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Original Article

Gait abnormalities in patients with chronic ankle instability can improve following a non-invasive biomechanical therapy: a retrospective analysis

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Abstract. [Purpose] The purpose of this study was to evaluate the changes in gait patterns and clinical outcomes of patients with chronic ankle instability (CAI) following treatment with a home-based non-invasive biomechanical device. [Subjects and Methods] Thirty-three patients with CAI were compared with 43 healthy controls. Patients underwent a spatiotemporal gait assessment before and three months following treatment. Clinical evaluation was recorded with SF-36 Health Survey and the Foot and Ankle Outcome Score (FAOS). [Results] Significant baseline differences were found between groups. Patients with CAI showed a statistically significant improvement in velocity, cadence, symptomatic limb step length and single limb support over time. Significant improvements in SF-36 PCS and FAOS outcome scores were found in patients with CAI. [Conclusion] Patients with CAI have baseline spatiotemporal gait abnormalities as compared with healthy controls. However, clinical and gait metrics improvement can be expected after 12 weeks of perturbation training using a non-invasive biomechanical device.
Key words: Neuromuscular control, Walking patterns, Biomechanical device

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INTRODUCTION

The pathophysiology of progression from acute lateral ankle sprain to chronic ankle instability (CAI) is not well understood. It is estimated that CAI can develop in up to 40% of ankle sprains[1–3)]. The prevalence of CAI in young adult population is estimated to be 1.1% in males and 0.7% in females[4)]. Chronic ankle instability is regarded to have multifactorial pathology, and can be caused by several co-existing etiologies. Mechanical instability[5, 6)], proprioception deficits[7–10)], neuromuscular control deficits[11–13)], postural control deficits[14–16)], and muscle weakness[9, 17, 18)] have all been studied and demonstrated to contribute to CAI.

A debate exists regarding gender-based differences and ankle instability. Some authors found that males had a higher incidence of ankle sprains compared to age-matched females[4, 19)]. Conversely, other authors found that ankle instability was more common in females[20)]. Several publications have shown that female athletes are more prone to lower extremity

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Table 1. Patient's characteristics

	CAI	Control
N	33	43
Age (years)	39.0 (16.0)	37.5 (14.2)
Height (m)	1.70 (0.1)	1.73 (0.09)
Weight (kg)	74.1 (15.9)	74.0 (13.0)
BMI (kg/m^2)	26.0 (4.8)	24.6 (2.9)

*p-values was set to $p<0.05$. No significant differences were found between patients with CAI and controls in terms of age, height, weight and BMI.

injuries, anterior cruciate ligament injuries in particular[21–25]. Other studies report more mixed results regarding an increased incidence of ankle sprains in females[26, 27].

Gait abnormalities have been previously described in patients with CAI. The majority of research has focused on ankle kinematics, showing reduced ankle dorsiflexion[28–30], with anterior talus displacement[31–33]. Nyska et al[34] showed that in patients with CAI, there is slower weight transfer with reduced impact at the stance phase, and a lateral shift of the foot's center of pressure.

A recent study[35] showed significant differences in spatiotemporal gait data of patients with CAI compared with healthy controls. Patients with CAI had lower walking velocity, lower cadence, and shorter step length. Furthermore, their base of support was wider, and single limb support time was shorter. These gait alterations might reflect modified gait adopted by patients, in order to compensate for their sense of instability or reflect deficits caused by the instability.

Treatment of CAI may include both surgical and conservative options. McKeon et al. conducted a systematic review on the clinical effectiveness of balance training for patients with CAI. They concluded that balance training can be used prophylactically or after an acute ankle sprain in an effort to reduce future ankle sprains, but current evidence is insufficient to assess this effect in patients with chronic ankle instability[36]. There are several non-invasive treatment options for patients with CAI amongst them are orthotics, ankle braces, strength training and balance board training[2]. In the last five years several publications have described the effect of a novel home-based biomechanical therapy (AposTherapy) on clinical symptoms and gait patterns in patients with different musculoskeletal conditions[37–39]. This device aims to apply functional balance training using a foot wear device. It is capable of a center of pressure manipulation and generation of perturbations which intend to challenge and train neuromuscular control[40–42].

The purpose of this study was to evaluate the changes in temporal-spatial gait parameters and clinical outcomes of patients with CAI following treatment with a home-based non-invasive biomechanical device and compare them to a group of healthy controls. The study hypothesis was that with the unique propensities of this therapy to train neuromuscular control, improved spatiotemporal gait metrics and clinical outcome scores can be expected.

SUBJECTS AND METHODS

The AposTherapy Centre database was retrospectively searched for patients treated for chronic ankle instability between May 2009 and September 2014 (Commencement of data collection at the therapy center and three months from starting data analysis, to allow three months' follow-up period). Data were retrieved from the patients' medical files and the controls' records. Approval from the Institutional Review Board was obtained before initiating this study. The study is registered in the NIH clinical trial registration system (No. NCT00767780).

To enhance the validity of clinical research conducted in this patient population, strict inclusion and exclusion criteria were used, based on the criteria endorsed by the International Ankle Consortium[43]. Inclusion criteria included a history of at least one significant ankle sprain, history of the previously injured ankle joint 'giving way' and/or recurrent sprain and/or 'feelings of instability', and a Foot and Ankle Outcome Score (FAOS) less than 75 in three or more categories as specified in the International Ankle Consortium work[43]. Accordingly, excluded from the study were patients with a history of previous surgeries or fractures involving the lower extremity, and patients with an acute injury in the previous 3-months period resulting in at least one interrupted day of desired physical activity.

Patients underwent a comprehensive assessment during their first visit to the therapy center, by a certified physical therapist including a physical examination, spatiotemporal gait analysis, and clinical outcome scores assessment.

A total of 33 patients met the inclusion criteria, 18 males and 15 females, with a mean age of 39.0 years (range 16 to 77, SD 16), and mean body mass index (BMI) of 26.0 kg/m^2 (range 20.1 to 36.9, SD 4.8). Four patients had bilateral ankle instability, with one limb being more symptomatic (based on their answer to the question: "which ankle is more symptomatic?"). The control group consisted of 43 healthy individuals matched for age and anthropometric data (Table 1). The control group was evaluated by gait analysis as same as the study group.

Gait was measured using a computerized mat with embedded sensors to calculate spatiotemporal data (GaitMat system,

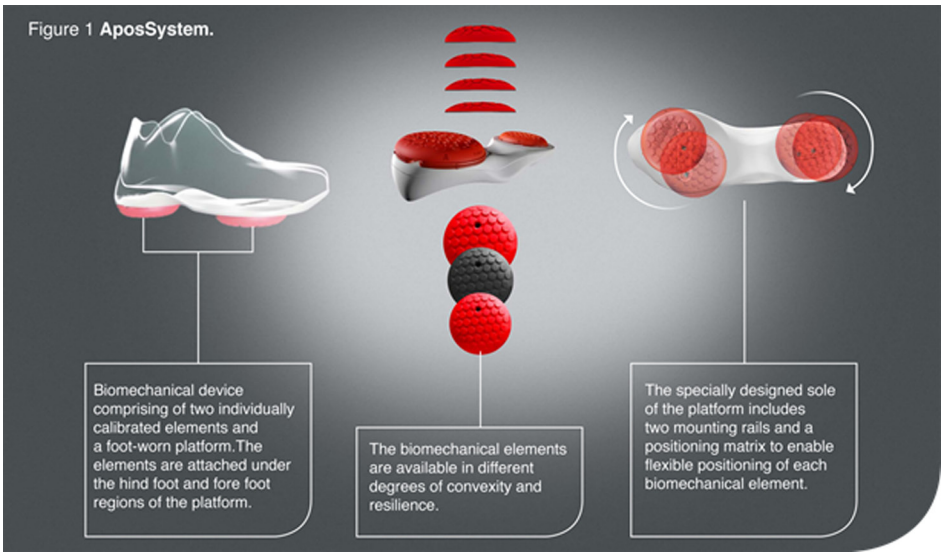

Fig. 1. The biomechanical device (Apos system)

E.Q., Inc. Chalfont, PA, USA)[44]. Spatiotemporal metrics is considered the most immediately clinically applicable out of all gait data, and have been referred to as the 'vital signs of gait'. Moreover, they make intuitive sense, can be easily interpreted and have been well correlated with levels of disability and function across multiple pathologies[45]. During gait analysis patients with CAI and controls were asked to walk barefoot at a self-selected speed. Each examination included four trials, and the mean value of all trials was calculated for the following parameters: gait velocity (cm/s), step length (cm), cadence (steps/min), base of support (cm), stance (% gait cycle [GC]), and single limb support (SLS) (%GC). Left and right values were determined based on the leading limb during heel strike. The analysis included values of the more symptomatic limb and less symptomatic limb. This was determined by the patient's history and physical examination findings. For the control group, the results of the left limb were arbitrarily defined as the more symptomatic limb.

Clinical outcomes were evaluated with the SF-36 Health Survey and the Foot and Ankle Outcome Score (FAOS)[46].

Following first assessment, patients with CAI were calibrated with a unique non-invasive biomechanical device. The biomechanical device (AposTherapy, Apos-Medical and Sports Technologies Ltd., Herzliya, Israel) consists of two convex-shaped biomechanical elements attached to each foot using a platform in the form of a shoe, allowing customized calibration (Fig. 1). The device can be individually calibrated to shift the trajectory of the foot's center of pressure during gait, thereby altering the orientation of the ground reaction force vector as demonstrated by Haim and Rozen[41, 42, 47]. Also, the convexity of the biomechanical elements generates perturbations while walking, enabling dynamic, functional, and repetitive training intended to improve neuromuscular control[40].

Following calibration, patients received usage instructions to be performed during their daily routine. Patients were instructed to walk with the biomechanical device for 10 minutes once a day during the first week and gradually increase walking time reaching 60 minutes once a day after 12 weeks. In addition, after four weeks of therapy patients were encouraged to walk outdoors with the biomechanical device for 10–15 minutes once a day. Patients underwent a second clinical outcome assessment and gait analysis following three months of treatment.

All statistical analysis was carried out by an independent biostatistician. Data were analyzed with IBM SPSS software version 21.0 and the significant level was set at 0.05. The following dependent parameters were evaluated: spatiotemporal gait measures including velocity, cadence, more and less symptomatic step length, base of support, more and less symptomatic stance phase, and more and less symptomatic SLS phase. SF-36 measures included the SF-36 Physical Score (average of 4 sub-categories) and the SF-36 Mental Score (average of 4 other sub-categories). FAOS measures included a total score and five sub-categories including pain, symptoms, ADL, quality of life and sports. Results were presented as a mean and standard deviation, followed by 95% confidence interval for the two time periods. Non-parametric one-sample Kolmogorov-Smirnov tests were calculated to compare the observed cumulative distribution function for the continuous variables with the Normal theoretical distribution.

Differences between CAI patients and the healthy group were measured by the unpaired t-test and differences over time were measured by paired t-test. Furthermore, differences within gender were evaluated with The GLM Repeated Measures procedure to demonstrate the differences over time, the interaction of the differences between the groups over time and the interaction of the differences with gender.

Table 2. Gait pattern of patients with CAI and healthy population. Results are presented as mean (SD) [95% CI]

	CAI pre-treatment	CAI post 3 months of treatment	Effect size	Healthy
Velocity (cm/s)	104.3 (17.9) [100.4–113.4]	114.8 (17.7)$^{\beta}$ [110.0–123.1]	0.59	126.5 (18.5)*§ [120.8–132.2]
Cadence (steps/min)	70.4 (7.4) [68.0–74.1]	73.6 (5.8)$^{\beta}$ [71.6–76.5]	0.43	75.8 (5.2)* [74.1–77.4]
More symptomatic step length (cm)	55.9 (6.1) [58.1–62.2]	62.6 (6.9)$^{\beta}$ [60.7–68.8]	1.09	66.8 (7.7)*§ [64.4–69.2]
Less symptomatic step length (cm)	58.6 (7.0) [58.0–61.7]	61.6 (7.8)$^{\beta}$ [60.1–64.9]	0.43	67.2 (7.5)*§ [64.8–69.5]
Base of support (cm)	6.8 (3.5) [5.4–8.6]	6.9 (3.9) [5.4–8.9]	0.03	4.7 (2.2)*§ [4.0–5.4]
More symptomatic Stance (%GC)	60.9 (1.8) [60.0–61.3]	60.2 (1.9)$^{\beta}$ [59.5–60.8]	0.39	59.8 (1.3)* [59.4–60.2]
Less symptomatic stance (%GC)	61.4 (1.9) [60.5–61.9]	60.7 (1.7)$^{\beta}$ [59.8–60.9]	0.37	59.9 (1.8)* [59.4–60.5]
More symptomatic SLS (%GC)	38.6 (1.9) [38.1–39.5]	39.4 (1.7)$^{\beta}$ [39.1–40.2]	0.42	40.0 (1.6)* [39.5–40.5]
Less symptomatic SLS (%GC)	39.3 (1.7) [38.8–40.1]	39.8 (1.9) [39.2–40.6]	0.29	40.1 (1.4)* [39.7–40.5]

Significance was defined as $p<0.05$. *Significance between CAI (pre-treatment) vs. Healthy; §Significance between CAI (post-treatment) vs. Healthy. $^{\beta}$Significance between CAI pre-treatment vs. post-treatment.
Effect size was calculated as the difference between the 3 months assessment and pre-treatment assessment divided by the standard deviation at the pre-treatment assessment.

RESULTS

All patients complied with the treatment and completed the study protocol, with no adverse events reported.

Results of gait analysis are summarized in Table 2. Significant differences were found for all gait parameters (velocity, cadence, step length, base of support, stance, single limb support), except for SLS for the less symptomatic limb, when comparing pre-treatment gait metrics of patients with CAI with healthy controls.

In patients with CAI, a comparison of pre-treatment gait metrics with post-treatment, demonstrated a statistically significant improvement in velocity from 104.3 to 114.8 cm/s, cadence from 70.4 to 73.6 steps/min, symptomatic limb step length from 55.9 to 62.6 cm, less symptomatic limb step length from 58.6 to 61.6, and symptomatic limb single limb support from 38.6 to 39.4%GC. When comparing post-treatment gait metrics of patients with CAI with healthy controls, statistically significant differences still existed for velocity, symptomatic limb step length, less symptomatic limb step length, and base of support. A small-large effect size was calculated for the gait parameters, ranging from 0.37 to 1.09.

Results of clinical outcome scores are summarized in Table 3. Significant improvements in clinical outcome scores were found in patients with CAI following treatment. The SF-36 PCS component increased from 56.2 to 64.5, total FAOS score increased from 66.6 to 74.8. A similar improvement was found in all the subcategories of the FAOS score (pain, symptoms, ADL, QoL, and sport).

A gender interaction analysis was performed to evaluate whether this treatment has a different effect on males and females with regards to gait and clinical outcome scores. A small-medium effect size was calculated for the different subcategories, ranging from 0.29 to 0.54. In terms of gender differences, a significant interaction was found in gender treatment in several gait parameters including velocity ($p=0.038$), more and less symptomatic limb step length ($p=0.016$ and $p=0.038$, respectively), more symptomatic limb stance phase ($p=0.005$) and less symptomatic limb SLS ($p=0.022$). In other words, although both genders improved significantly following treatment, males have improved to a greater extent compared to females. There was no significant interaction in the clinical outcomes.

DISCUSSION

This study evaluated changes in spatiotemporal gait parameters and clinical outcomes of patients with CAI following treatment with a non-invasive biomechanical device, intended to improve neuromuscular control.

Table 3. Clinical outcomes of patients with CAI and healthy population

	CAI pre-treatment	CAI post 3 months of treatment	Effect size	Healthy
SF-36 Physical score	56.2 (21.5) [48.9–66.7]	64.5 (19.9)$^{\beta}$ [56.6–72.3]	0.39	85.4 (10.4)*§ [82.2–88.6]
Sf-36 Mental Score	70.6 (19.2) [62.7–78.4]	72.1 (17.8) [68.2–80.7]	0.08	83.1 (12.2)*§ [79.4–86.9]
FAOS				
Total	66.6 (17.2) [59.3–73.8]	74.8 (14.8)$^{\beta}$ [68.6–81.0]	0.48	-
Pain	62.0 (21.9) [52.8–71.3]	73.8 (17.3)$^{\beta}$ [66.5–81.2]	0.54	-
Symptoms	61.8 (21.6) [52.6–70.9]	71.4 (20.4)$^{\beta}$ [62.8–80.0]	0.44	-
ADL	83.6 (14.9) [77.3–89.9]	89.0 (10.7)$^{\beta}$ [84.5–93.5]	0.36	-
QoL	33.9 (25.1) [23.2–44.5]	40.9 (24.5)$^{\beta}$ [30.5–51.2]	0.29	-
Sport	50.0 (24.0) [39.9–60.1]	60.6 (27.4) [49.0–72.2]	0.44	-

Significance was defined as $p<0.05$. Significance was defined as $p<0.05$. *Significance between CAI (pre-treatment) vs. Healthy; §Significance between CAI (post-treatment) vs. Healthy. $^{\beta}$Significance between CAI pre-treatment vs. post-treatment.
Effect size was calculated as the difference between the 3 months assessment and pre-treatment assessment divided by the standard deviation at the pre-treatment assessment.

When analyzing gait of patients with CAI compared with healthy controls, significant differences were found for the majority spatiotemporal parameters (velocity, cadence, step length, base of support, stance, and single limb support). This is in accordance with several studies documenting gait alterations in patients with chronic ankle instability[29–34, 48]. Wikstrom et al. studied neuromuscular and biomechanical control in CAI patients during planned and unplanned gait termination, compared with controls. Authors showed altered biomechanical strategies during both planned and unplanned gait termination indicating alterations in feed-forward neuromuscular control and suggestive of feedback neuromuscular control deficits[48]. Nyska et al. reported on a longer ground contact time of the heel and midfoot as well as lateralization of the center of pressure[34]. Authors have reported on balance impairments in patients with ankle instability[14, 16], and sensorimotor deficits are well documented[9, 49]. These gait alterations could reflect the deficits caused by ankle instability or reflect compensation mechanisms adopted by patients to overcome their instability.

The basis for neuromuscular training to treat ankle instability is directly linked to our current understanding of ankle instability pathogenesis. Mechanical instability, describing objective physical and radiologic findings of ligamentous insufficiency, and functional instability with no objective evidence of insufficiency of static ankle stabilizers as previously described by Freeman et al.[50] should not be considered as two strictly separate entities. In 2002, Hertel et al.[51] suggested a model in which mechanical and functional instability are considered as part of a continuum, and later Hiller et al.[52] updated this model suggesting a group of different instability subsets, depending on the complex interaction of mechanical instability, perceived instability, and frequency of recurrent sprain.

The biomechanical device used in the study has been extensively examined in previous studies. The device is a foot-worn platform comprising two adjustable convex elements attached to its base. Through the adjustment of the elements, the device is capable of changing the patient's center of pressure in both sagittal and coronal planes during ambulation, thus generating perturbations[40]. Perturbation training can improve neuromuscular control, and was found to be beneficial in the treatment of various musculoskeletal pathologies[53–58]. In the current study, patients with CAI exhibited a significant improvement in gait velocity, cadence, symptomatic limb step length, less symptomatic limb step length, and symptomatic limb single limb support. Also, significant improvements in clinical outcome scores following treatment were found. The SF-36 PCS component increased, total FAOS score increased and in all the subcategories of the FAOS score. Interestingly, even after a short time of training, gait and clinical improvements have been recorded, although biomechanical deficits leading to chronic ankle instability have been present for an extended period, showing the plasticity of the neuromuscular system, with proper training. Several authors have published similar findings. Sefton et al.[58] showed that after six weeks of balance training, individuals with CAI demonstrated enhanced dynamic balance, proprioception, and changes in motor neuron pool

excitability compared with controls. Lee et al.[8] showed improved postural stability and ankle proprioception after 12 weeks training with an ankle platform system. The advantage of the device studied in the current work is the fact that it is used in the patient's environment allowing thousands of repetitions done while performing daily activities.

Several limitations of this study should be recognized. First, data was collected retrospectively from one therapy center database. Apart from the inherent limitations of a retrospective study, it is important to acknowledge that all patients in this database were referred for treatment indicating a possible selection bias. Patients were included in this analysis based on the Ankle Consortium criteria. However, other tools (combination of the CAIT and AII) should be considered to allow a more specific characterization the population. Second, four patients in this study had bilateral ankle instability. It might be that this subgroup has adopted different compensation gait strategies. Third, only spatiotemporal gait data were collected. Future studies should consider using a 3-dimentional gait analysis incorporated with electromyography analysis. Fourth, a longer follow-up period is needed to examine whether the clinical and gait metrics improvements achieved following treatment are sustainable or may continue to improve over time. Lastly, the healthy control group had missing data for the FAOS, which affects the ability to compare the results of the CAI following treatment with those of healthy controls. Furthermore, this study lacked a control group of CAI patients. Having such a control group would have allowed drawing a conclusion regarding the efficacy of the treatment. Currently, the results of this study showed an improvement in gait patterns and clinical outcomes, however without a control group we cannot determine whether the improvement was due to the treatment alone or other reasons. Future studies should consider a randomized controlled trial methodology.

In conclusion, significant differences in the baseline spatiotemporal gait metrics of patients with CAI and healthy controls were noted. Clinical and gait metrics improvement can be expected after 12 weeks of perturbation training using AposTherapy.

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Conflict of interest

Avi Elbaz and Amit Mor hold shares in AposTherapy. Ganit Segal is a salaried employee of AposTherapy. Shay Tenenbaum, Ofir Chechik, Jason Bariteau, Nathan Bruck, Yiftah Beer, and Mazen Falah are co-researchers in a number of studies. They do not receive and are not entitled to any financial compensation from AposTherapy.

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