

ORIGINAL ARTICLE

Effects of textured insoles on static balance tests in patients with multiple sclerosis

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Purpose: The purpose of this study was to investigate the effects of textured insoles on static balance parameters in patients with Multiple Sclerosis (MS). It is hypothesized that utilization of textured insoles will cause positive changes on static parametric postural control values.

Methods: Eighteen patients, with similar age, height, weight, and relapsing-remitting and secondary progressive type MS (Nine patients study group, nine patients control group) were recruited for this study. Static balance parameters were assessed by using a platform (Balance Master, NeuroCom® International Inc. USA) in 4 conditions (eyes opened-closed and on foam-firm surfaces). The study group used the 3 mm textured insoles and the control group used 2 mm sham surface material for 4 weeks. Possible changes in the movement pattern of the center of gravity with the use of insoles have been objectively assessed in different conditions.

Results: There were no significant differences in age, height, weight and body mass index and also in terms of balance tests between groups before insole usage ($p>0.05$). On the other hand, with the use of 4-weeks of usage of textured insoles were found to decrease significantly balance parameters in eyes closed on foam surface condition ($p<0.05$).

Conclusion: It was shown that textured insoles usage with a duration 4 weeks decreased the postural sway velocities in eyes closed on foam surface condition. This result suggests that textured insoles may improve balance parameters of patients with MS have balance difficulties.

Keywords: Multiple sclerosis, Orthotic insoles, Postural balance.

Dokulu tabanlıkların multipl skleroz hastalarında statik denge testleri üzerine etkileri

Amaç: Bu çalışmanın amacı, dokulu tabanlıkların, Multipl sklerozlu (MS) bireylerin statik denge parametreleri üzerine etkilerinin araştırılmasıydı. Çalışma dokulu tabanlık kullanımının statik postüral kontrol parametrelerine olumlu etkileri olabileceği hipotezi ile yapıldı.

Yöntem: Çalışmaya benzer yaş, boy, kilo ve beden kütle indeksine sahip 18 relapsing remitting ve sekonder progresif MS hastası (çalışma grubu, N=9, kontrol grubu, N=9) dahil edildi. Statik denge parametreleri bir kuvvet platformu (Balance Master, NeuroCom® International Inc. USA) yardımı ile 4 farklı koşulda (gözler açık-kapalı ve sert-yumuşak zemin) değerlendirildi. Çalışma grubu 3 mm kalınlığında dokulu tabanlık, kontrol grubu ise 2 mm plasebo tabanlılığı 4 hafta süre ile kullanmışlardır. Farklı koşullarda, tabanlık kullanımı ile gravite merkezinin hareket paternindeki olası değişimler objektif olarak değerlendirilmiştir.

Bulgular: Demografik özellikler ve denge testleri açısından tabanlık kullanımı öncesi gruplar arasında fark bulunmadı ($p>0,05$). Buna karşılık, 4 haftalık dokulu tabanlık kullanımının yumuşak zeminde gözler kapalı denge parametrelerini önemli derecede azalttığı bulundu ($p<0,05$).

Sonuç: Dokulu tabanlıkların 4 haftalık kullanımları ile yumuşak zemin gözler kapalı denge değerlendirmelerinde postural salınım hızlarının anlamlı olarak azaldığı saptandı. Bu sonuç, dokulu tabanlık kullanımı ile denge problemi yaşayan MS hastalarının denge parametrelerinin gelişebileceğini göstermektedir.

Anahtar kelimeler: Multipl skleroz, Ortotik tabanlıklar, Postüral denge.

Elvan A, Selmani M, Kara B, Angin S, Şimşek İE, İdیمان E. Effects of textured insoles on static balance tests in patients with multiple sclerosis. J Exerc Ther Rehabil. 4(3):111-117. *Dokulu tabanlıkların multipl skleroz hastalarında statik denge testleri üzerine etkileri.*



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Received: September 18, 2017.
Accepted: November 12, 2017.

Individuals with Multiple Sclerosis (MS) are at higher risk of fall compared to healthy individuals.^{1,2} There are numerous studies about MS and fall prevalence in the recent years. It was found that almost half of all the individuals with MS fall at least once in the previous 6 months, therefore become more vulnerable to further injuries.³ MS, in which lack of postural control and balance problems were often reported, directs researchers to study over balance and postural control because of disruption in somato-sensorial system.⁴ Studies that report effects of somato-sensorial system over balance focuses on tactile sensorial formation. Somato-sensorial, visual, auditory and vestibular systems provide the information required to control posture and balance.⁵ Somato-sensorial system is divided into two subgroups; tactile and proprioceptive systems. Both tactile and proprioceptive inputs play an important role in maintaining postural control and balance.⁶ The displacement of the center of gravity, the provision of information about the body position and the correct continuation of the interaction with the environment are possible through complex integration of the sensory and musculoskeletal systems.⁷ Somatosensory disturbances, which cause problems in transmitting the inputs from muscle spindles, joint receptors and cutaneous receptors from the lower extremities to the upper centers, lead to negative results on balance and postural control.⁸

Somatosensory inputs which are obtained from the lower segments has been the subject of various research since 1980s.⁹⁻¹¹ In particular, there are numerous studies that examine the behavior of the center of gravity in various conditions (e.g. cold application and/or nerve blockage) that reduce the tactile sensation of the plantar surface.¹² There is close association between plantar sensation, standing balance and falls in MS.^{13,14} Postural control mechanisms may be enhanced by increasing the amount of afferent information obtained from the plantar surface. Increased basal tactile stimulation, which can be achieved by stimulation of plantar mechanoreceptors, is thought to improve postural control in both standing and ambulatory activities.^{15,16} For these reasons studies that focus on textured insoles were more frequent in literature lately. It was

reported that textured insoles may improve balance by increasing plantar stimulation and providing extra ankle proprioception sense.^{15,17} However, there are not numerous studies about the effects of textured insoles on people with MS. Dixon et al. stated that textured insoles had no significant effects on balance in acute and chronic phase.¹⁸ On the other hand Kalron et al. indicated that textured insoles decreased postural sway in standing position, yet it is important to mention that Kalron et al. had no control group. Dixon et al. implemented 2 weeks usage of textured insoles in order to observe its chronic effects. Though other studies about this subject suggest that 4 weeks of textured insole usage in addition to assess and compare parameters to results of control group.^{17, 19} The aim of this study was to examine the possible effects of textured insoles on individuals with MS on static standing balance. With this aim, the study was designed to have a longer follow-up duration and a similar control group having similar functional level as advocated in the literature for future studies.

METHODS

The study was conducted between April 2014 and May 2017 at Dokuz Eylul University, School of Physical Therapy and Rehabilitation, Movement Analysis Laboratory. The study was approved by the Board of Non-invasive Research Ethics Committee of University in 2015/19-38. The participants were informed about the study, and signed informed consent forms. Inclusion criteria were as follows: having The Expanded Disability Status Scale (EDSS) EDSS Score of 2-4, absence of any accompanying orthopedic problem, having relapsing-remitting or secondary progressive type MS, having diagnosed with lower extremity sensory deficits in somatosensory evoked potential (SEP) test. Individuals with frequent acute MS attacks and individuals with other neuromuscular disease(s) or cognitive impairment were not included in the study. The demographic data and the medical history were recorded after the participants were divided randomly into two groups as study and control groups. The cases were randomized according to their first appointment order.

Balance assessment

Balance assessment in static standing position was performed using the Balance Master device (NeuroCom System Version 8.1.0, B100718, 1989-2004 NeuroCom® International Inc. USA). The tests were performed 3 times on 4 different conditions including eyes open/closed and firm/foam surfaces. During the tests, center of gravity (CoG) sway velocity data was taken.

Intervention

Immediately after the baseline assessment (1st Assessment), the study and control groups received a pair of insoles with 3 mm (textured) and 2mm of thickness covered with sham surface material, respectively. Both type of insoles had no biomechanical correction effect. Participants were allowed to use any kind of shoes they choose that fit with the insoles provided. Insoles were fitted in the selected shoes and the tests were repeated in order to determine the early effects of insole usage (2nd assessment). Then, participants were asked to use the same insoles placed into their same regular shoes for 4 weeks constantly (as long as they walk) throughout the day. At the end of four weeks, the tests were repeated (3rd Assessment). The usage duration of insoles were chosen in accordance with the study done by Kalron et al.¹⁹ The patients have not being participated any rehabilitation program last 6 months and did not participate any rehabilitation program during our study. The textured insoles used in the study were produced from " ethyl vinyl acetate (EVA) " material to include 4 semi-spherical projections per cm² (Figure 1). The production method and texture of the insoles were followed by in accordance with the technique described by Waddington et al.¹⁵ The height of each spherical protrusion from the EVA floor is 2 mm (Figure 1). The textured insoles were prepared from the EVA layer to accommodate these features, in accordance with the patient's footwear footprint. Sham surface material was provided from 2 mm plastazote sheets. Both types of insoles were easy to use and versatile (can fit all kinds of footwear).

Statistical analysis

Statistical analysis were performed using the SPSS software version 20. Descriptive analyses were presented using medians and interquartile range for nonparametric

variables. Mann-Whitney U test was conducted to compare age, height, weight, body mass index (BMI) at initial assessments. Chi-square test was used to test for gender and EDSS score differences between groups. The Wilcoxon test was used to compare the change in sway velocities of center of gravity between baseline assessment, early phase and late phase assessment with textured insole application and 4 weeks usage. The Wilcoxon test was performed to analyze the significance of pair wise differences using Bonferroni correction to adjust for multiple comparisons. A p-value of less than 0.017 was considered to show a statistically significant result.

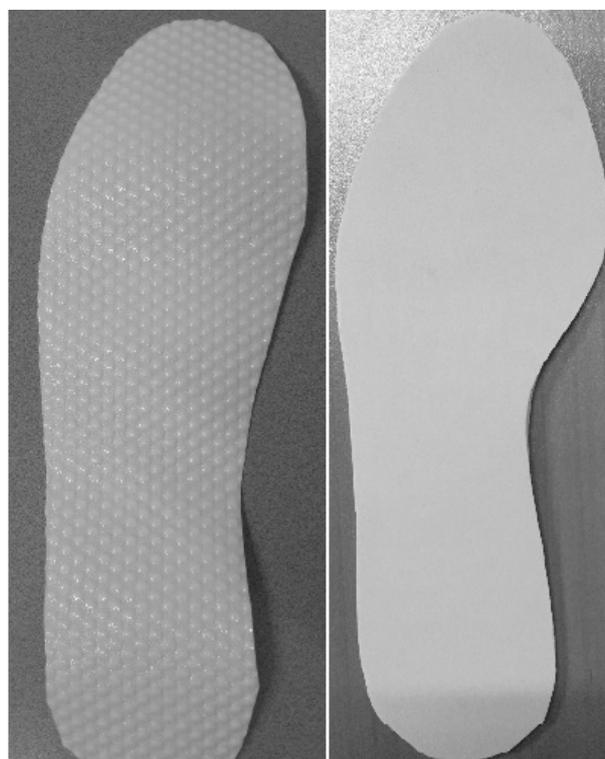


Figure 1. Textured insole (left) and Sham insole (right).

RESULTS

The demographic characteristics of the participants are shown in Table 1. There were eight female and one male participants in the study group and five females and four males in the control group and gender was significantly different between groups ($p < 0.05$) (Table 1).

There were six relapsing-remitting type MS, three secondary-progressive type MS in the study group and two relapsing remitting type MS and 7 secondary-progressive type MS in the control group (Table 1). There were no significant differences between groups in terms of age, body height, body weight and body mass index and EDSS scores ($p>0.05$) (Table 1). There was no significant difference between the study and control groups in terms of balance assessments before insole usage ($p> 0.05$) (Table 2).

For balance parameters, the effects of textured insoles were divided into two as early (2nd assessment) and late phase (3rd assessment) effects. According to the results, the textured insoles did not make any significant difference between 1st and 2nd assessments of the static balance tests ($p>0.05$). However, with 4 weeks of usage (3rd assessment), textured insoles significantly reduced the rate of sway velocities in the eyes closed, foam surface balance assessments ($p<0.05$) (Table 3).

DISCUSSION

The aim of this study was to examine the possible effects of textured insoles on balance parameters in MS patients. In this study, it was shown that the extra stimulus created by the texture insoles (which is also called plantar stimuli/noise in the relevant literature) with a duration of 4 weeks decreased the postural sway velocities in MS patients, suffering from the conduction of sensory stimuli in conscious and subconscious levels (dorsal colon involvement) due to various reasons, in eyes closed and foam surface condition.

It is thought that plantar stimulation reduces postural oscillations, although, in the literature, the studies related to this subject are scarce. The comparative studies are limited due to the different methods used in various studies (e.g. surface topography and stimulation technique).^{17,20} There are no consensus that determines both the height and shape of the texture and homogenous distribution of topographical features of the insoles. In a study published in 2000 by Waddington et al., it was reported that insoles with 4 or more protrusions per cm² increase

sensorial stimulation over the plantar mechanoreceptor threshold rather than causing a massage effect.¹⁵ In addition, in some studies protrusions were formed as pyramidal whereas semi-spheres in other studies. In this study, 4 pieces of semi-spherical textures were used per cm².

Studies on textured insoles continue in neurological diseases such as Parkinson's and MS. In a systematic review published in 2017, textured insoles were reported to have a significant effect on CoP sway velocities.¹⁷ However, it has been reported that there is no significant effect of insoles on the long-term outcomes.¹⁷ For future long term studies, it is recommended that the usage of insoles should be longer than 4 weeks. In our study, participants were asked to use insoles in their activities of daily living for 4 weeks following the initial measurements were conducted. Dixon et al. reported no significant effect after 2 weeks of usage, although the step length increased.¹⁸ Researchers thought that this result could be considered as a learning effect. Unlike the aforementioned study, the effects of textured insoles in this study are presented in comparison with the control group data. When the data of the control group is examined, it is obvious that there are no learning effects as indicated by the insignificance of the differences between the initial and following measurement results.

Another study by Kalron et al. reported that the balance parameters in eyes open/closed conditions were improved due to additional sensory feedback from the plantar surface.¹⁹ The pilot results of the randomized controlled trial conducted by Hatton et al. are also similar to this aforementioned study.²¹ Kalron et al. reported that the decrease in CoP sway velocity rates after 4 weeks of usage were in medio-lateral direction only. Regarding the CoP parameters examined in our study, the only significant result is the reduction of CoP oscillation velocities detected after 4 weeks of textured insoles usage in eyes closed/foam surface condition. Unlike Kalron et al., in this study, reduction of the sway velocities in conditions with eyes closed and foam surfaces suggests that vestibular inputs may gain priority and interpreted by the central nervous system as the primary afferent data in the condition of visual impairment on foam surface.

Table 1. Comparison of demographic characteristics of the participants.

	Study Group Median - (IQR)	Control Group Median - (IQR)	p
Age (years)	40 - (30.5-50)	42 - (35-55)	0.596
Gender (Female / Male) (n)	8 / 1	5 / 4	0.046*
Body height (cm)	165 - (159-169.5)	170 - (161.5-179.5)	0.251
Body weight (kg)	72 - (56-74)	80 - (61.5-84.5)	0.185
Body mass index (kg/m ²)	26.17 - (21.74-27.79)	24.69 - (22.25-29.63)	0.965
EDSS Scores	2.5 (2-3)	3 (2-4)	0.241

* p<0.05. IQR: Interquartile range.

Table 2. Comparison of initial balance assessment of the participants.

	Study Group Median - (IQR)	Control Group Median - (IQR)	p
CTSIBSwayFirmEO1 (°/ssec)	0.40 - (0.33-0.60)	0.50 - (0.32-0.68)	0.626
CTSIBSwayFirmEC1 (°/sec)	0.79 - (0.67-0.92)	0.53 - (0.39-1.25)	0.627
CTSIBSwayFoamEO1 (°/sec)	0.56 - (0.47-0.65)	0.67 - (0.42-1.11)	0.215
CTSIBSwayFoamEC1 (°/sec)	1.34 - (1.12-1.6)	1.0 - (0.55-1.40)	0.825

IQR: Interquartile Range. CTSIBSwayFirmEO1: Initial assessment of sway velocity in eyes opened and on firm surface. CTSIBSwayFirmEC1: Initial assessment of sway velocity in eyes closed and on firm surface. CTSIBSwayFoamEO1: Initial assessment of sway velocity in eyes opened and on foam surface. CTSIBSwayFoamEC1: Baseline assessment of sway velocity in eyes closed and on foam surf.

Table 3. Comparison of static balance assessment outcomes between each assessment phases.

	Study Group			Control Group		
	2 nd -1 st Assessment p - (2 nd - 1 st Median)	3 rd -1 st Assessment p - (3 rd -1 st Median)	3 rd -2 nd Assessment p - (3 rd -2 nd Median)	2 nd -1 st Assessment p - (Median)	3 rd -1 st Assessment p - (Median)	3 rd -2 nd Assessment p - (Median)
CTSIBSway FirmEO (°/sec)	0.858 (0.43-0.40)	0.440 (0.40-0.40)	0.932 (0.40-0.43)	0.115 (0.47-0.50)	0.398 (0.48-0.50)	0.574 (0.48-0.47)
CTSIBSway FirmEC (°/sec)	0.066 (0.49-0.79)	0.028 (0.40-0.79)	0.066 (0.40-0.49)	0.212 (0.60-0.53)	0.672 (0.63-0.53)	0.325 (0.63-0.60)
CTSIBSway FoamEO (°/sec)	0.593 (0.50-0.55)	0.678 (0.53-0.55)	0.574 (0.53-0.50)	0.228 (0.60-0.67)	0.752 (0.63-0.67)	0.611 (0.63-0.60)
CTSIBSway FoamEC (°/sec)	0.038 (0.93-1.34)	0.011* (0.91-1.34)	0.514 (0.91-0.93)	0.528 (1.00-1.00)	0.833 (1.01-1.00)	0.233 (1.01-1.00)

*: p<0.017 (p values were corrected with Bonferroni correction). CTSIBSwayFirmEO: Assessment of sway velocity in eyes opened and on firm surface. CTSIBSwayFirmEC: Assessment of sway velocity in eyes closed and on firm surface. CTSIBSwayFoamEO: Assessment of sway velocity in eyes opened and on foam surface. CTSIBSwayFoamEC: Assessment of sway velocity in eyes closed and on foam surface. 1st Assessment: Assessment before usage of textured insole. 2nd Assessment: Assessment the early effects of textured insole usage. 3rd Assessment: Assessment the late effects of textured insole usage.

Still, when the data is investigated thoroughly, it is obvious that the baseline and 3rd assessment on firm surface-eyes open condition the CoG sway velocities were almost the same for the study group, however, when the eyes

were closed (again firm surface) the CoG sway velocity insisted on stay the same after 4 weeks of textured insole usage. The insistence of CoG sway velocity to stay its ground seems to be related to both plantar somato-sensorial

enhancements caused by the textured insoles and the usual vestibular dominance in maintaining balance. This may also support an interesting paradigm indicating that the central nervous system uses afferent data in a selective manner, which means for each data obtained the central nervous system may assign a priority setting. The mechanisms of this priority assignment are still obscured.

The effects of creating extra mechanical stimulus on the plantar surface by any means (different textures, vibration, material choice etc.) seems to have positive results on human stability. The ability of carrying a weak plantar signal over a threshold (possibly using unison in resonance) using mechano-transduction may be the focus of next generation technologies targeting optimization and enhancement of human balance.

Limitations

The current study has three basic limitations that are noteworthy to consider. First, the volunteers were instructed to use their insoles as long as they walk throughout the day. However, the duration and frequency of this usage were not evaluated. Secondly, the groups did not include the same number of volunteers with respect to gender. Third, although we have found better CoG sway values on foam surface-eyes closed condition which may be attributed to enhanced data usage supplied by the vestibular system, the values obtained on firm surface-eyes closed condition also showed a decrease in CoG sway. However, no significance was detected due to the statistical nature of repeated measures analysis, which reduces the level of significance. Increasing the number of participants may carry on this trend towards a significant level in future work. The reader is encouraged to take note of these limitations before making any further assumptions over the results and future work.

Conclusion

It may be concluded that the input of increased somatosensory data from the plantar surface is selectively processed by the central nervous system. More studies are needed to quantitatively reveal the neural mechanisms of this assumption related to data processing of the central nervous system. Readers are encouraged to consider this work as a pilot study, since the impact size may be considered

as the primary limitation of this study.

Acknowledgement: *None.*

Conflict of interest: *None.*

Funding: *None.*

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