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Running head: Unloader Brace & Knee Function, Strength

Does Valgus Unloader Brace Dosage Alter Knee Pain, Function and Muscle Strength?

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Abstract

Objective: Valgus unloader braces are advocated in knee osteoarthritis management guidelines to reduce joint loading. This study examined whether there was a dose response for brace wear on knee pain, function and muscle strength. **Design:** In this cohort study, 24 participants were followed for approximately 6 months. **Setting:** Recruitment was conduced in the general community, and testing was performed in the Dynamics of Human Motion laboratory at Dalhousie University. **Participants:** A convenience sample of 33 patients with medial compartment knee osteoarthritis, who were prescribed a valgus unloader brace agreed to participate, met the inclusion criteria and completed the baseline data collection. Twenty-four participants (20 men, 4 women) completed baseline and follow-up collections. **Interventions:** Participants wore their valgus unloader brace as needed. **Main Outcome Measures:** Knee extensor, flexor and plantar flexor strength was tested at baseline and follow-up. Participants filled out WOMAC and SF-36 questionnaires to assess pain and function. Brace usage (dose) and activity (step count) were recorded at least four days/week for the study duration. **Results:** At follow-up, there were trends toward improvements in pain ($p=0.059$), function ($p=0.089$), and hamstrings strength ($p=0.013$). Positive relationships existed between brace wear usage and percent change in step count ($r=0.59$, $p=0.006$) and percent change in hamstrings strength ($r = 0.37$, $p = 0.072$). **Conclusions:** Our results agree with previous literature showing improvements in pain and function, but these were not related to brace wear dose. But more important was the finding of no decreased muscle strength, and a positive relationship showing improved hamstrings strength and physical activity with increased dose, not previously reported.

Key Words: Osteoarthritis, Knee, Braces, Muscle Strength

Abbreviations:

ACL: Anterior Cruciate Ligament

KL: Kellgren-Lawrence

MVIC: Maximum Voluntary Isometric Contraction

NSAIDs: Non-Steroidal Anti-Inflammatory Drugs

OA: Osteoarthritis

Osteoarthritis (OA), particularly knee OA, is one of the most common musculoskeletal disease-related causes of disability. Prevalence has increased dramatically recently; the National Arthritis Data Workgroup estimated nearly 27 million U.S. adults are diagnosed with OA, up from 21 million in 1995[1]. This number is expected to rise to 67 million people (30% of the adult population) by 2030[1] with similar increases projected in Canada[2]. OA results in huge economic burden; with direct health care expenditures related to arthritic conditions costing $328.1 billion in the U.S. in 2003[3] and $4.4 billion in Canada[2]. Because of the progressive nature of knee OA, those in the moderate stage have the most potential to benefit from conservative interventions aimed at slowing disease progression. In fact, conservative interventions have been named as the most important healthcare need for those with OA[4].

Biological and mechanical factors are important in genesis and progression of knee OA[5-8]. Most pharmaceutical treatments aim to relieve symptoms, and include non-steroidal anti-inflammatory drugs (NSAIDs) and acetaminophen. These symptom-modifying interventions are advocated in management guidelines[9,10] with few treatments aimed at cartilage repair[6,11,12]. Concern has been raised over the effect of masking pain on joint loading. Gait studies have shown increased knee loads following pain reduction[13,14]. This could lead to disease progression. Ding et al[15] confirmed this by reporting increased long-term cartilage loss with NSAIDs users compared to non-users. Interventions aimed at modifying the knee mechanical loading environment, while included in guidelines[6,9,16,17], have not been studied as extensively and our understanding of their effectiveness and potential value in slowing disease progression is not well understood. Knee unloader braces are one example of a conservative intervention aimed at altering knee loads.

Since knee OA typically occurs in the medial tibiofemoral compartment[18,19], the most common type of unloader brace is the valgus knee brace. This brace is designed to apply a valgus moment about the knee joint, altering the frontal plane knee alignment, and shifting the load laterally[20]. Valgus unloader braces have been shown to improve pain[21-30] and self-reported function[25,27,28,31]. Objectively, increases in walking distance and speed have been reported[30,31]. Three-dimensional gait analysis studies have provided evidence that the brace does reduce the knee adduction moment during stance[20,22,30,32], indicating reduced medial compartment loading[33]. Controversy exists however with respect to long-term improvements in joint loading[34] and with respect to the mechanism by which the braces work to improve the mechanical environment[35-37].

One area not well understood is brace wear prescription. There is a wide spectrum of prescription in the literature[21,23-25,28,31,34,36,38]. How this translates into understanding brace prescription is difficult, particularly because poor compliance rates have been noted[31,39]. Giori et al (2004)[39] found a 49% drop-out rate over 2.5 years, and Brouwer et al (2006)[31] found that 42% of participants stopped using the brace within one year. The most common reason for non-compliance reported in this study was that there were no noticeable effects of brace wear[31]. Unfortunately, neither study indicates how often nor for what duration the participants wore their brace, making it impossible to modify guidelines to improve compliance. Only one study asked participants to report hours of daily brace wear[34]. Participants were asked to wear the brace as needed and reported brace wear of 6.9 (4.6) hours/day, 5.2 (2.1) days/week. Again, poor compliance was demonstrated, with a drop-out rate of 35% after 9 weeks. Hurley (2003)[40] recognized that traditional randomized controlled trials may be too restrictive in evaluating interventions in which participants reside in the community and have comorbidities and uncontrollable external variables that might influence their ability to comply with the intervention. For these reasons, monitoring how often and for how long participants wear their brace, and looking at brace wear dose response may be a more realistic study design.

In addition to not fully understanding prescription, a detrimental side-effect of braces that has not been examined is the association between brace wear and muscle impairment. Thigh muscle atrophy has been associated with functional knee bracing in anterior cruciate ligament (ACL) deficient knees[41], as has decreased hamstrings performance[42], decreased quadriceps torque[43,44], and premature muscle fatigue[45]. Impairment is hypothesized to result from poor tissue oxygenation caused by decreased blood flow to the muscle during relaxation, due to increased external compression from the brace straps[45]. Only one study has looked at the effect of valgus knee bracing on strength[23]. Matsuno et al (1997)[23] had 20 participants (76 years) with severe knee OA (Kellgren-Lawrence (KL) grade of 3 or more and surgical candidates) wear a valgus brace "as much as possible" for one year. At follow-up, peak isokinetic knee extensor torque had significantly increased. However, no indication of how often and for what duration the participants wore the brace was provided. The effect of valgus bracing on strength of the periarticular muscles in those who are less severe and not surgical candidates has not been explored. This is an important area to address, as decreased muscle function has been proposed as a risk factor for knee OA progression[46,47].

The study objectives were to determine whether there was a dose response for valgus unloader brace wear over 6 months on i) pain, ii) function (self report and objective) and iii) knee extensor, flexor and plantar flexor strength. Participants were asked to fill out weekly questionnaires detailing brace usage. We hypothesized pain and function would improve with brace wear, consistent with the literature, but participants who wore the braces for longer durations would show greater strength decreases compared to those who wore the brace less.

Methods

Patients were referred to the study if they had medial compartment primary knee OA (i.e. of non-traumatic origin) confirmed with radiographs or magnetic resonance imaging and clinical symptoms according to Altman (1987)[48]. Patients were prescribed a valgus unloader brace by one orthopaedic surgeon (WDS). To be included patients had to meet a moderate classification based on i) their self reported ability to perform three functional tasks (walk a city block, jog 5 meters and walk up a flight of 10 stairs in a reciprocal manner), and ii) that they were not on a total knee arthoplasty wait list[49] Patients were excluded if they had prior surgery to the involved lower limb (excluding exploratory arthroscopy, lavage of the knee and partial menisectomy at least one year prior to study entry), or any neurological, cardiovascular or other musculoskeletal condition that would affect their gait or safety while participating. All patients prescribed a brace were given the option to participate, regardless of whether they intended to use it. Of the 44 patients identified who met the inclusion criteria, 32 agreed to participate and completed the baseline data collection (73%).

Valgus unloader braces were custom-fit by one physiotherapist and applied a 5-degree angle offset to the participant's varus knee angle. After a two-week accommodation period, participants returned to the physiotherapist to ensure they were wearing the brace correctly and were instructed to 'wear as needed'. Following this appointment, participants visited the Dynamics of Human Motion laboratory at Dalhousie University. Participants signed an informed consent and the study protocol was approved by the Dalhousie University Ethics Review Board.

Data for this study is part of a larger study examining three-dimensional gait biomechanics and neuromuscular control parameters associated with brace wear. This study focused on strength, self reported pain and function and temporal gait measures. At baseline, participants filled out WOMAC[50] and SF-36[51] health outcome questionnaires. Mass, height and other anthropometric measures were recorded, and participants were asked about their current OA-related medication usage. The presence of effusion was assessed using the brush test and graded as present or absent. This measure has been found to have a reliability coefficient of 0.97 when assessing those with knee OA[52]. Participants walked along a 6 m walkway at their self selected pace and velocity and stride length were determined from force plate and motion data consistent with our previously published standardized protocol[53-55]. Strength was measured using maximum voluntary isometric contractions (MVIC) against a dynamometer (Cybex International, Medway, MA, USA). Five standardized exercises were performed: i) knee extension with the participant seated and the knee at 45º of flexion (KE45), ii) knee extension with the participant supine and the knee at 15º of flexion (KE15), iii) knee flexion with the participant seated and the knee at 55º of knee flexion (KF55), iv) knee flexion with the participant supine and the knee at 15º of knee flexion (KF15), and v) plantar flexion with the participant in long-sitting with the ankle in neutral (PF)[56]. Each contraction was held three-seconds and performed twice, with 90 seconds of rest between contractions. Verbal and visual feedback and opportunity to practice was provided.

Custom software written in Matlab™ (MathWorks Inc, Natick, MA, USA) was used for all data processing. The maximum, gravity-corrected torque was determined for each exercise using a one-second window of steady-state torque from each contraction[56]. Torques in Nm were normalized to body mass (kg).

Following the walking trials and strength assessment, participants received instruction on completing the standardized weekly brace wear questionnaire, and were given a pedometer (StepsCount™, Deep River, ON, Canada) to wear on their waistband during their waking hours. The questionnaire included tables to log brace wear (hours per day), as well as step counts. Participants also recorded whether they had any physiotherapy treatment each week. Step count was calculated as the mean step count per week, averaged over the first three weeks (for baseline) or the last three weeks (for follow-up) of the study. Participants were instructed to complete the questionnaire at least four days/week: three weekdays, one weekend day. They could submit weekly questionnaires electronically or through mail. Compliance was monitored via email or telephone biweekly.

Approximately 6 months later, participants returned to the laboratory for follow-up testing. The same protocol described above was completed. Between baseline and follow-up, 8 participants dropped out of the study or were excluded (2 had surgery (1 high tibial osteotomy, 1 microfracture surgery), 1 was added to the total knee arthroplasty waitlist, 3 could not be contacted for follow up, 1 had a hamstring tear, and 1 was non-compliant filling out brace wear data on the questionnaire), leaving 24 participants (75%) who completed both baseline and follow-up collections. The mean time between baseline and follow-up was 193 (21) days.

Radiographic images were scored (WDS) based on the Kellgren Lawrence scale[57] with 2 participants having a KL score of 4, 9 with a KL score of 3, 5 with a KL score of 2, and 3 with a KL score of 1. Medial and lateral joint space narrowing was scored based on the Scott Feature Based Scoring System[58]. Seventeen participants had greater joint space narrowing in the medial compartment, and 1 participant had equal joint space narrowing in the medial and lateral compartments. No radiographic data was available for 5 of the 24 participants, and no joint space narrowing scores were available for an additional 1 participant.

Descriptive statistics were calculated for age, anthropometric measures, WOMAC component scores, SF-36 physical subscale score, gait velocity, stride length, brace wear duration, step count and strength. All data were checked for normality using the Ryan-Joiner test ($\alpha = 0.05$). Non-normal data were transformed using a Johnson transformation. Paired t-tests were used to detect significant baseline to follow up changes in the gait velocity, stride length, step count, and strength measures. Wilcoxon signed rank tests were used to detect significant baseline to follow up changes in the WOMAC component and SF-36 physical subscale scores. Correlation analyses were performed to determine if linear relationships existed between brace wear duration and percent changes in pain, function, step count and strength. Four participants did not record their daily step counts, therefore only 20 participants were used for the step count correlation analysis. The significance level was $\alpha = 0.05$. Statistical analyses were completed in Minitab™ (version 15, Minitab Inc, State College PA, US).

Results

Means and standard deviations for anthropometrics and brace wear duration are in Table 1. The mean daily brace wear usage was 4.7 hours, but there was large variation, evidenced by the large standard deviation of 4.4 hours. Most participants did not systematically increase or decrease their brace wear, with the exception of one who reported 4 hours per day in month one, up to 8 hours per day in month three and then between 9-11 hours per day in the remaining three months. Typical within-participant brace wear variation was 2 hours per day. Body mass index (BMI) of the participants did not change from baseline to follow up (31.8 (5.5) kg/m^2 at baseline and 31.8 (5.5) kg/m^2 at follow up). OA-related medication usage and the presence of knee effusion did not seem to be affected by brace wear, with the majority of participants not changing. Eight of 24 participants did not take medication at baseline or follow up, 8 participants reported the same medication usage (dose and frequency) at baseline and follow up, 6 participants reported requiring no or less medication at follow up (5 of these required no medication at follow up), and two participants reported requiring more medication at follow up. There was no change in knee effusion status for 15 of 24 participants (8 had effusion, 7 did not), 7 participants had effusion at baseline and no effusion at follow up, and 2 participants had no effusion at baseline and effusion at follow up. Only 3 of 24 participants received physical therapy between baseline and follow up, with treatment duration ranging between 1 and 8 weeks.

Pain and function measures can be found in Table 2. WOMAC pain and function scores decreased (21% and 14%, respectively) from baseline to follow-up, indicating a perceived improvement in both, however these changes were not significant, with p-values of 0.059 and 0.089 respectively. The other measures of function (SF-36 physical subscale score, walking velocity and stride length) and mean daily step count did not change ($p>0.05$). Brace wear usage was not correlated with any of the pain or function measures (p>0.05) with correlations ranging from r = -0.195 for change in WOMAC pain to r = -0.010 for change in velocity. However, brace wear usage was positively correlated with step count percent change (Figure 1, r = 0.59, p = 0.006).

Strength measures at baseline and the 6 month follow up are in Table 3. There were increases in quadriceps and hamstrings muscle strength measures between the baseline visit and the 6-month follow-up (Table 3), however only the hamstrings torque increased significantly by 13% for the KF15 exercise (p=0.013) with the quadriceps torque increase (8%) for KE15 close to significant (p=0.076). Correlations were weak between brace wear and change in strength measures. The only positive correlation that approached significance was brace wear with KF55 percent change (Figure 2, r = 0.37, p = 0.072). Other correlations between brace wear and change in strength measures ranged from r = -0.187 (p=0.323) for KE45 to r = 0.27 (p=0.247) for the PF.

Discussion

The objective of this study was to determine whether there was a dose response for brace wear on knee pain, function and muscle strength. Consistent with the literature and with our original hypothesis, self-reported pain and function improved from baseline to follow up, though this change was not significant. There was however no dose response for these variables. Contrary to our hypothesis there was a small dose response of brace wear for hamstrings strength, with those wearing the brace more showing a trend toward greater improvements in hamstrings strength.

We also found a dose response of brace wear for step count, with those wearing the brace more showing greater increases in this physical activity measure.

The wide range of brace wear prescription[21,23-25,28,31,34,36,38] and lack of objective monitoring of brace wear duration makes comparisons between studies difficult. The consequence is subjectivity in brace wear prescription contained in guidelines and lack of understanding of dose response. Our study examined brace wear usage and determined whether duration affects symptoms, function and strength. Participants were instructed independent of our study by a physiotherapist to use their brace "as needed". While our method of brace wear instruction was similar to previous studies[31,34,36], only Hewett et al (1998) asked participants to report daily brace wear duration[34]. They reported participants wore their brace 6.9 (4.6) hours per day, 5.2 (2.1) days/week, and excluded anyone who wore their brace less than 1 hour over a two week period. For our study, daily brace wear was 4.7 (4.4) hours/day; lower than reported by Hewett et al but with similar variation. Since we were interested in dose response, and thus had a different objective and design than Hewett's study we included all participants.

The correlation analysis revealed a dose response with brace wear for hamstrings muscle strength that approached significance. Contrary to our hypothesis, there was a moderate[59] positive relationship between percent change in knee flexor torque at 55 degrees and increasing brace wear. Previous studies looking at functional braces have found decreased hamstrings performance[42] and premature muscle fatigue[45] with brace use. While the strength percent changes for the other muscles were uncorrelated with brace wear dose, the lack of a negative relationship indicates that concerns of thigh muscle atrophy[41] and/or decreased quadriceps strength[43,44] with brace use (seen in ACL literature) may not apply to this population over the time duration. In addition to the hamstrings strength change, a positive brace wear dose response was observed for step count percent change. Increases in physical activity with brace wear may help to support the finding of hamstrings strength improvement with increased brace wear. The lack of significant increase in the quadriceps muscle strength at follow up differs from the significant increase reported by Matsuno et al (1997)[23]. While low statistical power may be an explanation, our study had a higher number of participants than theirs. An alternate explanation may be that they included older, more severe and very weak participants in their study, hence the effect of the brace may also be associated with these baseline characteristics.

Pain and function measures were more difficult to interpret. There was no brace wear dose response on these measures, however self-reported pain and function improved by over 14% at follow-up. Our results agree with previous literature, demonstrating improvements in self-reported pain and function with brace wear, supporting the usage of valgus unloader braces as an alternative conservative treatment to NSAIDs or other medications[6,9,16,17]. While unloader braces and analgesics such as NSAIDs both reduce symptoms, NSAIDs may increase medial compartment loading[13,14], leading to cartilage degradation, whereas unloader braces potentially alter this load[22,30,32,37]. The mechanism by which the brace works is still not clear with recent studies suggesting a neuromuscular mechanism related to increased stability[36]. Further work is needed to ascertain the mechanism so brace prescription can be improved. Given the degenerative nature of OA, expected changes over time would be decreased strength and function, and increased pain. This did not occur. As well, OA-related medication usage either remained constant or decreased for 22 of 24 participants over the 6-month follow up period.

Furthermore, knee effusion remained constant or decreased for 22 of 24 participants between baseline and follow up. The results of this study support the merit for the unloader braces as an effective conservative management strategy related to specific outcome measures, but most outcomes were not influenced substantially by dosage of brace wear. This has implications with respect to design of studies examining long-term brace wear that require high minimal brace wear dosages to meet compliance standards (possibly explaining the high drop out rates in these studies[31,39]). Longer term follow-up studies measuring joint loading and structural progression however are needed to confirm efficacy.

Study Limitations

The main study limitation is small sample size, thus low statistical power for detecting significant correlations among variables or differences between baseline and follow up. While the correlation for KF55 would likely reach statistical significance with a larger sample size, the extremely low correlations found for the other variables would likely not reach significance even with larger samples. Another limitation is the self-reported nature of the brace wear data. Any self-report measure can suffer from bias; however we feel that we reduced self-report bias by telling the participants to wear their brace "as needed". Therefore, there was no pressure for participants to report higher durations to meet a specific brace dosage. We also told participants that it was okay if they did not wear the brace, as long as they recorded that they did not wear it. Study strength included high compliance for completing both testing sessions (75%) and weekly questionnaires, as well as providing an objective measure of physical activity. This preliminary study provides insight for future work to help ascertain features associated with brace wear to be included in future guidelines.

Conclusion

Our preliminary study showed large variability in brace wear usage with positive relationships between longer brace wear and hamstrings strength and objective physical activity measures. While the only muscle strength correlation that approached statistically significant was the change in knee flexor strength at mid range, more importantly; brace wear duration was not associated with decreased strength. Our findings do not support muscle impairment with increased brace use over the 6-month study duration. In addition, the positive relationship between step count and brace wear dose indicates that participants wearing their brace for longer durations are increasing physical activity. Regardless of brace wear duration, increased hamstrings strength between baseline and follow-up was seen, as well as trends for decreased pain and increased function. Further exploring these differences and dose responses is needed to establish sound principles for brace wear guidelines.

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Figure Legends

Figure 1. Relationship between step count percent change from baseline to follow up and mean daily brace wear usage. Brace wear usage was positively correlated with step count percent change (r = 0.59, p = 0.006).

Figure 2. Relationship between KF55 (knee flexion at 55 degrees) torque percent change from baseline to follow up and mean daily brace wear usage. Brace wear was positively correlated with KF55 percent change (r = 0.37, p = 0.072).

Table 1

Table 1. Group demographics and average daily brace wear*.

N	Age (years)	Sex (F/M)	Height (m)	BMI[†] (kg/m^2)	Daily Bracewear Usage (hours)
24	57.8 (8.1)	4/20	1.76 (0.08)	31.8 (5.2)	4.7 (4.4)

* Data are presented as mean (standard deviation)

[†] BMI = Body Mass Index

Table 2

Table 2. Pain, function, and activity measures at baseline and follow-up sessions*.

Session	WOMAC†			SF-36 Physical	Walking Velocity (m/s)	Stride Length (m)	Mean Daily Step Count
	Pain	Stiffness	Function				
Baseline	6.2 (2.6)	3.3 (1.4)	18.5 (9.4)	65.3 (14.0)	1.21 (0.17)	1.39 (0.15)	5740 (3313)
Follow Up	4.9 (3.3)	2.9 (1.8)	15.9 (9.8)	66.8 (14.3)	1.24 (0.15)	1.40 (0.14)	5869 (4160)
% Change‡	-21.0%	-12.1%	-14.1%	2.3%	2.5%	0.7%	2.2%
P-value	0.059	0.313	0.089	0.376	0.203	0.112	0.828

* Data are presented as mean (standard deviation)

† WOMAC = Western Ontario McMaster University Index

‡ Positive percent changes indicate an increase at follow-up visit

Table 3

Table 3. Maximum torques normalized to body mass (Nm/kg) for 5 different exercises* between baseline and follow-up†.

Session	KE45	KE15	KF15	KF55	PF
Baseline	1.33 (0.44)	0.87 (0.30)	0.53 (0.18)	0.71 (0.27)	1.10 (0.28)
Follow Up	1.40 (0.40)	0.94 (0.34)	0.60 (0.17)	0.76 (0.24)	1.03 (0.27)
% Change‡	5.3%	8.0%	13.2%	7.0%	-6.4%
P-value	0.246	0.076	0.013§	0.167	0.184

*KE45 = Knee Extension 45°, KE15 = Knee Extension 15°, KF15 = Knee Flexion 15°, KF55 = Knee Flexion 55°, PF = Plantar Flexion

†Data are presented as mean (standard deviation)

‡ Positive percent changes indicate an increase at follow-up visit.

§ Denotes a significant change, with $p<0.05$.

Figure 1
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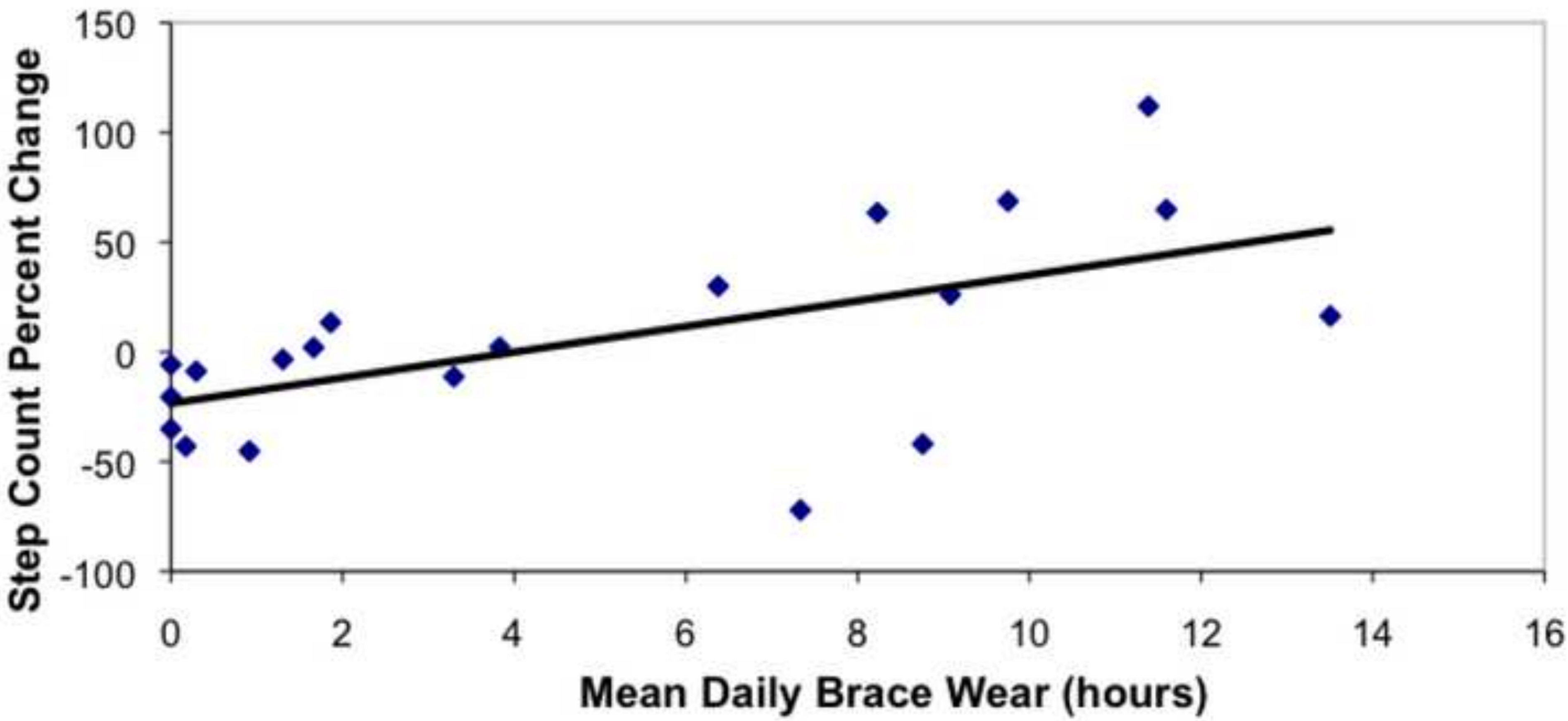

Figure 2

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