Randomized controlled clinical trial

A prospective, randomized, controlled trial evaluating the efficacy Tendoactive associated to eccentric training or passive stretching

EXPERIMENTAL DESIGN:

- Randomized, controlled clinical trial (level of evidence:1)
- Multicenter: 6 clinical centres in Spain
- 59 Patients with Achilles tendinopathy

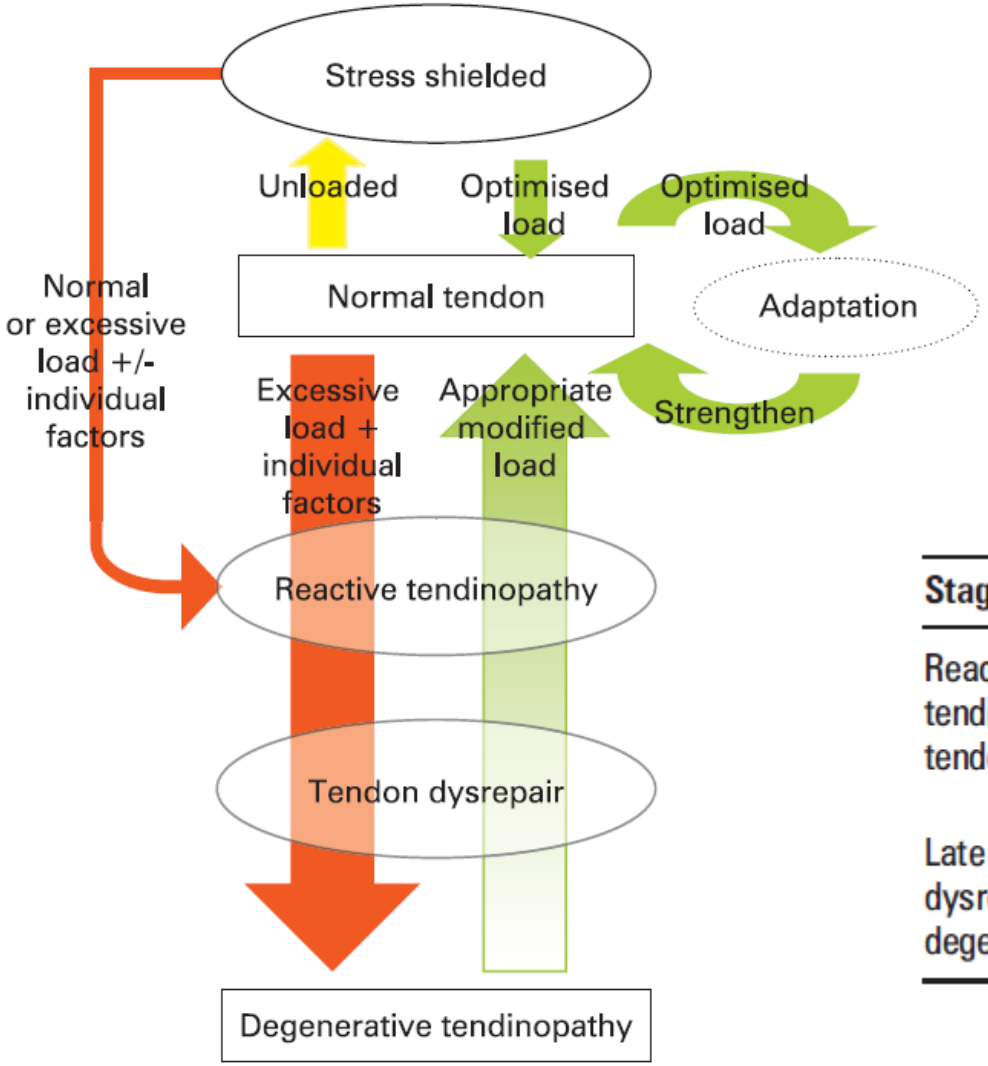
  (chronic noninsertional Aquiles tendinopathy of the midportion)
- Treatments (proportion among treatments 1:1:1)
  1. Eccentric training
  2. Passive stretching + Tendoactive®
  3. Eccentric training + Tendoactive®
- Subgroups according to structural severity
  1. Reactive tendinopathy
  2. Degenerative tendinopathy

Pending for publication

Is tendon pathology a continuum? A pathology model to explain the clinical presentation of load-induced tendinopathy

J L Cook,[1] C R Purdam[2]

Br J Sports Med 2009;**43**:409–416. doi:10.1136/bjsm.2008.051193



Stage	Physical management
Reactive tendinopathy/early tendon dysrepair	Load management. Reduction in frequency ± intensity of tendon load
Late tendon dysrepair/ degeneration	Exercise with eccentric component, ESWT, frictions, ultrasound

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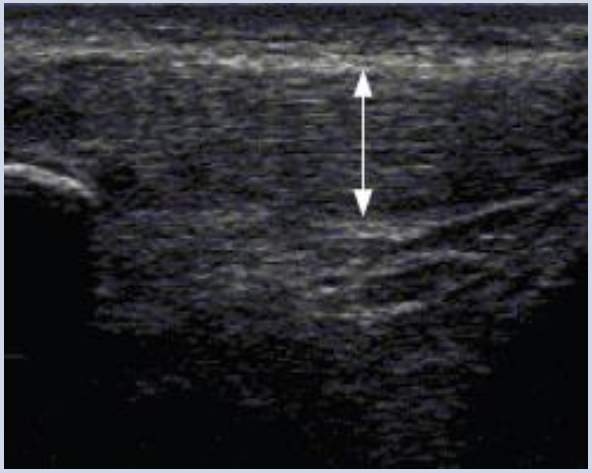
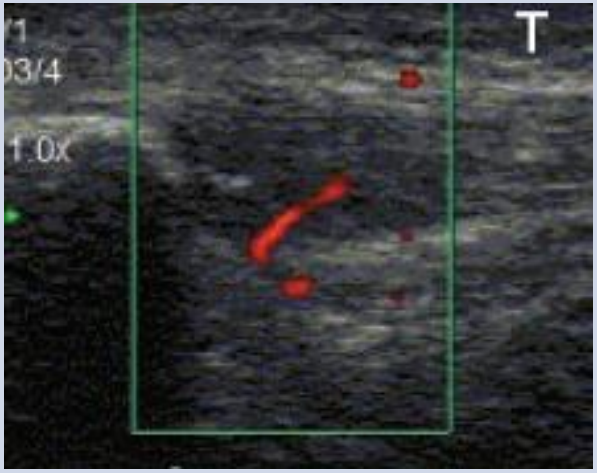
Reactive tendinopathy

Tendon swollen
Intact collagen structures



Degenerative tendinopathy

Increased tendon size
Hypoechoic regions
Clear neovascularization



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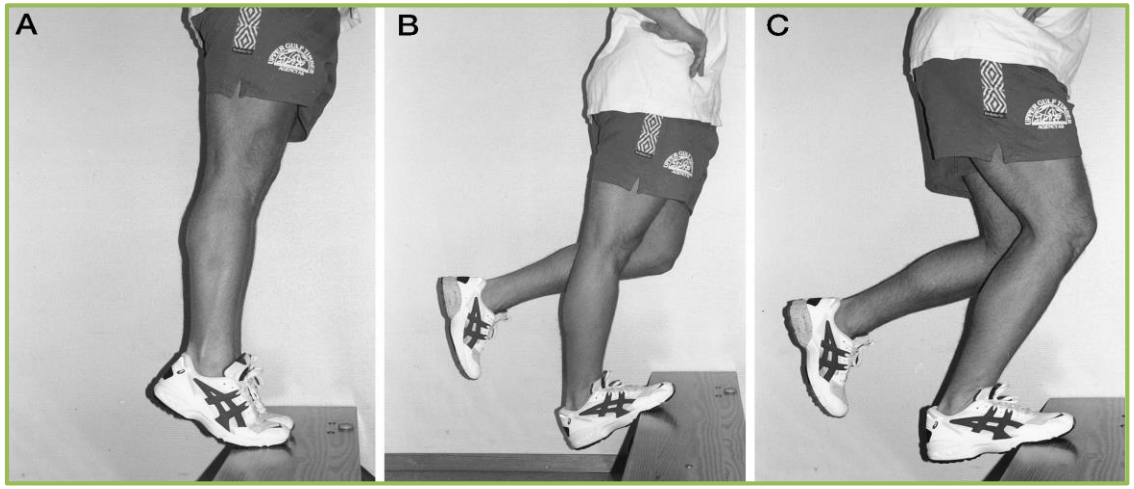
Eccentric exercises (active stretching)



Protocol:

- 15 repetitions x 3 series
- 2/day
- 7 days/week
- 12 weeks

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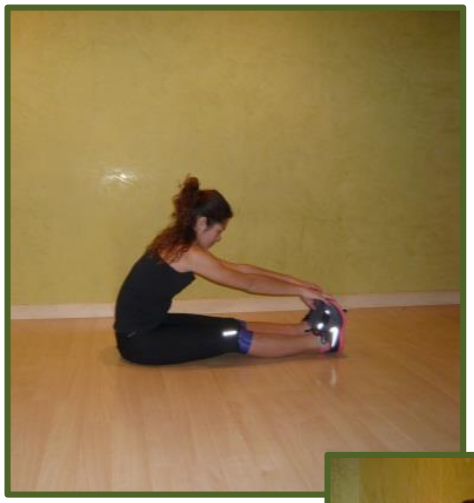
Passive stretching



Gastrocnemius

Soleus

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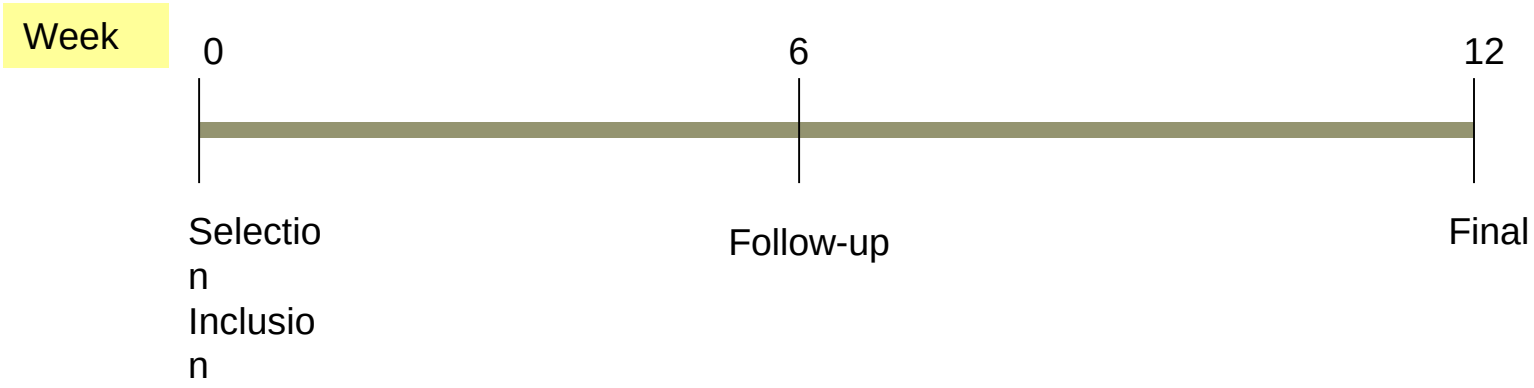
VISITS:



Primary outcome: VISA-A Score (index of severity of symptoms)

Secondary outcomes:

- Pain (VAS) during rest / activity
- Ultrasonographic Tissue Characterization/Power Doppler sound
- Return to sport
- SF-36 v2 quality of life survey
- Patient satisfaction
- Consumption of rescue medication

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Study website:

A specific website has been designed for the study including:

- Electronic CRD
- Study Database
- Unified Randomization program
- Blinding system for statistical analysis

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CENTERS:

CENTER	INVESTIGATOR
CEARE (Centre d'Estudis de l'Alt Rendiment Esportiu) – Consell Català de l'Esport	Dr. Ramon Balius*
Clínica AMS Alavi - Málaga	Dr. Guillermo Álvarez
Clínica Traumatológica - Valladolid	Dr. Fernando Baró
Centro de Medicina y Deporte - Toledo	Dr. Fernando Jiménez
Clínica Diagonal – BCN / Tarragona	Dr. Carles Pedret

* Main investigator

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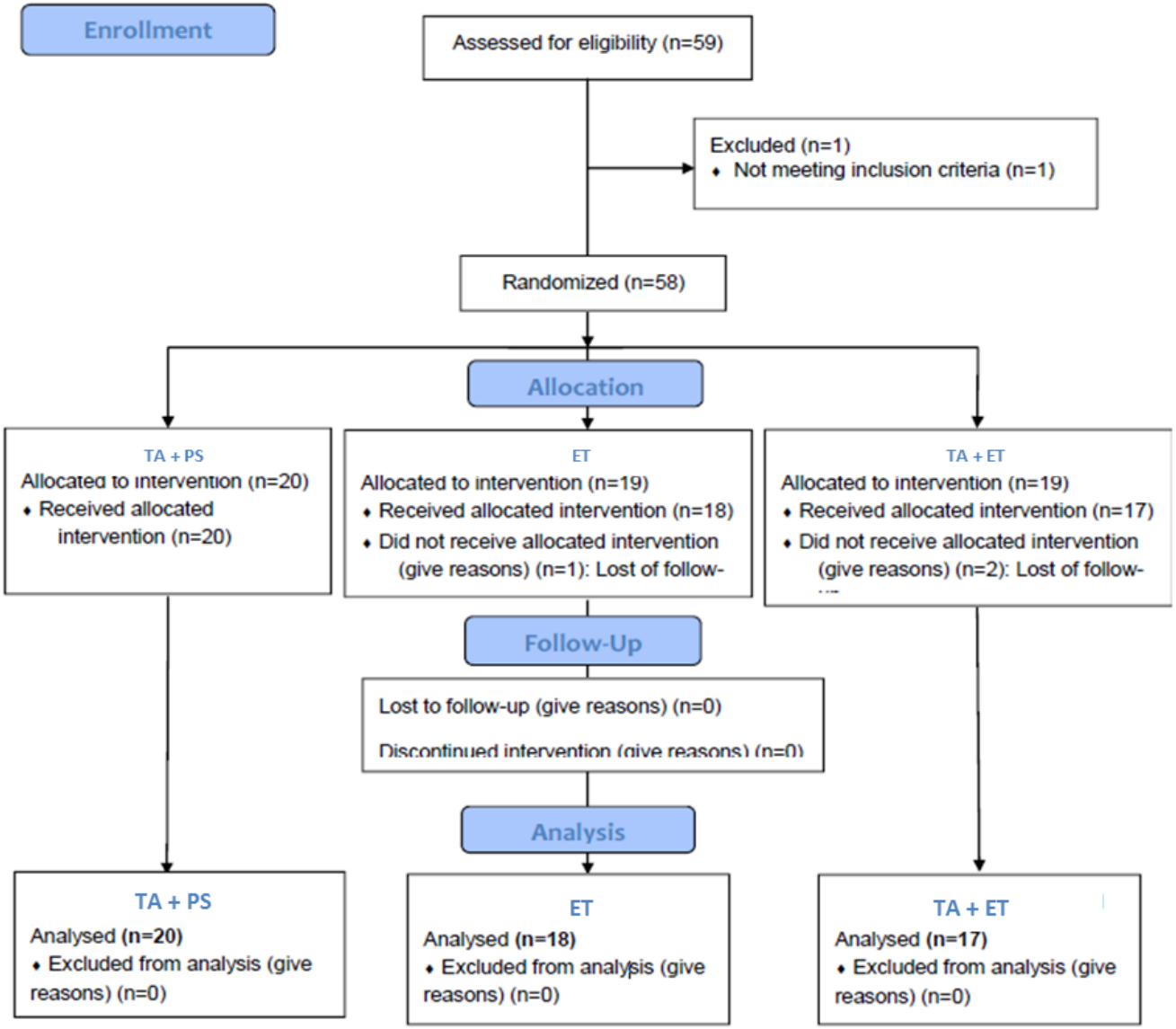

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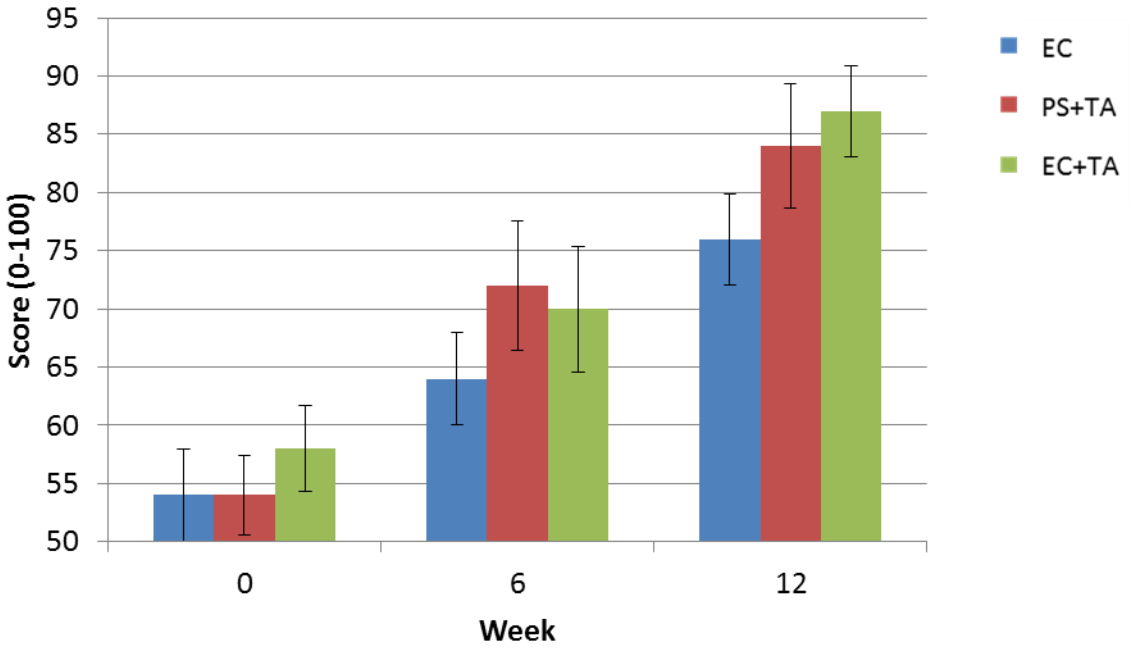
VISA-A (Functional Index):



- Significant improvement in all 3 treatment groups
- No differences between groups were detected at the end of the study

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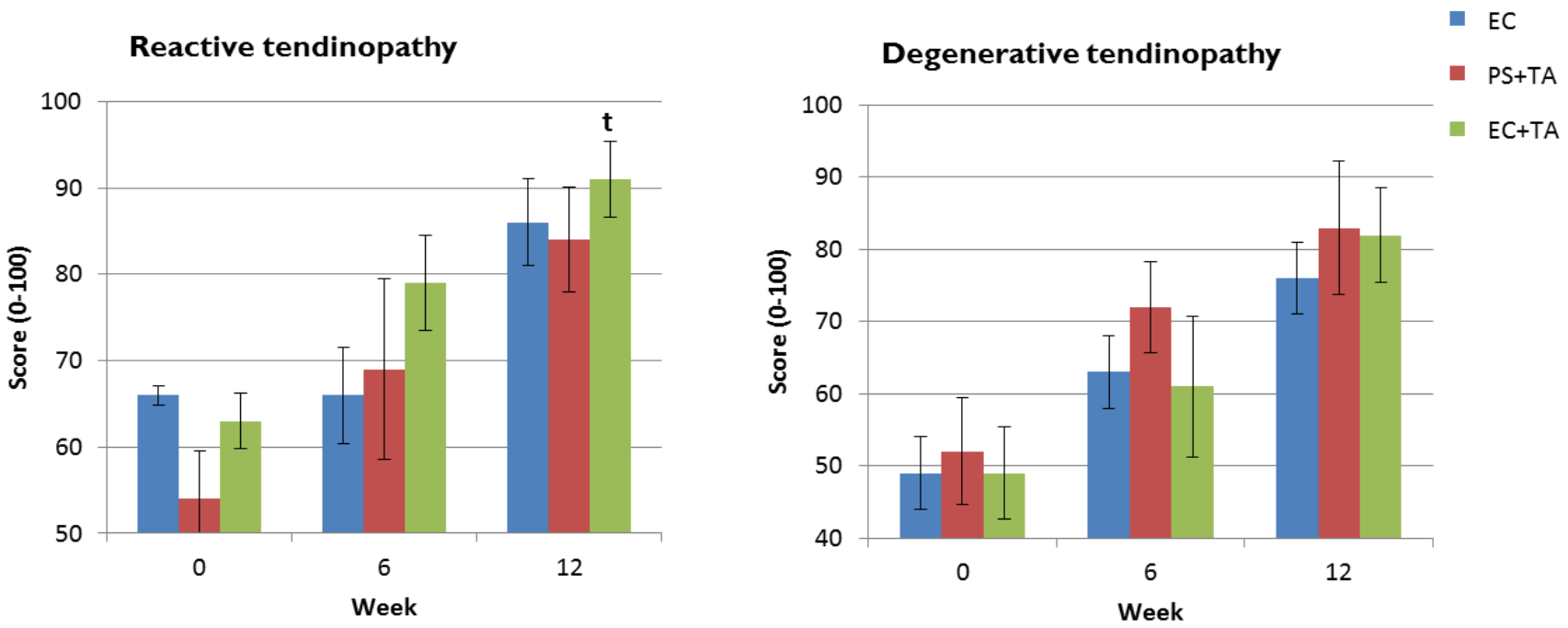
VISA-A (Functional Index):



- In patients with reactive tendinopathy, the EC+TA treatment tended to obtain a better recovery than the eccentric training alone (t P=0.069)

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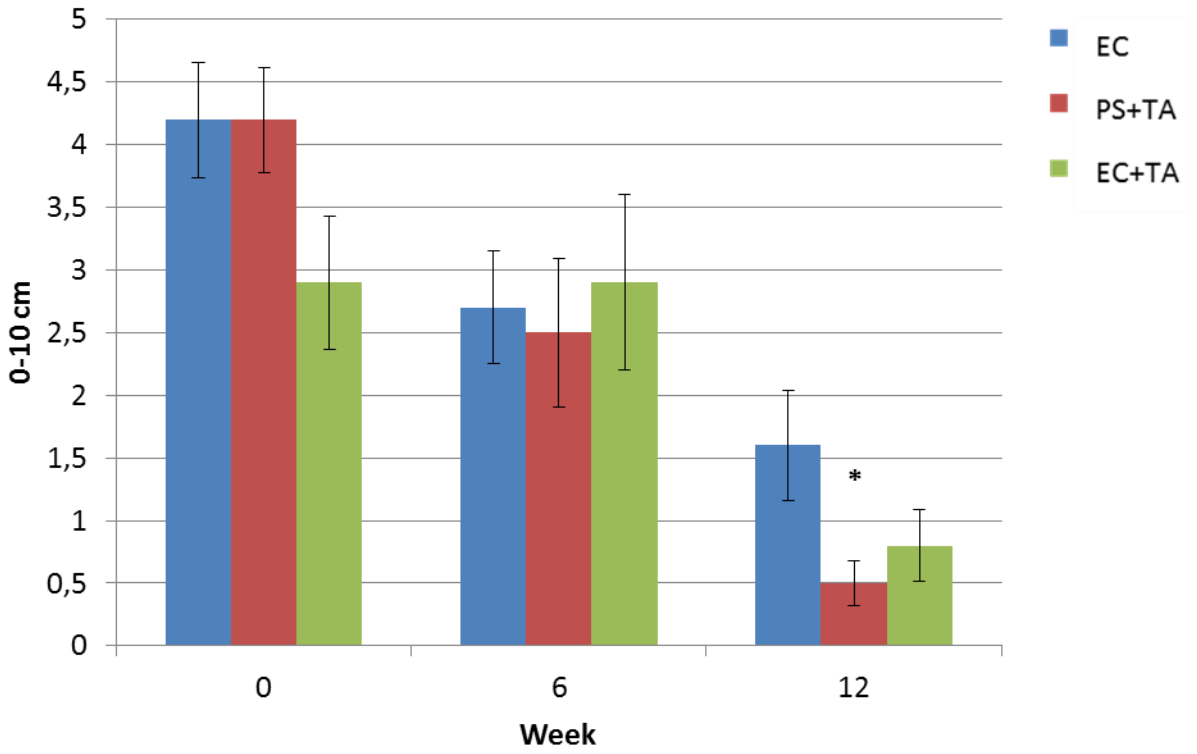
INTENSITY OF PAIN DURING REST (VAS)



- Significant improvement in all 3 groups
- Significantly greater reduction in the PS+TA group compared to the eccentric group (*P<0.05)

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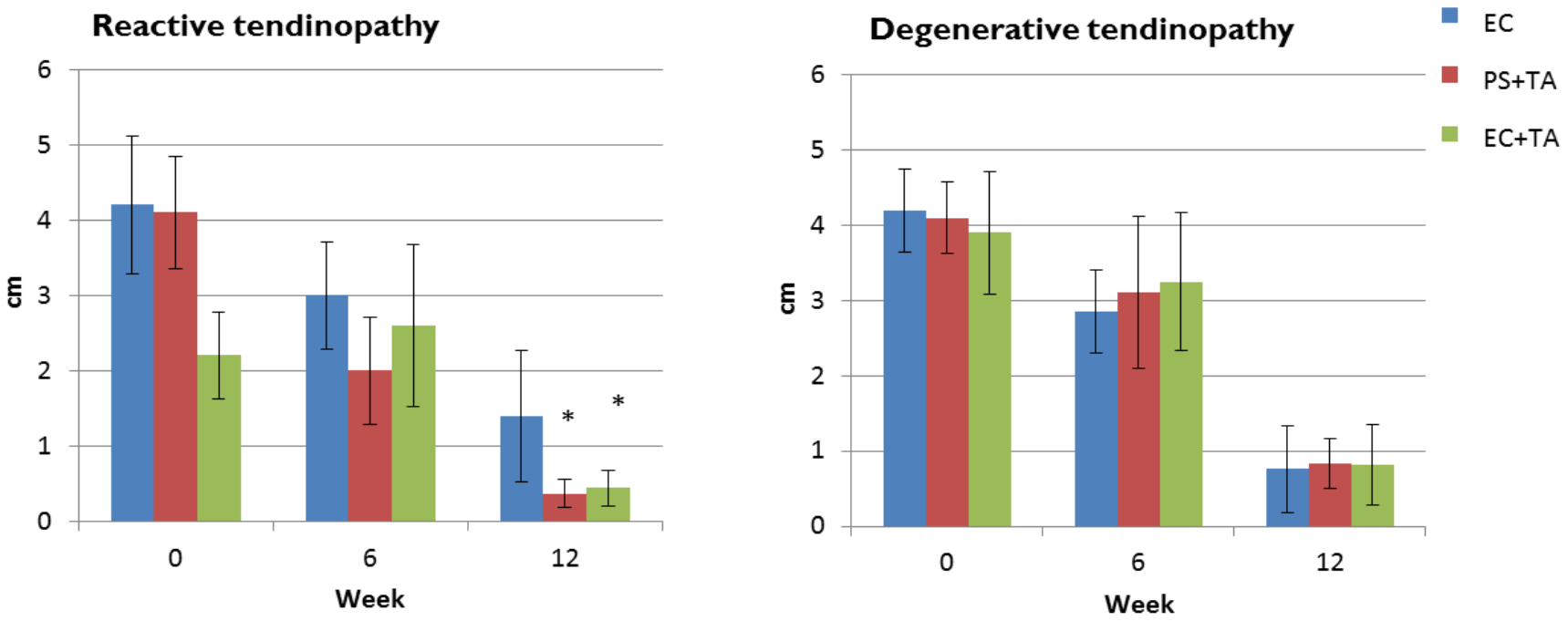
INTENSITY OF PAIN DURING REST (VAS)



- In patients with reactive tendinopathy the reduction on pain level was significantly greater in both groups supplemented with TA than in the EC group (*P<0.05)

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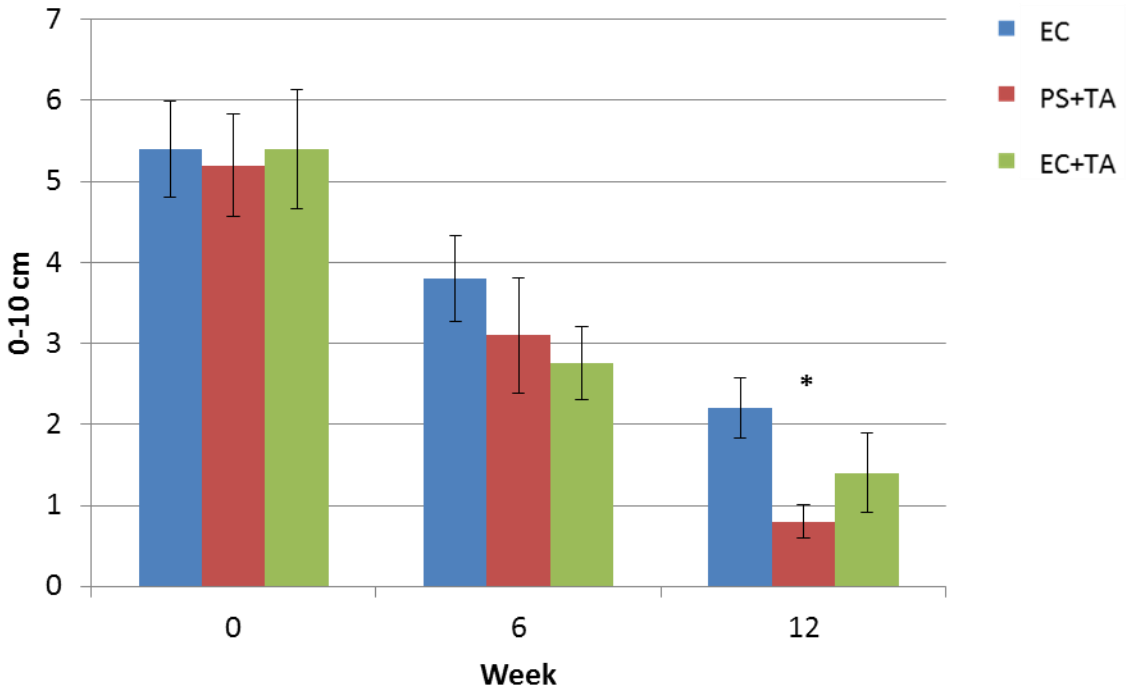
INTENSITY OF PAIN DURING ACTIVITY (VAS)



- Significant improvement in all 3 groups
- Significantly greater reduction in the PS+TA group compared to the eccentric group (*P<0.05)

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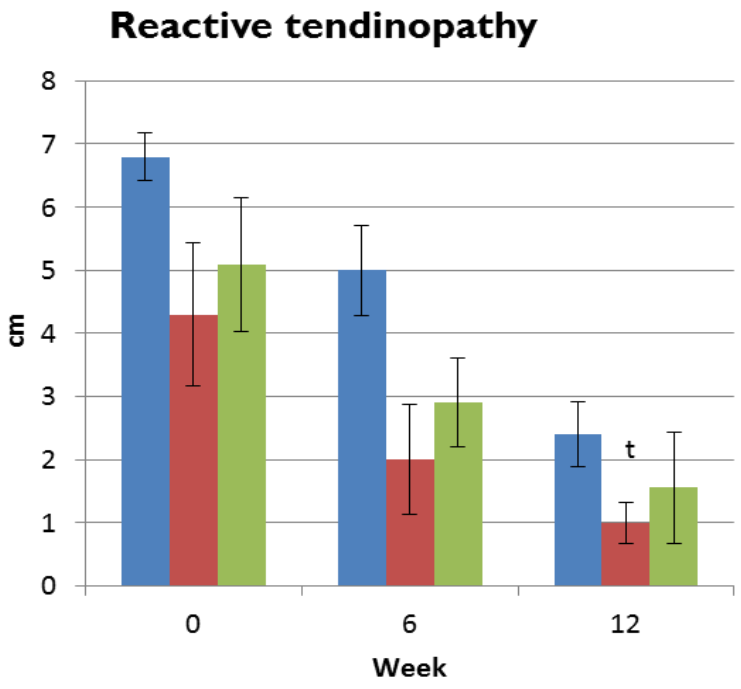

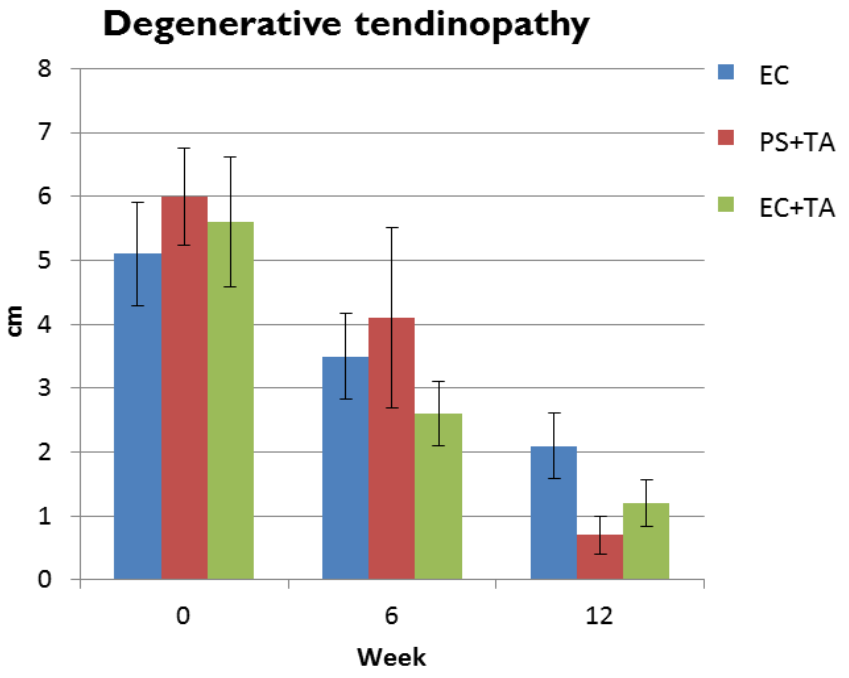

- In patients with reactive tendinopathy, greater pain reduction in PS+TA group compared to EC group (t P=0.074).

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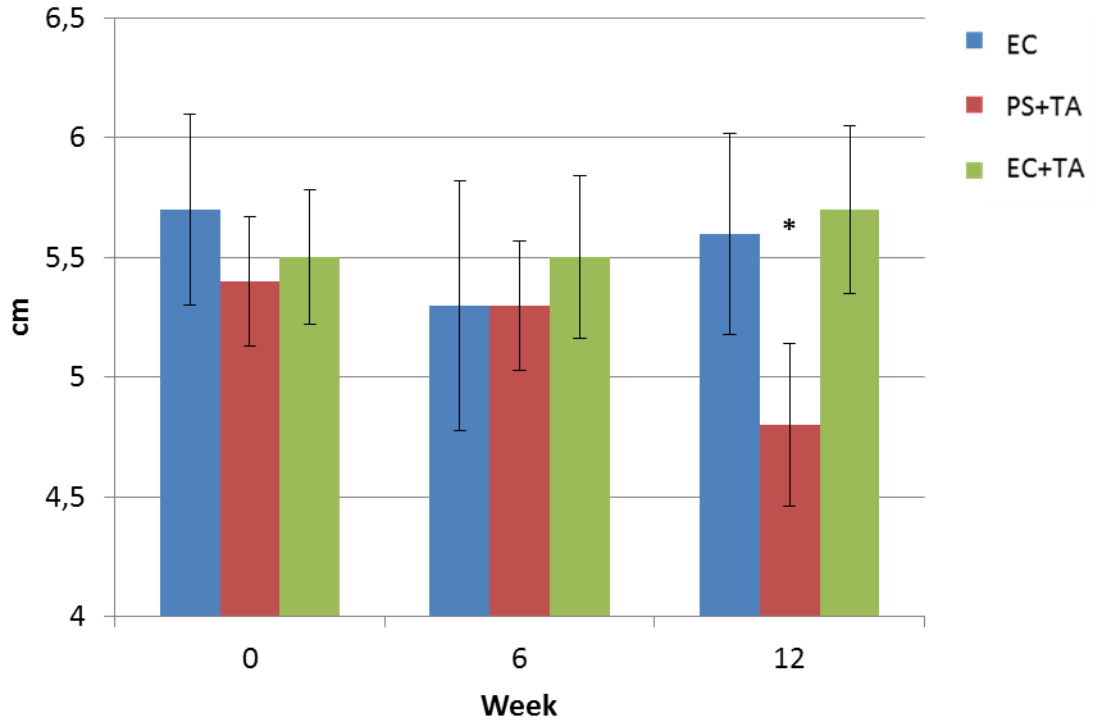
BILATERAL THICKNESS OF THE AFFECTED TENDON



- In eccentric and combination groups thickness of the tendon was constant
- A significant reduction of 27% was detected in the Tendoactive group (*P<0.05)

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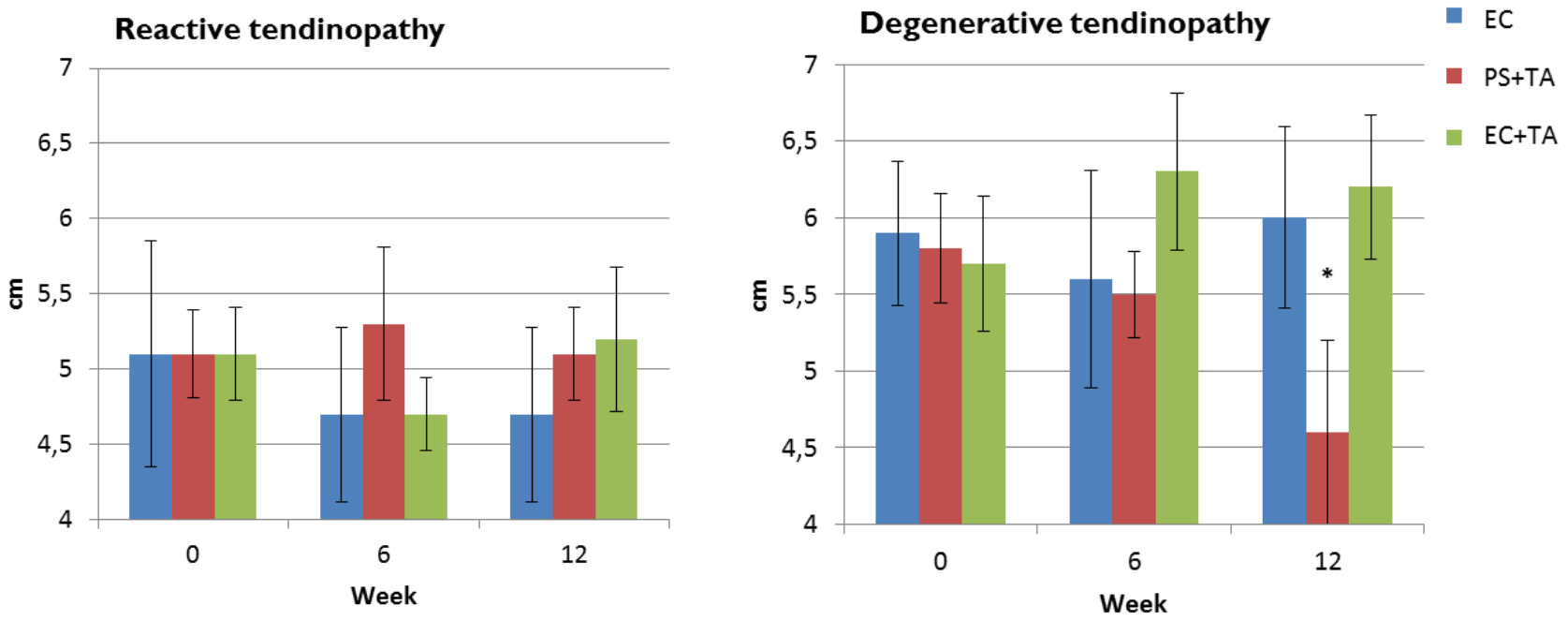
BILATERAL THICKNESS OF THE AFFECTED TENDON



- In patients with reactive tendinopathy bilateral thickness of the affected tendon was constant during the studied period
- In patients with degenerative tendinopathy, a 27.3% reduction was detected in the PS+TA group as compared to baseline, resulting in significant differences among treatment groups at 12 weeks follow-up (*P<0.05)

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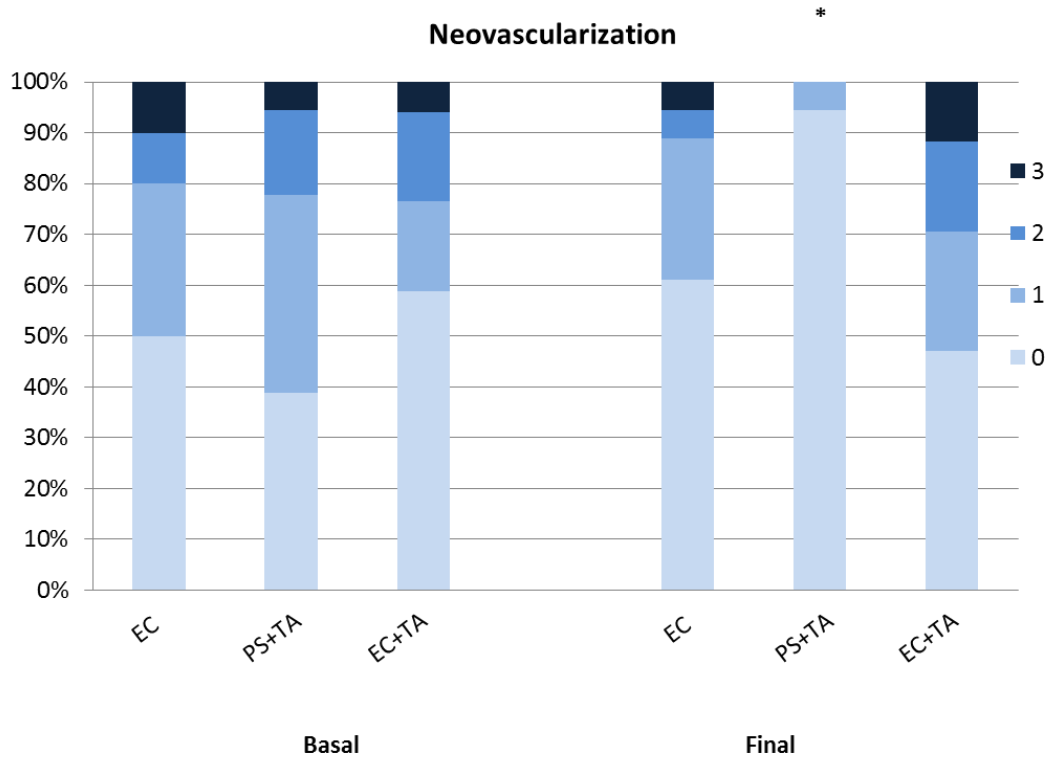
ULTRASONOGRAPHIC ASSESSMENT



*P<0.05

- The degree of neovascularization was significantly reduced in the PS+TA group compared to EC (*P<0.05)

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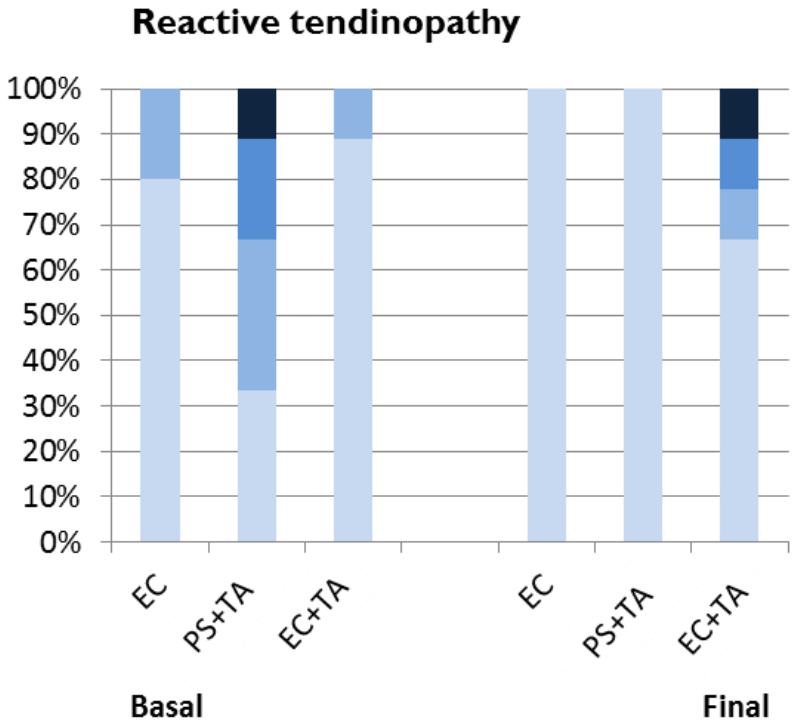
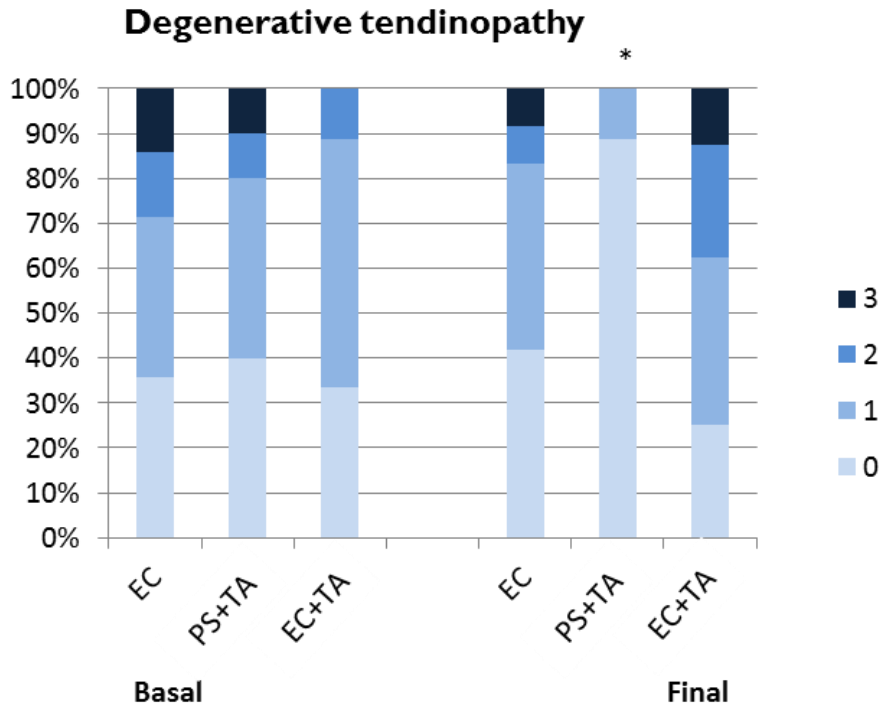
NEOVASCULARIZATION





- The degree of neovascularization was significantly reduced in the PS+TA group compared to EC, only in degenerative tendinopathy (*P<0.05)
- No differences between groups were detected in reactive tendinopathy.

CONCLUSIONS

EFFICACY

- The addition of Tendoactive to the eccentric protocol results in a significant improvement in terms of pain and also tends to improve the function as measured with VISA-A
- When splitting the sample according to severity, results remained significant in patients with reactive tendinopathy
- A protocol of passive stretching supervised by a physiotherapist has been shown to be as effective as a standard eccentric training for management of Achilles tendinopathy when combined with Tendoactive

SAFETY

- No adverse effects related to the treatment were reported during the clinical trial

Tendoactive is safe and effective for management of Achilles tendinopathies, providing an additional benefit to eccentric training, especially at early stages.