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## Effect of active resisted exercise on plantar ulcer in subjects with leprosy

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### Abstract

**Background of the study:** Leprosy is a wide spread infectious disease caused by mycobacterium leprae & usually starts as a patch on the skin, but it can also affect & damage the nerves leading to secondary impairments in the face, hands and feet. Plantar ulceration is one of the common impairment occurring in subjects of leprosy, which punched out ulcer surrounded by thickened skin due to direct pressure, shearing force, direct injury, heat. It may occur as sinuses or as shallow ulcers involving the tissues at various level and usually heal with good wound care and dressings, but takes longer time.

**Objective of the study:** To evaluate and compare the improvement of healing of plantar ulcer during 4-week intervention period in leprosy subjects treated with active resisted exercise vs subjects treated conventionally.

### Methods

**Design:** Quasi randomised trial.

**Study settings:** The central leprosum, govt hospital, magadi road, bengaluru.

**Sample size:** 26

**Outcome measures:** Wound area measurement in mm<sup>2</sup> on a graph paper.

**Results:** The mean value of ulcer area at baseline for group A was 1038.15(599.77) mm<sup>2</sup> & group B was 997.07(804.47) mm<sup>2</sup> and at day 30 the value for group A is 318(311.65) mm<sup>2</sup> & for group B is 720.84(673.19) mm<sup>2</sup>. This study showed a significant improvement in reduction of ulcer area in both the groups. Group A demonstrated significantly better improvements than Group B.

**Conclusion:** Active resisted exercise showed a significant improvement in healing of planter ulcer of leprosy subjects compared to control group.

**Keywords:** Chronic low back pain, Interferential current electrotherapy, physiotherapy, rehabilitation

### Introduction

#### Background of the study

**Leprosy** is a wide spread infectious disease caused by mycobacterium leprae. India accounts for 55 per cent of the world's leprosy cases <sup>[1]</sup>. It usually starts as a patch on the skin, but it can also affect & damage the nerves leading to secondary impairments in the face, hands and feet <sup>[2]</sup>. The skin may crack, become ulcerated and become infected <sup>[3]</sup>. Primary neural impairments may lead to severe joint deformity <sup>[3]</sup>. Loss of sensation and sweat over the affected part, chronic nerve pain, nerve abscesses, and motor paralysis <sup>[4]</sup>. Secondary impairments are clawing of fingers and toes, wrist drop, foot drop, lagophthalmos, corneal ulcer and recurrent wounds of hands and feet <sup>[4,5]</sup>.

**Plantar Ulceration:** Is a punched out ulcer which is surrounded by thickened skin due to direct pressure, shearing force, direct injury, heat and is common impairment occurring in subjects of leprosy <sup>[6]</sup>. Common sites of ulceration are heel, mid-lateral border of sole, forefoot, head of first metatarsus and heads of other metatarsus <sup>[6]</sup>. Predisposing factors are reported to be Sensory loss, Motor paralysis and Autonomic nerve damage, among those with plantar ulceration, ulcers of the forefoot contribute 70% and over the metatarsal heads contribute 55% <sup>[7]</sup>. It usually heal with good wound care and dressings <sup>[8]</sup>. Multiple intervention in physiotherapy aspects like bed rest, crutch walking, POP boot or B.K Plaster, dressing, self-care like soaking, scraping, oiling, Electrotherapy modalities like ultrasound, TENS, wax bath, and low level laser therapy and also Exercise therapy like active exercise <sup>[4,9]</sup>.

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Exercise therapy increases strength and joint ROM, improves quality of movement, increases ADL, improves QOL perception, increases blood flow to the extremities, restores the normal tone of muscles and preserves the physiological properties of paralysed muscles, Prevents contractures, makes the skin soft and supple [10].

### Impairments (Primary or Secondary to leprosy)

Primary neural impairments may lead to severe joint deformity with loss of sensation and sweat over the affected area, chronic nerve pain, nerve abscesses, and motor paralysis.<sup>3,4</sup> Secondary impairments are clawing of fingers and toes, wrist drop, foot drop, lagophthalmos, corneal ulcer and recurrent wounds of hands and feet [4, 5] Nerve damage effects of sweat gland function in anaesthetic sole of the feet of leprosy patient. Fissure and cracks develop in the dry skin and these get infected over a period of time leading to plantar ulcers.<sup>11</sup> Impairment of motor, sensory and autonomic nerve function produces lower thresholds for tissue damage.<sup>12</sup> Plantar metatarsal ulcers and sinuses are frequently seen in anaesthetic feet occurs as a result of pressure or friction on areas which have become anaesthetic due to peripheral neuropathy [7, 13].

### Factors affecting wound healing

- Psychological stress may exacerbate delays in wound healing among healthy older adults [14].
- Poor circulation may in some cases delay wound healing [15].
- High levels of inflammation are known to delay wound healing [16].

**Wound assessment:** Various methods of wound/ulcer assessment exists in literature. The most common methods include surface area [17], digital photography [18], acetate grid tracing [19] and the ICC values for intertester wound area measurements for Ruler-0.97, Graph paper-0.99, Planimeter-0.98, Digitizer-0.99 [20].

### Treatment of ulcers

scraping and oiling have been traditionally used for the restoration of the dry skin to its normal level of suppleness.<sup>4</sup> Other reported treatments include antibiotic therapy-MDT (Multi drug therapy) [2], crutch walking, POP boot or B.K Plaster, dressing by using gauze pieces, bandage rolls betadine solution, soap and Savlon, Static dynamic splinting [4, 9] surgery with local superficial flaps [6], toe web flap [7], Self care foot soaks [11], cuneo-metatarsal articulation [21], surgical decompression [22].

**Physical therapy treatment:** Physical therapy of ulcer in leprosy use Electrotherapy and Exercise modes.

**Electrotherapy:** Electrotherapy modalities, specifically use of low amplitudes of direct current (high galvanic) provides the most effective means for promoting wound healing. Blood cell migration occurs with the use of electrical stimulation and may have a beneficial influence in wound healing.<sup>23</sup>

**Exercise therapy:** Physical exercise is a viable intervention to mitigate the negative effects of age and psychological stress in the wound-healing process [24], also it speeds healing by reducing inflammation to healthier levels [16]. Exercise improved calf pump hemodynamic, specifically, ejection fraction and residual volume fraction [25], and has shown to

increased joint mobility and blood flow to the extremities [26]. However, exercise effects have been documented for other types of ulcers like in diabetes ulcer, venous ulcer and ulcers in older age groups, So physical exercise has been recommended for patients with an ulcer [27].

### Methodology

**Study Design:** Quasi randomised trial.

**Study Setting:** The leprosy mission community Hospital, Naini, and Allahabad. (U.P)-211008

The central leprosum, govt hospital, magadi road, bengaluru.

### Inclusion Criteria

- Subjects diagnosed with leprosy.
- Plantar ulcer with unilateral involvement.
- Subjects age 15-69yrs.
- Both males and females.
- Co-operative with exercise program.

### Exclusion Criteria

- Ulcer infected
- Bilateral ulcer
- Weak hamstrings/quadiceps (< 3+)
- Depression/uncooperative subjects.
- Wounds secondary to burns.

### Materials

- 2 Transparent tracing sheet.
- Marker.
- Graph paper.
- Pen and paper.
- Weight cuff.

**Sampling:** Convenient sampling.

**Procedure:** The population of Leprosy subjects were selected from the Leprosy mission, Naini & central Leprosium hospital, Bangalore, who were admitted in the hospital. They were scrutinized for inclusion & exclusion criteria & those who satisfied the criteria & interested to participate in the study were given a informed consent form & were included in the study sample.

**Subject's allocation into groups:** Allocation of subjects was done by tossing a coin for each pair. A coin was tossed and the subject was entered into group 'A' when head occurred and vice versa. Subjects were assigned into two groups. Group A was interventional & Group B was control. All the participated subjects were explained about the procedure & aim of the study & subjects underwent a general assessment. The MMT was conducted in the beginning of the intervention to check the strength/power of hip and knee muscles. Patient position was lying over bed, SLR with full ROM against gravity without resistance. Assessment of sensory and motor impairment was done by using The Leprosy Mission Impairment Record and Sensory assessment chart.

**Measurement:** Subjects were measured for outcome measures at baseline. Measurement of the wound for all participants was conducted by using transparent tracing sheets. Before taking measurement, the wound was cleaned so that the margin of the wound to be clearly visible. One sheet was placed directly over the wound and the other over previously placed sheet. The margin of the wound surface area was marked with marker. Two tracing were taken for accuracy. The measurements were taken on day 0, 15<sup>th</sup>, and

30<sup>th</sup>. The same again was plotted on graph paper where the full squares (mm<sup>2</sup>) falling inside the plotted wound margin was counted as the surface wound area. The progression was seen on day 15<sup>th</sup> and 30<sup>th</sup>.

**2.7.3 Intervention:** Both the groups underwent conventional treatment & the regular dressings were done for wound. All the subjects of group A were explained verbally & demonstrated the resisted exercises what they had to perform, 2kg weight cuff was used for the resistance while performing

the exercise & asked the subjects to perform the following movements of hip & knee. The resistance was applied for all the hip muscles (flexors, extensors, adductors & abductors) Participants of group A were given active resisted exercise to hip and knee joint. The exercise were performed by the subjects are Hip – flexion, extension, abduction, adduction, with strong resistance, knee – flexion, extension, with strong resistance and isometric exercise for hamstrings and quadriceps. (Table 1)

**Table 1:** Resisted exercises performed by the subjects: All the above exercise were performed for 8-10 repetitions X 3 sets.

Physiological movement	Position of subject	Movement Performed by subject	Position of wt cuff	Stabilization
Hip flexion	Supine	SLR	Ankle	Pelvis
Hip abduction	Side lying	Side SLR	Ankle	ASIS
Knee flexion	Prone	Knee bending	Ankle	Knee
Knee extension	High sitting	SLR	Ankle	Knee

### Calculations

The difference in wound surface area was calculated in the form of ratio by using following calculation,  $a-b/a=c$ ,  
Where, a = Initial wound area.

b = wound area after therapy.

c = percentage of improvement in wound area.

Then the difference was noted as progression of wound healing.

**Outcome measures:** Wound area measurement in mm<sup>2</sup> on a graph paper.

### Data analysis

- Demographic data analysed by mean (SD) & frequency distribution.
- Homogeneity of ulcer area between both groups at baseline compared by independent sample 't' test
- Pre and post comparison of wound surface area with repeated measure ANOVA.
- Between group comparison of wound surface area with

independent sample 't' test.

- Comparison of wound healing between male & female and different WB status between groups by Mann Whitney U test.

### Results

A total of 26 subjects were recruited for the study. All 26 subjects met the inclusion and exclusion criteria as they were associated with leprosy. A total of 26 plantar ulcer subjects with a Mean (SD) age of 52.69(12.25) yrs and Median age of 53.5, with 4 females and 22 males participated in the study. For all the subjects assessment was taken on day 1, day 15, and day 30.

The variables – age & baseline ulcer area were checked for homogeneity between the groups. An independent sample t-test showed insignificant difference between the groups for the variables. The statistical value noted for age was  $t = -1.229$ ,  $df = .24$ ,  $p = .231$  and for baseline ulcer area was  $t = .148$ ,  $df = 22.191$ ,  $p = .884$ . in Table No. 2

**Table 2:** The primary outcome measure (ulcer area) assessed in the study is presented

Group	Baseline Mean (SD)mm <sup>2</sup>	Day 15 Mean (SD)mm <sup>2</sup>	Day 30 Mean (SD)mm <sup>2</sup>	Within group comparison repeated measures
Experimental	1038.15(599.77)	454.15(372.34)	318(311.65)	9.586, 0.000
Control	997.07(804.47)	952.53(970.72)	720.84(673.19)	0.420, 0.660

Statistical analysis to compare the improvement in the ulcer area was performed within the group using repeated measures. The ulcer area of improvement was converted into a ratio using the formula  $(a-b)/a$ , where a – pre-therapy ulcer area, b – post-therapy ulcer area. This ratio data was used to compare the differences between the groups, using independent sample t-test.

The independent sample t-test for comparison of improvements in ulcer between groups from day 0-15 showed a significant improvement with  $t = 5.321$ ,  $df = 24$ ,  $p = .000$  & from day 15-30 showed insignificant improvement with  $t = 1.621$ ,  $df = 20.441$ ,  $p = .120$ . Group A had shown significant improvement in ulcer area reduction than Group B.(Table 3)

**Table 3:** Improvement in ulcer area (%).

% (a-b/a)	0-15	15-30
Group A	0.57(0.19)	0.39(0.29)
Group B	0.12(0.23)	0.23(0.19)
Statistics (t, df, p)	5.31, 24, 0.000	1.62, 20.44, 0.120

### WB status

The mean, median and CI values of group A (N-6) & B (N-8) for those who were w/o AD, & group A (N-4) & group B (N-4) of those using BLC for day 0-15, 15-30 & 0-30, are represented in Table no 5 & 6 respectively. When the comparison was done between the groups by Mann Whitney test, Both w/o AD & BLC showed significant improvement for day 0-15 & 0-30, and no significant improvement for day 15-30 for both the groups shown in Table 4 and Table 5 respectively.

### Ulcer healing between genders

The variable for Male vs female within the group A & group B showed insignificant differences when done by non-parametric Mann Whitney test (U). The values are shown in Table no 6.

**Table 4:** Improvement (%) in ulcer healing in w/o AD

Days of comparison	Group	N	Mean(SD)	CI	Median	Statistics z,p
0-15	A	6	0.64(0.20)	0.42-0.85	0.66(0.31-0.96)	-2.71, 0.007
	B	8	0.16(0.27)	-0.06-0.39	0.08(-0.25-0.59)	
15-30	A	6	0.41(0.36)	0.03-0.80	0.25(0.10-1.00)	-0.25, 0.796
	B	8	0.29(0.15)	0.16-0.42	0.27(0.07-0.60)	
0-30	A	6	0.74(0.20)	0.53-0.95	0.72(0.43-1.00)	-2.32, 0.020
	B	8	0.40(0.22)	0.22-0.59	0.32(0.18-0.82)	

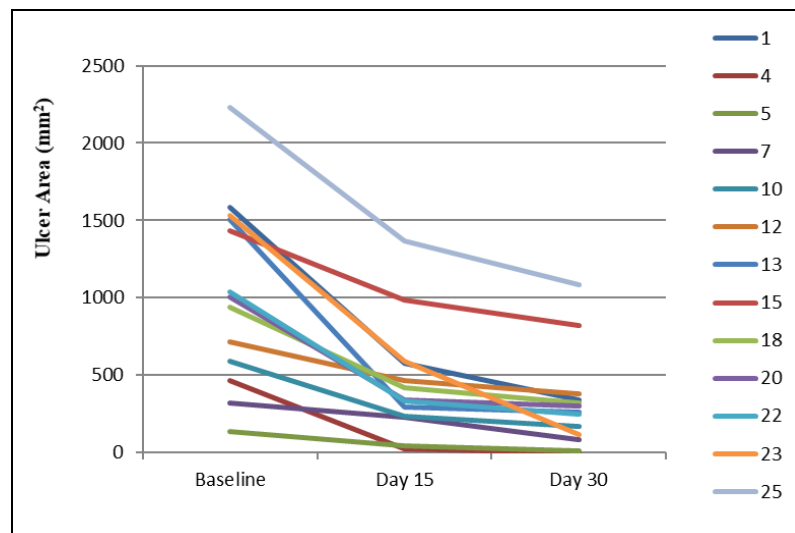
**Table 5:** Improvement (%) in ulcer healing in BLC

Days of comparison	Group	N	Mean(SD)	CI	Median	Statistics z,p
0-15	A	4	0.49(0.14)	0.26-0.73	0.50(0.35-0.64)	-2.30, 0.021
	B	4	0.05(0.17)	-0.22-0.33	0.03(-0.12-0.25)	
15-30	A	4	0.27(0.09)	0.11-0.42	0.24(0.19-0.41)	-1.44, 0.149
	B	4	0.09(0.22)	-0.26-0.44	0.12(-0.21-0.32)	
0-30	A	4	0.62(0.15)	0.38-0.86	0.61(0.48-0.79)	-2.30, 0.021
	B	4	0.16(0.08)	0.04-0.29	0.16(0.10-0.25)	

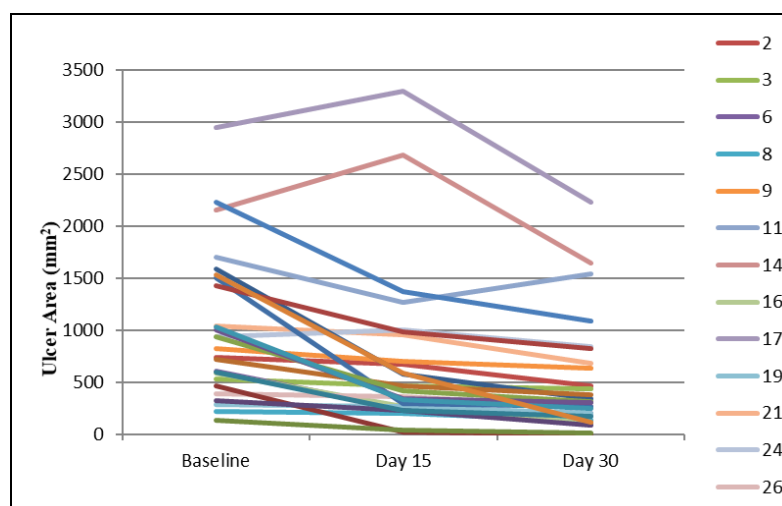
**Table 6:** Comparison of ulcer healing (%) between Male & female within groups

Group	N	0-15	15-30	0-30
Group A	M = 11 F = 2	-0.790, 0.430	-0.592, 0.554	-0.395, 0.693
Group B	M = 11 F = 2	-0.692, 0.489	-0.592, 0.554	-0.790, 0.430

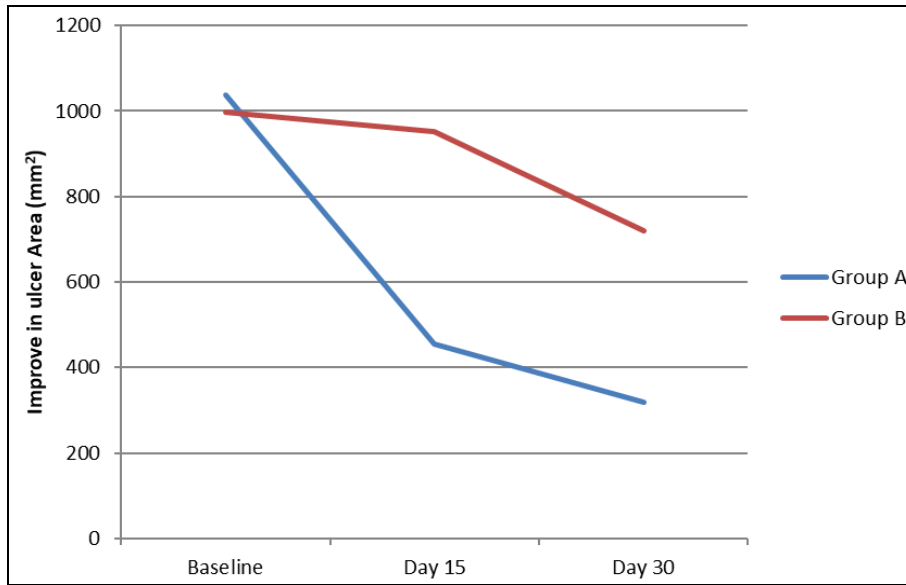
The graph is plotted on Ulcer area of individual subjects (mm<sup>2</sup>) for Group A and Group B respectively in Fig: 1 and Fig: 2 respectively.



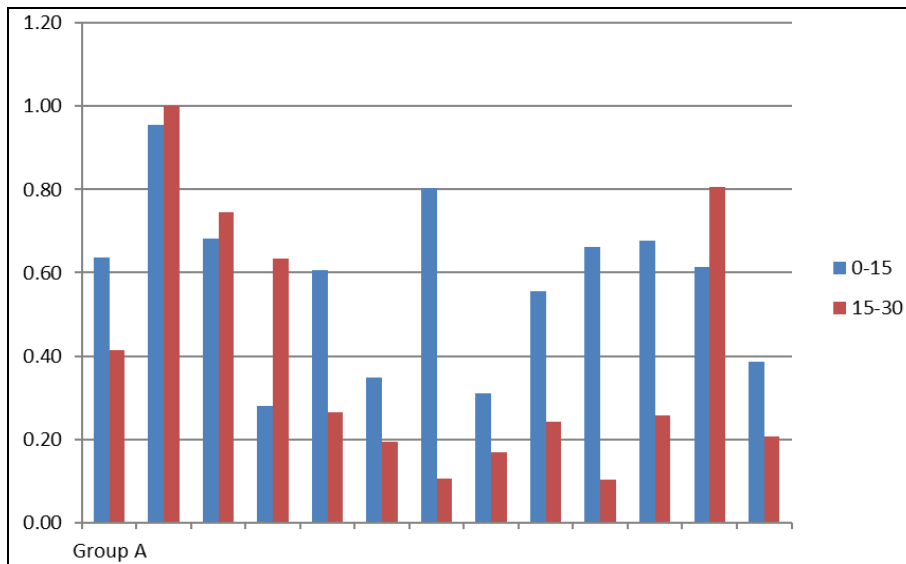
**Fig 1:** Ulcer area of individual subjects(mm<sup>2</sup>) in Group A



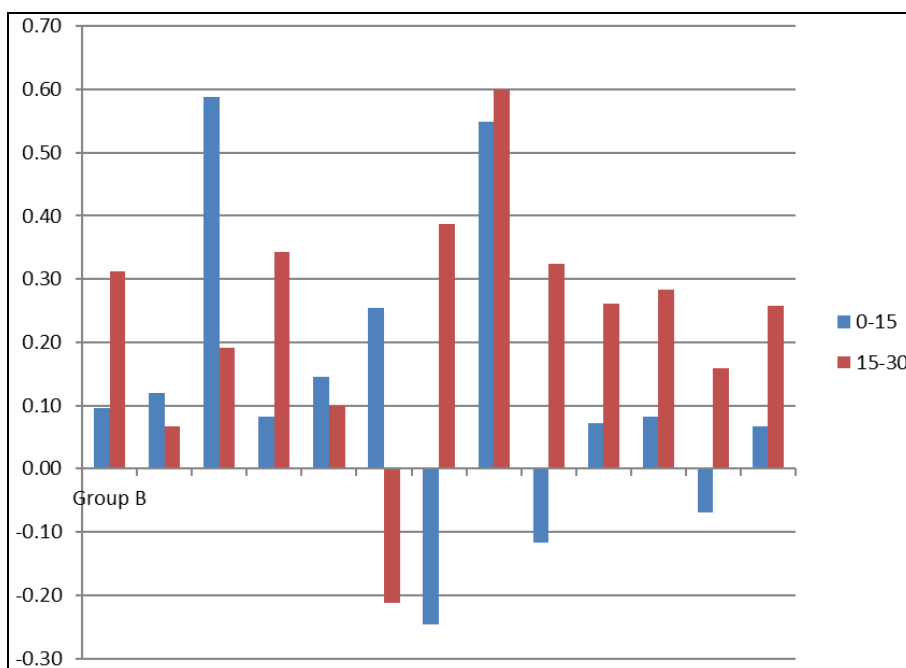
**Fig 2:** Ulcer area of individual subjects (mm<sup>2</sup>) in Group B



**Fig 3:** Trendline of improvement in ulcer area for both groups



**Fig 4:** Comparison of ulcer healing between day 0-15 & 15-30 in group A



**Fig 5:** Comparison of ulcer healing between day 0-15 & 15-30 in group B

## Discussion

The aim of study was to find the effects of active resisted exercise on subjects with plantar ulcer in leprosy with respect to its healing.

A total of 26 subjects were screened for the study. All 26 subjects met the inclusion-exclusion criteria. Subjects were included with a Mean (SD) age of 52.69(12.25) years and Median age of 53.5, with 4 females and 22 males. The subjects followed conventional treatment for their leprosy & regular dressings were done for ulcer as per the hospital protocol. Participants of experimental group were given active resisted exercise to hip & knee muscles.

The mean value of ulcer area at baseline for group A was 1038.15(599.77) & group B was 997.07(804.47) mm<sup>2</sup>. This study demonstrated a significant improvement in reduction of ulcer area in both the groups. Group A demonstrated significantly better improvements than Group B. Exercise offers the potential to improve circulation, wound healing outcomes, and functional and emotional wellbeing for adults experiencing leg ulceration [28]. This may be attributed to increasing blood flow to the extremities which increases oxygen & nutrition supply to the ulcer. Strength training has been shown to increase blood flow & improve vascular conductance in sedentary middle-aged & older adults.<sup>29,30</sup> Improved blood circulation enhance healing of tissues. Regular debridement & dressing of ulcers, along with improved circulation may have enhanced improvement of ulcer area in experimental subjects.

In this study, subjects in group A did better in 0-15 days (n=9) in comparison to group B (n=4) may be because of small ulcer area, better support and care taken by their family members, or nutrition and medicinal effects which was taken by them for their co-morbid conditions might have influenced for better healing. The subjects who were mobilized w/o AD in group A improved better in 0-15 days than 15-30 days & vice versa in group B. We feel this was influenced also by the wound debridement procedure which potentially increased the ulcer area, that could have biased the measurement. Similarly, WB status, intergroup comparison might have been biased due to the dressing procedure. Even the gender M/F is 11/2 in both the groups showed insignificant difference which is not feasible.

Two factors which may have influenced the healing of ulcers, which were recorded during the trial include gender and weight bearing status. Statistical tests demonstrated insignificant effect of the factors on reduction of ulcer area. The number of subjects was very less, in each categories, to perform parametric tests. Hence, non-parametric statistics were used, which showed insignificant differences between the primary outcome measures in males vs females and varying weight bearing status.

## Conclusion

Active resisted exercise showed a significant improvement in healing of planter ulcer of leprosy subjects within 4-week intervention compared to control group. Hence it may be included in early rehabilitation for leprosy subjects with planter ulcer.

## Limitation of study

- Smaller sample size.
- Ratios of female subjects were very less.
- Duration of intervention was short, so no follow up conducted.
- No restriction about weight bearing.

- No control about nutrition and the drugs prescribed to subjects were different based on their co-morbid conditions.
- Routine wound debridement & dressing might have biased measurement.

## Further recommendations

- Further study recommended with a larger sample size.
- Further studies can be done with long duration of intervention.
- Subjects must be educated about their weight bearing & their mobilization.
- Nutrition & the drugs prescription should be under control & should be same for all the subjects participating.

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