RESEARCH PAPER

Demographic and Baseline Clinical Characteristics of Patients with Lateral Epicondylitis Using a Novel Tennis Elbow Splint: A Prospective Study

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Abstract

Background: Lateral epicondylitis (tennis elbow) is a common musculoskeletal disorder characterized by lateral elbow pain and functional limitation, often associated with repetitive wrist and forearm activities. Although conservative treatment remains the mainstay of management, adherence to orthotic therapy may influence treatment outcomes. The present study was undertaken to assess pain reduction following use of a novel tennis elbow splint and to evaluate patient compliance with splint usage.

Methods: A prospective observational study was conducted among 50 patients diagnosed with lateral epicondylitis. Pain intensity was assessed using the Visual Analog Scale (VAS) at baseline and at 2, 4, and 8 weeks following initiation of splint use. Patient compliance was assessed based on daily brace usage and categorized as good, moderate, or poor. Adverse effects during splint use were also recorded. Changes in VAS scores were analyzed using the paired *t*-test, with a *p*-value <0.05 considered statistically significant.

Results: The mean VAS score progressively decreased from 6.86 ± 0.78 at baseline to 5.32 ± 0.87 at 2 weeks, 3.72 ± 0.97 at 4 weeks, and 2.58 ± 1.19 at 8 weeks. The overall reduction from baseline to 8 weeks was 4.28 points (95% CI: 3.981–4.579) and was statistically significant (t=28.808, $p<0.001$). Significant reductions were also observed between each consecutive follow-up assessment ($p<0.001$). Daily splint usage ranged from 4 to 10 hours, with the highest proportion of participants using the splint for 5 hours/day (18.0%). Good compliance was observed in 38.0%, moderate compliance in 50.0%, and poor compliance in 12.0% of participants. Overall, 88.0% demonstrated moderate-to-good compliance, while 74.0% reported no adverse effects.

Conclusion: Use of the novel tennis elbow splint was associated with a significant progressive reduction in pain over the 8-week follow-up period. Most participants demonstrated moderate-to-good compliance with splint usage, and the majority reported no adverse effects. These findings suggest that the novel splint may be a useful non-invasive option for pain management in patients with lateral epicondylitis, although comparative studies with larger samples and longer follow-up are warranted.

Keywords: *Lateral epicondylitis; Tennis elbow; Novel splint; Visual Analog Scale; Compliance*

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INTRODUCTION

Lateral epicondylitis, commonly known as tennis elbow, is a frequently encountered condition in orthopaedic practice and affects individuals involved in repetitive occupational and recreational activities requiring forceful gripping, lifting, forearm movements, and repetitive wrist extension. Although traditionally described as an inflammatory disorder, it is now recognized predominantly as a degenerative tendinopathy involving the common extensor tendon, particularly the extensor carpi radialis brevis (ECRB), with collagen disorganization, angiofibroblastic changes, neovascularization, and impaired tendon healing contributing to persistent symptoms (1–4). The condition commonly presents with localized lateral elbow pain, tenderness, pain during resisted wrist extension, reduced grip strength, and difficulty performing routine activities. Diagnosis is primarily clinical and is supported by characteristic provocative tests, while ultrasonography or magnetic resonance imaging may be used in chronic or atypical cases (5,6). Persistent symptoms may substantially interfere with occupational activities, recreational participation, and upper-limb function.

Management is predominantly conservative and includes activity modification, analgesics, physiotherapy, strengthening exercises, injections, and orthotic devices. Splinting is particularly

relevant because it is non-invasive, relatively inexpensive, and can be incorporated into routine activities. Counterforce braces and wrist-extension splints aim to reduce mechanical loading of the common extensor tendon and may provide symptomatic and functional benefits (7–10). However, conventional splints have limitations, including inadequate wrist stabilization, discomfort, restricted hand function, poor fitting, bulkiness, skin irritation, and interference with daily activities. These factors may influence patient acceptance and adherence to prescribed splint use (11,12). In addition, variations in splint design, materials, biomechanical principles, and wearing schedules make comparison between different orthotic interventions difficult.

The development of novel orthotic designs incorporating counterforce support, wrist stabilization, ergonomic construction, and localized cryotherapy may address some of these limitations and potentially improve usability and patient acceptance (13,14). However, before evaluating therapeutic efficacy, it is important to understand the demographic and baseline clinical profile of patients for whom such an intervention is being considered. Characteristics such as age, gender, occupation, hand dominance, affected side, and duration of symptoms may provide important context for understanding the clinical population and the applicability of the intervention.

Therefore, the present paper was designed specifically to describe the demographic and baseline clinical characteristics of patients with lateral epicondylitis enrolled for novel tennis elbow splint therapy. The study focused on age, gender, occupation, hand dominance, affected elbow, and duration of symptoms. Establishing this baseline profile provides a clearer characterization of the study population and forms the foundation for interpretation of the therapeutic outcomes evaluated separately in the subsequent papers.

1.MATERIALS AND METHODS

2.1. Study Design

This study was conducted as a **prospective single-arm quasi-experimental interventional study** among patients diagnosed with lateral epicondylitis who were enrolled for treatment with a novel tennis elbow splint. For the present paper, the analysis was restricted to the **demographic and baseline clinical characteristics** of the study participants, corresponding to Objective 1 of the parent study.

2.2. Study Setting

The study was conducted in the **Department of Orthopaedics, Saveetha Medical College and Hospital**. Participants were also recruited from associated sports clinics, physiotherapy centres, and workplaces involving repetitive upper-limb activities. These settings provided access to patients with clinically diagnosed lateral epicondylitis having occupational, recreational, or daily-use-related upper-limb symptoms.

2.3. Study Duration

The study was conducted over a period of **one year, from 1 December 2024 to 1 December 2025**. During this period, eligible patients were screened, enrolled, and their demographic and baseline clinical characteristics were recorded before initiation of the splint intervention.

2.4. Participants

The study included patients with clinically diagnosed lateral epicondylitis who fulfilled the predefined eligibility criteria.

Inclusion Criteria

Participants were included if they:

- Were diagnosed with lateral epicondylitis.
- Were aged between 18 and 65 years.
- Had subacute or chronic symptoms lasting more than 6 weeks and less than 12 months.
- Reported moderate-to-severe pain with a Visual Analog Scale (VAS) score between 4 and 8 out of 10.
- Were willing to participate in the study.
- Were able to attend regular follow-up.
- Had active daily use of the affected upper limb, including athletes, manual workers, office workers, or individuals involved in repetitive arm activities.

Exclusion Criteria

Participants were excluded if they:

- Had undergone previous surgery for lateral epicondylitis.
- Had received corticosteroid or platelet-rich plasma (PRP) injections.
- Had a history of previous fracture or recent trauma involving the affected limb.
- Were younger than 18 years or older than 65 years.
- Were unable to participate in the study procedures.
- Were unable to attend the required follow-up.
- Had severe arthritis or rheumatic conditions affecting upper-limb function.

2.5. Study Sampling

A **convenience sampling technique** was used for participant recruitment. Patients presenting with lateral epicondylitis were screened according to the predefined inclusion and exclusion criteria. Eligible participants who provided consent were consecutively enrolled during the study period until the available study sample was obtained.

2.6. Study Sample

The parent study included **50 patients with lateral epicondylitis**. Although the sample size for the parent interventional study was calculated using a paired-mean comparison approach and was estimated at approximately 52 participants, 50

eligible participants were ultimately included in the study. For the present objective-specific paper, all **50 participants** were included in the descriptive analysis of demographic and baseline clinical characteristics.

2.7. Study Parameters

As the present paper addressed **Objective 1 only**, the following demographic and baseline clinical variables were evaluated:

- **Age** – categorized into 18–30, 31–40, 41–50, 51–60, and >60 years; mean age was also recorded.
- **Gender** – male and female.
- **Occupation** – athlete, office worker, and manual worker.
- **Hand dominance** – right or left.
- **Affected side** – right or left elbow.
- **Duration of symptoms** – categorized according to duration in weeks, with mean duration also documented.

The thesis specifically recorded age, gender, occupation, dominant hand, affected side, and duration of symptoms as baseline characteristics.

2.8. Study Procedure

After screening for eligibility, participants who fulfilled the inclusion criteria and provided informed consent were enrolled in the study. A structured study proforma was used to record demographic and baseline clinical information.

Age and gender were documented for each participant. Occupational status was recorded and categorized as athlete, office worker, or manual worker. Hand dominance was documented as right or left. The clinically affected elbow was recorded as either right or left. The duration of symptoms was documented in weeks based on the patient's history and subsequently categorized for analysis.

All demographic and clinical characteristics were recorded **before initiation of the novel tennis elbow splint**, thereby providing a baseline profile of the study population.

2.9. Study Data Collection

Data were collected prospectively using a structured case-recording proforma. The demographic variables included age, gender, and occupation, while clinical characteristics included hand dominance, affected side, and duration of symptoms.

Continuous variables such as age and duration of symptoms were recorded as numerical values, while categorical variables were classified into predefined categories. The collected information was checked for completeness before statistical analysis.

2.10. Statistical Analysis

As the present paper addressed **Objective 1, which was descriptive in nature**, statistical analysis was primarily descriptive.

Continuous variables were summarized using **mean and standard deviation (SD)**. Categorical variables were expressed as **frequency and percentage**. Age and duration of symptoms were summarized using mean ± SD, while age groups, gender, occupation, hand dominance, affected side, and symptom-duration categories were presented as frequencies and percentages.

No pre- versus post-intervention comparison was performed in this paper because the present analysis was restricted to the demographic and baseline clinical characteristics of the participants.

2.11. Ethical Considerations

Ethical approval for the parent study was obtained from the **Institutional Ethics Committee of Saveetha Medical College and Hospital** (IEC Approval No. **021/02/2026/IEC/SMCH**) before commencement of the study. Written informed consent was obtained from all participants before enrolment. Participant confidentiality and privacy were maintained throughout the study. Participants were informed about the voluntary nature of participation and their right to withdraw from the study at any stage without any consequences.

3.RESULTS

A total of 50 patients with lateral epicondylitis who fulfilled the eligibility criteria were included in the present analysis. The demographic and baseline clinical characteristics of the participants were evaluated with respect to age, gender, occupation, hand dominance, affected elbow, and duration of symptoms.

Table 1. Demographic Characteristics of Study Participants (n=50)

Variable	Category	n	%
Age group (years)	18–30	14	28.0
	31–40	11	22.0
	41–50	6	12.0
	51–60	14	28.0
	>60	5	10.0
Mean age (years)	43.2 ± 12.6	—	—
Gender	Male	33	66.0
	Female	17	34.0
Total		50	100.0

The mean age of the study participants was 43.2 ± 12.6 years. The largest proportions were observed in the 18–30 years and 51–60 years age groups, each accounting for 28.0% of participants, followed by the 31–40 years group (22.0%). Participants aged >60 years constituted 10.0%. Males represented the majority of the study population (66.0%), while females accounted for 34.0%.

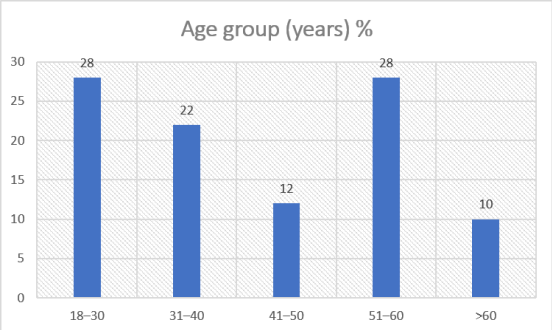


Table 2. Occupational and Baseline Clinical Characteristics of Study Participants (n=50)

Variable	Category	n	%
Occupation	Athlete	20	40.0
	Office worker	16	32.0
	Manual worker	14	28.0
Dominant hand	Right	44	88.0
	Left	6	12.0
Affected elbow	Right	29	58.0
	Left	21	42.0
Total		50	100.0

Athletes constituted the largest occupational group, accounting for 20 participants (40.0%), followed by office workers (32.0%) and manual workers (28.0%). The majority of participants were right-hand dominant (88.0%), whereas 12.0% were left-hand dominant. The right elbow was affected in 58.0% of participants, while the left elbow was affected in 42.0%.

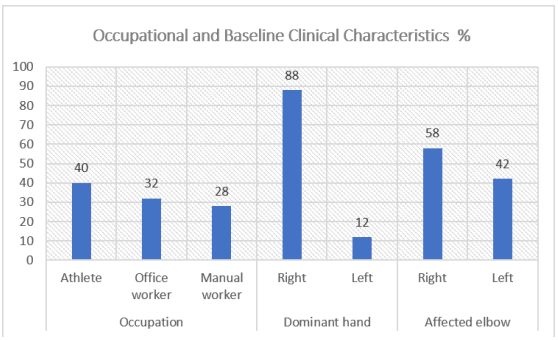


Table 3. Duration of Symptoms Among Study Participants (n=50)

Duration of symptoms (weeks)	n	%
6–10	19	38.0
11–15	9	18.0
16–20	16	32.0
21–24	6	12.0
Total	50	100.0
Mean duration (weeks)	13.4 ± 5.3	—

The mean duration of symptoms was 13.4 ± 5.3 weeks. The largest proportion of participants had symptoms for 6–10 weeks (38.0%), followed by 16–20 weeks (32.0%). Participants with symptoms lasting 11–15 weeks constituted 18.0%, while 12.0% had symptoms for 21–24 weeks. Thus, most participants had subacute symptoms at the time of enrolment.

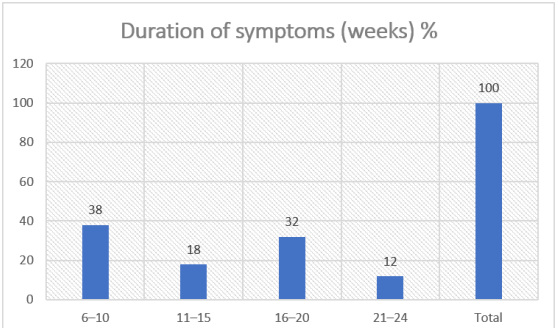


Table 1. Comparison of VAS Scores at Different Time Intervals Following Novel Tennis Elbow Splint Use (n=50)

Comparison	Mean ± SD	Mean Difference	95% CI	t (df=49)	p-value
Pre-intervention vs 2 weeks	6.86 ± 0.78 vs 5.32 ± 0.87	1.54	1.397–1.683	21.629	<0.001
2 weeks vs 4 weeks	5.32 ± 0.87 vs 3.72 ± 0.97	1.60	1.459–1.741	22.862	<0.001
4 weeks vs 8 weeks	3.72 ± 0.97 vs 2.58 ± 1.19	1.14	0.910–1.370	9.972	<0.001
Pre-intervention vs 8 weeks	6.86 ± 0.78 vs 2.58 ± 1.19	4.28	3.981–4.579	28.808	<0.001

The mean VAS score demonstrated a progressive reduction in pain following use of the novel tennis elbow splint. The mean score decreased from 6.86 ± 0.78 at baseline to 5.32 ± 0.87 at 2 weeks, further to 3.72 ± 0.97 at 4 weeks, and 2.58 ± 1.19 at 8 weeks. The overall reduction from baseline to 8 weeks was 4.28 points (95% CI: 3.981–4.579) and was statistically significant (t=28.808, p<0.001). Significant reductions were also observed at every consecutive follow-up interval (p<0.001), indicating continuous improvement in pain intensity during the 8-week follow-up. These values are directly reported in the Shanthosh thesis/paper.

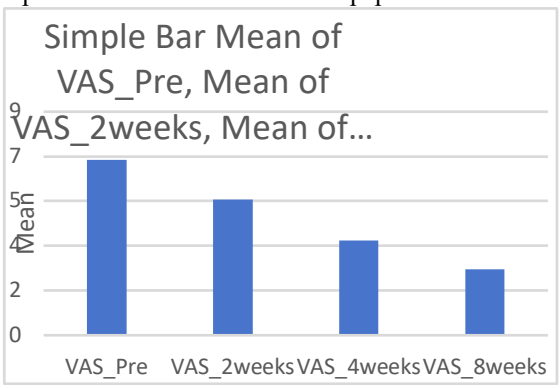


Table 2. Distribution of Brace Usage Hours per Day Among Study Participants (n=50)

Brace usage (hours/day)	n	%
4	6	12.0
5	9	18.0
6	8	16.0
7	8	16.0
8	6	12.0
9	8	16.0
10	5	10.0
Total	50	100.0

Daily brace usage ranged from 4 to 10 hours. The largest proportion of participants (18.0%) used the splint for 5 hours/day, followed by 6, 7, and 9 hours/day (16.0% each). Thus, participants generally followed the prescribed daily splint-use schedule, with usage distributed across 4–10 hours per day.

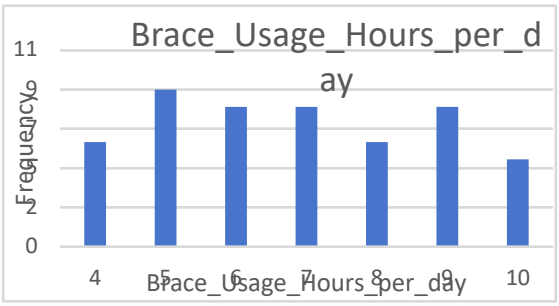


Table 3. Distribution of Compliance with Novel Tennis Elbow Splint Usage (n=50)

Compliance level	n	%
Good	19	38.0
Moderate	25	50.0
Poor	6	12.0
Total	50	100.0

The majority of participants demonstrated moderate compliance (50.0%), followed by good compliance (38.0%), while only 12.0% demonstrated poor compliance. Overall, 88.0% of participants had either moderate or good compliance with splint usage, indicating generally satisfactory adherence to the prescribed intervention.

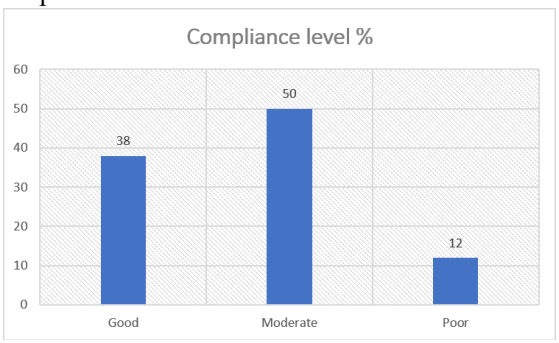
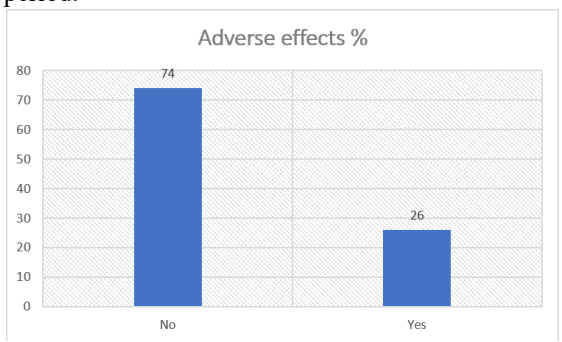


Table 4. Adverse Effects During Splint Use (n=50)

Adverse effects	n	%
No	37	74.0
Yes	13	26.0
Total	50	100.0

Most participants (74.0%) did not report adverse effects during splint use, whereas 26.0% reported some adverse effects. The findings suggest that the splint was generally well tolerated during the study period.



4.DISCUSSION

The present prospective observational study evaluated the demographic and baseline clinical profile, pain reduction, and compliance with use of a novel tennis elbow splint among 50 patients with lateral epicondylitis over an 8-week follow-up period. The mean age of the study population was 43.2 ± 12.6 years, with the largest proportions belonging to the 18–30 years and 51–60 years age groups (28.0% each), followed by 31–40 years (22.0%), 41–50 years (12.0%), and >60 years (10.0%). Males constituted 66.0% of participants, while females accounted for 34.0%. Athletes formed the largest occupational group (40.0%), followed by office workers (32.0%) and manual workers (28.0%), supporting the relevance of repetitive upper-limb activity in this clinical population. The majority were right-hand dominant (88.0%), and the right elbow was affected in 58.0% of cases. The mean duration of symptoms was 13.4 ± 5.3 weeks, with 38.0% presenting with symptoms of 6–10 weeks and 32.0% with 16–20 weeks. The demographic profile was broadly comparable with Nowotny et al. [15], who studied patients with lateral epicondylitis and reported a mean age of 46 years, with 43% males and 66% right-elbow involvement. Their study therefore demonstrated a similar middle-aged clinical population and identical proportion of right-sided elbow involvement, although the male proportion in the present study was higher.

The principal finding of the present study was a progressive and statistically significant reduction in pain following use of the novel splint. Mean VAS decreased from 6.86 ± 0.78 at baseline to 5.32 ± 0.87 at 2 weeks, 3.72 ± 0.97 at 4 weeks, and 2.58 ± 1.19 at 8 weeks. The overall mean reduction between baseline and 8 weeks was 4.28 points, with a 95% confidence interval of 3.981–4.579 and a paired *t* value of 28.808 ($p<0.001$). Importantly, significant improvement was observed at every consecutive interval, with reductions of 1.54 points from baseline to 2 weeks, 1.60 points from 2 to 4 weeks,

and 1.14 points from 4 to 8 weeks, with $p<0.001$ for each comparison. This pattern demonstrates that pain reduction was progressive throughout the intervention rather than occurring only during the initial treatment period. These findings are consistent with Nowotny et al. [15], who reported that VAS decreased from 6.5 to 3.7 at 12 weeks (p=0.001) in their physiotherapy plus orthosis group. They also reported further reduction in VAS to 1.1 at 12 months (p<0.001). Thus, the direction and statistical significance of pain improvement in the present study are consistent with the findings of the orthosis group in the study by Nowotny et al., although the present study involved a shorter 8-week follow-up. Aydın and Atiç [16] similarly reported significant improvements in pain at rest and during activity in patients receiving wrist extensor splinting, with significant improvement from pretreatment values at 4, 12, and 24 weeks (p<0.001). Their findings support the observation that orthotic treatment can produce meaningful improvement in pain symptoms in patients with lateral epicondylitis.

Patient adherence represented the second major outcome of the present study. Daily brace use ranged from 4 to 10 hours, with the largest proportion of participants using the splint for 5 hours/day (18.0%), while 6, 7, and 9 hours/day were each reported by 16.0% of participants. Compliance was categorized as good in 38.0%, moderate in 50.0%, and poor in 12.0%, indicating that 88.0% of participants demonstrated either moderate or good compliance. This suggests that the novel splint was reasonably acceptable for incorporation into daily activities over the study period. The findings compare favourably with Ozden et al. [17], who specifically evaluated adherence to orthotic treatment in 120 patients with lateral epicondylitis. Their wrist-splint group demonstrated a compliance rate of 90.3%, significantly higher than the 60.3% observed among patients using an epicondylitis band (p<0.001). The 88.0% moderate-to-good compliance observed in the present study was therefore broadly comparable with the high adherence reported for wrist splint use by Ozden et al. [17]. Their study also reported significant improvement in VAS scores in both treatment groups compared with baseline (p<0.001), although the between-group difference in VAS at six weeks was not statistically significant (p=0.149).

Tolerance of the novel splint was also generally favourable. In the present study, 37 patients (74.0%) reported no adverse effects, whereas 13 patients (26.0%) reported adverse effects during splint use. Although the exact nature and severity of individual adverse effects were not specified in the available results, the absence of adverse effects in nearly three-fourths of participants supports the overall tolerability of the device. The compliance findings are particularly relevant because sustained use of an orthosis is necessary for it to exert its intended mechanical effect. Ríos et al. [20] evaluated another orthotic device, the ArmLock sleeve, in 19 individuals using the device for 30 minutes daily for 12 weeks and reported significant improvements in 6 of 7 (85.7%) outcome measures, including pain intensity and grip strength. Although the device, treatment schedule, and study design differed from the present investigation, these findings similarly indicate potential clinical benefits from structured orthotic use.

Overall, the present study demonstrated a substantial reduction in pain, with VAS decreasing from 6.86 ± 0.78 to 2.58 ± 1.19 over 8 weeks (mean reduction 4.28; p<0.001), together with favourable adherence, as 88.0% of participants demonstrated moderate or good compliance. Daily use ranged from 4–10 hours, and 74.0% reported no adverse effects. The findings are broadly consistent with the orthosis-related improvements reported by Nowotny et al. [15], Aydın and Atiç [16], Ozden et al. [17], and Ríos et al. [20]. However, because the present study was observational, included only 50 participants, and lacked a control group, the observed improvement cannot be attributed exclusively to the splint without qualification. Larger randomized comparative studies with longer follow-up would therefore be required to establish the independent effectiveness and long-term adherence associated with the novel tennis elbow splint.

CONCLUSION

The present study demonstrated that use of the novel tennis elbow splint was associated with significant reduction in pain among patients with lateral epicondylitis. The mean VAS score decreased from 6.86 ± 0.78 at baseline to 2.58 ± 1.19 at 8 weeks, with an overall reduction of 4.28 points (p<0.001). Patient adherence was also favourable, with 88.0% demonstrating moderate or good compliance and daily splint use ranging from 4 to 10 hours. The splint was generally well tolerated, with 74.0% of participants reporting no adverse effects. Overall, these findings suggest that the novel tennis elbow splint may be a practical and acceptable conservative option for pain management in lateral epicondylitis. However, larger controlled studies with longer follow-up are required to confirm its effectiveness and long-term compliance.

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