

TENDONCEL PHASE II PLACEBO CONTROLLED RANDOMIZED CLINICAL TRIAL RESULTS FOR A NOVEL ALLOGENEIC REGENERATIVE TOPICAL MEDICINE IN TREATMENT OF CHRONIC TENDON INJURY



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Abstract: Celixir Limited has developed a novel topical gel (Tendoncel) for the treatment of lateral epicondylitis (also known as tennis elbow). Tendoncel is a proprietary regenerative allogeneic gel that incorporates a unique combination of platelet growth factors, including PDGF-BB, VEGF, PDGF-AA, thrombospondin and angiopoietin, within a cellulose-derived gel.

We investigated Tendoncel in a double blind placebo controlled Phase II clinical trial in lateral epicondylitis. Patients were randomized to receive either treatment (Tendoncel and physiotherapy) or placebo (placebo gel and physiotherapy) once daily for 21 days with follow up over a period of 3 months. The Tendoncel treated patients showed a statistically and clinically significant improvement in all measurements taken (Disabilities of the Arm, Shoulder and Hand (DASH) score, Patient-rated Tennis Elbow Evaluation (PTREE) score and PTREE pain score) at all time points (two of which are shown below in Table 1).

These results clearly show that Tendoncel is both efficacious and safe in the treatment of lateral epicondylitis.

Test	Treatment score at 4 weeks	Treatment score at 3 months
DASH	52% of placebo (p<0.05)	60% of placebo (p<0.05)
PTREE	48% of placebo (p<0.05)	52% of placebo (p<0.05)
PTREE pain	60% of placebo (p<0.01)	69% of placebo (p<0.05)

Table 1. DASH, PTREE and PTREE pain scores at 4 weeks and 3 months compared to placebo treatment.

Introduction: Lateral epicondylitis (LE) or “tennis elbow” is a degenerative tendinopathy characterised by pain at the lateral epicondyle. Although often self limiting, with up to 90% of LE patients reporting recovery within 12 months, 5 to 10% of patients develop chronic symptoms. The pathophysiology of LE is incompletely understood and the optimum treatment regime has yet to be established (Luk *et al.*, 2014). *In vitro* studies have shown that platelet derived growth factors promote fibroblast proliferation, based on this observation Tendoncel was investigated in a double blind randomised placebo controlled study with LE as an example of a chronic tendinopathy.

Method: Thirty patients, who were (a) aged 18 years or over and (b) diagnosed with lateral epicondylitis confirmed with Cozen’s test were randomized to receive either Tendoncel gel or placebo gel. The gels were applied topically at the lateral epicondyle once daily for 21 consecutive days. The follow up was for a period of 3 months. Outcomes were assessed using the Disabilities of the Arm, Shoulder, and Hand (DASH) Questionnaire, the Patient-rated Tennis Elbow Evaluation (PRTEE) Questionnaire and blood IgE levels to assess systemic effects. The trial was a single centre double blind.

Results: Analysis of the results revealed that Tendoncel treatment led to both a statistically and clinically significant improvement in both DASH and PRTEE from baseline to 3 months follow up compared to placebo. DASH scores were 60% of placebo (p<0.05) while scores for PRTEE and PRTEE PAIN were 52% (p<0.05) and 69% (p<0.05) of placebo respectively. There were no serious adverse events or changes in blood IgE levels. Mean DASH and modified PRTEE and PRTEE PAIN scores are shown in Figure 1.

Discussion: The Tendoncel clinical trial results demonstrated statistically significant improvement in both DASH and PRTEE scores indicating the utility of Tendoncel in tendon repair. Applications include chronic tendinopathies that are amenable to topical treatment including ~1.5 million Achilles, shoulder and elbow injuries. And may delay or allay the requirement for surgery or other invasive treatment options.

Conclusion: Tendoncel, a novel allogeneic regenerative topical medicine, is both efficacious and safe in the treatment of severe tendon injury - lateral epicondylitis.

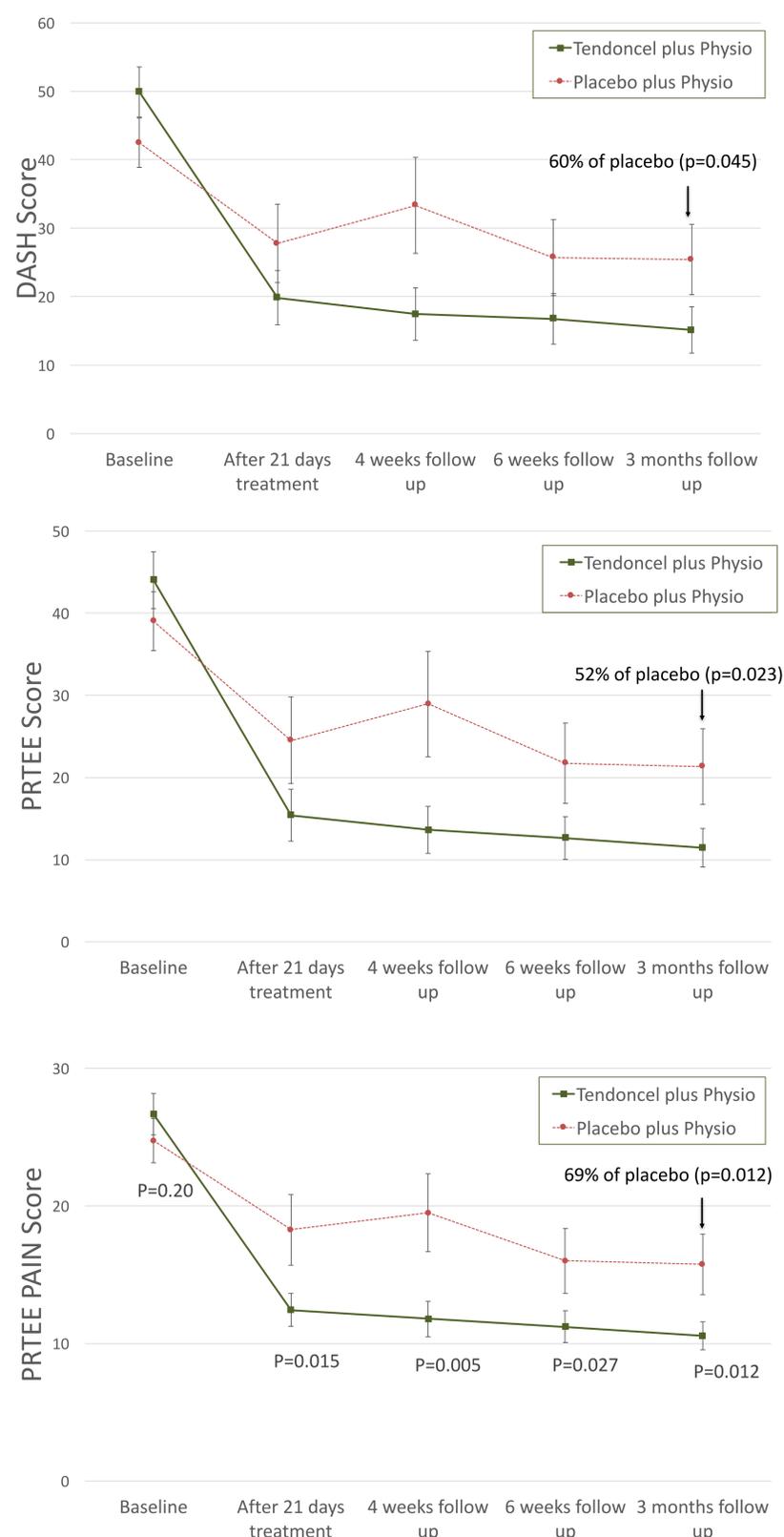


Figure 1. Mean DASH and modified PRTEE and PRTEE PAIN scores. Treatment with Tendoncel (test) resulted in a significant improvement in DASH, PRTEE and PRTEE PAIN scores compared to controls.