Percutaneous Tenolig® repair under intra-operative ultrasonography guidance in acute Achilles tendon rupture

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\textbf{A B S T R A C T}

\textbf{Background:} Acute Achilles tendon rupture can be treated conservatively or surgically. Open surgery restores tendon continuity but carries a risk of skin complications. Tenolig® is a device designed for the percutaneous biological treatment of acute Achilles tendon rupture. Earlier studies found high rates of recurrent tears and nerve injury after Tenolig® repair.

\textbf{Hypothesis:} We hypothesised that intra-operative ultrasonography during Tenolig® repair would decrease the post-operative complication rate and improve functional outcomes.

\textbf{Materials and methods:} We studied 75 consecutive patients with a mean age of 39.9 years. The injury was sports-related in 82.8% of cases. Mean distance from the calcaneal tendon attachment to the tear was 5 cm and mean time from injury to repair was 4.2 days. All patients underwent Tenolig® repair under ultrasonic guidance followed by early rehabilitation therapy with partial weight bearing started after 3 weeks.

\textbf{Results:} Mean follow-up was 20.7 months and no patient was lost to follow-up. A single patient (1.3\%) experienced rerupture and none had permanent sural nerve damage. Mean time to sports resumption was 8.6 months, with two-thirds of patients returning to their previous level of sporting activities. The mean AOFAS functional score was 95 and the mean ATRS score was 91.3.

\textbf{Discussion:} Our experience suggests that intra-operative ultrasonography, a non-invasive, widely available, and accurate tool, provided improved control of Tenolig® suture position. Ultrasonography provided valuable guidance during this demanding procedure and allowed the very early initiation of rehabilitation therapy. Another crucial factor is patient education about the physical therapy programme. Attention to this point allowed us to obtain robust and reliable functional outcomes in a population predominantly composed of athletes.

\textbf{Level of evidence:} Level IV.

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1. Introduction

The management of acute Achilles tendon rupture has long been a focus of debate between those who advocate conservative methods and those who prefer surgery [1]. The first standardised orthopaedic treatment was developed by Lea et al. in 1968 [2]. Conservative treatment carries no risk of skin complications or infection. Its main drawbacks consist in high rates of rerupture, tendon stretching, and muscle wasting [3].

No consensus exists about the best surgical treatment. Open surgery restores tendon continuity but carries a risk of skin adhesions and infection, as well as of nerve injury, with a complication rate of up to 34.1\% [4]. Several percutaneous techniques have been reported since the seminal description by Ma and Griffith in 1977 [5]. Tenolig® (FH Orthopedics, Heimsbrunn, France) is a device developed by Delpont et al. [6] to maintain the tendon stumps in contact with each other. Although the risk of infection is low, Maes [7] has reported rerupture in 10\% of cases and sural nerve injury in 6.4\%. In a study of 21 patients, Soubeyrand et al. [8] found that the Tenolig® needle was located outside the tendon in 45\% of cases.

We sought to improve the outcomes of Tenolig® repair in patients with acute Achilles tendon rupture. Our goal was to increase the reliability of suture positioning while preserving the sural nerve and allowing early rehabilitation therapy in accordance...
with current recommendations [9]. Our working hypothesis was that intra-operative ultrasonography to guide Tenolig® repair would decrease the post-operative complication rate and improve the functional outcomes.

2. Material and methods

Between 2008 and 2012, 85 patients were managed in our department for Achilles tendon rupture. For this study, we prospectively enrolled consecutive patients.

2.1. Inclusion and exclusion criteria

Acute Achilles tendon rupture was the only inclusion criterion. Exclusion criteria were chronic tendon rupture (time since rupture longer than 21 days), recurrent tendon rupture, proximal rupture at the muscle-tendon junction, distal tendon detachment, and contraindications to surgery.

2.2. Patients

We included 75 patients, all of whom were managed by percutaneous implantation of the Tenolig® device under intra-operative ultrasonography guidance, followed by early rehabilitation therapy.

Table 1 reports the main epidemiological data. The patients fell into three categories based on the type of sports they engaged in: pivoting-contact sports (badminton, volleyball, tennis, basketball, judo, handball, and hip-hop), straight-line sports (swimming, running, hiking, all terrain bicycling), and both (pivoting and straight-line). Three patients had a remote history of contralateral Achilles tendon rupture; 1 had been treated by open surgery and 2 by Tenolig® repair.

2.3. Operative technique

The patient was prone with a pad under the ankle (Fig. 1). The procedure was performed without a tourniquet. The ultrasound machine was a portable M-Turbo® (SonoSite Inc., Bothell, WA, USA). A Tenolig® kit was used.

After palpation of the gap, the surgeon identified the ultrasound landmarks alone. None of the surgeons received any specific training from radiologists. Ultrasonography was used to determine the location of the stumps and to identify the lateral and medial posterior edges of the tendon. Disappearance of the gap upon flexion of the foot was checked on the ultrasound images. The sural nerve was identified from the lateral retro-malleolar groove near the saphenous vein to the intersection with the lateral edge of the tendon (Figs. 2–4), with the help of the anaesthesiologists given their expertise in this area. The proximal stab incisions and distal exit points were determined based on the location of the tear. If required by the level of the intersection with the sural nerve, the lateral entry point was shifted medially to avoid injuring the sural nerve during insertion of the needle (Fig. 5). Progression of each needle was monitored on the transverse ultrasound image to allow proper positioning within the tendon down to the exit point (Fig. 6). After tensioning and tightening of the sutures, ultrasonography was used to check that the two tendon stumps were in close contact with each other.

2.4. Post-operative care

Anticoagulation in prophylactic dosages was given for 45 days. An anterior splint maintaining the ankle in 30° of plantar flexion

Fig. 1. The patient is in the prone position with a pad under the ankle. Note the ultrasound machine and transducer.

Fig. 2. Identification of the sural nerve, starting at the retro-malleolar groove.
Fig. 3. Transverse view of the sural nerve (arrow) at the lateral edge of the tendon sheath.

Fig. 4. Intersection of the sural nerve and lateral edge of the tendon.

was worn for 21 days, during which weight bearing was eliminated. Mobilisation was started immediately and consisted in passive and assisted active plantar flexion and dorsal flexion to no more than 90° by day 45. Partial weight bearing with a walking orthosis and a heel lift to maintain 30° of plantar flexion was started after 3 weeks. The Tenolig® sutures were removed after 6 weeks, and full weight bearing was then started, with stepwise decreases in the height of the heel lift at 2-week intervals. Triceps-strengthening exercises and resumption of sports training were started after 3 months.

2.5. Evaluation criteria

We evaluated our working hypothesis based on the duration of post-operative follow-up, occurrence of post-operative complications, and functional outcome. We considered three categories of post-operative complications: systemic, local major (rupture, permanent sural nerve damage, and deep infection), and local minor (rupture at the muscle-tendon junction, transient sural nerve damage, superficial infection, and distal skin ulcer). To assess the functional outcome we used the time to work resumption, sporting activities (return to the same sport or change to another sport, level of sporting activity, and time to sports resumption), gait analysis, range of passive dorsal flexion comparatively to the contralateral ankle, symmetry of physiological equinus in the prone position with the knees flexed, and subjective apprehension. We also determined the functional American Orthopaedic Foot and Ankle Society (AOFAS) Ankle-Hindfoot score (maximum, 100 points) [10] and the functional Achilles Tendon Rupture Score (ATRS) (maximum, 100 points) [11].

3. Results

Mean follow-up was 20.7 months (12–36). No patients were lost to follow-up.

3.1. Post-operative complications

A single patient (1.3%) experienced a rerupture. This 57-year-old male was an athlete with no history of smoking or tendinopathy. He underwent surgery 4 days after the injury. The tendon repair was satisfactory and the post-operative course uneventful. Time to the rerupture was 9 weeks, i.e., 3 weeks after removal of the Tenolig® device. He had resumed full weight bearing and no longer used the heel lift. The rupture occurred during brisk walking in the absence of a well-characterised trauma.

Rupture at the muscle-tendon junction occurred in 3 (3.9%) patients, after 2.5 months, during physical therapy sessions. These ruptures were located proximally, at a considerable distance from the tendon, which was continuous and painless. They were treated functionally, without discontinuing the rehabilitation therapy programme.

Paraesthesia in the territory of the sural nerve was reported by 2 (2.6%) patients and resolved spontaneously within 4 months. Superficial infection developed in 3 (3.9%) patients and distal skin ulcers in 8 (10.7%) patients.

No patient experienced permanent sural nerve damage or deep infection.
3.2. Functional outcome

Mean time to work resumption was 54 days (0–90). Of the 75 patients, 55 (73.3%) were able to return to their previous sport and 35 (46.7%) of these 55 returned to the same level of sporting activity, whereas 20 (36.4%) reported resuming the same sport at a lower level because of apprehension, which they described verbally as a mental block driven by fear or by recollections of the injury. The 20 (20/75, 26.7%) patients who switched to another sport reported that apprehension was the reason for this decision; they changed from pivoting sports to sports involving straight-line activities or postures (surfing or tai chi). Mean time to sports resumption was 8.6 months (4–12) (Fig. 7). Some of the patients reported high-level performances: 47 km all terrain bicycling competition after 5 months, return to professional hip-hop practice after 4 months (Fig. 8), and national judo competition after 8 months (these last 2 patients had a remote history of contralateral Achilles tendon rupture).

A single patient (1.3%) had an abnormal gait, even at last follow-up. This was the patient with a rerupture. Dorsal flexion was limited compared to the other side in 4 (5.3%) patients and increased in 5 (6.7%) patients. Physiological equinus was asymmetrical in 5 (6.7%) patients. Subjective apprehension was reported by 40 (53.3%) patients. The mean AOFAS score was 95 (80–100) and the mean ATRS was 91.3 (70–100).

4. Discussion

In our prospective study of consecutive patients, the functional outcomes were satisfactory, with all patients being able to resume sporting activities, after a mean of 8.6 months and at the previous level in 63.6% of cases. The post-operative complication rate was very low. No patients experienced complications related to ultrasoundography, which we believe is helpful during surgery to repair acute Achilles tendon ruptures.

No previous studies have evaluated Tenolig® repair under ultrasound guidance. Intra-operative ultrasonography is a non-invasive, non-irradiating, and inexpensive investigation that can be performed in the operating room with help from the anaesthesiologists. The intra-operative use of ultrasonography does not significantly increase the operating time [12]. Ultrasonography improves the reliability of suture positioning by providing real-time images of the boundaries of the tendon and their relationships with the sural nerve.

The sample size was substantial in our study, and all our patients practiced sports regularly. The characteristics of our population are consistent with previously published data. We had a very low rerupture rate (1.3%) after a mean follow-up of 20.7 months. None of the patients experienced permanent damage to the sural nerve. The learning curve for ultrasound evaluation of the Achilles tendon was extremely short. Evaluation of the sural nerve proved more challenging but was facilitated by the clear visibility of the external saphenous vein travelling alongside the nerve. This point may explain the 2 (2.6%) cases of transient sural nerve damage at the
beginning of our experience. In a study comparing Tenilig® repair with and without ultrasonography, we found that ultrasound guidance significantly decreased the risk of sural nerve injury [12]. In a cadaver study of the anatomic relationships between the sural nerve and the lateral tendon edge, Webb et al. [13] showed that the intersection was located 6.55 to 10 cm proximal to the calcaneal tendon attachment. Thus, the trajectory of the sural nerve varies widely across individuals.

The only rerupture in our study was seen in a 57-year-old male whose time to surgery was well within recommendations and whose post-operative course was uneventful. The reasons of the recurrence are unclear but may involve the relatively advanced age of the patient and excessively rapid discontinuation of use of a heel lift. The skin healing disturbances seen in our study (10.7%) are inherent in the technique and may be viewed as among the limitations of Tenilig® repair. They consisted in distal skin ulcers at the points of contact with the buttons, which healed after Tenilig® removal (Fig. 9). The immediate initiation of rehabilitation therapy and resumption of partial weight bearing after 3 weeks may have increased the risk of skin ulcers. Apprehension was reported by 40 patients, of whom half switched to another sport and half returned to the same sport at a lower level. Tendon stretching was considerably less common. This point may have influenced the functional score values in our study. Two patients with a distant history of contralateral Achilles tendon rupture were able to resume intensive training very early, with no restrictions. They may have been particularly effective in coping with their apprehension during the recovery period.

Tenilig® is a compromise between open surgery and conservative treatment. Conservative treatment requires prolonged immobilisation and carries a high risk of rerupture. Open surgery is associated with skin complications (deep infection and tendon adhesions) and neurological injury [14]. Although Tenilig® repair was introduced many years ago, few studies have evaluated the outcomes. High rates of rerupture (10%) and sural nerve injury (6.4%) have been reported [7], as well as suboptimal positioning of the sutures [8]; Table 2 recapitulates the data from earlier studies of Tenilig®. The study by Maes et al. included a substantial number of patients but had a high rate of post-operative complications [7]. In a smaller sample size, Taglilavoro et al. [15] observed a higher rate of transient sural nerve injury (7.1% versus 2.6%), as well as a higher rate of rerupture (7.1% versus 1.3%) similar to that reported by Mertl et al. (7.7%) [17]. In a meta-analysis of randomised controlled trials comparing open surgery to percutaneous surgery, Khan et al. [14] found a significantly higher rate of deep infections with open surgery (19.6% versus 0% with percutaneous surgery). The difference in the rate of rerupture (4.3% with open surgery versus 2.1% with percutaneous surgery) was not statistically significant. These data should be interpreted with circumspection as Tenilig® repair was only one of several different types of percutaneous treatment used in the trials.

No published studies have compared Tenilig® repair to open surgery. A comparison of functional outcomes with these two treatments would be of interest. One possibility is that, regardless of the repair method used, obtaining good functional outcomes is dependent on early and prolonged rehabilitation therapy. A recent study found no significant difference in functional outcomes between open surgery and conservative treatment with immediate initiation of rehabilitation therapy in both groups [18].

Table 2
Data from studies of Tenilig®: post-operative complications and functional outcomes.

<table>
<thead>
<tr>
<th>Authors</th>
<th>Year</th>
<th>Number of patients</th>
<th>Rerupture</th>
<th>Sural nerve damage</th>
<th>Time to return to work</th>
<th>Time to return to sports</th>
<th>Level of return to sports</th>
<th>Scores</th>
</tr>
</thead>
<tbody>
<tr>
<td>Our study</td>
<td>2013</td>
<td>75</td>
<td>1 (1.3%)</td>
<td>0</td>
<td>54 days (0–90)</td>
<td>8.6 months (4–12)</td>
<td>Same: 63.6%</td>
<td>AOFAS 95 (80–100)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>ATRS 91.3 (70–100)</td>
</tr>
<tr>
<td>Taglilavoro [15]</td>
<td>2011</td>
<td>28</td>
<td>2 (7.1%)</td>
<td>0</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>Gigante [16]</td>
<td>2008</td>
<td>20</td>
<td>0</td>
<td>0</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>McComis 65.12</td>
</tr>
<tr>
<td>Maes [7]</td>
<td>2006</td>
<td>124</td>
<td>12 (10%)</td>
<td>8 (6.4%)</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>Mertl [17]</td>
<td>1999</td>
<td>26</td>
<td>2 (7.7%)</td>
<td>0</td>
<td>9: &lt;2 months</td>
<td>14: 3 months</td>
<td>Same: 55%</td>
<td>NR</td>
</tr>
<tr>
<td>Delporte [6]</td>
<td>1992</td>
<td>28</td>
<td>0</td>
<td>NR</td>
<td>7–30 days</td>
<td>45–139 days (1.5–4.6 months)</td>
<td>NR</td>
<td>NR</td>
</tr>
</tbody>
</table>

NR: not reported.
These data emphasise the need for early rehabilitation therapy and for patient education and adhesion to the rehabilitation programme. A prerequisite to early rehabilitation therapy is proper suture position and close approximation of the tendon stumps. Ultrasonography ensures that these conditions are met. It would be unacceptable now to contraindicate immediate rehabilitation therapy after stable percutaneous internal fixation because of the lack of intra-operative imaging. The certainty and confidence provided by intra-operative ultrasonography are communicated to the patient via empathy, thereby reassuring the patient during the recovery phase and combating the subjective limitations related to apprehension, on which we have little control. Special caution is required during the period from device removal to the end of the third postoperative month, during which the height of the heel lift should be decreased gradually, most notably in patients older than 50 years of age.

Disclosure of interest

The authors declare that they have no conflicts of interest concerning this article.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at doi:10.1016/j.otsr.2014.09.018.

References
