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COMPARISON BETWEEN EFFICACY OF A NEW ELECTRO PHYSICAL AGENT "AVAZZIA BEST", THERAPEUTIC ULTRASOUND TAPING AND HOME EXERCISE IN MANAGEMENT OF PLANTAR FASCIITIS [PF] HEEL PAIN: A CASE CONTROLLED STUDY

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ABSTRACT

Objective: *To study the efficacy of new electro physical agent "Avazzia BEST" in adults presenting Plantar Fasciitis.*

Design and Setting: *108 individuals (male and female) between the age group of 18-50 years were tested for inclusion criteria of LEFS. Candidates who fulfilled the criteria were selected as experimental group. They were given intervention using Avazzia BEST, Therapeutic ultrasound, and taping with Home Exercises (H.Exs) for thrice a week for 3weeks on alternate days. Each session lasted for 30 minutes.*

Subjects: *108 subjects with unilateral as well as bilateral functional ankle instability participated in this study.*

Measurements: *Pre and Post Intervention outcome measures were taken including LEFS, FAAM and VAS*

Results: *Statistical Analysis was done using SPSS version 16. Significant differences were seen in the Pre and Post Intervention Scores for LEFS, FAAM and VAS.*

Conclusion: *Intervention with 'Avazzia BEST' was found to be most effective in subjects with Plantar Fasciitis.*

Keywords: Plantar Fasciitis, Foot and Ankle Ability Measure, Visual Analog Scale, Therapeutic Ultrasound, Taping, Home exercises.

Introduction

Plantar heel pain is commonly referred to as "plantar fasciitis"; however, recent research suggests that the condition manifests itself as a non-inflammatory degenerative process, thus the term "fasciosis" maybe more appropriate.[1] Lemont and colleagues[1] reviewed the histological findings of 50 patients with heel pain. findings revealed that none of the samples exhibited any evidence of inflammation but, rather, degenerative changes in the fascia..[1]Perhaps this is the reason why corticosteroid injections have been found to be ineffective and, in fact, often result in serious side effects, including plantar fascia ruptures.[2,3]

Patients with plantar heel pain often report that pain is located along the medial border of the plantar fascia to its insertion at the medial tuberosity of the calcaneus[4]. The pain is worse in the morning when taking the first few steps after getting out of bed, after prolonged sitting, or at the beginning of a workout [5]. The pain pattern lessens during a day of ordinary activity, but increases as the activity intensifies and may linger after the increased intensity has ceased [6]. These symptoms can lead to considerable functional limitations and prolonged disability [4,7]. Plantar fasciitis is a common clinical condition treated by physical therapists.

Interventions such as iontophoresis, ultrasound, mobilization/manipulation, and therapeutic exercise are utilized by physical therapists to manage patients with plantar heel pain; however, these have varying levels of evidence in regard to their effectiveness[8, 9]. Of these interventions, iontophoresis, with either dexamethasone or acetic acid, and stretching of the gastrocnemius muscle and/or plantar fascia are recommended based on moderate evidence[8, 9]. However, the available evidence indicates that the effects do not endure beyond the short term, with differences between groups disappearing beyond 3 months in most trials[8, 9]. Despite the lack of convincing evidence in support of these modalities for the long-term management of plantar heel pain, clinicians continue to use iontophoresis, stretching, strengthening, ultrasound, and cryotherapy. [8, 10-12]

Only weak evidence exists to support the use of manual therapy interventions and therapeutic exercise in the patient population with plantar heel pain.[9, 13] Young et al [13] reported the outcomes of a series of 4 patients with heel pain who were managed with manual physical therapy, which was augmented by therapeutic exercise. Although all patients received 7 or

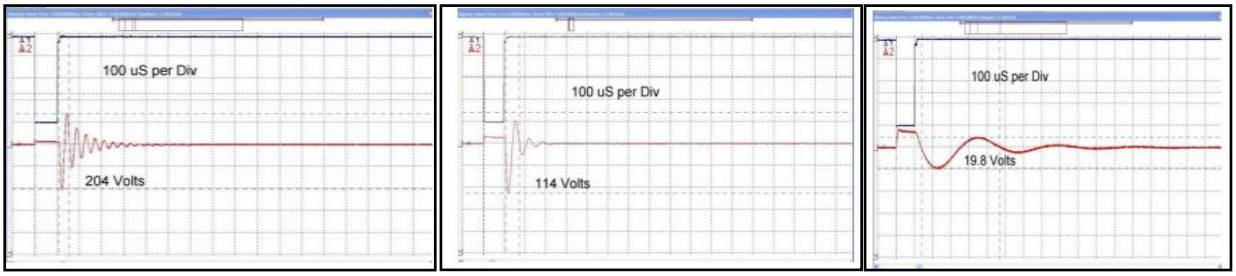
fewer treatments in physical therapy, they all reported a clinically meaningful reduction in pain and improvement in function. However, a cause-and-effect relationship cannot be inferred from a case series; therefore, further research is warranted to compare the effectiveness of the "traditional modalities" approach [8] in treatment of plantar fasciitis. The purpose of this study is to determine the efficacy of electrotherapy comprising traditional Ultrasount therapy, Avazzia BEST, Taping and exercise in patients referred to physiotherapy with plantar heel pain.

To establish the efficacy of EPAs in treatment of Plantar Fasciitis, we have used Avazzia Biofeedback Electro-Stimulation Technology (BEST™) microcurrent devices and Therapeutic Ultrasound along with Home exercises as it is most popular treatment methods used for pain relief and healing in Plantar Fasciitis. These were compared with Taping and Home exercise program.

Equipment called AVAZZIA BEST works on the principle of micro-current is one of the new EPA. The Avazzia BEST (Best Electro-Stimulation Technology) device was created for "symptomatic relief and management of chronic, intractable pain, and adjunctive treatment in the management of post-surgical and posttraumatic pain". BEST devices produce micro-current impulses, transmitted through the skin to interface with the body's internal peripheral nervous system for the purpose of therapeutic intervention. An electrical feedback loop is established between the tissue and the device. Changes in electrical properties of the tissue result in changes of the output signal properties. The body's response is measurable, creating information for the loop. When a signal is emitted and penetrates deep into the tissue, the impedance of the tissue (analogous to resistance in DC circuits but dynamic in nature) modulates the next waveform. The degree of modulation is based upon the changes of impedance of skin. This sets up a constantly changing interactive bio-loop processing non-repeating signals. Eventually the change in impedance diminishes in significance until a plateau occurs (Refer Figures 1a, 1b and 1c). This feedback is between tissue (bio) and an electrical circuit; hence, biofeedback.

Initial stage: In air, the output signal waveform appears as shown **Transition state** : The device detects when the electrodes are placed on tissue. **Treatment complete** : In Relax/Assess mode, the device will 'ring' when it detects the optimum condition

Fig 1a: Initial stage Fig 1b: Transition state Fig 1c: Treatment complete



Researchers' claim that Avazzia BEST have better results than TENS [14]. TENS was developed for the control of chronic and post-operative pain by saturating subcutaneous nerve receptors with low-intensity electrical stimulation. TENS deliver constant voltage with fluctuating current and resistance/impedance. BEST™ delivers a driving signal based upon the change in microcurrent and impedance over the active pulse interval. Unlike TENS, which relies on constant and externally generated signaling principles, BEST™ is based upon the development of a cybernetic feedback loop.

The four modes of operation include: Relax Mode, Deep Stimulation Mode, RSI Mode, Acute Mode. In the study we have used RSI mode. RSI Mode: for chronic pain relief. Apply to areas of intense pain, or trauma over 24 hours. Apply directly to the skin 5 to 10 minutes 2 or 3 times per day directly over the area of pain or trauma. Typical treatment time is 5 to 10 minutes or longer as indicated. RSI mode is a set of 12 pulses issued at approximately 30 Hertz.

Materials and Methodology

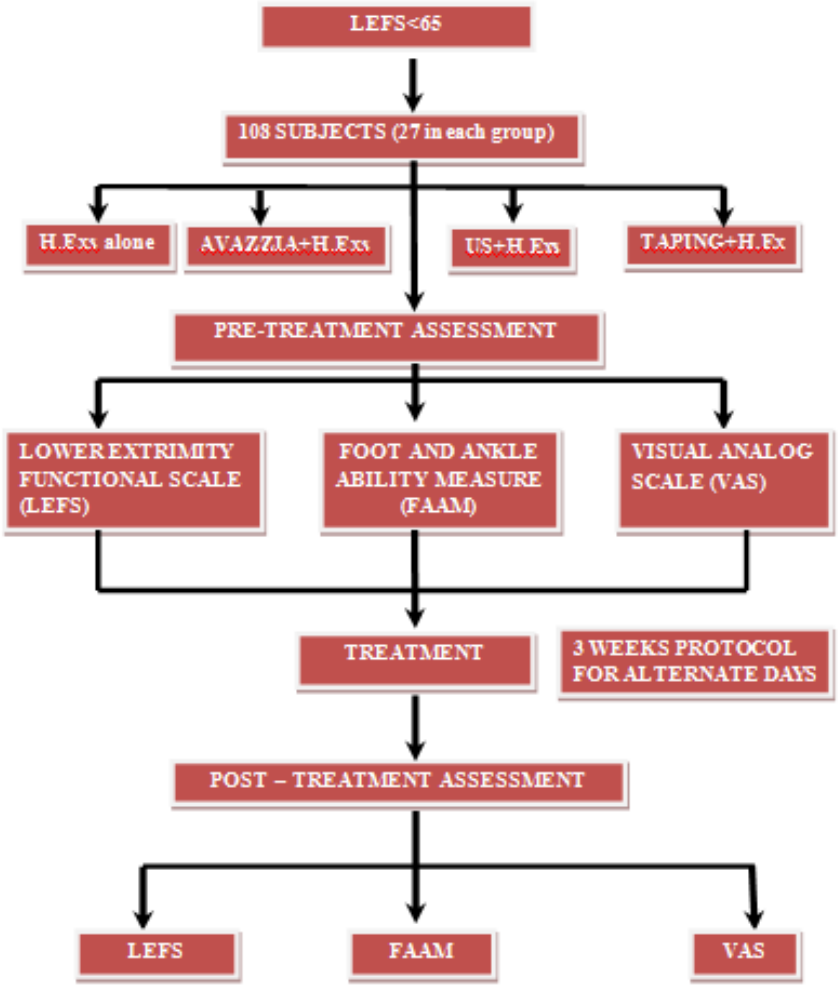
Subjects were taken between the age group of 18-50 years. They were tested for inclusion criteria that is LEFS score <65 and plantar fascia stretch is positive. Subjects falls under exclusion criteria were removed from the study like 1) pain of infective origin 2) Rheumatic arthritis 3) Osteoporosis 4) persons with a demand-type cardiac pacemaker 5) pregnant women 6) people with organ transplants 7) prolonged H/O steroid use 8) prior fracture/surgery of ankle joint 9) severe vascular diseases 10) personal intolerance.

108 male and female individuals between the age group of 18-50 years were enrolled in the study. These subjects were made to understand the purpose of enrolment and their role in the language they understand best using a patient information sheet. A written consent was also procured from the enrolled subjects. The methodology of the study was passed by the Ethics Committee of Pad. Dr. D. Y. Patil University, Nerul, Navi Mumbai.

Case control study of 108 individuals (male and female) were taken and assigned randomly into 4 groups and conducted for 1 year. Group1 - (control group) Home exercise (H.Exs) alone, Group 2 - AVAZZIA + H.Exs, Group 3 - Therapeutic ultrasound+ H.Exs, Group 4 - Taping +H.Exs

We used Scales like the Lower Extremity Functional Scale (LEFS), FAAM and visual analogue scale (VAS) as the pre and post evaluative measurements in our study. (Refer Figure 2 for Flowchart of the methodology of the study)

Figure 2: Flow chart of the methodology of the study



Data analysis and Interpretation

Data analysis was done using SPSS version 16.

The 4 groups in the study were considered as the independent variables, and the 3 outcome measures were considered as the dependant variables.

Comparison of the proportion of male and female gender in all 4 groups was done using chi-square test. The values of level of significance was compared to p value and significance set at $p<0.05$.

Comparison of age in the 4 groups was done using One-way ANOVA test.

Comparison of pre-post effect of treatments in-between the subjects were done using Wilcoxon's signed ranks test for all three parameters.

Since LEFS, FAAM are scores and measured on interval scale & VAS is measured on ordinal scale, we used wilcoxon signed Rank test to compare pre-post effect between each measurement technique (we can calculate mean & SD for FAAM & LEFS but assumption of normality is not fulfilled so to compare pre- post effect of these two variable we use non parametric Test of significance Wilcoxon signed Rank test)

Table 1: Mean Rank & P value of Pre-Post LEFS

		N	Mean Rank	Sum of Ranks	P value
LEFS Post – LEFS Pre	Negative Ranks	1	1.00	1.00	0.000
	Positive Ranks	26	14.50	377.00	
	Ties	0			
	Total	27			

Out of 27 cases we got positive result in 26 cases and in one case we got negative result (positive means post score is greater than pre score) sum of mean rank of positive cases =14. 50 and for negative cases mean rank =1

The difference between the mean rank is statistically significant since P value < 0.05 (p= 0.000) (Refer Table 1)

Table 2: Mean Rank & P value of Pre-Post FAAM

		N	Mean Rank	Sum of Ranks	P value
FAAM Post – FAAM Pre	Negative Ranks	0	.00	.00	.000
	Positive Ranks	27	14.00	378.00	
	Ties	0			
	Total	27			

Out of 27 cases we got positive result in all 27 cases and in not a single case of negative result (positive means post score is greater than pre score) sum of mean rank of positive cases =14. 00 and for negative cases mean rank =0.00 (Table 2)

The difference between the mean rank is statistically significant since P value < 0.05 (p= 0.000)

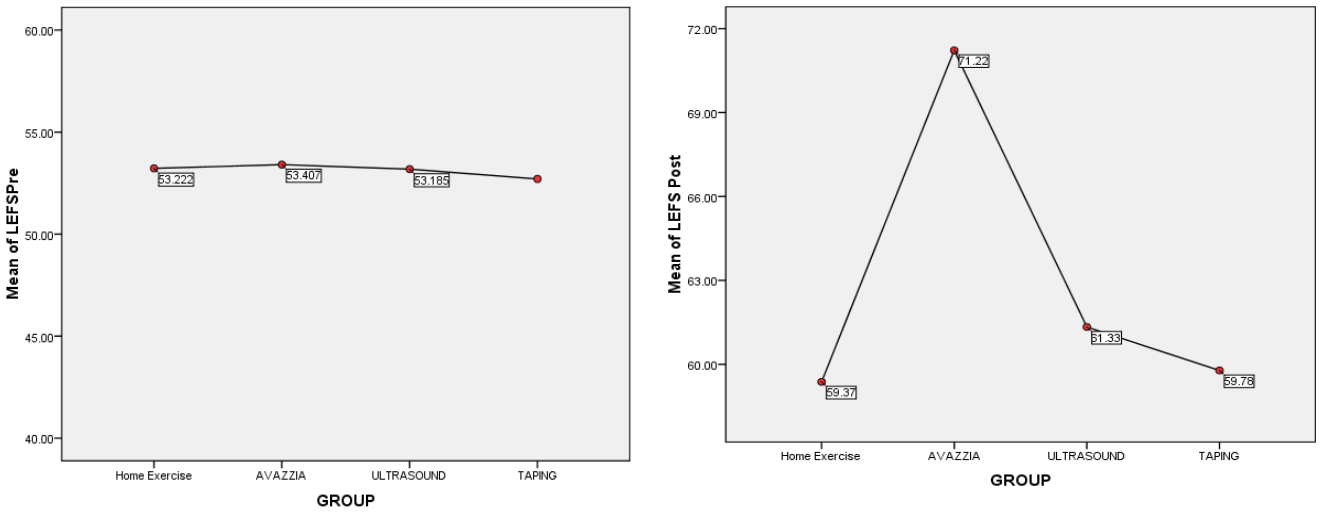
Table 3: Mean Rank & P value of Pre-Post VAS

		N	Mean Rank	Sum of Ranks	P value
VAS Post – VAS Pre	Negative Ranks	27	14.00	378.00	.000
	Positive Ranks	0	.00	.00	
	Ties	0			
	Total	27			

The mean rank for positive cases 0 where as for negative cases mean rank is 14 which suggest that in all 27 cases there pain get decreased as compare to their pre test evaluation and difference is statistically significant since P< 0.05 (p = 0.000)

Comparison of differences due to mode of treatment to decide which method of treatment provides superior results Kruskall Wallis test was used. (Table 3)

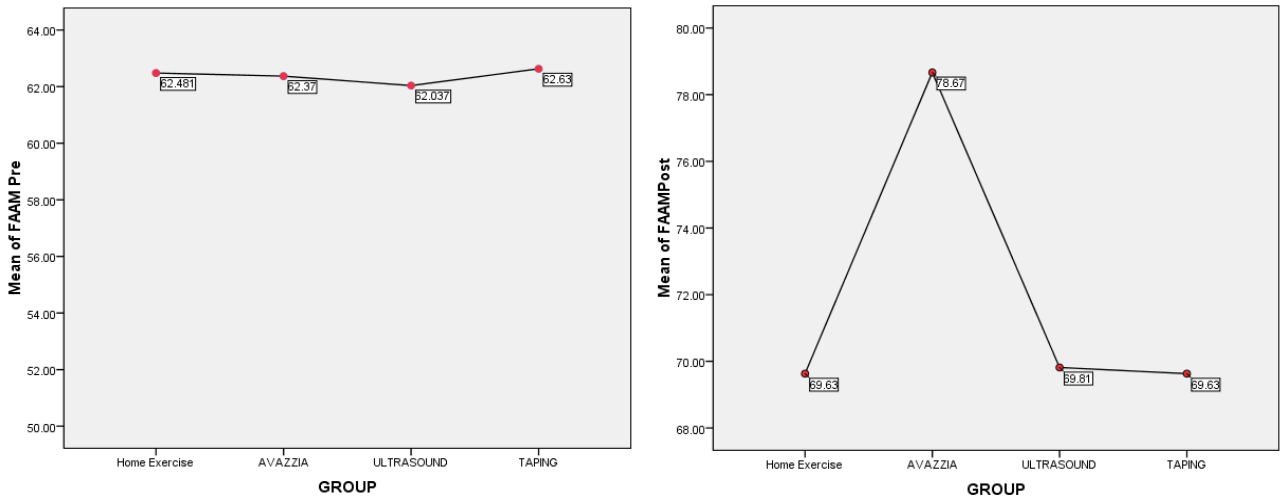
Figure 3: Comparison of mean ranks of pre and Post LEFS in Home exercise, AVAZZIA,Ultra sound and Taping.



For pre-test mean ranks of LEFS for Home exercise, AVAZZIA, Ultra sound and Tapping are 54.52, 55.74, 54.96 and 52.78 respectively which shows insignificant difference between these four groups, since P > 0.05 (which shows that at base line the subjects in these four groups having near about same LEFS score). Refer Figure 3.

For post-test mean ranks of LEFS for Home exercise, AVAZZIA, Ultra sound and Tapping are 39.50, 88.24, 48.69 and 41.57 respectively which shows significant difference between these four groups, since P < 0.05 [which shows that at post-test AVAZZIA having significantly higher values (that is 88.24) as compare to remaining three . The Home exercise, Ultra sound and Tapping having near about same LEFS score]

Figure 4: Comparison of mean ranks of Pre and Post FAAM in Home exercise, AVAZZIA, Ultra sound and Tapping.



As shown in Figure 4; for pre-test mean ranks of FAAM for Home exercise, AVAZZIA, Ultra sound and Tapping are 55.28, 53.89, 53.00 and 55.83 respectively which shows insignificant difference between these four groups, since P > 0.05 (which shows that at base line the subjects in these four groups having near about same FAMM score)

For post-test mean ranks of LEFS for Home exercise, AVAZZIA, Ultra sound and Tapping are 42.89, 90.44, 42.78 and 41.89 respectively which shows significant difference between these four groups, since P < 0.05 (which shows that at post-test AVAZZIA having significantly higher values as compare to remaining three. The Home exercise, Ultra sound and Tapping having near about same FAAM score)

VAS - Interpretation

For pre-test mean ranks of VAS for Home exercise, AVAZZIA, Ultra sound and Tapping are 51.00, 50.44, 52.61 and 63.94 respectively which shows insignificant difference between these four groups, since P > 0.05 (which shows that at base line the subjects in these four groups having near about same FAMM score)

For post-test mean ranks of VAS for Home exercise, AVAZZIA, Ultra sound and Tapping are 62.54, 36.56, 54.96 and 63.94 respectively which shows significant difference between these four groups, since P < 0.05 (which shows that at post-test AVAZZIA having significantly higher values as compare to remaining three. The Home exercise, Ultra sound and Tapping having near about same FAAM score)

Table 4: Summary of Pre-Post Mean values

Oneway

		N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum
						LB	UB		
LEFS Pre	Home Exercise	27	53.2222	5.47254	1.05319	51.0574	55.3871	44.00	66.00
	Avazzia	27	53.4074	5.83925	1.12376	51.0975	55.7173	44.00	63.00
	Ultrasound	27	53.1852	5.24798	1.00997	51.1092	55.2612	44.00	62.00
	Taping	27	52.7037	5.45481	1.04978	50.5459	54.8616	42.00	63.00
	Total	108	53.1296	5.43628	.52311	52.0926	54.1666	42.00	66.00
LEFS Post	Home Exercise	27	59.3704	4.86074	.93545	57.4475	61.2932	48.00	70.00
	Avazzia	27	71.2222	5.40180	1.03958	69.0853	73.3591	58.00	79.00
	Ultrasound	27	61.3333	6.22649	1.19829	58.8702	63.7965	50.00	73.00
	Taping	27	59.7778	5.71323	1.09951	57.5177	62.0379	51.00	69.00
	Total	108	62.9259	7.34046	.70634	61.5257	64.3262	48.00	79.00
FAAM Pre	Home Exercise	27	62.4815	5.55650	1.06935	60.2834	64.6796	52.00	72.00
	Avazzia	27	62.3704	6.12151	1.17809	59.9488	64.7920	51.00	78.00
	Ultrasound	27	62.0370	5.04199	.97033	60.0425	64.0316	52.00	72.00
	Taping	27	62.6296	4.82101	.92780	60.7225	64.5368	55.00	74.00
	Total	108	62.3796	5.33673	.51353	61.3616	63.3976	51.00	78.00
FAAM Post	Home Exercise	27	69.6296	6.10894	1.17567	67.2130	72.0462	56.00	78.00
	Avazzia	27	78.6667	2.44949	.47140	77.6977	79.6357	73.00	84.00
	Ultrasound	27	69.8148	5.03860	.96968	67.8216	71.8080	62.00	79.00
	Taping	27	69.6296	4.42152	.85092	67.8805	71.3787	62.00	80.00
	Total	108	71.9352	6.05778	.58291	70.7796	73.0907	56.00	84.00

Summary of Results

In all four treatment groups AVAZZIA BEST group has shown significantly greater improvement in all outcome measures LEFS, FAAM & VAS after four weeks of treatment.

In Home exercises group, exercises were given to improve flexibility of grastrocnemius, soleus and plantar fascia only, but other causative factors were not taken into account. In this group since it was a home program patient may not have done exercises on daily routine basis. Effect of home exercises was found long lasting & significant in pain reduction and functional ability improvement but it was not as effective as others.

In Taping group only plantar fascia was treated and was taped in such a manner that patient should not experience pain but that effect was found temporary because when tape was there plantar fascia was in protective phase but on removal of tape when patient started with ADL activities patient started experiencing pain. Thus taping could help in reduction of pain and improvement in functional ability significantly but effect was not as much as AVAZZIA & Therapeutic Ultrasound with which it was long lasting.

In Therapeutic Ultrasound group treatment was mainly over the site of pain and stretching targeted to gastro-soleus and plantar fascia but in this group also other causative factors were not taken into account. Thus Therapeutic Ultrasound gave temporary relief of pain and improved functional ability but again when compared it was not found as effective and long lasting as AVAZZIA.

Amongst all four treatment techniques AVAZZIA was mainly targeted on foot and ankle complex as a whole.Stretching techniques further added to flexibility improvement in supporting structures like gastro-soleus and plantar fascia. This led to improved functional ability of the patient. Thus AVAZZIA BEST was found to be superior to remaining three treatment techniques.

Discussion

From the graphs and statistical analysis it's clear that all four treatment techniques Home exercises (control group), Taping, Therapeutic ultrasound, AVAZZIA BEST are effective in reducing pain and improving functional ability of patients which is statistically significant. Whereas AVAZZIA BEST was found most superior treatment protocol than other three treatment protocols.

Home exercise

Static stretching is one of the most widely used modes of increasing extensibility of muscles and soft tissues. Stretching causes viscoelastic changes to take place. These viscoelastic changes were thought to occur due to the hysteresis response of the muscle tendon unit during passive static stretching. The heat generated during the loading phase is said to increase the temperature of the non-contractile tissues causing increase in flexibility and elongation of tissues. There is also increase in cross bridge distance with passive static stretching.

The purpose of stretching is to relieve stress on the tightened fascia and tendon and to restore the normal range of motion of the ankle and the 1st metatarsophalangeal joint. The rationale is that when stretching is applied to a tissue, the tissue responds through either the elastic (temporary lengthened state) or plastic (permanent lengthened state) changes. To effectively treat the shortened plantar fascia, the goal of the stretching program is to reach the plastic deformation state.

If a tissue is held under a constant length, force relaxation occurs. This means that collagen fibers are realigning along the lines of stress and that ground substance is perhaps also being redistributed.

Home exercises group showed significant improvement in pain reduction and improved functional ability.

Taping

Mechanism of actionis Mechanical stabilizer & Proprioception or kinesthetic sense. Taping done by Macdonald method works by supporting the medial longitudinal arch. As the arch is supported in an elevated position it also restricts the extremes of pronation which is a main factor in causing strain on the planter fascia. The planter fascia gets relived of the continuous tug and strain helps in healing of the formerly inflamed fascia.

Proprioceptive stimulation or kinesthetic sense: - This is brought about through activation of the skin receptor which in turn facilitates muscle contraction. The sense of proprioception is produced by afferent of the skeletal muscle receptors as well as cutaneous receptors. The cutaneous receptors contribute to joint position of sense of the distal joints and provide afferent kinesthetic information when the skin overlying the joint is stretched. Taping further enhances these senses by stimulating the cutaneous pressure and touch receptors to provide

an overall increase in kinesthetic information addition to the normally provided by muscles and structure Taping works on the principle of unloading inflamed soft tissues to break the endless cycle of increased pain and decreased functional ability.

Therapeutic Ultrasound

Therapeutic Ultrasound is a high frequency sound wave with an affinity for soft tissue. It heats these tissues and the tissues absorb the energy, resulting in an increase in tissue temperature and metabolism, tissue softening, and an increase in circulation.It has been reported to increase chemical activities in tissue and alter diffusion and protein synthesis rates, all of which potentially affect the speed of tissue repair. Thermal Therapeutic Ultrasound has been suggested to have therapeutic effects including reduced scar tissue and adhesions, reduced pain, increased metabolism and increased healing. Flexibility of plantar fascia is subsequently improved by increase in the extensibility of collagen and the viscosity and plastic deformation of tissues. Thus Therapeutic Ultrasound along with stretching has shown to improve functional ability and reduction of pain.

AVAZZIA BEST

Avazzia Biofeedback Electro-Stimulation Technology (BEST) device features non-invasive neuromodulation. They have used proprietary software and microchips in its neuromodulation applications. This non-pharmaceutical, non-invasive technology is designed to stimulate the body's natural release of nitric oxide, endorphins and neuropeptides into the blood stream.

Nitric oxide causes vascular dilation and thereby increases blood circulation. This is critical to wound healing, reduction of edema and treatment of diabetic neuropathy.

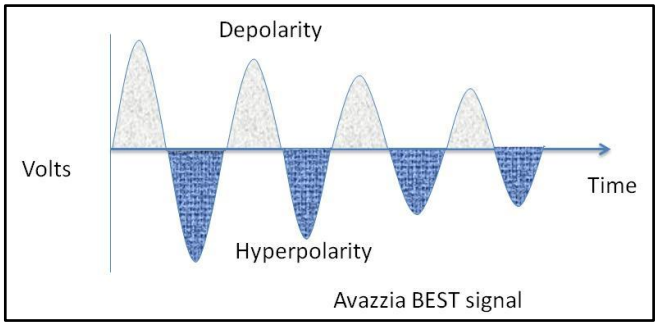
Endorphins are the body's natural pain management chemicals.[15, 16]

Neuropeptides are the body's regulatory elements that promote accelerated healing.[17]

Avazzia BEST electrical signals, different than other TENS signals, allow this to happen because they are short duration pulses of high voltage amplitude and very low duty cycle. The average currents are in the microcurrent range. These are damped biphasic, sinusoidal waveforms. The process is further enhanced by signals that change and adapt as the electrical properties of the tissue being treated change (biofeedback readings).

BEST™ devices stimulate the neuro-endocrine system through direct touch to the skin. The BEST™ device electrodes can detect (via biofeedback) impedance on skin by "sticking" (dramatic increase in friction) to acupuncture or electron deficient sump points when gliding the instrument over the skin.[18,19]

Figure 5: Tissue electrical changes with Avazzia treatment



Published medical research has identified the electrical signal characteristics that impact "C" fibers,[20] resulting in the stimulation of nitric oxide, hormones, endorphins and neuropeptides. Other publications indicate the signal characteristics and treatment locations that balance the sympathetic and parasympathetic nervous systems.[21

The signals sent from the tissue is measured by a computer within the device and various results are reported to the practitioner. The signals stimulate the nervous system to produce its regulatory peptides, thereby prompting the body to achieve "balance" or "homeostasis." The signal catalyses production of neuropeptides for use where necessary; to re-establish the body's natural physiological state and cause a return to normalcy. Because these peptides last up to several hours, the process continues long after the treatment is over.These changes suggest a non-inflammatory condition and dysfunctional vasculature. With reduced vascularity and a compromise in nutritional blood flow through the impaired fascia, it becomes difficult for cells to synthesize the extracellular matrix necessary for repairing and remodeling.[22]

Avazzia BEST signals delivers voltage (Figure 5) to the neuronal cell membrane to open ion channels and effect depolarization and reduces voltage to close ion channels by hyperpolarization of neuronal membranes. Impedance determines the phase signals time and damped amplitude characteristics based upon cybernetic feedback information delivered back to the device by the target tissue and based upon up to a million operations per second measurements by the microprocessor and software in the Avazzia device

C-fibers are difficult to stimulate to depolarization by conventional electro-stimulation devices including TENS. Avazzia BEST signalling in high voltage 200-300 volts, extremely short duration (micro seconds 10^{-6} seconds pulse width), extremely low current (micro amps 10^{-6} amps) damped, biphasic sinusoidal waveform that is impedance modulated by a

cybernetic feedback loop between the target tissue and the microprocessor driven circuit in the device. Return signalling influences the next output.

Avazzia best generates rapid depolarization in C-fibers with very short time constants and large length constant. Resistance component is high due to small cross sectional area. High voltage and very short duration and duty cycle are used to overcome the high resistance and low capacitance of C-fibers.[23]

Conclusion

All the four forms of treatment methods viz Home exercise AVAZZIA –BEST, Therapeutic Therapeutic Ultrasound, and Taping are effective in treatment of plantar fasciitis. However, as compared to other treatment techniques it can be ascertained that Avazzia BEST was the most superior form of treatment technique based on the results of the outcome. Therefore the efficacy of treatment of plantar fasciitis can be mentioned as given below:

Avazzia Best > Therapeutic Ultrasound> Taping > Home Exercise

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