

***The Effect Of The Myobac To Produce Increased Gross
Range Of Motion Of Flexion And Extension, In The Thoracic
Spine.***

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Structured Abstract

Study Design. 2 week trial of the Myobac orthosis was conducted using 2 intervention groups, those without thoracic spine dysfunction, and those with. Results were compared to a control group.

Objectives. To determine the biomechanical effect of the 'Myobac' orthosis on the thoracic spine, in flexion and extension.

Summary of Background Data. There is no previous research or literature regarding the 'Myobac'. The effect of orthoses on the spine has been well documented in the lumbar spine, but not in the thoracic spine.

Methods. Gross flexion and extension range of motion (ROM) of the thoracic spine was measured. Pre and post intervention measurements were analysed for treatment groups, measurements at week 0 and at week 2 were analysed for control group, using One-Way ANOVA and the Kruskal-Wallis Test, to determine the effect of the Myobac on thoracic spine flexion and extension.

Results. The treatment groups, both with and without dysfunction, had statistically significant increases in gross thoracic ROM in flexion and extension post intervention, compared with the control group. There was no significant difference found between the two treatment groups post intervention.

Conclusions. The Myobac orthosis produces an increase in gross thoracic spinal ROM in flexion and extension. However this is not proven to be clinically significant without further research.

Key Words

Orthosis
Thoracic Spine
Flexion
Extension
Myobac

Key Points

- * 2 week trial of Myobac Orthosis using 2 intervention groups, those without thoracic spine dysfunction, and those with. Results were compared to a control group.
- * Statistically significant difference found between 2 intervention groups compared to control group.
- * Myobac clearly demonstrates efficacy to increase spinal gross ROM of flexion and extension in the thoracic spine.

Mini Abstract/Precis

A 2 week trial of the thoracic orthosis 'Myobac' was performed. Significant differences were found in the normal and thoracic spine dysfunction group, in comparison to the control group. The results clearly demonstrate the efficacy of the Myobac to increase spinal mobility (flexion and extension) in the thoracic spine.

The Efficacy Of The Myobac To Produce Increased Gross Range Of Motion Of Flexion And Extension, In The Thoracic Spine.

INTRODUCTION

Orthopaedists have recommended that active and passive range of motion (ROM) exercises be used to maintain joint motion and flexibility, with passive exercise performed by an external source such as a therapist or a device¹.

Exercise programs and the use of orthoses (both bracing and external devices), are the two most common modalities used in treating a variety of conditions affecting the spine^{2 3}. Orthoses are commonly utilized in the management or rehabilitation of mechanical spinal dysfunctions, as they are designed, depending on the device and dysfunction, to restrict or increase mobility⁴.

Lumbar orthoses produce a correctional alignment of the spine. Whilst lumbar braces are designed to restrict spinal mobility, treat scoliosis or to provide spinal stability, the external lumbar orthoses decrease lordosis. The biomechanical change that occurs in the lumbar spine produces a natural secondary alignment of the thoracic spine. This outcome was highlighted in a prospective study that examined the biomechanical changes in the spine with various spinal orthoses, where lumbar lordosis showed significant reduction, with a secondary reduction in thoracic kyphosis⁵. Whilst the effects of the orthoses in the above study were investigated over a long period (20 months), participants were all moderate sufferers of adolescent idiopathic scoliosis (AIS). The research only investigated symptomatic subjects in adolescence, making

the results of this study difficult to extrapolate to other populations. Further research has documented that the use of lumbar orthoses improved symptoms of low back pain in 30-80% of users⁶ as well as improved posture in sitting and standing^{7 8}. Whilst these results were produced from an extension force applied to the lumbar spine, the force was applied using a corset or brace, not an external spinal mobilization device.

The effects of lumbar orthoses, both braces and external mobilization devices, on the spine have been well documented^{2 3 5 7}. In the thoracic spine, whilst the effect of some braces has been investigated, there is no literature on the role of external mobilization devices. This may be attributed to the fact that there have been, up to now, very few orthoses designed specifically for the thoracic spine.

The Myobac is an orthopaedic auto mobilizing device⁹ that produces a controlled extension mobilization of the thoracic spine, at the joints, and also provides both an indirect and direct effect on paraspinal myofascial tissue.

The device comprises a body that is arched or curved along a longitudinal centre line and with lateral extension, sloping downwards (Figure 1). When placed upon a firm flat base, the patient lies supine on the device with the longitudinal centre line of the device aligned with the upper/mid thoracic vertebrae. As a result of the weight and position of a person lying on the device, a passive extension moment of the thoracic spine is produced.

The most common musculoskeletal dysfunctions in the thoracic region are disorders of the thoracic intervertebral joints, presenting as hypomobility of one or more

intervertebral segments, often with associated abnormalities of the paraspinal and periscapular muscles¹⁰. Most common is excessive rounding of the upper spine, which is most often associated with, or as a result of poor posture or degeneration¹¹. Previous literature states that whilst this increased thoracic kyphosis is the main focus in rehabilitation and intervention¹¹, symptomatically it is the pain associated with the increased thoracic kyphosis that is debilitating¹².

Past studies have found that interactions between thoracic spine posture and mobility play a role in spinal pain syndromes¹³. In the thoracic spine a controlled extension mobilization, as produced by the Myobac, may lead to a decrease in thoracic kyphosis, effecting some relief from the pain associated with postural dysfunction. This potential effect is the significance of investigating the Myobac device.

Normally, mobilization of the vertebral joints causes an increased range of motion available at that spinal level. The superior zygapophyseal facets are oriented superiorly and laterally, whilst the inferior zygapophyseal facets face anterior and medial¹⁴. It is claimed that the extension moment created by the Myobac would causes a posterior-anterior glide of these facet joints, as well as produces a mobilizing effect by gradually increasing the duration of stretch on collagen structures, allowing plastic deformation to increase capsular mobility and improve joint play¹⁵.

The Myobac, via additional nodules on its superior surface, also provides a direct mechanical/ischaemic compression and stretch effect to the musculature of the thoracic spine, which is claimed to deactivate and release trigger point activity⁹. The effects of this type of inhibition/release technique have long been used in manual

treatment of muscle pain¹⁶ and can be described as increasing the range of motion, which is normally restricted by pain.

Karjalainen et al, showed that controlled extension of the spine using an extension brace in the thoracolumbar region effectively improved patient symptoms of pain. This study, however, did not use a control group¹⁷ so we do not know whether the results are just normal variants or an outcome of the use of the brace. The present study utilised a control group to monitor changes in a period of two weeks and compares these results to treatments groups, post intervention. This aims to isolate the results as being a direct outcome of the use of the Myobac device. In patients with neuromuscular scoliosis, Bayar et al found that spinal orthoses increased the spinal range of motion¹⁸. This study design also had no control group, included an exercise programme and only investigated symptomatic patients. Due to the orthoses being used in conjunction with an exercise programme, it is difficult to determine whether the results were due to the exercises or the orthosis. This study did not include exercises in order to isolate the results directly to the orthosis, and investigated both asymptomatic and symptomatic participants, to determine if dysfunction would influence the outcome of the use of the Myobac.

Further research supports intervention in the sagittal plane to treat back pain, with Dettori et al investigating flexion and extension exercise. In this randomised clinical trial, results showed a decrease in pain severity, as well as an increase in spinal mobility and functional status¹⁹. Using an identical method to the present study, Dettori et al measured spinal mobility with a flexible tape measure, determining the

amount of distraction and attraction between two points on the lumbar spine during flexion and extension.

The present study investigates the biomechanical effect of an extension moment on the thoracic spine, via the Myobac orthosis, and investigates the effect of the device on spinal mobility, in thoracic gross range of motion of flexion and extension in both intervention groups.

MATERIALS AND METHODS

The study was approved by the Victoria University Human Research Ethics Committee. Twenty four (24) volunteers (10 male, 14 female; age range 20-54; mean 28.5) were recruited for this study after completing a consent form and a questionnaire to exclude acute injury in the thoracic region such as fractures, due to the risk of causing delayed healing or further aggravation/damage by using the orthosis.

Volunteers were assigned to either the control group (n=7), the treatment group without thoracic dysfunction (n=6) or the treatment group with thoracic dysfunction (n=11). The control group had no presence of dysfunction. The presence or absence of dysfunction was determined by the use of a survey. Questions regarding current and past history of thoracic pain were used to determine dysfunction. Participants with no current or past history of thoracic pain were assigned to the control group or the treatment group without thoracic dysfunction. There was no order effect, participants were assigned to the groups in random order.

Each participant was instructed to adopt a comfortable stance. The researcher then palpated the spinous process of T1 and marked it using a non-permanent skin marker pencil. The same was repeated for the spinous process of T12²⁰.

The distance between the spinous processes of T1 and T12 was measured using a tailor's tape measure (centimetres). Participants were then asked to actively bend forward as far as possible, keeping their knees straight, and the distance between the two marked levels re-measured. The difference between the two measurements was defined as the gross ROM of flexion²¹.

Each participant was then asked to lie prone on the examination table. A velcro strap was placed over the pelvis to stabilise it during testing. Their hands were positioned on the table, by their shoulders. Participants were asked to straighten their elbows, coming up into a push-up position and lifting their upper body, to extend their back as far as possible. The distance between the two marked levels was defined as the gross extension ROM²². (Figure 2)

Participants repeated all movements 3 times in order to establish a mean value. Previous literature has utilized this procedure to measure spinal mobility in flexion and extension¹⁹.

Intervention using the Myobac

Using the manufacturer instructions and guidelines⁹, the examiner trained/instructed the participants in the two treatment groups in the use of the Myobac (Myomedics Pty Ltd, Springvale Victoria). The Myobac towel was placed on a flat surface and the device positioned on the marked area (Figure 1). Participants lay on the Myobac in the supine position, for 5 minutes a day for a period of 2 weeks. Participants were asked to continue their normal daily activities, including work/sports/hobbies, however were required to refrain from any treatment in the form of manual therapy.

At the end of the 2 week period, all participants, including the control group, had their gross ROM of flexion and their extension ROM measured. The post-intervention measurements followed the same procedure as the pre-intervention measurements. All measurements were performed at the same time of day, to compensate for the normal variation in disc height over the duration of the day.

Pre and post-intervention ROM measurements were then analysed for both intervention groups and the control group using One-Way ANOVA and the Kruskal-Wallis Test, using SPSS version 11. Significance was set at the $\alpha < 0.05$ level.

RESULTS

The Average Measure ICC for researcher ROM measurements 1, 2 and 3 was 0.994 (95% C.I.:0.989-0.997) for flexion and 0.991 (95% C.I.:0.983-0.996) for extension, indicating a high level of reliability for the three readings.

The mean gross thoracic ROM measurements (+/- SD) of the control and both treatment groups in both flexion and extension are presented in Table 1 and 2. The mean gross thoracic ROM remained relatively unchanged in the control group in both flexion (-0.38cm, SD=0.01) and extension (-0.53cm, SD=0.87) at the end of the intervention period. As differences were calculated in centimeters, a negative reading indicates a loss or decrease in ROM. The range of active thoracic flexion increased after the Myobac intervention in the treatment group without dysfunction (0.79cm, SD=-0.4), whilst it remained relatively unchanged in the treatment group with dysfunction (0.35cm, SD=0.21). The range of active thoracic extension increased post Myobac intervention in both the treatment group without dysfunction (1.04cm, SD=-0.07) and treatment group with dysfunction (0.78cm, SD=-0.38)

One-way ANOVA and the Kruskal-Wallis Test were used to compare the mean pre- and post-treatment ROM values for the three groups. Statistical analysis is presented in Table 3 and Table 4.

A statistically significant difference was found between the control group and both the treatment groups in flexion ($F=5.32$, $p=0.014$, $\text{Eta}^2=0.297$). Further analysis as to where this significance lay was achieved by post-hoc analysis. There was a significant difference in gross thoracic flexion ROM after Myobac intervention, between the control group and the treatment without dysfunction group (Mean Difference 1.17, $p=0.015$). The treatment group with dysfunction also demonstrated a statistically significant increase in gross thoracic flexion ROM after Myobac intervention (Mean Difference 0.84, $p=0.046$). No other significance was reported.

Examination of the chi-square value, which has been corrected for ties, indicates that there is a statistically significant difference between thoracic extension ROM results between the 3 groups. The treatment group without dysfunction had the highest increase in ROM (mean rank 16.67), followed by the treatment group with dysfunction (mean rank 13.86)

Measurements post intervention showed that the treatment without dysfunction group had a slightly higher increase in ROM than the treatment with dysfunction group post intervention (mean difference flexion: 0.32cm, extension: 0.26cm). However analysis showed that there was no statistically significant difference in post intervention ROM between the two treatment groups (with and without dysfunction).

DISCUSSION

The study demonstrated an increase in active thoracic flexion and extension for subjects using the Myobac, but no significant change in the control group, and so it complements the findings of a previous study that investigated the effect of an extension-force orthosis on the lumbar spine⁵. The active flexion and extension ROM available at the thoracic spine remained relatively unchanged in the control group over the two week period, as expected. A large effect size was achieved (flexion $\eta^2=0.29$, extension $\eta^2=0.37$), further adding to the validity of the results.

The increase in thoracic flexion and extension mobility, produced by the Myobac, may have a direct effect on those with thoracic kyphosis. Results of the study

suggests that the excessive rounding (flexion) of the thoracic spine may benefit from the extension mobilization, by increasing spinal mobility. This increase in ROM may potentially decrease the symptomatic pain associated with thoracic kyphosis, as previous literature has linked both thoracic spine posture and mobility to spinal pain syndromes¹³.

The findings suggest that the Myobac orthosis can be utilised at home by the public to increase their spinal mobility. The study supports use of the orthosis by those with symptomatic biomechanical thoracic dysfunction, as well as asymptomatic people. Those who are limited by restricted movement of the spine can benefit from the Myobac, as daily use indicates that this restriction can be improved over a two week period. However, whilst there was found to be an increase in ROM, it has not been shown whether or not this increase is maintained after the two week period. Follow up investigations are warranted to determine the long-term effect of the Myobac on spinal mobility.

The results indicate that the Myobac orthosis can increase spinal ROM in the sagittal plane, it has not been ascertained whether this is clinically significant. The study did not attempt to investigate clinical changes in symptoms, but was confined to an investigation of changes in measured ROM. Restricted ROM in symptomatic individuals may be, but is not necessarily always a feature of spinal pain or dysfunction, and may simply represent normal variation of asymmetry²³. To determine the clinical significance of an increase in spinal ROM, pain and functional outcome measures should be looked at in further research.

Limitations of study

Data collection took place at the same time of the day for each participant pre and post intervention to compensate for the normal variation in disc height over the duration of the day. It is possible that the daily activities undertaken by individual participants may also have been responsible for some variation.

Correct use of the Myobac by participants could not be monitored due to the nature of the study, which required participants to use the device unsupervised. However steps were undertaken to minimise the risk of error. The researcher educated by the manufacturer and then in turn trained, instructed and demonstrated the correct way to use the Myobac with each participant prior to its use, strictly adhering to the manufacturer's guidelines.

CONCLUSION

This study demonstrates that the Myobac can increase the gross thoracic ROM of flexion and extension. There was a significant increase in flexion and extension ROM in both intervention groups after using the Myobac, compared to the control group. This indicates that the device is efficacious in increasing spinal mobility in people with normal spines as well as those with thoracic spine dysfunction, thus making a strong argument for further research using functional outcome measures in order to determine the clinical significance of the changes in ROM.

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Figure Legend

- Figure 1.** The Myobac Orthosis. Placed on a hard surface on the included Myobac towel.
- Figure 2.** Patient positioning for measurement of the thoracic spine, extension range of motion.

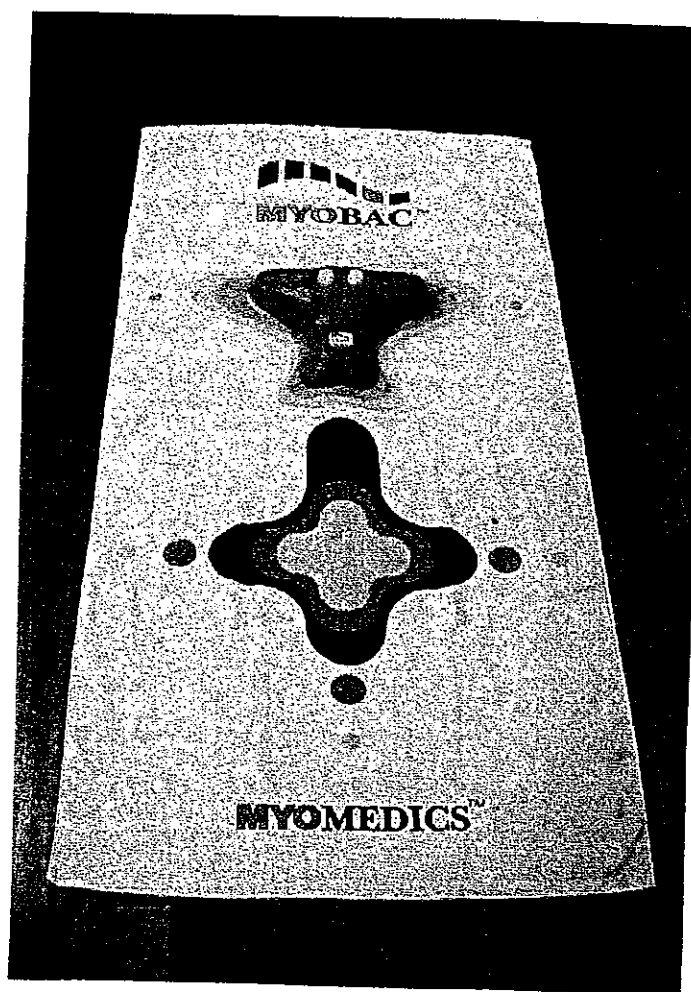


Figure 1. The Myobac Orthosis. Placed on a hard surface on the included Myobac towel.

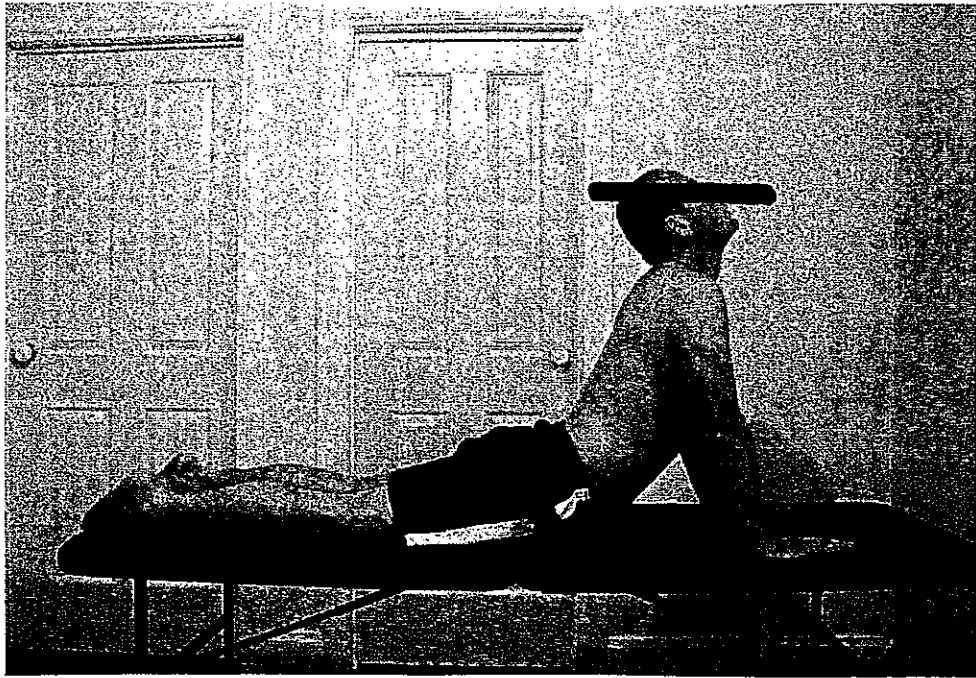


Figure 2. Patient positioning for measurement of the thoracic spine, extension range of motion.

Table 1. Group means (+/- SD) for the control and pre- and post intervention for both treatment groups (flexion range)

Gross thoracic range of motion in flexion, mean scores (centimetres), (+/-SD)

	Control	Treatment without Dysfunction	Treatment with Dysfunction
	Mean (SD)	Mean (SD)	Mean (SD)
Pre Intervention	4.10 (0.54)	3.28 (0.79)	3.61 (0.96)
Post Intervention	3.72 (0.53)	4.07 (1.19)	3.96 (0.75)
Difference	-0.38 (0.01)	0.79 (-0.4)	0.35 (0.21)

Table 2. . Group means (+/-SD) for the control and pre- and post intervention for both treatment groups (extension range)

Gross thoracic range of motion in extension, mean scores (centimetres), (+/-SD)

	Control	Treatment without Dysfunction	Treatment with Dysfunction
	Mean (SD)	Mean (SD)	Mean (SD)
Pre Intervention	4.12 (1.80)	3.45 (0.99)	3.31 (0.69)
Post Intervention	3.59 (0.93)	4.49 (1.06)	4.09 (1.07)
Difference	-0.53 (0.87)	1.04 (-0.07)	0.78 (-0.38)

**Table 3. Statistical Analysis for Flexion results.
One way ANOVA: Multiple Comparisons**

Dependent Variable: flexion
Tukey HSD

(I) group	(J) group	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
control	ttt without dysf	-1.17071*	.38124	.015	-2.1317	-.2098
	ttt with dysf	-.84935*	.33132	.046	-1.6845	-.0142
ttt without dysf	control	1.17071*	.38124	.015	.2098	2.1317
	ttt with dysf	.32136	.34778	.631	-.5552	1.1980
ttt with dysf	control	.84935*	.33132	.046	.0142	1.6845
	ttt without dysf	-.32136	.34778	.631	-1.1980	.5552

*. The mean difference is significant at the .05 level.

Table 4. Statistical Analysis for Extension results.
Kruskal-Wallis Test

Ranks

	group	N	Mean Rank
extension	control	7	6.79
	ttt without dysf	6	16.67
	ttt with dysf	11	13.86
	Total	24	

Test Statistics^{a,b}

	extension
Chi-Square	7.079
df	2
Asymp. Sig.	.029

a. Kruskal Wallis Test

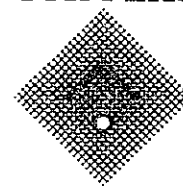
b. Grouping Variable: group

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INFORMATION TO PARTICIPANTS FORM

The efficacy of the Myobac to produce increased gross range of motion (ROM) of flexion and extension, in the thoracic spine

The Myobac is a health related product that is already available for purchase, despite having no previous research or literature. There is no current evidence that explores the effects of the Myobac on consumer health, particularly the effects to their thoracic spine mobility.

The aim of the study is to determine this relationship, by investigating the effects of the Myobac on thoracic spine movement, particularly forward and backward bending.

We aim to ascertain this by measuring these two movements on two occasions, before and after the use of the Myobac.

We invite you to be part of this study to determine the effects of the Myobac on thoracic spine forward and backward bending. You will be required to sign a consent form explaining you have read the information provided and wish to participate in the study. The testing procedure will then be undertaken.

Testing procedure

Two levels will be marked on your spine using a non permanent marker. A measurement between these two levels will be taken using a tape measure. You will be asked to stand and actively bend forward, within your limits of comfort and ability.

You will be then asked to lie on the practitioner table with your hands positioned on the table at shoulder

level. A velcro strap will be placed over your hips to stabilise them. You will be asked to straighten your elbows and actively arch your back into extension. A measurement will be taken.

You will be asked to repeat this 3 times and we expect that the measurement will take approximately 5-10 minutes. This procedure will be repeated in 2 weeks.

You may be asked to trial the Myobac device for 5 minutes a day over a period of 2 weeks, which requires you to lie on your back on a flat surface, with the device placed under your upper back. If so you will be shown the correct and safe way to use the Myobac.

You will be asked to somewhat disrobe, in order to mark levels on your back. A robe will be made available for you to wear. The testing procedures are neither invasive, nor painful and should not produce any adverse affects on you. Should you require at any time, a psychologist will be made available. (Students of Victoria University: Linda Van Draaneu ph: 99191132, Members of public: Mark Andersen ph: 99191132)

The researchers recognise that participation is on a voluntary basis, and that individual participants may withdraw from the study at any time.

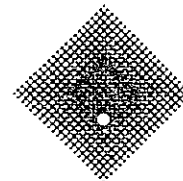
Any queries about your participation in this project may be directed to the researcher (Dr. Jim Kiatos ph. 99181191, or Angela Tran ph. 99191111). If you have any queries or complaints about the way you have been treated, you may contact the Secretary, University Human Research Ethics Committee, Victoria University of Technology, PO Box 14428 MCMC, Melbourne, 8001 (telephone no: 03-9688 4710).

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CONSENT FORM

We would like to invite you to be a part of a study into the effects of the Myobac orthosis on thoracic spine flexion and extension.

CERTIFICATION BY SUBJECT

I,
of

certify that I am at least 18 years old* and that I am voluntarily giving my consent to participate in the study entitled:

The efficacy of the Myobac to produce increased gross range of motion (ROM) of flexion and extension, in the thoracic spine

being conducted at Victoria University of Technology by:

Dr. Jim Kiatos (School of Health Sciences) and Angela Tran (student in Masters of Health Sciences, Osteopathy)

I certify that the objectives of the study, together with any risks and safeguards associated with the procedures listed hereunder to be carried out in the research, have been fully explained to me by Dr. Jim Kiatos or Angela Tran and that I freely consent to participation involving the use on me of these procedures.

Procedures:

Pre-test procedure

Prior to testing you are asked to read a document outlining the study aims and procedures, a brief questionnaire regarding current or previous upper/mid back pain, as well as to sign a consent form for participation in the study.

Testing Procedure

Two levels will be marked on your spine using a non permanent marker. A measurement between these two levels will be taken using a tape measure. You will be asked to stand and actively bend forward, within your limits of comfort and ability. Another measurement will be taken using a tape measure.

You will be then asked to lie on the practitioner table with your hands positioned on the table at shoulder

level. A velcro strap will be placed over your hips to stabilise them. You will be asked to straighten your elbows and actively arch your back into extension. A measurement will be taken.

You will be asked to repeat this 3 times and we expect that the measurement will take approximately 5-10 minutes. This procedure will be repeated in 2 weeks.

You may be asked to trial the Myobac device for 5 minutes a day over a period of 2 weeks, which requires you to lie on your back on a flat surface, with the device placed under your upper back. If so you will be shown the correct and safe way to use the Myobac.

These procedures are not invasive, nor painful and should not produce any adverse affects on you

I certify that I have had the opportunity to have any questions answered and that I understand that I can withdraw from this study at any time and that this withdrawal will not jeopardise me in any way.

I have been informed that the information I provide will be kept confidential.

Signed: }

Witness other than the researcher: }

Date:

.....}

Any queries about your participation in this project may be directed to the researcher (Dr. Jim Kiatos ph. 99181191, or Angela Tran ph. 99191111). If you have any queries or complaints about the way you have been treated, you may contact the Secretary, University Human Research Ethics Committee, Victoria University of Technology, PO Box 14428 MCMC, Melbourne, 8001 (telephone no: 03-9688 4710).

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QUESTIONNAIRE

Name.....

Please answer the following questions to the best of your ability. If you are unsure about an answer please ask researcher.

- 1. Age.....
- 2. Contact details (Note this information will only be used to remind you of re-testing in 2 weeks)
.....
.....
- 3. Have you **previously** had any injury or problems with you upper/mid back?
Yes/No
(please circle)
- 4. If yes, please describe
.....
.....
.....
- 5. Are you currently experiencing any upper/mid back pain or have a current upper/mid back injury?
Yes/No
(please circle)
- 6. If yes, please describe
.....
.....
.....

Thankyou.