

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

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1. AGENCY USE ONLY (Leave blank)		2. REPORT DATE October 1990		3. REPORT TYPE AND DATES COVERED Final 15 Jul 89 - 14 Jan 90	
4. TITLE AND SUBTITLE Biotechnology Symposium				5. FUNDING NUMBERS 61102F 2303/B2 61101F 6101/00 2	
6. AUTHOR(S) Dr Som Soni					
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) American Society for Composites Dayton, OH 45432-2698 AFOSR-TR-				8. PERFORMING ORGANIZATION REPORT NUMBER 90 1172	
9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES) AFOSR/NC Building 410 Bolling AFB, DC 20332-6448				10. SPONSORING/MONITORING AGENCY REPORT NUMBER AFOSR-89-0372	
11. SUPPLEMENTARY NOTES					
12a. DISTRIBUTION/AVAILABILITY STATEMENT Approved for public release; Distribution is unlimited				12b. DISTRIBUTION CODE	
13. ABSTRACT (Maximum 200 words) A symposium session on Biotechnology for Materials was organized and run in conjunction with the 4th American Society for Composites Conference held at Virginia Polytechnic Institute, Blacksburg, Virginia from 3 to 5 October, 1989. The following six papers were presented in the biotechnology session: 1. <u>Biotechnology for Aerospace Materials</u> , by H. M. Burte, and F. L. Hedberg 2. <u>The Components and Structure of Insect Exoskeleton Compared to Man-Made Advanced Composites</u> , by R. Schiavone, and S. Gunderson 3. <u>Long-Term Behavior of Biomedical Composites</u> , by K. L. Reifsnider, R. D. Jamison, A. J. Gavens, and G. R. Maharaj 4. <u>Biocomposites with Variable, Controllable Properties</u> , by S. A. Wainwright, and T. Motokawa 5. <u>Whale Blubber as a Structural Material</u> , by L. Schichtel Orton, and P. F. Brodie 6. <u>Design of a Composite Hip Prosthesis</u> , by F. K. Chang, J. Perez, and J. A. Davidson					
14. SUBJECT TERMS				15. NUMBER OF PAGES 52	
				16. PRICE CODE	
17. SECURITY CLASSIFICATION OF REPORT UNCLASSIFIED		18. SECURITY CLASSIFICATION OF THIS PAGE UNCLASSIFIED		19. SECURITY CLASSIFICATION OF ABSTRACT UNCLASSIFIED	
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SESSION 8A

Biotechnology—I

Co-Chair: R. C. Schiavone, WPAFB

Co-Chair: J. W. Grant, VPI&SU



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Biotechnology for Aerospace Materials

H. M. BURTE AND F. L. HEDBERG

For several years, a small cadre of senior scientists at the Air Force Materials Laboratory has been attempting to stimulate interaction between the biotechnology and materials communities. Our purpose was to explore whether some aspects of the recent major advances in various areas of biotechnology might offer significant benefits to materials technology (our particular emphasis was on aerospace materials technology). From these interactions, we have concluded that these benefits might most likely evolve along either of the following broad categories:

- low cost approaches to synthesis or processing of known products;
- new insight into structure-property relationships to guide the development of new or improved materials;

and, of course, the possible combination of these:

- the use of biosynthetic pathways to obtain novel and useful structures (and properties) which are either unobtainable or obtainable only with great difficulty by multi-step chemical syntheses or complex processing methodology.

Our approach was through informal dialogues, papers such as these [1], and workshops [2, 3, 4]. We presented "wish lists" of possible applications from our own awareness of important requirements within materials technology and an initially minimal knowledge of the current and future capabilities of biotechnology. As the community considering these has grown, so has the lists of possibilities with materials needs stimulating biotechnological approaches and biotechnological approaches not only meeting needs but suggesting new uses. It has been a productive and satisfying experience. Initial "wish lists" and admittedly unsophisticated suggestions for biotechnological approaches served the purpose of stimulating thinking and communication, and new areas for research and development have evolved. A few of these now being pursued are:

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bioleaching and bioaccumulation of gallium;
biosynthesis of acetylenic molecules;
enzymatic paint removal;
biosynthesis of 2-aminophenols;
processing of ceramics with biopolymers;
biomaterials with novel electro-optical properties.

Most, but not all, progress has been made toward the first category - low cost approaches to synthesis and processing of known products. My purpose here is to continue to stimulate interaction, as just described, with particular emphasis on the second category - the study of structure/property relationships in naturally occurring materials to obtain insight that may guide the development of new or improved synthetic materials. Materials development in the natural world has been underway since the dawn of life with the survival of species as the reward for successful developments. It seems reasonable to conclude that there may be some lessons to be learned in this area.

The number of people involved in research on naturally occurring materials appears to be relatively small, and they come from many diverse backgrounds. Some of the more prominent ones who have visited our Laboratory for stimulating interchange of ideas include Professors Stephen Wainwright from Duke University who is an author and editor of an excellent treatise on the area [5], John Currey from the University of York, Eric Baer and Anne Hiltner from Case Western University, George Jeronimidis from the University of Reading, and Steven Weiner from the Weizmann Institute. Our further comments owe as much to their input as to our own.

First, and appropriate for this meeting, let us review a few of the development requirements now being pursued for aerospace composites.

1. Extremely high tensile strength and stiffness fibers are evolving from both carbon and ordered polymer systems. The compressive strength of the fibers or the polymer matrix composites prepared from these fibers has not kept pace with improvement in tensile properties and may limit the potential for weight saving which they suggest.

2. As polymer matrix advanced composites are considered for more demanding applications and/or used closer to their weight saving potential, there will be increased attention to improvement in characteristics beyond simple strength, stiffness and density. Toughness, damage tolerance, impact resistance and similar characteristics may require improvement.

3. The concept of multifunctional materials which display useful combinations of diverse behavior such as structural, electrical and optical is beginning to emerge.

4. For very high temperature uses, in the range where ceramics

provide strength and environmental resistance, the pacing problem is what approaches, such as composites, will provide resistance to the propensity for unexpected catastrophic failure which has limited the applicability of monolithic ceramics.

Are there areas in the study of naturally occurring materials which could be especially fruitful in yielding concepts applicable to these problems? Natural composites are comprised of the same two basic constituents as synthetic ones, fibers and matrix materials. The formation of the natural materials might seem, in some respects, to be subject to more constraints in that they must be formed in place from an aqueous environment. In spite of, or in some instances perhaps, because of these constraints, wide variations in materials design are found, such as cross-section size and shape for the fibers, crosslinking degree and distribution for the matrix, and laminar and hierarchical arrangements for the fiber-matrix combination. Current synthetic composites have much simpler structures. What is the advantage to be gained in utilizing the variations, (if the properties arising from the structure of these natural materials are the result of some advantage for survival to their host organism rather than the structure being only a consequence of the biosynthetic pathways available to the organism) and is the advantage associated with improved materials properties in such a way that it might also benefit the area of aerospace materials? You will be hearing today from Rebecca Schiavone of the University of Dayton Research Institute about the intriguing similarities and differences between natural and synthetic composite architecture which were discovered during her Air Force sponsored study of insect exoskeletons. Would detailed micromechanical analysis of the complex structures which she and others have seen yield not only understanding but useful new insight?

We have not learned of any natural fibers with high compressive strength. Are there some or are there fibers where their complex hierarchical structure provides some compressive strength advantage? Even if there is little to learn here will the ingenious ways in which nature designs around the compressive strength limitation of naturally occurring fibers offer nontrivial insight to the designer of synthetic composites?

The inorganic/ceramic materials found in the natural world are always, to our knowledge, associated with some polymeric material in a composite. The polymeric material provides "templates" and/or pathways for deposition of the inorganic material. Are there instances where its residue is negligible and the complex structure of the inorganic portion alone (itself often a composite) governs behavior? Can we learn something of use to the development of reliable ceramic composites from these structures? Alternatively does the polymeric material always serve the dual purpose of providing toughness or resistance to catastrophic failure? If so, is nature telling us something we should consider in the development of high temperature composites?

Organisms must often deal with a variety of environmental stresses including thermal, mechanical, chemical, abrasive, etc. Often they contain unique sensors which can detect extremely low levels of energy or matter. Examples are sonar detection by bats (with the converse evolution of "nonedible" shapes by insects); infrared detection by rattlesnakes; magnetic field sensing by various bacteria, fish, and birds; light detec-

tion by many species in both the plant and animal world; and chemical detection at a threshold as sensitive as ten molecules of sex attractant by the cockroach. In coping with these diverse demands have they evolved multifunctional composite materials from which we might learn useful approaches?

In an even more speculative mode, is there anything to be learned from the manner in which the often complex fiber arrangements in naturally occurring composites are created that would be useful to the synthetic materials developer? Might a molecular template for synthetic growth be built into a polymeric matrix chemistry such that three dimensional fiber array could then be deposited or synthesized within it?

Might an approach of continuous repair/rejuvenation, such as occurs in bone, have application to synthetic materials? Perhaps diffusional access to the interior, even if only along grain boundaries, could provide a route to repairing microdamage before it accumulates to a failure causing extent.

The study of naturally occurring materials, simply from the viewpoint of expanding knowledge through truly basic research, presents fascinating and complex challenges. Even for relatively well known materials such as wool and hair (keratin fibers) which one of us studied several decades ago [6], the structure/property relationships which govern its complex behavior are not adequately understood. Multidisciplinary interaction between the widely scattered, diverse background individuals in the field, and a willingness to consider increasingly speculative questions should be very productive. We support this both because of personal interest and the conviction that the pool of knowledge it creates will eventually have use beyond anything we can now anticipate. However, our particular desire today is to stimulate you in a more applied mode. Which areas of research might be productive of what useful insight within a few years? What specific research approaches on what specific naturally occurring materials should be pursued? For speculative questions can we even define useful experiments or must we let the state of the science mature to support evaluation of practical implications? We believe that some useful answers will emerge, and we encourage the hard thinking that will yield them.

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The Components and Structure of Insect Exoskeleton Compared to Man-Made Advanced Composites

R. SCHIAVONE AND S. GUNDERSON

ABSTRACT

The insect cuticle is an excellent example of a natural composite that closely resembles man-made advanced composite systems. Similar to advanced composites, the cuticle is made up of fibers (chitin) which are embedded in a matrix (protein) forming unidirectional sheets which are arranged in various layup orientations. SEM studies of three sections (leg, pronotum, and elytra) of the Bessbug revealed a dual helicoid layup with a variance in ply thickness and number of plies. The chitin fibers, unlike advanced composites, were found to vary in size and shape throughout the thickness of the cuticle.

INTRODUCTION

Nature provides many examples of structural composites with unique designs optimized for specific mechanical properties. Some of these include: arthropod exoskeletons, wood, mollusc shells, bone, tendons, ligaments, and cartilage. Many of these natural composites are composed of materials that closely resemble man-made advanced composites. The materials that make up the natural composites vary from polysaccharides, such as chitin and cellulose, to various proteins and calcium carbonate. These materials could not be used in advanced aerospace composite systems because of their poor mechanical properties and lack of thermo-oxidative stability; however, the novel designs of the natural composites may provide information that will aid in designing new advanced composite structures for ultra lightweight applications.

The natural composite system selected for this investigation was the insect exoskeleton, or cuticle. The investigation was divided into three parts. The first part, which will be addressed in this presentation, was to determine the structural characteristics of several sections of the insect cuticle. The second part is to determine the mechanical properties of the selected sections of cuticle and make a correlation between the structure and mechanical properties of the insect cuticle. The third part is to translate that information to advanced composite systems and monitor its effects. -

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BACKGROUND

The insect cuticle is an excellent example of a natural complex composite system. This structure is used in lightweight applications combining strength and stiffness into a remarkably tough material [1]. Like many man-made advanced composites, the cuticle is a fiber reinforced laminate. The fibers, a high-molecular weight polysaccharide called chitin, are embedded in a proteinaceous matrix and arranged in plies at various angles. The materials which compose the natural composite, a sugar and a protein, are structurally poor materials; however, the insect is able to combine these materials in unique designs producing various strong and stiff structures. These unique designs which have been perfected over the years may provide information for new design concepts which can be translated to advanced aerospace composites for improved properties.

The insect exoskeleton, or cuticle, is divided into two primary sections: the epicuticle and the procuticle (Fig. 1). The epicuticle is the outermost layer of the cuticle and consists primarily of waxes, lipids, and proteins without chitin fibers. This 0.1 to 3 μm layer contributes little to shape or strength but acts as an environmental barrier.

The procuticle, the largest structural division of the cuticle, ranges in thickness from about 10 to 100 μm and provides shape and mechanical stability [2]. It is divided into the exocuticle and the endocuticle, both of which contain chitin fibers and a protein matrix. In the outer exocuticle, the protein matrix is sclerotized. This is an irreversible process which means the matrix has crosslinked, similar to a thermoset, becoming water insoluble, darker in color, and stiffer. The inner endocuticle is not sclerotized making it softer and more ductile. The procuticle may consist of completely sclerotized, completely unsclerotized, or a combination of both matrix states all containing chitin fibers.

The chitin fibers, made up of bundles of microfibrils, are embedded in a proteinaceous matrix and arranged in a series of thin sheets or lamina of various layup orientations. Several theories have been proposed as to the specific orientation of these fibers in various sections of the cuticle. The theory that has received the most attention and acceptance is the "helical" model proposed by Y. Bouligand [3]. Bouligand's model describes the structure as a series of thin unidirectional sheets stacked on top of each other with the fiber directions rotated by a small, nearly constant angle through the thickness of the cuticle. Each section of plies that rotates through 180 degrees is defined by Bouligand as one lamella. A variation of this model, proposed by A. C. Neville, involves the same type of stacking sequence, except the fibers within each ply are curved [4]. Several other models have been proposed including the screw-carpet model by T. Weis-Fogh and the cross-hatch model which is in the form of a woven cloth or fabric [5]. It should also be noted that the structure of insects varies from species to species as well as within species based on such factors as age and the environment in which it was raised.

MATERIALS AND METHODS

The insect selected for structural analysis was the Passalus cornutus, or Bessbug beetle, because of its highly sclerotized, stiff, strong exoskeleton, its large size (approx. 1.5"), and live availability. The sections of cuticle selected for study were: the leg, elytra (wing covering) and pronotum (covering for the prothorax) (Fig. 2). These three sections were selected on the assumption that each would offer a unique

structure to correspond to its related function producing a variety of structure/property relationships. Each of the above sections was examined with the scanning electron microscope (SEM) and light microscope.

The SEM specimens were prepared by removing the selected section from the insect, submerging it in liquid nitrogen for approximately one minute, and then cutting (or cracking) the section transversely with a scalpel. The specimens were then placed on aluminum plugs using low-resistance contact cement as an adhesive. A 10 nm coating of gold-palladium was applied using a sputter coater. The specimens were then examined using a JEOL JSM-840 scanning electron microscope. A current of 6×10^{-11} amps and a voltage of 10 kV were used. Magnifications ranged from 30x to 7000x. Optical microscopy specimens were prepared by breaking a piece of the desired section, potting the specimen in an epoxy plug, and then polishing the surface.

The photomicrographs were used to determine the overall structure and substructure of each section as well as identify the constituents contained therein. Each specimen was analyzed for size, shape and organization. Cuticle thickness, chitin fiber cross-sectional area, fiber geometry and distribution, orientation of plies, and any unique design characteristics were determined in each specimen. Linear distances were measured directly from the SEM micrographs using the micron marker bar for calibration. The cross-sectional areas were determined by a weight/area ratio method from the SEM photos. The geometries and distribution of fibers and any unique design characteristics were observed optically from the photomicrographs.

Establishing the fiber orientation was the most difficult task. Photographs of chipped edges of each section were taken from above at such an angle so the direction of the fibers in each ply were visible in step form through the thickness of the cuticle. A straight edge and protractor were used to determine the ply directions and associated angles. From this information schematic diagrams were constructed of the layup of each section to better visualize the orientation and any patterns present.

The above results were analyzed to determine similarities and differences in structural organization between the sections selected from the leg, pronotum (prothorax covering) and elytra (wing covering). These results were then compared to man-made advanced polymeric composites.

RESULTS

The SEM studies revealed both structural similarities and differences between the leg, pronotum (prothorax covering) and elytra (wing covering). The leg was found to be a hollow cylindrical structure composed of a fiber and matrix material similar in appearance to man-made composites (Fig. 3a&b). The pronotum displayed the same composite structure as the leg but was in the form of a large, curved plate (Fig. 4a&b). The elytra offered the most unique structural design of the three sections revealing two separate and distinctly different, curved plate-like halves, connected together by a series of joints and stiffeners called trabeculae (Fig. 5a). The trabeculae are believed to serve not only as joints for the connection of the top and bottom halves of the elytra but also as vertical stiffeners to improve rigidity. Also the trabeculae create a space between the two halves which is believed to improve impact resistance while maintaining its lightweight characteristics. The top half of the elytra was found to be similar in construction to the leg and pronotum, but the bottom half appeared to be composed of a series of oriented sheets, or laths, consisting mostly of microfibrils, instead of distinct fibers, embedded in a matrix. Any fibers that could be detected appeared square in shape (Fig. 5b). Another unique structural characteristic discovered in the insect

cuticle was the presence of holes called pore canals that aid in the transfer of wax through the thickness of the cuticle to the epicuticle surface for waterproofing. In contrast to synthetic composites, it is believed that cracks travel around the pore canals instead of through them, increasing the amount of energy needed for crack propagation.

The chitin fibers in the three sections studied were found to vary not only in size but also in geometry throughout the thickness of the cuticle. Smaller fibers were found in the outermost layers of the cuticle and appeared more circular in shape, while larger fibers were located in the mid-cuticle region and appeared more elliptical (Fig. 4b). The average cuticle thickness which included the epicuticle and procuticle for the elytra (wing covering), leg and pronotum (prothorax covering) was found to be 124, 98, and 166 microns, respectively, with an average number of plies of 31, 19, and 23. Each ply consisted of a single row of fibers so the ply thickness was directly related to fiber dimension and size ranging from about 1 to 7 microns.

The fiber orientation in the cuticle has received much attention in past literature but is surrounded by controversy. The most widely accepted theory for fiber orientation is a helicoid arrangement. This study supports the helicoid layup with a slight variation in that two intertwining helicoids were found. This is being described as a dual helicoid. The dual helicoid appears to be similar in all three cuticle sections studied, with the leg and pronotum being the most closely related.

The dual helicoid can be described as two alternating helicoids which rotate in a clockwise direction from the outside to the inside (Fig. 6). The dual helicoid detected in the leg has an average angle difference between alternating plies (same helicoid) of approximately 24 degrees and between successive plies (different helicoids) of about 82 degrees (Fig. 7). Similarly, in the pronotum the average angle difference between alternating plies and successive plies was approximately 24 and 93 degrees, respectively. In the elytra the average angle difference between alternate and successive plies was about 21 and 96 degrees, respectively. It appeared that the two helicoids repeated angles every seven plies in the leg and pronotum and every nine plies in the elytra.

CONCLUSIONS

The insect cuticle, a true natural composite structure, displays an astonishing likeness to man-made polymeric composite structures. Several comparisons can be made between man-made composites and insect cuticle in the areas of laminate structure, fibers, fiber orientation and structural design.

Both insect cuticle and man-made composites are fiber-reinforced laminated structures utilized in applications where specific strength and modulus are critical issues. Both laminates are composed of unidirectional plies of fibers embedded in a matrix material with the fibers capable of being oriented in such a way as to optimize certain mechanical properties. The fibers act as the load-bearing component of the composite, while the matrix performs the transfer and even distribution of the load between the fibers. The protein matrix in insect exocuticle behaves similar to a thermoset by crosslinking (or sclerotizing) to form a stronger and stiffer material. Finally, both insect cuticle and man-made composites must deal with various design structures. Some of these structures found in insect cuticle include pore canals and trabeculae. These same structures are mimicked in man-made composites in the form of voids, I-beams, and mechanical fasteners.

In contrast to the many similarities between insect cuticle and man-made composites, there are also several differences. The plies making up a man made laminate are of a uniform thickness and consist of multiple fibers distributed through the thickness of each ply. The highly ordered plies of the insect cuticle each consist of a single layer of fibers with each ply varying in thickness. The fibers found in man-made composites are generally of a uniform geometry and cross-sectional area, whereas the chitin fibers in insect cuticle vary in geometry and cross-sectional area. This variation in fiber size and shape may allow for a greater fiber volume and more tailorability of mechanical properties in the natural composite. It appears microfibrils extend from the chitin fibers into the matrix increasing the fiber surface area. Finally, the fiber orientation of man-made composite systems is almost always symmetrical and balanced; however, the orientation of fibers found in the insect cuticle is unsymmetrical and unbalanced. The insect can thus keep the number of plies to a minimum without concern about adding plies for symmetry to prevent warpage and microcracks.

FUTURE WORK

Future work includes continued structural studies on the leg, elytra and pronotum with emphasis placed on fiber size, geometry, and construction; fiber orientation; and unique structural components such as the trabeculae. Also, a series of physical tests are planned such as fiber volume, resin content and moisture content before moving on to the second and third parts of our investigation.

ACKNOWLEDGEMENTS

This research effort is supported by the Air Force Office of Scientific Research (AFOSR) and the Materials Lab of the Wright Research and Development Center. The authors would also like to acknowledge Dr. F. Hedberg, Dr. D. Anderson, R. Cornwell, K. Haight, M. Ramsey, and S. Lindsay for technical support and review of the manuscript.

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INSECT CUTICLE CROSS SECTION

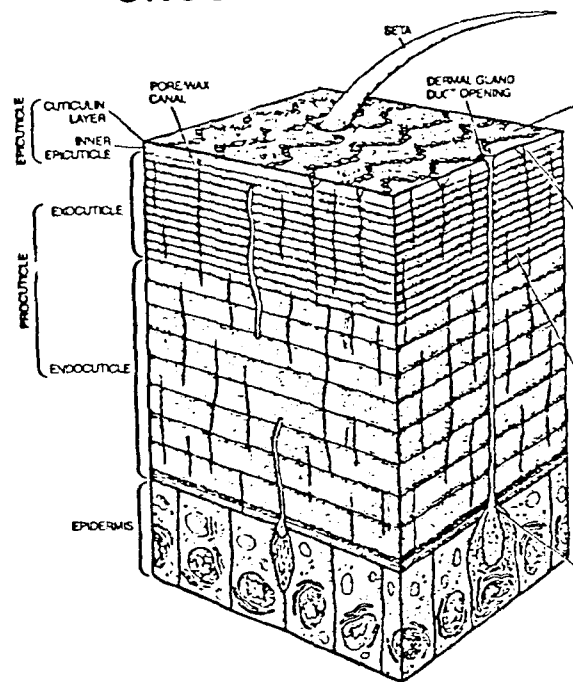


Fig. 1. Schematic diagram of the insect cuticle cross section displaying its major divisions [2].

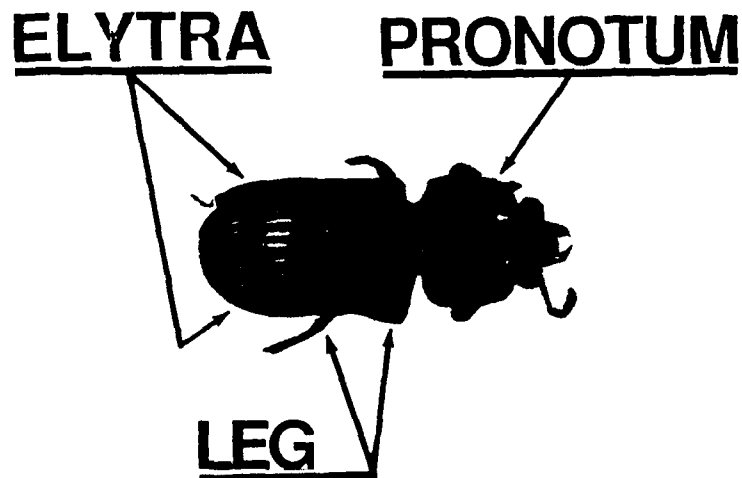
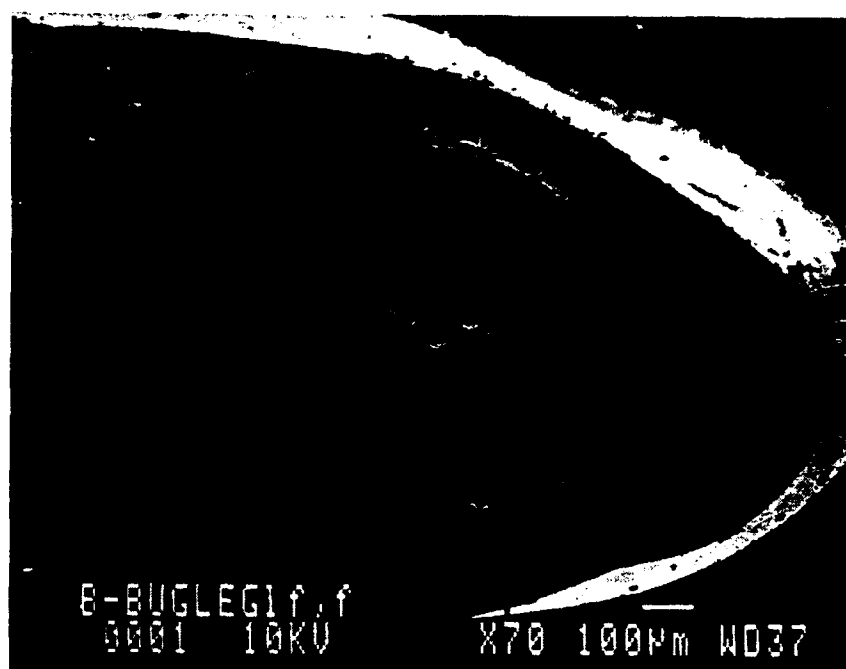
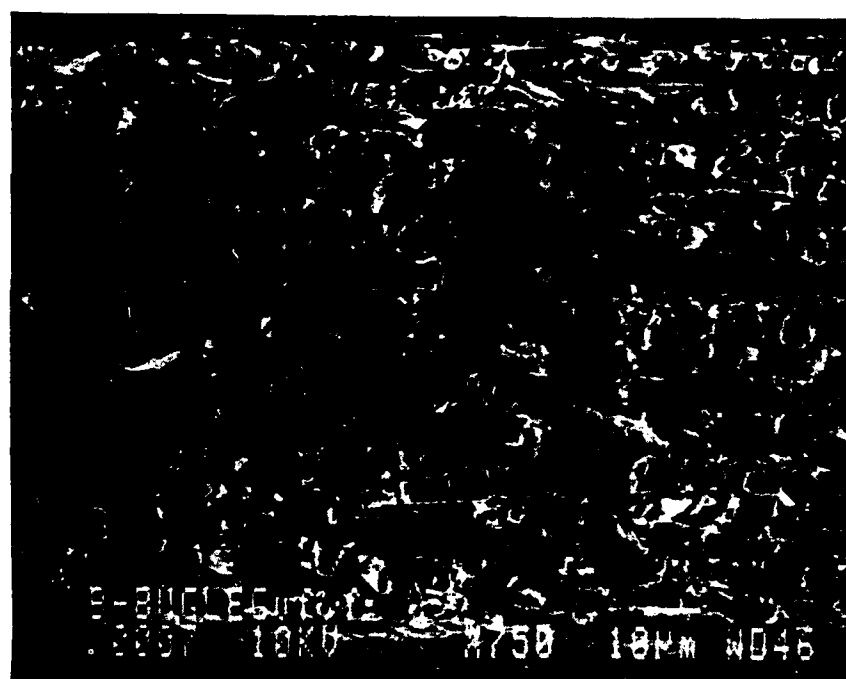


Fig. 2. Diagram of the *Passalus cornutus*, or Bessbug, labeling the sections studied.

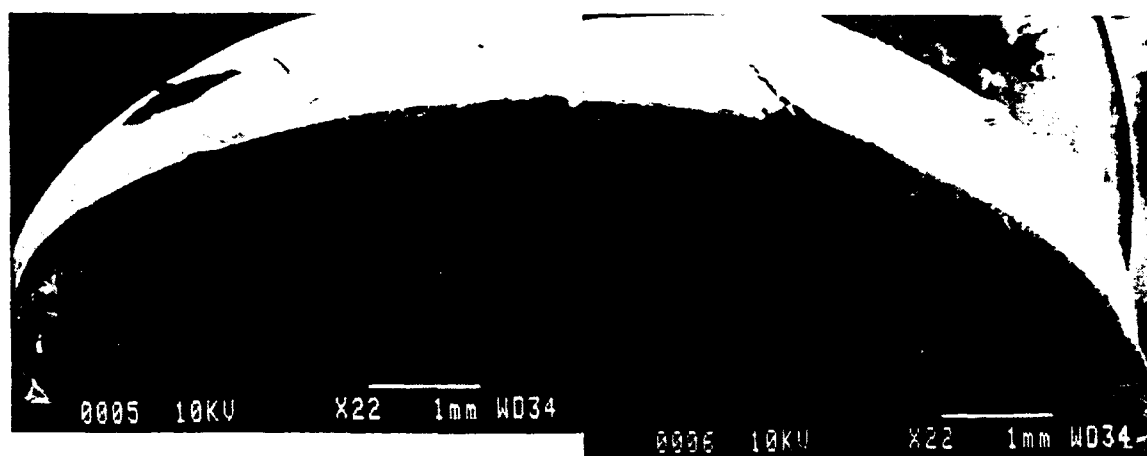


(a)

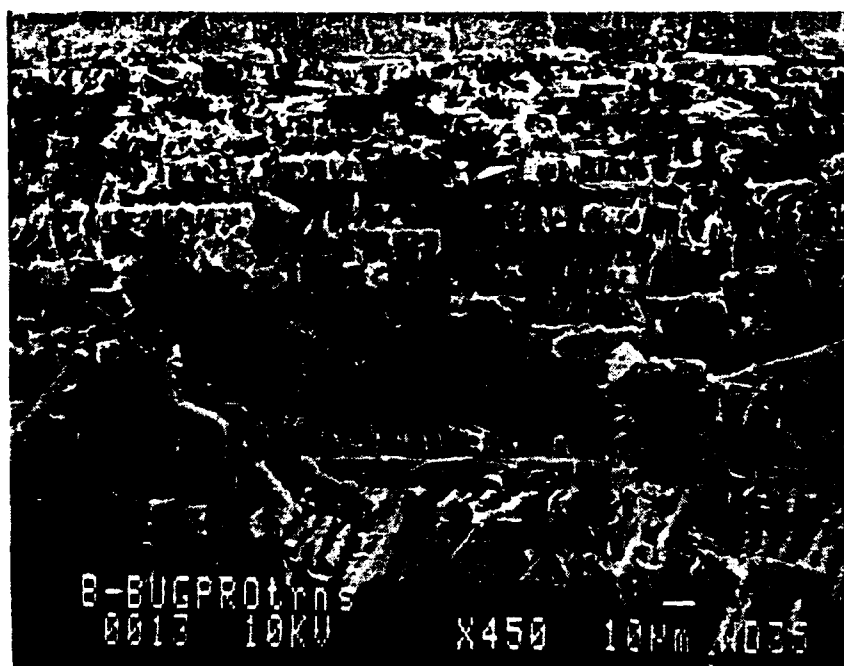


(b)

Fig. 3. (a) Overall transverse cross section of the Bessbug mid-femur, and (b) close-up view of the cuticle. Note the variance in size and geometry among the fibers.



(a)

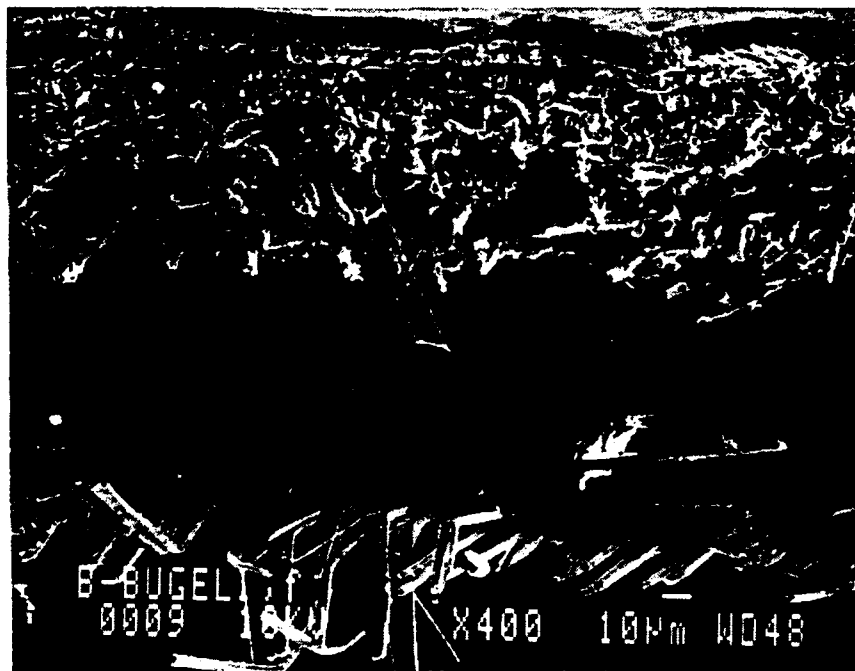


(b)

Fig. 4. (a) Overall transverse cross section of the Bessbug pronotum, and (b) higher magnification of the cuticle cross section.



(a)



(b)

Fig. 5. (a) Overall transverse cross section of the Bessbug elytra displaying its two halves and the trabeculae which connect them, and (b) close-up transverse view of the bessbug elytra showing the top and bottom halves and their different structures.

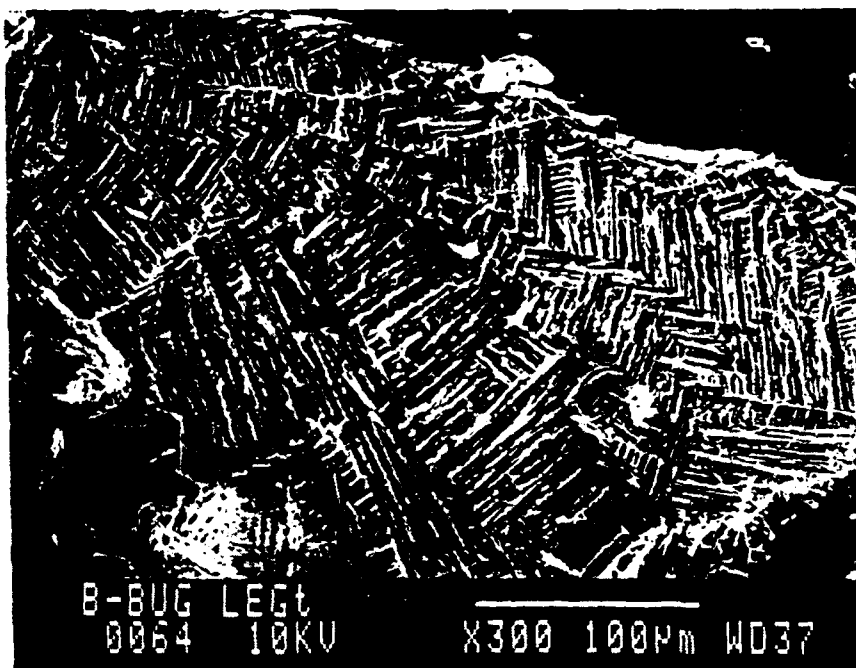


Fig. 6. SEM photo exhibiting the dual helicoid fiber orientation found in the Bessbug cuticle. This photo is of a chipped edge of leg cuticle.

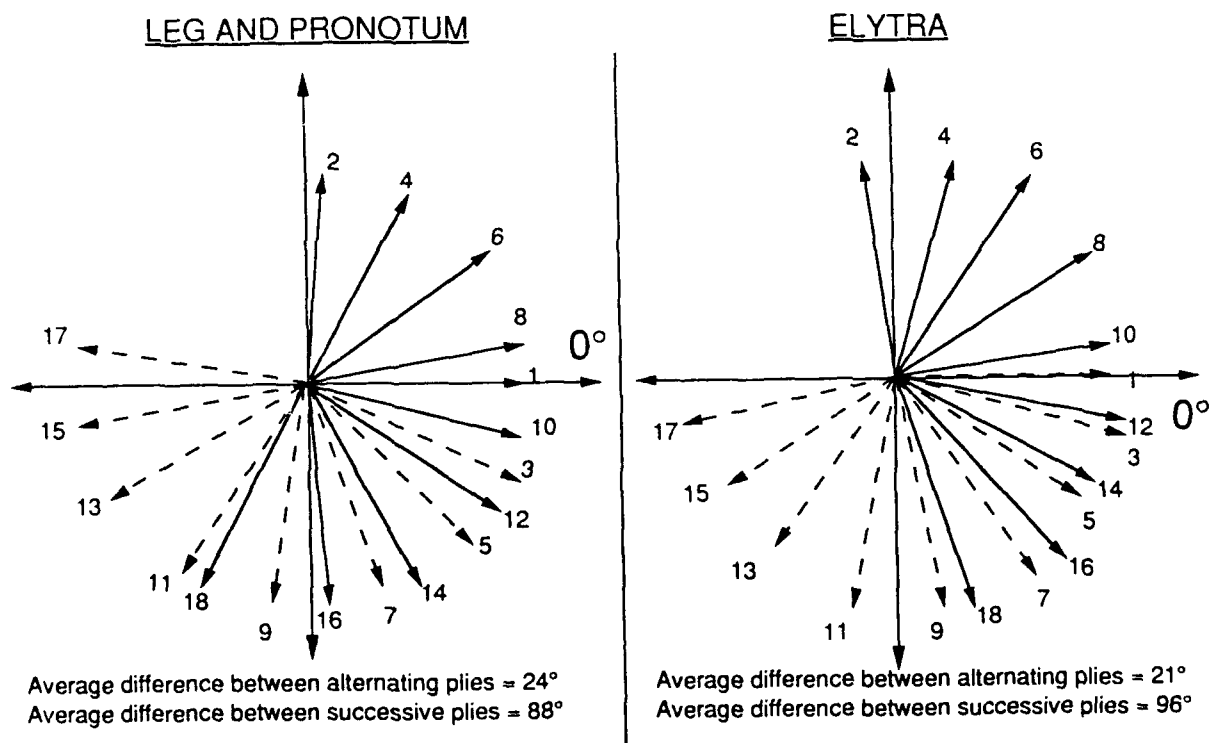


Fig. 7. Schematic diagrams representing the layup of the various sections of Bessbug cuticle.

Long-Term Behavior of Biomedical Composites

K. L. REIFSNIDER, R. D. JAMISON, A. J. GAVENS AND G. R. MAHARAJ

ABSTRACT

Important factors which affect the performance, durability, and safety of composite material biomedical implant devices are presented. These factors are dominated by long-term behavior issues, not only mechanical behavior but also long-term biocompatibility of the material. Using the total hip prosthesis as an example, the design and testing requirements for such a device are described in the context of these long-term issues. The mechanics problem is presented in terms of the complex joint and muscle forces which occur during normal activity. The fatigue problem presented by these time-varying biaxial loads is described along with analytical and experimental approaches to predicting performance. The effect of the aggressive body fluid environment, requiring *in vitro* testing of both composite coupons and prototypes, is discussed along with issues related to intraoperative impact.

INTRODUCTION

Continuous fiber reinforced composite materials present a unique opportunity for application to biomedical devices, particularly implanted orthopaedic prosthetic devices. These materials can be designed with stiffness and strength optimum for a given application and are, as a class of materials, extremely resistant to fatigue and environmental degradation. At the same time the use of composites in such an application poses serious questions regarding long-term performance which require new analytical and experimental approaches.

There exists relatively little data or experience with the design and long-term use of composite material components which are thick, geometrically complex, and subject to multi-axial dynamic loads. General rules for the design and testing of such components are not yet available. Projection of long-term in-service performance is particularly problematic. Prediction of residual mechanical properties such as strength, stiffness, and lifetime is a major concern since the inaccessibility of implanted components postoperatively generally precludes in-service inspection.

The statistical variations of properties and performance, along with the coupled effects of environment, creep, sterilization, and intraoperative impact must be accounted for in evaluating the suitability of composite materials in biomedical applications.

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The purpose of the present paper is to identify some of the issues which are considered by the authors to be central to the conduct of such an evaluation. For the purpose of discussion a specific example, the hip prosthesis, has been chosen because it embodies all of the issues mentioned and because it promises to be the first major application of composite materials technology in the area of orthopaedic surgery.

BACKGROUND

Replacement of the hip joint has become an accepted procedure for patients suffering loss of mobility and pain due to degenerative bone diseases such as osteoarthritis or to trauma. This surgical procedure, termed total hip arthroplasty (THA), is performed over 200,000 times per year in the United States alone with that number expected to increase as the population ages. The procedure is shown schematically in Figure 1. The stem component is currently made of high alloy steels like Co-Cr-Mo or titanium alloys like Ti-4Al-6V. The acetabular component consists of a metal cup of one of these materials lined with a polymer bearing/articulation surface, typically ultrahigh molecular weight polyethylene (UHMWPE). The metallic components have elastic moduli ranging from 120 GPa to 250 GPa. These substantially exceed the elastic modulus of the human femur which ranges from 7 to 30 GPa.

As a result of the "modulus mismatch" between the the metal stem and the bone into which it is either press-fit or cemented, a disproportionate share of the joint load is borne by the stem. Such "stress shielding" of the femur can lead to bone resorption over time. Bone resorption is particularly problematic in reconstructive procedures of the hip in which the stability of the implant device is dependent in large part upon the quality and vitality of bone remodelling around the bone postoperatively. Bone resorption can lead to stem loosening which in turn is associated with ambulatory pain and, in isolated cases, mechanical failure of the prosthesis. In cases where the implant has been cemented into the bone to provide initial stability, bone resorption can lead to fragmentation of the cement mantle and thereby cause pain and an adverse biological response. In cases of implant loosening, revision surgery may be required. The incidence of implant loosening has been estimated to be twenty percent after five years and thirty percent after ten years [1].

Bone is a composite material composed of hydroxyapatite ceramic reinforced collagen organized into oriented osteons. Man-made composites which mimic this physiologic structure have been viewed for a number of years as candidates for orthopaedic applications including the hip endoprosthesis [3-5]. Compared to conventional

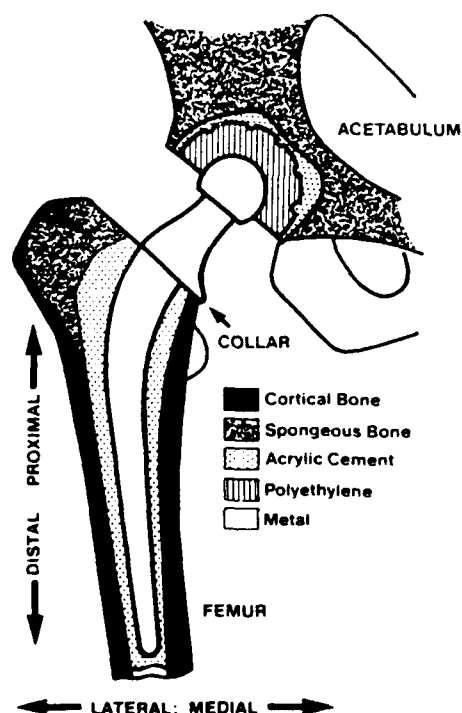


Fig. 1. Schematic of a total hip arthroplasty (THA) [2].

metallic materials they alone offer the prospect of lower modulus without unacceptable compromise of strength. They also present some new and unique challenges to the way in which composite structures have been designed and tested. These issues are addressed in the following sections.

LONG-TERM MECHANICAL BEHAVIOR

Analysis and Design

The inhomogeneous internal structure of composite materials introduces the possibility of a variety of damage and failure modes during service, in contrast to the "simple" case of self-similar through-crack propagation common to metals. It is essential that these damage modes and failure modes be clearly identified, precisely characterized, and correctly described by mechanics analysis as the basis for a performance prediction effort. This must be done for the geometries, loads, and environmental conditions known to exist in the application considered. Extrapolations are difficult. However, it is possible to use well-established methods to infer the behavior of one composite device design based on the tests of other designs in some cases. In fact since composite materials themselves are "man-made" it is possible (indeed essential) to design the material when designing the device so that damage modes and failure modes are "controlled" to make the best possible use of the material properties and performance characteristics.

The complex geometry and loading conditions which characterize the hip stem application make this design effort difficult. Failure modes in thick composites are substantially different than in thin composites in many cases. The three-dimensionality of loading specifically tends to introduce failure modes that are not well-documented in the literature of experimental experience. This requires special attention and care in the mechanics analysis, and in the laboratory, especially in the representation of details of the loading itself as well as in the design of the device.

Once a proper representation of damage and failure modes has been established, a method of predicting long-term behavior must be found. The method must include an account of the evolution of properties associated with the service behavior, i.e., changes in stiffness and strength as a function of service history. Since it is not possible to generate a phenomenological data base of failures in service for this modeling effort, it is necessary to establish a mechanistic model which includes the correct mechanics and physics representations so that the behavior can be anticipated with reasonable accuracy before the device is implanted. This is also a distinct advantage in subsequent efforts to improve the devices.

There are very few mechanistic models of long-term performance of composite material components. One modelling approach developed by one of the authors (KLR) is called the "critical element method". It serves as the basis for the "MRLife" code series which have been applied to a variety of such problems with reasonable success [6-8]. The model, shown schematically in Figure 2, predicts remaining strength and life based on precise representation of the state of material and state of stress in "critical elements"

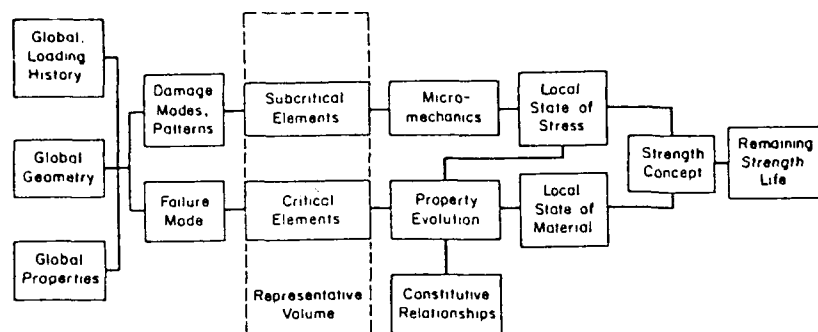


Fig. 2. Schematic of the critical element method model.

simulation codes to identify sensitivity to design factors, loading conditions, and statistical variations. Based on our experimental observations of damage and failure modes, and on mechanics representations of critical element behavior for those modes, a version of the MRLife performance simulation code is being developed for composite hip stems. The code represents the effects of multiaxial cyclic loading and predicts remaining strength and life.

Static and Fatigue Testing

During gait the peak joint reaction force is applied to the head of the stem directed 20 degrees medial to lateral and 10 degrees anterior to posterior as shown in Figure 3 [9]. This loading produces a complex stress on the stem due to the biaxial nature of the loading (compression, bending in two planes, and torsion). The magnitude of the peak joint force during gait may reach six times body weight and can be greater for other activities [10]. Muscle forces are applied over the surface of the femur and have a significant effect on the stem loading.

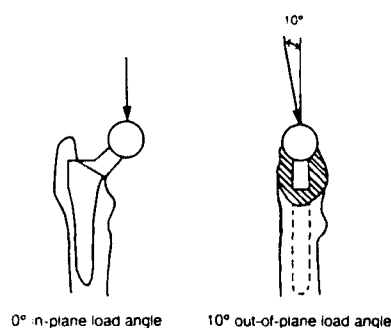


Fig. 3. Direction of the peak joint force applied to the hip.

A standard test method for cyclic testing of metal hip stems has been proposed by ASTM [10]. This standard, however does not currently include an out-of-plane load component. The standard also assumes an extreme situation in which the proximal bone support has been completely lost due to resorption. For metal stems this may be reasonable since the total deflection at the peak load is small. However, for composite stems designed for low stiffness the deflection can be extreme and physiologically unrealistic unless some proximal support is provided.

A laboratory fixture was designed for biaxial testing of composite hip stems *in vitro*. The fixture securely holds the distal portion of the stem while allowing for a limited amount of proximal displacement. The amount of displacement was based on the gap between metal stems and bone observed in post-operative radiographs of patients in whom bone resorption had occurred [12].

Quasi-static testing of composite stems performed in this test fixture provided information on the stem's strain profile, static failure mechanisms, and the effect of material, ply orientation, and load angle on static strength. A comparison of prototype stems

of material which are known to control the failure of the component for a given failure mode.

Mechanistic modes which can predict performance can also be used in reverse to design optimum materials. And they can be used as performance

made using two different thermoplastic resin systems showed that the stem strength could be increased by 25 percent with a 30 percent increase in the tensile strength of the matrix. Testing of stems having two different ply orientations for one of these material systems resulted in a strength differential of 12 percent. By increasing the out-of-plane load angle from 10 degrees to 20 degrees, a 17 percent reduction in static strength was observed. Among the factors which most strongly influence the static strength of composite hip stems, it appears, both from finite element analysis and laboratory testing, that the angle of loading is dominant. Results, for a different design approach, are shown in Table 1 indicating predicted strength differentials for a single candidate material and choice of ply orientations. Here the full interplay of load angles can be seen. Results such as these suggest the importance of choosing physiologically-based load angles, magnitudes, and boundary conditions for *in vitro* testing of these devices.

Table 1 - Predicted load angle dependence of stem static strength.

Out-of-Plane Load Angle (degrees)	In-Plane Load Angle (degrees)			
	5	10	15	20
10	0.59	0.70	0.88	1.00
20	0.59	0.67	0.74	0.82
30	0.54	0.57	0.62	0.68
40	0.46	0.49	0.52	0.56

Fatigue lifetime is a primary design criterion for the hip stem since *in vivo* the load is applied cyclically during gait. It has been estimated that a normally active patient will undertake one to two million repetitions of a walking load cycle like that show in Figure 4 and a lesser number of cycles of loading associated with activities like rising from a chair or walking up and down stairs [13].

Fatigue testing was conducted to determine the lifetime of the hip stem under physiological loading. Measurement of stem compliance and monitoring of acoustic emission activity are used along with periodic microscopic examination to assess the initiation and progression of fatigue damage and the onset of failure. It has been observed experimentally that the

mode of failure in static loading and the mode of failure under cyclic loading are significantly different. There are in fact competing mechanisms of damage accumulation which result in shear failure of the neck in one case; compression failure on the medial side of the stem in the other. Damage accumulation and compliance change during fa-

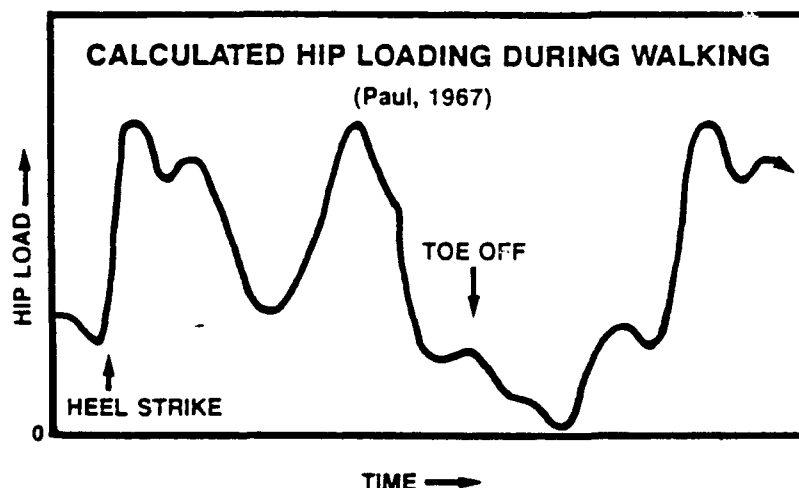


Fig. 4. Calculated hip joint load during gait [14].

tigue of prototype stems of several thermoplastic materials have been observed to follow the same general three stage process observed by a number of investigators of epoxy-based systems in the past [15,16]. It is noteworthy that such patterns appear to transcend the significantly different stress states represented by the present case and that of

the earlier work cited.

Because the composite hip stem must ultimately function for many years in the physiological environment, *in vitro* testing which simulates this environment is essential. For such testing the stem is preconditioned to simulate long-term exposure to the synovial fluid of the joint and other body fluids. The effects of this fluid on the material are typically screened through coupon level testing as described in the following section. While such screening is a necessary condition for assessing the suitability of a particular material for this application, it is not a sufficient condition. It is only through testing of prototype composite stems in simulated body fluids that the coupling between environment and loading can be adequately assessed. For this purpose the test fixture serves as a containment vessel in which the preconditioned stem is immersed in the medium and in which the level, the temperature, and the chemistry are monitored and maintained.

Environmental Effects

All implant devices are continuously exposed to a fluid environment in the body at a temperature of 37° C. Orthopaedic implant devices are exposed to blood, synovial fluid, and bone marrow. Each of these constituents is biochemically complex. Synovial fluid for example, which acts as a lubricant in the articulating ball and socket mechanism of the unreconstructed hip joint, consists of fatty acids, cholesterol, phospholipids, oxidants, and glucose. The susceptibility of composite materials to any one of these agents has not, to the authors' knowledge, been satisfactorily characterized. It is of course known that composites exposed to wet environments absorb moisture which can lead to a degradation of properties [17]. Thermoplastic composites as a class have been shown to absorb less water than most epoxies and are highly resistant to many chemicals [18]. For these reasons thermoplastic composites are viewed as attractive candidates for orthopaedic applications.

To evaluate the effect of body fluids on composite materials, flexural and compression coupons of a thermoplastic composite were soaked in lactated ringer's solution at 37° C. A mean saturated weight gain of 0.27% (Figure 5) was measured for multi-axially oriented laminates. Flexural properties were evaluated using ASTM methods. A mean reduction in flexural strength of 6 percent was measured with a modulus reduction of 3 percent.

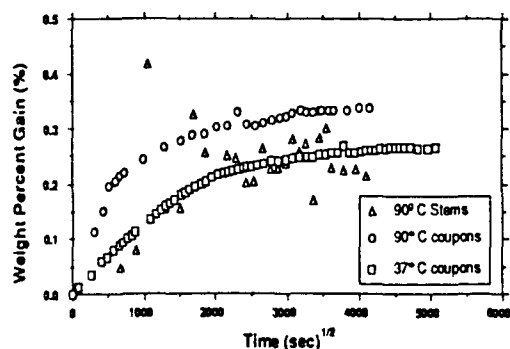


Fig. 5. Moisture uptake versus time for stems and coupons at two temperatures.

The hip stems, having thick sections, require long time periods for complete saturation to occur at 37° C. Raising the temperature of the Ringer's solution to 90° C increased the diffusion constant almost 30 percent. Determining the diffusion constants of two different sized coupons allows for the diffusivity parallel and transverse to the plies to be obtained [19]. The diffusion constant parallel to the plies was 23 percent greater than that transverse to the plies. These results on coupons were used to predict

the saturation time for a hip stem under the same conditions. The predicted time of six months was in good agreement with experimental results.

Intraoperative Impact

Non-cemented hip stems are designed for a rigid press fit in the medullary canal of the femur. To achieve an interference fit the femoral canal is reamed with specially sized tools so that the final shape of the canal is similar to the implant but slightly smaller [20]. The implant is then impacted into the canal with a hammer until it is at the proper anatomical level in the femur. Large impact forces can be generated by the surgeon during the insertion of the stem in order to achieve the required degree of fit into the femur. From a materials standpoint, the implant must be able to withstand the worst possible impact (a strong surgeon driving an oversized stem into a strong femur) without the initiation of damage which could compromise the long-term behavior of the stem *in vivo*. Impact tolerance thus becomes one of the screening criteria for new composite materials and composite hip stem designs.

In order to determine the effect of intraoperative impact on the subsequent performance of a composite hip stem, the impact force, energy and number of hits must first be characterized. Using these predetermined parameters prototype stems can be impacted in the laboratory with a drop-weight impact device and any impact-induced effects determined by nondestructive evaluation techniques (NDE) and by fatigue and residual strength testing.

Intraoperative impact of a composite stem is unique in several respects. First, the direction of the impact is parallel to the plane of the laminae as opposed to the more commonly studied transverse direction. Second, the implant is not rigidly constrained but able to wedge further into the femur with each impact, as well as being subject to damping due to attached muscles and ligaments. Thus, boundary condition effects must also be determined and simulated.

By measurement of the hammer velocity just prior to impact and the force-time profile of the impact event, the impact energy can be characterized [21]. Previous studies by the authors [22] have used a high-speed video technique to monitor the hammer velocity and a piezoelectric impact force transducer to measure the impact force in single femurs as well as cadavers. Six impacts were required to drive the stem completely into the bone with an average intraoperative impact force of $6.20 \text{ KN} \pm 0.74 \text{ KN}$ and an average impact energy of $4.50 \text{ J} \pm 0.54 \text{ J}$. Microscopic evaluation of the implant surface after multiple impacts revealed no damage.

The drop-weight device shown (Figure 6) was used to impact prototype composite hip stems at an energy of 9 J (factor of safety of two) as a preconditioning step for subsequent fatigue testing. Because of the large number of stems to be tested and the inevitable vari-

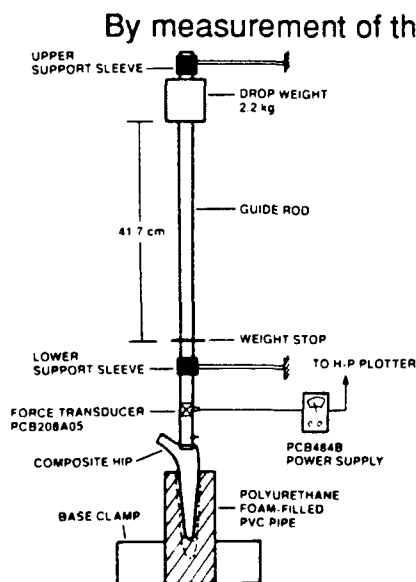


Fig. 6. Schematic of drop weight impact test apparatus.

ation in geometry among human cadaveric femurs, the stems were impacted into polyurethane foam-filled PVC cylinders (supplied by Pacific Research Laboratories Inc.) prepared in a standard surgical manner and which closely simulated the damping and stiffness constraints of the natural femur [22].

The final phase of this study constitutes work in progress and involves fatigue and static strength testing with acoustic emission monitoring of both impacted and non-impacted controls under anatomical loading to determine the effect of intraoperative impact on fatigue performance.

BIOCOMPATIBILITY

Even though selected composite materials may possess the required long-term mechanical properties for medical applications, the biocompatibility (biological reaction) of the material may not be acceptable. The tests used to evaluate a specific material's biocompatibility are dependent on the medical application. Implant devices like the hip stem represent long-term exposure and are subject to the most severe Food and Drug Administration requirements. ASTM has recommended tests based on the end use of the material [23] and the FDA has defined guidelines for the evaluation of certain non-metallic devices [24]. It is expected that composite material devices will be subjected to similar requirements. The biocompatibility tests can be grouped into several categories, each examining a different *in vivo* response to the material. These categories include cytotoxicity, mutagenicity, hemocompatibility, carcinogenicity, and chronic implantation in a suitable animal model to assess long-term safety and efficacy of the device. Individual tests can last from one day to several years and represent a significant investment of time and money.

Few composite materials have been evaluated for their biocompatibility. However, carbon has been shown to elicit a minimal biological response [25,26]. Carbon fibers have been used as an artificial ligament, and carbon/carbon, carbon/epoxy and carbon/thermoplastic devices have been proposed [3-5,27-29]. Most of the polymers that have acceptable mechanical properties and which are commonly used as matrices for fiber reinforced composites have not been subjected to the types of biocompatibility testing which will be required for long-term implantation. Epoxies, which might seem to be logical choices because of their acceptance as aerospace materials, may not be biocompatible, particularly if residual monomer remains after curing. They also may not possess the required environmental resistance for the biological environment [30,31].

Thermoplastic matrix composites are attractive candidates both because of their low reactivity and good environmental stability. Except for the polysulfones however, evidence of the biocompatibility of thermoplastics which would be suitable for composite applications has not been presented. For many thermoplastics the presence of solvents, sizing, or other additives in the prepreg may pose hazards if they persist in the finished part. Biocompatibility testing of the polymer and the fiber separately does not necessarily establish the biocompatibility of the composite component since these residual products in the material or fabrication contaminants like mold release agents or machining coolants may constitute a risk. A prudent course is to establish biocompati-

bility of the product as fabricated, although fixing the fabrication technique for the several years required for testing may not always be feasible.

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Biocomposites with Variable, Controllable Properties

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ABSTRACT

Soft connective tissues in animals are composites of collagen and polyanionic glycosaminoglycans (GAG) permeated by an ionic aqueous fluid. Seastars and their relatives apparently have neural control over the ionic composition in their tissue fluids. This allows them to control the degree of masked charges and cross-linking of GAGs, which in turn controls the viscoelastic properties of the materials. Possible future robotic and medical applications of such synthetic composites will be described.

INTRODUCTION

Imagine preparing to lift a heavy weight by concentrating and purposefully causing the soft pads between the vertebrae in your backbone to stiffen. Afterward you could just as readily soften the pads to allow your back its normal flexibility. For an entire phylum of animals, the Echinodermata (seastars, sea urchins, sea cucumbers, sea lillies, and brittle stars), the voluntary control of mechanical properties of soft skeletal materials is a way of life, not science fiction [10,17,19].

The major factor controlling the mechanical properties of all materials is the nature and density of electrical charges. Whether atoms and molecules stick to each other and how much energy it takes to separate them depends on the interactions of positive and negative charges on the molecules and in the surrounding medium.

A BIZARRE MATERIAL

Seastars and their relatives have soft connective tissues whose structure and

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composition are much like our own: they are highly hydrated composites of fibrillar collagen and amorphous polyanionic glycosaminoglycans (GAG) suspended in an aqueous fluid that saturates and permeates the tissues. The fluid contains most of the common ions found throughout all animal tissues and in sea water: H^+ , OH^- , Na^+ , Cl^- , HCO_3^- , Ca^{++} , Mg^{++} , etc. These animals appear to have the ability to attach tightly, loosen, dissociate, and re-attach the collagen fibers and GAGs in their soft connective tissues by varying the concentrations of cations in the permeating solution. Because any of these materials can vary from stretchy to rigid, they are called catch connective tissues [10].

At the base of each rigid calcitic spine of a sea urchin, a ring of muscle and the ligament (a ring of catch connective tissue) attach the spine to the test. The muscle causes the spine to rotate about the ball and socket joint: the urchin can point the spine in any direction and also use it as a stiff leg to walk on. If you, or some other predator, touch the spine, the urchin will immobilize the joint so that additional force will break the rigid spine before it will bend the joint. [9,16, 17,18].

In the same fashion, a sea cucumber is like a fat worm, crawling over the sea floor. But unlike a worm, when handled gently, it increases the stiffness of its soft flexible body. If it is then handled roughly, the tissues completely soften into sticky goo that repels predators and most curious humans [10]. After the stimulus stops, the urchin can resoften the spine joints and the cucumber restores normal viscoelastic properties to its body wall. In neither case is muscle involved in the changes in stiffness.

CONTROL OF PROPERTIES

When the catch connective tissue is isolated in a bath of physiological saline solution, a photoflash, an electrical stimulus, a mechanical stimulus [6, 7, 8, 11], the body fluid or increased concentrations of Ca^{++} , Na^+ , and H^+ will cause the material to stiffen [4, 7, 8, 14]. This is accomplished by increasing the viscosity (resistance to the rate of deformation) rather than in increasing the modulus (resistance to deformation) [3, 5]. Decreased cationic concentrations can cause extreme softening and, in some cases, dissolution of the tissue. The effects of adding specific neuro-inhibitors to the saline bath indicate that the control of properties is neuronal and biphasic: there are two types of neuronal receptors: nicotinic and muscarinic. There are also two types of acetylcholine receptors and, judging from knowledge of other animals, this leads us to suspect that there is one nerve for stiffening and another one for softening [6, 13, 18]. It is pretty obvious that the mechanical properties of connective tissues in these marine animals are controlled by the ionic environment [2].

In the spine ligament of sea urchins there is a ganglion (cluster of nerve cells) attached to each ligament. Axons extend from nerve cell bodies in the ganglion

and penetrate the ligament between the collagen fibers. The axons do not appear to have synaptic structures such as they would have if they connected to muscle cells or other nerve cells, but they contain large numbers of fluid-filled vesicles. The current hypothesis is that the chemicals in these vesicles have a critical role in controlling the ionic environment within the ligament [16]. There is no evidence that the cations that affect properties are stored in cells. It is more likely that cations are plentiful in the liquid phase of the ligament and that cationic effects are mediated by larger molecules (possibly stored in the axonal vesicles) that can mask or expose charged sites on the big structural macromolecules.

It is known that the sea cucumber body wall contains sulfated GAGs that are similar to chondroitin sulfate, a major constituent of human cartilage [1]. When these GAGs are isolated and subjected to increased concentrations of Ca^{++} and Na^+ , their molecular weight increases: this suggests that part of the increased viscosity of catch connective tissue may be due to the cross-linking of GAGs.

APPLICATIONS

The way the bodies of humans and most other animals are built, they depend on constancy of a narrow range of properties in their connective tissues. If our ligaments didn't maintain their stiffness, our knees, ankles, and hip joints would simply come apart when we walk or run. Echinoderms are unique in having connective tissue with variable, controllable properties. This means that their entire locomotor system must have a basically different design than our own.

Why might this be of interest to members of the American Society of Composites? If we cannot imagine an application of a material with variable, controllable properties, it is probably because we've never had one to work with. The main reason to create new materials is to use them in new applications.

It seems likely that we could find immediate use for such materials in medical biotechnology and in robotics. Current research on human cartilage shows that isolated samples in the laboratory undergo a restricted range of changes in viscoelastic properties when treated with varying concentrations of ions, particularly Ca^{++} [15]. Further research should show if such changes can be caused in the body, either from injected ionophores or other regulatory substances. Such technology might be used to stiffen aging intervertebral discs that would, in turn, reduce lower back pain. Lower back pain is a major medical cause of absenteeism in the work place.

In robotics, a recent design has been inspired by the elephant's trunk and its fingerlike, peanut grabbing tip [20]. It is a hydrostatically actuated manipulator (finger and thumb) on the end of a hydrostatic arm. As is the case in the elephant's trunk, there is no rigid element in the arm or the manipulator. The polymeric materials of which the entire mechanism is made have been specially

designed for the dynamic loading regimes required to make it work rapidly. For some uses, the robotic trunk works faster and is simpler to program and operate than the usual mechanical arm. The robotic trunk is also much cheaper to build. It is apparent that a material with controllable elastic modulus or viscosity could be used to improve efficiency when operation is switched from handling very light loads to very heavy ones.

Structural biomaterials show a high complexity of structure, function, and control of function whose mechanisms are still being revealed through research. After several decades of mastering simple synthetic composites, industry is in a position to profit from concepts of natural design gleaned from hierarchically complex biocomposites.

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Whale Blubber as a Structural Material

L. SCHICHEL ORTON AND P. F. BRODIE

ABSTRACT

As a composite material, whale blubber is a feltwork of highly oriented collagen and elastin fibers embedded in fat. The presence and orientation of these fibers allow blubber to have mechanical and structural functions in swimming and in feeding.

INTRODUCTION

Fin whales are large, streamlined mammals. Two behavioral characteristics are prominent in fin whales. They swim constantly to avoid sinking because they are denser than water, and they feed by engulfing and filtering large volumes of water (nearly 50 % of the body mass). Two types of blubber have been identified, and the mechanical properties of these two types of blubber are essential to mechanisms of swimming and feeding. Locomotor blubber is the stiff blubber surrounding most of the body. It is capable of transmitting mechanical forces and of storing and releasing elastic energy as the tail moves up and down during swimming. Ventral groove blubber is the grooved covering over the throat, covering the under surface of the whale from the snout to the naval. It can stretch up to four times its original length when the whale engulfs water and prey.

LOCOMOTOR BLUBBER

On the light microscope level, whale blubber is a feltwork of highly oriented collagen and elastin fibers embedded in fat. Locomotor blubber can contain up to 75 % by volume of collagen fibers. Trace fibers of elastin occur within the collagen fibers. There are two sets of these collagen fibers. One set is oriented radially into the whale. Some of these fibers are oriented with positive and negative acute angles with respect to the radial direction. The second set is in the plane of the body surface. These planar fibers appear to be in layers. All fibers within a layer are parallel. Fibers in alternate layers describe right and left handed helical patterns around and along the body of the whale. While these fibers are parallel to the body surface, there appears to be some weaving of fibers between layers [7].

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In many locomoting cylindrical biological systems, for example worms [1], squid [10], sharks [9], eels [2], spot, and tuna [3], the function of crossed helically oriented collagen fibers is to transmit forces, and to store elastic energy.

Tensile tests on locomotor blubber show a J-shaped stress-strain curve, common to most soft biological materials. We can arbitrarily divide the stress-strain curve into a 'compliant' region and a 'stiff' region by drawing a line tangent to the curve at its maximum slope. The point where the tangent line crosses the strain axis is the division between the two regions. The tangent elastic modulus in the stiff portion of the tensile curve is on the order of 10 MPa. Compression tests show a limiting modulus of the same magnitude. By comparison, rat tail tendon that is a bundle of parallel collagen fibers has an elastic modulus of 1 GPa [8]. The blubber is capable of elastically releasing approximately 70 % of the energy stored.

We performed sequential tests on blubber samples taken around the circumference of the tail stalk at a constant distance from the tail. These tests show that the length of the compliant 'toe' region of the stress-strain curve has a minimum of about 10 % strain near the midline. This toe length increases monotonically away from the midline to a maximum of approximately 25 % at the upper (dorsal) and lower (ventral) surfaces of the tail stalk. This allows locomotor blubber to distribute stress uniformly around the circumference of the bending whale. Therefore, contrary to intuition, a swimming whale cannot be modeled as a bending beam. In a bending beam stress concentrates at the top and bottom, away from the neutral plane.

Calculations of the amount of elastic energy potentially stored and released by the locomotor blubber have been made using several models [6]. Data used in the models included published data on volume and geometry [4], data from our tension and compression tests, and data from our tests to determine the maximum range through which the blubber stretches and compresses during swimming. These last data were obtained by observing the length changes in marked intervals along the blubber of a dead fin whale while we caused the whale to 'swim' on land using steam winches to bend the 45 ton carcass.

These models show that the blubber can store and release a maximum of between 20 and 40 KJ of energy during one up or down swimming stroke, depending on the assumptions in the models. This amount of elastic energy potentially stored and released by the locomotor blubber compares favorably with calculations of the amount of kinetic energy that the tail stalk has at its highest velocity during the swimming stroke (25 KJ). The kinetic energy calculation does not include the effect of the added mass of the water, which may increase the result by a factor of two.

VENTRAL GROOVE BLUBBER

Ventral groove blubber is the blubber that covers the throat of the whale and permits the whale to change its shape while feeding from that of a streamlined cigar to that of an elongated, bloated tadpole.

On a gross scale, ventral groove blubber consists of longitudinally oriented stiff ridges riding atop a compliant blubber. The ridges are separated from each other and mechanically isolated from the blubber below in the circumferential direction by grooves between the ridges. On the light microscope level, the ventral groove blubber differs from the locomotor blubber by having more and larger elastin fibers. In ventral groove blubber, elastin can be up to 15 - 20 % by volume. These elastin fibers can be up to 2 mm thick, and appear to the naked eye as yellow strands wound around the body in crossed helices.

In tensile tests, ventral groove blubber also shows a J-shaped stress-strain curve (see Figure 1, reproduced from [5]). In the compliant region of the curve however, ventral groove blubber is far more extensible than is locomotor blubber. Ventral groove blubber can

stretch reversibly to approximately four times its original length circumferentially and to one and one half times its original length along the longitudinal axis of the body. This is compared to less than 25 % compliant strain for locomotor blubber. The tangent elastic modulus in the stiffest region of the stress-strain curve for longitudinally stretched ventral groove blubber is approximately 17 MPa, and the modulus in the circumferential direction is approximately 10 MPa. The collagen fibers likely limit the deformation in the stiff region of the curves for both locomotor and ventral groove blubber since the limiting elastic moduli are similar.

Calculations show that the enormous stretch found in ventral groove blubber can be effected passively in the feeding whale in two ways [5]. We modeled the walls of the throat cavity as a cylinder, and calculated the force on the walls of the cavity generated by water crashing to a stop inside the mouth of a feeding whale moving at 3 - 6 kts. This force is enough to expand the throat cavity to its full capacity in both the longitudinal and circumferential directions.

In addition to this force, as the water moves from the tip of the snout to the tail, it must speed up to go around the expanding cavity. This speeding up creates an outward force on the cavity wall that tends to expand the cavity. Passive expansion allows the engulfing process to be powered by the locomotor muscles.

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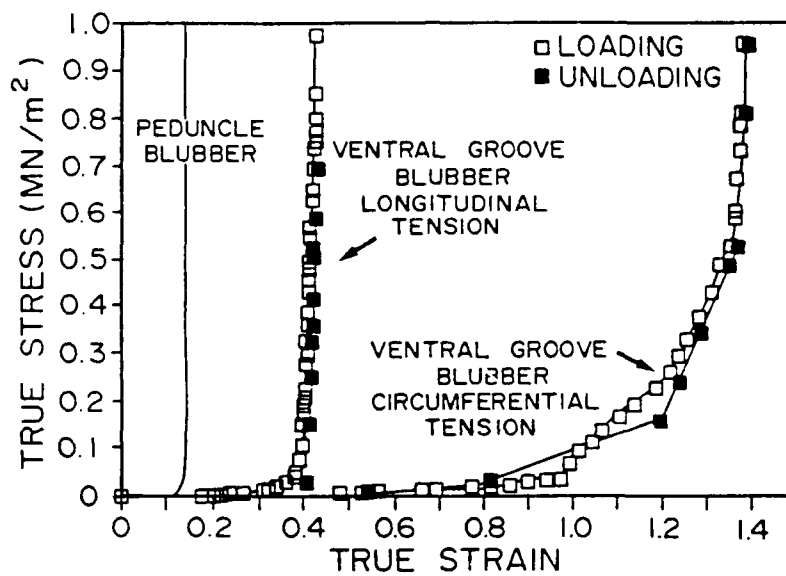


Figure 1. Stress-strain result from longitudinal and circumferential tension tests of ventral groove blubber compared to a tension test of locomotor blubber from the tail stalk (reproduced from [5]).

Design of a Composite Hip Prosthesis

F. K. CHANG, J. PERÉZ AND J. A. DAVIDSON

ABSTRACT

This work was concerned with the design of a hip prosthesis by using advanced fiber reinforced composite materials. The major focus of the study was to evaluate how the stiffness and strength of composite hip prostheses can be tailored by appropriately selecting ply orientation and stacking sequence for a selected manufacturing method. This investigation involved both analytical and experimental work. An analytical model was developed for analyzing the response of composite hip stems. Experiments were also performed to verify the analysis. Based on this study it was found that ply orientation and fiber layout could significantly affect the properties and the mechanical behavior of composite hip prostheses. Therefore, an optimal design of hip implants could be achieved by using advanced fiber-reinforced composite materials. However, it is very important that the ply orientation and stacking sequence are selected appropriately in order to achieve such a design.

INTRODUCTION

It is well documented that metal hip prostheses can cause stress shielding effect, resulting in bone-prosthesis loosening and implant fracture [1-5]. Such an effect can be attributed to the mechanical property mismatch between the prosthesis and the bone. However, because of the high strength requirement for hip prosthesis design, materials available for hip implants are very limited.

Due to recent advances in design and manufacturing technologies, advanced fiber-reinforced composite materials can offer a higher strength and a more flexible stiffness than metals. For instance, carbon fibers embedded in PEEK or Polyisofone, which are biocompatible polymer matrices, can have strengths ranging from 70 Mpa to 1900 Mpa and stiffnesses ranging from 1 Gpa to 1700 Gpa, compared with Titanium alloy with a strength of 800 Mpa and a stiffness of 1100 Gpa. Moreover, strength and stiffness of composites can be tailored according to a specific need. Such tailorability makes

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composites a possibly ideal substitute for metals for hip prosthesis design. It seems feasible that, using advanced composites, an optimal design of orthopaedic implants could be achieved.

Due to the complex geometry and the loading and boundary conditions of a hip prosthesis in a femur, tailoring composite hip implants demands a sophisticated analysis and appropriate manufacturing techniques. An inadequate design can cause premature failure of the implants and result in unacceptable quality. Therefore, the objective of this investigation was to develop analytical tools and techniques for tailoring the stiffness and strength of composite hip prostheses.

DESIGN CONSIDERATION

The major steps involving design of composite hip implants can be classified in sequence as follows: selection of a manufacturing method, design and analysis, processing and machining, and laboratory and clinical tests. Selecting an appropriate manufacturing method is the first and most influential step for the design of composite hip implants. Different manufacturing methods would subsequently affect the design of fibers and matrix layups, change processing and machining techniques, and, consequently, result in composite hip stems with different mechanical properties.

Once the manufacturing method is determined, a comprehensive analysis is required to determine proper fiber orientations for the design which could achieve the desired mechanical response of the implants (stiffness, strength and bone-implant reactions). Since changing fiber orientations leads to completely different mechanical properties and behavior of the implants, an optimal configuration of composite implants could be selected by properly determining the fiber orientation and the geometry of the implants. Apparently, this step is very crucial toward the design of an optimal composite hip prosthesis.

The next step is to select appropriate processing parameters for fabricating the composite implants and developing machining techniques, if necessary, for cutting and shaping the implants into a desired configuration. The processing parameters include fabrication temperature and pressure as a function of time and the duration of time of fabrication, all of which strongly depend upon the material selected and the thickness of the composite parts considered [6-7]. Because of the thick dimension of hip implants (normally involving more than one hundred layers), selecting appropriate parameters is an essential task in manufacturing [6-7]. Inappropriately selecting processing parameters could result in serious internal damage in the fabricated parts.

Machining of composites should also be dealt with great care to minimize any surface damage such as matrix cracking and fiber damage which could result in premature failure of the implants due to fatigue loading [8]. Finally, laboratory and clinical tests are necessary to evaluate the properties and the behavior of the implants and to further improve the quality of the products.

Accordingly, all of the aforementioned steps strongly influence each other. Each step is important and requires extensive efforts in research and development in order to achieve an optimal hip prosthesis surpassing the existing ones made of metals. The focus of this study was on tailoring the stiffness and strength of a hip prosthesis using advanced fiber-reinforced unidirectional prepreps. Therefore, in this paper, the major attention will be placed on development of an analytical tool for analyzing and designing

composite hip implants based on two selected manufacturing methods. Processing and machining issues will not be discussed here.

Apparently, there are many ways to manufacture stems with preregs, however, two typical methods were investigated in this study: a bend-mold method and a plate-cut method. The former first involves fabricating a thick curve composite panel from a mold, and then cutting and machining the panel into hip prostheses (see Figure 1). The latter involves fabricating a thick flat panel, and then cutting and machining the panel into hip prostheses (see Figure 1).

ANALYSIS

In order to select proper ply orientations, an analytical model is required to analyze composite hip implants. Although finite element methods have been extensively utilized as an effective tool for the design of metal hip prostheses, there is still a lack of an adequate finite element analysis for composite hip design. This is because a typical hip implant could contain more than one hundred layers of composites with mechanical properties varying from layer to layer, hence, a very large computer memory and a very powerful super-speed computer will be required to perform the calculations.

During this investigation, a specially designed finite element analysis was developed for composite hip stem design. The analysis involved developing a composite finite element which can accommodate several layers in an element and also can provide reasonably accurate solutions of calculations. Therefore, considerably less memory and computing time are required based on the proposed finite element analysis for analyzing thick composite implants. Detailed description of the analysis is given in [9], hence it will not be elaborated on here.

In this investigation, first ply failure and delamination were predicted by Tsai-Hill failure criterion, and Chang-Springer failure criterion [10], respectively. Failure of the composite implants was predicted in this analysis as stresses calculated from the finite element analysis satisfying either one of the criteria anywhere inside the implants. Note that the free edge stresses were not considered in the failure analysis.

EXPERIMENTS AND VERIFICATIONS

A prototype of simplified composite hip implants was selected, manufactured, and tested to verify the proposed finite element analysis. The configuration of the prototype implants (referred to as composite stems) is given in Figure 2. The first manufacturing method (curved panels) was considered for fabricating specimens. A composite mold was designed and built from a master during the investigation. Composite panels with a 120 layer thickness of preregs were manufactured from the mold in an autoclave. The panels were then sliced into the prototypes. T300/976 graphite/epoxy preregs were used to fabricate the prototypes. The reason for selecting this material is because its properties and curing procedures have been well established in the literature, even though the material is not necessarily biocompatible.

Each specimen was inserted into a designed fixture shown in Figure 3 and tested under conditions simulating, as closely as possible, a typical hip prosthesis test. Two

strain gauges were mounted on the lateral and medial sides of each specimen. A MTS testing machine was used with a loading speed of 0.01 inches/sec.

The strain measurements from the tests were compared with the calculations based on the analysis. Overall, this agreement was exceptionally good for all the tests; the calculations agreed with the data within 15 percent. Typical results from the comparisons between the calculated and the measured strains are presented in Figure 4. More results can be found in [9].

NUMERICAL RESULTS AND PARAMETRIC STUDIES

In the following, numerical results are presented to demonstrate the effects of design parameters, such as ply orientation and geometries, on the stiffness and the response of composite stems. The material used in the calculations were either Carbon/Polysulfone or Graphite/Epoxy T300/976 composites. The direction of the applied load P on the stems is shown in Figure 5. The magnitude of the out-of-plane load P_z was chosen to be one-fifth of the applied load P . The detailed geometric configuration and the dimensions of the stems are given in [9].

Bend-Mold Manufacturing Method

Figure 6 presents the stiffness of composite stems as a function of ply orientation. It clearly indicates that ply orientation significantly changes the stiffness of composite stems. Similarly, as shown in Figure 7, strength of composite stems also strongly depends on the ply orientation. It is worth noting that $[90]_s$, $[\pm 30/\pm 40/\pm 50]_s$, and $[\pm 15/\pm 40/\pm 55]_s$ stems failed in the inplane failure mode, but for $[0/90]_s$ and $[0]$ stems, the failure was caused by delamination. Therefore, in order to properly design a composite hip prosthesis, the ply orientation has to be selected adequately.

Plate-Cut Manufacturing Method

The stiffness and strength distributions of the stems made from flat composite plates as a function of ply orientation was also studied. The results of the calculations are presented in Figure 8, where, apparently, the $[45/60/-30/90]_s$ and $[30/45/-30/90]_s$ ply orientations offer the highest strengths among the others selected. However, as also demonstrated in the figure, when the stacking sequence of $[45/60/-30/90]_s$ laminates changes to $[-30/60/45/90]_s$ (the position of each ply in the laminates throughout the thickness), the stem strength decreased substantially. As a result, the stacking sequence also plays a significant role on the behavior of a composite hip prosthesis. This through-thickness effect can only be evaluated by a three-dimensional analysis, such as the one presently proposed.

CONCLUDING REMARKS

During the investigation, an analytical model was developed to study the effects of manufacturing method and ply orientation on the mechanical properties of composite stems (a simplified hip prosthesis configuration). A three dimensional finite element program was developed based on the analysis. Experiments were also performed to verify the model and the computer simulations.

Based on the parametric study, it was found that

- (1). the selection of ply orientation strongly depends on the manufacturing method chosen.
- (2). the manufacturing method and the ply orientation significantly affect the mechanical properties of composite hip prostheses.
- (3). an optimal design for a composite hip prosthesis could be achieved by selecting the appropriate ply orientation and manufacturing method.

ACKNOWLEDGEMENT

The support of Richards Medical Company for the project is gratefully appreciated.

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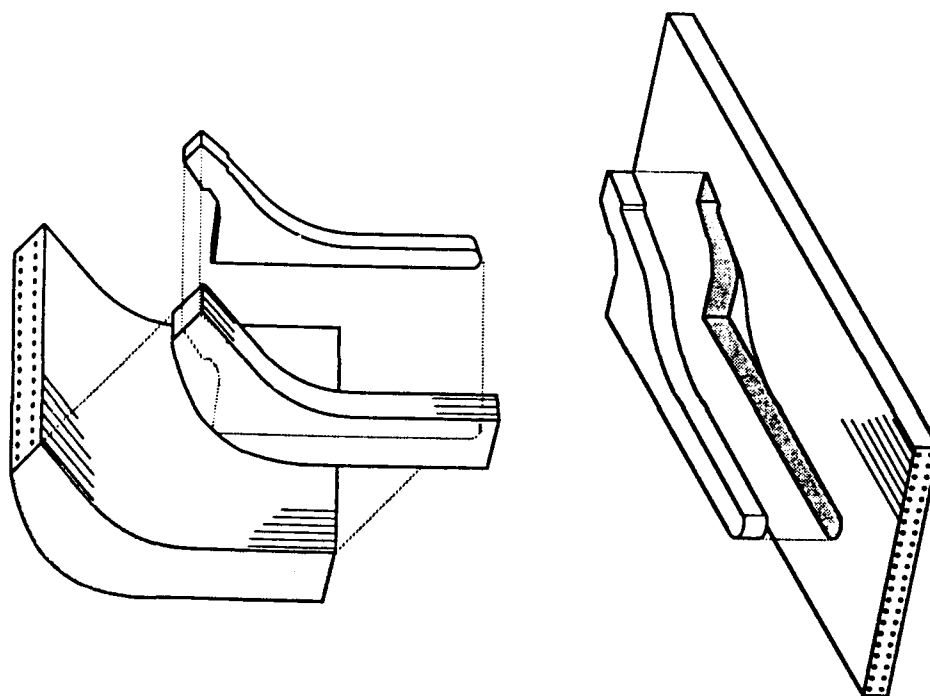


Figure 1. Manufacturing the composite prostheses: (top) a bend mold method, (bottom) a plate-cut method.

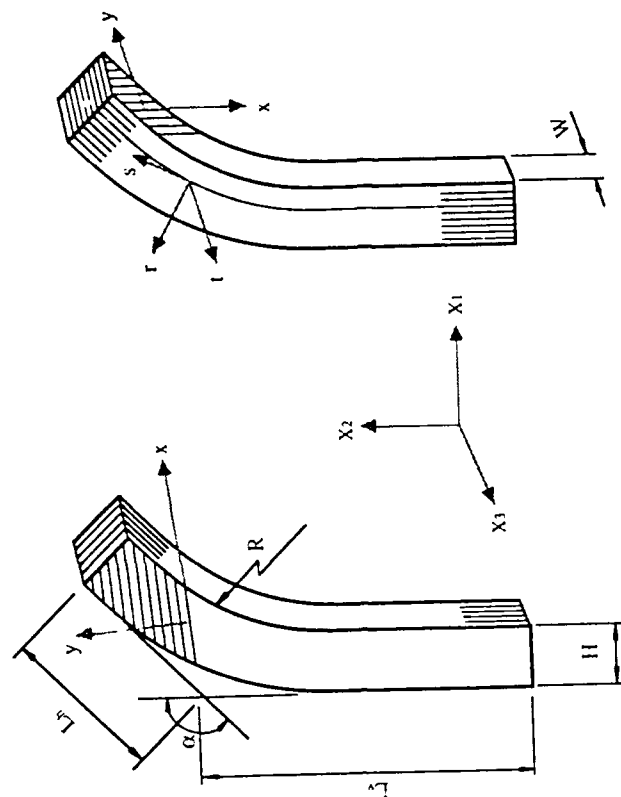


Figure 2. The simplified configurations of composite hip stems considered in the analysis. (right) A plate-cut stem, (left) a bend mold stem.

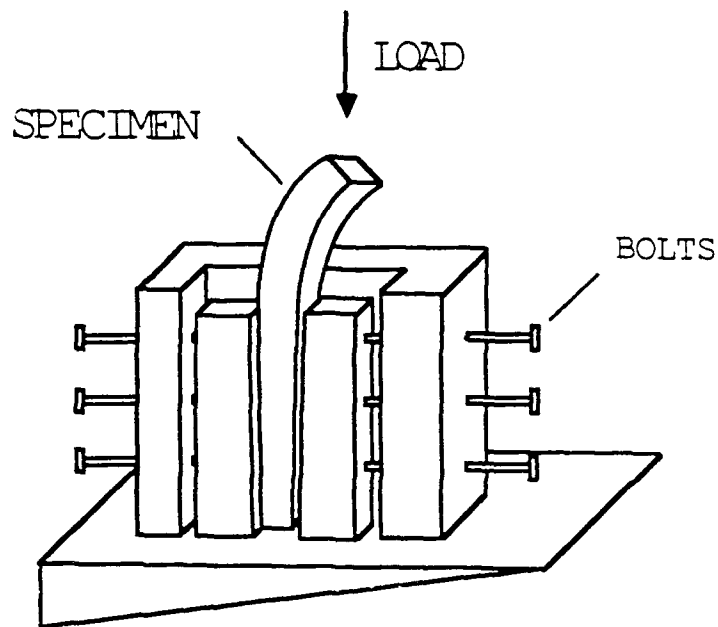


Figure 3. A schematic of the test fixture.

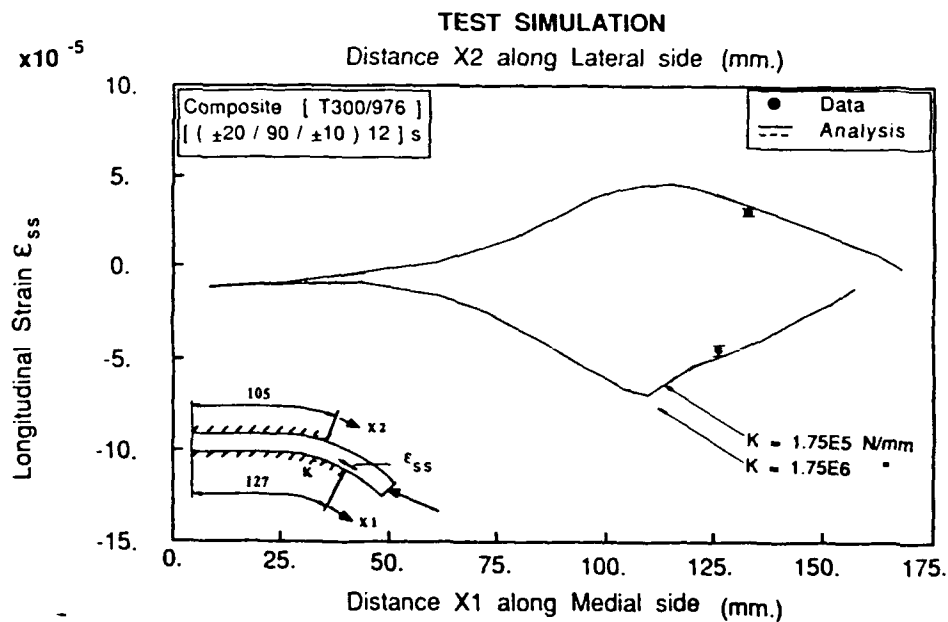


Figure 4. Strain distribution along the medial and lateral sides of a composite bend stem of $[(\pm 20/90/\pm 10)_{12}]_S$ with high side supports. Comparison between the data and the results calculated from the present finite element analysis.

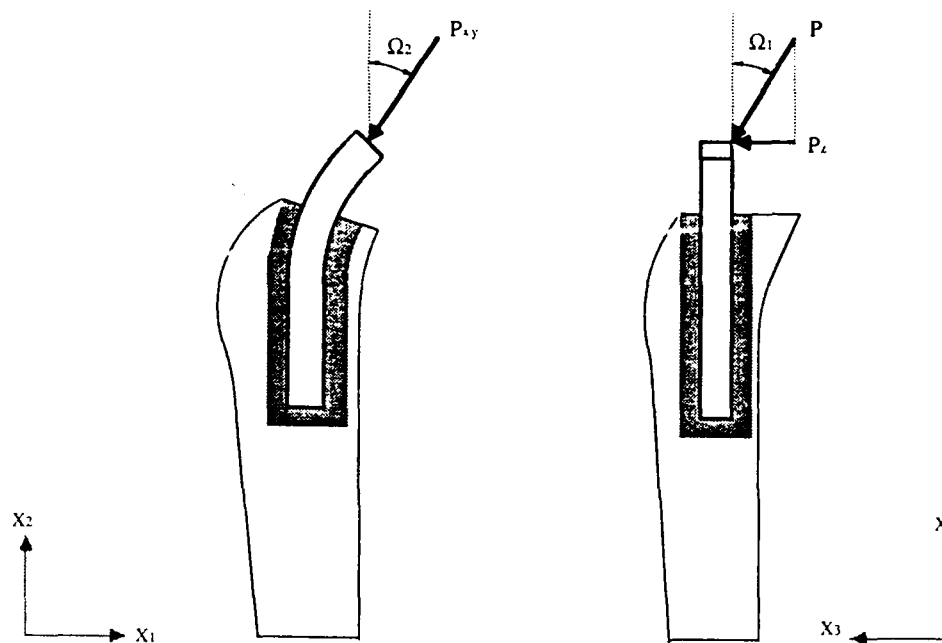


Figure 5. Description of loading directions and boundary conditions of composite stems considered in the analysis.

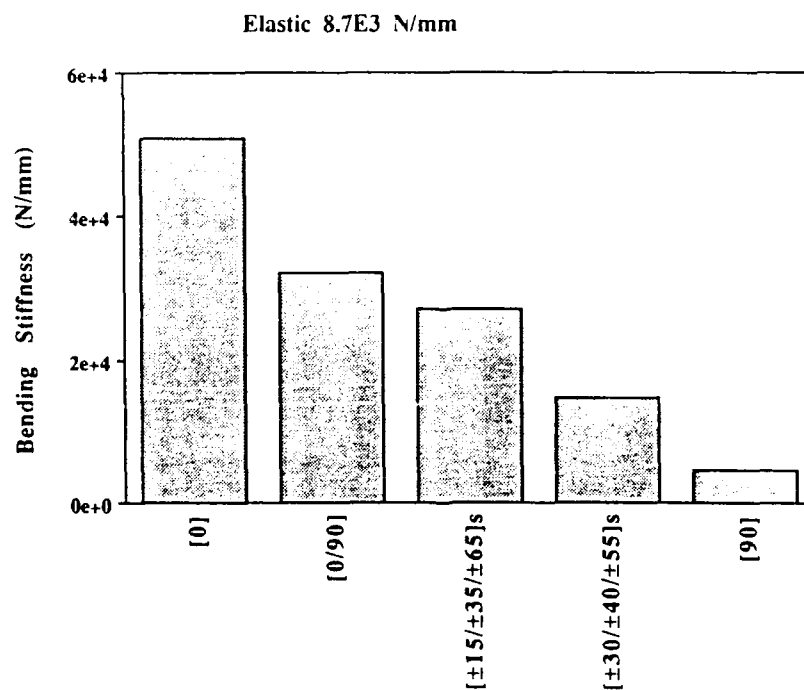


Figure 6. Bending stiffness distribution of composite bend stems as a function of ply orientation.

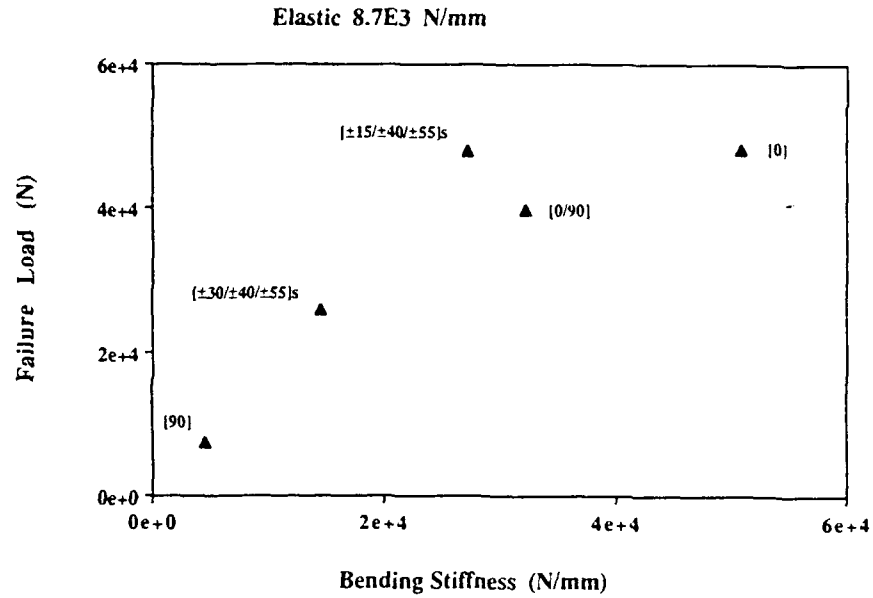


Figure 7. Strength distribution of composite bend stems as function of ply orientation.

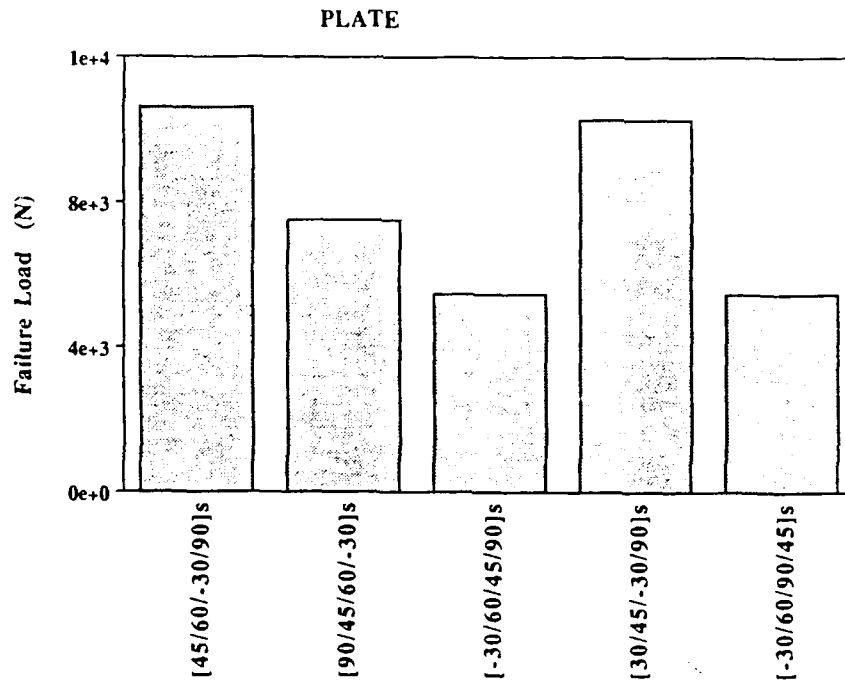


Figure 8. Strength distribution of composite plate-cut stems as a function of ply orientation and stacking sequence.