3] Lindenfdd TN, Hewett TE, Andriacchi TP. Joint loading with valgus bracing in patients with varus gonarthrosis. 1997.

[4] Komistek RD, Dennis DA, Northcut EJ, Wood A, Parker AW, Traina SM. An in vivo analysis of the effectiveness of the osteoarthritic knee brace during heel-strike of gait. The Journal of arthroplasty. 1999;14(6):738-42.

[5] Pollo FE, Otis JC, Backus SI, Warren RF, Wickiewicz TL. Reduction of medial compartment loads with valgus bracing of the osteoarthritic knee. The American journal of sports medicine. 2002;30(3):414-21.

[6] Draganich L, Reider B, Rimington T, Piotrowski G, Mallik K, Nasson S. The effectiveness of self-adjustable custom and off-the-shelf bracing in the treatment of varus gonarthrosis. The Journal of Bone & Joint Surgery. 2006;88(12):2645-52.

[7] Self BP, Greenwald RM, Pflaste DS. A biomechanical analysis of a medial unloading brace for osteoarthritis in the knee. Arthritis Care & Research. 2001;13(4):191-7.

[8] Gaasbeek RDA, Groen BE, Hampsink B, van Heerwaarden RJ, Duysens J. Valgus bracing in patients with medial compartment osteoarthritis of the knee: a gait analysis study of a new brace. Gait & Posture. 2007;26(1):3-10.

[9] Kerrigan DC, Lelas JL, Goggins J, Merriman GJ, Kaplan RJ, Felson DT. Effectiveness of a lateral-wedge insole on knee varus torque in patients with knee osteoarthritis. Archives of physical medicine and rehabilitation. 2002;83(7):889-93.

[10] Kakihana W, Akai M, Nakazawa K, Naito K, Torii S. Inconsistent knee varus moment reduction caused by a lateral wedge in knee osteoarthritis. American journal of physical medicine & rehabilitation. 2007;86(6):446-54.

[11] Hinman RS, Payne C, Metcalf BR, Wrigley TV, Bennell KL. Lateral wedges in knee osteoarthritis: What are their immediate clinical and biomechanical effects and can these predict a three-month clinical outcome? Arthritis Care & Research. 2008;59(3):408-15.

[12] Stamenović D, Kojić M, Stojanović B, Hunter D. Pneumatic osteoarthritis knee brace. Journal of biomechanical engineering. 2009;131(4):045001.

[13] Fantini Pagani CH, Potthast W, Brüggemann GP. The effect of valgus bracing on the knee adduction moment during gait and running in male subjects with varus alignment. Clinical Biomechanics. 2010;25(1):70-6.

[14] Fantini Pagani CH, Böhle C, Potthast W, Brüggemann GP. Short-term effects of a dedicated knee orthosis on knee adduction moment, pain, and function in patients with osteoarthritis. Archives of physical medicine and rehabilitation. 2010;91(12):1936-41.

[15] Esrafilian A, Karimi MT, Eshraghi A. Design and Evaluation of a New Type of Knee Orthosis to Align the Mediolateral Angle of the Knee Joint with Osteoarthritis. Advances in Orthopedics. 2012;2012.

[16] Draganich L, Reider B, Rimington T, Piotrowski G, Mallik K, Nasson S. The effectiveness of self-adjustable custom and off-the-shelf bracing in the treatment of varus gonarthrosis. The Journal of Bone and Joint Surgery. 2006;88(12):2645.

[17] Draper E, Cable J, Sanchez-Ballester J, Hunt N, Robinson J, Strachan R. Improvement in function after valgus bracing of the knee: an analysis of gait symmetry. Journal of Bone and Joint Surgery-British Volume. 2000;82(7):1001.

[18] Kirkley A, Webster-Bogaert S, Litchfield R, Amendola A, MacDonald S, McCalden R, et al. The effect of bracing on varus gonarthrosis. The Journal of Bone and Joint Surgery. 1999;81(4):539.

[19] Jones RK, Nester CJ, Richards JD, Kim WY, Johnson DS, Jari S, et al. A comparison of the biomechanical effects of valgus knee braces and lateral wedged insoles in patients with knee osteoarthritis. Gait & Posture. 2012.

[20] Felson DT, Naimark A, Anderson J, Kazis L, Castelli W, Meenan RF. The prevalence of knee osteoarthritis in the elderly. The Framingham Osteoarthritis Study. Arthritis & Rheumatism. 2005;30(8):914-8.

[21] Richards J, Sanchez-Ballester J, Jones R, Darke N, Livingstone B. A comparison of knee braces during walking for the treatment of osteoarthritis of the medial compartment of the knee. Journal of Bone and Joint Surgery –British volume.2005;87(7):937.

[22] Kellegren J, Lawrence J. Radiological assessment of osteoarthritis. Ann Rheum Dis. 1957;16:494- 501.

[23] Arazpour M, Bani MA, Maleki M, Ghomshe FT, Kashani RV, Hutchins SW. Comparison of the efficacy of laterally wedged insoles and bespoke unloader knee orthoses in treating medialcompartment knee osteoarthritis. Prosthetics and Orthotics International. 2013;37(1):50-7.

[24] Miyazaki T, Wada M, Kawahara H, Sato M, Baba H, Shimada S. Dynamic load at baseline can predict radiographic disease progression in medial compartment knee osteoarthritis. Annals of the Rheumatic Diseases. 2002;61(7):617-22.

[25] Schmalz T, Knopf E, Drewitz H, Blumentritt S. Analysis of biomechanical effectiveness of valgus-inducing knee brace for osteoarthritis of knee. J Rehabil Res Dev. 2010;47(5):419-29.

[26] Harrington IJ. Static and dynamic loading patterns in knee joints with deformities. The Journal of bone and joint surgery American volume. 1983;65(2):247.

[27] Larsen BL, Jacofsky MC, Brown JA, Jacofsky DJ. Valgus Bracing Affords Short-Term Treatment Solution Across Walking and Sit-To-Stand Activities. The Journal of arthroplasty. 2013.

[28] Astephen JL, Deluzio KJ, Caldwell GE, Dunbar MJ. Biomechanical changes at the hip, knee, and ankle joints during gait are associated with knee osteoarthritis severity. Journal of Orthopaedic Research. 2008;26(3):332-41.

[29] Al-Zahrani K, Bakheit A. A study of the gait characteristics of patients with chronic osteoarthritis of the knee. Disability & Rehabilitation. 2002;24(5):275-80.