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Original Research Article

Effect of Low Frequency PEMF Therapy on Bone Healing and Quality of Life in Subjects with Delayed or Non-Union Lower Limb Fractures

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ABSTRACT

Background: Delayed union and non-union remain as intractable complications after long-bone fractures. Low frequency PEMF Therapy has effect in osteogenesis and bone healing. Objective of the study was to determine the effects of low frequency PEMF therapy in bone healing and quality of life in subjects with delayed or non-union fracture of lower limb.
Methods: A prospective, intervention study conducted in which 18 participants with delayed or non-union lower limb fractures recruited according to inclusion and exclusion criteria and Low frequency PEMF therapy was given at fracture site using MAGNETODYN- Therapy device M80 with coil applicator, Frequency: 20 Hz, Sinusoidal current: 3mA, 30minutes for 6 days in a week for 8 weeks - 12 weeks. Lane and Sandhu radiologic score taken for radiological assessment, Lower extremity functional score (LEFS) to assess quality of life and Visual analog scale (VAS) for Pain intensity were taken at Baseline, week 4, week 8 and week12.
Results: Our results show statistically significant improvement in Lane and Sandhu radiologic score ($p< 0.01$), Lower extremity functional score (LEFS) ($p< 0.01$) and in VAS ($p< 0.01$).
Conclusion: Low frequency PEMF therapy enhances bone healing and quality of life in subjects with delayed or non-union lower limb fractures.

Keywords: low frequency PEMF therapy, fracture, delayed union, non-union, bone healing, quality of life

INTRODUCTION

Despite recent improvements in fracture management, delayed union and non-union remain as intractable complications following surgical reduction and fixation of long-bone fractures. It is estimated that 5–10% of all fractures show impaired healing [1, 2]. It may result into further surgery with subsequent prolonged hospitalization, disability, and delays in returning to the work [3,4].

Electrical stimulation in the treatment of non-union has been used in different forms since many years [5]. The effectiveness of Electrical Stimulation and Pulsed Electro Magnetic Field (PEMF) Stimulation for enhancement of bone healing has been reported by many authors [6].

However, most of the published trials were done using longer treatment time for 6- 8hrs [2, 5, 7]. Recent therapy devices recommended low frequency PEMF Therapy with 12Hz to

20Hz frequency for 30 – 60min is effective for osteogenesis [7-10]. So the objective was to study the effects of low frequency PEMF therapy in bone healing and quality of life in subjects with delayed or non-union fracture.

2. METHOD

2.1 Design

This study was prospective, intervention study, pre-test - post-test design. Low frequency PEMF therapy was given in subjects with delayed or non-union lower limb fractures for 8-12 weeks and changes in radiological and quality of life was measured at Baseline, week 4, week 8 and week12. Subjects served as self- control. Their pre-PEMF treatment failure was compared to their post-PEMF treatment results. Self-pairing, as a study design, is valid because the constancy of the individual patient's biological mechanisms and other patient-specific factors essentially eliminates differences between the treatment and the control. It is scientifically valid and medically appropriate to use a paired design technique to study the therapy effect in a medical condition such as non-union, which has a predictable outcome (e.g., unfavourable in case of no treatment)[11-13].

A prior permission from Institutional Review Board of NHL Municipal Medical College (NHLIRB) was obtained. Nature and duration of the study was explained to all participants and a written informed consent was taken from all the subjects.

2.2 Participants, therapists, centers

Study was conducted at physiotherapy outpatient department of S. B. B. College of Physiotherapy, V.S. Hospital, Ahmedabad. Males and females aged between 18 and 60 years having lower limb fracture with delayed or non-union diagnosed by orthopedic surgeon were included. Individuals were excluded if they had Infection at fracture site, pregnant women, and epileptic patients.

2.3 Intervention

As per inclusion and exclusion criteria all the participants enrolled during the year Jan'2017-Sept'2018 included in the study. In all selected participants low frequency PEMF therapy was given at fracture site using MAGNETODYN- Therapy device M80 with coil applicator, Frequency: 20 Hz, Sinusoidal current: 3mA, 30minutes [14] for 6 days a week for 8 weeks -12 weeks[7,15] depending on patient's healing status (**FIGURE.1)**. Treatment was ceased in all participants when union was achieved or no radiographic progress to union was observed for a continuous 8weeks period. Maximum treatment period was 12 weeks. And clinical assessment and radiological assessment was done at Baseline, 4weeks, 8 weeks & 12 weeks interval. Radiological evaluation was done by orthopedic surgeon.

Figure 1. Application of low frequency PEMF Therapy using MAGNETODYN- Therapy device M80 with coil applicator

2.4 Outcome measures

Primary outcome measure:

Lane and Sandhu radiologic score [16] was used for Radiological assessment of fracture healing.

Secondary outcome measure:

To assess quality of life Lower extremity functional score (LEFS)[17] and to measure Pain intensity Visual analog scale (VAS)[18] was used. Lower extremity functional score (LEFS) was translated into Guajarati and Hindi language.

2.5 Data analysis

All study data were entered into an electronic database after being collected. Participant confidentiality was maintained through secure data storage, both during and after the study. Level of significance was kept at 5%. All data are represented as the mean ± SD and were analyzed using SPSS version 20. A Friedman test was carried out to compare the total understanding scores for the repeated measures at Baseline, week 4, week 8 and week12 for all outcome measures. Dunn-Bonferroni post hoc tests were carried out for pair wise comparison. Kendall's W (Coefficient of concordance) used to calculate Effect size.

3. RESULTS

3.1 Flow of participants, therapists, center through the study

During the study period total 18 participants were recruited. 2 participants were dropped out after short treatment time because of far distance and inconvenient in transportation. Remaining 16 participants were included for statistical analysis which includes 14 males (87%) and 2 females (13%) with mean age of 32.94 ± 13.7. There were 7 participants with fracture sites of femur, 8 with tibia – fibula fracture and 1 with metatarsal fracture were included for the study. For 3 participants 8weeks intervention was given due to good fracture union at 8 weeks follow up and for rest of 10 subjects 12 weeks intervention was given. Last observation carries forward (LOCF) in 12 weeks was done for 8 weeks interventional subject.

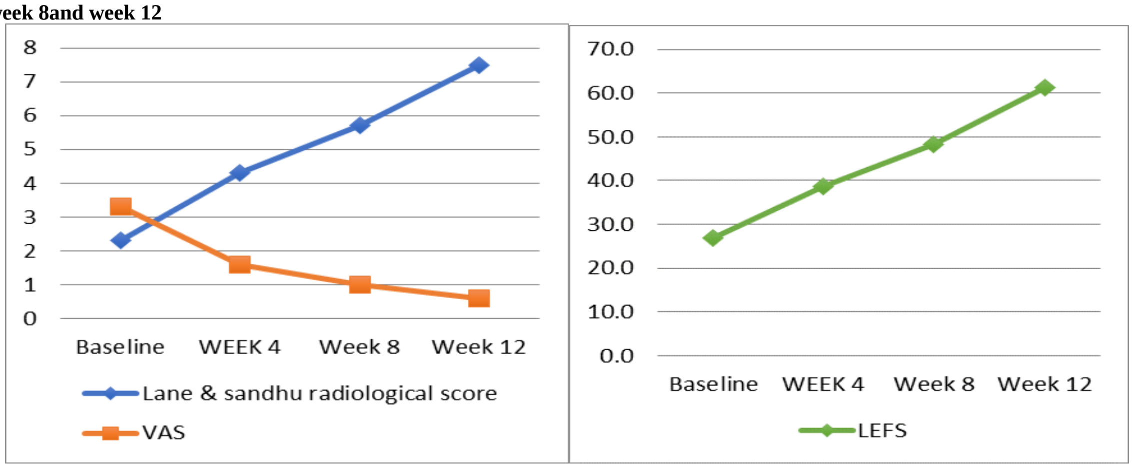
3.2 Effects of the intervention

Mean ±SD of intervention at Baseline, week 8and week 12 for Lane & Sandhu radiological score, VAS, LEFS (lower extremity functional scale) shown in table 1 and Graph 1.

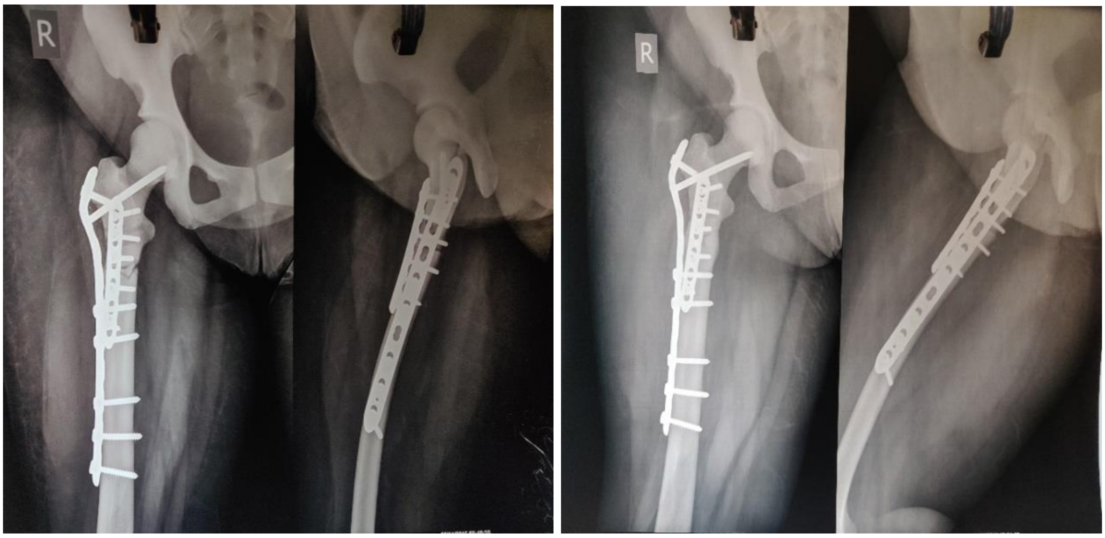
Table 1 Mean ± SD difference each intervention at Baseline, week 8and week 12 lane & sandhu radiological score, LEFS (lower extremity functional scale) and VAS

Outcome	Difference within Intervention			P value
	Week 4 minus Baseline	Week 8 minus Baseline	Week 12 minus Baseline	
Lane & sandhu radiological score	1.9± 1.2	3.4± 1.9	5.1± 2.4	<0.01
LEFS	11± 6.8	21± 7.3	34± 11	<0.01
VAS	-4.9±4.6	-2.3± 2.0	-2.7± 2.4	<0.01

Graph 1: Mean difference of lane & sandhu radiological score, LEFS (lower extremity functional scale) and VAS at Baseline, week 4, week 8and week 12

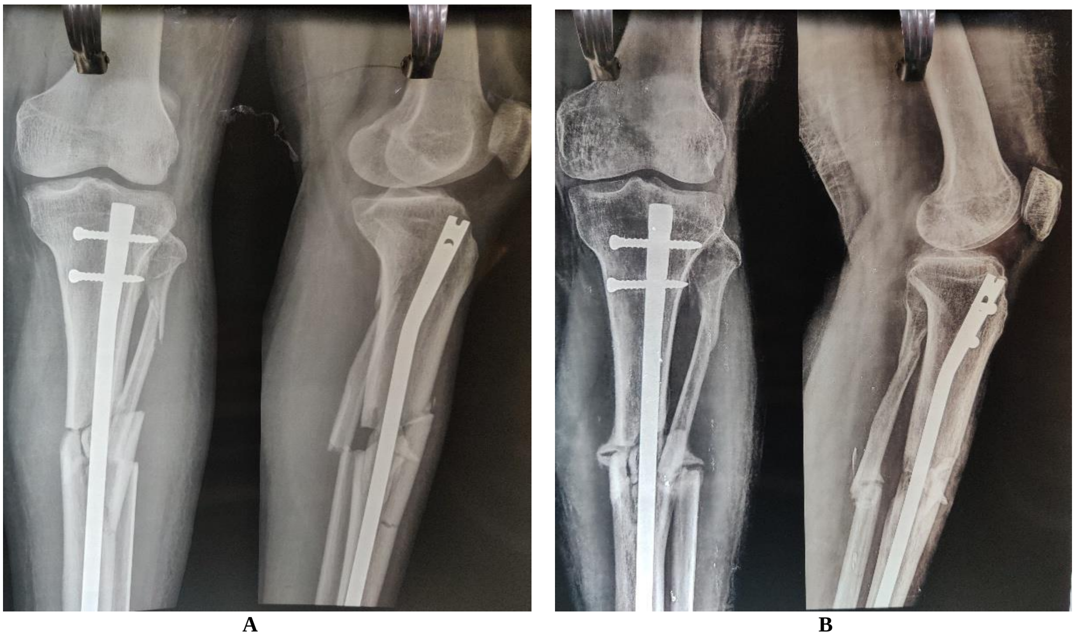


There was a statistically significant overall difference in lane and Sandhu radiological score, LEFS and VAS for Baseline, 4 weeks, 8 weeks and 12 weeks (p< 0.01). (**FIGURE. 2 AND 3**) There was statistically significant differences between the Baseline to 8 weeks (p < 0.01) and Baseline to 12 weeks (p < 0.01) and between week 4 to week 12 (p< 0.01) in all the outcome measures. Further The Kendall's W for Lane and Sandhu radiological score, LEFS and VAS was 0.92, 0.98 and 0.64 respectively which indicate strong effect size.



A B

Figure 2. Radiology of fracture upper shaft of femur A) Before intervention B) After 12 weeks of intervention



A B

Figure 3. Radiology of fracture shaft of tibia-fibula. A) Before intervention B) After 12 weeks of intervention

4. DISCUSSION

Present study found that application of low frequency PEMF therapy with 20Hz frequency, 30 minutes for 8- 12 weeks showed increased in radiological score in subjects with delayed or non-union fractures of lower limb which suggest improvement in bone healing after low frequency PEMF application. The results are in accordance with those of X.L. Griffin et al. [5] who suggest that electromagnetic stimulation is an effective adjunct to conventional therapy when used in the management of non-union of long bone fractures.

Fredericks et al[19] had given 30 and 60 minutes low-frequency, low-amplitude PEMF, in animal model, accelerated callus formation and osteotomy healing. Also Linovitz et al[14] demonstrated that combined magnetic field treatment of 30 min/day increases radiographic spinal fusion and showed an acceleration of the healing process. This result supports that low frequency PEMF therapy with short treatment duration is also effective in bone healing.

Hannay et al [20] concluded that an osteoblast-like cell line is responsive to a 15 Hz PEMF stimulus, by reduced proliferation and increased alkaline phosphatase activity, which is related to bone cell differentiation and bone mineralisation. These results support the hypothesis that a PEMF device with 15 hz frequency will stimulate an osteoblast-like cell line into an increasing state of maturity. Streit A et al[21] had use PEMF for fifth metatarsal fracture non-unions and analyzed biopsy for messenger-ribonucleic acid (mRNA) levels which shows significant increase in local placental growth factor, brain-derived neurotrophic factor (BDNF), bone morphogenetic protein (BMP) -7, and BMP-5 and faster average time to radiographic union compared to controls.

Brinker MR et al[22] evaluated 243 tibial shaft fracture non-unions and concludes nonunion is a distressing chronic condition that adversely affects both physical and mental health and quality of life. Present study shows significant improvement in lower extremity functional scale which suggests improvement in quality of life in lower limb non -union and delayed union fracture. These results are in accordance with Martínez-Rondanelli A et al[7] who suggests that an electromagnetic field stimulus can promote earlier bone healing in femoral diaphyseal fractures. Rapid bone healing translates into early weight bearing, which permits earlier return to function. This suggests that low frequency PEMF therapy improve quality of life in non-union and delayed union lower limb fracture.

Further studies can be designed to determine effectiveness of PEMF therapy in delayed and non- union fractures of upper limb. Also longitudinal study with the long-term follow-up are needed to find out bone remodeling time. And early application of PEMF therapy can be given after fracture to determine reduction in fracture healing time and immobilization period.

Our findings demonstrated that low frequency PEMF therapy is effective in enhancing bone healing and quality of life in subjects with delayed or non-union fractures of lower limb.

Declaration by Authors

Ethical Approval: Approved

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Conflict of Interest: The authors declare no conflict of interest.

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