Repair of Fascial Defects in Dogs Using Carbon Fibers

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Hernia repair may involve the use of an implant to augment or replace autologous tissue, but the best material for use in this application has not been established. We developed a dog model to evaluate the mechanical strength of fascial defects repaired using carbon fibers, compared with the strength of similar defects repaired using polypropylene mesh (Marlex). Unrepaired defects were included as an additional control. Bilateral defects (1 cm square) were made in the fascia of the back, and the ultimate mechanical strength and stiffness at the repair sites were measured 3–12 months after operation. Defects repaired with carbon fibers were significantly stronger 12 months after operation compared with defects repaired with polypropylene mesh and compared with unrepaired defects. It is concluded that carbon fibers are biocompatible and significantly increase mechanical strength at the repair site. A randomized clinical trial involving patients undergoing hernia repair seems justified to determine whether carbon fibers are superior to standard therapy. © 1998 Academic Press

Key Words: hernia repair; carbon fibers; polypropylene; surgical implants.

INTRODUCTION

Patients undergoing either open or laparoscopic hernia repair frequently have some type of implant to add strength or otherwise augment autologous tissue at the repair site. Polypropylene mesh has been successfully used for this purpose as an overlay or a cuff, but because clinical data beyond 4 years after operation are not available, the long-term clinical benefits of polypropylene mesh are uncertain [1]. It is possible that other materials would be more beneficial for augmenting hernia repair.

In previous animal and human studies, we described the safety and efficacy of carbon fibers as an implant material for surgical repairs [2–4]. Implants composed of carbon fibers were biocompatible and caused the ingrowth of more tissue in healing full-thickness abdominal

wall defects in rats compared with polypropylene mesh [2]. In another study involving treatment of lesions in the superficial and deep flexor tendons in thoroughbred racehorses, carbon fibers implanted in but not attached to the injured tendon significantly increased tendon healing compared with both operative and nonoperative standard therapy, as judged by the ability of the horses to return to racing [3]. Carbon fibers were used successfully to reconstruct the anterior cruciate ligament in a consecutive series of 26 patients who had suffered occupation-related injuries [4].

Based on these studies, we hypothesized that a carbon fiber implant could be used as an onlay patch to improve the tensile strength at the site of a fascial defect. We therefore developed an appropriate dog model, and compared the strength of repairs using carbon-fiber implants with that obtained using polypropylene mesh.

METHODS

Animals. A total of 21 adult mongrel dogs (20–40 kg) of both sexes were used. After the dog was tranquilized (Ketamine) and intubated, and anesthesia was induced (Halothane), the back was shaved and prepped, and a 10-cm skin incision was made in the center of the midback and carried down so that the spine could be palpated. The fascia on the right side of the back was exposed, and a metal template containing a square hole with sides of 1 cm was placed 2–4 cm from the midline (depending on the size of the dog). Ink marks were made on the tissue at each corner of the template, and a 1-cm square defect was produced by cutting between the marks and removing the fascia to expose muscle. The process was repeated at a location 5 cm caudal to the first defect, and two corresponding defects were placed on the left side in the same manner. Carbon-fiber and polypropylene mesh implants were then used to repair the cranial defects on the right and left sides, respectively, and both caudal defects were allowed to heal by scar formation. The corners of the control defects were marked with nonresorbable suture to permit location of the defect at the time of sacrifice. After verifying hemostasis, the wound was closed with a running stitch (2-O chromic), with care taken not to sew the skin to normal fascia. The dog was wrapped with a pressure dressing and returned to its cage after recovery from anesthesia. All animal procedures were approved by the Institutional Animal Care and Use Committee.

The dogs were sacrificed 3, 6, and 12 months after operation (seven dogs at each time). One dog recovered at 3 months developed a large hematoma that was subsequently confirmed histologically as a benign process, and another 3-month dog developed an infection at the

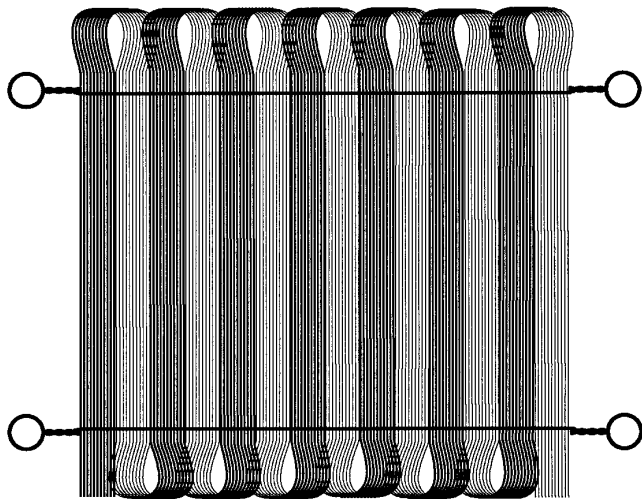[1] To whom all correspondence should be addressed. Fax: (318) 675–6186. E-mail: amarino@lsumc.edu.

FIG. 1. Carbon-fiber implant. Each of the 14 parallel bundles was formed from a continuous yarn consisting of 6000 carbon fibers. Ligature wire maintained the implant in a planar configuration and facilitated tissue attachment via the corner rings.

operative site. In both cases, an extensive fibrotic reaction occurred at the implant sites, and consequently the dogs were excluded from the study. The relation between the complications and the implants could not be ascertained. In two additional cases, the carbon-fiber repair sites were inadvertently destroyed during preparation of the specimens for mechanical testing (one each at 3 and 6 months after operation), and both dogs were therefore excluded.

Implant materials. In some earlier studies involving carbon-fiber implants, the fibers were coated with epoxy (sized) during the manufacturing process, and adverse tissue reactions were observed that could be attributed either to the epoxy sizing or to residues of the organic solvent used in an attempt to dissolve the epoxy prior to implantation [5–8]. Consequently, as previously [2–4], pure unsized carbon fibers were used in this study. The fibers were 92% carbon, 7% nitrogen, with trace amounts of oxygen (Plastafil, Johannesburg, Republic of South Africa), and had a diameter of 7 μm and a density of 1.77 g/cm^3. Implants, 2 × 2 cm were constructed from 6000-fiber yarn that was arranged in 14 parallel bundles held together by stainless-steel wires looped at each end to permit fixation of the implant to tissue (Fig. 1). Adhering fiber debris produced during manufacturing of the fibers was removed in an ultrasonic bath and was coated with gelatin/glycerol to facilitate implant fabrication and handling during surgery. Based on previous work [2], the implant was designed without the use of a weave to maximize the implant surface area exposed to the biological environment.

Two implants with their fiber axes at 90° were used to repair each right-side cranial defect. Each implant was sewn into place with 5-O proline, employing the suture attachment rings. A 2-cm-square piece of polypropylene (Marlex) that was sewn with interrupted sutures (5-O proline) at the corners was used to repair the contralateral defect. Both caudal defects were allowed to heal by scar formation.

Mechanical testing. Following sacrifice, the fascia containing the operative sites was removed and frozen. In preparation for mechanical testing, the fascia was thawed, the fixation wires were removed from the carbon-fiber implants, and the operative sites were separated. Both implants were recovered from each dog, but half of the control defects could not be identified because the suture tags placed at the corners of the defect during the operation were missing.

The two to four specimens from each dog were cut into strips so that the implant material was exposed at both edges, and the specimens were notched to ensure that failure occurred in the region of the implant that covered the original defect (Fig. 2). The unimplanted tissue was trimmed and notched as if the defect had been repaired. The specimens were mounted in a mechanical testing machine (Instron, Model 4202) by clamping normal fascia above and below the implant or scar, and tested to failure at a cross-head speed

of 25 mm/min. The tissue was kept moist with normal saline during testing, which was done at room temperature. The ultimate mechanical strength reported here was the force required to rupture the specimen at the level of the notch, and was identified as the maximum in the force–displacement curve. The slope of the linear portion of the curve was regarded as the specimen stiffness.

Statistics. Because of unequal variance in some of the data, nonparametric statistical tests were used. The relative strength and stiffness of the carbon-fiber and polypropylene implants were compared 3–12 months after operation using the Wilcoxon signed rank test. Since half of the control defects could not be recovered, paired analyses could not be used to compare the repaired and unrepaired defects. Those comparisons were therefore made using the Mann–Whitney *U* test.

RESULTS

All implants were intact at recovery, and no evidence of migration or breakage of the carbon fibers was seen. Each dog was examined clinically for evidence of lymphadenopathy, but none was observed.

The force–displacement curves (Fig. 3) were linear over most of the displacement range. Two relative maxima occurred occasionally in all three types of specimens at roughly equal frequencies, suggesting that the origins of the behavior were related to the nature of the reparative tissue rather than to the presence or type of implant. With one exception (a carbon-fiber implant recovered at 12 months) all tested specimens failed at the notch.

The ultimate mechanical strength and the stiffness of the carbon-fiber repair increased progressively during 3–12 months after the operation (Figs. 4 and 5). The repairs augmented using polypropylene mesh increased in strength and stiffness between 3 and 6 months after operation, but neither parameter changed thereafter. The strength and stiffness at the unrepaired defect did not change during the study (Figs. 4 and 5).

Six months after operation, the defect repaired with carbon fibers was significantly stronger than the unrepaired defect, but no difference in strength was found
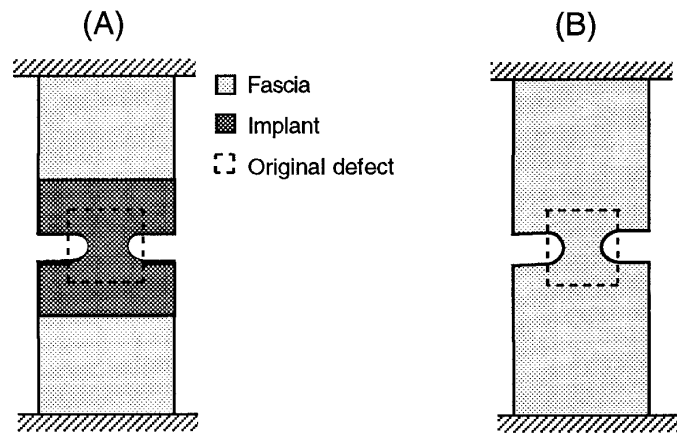

FIG. 2. Configuration used for mechanical testing of repaired (A) and unrepaired (B) fascial defects. Dotted line indicates location of original defect. The specimen dimensions (interclamp length and width in mm) were 4.4 ± 0.1 and 2.1 ± 0.1, 3.9 ± 0.2 and 1.8 ± 0.1, 3.3 ± 0.2 and 1.4 ± 0.1 for the specimens containing carbon fibers, polypropylene mesh, and scar, respectively. In all cases, the width at the notch was 5 mm.
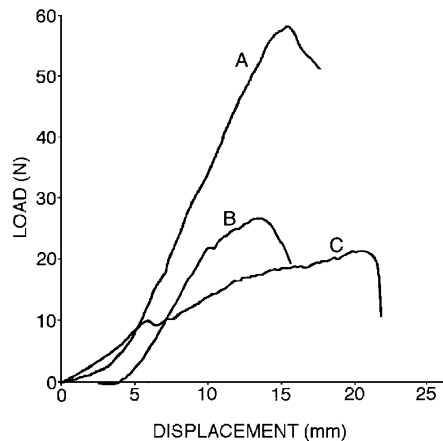
FIG. 3. Typical force–displacement curves for specimens from a dog sacrificed 12 months after operation. (A) Carbon fibers; (B) polypropylene; (C) scar.

*P < 0.05 vs. polypropylene mesh
†P < 0.05 vs. scar

FIG. 5. Mean stiffness (and SE) of repaired and unrepaired fascial defects 3–12 months after operation.

between the carbon-fiber and polypropylene-mesh repairs. Twelve months after operation, however, the carbon-fiber repair was significantly stronger and stiffer than both polypropylene-mesh-repaired and unrepaired defects (Figs. 4 and 5).

DISCUSSION

Carbon fibers have been used to reconstruct tendons and ligaments in animals and in humans with mixed results. Some investigators concluded that carbon fibers induce the growth of a neotendon and that carbon fibers are safe and effective for treating knee instabilities [9–12]. Others disputed these observations, and described fiber migration, persistent effusion, and synovial thickening in patients who had been treated by carbon-fiber reconstruction [5–8].

We hypothesized that the controversies did not involve any fundamental aspect of carbon fibers as a material, but rather stemmed from inadequate implant design and the use of impure carbon fibers. Subsequently, we showed that pure carbon fibers, when configured in a fashion appropriate for the lesion to be treated, were
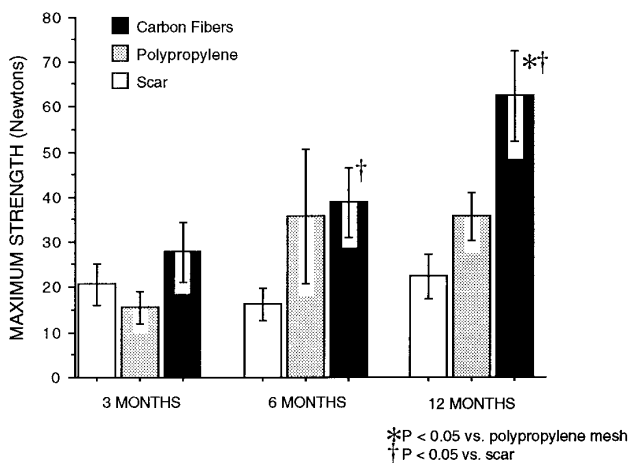
biocompatible and could be successfully employed to repair abdominal wall defects in rats [2], treat tendon injuries in thoroughbred racehorses [3], and reconstruct anterior cruciate ligaments in patients [4].

In the present study, we addressed the narrow question whether an appropriately designed implant made of pure carbon fibers would be biocompatible and would result in greater strength at the site of a fascial defect, compared with polypropylene mesh. We previously showed in a rat model that carbon-fiber implants remained intact and induced more tissue ingrowth than polypropylene mesh [2]. The issue of whether the increased tissue ingrowth at the repair site resulted in increased mechanical strength was addressed in this study. Dogs were used to obtain specimens of adequate size, and the specimens were tested in such a manner that only the tissue found in response to the injury and the implant (where present) could contribute to the measured strength. That is, the configuration used for mechanical testing (Fig. 2) resulted in the direct measurement of the tensile strength of the new tissue. Neither the strength of the implants themselves nor the strength of the implant/new tissue interface (if any) contributed to the measurements.

The standardized fascial defects healed by scar formation within 3 months of operation, and neither the strength nor stiffness of the scar tissue increased when evaluated at 6 or 12 months. At 6 months, the strength of the defects repaired with carbon fibers was significantly greater than that of the defects that healed by scarring, but it did not differ from the strength of defects repaired with polypropylene mesh. Twelve months after operation, the carbon-fiber group was significantly stronger and stiffer than both other groups. The strength of the polypropylene mesh group was essentially unchanged between 6 and 12 months.

On gross examination of the implants after recovery, they were found to be intact, with no evidence of inflammation, fiber breakage, or migration. Thus the biocompatibility of pure carbon fibers described previously in histological studies [2–4] was confirmed in

*P < 0.05 vs. polypropylene mesh
†P < 0.05 vs. scar

FIG. 4. Mean ultimate mechanical strength (and SE) of repaired and unrepaired fascial defects 3–12 months after operation.

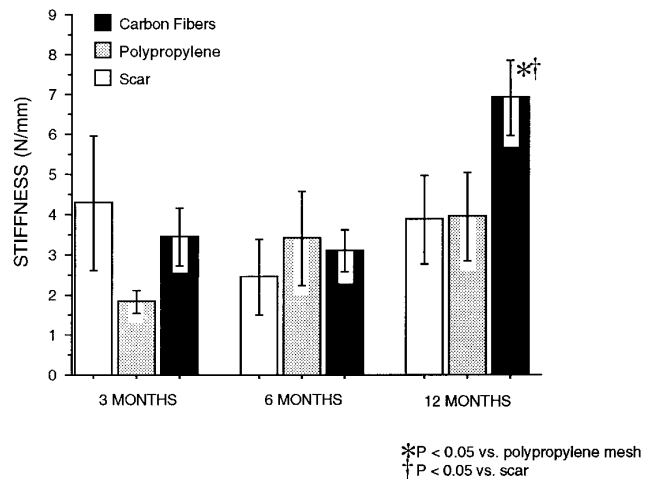this study. We therefore conclude that the carbon fibers were well tolerated and that their presence augmented the mechanical strength of the reparative tissue formed at the defect site.

Many plastics are carcinogenic in animal models [13, 14]. In contrast, there have been no reports indicating that carbon in any form is a mutagen or carcinogen. Attempts to induce tumors with carbon implants in animal models have failed [15]. On the basis of the present evidence, it appears any carcinogenic risk associated with the implantation of pure carbon fibers is negligible, especially compared with presently used materials.

The mechanism of action of the carbon fibers could have involved the connective tissue induced by the implant which was oriented along the carbon fibers. The induced tissue may have functioned as an internal stent, thereby adding mechanical strength at the site of the defect. All mechanical testing was performed in the cranial–caudal direction because specimens of suitable length in the medial–lateral axis could not be obtained in dogs. Nevertheless, since two implants oriented at right angles to each other were used, it is reasonable to assume that the mechanical strength along directions other than that actually examined was also increased.

Alternatively, the mechanism of action might have involved an increase in blood supply. Increased vascularization induced by the implant may have favorably altered the amount or quality of the repair tissue at the site of the lesion. However, the mechanism responsible for the effect of carbon fibers on tissue strength was not addressed in the present study.

An estimated 680,000 groin hernia repairs are performed annually in the United States [16]. The failure rate of primary repairs is difficult to establish based on the existing clinical evidence, but is probably around 10% [17]. The failure rate after an initial repair is even more difficult to ascertain because many authors lump direct and recurrent hernias together, but it is probably 25–30% [18]. Our finding that carbon-fiber implants increase the strength of the repair when compared with the most commonly used material for onlay reinforcement of inguinal hernia repairs suggests to us that an onlay patch of carbon fibers should be tested in an appropriate clinical study to assess whether carbon-fiber implants might be a useful adjunct in the primary repair of inguinal hernias.

ACKNOWLEDGMENT

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