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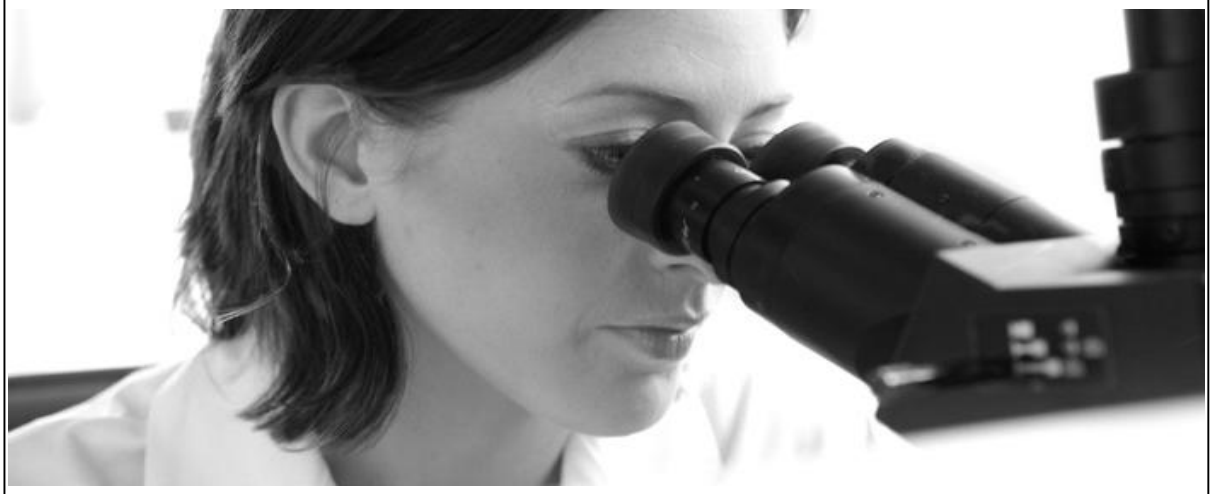

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RESEARCH ARTICLE

EFFICACY OF CALIBRATED AND UN-CALIBRATED THERAPEUTIC ULTRASOUND IN ADULTS PRESENTING WITH PLANTAR FASCIITIS

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ABSTRACT

Objective: To study the efficacy of Calibrated and Un-calibrated Therapeutic Ultrasound in adults presenting with Plantar Fasciitis. **Design and Setting:** 108 individuals between the age group of 18-50 years were tested for inclusion criteria of Lower Extremity Functional Scale (LEFS). Patients with heel pain and LEFS Score < 65 were included in the study. They were treated using Calibrated Therapeutic ultrasound and Un-calibrated Therapeutic Ultrasound with Home Exercise. The patients were treated every day. The treatment was discontinued as and when the patient reported a drop in the VAS of pain experienced at the heel. **Subjects:** 108 subjects with unilateral as well as bilateral plantar fasciitis participated in this study. **Measurements:** Pre and Post Intervention outcome measures were taken including LEFS, Foot and Ankle Ability Measure (FAAM) and Visual Analogue Scale 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 Calibrated Therapeutic ultrasound was found to be more effective than Un-calibrated Therapeutic Ultrasound in subjects with Plantar Fasciitis.

INTRODUCTION

Purpose and Rationale of The Study

Therapeutic ultrasound (US) is frequently incorporated into treatment regimens used by physiotherapists [Robertson V. *Et al*, 2006] In fact, survey data demonstrates that US is now the most frequently used electrophysical agent worldwide, used at least daily for patient treatment by the majority of physiotherapists [Goh AC, *et al*. (1999), Lindsay *et al*. 1990, 1995, Robertson VJ (1998), Chipchase LS *et al*. (2003)]. This high frequency of usage makes the need for equipment accuracy imperative. There is limited clinical research support for using it and the literature on the effectiveness of ultrasound in physiotherapy is inconclusive. Absence of evidence of effect does, however, not mean evidence of lack of effect. The development and evaluation committee in 1998 [Bryant J, Milne R, 1998] expressed concern about the variability of machine calibration, and highlighted the need for well conducted randomised controlled trials to establish clinical and economic benefits of therapeutic ultrasound.

Equipment accuracy ensures that patients receive correct therapeutic dosages and underpins patient safety. In cases in which equipment fails to be accurate, two potential scenarios exist. The first is that a higher, harmful dosage may be received by the patient, potentially compromising patient safety [Goh AC *et al*, 1999; Pye S, Milford C (1994); Artho PA. *et al*. (2002)]. For example, tissue destruction and blood cell stasis may occur with high doses of US therapy Roberston *et al*. (2006). In the second scenario, the patient may receive a lower dosage than the therapist intended, potentially compromising treatment efficacy [Pye S., 1996] To ensure consistent, safe and efficacious outcomes with US therapy, machine accuracy is of the utmost importance. The importance of US accuracy was first identified in 1956 when the United States established standards for calibration [Rivest M. *Et al*., 1987] The current International Electrotechnical Commission standard for US power output is ±15% [International Electrotechnical Committee], with the current Australian/New Zealand standard at ±20% [Australian and New Zealand Standards. 1996, 2005]. This means that the output produced by an US machine should not deviate by 20% from the value indicated on the meter [Pye S, Milford, 1994; Kollmann C, 2005]. A similar standard applies to the accuracy of the US timing device, with a ±5%

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difference considered acceptable [Pye *et al*. 2001]. Previous literature has reported startlingly high levels of inaccuracy [Rivest M, 1987; Stewart HF, 1974; Allen KG, 1978; Snow CJ, 1982; Lloyd JJ, 1988]. In fact, on average, 65% of US machines have been demonstrated to be inaccurate [8,10,14,16]. However, the majority of available research was conducted more than 20 years ago, and US machines have since become digital in nature and are often multifunctional [Robertson V, 2006]. Thus, there is a paucity of published research on the accuracy of such machines. In addition, US accuracy is dependent upon several machine variables, including the intensity setting, US wave frequency (commonly 1 or 3 MHz), and whether US therapy is delivered in a continuous or pulsed mode [Robertson V, 2006]. To date, no study has examined US accuracy at the complete range of settings available for patient treatment. Unlike other non-conclusive studies [Whiting M F, 1975; Clark G R, Stenner L, 1976; Bruno J, Hefland, 1976; Binder A, 1985; Fay Crawford, 1996; Snook G A, 1972], we hypothesized that the reason for these studies to demonstrate varying results could be due to the lack of using calibrated EPAs. Hence our main objective was to evaluate the differences between the efficacy of treatment using calibrated and non-calibrated therapeutic ultrasound equipment.

INTRODUCTION

Over 20 conservative treatments for plantar fasciitis are reported ranging from common modalities such as exercise to electrotherapy, acupuncture and injection therapy. The physiotherapist has an important role to play in managing this difficult and troublesome condition.

Evaluative self-reported instruments use the response patterns of patients or subjects to measure changes in health status over time. If the instrument is created properly and evidence of validity is obtained, then the information collected can be used to interpret the effect of pathology and subsequent impairment on physical function. Information from this instrument also could be used to compare and assess the effectiveness of treatment interventions. In the present study we used Scales like LEFS, FAAM and VAS as the pre and post evaluative measurements in our study.

Conservative treatment focuses predominantly on physiotherapy management of plantar fasciitis, with a brief acknowledgement of additional treatment approaches. Electrotherapy has an established role in management of wide range of musculoskeletal and neurological problems. Therapeutic ultrasound is used routinely by podiatrists and physiotherapists, and is prescribed by physicians in their treatment of plantar fasciitis and plantar heel pain. [Whiting M F, 1975; Bruno J, Hefland A, 1976; Clark G R, 1976]. Although there is much literature detailing the cellular and physiological benefits of ultrasound [Windsor A M, 1979; McDiarmid T, 1987; Dyson M, 1987; Chapman I V, 1976] few evaluative clinical trials have produced conflicting conclusions as to the effectiveness of high frequency sound waves as a treatment for painful conditions in other parts of the body. [Grynbaum B B, 1954; Binder A, 1985, Meuller E E, 1953; Swan Downing D, 1986] As therapists report variable results when treating painful heels, there was a clear need to evaluate the reason of conflicting conclusions in efficacy of ultrasound treatment in heel pain. The researchers concluded that the methodological quality of the studies is low, and evidence of the efficacy or not of ultrasound was not convincing [H Beckerman, 1993]. Concern has been raised with regards the accuracy of clinical ultrasound machines. We thus hypothesized that Calibration of ultrasound equipments would check the accuracy of output of US that would ensure appropriate and accurate dosimetry being imparted to the patients hence improve the results of treatment of plantar fasciitis using the same.

MATERIALS AND METHODS

A multi-centre case control study was conducted with 110 patients between the age group of 18-50 years. Ethical permission was granted by the Ethics committee of D.Y.Patil University, Nerul, Navi Mumbai. Prior to enrolling the patients they were explained the entire procedure of the study via an information sheet and a written consent was procured before enrolling the patients for the research study. After which they were screened for Lower Extremity Functional Scale (LEFS) for fulfilling the inclusion criteria. All the patients who had a LEFS Score < 65 and plantar fascia stretch test is positive were included in the study.

Patients presenting with pain of infective origin, Rheumatic Arthritis, Osteoporosis, Prolonged H/O steroid use, severe vascular disease, H/O prior surgery or fracture of distal tibia-fibula, ankle joint or hind foot, Intoxicated individuals, pregnant women, epilepsy or another medical condition that could be impacted by ultrasound therapy were all excluded from the research program.

110 individuals were screened initially for the study. Two patients did not fit the inclusion criteria. 108 patients presenting with plantar fasciitis were assigned randomly into 2 groups

- Group1 - Calibrated branded US
- Group 2 – un-Calibrated US machine

These were then treated with ultrasound at 1MHz of Ultrasound at continuous mode for 4 minutes initially increasing it to 7 minutes on plantar fascia attachment to the calcaneus i.e. the site of pain.

The calibrated US unit was a combo Chattanoga machine and un-calibrated US unit was a unit procured from the local equipment provider. The plan of the study is depicted in Figure1.

The following treatment parameters were used in both the groups

- Frequency: 1 MHz
- Duration: 4-7 minutes
- Intensity: 1 W/cm^2
- Mode: Continuous.
- Direct Dynamic method of application

- Transducer head: 5 sq.cm; ERA= 4sq.cm

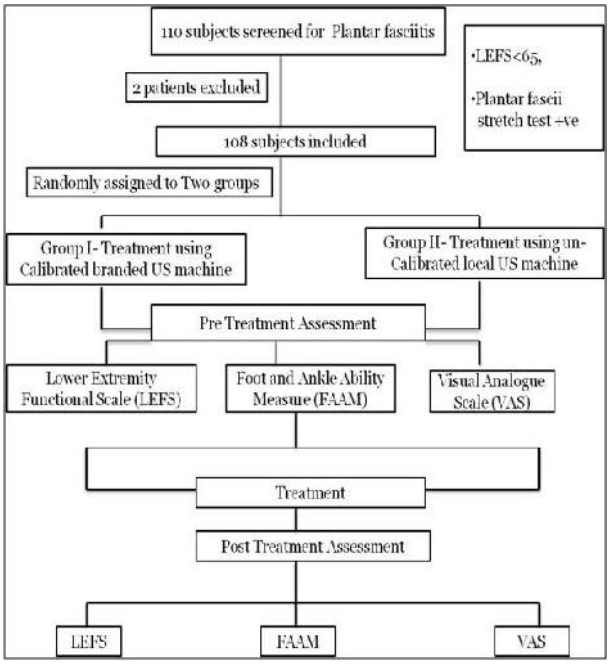

Fig.1 Flowchart of Methodology

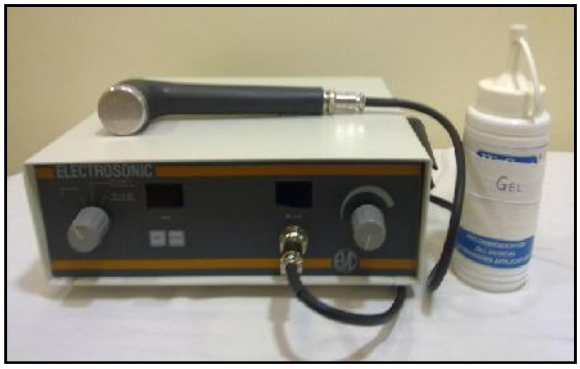

Figure 2 Un-calibrated US machine

The local unbranded machine (refer Figure 2) provided with only one frequency of 1MHz and pulsed and continuous modes of treatment. However, on could not select a duty cycle for treatment. It provided with fixed pulse durations of short, medium and long duty cycle. The size of the transducer head was 5 square cm, with no specification of Beam non-uniformity ratio (BNR).

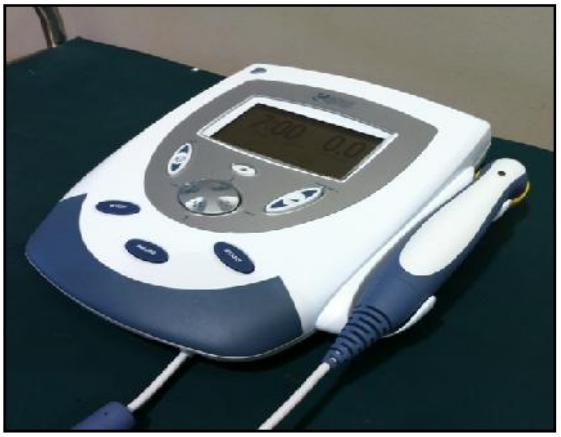

Figure 3 Calibrated Chattonoga US machine

Chattonoga machine (Figure 3) had a CE marking and was provided with 1MHz and 3MHZ applicator. It provided two different modes of operation, Continuous or Pulsed with duty of 10%, 20%, and 50%. The brochure mentioned it having a low BNR

Direct, Dynamic method comprising slow, circular transducer movements covering the entire treatment surface area with aquasonic Gel as a coupling media was used, in both the groups The patients were made to lie down, either in supine or prone position, depending of their comfort level and US treatment was given for 4 minutes initially and progressed to 7 minutes. The patients were treated every day. The treatment was discontinued as and when the patient reported a drop in the VAS of pain experienced at the heel. Both the group of patients were taught home exercise program on discharge and were advised footwear modification wherever applicable.

Data Analysis & Interpretation

Data analysis was done using SPSS version 16. The 2 groups in the study were considered as the dependent variables, and the 3 outcome measures were considered as the independent variables. Comparison of the proportion of male and female gender in both the 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 both the groups was done using unpaired T test. Comparison of pre-post effect of treatments in-between the subjects were done using Mann Whitney U test for all three parameters. Comparison of differences due to type of treatment to decide which method of treatment provides superior results Mean ranks of Mann Whitney U test was used.

RESULTS

Gender Distribution

Table 1 Gender* GROUP Cross tabulation

			Cal US	Un-Cal US	Total
SEX	Male	Count	21	23	44
		% within GROUP	38.9%	42.6%	40.7%
	Female	Count	33	31	64
		% within GROUP	61.1%	57.41%	59.3%
Total		Count	54	54	108
		% within GROUP	100.0%	100.0%	100.0%

21 males and 33 females were included in the study in Group I, and 23 males and 31 females in Group II. Table 5.1 shows the gender distribution in both the groups

Chi-Square Test

We compared the proportion of male and female in both the groups using Chi-Square test; which suggested insignificant difference between the proportion of male and female since $p>0.05$ (Table 2) (Figure 4)

Table 1 Mean and std.dev of age of the patients included in both the groups

Age	N	Mean	Std. Deviation	Std. Error Mean
Cal US	54	33.69	7.296	.993
un-Cal US	54	33.52	7.205	.981

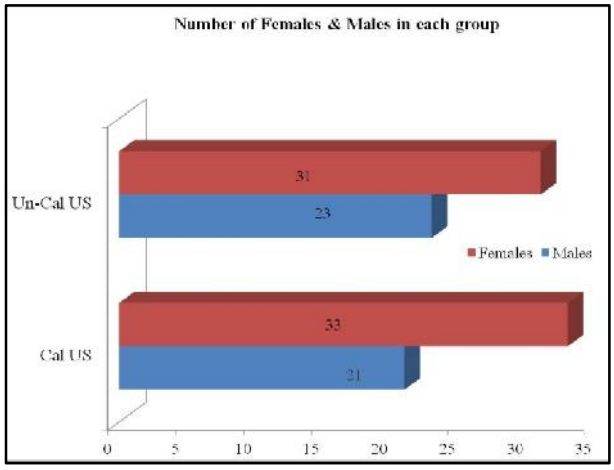

Figure 4 Graph depicting number of males and females in each group

Table 2 Chi-Square Tests comparing the gender distribution in both the groups

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	.153	1	.695

Comparison of age in 2 groups

Independent T test was used to compare the means of age of all the patients in both the group.

It was ascertained that there was an insignificant difference of age in between the two groups as F value is 0.028 and p=0.867.

Table 3 Independent T Test for comparison of mean of age

Levene's Test for Equality of Variances			t-test for Equality of Means			
Age	F	Sig.	t	df	Sig. (2-tailed)	Mean Difference
Equal variances assumed	.028	.867	.119	106	.905	.167
Equal variances not assumed			.119	105.983	.905	.167

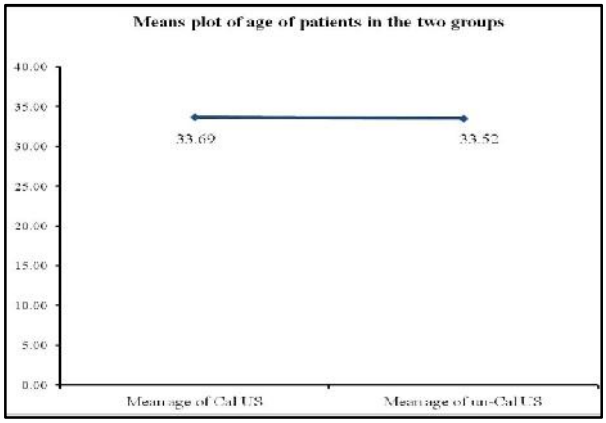

Figure 5 Means plot depicting the average age of the patients in the two groups.

Comparison of outcome measures

Mann Whitney U Test

Since LEFS, FAAM are scores and measured on interval scale & VAS is measured on ordinal scale, we used Mann Whitney U test to compare pre-post effect between each measurement technique. Following is the descriptive analysis of all three variables in the two groups. Descriptive analysis of LEFS, FAAM and VAS

Table 4 Mean and std.dev of outcome measures

	Groups	N	Mean	Std. Deviation	Std. Error Mean
Pre LEFS scores	Cal US	54	53.41	5.784	.787
	un-Cal US	54	53.19	5.198	.707
Pre FAAM scores	Cal US	54	62.37	6.063	.825
	un-Cal US	54	62.04	4.994	.680
Pre VAS	Cal US	54	7.07	.949	.129
	un-Cal US	54	7.19	1.100	.150
Post LEFS scores	Cal US	54	71.22	5.351	.728
	un-Cal US	54	61.33	6.167	.839
Post FAAM scores	Cal US	54	78.67	2.426	.330
	un-Cal US	54	69.81	4.991	.679
Post VAS	Cal US	54	2.67	.614	.084
	un-Cal US	54	3.26	1.049	.143

The mean values of all the three variables, viz; LEFS, FAAM and VAS in both the groups are comparable which is further confirmed using Mann Whitney U test which yielded a non-significant difference between the variables measured in both the groups. (Table 4) (Figure 6 & 7)

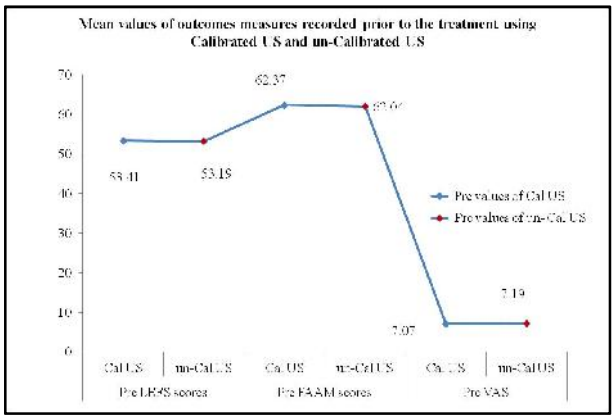

Figure 6 Graph depicting the mean LEFS scores, FAAM scores and VAS values assessed prior to beginning the treatment protocol.

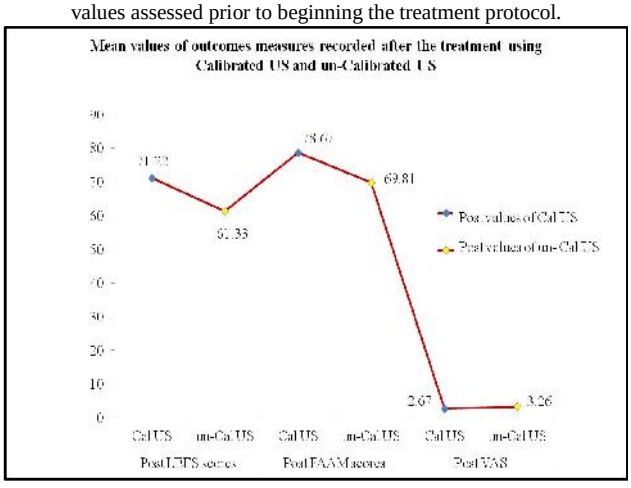

Figure 7 Graph depicting the mean LEFS scores, FAAM scores and VAS values assessed after the treatment protocol.

Comparison of means of the outcome measures

Mean Ranks of all the three outcome measures was computed using Mann Whitney U test and the findings are as follows

Mann-Whitney Test

Table 5 Mean Rank Comparison of LEFS, FAAM and VAS in patients of both the groups.

	Groups	N	Mean Rank	Sum of Ranks
Pre LEFS scores	Cal US	54	54.98	2969.00
	un-Cal US	54	54.02	2917.00
	Total	108		
Post LEFS scores	Cal US	54	75.17	4059.00
	un-Cal US	54	33.83	1827.00
	Total	108		
Pre FAAM scores	Cal US	54	54.87	2963.00
	un-Cal US	54	54.13	2923.00
	Total	108		
Post FAAM scores	Cal US	54	78.24	4225.00
	un-Cal US	54	30.76	1661.00
	Total	108		
Pre VAS	Cal US	54	53.50	2889.00
	un-Cal US	54	55.50	2997.00
	Total	108		
Post VAS	Cal US	54	45.57	2461.00
	un-Cal US	54	63.43	3425.00
	Total	108		

Table 6 Test Statistics to check the significance of difference in the three groups

	Pre LEFS scores	Post LEFS scores	Pre FAAM scores	Post FAAM scores	Pre VAS	Post VAS
Mann-Whitney U	1432.00	342.00	1438.00	176.00	1404.00	976.00
Wilcoxon W	2917.00	1827.00	2923.00	1661.00	2889.00	2461.00
Z	-.160	-6.865	-.123	-7.913	-.347	-3.207
Asymp. Sig. (2-tailed)	.873	.000	.902	.000	.729	.001

Findings of Mann-Whitney U test

Pre Treatment Values

For pre test mean ranks of LEFS for both the groups is 54.98 and 54.02 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)

For pre test mean ranks of FAAM for both the groups is 54.87 and 54.13 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 FAAM score)

For pre test mean ranks of VAS for both the groups is 53.50 and 55.50 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 VAS)

Post treatment values

The Mean Rank values of Post treatment in both the groups, i.e., Calibrated US and un-calibrated US for LEFS is 75.17 and 33.83; the distribution in two groups differ significantly assuming the 2 tailed significance value at p<0.00, which is considered highly significant, with better results using Calibrated Ultrasound equipment

The Mean Rank values of Post treatment in both the groups, i.e., Calibrated US and un-calibrated US for FAAM is 78.24 and 30.76; the distribution in two groups differ significantly assuming the 2 tailed significance value at p<0.00, which is considered highly significant, with better results using Calibrated Ultrasound equipment.

Also, The Mean Rank values of Post treatment in both the groups, i.e., Calibrated US and un-calibrated US for VAS is 45.57 and 63.43; the distribution in two groups differ significantly assuming the 2 tailed significance value at p<0.00, which is considered highly significant, with better results using Calibrated Ultrasound equipment as compared to un-Calibrated US.

Summary

Calibrated US equipment shows better results in terms of improving function in patients presenting with plantar fasciitis as depicted from the LEFS and FAAM values. VAS showed that it improved better with Calibrated US equipments.

Duration of Treatment/ Number of sessions

The mean length of treatment time (number of sessions) is shown in Table 7.

Table 7 Mean and std.dev of number of sessions required for treatment using the two equipments

	Groups	N	Mean	Std. Deviation	Std. Error Mean
Sessions	Cal US	54	6.09	1.069	.145
	un-Cal US	54	8.39	1.156	.157

Independent Samples Test for used to compare the means of the number of sessions (Table 8)

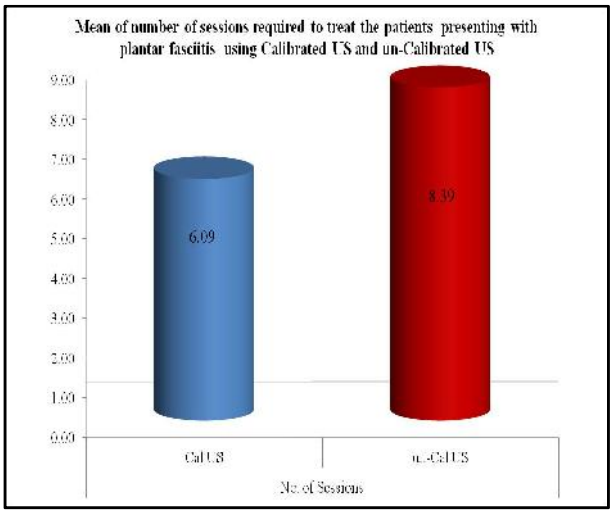

Figure 8 Graph depicting the means of number of sessions required for treatment using Cal US and un-Cal US

Using the Independent T test for assessing the difference in treatment duration it was found that Calibrated US gave results much earlier in an average duration of 6 sessions, whereas un-Calibrated US gave the results in 8 session on an average.

The difference in the duration of treatment is highly significant at p<0.05.

Table 8 Independent T test for comparing the equality of means of number of sessions used for treatment in the two groups

		Levene's Test for Equality of Variances		t-test for Equality of Means						
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
									Lower	Upper
Sessions	Equal variances assumed	.286	.594	-10.718	106	.000	-2.296	.214	-2.721	-1.872
	Equal variances not assumed			-10.718	105.353	.000	-2.296	.214	-2.721	-1.872

SUMMARY OF RESULTS

Therefore from the present research study it is evident that calibrated US yields superior and more accurate results which is projected in the efficacy of the same over un-Calibrated US in treatment of plantar fasciitis in young adults.

Functional abilities measured through LEFS, FAAM and pain relief showed improvement more profoundly in the group treated with Calibrated US equipment. The number of sessions required (length of treatment) was lesser with calibrated US than with un-calibrated US

DISCUSSION

This is the first study to be conducted within the Indian Physiotherapy community to evaluate the performance of one of the professions most commonly used therapeutic tools, therapeutic ultrasound on the basis of calibration. The aim of this study was to investigate the efficacy of the Calibrated US and compare the same with un-Calibrated US used in treatment of plantar fasciitis in young individuals. From the results and statistical analysis of the present research it can be ascertained that Calibrated US yields better results than un-Calibrated US in treatment of plantar fasciitis.

Importance of Calibration In Ebp To Prove The Efficacy of US

This study leads us to understanding various factors associated with appropriate output of therapeutic US that can be used in physiotherapy practice to maximise its effectiveness in patients. Many reviews fail to support the efficacy of ultrasound [Gam, A.N, Johannsen, F, 1995; van der Heijden, *et al*. 1997; van der Windt *et al*. 1999, 2002]. However, a common finding amongst many reviews is the lack of methodologically acceptable studies [Robertson V, *et al*. 2006]. Problems cited often include; lack of calibration, inappropriate dosage, and lack of reliable outcome data. Furthermore, many reviews have considerable overlap in authors. There is no availability of research work in the field of electrotherapy which would evaluate the differences between the outputs and efficiency of calibrated EPAs versus un-calibrated EPAs.

In a survey conducted by Frost and Sullivan it was estimated that the 4,600 hospitals that provided physical therapy services in 1974 had slightly over 11,000 ultrasound units. Assuming that 50 percent of the remaining hospitals had a physiotherapy unit, Frost and Sullivan estimated that there are slightly over 12,000 units in use in hospitals.

They believe there is a good chance that these units are used routinely for long periods without having an output calibration check because ultrasound therapy units are relatively inexpensive and are seldom serviced. This lack of service could result in the use of un-calibrated units.

In addition, the lack of calibration of ultrasonic therapy equipment was listed as one of the 24 significant medical equipment problems in a study conducted for the California Hospital Association in 1971[Walsh TE, Hanks TG] The need for calibration has also been stressed by the users of ultrasonic therapy equipment. For example, Reid and Cummings reported that using a specific dosage is critical for obtaining a specific effect [Reid DC, Cummings GE, 1973] Also, the importance of determining dosage for comparative analysis of results has been pointed out [Buchtala V, 1952]. Without properly calibrated equipment, these dosage determinations are impossible. Thus, routine calibration of the outputs of these units is definitely needed to ensure that the units can provide a prescribed amount of radiation not only when manufactured and delivered to the user, but also throughout their lifetime. The standard requires the manufacturers to specify how often their equipment should be recalibrated, and although there are no legal requirements compelling the user to adhere to the recommendations, it is in the best interests of all concerned to do so.

Perhaps the most important variable other than ultrasonic power and intensity in using this modality is duration of exposure. All units are required to have an accurate timer with automatic shut-off of ultrasound after a preset time. In addition, all units must be capable of being turned off at any time.

Importance of calibration in ascertaining the Field distribution specifications

There is a need for displaying specific information about the spatial-intensity variations within the ultrasonic beam. As discussed by Lehmann, the ultrasonic intensity distribution across the sound field is not uniform. Because of the nature of the ultrasonic field; "hot spots" can be produced, possibly resulting in excessive heating in small regions of the volume of tissue being treated. Lehmann suggests a stroking technique to ameliorate this situation, [Schabrun, S, 2006] but the therapist should have knowledge of the sound field distribution in order to apply therapeutic ultrasound judiciously. To this end, the standard requires that the manufacturer describe the spatial distribution of the ultrasonic field in the user's manual and give, on the applicator label, the ratio of the spatial-maximum intensity to spatial-average intensity. This ratio, called the beam non-uniformity ratio (BNR), can be used to determine the maximum point intensity in the ultrasonic beam for a given

spatial-average intensity setting on the meter. For instance, if a BNR value of 5 were given on the applicator label and the meter were set for a spatial-average intensity of 1.5 W/cm2, then the maximum point intensity would be the product of the two quantities, or 7.5 W/cm2. Obviously a BNR of one is desirable, but unfortunately not physically realizable. The BNR can be used, however, when comparing different units for a specific application, particularly if a stationary technique is being considered.

The applicator label must also classify the ultrasonic beam as being focusing, collimating, or diverging and must state the effective radiating area (ERA). Laboratory measurements have shown that large discrepancies can exist between the advertised radiating area, based on transducer crystal size or other information, and the actual area radiating ultrasound.

Many users of ultrasonic therapy use a simple technique for verifying that the sound head is emitting ultrasonic radiation. A thin layer of coupling medium (water, gel, or mineral oil) placed on the surface of the applicator will show bubbles when power is supplied to it. Although this technique may be useful, using high power in the test could damage the sound head. This method would not assert the effective radiating area, although one could ensure that the transducer head is at least emitting sound waves.

Hazards of Use of Un-Calibrated Therapeutic US

Ultrasound is not without its hazards to both patient and therapist. Recent equipment surveys have highlighted an infection risk [Schabrun, S, 2006], major calibration problems [Artho PA, 2002] and electrical safety issues [Daniel, D.M., & Rupert, R.L, 2003]. These findings substantiate the need for regular training in machine testing.

Regardless of how well the equipment is calibrated, a potential risk is associated with the use of ultrasonic therapy equipment. For example, the literature reports one individual who received treatments for a sprained ankle. On the third visit she had developed a large blister on her foot, resulting in two months of hospitalization and permanent partial disability of the foot. Simulating the conditions under which ultrasonic therapy is given, Herrick was able to destroy the sciatic nerve in dogs without affecting the histologic structure of the surrounding muscles [Herrick F, 1953]. Also, patients have had swelling and thrombus formation after ultrasonic therapy treatments.[Chieppo, 1960] Sykes and Williams report there is available evidence obtained both in vitro and in vivo indicating that ultrasound can initiate blood coagulation and thrombus formation [Sykes SM, Williams , 1977]. Thrombus formation has been reported by Kahlert in a few patients in a follow-up study of individuals treated with therapeutic ultrasound [Kahlert VW, 1950]. Dyson and Pond experimentally showed reversible blood stasis in chick embryos, along with some cellular endothelial damage, upon exposure to ultrasound from a stationary transducer [Dyson M, Pond JB, 1973]. Bone damage has been observed in dogs after exposure to ultrasound. Kolar and associates refer to various Eastern European publications that report reduced skeletal growth after ultrasound exposures of between 3 to 4 W/cm^2 [Kolar J, 1965]. Barth and Wachsmann found that at exposure levels of 0.5 to 1 W/cm2 from a stationary transducer, young dog bones showed thickening, followed by loss of the periosteum [Barth G, Wachsmann F, 1949]. Older bone showed similar effects, but the effects took longer to develop. Barth and Wachsmann report that for a moving sound field, the threshold limit for bone damage in dogs is about 3 W/cm2. This threshold would also be expected to depend on the treatment area and the exposure time. They suggested that the use of therapeutic ultrasound over any bony area, especially in the young, is contraindicated. Barth and Wachsmann's evidence, along with Dyson and Pond's, indicated that the probability of damaging effects occurring is higher when using a stationary applicator. To minimize this possibility, a therapist considers avoiding the use of a stationary applicator.

Summary

The literature and the findings in the present study conclusively show that ultrasonic therapy devices can produce potentially hazardous levels of radiation. An equipment-performance standard designed to require manufacturers to provide properly calibrated and labeled ultrasonic therapy instruments to ensure maximum safety and efficacy needs to be instituted. Physiotherapists, however, must still maintain their equipment in proper working condition and be well informed about both the beneficial and harmful biological effects of ultrasonic radiation.

CONCLUSION

Although research findings are equivocal, the use of ultrasound remains extensive. Evidently, further high quality research is warranted to fill the gaps, especially in the clinical arena as opposed to the laboratory.

For the physiotherapists to provide effective treatment and minimize the risk of harming a patient, yearly calibration and safety checks are essential. This warning applies not only to ultrasound but also to all forms of therapy in the therapist's clinic which utilize electric current.

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