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Long-Term Follow-up of Achilles Tendon Repair With an Absorbable Polymer Carbon Fiber Composite

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ABSTRACT

In this cooperative multicenter study for surgical repair of Achilles tendon rupture using a composite implant, 48 patients underwent 52 procedures. This implant is composed of filamentous uniaxially aligned carbon fibers coated with an absorbable polymer. This highly biocompatible implant acts as a scaffold for regrowth of collagenous tissue. The early strength of this repair is provided by the composite implant and by the rapid ingrowth and attachment of new tissue, which allows for an earlier and more vigorous rehabilitation program. Patients with a minimum follow-up of 1 year form the basis of this article. The overall average follow-up is 2.1 years. Three cohort groups were observed on a temporal basis and quantitatively evaluated at 1 year (N = 29), 18 months (N = 22), and 2 years (N = 20), respectively. These three groups demonstrated continuous improvement during the first postoperative year. A high level of function was maintained throughout the second year. Repair of chronic injuries (N = 15) was compared with repair of acute injuries (N = 12) at 1 year following surgery. Both groups greatly improved. However, the acute group had more serious preoperative deficits but improved to a slightly better overall level. Of the patients having at least 1 year follow-up, 86% had a good or excellent result. There was no increased morbidity associated with the use of the carbon implant.

Treatment of the ruptured Achilles tendon is controversial. A variety of surgical procedures have been advocated,^{1,4,5,10,11,17} including simple suture,¹² pull-out wire techniques,¹⁶ fascial reinforcement,^{1,4} and rein-

forcement with tendinous structures.^{8,15} Simple end-to-end anastomosis is usually reserved for acute ruptures that can easily be approximated at the time of surgery. Autogenous tissues are sometimes needed to bridge large gaps found in chronically ruptured Achilles tendons¹⁴ or in those acute instances with "mop end tears." Adding to the confusion was the suggestion in a 1972 report⁹ that conservative nonoperative methods may be the treatment of choice. Lively debate as to the best treatment continues as do the controversies of pathogenesis of the rupture and the timing of surgical repair.⁸

The purpose of this article is to demonstrate the efficacy and advantages of using an absorbable polymer-carbon fiber composite in surgical treatment of the ruptured Achilles tendon.

The background information was presented by Aragona et al.² and Parsons et al.^{13,14} Aragona et al. demonstrated excellent results in the repair of large defects in the rabbit Achilles tendon using a ribbon of filamentous carbon coated with an absorbable polymer. Mechanical testing revealed the tensile strength to be equivalent to the contralateral nonoperated tendon as early as 4 weeks postoperatively. It was demonstrated that within the implant, as well as at its anchoring points, there was well-organized and vascularized regrowth of tissue.

Parsons et al.¹⁴ suggested that the carbon composite implant would be useful in repairing Achilles tendon rupture because it provided immediate mechanical continuity and support and provided a scaffold for soft tissue ingrowth. A multicenter trial was initiated using this investigational device. A preliminary report demonstrated encouraging results.¹⁴ However, the patient pool consisted of only 27 patients with a mere 14 having at least a 9-month follow-up. This article is an update and extension of that preliminary study.

MATERIAL AND METHODS

In the following article, data are presented from 14 medical centers where 48 patients underwent 52 pro-

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cedures for closed Achilles tendon rupture during the period April 1981 to September 1985. One of these patients had a bilateral rupture. Reoperations in three other patients were necessary.

The following cohort groups were analyzed: (1) 29 patients who had at least a 1-year follow-up evaluation, (2) 22 patients who had at least an 18-month follow-up evaluation, and (3) 20 patients who had at least a 2-year follow-up evaluation. There were an additional five patients who had 4-year evaluations. The average follow-up for the entire body of patients was 2.1 years.

It should be noted that not every patient returned for every suggested follow-up evaluation. To maintain the cohort group, if a visit were missed, calculations were performed to estimate what score the visit would have produced. For example, if the 9-month visit was missed but the 6-month and 12-month scores were tabulated, the 9-month visit could be extrapolated. Extrapolation was infrequently necessary and evaluation estimates were made only between two known clinical examinations. Final evaluations were always the results of clinical examination. A uniform scoring system was employed.

The entire patient pool has the following characteristics. There were 39 men and 8 women (one patient's sex was not reported). The average age for women was 47.8 years and for men, 42.3 years. The left side was operated on in 30 instances, and the right side was involved in 22 instances.

The average postinjury time to surgery was 20.4 months. A total of 27 patients were considered to have chronic injuries and were treated more than 4 weeks after injury (average, 3.1 years), 21 acutely injured patients had operative repair less than 4 weeks after surgery (average, 5 days), 4 patients had no record of the original date of injury, 16 patients had a prior surgical procedure for Achilles tendon rupture, and 17 patients had prior conservative treatment. The mechanism of injury was related to sports in 30 patients, related to work in 4 instances, and related to vehicles in 3 patients. Fifteen patients were injured in other activities. There were no open injuries reported.

Diagnosis was made primarily by history and physical examination, including the use of the Thomson or squeeze test, the finding of a palpable depression over the area of tendon rupture, and plantarflexion weakness. Diagnosis was confirmed intraoperatively. Complete rupture was found in most instances. In a small number of patients, there was continuity of the Achilles tendon. It was greatly attenuated and remained intact only by way of fibrosis and scar, however.

Patients were given subjective and objective evaluation preoperatively. Postoperative evaluation was performed at 3-month intervals during the first year and at 6-month intervals thereafter. A total maximum score of

50, indicative of normal function, has the following breakdown of categories and maximum scores: pain, 25; gait, 10; standing ability, 3; walking, 3; stairs, 4; and adjacent supports, 5. A score in the 40 to 50 range was considered excellent/good. A score in the 30 to 39 range was considered fair, and <30 was designated as a poor result. In a subset of patients, we have also been able to examine various parameters comparing preoperative and postoperative evaluations (at last evaluation with at least 1 year following surgery). These parameters include swelling, Achilles function, range of motion, running, and return to sports.

The implant (Integraft Stent, Hexcel Medical, Livermore, CA) used in this multicenter cooperative study consisted of carbon fiber coated with a rapidly absorbable polymer. The ribbon was 1-m long and was composed of uniaxially aligned continuous fibers with surgical needles attached to both ends.

The patient was placed in the prone position and a tourniquet applied to the thigh. The type of anesthesia, spinal or general, was chosen at the discretion of the surgeon. After appropriate preparation and draping, an 18-cm posteromedial incision was made, centered at the level of the defect. The area of rupture was clarified by removal of any attenuated and disorganized scar. A "locking weave" as proposed by Aragona et al.⁴ was used by passing the flexible carbon fiber implant through the proximal and distal stumps of the tendon. The incorporation of a proximal tendon flap was at the surgeon's discretion. Six to eight passes were made to bridge the defect. Subcutaneous tissue closure over the repair is important to prevent exposure of the implant and to minimize adhesion. This was performed with fine, plain interrupted sutures and the skin was closed using fine nylon. Weiss et al.¹⁸ described this protocol in detail.

A short leg cast was applied postoperatively. The casted position, which was determined intraoperatively, restored appropriate original length to the tendon. The implant was placed in a moderate amount of tension in the casted position. Cast time ranged from 3 to 6 weeks. Following cast removal, active and assisted range of motion was prescribed. The patient was told to follow a course of supervised physical therapy. Resistive strengthening and isokinetic training were started at 3 months. A $\frac{5}{8}$ -in (1.56-cm) heel lift was worn as needed.

RESULTS

Patients in this multicenter cooperative study of Achilles tendon repair had severe functional deficits. We divided the study into three cohort groups observed for 12 months (N = 29), 18 months (N = 22), and 24 months (N = 20), respectively. Five patients are in-

cluded who were observed for at least 4 years postoperatively. In the 12-month cohort group, the overall preoperative evaluation score was 17.9 (maximum 50). Continuous improvement was noted throughout the first year, resulting in a final average score of 46.6, an improvement of 153% (Fig. 1). At all postoperative periods, the improvements were statistically significant when compared with preoperative values ($P \ll 0.05$, paired t -test).

At the 12-month follow-up, repair of acute versus chronic injuries were also compared (Fig. 2). Data was available concerning 12 acutely injured patients who had operative repair less than 4 weeks after injury (average, 4.7 days). The average preoperative orthopaedic evaluation score was 7.3. At 1 year following

surgery, the score achieved was 49.0. Data were available regarding 15 patients who were considered to have chronic injuries (average, 3.9 years; range, 2 months to 25 years) and were treated more than 4 weeks after injury (2 patients had no record as to date of injury). This chronic group had an average preoperative evaluation score of 24.5. Continuous improvement was similarly noted throughout the first year, resulting in a score of 45.5. For both the chronic and acute groups, improvements were statistically significant when compared with preoperative values ($P \ll 0.05$; paired t -test).

Similar results were seen in the 18-month follow-up cohort group for Achilles tendon repair ($N = 22$; Fig. 1). The average preoperative total score was 16.4. Continuous improvement was achieved during the first year, with results leveling off by 18 months with a score of 45.7 (146% improvement from preoperative levels). At all postoperative periods, the improvements were statistically significant when compared with preoperative values ($p \ll 0.05$, paired t -test). The 24-month ($N = 20$) cohort group further demonstrates this point (Fig. 1). The average preoperative evaluation score was 22.3. Once again, improvement was achieved throughout the first year, reaching a plateau at 18 months and 24 months. The average score at 24 months was 45.0, an improvement of 101.8%. At all postoperative periods, the improvements were statistically significant when compared with preoperative values ($P \ll 0.05$, paired t -test). Furthermore, 5 patients were observed for at least 4 years. Although the small number of patients in this group does not warrant statistical analysis, it should be noted that all 5 patients had excellent results.

Continuous improvement was seen in all of the tested categories. Because pain is a major contributor to the overall score, this parameter should be examined (see Fig. 3). The 12-month cohort group achieved a preop-

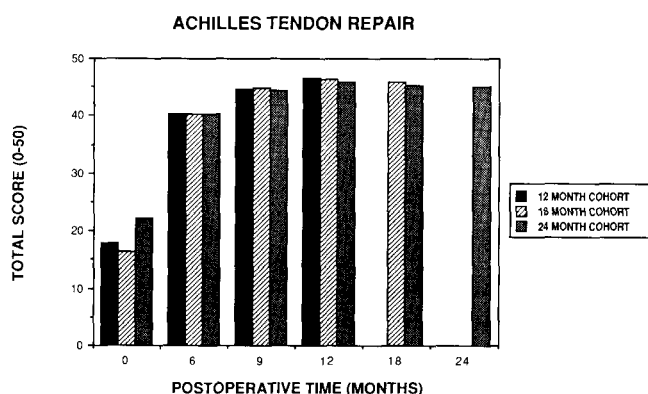


Fig. 1. The total orthopaedic evaluation scores for Achilles tendon repairs improved continuously over the first year for all three cohort groups. At 18 months and 2 years the scores remained high, indicating the excellent return of function has not deteriorated with time. All groups at all time periods postoperatively demonstrated statistically significant improvement when compared with the corresponding preoperative (time zero) values ($P < 0.05$, paired t -test).

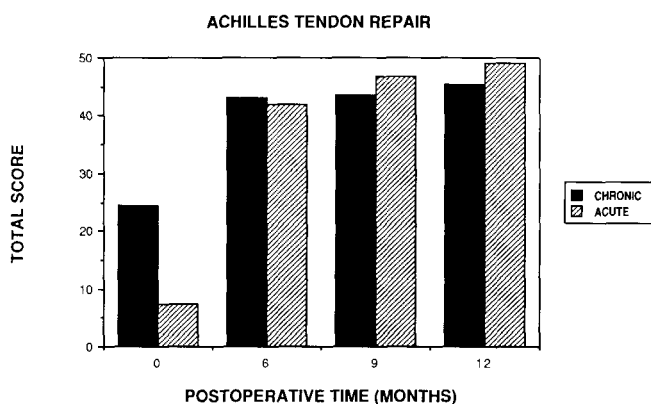


Fig. 2. Chronic Achilles tendon repairs (>4 weeks postinjury) and acute repairs (<4 weeks postinjury) responded in similar fashion, that is, both groups rapidly improved and stabilized at 9 months to 12 months. Although the acute patient had more serious initial deficits, as evidenced by their lower average preoperative (time zero) score, they improved to a slightly greater level.

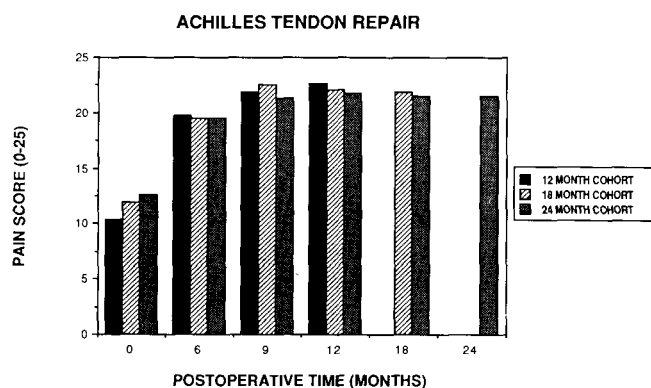


Fig. 3. The pain associated with Achilles tendon deficits and subsequent repair diminished to an almost pain-free state by 9 months. A maximum score of 25 indicates no pain. This reduction of pain was typical of all three cohort groups.

erative pain score of 10.4 (maximum, 25, no pain). The 12-month evaluation yielded a score of 22.7. The 18-month cohort group revealed a preoperative score of 11.9. The last follow-up at 18 months revealed a score of 21.9. The 24-month cohort group has a preoperative score of 12.6 and a 24-month score of 21.5 (Fig. 3). In all cases, the improvements in pain were statistically significant when compared with preoperative values ($P \ll 0.05$, paired t -test).

The pain score was also examined at 1 year in the analysis of chronic versus acute injuries. The chronic ($N = 15$) preoperative pain score was 14.1 and the continuous reduction of pain resulted in a 12-month score of 22.3. Even more dramatic was the loss of pain in the acutely repaired group. The preoperative pain score was 4.5. By the end of 1 year the score had risen to 24.0, at which time the patients were essentially pain-free.

In a subset of the main patient group, we have been able to compile data concerning the following parameters: (1) swelling, (2) Achilles function, (3) range of motion, (4) ability to run, and (5) return to sports. The preoperative evaluation was compared with that of the last follow-up visit, with 12 months as the minimum follow-up period. With regard to amount and presence of swelling ($N = 20$, average follow-up 25 months) preoperatively, 5 patients had chronic swelling of moderate to marked levels, 8 patients had frequent swelling of moderate levels, 4 patients had occasional mild swelling with activity, and 3 patients had no swelling. Postoperatively, all 20 patients had no swelling.

With regard to achilles function ($N = 17$, average follow-up 18 months), preoperatively 6 patients were unable to stand on the toes of one foot, 2 patients could stand on the toes of one foot but with severe difficulty, 5 patients could stand on the toes of one foot with mild to moderate difficulty, and the remaining 4 patients could stand on the toes of one foot without difficulty. Postoperatively, all 17 patients could stand on the toes of one foot without difficulty.

Range of motion data ($N = 29$, average follow-up 24 months) show that preoperatively 13 patients had markedly restricted range of motion, 4 patients had moderate restriction, and 12 patients had normal motion. Postoperatively, 26 patients had normal range of motion, and 3 patients had moderately restricted range of motion.

Ability to run was analyzed ($N = 16$, average follow-up 19 months). Preoperatively, 13 patients were unable to run without instability, 2 patients could run less than $\frac{1}{4}$ mile (0.4 km), and the remaining patient was able to run more than $\frac{1}{4}$ mile. Postoperatively, 15 patients were able to run more than $\frac{1}{4}$ mile and 1 patient was able to run less than $\frac{1}{4}$ mile.

Return to sports was similarly evaluated ($N = 15$, average follow-up 19 months). Preoperatively, 13 patients were unable to participate in sports, 1 patient could be active in sports with the use of a brace, and one patient was able to be active in sports without the use of a brace. Postoperatively, 3 patients were unable to participate in sports, 1 patient could be active in sports with the use of a brace, and 11 patients could be active in sports without a brace.

Usually cast times were 3 to 6 weeks. With increasing experience, most cast times approached 4 weeks.

Unlike the follow-up evaluations, for which a minimum of 1 year follow-up was required, all complications, regardless of length of follow-up, are presented here. Complications for the 52 Achilles tendon repairs included two reruptures, two deep infections, and three superficial infections. One rerupture occurred 2 months postoperatively when the patient fell down a flight of stairs, sustaining multiple injuries in addition to the rupture. This patient was again treated surgically with the carbon implant, which yielded an excellent result at 2 years (score = 50). The second rerupture occurred at 3 months postoperatively when the patient was playing tennis against medical advice. The rerupture was treated surgically, yielding a fair result at 3 years. The two deep infections were debrided in the operating room. Both patients had the original carbon implant removed. The first patient then had the Achilles tendon repaired conventionally, with a fair result at 1 year. The second patient received IV antibiotics and replacement of the carbon implant. This patient had a good result at 9 months. The three patients with superficial infections were treated conservatively with oral antibiotics and all infections resolved without additional complication. One patient experienced tendonitis 6 months postoperatively that resolved with conservative therapy. Finally, one patient at 2 years postoperatively first noticed a 2- \times 2-cm soft, nontender lump at the insertion of the Achilles tendon. There was no sign of infection and the lump did not interfere with function. The patient is being observed for this problem. There has been no significant loss of motion, episodes of scar adherence, regional lymphadenopathy, or systemic signs of carbon involvement.

DISCUSSION

In April 1981, a cooperative multicenter study involving 14 different medical centers was begun to investigate the use of a carbon composite ligament in the repair of the ruptured Achilles tendon. Because this lesion is relatively uncommon, a number of centers were necessary to provide a sufficient patient data base. Furthermore, it was necessary to demonstrate

that a cross-section of orthopaedic surgeons located in a variety of settings could successfully use the carbon composite implant, because it is an investigational device.

The study patient population was similar to that of various other reports^{8,12,15} in terms of distribution of age, mechanism of injury, and sex distribution. The patients typically were a healthy and active group with a large male preponderance. Usually the patients were in their third to fifth decades of life. Recreational activities contributed to a major portion of the ruptures.

Results in all three cohort groups revealed a distinctive pattern. Regardless of the chronic nature of the injury, we observed a continuous improvement in function and lessening of pain during the first postoperative year. The improvement plateaued and was maintained through the second postoperative year. Although many patients had had previous surgery with severe debilitating injuries, 86%, with an overall average of 2.1 years postoperative follow-up, were in the excellent or good categories. This result is in agreement with those of other available studies.^{3,6,8} In fact, at 4-year follow-up all 5 of our patients have excellent results.

Our results indicate that acutely repaired ruptures, as well as repairs performed greater than 4 weeks after injury, show similar trends. However, the acutely repaired injuries (average 4.7 days) showed a more dramatic improvement and tended to fare slightly better at the end of 1 year follow-up (49.0 versus 45.5). All categories examined showed similar trends. Data were available on a smaller subset of patients regarding swelling, foot strength, ankle range of motion, ability to run without instability, and the return to sports. At a minimum of 1 year following surgery, by the above parameters, all patients were significantly improved.

Only 4 patients (13.8%) were classified as fair results. One 77-year-old rheumatoid person was taking prednisone and had a limited, painful range of motion preoperatively as well as postoperatively. In the second patient, who was 50 years of age and had a preoperative evaluation score of only 10 (of a possible 50), tendonitis developed 6 months postoperatively. The third fair result involved a patient who had a deep infection postoperatively, necessitating the removal of the original carbon implant. The final fair result was the patient who required reoperation due to rupture while playing tennis against medical advice.

Neither of the two reruptures occurred with activities of daily living. One patient was involved in a bad fall down a flight of stairs that resulted in numerous additional injuries. The other patient disregarded medical advice and to become involved in sports at too soon postoperatively.

Calf atrophy was not reported by most researchers

in this study. However, Inglis and Sculco⁸ did not find a statistical correlation between these measurements and power, strength, or subjective functional results. Nistor¹² stated in his report that no author found any relationship between reduced calf circumference and reduced strength of plantarflexion.

In the literature, cast immobilization was advocated for a 10-week period by Christensen⁶ and a 4- to 6-week period by Arner and Lindholm.³ Although many authors initially use a long leg cast,⁸ we prefer a short leg cast. Our cast times ranged from 3 to 6 weeks, with 3 to 4 weeks being more common. Because we believed small loads favors healing, the ankle position was determined intraoperatively. This assured a nearly normal tendon length. Over time, with added experience, our postsurgical treatment and rehabilitation have become increasingly aggressive. We believe that this earlier, more vigorous rehabilitation course is a major advantage in the use of the carbon composite implant and that this implant is extremely useful in chronic and acute injuries alike.

Most complications in surgical repair of the Achilles tendon included wound complications and rerupture. In a review of the literature, Nistor¹² found deep infections (1%), fistulae (3%), necrosis of the skin, or tendon or both (2%), and rerupture (2%). In our series, results were as follows: deep wound infections 3.8% (2 patients), no instances of fistulae, no instances of skin or tendon necrosis, tendonitis 1.9% (1 patient), and rerupture occurred in 3.8%. The overall complication rate in our study was similar to that reported elsewhere. Quigley and Scheller¹⁵ had an overall complication rate of 15% (6 of the 40 patients had 7 complications) and a rerupture rate of 5%. Reruptures must be examined carefully regarding etiology. The overall complication rate for our study was 17.3%, which includes the three superficial infections in our study (5.8%) that resolved without sequelae and did not compromise the end result.

There remain a great many controversies in the treatment of the Achilles tendon rupture. Whether or not surgery should be performed, timing of the repair, and type of surgical procedure to be used are continuously being analyzed.^{7,8,9,12} Adding to the debates is the question of implant use. Weighing the risks and potential benefits of surgical versus conservative therapy, we believe that, unless contraindicated, operative repair is the treatment of choice. Others have voiced similar opinions.^{7,12} Furthermore, the utilization of the carbon fiber composite may have some special advantages over conventional repairs. In both the acute and chronic case, continuity is immediately restored. Autogenous structures need not be sacrificed. Large gaps due to resorption or excision of scar, fibrosis, or mop end

tears may be bridged and the length of the repair adjusted intraoperatively. Earlier and more aggressive rehabilitation may be instituted.

SUMMARY AND INDICATIONS

Fifty-two surgical procedures were performed at 14 medical centers for chronic and acute Achilles tendon rupture. Cohort groups of 29 patients with 1-year follow-up, 22 patients with 18-month follow-up, and 20 patients with 2-year follow-up form the basis of this report. The maximum follow-up period was 4 years. A detailed objective/subjective scoring system showed continuous patient improvement 1 year postoperatively.

A plateau with near perfect functional result is then maintained. The postoperative cast time is somewhat less than previous reports have suggested. No increased morbidity has been associated with the use of the carbon composite implant.

We believe that the use of the carbon-absorbable polymer implant is a valuable addition to the surgeon's repertoire. Immediate continuity is restored in the acute and chronic situation alike. Autogenous tissues need not be sacrificed, scar and fibrosis may be resected, and mop end tears may be excised. Large gaps may be bridged and the length of the structure may be adjusted intraoperatively, allowing for the formation of a neotendon. Earlier and more aggressive rehabilitation may be instituted. We remain highly encouraged and optimistic. A longer follow-up of this body of patients will further delineate the rehabilitation guidelines.

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