A. Comparative or parallel studies

1. Open versus minimal invasive repair with Achillon® device

Foot Ankle Int. 2009 May;30(5):391-7.

Aktas S, Kocaoglu B.

BACKGROUND

We prospectively analyzed and compared the functional and clinical results of patients with standard open and minimally invasive repair with the Achillonsuture system at mid-term follow-up.

MATERIALS AND METHODS

From February 2004 to May 2007, 40 consecutive patients were operated for the treatment of acute Achilles tendon rupture with two different methods. None of the cases required adjunctive procedures like plantaris, flexor hallucis longus or gastrocnemius augmentation (Lindholm, Bosworth) to allow for acceptable end to end apposition. The patients were divided equally into two groups. In Group 1, only Krakow end-to-end suturing technique and in Group 2, Minimal invasive repair with Achillonsuture system (Integra Life Sciences Corporation, Plainsboro, NJ) was used respectively. The average age of the patients was 40 years. Patients in study groups were followed up at mean of 22.4 (range, 10 to 48) months after surgery. At the end of the followup time, functional outcome scores and complications were evaluated.

RESULTS: The AOFAS hindfoot clinical outcome scores were 98.7 in Group 1, 96.8 in Group 2. Minimal invasive repair with Achillonsuture system is better in the function scores compared to Krakow but statistically significant difference.

CONCLUSION

Although functional outcomes of both treatment groups were the same, minimally invasive repair with the Achillonsuture system provided safe, reliable and practical treatment with low risk of complications in the treatment of acute Achilles tendon ruptures.

Clinical Data

- Randomized single blind study (evaluator not blinded): Achillon® (20 patients) vs. Krakow end-to-end suturing technique (20 patients)
- Mean follow-up: 22.4 months
- AOFAS (no difference): Achillon: 96.8/100 (87 to 100) – Krakow: 98.7/100 (88 to 100)
- Complications (p=0.0012): 5% for Achillon vs. 35% for Krakow

Take home message

This randomized study reports equivalent functional results for both techniques but statistically safer outcome with Achillonsuture technique compared to Krakow end-to-end technique.
### 2. Repair of acute Achilles tendon rupture. Comparative study of two surgical techniques

Avina Valencia JA, Guillén Alcalá MA.

**Background**
The treatment of Achilles tendon rupture has been controversial, and attempts are made to attenuate the complications arising from invasive procedures with minimally invasive techniques. This paper is a comparison between the results of Lynn’s traditional open technique and those of minimally invasive surgery assisted with the Achillon instrument guide.

**Materials And Methods**
A prospective, randomized study was carried out in fifty-six patients with acute rupture of the Achilles tendon. Twenty-eight of them underwent surgery with Lynn’s technique and 28 underwent minimally invasive surgery assisted with a mechanical guide. Patients were assessed at postoperative weeks 4, 6, 8, 10 and 16. They were examined for pain, muscle strength, presence or absence of Thomas sign, Merkel scale, ranges of motion, degree of amyotrophy, time to healing, degree of functional recovery, and complications. Data analysis was done with central trend measurements and nonparametric analyses.

**Results**
The following were reported for Lynn’s technique (LT) and the minimally invasive approach (MI):
- Mobility in extension: (LT) 40.3 +/- 0.59 degrees vs. (MI) 50.0 +/- 0.42 (p < 0.01);
- Flexion: (LT) 13.9 +/- 0.12 degrees vs. (MI) 18.2 +/- 18.2 degrees (p < 0.01);
- Amyotrophy: (LT) 3.9 +/- 0.09 cm vs. (MI) 1.5 +/- 0.13 (p < 0.01);
- Time to healing: (LT) 9.0 +/- 0.13 vs. (MI) 6.1 +/- 0.09 weeks (p < 0.01);
- Return to work: (LT) 9 weeks vs. (MI) 6 weeks.

**Conclusions**
The MI approach had statistically significant advantages over Lynn’s technique, which we attribute to a lesser tissue and neurovascular trauma.

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### 3. Achilles tendon rupture and our experience with the Achillondevice

**Feldbrin, Z., Hendel, D., Lipkin, A., Zin, D., and Schort, L.**

**Background**
Open repair of the Achilles tendon is still the gold standard for treating rupture. This technique has the disadvantages of a long and problematic operative scar and thickly scarred Achilles tendon. To improve the surgical outcome minimally invasive techniques have been developed.

**Objectives**
To analyze our results of Achilles tendon repair using the Achillondevice and compare them with published studies.

**Methods**
We performed surgical repair of the Achilles tendon in 28 patients during a 4 year period (2004-2008): 14 patients were treated with the Achillondevice, 12 with the open suture technique and 2 with the percutaneous method. Fourteen patients were available for follow-up: 9 patients with the Achillondevice, 3 patients with open suturing and 2 patients with the percutaneous technique. Follow-up ranged from 1 to 4 years.

**Results**
The average score of the AOFAS Ankle-Hindfoot Scale for the group treated with the Achillondevice was 95.6 points (range 84-100) and for the group treated with the open method, 90 points (range 84-98). The length of the scar in patients operated with a minimally invasive technique was 3.81 cm (range 1-6 cm) as compared to 9.16 cm (range 8-10.5 cm) with the open suture.

**Conclusions**
This is the first review on this procedure in Israel. Excellent functional results were achieved with this technique. Our outcomes were similar to those of two other studies.
4. Mini-invasive surgical repair of the Achilles tendon — Does it reduce post-operative morbidity?

Bhattacharyya M, Gerber B.

Background
The surgical benefit of minimally invasive tendo Achilles repair (n = 25) with early weight-bearing mobilisation after rupture of the tendo Achilles was compared with operative treatment using an open technique (n = 34) with full weight-bearing after 8 weeks of surgical repair. The minimally invasive technique provided no evidence of wound problems and a functional benefit from early weight-bearing mobilisation. However, we noted that increased post-operative morbidity in terms of wound infection (n = 7) leading to delayed wound healing and wound pain requiring opiate-based analgesia post-operatively in the open repair group may have an additional impact on the patients and health care providers. This study showed that the mini-invasive open surgical repair of the Achilles tendon with the Achillon instrument and early weight-bearing mobilisation in an orthosis for the accelerated rehabilitation may offer cost-effectiveness and less financial burden on the health care provider in terms of associated nursing and physiotherapy costs.

B. Non comparative studies

5. Treatment of acute Achilles tendon ruptures with Achillon device: clinical outcomes and kinetic gait analysis

Carrido, I. M., Deval, J. C., Bosch, M. N., Medavilla, D. H., Garcia, V. P., and Gonzalez, M. S.

Take home message
This non comparative article reports results shows that Achillon repair technique is a valuable alternative to other techniques for acute Achilles tendon repair. The authors concluded that their results are promising.
6. Outcome of achilles tendon ruptures treated by a limited open technique.


Background
The optimal surgical management of Achilles tendon ruptures remains a topic of active debate. Recently, many authors have preferred the limited open method because it afforded sufficient visualization to ensure anatomic apposition of disrupted tendon fibers, minimized local blood supply disturbances, guaranteed free tendon movement, and produced excellent cosmesis. We report our initial experience with this technique and review the literature.

Materials And Methods
The outcomes of 30 consecutive patients that underwent limited open repair for Achilles tendon rupture using Achillon® (Newdeal SA, Lyon, France) from June 2003 to May 2006 were retrospectively reviewed. There were 20 men and 10 women, of average age 38.6 years, and the average followup period was 18.5 months. Twenty of the injuries were sports-related, eight were caused by a fall, and two by a laceration. The clinical results were assessed using patient satisfaction, the ankle-hindfoot scale of the American Orthopaedic Foot and Ankle Society (AOFAS), and the occurrence of complications.

Results
At last followup, sixteen patients were very satisfied, 11 were satisfied, and the remaining three were dissatisfied. Mean patient AOFAS score was 93.0 points. Surgical complications noted were re-rupture in two cases, deep infection in one, and sural nerve injury in one. All patients except the three patients with a re-rupture or infection, returned to work 2 months postoperatively and resumed light exercise at 3 months, and previous sporting activities by 6 months.

Conclusion
The described limited open repair technique for Achilles tendon ruptures provided excellent cosmetic results, satisfactory functional results, and a high level of patient satisfaction.


Objective
To study the clinical outcomes of minimally invasive repair of ruptured Achilles tendon.

Design
Retrospective study.

Setting
Orthopaedics and Traumatology Department of a public hospital in Hong Kong.

Patients
Fifteen consecutive patients admitted to the hospital from August 2002 to April 2005 with closed Achilles tendon rupture, had it repaired by a minimally invasive method. Parameters including patient epidemiology, nature of injuries, and isometric force measurement of ankle plantar flexion were recorded to justify the effectiveness of the Achilles tendon repair.

Results
Isometric peak force measurement of ankle plantar flexion 1 year after injury showed an average regain of 95% of the calf muscle strength, compared to the normal side. Al wounds healed well, without major complications such as deep infection, sural nerve injury, or re-rupture of the Achilles tendon. All patients were able to resume their pre-injury activity level and previous occupation.

Conclusion
This minimally invasive surgical technique using the Achillonsuture guide produces encouraging results in the operative management of ruptured Achilles tendon.

Clinical Data
- Retrospective case series study: Achillon® (15 patients)
- Mean follow-up: 31 months
- Isometric force measurement of Achilles tendon (mean): Injured side: 61 lbs (18 to 98), Uninjured side: 64 lbs (27 to 97)
- Range of motion: Injured ankle regained normal range of motion (as on the contralateral ankle)
- Complications: No major complication – Minor complications: 1 patient (with a history of Diabetes mellitus) developed a stitch abscess 3 weeks after the operation, 1 patient endured skin tethering to the underlying tissue
- Satisfaction: All patients satisfied with results of operation and wound’s appearance
8. Independent evaluation of a recently described Achilles tendon repair technique.

Foot Ankle Int. 2006 Feb;27(2):93-6.
Calder JD, Saxby TS.

Background
We investigated a previously reported technique for the repair of acute Achilles tendon ruptures using the percutaneous Achillonsuture system (Integra Life Sciences Corporation, Plainsboro, NJ).

Methods
Twenty-five patients with Achilles tendon ruptures were studied prospectively with a minimum of 12 months followup. A single 2- to 3-cm horizontal incision and the Achillonsuture system were used. Early rehabilitation and an active range-of-motion brace were instituted.

Results
There were no wound problems, sural nerve injuries, or re-ruptures. All patients were able to return to their previous sporting activities by 6 months.

Conclusions
This independent study confirms that the technique offers patients a safe operative procedure for repair of acute Achilles tendon ruptures that allows early active rehabilitation.


Calder JD, Saxby TS.

Objective
To assess the use of a supervised active rehabilitation program following repair of acute Achilles tendon ruptures using a minimally invasive suture system.

Methods
We performed a prospective study on 46 patients undergoing surgical repair of acute Achilles tendon ruptures using the Achillonsuture system. All patients began a supervised active rehabilitation program from 2 weeks postoperatively. Patients were placed in a range of motion brace fixed at 20 degrees equinus for 2 weeks to allow wound healing followed by active movement from neutral to full plantar flexion for 4 weeks.

Results
At a minimum follow up of 12 months there were no re-ruptures. All patients were able to return to their previous sporting activities by 6 months post operation. The average American Orthopaedic Foot and Ankle Society (AOFAS) score at 6 months was 98, with 42 patients having excellent and four patients good Leppilahti scores. The average time to return to work was 22 days. One patient had a superficial wound infection which settled with 5 days of oral antibiotics. Two patients had altered sensation in the distribution of the sural nerve which settled spontaneously within 3 months.

Conclusion
The Achillonsuture system appears to allow a safe early active rehabilitation program and achieves a high rate of success. Further evaluation is necessary with regard to potential damage to the sural nerve.

Clinical Data
- Prospective case series study: Achillon® (25 patients)
- Mean follow-up: 12 months
- Satisfaction at 3 months (Leppilahti score): 88 (range 65 to 100) with 7 patients excellent, 17 good, 2 fair
- Satisfaction at 6 months (Leppilahti score): 97 (range 88 to 100) with 24 patients excellent, 1 good
- AOFAS at 3 months: 96.5/100 (87 to 100)
- AOFAS at 6 months: 99.7/100 (97 to 100)
- Complications: None reported
- Return to work: 19 days (6 to 77)

Take home message
This non comparative case series study reported the outcome of patients operated for acute Achilles tendon rupture using Achillon device. Despite a non comparative study design, the results support the use of this technique as a safe method for repair of acute spontaneous Achilles tendon ruptures.

Clinical Data
- Retrospective case series study: Achillon® (46 patients)
- Mean follow-up: 6 months
- Satisfaction at 3 months (Leppilahti score): 86 (60 to 90) with 12 patients excellent, 28 good, 6 fair
- Satisfaction at 6 months (Leppilahti score): 96 (82 to 100) with 42 patients excellent, 4 good
- AOFAS at 3 months: 95.8/100 (85 to 100)
- AOFAS at 6 months: 98.4/100 (95 to 100)
- Complications: No re-ruptures, 1 superficial infection, 2 paraesthesia in the distribution of the sural nerve (settled spontaneously by 3 months)
- Return to work: 22 days (4-77)

Take home message
The authors reported prospectively a series of 46 consecutive patients with a spontaneous rupture of the Achilles tendon who underwent operative repair using the Achillonsystem and followed a supervised active rehabilitation program from 2 weeks post-operatively. According to the authors, this association results in a rapid return to work and recreational activities without an increase in wound problems or re-rupture.


Background
Controversy persists regarding the ideal surgical technique for repair of a ruptured Achilles tendon. We propose a limited open procedure with use of an instrument that provides the advantage of an open repair but avoids the soft-tissue problems with which open repair has been associated.

Methods
We first performed a cadaveric study in order to develop an instrument and a technique for a limited open repair and then, using this procedure in conjunction with an early functional rehabilitation protocol, we began a prospective multicenter study. We are reporting on the first eighty-seven patients consecutively treated with the new instrument and followed for an average of twenty-six months (range, eighteen to forty-two months). All patients were assessed clinically and with an enhanced American Orthopaedic Foot and Ankle Society (AOFAS) rating score. In addition, all fifty patients who had been followed for at least twenty-four months were further evaluated with isokinetic dynamometry.

Results
Four patients were lost to follow-up and one patient died, which left eighty-two patients for analysis. There were no problems with wound-healing, and there were no infections. No patient noted a sensory disturbance in the sural nerve distribution. All patients returned to their previous professional or sporting activities. The mean AOFAS score was 96 points (range, 85 to 100 points). Isokinetic dynamometry showed no significant difference in strength between the injured and uninjured sides of the fifty patients who were tested. Complications occurred in three patients. Two of them were noncompliant and removed the orthosis, so that the repair was disrupted by a new injury within the first three weeks postoperatively. One patient fell twelve weeks after the surgery and sustained a rerupture. All three new injuries were repaired with an open surgical procedure.

Conclusions
This new procedure allows the surgeon to precisely visualize and control the tendon ends while avoiding excessive dissection and disturbance of local vascularity and minimizing nerve and wound-healing problems. Such a technique, along with an early functional rehabilitation program, allowed us to achieve a high rate of successful results with minimal morbidity.

Clinical Data
- Prospective multicenter cohort study: Achillon (87 patients – 3 centres in Switzerland)
- Mean follow-up: 26 months (18 to 42)
- AOFAS: 96/100 (85 to 100)
- Isokinetic result: no difference between injured and uninjured sides
- Complications: no wound healing problem, no infection, no venous complication, no neurologic complication. Re-rupture: 3 patients

Take home message
This non comparative multicenter cohort study reported the outcome of patients operated for acute Achilles-tendon rupture using Achillon. All patients were also treated with the same postoperative orthosis and rehabilitation program. According to the authors, the limited open technique with Achillon allows a precise apposition of the tendon ends while limiting the surgical dissection. Wound healing was uneventful in all patients. Despite a non comparative study design, the results showed that Achillone repair leads to good functional results and low level of complications.


Background
Limited open repairs of acutely ruptured Achilles tendon, using the Achillone device, are becoming a frequently used method of treatment. To date there are no biomechanical studies comparing the strength of the Achillone repair to the Krackow repair. This study provides a direct comparison of the strength of these two repair techniques.

Methods
Using 10 paired cadaveric Achilles tendon specimens; repairs were performed using a Krackow technique on one specimen and a repair with the Achillone System on the contralateral specimen. All repairs were made with identical suture material. Specimens were tested for ultimate strength using a servohydraulic testing device.

Findings
The mean load to failure of the control group (Krackow suture) was 276N (standard deviation 81.6), and for the experimental group (Achillone suture) was 342N (standard deviation 92.8). Using a Wilcoxon test this result was found to be statistically significant (P=0.03). The mean load to failure of the Achillone group was 53% higher than that of the Krackow group (P=0.03). Using a Wilcoxon test this result was found to be statistically significant (P=0.03).

Interpretation
The current study has demonstrated that the Achillone repair is stronger in a cadaveric biomechanical study than the Krackow repair using identical sutures. This provides biomechanical evidence to support the continued use of the limited open repair as opposed to the traditional open repair.

C. Biomechanical and animal studies
12. The Achillon achilles tendon repair: is it strong enough?

Ismail M, Karim A, Shulman R, Amis A, Calder J.

Background
Open repair of the Achilles tendon is associated with wound breakdown, infection and percutaneous methods risk sural nerve injury. The Achillon mini-incision technique can reduce these risks and may provide the opportunity for early active rehabilitation. The aim of this study was to compare the strength of the Achillon method with the commonly used Kessler method and to assess whether the strength of the repair was related to tendon diameter.

Materials and Methods
Simulated ruptures in sheep Achilles tendons were repaired using either the Achillon method or a two-strand Kessler technique with a No. 2 Ticon suture (Tyco Healthcare, UK). Each tendon diameter was measured, and matched for both groups. Specimens were loaded to failure using an Instron tensile testing machine (Instron Limited, UK).

Results
Mean load to failure for the Achillon repair was 153 N +/- 60 (range, 65 to 270), and the mean load to failure for the Kessler Repair was 123 N +/- 24 (range, 75 to 150). This difference was not statistically significant (p=0.21). There was a statistically significant higher mean load to failure for wider tendons repaired by the Achillon method (p=0.05), however mean load to failure was not related to tendon width in Kessler repairs (p=0.23).

Conclusion
This is the first study to compare these two methods of repair. The Achillon repair has comparable tensile strength to the Kessler Repair.

Clinical Relevance
The Achillon repair appears to be a biomechanically sound method of repair for the acutely ruptured Achilles tendon.

Take home message
The authors reported the results of their animal study comparing the strength of the Achillon repair to the Kessler open repair technique in sheep Achilles tendons. The results show that tensile strength of the repair in ovine tenotomized tendons is not statistically different between both techniques.

References
A literature search was performed using the keyword Achillon® and 17 abstracts were retrieved.

A total of 12 articles were selected reporting studies about Achillon® use. Out of them, 10 were clinical studies and 2 were biomechanical or animal studies.

A total of 2 articles reported comparisons between Achillon® repair and other open repair techniques (1;2). Both showed functional results better or equivalent as open repair technique. They also evidenced that repair of the Achilles tendon with the Achillon® system is related to fewer complications (1;2).

One recent article (3) reported the functional evaluation of parallel groups of patients treated with either Achillon® or open repair. No statistical analysis was performed, but results seem in favor of Achillon® use over open repair.

Another article published in 2009 reported patients’ outcome after acute Achilles tendon injury treated with either Achillon® or by open repair (4). The study was non-comparative and no statistical comparison was made. However, results seemed again in favor of Achillon® use (3).

The 6 other clinical studies were case series between 15 and 87 patients. All results reported in these articles were consistent and show good clinical outcome with a low rate of complications and a high rate of satisfaction.

The biomechanical study (11) showed superiority of Achillon® over Krakow open repair technique and the animal study (12) showed equivalent results between Achillon® and Kessler open repair technique in sheep Achilles tendons.

Abstracts and main results of each article are provided in this document.