Performance of a Prosthetic Intervertebral Disc

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SUMMARY: Various flexible composite materials were investigated for replacement of the intervertebral disc, the cartilage in the spine between the vertebrae. Four prototype designs were considered. The prototypes consisted of a thermoplastic polyurethane matrix reinforced with aramid or polyethylene fibers. The laminated and the unidirectional composites were strength sensitive to the wet, simulated physiological environment. These two prototypes failed in shear by debonding between the fiber and matrix. The biaxially and triaxially braided designs maintained most of their mechanical properties in the simulated physiological environment, and their strength was shown to be independent of the presence of an interfacial bond between the braided fibers and the elastomeric matrix.

KEYWORDS: prosthetic disc, polyurethane elastomer, aramid fiber, polyethylene fiber, braided composite.

INTRODUCTION

Research has been conducted on replacing the natural intervertebral disc (NID) with a prosthetic intervertebral disc (PID) for over 30 years (1). Steffee (2) reported the implantation of a vulcanized, carbon black reinforced, polyolefin rubber core PIDs in humans in 1989. McMillin and Steffee (3) later reported that 2 of 6 implanted devices fractured during the implant period. Other investigators (4,5,6,7,8) have experimented with flexible composite materials, and others have devised metallic devices (9) or polyethylene devices (10) to ensure the strength of the PID. The strength of a material or device for biological implantation is one of the paramount design criteria.

Strength of a flexible composite material implanted into the human body presents a special challenge. The human body creates a wet service environment, and moisture is known to degrade the strength of many polymer composites (11,12). Similar decreases in compressive strength of a PID in a simulated physiological environment with normal saline were noted by Hudgins (13).

Table 1 shows the target material properties for a PID, which are based upon literary data for the NID. The properties in Table 1 apply to total NID replacements or to nucleus replacements that bear a substantial portion of the spinal load, such as the device of Ray et al. (8). A NID is illustrated in Figure 1.

Table 1: Target Mechanical Properties for a PID

Compressive Modulus (4, 18,20)	4.0 to 16.0 MPa
Minimum Compressive Strength (8, 14)	6.0 MPa
Acceptable Failure Strain (17)	$0.15 \leq \varepsilon_f \leq 0.41$
Minimum Toughness (23)	8.0 J.
*RE (20,21)	0.09 to 0.18

*RE was defined as the ratio of the hysteresis to the energy input.

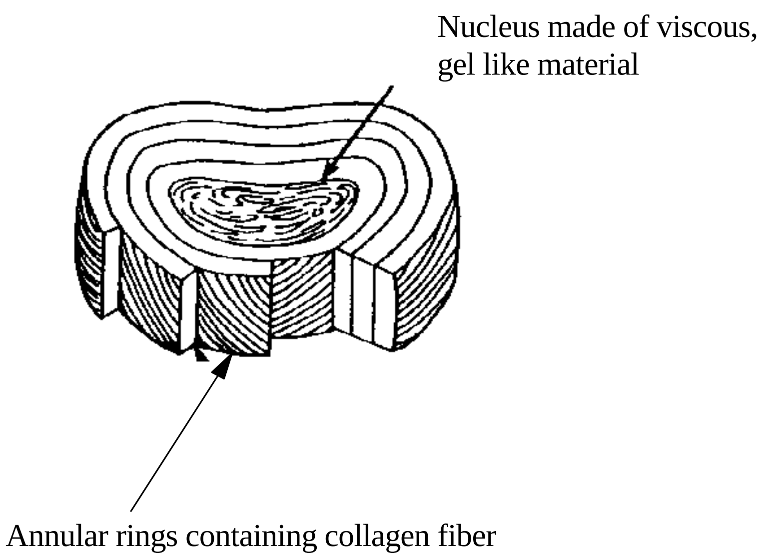

Figure 1: Illustration of the natural intervertebral disc (NID) structure (Yoganandan, (22)).

MATERIALS AND TEST METHODS

Four prototype PID configurations were developed to test concepts governing strength of flexible, fiber reinforced, polymer composite materials subjected to axial compressive loading: 1) laminated aramid fiber/polyurethane, 2) unidirectional (UD) aramid fiber/polyurethane, 3) biaxially braided aramid fiber/polyurethane, and 4) triaxially braided polyethylene fiber/polyurethane devices. The aramid fiber used for PID fabrication was Kevlar ™ 49 (DuPont, Inc.), and the polyethylene fiber was Spectra 1000 ™ (Allied Signal, Inc.). Also, neat polyurethane resin specimens were fabricated by compression molding. Detailed information on the fabrication of samples can be found in Hudgins (13). The materials used in this study are biocompatible (8, 13).

The laminated aramid fiber/polyurethane samples were fabricated from Shore 80A polyurethane and 195 denier aramid fiber. The prototype material is shown in Figure 2. The fibers were oriented in the hoop direction and were confined to thin plates in the r-θ plane. The fiber content was approximately 5% by weight.

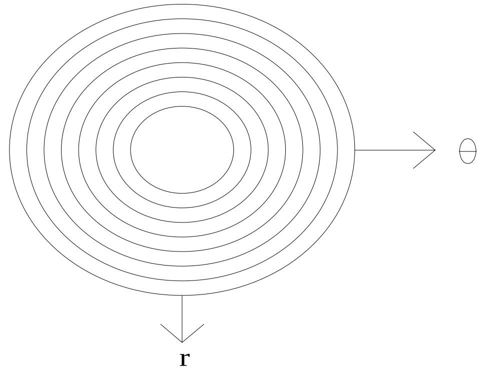

Figure 2a: Concentrically Wound Aramid Fiber Preform

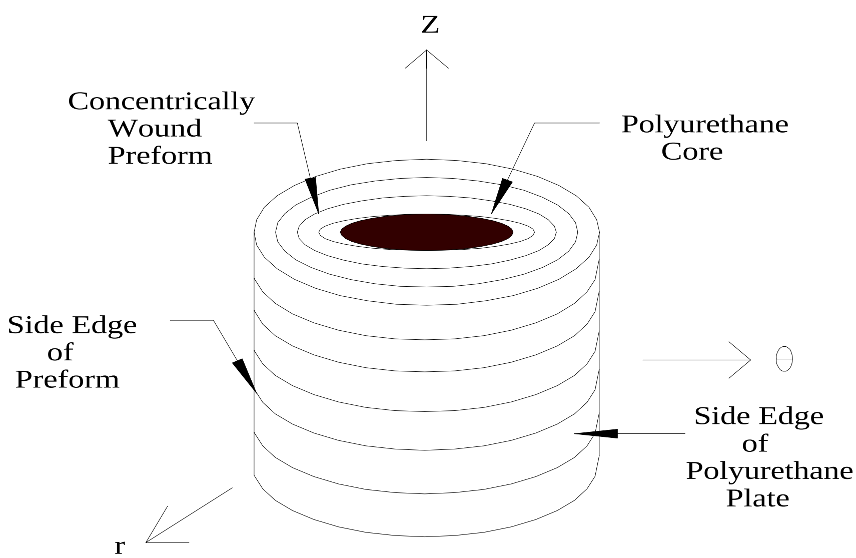

Figure 2b: Consolidated Laminated PID Structure. Alternating layers of polyurethane plates and aramid preforms are stacked vertically and laminated using a compression molding process.

The unidirectional (UD) aramid fiber/polyurethane specimens were fabricated to determine their ultimate compression strength. The unidirectional sleeve was laminated from polyurethane film and unidirectional aramid pre-preg tape. The tape was rolled around a polyurethane core and the entire structure was consolidated in a vacuum hot press. The final prototype is illustrated in Figure 3. The fibers were oriented in the hoop direction and were confined to an external cylindrical sheath. The fiber content was 5% by weight.

Figure 3a: Unidirectional Aramid/Polyurethane tape made from a solution coating process.

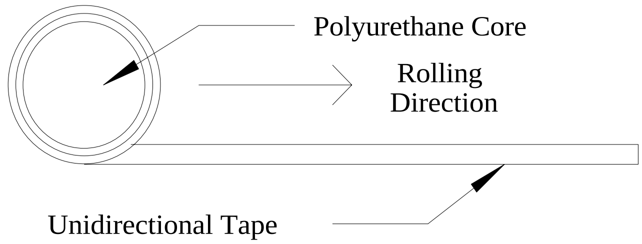

Figure 3b: Unidirectional Tape Rolled Around Core

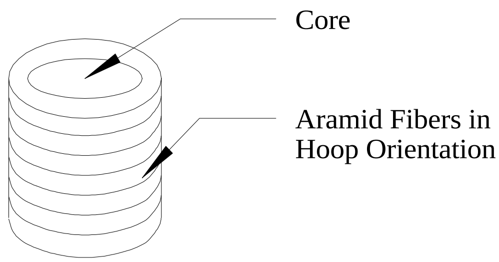

Figure 3c: Finished Rolled Prototype with Hoop Oriented Fibers. The unidirectional fiber tape layers were laminated in a compression molding process.

A third set of PID specimens were prepared with a polyurethane core and a biaxially braided aramid sleeve. The braided sleeve was made of 1420 denier yarn with a 45^o braid angle with respect to the cylindrical axis. The aramid sleeving was dip coated in polyurethane solution and allowed to air dry. Some of the samples were fabricated by coating the core with polyurethane solution and placing the wet core in the braided sleeve to bond the sleeve and core together. The edges of the sleeve were pulled over the ends of the core and sealed together so that the core was completely encapsulated by the braid. The remaining samples were assembled with a dry core and braid so that no significant bonding would occur between the core and the sleeve. The edges of the sleeve were pulled over the ends of the core and sealed together so that the core was completely encapsulated by the braid. Figure 4 illustrates the prototype. The fiber volume fraction in the sleeve was approximately 85 percent, and the final weight fraction of fiber in the combined sleeve and core was approximately 10%.

A fourth set of PID samples were prepared with a polyurethane core and a triaxially braided, highly oriented, polyethylene fiber sleeve. The triaxially braided sleeving incorporated axial yarns parallel to the braiding direction along with the standard biaxially oriented braider yarns (Figure 5). The braided sleeve was made of 1300 denier yarn and an 81^o braid angle with respect to the cylindrical axis. The cores were placed on a mandrel, and the braid was manufactured as a net shape around the cores. The core and sleeve assembly were dip coated in polyurethane solution and allowed to air dry. Figure 5 illustrates the prototype. The fiber volume fraction in the sleeve was approximately 85 percent, and the final weight fraction of fiber in the combined sleeve and core was approximately 7%.

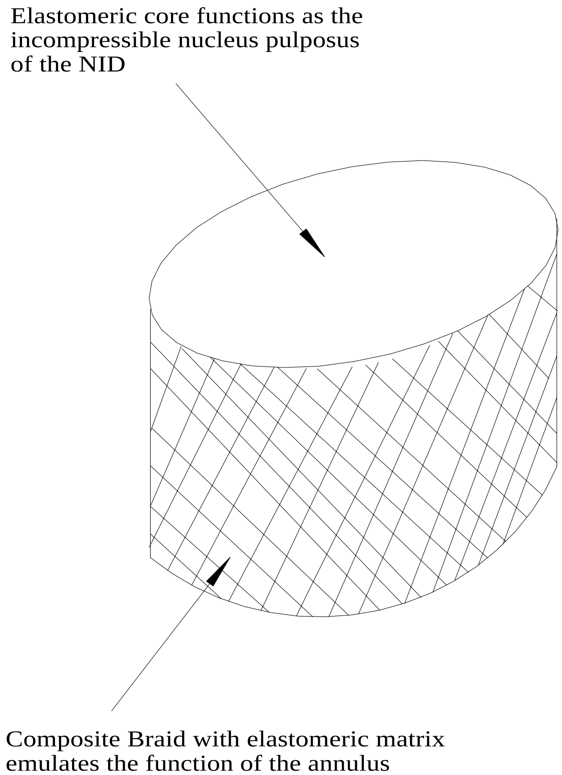

Figure 4. Biaxially braided PID

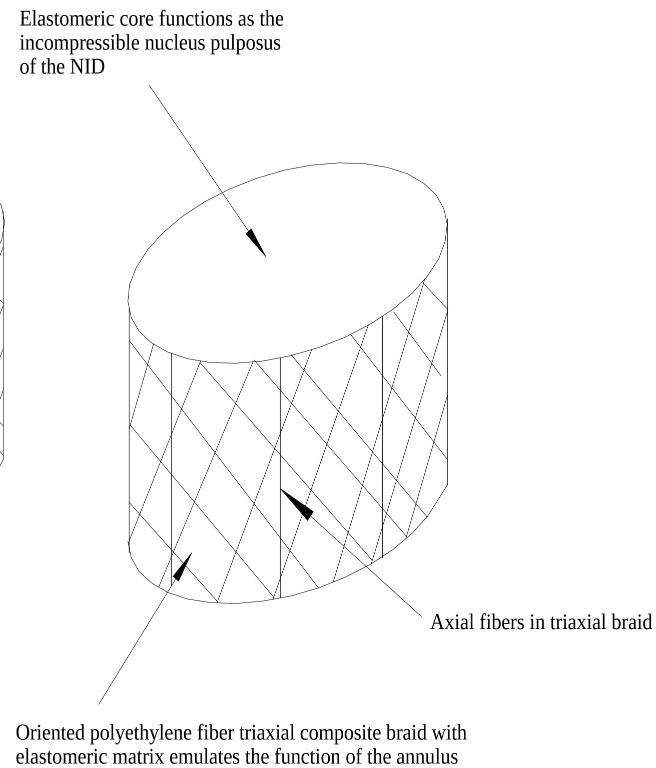

Figure 5. Triaxially braided PID

Axial compression tests were performed on prototype PIDs to determine their ultimate compression strength. An MTS 810 servohydraulic testing machine with flat, parallel compression fixtures was used to conduct the compression tests. Testing was performed with a displacement rate of 25.4 mm/min in ambient conditions and also in simulated physiological conditions. Physiological conditions were simulated by testing samples while immersed in normal saline at 37^{o} C. The prototypes tested in simulated physiological conditions were immersed in 0.9% saline for a minimum of 475 hours. Compression failure was defined as specimen cracking, visible fiber rupture, or delamination. The compressive strength of specimens that failed was defined as the stress applied at failure, and the compressive strength of specimens that did not fail was defined as the stress applied when a finite axial strain of 0.41 was reached. Physiologically, finite axial strains equal to 0.41 can cause damage to spinal structures, such as the discs or the joints toward the back of the vertebrae called the facet joints (17). Therefore, PID devices should support a minimum stress of 6 MPa before reaching a finite axial strain of 0.41 if no other failure occurs (Table 1). Similar compression tests were performed using cyclic loading with resulting peak loads ranging from 675 N to 800 N to determine the modulus and RE value under physiologic loading conditions (18, 19, 20). Koeller et al. (21) defined the RE value as the ratio of the hysteresis to the energy input during a single loading cycle.

RESULTS

Table 2 compares the compressive modulus, the strain at failure, and the toughness of the prototypes in the wet environment. Figures 9 through 12 show typical compressive stress-strain plots of each of the different prototypes. Figure 6 shows the compressive strength plots for neat resin and for each of the prototype configurations. The decrease in strength from the ambient environment to the wet, simulated physiological conditions can be seen for each of the prototypes. Also, a decrease in the compressive modulus can be seen for the neat resin, the UD PID, and the laminated PID from the ambient to the simulated physiological conditions. The compressive strength of the neat resin decreased by approximately 38% from the ambient to the wet environment. The strength of the laminated PID and the unidirectional PID degraded significantly in the simulated physiological environment. The laminated PID strength decreased by 63%, and the unidirectional PID strength decreased by 53%. The strength of the braided specimens degraded much less. The strength of the braided aramid/polyurethane prototype decreased 18% from the ambient to the wet environment, and the strength of the triaxially braided polyethylene fiber/polyurethane prototype decreased 12% from the ambient to the wet environment.

Table 2: Average Mechanical Properties of PID Prototypes in a Simulated Physiological Environment (Range in parenthesis)

Property	Laminated PID	Rolled UD PID	Biaxially Braided PID	Triaxial PE Braided PID
Compressive Strength (MPa)	7.0 (6.7 to 7.2)	7.0 (6.9 to 7.5)	18.0 (16.7 to 20.1)	23.0 (22.1 to 24.0)
Compressive Modulus (MPa)	43.5 (40.5 to 45.0)	37.0 (35.8 to 39.5)	8.0 (6.9 to 8.8)	17.8 (15.5 to 19.2)
Failure Strain	0.13 (0.12 to 0.14)	0.14 (0.135 to 0.145)	0.37 (0.36 to 0.39)	0.18 (0.17 to 0.19)
Toughness (J)	1.5 (0.9 to 1.7)	6.9 (6.2 to 7.5)	28.8 (27.0 to 29.5)	33.9 (31.8 to 34.2)
RE	*	0.012 (0.010 to 0.013)	0.10 (0.95 to 0.12)	0.18 (0.15 to 0.20)

*RE value not available because of sample failure on first compression cycle

The compressive strength of all prototypes and the neat resin was greater than the 6 MPa design criterion, and the strains at the maximum compressive load were within or exceeded the specified range of 0.15 to 0.41 in the ambient environment. The laminated and unidirectional PID prototypes failed at strains less than 0.15 in the simulated physiological environment, and the toughness of the prototypes fell below the design minimum of 8 J. All of the laminated aramid/polyurethane and unidirectional aramid/polyurethane prototypes failed by fiber/matrix debonding in the wet, simulated physiological environment. The triaxially braided polyethylene fiber/polyurethane prototypes demonstrated high strength, and the failure strains exceeded 0.15. The toughness was well beyond the minimum design criterion of 8J. The triaxially braided samples eventually failed by buckling. The braided aramid/polyurethane specimens exceeded the minimum strength and toughness, and they performed almost to the 0.41 strain limit at which the minimum stress applied to the prosthesis must be at least 6.0 MPa in the ambient and wet conditions. Fibers ruptured at the cylindrical ends of these specimens.

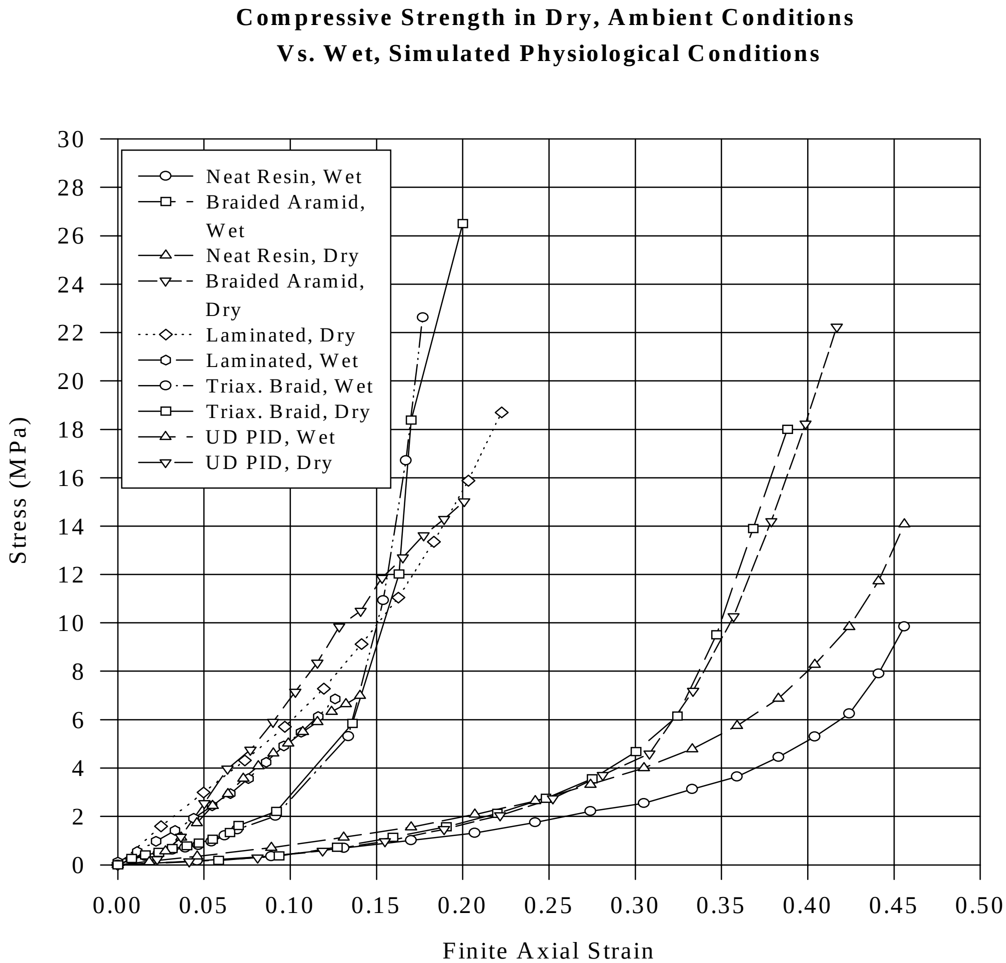

Figure 6: Compressive strength plots for each PID prototype configuration in ambient and simulated physiological conditions

The compressive strengths of the bonded and the unbonded braided aramid fiber/polyurethane samples were virtually the same in the simulated physiological environment. The two bonded samples had an average compressive strength of 19 MPa, and the two unbonded samples had an average compressive strength of 17 MPa. Thus, the compressive strength of the aramid/polyurethane specimens was averaged at 18 MPa since there is little difference between the two sample configurations based on two test samples for the bonded and two test samples for unbonded prototypes.

Table 2 shows that the triaxially braided polyethylene fiber/polyurethane prototypes had a high strength in the wet environment also, 23 MPa. However, the fiber and the matrix could be peeled apart by hand with little effort for either the dry or wet samples. Therefore, these samples demonstrated high compression strength with little or no interfacial bonding between the fiber and matrix.

The properties in Table 2 can be compared to the design criteria in Table 1. All compression properties of the braided aramid fiber/polyurethane device were within acceptable ranges. The triaxially braided polyethylene fiber/polyurethane PID met all design criteria with the exception that the modulus was too high. A number of the compressive properties of the laminated and unidirectional PID prototypes did not meet the design requirements.

DISCUSSION

The compressive strength of the braided PID prototypes was significantly greater than the strength of the laminated or unidirectional PID prototypes. The decrease in the strength of the braided prototypes in the wet environment was minor compared to the laminated and unidirectional prototypes. It is reasonable to speculate that the strength decrease of all the PIDs from the ambient to the simulated physiological condition was due to moisture absorption of the PID. Moisture absorption was shown to occur in saline absorption testing of the materials. The design premise for the braided prototypes was that the braided sleeve would act as a containment vessel and restrict the radial deformation of the polyurethane core. The pressure applied to the sleeve by the radial expansion of the core is perpendicular to the inside surface of the braided sleeve, and the pressure induces a tensile hoop stress in the braided sleeve. Thus, the strength of the braided PID is dependent on the braided sleeve’s ability to resist the resulting hoop stress instead of the ability of the fiber/matrix interface to resist a shear stress.

The strength of the unbonded test specimens shows that the compressive strength of the braided PID was not completely dependent on the interfacial bonding between the braided fiber sleeve and the elastomeric core. The compressive strength of the triaxially braided polyethylene fiber/polyurethane PID further verifies that the PID strength was not completely dependent on the interfacial bonding of the fiber and the matrix. Polyurethane and polyethylene are incompatible materials, and the lack of bonding was demonstrated by easily removing the polyurethane matrix from the polyethylene fibers.

CONCLUSIONS

The laminated and unidirectional PID prototypes showed significant compressive strength degradation in the wet, simulated physiological environment compared to the ambient environment. Substantial fiber/matrix debonding occurred at significantly lower stresses in the wet environment for these two PID designs. The braided PID designs retained most of their compressive strength in the wet environment. Furthermore, the braided specimens were shown to be strong in compression without bonding between the fiber and matrix. Thus, the braided sleeve provides compressive strength that is less dependent on either the service environment or the degree of interfacial bonding between the fiber and matrix compared to the laminated or unidirectional designs. Furthermore, bonding between the core and sleeve is not required. The braid for the triaxially braided polyethylene/polyurethane prototypes could be redesigned to decrease the modulus, and likely the other compressive properties would remain acceptable for a PID material. The braided aramid/polyurethane design presented in this study possesses acceptable performance properties compared to the NID.

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