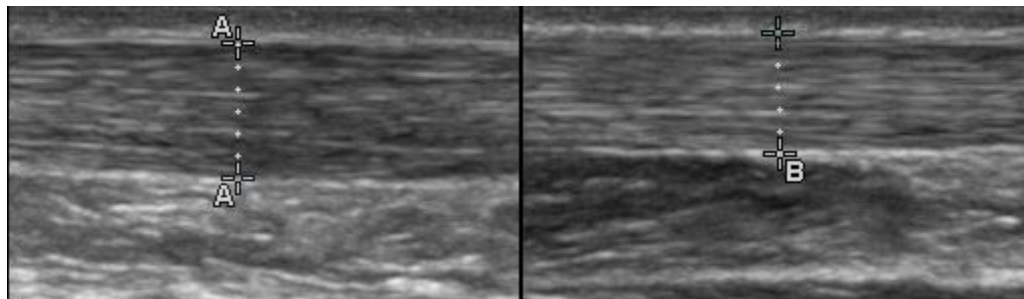




Total Tendon Repair

- PROSPECTIVE, OPEN-LABEL, MULTICENTER, OBSERVATIONAL STUDY TO ASSESS THE EFFICACY OF TENDOACTIVE® IN PATIENTS WITH TENDINOPATHY



PARTICIPATING CENTERS

CENTRO

CAR de Sant Cugat (Sant Cugat)
Clínica Teknon (Barcelona)
Artro Esport (Barcelona)
Mútua Catalana de Fútbol (BCN)
Clínica Diagonal (Esplugues)
Traumasalut (Sabadell)
Xarxa Sanitària i Social de Sta. Tecla (Unitat de medicina de l'esport) - Centre Mèdic Rambla Nova
Lenox Corachan (Barcelona)
Activa Mútua (Barcelona)
Clínica CEMTRO (Madrid)
Asepeyo (Madrid)
Clínica Karin Freitag (Madrid)
Hospital Universitario Montepíncipe
Hospital Ruber Internacional (Madrid)
Clínica DEYRE (Madrid)
Clínica Nuestra Señora Avda. América
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Dr. Dr. José Gonzalez /Guillermo Rodríguez Fabián
Dr. Horacio Rodríguez Cazar
Dr. Carlos T. Simorte

METHODS

OBJECTIVES:

- Primary objective: To assess the effect of Tendoactive® on the clinical symptoms of tendinopathies
- Secondary objectives:
 - To assess the effect of Tendoactive® on tendon structure
 - To quantificate the consumption of analgesics during the treatment with Tendoactive®
 - To assess the satisfaction of patients treated with Tendoactive®

METHODS

- Study population: 98 patients with tendinopathy (32 Achilles tendon, 34 patellar tendon and 32 epicondylitis) were included
- Study duration: 3 months (1 control/month)
- Efficacy outcomes
 - Functional score (VISA-A, VISA-P, PRTEE)
 - Pain (VAS) during rest/activity
 - Ultrasonographic tissue characterization
 - Patient's satisfaction
 - Analgesics consumption
- Safety: Adverse events were recorded

METHODS

Inclusion criteria:

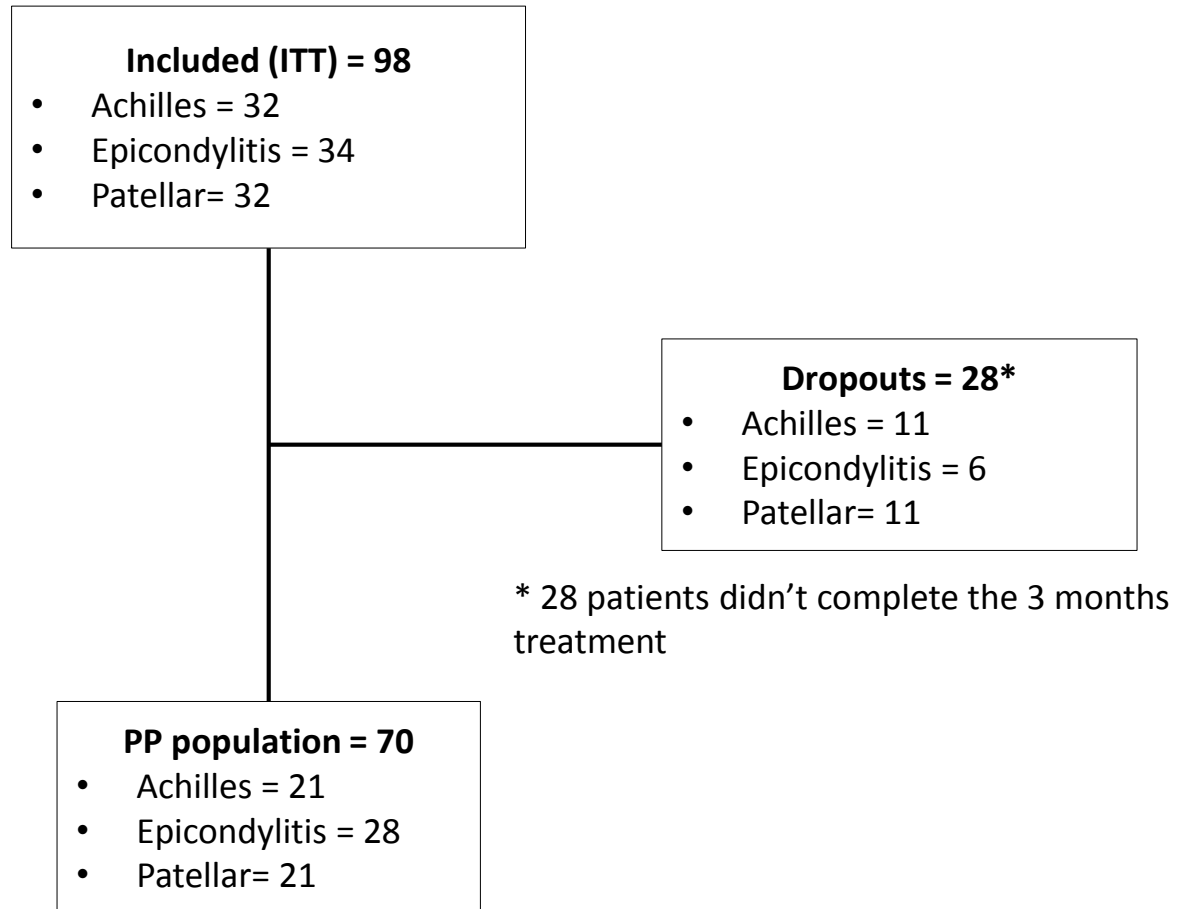
- Men and non-pregnant women > 18 years old
- Patients with tendinopathy in Achilles tendon, patellar tendon or epicondylitis

(Diagnosis based on clinical examination showing a painful thickening of the tendon, and confirmed by ultrasonography: local thickening of the tendon, irregular tendon structure with hypoechoic areas and irregular fiber orientation)

Exclusion criteria:

- Patients < 18 years old
- Known presence of a pregnancy
- Clinical suspicion of neurological disorder
- Clinical suspicion of internal disorders (spondyloarthropathy, gout, hyperlipidemia, rheumatoid arthritis and sarcoidosis)

PATIENTS

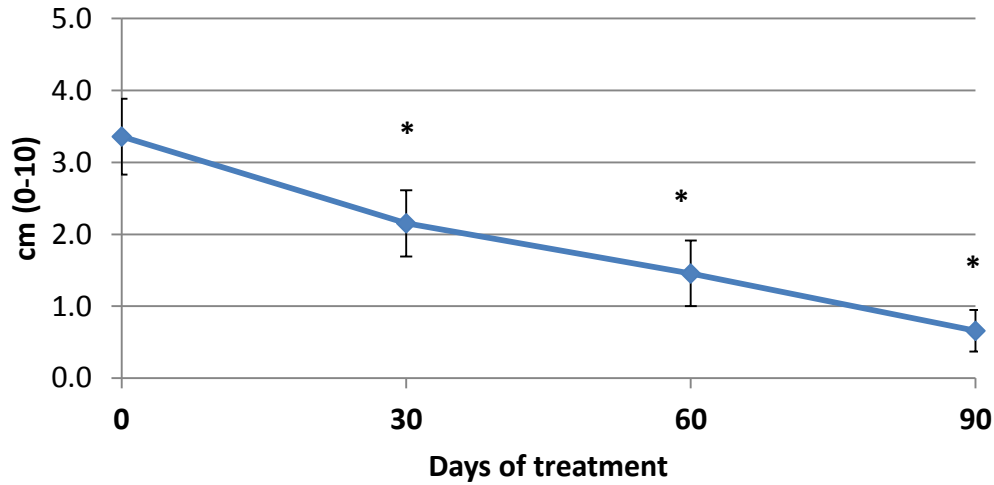


BASELINE CHARACTERISTICS

	ACHILLES	EPICONDYLITIS	PATELLAR
Age (years)	49,2	47,7	39,0
Sex (n, M/W)	13/8	14/14	13/8
BMI (Kg/m ²)	24,1	25,6	23,1
Functional Score (0-100)	63,0	51,25	58,25
VAS during rest (0-10)	3,3	3,4	4,1
VAS during activity (0-10)	5,6	6,5	6,3
Activity level (0-10)	4,5	5,3	5,6
Bilateral thickness of the affected tendon (mm)	9,5	7,7	10,4
Paratenon blurring (n, 0/1/2/3)	6/7/4/1	10/12/2/1	8/8/3/0
Heteroechogenicity (n, 0/1/2/3)	5/6/6/1	4/11/6/3	3/11/2/4
Hipoechogenicity (n, 0/1/2/3)	4/7/8/0	4/4/8/10	5/3/7/3
Neovascularization (n, 0/1/2/3)	7/8/5/0	7/10/5/5	8/5/3/4
Isolated intratendinous rupture (n)	5	1	4

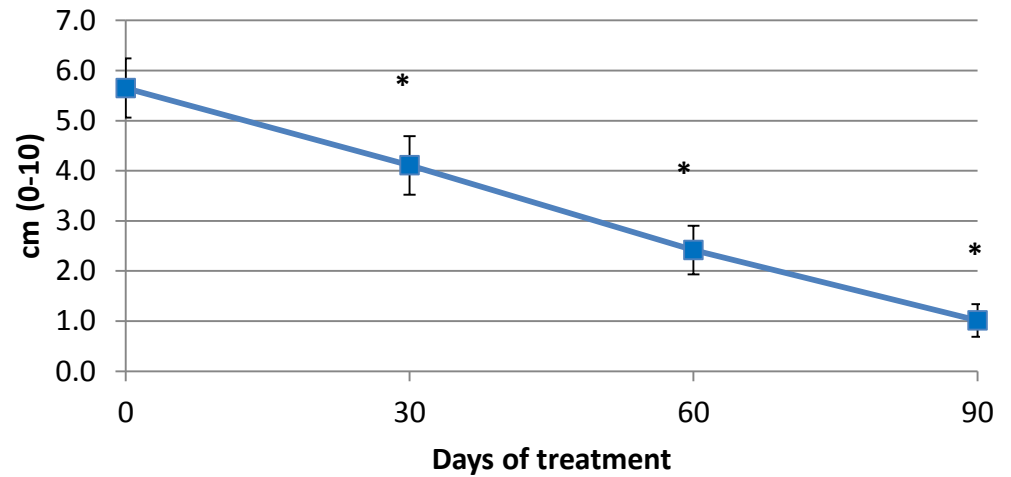
RESULTS: PAIN (VAS)

VAS during rest



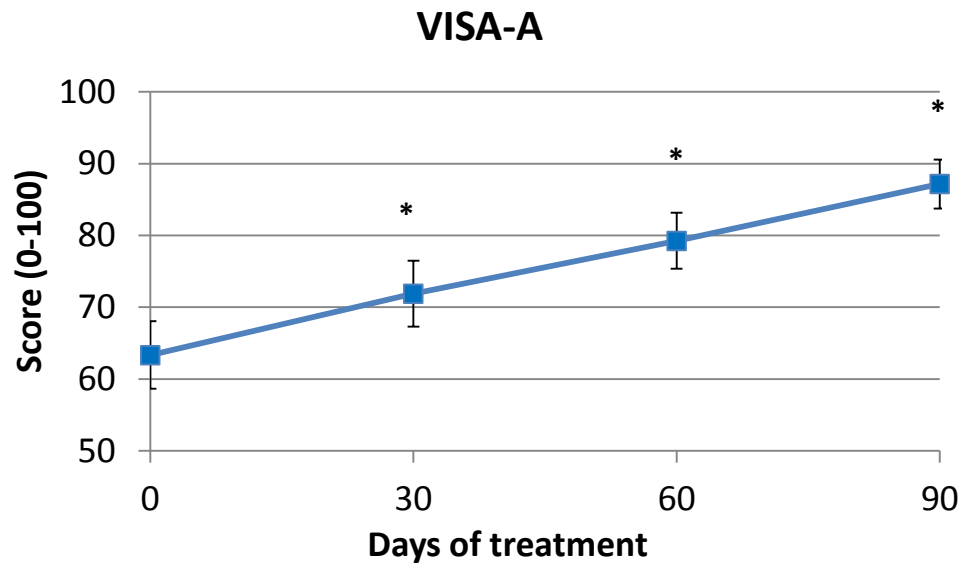
ACHILLES TENDINOPATHY

VAS during activity

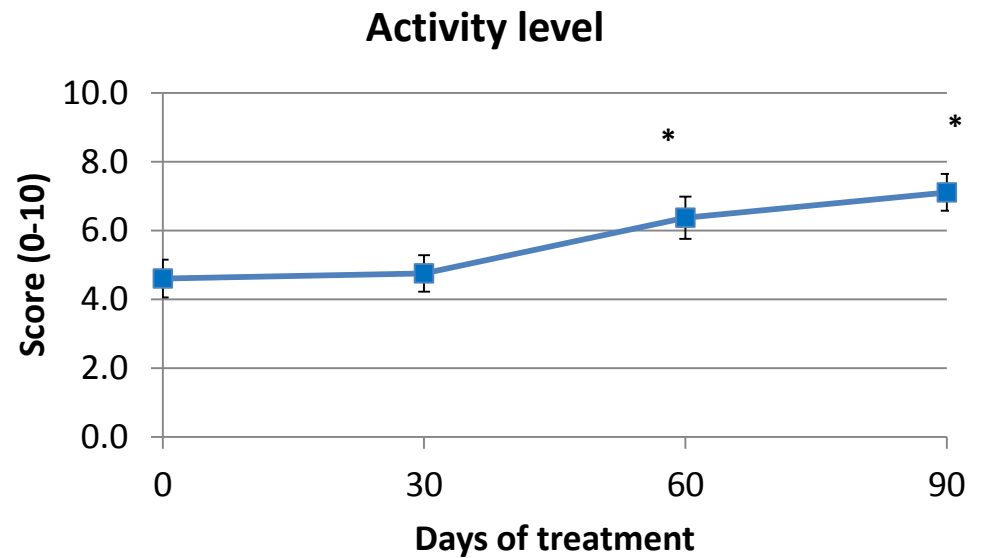


* p<0.05 compared to baseline

RESULTS: FUNCTIONAL SCORE – ACTIVITY LEVEL



ACHILLES TENDINOPATHY

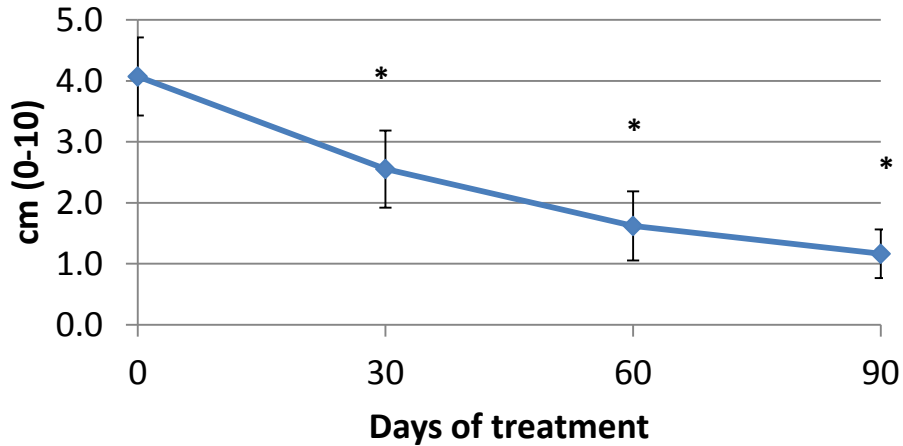


* $p < 0.05$ compared to baseline

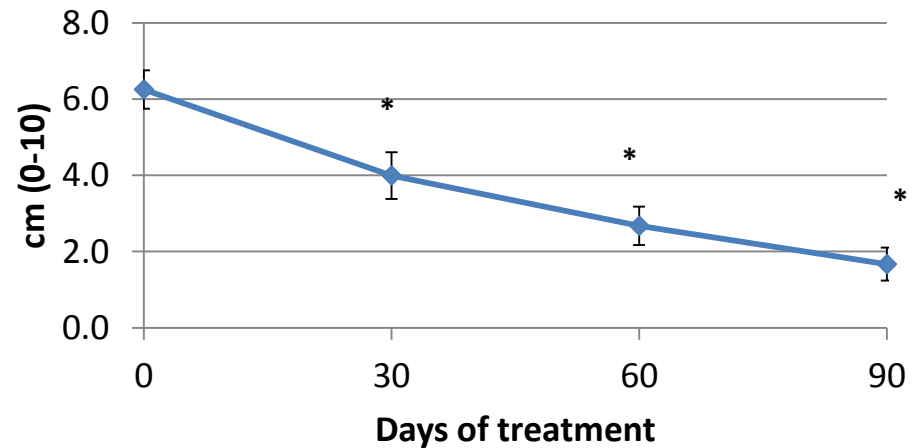
RESULTS: PAIN (VAS)

PATELLAR TENDINOPATHY

VAS during rest



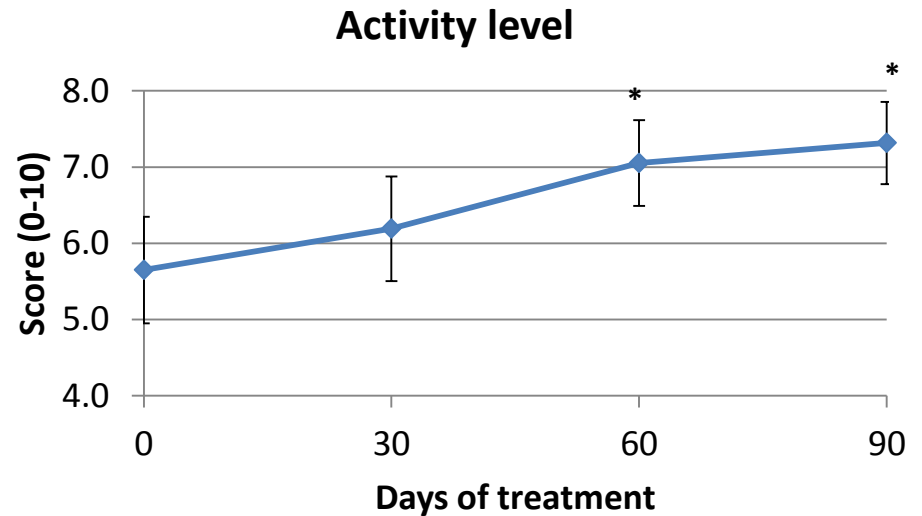
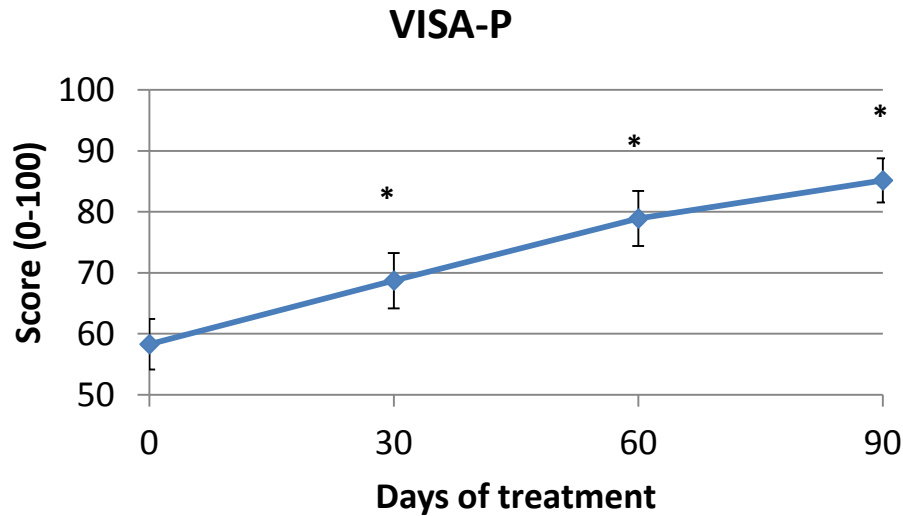
VAS during activity



* $p < 0.05$ compared to baseline

RESULTS: FUNCTIONAL SCORE – ACTIVITY LEVEL

PATELLAR TENDINOPATHY

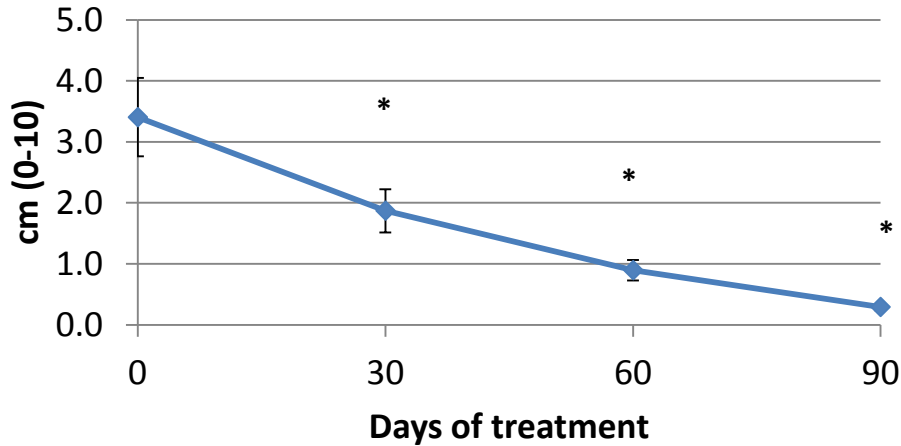


* p<0.05 compared to baseline

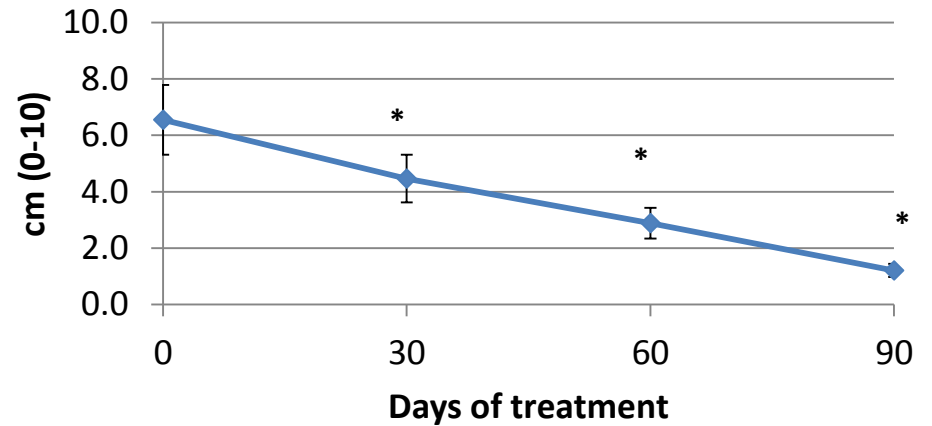
RESULTS: PAIN (VAS)

EPICONDYLITIS

VAS during rest



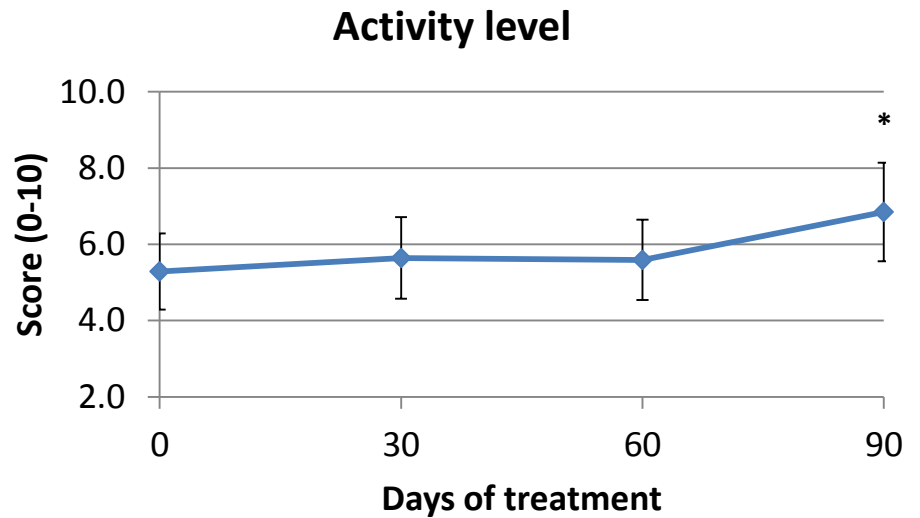
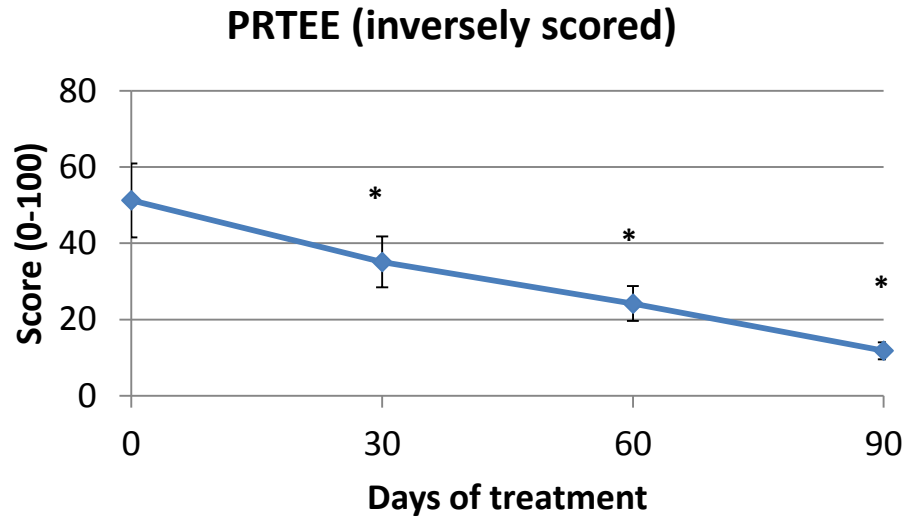
VAS during activity



* p<0.05 compared to baseline

RESULTS: FUNCTIONAL SCORE – ACTIVITY LEVEL

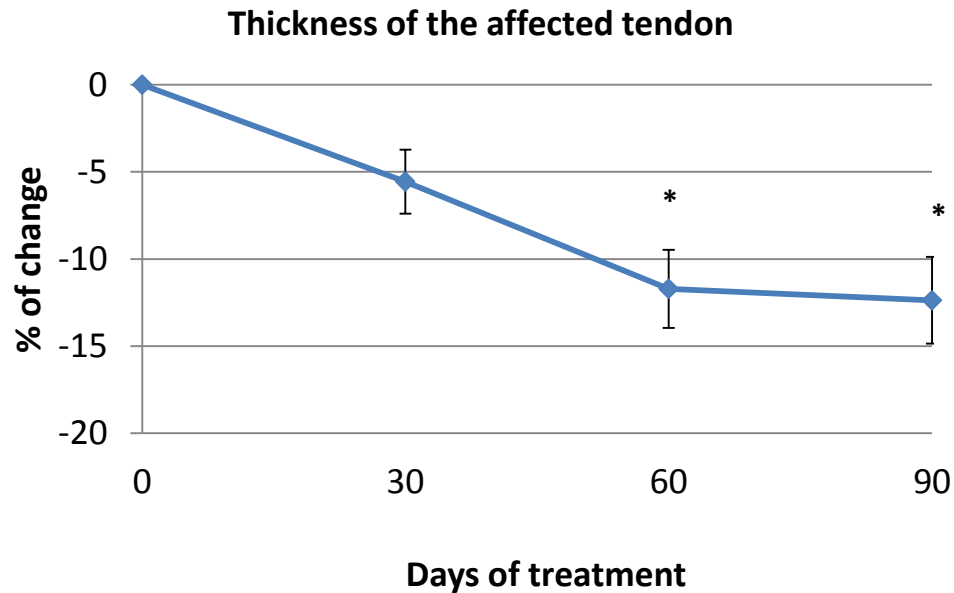
EPICONDYLITIS



* $p < 0.05$ compared to baseline

RESULTS: ULTRASONOGRAPHIC ASSESSMENT

ACHILLES TENDINOPATHY

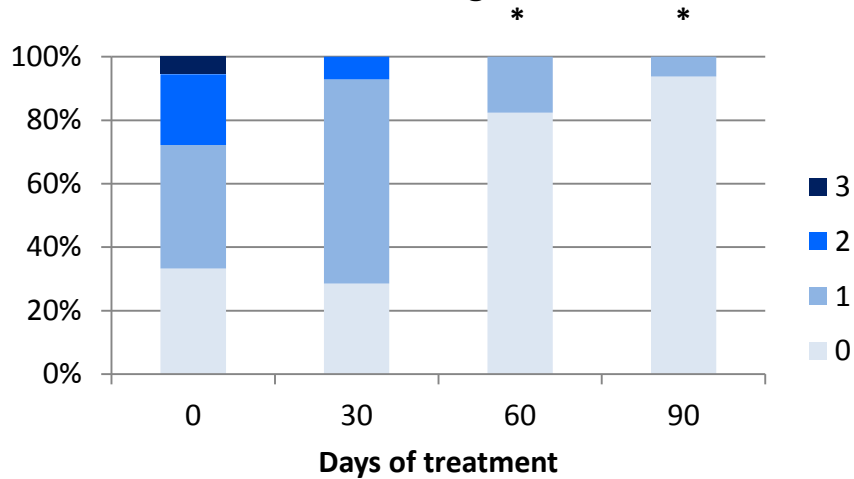


* $p < 0.05$ compared to baseline

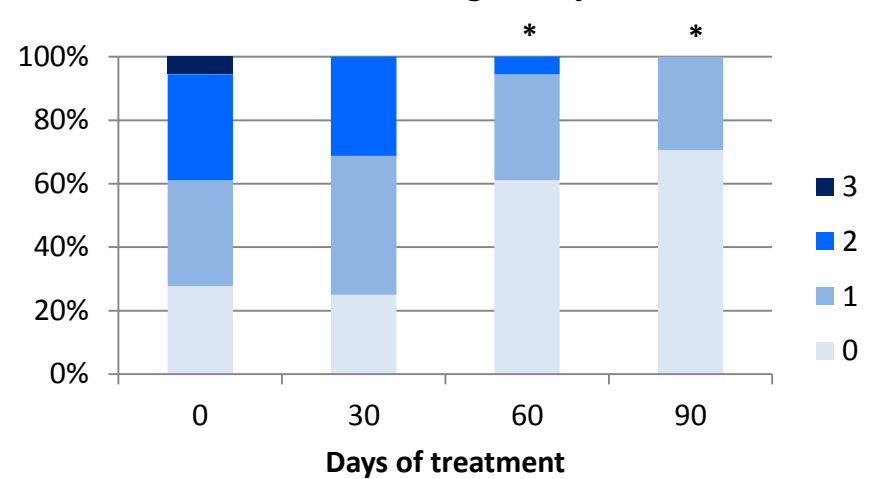
RESULTS: ULTRASONOGRAPHIC ASSESSMENT

ACHILLES TENDINOPATHY

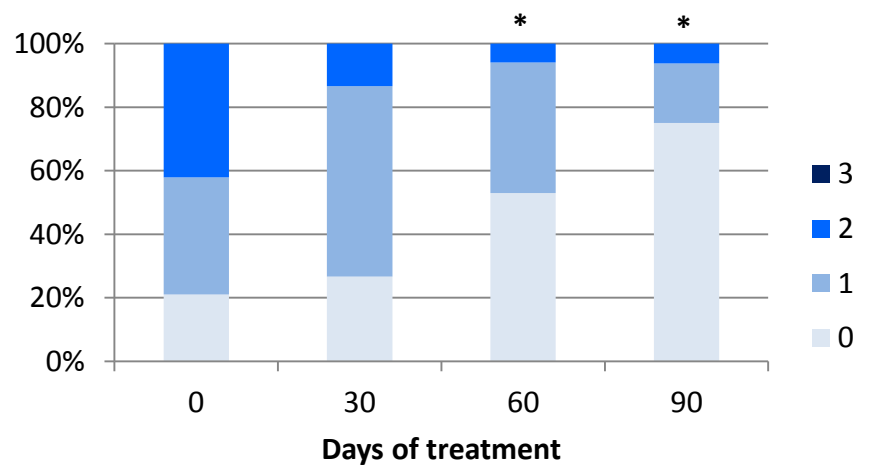
Paratenon blurring



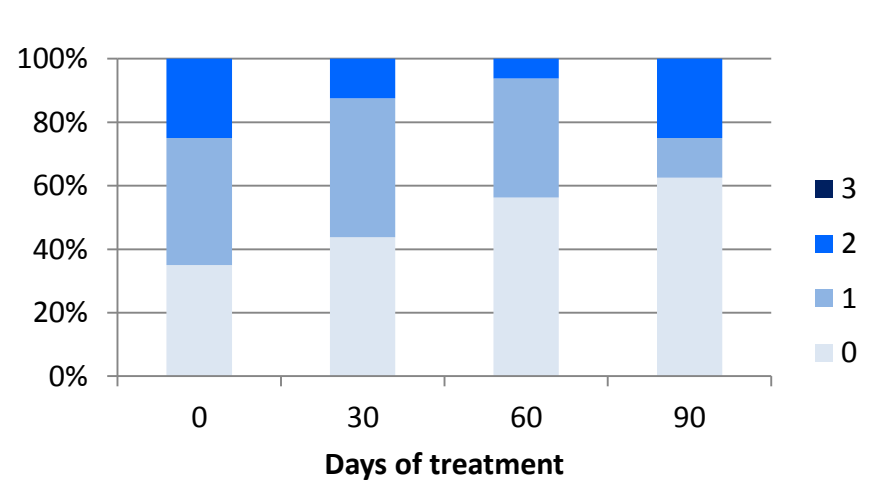
Heteroechogenicity



Hipoechogenicity



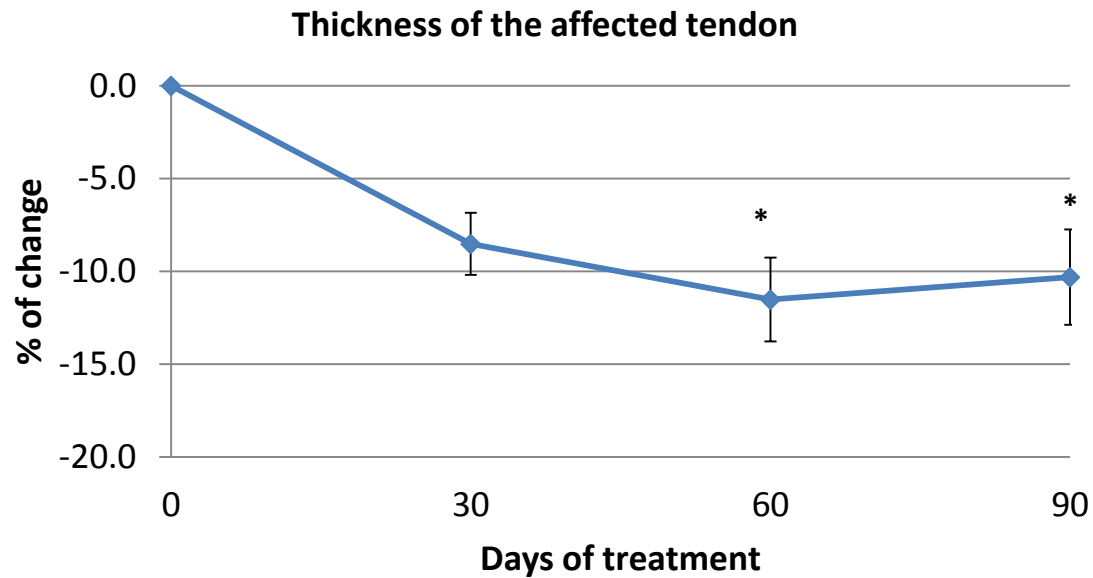
Neovascularization



* $p < 0.05$ compared to baseline

RESULTS: ULTRASONOGRAPHIC ASSESSMENT

PATELLAR TENDINOPATHY

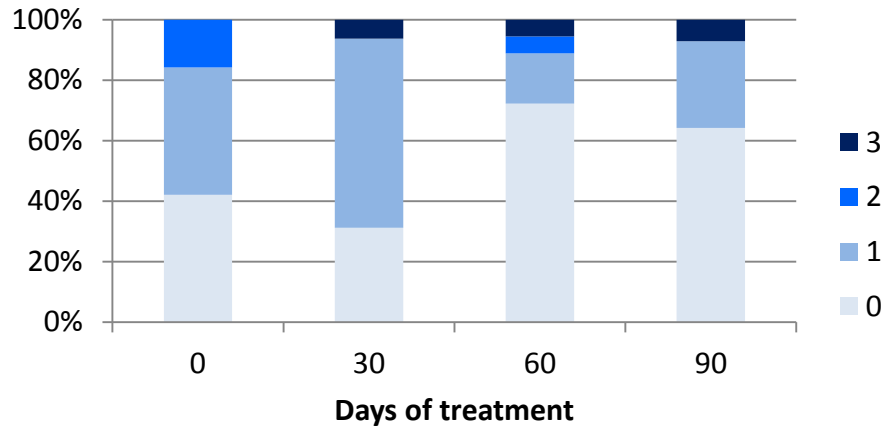


* $p < 0.05$ compared to baseline

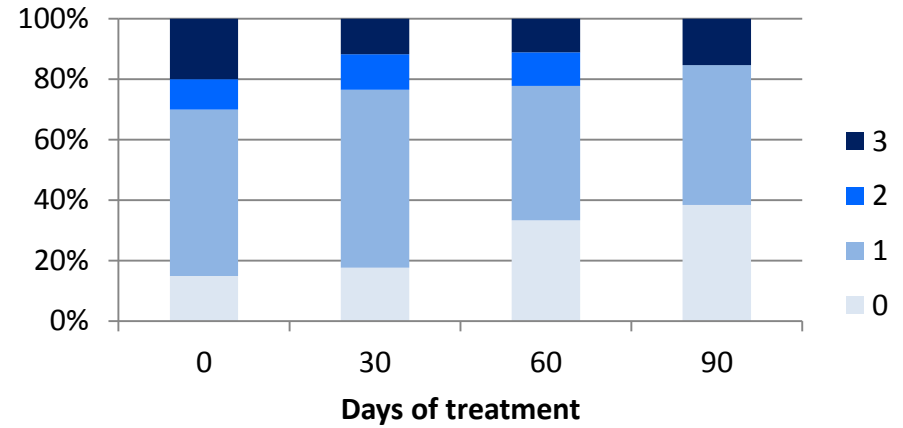
RESULTS: ULTRASONOGRAPHIC ASSESSMENT

PATELLAR TENDINOPATHY

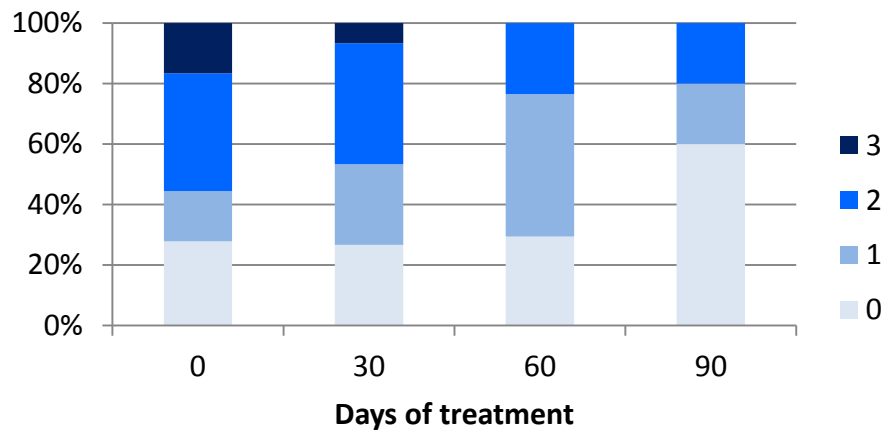
Paratenon blurring



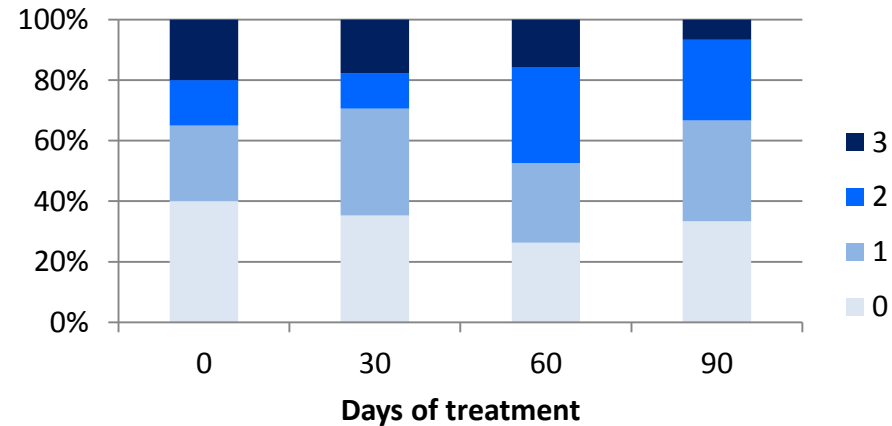
Heteroechogenicity



Hipoechogenicity



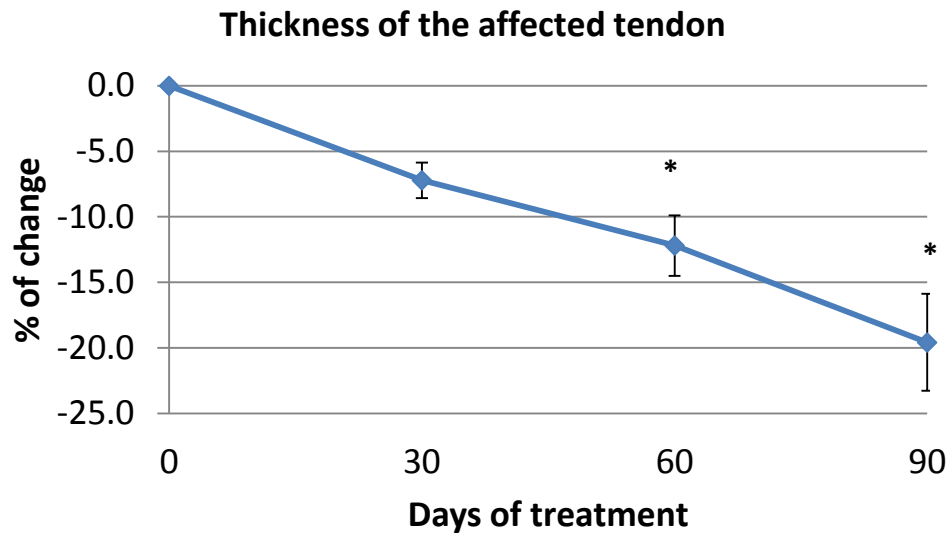
Neovascularization



* $p < 0.05$ compared to baseline

RESULTS: ULTRASONOGRAPHIC ASSESSMENT

EPICONDYLITIS

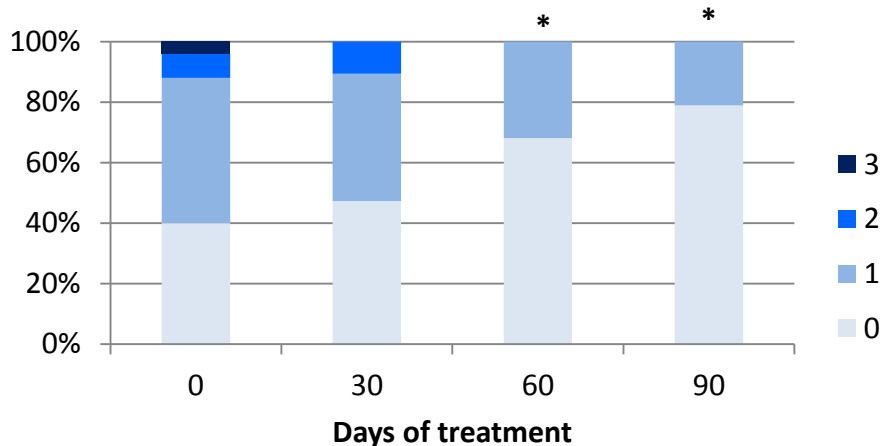


* $p < 0.05$ compared to baseline

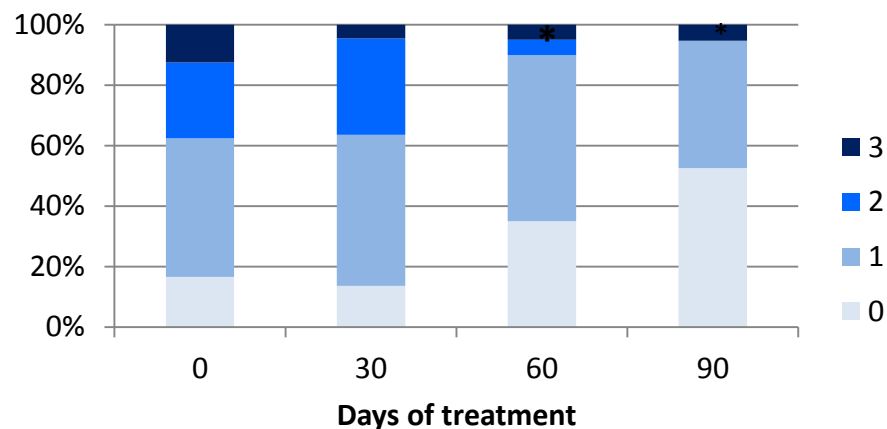
RESULTS: ULTRASONOGRAPHIC ASSESSMENT

EPICONDYLITIS

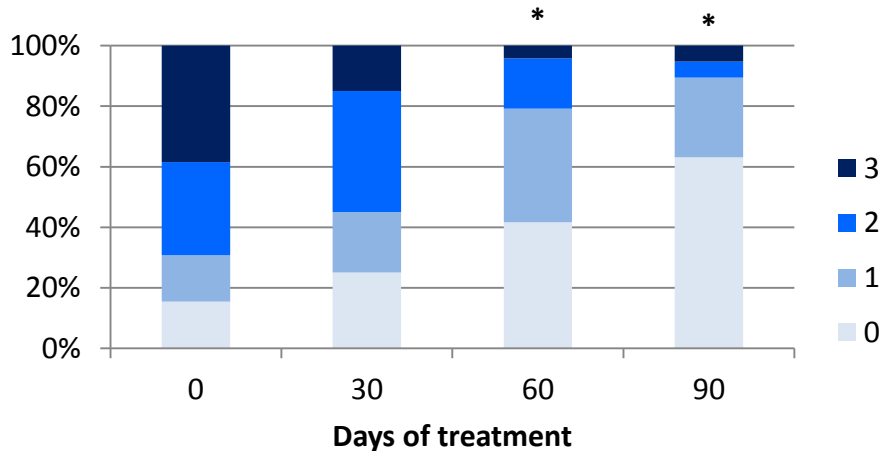
Paratenon blurring



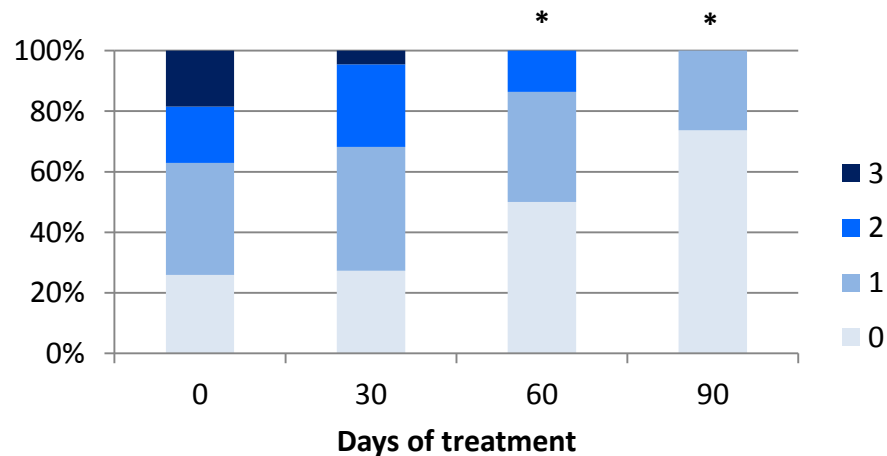
Heteroechogenicity



Hipoechogenicity

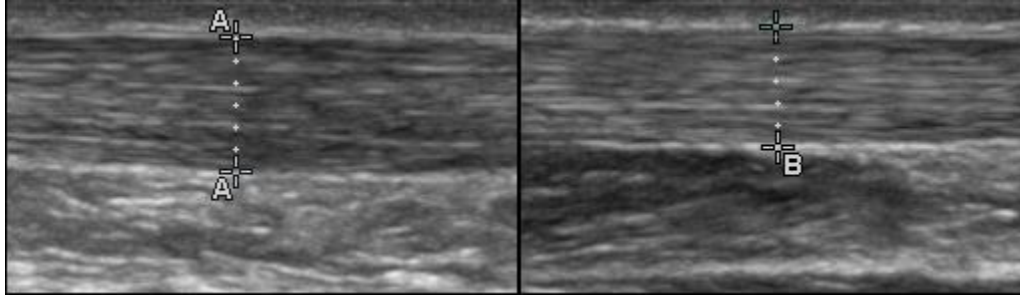


Neovascularization

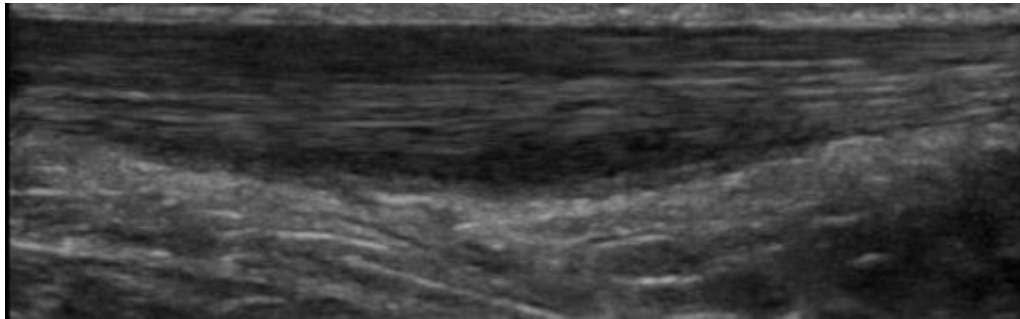


* $p < 0.05$ compared to baseline

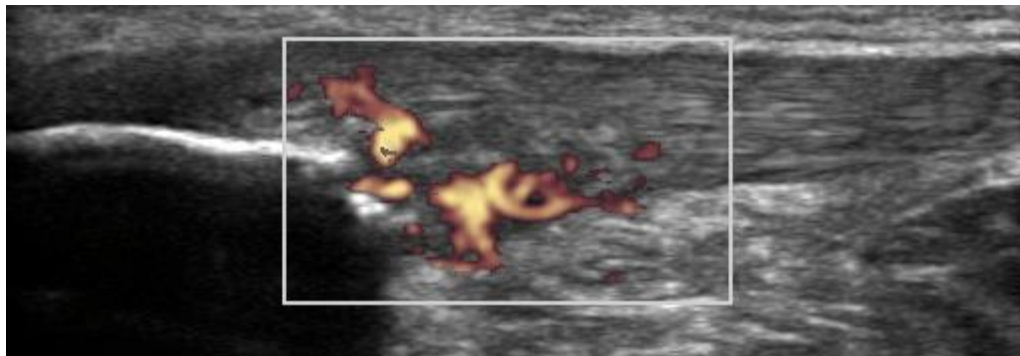
RESULTS: ULTRASONOGRAPHIC ASSESSMENT



Thickness of the achilles tendon L: Baseline (0.67 cm). R: Final (0.60 cm)



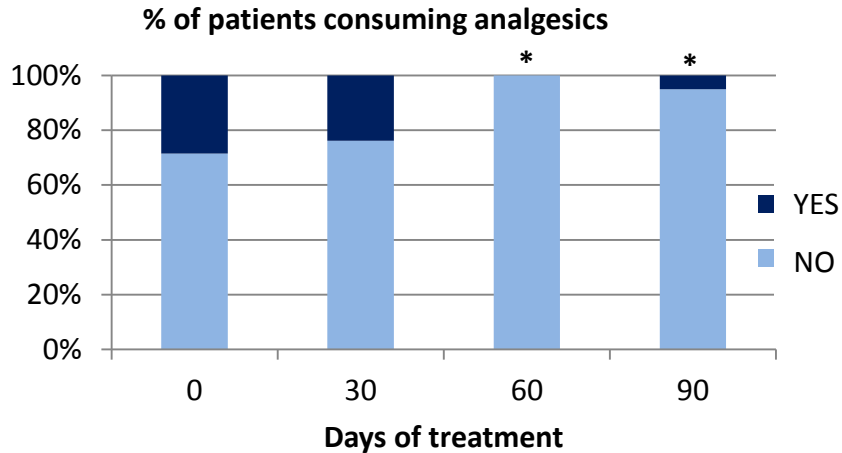
Achilles tendon showing hetero-hypoechogenecity and paratenon blurring



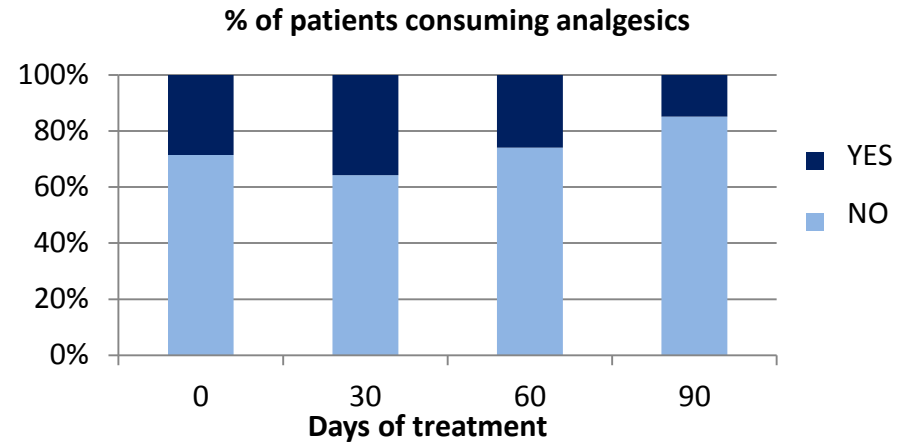
Patellar tendon showing neovascularization (Power Doppler)

RESULTS: ANALGESICS CONSUMPTION

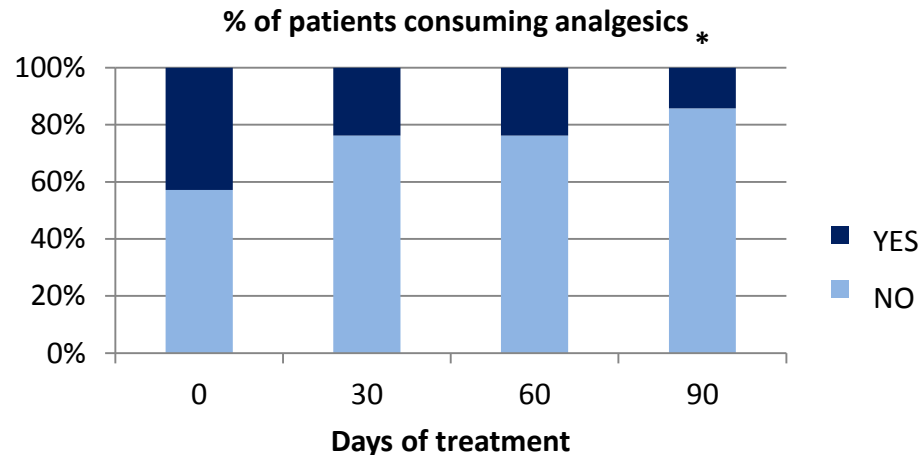
ACHILLES TENDINOPATHY



EPICONDYLITIS



PATELLAR TENDINOPATHY

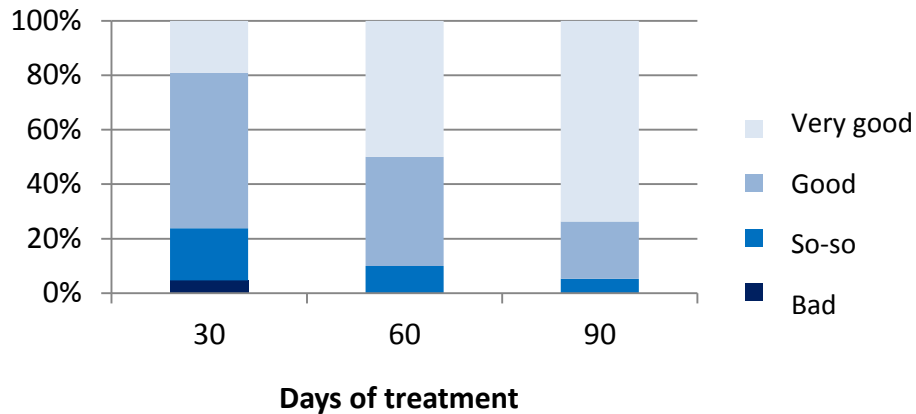


Results are presented as the percentage of patients taking at least one dose of analgesics within the previous month to each visit

RESULTS: PATIENT'S SATISFACTION

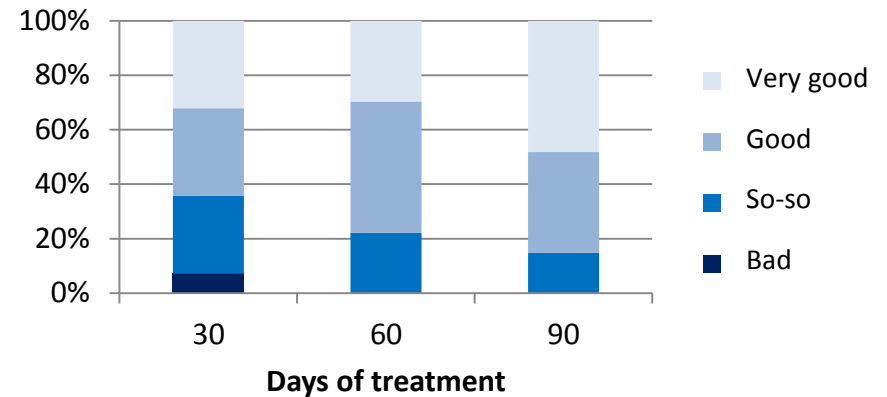
ACHILLES TENDINOPATHY

Patient's satisfaction



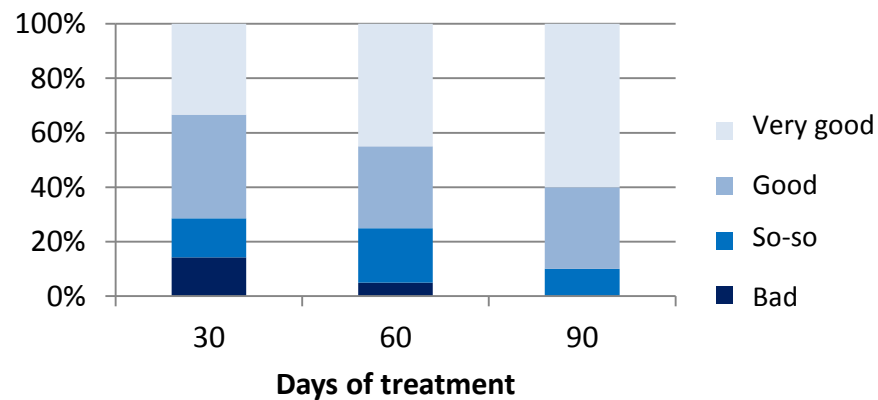
EPICONDYLITIS

Patient's satisfaction



PATELLAR TENDINOPATHY

Patient's satisfaction



CONCLUSIONS

EFFICACY

Treatment with Tendoactive® in patients with tendinopathy of achilles tendon, patellar tendon or epicondylitis:

- **Improves pain and tendon function**
- **Favors structural recovery of the tendon**
- **Reduces analgesics consumption**
- **Favors the return to activity**

The global patient's assessment of the treatment was very good

SAFETY

No adverse event related to the treatment was reported during the study

Pending for publication in "Apunts Medicina de l'Esport"

Indexed scientific journal dedicated to sports medicine, containing original research articles in English language, and subjected to an anonymous external peer review process.