# Eccentric training vs muscle energy technique in adjunct to low-level laser therapy for lateral epicondylitis

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#### Abstract

**Introduction.** Low-level laser therapy (LLLT) is considered a mainstay intervention for lateral epicondylitis (LE) with clear evidence. Eccentric Exercises (EE) and Muscle Energy Technique [MET] have been shown to be beneficial individually. However, trials are lacking where the above two approaches are compared. Further, no comprehensive EE protocol exists for LE. Hence, this study aimed to develop an EE protocol and evaluate the effectiveness of the EE protocol versus MET as adjuncts to LLLT for the management of LE.

**Methods.** A total of 34 (n = 17 in each group) participants with LE were randomly allocated to two study groups (EE and MET). The participants received either EE or MET along with LLLT as a common intervention over 3 weeks. The outcomes measured were pinch strength, grip strength, and pain pressure threshold, assessed at pre-intervention and post-intervention ( $3^{rd}$  week). The patient-rated tennis elbow evaluation (PRTEE) questionnaire was assessed at 4 points in time: pre- and post-3 weeks with follow-up in the 6<sup>th</sup> week and 12<sup>th</sup> week.

**Results.** When compared between the groups, a statistically significant difference was noted with the EE group being more effective than the MET group for pain pressure threshold (p = 0.001), key pinch strength (p = 0.003), tripod pinch strength (p = 0.107), grip strength (p = 0.046), pain and functional disability (p = 0.001).

**Conclusions.** Although both EE and MET were effective in treating lateral epicondylitis, eccentric exercises were superior to the MET group even at the 6th and 12<sup>th</sup> week follow-up, suggesting a longer-lasting effect of EE without recurrences. **Key words:** lateral epicondylitis, low-level laser therapy, manual therapy, exercise therapy

#### Introduction

Lateral epicondylitis (LE) is also referred to as tennis elbow, which presents with tendonitis of common extensor origin. Pain and discomfort on the lateral epicondyle of the humerus, as well as painful resisted dorsiflexion of the wrist, middle finger, or both, are symptoms of tennis elbow [1]. Even though LE is usually referred to as 'tennis elbow', only 10% of the patient population are tennis players. Working age individuals are more likely to be affected. Smoking, obesity, repetitive movements, and intense workload (handling weights more than 20 kg) are the other associative causes of this condition in the population other than athletes [2]. Also, due to an overuse degenerative process, the extensor carpi radialis brevis and common extensor tendon (CET) are predominantly involved in this disorder.

The main goal of LE treatment is controlling pain and reducing tenderness. Rest from the offending activity, analgesics, and wearing lower arm counterforce belts are common conservative approaches to minimise strain on the lateral epicondyle [3]. A combination of physical therapy and corticosteroid injections is considered a conventional method of managing the condition. However, LE presents with greater recurrence rates within 6 weeks after treatment [3].

Physiotherapy treatments such as cryotherapy in combination with either ultrasound therapy or low-level laser therapy (LLLT) along with manual therapy and exercise routines, including stretching and grip strengthening exercises, have shown to be beneficial in treating LE [4]. The physiological impact of LLLT irradiation on cellular functions appears to aid tissue regeneration, leading to anti-inflammatory and analgesic effects. LLLT has been suggested as a treatment approach that promotes tissue restoration, which could assist in speeding up the healing process and accelerating tendon repair [5].

Muscle Energy Technique (MET) is an isometric mobilisation technique that has been prominently used in a wide range of musculoskeletal conditions. It causes elongation of the shortened musculotendinous structures and improves the joint movement range. It uses muscular facilitation and inhibition to mobilise the muscle, thereby regaining muscle normalcy [6]. It is a mild manual therapeutic technique that requires the patient's voluntary contraction against the therapist's counterforce to produce hypertonic muscular relaxation and provide appropriate muscle stretching [7, 8].

The eccentric exercise (EE) training approach is gaining popularity for tendinopathy conditions and has been proven for its effects on pain and tendon normality in people with tendinopathy. Mechanically and actively straining the sore and aberrant structures with eccentric exercises is currently the most popular therapeutic exercise plan for tendinopathy treatment. The musculotendinous unit is lengthened as weight is applied to create eccentric contraction during EE. In recent times, EE has shown promising outcomes in the management of LE [9].

However, in the literature on EE for LE, only one single eccentric exercise has been compared, indicating a lack of a comprehensive protocol that includes a set of different eccentric exercises along with the proper dosage. There is meagre evidence where LLLT is given as an adjunct to eccentric training or MET. Further, comparative trials are lacking where an eccentric training protocol is compared with the MET approach. In addition, considering the recurrence rate of LE, the carry-over effects of these treatment techniques in LE are

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less explored. Hence, the present study was undertaken with two objectives. The primary objective was to develop a comprehensive EE protocol and explore its efficacy by conducting a pilot study. The secondary objective was to compare the effect of eccentric training protocol and the MET approach for LE and also to explore their carry-over effects by conducting a follow-up study in the 6<sup>th</sup> and 12<sup>th</sup> weeks.

# Subjects and methods

# Study design, setting

The present study was a prospective parallel-arm randomised clinical trial with an assessor-blinded design, conducted in the physiotherapy outpatient department in a tertiary care centre of Belagavi city, India. Thirty-four (n = 34) participants were randomly assigned to 2 study groups (1:1 ratio): the EE group (n = 17) and the MET group (n = 17). A chit randomisation method was applied. A total of 4 participants, two in the EE group and two in the MET group, dropped out of the study (Figure 1). For better reporting of the trial, CON-SORT-2010 statement guidelines were followed.

Figure 1. CONSORT flow diagram

## Sample size calculation

The study's sample size was 34 (17 in each group), based on the reference article [10], which was calculated using the formula with 85% power and a 5% level of significance and a 10% attrition rate.

# Study participants

Inclusion criteria for the current study were participants who were clinically diagnosed with lateral epicondylitis; aged 18–60 years; had a positive Cozen test [11], and reported a score of less than 3 out of 10 on the visual analogue scale (VAS). Exclusion criteria were participants having: injuries of the affected upper limb; primary carcinoma or secondary metastasis over the treatment site; cervical radiculopathy; local steroid injections in the past 6 months; presently on medication for lateral epicondylitis; history of upper limb fractures; pregnancy; epileptic patients.

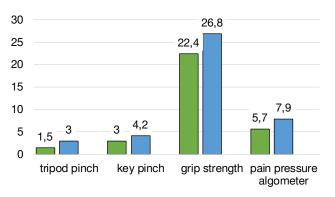
# Development of eccentric exercise protocol and pilot study

A pilot study was carried out to develop a comprehensive eccentric exercise training protocol and determine the effect of the same with respect to pain, grip, and pinch strength. Exercises that were included for the intervention were the Tyler twist [12] performed using a flexible rubber bar (Thera-Band FlexBar), eccentric pronation and Scaption movements performed using a Thera-Band, eccentric wrist flexion, and forearm pronation using a dumbbell [13]. The protocol was made by including eccentric exercises and by providing a dosage along with their progression according to the patient's tolerance (Table 1). All the outcomes, including the pain pressure threshold, grip strength, pinch strength, pain, and functional disability, exhibited a significant difference at 3<sup>rd</sup>-week post-intervention (Figures 2a and 2b).

	Repetitions (over 3 weeks)		Hold time (s) (over 3 weeks)			Progression of load			
Exercise	days 1 and 2 / week	days 3 and 4 / week	days 5 and 6 / week	days 1 and 2 / week	days 3 and 4 / week	days 5 and 6 / week	week 1	week 2	week 3
Tyler twist	5	10	15	3	5	10	Red flexible rubber bar		
Eccentric supination	5	10	15	3	5	10	Yellow TB	Green TB	Red TB
Scaption	5	10	15	3	5	10	Yellow TB	Green TB	Red TB
Eccentric wrist flexion	5	10	15	5	10	15	½ kg DB	1 kg DB	2 kg DB
Forearm pronation and supination	5	10	15	5	10	15	½ kg DB	1 kg DB	2 kg DB

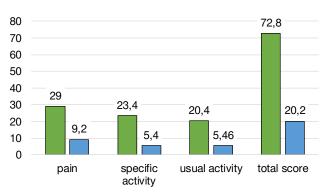
#### Table 1. Eccentric exercises protocol with progression (pilot study)

TB - Thera-Band, DB - dumbbell



#### ∎pre ∎post

Figure 2a. Comparison of pre-test and post-test for tenderness (algometer), grip, and pinch strength in a pilot study (EE protocol efficacy)



#### ∎pre ∎post

Figure 2b. Comparison of pre-test and post-test for PRTEEQ (Patient-Rated Tennis Elbow Evaluation Questionnaire) scores in a pilot study (EE protocol efficacy)

#### Intervention

These interventions were provided face-to-face with an individualised approach by a qualified physiotherapist in the physiotherapy OPD. To maintain the quality of reporting of interventions, the Template for Intervention Description and Replication (TIDieR) checklist was referred to. No adverse effects were reported at the end of the trial.

LLLT was a common intervention given to both study groups. LLLT class 3B was given using Zimmer (manufactured by Zimmer MedizinSysteme, Germany). A 904 mm wavelength laser in pulsed mode by setting the frequency at 50 Hz and 40 mW power intensity was given with a point/section size of 0.5 cm<sup>2</sup> and an energy density of 2.4 J/cm<sup>2</sup>. The duration of the treatment session was 30 s at each point/section [14] The participants sat comfortably on a chair or couch with their elbows resting on the couch or a pillow (Figure 3). The LE region was cleansed with sterile spirit before the laser treatment. Protective eyeglasses were worn by the patient and therapist before the administration of laser. The laser beam was applied over 6 sections around the lateral epicondyle's facet. The laser beam was delivered through a handheld probe of 1 mm size that was placed perpendicular to the section/point. All participants in both groups received 5 sessions of LLLT over the three weeks, with 2 sessions a week. Only 5 laser sessions were given since the participants included were to have pain intensity less than 3/10 on the VAS, which indicates mild pain.

The participants in the MET group (n = 17) received 18 sessions of MET and 5 sessions of LLLT over 3 weeks. MET was performed for forearm pronation and supination, ulnar deviation and radial deviation, and wrist flexion extension [6]. The participants were asked to contract the forearm muscles with 15% of their total strength against the force given by the therapist for 5 s, subsequently doing the counter move-



Figure 3. Application of low-level laser therapy (LLLT) to study participants

ment until the force is felt. Participants were made to perform the same movement 5 times with 5 s of hold and a 1-minute rest period between each repetition [7]. The MET aimed to isometrically contract the forearm muscles (Figure 4). A total of 2 participants were lost to follow-up in the MET group, as one participant had a family emergency and another participant was lost for reasons unknown.

The participants in the EE group (n = 17) received 18 sessions of the eccentric training protocol that was designed along with LLLT, as described above. The EE protocol was as designed and explained in the pilot study (Table 1). Each

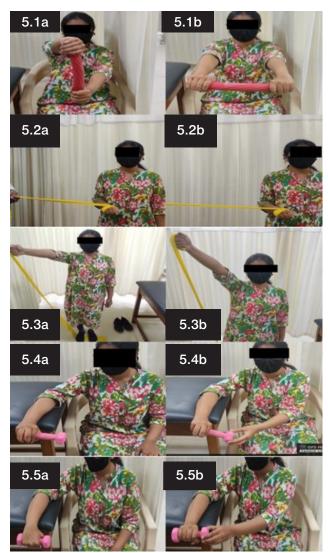


Figure 5. Eccentric exercises: 5.1 a, b – Tyler twist, 5.2 a, b – eccentric supination, 5.3 a, b – Scaption, 5.4 a, b – eccentric forearm supination and pronation, 5.5 a, b – eccentric wrist flexion



Figure 4. MET exercises: 4.1 – MET for wrist flexion and extension, 4.2 – MET for forearm pronation and supination, 4.3 – MET for wrist ulnar deviation and radial deviation

exercise started with 5 repetitions per set and progressed to 15 repetitions per set over the course of 3 weeks, whereas the load and hold time progressed according to the protocol (Figure 5). A total of 2 participants were lost to follow-up in the EE group, as one was infected with COVID-19 and another was unreachable. Since the 4 participants were lost to follow-up before they completed 50% of their intervention sessions, they were not included in the statistical analysis.

#### Outcome measures

The outcome measures included pain pressure threshold (PPT) using a pain pressure algometer (PPA), grip and pinch strengths with a Jamar hand evaluation kit that were assessed at two-time points: T1 before the treatment and T2 after the 18<sup>th</sup> session – i.e., at 3rd week. The patient-rated tennis elbow evaluation questionnaire (PRTEEQ) was administered at four-time points: T1, before treatment, T2, after the 18<sup>th</sup> session, T3, at the 6<sup>th</sup>-week follow-up, and T4, at the 12<sup>th</sup>-week follow-up.

#### Pain pressure threshold

A pain pressure algometer (Fabrication Enterprises Inc., New York, USA; Model: 056009-30014) was used to evaluate deep muscle tissue sensitivity/PPT. The test was used to quantify the pain tolerance of the participant by applying pressure to the lateral condyle on the affected side. For this, the participant was made to sit with the elbow flexed and supported on a couch. The pressure was applied with the algometer probe, which was placed perpendicular to the lateral epicondyle by the assessing physiotherapist until the point at which the patient felt pain. The value was noted in units of kilograms and has been compared with the painful pressure they felt after 3 weeks of intervention. Two measurements were taken with an interval of 2 min and the average of the two readings was noted [15].

#### Pinch grip strength

This was assessed with the help of a pinch meter (Jamar Hand evaluation kit: Sammons Preston Rolyan, UK, model No. 0205010). The strength of key and tripod pinches was assessed in the present study. The participants were comfortably seated on a chair with back support and were instructed to maintain their shoulder in a neutral position, elbow flexed to 90°, forearm neutral, wrist neutral, and the pad of the thumb positioned against the middle radial aspect of the index finger in a position of modest IP flexion (15 to 20%) for key pinching. The index and middle fingers were placed against the pad of the thumb for tripod pinching. Participants were instructed to hold the pinch for 5 s. 2 trials were done with a 30-second rest interval between each trial and the average of the two readings noted [16].

#### Hand grip strength

A Jamar hand dynamometer was used to assess grip strength. The participants were seated in comfortable positions and the therapist held the instrument around the casing of the readout dial of the dynamometer, to prevent the instrument's dropping. One submaximal practice trial was allowed for each participant to get comfortable with the instrument. Participants were then instructed to squeeze the handle maximally for 3 s and asked to avoid undue pain. All trials were timed for 3 s with the same stopwatch. Two trials of the same were done with 1-minute intervals between each trial and the average of the two readings was noted [17].

#### Patient-Rated Tennis Elbow Evaluation Questionnaire (PRTEEQ)

This has 2 components for evaluation: pain and functional disability. It is a self-administrating scale with 15 questions that address pain and day-to-day activities that may be affected due to LE [18]. It was taken at pre-intervention, post-intervention, 6<sup>th</sup>-week follow-up, and 12<sup>th</sup>-week follow-up using the telephone method. Only 2 participants could not comprehend the English language, so for these participants, the questions were orally translated in such a way that the meaning of the questions was not changed.

## Statistical analysis

Data was analysed using SPSS version 23.0. Categorial variables are presented in the form of a frequency and percentage. Continuous variables are given in mean  $\pm$  standard deviation (*SD*) form. A comparison of differences within-groups was done using the Wilcoxon signed-rank test / paired sample *t*-test. A comparison of differences between-groups was done using the Mann–Whitney *U*-test. A *p*-value of < 0.05 was regarded as being statistically significant.

#### Results

The demographic characteristics of the study participants of both interventional groups are presented in Tables 2a and b.

Table 2a. Analysis of EE group and MET group for
categorical variables

Variables		Group		Total	<i>p</i> -value	
		EE	MET	TOLAI	p-value	
Sex	male	8	4	12	0.136	
Sex	female	7	11	18	0.130	
	left	0	1	1	0.309	
Hand dominance	right	15	14	29	0.309	
Side effected	left	3	7	10	0.121	
Side ellected	right	12	8	20		
Neck pain	present	1	1	2	0.999	
песк раш	absent	14	14	28		
Chaudalau nain	present	3	2	5	0.624	
Shoulder pain	absent	12	13	25		

EE – eccentric group, MET – muscle energy technique p < 0.05 is statistically significant

Table 2b. Analysis of EE group and MET group for
continuous variables

Variables	Group	Mean ± SD	<i>p</i> -value	
	EE	41.40 ± 14.23	0.500	
Age (years)	MET	37.60 ± 16.14		
Lloight (m)	EE	163.60 ± 7.93	0.494	
Height (m)	MET	165.60 ± 7.89	0.494	
Maight (kg)	EE	66.07 ± 9.81	0.952	
Weight (kg)	MET	65.80 ± 13.76		

EE - eccentric group, MET - muscle energy technique

Variable	Group	Pre mean ± <i>SD</i>	Post mean ± <i>SD</i>	Difference mean ± <i>SD</i>	Effect size	<i>p</i> -value
Pain pressure algometer	EE	5.63 ± 1.25	7.57 ± 1.58	-1.93 ± 0.82	2.36	0.001*
	MET	4.83 ± 1.25	5.57 ± 1.49	-0.73 ± 0.84	0.87	0.001*
Crip atranath	EE	17.13 ± 8.49	20.53 ± 9.43	-3.40 ± 2.06	1.65	0.001*
Grip strength	MET	12.87 ± 6.51	14.17 ± 7.08	-1.30 ± 0.98	1.33	0.001*
Kausiaah	EE	2.67 ± 0.86	4.06 ± 1.34	-1.39 ± 0.76	1.83	0.001*
Key pinch	MET	2.01 ± 0.85	2.71 ± 0.93	-0.69 ± 0.56	1.24	0.001*
Tripod pinch	EE	1.68 ± 0.67	2.91 ± 1.03	-1.23 ± 0.77	1.60	0.001*
	MET	1.55 ± 0.73	2.35 ± 0.80	-0.80 ± 0.59	1.35	0.001*
PREREQ						
Pain	EE	32.33 ± 7.02	12.67 ± 6.87	19.67 ± 7.91	2.49	0.001*
	MET	32.00 ± 4.05	21.80 ± 4.71	10.20 ± 4.99	2.04	0.001*
Specific activity	EE	29.53 ± 9.41	12.13 ± 9.91	17.40 ± 6.12	2.85	0.001*
	MET	35.67 ± 4.81	22.27 ± 6.80	13.40 ± 5.95	2.25	0.001*
Usual activity	EE	24.40 ± 6.49	10.00 ± 5.95	14.40 ± 6.48	2.22	0.001*
	MET	27.40 ± 4.22	18.87 ± 3.66	8.53 ± 5.10	1.67	0.001**
Total score	EE	86.27 ± 20.66	34.80 ± 22.15	51.47 ± 18.57	2.77	0.001*
	MET	95.00 ± 9.92	63.00 ± 13.84	32.00 ± 13.28	2.41	0.001*

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Table 3.	. Within-group analysis of pre-	and post-scores for	both study aroups

EE – eccentric group, MET – muscle energy technique group, PRTEEQ – Patient-Rated Tennis Elbow Evaluation Questionnaire # Wilcoxon test, \* significance at 5% level

#### Within-group analysis

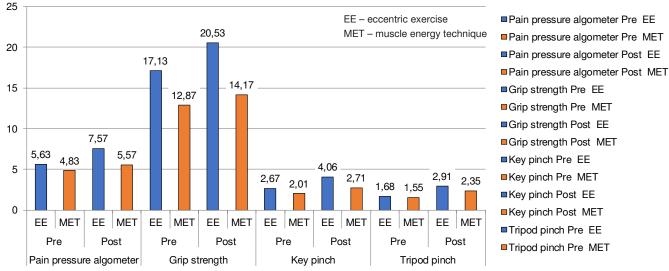
Analysis of the outcome parameters at pre- to post-intervention resulted in a statistically significant difference with a *p*-value of 0.001 for all outcomes in the EE group, including PPT, key pinch strength, tripod pinch strength, and grip strength. Similar outcomes were noted for PPT, key pinch strength, tripod pinch strength, and grip strength for the MET group, with p = 0.001, indicating a statistically significant difference (Table 3).

## Between-group analysis

The EE group was significantly better for PPT (p = 0.001), key pinch strength (p = 0.003), tripod pinch strength (p = 0.107), and grip strength (p = 0.046) at the 3<sup>rd</sup>-week post-intervention compared to the MET group (Figure 6).

## Pain and functional disability using PRTEEQ

The total score was significantly better at the post-intervention time point for the EE group (p = 0.001) as well as for the MET group (p = 0.001). When the post-intervention scores



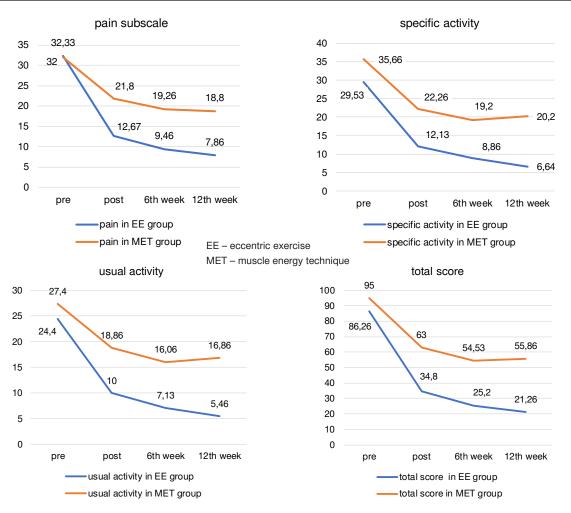


Figure 7. Changes in scores of subscales of PRTEEQ at 4 different time points

in the 3<sup>rd</sup> week of both groups were compared, the EE group showed better improvement than the MET group. The improvement was maintained at the 6<sup>th</sup>-week follow-up in both the EE and MET groups. However, at the 12<sup>th</sup>-week follow-up, the EE group alone maintained an improvement over the MET group (p = 0.001) (Table 3) (Figure 7).

#### Discussion

The present prospective parallel-arm trial aimed to check and evaluate the results of EE and MET interventions in subjects with LE. The comparison was done in terms of pain pressure threshold, grip strength, pinch strength, pain, and disability. There was a significant difference in all outcomes at the post-intervention time point within both the EE group and the MET group in terms of all outcomes. However, eccentric exercises were more effective than MET for LE.

Pain as a result of tendinitis is correlated with neovascularisation. Eccentric contractions result in reduced vascularity in cases of tendinitis. The growth of blood vessels as a result of neovascularisation can be controlled by EE. This is probably related to the mechanical shear force stimulation between the tendon and the peritendon as well as the stresses produced within the tendon. The nociceptive input may be altered by these stresses, which may also impede and possibly diminish vascular infiltration into the tendon. The sensitivity to pain and the ability to load the tendon are therefore impacted by this [10].

According to a study by Page [19], some people with LE had lower pain PPT and greater referred pain distributions

that would arise merely owing to the existence of trigger points, implying that pain is regulated by the central nervous system. Mechanically stressing the sore or aberrant tissue with eccentric exercises is currently the most effective therapeutic exercise plan for tendinopathy treatment. During eccentric activities, the musculotendinous unit elongates as stress is placed on it. While EE has long been used, little is known about eccentric workouts' effects on pain and tendon normalisation for people with tendinopathy [9]. According to current research evidence, a therapeutic exercise regimen for painful tendinopathy should include eccentric exercises that target the problem area with 3 sets of 15 repetitions performed once to twice daily for at least 12 weeks [20]. In the present trial, even though eccentric exercises were only administered for 3 weeks, coupled with 5 laser sessions, significant changes were seen in the pain pressure threshold, grip strength, and pinch strength.

According to Chaitow et al. [8], MET is an active muscular relaxation method in which normal blood circulation is restored, which removes nociceptive stimulants from the site of pain, thereby relieving the pain. MET can release articular restrictions, lengthen muscle fibres, and increase the range of motion through a combination of creep and plastic change in the connective tissue [7]. In the current study, although MET did show a prognostic effect, it lacked statistical significance when compared with EE. Hariharasudhan et al. [21] conducted a study to compare the effects of MET and Mobilization with Movement (MWM) in tennis elbow and concluded that MET did not show as much significance as MWM at the 3<sup>rd</sup>-week follow-up and stated that it could be because MET targets mainly soft tissues and primarily muscles. In agreement with the findings of the above studies, the improvement in the pain pressure threshold, pinch strength, grip strength, and decrease in pain and functional disability is more significant in the EE group and could be attributed to similar physiological and therapeutic effects as those mentioned.

According to Parmar et al. [10], patients who received EE in addition to traditional physiotherapy saw a considerable improvement in grip strength. They emphasised that eccentric exercise would stretch the muscle-tendon framework, which would relieve the tendon of its continual tension. Due to loading-induced hypertrophy, eccentric training will increase tensile properties. This could be the reason for the increased grip strength in the EE group. According to Murtaugh et al. [9], EE was reported to affect generating tendon-healing substances. These alterations were accompanied by a reduction in pain. In addition, it was found that this protocol did not affect healthy tissues. Rees et al. [22] stated that the therapeutic benefit of EE is not only due to the amplitude of the applied resistance but also a result of the stress applied to the structures. These force fluctuations may act as an essential trigger for tendon remodelling. This may explain the decrease in functional disability in the EE group. According to a histological study done by G Barbra et al., there was a production of type 3 collagen fibres instead of type 1 in LE. Also, collagen fibres have exhibited disorganisation with unstructured fibres. i.e., instead of the straight parallel arrangement of collagen fibres that is observed in a normal tendon, they exhibited a wave-like pattern. With increasing severity, fibres become more fragmented and disorganised [23]. Progressive eccentric tendon loading is said to significantly increase the production of type 1 collagen, which helps in the reduction of tendon thickness and also helps in remodelling the collagen fibres by converting the stimulus into a cellular response, promoting tissue repair, and rearranging the fibres by a process known as mechano-transduction [24]. These changes corresponded with a decrease in pain and disability in the present study.

Hence, as per the outcomes of the present study, the alternative hypothesis was accepted, and the null hypothesis was rejected.

# Limitations

The present study had a few limitations. (1) The duration of intervention was only 3 weeks, which should have been a longer duration as there was reduced patient compliance due to the COVID-19 pandemic. (2) Follow-up was done only for pain and functional disability of LE and not for other outcomes due to the pandemic issue. (3) The self-reported questionnaire used was not translated into the regional language, which poses reservations about its reliability and cultural adaptation.

# Future scope of the study

Future studies can assess the effects of the protocol used in the current study with blood flow restriction therapy. Studies can be done comparing the effects of eccentric exercises that can be developed in other tendinopathies, such as rotator cuff tendinopathy and patellar tendinopathy.

# Conclusions

The present study concludes that eccentric exercise protocol was more effective than MET in improving pain pressure threshold, pinch strength, and grip strength, as well as decreasing pain and functional disability in patients with lateral epicondylitis. The effects were well maintained even at the 6<sup>th</sup>-week and 12<sup>th</sup>-week follow-up, with the EE group indicating lower rates of recurrence. The newly designed eccentric exercise training protocol in the pilot study shows promising outcomes for the rehabilitation of lateral epicondylitis.

# **Ethical approval**

The research related to human use has complied with all the relevant national regulations and institutional policies, has followed the tenets of the Declaration of Helsinki, and has been approved by the ethics committee of KLE Institute of Physiotherapy, KLE Academy of Higher Education and Research (KAHER) University (approval No.: KLE/16/7/21.584). The trial was registered prospectively in the Clinical Trials Registry – India, with CTRI number CTRI/2021/09/036758.

Participants' anonymity and confidentiality were assured, and their rights were protected throughout the trial. All COV-ID-19 precautions were taken according to the ICMR guidelines.

# **Informed consent**

Informed consent has been obtained from all individuals included in this study.

# **Disclosure statement**

No author has any financial interest or received any financial benefit from this research.

# **Conflict of interest**

The authors state no conflict of interest.

# Funding

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