Evaluation of Methods for Monitoring Back Stiffness Response to Spinal Mobilisation Using an Automated Back Therapy Device

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Abstract

Background: There are many products available that help to mitigate back aches and pain but there are very few ways to measure the effects of using those products without medical devices. The aim of this study was to determine if BackHug (automated back therapy device) can detect intra-session change in back tension.
Methods: 13 volunteers participated in an intra-subject repeated measures study. All took part in both intervention and control sessions, using a Myometer (Myoton Pro) to verify change in back tension (stiffness reading on Myometer). Three channels of data collection were used: 1) Back Tension Tracking software using direct electrical current feedback from the BackHug device, 2) Stiffness reading using the Myoton Pro, 3) Subjective back discomfort score.
Findings: There was a total average stiffness reduction post intervention vs control of (measurements taken with Myoton), an average reduction in subjective back discomfort score of 44% from pre-study to completion of the last intervention session and evidence that Back Tension Tracking can detect a change in intra-session electrical current data.
Interpretation: The reduction of total average intra-session change in stiffness using the Myoton Pro verified that BackHug does reduce back tension and supports the subjective back discomfort results with objective results. BackHug can detect change in intra-session electrical current data but further refinement of its back tension tracking software and studies with increased number of participants are required to solidify the findings of this study.

Introduction

Back aches and pain causes so many problems and greatly reduces human productivity. Many individuals with back aches cannot perform usual activities, some cannot even stand and walk normally. There are also plenty of products that help to mitigate the aches and pain, however, we do not have an easy way to measure the effects of using those products on our backs. People who decide to buy those products rely on the advertisement and other people's feelings.

In this study, we conducted experiments on our product, BackHug, using a medically approved device called Myoton Pro to see exactly what extent it can help to reduce back stiffness. The result indicated that, (1) our product can reduce up to 44% of back tension after using 3 times over a 2 week period. And (2) we also see the same tendency between subjective participant discomfort rating and the machine score.

And finally, we developed a method, called Back Tension Tracking, that automatically analyzes the back aches and pain reduction over time (stiffness), which helps our customers to see their back condition after every treatment and adjust usage to achieve the best result.

Aims

1. To determine if BackHug could detect intra-session change in back tension using a new smart software feature - Back Tension Tracking (BTT).
2. To verify BackHug's effectiveness with an independent, medically approved, soft tissue stiffness measurement tool - Myoton Pro.
3. To establish if there is a connection between subjective participant back discomfort ratings, Myoton back stiffness measurements and Back Tension Tracking feedback.

What is BackHug & Back Tension Tracking?

BackHug is an automated back therapy device designed to reduce back tension. It applies deep tissue pressure to carefully selected locations along the centre of the back. The treatment was transferred from a manual therapy technique devised by a qualified physiotherapist and the Founder of BackHug - Chongsu Lee. A recent development in the design means that BackHug also treats the shoulder blade area in addition to the centre of the back through a smartphone app. Users can control their session strength, speed, duration and program on the app - all in real time.

Back Tension Tracking is a new software feature that aims to monitor user back tension changes with BackHug, analyse the back tension data and to turn it into meaningful feedback for the user. Initial

testing will evaluate whether Back Tension Tracking can recognise a change in intra-session user back tension data.

What is the Myoton Pro?

The Myoton Pro is a scientifically approved hand held device that measures soft tissue stiffness and was used as a gold standard benchmark for the results obtained from Back Tension Tracking (Bizzini and Mannion, 2003; Schneider et al., 2014). Participants were asked if they were willing to have their back stiffness measured with the Myoton Pro before and after each session. The participant could advise if they preferred the BackHug employee performing the Myoton test to be male or female. The measurement required direct access to the skin from the neck to the waist so the participant was asked to lie on their front and lift their top up or remove their top to expose this area. The Myoton palpates the skin gently with a plastic probe to generate back stiffness results. For further information and a video of how the Myoton works please visit: https://www.myoton.com/technology/

How were Subjective Back Discomfort Scores Recorded?

Each Participant was asked their subjective back discomfort score on a scale of 1-10. A score of 1 indicating little to no back discomfort and 10 meaning difficulty walking and sitting with severe back discomfort. The participant was asked their back discomfort score before their first session and one day after each session by text to reduce bias (so the scores were not influenced by the study organisers). The participant was asked for their back discomfort score in person before the 2nd, 3rd and 4th session to ensure that a before and after score was available for each session. All of the study organisers were asked to remain as neutral as possible when asking for a participant's back discomfort score.

Method

Participants

Participation in the study was completely voluntary and all participants were advised that they could remove themselves from the study at any point. The distribution of participants is seen in Figure 1.

Gender	Number of participants
Male	6
Female	7
Total	13

Figure 1 - Participant distribution

Their ages ranged from 35-59 years old and all participants were recruited through an online advertisement agency then an in-house screening process to ensure the participants had genuine back

tension. In the screening process, the participants were asked to fill in an online questionnaire and phoned by a member of the BackHug team to discuss their answers further. Each participant was given a detailed information sheet outlining what BackHug is and what the study entailed before signing a consent form. The study was for research purposes only.

Evaluation Preparation

The participants wore light clothing (t-shirt, thin jumper etc) on their upper half to experience the best results from the session. The participant was asked to remove any obstructions from their waist and torso area such as belts (women were advised to wear soft bras without clips if possible as hard obstructions could cause discomfort during a session). The participant was asked to wear similar clothing to each session they attended for test repeatability.

It was advised that BackHug is not suitable for persons with reduced physical, sensory or mental capabilities unless they have been given supervision or instruction. In addition, BackHug should not be used by pregnant women or persons who are ill. If a participant had back/neck/shoulder/hip injuries, was receiving medical treatment in any area of their body or had any back/neck/shoulder/hip related medical conditions, they were asked to consult a physician before use.

Common side effects were stated to all participants and include red marks, bruising, headaches, dehydration or feel lethargic after BackHug sessions. These reactions are not uncommon after a good therapy session, similar to a deep tissue massage from a manual therapist. It was advised to drink plenty of water before and after BackHug sessions and avoid strenuous exercise immediately after a session. Any red marks/bruising should disappear within 24-48 hours post therapy and are similar to reactions from common massage sessions.

Any personal participant information collected for study purposes was kept strictly confidential and any data used out with the study will have their name and address removed.

Procedure

The participant was asked to take part in four BackHug sessions over two weeks. The sessions lasted 1.5hrs each with 30 minutes allocated to the session on BackHug and the time before/after the sessions were used for Myoton measurements, subjective back discomfort scores and other administrative tasks. The first session was a control where the participant lay on a massage table for 30 minutes in the supine position and did not receive a BackHug session. The remaining 3 sessions were intervention sessions where the participant received a session on BackHug.

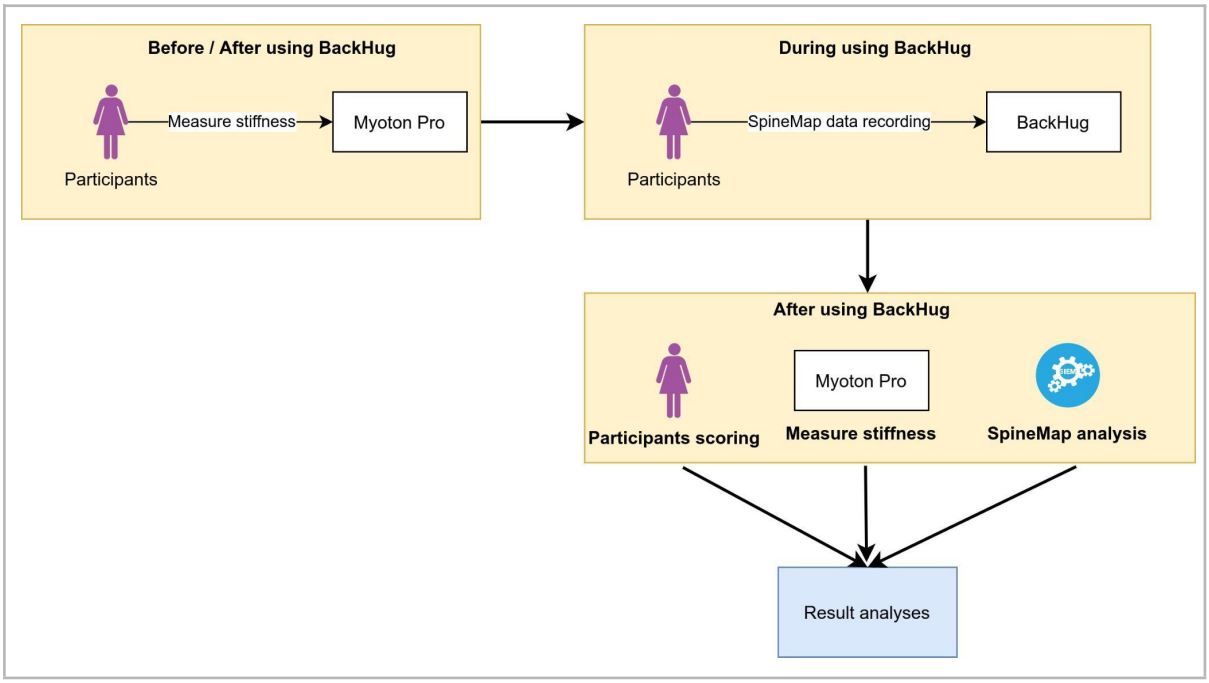

Figure 2 - Experimental setup

Figure 2 demonstrates the 3 phases in our experimental setup, these steps are repeated for every session over the 2 week period.

1. Before using BackHug: we measure participants's stiffness using Myoton Pro. The data will be compared with the stiffness after using the device to see if there are any changes to the stiffness.
2. During using BackHug: we record Back Tension Tracking data, which is electrical current that controls the strength of pressure applying fingers.
3. After using BackHug: Participants will give a score that measures their discomfort, or in other words, their back aches and pain. We also run analysis on BTT software and Myoton.

The 3 intervention sessions used the BackHug device with the following settings:

- The device program was set to "Full Back" for every session.
- The number of fingers enabled was as recommended by the BackHug User app for the height of the participant.
- The session time was set to 30 minutes.
- The session speed was set to "Medium".
- The device strength settings were selected by the participant on the first session within the first 2 minutes of the session to a point where they feel proper treatment and then kept consistent for all sessions. At the beginning of each of the sessions the participant was

allowed 2 minutes to warm up to their specified strength.

All sessions took place at the BackHug therapy room located at - 21 Lansdowne Crescent, Edinburgh, EH12 5EH. The participants provided their availability through an online booking system - Calendly. This prevented any overlap and gave flexibility to participants who had to schedule around work and personal life.

The BackHug team demonstrated how to use BackHug before the participant's first session. The participant was taken through the following:

1. How to use the BackHug User App
2. How to get on/off the device
3. How to position themselves on the device

All sessions were carried out in the Edinburgh BackHug therapy room where the environment was monitored closely. The BackHug device, massage table and contact points were sanitised/cleaned before and after each session to maintain a clean, safe environment for the participant. It was important to record temperature, humidity and time of the session as these are all factors that can influence the results. Other variables recorded were exercise completed in the last 12hrs and clothing worn to each session. The individual BackHug settings were recorded automatically in the BackHug WebApp for each participant.

Myoton Measurement Procedure

The Myoton measurements were recorded with the participant laying in the prone position on the massage table. There were 6 measurement locations as illustrated in figure 1. An 'x' was marked on the head of the muscle on the LHS and RHS of the vertebral column horizontally in line with the locations illustrated in Figure 3. The solid black dots show the 6 measurement locations:

- Halfway between the top and bottom of the scapulae.
- In line with the base of the scapulae.
- Half way between the bony protrusion of the iliac crest and the lowest rib.

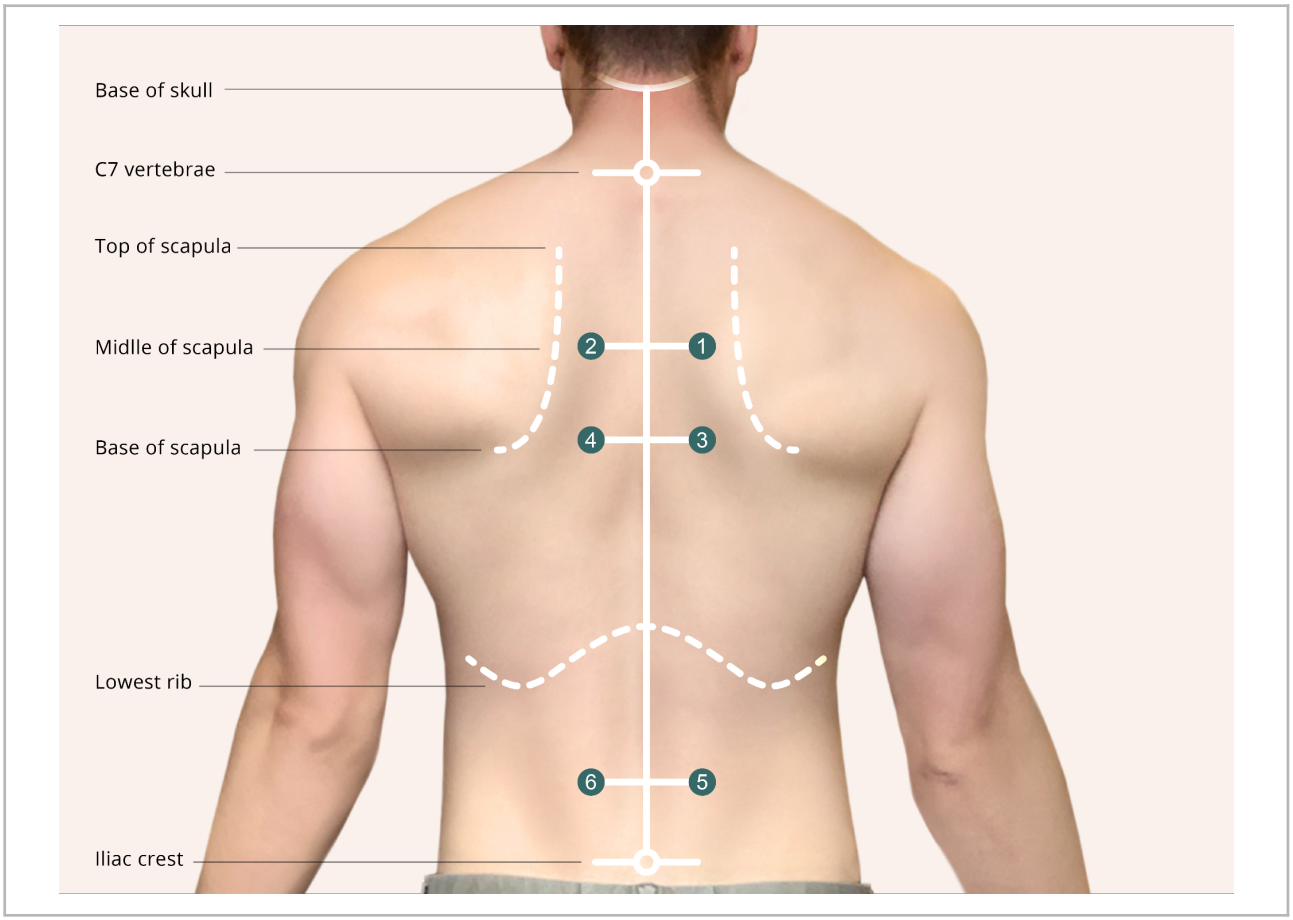

Figure 3 - Myoton measurement locations

The 6 measurement locations were selected as they mirror the contact points between the BackHug fingers and the participants back. One measurement was taken with the Myoton at each location immediately before and after each session. Before the study commenced, the Myoton device was pre programmed with all of the participant's data (height, weight, age and gender) and the treatment pattern was standardised for all measurements (average of three pulses). It was possible to measure soft tissue tone, stiffness, elasticity, relaxation and creep with the Myoton. For the purpose of the study, stiffness was selected as the most important property to use as it represents back tension as a biomechanical measure. Each measurement had to be below a 3% coefficient of variation (CV) to be considered valid.

Results

Myoton Results

The Myoton was used to measure back stiffness before and after each session, including the control session. The Myoton measurement location with greatest average change in stiffness over the 3 intervention sessions compared to the control session change in stiffness was used for each participant. The total average stiffness reduction vs control for the study was 376%, seen in Figure 4, and takes the

average of the measurement location with greatest change in stiffness vs control for each participant (the measurement location was not the same for each participant as they had tension in different areas of their back).

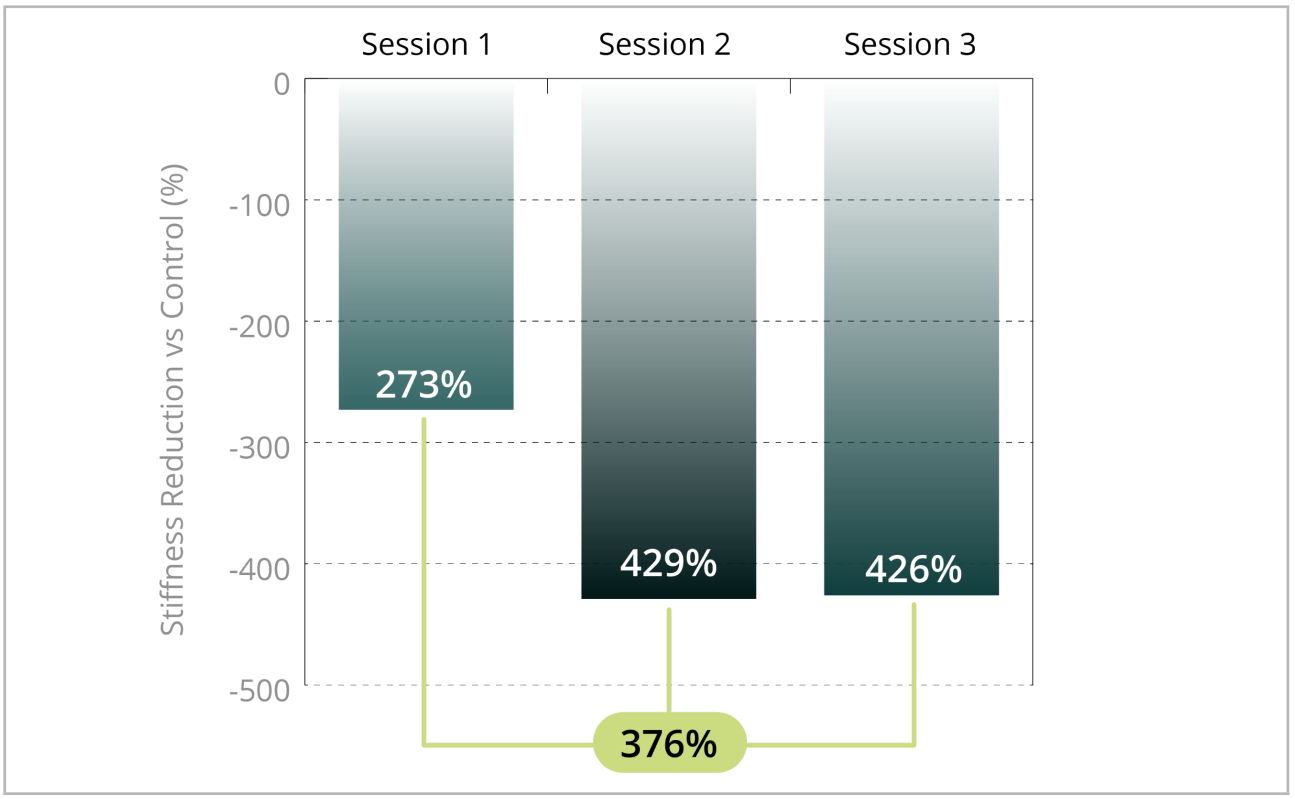

Figure 4 - Average reduction in back stiffness compared to the control session for all participants.

Subjective Back Discomfort Score Results

The average reduction in subjective back discomfort score from the before 1st session score to the post 4th session score was 44% (Figure 5). This is an average of all participants who took part in the study.

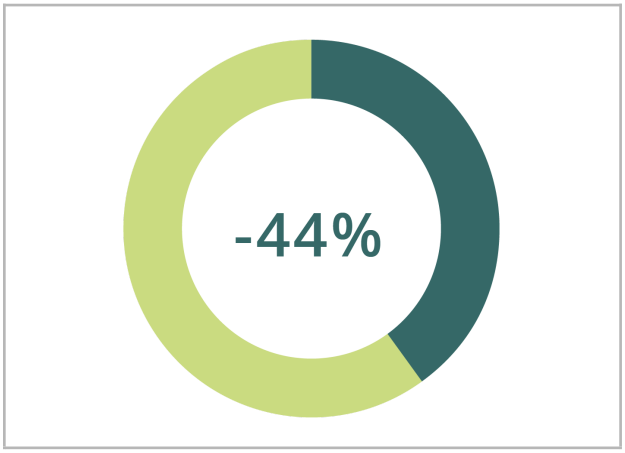

Figure 5 - Average reduction in back discomfort score from the start to completion of the study for all participants.

Electrical Current Results

The feedback from BackHug is by means of electrical current. Figure 6 shows an example from one of the participant's sessions where the RHS shoulder region is targeted by BackHug. The electrical current feedback is graphed to show the average current for an upstroke of the first 5 strokes vs the last 5 strokes in a session. This gives a visual representation of how the current behaves when pushing into the body. The critical value from Figure 6 is the 'stiffness improvement average' which indicates the change in average current from the first 5 to the last 5 strokes. In Figure 6, the average current has increased by 437 from the first 5 to the last 5 strokes. The current is amplified by 10,000 so the average current change is actually 0.437A.

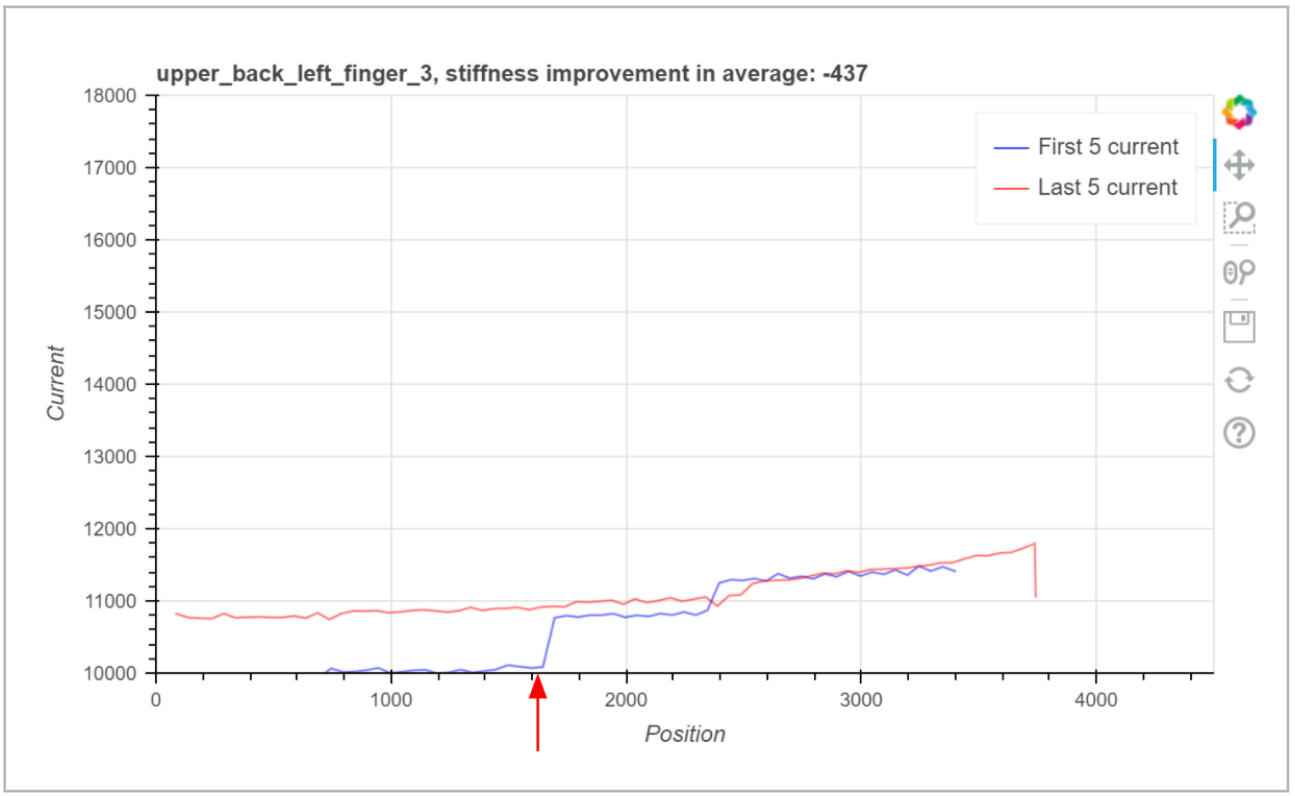

Figure 6 - Example of electrical current feedback from one participant.

The average change in electrical current from the first 5 to last 5 strokes was recorded for all 12 finger motors. In order to compare the electrical current to the Myoton results, the motors were split up into 6 zones as shown in Figure 7.

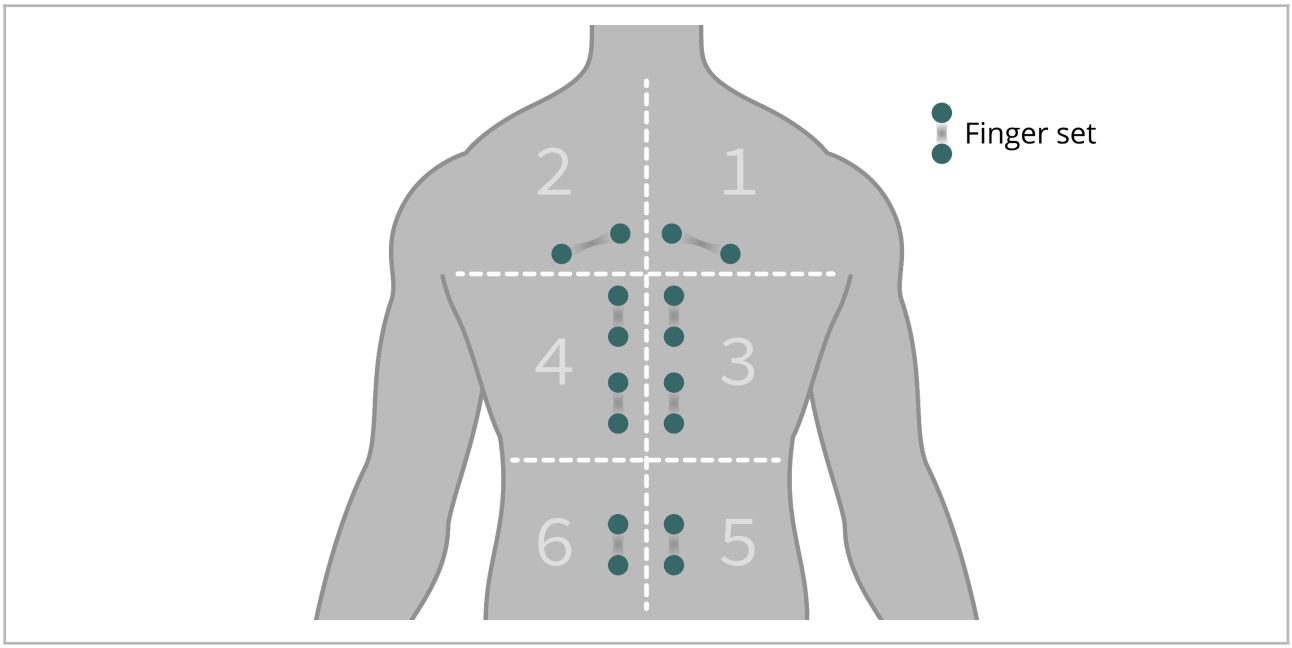

Figure 7 - Back score illustration

The zone numbers match the Myoton measurement locations like for like. Figure 8 provides the zone with greatest change in electrical current for each participant and compares it to the Myoton measurement location with greatest change in stiffness. The negative scores for electrical current represent the average current of the last 5 strokes being greater than the average current of the first 5 strokes.

Participant No.	Results						Greatest Increase in Electrical Current	Myoton - Greatest Change in Stiffness
	Zone 1	Zone 2	Zone 3	Zone 4	Zone 5	Zone 6		
1	**-160**	-105	-84	-38	-81	-53	Zone 1	2
2	**-320**	-9	-246	-288	69	-314	Zone 1	5
3	19	-149	-122	-180	**-234**	-150	Zone 5	2
4	-22	34	3	94	-41	**-212**	Zone 6	5
5	-221	-104	-154	**-244**	-243	-138	Zone 4	6
6	-165	92	**-192**	-189	-59	-140	Zone 3	1
7	-82	-58	-61	19	**-491**	-167	Zone 5	1
8	-118	-78	-108	-125	-73	**-176**	Zone 6	5
9	-247	-68	-214	4	**-254**	-186	Zone 5	6
10	-228	-137	-278	-1	-276	**-573**	Zone 6	4
11	**-216**	25	-145	-199	57	-26	Zone 1	4
12	-176	-203	-157	**-213**	-139	-25	Zone 4	2
13	-181	196	-211	-177	-184	**-331**	Zone 6	6

Figure 8 - Greatest change in electrical current feedback from BackHug over the 3 intervention sessions

Discussion

The aims of the study were to:

1. To determine if BackHug could detect intra-session change in back tension using a new smart software feature - Back Tension Tracking (BTT).
2. To verify BackHug's effectiveness with an independent, medically approved, soft tissue stiffness measurement tool - Myoton Pro.
3. To establish if there is a connection between subjective participant back discomfort ratings, Myoton back stiffness measurements and BackHug BTT feedback.

From the data collected, BackHug can provide intra-session change in back tension through means of electrical current feedback. Figure 8 illustrates how the electrical current feedback can be split into zones for analysis. Although the greatest change in electrical current did not match the greatest change in Myoton stiffness measurements for all participants, there was a pattern found with the electrical current feedback. It was first thought that the average electrical current would decrease for the last 5 strokes as the soft tissue relaxes but the study found the opposite - the average electrical current increased for the last 5 strokes. This shows initial findings that as the soft tissue relaxes, the body gradually sinks into BackHug's fingers throughout an intervention session and therefore meeting the solid bodyweight of the user earlier in the finger stroke. As a result, the average current for a stroke increases as the bodyweight of the user is seen for a greater percentage of the total push stroke. Further testing is required to verify this claim as there were a limited number of participants in this study.

The Myoton Pro verified that BackHug can reduce back stiffness as the total average reduction in back stiffness for all participants was 376% from the control. This is the first objective verification from a medically approved device that BackHug provides a significant method of reducing back stiffness in users with back discomfort (Bizzini and Mannion, 2003; Schneider et al., 2014).

All three data collection methods used (Myoton Pro, electrical current feedback from BackHug and subjective back discomfort score) showed that BackHug can reduce back tension but it is important to analyse all three together to check for overlapping patterns. The total average reduction in subjective back discomfort score backs up the total average reduction in back stiffness measured with the Myoton. This provides a subjective view from the participant verified by an objective measure which strengthens the claim that BackHug reduces back tension. As stated above, the electrical current feedback was compared with the Myoton results using zones. Figure 8 shows that the electrical current for 12 out of 13 participants increased for the zone associated with the Myoton measurement location with greatest decrease in stiffness. If the suggested claim that an increase in average electrical current from first 5 to last

5 strokes means a decrease in back tension then this provides an objective measure from BackHug which agrees with the objective measure from the Myoton.

Limitations & Future Study

Participants with subcutaneous fat greater than 20mm are less likely to give reliable soft tissue stiffness measurements according to Myoton Pro manufacturers. Owens et al. (2007) found that participants with higher BMI displayed lower stiffness and concluded that this was due to a thicker layer of adipose tissue at the measurement location. BMI does not take into account the muscle to fat ratio so may not be an accurate description. It would therefore be beneficial, if the Myoton Pro is used for future studies, to ensure that participants are assessed pre-study to make sure their adipose tissue is ⩽ 20mm. Furthermore, the Myoton measurements were taken immediately post-intervention and no record of lasting effects of BackHug were measured. Ideally, the participants would have their Myoton measurements taken multiple times over a 24hr period post-intervention.

The study had a limited number of participants and few participants with high levels of back discomfort. Increasing the number of participants with high levels of back discomfort would have strengthened the findings, in particular the proposed method for analysing back tension through electrical current feedback. Also, the schedule for the 3 intervention sessions was left up to the participant as long as all were completed within 2 weeks from the control session as the study had to work around the participant's work and personal life. If all participants were able to complete the 3 intervention sessions with the same time period in between each one then it would have reduced the variables in the study and strengthened the results.

The proposed electrical current data collection and analysis method needs further refining to provide a solid claim that this can be used as a measure of change in back tension. The data collection is still noisy and the pattern exhibited by average change in intra-session electrical current needs to be backed up by a greater number of participants.

Conclusion

The findings of this study present strong evidence that BackHug can reduce back tension in users with back discomfort. Previously, BackHug had only been verified by subjective questionnaires but now, through the use of a Myoton Pro, there is objective proof that BackHug works. The key takeaway is that not only did the objective Myoton back stiffness data agree with the subjective back discomfort score data but there are strong signs that the electrical current feedback from BackHug also agrees. The proposed method of electrical current feedback analysis proposes that an increase in average electrical current from the first 5 strokes to the last 5 strokes is a measure of back tension reduction. This claim needs further research and testing to prove its validity.

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