Knee Surg Sports Traumatol Arthrosc
DOI 10.1007/s00167-012-2174-4

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Is valgus unloader bracing effective in normally aligned individuals: implications for post-surgical protocols following cartilage restoration procedures

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Received: 9 April 2012 / Accepted: 30 July 2012

Abstract
Purpose Utilizing valgus unloader braces to reduce medial compartment loading in patients undergoing cartilage restoration procedures may be an alternative to non-weightbearing post-operative protocols in these patients. It was hypothesized that valgus unloader braces will reduce knee adduction moment during the stance phase in healthy subjects with normal knee alignment.
Methods Gait analysis was performed on twelve adult subjects with normal knee alignment and no history of knee pathology. Subjects were fitted with an off-the-shelf adjustable valgus unloader brace and tested under five conditions: one with no brace and four with increasing valgus force applied by the brace. Frontal and sagittal plane knee angles and external moments were calculated during stance via inverse dynamics. Analyses of variance were used to assess the effect of the brace conditions on frontal and sagittal plane joint angles and moments.
Results With increasing tension in the brace, peak frontal plane knee angle during stance shifted from 1.6° ± 4.2° varus without the brace to 4.1° ± 3.6° valgus with maximum brace tension ($P = 0.02$ compared with the no brace condition). Peak knee adduction moment and knee adduction impulse decreased with increasing brace tension (main effect of brace, $P < 0.001$). Gait velocity and sagittal plane knee biomechanics were minimally affected.
Conclusion The use of these braces following a cartilage restoration procedure may provide adequate protection of the repair site without limiting the patient's mobility.
Level of evidence Therapeutic prospective comparative study, Level II.

Keywords Knee adduction moment · Valgus unloader brace · Gait analysis

Introduction

Due to limited healing abilities and the propensity to further degenerate, large osteochondral lesions are often treated by surgical intervention (i.e. mosaicplasty, microfracture or autologous chondrocyte implantation) [1, 4, 14, 22, 26]. Following cartilage restoration procedures, reduced loading at the repair site is essential for healing and graft incorporation [6, 12]. Typical protocols recommend 6–12 weeks of non- or partial weightbearing [6, 12]. Patients undergoing these procedures are often young and lead a physically active lifestyle, which could lead to difficulty in maintaining the required limited weightbearing status [7]. Non-compliance with the post-operative protocol could overload the repair and jeopardize the success of the procedure. Additionally, some patients, when faced with prolonged limited weightbearing during the rehabilitation period, will elect not to have the surgery, which greatly increases their chances of developing further cartilage degeneration [4, 14, 22, 26]. Therefore, maintaining patient mobility while unloading the repair site is an important post-surgical consideration.

Clinically, utilizing valgus unloader braces to reduce medial compartment loading while maintaining patient mobility may be an alternative to a non- or partial weightbearing protocol in these patients. Given the difficulty in measuring medial compartment load in vivo, knee adduction moment is often used as a surrogate measurement [3]. Knee

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adduction moment during the stance phase is a typical characteristic of normal human gait and is present due to the resultant ground reaction force passing medial to the centre of the knee joint [10]. Consequently, as much as 60–80 % of the total load across the knee passes through the medial compartment [2, 3, 10, 20, 21].

Valgus unloader braces have been shown to be an effective, non-invasive treatment option for patients with isolated medial compartment arthritis and varus alignment [24]. Studies have shown that by shifting the knee to a more valgus position, patients experience a reduction in pain and knee adduction moment during the stance phase of gait [5, 9, 11, 19]. However, the effectiveness of these braces in normally aligned subjects has not been evaluated. If shown to be effective in normally aligned individuals, valgus unloader braces could provide adequate protection of the repair site following cartilage restoration procedures without limiting the patient's mobility and allow patients to maintain a higher level of activity during the recovery and rehabilitation period. The purpose of this study was to evaluate the effect of a valgus unloader brace on knee adduction moment during gait in normally aligned healthy individuals with no evidence of arthrosis. Based on previous results seen in subjects with medial compartment osteoarthritis, we hypothesized that valgus unloader braces will reduce knee adduction moment during stance phase in healthy subjects with normal knee alignment.

Materials and methods

Gait analysis was performed on twelve (9 males, 3 females; age: 32 ± 10 years; height: 1.74 ± 0.10 m; weight: 75.2 ± 11.2 kg) healthy adult subjects. For inclusion in this study, subjects were required to have normal frontal plane knee alignment and no current knee pain. Subjects were excluded if they had lower extremity injury or surgery within the past year, any pre-existing gait abnormality or evidence of symptomatic knee osteoarthritis. Symptomatic osteoarthritis was ruled out by physical examination by an orthopaedic surgeon and by subject self-report. Prior to participation, subjects provided informed consent in accordance with the Institutional Review Board.

Subjects were fitted with an off-the-shelf adjustable valgus unloader brace (DonJoy OA Adjustor Medial Unloader Brace, *DonJoy Orthopaedics*, *Vista*, *CA*) and tested under five conditions: one with no brace and four with increasing valgus force applied by the brace. Valgus force was increased by turning the screws located above and below the joint on the side of the brace. The test conditions involving the brace were neutral position (screws at loosest setting), screws tensioned one half-turn, screws tensioned one full-turn and screws tensioned maximally (approximately one-and-a-half turns).

Kinematic and ground reaction force data were recorded as subjects walked at self-selected pace across a six-metre walkway. Reflective markers were placed over the calcaneus, first and fifth metatarsals, medial and lateral malleoli, anterior lower leg, medial and lateral femoral condyles, anterior thigh, greater trochanter, sacrum and anterior superior iliac spine of the dominant leg and the greater trochanter and anterior superior iliac spine of the contralateral leg. Marker positions were collected at 60 Hz using five infrared cameras (Qtrac, Qualisys, Gothenburg, Sweden). The motion data were then filtered with a fourth-order Butterworth low-pass filter with a cut-off frequency of 10 Hz in order to eliminate any high-frequency noise. Ground reaction forces (GRF) were recorded at 960 Hz with a multi-component force plate (Kistler Instrument Corp., Amherst, NY, USA) incorporated into the walkway. Subjects performed three trials under each condition and were instructed to walk as naturally as possible contacting the force plate with only the instrumented limb. Trials in which the foot did not land completely on the force plate or the subject altered his or her gait pattern to target the force plate were discarded, and the trial was repeated.

The static frontal plane knee alignment of each subject was measured from the neutral-posture standing trial taken before the start of the gait trials (Fig. 1). Sagittal (flexion/extension) and frontal plane (adduction/abduction) knee angles and external moments were calculated during the stance phase of gait (heel strike to toe off) using specialized computer software (Visual 3D, C-Motion, Inc., Rockville, MD, USA). Knee flexion, knee flexion moment, knee adduction and knee adduction moment were defined as positive values. Knee adduction impulse was then calculated by determining the area under the knee adduction moment curve over the duration of the stance phase.

Statistical analysis

The effect of the brace conditions on the first and second peaks in the knee adduction moment, as well as the knee adduction impulse, was assessed via repeated-measures ANOVA. Additional repeated-measures ANOVA were used to assess the effect of the brace on gait velocity, stance time, frontal plane knee angle at heel strike, peak frontal plane knee angle during stance, peak flexion angle during early stance and peak knee flexion moment. Bonferroni corrections were applied to planned post hoc comparisons between the no brace condition and each condition of increasing brace tension where applicable. $P < 0.05$ was considered significant. Previous reliability analysis on gait data from our laboratory has shown that with 12 subjects, we can detect changes of 5° for peak knee

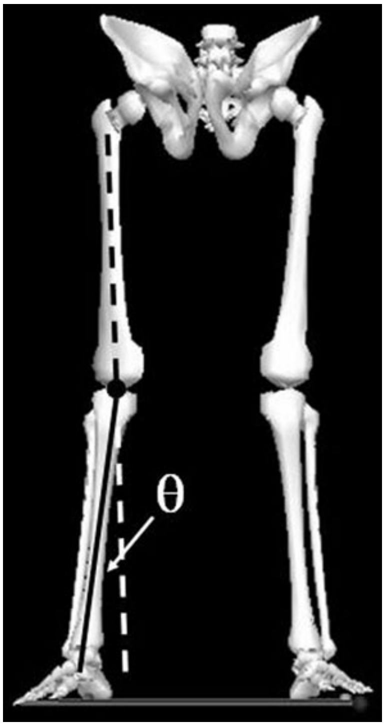

Fig. 1 Determination of frontal plane knee alignment from the standing neutral trial. Subjects stood stationary in the centre of the recording area in their normal upright posture. Frontal plane knee alignment (θ) was defined as the angle of the lower leg relative to the thigh. A *negative* value indicates valgus alignment, while a positive value indicates varus

adduction angle and 15 % for knee adduction moment ($P < 0.05$, 80 % power). [18].

Results

Mean static frontal plane knee alignment was −2.2° ± 3.8° with a range of −7.3°–3.7°. These values are in agreement with previously published measures of frontal plane lower extremity alignment in healthy, normal subjects [15, 17].

During gait, frontal plane knee angle at heel strike decreased from −1.3° ± 4.3° in the no brace condition to −5.7° ± 4.3° in the full-turn condition ($P = 0.012$) and further to −6.7° ± 5.0° with the brace at maximal tension ($P = 0.02$). Peak frontal plane knee angle during stance shifted from 1.6° ± 4.2° in the no brace condition to −3.4° ± 4.3° in the full-turn condition ($P = 0.031$). With the brace maximally tensioned, peak frontal plane knee angle further decreased to −4.1° ± 3.8° ($P = 0.02$ compared with the no brace condition) (Fig. 2a).

Both peaks in knee adduction moment decreased with increasing brace tension (Fig. 2b). Compared with the no brace condition, the first peak in knee adduction moment was decreased by 24.7 % in the full-turn condition and 29.4 % in the maximal tension condition ($P = 0.020$, $P = 0.002$, respectively). The second peak in knee adduction moment was decreased by 25.7 % in the half-

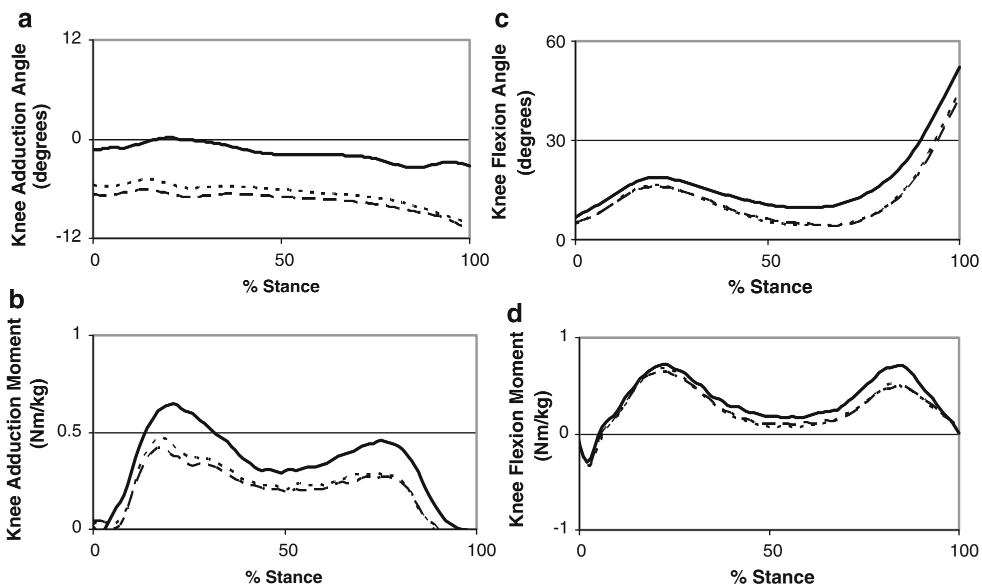

Fig. 2 Ensemble averages of frontal (**a**, **b** adduction positive) and sagittal (**c**, **d**; flexion positive) plane knee angles and moments during stance phase. For clarity and due to the fact that most significant pairwise differences were found between these conditions, only the no brace (*solid line*), full-turn (*doted line*) and the maximal tension (*spaced line*) conditions appear in the figures. As the brace tension is increased, frontal plane knee angle shifted to a more valgus position (**a**). Additionally, both the first and second peaks of the knee adduction moment were significantly reduced (**b**). Sagittal plane knee angle and moment were minimally affected (**c**, **d**)

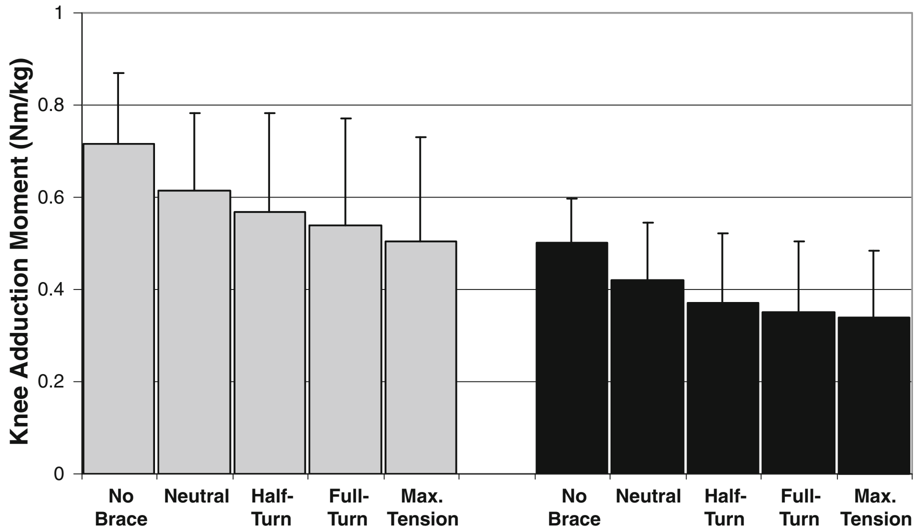

Fig. 3 Changes in first (*grey bars*) and second (*black bars*) peak knee adduction moments by brace status. The first peak in adduction moment was significantly reduced in the full-turn ($P = 0.02$) and the maximal tension conditions ($P = 0.002$) compared with the no brace condition. The second peak in adduction moment was significantly reduced in the half-turn ($P = 0.041$), full-turn ($P = 0.021$) and the maximal tension conditions ($P = 0.007$) compared with the no brace condition

turn, 30.1 % in the full-turn and 32.3 % in the maximal tension conditions ($P = 0.041$, $P = 0.021$, $P = 0.007$, respectively) (Fig. 3). Knee adduction impulse was significantly decreased in the full-turn (31.1 %, $P = 0.049$) and maximal tension conditions compared with the no brace condition (36.9 %, $P = 0.021$) (Fig. 4).

Gait velocity and stance time were unaffected by the brace. Knee flexion at heel strike was not affected by the brace, while peak knee flexion angle during early stance was significantly decreased in the braced conditions (main effect brace: $P = 0.039$). Wearing the brace resulted in a non-significant decrease of approximately 18 % in peak knee flexion moment during stance (Table 1; Fig. 2c, d).

Discussion

The most important finding of the present study was that using an off-the-shelf valgus unloader brace reduced knee adduction angles and moments in normally aligned subjects. With the adjustment screws tightened one full-turn, peak frontal plane knee angle during stance decreased approximately 4° into valgus alignment. The first and second peaks in knee adduction moment decreased 25 and 30 %, respectively, compared with the unbraced condition. Additionally, knee adduction impulse decreased 31 %. Under these conditions, subjects were able to maintain a gait velocity similar to that achieved in the unbraced condition, and there were minimal effects on sagittal plane knee biomechanics.

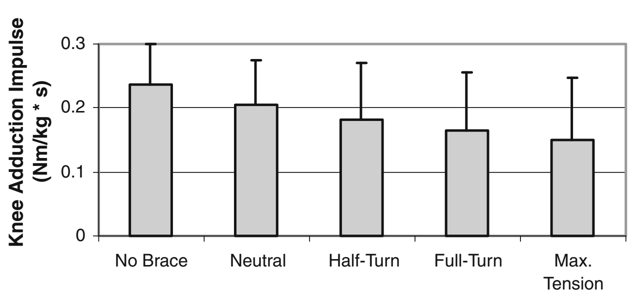

Fig. 4 Changes in knee adduction impulse by brace status. Knee adduction impulse over the stance phase was significantly reduced in the full-turn ($P = 0.049$) and the maximal tension conditions ($P = 0.021$) compared with the no brace condition

These results compare favourably with previous studies investigating the effects of custom-fit unloader braces on knee adduction moment in patients with osteoarthritis. Pollo et al. [19] reported reductions of 13–20 % in knee adduction moment compared with the unbraced condition [19]. Similar decreases have also been reported by Draganich et al. [5] (15 %) and Lindenfeld et al. [13] (10 %). In all of these studies, patients were symptomatic and had joint space narrowing or varus deformity as measured by standing radiographs. In the current study, static frontal plane knee alignment as measured from each subject's standing posture ranged from −7.3° (valgus) to 3.7° (varus) and was within previously published ranges of frontal plane lower extremity alignment in healthy, normal subjects [15, 17]. Considering our results in the context of previous research, valgus unloader braces seem to be just as effective in reducing knee adduction moment during gait in normally aligned subjects as they are in patients with osteoarthritis and varus deformity. From a clinical point of view, unloader braces reduce a surrogate measurement and key contributor to medial compartment load (i.e. knee adduction moment). Thus, these braces may provide adequate protection of the repair site following cartilage restoration procedures without limiting the patient's mobility and allow patients to maintain a higher level of activity during the recovery and rehabilitation period.

Table 1 Gait velocity and sagittal plane biomechanical data in the no brace and various braced conditions

	No brace	Neutral	Half-turn	Full-turn	Max	*P*
Gait velocity (m/s)	1.3 ± 0.1	1.3 ± 0.1	1.3 ± 0.1	1.3 ± 0.1	1.3 ± 0.1	n.s.
Stance time (s)	0.7 ± 0.03	0.7 ± 0.05	0.7 ± 0.04	0.7 ± 0.03	0.7 ± 0.03	n.s.
Knee flexion at heel strike (°)	6.7 ± 4.7	5.0 ± 6.6	4.9 ± 6.3	4.6 ± 6.3	5.0 ± 6.5	n.s.
Peak flexion angle during early stance (°)	19.6 ± 5.1	15.5 ± 7.5	15.5 ± 7.9	15.9 ± 6.9	16.0 ± 7.1	0.039
Peak flexion moment (Nm/kg)	0.9 ± 0.2	0.8 ± 0.3	0.8 ± 0.4	0.7 ± 0.3	0.8 ± 0.3	n.s.

There are some limitations that warrant mention. First, this study had a small sample size (12 subjects) that was predominantly male. The greater degree of lower extremity valgus alignment documented in females compared with males may influence the effectiveness of the valgus unloader brace in shifting the knee to a more abducted position [17, 23]. Therefore, more studies are needed to investigate the brace's effectiveness in females and to compare these biomechanical changes between genders. Second, the level of medial compartment load needed to protect a cartilage restoration procedure and to promote healing is not known. More studies are needed to identify the tolerances of these repair techniques to compressive loads and to assess the effects of other factors such as the size and the location of the repair on these tolerances. Third, the relationship between frontal plane knee alignment, knee adduction moment and medial compartment contact pressure is not well defined. In a radiographic study, Hsu et al. [8] found that medial joint load decreased with increasing valgus alignment. However, it cannot be assumed that this relationship is valid during a dynamic activity such as walking. While knee adduction moment is often used as a surrogate measure for medial compartment contact pressure, studies have shown that peaks in medial compartment contact forces during gait are best predicted by a combination of frontal and sagittal plane moments [16, 25, 27]. However, as medial compartment compressive force may not decrease with decreasing knee adduction moment alone, supplementary measurements such as joint space width may be needed to ascertain the true level of medial compartment off-loading.

Conclusion

Valgus unloader braces effectively shift the knee into a more valgus position and decrease knee adduction moment during gait in healthy subjects with normal alignment. These braces may provide adequate protection of the repair site, following cartilage restoration procedures without limiting the patient's mobility. More research, in the form of prospective trials, is needed to determine the most favourable time in the recovery and rehabilitation process to introduce them in order to optimize healing and function.

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