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Comparison of Outcome on Knee Related Function by 2 Different Mode of Progressive Resisted Exercises (PREx) Intervention in Patients with Knee Osteoarthritis

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Abstract

Background: Lower limb muscles strengthening is crucial in knee joint rehabilitation. Weight training as evolved by DeLorm is a more traditional robust form of Progressive resistive exercises (PREx) program in which muscles are exercised against constant resistance through the arc of motion. Use of Elastic bands is yet another tool used in strengthening exercise regimens. What popularly known as Theraband exercises, resistance varies through the arc and relies on various components such as modulus of elasticity. The characteristic differences of theses 2 modes of resisted exercise was assumed to result in different outcomes on measured knee related functions. Hence, this study has been undertaken to compare the short term effects PREx using weight cuffs versus Theraband resistance exercise in patients suffering from knee osteoarthritis.

Methods: Eighty-nine participants completed this trial over the period of 14 months. Study participants were randomly allocated to 3 study groups which received PREx (DeLorm) (n=30), Theraband exercises (n=30) and conventional treatment (n=29) for 3 week period.

Results: Interaction between time and function was significant when compared with control whereas both experimental groups improved equally (P>0.05) over the period of time. Post treatment Weight cuff (DeLorm) and Theraband PREx between group differences (median difference and probability of superiority (PS) is presented for 5 Knee injury and Osteoarthritis Outcome Score (KOOS) subscales and patient specific function are as follows. Pain: 6.5 (36%); symptoms 11(43%); ADL 5.5(45%), Sport and recreation 5(35%), QOL, PSFS 0.75(37%)

Conclusion: Both the weight cuff PREx (DeLorm) and Theraband resistance exercises resulted in improvement of knee functions as measured on KOOS and patient specific functional scale in population suffering from knee osteoarthritis with better probability of superiority for weight cuff exercises.

Introduction

Progression models in resistance training for muscle strengthening provide a framework for conditioning of muscles [1] which can influence the outcome of pathology [2]. Around 1945 Thomas DeLorm recommended a progressive resistance exercise (PREx) program based on 10 repetitions maximum (10RM) with weights [3].

On the other hand, Resistance training using elastic bands is distinctive. Resistance properties of tubing are often compared to the dynamics of a spring, whereby the change in length (applied force), type of material (modulus of elasticity), and cross-sectional area determines the amount of potential energy stored and hence the magnitude of resistance [4]. Specific protocols and methods have been used with exclusive use of elastic bands in strengthening of the lower limbs muscles. [5] Due to its low cost, simplicity, portability, versatility, and no reliance on gravity for resistance [6].

Volume, intensity, frequency of training, and mode of resistance are modifiable factors in strength training [7] which can influence the outcome of pathology. [2] A huge body of evidences [8-10] suggests role of hip and knee joint muscle weakness in pathogenesis and maintenance of symptoms and positive role of resisted exercises to target hip and knee joint muscle [11].

The magnitude of resistance applied throughout the arc of movement by weight cuff and Theraband different expected to result in distinct outcome on strength gains and consecutively on functions associated with the body part which was exercised.

A huge body of evidences [8-10] suggests role of hip and knee joint muscle weakness in pathogenesis and maintenance of symptoms resulting in long term disability in functions related to lower limb. The role of resisted exercises to target hip and knee joint muscle has been emphasized throughout literature [11].

One of these 2 distinct modes of progressive resisted exercise interventions used in this trial is an age old and robust method. However, Evidences related to the effectiveness of both of these methods on knee related functional improvement are scarce. It is not known that to what extent these exercises can effectively be prescribed to patients suffering from knee osteoarthritis

Objective of this pilot trial was to evaluate the short term effect of weight cuff training (Delorm) and Theraband PREx on disease specific function scale (KOOS) and patient specific function scale (PSFS). This pilot study also aims to provide a preliminary database of functional

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index change such as Knee injury and Osteoarthritis Outcome Score (KOOS) in order to provide basis for future studies.

Methodology

This randomized control trial is a one-factor experiment looking at the effect of two strength training program on multiple dependent non parametric functional outcome measures [12]. The allocation ratio of participants to each group was 1:1:1.

An estimate of sample size was obtained with consideration of 30% loss to follow up as observed in previous research [13] and was calculated in two ways (2-tailed test, power 90%, and significance level alpha=0.05). Mean and variance of the previous dataset was used to calculate the sample size. Pre and post exercise within group difference of WOMAC before and after Theraband resisted exercise program (41.09+/-1.85, 35.30+/-1.83) was considered [5]. This data indicated that the difference in the response of matched pairs is normally distributed with standard deviation 1.8 with true difference in the mean response of matched pairs was 5.79. A between group calculation was also computed using Knee extension strength [13] from a knee OA patients. Effect size for mean differences of groups within a pre-post design was calculated. Based on these two calculations, and with due consideration for loss to follow up at least 35 participants per group were needed to be able to reject the null hypothesis that this response difference will be zero with probability (power) 0.9. The Type I error probability associated with test of this null hypothesis is 0.05.

Study population

A total of 105 patients previously diagnosed with knee OA volunteered and participated in the present study. They were randomly assigned to weight cuff (DeLorme) Theraband and control. Demographic data is presented in Table 1.
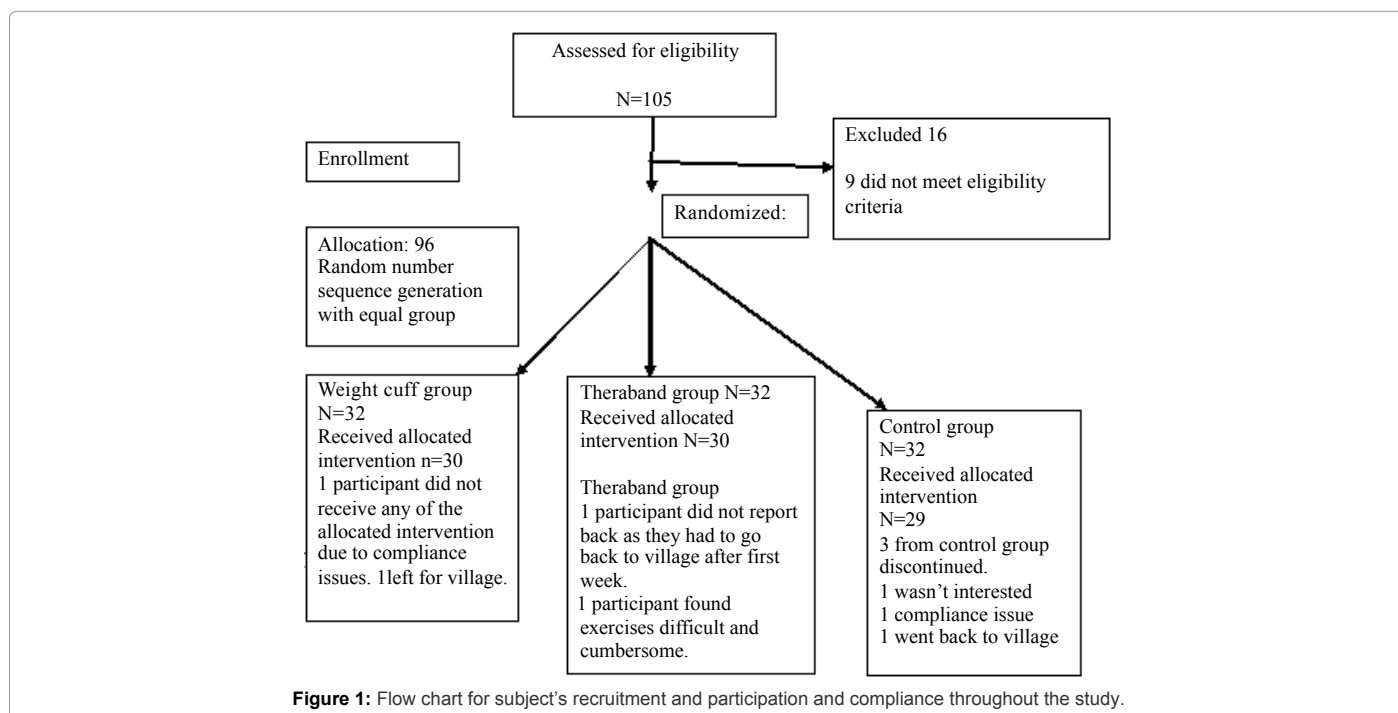
Participants were recruited from two municipal corporation public hospitals and, one public charitable trust's hospital. Patients were referred by different medicine consultants and physical therapy consultants in the hospital. Theses consultants identified patients as per the set eligibility criteria provided to them by the research team. Once selected a registration personnel (therapist) who was not directly involved with the trial explained them the objectives of the trial in the language best understood by them. A written summary of the trial and its purpose was handed over to the eligible candidates and a written informed consent was obtained after their willingness to participate in the trial. Participants were blinded to the study group allocation.

Participants were allotted to the study groups according to random number sequence generated by the bio-statistician. This table of 96 random numbers was produced according to the following specifications: Numbers were randomly selected from within the range of 1 to 3. Duplicate numbers were allowed. Therapists involved in trial were blinded to the identification and allocation of participants to the treatment groups to nullify the selection bias. Participants flow during trial is presented in flow chart diagram Figure 1.

Characteristic	Weight cuff group	Theraband group	Control
Sample size	N=30	N=30	N=29
Gender (female %)	50%	56%	68%
Age (Yr), mean (SD)	52.16 (4.10)	52.70 (3.33)	51.37 (3.74)
Normal distribution	0.54	0.94	0.52
Difference between age groups	F ratio=0.929, P=0.399, NS		
Yr=years, SD= standard deviation, NS=non-significant, n=sample population in each group			

Table 1: Baseline descriptive characteristics of participants by intervention group.

Figure 1: Flow chart for subject's recruitment and participation and compliance throughout the study.

Set eligibility criteria for the participants was as follows

Participants suffering from mild-moderate intensity [14] intermittent knee pain, stiffness, age over 45-50 years, swelling of soft tissues, pain on climbing stairs, history of swelling, pain on rising from chair [15] and radiographic Kellergen-Lawrence [16] grading scale 1 to 3. Additionally participants were require to compliant with 1 week of supervised and 2 week of home based treatment program and be available for the telephonic communication. Participants were excluded from trial if they suffered from any following conditions which could prohibit them from exercising such as H/O metabolic, sero-positive, & sero- negative arthropathy (RA, Gouty Arthritis etc.), uncontrolled angina, severe cardiomyopathy, electrolyte or metabolic disturbances etc. tissue injury, macro or micro trauma resulting in dysfunction of lower limb. Constant unremitting severe intensity [14] and high irritability [17] knee joint pain and if currently participating in an organized exercise program or involved with yoga or fitness exercises for an hour daily etc. Ethical permission for the commencement was obtained as per the guidelines given by MUHS, Nashik. Participants were treated in the outdoor patient department of respective hospitals. These hospitals were located in Neural, Vashi, Navi Mumbai and Thane District, Maharashtra State.

Interventions

Baseline data was recorded on the all the outcome parameters and demographic information along with general history findings were recorded on a case assessment sheet. Participants were randomly allocated to one of the following treatment groups; weight cuff (DeLorm's) PREx (experimental group1), Theraband PREx (experimental group 2), conventional treatment group (control group3). Both the groups received warm up exercises on bicycle for 5 minutes followed by general stretching exercises such as 90-90 hamstring stretch [18] and passive hip flexor stretch [19] if required. Resistance exercise sessions briefly consisted of knee flexion (prone), knee extension (sitting), hip flexion (supine), hip extension (prone), hip abduction and adduction exercises in side lying.

Determination of 1 RM (repetition maximum)

To minimize possible errors in the 1 RM testing, the following strategies were employed:

(a) All subjects received standard instructions on exercise technique

(b) Exercise technique was monitored and corrected as needed, and

(c) All subjects received verbal encouragement. All three week program was supervised in clinical settings. Participants' were initially assessed for the performance of 1RM. 10 RM was then calculated from 1RM. It is reported in literature that about 78% of weight lifted for 1 RM would be subject's 10 RM working weight for the concentric work for that muscle group [2]. The baseline 10 RM weight is lifted by individuals on the first day of assessment is shown in Table 2.

Each hip and knee exercise was performed with set dosage of 10 repetitions /set x 3 set with 2 minute rest between each set. First set was performed with 50% of 10 RM, second with 75% of 10 RM and third with 100% 10 RM 3. Participants performed supervise exercises on 5 days/ week. 2 day rest was given after the completion of 5 days. The strength training was then commenced for the second week with newly gained 10 RM. Same procedure was followed for the third week [20].

Theraband exercises

The progressive resisted training program used consisted of 4 hip and 2 knee joint muscle group strengthening program. On first day of exercises each participant was assessed for the resistance and appropriate Theraband color. Total number of participants in a particular color code category is shown in Table 3. Theraband color that allows the individual to complete 10 repetitions per set to the point of fatigue was chosen. This is called the "multiple repetition maximum," [21] the eccentric phase of exercise was emphasized. Subjects were instructed to not let go and recoil the band and it should be a slow release and might take longer than concentric phase.

Selection of elastic Theraband

We used a general guideline to determine the color of band as per the guidelines govern by [21,22] Theraband academy Appendix 1.

Theraband exercises

Theraband exercises were given in Knee Extension (sitting), Knee flexion (prone), Hip Flexion (Standing), Hip Extension (standing), Hip Abduction (standing), hip adduction (standing). Detailed exercise position and related instructions are presented in Appendix 2 [23].

Guidelines for the prescription of the length of the band and progression are adopted from the previously conducted intervention trial by Richards et al. [24] Appendix 3. Each subject was then provided with a length of Theraband of measuring same as the length of moving part of limb and of appropriate resistance of the length. Extra length of the band was i.e. (15 cm tied to anchor point and 15 cm to the ankle=30 cm) was used to fixate the band. Hence, 30 cm of the Theraband didn't contribute to the resistance. As the lower limb had to be lifted away from the trunk an average height individual required an 80-90 cm of length Theraband with a particular color to begin with exercises. For

KOOS	PRE [b] Weight cuff group			PRE Theraband group			Control			
SS[a]	Median	95% CI	Normal Distr.	Median	95% CI	Normal Distr.	Median	95% CI	ND[c]	P[d]
Pain	47.0	42.0-56.3	0.56	44.0	42.0-53.0	0.16	47.0	41.29-53.0	0.32	0.84
Symp	48.0	39.0-61.0	0.59	46.0	39.7-56.4	0.26	50.0	43.0-57.9	0.11	0.65
ADL	51.0	46.0-56.8	0.10	49.0	43.0-54.0	0.81	50.0	46.0-54.0	0.001	0.88
Sport	60.0	55.0-69.1	0.38	57.5	50.8-60.0	0.96	60.0	55.0-65.0	0.13	0.15
QOL	38.0	26.0-44.0	0.61	38.0	38.0-44.0	0.13	44.0	38.0-50.0	0.9	0.31
PSFS	5.00	3.83-5.30	0.00	4.27	4.0-5.0	0.47	4.7	4.28-5.0	0.61	0.5

* Knee Injury and Osteoarthritis Outcome Score
: Each item of 5 subscale is graded on 5 point likert scale. Score is calculated sepretely for each scale as percentage. Higher score reflecting improvement
**Patient specific function scale
Values are median, confidence interval of the median and NDC=normal distribution at baseline
a=subscale score, b=Progressive resisted exercise PRE
d= Kruskall-Wallis test for independent group difference

Table 2: Baseline KOOS* 5 subscales scores and PSFS** score.

Measures	PRE[b] Weight Cuff (Delorm) (n=30)		PRE Theraband (n=30)		Control (n=29)		Kruskal-Wallis test (N=89)	
SS[a] KOOS*	Median	95% CI	Median	95% CI	Median	95% CI	X^2 (df) [c]	P[d]
Pain	73.50	69.0-81.00	67.0	64.0-69.0	53.0	50.0-56.0	0.33(2)	0.84
Symp[e]	79.00	68.52-79.00	68.0	64.0-75.0	57.0	50.0-64.9	0.83(2)	0.65
ADL[f]	73.50	62.17-80.47	68.5	68.0-72.0	51.0	47.0-57.0	0.24(2)	0.88
Sport[g]	75.00	70.00-80.00	70.0	65.0-75.0	60.0	58.83-65.0	3.62(2)	0.15
QOL[h]	56.00	50.00-63.00	56.0	50.0-56.0	44.0	38.0-50.0	2.26 (2)	0.31
PSFS**	6.75	5.79-7.50	6.0	5.25-6.60	4.7	4.50-5.0	26 (2)	0.000002

*Knee Injury and Osteoarthritis Outcome Score
**Patient specific function scale
Values are median, confidence interval of the median and C=chi-square test statistics and degree of freedom
a=subscale score, b=Progressive resisted exercise PRE
d= Kruskall-Wallis test for independent group difference
e=symptoms
f=activities of daily living
g=sport and recreation
h=quality of life

Table 3: KOOS* 5 subscales scores and PSFS** score at the end of 3 weeks by intervention group.

the knee exercises Thera-Band length was adjusted as per the length of leg (40-50 cm). 200% stretch was utilized to prescribe 80-90 cm lengths of Thera-Band to each subject. The Thera-Band prescription was matched to each subject's weakest calculated 10RM. Subjects were then taught how to adjust the resistance provided by a given Thera-Band appropriately by tying the band .(i.e., by tying 20 cm of Thera-Band in either ends instead of 15 cm) . Hence, length providing resistance becomes shorter and the exercise became more difficult. This enabled each subject to adjust the resistance in their exercise program according to their height and their relative strength in each plane of movement. Subjects were advised that with correct resistance prescription they should experience fatigue at the end of the first 2 sets of exercises in each plane and should "fail" toward the end of the third and final set. Participants were progressed to higher resistance band when they were able to perform exercises with a Theraband of particular weight with 200% stretch.

Control group

Participants in this group received, free mobility ROM exercises for hip and knee and passive lower muscle stretching exercises as needed (hip flexor, hamstrings, TFL, calf muscle) along with ergonomic advice. This program was supervised for first week. Thereafter, participants were instructed for home exercises and were reviewed at the end 2nd and 3rd week. Outcome parameters: Participants were assessed and re-assessed on all the outcome parameters at baseline and after 3 weeks & post treatment scores on each of scale were recorded in excel sheet. Primary outcome measure: Perceived Pain (P1-P9), symptoms (S1-S7), activities of daily living (ADL) (A1-A17), sport and recreation (sport) (Sp1-Sp5) and quality of life (QOL) (Q1-Q4) was assessed on Knee Injury and Osteoarthritis Outcome Score (KOOS) English, Hindi and Marathi version [25]. Roos et al. [26] reported acceptable reliability. English scale has shown to be responsive (effect sizes = 0.84-0.94) post operatively and in various other conditions [27-30]. Secondary outcome measure: Functional disability also measured with the Patient-Specific Functional Scale. Test-retest reliability and sensitivity to change is proved as excellent (intra-class correlation coefficient [type 2,1] R=0.84 and Pearson's r=0.78 in patients with knee dysfunction [31].

Results

An analysis of the data was undertaken to examine the sample at baseline for group differences in potentially confounding demographic and outcome variables. Table 1 presents comparisons between the continuous and discrete demographic variables collected from the sample at baseline. These analyses indicated no significant differences between the groups on the variables of age (mean, 52.16, 52.70, 51.37 y; p<0.39), Table 1 shows gross distribution of women to men of approximately 58.4%% women and (41.6%) % men. Chi-square analyses indicated no significant difference (x^2=2.24; P=0.32) between 3 study group for gender distribution, Table 2 presents the significance for group differences at baseline, for patient specific functional scale (PSFS) and subscales of the KOOS. Second step of the analysis addressed the research questions. Non-parametric between group analysis was employed to determine the effect(s) of group, time, and the interaction of groups by time on the pain and functional ability variables. Table 3 presents the median, confidence interval of the median, and significance for group, time, and/or interaction for the perceived pain, symptoms, and activities of daily living, sport and recreation and quality of life subscales of the KOOS. Results in Table 4 indicates that significant pre and post treatment intragroup interaction for KOOS subscales and patient specific functional scale (PFSF) for weight cuff and Theraband PREx groups. For control Pre-post treatment group difference were so small due to many of missing responses that z statistics and P value could not be determined for quality of life. A Kruskal-Wallis test was conducted to evaluate differences among the three treatment groups (weight cuff, Theraband, and control) on median change in five KOOS subscales scores. The test, which was corrected for tied ranks, was NOT significant for Pain, χ^2 (2, N=89)=0.33, P=0.84. Results for other KOOS component subscales and PSFS is shown in table no. 4. Post hoc tests were conducted to evaluate pairwise differences among the three treatment groups. wide variety of literature suggests that the effect sizes for each pairwise differences between two experimental groups can be effectively explained with calculation of rank biserial correlation coefficient (r) or variability statistics (r^2) which is the common language of effect size for Mann Whitney U test alongwith probability of superiority (PS) [32]. The change in treatment mode would be accounted for just (r=0.27, r2=0.07)7 % variability for difference in pain score (KOOS) between weight cuff and Theraband PREx group. A PS score of 0.36 indicates that if subject randomly sampled from the all possible pairs (30 × 30=900 pairs) from both the groups subject in weight cuff group would score 36%higher on pain subscale than a subject randomly sampled from the Theraband group. Although the results indicating a weak relationship between weight cuff treatment

Measures	PRE [b] Weight Cuff (Delorm) (n=30)		PRE Theraband (n=30)		Control (n=29)	
KOOS	Z Stat*	P value	Z Stat	P value	Z Stat	P value
Pain	4.78	P<0.0001	4.70	P<0.0001	4.22	P<0.0001
Symp	-4.78	P<0.0001	-4.68	P<0.0001	-4.54	P<0.0001
ADL	4.78	P<0.0001	4.70	P<0.0001	3.87	P=0.0001
Sport	-4.70	P<0.0001	-4.70	P<0.0001	--- **	
QOL	-4.70	P<0.0001	-4.59	P<0.0001	---	
PSFS	-4.78	P<0.0001	-4.59	P<0.0001	0.00	P=0.031

*pre – post single group non-parametric (Wilcoxon test) statistics
**couldn't estimate p value due to many of missing responses to the items of these subscales in control group and insufficient cases were available for the analysis

Table 4: Within group difference by time interaction at 3rd week of treatment for all groups.

Outcome measures	Post Hoc analysis (Mann–Whitney)								
	Weight cuff vs Theraband group			Theraband vs control			Weight cuff vs. control		
KOOS	Z statistics Effect size (r*,PS**)	Avg rank	p value	Z statistics Effect size (r*,PS**)	Avg rank	p value	Z statistics Effect size (r*,PS**)	Avg rank	p value
Pain	1.84 (0.28,0.36)	34.63, 26.36	0.07	5.62 (0.86,0.07)	42.33, 17.24	<0.0001	5.42 (0.82,0.90)	41.88, 17.70	<0.0001
Symp	0.89 (0.14,0.43)	32.50, 28.5	0.37	3.33 (0.51,0.24)	37.30, 22.44	0.0009	3.51 (0.54,0.23)	37.70, 22.03	0.0004
ADL	0.62 (0.1,0.45)	31.9 29.1	0.53	5.97 (0.91,0.04)	43.11, 16.43	<0.0001	5.39 (0.82,0.09)	41.85, 17.74	<0.0001
Sport	2.01 (0.3,0.35)	35., 26	0.04	3.19 (0.48,0.26)	36.95, 22.81	0.0014	4.56 (0.69,0.15)	39.96, 19.68	<0.0001
QOL	0.25 (0.04,0.48)	31.06, 29.93	0.8	3.68 (0.56,0.22)	38.01, 21.7	0.0002	3.31 (0.50,0.25)	37.21, 22.53	0.0009
PSFS	1.687 (0.26,0.37)	34.30, 26.7	0.091	4.147 (0.63,0.18)	39.10, 20.58	<0.0001	4.44 (0.68,0.16)	39.75, 19.91	<0.0001

*Rank biserial (r) correlation from Mann Whitney U is presented as the determinant of effect size statistics, when squared (r2) yields a measure of proportion of variance in the continuous variable accounted for by classification on the dichotomous predictor variable (treatment mode). Hence (r) 2=7% can tell us the amount of shared variance between pain subscale of weight cuff and Theraband group can be accounted for treatment received by the patients in weight cuff group (average rank=34.63) than Theraband group (average rank=26.36)
**probability of superiority (PS) for eg: 36% (0.36) suggests 36 (%) times in 100 (%) a subject (30 × 30=900 pairs) randomly sampled from the weight cuff group would score higher on pain subscale than a subject randomly sampled from the Theraband group

Table 5: Between group difference and treatment effects sizes parameters at 3rd week of post treatment.

and the change in pain score given that subjective well-being is an important variable, and that 36% of the weight cuff group reported higher levels of well-being than the Theraband at the end of the study, these results point to the potential practical value of the intervention [33]. Similarly, the following case summaries in table 5 needed to better understand the remaining items of KOOS subscales and patient specific scale (PSFS) for common language of effect sizes and their interpretation. Post treatment improvement in strength was thought to occur if participants could exercise with higher grade Theraband at end of treatment as compared to beginning of treatment sessions. A strength gain was measured by change in color pre and post treatment. Pearson's Chi square test statistics and Contingency Coefficient, was used to determine the strength of association between observed frequencies and type of Theraband used. Significant association was observed as almost all the individuals switched over to higher resistance (p<0.000) for hip and knee muscle groups post treatment (Table 6) Similar results were observed in Delorm weight cuff group as there was notable change in 10 RM weight post treatment as compared to pretreatment status (Table 7).

Discussion

The overall increase in KOOS and improvement in PSFS scores by the resistance exercise groups suggests that patients with chronic subacute OA of the knee can be subjected to either of weight cuff or Theraband systematic resistance exercise program without compromising the outcome on improvement in symptoms. Feasibility, cost, settings to accommodate the equipment, patients comfort and choice of equipment should be taken into account while prescribing the resistance exercises. The protocols however cannot be compromised. The prescribed dosage in terms of frequency, intensity and duration with

strict adherence to guidelines for progression should be kept in mind to obtain optimal symptomatic and clinical benefits. Compared with baseline, the pain, symptoms and function seems to improve (KOOS and PSFS scores) in both weight cuff and Theraband group by 61% to 60% at 3rd week and by 50% for control group. These findings indicate that both weight cuff and Theraband resistance exercise program are effective for improving short-term pain and functions. Although both treatments were effective in increasing short-term pain and functions weight cuff can be said have slightly better effects than Theraband group. Weight cuff resistance exercises program can be accounted for 30%-10% variance observed in KOOS and PSFS SCORE when compared with Theraband group (Table 5). Similar findings presented by the previous researchers who measured Electromyographic (EMG) activity in 5 selected shoulder exercise task. Graded loading was applied with dumbbell and Theraband and normalized EMG was analyzed. EMG activity of the prime muscles was not significantly different between dumbbells (59-87%) and elastic tubing (64-86%). Comparably high levels of muscle activation were obtained during resistance exercises with dumbbells and elastic tubing. Authors suggested that either of these tools can be utilized in the clinical practice as means for PREx [34]. Another randomized control trial reported similar results after a long term intervention with home based strength training program on WOMAC (22.5%) as compared to control (6.2%) [35]. A home based strength training program undertaken on thirty eight community older adults had 71% improvement in knee extension strength as compared to 3% improvement in control group which received nutritional advice and had greater attrition rate [13]. The increases in muscular strength is evident in our study as suggested by change in amount of weights lifted and change in the Theraband resistance level in both the experimental group (Tables 6 and 7). The effects observed during 3 week treatment regimen employed in this study can be attribute to

Muscles	Color/ t/t stage	Tan (n*)	yellow	red	Green	blue	black	Total N	X^{2a} (cont-coeffi)[b]	P value[c]
Hip flexor	Pre	1	9	19	1			30	12 (0.53)	0.06
	Post				3	15	12	30		
Hip extensor	Pre	1	11	18				30	13.7 (0.056)	0.008
	Post				6	16	8	30		
Hip abductors	Pre	1	13	16				30	12.948 (0.54)	0.0115
	Post				6	16	8	30		
Hip adductors	Pre	1	15	14				30	10.603 (0.511)	0.0314
	Post				6	14	10	30		
Knee flexors	Pre	1	15	14				30	13.480 (0.557)	0.0092
	Post				7	15	8	30		
Knee extensors	Pre	1	15	13				30	13.738 (0.560)	0.0327
	Post				5	13	12	30		

*Frequency of participants using a particular color of Theraband for specific muscle group exercise is shown in shown in numbers
Pre and post statistical change in numbers of participants in particular category of Theraband was presented in form of chi square statistics [a], contingency coefficient [b] and significance [c]

Table 6: Change in type of Theraband used by participants in group 2 over the 3week period.

Muscles	t/t stage	Mean*	SD	95% CI	T* value (df)	P value**
Hip flexor	Pre	1.95	0.54	1.74-2.15	20.6 (29)	P<0.0001
	Post	3.58	0.72	3.31-3.85		
Hip extensor	Pre	1.88	0.55	1.67-2.09	20.72 (29)	P<0.0001
	Post	3.56	0.71	3.29-3.83		
Hip abductors	Pre	1.80	0.56	1.58-2.01	21.29 (29)	P<0.0001
	Post	3.55	0.72	3.28-3.82		
Hip adductors	Pre	1.75	0.59	1.52-1.97	23.90 (29)	P<0.0001
	Post	3.53	0.71	3.26-3.80		
Knee flexors	Pre	3.53	0.73	3.26-3.80	20.65 (29)	P<0.0001
	Post	1.76	0.59	1.54-1.99		
Knee extensors	Pre	1.90	0.56	1.69-2.11	19.79 (29)	P<0.0001
	Post	3.56	0.73	3.29-3.84		

Student t test was applied to determine the significance of pairwise difference* and presented as t value and significance level** P<0.05

Table 7: Change in weight lifted by participants in group 1 from baseline to 3 week of treatment.

neural adaptations [36], which encompass the development of more efficient neural pathways along the route to the muscle. The motor unit (motor nerve fiber and the muscle fibers it innervates) recruitment is central to the early (2 to 8 weeks) gains in strength. Collectively, the learned recruitment of additional motor units, which may respond in a synchronous (the coincident timing of impulses from 2 or more motor units) fashion [37], the increased activation of synergistic muscles, and the inhibition of neural protective mechanisms, all contribute to enhance the muscle's ability to generate more force [38]. PSFS was used to measure the functional improvement in activities which are more patient centric and cultural specific. Although we used English, Hindi and Marathi version of KOOS, sport and recreation subscale doesn't seems to reflect the activities which are cultural specific. Hence, many items of this subscale had of missing responses.

A Cultural validation of the translated version is indicated to achieve construct equivalence based on the region or country. To address this cultural equivalence subjects were asked to identify any of three activities w.r.t. to their knee OA related dysfunctions, and depict the difficulty in carrying out those activities on PFSF. We assumed in this way subjects were most likely identify those activities which are routine to their daily chores. Hence, PSFS can be said to better reflect the improvements in the activities which were cultural specific [39].

The interventions in present trial were comprised of supervised exercise program given for 3 weeks. This pilot trial was undertaken to evaluate the short term benefits of 2 techniques on functional outcome measures. Telephonic communications showed the improved functions at the end of 6 months in 9 out of 30 patients in weight cuff group and 7 out of 30 patients in Theraband group. Some of patients couldn't be traced back as participants were lacking the resources for communications such as unavailability of telephone etc. Hence, it is difficult to derive and document any conclusion regarding long term benefits of exercise interventions. It is suggested that future trials should be designed to eliminate these technical issues so that the long term effects of the trial can be noted.

Adverse events

Operational definition for adverse events was defined as any symptoms arising within 24 hours of a treatment session and persisting for more than 24 hours after onset. Participants were instructed to report about any discomfort they may have experienced during execution of exercise. Since, participants were supervised for the first week, any soreness reported was managed with reduction in intensity of resistance or post treatment soreness was managed with application cold packs. Two participants in weight cuff group reported mild soreness in hamstring region. Also, one participant in Theraband

reported soreness in quadriceps. The treatment techniques was revaluated for the same and corrected. Following two week of exercise program none of the participants reported any of the adverse events.

Conclusion

The results of the present study support the effectiveness either of graded resistance-training programs. Both modes can be used to manage pain and functions and can form essential component of knee osteoarthritis therapy. Feasibility, patient's preference and setting can be important determinant factors for preference of one method over another.

Suggestion

The findings of this clinical trial can be verified using larger sample size to magnify the minute differences between weight cuff and Theraband. Also, muscle recruitment pattern can be studied to determine the differences in muscle contraction with EMG studies.

Limitation

Long term follow up of all the subjects couldn't be kept as many of participants came from nearby villages and unable to maintain even the telephonic communications after returning back to home.

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