The Research, Design and Production of Cortical Bone Pins and Screws for the Fixation of Broken Bones in the Hand and Wrist

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ABSTRACT

Investigators at the University of Missouri at Rolla have entered into a joint venture with surgeons at Saint Louis University Hospital to develop a superior method of fixing broken bones of the human hand and wrist. This method involves the production of pins and screws from human cortical bone which will be used to fix broken bones for healing. The cortical bone fasteners will provide many advantages to the currently used metal fasteners. To date, prototype fasteners have been developed and are pending mechanical testing as a result of this undergraduate research project. Results of this project potentially include a greatly improved technique for orthopedic medicine as well as patent benefits for the University of Missouri.

INTRODUCTION

This project represents the true relevance of mechanical engineering in combination with surgical procedures to provide benefits to mankind in a practical and important way. This is an exciting area of research for us at the University of Missouri at Rolla. The ties and associations made through this project may set a precedence for continued research of this type at UMR with such reputable institutions as Saint Louis University Medical School.

This project has progressed from conception of a new idea to the production of actual trial samples of cortical bone fixation pins. Following intensive literature review and manufacturing research at UMR, the use of cortical bone fasteners has now been approved for human studies pending successful animal studies at Saint Louis University Hospital. Furthermore, continued work on the project is now progressing on several fronts. These include advanced design research, advanced manufacturing research, mechanical testing, animal studies, and the possible commercialization of the process by the University of Missouri Patents and Licensing Office.

BACKGROUND

Standard practices and techniques among orthopedic surgeons in the fixation of small bone fractures begin with the requirement for reduction of the fracture site using fasteners [1, 2, 3]. In this research, the small bones under consideration are those of the hand and wrist, metacarpals and carpals, respectively. The reduction of the fracture involves assuring that the bone pieces are properly aligned and that the fractured surfaces are as close together as possible. Proper reduction is essential to the healing process of bone due to the physiological processes involved in the body's self-repair mechanism [4, 5].

Open reduction is that reduction wherein surgical procedures are used to open surrounding soft tissue at the fracture site for direct access to the bones needing fixation. Open reduction is often used in the treatment of carpal and metacarpal fractures. The reduction of these bones is most often done with Kirschner wires (K-wires) which are chisel-tipped stainless steel wires in the general size range of one-millimeter in diameter. Other synthetic fasteners used include metal screws, ceramic based pins, and biodegradable polymer pins.

The problems associated with the use of the K-wire is that it is either inserted, cut, and buried in the surrounding tissue or it is left protruding through the skin surface [6]. The buried technique has a disadvantage in that a subsequent surgical procedure is required to remove the wire as recommended by standard orthopedic practice. The alternate technique carries the obvious disadvantage that a great amount of care is required to prevent infection of the open tissue surrounding the pin. Disadvantages also occur in the use of the other synthetic fixation devices. The metal screws and plates must be removed over time; ceramic pins do not always integrate well with surrounding bone tissue; and biodegradable polymers are often associated with surrounding tissue reactions resulting in swelling of the fractured region. For these reasons and more, an alternative method is desirable in the fixation of small bone fractures.

Bone tissue is used in many orthopedic procedures in both a slurry form and in a natural rigid form as graft techniques [7, 8, 9, 10, 11]. Grafting is commonly of the self-donor (autograft) type or as the non-self-donor (allograft) type [12]. Bone grafting is common practice and offers many advantages in human care compared to synthetic materials. Bone is an amazing tissue which is integrated into the host body over time. It is used to provide strength and fixation in standard orthopedic care. The ideal use of cortical bone fasteners would not require their removal as the bone would actually be absorbed by the body over time. For these reasons, cortical bone has been chosen for the research, design and production of fracture fixation devices.

LITERATURE REVIEW

Since the start of this project more than 125 research articles [13] have been reviewed and compiled regarding many aspects of the research [14]. These topics include bone material properties, surgical procedures, grafting techniques, bone physiology, bone microstructure, bone sterilization techniques, synthetic fixation devices, and so on [15, 16, 17, 18]. This study provided a vast understanding of the properties and phenomena related to bone tissue. This information proved invaluable in performing the most efficient and effective research for cortical bone fixation devices.

Aside from the understanding of the many aspects of this project listed above, the literature review most importantly revealed no evidence of previous research or current use of cortical bone fasteners. Furthermore, the literature supports the need for an improved fixation technique through articles regarding the complications associated with K-wires, biodegradable pins, etc. Thus, the final outcome of the literature review was essentially the go-ahead to begin research on the design and production of cortical bone fasteners knowing that new information would be discovered.

MECHANICAL TESTING

A very important question facing the successful development of cortical bone fasteners is that of the material properties of cortical bone. Not only is the understanding of bone properties important, but also the stresses placed upon the fracture site due to motion of the hand and/or wrist. The literature revealed a great deal of information regarding the material properties of cortical bone. More vague and uncertain however are the forces and stresses which could be anticipated in the hand and wrist. As a result of this lack of information, it is very difficult to theoretically ascertain whether or not the cortical bone devices can provide sufficient strength. In fact, this information may only be available through the testing of cadaver specimens, animal studies, and finally human trial studies.

The information in literature regarding the material properties of bone was found to be very complicated [19, 20, 21]. Although significant research has been done on determining properties of cortical bone, there is great variation depending on the source of the information. For example, the range of values for the modulus of elasticity of cortical bone is 16 - 28 GPa [22, 23, 24, 25]. This leads to a more qualitative approach regarding the characteristics of cortical bone. In pursuit of the qualitative nature of bone, bovine samples were used to determine both the modulus of elasticity and the hardness of the bone tissue. Bovine bone does not share identical properties with human bone. It was used, however, for comparative research due to its similar properties to human bone, its availability, and its very inexpensive cost.

The hardness testing was particularly important in providing information about the toughness of bone. Instruments at McNutt Hall were used to determine the modulus of elasticity and the Vickers hardness of bovine cortical bone. The modulus of elasticity was determined using a Grindo-sonic model ultrasonic testing instrument. This resulted in a stiffness of 22.5 GPa which is seen to be within that range found in literature sources. The Vickers hardness testing was done using a Leco DM400 Hardness Tester. This utilized a diamond pyramid indentor with a 1000 gram load upon a polished bone surface. The obtained data resulted in a Vickers hardness number of 50.1 kilograms per square millimeter. This may be referenced on the 1-10 Mohs scale as a value between 1 and 2 which characterizes talc and gypsum hardnesses, respectively [26]. Thus, cortical bone, despite one's expectations, is a relatively soft material.

Despite its determined softness, cortical bone exhibits remarkable toughness which characterizes the resistance of the material to fracture. The bone samples tested were subjected to both 10 and 30 kilogram indentation tests which both resisted the propagation of fractures at the corners of the diamond shaped indentor. In other words, bone is a very tough material which neither fractures easily nor allows fractures to propagate.

An understanding of the composition of bone reveals the source of its hardness and toughness characteristics. Bone is in all senses a true composite, consisting of a matrix of organic and inorganic materials. The organic portion is made of proteins, the most prevalent being collagen which provides the strength and toughness of bone. The inorganic portion is a calcium complex (hydroxyapatite) which provides the rigidity and hardness of the composite. Furthermore, bone is an active tissue of the body which is continually remodeling its microstructure to adapt to the body's needs for strength and protection [27].

The material properties of cortical bone are dependent on many factors. Specific bone density and strength depend on the health and activities of the individual as well as on the location of the bone within the body. Bone is truly an anisotropic material due to the preferred orientation of the bone cells and collagen fibers and bone microstructure contains many channels and canals which provide metabolic support [28]. Finally, the storage and treatment of bone can greatly affect the strength and grafting properties of the bone. In essence, bone is very complex and difficult to determine specific quantitative material property values. This results in the qualitative question, "Is bone suitable in strength for the fixation and reduction of fractures?" This question is yet to be completely answered as research continues.

MANUFACTURING RESEARCH

The ability to produce cortical bone fasteners was a challenging part of the project which developed along with the understanding of the material properties of bone. Early thoughts were that bone is a very hard material. These lead to investigating the use of high pressure water jet cutting or diamond saw methods which can cut very hard materials. Later, bone was found to be a relatively soft material and it was found that cortical bone could be fashioned into pins using conventional grinding procedures. Prototypes of pins were made using a crude assembly consisting of a high speed grinder and a manual lathe. It was discovered that the 20,000 r.p.m. grinder produced unacceptable vibrations and the high cutting rate produced an enormous amount of airborne particulate and noxious smell. Although pins could be produced, the resulting rough surface finish and overwhelming stench lead to further refinements of the procedure.

Following additional research of equipment which could be used to make pins of 30-mm length by 1-mm diameter, it was decided that a Harrison M250 lathe in the Mechanical Engineering machine shop would be used to manufacture the bone pins. The Harrison lathe allowed the mounting of a typical bench grinder and the use of an added water cooling and lubricating system. The water cooling system prevented the large amount of airborne bone particles and eliminated the bad smell which was due to the overheating of the bone matrix proteins caused by high cutting rate of the high speed grinder. The lathe also allowed the ability to precisely control the head stock speed and the axial feed rate of the grinder. Refinements in the mounting of starting material allowed the accurate production of bone pins of 40-mm length by 1-mm diameter and larger.

The successful production of bone pins allowed work to be done on the production of cortical bone screws by threading bone pins. The threading process was found to be much more difficult than the now simple method of grinding smooth pins. Standard metric machine shop taps and dies were obtained through Rutland Tool and Supply Company. Bovine cortical bone pins were carefully threaded using dies and plenty of water for lubrication and cleaning. The resulting bone screws were suitable but the threads produced were not ideal. Due to the sharp edges of standard machine screw threads, the finished screw contained some threads which were rough or not of full depth. Screw samples were made [29], but the threading process requires additional research to determine the most efficient method of producing clean, sharp threads. Speculation suggests that another grinding procedure may be the most successful means of producing threads on cortical bone pins due to the properties of cortical bone.

Bovine cortical bone pin and screw samples were produced and given to Saint Louis University Hospital surgeons for examination [30]. The surgeons used the samples to fix cadaveric specimens and reported favorable results on the fixing ability of the fasteners [31, 32]. Subsequently, a manufacturing procedure for bone fixation devices was written [33] and given to Saint Louis University to assist in their production of human cortical bone fixation devices. Human bone pin samples were produced by a machinist at Saint Louis University Hospital and used to fix human cadaveric metacarpals. These specimens will be used to determine mechanical fixation properties of the fixation pins.

ADVANCED DESIGN AND MANUFACTURING

As preliminary research on the manufacturing and use of cortical bone for surgical fasteners showed success, the next step was to pursue more ideal methods of manufacturing cortical bone pins and screws. Advanced manufacturing processes are under current investigation to determine a more rapid and efficient method of producing bone pins and screws. Advanced design techniques have been used to determine the optimal thread design for cortical bone screws using I-DEAS finite element software [34]. Bone screws are the most desirable fastener since the threads provide a more secure fixation than pins. The pursuit for an ideal cortical bone screw focuses on the ability to produce threads on a bone pin. The profile of the thread is very important as it will determine the manufacturing technique used to produce the threads. The profile is also very important in that it will determine the strength of the fastener as a result of the internal stresses of the thread. Hence, it is desired to optimize the thread design used on cortical bone fixation screws.

The research for the optimal design thread design began with an analysis of the thread design used on standard orthopedic screws. This is a logical point to study since these screws are a standard device used in current bone fixation procedures. The orthopedic screw thread profile analysis is unique and distinctly different from the standard machine screw profile. This difference in profiles is seen in the figures below.

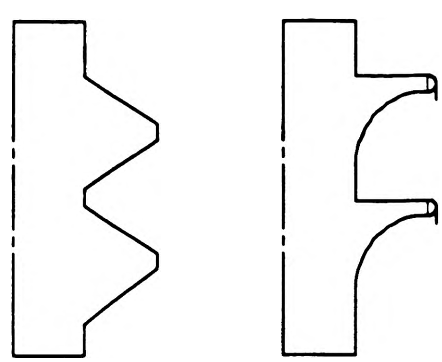

Figure 1. Standard Machine Thread Profile (left) and Orthopedic Thread Profile (right).

In addition to the unique orthopedic thread design, no information is available regarding the specific purposes of the design such as strength or stresses. This is due to the fact that the screws are made by a European company which does not release this information. To gain a better understanding of the orthopedic screw, the dimensions of the thread profile were approximated as accurately as possible from a published profile such as the one shown above. This approximate profile was then used to optimize the thread profile by minimizing the stresses within the thread region. The optimization was done using I-DEAS finite element modeling and optimization software on Hewlett Packard workstations in the Mechanical Engineering Department at Rolla. The criteria used for the optimization were such that the thread thickness was incrementally increased to reduce the internal stresses to an acceptable level. This design optimization resulted in the preliminary but successful redesign of the orthopedic screws currently used. Additional research on the optimization of the threaded fastener will continue in an effort to examine all possible optimization parameters for the optimal thread design.

Research is continuing on the manufacturing process of the cortical bone pins. Advanced manufacturing methods are being considered such as high pressure water jet technology and the use of diamond-edged cutting blades. Although these methods were considered unnecessary before, they may now provide more efficient means for producing the fasteners. With a more efficient manufacturing process, it would be possible to produce large numbers of devices for testing and eventually for commercialization of the cortical bone fixation devices.

PROJECT POTENTIAL

The research that has been done on the design and production of cortical bone fasteners carries significant potential in at least three main areas. Firstly, an improved method for fixing broken bones of the hand and wrist may produce a more effective method of orthopedic surgery. Secondly, this research and its continuation may lead to the commercialization and patenting of a manufacturing process for the University of Missouri. Thirdly, the interest and associations formed as a result of this project open a vast potential for research, design and manufacturing in biomechanical and biomedical engineering at the University of Missouri at Rolla.

The patent process for this research is being handled through the University of Missouri Office of the Coordinator for University Patents and Licensing. A patent disclosure was filed on September 11, 1992 entitled "Design and Fabrication of Human Cortical Bone Pins and Fasteners for Use as Fixation in Orthopedic Surgery," number 93-UMR-009 [35]. A non-confidential abstract of the project has been sent to at least 50 companies for commercialization opportunities. The commercialization of this project will lead to continued research funding, publications, and recognition for the University of Missouri at Rolla as well as other financial benefits for the University of Missouri.

SUMMARY

This project has progressed over the last year from the efforts of one undergraduate to now include two undergraduates and one graduate student with the research advisor, Dr. Daniel Stutts. Following significant literature and manufacturing research and five visits to Saint Louis University Hospital, the project has progressed from a concept to the production and implementation of trial samples of cortical bone fasteners. The work of this project has received initial funding from the University of Missouri Alumni Association and from Saint Louis

University Hospital. Continued funding is being sought through grant applications with the American Hand Institute, the Whitaker Foundation, and the University of Missouri Research Board. It is exciting to see how this project has progressed the research of the use and implementation of cortical bone for use as fixation devices in orthopedic surgery. Research projects of this nature are the source for advancements in engineering and science, and certainly build a sense of satisfaction and pride at the University of Missouri at Rolla.

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