Total Tendon Repair

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

**CENTRO**
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- Clinica 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)
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- Dr. Dr. José González / 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

Included (ITT) = 98
- Achilles = 32
- Epicondylitis = 34
- Patellar= 32

PP population = 70
- Achilles = 21
- Epicondylitis = 28
- Patellar= 21

Dropouts = 28*
- Achilles = 11
- Epicondylitis = 6
- Patellar= 11

* 28 patients didn’t complete the 3 months treatment
## BASELINE CHARACTERISTICS

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

ACHILLES TENDINOPATHY

* p<0.05 compared to baseline
RESULTS: FUNCTIONAL SCORE – ACTIVITY LEVEL

ACHILLES TENDINOPATHY

* p<0.05 compared to baseline
RESULTS: PAIN (VAS)

* p<0.05 compared to baseline
RESULTS: FUNCTIONAL SCORE – ACTIVITY LEVEL

VISA-P

![Graph showing VISA-P score over days of treatment]

Activity level

![Graph showing activity level over days of treatment]

* p<0.05 compared to baseline
RESULTS: PAIN (VAS)

* p<0.05 compared to baseline
RESULTS: FUNCTIONAL SCORE – ACTIVITY LEVEL

PRTEE (inversely scored)

* p<0.05 compared to baseline

Activity level

* p<0.05 compared to baseline
RESULTS: ULTRASONOGRAPHIC ASSESSMENT

ACHILLES TENDINOPATHY

Thickness of the affected tendon

* p<0.05 compared to baseline
RESULTS: ULTRASONOGRAPHIC ASSESSMENT

ACHILLES TENDINOPATHY

Paratenon blurring

Heteroechogenicity

Hipoechoogenicity

Neovascularization

* p<0.05 compared to baseline
RESULTS: ULTRASONOGRAPHIC ASSESSMENT

* p<0.05 compared to baseline
**RESULTS: ULTRASONOGRAPHIC ASSESSMENT**

**PATELLAR TENDINOPATHY**

* p<0.05 compared to baseline

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**Paratenon blurring**

- 0% at 0, 30, 60, 90 days
- 100% at 0, 30, 60, 90 days

**Heteroechogenicity**

- 0% at 0, 30, 60, 90 days
- 100% at 0, 30, 60, 90 days

**Hipoechochogenicity**

- 0% at 0, 30, 60, 90 days
- 100% at 0, 30, 60, 90 days

**Neovascularization**

- 0% at 0, 30, 60, 90 days
- 100% at 0, 30, 60, 90 days
RESULTS: ULTRASONOGRAPHIC ASSESSMENT

EPICONDYLITIS

* p<0.05 compared to baseline
RESULTS: ULTRASONOGRAPHIC ASSESSMENT

EPICONDYLITIS

Paratenon blurring

Heteroechogenicity

Hipoechoogenicity

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-hypoechochogenecity and paratenon blurring

Patellar tendon showing neovascularization (Power Doppler)
RESULTS: ANALGESICS CONSUMPTION

ACHILLES TENDINOPATHY

% of patients consuming analgesics

Days of treatment

0% 20% 40% 60% 80% 100%

0 30 60 90

EPICONDYLITIS

% of patients consuming analgesics

Days of treatment

0% 20% 40% 60% 80% 100%

0 30 60 90

PATELLAR TENDINOPATHY

% of patients consuming analgesics

Days of treatment

0% 20% 40% 60% 80% 100%

0 30 60 90

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

Days of treatment

0% 20% 40% 60% 80% 100%

30 60 90

Very good
Good
So-so
Bad

EPICONDYLITIS

Patient’s satisfaction

Days of treatment

0% 20% 40% 60% 80% 100%

30 60 90

Very good
Good
So-so
Bad

PATELLAR TENDINOPATHY

Patient’s satisfaction

Days of treatment

0% 20% 40% 60% 80% 100%

30 60 90

Very good
Good
So-so
Bad
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.