Effect of IASTM on Parameters Like Pain, Range of Motion and Level of Function in Activities of Daily Living in Low Back Pain Patients - A Study Protocol for RCT

[1]Dr. Noel Samuel Macwan, MPT (Phd) & [2]Dr. Vandit Gandhi (BPT)

[1]Asst. Professor, College of Physiotherapy, Sumandeep Vidyapeeth, Piparia, Waghodia, Vadodara, Gujarat, India, 391760

[2] 2nd year MPT Student (Batch 2022-2024), College of Physiotherapy, Sumandeep Vidyapeeth, Piparia, Waghodia, Vadodara, Gujarat, India 391760

Abstract:

Background: Low back pain (LBP) located above the gluteal curvature and below the costal edge is a significant public health issue that may frequently result in referrals to medical services as it is linked to both disability and absenteeism. LBP is the most prevalent musculoskeletal condition as up to two-thirds of adults have LBP at some point in their lives. Many treatment approaches for LBP have been found in the literature depending on the persistence of the symptoms ranging from Electro-physical agents to as simple as patient education. Even after treating LBP its recurrence is common so the need of more efficient technique in form of IASTM is required. It is a well-liked treatment approach for myofascial restriction in recent years, and it is used in addition to traditional treatment for low back pain. Literature search shows very few articles that have seen the effect of IASTM on Low back pain. Therefore the purpose of this study is to see the effectiveness IASTM on low back pain subjects. **Methodology:** All participants coming to Physiotherapy OPD will be screened as per the routine musculoskeletal assessment. Those who meet the inclusion criteria and are willing to participate in the study will be requested to fill the informed consent form. Those participants who fall under the exclusion criteria will be excluded from the study. Participants will be randomly allocated to either to the Interventional group or the control group with the use of simple randomization. Once the assessment is completed the patient will be treated as per the treatment protocol devised for the Interventional group or control group respectively. Patients in both the groups (Interventional group and control group) will receive 2 days treatment (on 1st day and 7th day) in a week. **Outcome Measures:** Primary outcome: Modified modified schober's test, Secondary outcome: Visual Analog scale, Oswestry disability index **Statistical Analysis:** Descriptive statistics will be done by taking help of a Biostatistician. The latest version of SPSS software available with the Biostatistician will be used for doing the statistical analysis. **Conclusion:** This study protocol presents a RCT on the efficacy of IASTM and General Back exercises in patients with Low back pain. The results of this RCT will be helpful in contributing better insights on the efficacy of IASTM on pain levels, range of motion of lumbar spine and activities of daily living performance in LBP subjects. **Clinical Trial Registration:** The study is registered with Clinical Trials Registry- India (CTRI), with the registration number for the trial being CTRI/2023/05/052764.

Keywords: Low back pain, Exercises, Instrument Assisted soft tissue mobilisation, myofascial technique, flexibility, activities of daily living

Low back pain (LBP) is linked to both disability and absenteeism; is a significant public health issue that may frequently result in referrals to medical services. [1, 2] Dorsal pain located above the gluteal curvature and below the costal edge is referred to as low back pain (LBP). [3] Among the Musculoskeletal problems, LBP is the most prevalent condition that causes

medical, social, economic, and public health issues. Up to two-thirds of adults have LBP at some point in their lives. [4] Patients have low back pain when bending forward and/or returning to the starting posture because of an imbalance in the posterior components, including the erector spinae muscle and ligaments. [5]

Depending on classification for how long the symptoms have lasted, many treatment approaches for LBP have been found in the literature. These interventions fall into one of the following categories: electro-physical agents, manual therapy, kinesio-taping (KT), spinal stabilization exercises, general exercises, patient education, and behavioural and cognitive therapy [1, 6]

Even when LBP is treated with these widely used techniques, recurrence of the back pain is common following recovery. As a result, the management of LBP requires more efficient techniques. [1, 7] The use of tools that enable physiotherapists to assess and treat patients has been introduced in clinics with treatments like massage, manual therapy, and soft tissue mobilization [1, 8, 9] Instrument-assisted soft tissue mobilization (IASTM) has been a well-liked treatment approach for myofascial restriction in recent years, and it is used in addition to traditional treatment for chronic pain. [1, 10, 11]

This skilled myofascial technique is based on the principles of the cross-friction massage theory developed by James Cyriax. [11] It is applied with tools that are often composed of stainless steel and have bevelled edges and curves that allow them to fit into various body anatomical parts and penetrate deeper. [12] Soft tissue problems are detected and treated using it. [13] The procedure itself is thought to have developed from a Chinese medicinal technique called Gua sha. [14] Gua sha scrapes the skin until red spots appear using tools with smoothed edges. Gua sha, however, uses a different application method, goals, and beliefs than IASTM. [11] These tools make it possible to treat a particular area and penetrate the tissue more deeply. Because it lessens the strain on the hands, it is thought that this also offers the clinician a mechanical advantage. [15, 16]

The advantages of IASTM at the cellular level have been studied. After IASTM application, there is an increase in fibroblast proliferation, collagen synthesis, maturation, and remodelling of the unorganized collagen fiber matrix due to the inflammatory response that was triggered by micro trauma to the affected tissues, which causes the breakdown of facial restrictions, adhesions, and scar tissues. [11, 12]

IASTM have a neurophysiological effect because the instrument deforms the skin, stimulating mechanosensitive neurons has been demonstrated by Weiquing Ge in one of the study. Mechanoreceptors, which are in charge of two-point discrimination, and mechano-nociceptors, which are in charge of pain perception, are examples of mechanosensitive neurons. [13] IASTM increases blood flow, which thereby influences the vascular response to the injured soft tissue. As demonstrated by Loghmani et al., who examined the impact of IASTM and discovered that the treated leg had a higher percentage of arteriole-sized blood vessels and increased tissue perfusion. [17]

Searching through the literature it has been found that very few articles have seen the effect of IASTM on Low back pain, there are articles which have shown the effect of IASTM on pain other than back pain and flexibility of soft tissues. Therefore the purpose of this study is to see the effectiveness IASTM on low back pain subjects.

Objectives of the study are to:

- To measure the changes in intensity of low back pain using the Visual Analog Scale.
- To measure changes in lumbar range of motion with Modified modified Schober's Test.
- To measure changes in the level of function in activities of daily living with Oswestry disability index (ODI).

Ethical Approval:

All the procedures that will be involved in this trial had been taken approval from the Sumandeep Vidyapeeth Institutional Ethics Committee. The approval received from the Sumandeep Vidyapeeth Institutional Ethics Committee had the outward number, SVIEC/ON/Phys/BNMPT22/April/23/10 dated on 29/04/2023.

Clinical Trial Registration:

The study is registered with Clinical Trials Registry- India (CTRI), with the registration number for the trial being CTRI/2023/05/052764.

Sample size calculation:

Group sample sizes of 15 and 15 achieve 80% power to detect a difference of 19.10 between the null hypothesis that both group means are 25.5 and the alternative hypothesis that the mean group 2 is assumed 44.6 with group standard deviations of 26 and with a significance level (alpha) of 0.050 using a two-sided two-sample t-test.

The following formula had been used to calculate the sample size:

$$\boldsymbol{n = 2 * \frac{(zalfa/2 + Z1 - beta)2}{(m1 - m2/sigma)2}}$$

Where,

$Zalfa/2$=1.96

Z1-beta=0.84

M1=mean of group 1=25.50

M2=mean of group 2=44.60

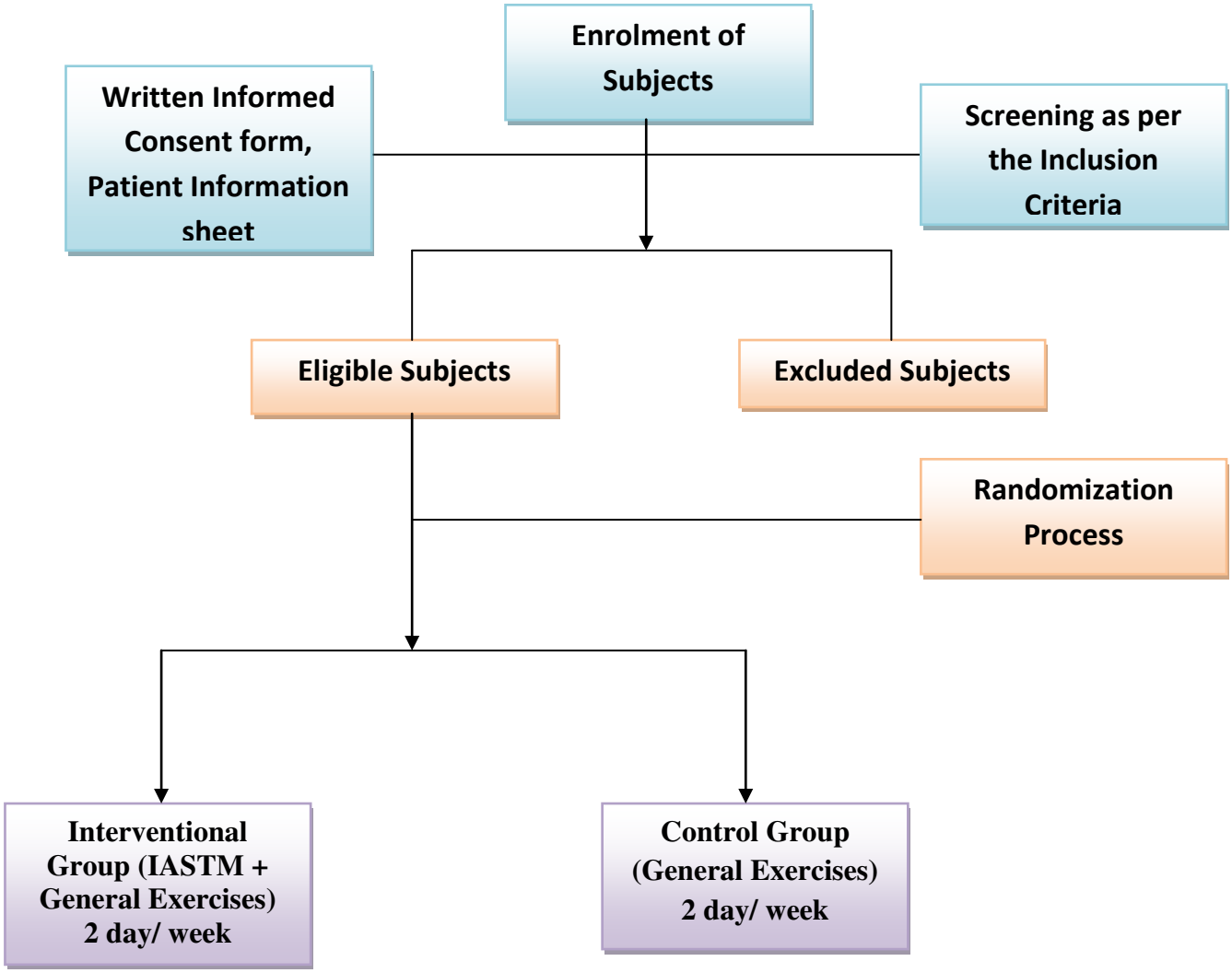
Sigma=standard deviation=26

Thus the final sample size is 30 and per group sample sizes are 15.

Method:

Participants visiting the Physiotherapy OPD, Dhiraj hospital, Sumandeep Vidyapeeth will be approached and explained about the study. All participants coming to Physiotherapy OPD will be screened as per the routine musculoskeletal assessment. Participants who meet the inclusion criteria and who are willing to participate in the study will be requested to fill the informed consent form. Those participants who fall under the exclusion criteria will be excluded from the study. Participant information sheet which describes in detail about patient participation during the study will be given to the participants. Participants will be randomly allocated to either to the Interventional group or the control group with the use of simple randomization. Once the assessment is completed the patient will be treated as per the treatment protocol devised for the Interventional group or control group respectively. Patients in both the groups (Interventional group and control group) will receive 2 days treatment (on 1st day and 7th day) in a week. Details of the treatment are given in table 1. Both primary and secondary outcome measures will be taken as per the schedule.

Fig 1: Flowchart summarises the overall design of trial



Randomization:

This study is a single blinded randomized controlled trial, where the subjects will not be able to know in which group they are going to get allotted. The allocator and the assessor are not blinded during the study as they are aware about the study groups i.e. the Intervention group and the control group in which the subjects are going to be distributed and are also aware regarding the intervention the subjects are going to undergo.

In this study, subjects will be divided randomly using simple randomization technique i.e. the lottery method in which half chits will be marked with number 1 representing Interventional group and half chits will be marked with number 2 representing the Control group on it which will be picked by the allocator for group allotment of patients. Total number of chits in this trial represents the total sample size of the LBP patients.

Table 1: The schedule of enrolment, interventions and assessments in accordance with the Standard Protocol Items: Recommendation for Interventional Trials (SPIRIT)

Time Point	Study Period							
		Enrolment & Allocation	**Day 1 Pre Rx**	**Day 1 Rx**	**Day 1 Post Rx**	**Day 7 Pre Rx**	**Day 7 Rx**	**Day 7 Post Rx**
Enrolment	Eligibility Screen	×						
	Informed Consent	×						
	Patient Information Sheet	×						
Intervention	IASTM Application			×			×	
	General Exercises			×			×	
Assessments	Baseline	×						
	Modified modified Schober's test		×		×	×		×
	Visual Analog Scale		×		×	×		×
	Oswestry disability index		×					×

(where, Rx represents Treatment)

Group-1 (Interventional Group):

IASTM application:

Patient position: Prone lying with arms at the sides of the body and legs parallel to each other. The patient was undressed enough to access the thoraco-lumbar fascia (TLF) between T12 and S1.

Procedure: At the beginning of an IASTM Technique treatment, the therapist will rub the adhesion to encourage mobility. With the aid of a convex metal therapy tool, a physiotherapist used IASTM. During this technique, the tool was moved paravertebrally at a speed of 3 cm/s on both sides of the TLF in a cranio-caudal direction. Prior to treating the muscles in a direction perpendicular to the muscle fibres, IASTM was administered in a direction parallel to the muscle fibres being treated with the instrument at a 45° angle. The detail about application time for every method along with its sets/ repetitions is given in the table 2.

Fig. 2: shows application of IASTM

General Exercises

- **Cat and Camel**
  - Patient's position- Quadruped position
  - Procedure- Inhale while bending your spine towards the floor and raising your eyes to the ceiling.
  - Exhale while bringing your chin to your chest and bending your spine upwards towards the ceiling.

Fig. 3: shows subject performing Cat and camel exercise

- **Pelvic rotation**
  - Patient's position- Supine lying with hip and knees flexed.
  - Procedure- Gently twist your knees to one side, stopping when you feel your hips begin to lift off the mat or table. Hold your upper body.
  - Then, on the opposite side, bring your knees back the opposite direction.

Fig. 4: shows subject performing pelvic rotation exercise

- **Child pose**
  - Your lower back will open up and feel pain-free after performing this easy stretch.
  - Patient's position-Kneeling position.
  - Procedure- Lean forward until your forehead touches the floor while keeping your arms out in front of you.

Fig. 5: shows subject performing the child pose exercise

- **Press ups**
  - Patient's position- Prone on elbow
  - Procedure- Lifting your chest off the floor requires pulling your shoulder blades in and back.
  - Make sure your legs and hips remain in touch with the floor or mat during the whole five-second hold.
  - The entire time, your neck should remain long and parallel to your upper spine. Lay your chest back down gradually.

Fig. 6: shows subject performing press ups exercise

- **Prone cobra**
  - Patient's position- Prone lying position
  - Procedure- Without using your hands, raise your chest off the floor while maintaining a long, straight neck.
  - Before slowly lowering your upper body back to the mat or floor, hold for 3 to 5 seconds.

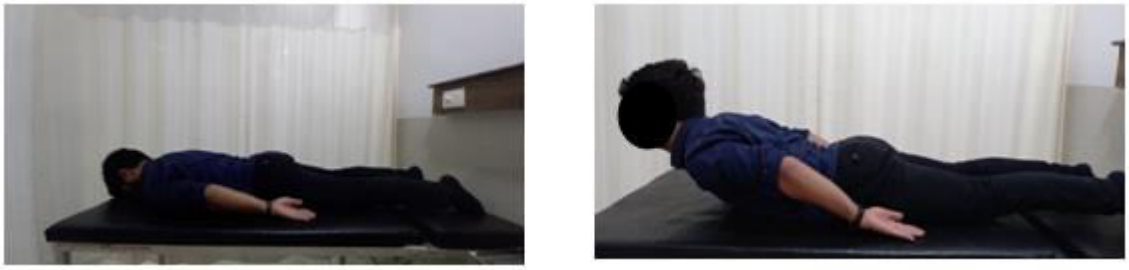


Fig. 7: shows subject performing Prone Cobra exercise

- **Bridging**
  - Patient's position- Supine lying with hip and knees flexed.
  - Procedure- Lifting your hips off the floor to form a "bridge" while keeping your arms on the floor and also by keeping your body in a single straight line.
  - Hold for 5 to 10 seconds, keeping your shoulders and neck on the floor.
  - Bring your hips down gradually.

Fig. 8: shows subject performing Bridging exercise

Measurements were taken before treatment, immediately after the IASTM treatment and General exercises, and 1 week before and after the intervention to examine the time course of the intervention

effects. ODI is the only outcome which is taken pre intervention on day 1 and post intervention on day 7.

- **Group -2 (Control Group):**

The General exercises performed by Intervention group participants were the same which the control group participants were going to perform.
Similar to the Intervention group, measurements were taken before treatment, immediately after the General exercises on day 1, and 1 week after the intervention to examine the time course of the treatment effects. Here also ODI is the only outcome which is taken pre intervention on day 1 and post intervention on day 7.

Outcome measures

Primary Outcome:

- Modified modified Schober's test for measuring the lumbar spine range of motion (Reliability & validity 0.89-0.97) [18]

Secondary Outcome:

- Visual Analog Scale for measuring Pain levels (Reliability & validity 0.84) [19]
- Oswestry disability index for measuring the levels of Activities of Daily Living (Reliability & validity Cronbach's alpha 0.86) [20]

Data Management:

A master chart file will be generated in Microsoft excel sheet, the data collected from the assessment of the outcome measures on day 1 (pre & post) and on day 7 (pre & post) along with the baseline assessment of the subjects will be entered on daily basis for the number of subjects included for that particular day. Once the data collection will be completed, the fully filled master chart Microsoft excel sheet will be sent to the Biostatistician for the statistical analysis process.

Table 2: shows the treatment received by the subjects in the Interventional group and the Control group

Group	Treatment on Day 1	Sets/ Repetition (Reps) /Time	Treatment on Day 7	Sets/ Repetition (Reps) /Time
Interventional Group	**IASTM**	1set of 3 Mins	**IASTM**	1set of 3 Mins
	General Exercise:		**General Exercise:**	
	Cat and Camel	1set with 10-15 Reps	Cat and Camel	1set with 10-15 Reps
	Pelvic rotation	1set with 10-15 Reps	Pelvic rotation	1set with 10-15 Reps
	Child pose	1set with 30 sec hold for 3-5 Reps	Child pose	1set with 30 sec hold for 3-5 Reps
	Press ups	1set with 5 sec hold for 15-20 Reps	Press ups	1set with 5 sec hold for 15-20 Reps
	Prone cobra	1set with 3-5 sec hold for 10-15 Reps	Prone cobra	1set with 3-5 sec hold for 10-15 Reps
	Bridging	1set with 5-10 sec hold for 15-20 Reps	Bridging	1set with 5-10 sec hold for 15-20 Reps

Control Group	**General Exercise:**		**General Exercise:**	
	Cat and Camel	1set with 10-15 Reps	Cat and Camel	1set with 10-15 Reps
	Pelvic rotation	1set with 10-15 Reps	Pelvic rotation	1set with 10-15 Reps
	Child pose	1set with 30 sec hold for 3-5 Reps	Child pose	1set with 30 sec hold for 3-5 Reps
	Press ups	1set with 5 sec hold for 15-20 Reps	Press ups	1set with 5 sec hold for 15-20 Reps
	Prone cobra	1set with 3-5 sec hold for 10-15 Reps	Prone cobra	1set with 3-5 sec hold for 10-15 Reps
	Bridging	1set with 5-10 sec hold for 15-20 Reps	Bridging	1set with 5-10 sec hold for 15-20 Reps

Statistical Analysis

Descriptive statistics will be done by taking help of a Biostatistician. The latest version of IBM SPSS 25 for windows statistical software available with the Biostatistician will be used for doing the statistical analysis. Statistical analysis using a paired and unpaired t test will be used to see the difference in the means of the same group and in between two groups respectively. The quantitative analysis of the primary and the secondary outcomes will be also be done. The amount of change in the outcome measures will be evaluated using repeated measures analysis of variance (ANOVA), at 95% confidence intervals. For all statistical analyses, probability levels of $p < 0.05$ will be consider as statistically significant.

Discussion

The number of studies of research evaluating IASTM's effects is still developing. The systematic review findings cast question on IASTM's effectiveness in treating common musculoskeletal pathologies; this could be because different studies use different methodologies. Its capacity to improve short-term joint range of motion appears to be supported by some evidence. [21]

Thus systematic review requests more RCTs evaluating IASTM application which may contribute in the knowledge of dose–response relationship in LBP subjects. We have presented the rationale and design of a RCT for investigating the efficacy of IASTM along with General exercise interventions on patient with LBP. Our argument is there about this study that it will contribute with important knowledge that is requested. If the results of the study demonstrate significant positive effect on pain, range of motion & activities of daily living, the potential benefit is going to be large as there are an increasing number of subjects who are affected from LBP in the society.

Conclusion:

This study protocol presents a RCT on the efficacy of IASTM and General Back exercises in patients with Low back pain. The results of this RCT will be helpful in contributing better insights on the efficacy of IASTM on pain levels, range of motion of lumbar spine and activities of daily living performance in LBP subjects.

Conflicts of Interest

The authors hereby state that we have no potential conflicts of interest to declare.

Funding

This research received no particular grants from any funding agency in either, the public, commercial or not-for-profit sector.

References:

1. Çakmak Ö., Atıcı E., Gülşen M., The Effects of Instrument-Assisted Soft Tissue Mobilization and Kinesio Taping on Pain, Functional Disability and Depression in Patients with Chronic Low Back Pain: A Randomized Trial, Turk J Physiother Rehabil. 2022; 33(3):179-186.
2. Hoy D, Bain C, Williams G, March L, Brooks P, Blyth F, Woolf A, Vos T, Buchbinder R. A systematic review of the global prevalence of low back pain. Arthritis Rheum. 2012; 64(6):2028-37.
3. Negash NA, Tadele A, Jember Ferede A. Prevalence and Associated Factors of Low Back Pain Among Healthcare Professionals at University of Gondar Comprehensive and Specialized Hospital, Northwest Ethiopia: Cross-Sectional Study. J Pain Res. 2022 May 25; 15:1543-1552.
4. Treloar, J 2018, 'Therapeutic effects of instrument-assisted soft tissue mobilization and the use in athletic populations: a literature review', BS thesis, University of Nebraska-Lincoln, Lincoln, NE.
5. Lee JH, Lee DK, Oh JS. The effect of Graston technique on the pain and range of motion in patients with chronic low back pain. J Phys Ther Sci. 2016 Jun;28(6):1852-5.
6. da Silva T, Mills K, Brown BT, Pocovi N, de Campos T, Maher C,Hancock MJ. Recurrence of low back pain is common: a prospective inception cohort study. J Physiother. 2019; 65(3):159-165.
7. Alahmari KA, Rengaramanujam K, Reddy RS, Samuel PS, Tedla JS, Kakaraparthi VN, Ahmad I. The immediate and short-term effects of dynamic taping on pain, endurance, disability, mobility and kinesiophobia in individuals with chronic non-specific low back pain: A randomized controlled trial. PLoS One. 2020; 15(9):e0239505.
8. Portillo-Soto A, Eberman LE, Demchak TJ, Peebles C. Comparison of blood flow changes with soft tissue mobilization and massage therapy. J Altern Complement Med. 2014; 20(12):932- 6.
9. Fousekis K, Eid K, Tafa E, Gkrilias P, Mylonas K, Angelopoulos P, Koumoundourou D, Billis V, Tsepis E. Can the application of the Ergon® IASTM treatment on remote parts of the superficial back myofascial line be equally effective with the local application for the improvement of the hamstrings' flexibility? A randomized control study. J Phys Ther Sci. 2019; 31(7):508-511.
10. Seffrin CB, Cattano NM, Reed MA, Gardiner-Shires AM. Instrument- Assisted Soft Tissue Mobilization: A Systematic Review and Effect-Size Analysis. J Athl Train. 2019; 54(7):808-821.
11. Cheatham SW, Baker R, Kreiswirth E. Instrument assisted soft-tissue mobilization: A commentary on clinical practice guidelines for rehabilitation professionals. International journal of sports physical therapy. 2019 Jul;14(4):670.
12. Lambert M, Hitchcock R, Lavallee K, Hayford E, Morazzini R, Wallace A, Conroy D, Cleland J. The effects of instrument-assisted soft tissue mobilization compared to other interventions on pain and function: a systematic review. Physical Therapy Reviews. 2017 Mar 4;22(1-2):76-85.
13. Ge W, Roth E, Sansone A. A quasi-experimental study on the effects of instrument assisted soft tissue mobilization on mechanosensitive neurons. Journal of physical therapy science. 2017;29(4):654-7.
14. Nazari G, Bobos P, MacDermid JC, Birmingham T. The effectiveness of Instrument-Assisted soft tissue mobilization in athletes, participants without extremity or spinal conditions, and individuals with upper extremity, lower extremity, and spinal conditions: a systematic review. Archives of Physical Medicine and Rehabilitation. 2019 Sep 1;100(9):1726-51.
15. Ikeda N, Otsuka S, Kawanishi Y, Kawakami Y. Effects of Instrument- assisted Soft Tissue Mobilization on Musculoskeletal Properties. Med Sci Sports Exerc. 2019; 51(10):2166-2172.
16. Hammer WI. The effect of mechanical load on degenerated soft tissue. J Bodyw Mov Ther. 2008; 12(3):246-56.
17. Kim J, Sung DJ, Lee J. Therapeutic effectiveness of instrument-assisted soft tissue mobilization for soft tissue injury: mechanisms and practical application. Journal of exercise

rehabilitation. 2017 Feb;13(1):12.
18. Tousignant M, Poulin L, Marchand S, Viau A, Place C. The Modified-Modified Schober Test for range of motion assessment of lumbar flexion in patients with low back pain: a study of criterion validity, intra- and inter-rater reliability and minimum metrically detectable change. Disabil Rehabil. 2005 May 20;27(10):553-9.
19. Boonstra AM, Schiphorst Preuper HR, Reneman MF, Posthumus JB, Stewart RE. Reliability and validity of the visual analogue scale for disability in patients with chronic musculoskeletal pain. Int J Rehabil Res. 2008 Jun;31(2):165.
20. David J. Magee, PhD, BPT, C.M. Professor Department of Physical Therapy Faculty of Rehabilitation Medicine University of Alberta Edmonton, Alberta, Canada. Orthopedic physical assessment, ed 6.Publishing Services Manager: Deborah Vogel,2014. P-588,594.
21. Cheatham SW, Lee M, Cain M, Baker R. The efficacy of instrument assisted soft tissue mobilization: a systematic review. J Can Chiropr Assoc. 2016 Sep;60(3):200-211. PMID: 27713575; PMCID: PMC5039777.