COMPOSITE REDESIGN OF OBSTETRICAL FORCEPS

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ABSTRACT

Due to the increase in the number of children being born recently, medical technology has struggled to keep pace in certain areas. In these areas, particular needs have arisen to which the subject of this paper is directed. In the area of obstetrics, the forceps design and function has remained relatively unchanged for a number of years. In an effort to advance the technology, NASA Marshall Space Flight Center has been asked by the obstetrical community to help in a redesign of the obstetric forceps. Traditionally the forceps design has been of tubular stainless steel, constructed in two halves which interlock and hinge to provide the gripping force necessary to aid in the delivery of an infant. The stainless steel material was used to provide for ease of cleaning and sterilization. However, one of the drawbacks of the non-flexible steel design is that excessive force can be placed upon an infants head which could result in damage or injury to the infant. The redesign of this particular obstetric tool involves applying NASA's knowledge of advanced materials and state of the art instrumentation to create a tool which can be used freely throughout the obstetrics community without the fear of injury to an infant being delivered.

INTRODUCTION

The major function of the Technology Utilization office at NASA Marshall Space Flight Center(MSFC) is to aid individuals or industry representatives that require assistance in solving technical problems. Such a request was given to NASA's TU office by Dr. Jason Collins, a private practicing OBGYN from Slidell, Louisiana. The request was for assistance in redesigning the current stainless steel Simpson type forceps, so as to reduce the risk of injury to infants and mothers during a forceps type delivery, while at the same time keeping as much of the traditional appearance and functionality of the forceps as possible.

The forces induced onto the fetal head during a forceps delivery are primarily the traction or pull force (tensile) and the compressive force needed to overcome the friction or resistance of the maternal tissues. According to previous studies by Fleming, Pearse, Wylie and Ullery, the major factors which influence the performance of forceps are (1) the structure of the instrument; (2) the fetal head which the forceps must grasp; (3) the resistance of the maternal tissues: and (4) the force applied by the attendant. To further complicate this we must also consider parity, age of the mother, position of the infant, station and infant size. To address these problems, alternate delivery aids other than forceps have been constructed. One example is that of the Vacuum Extractor, however each has not been without its drawbacks. Though 40 percent less pull force is required with the Vacuum Extractor, suggesting an increase in safety in the area of cerebral compression, the possible advantage of the vacuum extractor may be offset by the potentially dangerous traumata which it may inflict on the fetal scalp[1].

Studies of the amount of pull force and compressive force applied to infants during delivery have been limited. Strain gages for measuring total force and calibrated instruments like the axis-tractionometer for measuring traction have been used with limited success to gain useful data with respect to measuring those forces imposed on the infant by the use of the forceps for delivery. Although no limits have been established, measurements from these field tests do give valuable data which can be used in this redesign effort[2,3].

APPROACH

Design

Composite materials have properties which can be tailored in the design to give even load distribution on an infants head for a given amount of input pressure applied to the handle by the delivering physicians hand. By using newly developed, state of the art instrumentation technology, fiber optic sensors can be embedded into the composite during manufacture which will be able to give the physician the ability to read the amount of compression load and tensile load he is applying to an infants head, and adjust as needed so that the delivery process will not result in injury to the infant. In addition, by utilizing the elasticity of the composite material and a tailored thickness along the length of the forceps, a fail-safe method can be achieved which will not allow the physician to place an unsafe amount of force upon an infants head under normal delivery conditions.

The major goal of this redesign effort was to provide a means by which instrumentation could be effectively incorporated into the existing obstetrical forceps configuration. A secondary desire was to provide a fail-safe method by which the compressive force applied to the fetuses head would be limited. The main goal will be accomplished by using a thermoplastic type material to mold a basic configuration which would allow state-of-the-art fiber optic instrumentation technology to be embedded within the forceps. By using a thermoplastic type material, structural fibers via a dry preform may also be added to increase the stiffness and strength of the hinge area as well as along the length of the forceps arms. Two fiber optic sensors will be embedded just below the surface of the forceps along each arm to provide both a reading for the compressive force at the tips and a tensile force as seen in Figure 1 below. The fiber optic strands will be located on the inner and outer surfaces of the arm to determine the bending moment at the point of maximum bending which in turn will provide the maximum compressive force exerted on the fetuses head. Design loads to be used in the detailed forceps design are five pounds (force) for the compressive loading and forty pounds (force) tensile force on the fetuses head which are well documented within the medical community[2]. Using these loads an optimized design for the forceps will be produced centered around two criteria. The first criteria is that the curved section of the forceps that come into contact with the surface of the fetus head provide minor conformability yet are stiff enough that most of the bending due to compressive forces takes place in the forceps arms above the hinge. The second criteria is that when the handles come together (full compression) a maximum compressive force of five pounds be exerted at the forceps tips. The second criteria will be accomplished by using the elastic thermoplastic material and optimizing the cross-section of the forceps arms to produce the required bending deflection at the tip.

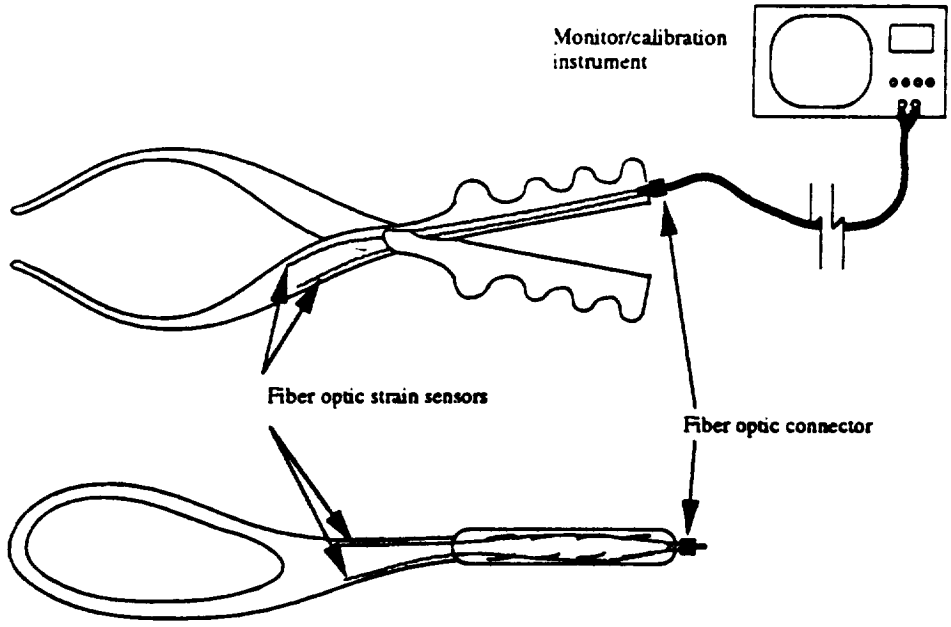

Figure 1. Typical Simpson type forceps with fiber optic strain sensors embedded into the composite.

The strain sensors selected to real time monitor the induced load will be embedded fiber optic grating reflectors. Dr. John Gilbert Ph.D. and Wei Su his associate, have developed a new technique using Bragg reflection gratings, with commercial fiber optics and modifying them to improve their ability to be used as strain sensors. Bragg reflection gratings and out-coupling taps for sensors are written holographically within the core of commercially available fibers. The process involves chemically germania doping the core of the optical fiber then writing in permanent holographic gratings. The gratings are made with a technique using interfacing beams of UV laser illumination on the side of the fiber. The formation of the grating forms a stop-band filter, as shown in Figure 2, by reflecting optical signals whose wavelength in the light guiding core is twice the grating spacing. This wavelength matching condition is known as the Bragg condition or Bragg Wavelength. When temperature and/or strain are applied to a section of fiber containing a grating, the grating spacing and index of refraction are modified and hence the Bragg wavelength changes. To separate the temperature and strain response, two grating elements may be required; one that is exposed only to the temperature and the other to both temperature and strain. The strain sensitivity of a fiber grating manifest itself through a change in grating spacing and the change in refractive index from the photoelastic effect. For a fiber grating placed under tension or compression, the change in Bragg wavelength per unit wavelength is typically 74% of the strain; i.e. $\delta\lambda/\lambda = 0.74\varepsilon$. To act as a generic sensor the fiber grating can be attached to or embedded in a material or on a diaphragm that changes shape under the action of the desired measureand. In an application as a strain sensor, for example, fiber gratings can be conveniently embedded in composite materials during fabrication for monitoring their cure, and later for monitoring their response in a completed structure[4].

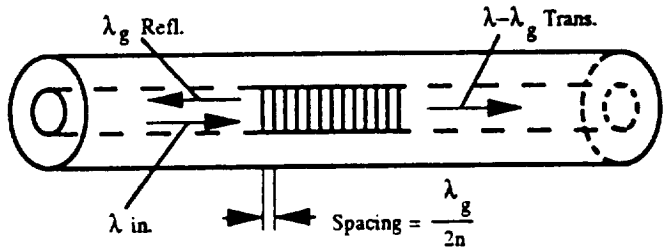

Figure 2. Illustration showing fiber grating reflector and the Bragg condition for reflection.

Material

The preliminary choice of material was between a thermoplastic composite which could be tailored to achieve a glass transition temperature (TG) high enough to facilitate sterilization in the current medical type autoclave, or which would be stable enough to allow sterilization by an alternate method like Beta radiation sterilization. The materials investigated which have a TG high enough to allow sterilization at autoclave temperatures were Polyetheretherketone (PEEK) and a Polyimide thermoplastic manufactured by Du Pont Polymers.

The other thermoplastic materials under consideration were three medical grade thermoplastics manufactured by NOVACOR Chemicals Inc. The materials being considered are ZYLAR® ST 94-560, ZYLAR® 93-546, AND NAS® 21. Each of these materials has been tested with Beta radiation sterilization and meet the USP XXI criteria for Class VI plastics for use in medical applications. The ZYLAR resins require little or no pre-drying when injection molded or extruded, which translates to savings in terms of machinery and energy costs. In addition, they can be blended with up to 15% regrind with no loss in color, clarity or physical properties, for a more complete utilization of the material without weakening the molded part. Plastics are playing an increasingly important role in medical applications, where a material's ability to withstand repeated radiation sterilization without yellowing or property loss is critical. Test data from the manufacturer indicate that ZYLAR resins exhibit less discoloration following Gamma and electron beam sterilization than other medical grade plastics, and will withstand the effects of alcohol exposure with no loss of key properties. These characteristics, as well as their good flow and molding

properties, helped to establish these materials as the materials of choice for use in the forceps redesign. These materials are all clear impact-grade thermoplastic resins and some of their typical properties are listed below in Table 1.

All data is for nominal 1/8 in. thick specimens.

Properties	NAS® 21	ZYLAR® 93-546	ZYLAR® ST 94-560
Tensile Strength, break,(psi)	$8.8x10^3$	$5.0x10^3$	$3.9x10^3$
Tensile Modulus, (psi)	$4.8x10^5$	$3.3x10^5$	$2.9x10^5$
Elongation, break, (%)	2.5	30	80
Flexural Strength, break,(psi)	$13.7x10^3$	$8.0x10^3$	$8.3x10^3$
Flexural Modulus, (psi)	$4.4x10^5$	$3.2x10^5$	$3.1x10^5$
Mold Shrinkage (in/in)	.002 - .006	.004	0.004
Water Absorption (24hr) (%)	0.11	0.1	0.1

Table 1. Properties of NOVACOR Thermoplastic material candidates.

Fabrication

The preferred method of manufacture for the forceps is by molding. The molding process can easily facilitate the use of the embedded fiber optic instrumentation as well as the use of any reinforcing fibers. Reinforcing fibers can be used to strengthen any portion of the forceps, i.e. the fulcrum or pivot point, by inserting the reinforcing fibers as a preform prior to molding, thereby achieving the proper stiffness and flexural properties. The fiber optics which are to be embedded can also be installed into the preform to hold it properly in place during molding.

RESULTS AND DISCUSSION

Testing

Once a prototype of the composite forceps has been built, complete with the embedded instrumentation, it must be tested in the laboratory, then ultimately in the clinical environment. The laboratory tests will be conducted in conjunction with Dr. John Gilbert Ph.D. and Wei Su of Optechnology, Inc., and will be performed at both the Optechnology,Inc. optics laboratory and NASA Marshall Space Flight Center. Once confidence is gained with the function of the prototype and its instrumentation, clinical field tests will be performed by Dr. Jason Collins at his clinic in Slidell, Louisiana.

Marketing

Following the successful testing of the prototype in the clinical environment, attention will be turned to the marketing of the product for use in the obstetrical community. As part of the design of the composite forceps the use of relatively inexpensive, high quality commercial materials and instrumentation allow the forceps to be relatively inexpensive as a unit. The high cost associated with this particular product would be the initial set up involving the purchase of the monitor/calibration device. The forceps themselves would arrive individually packaged as a sterile unit. When needed for use in a delivery, the package could be opened, the instrument quickly checked for calibration and then used and discarded into a container supplied by the manufacturer. The physician would then only be required to send the used forceps back to the manufacturer where they could be sterilized, the instrumentation checked and each unit checked for fatigue or microcracking, then repackaged for shipment back to the medical facility for reuse. Once the life cycle of the instrument is reached it could be destroyed and a new unit sent in its place. This alleviates the physician from the task of sterilization and handling of the used or contaminated instrument.

CONCLUDING REMARKS

Although this redesign attempts to make the use of the obstetrical forceps less complex and intends to reduce the amount of fetal injury during forceps deliveries, its use in the clinical environment must be combined with the knowledge and skill of the attending obstetrician. All of the elements which combine to contribute to the function of obstetrical forceps are interdependent and cannot be separated from one another. The obstetrician must be aware of the instrument, the resistance, and the force applied, and use this in conjunction with his knowledge of the delivery process. Comprehension of these factors and his ability to properly use these delivery tools are key ingredients in conducting a successful and safe forceps delivery.

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