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Acute Achilles Tendon Ruptures: Efficacy of Conservative and Surgical (Percutaneous, Open) Treatment—A Randomized, Controlled, Clinical Trial

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ABSTRACT

There is controversy regarding the best treatment for acute ruptures of the Achilles tendon. Multiple treatments present good results in the short and long term, none being superior to the other if a protocol of rehabilitation with full early weightbearing rehabilitation is followed. The objective of this study was to provide evidence on the efficacy and safety of conservative or surgical (percutaneous or open) treatment for acute Achilles tendon rupture. A randomized, controlled, parallel-groups, pilot clinical trial was performed in patients aged ≥18 years who arrived at the emergency room of our center experiencing acute Achilles tendon rupture. Patients were randomized via a computer-generated list to receive 1 of 3 treatments (conservative, percutaneous surgery, or open surgery). All patients followed the same protocol of rehabilitation with early weightbearing. A responder (i.e., successful treatment) was defined as capable of standing heelrise mono- and bipodally for 3 seconds, having a pain score ≤2 (verbal numerical rating scale) after walking, and having returned to active previous life (sport) at 1-year follow-up. From 2014 to 2017, 34 consecutive patients (median age, 41 years [range 18 to 59]; 32 male [94%]) were included: 11 conservative treatment, 11 percutaneous surgery, and 12 open surgery. At 1-year follow-up, the proportion of responders was 100% (11/11, 95% confidence interval [CI] 74% to 100%), 82% (9/11, 95% CI 52% to 95%), and 83% (10/12, 95% CI 55% to 95%), respectively. There was no case of total rerupture. Similar efficacy was found for conservative, percutaneous, and open surgery treatments for acute Achilles tendon rupture at 1-year follow-up with an early weightbearing rehabilitation program.

Acute Achilles tendon rupture is one of the most common tendon injuries: 11 to 37 of every 100,000 middle-aged people suffer this injury every year. There has been an increase in incidence in recent years, especially in older people. It is usually more frequent in males (ratio 2.9:1 to 5.7:1) and at 30 to 46 years of age (1–5). An area of the Achilles tendon 2 to 6 cm from the insertion on the calcaneus has relatively high avascularization (6), and it is this area where acute ruptures of the Achilles tendon occur most frequently.

There is controversy regarding the optimal treatment for acute ruptures of the Achilles tendon (7). Both conservative and surgical treatments present good results in the short and long term, none being superior to the other. In the past, surgical treatment was more often recommended for young, active patients and athletes, since conservative treatment led to a loss of muscle strength and a higher rate of reruptures. In recent times, it has become clear that with a rehabilitation protocol that includes early weightbearing (in some studies, at 10 days postinjury), similar rerupture rates are achieved in both treatments, with a similar return to daily life. However, more complications after surgical treatments (infections, intolerance, tendinitis) have been reported, even though this last difference was not statistically significant (5,8–17). Studies have demonstrated that early weightbearing of an injured tendon stimulates collagen and the healing process (18).

Our working hypothesis was that conservative treatment involving a rehabilitation protocol with early weightbearing is effective and safe for the treatment of acute Achilles tendon rupture.

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Therefore, the primary objective of this clinical trial was to provide evidence on the efficacy of conservative or surgical (percutaneous or open) treatment for acute Achilles tendon rupture with an early weightbearing rehabilitation protocol. Secondary objectives were to assess the safety of all treatments and the subsequent quality of life of patients.

Patients and Methods

This was a randomized, controlled, parallel-group, unicenter, pilot clinical trial. The study recruited patients with acute Achilles tendon rupture. The ethics committee of the center approved the study protocol. The study was conducted in agreement with the updated Declaration of Helsinki, the guidelines for Good Clinical Practice, and applicable Spanish regulatory requirements. All male and female patients aged 18 to 70 years who arrived at the emergency room of our center experiencing acute Achilles tendon rupture were eligible for the study. All patients provided informed written consent.

The clinical diagnosis of acute Achilles tendon rupture was made when the patient arrived at the emergency room of 1 of the 2 referring hospitals with acute severe pain at the level of the tendon, presenting with hematoma, depression, and discontinuity at the level of the tendon; loss of physiological equinus; inability to perform plantarflexion; and positive Thompson and Matles tests (19,20). For the final diagnosis, an ultrasonography of the tendon was performed where the rupture was identified, revealing the distance to the calcaneal insertion, the distance of the tendon gap, and the existence of signs of tendinosis or chronic tendinopathy. Exclusion criteria were a history of known tendinopathy, chronic ruptures, >10 days since the acute Achilles tendon rupture (21), calcaneal avulsion, myotendinous union lesions, other ipsilateral lesions, open sections of the tendon, or an injury <2 cm or >8 cm from the calcaneal insertion by ultrasound.

A computer-generated randomization schedule was prepared at the start of the study with stratification by 4 variables (to minimize possible bias) according to age (>40 years); whether the patient was a professional athlete or performed regular sports (>4 times per week for 30 min); whether the patient had a previous pathology such as diabetes mellitus, rheumatic diseases, or collagen diseases; and whether the patient had been treated with quinolones or systemic/local corticosteroids, as shown in Table 1. Access to this schedule was limited to the staff who generated it and the staff in charge of assigning the randomization. The investigator who evaluated efficacy was not involved in the treatment assignment, the treatment performed, or the follow-up visits of the patients.

The study comprised 6 on-site, postoperative/postinjury follow-up visits: randomization and treatment (visit 1); first control at day 10 (visit 2); following controls at 6 weeks (visit 3), 12 weeks (visit 4), and 24 weeks (visit 5); and final examination at 52 weeks (last visit or visit 6). All following control visits were performed at outpatient facilities.

Randomized patients were treated with 1 of the following 3 treatments:

1) Conservative treatment (orthopedic treatment): A cast was placed in 30° plantarflexion in the emergency department, and patients were discharged home with analgesic, antithrombotic treatment and no weightbearing of the injured limb. All patients were referred to the Foot and Ankle Unit to proceed with the rehabilitation protocol and the follow-up visits.
2) Percutaneous surgical treatment: Surgery was performed under sedation and local anesthesia and without ischemia cuff. Following the technique described by Ma and Griffith (22), 7 incisions were made in total: 1 transversal at the level of the rupture of the tendon and 3 on each side (2 proximal and 1 distal to the rupture). The proximal incisions were made 2 and 3 cm from the transverse incision, and the distal incision at 2 cm from the transversal incision. (When making the proximal incisions, the surgeon must take into account that the sural nerve crosses from posterior to lateral ~8 to 10 cm from the calcaneal insertion of the Achilles.) With a straight needle, a PDS 1 suture was passed from the proximal incisions crosswise to the proximal end, and similarly at the distal incision. The sutures were then knotted through the transverse incision with the foot in maximum plantarflexion to approximate the ends of the tendon as much as possible. The contralateral extremity was used as a guide for the restoration of proper tendon length. Closure of the incisions was performed with 3-0 prolene suture, and a cast was placed in 30° plantarflexion. Patients stayed for 24 h in the hospital and were discharged home with analgesic, antithrombotic treatment and no weightbearing of the operated limb. Patients were referred to the Foot and Ankle Unit to proceed with the rehabilitation protocol and follow-up visits.
3) Open surgical treatment: Surgery was performed under spinal anesthesia or femoropopliteal block and with ischemia cuff at the level of the thigh raised to 250 mmHg. A vertical posteromedial incision was made. The hematoma and the tendon ends were cleaned, and a double Bunnel suture was performed with a PDS suture of 1 mm (reabsorbable 1-mm braided polydioxanon) (23) with the foot in maximum plantarflexion to approximate the ends of the tendon as much as possible. The contralateral extremity was used as a guide for the restoration of proper tendon length. Suture of the paratendon and subsequent skin closure were performed with 3/0 prolene points, and a cast was placed in 30° plantarflexion. All patients stayed for 24 h in the hospital and were discharged home with analgesic, antithrombotic treatment and no weightbearing of the operated limb. Patients were referred to the Foot and Ankle Unit to proceed with the rehabilitation protocol and follow-up visits.

Table 1
Randomization: 8 strata groups

Group	Age (yr)	Sports?*	PB?†
A	<40	Y	N
B	<40	Y	Y
C	<40	N	N
D	<40	N	Y
E	>40	Y	N
F	>40	Y	Y
G	>40	N	N
H	>40	N	Y

* Athletes or usual sport (>4 times per week/>30 min)

† PB, pathological background: diabetes, rheumatic diseases, collagenopathies, gout; use of chronic glucocorticoids (systemic and/or local current or previous weeks) or fluroquinolones; other diseases not taken into account when stratifying.

Later Protocol for All Patients

All patients remained in the cast for 10 days with no weightbearing of the injured limb. After 10 days, at visit 2, the cast was removed; in the case of surgical treatments, the wound was checked for healing and sutures were removed. Then, a walker-type orthopedic boot below the knee was placed, adding some wedges to gain equine position. All patients followed a strict protocol with early weightbearing, starting load with the boot and wedges immediately, and remaining for 8 days with all the wedges. Subsequently, wedges were removed every 4 days (days 18, 22, 26, and 30), and finally patients remained 8 days more without wedges (from days 30 to 38), walking plantigrade with the boot (Table 2).

At 6 weeks (visit 3), all patients had started active rehabilitation, and the walker boot had been removed. At 12 weeks (visit 4), 24 weeks (visit 5), and 52 weeks (visit 6, final examination at 1-year follow-up), pain intensity, scar evaluation (in patients of the surgical groups), active articular balance, and ability to stand bi- or monopodal heelrise and hold for 3 seconds (form of validation of these patients) (24,25) was assessed. Magnetic resonance imaging was performed if the patient had pain during the posttreatment period. The following specific quality-of-life questionnaires were completed: Achilles tendon total rupture score (ATRS) and Victorian Institute of Sport Assessment (VISA); as well as less specific questionnaires such as the American Orthopaedic Foot and Ankle Society (AOFAS) score for the hindfoot. Also at visit 6, an ultrasound was performed; comparisons were made with the healthy extremity of calf circumference (with measure tape in cm, 10 cm distal from the anterior tibia tuberosity) (26,27); measurement of the physiological plantarflexion at rest and plantarflexion muscle strength were calculated with dynamometry (in Newtons); pain intensity after walking was assessed (verbal numeric rating scale [VNRS]; 0, no pain; 10, the worst pain); and the patient made an overall assessment (Patients' Global Impression) of the study treatment using a verbal rating scale (excellent, very good, good, fair, poor). The patient was then discharged.

Study Outcomes

The primary efficacy endpoint was the proportion of responders (i.e., successful treatment) at 1-year follow-up. A responder was defined as capable of standing heelrise mono- and bipodally for 3 seconds, having a pain score ≤2 (VNRS) after walking, and having returned to active previous life (sport). Secondary efficacy endpoints were the questionnaires, muscular strength for plantarflexion, calf circumference, physiological

Table 2
Rehabilitation protocol with early weightbearing

Postoperative/Postinjury	Plaster in Equine Position (30° PF)
Day 10 (first visit)	- Remove cast - Place orthopedic walker boot and 4 wedges (22° PF) - Weightbearing
Days 11 to 34	
Day 18	- Take off first wedge (16° PF) - Can take off boot at night and start ROM/passive exercises (assisted eversion, inversion and flexion, extension of the foot)
Day 22	- Take off second wedge (10° PF) - Start active exercises
Day 26	- Take off third and fourth wedges (0° PF)
Day 34 and onward	- Start active rehabilitation
Day 40	- Take off the walker boot completely

PF, plantarflexion; ROM, range of motion.

plantarflexion at rest (equinus), and the integrity of the Achilles tendon evaluated by ultrasound at 1-year follow-up, assessing the diameter and length of the tendon and signs of tendinopathy and hypervascularization.

Statistical Analysis

In line with the study protocol, for the primary efficacy analysis, 10 patients per treatment group was considered the minimum sample size necessary to properly evaluate the results of the study. The primary population for efficacy analysis was the whole analysis set (all randomized and treated patients). Baseline characteristics were summarized using standard descriptive statistics, and a descriptive analysis was carried out. Continuous variables were described as mean (standard deviation) or median (range), and categorical data was summarized as absolute frequency and percentages. The proportion of responders was estimated, and its 95% confidence interval (95% CI) was calculated. An exploratory analysis was done among the different groups of treatment. A P value of ≤ 0.05 was considered statistically significant. Data analysis was carried out using Stata/IC 15.0 for Mac (64-bit Intel, revision 25 set 2017).

Results

From February 2014 to February 2017, 34 patients came to the emergency department of our hospital experiencing acute Achilles tendon rupture. All of them were included in the study and were randomized and treated: 11 in the conservative treatment group, 11 in the percutaneous surgery treatment group, and 12 in the open surgery treatment group. Patient baseline characteristics are shown in Table 3. Values for demographic variables were not markedly different among treatment groups. Patients were predominantly young (median age 41 years), Caucasian (100%), and male (94%), and the lesion occurred in the left extremity in 76% (26 patients). Fig. 1 shows the study's flow chart.

Primary Objective: Proportion of Responders at 1-Year Follow-Up

At 1-year follow-up, the proportion of responders was 100% (11 of 11, 95% CI 74% to 100%) in the conservative group, 82% (9 of 11, 95% CI 52% to 95%) in the percutaneous surgery group, and 83% (10 of 12, 95% CI 55% to 95%) in the open surgery group. Four patients (2 in the percutaneous surgical group and 2 in the open surgical group) scored pain intensity >2, which is usually related to scar induration, or could not stand heelrise for 3 seconds.

Table 3
Patient baseline characteristics

	Conservative (n = 11)	Percutaneous Surgery (n = 11)	Open Surgery (n = 12)
Sex			
Female	1 (10)	1 (10)	1 (8)
Male	10 (90)	10 (90)	11 (91.2)
Age (years)	42 (26 to 51)	41 (18 to 50)	40.5 (28 to 51)
Achilles tendon rupture			
Right	2 (18)	1 (10)	4 (33)
Left	9 (82)	10 (90)	8 (66)

Data are n (%) or median (range).

Secondary Efficacy Objectives

Standing heelrise: Four patients (2 in percutaneous surgical group and 2 in open surgical group) could not stand heelrise for 3 seconds at 52 weeks. Therefore, 85.2% (30 of 34) of the patients could bipodally and monopodally stand heelrise and hold for 3 seconds. Fig. 2 shows the progress at 12, 24, and 52 weeks based on the number of patients who could stand heelrise bipodally and monopodally or only bipodally in each treatment group.

Pain: Pain intensity ≤2 by VNRS at 52 weeks was 100% (11 of 11, 95% CI 74% to 100%) in the conservative group, 82% (9 of 11, 95% CI 52% to 95%) in the percutaneous surgery group, and 83% (10 of 12, 95% CI 55% to 95%) in the open surgery group. Pain was related to scar indurations.

Return to sports: At 52 weeks of follow-up, 30 of 34 (88.2%) patients had returned to their active previous life (sports activity: paddle, soccer, climbing, etc.): 1 case in the conservative treatment group, 2 in the

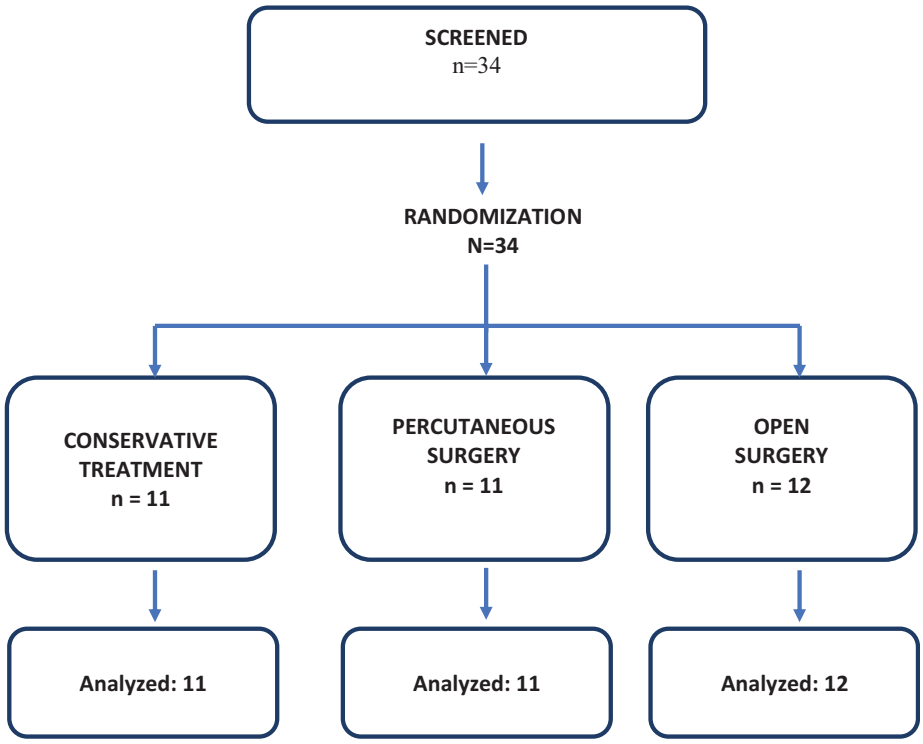

Fig. 1. Study flow chart.

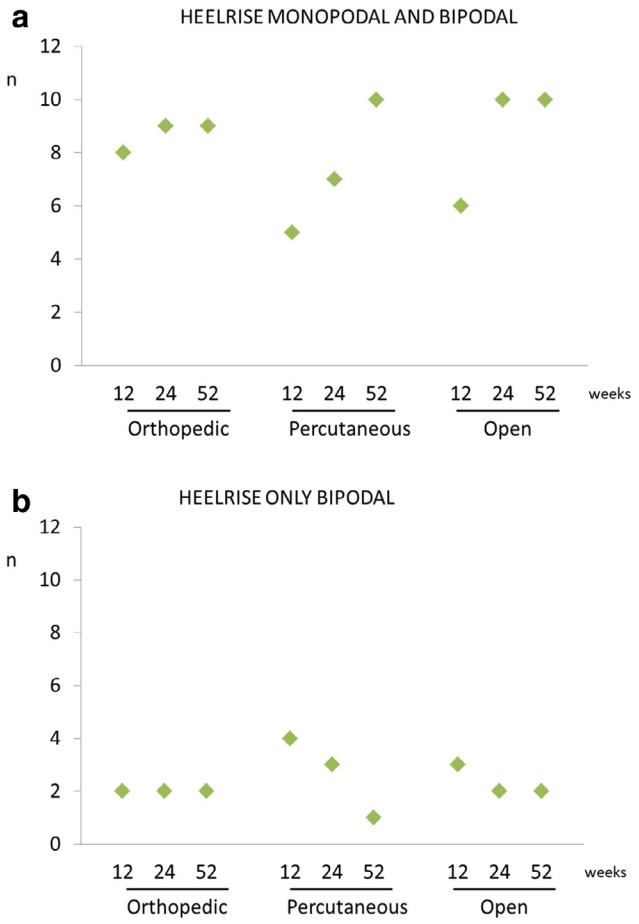

Fig. 2. Number of patients who could stand healrise, bipodal and monopodal (*a*) or bipodal only (*b*), holding for 3 seconds at 12, 24, and 52 weeks of each treatment group.

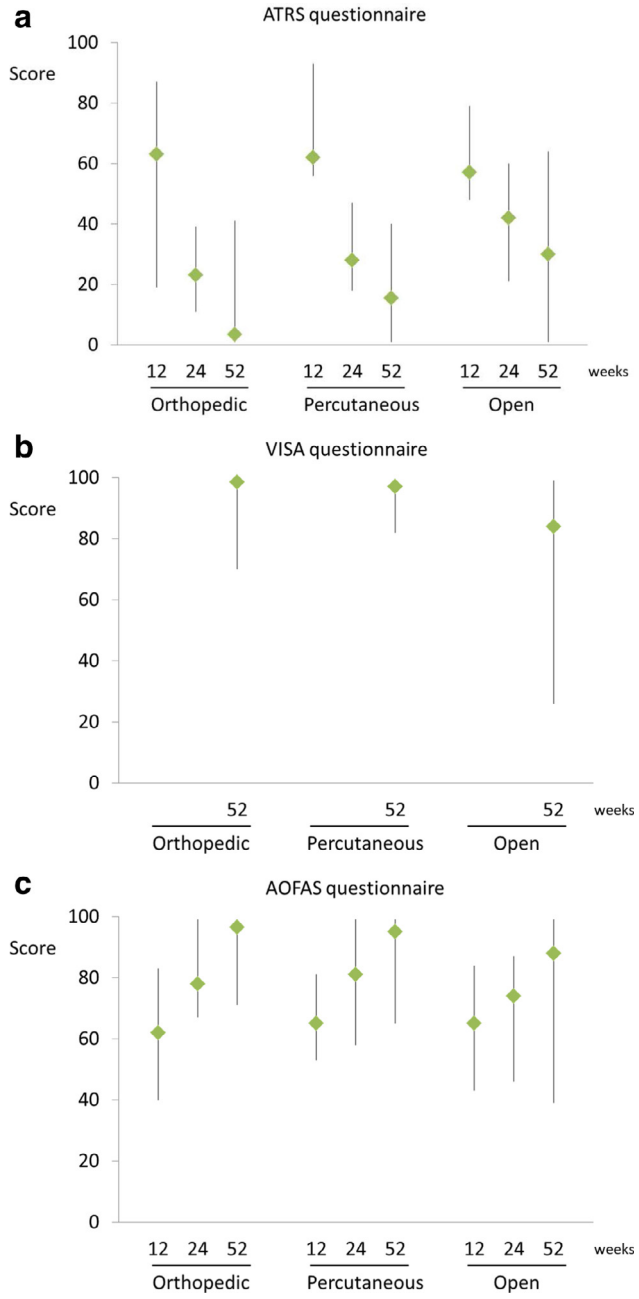

Fig. 3. Median (range) scores of Achilles tendon total rupture (*a*), Victorian Institute of Sport Assessment (*b*), and American Orthopaedic Foot and Ankle Society (*c*) questionnaires by treatment group: orthopedic (n = 11), percutaneous surgery (n = 11), and open surgery (n = 12).

percutaneous group, and 1 in the open surgery group did not perform their usual sports. One patient at baseline (belonging to the open surgery group) did not practice sports; this patient had returned to an active life at 52 weeks.

Questionnaires: Fig. 3*a* shows the median (range) ATRS questionnaire score at 12, 24, and 52 weeks by treatment group; Fig. 3*b*, the VISA questionnaire score; and Fig. 3*c*, the AOFAS questionnaire score. The open surgery group showed a different evolution in the ARTR (lower scores at 24 and 52 weeks) and AOFAS (greater scores at 52 weeks) questionnaires in comparison with the conservative and percutaneous treatment groups. Likewise, the open surgical group showed a lower score in the VISA questionnaire at 52 weeks.

Muscular strength: Fig. 4 depicts the median (range) of the muscle strength (in Newtons) of the sural triceps in the injured and contralateral (healthy) leg by treatment group at 52 weeks. All patients in the conservative group held with maximum strength for 10 seconds in the orthopedic group; in contrast, the strength of 1 patient in the percutaneous surgical group and 2 patients in the open surgery group decreased by 20 N.

Calf circumference: The median (range) of calf circumference at 52 weeks in the conservative group was of 35 cm (range 32 to 43) in the injured limb and 40 cm (range 33 to 43) in the healthy limb; in the percutaneous surgery group, 38 cm (37 to 39) in the injured limb and 41 cm (39 to 43) in the healthy limb; and in the open surgical group, 39 cm (30 to 45) in the injured limb and 41 cm (31 to 45) in the healthy limb.

Plantarflexion: The median (range) plantarflexion at rest (equine) at 52 weeks in the orthopedic group was 26° (range 20° to 30°) in the injured limb and 30° (range 28° to 30°) in the healthy limb; in the percutaneous surgery group, 20° (10° to 30°) in the injured limb and 30° (20° to 30°) in the healthy limb; and in the open surgical group, 15° (10° to 30°) in the injured limb and 30° (15° to 30°) in the healthy limb.

Ultrasound: Table 4 presents the median (range) of ultrasound results (depth and tendon elongation in injured and healthy limbs, heterogeneity, and vascularization) at 52 weeks. Hypervascularization of the tendon was visualized in 3 patients (27%) in the percutaneous surgical group and 4 (33%) in the open surgical group, without any signs of tendinosis or tendinitis in any patient.

Patients' global impression (excellent, very good, good, fair, poor): At 1-year follow-up, 10 patients (91%) in the conserative treatment

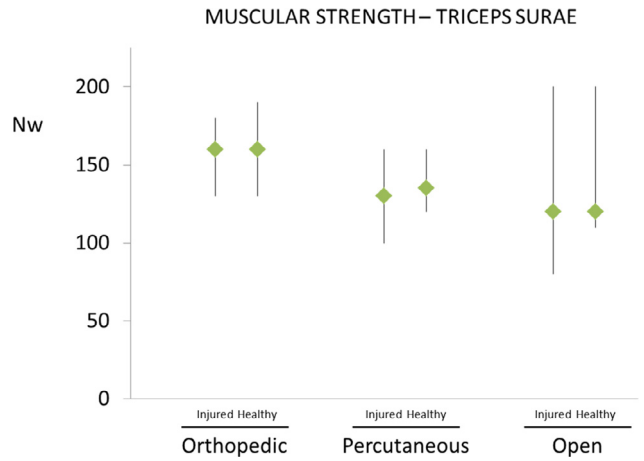

Fig. 4. Median (range) of the muscle strength (in Newtons) of the sural triceps in the injured and contralateral (healthy) leg by treatment group: orthopedic (n = 11), percutaneous surgery (n = 11), and open surgery (n = 12).

group reported excellent impressions of the treatment, and 1 patient (9%) reported very good. In the percutaneous surgery group 8 patients (72%) reported excellent impressions, 2 (18%) very good, and 1 (9%) good. In the open surgery group, 10 patients (83%) reported excellent impressions, and 2 (17%) reported very good.

Complications and Safety

No serious adverse events were reported during the follow-up, and no case of total rerupture. Magnetic resonance imaging was performed in 3 patients (1 of each group) who had pain at 24 weeks after injury. The images showed partial microtears at the level of the Achilles tendon and also in the musculotendinous union, which normally appear after starting more intensive exercises at 6 months. All patients improved with new rehabilitation sessions.

In the percutaneous surgery group, 2 patients had hyperalgesia in the territory of the sural nerve, which disappeared after a year. In the surgical groups, there was no infection of the wounds during the follow-up. At 1 year of follow-up, 5 patients (3 percutaneous surgery and 2 open surgery) had a fibrous and indurated scar. In both patients of the open surgery group, the hypertrophic and indurated scar prevented them from advancing in muscular potentiation because of pain, decreasing scores on quality-of-life questionnaires, and increasing pain (VNRS 3).

Discussion

There is a lot of controversy regarding the treatment of acute Achilles tendon ruptures, without clear advantages of any treatment. Surgical treatment is preferable in active patients, who require an early return to active life, although this treatment is more expensive and presents more complications than conservative treatment (16,22,28). Percutaneous surgery reduces many of the complications presented by open surgery (15,22), with fewer infections and the same incidence of rerupture. One study, however, showed the incidence of sural nerve injury to be higher in percutaneous surgery (5.5% in percutaneous vs 1.2% in open surgery) (29).

We did not find differences in terms of age, degree of previous sport (>4 times/30 minutes of exercise per week), or other antecedents. It should be emphasized that only 9 patients out of 34 performed regular sports at a high-intensity level (more than 4 times a week), none at a professional level.

We observed that patients who followed conservative treatment obtained better results at 1-year follow-up in the different questionnaires (ATRS, VISA, AOFAs), although in the first weeks, the assessment was lower. Although the differences in the results obtained were not statistically significant, we observed that patients who underwent surgical treatments, predominantly in those of the open surgical group, had problems with wound healing, such as keloids and adhesions, diminishing their final satisfaction. These good results of the different treatments are due to the rehabilitation protocol with early weightbearing that our patients followed, as shown by several studies (4,30–32). In recent studies, it has been seen that orthopedic treatment followed by early weightbearing rehabilitation reduces the incidence of rerupture, almost equaling to surgical treatment (1,2,4,5,9–12,33,34). Our study had no cases of rerupture.

Soroceanu el al. (1) compared the results of surgical treatment with conservative treatment, concluding that in those studies in which a rehabilitation protocol was performed with loading and early mobilization, the rate of reoperations was equalized between the 2 treatments. In contrast, 15.8% more complications (deep vein thrombosis, wound infections, necrosis of the skin and tendon, sural nerve injury, tendon elongation, decreased ankle mobility) occurred in patients who underwent surgical treatment.

In another prospective study of 60 patients (35), comparing surgery and orthopedic treatment, the authors observed that the results were similar with both treatments in terms of the questionnaires, but having surgery allowed better and faster recovery of the muscle strength of the triceps surae. However, neither treatment restored the same muscle strength as on the contralateral (healthy) side, similar to what we observed in our study, although we didn't find any differences between the treatments in terms of muscle strength. In our study, we observed that those patients who had scar problems showed inferior results in both the questionnaires and the recovery of the strength of the triceps surae.

We had 2 cases in the percutaneous surgery group of hyperalgesia in the territory of the sural nerve, with resolution before the first year after the injury. As described (36), because the percutaneous incisions are made longitudinally, if the sural nerve is injured, it is most often a result of longitudinal neurotomy instead of an axonotmesis or transverse neurotmesis, allowing the nerve to regenerate over time. As in other studies, we found a decrease in the calf circumference, an increase in the length of the tendon (elongation), and a decrease in the strength of the triceps sural compared with the healthy

Table 4
Results of ultrasound 1 year after injury

Surgery	Depth of tendon (cm)		Length of tendon (cm)		Heterogeneity	Hypervascularization
	Injured	Healthy	Injured	Healthy		
Orthopaedic (n = 11)	1.45 (1.09 to 2.23)	1.20 (0.40 to 1.47)	10.81 (10.69 to 12. 66)	10.98 (10.11 to 11.72)	0	0
Percutaneous surgery (n = 11)	1.72 (1.49 to 1.96)	1.31 (0.88 to 1.42)	12.27 (11.46 to 13.77)	11.02 (10.05 to 13.62)	11	3
Open surgery (n = 11)	1.71 (1.22 to 2.33)	1.42 (0.47 to 1.81)	11.76 (10.17 to 12.77)	10.96 (10.03 to 12.14)	12	4

Data are median (range) or n.

contralateral limb, without these differences being clinically significant (1,25,37,38).

Although we clinically found that patients who underwent conservative treatment had less elongation, these results were not very relevant for the patients, since 88.23% of them returned to their previous sports activity (paddle, soccer, climbing, etc.). Compared with other studies (39,40) that showed a 30% decrease in the muscle strength of the triceps surae at 1-year follow-up, we obtained better results, with only 8% in those who followed open surgical treatment, 6% in the percutaneous group, and 2% in conservative group, without statistically significant differences. We found no correlation between elongation and heelrise, as some studies have described (41).

Our study is subject to some limitations. Its small sample size (pilot clinical trial) and that it only involved 1 center might underestimate or overestimate the generalizability of the results beyond the population and conditions studied.

In conclusion, our results suggest that conservative treatment is just as effective as surgical treatments in the majority of patients, as long as a protocol of rehabilitation with early weightbearing is performed. It would be necessary to perform randomized clinical trials with a larger size to validate these results.

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