Orthotics and Prosthetics, Vol. 40, No. 4, pp. 44–58.

Evaluation of High Strength Materials for Prostheses

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INTRODUCTION

The weight of a prosthesis has always been a problem for prosthetic researchers.[1] According to Mooney,[2] most below-knee prostheses, laminated in the normal prosthetic laboratory, weigh about five pounds. Below-knee prostheses are usually attached to the limb by a strap around the thigh or with wedges pressing inwards above the condyles of the femur. With normal gravitational forces, this weight creates a friction between the residual limb and the prosthetic socket interface that may cause skin breakdown.

The weight of a prosthesis may cause excessive muscle work that will result in high energy consumption for amputees. Mooney[2] states that, "a standard prosthesis requires approximately 12 percent more energy consumption" and "energy consumption is the key to successful ambulatory activities."

Ganguli, et al.[3] stated that, "with respect to energy expenditure, the degree of departure from normal performance standards in the below-knee amputee fitted with a patellar tendon bearing (PTB) prosthesis is quite high." Cummings, et al.[4] states that, "a distally applied weight of 2½ pounds would be expected to add five to ten percent to the energy requirement of ambulation." Fisher and Gullickson[5] state that below-knee amputees "walk 36 percent slower, expending two percent more Kcal/min and 41 percent more Kcal/mtr than the normal person." Waters, et al.[6] found that vascular below-knee amputees walk 41 percent slower and expended 55 percent more Kcal/mtr/Kcal/kg than non-amputees.

The need for lighter weight prostheses is often cited in the literature[1,2,7,8] and occasionally an innovative procedure will surface;[9] however, when the technology differs from that in current practice, the prosthetic clinic team has difficulty adapting to it. The procedure described by Wilson[9] was not familiar to the prosthetist; as a consequence, this very lightweight prosthesis is not commonly fabricated.[17]

Prostheses are normally excessively heavy, which tends to increase residual limb trauma and energy expenditure with the likelihood of less successful prosthetic function. It is the intent of the clinic team to provide an appliance that will stand up under the strain of constant use. With these considerations in mind, the Rehabilitation Engineering Lab (REL) at the University of Texas Health Science Center at San Antonio (UTHSCSA) proposed to determine if a material could be designed which would utilize normal prosthetic laboratory techniques, yet allow the prosthetist to produce a below-knee prosthesis weighing less than two pounds and having the strength to adequately support normal ambulation loads.

CURRENT STATUS OF WORK IN THE AREA

Aramid™ fibers and carbon fibers were selected as new materials to be used as a reinforcement for the lamination of prostheses because:

- Aramid™ fibers have a very high tensile strength (Figure 1) and the elongation to break ratio is very low (Figure 2).
- Carbon fibers exhibit an excellent modulus and their density is lower than many other materials currently used for strength in prostheses (Tables 1 and 2).

The tensile strength of Aramid™ and carbon fibers is far superior to nylon, the material normally used by many prosthetists. The nearly linear stress/strain curve to failure of Kevlar® 29 (Aramid™ fiber) is similar to that of glass, but unlike those of other organic fibers (Figure 3). Because it is relatively insensitive to fiber surface defects, the tensile strength of Kevlar® 29 is uniform along the length of the fibers.

Research work in the area of orthotics and prosthetics using carbon fibers has been directed primarily toward orthotics. In 1976, N.A.S.A. published a technical brief in which they described a new, lightweight brace constructed of fiber rein-

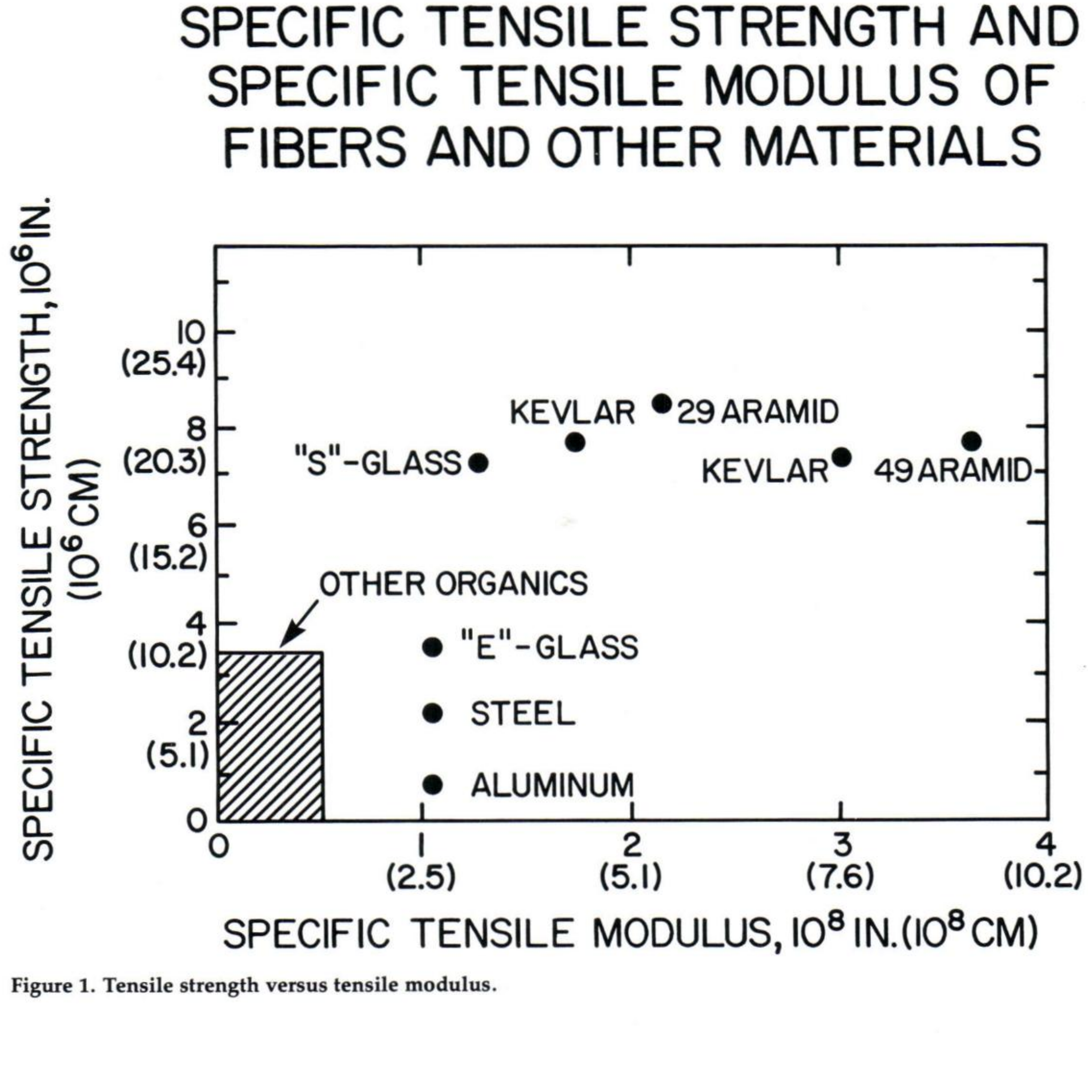


Figure 1. Tensile strength versus tensile modulus.

COMPARATIVE YARN PROPERTIES

	KEVLAR® 29 Aramid	DU PONT Nylon Type 728	DACRON® Polyester Type 68	"E-HTS" Glass	Stainless Steel
Tensile Strength, lb/in^2	400,000**	143,000**	162,500**	350,000***	250,000
(MPa)*	(2758)	(985)	(1120)	(2412)	(1724)
Modulus, lb/in^2	9,000,000	800,000	2,000,000	10,000,000	29,000,000
(MPa)	(62000)	(5512)	(13780)	(68900)	(199800)
Elongation to Break, %	4.0	18.3	14.5	3.5	2.0
Density, lb/in^3	0.052	0.041	0.050	0.092	0.284
(g/cm^3)†	(1.44)	(1.14)	(1.38)	(2.55)	(7.83)

*Mpa = $MN/m^2 = lb/in^2 \times 6.895 \times 10^{-3}$
**Unimpregnated twisted yarn test — ASTM D2256
***Impregnated strand test — ASTM D2343
†$g/cm^3 \times 27.68$

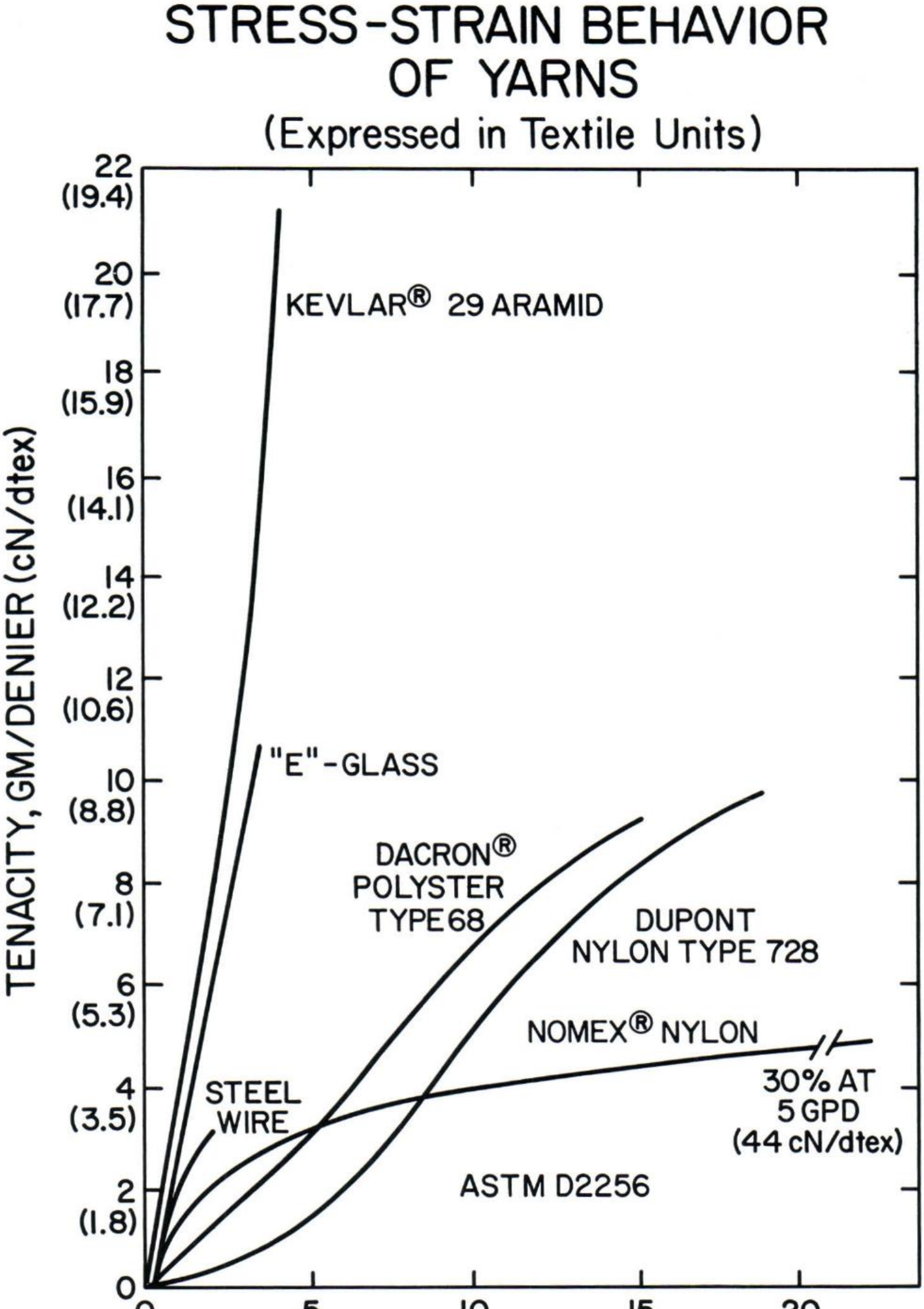
Figure 2. Reprinted with permission from Dupont's "A Preliminary Information Memo," Number 375, September 28, 1976.

forced polymer materials.[10] Also in 1976, the Southwest Research Institute published a final technical report prepared by S.R. McFarland and G.C. Grimer[11] in which they reported producing a pair of bilateral long leg braces from carbon fiber filaments. These braces weighed approximately 1½ pounds each, including the footplate which was formed of steel.

The orthoses produced by N.A.S.A. and the braces produced by McFarland at Southwest Research Institute both employed a very lengthy process which requires placing layers of composite materials on an intercore and laminating these materials together to be used as struts for the orthosis. Neelham, in his paper, "Carbon Fiber Reinforced Plastic Applied to Prosthetics and Orthotics,"[12] described a process similar to the one employed by N.A.S.A. and Southwest Research to fabricate a harness for externally powered upper extremity prostheses that were fitted to thalidomide damaged children. He also fabricated a thoracolumbosacral orthosis and a bilateral hip-knee-ankle-foot orthosis.

The fabrication process and the technology needed to fabricate these orthoses and prostheses require extensive retraining in laboratory techniques for prosthetists and orthotists in this country. New machines and tools would have to be installed. Richard Striebinger, in a letter to S.R. McFarland dated February, 1983,[13] stated that his group at the Rensselaer Polytechnic Institute in New York had fabricated an orthosis in a sandwich construction using graphite, Kevlar® 29, and an epoxy matrix along with a foam core. This process, like the others, requires a long, complicated curing process under vacuum at room temperature.

Hittenberger and Putzi,[14] at the V.A.M.C. lab in Seattle, Washington, reported they had developed a laminating procedure for lightweight prostheses which requires one of the laminations to be split and a foam core removed. This produced a prosthesis that weighed approximately 1½ pounds. However, the lab procedures, as described, require the prosthetist to cut the prosthesis posteriorly along the sagittal line. This would tend to weaken the prosthesis in an area that receives very high stress and might cause it to break. The "Ultralight Below Knee Prosthesis"[9,15] requires a "hand draped" vacuum formed fabrication procedure and polypropylene polymers. These are split posteriorly and later welded together. While the prostheses are ultralight when compared to conventional systems, the process requires new technology, additional tools and machines, and the end



CONVERSION FACTOR $\frac{LB}{IN^2} = \left(\frac{GM}{DEN}\right) \times$ DENSITY $\left(\frac{GM}{CM^3}\right) \times 12{,}800$

Figure 3.

	2024-T4 ALUMINUM	POLYPROPYLENE	CARBON FIBER/ EPOXY COMPOSITE
Tensile Strength			
$LB/IN^2 \times 10^3$	55.0	5.1	211.0
Comp. Yield Strength			
$LB/IN^2 \times 10^3$	32.0	5.0	171.0
Tensile Modulus			
$LB/IN^2 \times 10^3$	10.0	0.16	18.5
Density LB/IN^3	0.101	0.033	0.555
Tensile Strength			
Density $IN \times 10^5$	5.4	1.55	38.4
Tensile Modulus			
Density $IN \times 10^8$	1.0	0.15	3.4

*Taken from Table I, NASA Tech Brief 75-10303

Table 1.

Comparison of Tensile Strength of Graphite With That of Other Structural Materials

Type of Material	Strength, ksi		Density lb/in.^{3}
	0°	Isotropic	
Graphite AS/epoxy	225	84	0.056
Graphite HMS/epoxy	165	50	0.059
S Glass/epoxy	260	110	0.072
E Glass/epoxy	120	75	0.072
Aluminum (7046-T4)	55		0.100
Steel (SAE-980)	80		0.289
Nylon (6/6)	12		0.041

Table 2.

product is prone to failure,[17] due to the high stress placed on the ankle-foot components during the forming process, and because of inappropriate heating and cooling of the plastic. This procedure has not gained acceptance by the prosthetic profession.

OBJECTIVE OF THE RESEARCH PROJECT

This project was designed to study the following objectives:

- To establish manufacturing techniques and criteria for knitting Aramid™ and carbon fibers into stockinette materials suitable for lamination in prosthetic laboratories.
- To determine which fiber or combination of fibers would make the strongest and lightest weight prosthesis.
- To determine the best polymer (acrylic—epoxies—polyesters) for laminating these fibers in prostheses.

MATERIALS

Carbon fibers and yarns are made by several companies in the United States, however, most of these products cannot be knitted into materials that are suitable for normal prosthetic applications because the fibers are so soft. In their natural state the fibers must be braided into heavy bulky strands to eliminate breakage during the knitting process. These bulky braids result in an undesirable uneven surface on the completed prosthesis.

Aramid™ fibers and yarns in a variety of sizes are manufactured in the United States. Most of these are suitable for knitting purposes. In addition, the Otto Bock Company of Minnesota has developed a lamination technique using carbon fibers in a mat form,[16] but reinforcement materials in a mat form are not normally used in the prosthetic lab. The superior properties of Aramid™ and carbon fibers have prompted several companies to develop an assortment of fabrics to be used for prosthetic laminating.

Aramid™ fibers are used in Aralon.™* This product is described as a high strength "stockinette" made of high technology fibers next in strength to that of carbon. The manufacturer claims that Aralon™ "produced a prosthesis over 40 percent stronger and almost half the weight of conventional prostheses and that Aralon™ is 2½ times superior in ratio of fiber strength to weight than nylon." It also is claimed to have superior impact and fatigue resistance and excellent thermal stability with little change in dimension over normal temperature ranges. Aralon™ is said to be compatible with both polyester and epoxy resins, and stretches like regular "stockinette." Carbon fibers in combination with glass and Aramid™ were knitted into a stockinette material for this project by IPOS.**

A stockinette material made from a combination of carbon and glass fibers** has been available for several years, but most prosthetic facilities have not used it because it is very expensive, the glass fibers are health hazards to work with, and the knitted material when laminated does not have a smooth appearance. It is claimed this carbon fiber material is compatible with an acrylic resin, trade-named Carbon Acryl.™** According to the manufacturer, Carbon Acryl™ has an additive that makes it very compatible with the carbon fibers and causes a "chemical bond" during lamination.

- The following yarn specifications were obtained for knitting and testing by the Knit-Rite Company of Kansas City, Missouri:
  - —Aramid™: Kevlar® 29—14/1 and 20/1
  - —Carbon: Pyron—4/10 w.c. and 2/32 w.c. Panex (refired)—30Y800, 30Y300 and 30R
  - —Glass: Fiberglass—150—1/0-1
  - —Nylon: Stretch nylon—1/100 Type 66 D-4 Perma-Set

(The above yarns were knit in stockinette and rib stitch by Knit-Rite, Inc., of Kansas City, Missouri, as outlined in Figure 4.)

*Manufactured by Comfort Manufacturing Company of Burlington, New Jersey

**IPOS Komman Ditgesellschaft, Luner Renn Bahn 14.D2120 Luneberg

ARAMID, CARBON, NYLON, GLASS, FIBERS

	Kevlar 1/14	Kevlar 1/20	Pyron 4/10 W.C.	Pyron 2/32	Panex 30 Y 800	Panex 30 Y 300	Panex 30 R
Kevlar 1/14	1/1 lab 1/1 rib						
Kevlar 1/20		1/1 rib					
Pyron 4/10 W.C.	1/1 lab 1/1 rib		1 lab				
Pyron 2/32				4 rib refired			
Panex 30 Y 800		1/1 lab					
Panex 30 Y 300		1/1 lab					
Panex 30 R		1/1 lab					
Nylon 66					1/2 lab	1/2 lab	
Stretch Nylon Y 100		1/1, 2/1 lab 1/1 rib				1/1 lab 1/1 rib	1/1 lab
Fiberglas 150 - 1/0 - 1		1/1 lab* 1/1 rib			*3 stitch settings		

1. Top number refers to ends (strands) of vertically listed fiber.
2. Bottom number refers to ends (strands) of horizontally listed fiber.
3. Rib knit — circular machines.
4. Lab knit stockinette with every other needle out on 6" cylinder.
5. KEVLAR = ARAMID
6. PYRON = CARBON
7. PANEX = GRAPHITE

Figure 4. The top number refers to ends of vertically listed yarn. The bottom number refers to ends of horizontally listed yarn. Lab knit is stocknette; rib knit is knit-pearl stitch on the circular machine.

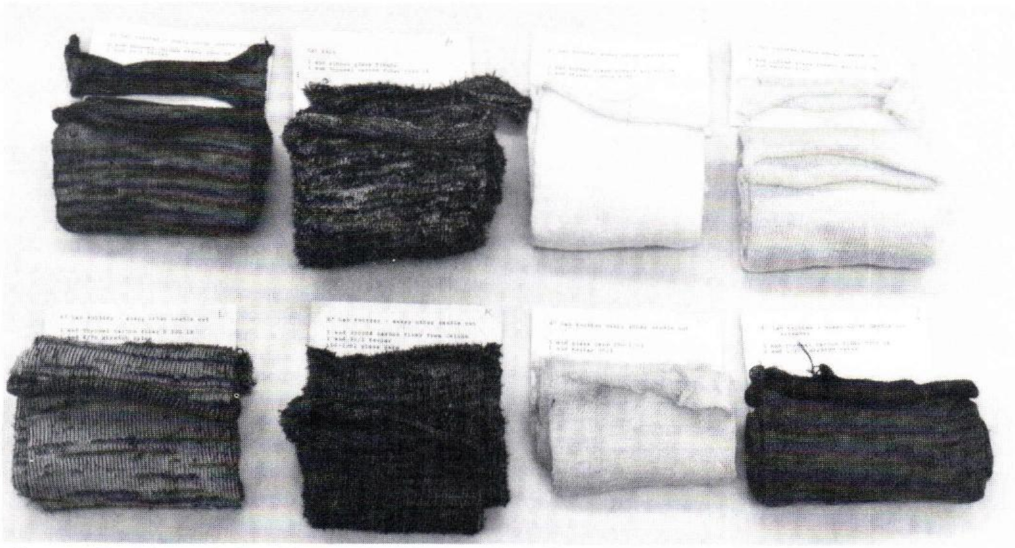


Figure 5. Stockinette knitted for use in this research project.

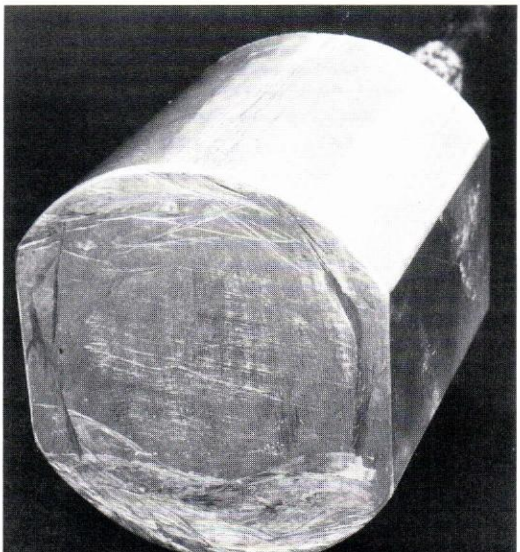


Figure 6. To restrict variability in strength measurements, a cylindrical aluminum mold with two flat sides of equal proportions was machined to be used as the model for laminating all of the test laminations.

Using the knitted stockinette materials from Knit-Rite and IPOS (Figure 5), we laminated a series of test models using the new stockinette material with:

- IPOS Carbon Acryl™ acrylic resin
- Epocast 502 epoxy resin
- Laminac 4110 polyester.

To restrict variability in strength measurements due to physical and geometrical factors, a cylindrical aluminum mold with two flat sides of equal proportions (Figure 6) was machined and fabricated to be used as the model for laminating all of the test laminations. Coupons measuring two and one half centimeters by five centimeters were cut from each of the laminations (Figure 7). These coupons were tested for strength using the Instron.™ The Instron™ conventionally measures strength and flexoral properties of plastics. It conforms to the American National Standard K6575-1971. This testing method has been approved for use by agencies of the Department of Defense to replace Method 1031 of Federal Test Methods Standard 406 and for listing in the DoD Index of Specifications and Standards. The instrument provides a graphic readout of the force (measured in Newtons) required to fracture the coupons.***

***1 Newton = .102 grams.

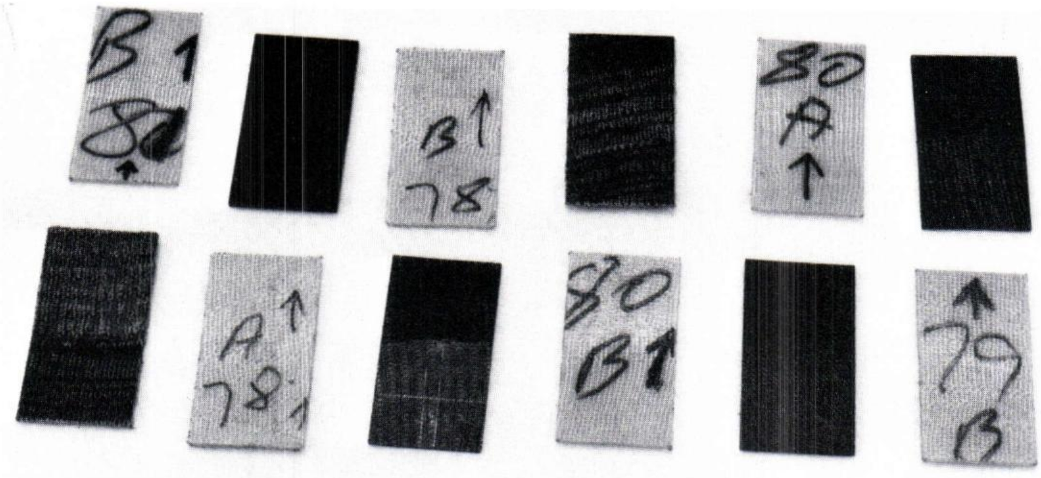


Figure 7. Coupons measuring two and one-half centimeters by five centimeters were cut from each of the laminations.

PROCEDURE

Using each of the different materials with each of the different resins, a series of test models were laminated under vacuum pressure over the custom designed aluminum mold.

- *Acrylic Resins*—Using the custom made mold, we laminated the stockinette made from the Aramid,™ nylon, and glass fibers separately and in combination using the acrylic resins, as follows:
  - —Over the custom mold, we pulled a poly vinyl alcohol sheet (PVA) and applied vacuum under the PVA to insure good mold clarification.
  - —We applied the stockinette, and over this stockinette we pulled a PVA bag to hold the acrylic resin.
  - —Vacuum was applied under this bag to insure good mold conformity.
  - —The laminating resin was prepared by combining 250 grams of carbon Acryl™ with enough hardening powder to effect a cure time of 30 minutes.
  - —This mixture was then poured into the PVA bag, allowed to impregnate the stockinette, and then cured.
  - —From the laminated model, we cut two coupons, 2½ cm by 5 cm.
  - —To test the strength of the coupons, they were placed in the Instron,™ using a three-point bending apparatus on supports spaced 30mm apart. A downward force was applied exactly at the center of the coupon at a rate of 10mm descent per minute. The strength of the material was measured as peak force at fracture.
- *Epoxy Resin*—Using the above described procedures, we laminated a new series over the custom made model using epoxy resin.
- *Polyester Resin*—Using the above described procedure, we laminated a new series over the custom made model using polyester resin.

At this time, our project has produced more than 300 laminated coupons using the various combinations of fibers. The strongest coupons obtained from the various combinations of Aramid,™ carbon, nylon, and glass fibers are listed in Table 3.

RESULTS

Coupons of standardized width and length, but variable thickness, were tested

Strengths of Various Resins and Fabric Combinations

Fiber	Strength N/mm^2	Resin	Std. Dev. + or −
Carbon/Nylon/Aramid	255.567	Acrylic	61.774
Carbon/Glass	193.908	Epoxy	30.604
Carbon/Aramid	176.651	Epoxy	50.791
Carbon/Aramid/Glass	152.781	Polyester	17.492
Aramid	151.851	Polyester	34.166
Carbon/Nylon	148.113	Epoxy	21.675
Aramid/Nylon	131.221	Polyester	10.393
Aramid/Glass	104.945	Epoxy	29.727
Nylon	70.581	Epoxy	5.774

Table 3.

in a three-point transverse loading apparatus using the Instron™ for administering a measured load. Thickness, maximum transverse breaking force, and the standardized width and length parameters were then compiled, and the transverse strength computed according to the formula,

$$S = \frac{F * L}{4 * z}$$

where S— is the maximum stress incurred by an "extreme fiber" most distant from the central bending axis;

F— is the transverse load in Newtons;

L— is the span between the two supports (30mm in this experiment);

z— is the "section modulus" characteristic of the cross-section geometry. For these coupons it is equal to: $\frac{1}{6}$ * width * Thickness.^{2}

Therefore,

$$S = \frac{3\ F\ L.}{2\ W\ T^2}$$

Coupons were grouped to the type resin and fiber combination; (See Figures 8, 9, and 10).

The appropriate individual transverse strength measurements were then pooled, and means and standard deviations computed (Table 3). The relatively large standard deviations in some of the groups are due in part to the nature of the laminating process currently in widespread use. When woven tubular stockinettes are pulled over a particular prosthesis shape, the orientation and overlap of fiber layers becomes arbitrary within certain bounds set by the stockinette manufacturer's knitting pattern. Accordingly, when test coupons are cut from the laminated prostheses, there is no way to control for direction or degree of offset of fiber layers. Since this element of randomness would creep into all tests, it was concluded that a mean strength estimate would reflect a fairly respresentative number for an "average" prosthesis made in this clinically typical manner.

To illustrate a comparison of "typical" prostheses weights using any of the several possible combinations, we choose a model below-knee prosthesis laminated in nylon/polyester by a local prosthetic facility. The facility was unaware that the below-knee prosthesis was to be used for this research project.

The finished prosthesis, including the socket, was first coated with a castable urethane elastomer produced by Smooth-on, Inc., of Gillette, New Jersey. After curing, the elastomer was carefully removed without stretching, then cut into eleven pieces

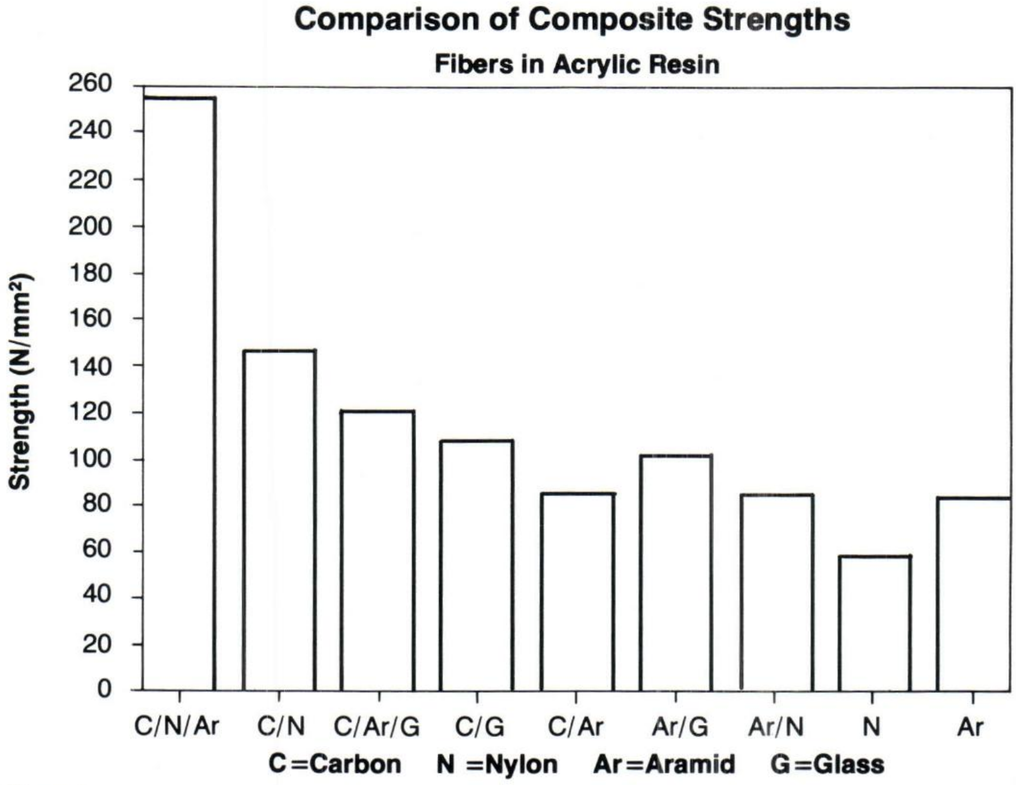


Figure 8.

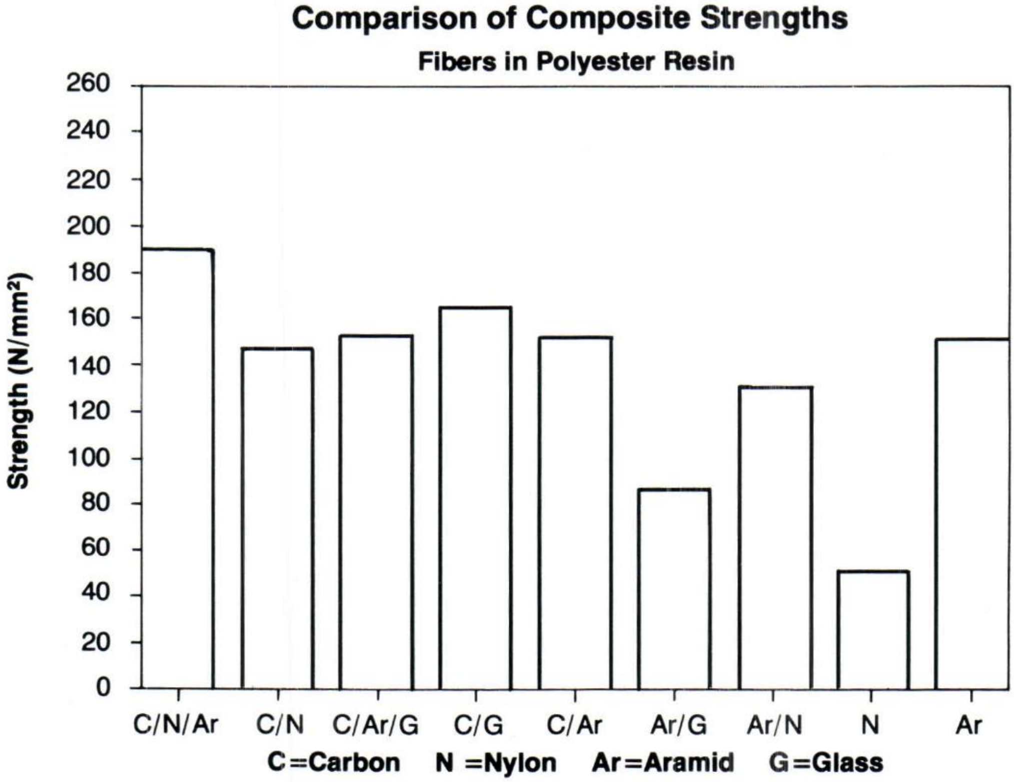


Figure 9.

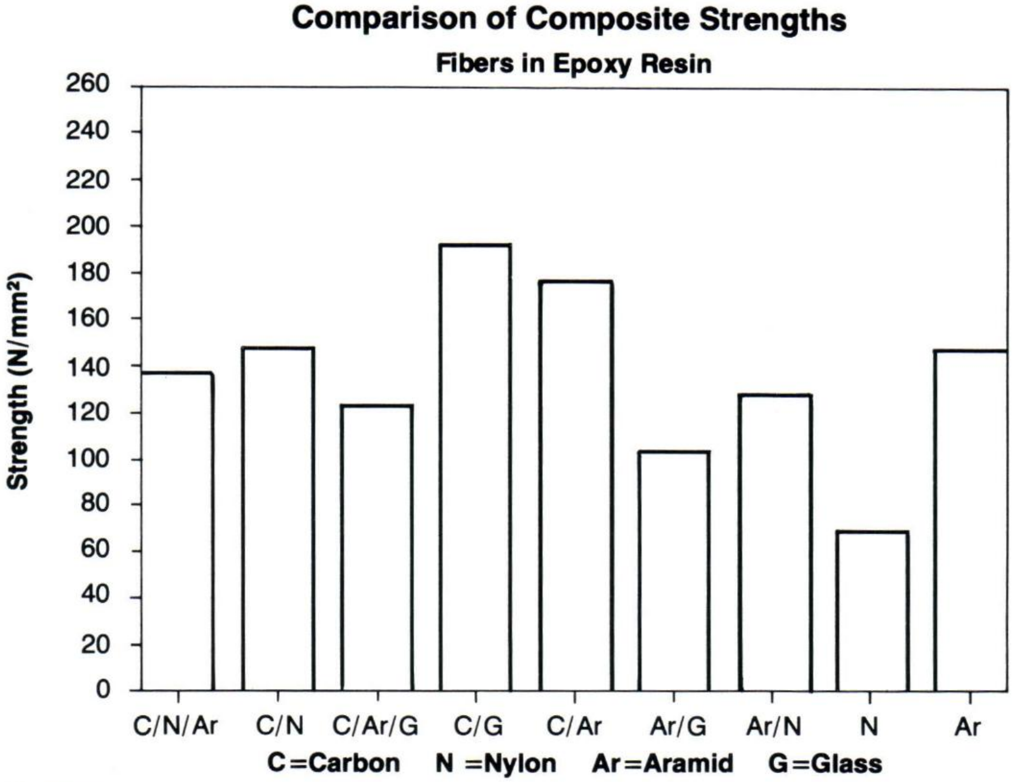


Figure 10.

Characteristics of a Below-knee Prosthesis Made of a Nylon/Polyester Composite

Model B-K Prosthetic Characteristics

Nylon/Polyester Composite

	Area cm^2	Thickness mm	Break Force Nwt
Surface Area Total cm^2:	2073.938		
Zone 1 Inner:	627.138	4.115	1982.024
Zone 1 Outer:	650.000	1.633	123.7539
Zone 2 Outer:	796.800	2.363	375.4693
Coupon Width (mm):	25.000		
Coupon Sep Dist (mm):	30.000	Used for Strength	
Coupon Length (mm):	50.000		
Coupon Tot Area (mm^2):	1250.000		
Coupon Wgt:	Changes		
Nylon/Polyester Stress:	51.200		

Figure 11.

ACRYLIC				
Abbrv.	Equ. Wgt. gm	Ave. Strength N/mm^2	Std. Dev. + or −	Density gm/cc
C/Ar/G	295	121	63	0.710
C/Ar	331	85	15	0.710
Ar/G	479	102	29	1.089
C/G	498	108	8	1.158
N	494	58	16	0.931
C/N	507	147	36	1.303
Ar/N	527	85	9	1.128
C/N/Ar	615	256	62	1.902
Ar	740	83	10	1.574

EPOXY				
Abbrv.	Equ. Weight gm	Ave. Strength N/mm^2	Std. Dev. + or −	Density gm/cc
Ar/G	274	105	30	0.630
C/N	294	148	22	0.757
C/Ar	385	177	51	1.052
N	431	71	6	0.868
C/N/Ar	490	138	14	1.233
Ar/N	525	129	30	1.294
C/G	541	194	31	1.526
C/Ar/G	564	124	16	1.371
Ar	606	149	25	1.564

POLYESTER				
Abbrv.	Equ. Weight gm	Ave. Strength N/mm^2	Std. Dev. + or −	Density gm/cc
C/N	156	147	25	0.402
C/N/Ar	292	190	24	0.818
C/Ar/G	414	153	17	1.080
C/G	422	166	58	1.131
Ar/G	499	87	23	1.078
C/Ar	518	152	50	1.350
Ar/N	605	131	10	1.500
Ar	544	152	34	1.451
N	691	51	6	1.250

Table 4.

in such a way that they would lay approximately flat. These pieces were then measured using a 2-D digitizing planimeter. This area figure was taken to represent the total surface area of the prosthesis, excluding the plantar surface of the prosthetic foot. For this prosthesis, the area totaled some 2,300 square centimeters.

Next, circular corings were taken in various areas or "zones" on the prosthesis: four in the socket wall, and three in various places down the leg. For the socket cores, which penetrated both the outer prosthetic wall and the socket inner wall, two distinct layers of hardened composite were visible. Measurements of layer thickness were made. Three zones emerged: Zone 1i, the inner lay-up thickness of the socket wall itself; Zone 1o, the outside wall thickness of the socket; and Zone 2o, the outside wall thickness everywhere else in the leg.

A set of nylon/polyester coupons were tested to obtain a figure for the material's strength (as maximum stress). By calculating the equivalent breaking force required to break a nylon/polyester coupon with thickness equal to that of each zone in the prosthesis, a "Design Break Force" figure was obtained for each zone (Figure 11). Then, using the stress numbers determined for each test material, an estimated thickness could be calculated for any new material used to build a prosthesis having a similar "Design Break Force" for each zone. Furthermore, knowing the density of each composite, the surface area (2,300 cm^2) and thickness of material requred, a weight figure was generated giving the minimum weight of composite materials required in an equivalent "typical" prosthesis (Table 4).

CONCLUSION

Knitted combinations of high-strength yarns were laminated with different resins and laboratory tested in order to obtain a material which could be used for making lightweight, high-strength prostheses and orthoses by facilities using techniques and equipment readily available to them.

This project has established knitting specifications for stockinette manufacture using Aramid™ and cotton yarns. These yarns and the combinations tested may not be the most suitable for prosthetic laminations because of the many variables, i.e., price, availability, combinations not tested, and the fact that newer and stronger fibers are waiting to be discovered.

Although prototypes of prostheses have been made by the Rehabilitation Engineering Laboratory, the actual clinical work still needs to be done. However, the results of this research indicate that materials have been identified which have potential and should be tested further using controlled experimental designs.

ACKNOWLEDGMENTS

The researchers would like to thank the following individuals and organizations for their help which made this project possible:

- National Institute of Health Research
- The Veterans Administration Research and Rehabilitation Department.
- Dr. Barry Norling, Department of Restorative Dentistry, UTHSCSA
- Dr. William Stavinoha, Department of Pharmacology, UTHSCSA
- Cono Farias, Photographer, Department of Radiology, UTHSCSA
- David Gipson, Orthotic Technician, Department of Physical Medicine and Rehabilitation

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