

Spring Mediated Cranioplasty for the Treatment of Craniosynostosis

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Abstract

Craniosynostosis is a disorder characterized by the premature fusion of one or more cranial sutures in the infant skull, resulting in an abnormal shape of the cranium. An effective surgical procedure for treatment of this disorder has been developed and is currently in use called “Dynamic Spring Mediated Craniofacial Reshaping.” This technique involves surgical removal of the fused suture and insertion of springs to expand the gap created by the suture removal in order to gradually reshape the skull to a more desirable shape. There were three primary objectives of this research: develop a device that could fabricate type 316 stainless steel wireform springs having consistent mechanical characteristics, evaluate the performance of the device, and develop a mathematical model to predict the mechanical characteristics of the fabricated springs. Use of the mathematical model facilitates further research to be performed that could determine the most effective use of the “Dynamic Spring Mediated Craniofacial Reshaping” surgical procedure.

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This research would not have been possible without the contributions and support of many people. First, and foremost I would like to thank Dr. Stefan Duma for providing guidance, support, and encouragement over the past two years. Second, I would like to thank Dr. Lisa David of the Department of Plastic and Reconstructive Surgery at the Wake Forest School of Medicine for allowing me to do this research and providing funding to support it. I would also like to thank Dr. Ian Herring and Dr. Elaine Scott for sitting on my committee and offering advice towards the final version of this thesis.

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CHAPTER 1: Introduction and Background

INTRODUCTION

Craniosynostosis is a disorder that occurs in 1 out of every 1,800 infants born each year (Aviv 2002). The disorder is characterized by a premature fusion of one or more of the cranial sutures of the skull, which causes an abnormal skull shape as well as a possible constriction of the brain. This constriction of the brain, while not usually lethal, may cause developmental problems for the child (David 1999, Panchal 2001).

There are several procedures used by physicians for the treatment of this disorder. One such procedure has been developed and is currently in use in Sweden by Dr. Claes Lauritzen *et al.* (1998). This technique involves surgical removal of the fused suture and insertion of springs to expand the gap created by the suture removal. This procedure can usually be performed in less than one hour, results in significantly lower loss of blood, as compared to other procedures, and has shown promising results for the patients. However, the springs currently used for the surgery are made of type 302 stainless steel, which is not approved by the Food and Drug Administration (FDA) for surgical implants.

The FDA has approved type 316 stainless steel for surgical implants in the form of wire. The problem with type 316 stainless steel is that it has a significantly lower yield strength than that of type 302 stainless steel which is currently used (Oberg 2000). Previous attempts have been made to construct type 316 stainless steel springs of similar geometry

to be used in the United States without success.

There were three primary objectives of this research. The first objective was to develop a device that could fabricate type 316 stainless steel wireform springs having consistent mechanical characteristics. The second objective was to evaluate the performance of the device by determining the mechanical properties of a sample of springs fabricated using the device. The final objective was to develop a procedure for using the device that would yield consistent results while still minimizing the complexity of the procedure.

ANATOMY

In order to understand how this disorder affects the growth of the skull it is necessary to understand the anatomy of the skull. The following sections outline the basic anatomy of the skull necessary to understand the different types of craniosynostosis. The adult human skull is explained first to provide the reader with an understanding of the target geometry of the skull after normal growth. The infant skull is then discussed in terms of the differences between it and the adult skull, as well as how the skull develops into its target geometry. The final section outlines the basic types of craniosynostosis and describes how the skull geometry is altered with respect to the different types. All figures were created by the author and adapted from figures created by Netter (1997) and Gray (1995) except where otherwise indicated.

ADULT HUMAN SKULL

The adult human skull is comprised of 22 bones: 8 cranial bones and 14 facial bones (Gray 1995, Netter 1997). The bones are flattened or irregular bones, which are joined by immovable joints with the exception of the lower jaw. The cranial bones encase and protect the brain and form part of the nasal cavity and orbits. Since craniosynostosis is a disorder that affects the cranium, only the cranial bones will be discussed in the remainder of this section.

The cranium is comprised of 8 bones: occipital, two parietal, frontal, two temporal, sphenoid, and ethmoid (Figure 1.1). The fibrous joints between the cranial bones are called sutures (Figure 1.2). A suture forms a united membrane which is continuous with the periosteum (Stedman 2000).

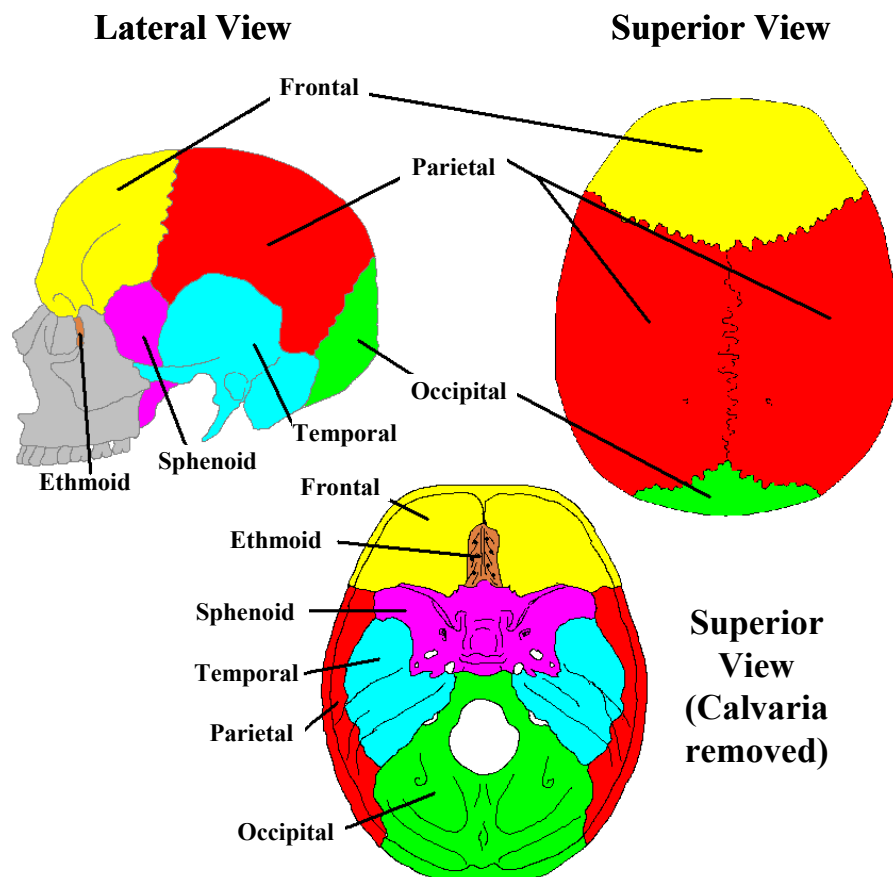


Figure 1.1: Cranial bones of the adult human skull.

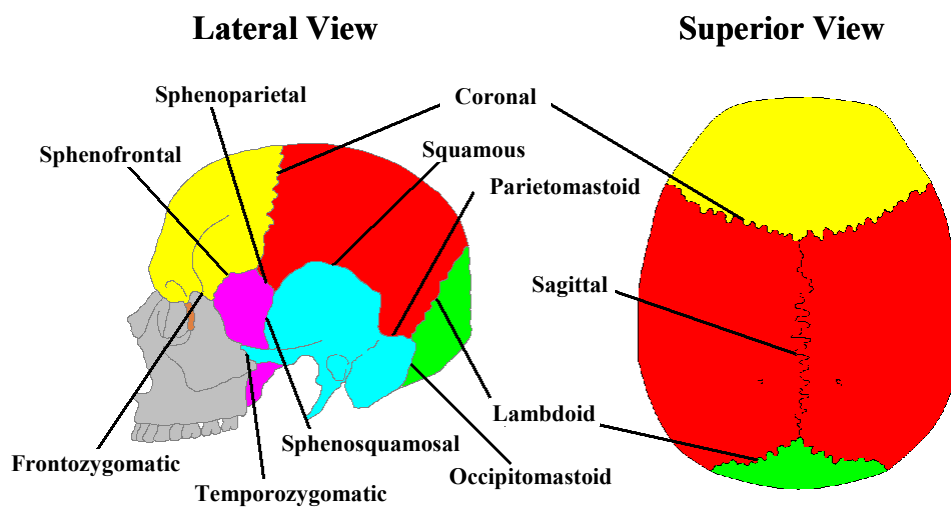


Figure 1.2: External cranial sutures of the adult human skull.

Occipital Bone

The occipital bone is located at the back of the cranium about the base (Figure 1.3). Its basic geometry is that of a trapezoidal shell. It is thick around the ridges, protuberances, condyles and the anterior portion of the basilar process, and it is thin at the bottom of the fossae. The occipital bone's external surface is convex. Located in the anterior region is the foramen magnum, which allows for the connection between the brain and spinal chord. On either side of the foramen magnum are the condylar portions, which allow articulation between the occipital bone and the atlas of the spine. The occipital bone's internal surface is concave and is referred to as the cerebral surface. The posterior portion is separated into four fossae by two lateral sinuses and two occipital sinuses. The two posterior fossae form around the occipital lobes of the cerebrum, while the two anterior fossae form around the cerebellum (Gray 1995, Netter 1997).

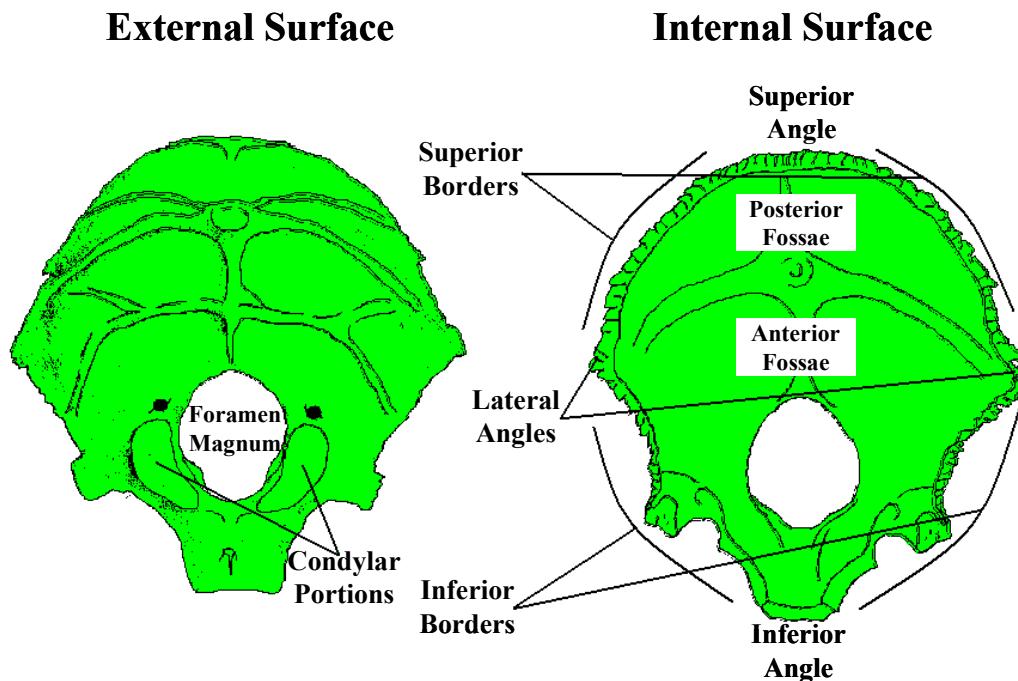


Figure 1.3: Occipital bone of the adult human skull.

The crest of the posterior edge of the occipital bone is called the superior angle. The crests of the lateral edges are called the lateral angles. The crest of the anterior edge is called the inferior angle. These angles stem from formations in the infant skull, which will be discussed later. The lateral portions of the posterior edge, extending from the superior angle to the lateral angles are called the superior borders, which articulate with the parietal bones and form the lambdoid sutures. The lateral portions of the anterior edge extending from the inferior angle to the lateral angle are called the inferior borders. The lower halves of these borders articulate with the petrous section of the temporal bone. The upper halves of these borders articulate with the mastoid section of the temporal bones and form the occipitomastoid sutures (Gray 1995, Netter 1997).

Parietal Bones

The two parietal bones form the upper portion of the cranium (Figure 1.4). Both have the geometry of a quadrilateral shell. The external surfaces of the parietal bones are convex. Arching through the middle of the surface from the anterior edge to the bottom edge are the upper and lower temporal ridges. The internal surfaces of the parietal bones are concave. The surface provides numerous depressions, which surround the external convolutions of the brain. The surface also contains furrows for the passage of the middle meningeal artery (Gray 1995, Netter 1997).

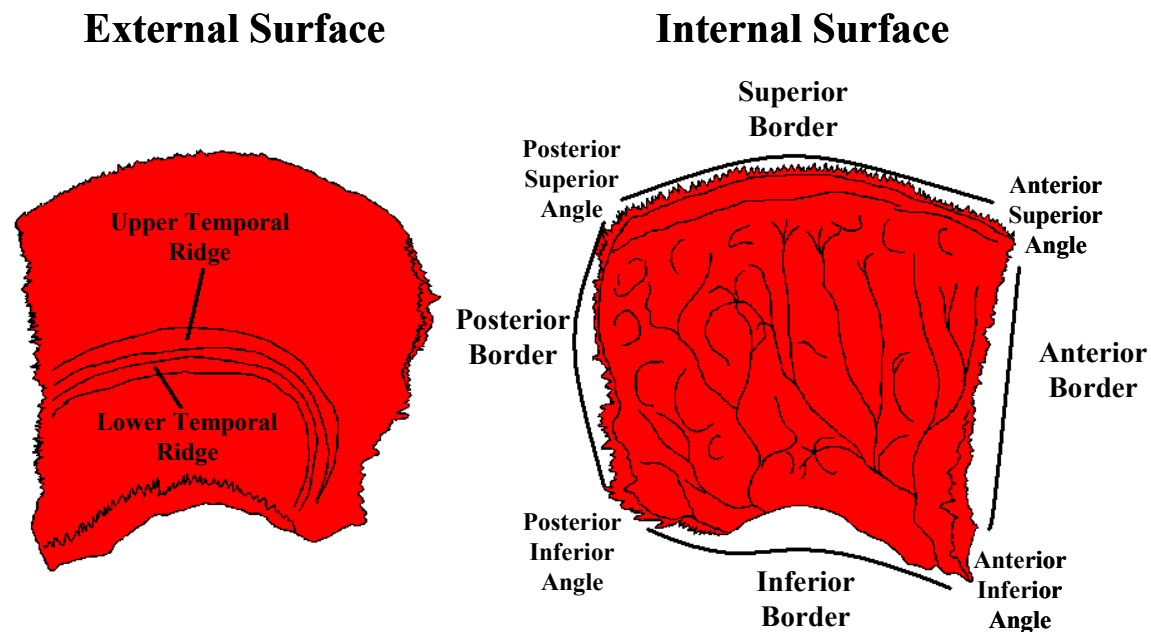


Figure 1.4: Left parietal bone of the adult human skull.

The top and bottom anterior vertices of the parietal bone are called the anterior superior and inferior angles, respectively. The top and bottom posterior vertices are called the posterior superior and inferior angles. These angles stem from formations in the infant skull, which will be discussed later. The upper edge of the bone extending from the anterior superior angle to the posterior superior angle is called the superior border. The superior border articulates with the opposite parietal bone and forms the sagittal suture. The lower edge extending from the anterior inferior angle to the posterior inferior angle is called the inferior border. The inferior border articulates with the temporal bone and forms the squamous suture. The anterior edge extending from the anterior superior angle to the anterior inferior angle is called the anterior border. The anterior border articulates with the frontal bones and forms the coronal suture. The posterior edge which extends from the posterior superior angle to the posterior inferior angle is called the posterior

border. The posterior border articulates with the occipital bone and forms the lambdoid suture (Gray 1995, Netter 1997).

Frontal Bone

The frontal bone is located at the anterior portion of the cranium (Figure 1.5). It resembles a cockleshell in form. It consists of two portions: the frontal portion and the orbito-nasal portion. The frontal portion is located in the anterior part of the cranium, commonly referred to as the forehead. The orbito-nasal portion forms the roof of the orbits and the nasal fossae. Structurally, it is very thin and composed entirely of compact (Gray 1995, Netter 1997).

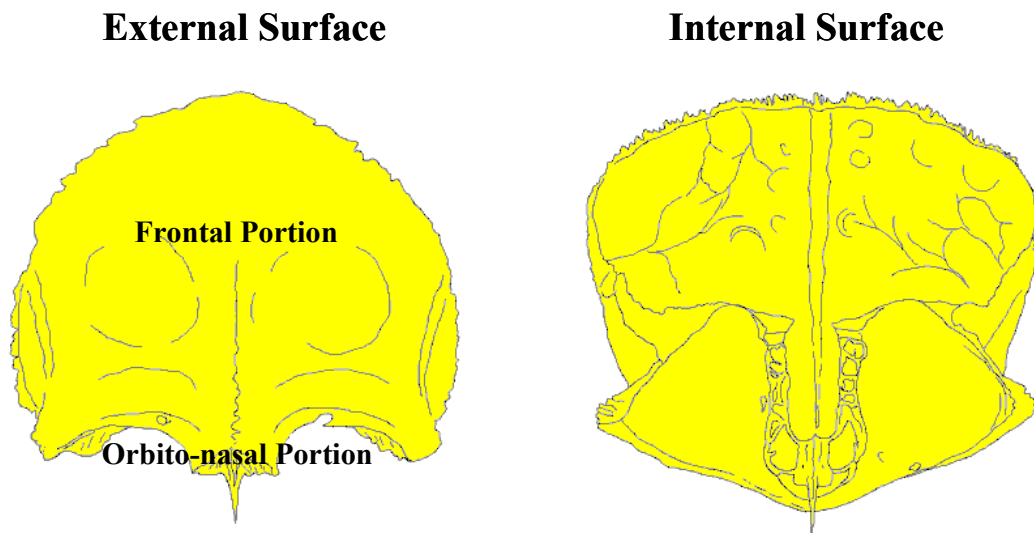


Figure 1.5: Frontal bone of the adult human skull.

The border of the frontal portion is thick and strongly serrated. It articulates with the parietal bones and the greater wing of the sphenoid bone. The border of the orbito-nasal portion is thin and not as strongly serrated. It articulates with the lesser wing of the sphenoid bone as well as several of the facial bones (Gray 1995, Netter 1997).

Temporal Bones

The temporal bones are irregular bones located at the sides and base of the cranium and are separated into three portions: squamous, mastoid and petrous (Figure 1.6). The squamous portion is the upper anterior portion of the bone. It is thin, smooth, convex, and grooved at the posterior end. Its upper edge forms the superior border, which articulates with the parietal bone, forming the squamous suture. Its anterior edge forms the anterior inferior border, which articulates with the great wing of the sphenoid, forming the sphenosquamosal suture. The mastoid portion is the lower posterior portion of the bone. Its outer surface is rough and has an irregular shape. Its upper edge forms the superior border, which articulates with the parietal bone forming the parietomastoid suture. Its posterior edge forms the posterior border, which articulates with the occipital bone and forms the occipitomastoid suture. The petrous portion is a thick and dense pyramid shaped process at the base of the skull (Gray 1995, Netter 1997).

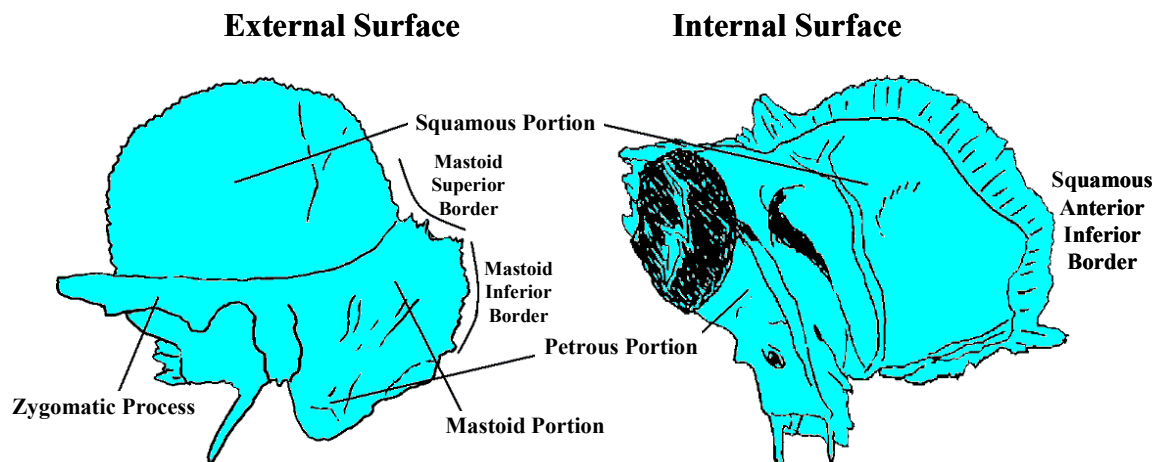


Figure 1.6: Left temporal bone of the adult human skull.

Sphenoid Bone

The sphenoid bone is located at the anterior portion of the base of the skull. The sphenoid bone articulates with all of the cranial bones (as well as five of the facial bones) and is the structural center of the cranium. Its irregular form resembles a butterfly in shape. The bone is separated into seven portions: the body, two greater wings, two lesser wings, and two pterygoid processes (Figure 1.7). The body is the hollowed central region, from which the remaining portions extend. The greater wings are two large processes that extend from the body outward to the lateral external surfaces of the cranium. The edges of the greater wings articulate with the frontal, parietal, and temporal bones at the sphenofrontal, sphenoparietal, and the sphenosquamosal sutures. The lesser wings are two thin plates of bone which extend from the superior and lateral parts of the body. The pterygoid processes extend from the junction between the body and the greater wings downward (Gray 1995, Netter 1997).

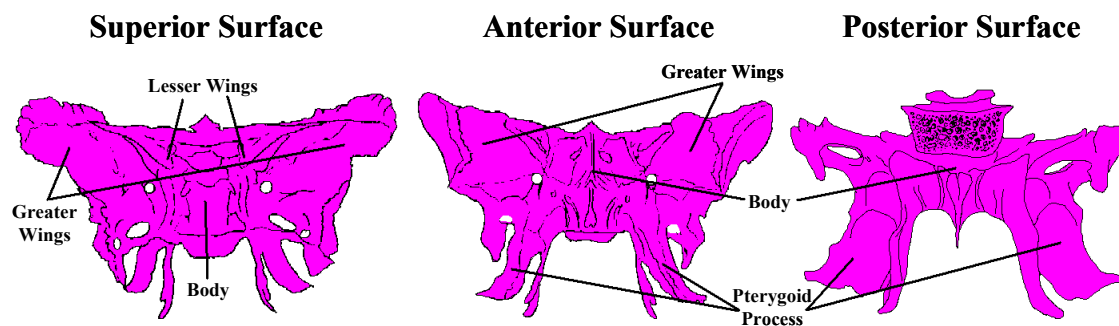


Figure 1.7: Sphenoid bone of the adult human skull.

Ethmoid Bone

The ethmoid bone is a light spongy bone located at the anterior base of the cranium (Figure 1.8). It consists of four parts: the two lateral masses, the cribriform plate, and the perpendicular plate. The lateral masses form the superior and middle nasal concha, which surround the posterior portion of the nasal cavity. The cribriform plate forms a section of the anterior fossa at the base of the skull and is located above the nasal cavity just below the orbito-nasal region of the frontal bone. The perpendicular plate is located within the nasal cavity and forms the beginning of the septum. The lateral masses are comprised of a number of cellular cavities between two plates. The outer plate forms part of the orbit, while the inner plate forms part of the nasal cavity (Gray 1995, Netter 1997).

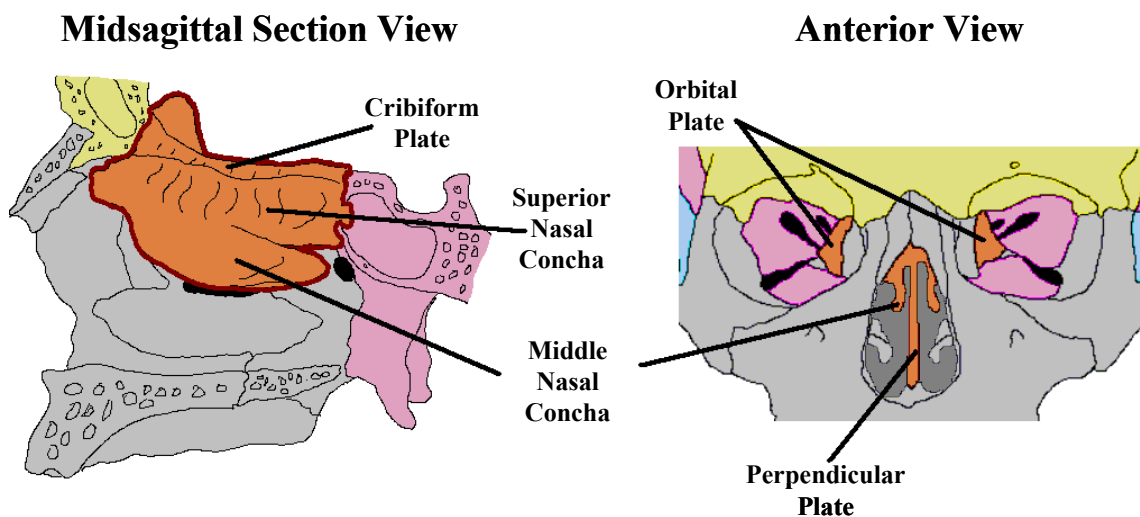


Figure 1.8: The ethmoid bone of the adult human skull (outlined in burgundy).

INFANT HUMAN SKULL AND CRANIAL DEVELOPMENT

The infant human skull contains the same cranial bones as the adult human skull (Figure 1.9). The cranium contains essentially the same sutures as the adult cranium except for several of the sutures which form from fontanelles and one suture which is commonly non-existent in the adult human skull. Fontanelles are membranous intervals of which will eventually form some of the sutures and angles found in the cranium of the adult human. The sphenoparietal, sphenofrontal, and sphenosquamosal sutures in the adult cranium are formed from the sphenoidal fontanelle in the infant cranium. The occipitomastoid and parietomastoid sutures in the adult cranium are formed from the mastoid fontanelles in the infant cranium. The anterior fontanelle is formed at the intersection between the metopic, coronal, and sagittal sutures. The posterior fontanelle is located at the intersection between the sagittal and lambdoid sutures (Figure 1.10). The metopic suture exists between the two halves of the frontal bone, and is usually non-existent in the adult (Gray 1995, Netter 1997).

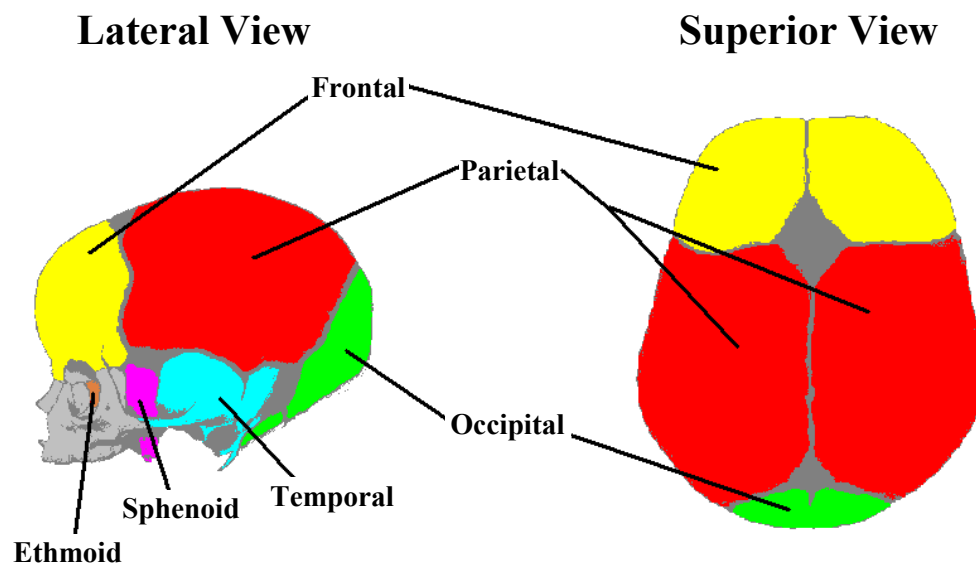


Figure 1.9: Cranial bones of the newborn infant human skull.

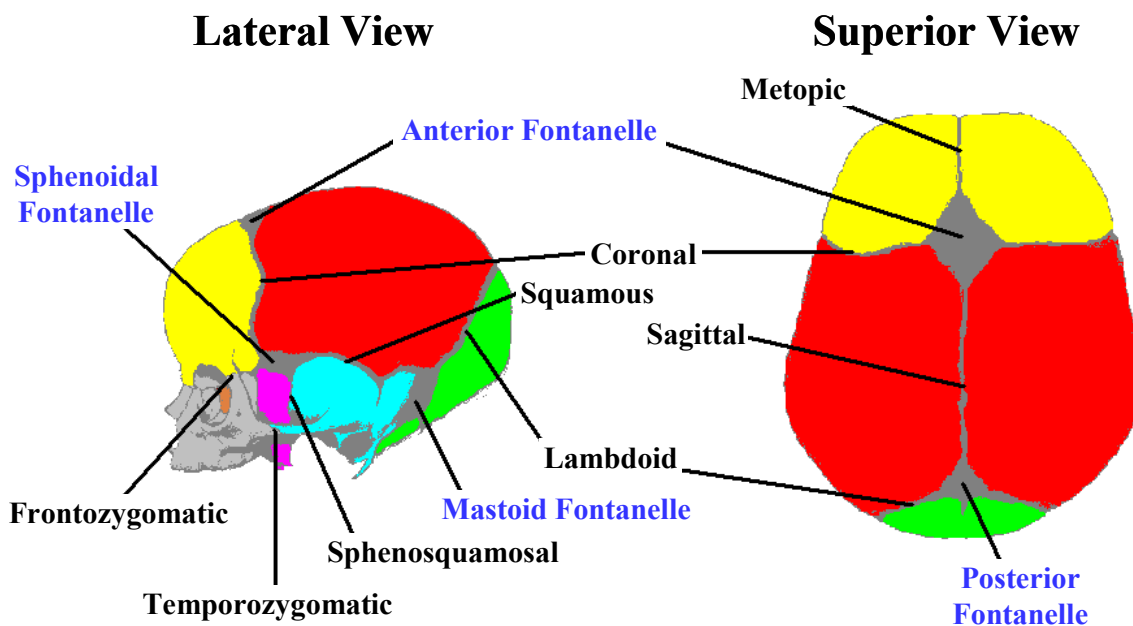


Figure 1.10: Cranial sutures and fontanelles (labeled in blue) of the newborn infant human skull.

The basic geometries of several of the cranial bones change significantly during development. Some of the bones start out as more than one ossified section, and later fuse to form a single bone (Figure 1.11). Each bone has a varying number of centers where ossification originates. The occipital bone contains seven centers: four for the occipital portion, one for each of the condylar portions, and one for the basilar portion. The parietal bones are each formed from a single center, a condition referred to as forming in membrane. The frontal bone is also formed in membrane but starts as two separate bones, each with their own center. The temporal bone contains ten centers: one for the squamous portion, one for the tympanic plate, six for the petrous and mastoid portions, and two for the styloid process. The sphenoid bone contains fourteen centers: one for each lesser wing, two for the anterior portion of the body, one for each internal pterygoid plate, one for each lingula, one for each greater wing and external pterygoid plate, two for the posterior portion of the body, and one for each sphenoidal turbinated bone. The ethmoid bone contains three centers: one for the perpendicular plate and one for each lateral mass (Gray 1995, Netter 1997).

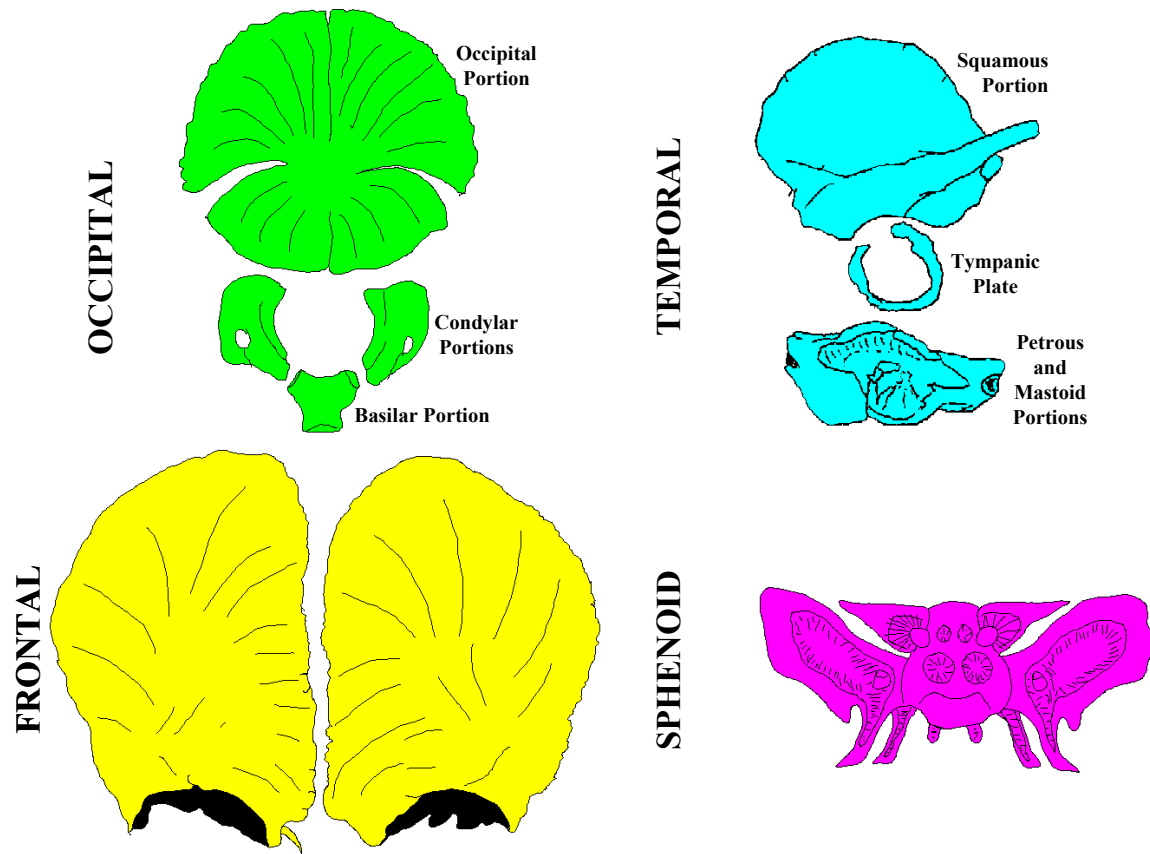


Figure 1.11: The occipital, frontal, temporal, and sphenoid bones at birth. Notice that some of the bones actually start out as more than one ossified section.

During normal skull growth, the bones are allowed to grow due to flexibility in the sutures and fontanelles. This flexibility is critical during the early stages of development when a significant amount of the skull growth occurs (Gray 1995, Netter 1997). Certain disorders may occur which can hinder this growth. One such disorder is called craniosynostosis.

CRANIOSYNOSTOSIS

Craniosynostosis is a premature ossification of one or more of the cranial sutures resulting in abnormal growth of the cranium (Stedman 2000, Marentette 2001). The type of craniosynostosis is determined by the applicable obliterated sutures (McIntyre 1997).

Scaphocephaly is the most common type of craniosynostosis and is caused by fusion of the sagittal suture (Figure 1.12). It is characterized by a broad forehead, a decrease in the lateral dimension, and an increase in anterior posterior dimension. The growth shape observed by the fusion of this suture is believed to be caused by the inability of the parietal bones to grow in the superior and lateral directions. However, these bones do continue to grow in the anterior and posterior directions causing the elongation of the skull.

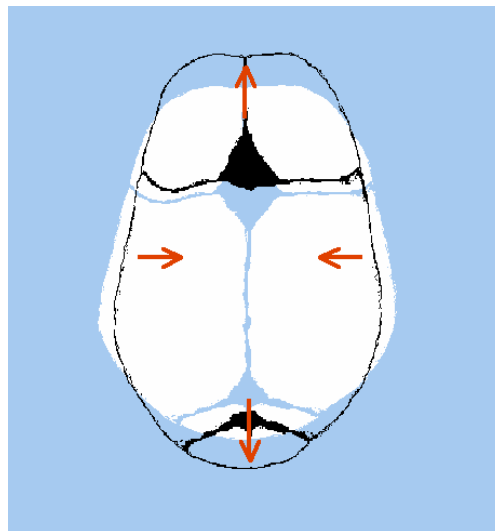


Figure 1.12: Scaphocephaly as a result of sagittal suture fusion (black lines indicate cranial deformation compared to the un-deformed cranium in blue).

Anterior plagiocephaly is the second most common type of craniosynostosis and is characterized by the premature fusion of the coronal suture (Figure 1.13). For the unilateral type, the frontal bone adjacent to the fused suture is somewhat recessed while the lateral-posterior end of the parietal bone on the opposite side is expanded.

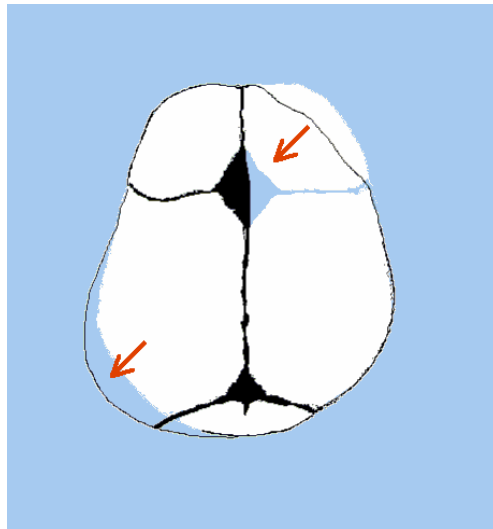


Figure 1.13: Anterior plagiocephaly as a result of unilateral coronal and sphenofrontal suture fusion.

Posterior plagiocephaly is characterized by the premature fusion of the lambdoid suture (Figure 1.14). Deformation resulting from this type of craniosynostosis is opposite of that observed in anterior plagiocephaly.

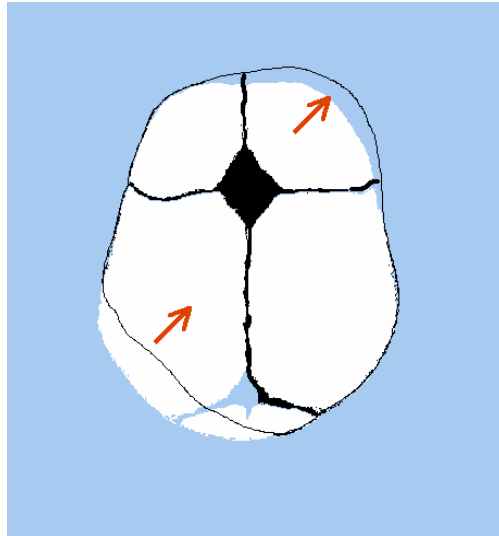


Figure 1.14: Posterior plagiocephaly as a result of unilateral lambdoid suture fusion.

Trigonocephaly is rare and is characterized by the fusion of the metopic suture (Figure 1.15). It results in a narrowing of the frontal bones and an expansion of the posterior portion of the parietal bones and the occipital bone.

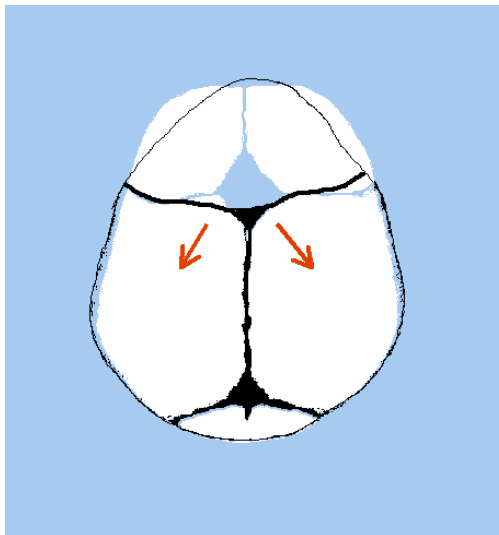


Figure 1.15: Trigonocephaly as a result of metopic suture fusion.

Brachycephaly is characterized by the premature fusion of the bilateral coronal sutures

(Figure 1.16). This causes the opposite effect of scaphocephaly, in that the skull's anterior posterior dimension decreases while the lateral dimension increases.

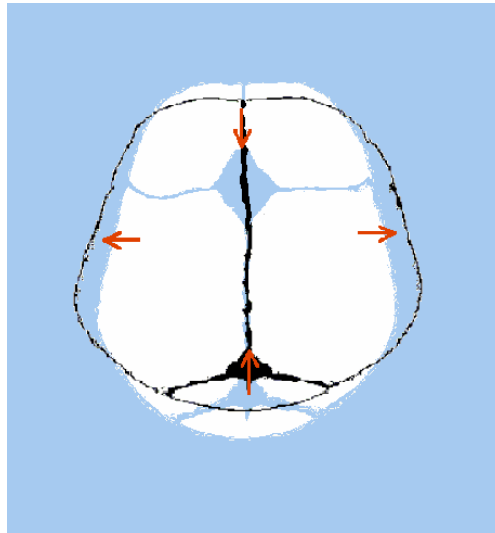


Figure 1.16: Brachycephaly as a result of bilateral coronal suture fusion.

Complications as a result of craniosynostosis can vary depending on the type and extent of the cranial distortion. Restriction of the cranial volume may cause an increase in intracranial pressure (ICP). The more sutures that are fused the greater the effect is. This increase in ICP is more common in syndromal cases than in non-syndromal cases. Venous drainage, respiratory embarrassment and abnormal cerebrospinal fluid flow are also contributing factors to the increase in ICP. An increase in ICP is believed to be one of several causes of mental retardation. The effect of an increase in ICP on the optic nerve is believed to cause the development of visual disturbance as well (Aviv 2002).

LITERATURE REVIEW

Several studies have been performed to investigate the effectiveness of different types of surgery to correct craniosynostosis. One study in particular reviewed 189 cases over a ten year period. Of these 189 cases, 44 patients underwent calvarium-reshaping surgery, three of which required secondary surgery. The study also indicated that 56% to 58% of reported cases of craniosynostosis were sagittal synostosis, occurring in one out of every 1,000 live births. Sagittal synostosis presents the least risk of abnormal brain development as compared to other types of craniosynostosis (Breugem 1999).

There are several procedures used by physicians for the treatment of this disorder. The most common of which is surgical cranial reshaping (Friede 1996, Williams 1999). This long procedure requires the removal of a large section of the skull, called the calvaria (Figure 1.17) and a physical remodeling of its shape. This reshaping involves numerous cuts into the bone (Figure 1.18). The reformed portion of the skull is fixed using resorbable plates for fixation (Figure 1.19) (Losken 2001, Surpure 2001). This procedure can last for over five hours and usually results in a significant loss of blood (Lauritzen 1995). This loss of blood is usually treated with blood transfusions from a family member.

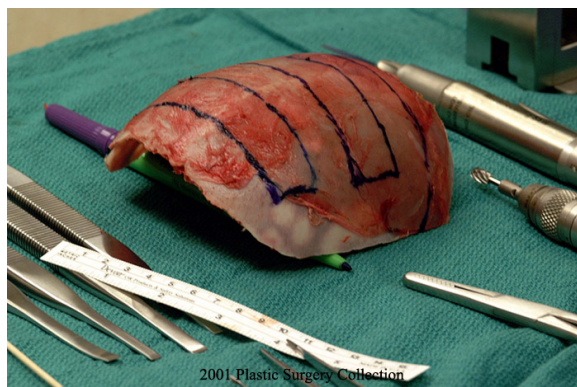


Figure 1.17: Calvaria removed from the patient. The lines indicate where the cuts will be made (Photographs courtesy of Wake Forest University).



Figure 1.18: Placement of the calvaria. The strips cut in the calvaria allow for the geometry to be adjusted while placing the calvaria back onto the patient (Photographs courtesy of Wake Forest University).

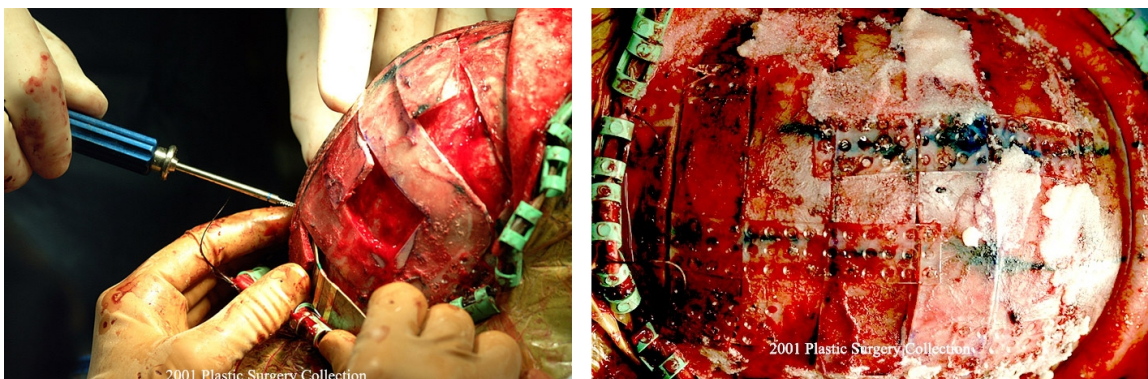


Figure 1.19: Fixation of the reformed calvaria is accomplished by the use of plates made of resorbable material (Photographs courtesy of Wake Forest University).

Another surgical technique that has been developed is gradual bone distraction (Amaral 1997, Imai 2002). This procedure utilizes a distraction device that can be gradually adjusted by the physician over a period of months until the desired reformed shape is achieved. The use of this device has shown promising results, however, it requires that a portion of the device pass through the skin after the initial surgical procedure. This not only increases the chance of infection, but also is very awkward in appearance. This technique is representative of a type of cranial remodeling that is commonly referred to as Dynamic Cranial Remodeling.

Dynamic Cranial Remodeling techniques have shown great promise with respect to cranial reshaping for craniosynostosis as well as other types of skull shape abnormalities. They are characterized by the use of some device to continue the reshaping process after the original surgery is complete (Guimarães-Ferreira 2002, Gewalli 2001b).

One form of this type of corrective surgery, developed and currently in use in Sweden by Dr. Claes Lauritzen, is called “Dynamic Spring Mediated Craniofacial Reshaping” (Lauritzen 1998, Gewalli 2001a). This technique involves surgical removal of the fused suture and insertion of springs to expand (or contract in some cases) the gap created by suture removal. For the case of scaphocephaly, fusion of the sagittal suture, the suture is removed and the springs are inserted between the parietal bones (Figure 1.20).

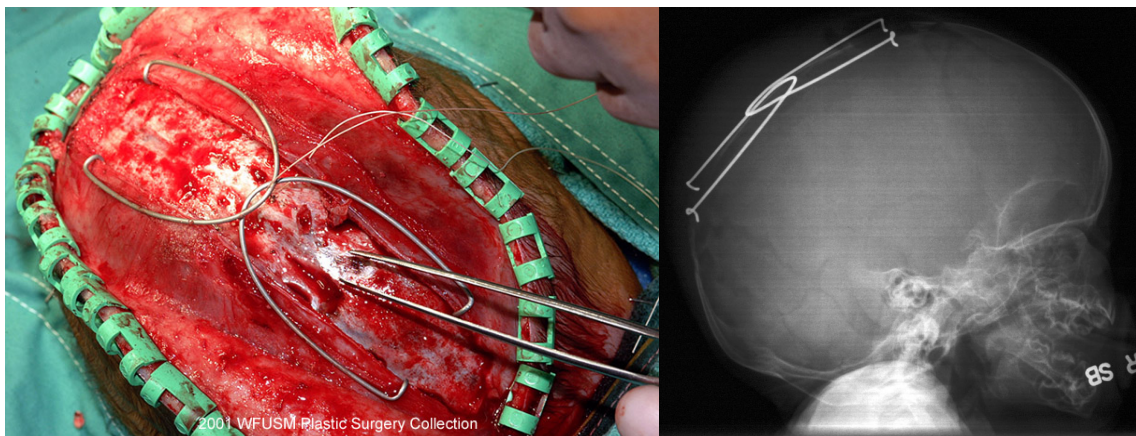


Figure 1.20: Spring mediated cranioplasty technique used to correct scaphocephaly (Photographs courtesy of Wake Forest University).

The removal of the suture allows for upward and outward expansion of the parietal bones due to normal membranous bone growth, reducing the elongation of the cranium. The springs apply an expansive force, which cause the narrowed skull to widen (Figure 1.21).

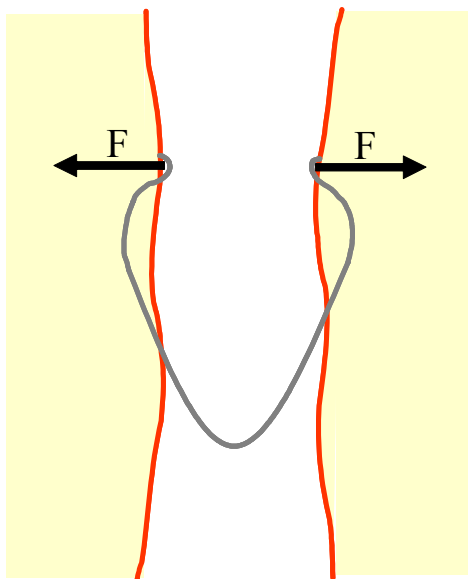


Figure 1.21: Free body diagram of springs acting on the parietal bones as shown in Figure 1.20.

This procedure can usually be performed in less than one hour, results in significantly lower loss of blood as compared to other procedures, and has shown promising results for

the patients. However, the current technique uses type 302 stainless steel wire for the fabrication of the springs by the physician, a material not authorized by the FDA for implant use. Furthermore, the springs are formed by hand, which limits the amount of control over the springs' mechanical properties that the surgeon has during their formation.

RESEARCH OBJECTIVES

There were three primary objectives to this research. The first objective was to develop a device that could fabricate type 316 stainless steel wireform springs having consistent mechanical characteristics. These springs need to mimic the mechanical characteristics of the type 302 stainless steel springs, while allowing a wider range of characteristics to be controlled consistently. The second objective was to evaluate the performance of the device by determining the mechanical properties of a sample of springs fabricated using the device. The final objective was to develop a mathematical model to facilitate accurate use of the device. This mathematical model was also used to develop a procedure for fabricating the springs.

By controlling and tracking the characteristics of these springs, it could be possible to determine the optimum spring design for a particular surgical application, not only with respect to the surgical procedure but also the patient's specific needs. Also, by tracking the performance of the springs being used, a determination of the mechanics during the reforming of the skull could be modeled. This model could help to further refine the

spring mediated dynamic cranioplasty procedure, and lead to the development of different, more effective procedures.

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CHAPTER 2: A Wireform Spring Bending Device for Use in the Dynamic Spring Mediated Craniofacial Reshaping Treatment of Craniosynostosis

ABSTRACT

Craniosynostosis is a disorder characterized by the premature fusion of one or more cranial sutures in the infant skull, resulting in an abnormal shape of the cranium. An effective surgical procedure using stainless steel springs for treatment of this disorder has been developed called “Dynamic Spring Mediated Craniofacial Reshaping.” A device was designed and fabricated that could consistently control the mechanical characteristics of the springs by means of controlling several key geometric parameters. Fifty-six wireform springs were fabricated using the device utilizing several variations of the geometric parameters. Spring stiffness testing was performed to determine the mechanical characteristics of the fabricated springs. The results of these tests were used to develop a mathematical model which predicts the mechanical characteristics of these springs based on combinations of the geometric parameters. Use of this mathematical model may facilitate further research and may determine the most effective use of the “Dynamic Spring Mediated Craniofacial Reshaping” surgical procedure.

INTRODUCTION

Craniosynostosis is a disorder that occurs in 1 out of every 1,800 infants born each year (Aviv 2002). The disorder is characterized by premature fusion of one or more sutures in the skull. This fusion results in an abnormal skull shape and may cause a constriction of the brain. This constriction, while not usually lethal, may lead to developmental problems for the child (David 1999, Panchal 2001).

There are several procedures used by physicians for the treatment of this disorder. The most common procedure involves surgical reshaping of the calvaria (Friede 1996, Williams 1999). This long procedure requires the removal of the calvaria and a physical remodeling of its shape. The reformed portion of the calvaria is commonly fixed using resorbable plates (Losken 2001, Surpure 2001). This procedure can last for over five hours and usually results in a significant loss of blood (Lauritzen 1995). This loss of blood is commonly treated with blood transfusions from a family member.

An alternative surgical procedure has been developed and is currently used in Sweden by Dr. Claes Lauritzen (1998). This technique involves surgical removal of the fused suture and insertion of hand formed springs to expand the gap created by the suture removal. This procedure can usually be performed in less than one hour, results in significantly reduced loss of blood as compared to the calvaria reshaping technique, and has shown promising results. However, the springs currently are formed by hand and are made of type 302 stainless steel; a material not approved by the Food and Drug Administration (FDA) for surgical wire implants.

The FDA has approved type 316 stainless steel for surgical implants in the form of wire. The problem with using type 316 stainless steel for the springs is that it has a significantly lower yield strength than that of type 302 stainless steel (Oberg 2000). Attempts have been made by Dr. Lisa David of the Department of Plastic and Reconstructive Surgery at Wake Forest University to construct type 316 stainless steel springs of similar geometry and characteristics to be used in the United States without success. The springs formed by hand have inconsistencies with respect to the dominant geometric parameters that determine the mechanical characteristics of the springs. Because the yield strength of 316 is significantly lower than that of 302, the geometry must be formed in a more controlled and repeatable manner that will allow the optimum performance of the fabricated springs.

There were three primary objectives to this research. The first objective was to develop a device that could fabricate type 316 stainless steel wireform springs having consistent mechanical characteristics, while still achieving the performance observed from the use of type 302 stainless steel springs. The second objective was to evaluate the performance of the device by determining the mechanical characteristics of a sample of springs fabricated using the device, including: stiffness, maximum deflection range, peak force, and maximum stored energy. The final objective was to develop a mathematical model to predict these mechanical characteristics in order to develop a procedure for the surgeon or surgical technician to use when forming the springs.

METHODOLOGY

DESIGN OF THE WIREFORM SPRING BENDING DEVICE

The first goal of this research was to develop a device that could fabricate type 316 stainless steel springs having consistent mechanical characteristics. It was determined that two primary geometric parameters would need to be controlled in order to accomplish this consistency: arm length (L) and bend diameter (B) (Figure 2.1).

Determination of the bend diameter from the original spring designs was not possible due to the extreme variability of the bends, as well as the non-symmetric shape that was apparent in the majority of the samples (Figure 2.2). A rough estimate based on the desired mechanical characteristics of the springs yielded a bend radius in the range between 10 to 30mm. It was decided to design the device capable of producing three different bend diameters: 12.7mm (0.5”), 19.05mm (0.75”), and 25.4mm (1.00”). The remaining design parameter, arm length, would be controlled after the initial bending using templates specifically designed to minimize errors during fabrication.

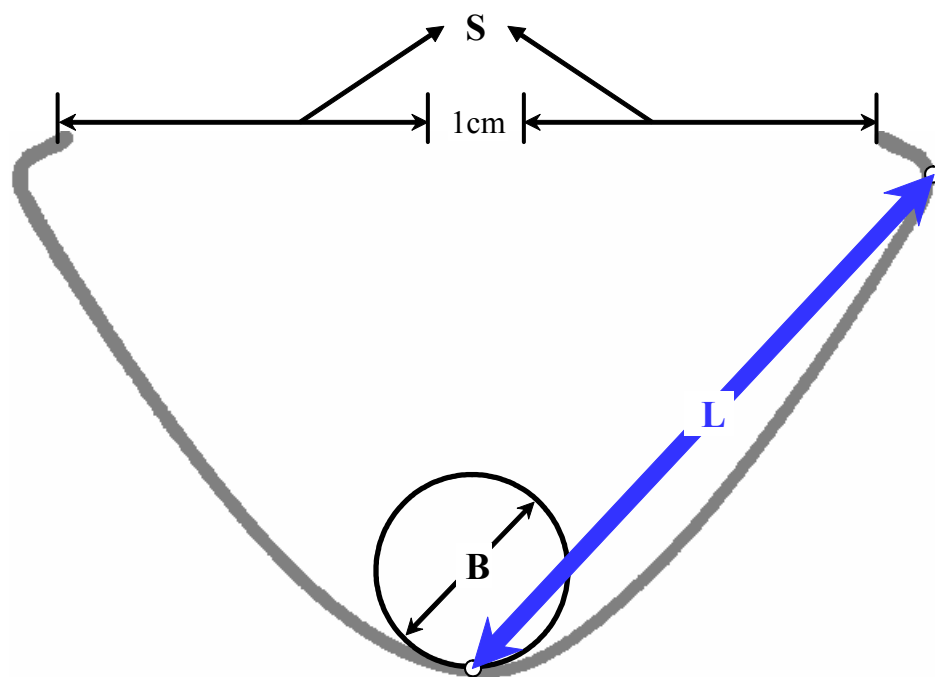


Figure 2.1: Wireform spring with indicated design parameters (arm length (L) and bend diameter (B)) and one of the resultant parameters (maximum deflection range (S)).



Figure 2.2: Examples of the bends of various wireform springs produced by hand forming the bend.

PERFORMANCE EVALUATION OF THE DEVICE

The second objective was to evaluate the performance of the device by determining the mechanical properties of a sample of springs fabricated using the device. For the first series of tests, twenty seven wireform springs were fabricated using various combinations of the design parameters. A test matrix was developed to incorporate three different wire diameters (1.016mm, 1.295mm and 1.626mm), three different bend diameters (12.7mm, 19.05mm and 25.4mm), and three different arm lengths (20mm, 40mm and 60mm). The fabricated springs were tested using an Instron Material Testing Machine (Model 4204, Instron, Canton, MA) in order to determine their force-displacement characteristics. This characteristic, also referred to as the stiffness of the spring, is a critical value which defines the overall mechanical characteristics of the spring.

In addition, five springs were fabricated using the device to have a constant bend diameter and arm length and were compared to five springs fabricated using the original method of forming by hand. The mechanical characteristics and resultant geometries were compared with respect to the comparative precision between the two forming processes.

The data from the first series of tests were analyzed to determine which parameters should be further refined. The second series of tests involved an additional 24 springs with geometric parameters determined from the first series of tests in order to match the

mechanical properties of the original type 302 stainless steel springs (Table 2.1). All of these tests utilized wires of 1.295mm in diameter for reasons discussed in the results.

Table 2.1: Test matrix for second series of spring tests.

Test No.	Bend Diameter - B			Arm Length – L							
	(mm)										
	12.7	19.05	25.4	L ₁	L ₂	L ₃	L ₄	L ₅	L ₆	L ₇	L ₈
S301	X			X							
S302	X				X						
S303	X					X					
S304	X						X				
S305	X							X			
S306	X								X		
S307	X									X	
S308	X										X
S309		X		X							
S310		X			X						
S311		X				X					
S312		X					X				
S313		X						X			
S314		X							X		
S315		X								X	
S316		X									X
S317			X	X							
S318			X		X						
S319			X			X					
S320			X				X				
S321			X					X			
S322			X						X		
S323			X							X	
S324			X								X

DEVELOPMENT OF THE MATHEMATICAL MODEL

The final objective was to develop a mathematical model to facilitate the prediction of the mechanical characteristics of the springs based on the design parameters. This prediction has reciprocal value in that the design parameters may be determined based on the desired characteristics.

The data from both series of tests were analyzed in order to develop a mathematical model that would allow for the springs to be fabricated with a specific set of mechanical properties: maximum deflection range (S) and peak spring force (F). The mathematical model would allow for the development of a procedure to control the fabrication of the springs with respect to the dominant geometric parameters (arm length (L) and bend diameter (B)), as well as provide a method of recording the spring characteristics to aide in further refinement of the design and use of the springs.

RESULTS

Based on the determined design parameters, the wireform spring bending device was designed and fabricated (Figure 2.3). The overall dimensions of the device are 12.7cm in length (when fully open), 5.08cm in width (when fully closed), and 3.175cm in height. There are three major portions of the device: spindle, left arm and right arm.

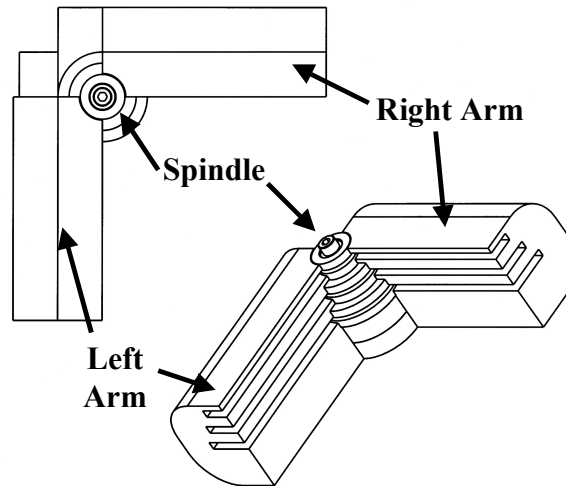


Figure 2.3: Multiple-diameter spring bending device.

The spindle is a three-stepped cylinder, one step for each of the three bend diameters. The spindle acts as the pivot of the bending device and imparts the desired curvature to the wire being formed. The left and right arms are joined at the spindle allowing 180 degrees of motion. Each arm contains three slots, which line up with grooves on the spindle to secure the wire during reshaping.

The device is fabricated out of type 316 stainless steel, and can be disassembled to facilitate sterilization before and after surgical use. In addition, all edges are specified to be rounded so that no sharp edges exist that could possibly cut through surgical gloves during their use in the operating room.

Analysis of the first series of tests provided a means to reduce the number of design parameters. The wire diameter parameter was eliminated as a variable and was set to a constant value of 1.295mm. The reason was that the target stiffness (0.1161N/mm) as

defined from data analyzed from the original type 302 stainless steel springs was outside of the range of the values seen for the 1.016mm and the 1.626mm diameter wires (Figure 2.4). Further testing focused on the two remaining parameters: arm length (L) and bend diameter (B).

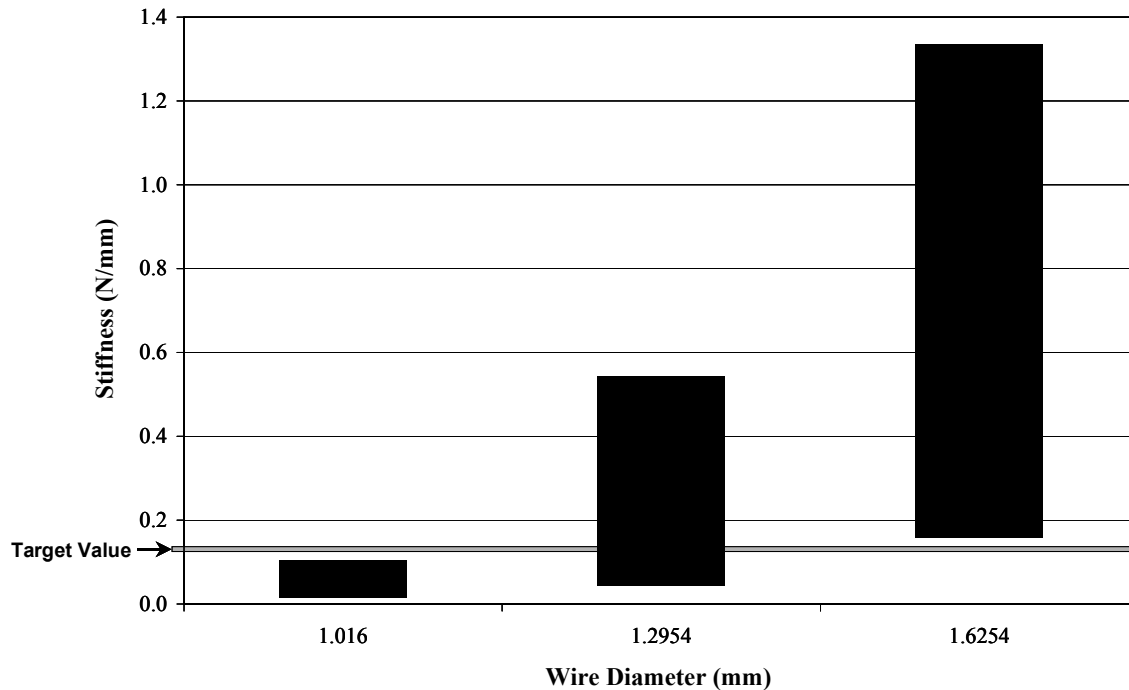


Figure 2.4: Range of stiffness values from the first series of testing grouped by wire diameter. The average stiffness of the type 302 stainless steel springs was 0.1161N/mm. This value was set as the target value.

The precision comparison between the two wire forming methodologies indicated that the precision of the springs formed using the device along with the use of the developed fabrication procedure (Appendix A) were significantly higher than those observed for the hand formed springs. The standard deviation of the stiffness k for the device formed springs was 2.42%, which was 2.32 times more precise than the hand formed springs (5.61%). The standard deviation of the maximum deflection range S for the device formed springs was 1.03%, which was 6.15 times more precise than the hand formed

springs (6.34%). These two parameter comparisons also indicated that the maximum force was 2.38 times more precise and the maximum stored energy was 4.90 times more precise for the device formed springs.

The data from the second series of tests were collected and analyzed in order to develop the mathematical model (Table 2.2). The design parameter L , and the resultant parameter S were directly measured during the experiment. The stiffness of the spring (k), was determined by performing linear regression on the force-displacement data ($R^2 = 0.9928 \pm 0.0038$). The peak force ($F_{\max}$) was determined from Equation 2.1, and the maximum stored energy was determined from Equation 2.2.

Table 2.2: Results from the second series of tests.

Test No.	L	k	S	F _{max}	E _{max}
	(mm)	(N/mm)	(mm)	(N)	(Nmm)
S301	37.5	0.6261	16.5	10.33	85.23
S302	42.5	0.4257	22	9.37	103.02
S303	47.75	0.312	23.5	7.33	86.15
S304	53.5	0.2308	30.5	7.04	107.35
S305	57.25	0.1779	29	5.16	74.81
S306	63	0.135	34	4.59	78.03
S307	67.25	0.1113	36.5	4.06	74.14
S308	73.25	0.0857	39	3.34	65.17
S309	43	0.4122	27.5	11.34	155.86
S310	49.5	0.2743	35	9.60	168.01
S311	53.25	0.2206	38.5	8.49	163.49
S312	58.5	0.1621	42.5	6.89	146.40
S313	62.75	0.1355	48	6.50	156.10
S314	67.75	0.1047	53	5.55	147.05
S315	73	0.0833	58	4.83	140.11
S316	79.25	0.0684	61	4.17	127.26
S317	47.25	0.336	32.5	10.92	177.45
S318	52.75	0.2329	43	10.01	215.32
S319	57.75	0.1745	51.5	8.99	231.41
S320	62.75	0.1394	56.5	7.88	222.50
S321	67.5	0.1113	62	6.90	213.92
S322	71.75	0.0926	68	6.30	214.09
S323	76.75	0.0745	71	5.29	187.78
S324	81.5	0.062	75	4.65	174.38

$$F_{max} = k \cdot S \quad (\text{Equation 2.1})$$

$$E_{max} = \frac{F_{max} \cdot S}{2} = \frac{k \cdot S^2}{2} \quad (\text{Equation 2.2})$$

As indicated by Equations 2.1 and 2.2, all of the desired spring mechanical characteristics may be derived from two primary resultant parameters: k and S . Therefore, only two regression models needed to be developed in order to provide an accurate prediction of the mechanical characteristics: k as a function of L and B , and S as a function of L and B .

The development of the mathematical model for k incorporated several theories and methods from mechanical engineering that are beyond the scope of this chapter and are outlined in detail in Chapter 3. Several models were attempted until the model that best fit the data was found (Equation 2.3). This model was found to predict the spring stiffness with a reasonable amount of precision ($0.0073 \pm 0.0115 \text{ N/mm}$ error). Figure 2.5 presents a comparison between the stiffness values obtained from the experiments to those obtained from the model ($R^2 = 0.999$).

$$k = \frac{32600}{L^3} \quad (\text{Equation 2.3})$$

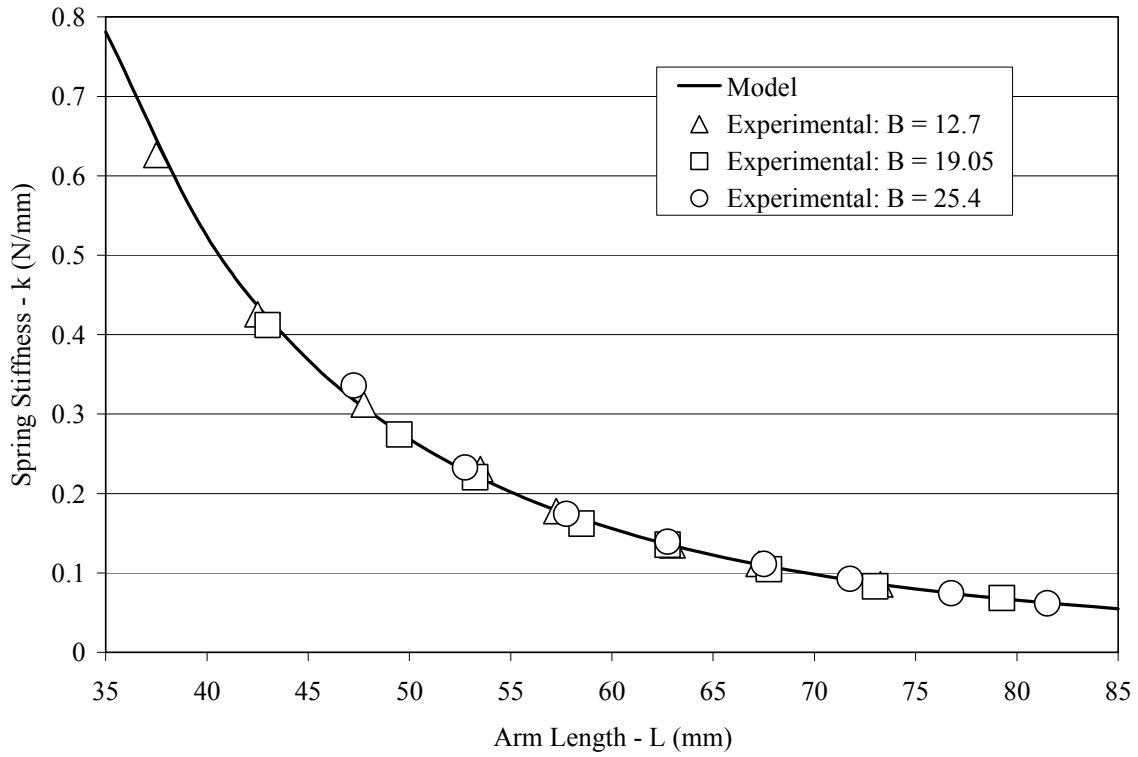


Figure 2.5: Comparison between the experimental results and the mathematical model of the spring stiffness resultant parameter (k).

The development of the mathematical model for S involved the evaluation of several different models until the model that best fit the data was found (Equation 2.4). The chosen model predicted the maximum deflection range with a reasonable amount of precision (1.244 ± 0.843 mm error). Figure 2.6 presents a comparison between the maximum deflection range values obtained from the experiments to those obtained from the model ($R^2 = 0.991$).

$$S = 0.3867 L^{0.8847} B^{\frac{1}{2}} - 19.35 \quad (\text{Equation 2.4})$$

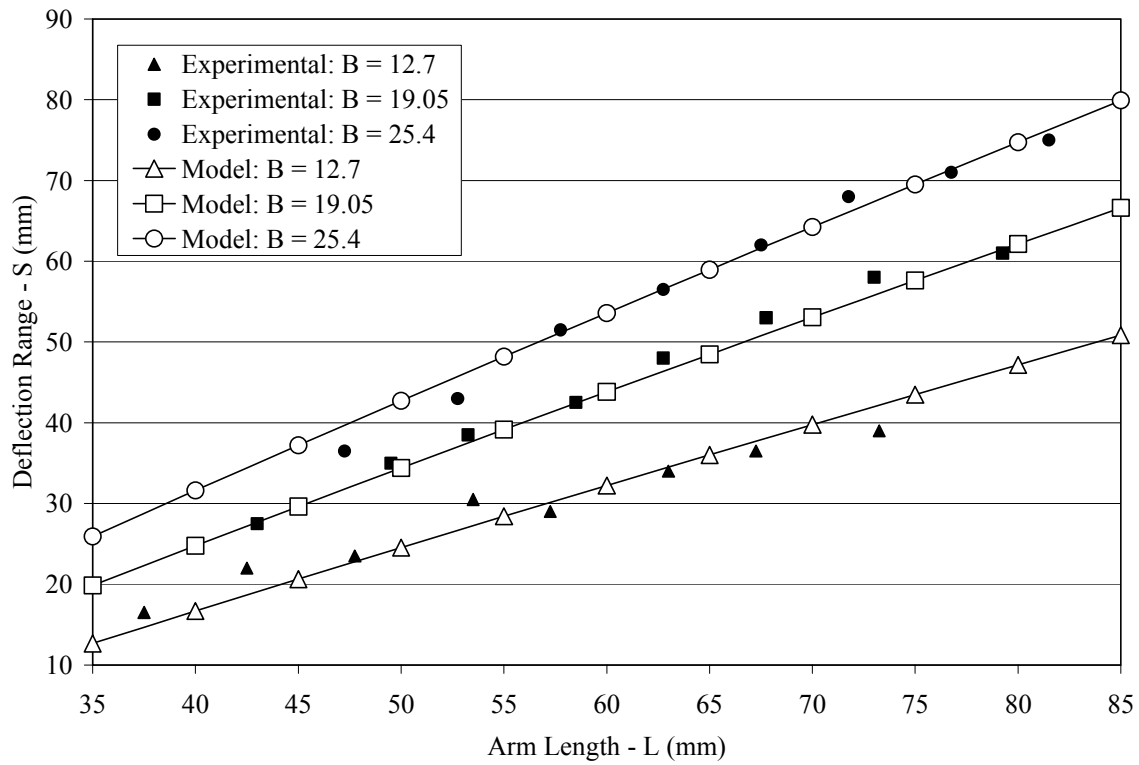


Figure 2.6: Comparison between the experimental results and the mathematical model of the maximum deflection range resultant parameter (S).

The maximum forces that each spring can generate may be determined using Equation 2.1 (Figure 2.7). Based on the thickness of the cranial bones to which the springs will be attached, the value of this maximum force becomes important in order to minimize any migration through the bone at the point of contact.

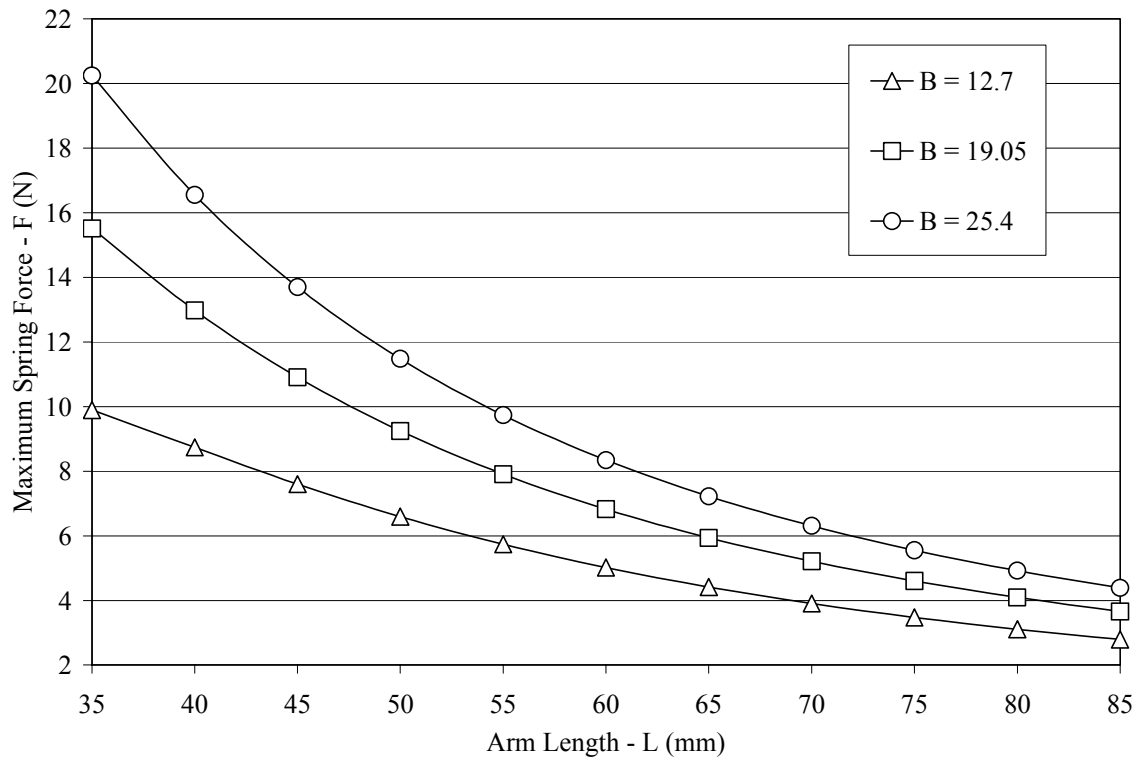


Figure 2.7: Maximum spring force determined from the regression models and Equation 1.

DISCUSSION

To determine the overall effectiveness of the implanted springs, it becomes necessary to observe the maximum amount of energy that may be stored using Equation 2.2 (Figure 2.8). These values provide information beyond force and deflection range. They provide a means to determine how efficiently the springs are being used, as well as how much total effect the springs can have on reshaping the calvaria.

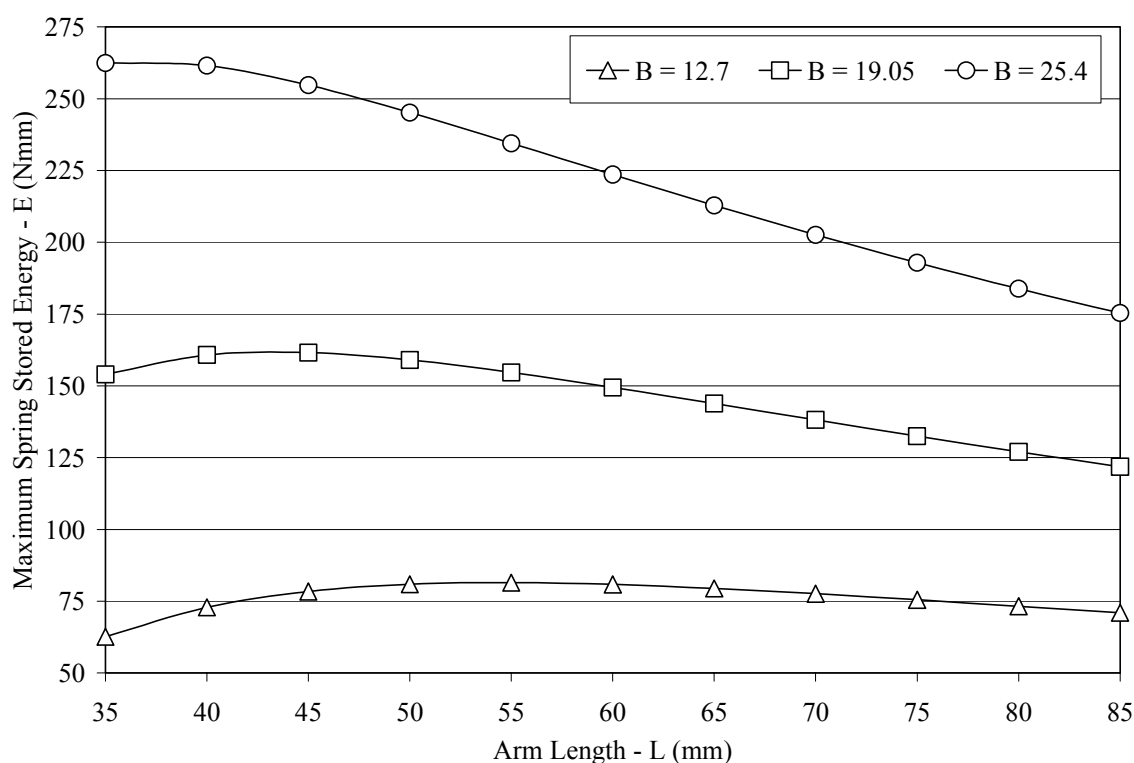


Figure 2.8: Maximum amount of energy that may be stored in the spring determined from the regression models and Equation 2.

CONCLUSION

Allowing the surgeon to fabricate springs based of the desired amount of cranial distraction is essential to the optimal use of the “Dynamic Spring Mediated Craniofacial Reshaping” surgical procedure. The use of the wireform spring bending device developed in this research, combined with the use of the procedure developed from the mathematical model (Appendix A), will produce springs with consistent mechanical characteristics that can be determined for the patient’s specific needs. By utilizing design parameters that can be measured using a ruler, the surgeon can determine these mechanical characteristics using the mathematical model. Because the initial and final

deflections of the springs may be determined, either by direct measurement during the surgical procedure or from measurement modalities available through medical imaging, the total energy used to reshape the skull may be determined. This information could be collected and evaluated to determine, for certain levels of cranial distortion, how much energy will provide the most effective means of cranial reshaping. Further exploration of this data could also be investigated using a computational model of the patient's skull so that the results of the procedure may be predicted based on decisions made by the surgeon with respect to spring design and tissue removal.

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CHAPTER 3: Mathematical Modeling

INTRODUCTION

The goal of this research was to develop a device and a procedure to fabricate type 316 stainless steel springs having consistent mechanical characteristics for use in the spring mediated cranioplasty surgical procedure. The final version of the device and the procedure require the use of mathematical models which allow for the prediction of the stiffness and maximum deflection range of the spring based on a determined set of design parameters.

The following chapter outlines the theory and methodology utilized for the development of the mathematical models. In addition, a brief discussion on the errors associated with the use of the mathematical models is included to provide the user with some important considerations that should be made when selecting values for the design parameters.

EXPERIMENTAL METHODS

It was originally determined that three primary geometric parameters would need to be controlled in order to generate reliable results: bend diameter, arm length, and wire diameter (Figure 2.1).

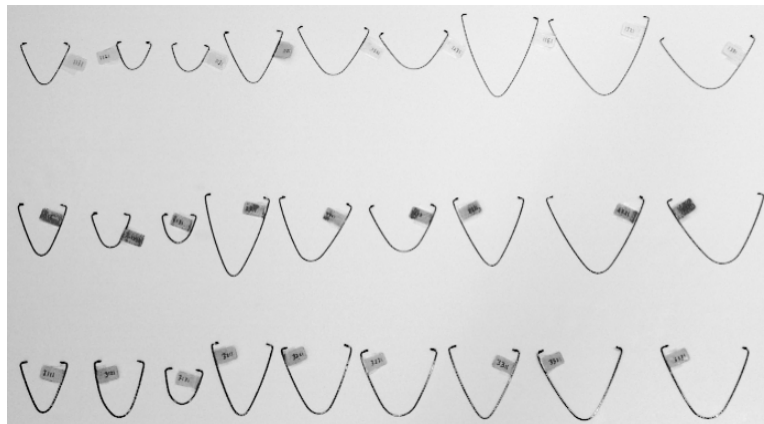
Determination of the bend diameter from the original spring designs was not possible due to the extreme variability of the bends, as well as the non-symmetric shape that was apparent in the majority of the samples. A rough estimate based on desired mechanical characteristics of the springs yielded a bend radius in the range between 10 to 30mm. It was decided to design the device capable of producing three different bend diameters (Figure 2.3): 12.7mm (0.5”), 19.05mm (0.75”), and 25.4mm (1.00”). The first series of tests utilized all three bend diameters.

The arm length was controlled after the initial bending using templates specifically designed for each bend diameter. For the first series of tests, arm lengths of 20mm, 40mm, and 60mm were used to generate the initial set of data for the first level of analysis. Three different wire diameters were selected based on the original design wire diameter, and the commonly available sizes of wire available: 1.016mm, 1.295mm, and 1.626mm.

The first series of tests was designed to analyze every combination of the selected values for the design parameters (Table 3.1). Twenty-seven springs were fabricated using the device and the initial procedure (Figure 3.1). The fabricated springs were tested using an Instron Material Testing Machine (Model 4204, Instron, Canton, MA) in order to determine their force-displacement characteristics or the stiffness of the springs (Figure 3.2)(Gere 1997).

Table 3.1: Test matrix for the first series of spring tests.

Test No.	Wire Diameter (mm)			Bend Diameter (mm)			Arm Length (mm)		
	1.016	1.2954	1.6254	12.7	19.05	25.4	20	40	60
S1001	X			X			X		
S1002	X			X				X	
S1003	X			X					X
S1004	X				X		X		
S1005	X				X			X	
S1006	X				X				X
S1007	X					X	X		
S1008	X					X		X	
S1009	X					X			X
S1010		X		X			X		
S1011		X		X				X	
S1012		X		X					X
S1013		X			X		X		
S1014		X			X			X	
S1015		X			X				X
S1016		X				X	X		
S1017		X				X		X	
S1018		X				X			X
S1019			X	X			X		
S1020			X	X				X	
S1021			X	X					X
S1022			X		X		X		
S1023			X		X			X	
S1024			X		X				X
S1025			X			X	X		
S1026			X			X		X	
S1027			X			X			X

**Figure 3.1:** Springs fabricated for the first series of tests.

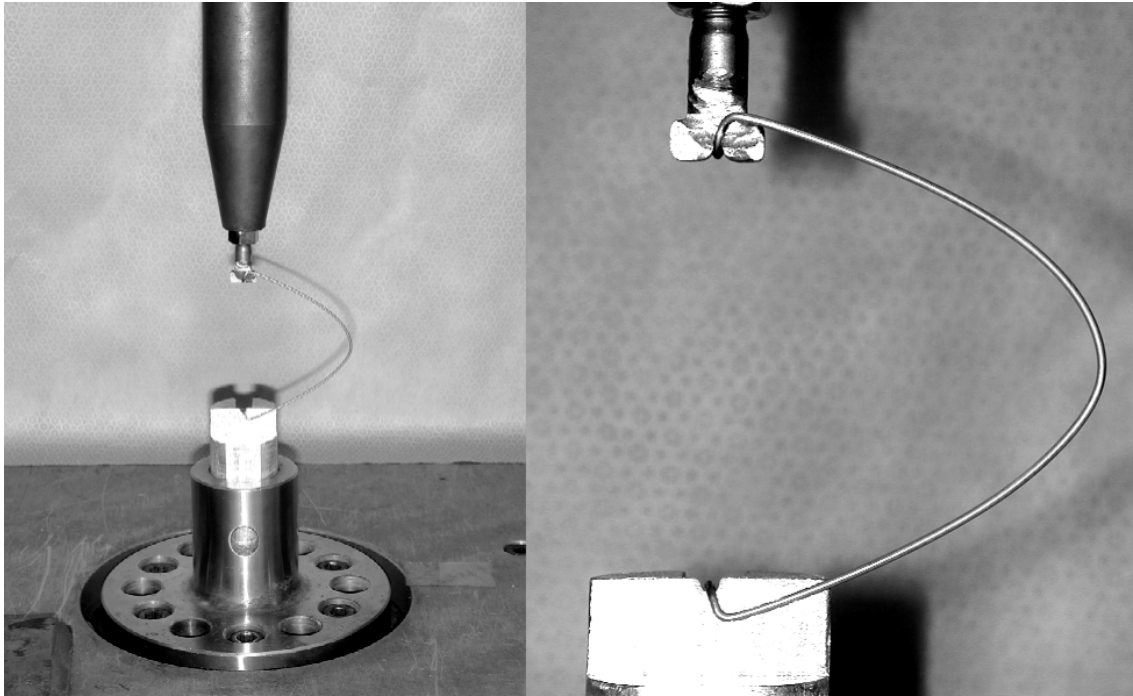


Figure 3.2: Testing of a wire-form spring using an Instron Material Testing Machine.

The data from the first series of tests were analyzed to determine which parameters should be further refined for the second series of tests. The wire diameter was eliminated as a variable and was set to a constant value of 1.295mm. The reason for this elimination was due to the target stiffness (as defined from data analyzed from the original type 302 stainless steel springs) was outside the range of the values seen for the 1.016mm and the 1.626mm wire (Figure 2.4). This elimination would also allow for a simpler mathematical model to be developed. Further testing focused on the two remaining parameters: arm length (L) and bend diameter (B).

Analysis of the effect of the bend diameter indicated an insignificant shift in the stiffness values for the same arm length. The range of values obtained from different bend

diameters (all with a constant wire diameter) indicated that the target stiffness value could be achieved by all three bend diameters. Thus, it was decided to keep the bend diameter parameter as an additional component to the model. An additional series of tests was performed to provide the data needed for the model development (Table 2.1 and Table 2.2).

DEVELOPMENT OF THE STIFFNESS MODEL

In order to determine what mathematical model would provide the best fit to the data, certain aspects of mechanical design needed to be considered. First, to simplify the model it was assumed that the spring could be separated into three distinct regions: two simple beams and one curved beam (Figure 3.3). The two different types of beams were analyzed independently, with respect to the selected design parameters, and then combined.

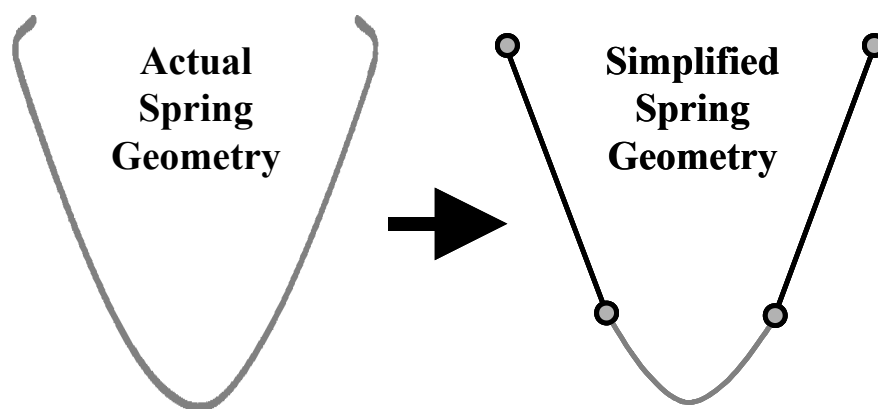


Figure 3.3: Simplification of spring geometry for qualitative analysis.

For a qualitative analysis it was assumed that the two arms of the spring act as cantilever beams (Figure 3.4). This assumption is based on the fact that the stiffness of the curved section of the spring is significantly higher than that of the straighter section of the spring. This places limits on this analysis which will be discussed later. Based on this assumption, Equation 3.1 may be applied to each of the arms (Young 2002). Because the stiffness of each arm is what will contribute to the stiffness of the spring, Equation 3.1 is modified to the form of Equation 3.2 (Shigley 2001).

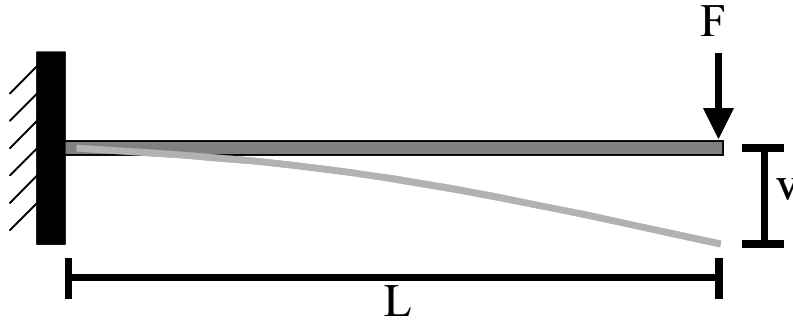


Figure 3.4: Simple cantilever beam model.

$$v = \frac{FL^3}{3EI} \quad (\text{Equation 3.1})$$

$$k = \frac{F}{v} = \frac{3EI}{L^3} \quad (\text{Equation 3.2})$$

The variable L in Equation 3.2 represents the arm length parameter of the spring (L) for the remainder of the qualitative analysis. For the springs analyzed for the final model, the modulus of elasticity ($E = 193\text{GPa}$, Oberg 2000) and the area moment of inertia ($I = 0.276\text{mm}^4$, Gere 1997) remain constant (same material used and same wire diameter).

Because Equation 3.2 would apply to the stiffness of only one of the arms, it must be divided by two in order to distribute half of the displacement to each arm. By substituting these values into Equation 3.2, Equation 3.3 is produced.

$$k_{spring} = \frac{1}{2} \left(\frac{3EI}{L^3} \right) = \frac{80,020 Nmm^2}{L^3} \quad (\text{Equation 3.3})$$

The primary investigator attempted to apply this equation to the model without success. It was determined that an empirical model would be needed to accurately describe the stiffness of the springs. A mathematical model was selected to mimic the simple cantilever beam model with respect to two special cases. The first special case considered was when L approaches zero (Equation 3.4). Although this case will be adhered to for the model, it should be noted that as the arm length gets shorter and the stiffness of the arms increases, the stiffness of the curved portion of the spring will provide a less rigid boundary condition with respect to the arms. This would no longer allow the assumption that the arms could be analyzed as simple cantilever beams. Also, because these springs are to be designed to operate over a designated deflection range, this high stiffness in the arms and the bend will cause the wire to yield, thus permanently changing the geometry.

$$\lim_{L \rightarrow 0} \frac{3EI}{2L^3} = \frac{3EI}{2(0)^3} = \infty \quad (\text{Equation 3.4})$$

The second special case considered was when L approaches infinity (Equation 3.5). This special case must be adhered to because as the arm length increases, the deflection of the curved section decreases significantly until the arms become essentially “true” cantilever beams.

$$\lim_{L \rightarrow \infty} \frac{3EI}{2L^3} = \frac{3EI}{2(\infty)^3} = 0 \quad (\text{Equation 3.5})$$

Based on the qualitative analysis, the following conditions must be met by the mathematical model with respect to the arm length parameter. The stiffness must be inversely proportional to some non-inverted function of L . This condition provides the only means to ensure that the stiffness will converge to zero as the arm length increases and will increase without bound as the arm length approaches zero. Second, minimum limits of the arm length must be determined in order to prevent yielding of the spring over the design range (the minimum arm length validated through experimental testing was 30mm).

A similar type of qualitative analysis is difficult to apply to the curved beam region. The experimental results indicate that the effective arc length of the curved beam varies significantly based on the bend diameter. To determine what affect the bend diameter (B) has on the stiffness, the results from the first series of tests were used as a guide.

The first aspect of the data that was noted was that as bend did not seem to effect the spring stiffness significantly. Various regression models indicated that if the bend diameter was included in the spring stiffness model, the accuracy of the model actually decreased. This analysis of data seems to indicate that the arm length is the only significant design parameter with respect to spring stiffness. However, the contribution of the bend diameter parameter was found to be significant to the development of the maximum deflection range model, which is outlined later in this chapter.

With the above conditions set, several models were attempted until the model that best fit the data was found:

$$k = a_0 L^{-a_1} \quad (\text{Equation 3.6})$$

where; a_0 and a_1 are real number constants obtained from linear regression. This model was selected because it met the conditions determined from the qualitative analysis of the geometry (Equations 3.7 – 3.9) and also provided a simple means to solve the equation in terms of the design parameter L .

$$k_{\infty} = \lim_{L \rightarrow \infty} a_0 L^{-a_1} \quad (\text{Equation 3.7})$$

$$k_{\infty} = a_0 (\infty)^{-a_1} \quad (\text{Equation 3.8})$$

$$k_{\infty} = a_0 (0) = 0 \quad (\text{for } a_1 > 0) \quad (\text{Equation 3.9})$$

In order to perform linear regression of this function using Matlab (Appendix C), Equation 3.5 needed to be converted into a linear function. This was accomplished by

taking the natural log of both sides of the equation (Equations 3.10 – 3.11). The regression analysis yielded a model with an R^2 value equal to 0.999 (Equation 2.3). The resulting values were found to be consistent with the original model in that a_1 was equal to 3 (same as the cantilever beam) and a_0 was on the same order of magnitude as the equivalent term in the cantilever beam equation. Other forms of beam theory were investigated to attempt to account for the difference that did exist, however, none of them accounted for the actual a_0 term being lower than expected (Gere 1997, Young 2002, Pilkey 1997, Fogiel 1999, Gieck 1997).

$$\ln(k) = \ln(a_0 L^{-a_1}) \quad (\text{Equation 3.10})$$

$$\ln(k) = \ln(a_0) - a_1 \cdot \ln(L) \quad (\text{Equation 3.11})$$

DEVELOPMENT OF THE MAXIMUM DEFLECTION RANGE MODEL

The deflection range (S) of the spring is defined, for this particular spring design, as the arm span with the length of the two hooks (approximately 5mm each) and the minimum gap of 1cm subtracted from it (Figure 2.1). The development of the maximum deflection range model required geometric analysis involving certain aspects of trigonometry. First, the basic shape of the springs is that of a parabola (Equation 3.12). Based on experimental observations it appears that the scalar multiplier a , of the parabolic equation, would be some function of the bend diameter parameter B . Also the x -coordinate for any given point on the parabola is directly related to half of the maximum deflection range.

$$y = ax^2 \quad (\text{Equation 3.12})$$

In order to incorporate the arm length parameter into the model, the distance formula or the Pythagorean Theorem must be used. Assuming that the apex of the spring is at the coordinate (0,0), the distance formula may be applied and manipulated as shown.

$$L^2 = x^2 + y^2 \quad (\text{Equation 3.13})$$

$$L^2 = x^2 + (ax^2)^2 = a^2x^4 + x^2 \quad (\text{Equation 3.14})$$

$$L^2 = x^2(a^2x^2 + 1) \quad (\text{Equation 3.15})$$

In order to simplify this model it is assumed that the a^2x^2 term in Equation 3.15 is significantly larger than 1 to develop the final theoretical model form, Equation 3.17. However, attempting to fit this form to the data yielded poor results. It did appear that the scaling due to B matched well, but the functions of L yielded curves which were not consistent with what was expected. There could be several factors that could contribute to this discrepancy. First, as outlined in Appendix A, the final step in forming the springs requires that the hooks be pinched together in order to complete any further yielding of the bend that might occur prior to the maximum deflection range measurement. This pinching decreased the maximum deflection range by over 1cm in some cases. This yielding would not be predicted by this model. Also, the simplifications made in the form of the model contribute to the inaccuracy of the predictive value of the model but

were required in order simplify the final form to allow for solving the equation for the different parameters.

$$x = \sqrt{\frac{L}{a}} \quad (\text{Equation 3.16})$$

$$S = a_1 f(B) L^{\frac{1}{2}} + a_0 \quad (\text{Equation 3.17})$$

After considering the fit of the model as well as the possible sources of error, it was decided to develop the model using an optimization technique to determine the power for the L term while maintaining the $f(B)$ term the same as predicted in the initial regression (Equation 3.18). For this model a_2 was optimized and converged to four significant figures ($R^2=0.993$). The power for L was determined to be 0.8847 (Equation 2.4, Appendix C).

$$S = a_1 B^{\frac{1}{2}} L^{a_2} + a_0 \quad (\text{Equation 3.18})$$

ERRORS ASSOCIATED WITH THE USE OF THE MATHEMATICAL MODELS

There are several sources of error which must be considered when using the mathematical models for predicting spring stiffness, force, and energy. Tracking of the data used to develop the spring as well as logging the final true geometry of the spring (with respect to the design parameters) will help to reduce these errors to a minimum, but will not eliminate them.

First, it must be remembered that this model was generated using linear regression. Since the R^2 value is less than one, the model does not fit the experimental data perfectly. One must also take into account the errors associated with manually measuring the design parameter components, and the errors associated with determining the stiffness values.

Another possible source of error would be due to the sensitivity of the spring stiffness to the design parameters during fabrication. The bend diameter parameter should not affect the error significantly, because the spindle that the wire is bent around is machined using a precision of 10^{-4} inches. The arm length parameter could significantly affect the errors based on Equation 3.11. By taking the partial derivative of the stiffness with respect to the arm length, a determination as to where the greatest sensitivity exists was made. In this case, the model was found to be more sensitive as the arm length gets shorter due to the exponent of the arm length being negative.

$$\left(\frac{\partial k}{\partial L}\right)\Delta L = \left(-3a_0L^{(-4)}\right)\Delta L \quad (\text{Equation 3.19})$$

Both of these models were developed in order to allow the surgeon to determine what set of parameters should be used to achieve the desired spring characteristics. Once the spring is actually formed, the true deflection range may be measured directly. In order to minimize the combined effect of using the models together to determine the forces and energies, the measured deflection range should be used.

CONCLUSION

The goal of this research was to develop a device and a procedure to fabricate type 316 stainless steel springs having consistent mechanical characteristics for use in the “Dynamic Spring Mediated Craniofacial Reshaping” surgical procedure. Mathematical models for the stiffness and the deflection range of the springs with respect to the design parameters, arm length and bend diameter, were developed. These models assisted in the development of a procedure (Appendix A) that allows for a surgeon to determine what parameters should be selected in order to fabricate a spring to meet a patient’s specific needs. These models, combined with the fabrication procedure, also allow for the tracking of the spring designs used and their associated mechanical characteristics, such as; stiffness, force and energy. Tracking of these characteristics along with specific information about the patient (type of craniosynostosis, skull thickness in the region of spring contact, skull shape change, etc.) could offer a significant amount of insight into

the most effective method to utilize this treatment procedure. This could lead to further refinement of the surgical procedure or may even extend into new procedures generated from these insights.

REFERENCES

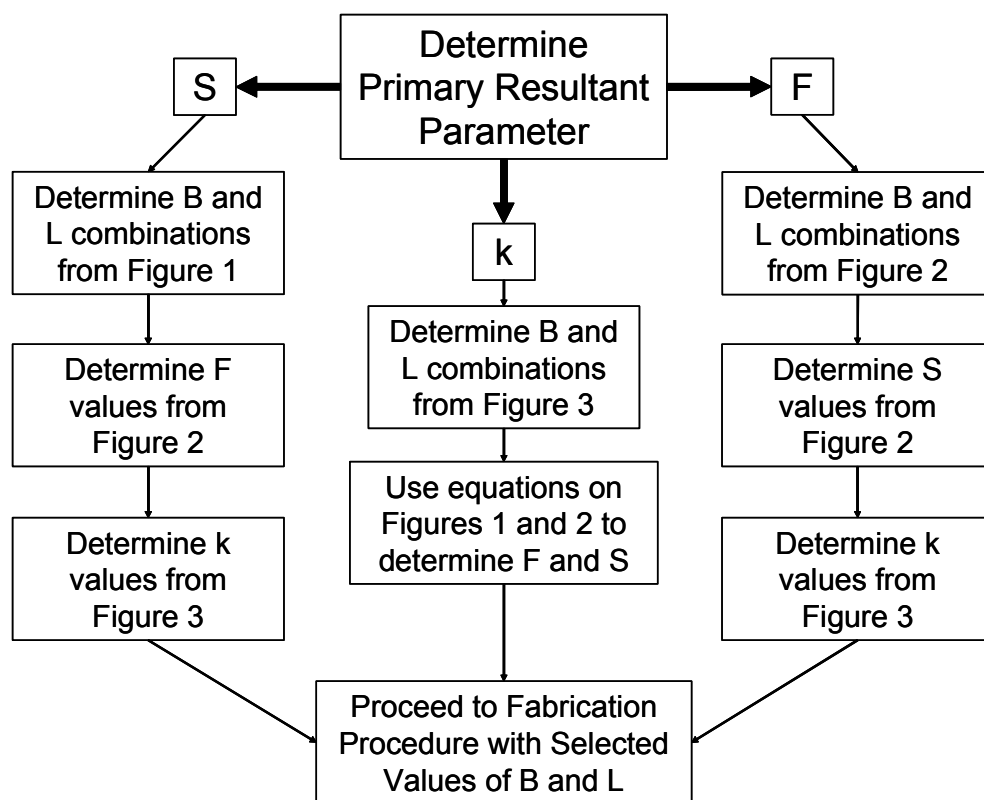
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Appendices

Appendix A: Spring Design and Fabrication Procedure

The following sections outline the procedure for designing and fabricating wireform springs for use in the Dynamic Spring Mediated Craniofacial Reshaping Treatment of Craniosynostosis.

Section 1: Design Procedure	65
Section 2: Fabrication Procedure	67
Section 3: Data Recording Procedure	71
Section 4: Figures, Templates, and Data Sheets	73



SECTION 1: DESIGN PROCEDURE***MAXIMUM DEFLECTION RANGE AS THE PRIMARY PARAMETER***

1. Determine the maximum deflection range (S) desired for the spring.
2. Using Figure A4.1, determine which combinations of bend diameter (B) and arm length (L) will yield the desired maximum deflection range (S).
3. Determine the maximum spring force (F) from Figure A4.2, for the combinations determined in step 2. Select the combination which yields the maximum force desired, or a value higher than desired. Modifications may be made to the length of the hooks to reduce the maximum force; however, this will also require a reduction in the deflection range.
4. Determine the spring stiffness from Figure A4.3. This stiffness value should be recorded to facilitate further analysis of the fabrication methodology used and for determining the force applied to the cranial bones as well as the total amount of energy transferred from the springs to the cranium while the springs are implanted.
5. Use the selected combination of B and L to fabricate the springs in accordance with **Section 2**.

MAXIMUM SPRING FORCE AS THE PRIMARY PARAMETER

1. Determine the maximum spring force (F) desired for the spring.
2. Using Figure A4.2, determine which combinations of bend diameter (B) and arm length (L) will yield the desired maximum spring force (F).
3. Determine the maximum deflection range (S) from Figure A4.1, for the combinations determined in step 2. Select the combination which yields the maximum deflection range desired, or a value higher than desired. Modifications may be made to the length of the hooks to reduce the maximum deflection range; however, this will also require a reduction in the maximum spring force.
4. Determine the spring stiffness from Figure A4.3. This stiffness value should be recorded to facilitate further analysis of the fabrication methodology used and for determining the force applied to the cranial bones as well as the total amount of energy transferred from the springs to the cranium while the springs are implanted.
5. Use the selected combination of B and L to fabricate the springs in accordance with **Section 2**.

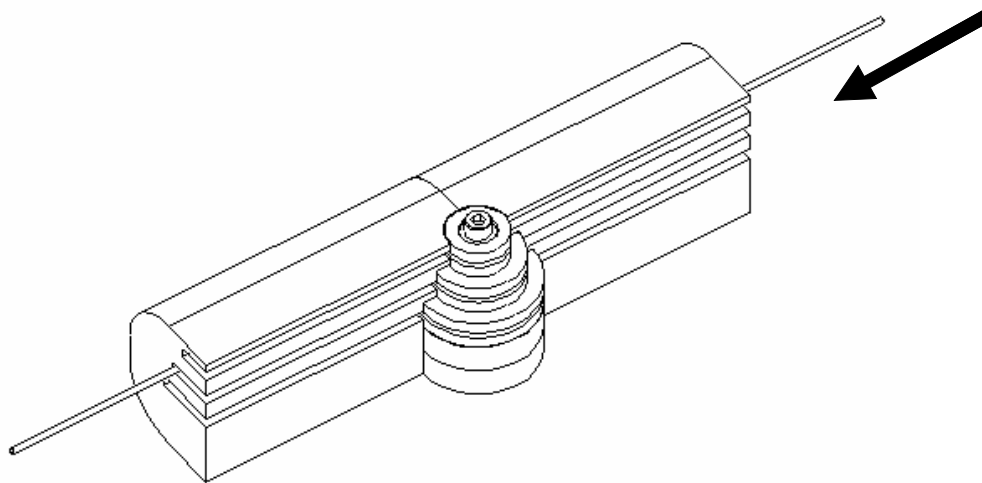
SECTION 2: FABRICATION PROCEDURE

1. Preparation:

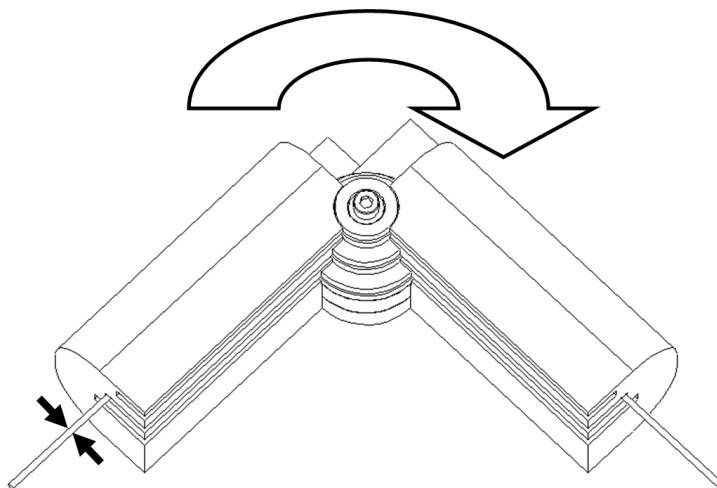
- a. Determine the bend diameter (B) and arm length (L) combination to be used for the fabrication of the spring.
- b. Obtain a copy of the *Spring Design Template and Data Sheet* and verify the dimensions of the grid by direct measurement.
- c. Obtain a piece of type 316 stainless steel wire, with a wire diameter of 1.2945mm (0.051"). Ensure that there is enough length to fabricate the spring (approximately 24cm).

2. Bending the wire:

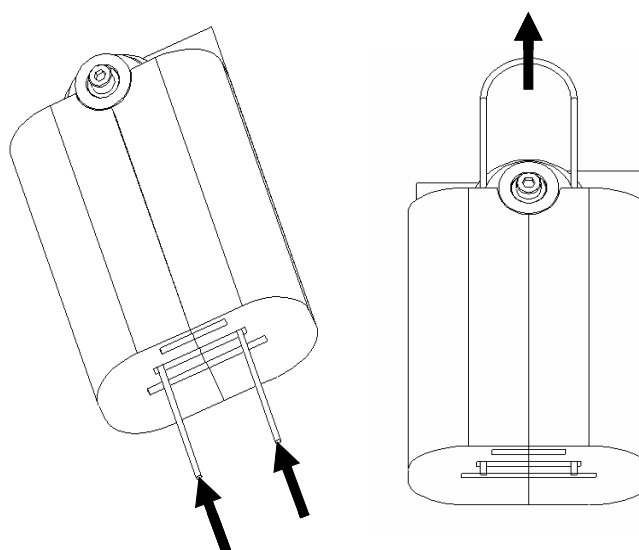
- a. Insert the wire into the bending device through the slot in the right arm which lines up with the appropriate bend diameter on the spindle. Line up the wire so that the left end is about 2cm shorter than the right end.



- b. While holding the left end of the wire, rotate the right arm 180 degrees until the bender is fully folded.

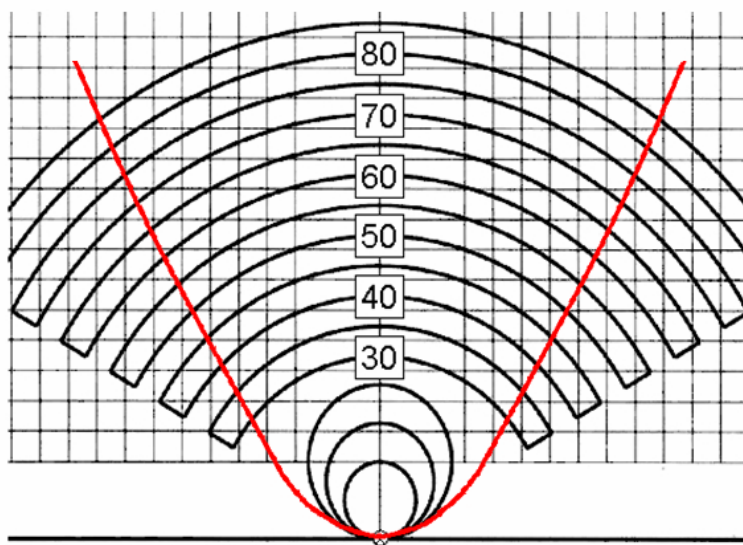


- c. Push the ends of the wire up until the wire loop gap is big enough to grab the wire and remove it completely. **Use caution when performing this step. Ensure that you have control of the wire at all times. If you do not have a good hold on the wire, it may eject from the device and possibly cause injury.**

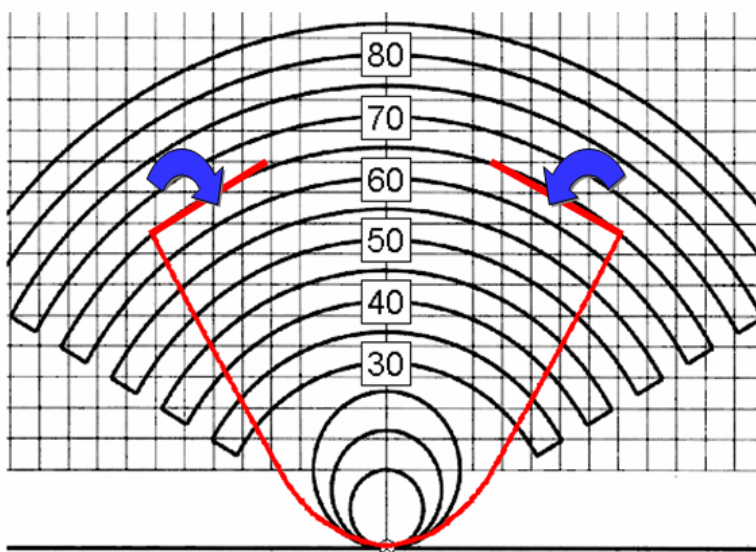


3. Setting the arm length:

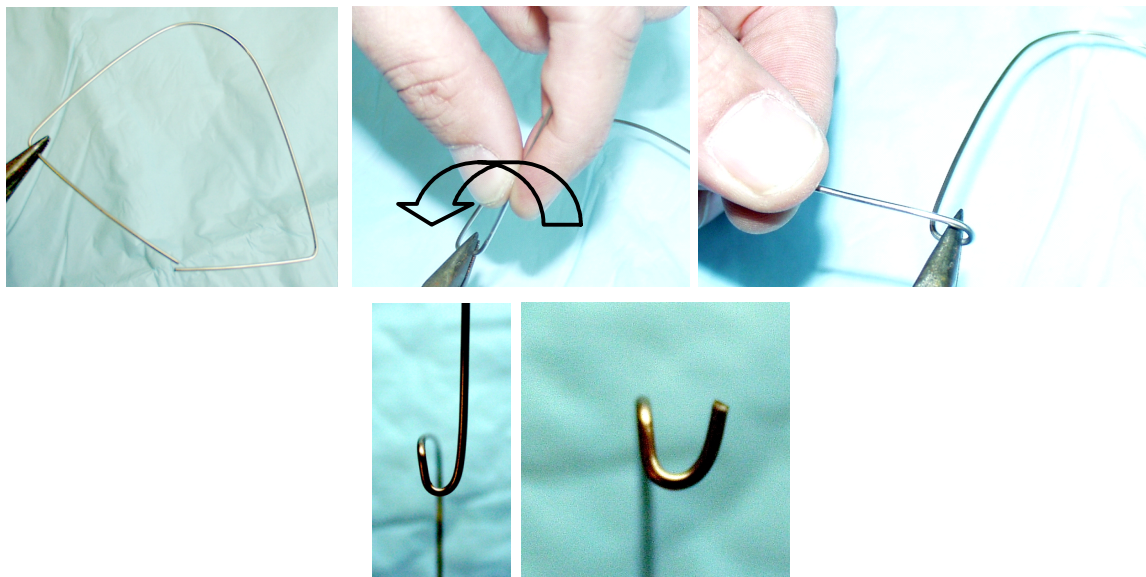
- a. Lay the wire on the *Spring Design Template and Data Sheet*, so that the bend covers the lower apex of the circle and the arms extend upward and are symmetric with respect to the vertical axis of the grid.



- b. Using the 5mm arcs as a reference, form a 90 degree bend in the arms at the selected arm length (65mm on the example figure).

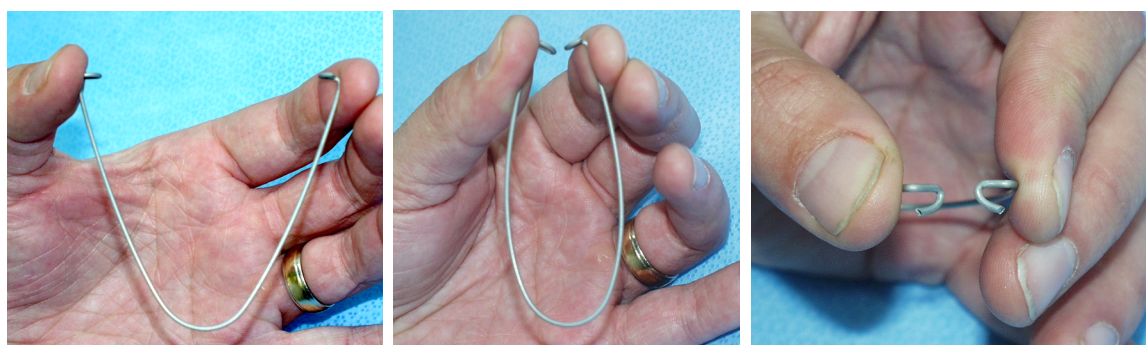


- c. Form the hooks and cut off the excess wire.



- d. Round off the tip of the hook.

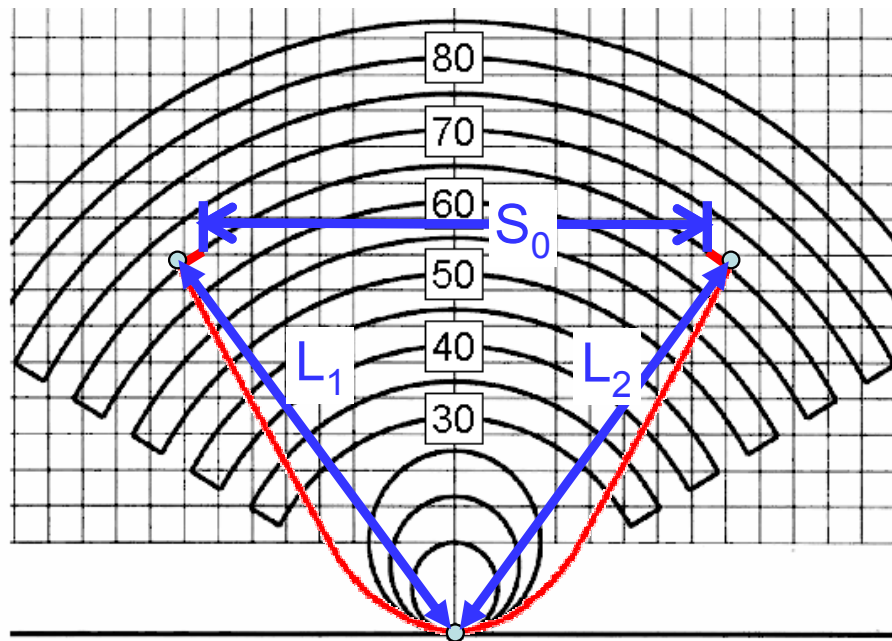
- e. Slowly “pinch” the hooks together to finish final deformed bend.



- f. Proceed to the Date Recording Procedure Section.

SECTION 3: DATA RECORDING PROCEDURE

1. Line up the bend of the spring with the bottom of the circles on the *Spring Design Template and Data Sheet* in the same manner used for Section 2, Step 3a.
2. Mark a dot at the tip of each arm on the sheet and draw a short vertical line along the inner surface of the hook.
3. Measure the distance between the bottom of the circles to the marked dots at the end of the arms. The average of these two lengths (L_1 and L_2) is the arm length (L). Measure the distance between the vertical lines between the hooks. This measurement is the original span (S_0).



4. Determine the resultant parameters using the following equations.

a. Spring stiffness (k) $k = \frac{32600}{L^3}$

b. Maximum Deflection Range (S) $S = S_0 - 10$

c. Maximum Spring Force ($F_{\max}$) $F_{\max} = k \cdot S$

d. Maximum Spring Stored Energy ($E_{\max}$)

$$E_{\max} = \frac{F_{\max} \cdot S}{2} = \frac{k \cdot S^2}{2}$$

SECTION 4: FIGURES

Figure A4.1:	Maximum Deflection Range	74
Figure A4.2:	Maximum Spring Force	75
Figure A4.3:	Spring Stiffness	76
Figure A4.4:	Spring Design Template and Data Sheet	77

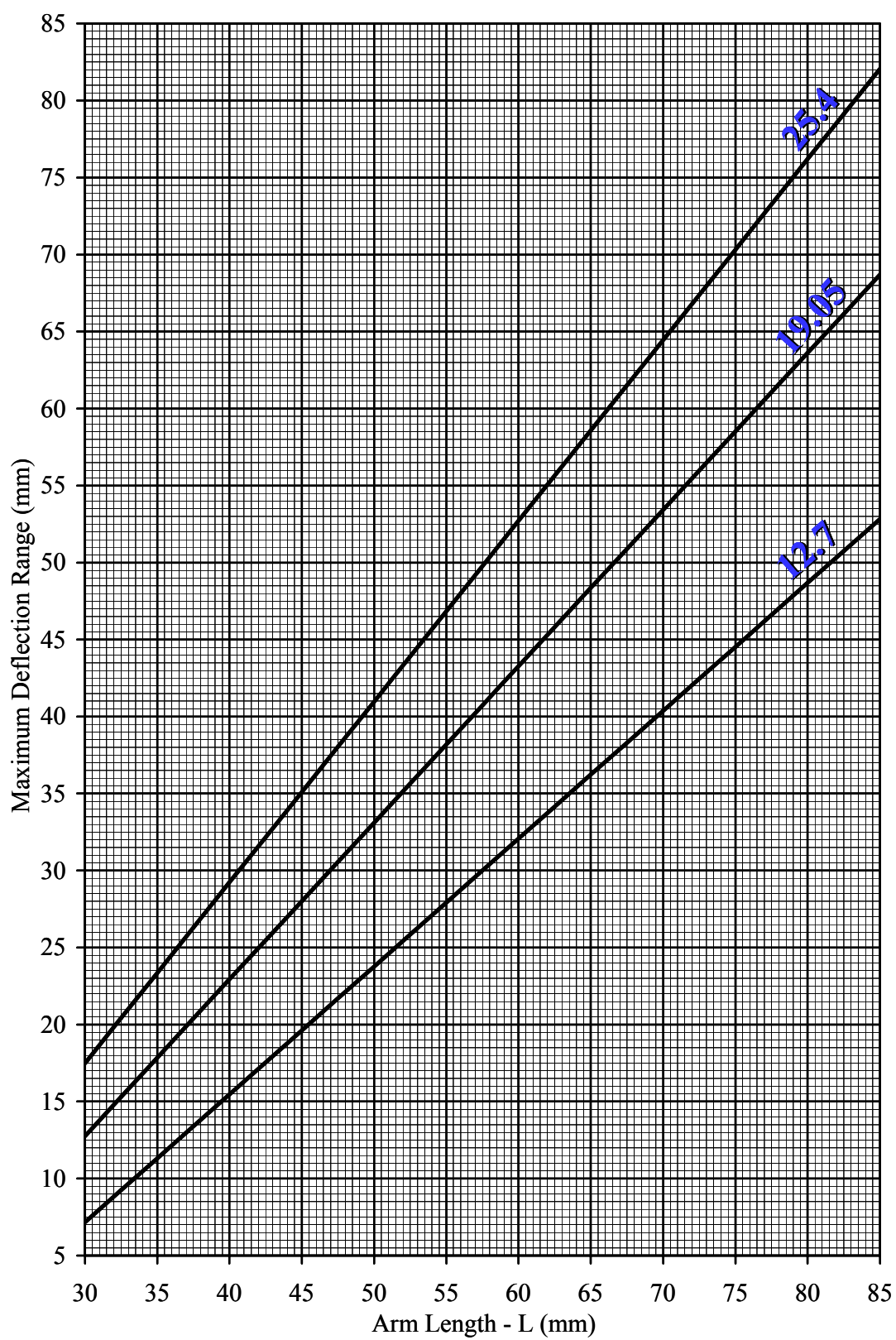


Figure A4.1: Maximum deflection range ($S_{\max}$).

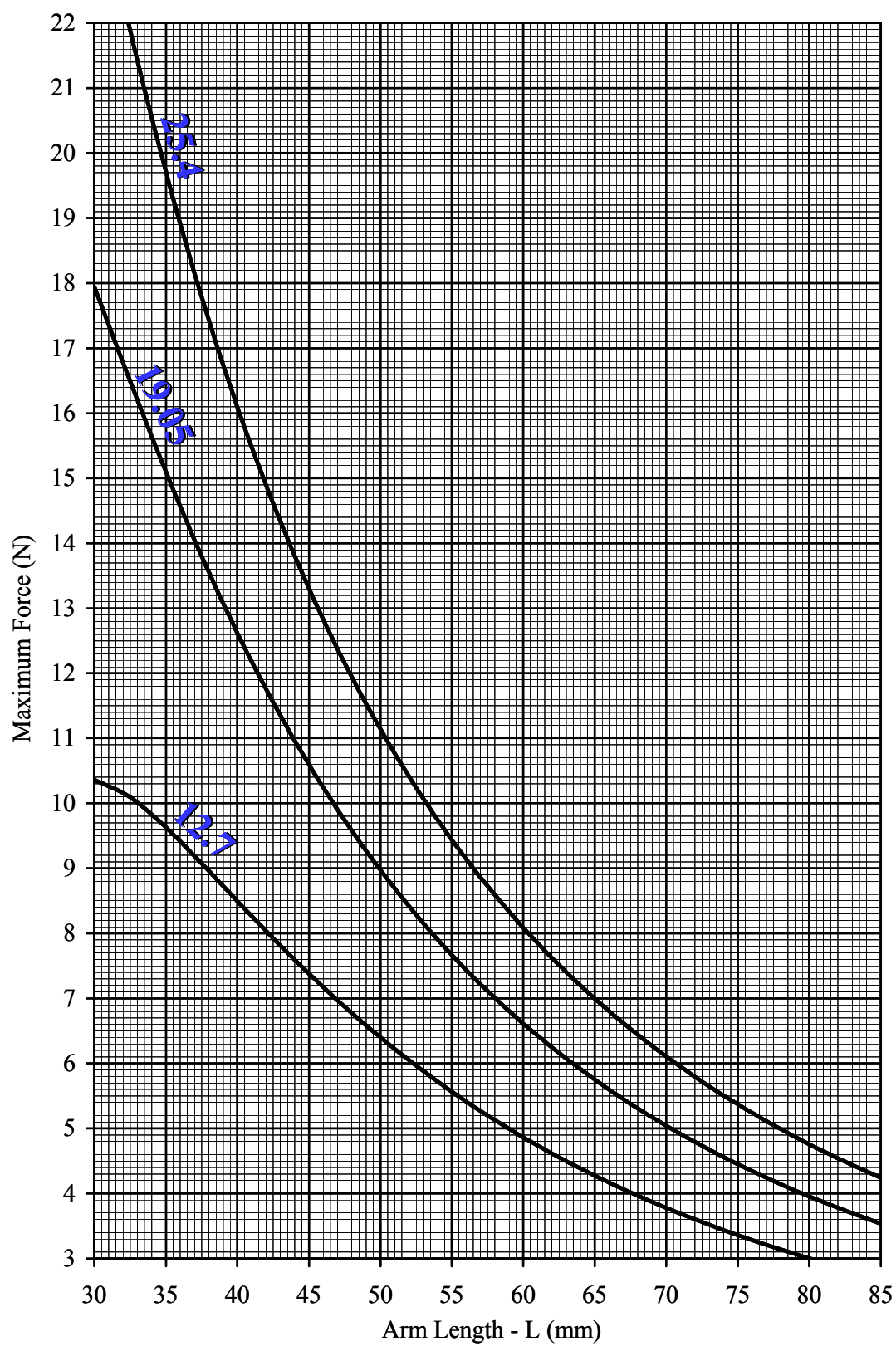


Figure A4.2: Maximum spring force ($F_{\max}$).

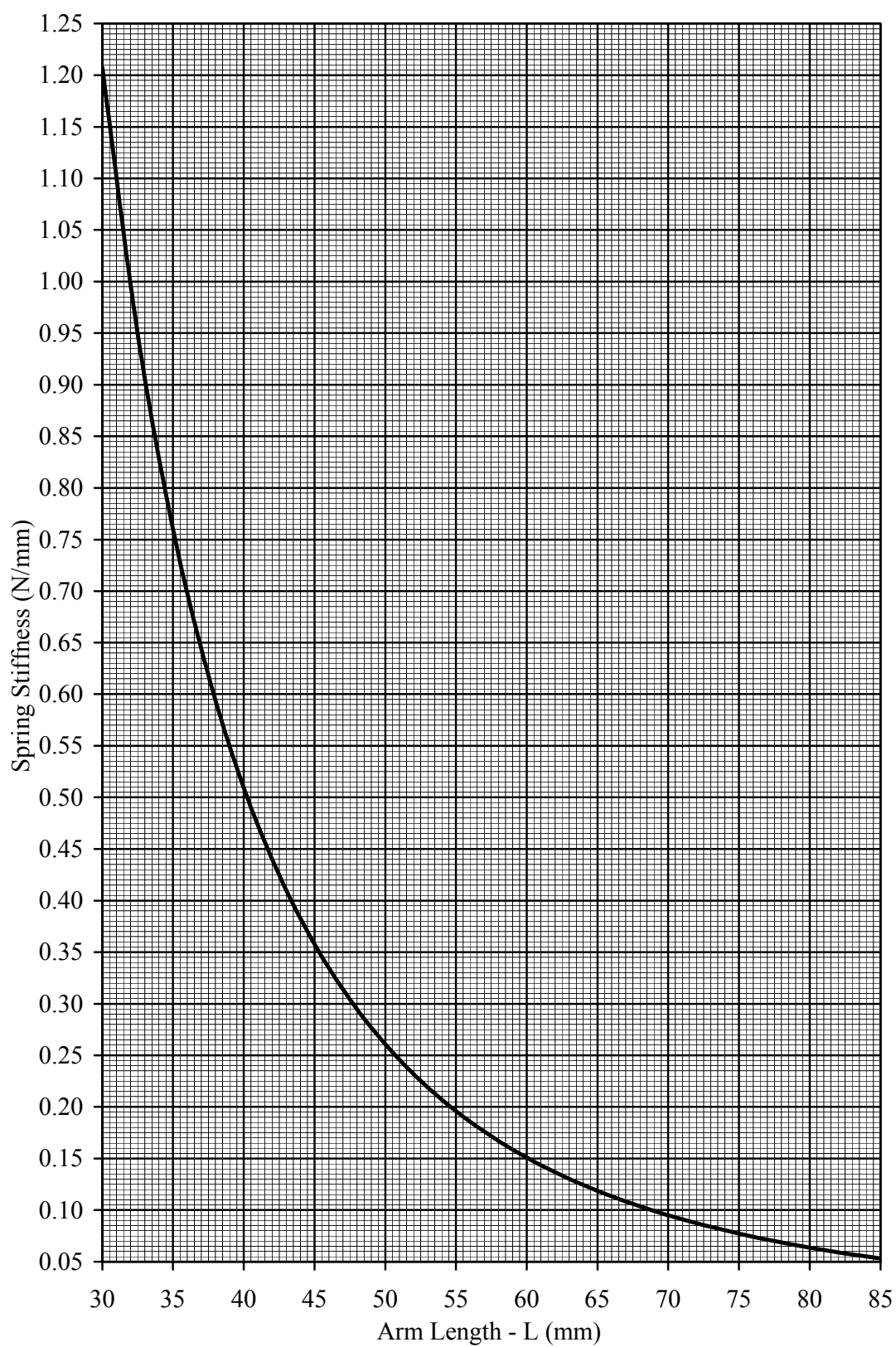


Figure A4.3: Spring stiffness (k).

Spring Design Template and Data Sheet

(All dimensions are in millimeters)

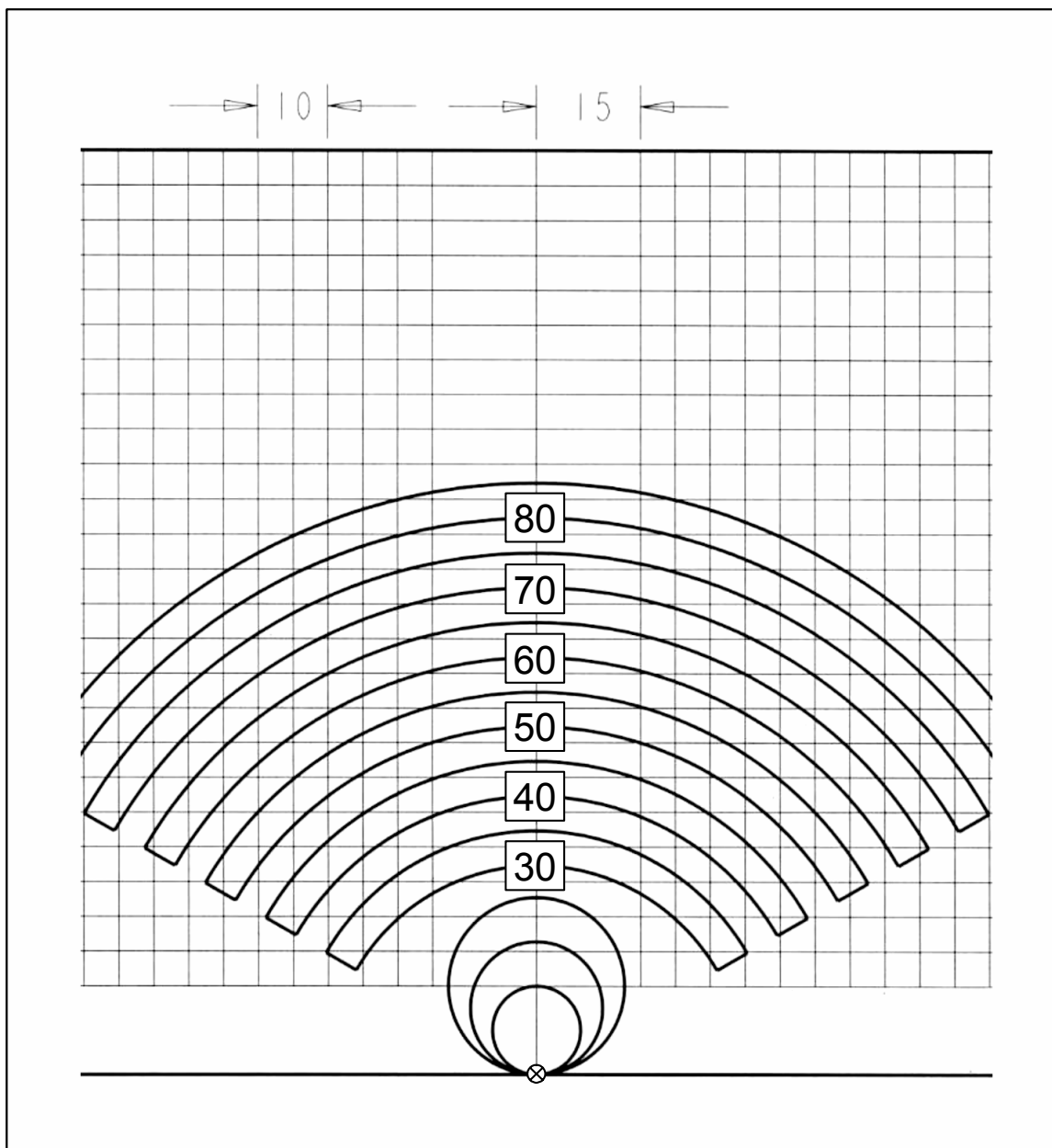


Figure A4.4: Spring design template and data sheet.

Appendix B: Matlab Data Analysis Code

The following sections contain the Matlab© code written for the analysis of the data for this research. The following four sets of code are presented:

1. Spring Stiffness Determined from Force-Displacement Data (page 79).
2. Spring Stiffness Model Linear Regression (page 81).
3. Maximum Deflection Range Linear Regression / Optimization (page 84).

SPRING STIFFNESS DETERMINED FROM FORCE-DISPLACEMENT DATA

```
clear all
close all
clc
disp('---Running Spring Stiffness Determination---')
% Initialization of character for data loading
% Format "S###.txt"

init = double('S301.txt');
disp('Loading Test Date and Performing Regression')
disp(' ')

% Regression Loop for Stiffness Determination

for i = 1:24;

    % load current data set

    iset = load(char(init));
    disp(char(init))

    % Define X-matrix for linear regression
    % format  $y = mx + b$ 

    X = [iset(:,2) ones(length(iset(:,2)),1)];

    % Define Y-array for linear regression

    Y = [iset(:,1)];

    % Perform linear regression

    [b,bint,r,rint,stats] = regress(Y,X);

    % Store stiffness value (m) and R-squared value

    results(i,:) = [b(1) stats(1)];

    % Re-index filename

    init(1,4) = init(1,4) + 1;
    if init(1,4) == 58
        init(1,3) = init(1,3)+1;
```

```
        init(1,4) = 48;
    end
end

% R-squared results for all regressions

mean(results(:,2))
std(results(:,2))
min(results(:,2))
max(results(:,2))

% Display Stiffness values to facilitate
% Copying and pasting into Excel file for
% Initial Processing

disp(results(:,1))
```

SPRING STIFFNESS MODEL LINEAR REGRESSION

```
clc
clear all
close all
format compact

disp('---RUNNING FINAL STIFFNESS MODEL REGRESSION---')

disp('Loading experimental data')

dataset = load('s3data1.txt');

L = dataset(:,1); % mm
B = dataset(:,2); % mm
%S = dataset(:,3); % mm
k = dataset(:,4); % N/mm

disp('Performing linear regression')

% Develop X-matrix
% Form  $k = a * L^b$ 

X = [log(L) ones(length(L),1)];

% Develop Y-array

Y = log(k);

% Perform linear regression analysis

[b,bINT,r,rINT,STATS] = REGRESS(Y,X);

% Disp R-squared value

RS = STATS(1)

% Ouput

disp('Developing final model plot')
disp('B = 12.70mm --- black')
disp('B = 19.05mm --- blue')
disp('B = 25.40mm --- red')

% Define bend diameter sets for plotting
```

```
B1 = 1.270E+01;% 0.50 in
B2 = 1.905E+01;% 0.75 in
B3 = 2.540E+01;% 1.00 in

% Define arm length range to be plotted

Lp = [28:0.1:66]';

% B1 set

count1 = 0;
for i = 1:length(B)
    if B(i) == B1
        count1 = count1 + 1;
        L1(count1,:) = L(i,:);
        k1(count1,:) = k(i,:);
    end
end

X1 = [log(Lp) ones(length(Lp),1)];
Y1 = exp(X1*b);

figure
plot(L1,k1,'Ok',Lp,Y1,'k')
hold

% B2 set

count2 = 0;
for i = 1:length(B)
    if B(i) == B2
        count2 = count2 + 1;
        L2(count2,:) = L(i,:);
        k2(count2,:) = k(i,:);
    end
end

X2 = [log(Lp) ones(length(Lp),1)];
Y2 = exp(X2*b);

plot(L2,k2,'Ob',Lp,Y2,'b')

% B3 Set

count3 = 0;
```

```
for i = 1:length(B)
    if B(i) == B3
        count3 = count3 + 1;
        L3(count3,:) = L(i,:);
        k3(count3,:) = k(i,:);
    end
end

X3 = [log(Lp) ones(length(Lp),1)];
Y3 = exp(X3*b);

plot(L3,k3,'Or',Lp,Y3,'r')
```

MAXIMUM DEFLECTION RANGE LINEAR REGRESSION / OPTIMIZATION

```
clc
clear all
close all
format compact
disp('---RUNNING FINAL MODEL DEVELOPMENT PROGRAM---')

disp('Loading experimental data')

dataset = load('s3data3.txt');

L = dataset(:,1);% mm
B = dataset(:,2);% mm
S = dataset(:,3);% mm
%k = dataset(:,4);% N/mm

disp('Creating Y-array for linear regression')

Y = S;

disp('Initializing L parameter exponent optimization')

% Set significant figure convergence

sigfig = 0.0001;
test = 1;

% Define initial range and step

ind = 0.01;
u = 1;
d = 0.01;
RS(1) = 0;
count = 1;
regcount = 0;

for i = d:ind:u
    X = [B.^0.5.*L.^i, ones(length(L),1)];
    [b,bINT,r,rINT,STATS] = REGRESS(Y,X);
    regcount = regcount + 1;
    count = count +1;
    RS(count) = STATS(1);
```

```

        iset(count) = i;

        if RS(count) > RS(count - 1)
            imax = i;
        end
    end
end

disp('Performing L parameter exponent optimization')

loopcount = 1;

while test > sigfig

    d = imax - ind;
    u = imax + ind;
    ind = ind/10;
    imaxold = imax;
    count = 1;
    clear iset
    clear RS
    for i = d:ind:u
        X = [B.^0.5.*L.^i, ones(length(L),1)];
        [b,bINT,r,rINT,STATS] = REGRESS(Y,X);
        regcount = regcount + 1;
        count = count + 1;
        RS(count) = STATS(1);
        iset(count) = i;
        regcount = regcount + 1;
        if RS(count) > RS(count - 1)
            imax = i;
            RSmax = RS(count);
            bmax = b;
        end
    end
    test = abs(imaxold-imax);
    loopcount = loopcount + 1;
end

disp('Optimization complete')
disp('Loop Count')
disp(loopcount)
disp('Regression Count')
disp(regcount)
disp('Optimized exponential power of L')
format long

```

```

disp(imax)
disp('R^2 Value')
format short
disp(RSmax)

disp(' ')

disp('Plotting final optimization run')
iset = iset(2:length(iset)-1));
RS    = RS(2:length(RS)-1));
plot(iset,RS-mean(RS))
axis off
hold
plot(imax, RSmax-mean(RS), 'O')

disp('Final model form')
disp(' S = a1*B^0.5*L^a2+a0')

a1 = bmax(1)
a0 = bmax(2)
a2 = imax

disp('Regression constant array length')
disp(length(b))

disp('Developing final model plot')
disp('B = 12.70mm --- black')
disp('B = 19.05mm --- blue')
disp('B = 25.40mm --- red')
B1 = 1.270E+01;% 0.50 in
B2 = 1.905E+01;% 0.75 in
B3 = 2.540E+01;% 1.00 in

Lp = [0:1:90]';

count1 = 0;

for i = 1:length(B)
    if B(i) == B1
        count1 = count1 + 1;
        L1(count1,:) = L(i,:);
        S1(count1,:) = S(i,:);
    end
end

X1 = [B1.^0.5.*Lp.^a2, ones(length(Lp),1)];

```

```
Y1 = X1 * bmax;
figure
plot(L1,S1,'Ok',Lp,Y1,'k')
hold

count2 = 0;

for i = 1:length(B)
    if B(i) == B2
        count2 = count2 + 1;
        L2(count2,:) = L(i,:);
        S2(count2,:) = S(i,:);
    end
end

X2 = [B2.^0.5.*Lp.^a2, ones(length(Lp),1)];

Y2 = X2 * bmax;

plot(L2,S2,'Ob',Lp,Y2,'b')

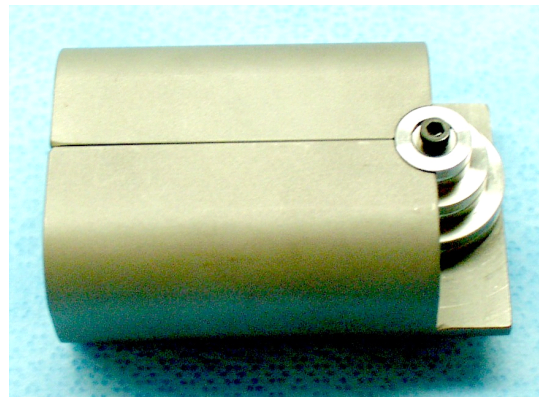
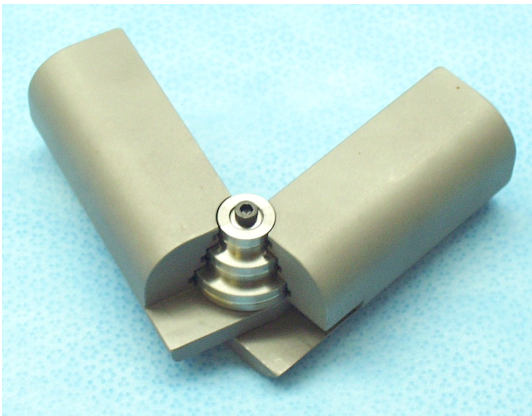
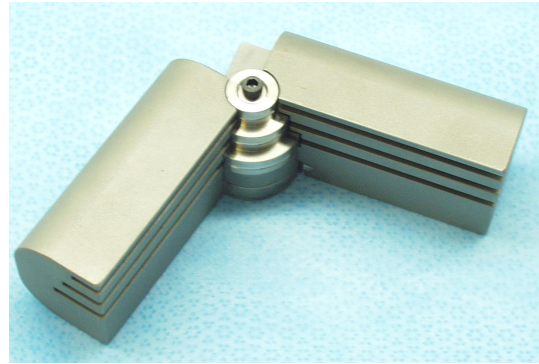
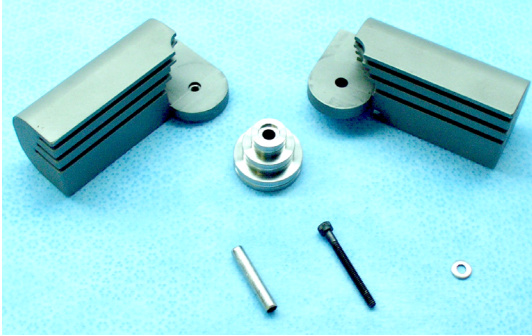
count3 = 0;

for i = 1:length(B)
    if B(i) == B3
        count3 = count3 + 1;
        L3(count3,:) = L(i,:);
        S3(count3,:) = S(i,:);
    end
end

X3 = [B3.^0.5.*Lp.^a2, ones(length(Lp),1)];
Y3 = X3 * bmax;

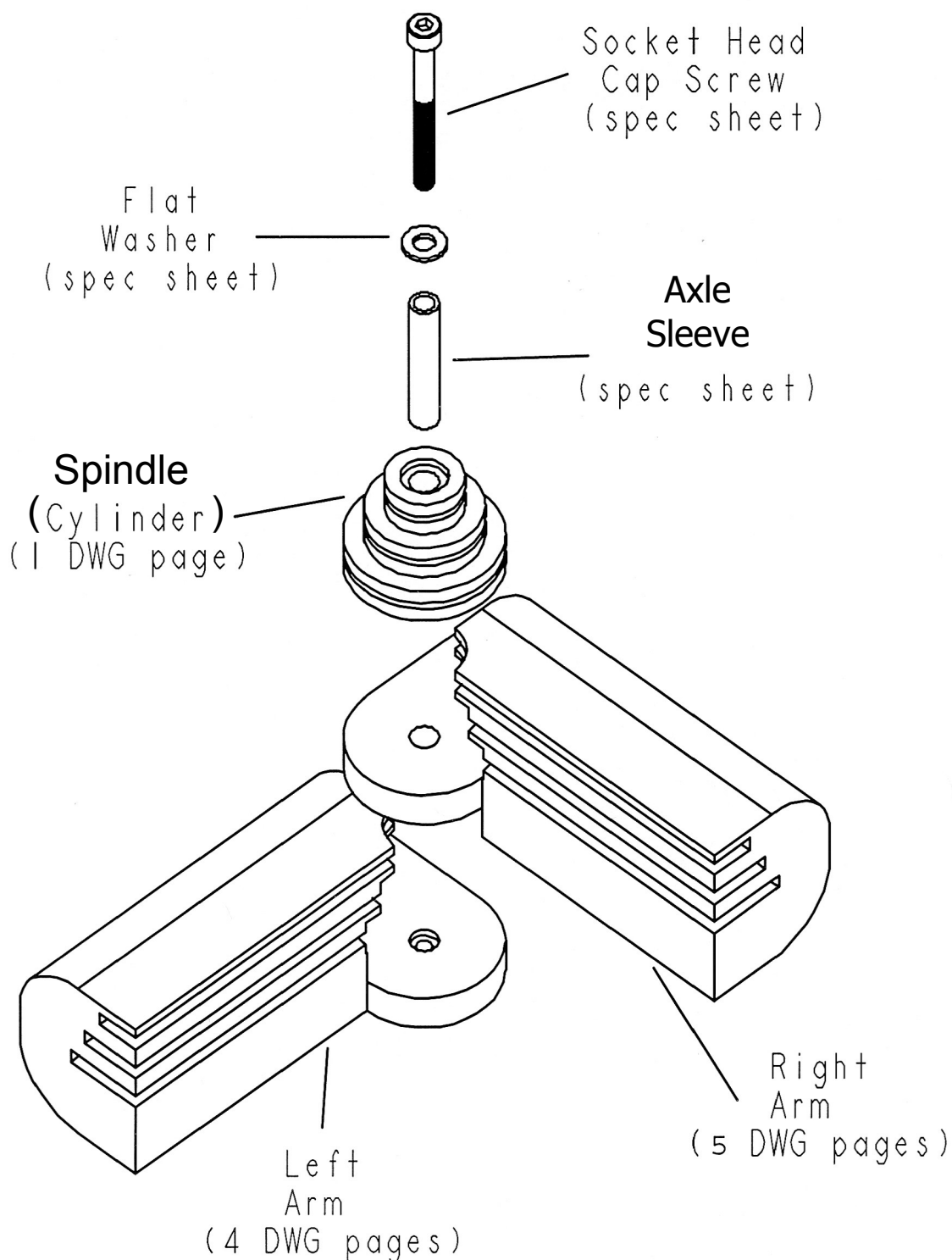
plot(L3,S3,'Or',Lp,Y3,'r')
```

Appendix C: Wireform Spring Bending Device Specifications



Section 1: Exploded View	89
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Combination Bender



Specifications Sheet

Socket Head Cap Screw – Size 5-40 X 1 1/4” – 18-8 Stainless Steel

Flat Washer – Size 5 – 18-8 Stainless Steel

Axle Sleeve – 3/16” X 0.028” X 1” Stainless Steel Tube – 316 Stainless Steel

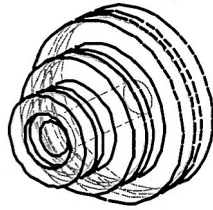
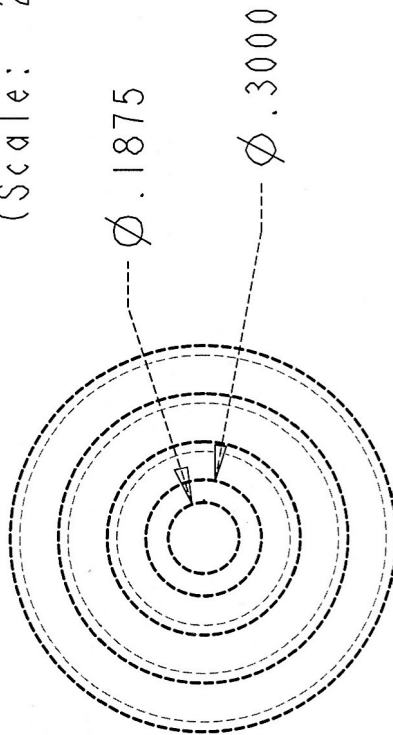
Spindle – Custom Machined – 316 Stainless Steel

Right Arm – Custom Machined – 316 Stainless Steel

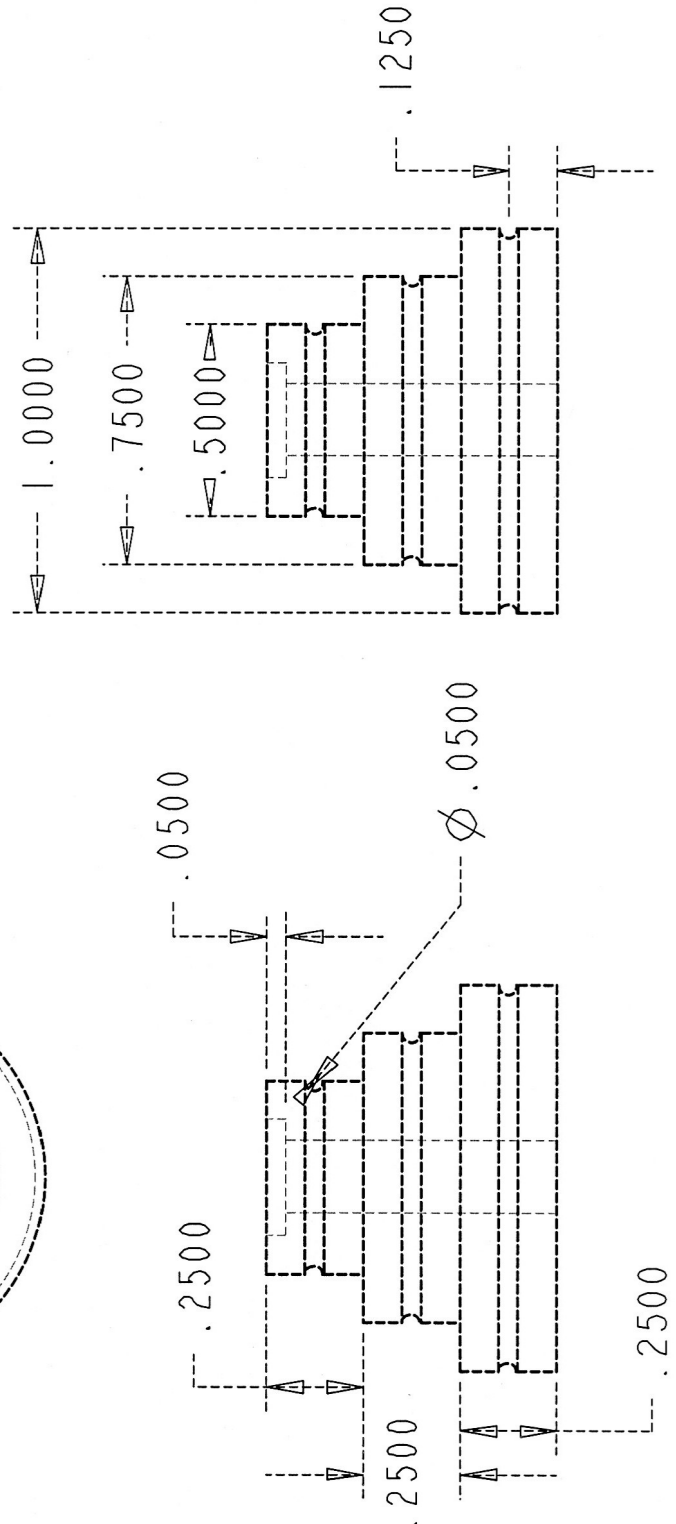
Left Arm – Custom Machined – 316 Stainless Steel

Combination Bender - (Cylinder) Spindle
Type 316 Stainless Steel
All Edges Rounded

(Dimensions are in INCHES)
(Scale: 2.000)

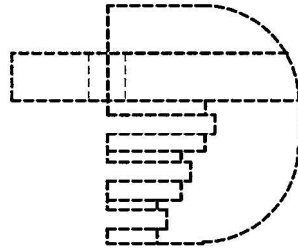


SCALE 1.000

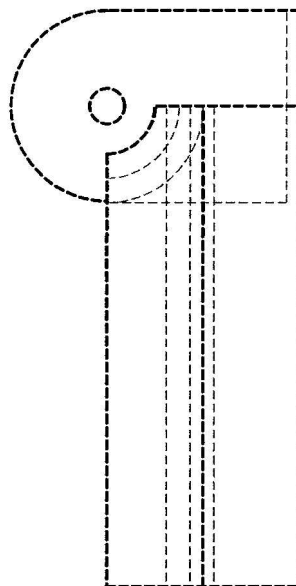
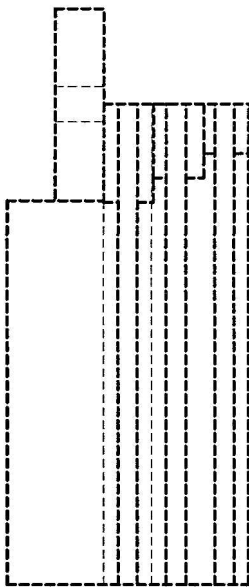


Spindle (Cylinder)

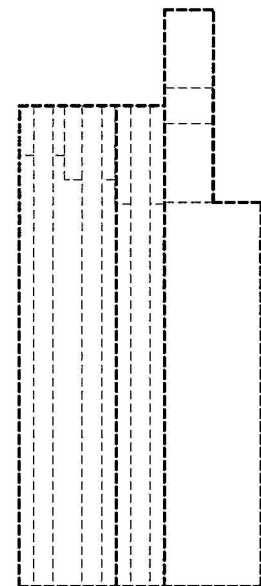
Combination Bender
Right Arm
Type 316 Stainless Steel
(Scale: 1.000)



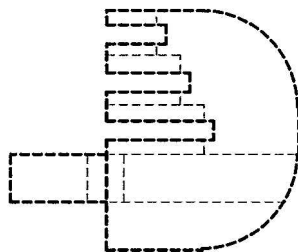
Sheet 3 and 4



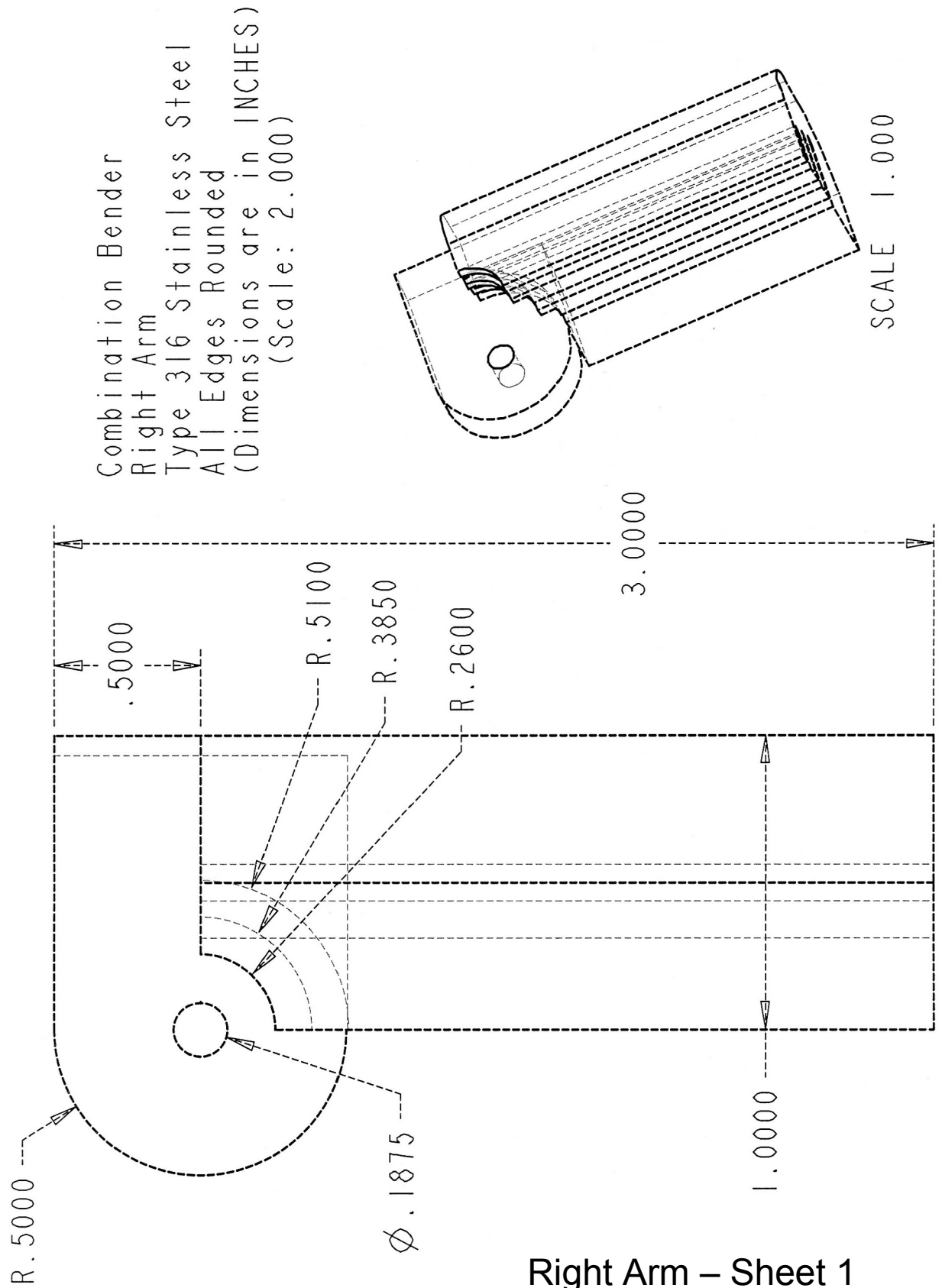
Sheet 1



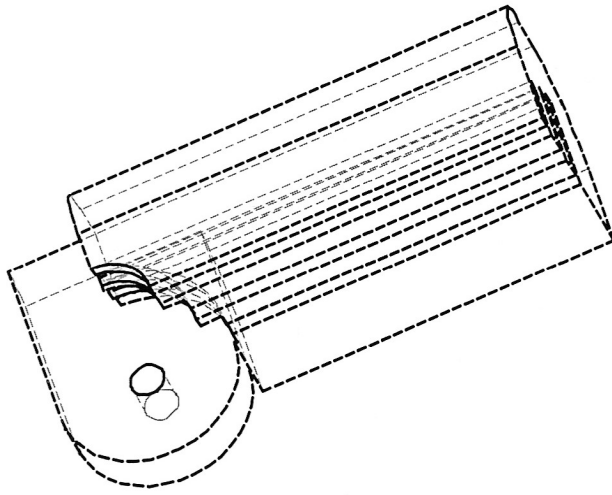
Sheet 2



Right Arm

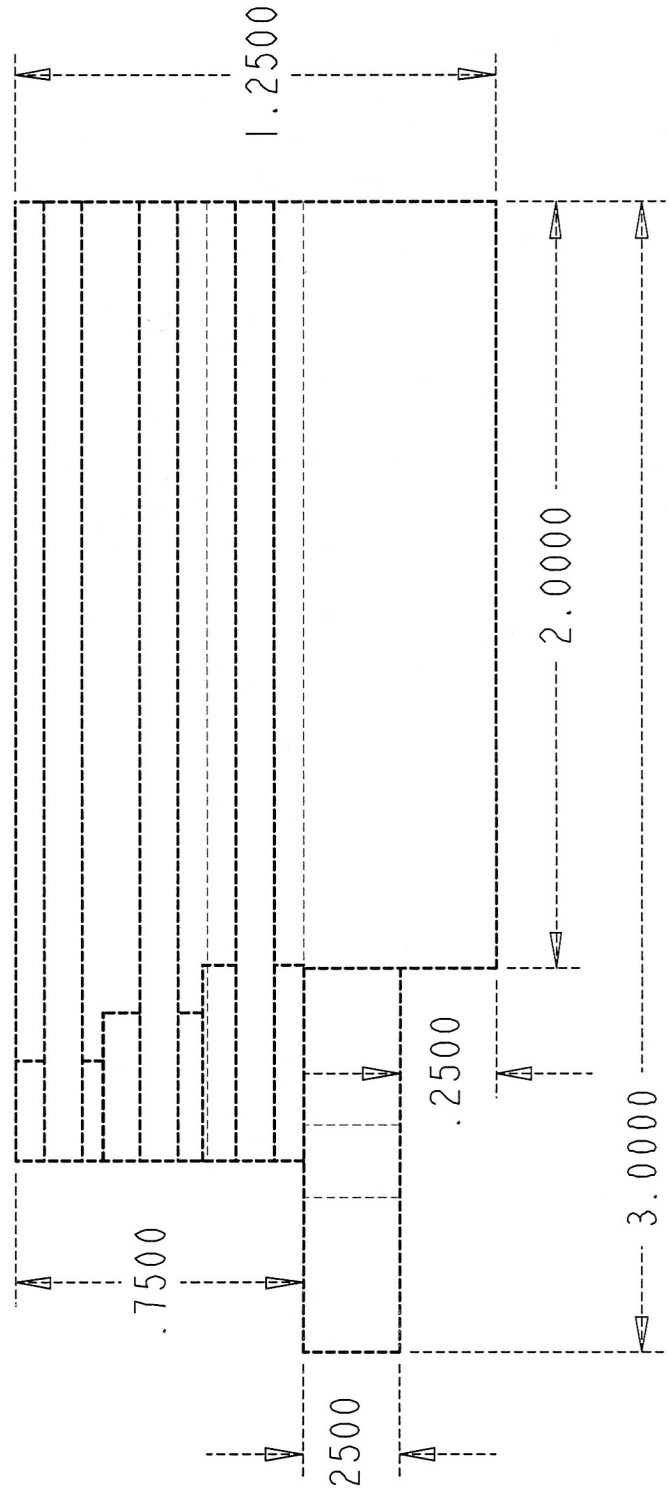


Right Arm – Sheet 1

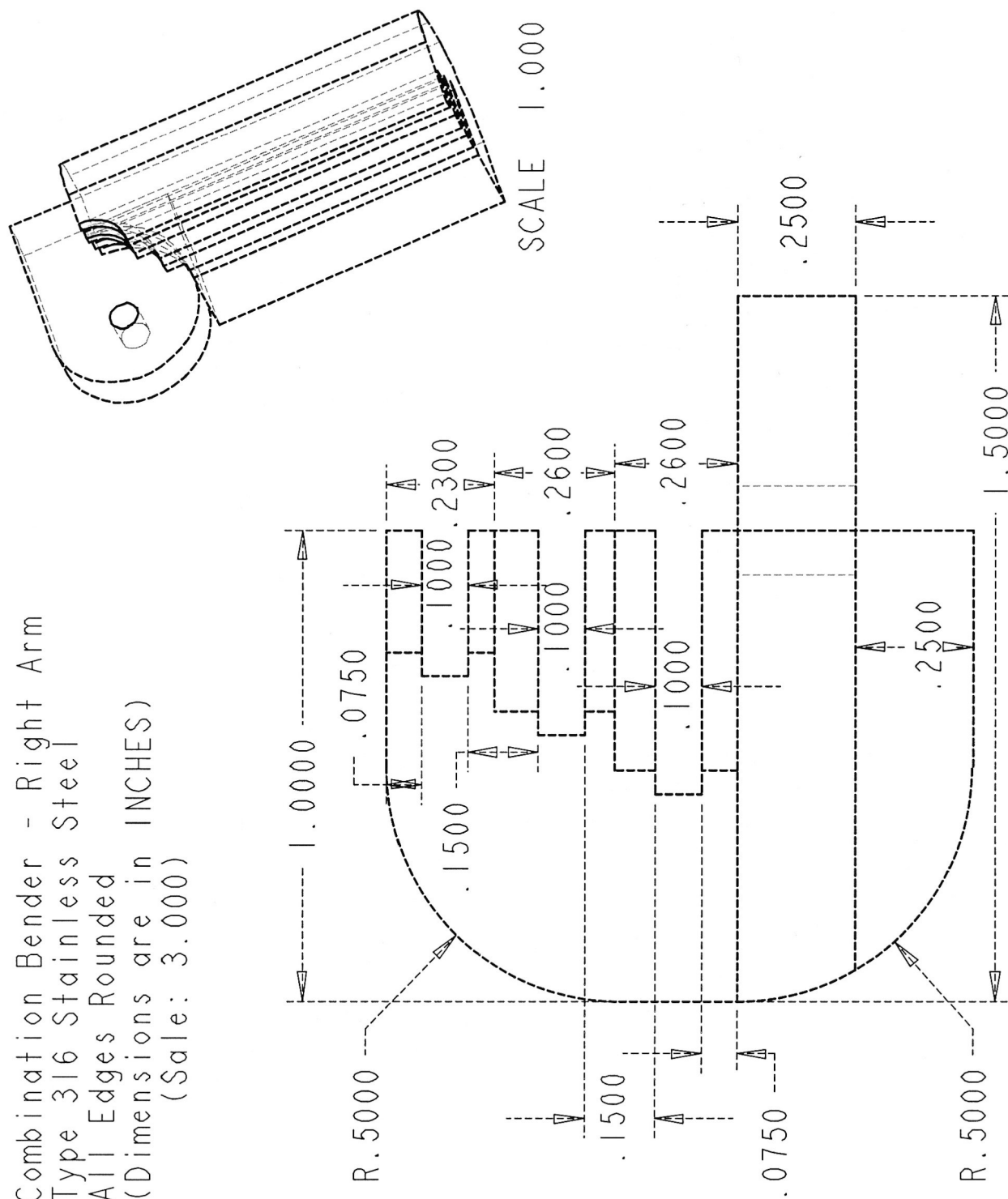


SCALE 1.000

Combination Bender - Right Arm
Type 316 Stainless Steel
All Edges Rounded
(Dimensions are in INCHES)
(Scale: 2.000)

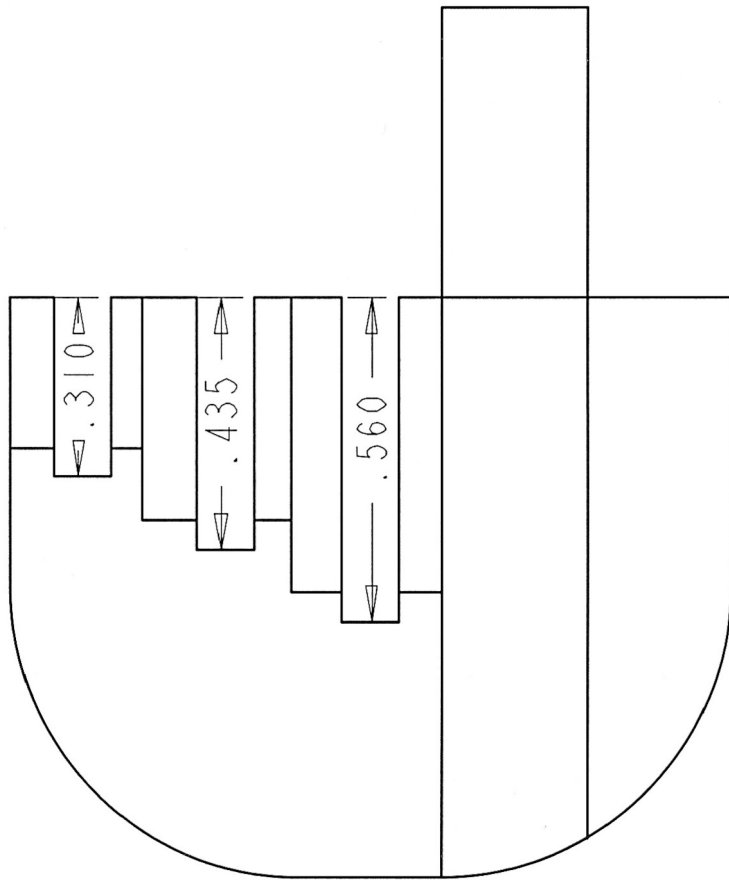


Right Arm - Sheet 2



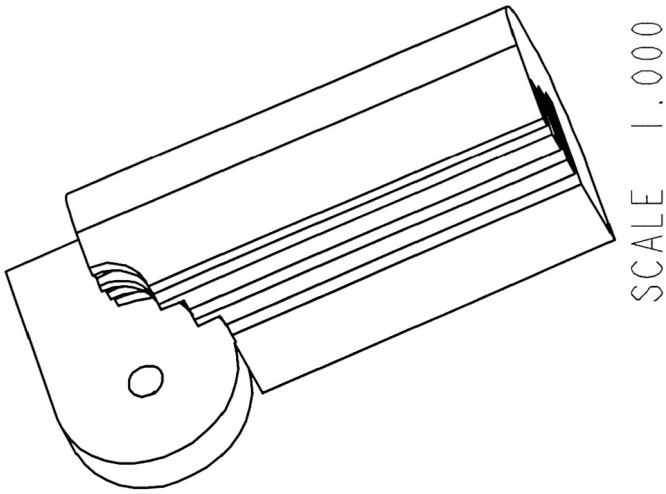
Right Arm – Sheet 3

Combination Bender - Right Arm
 Type 316 Stainless Steel
 All Edges Rounded
 (Dimensions are in INCHES)
 (Scale: 3.000)



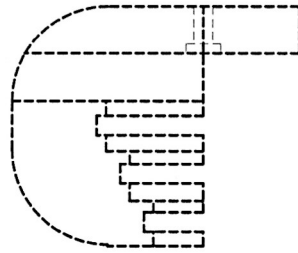
Dimensions for the depths of the
 channels on the Left Arm are the same.

Right Arm – Sheet 4

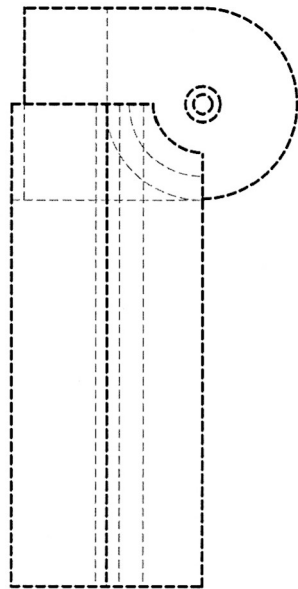
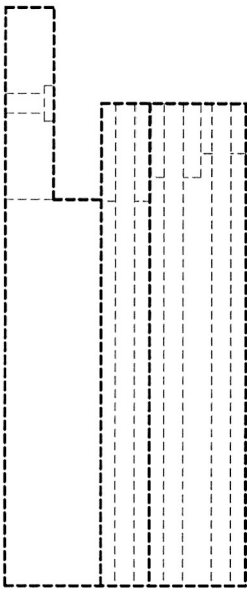


SCALE 1.000

Combination Bender
Left Arm
Type 316 Stainless Steel
(Scale: 1.000)



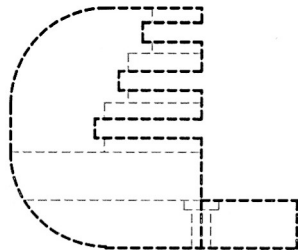
Sheet 3



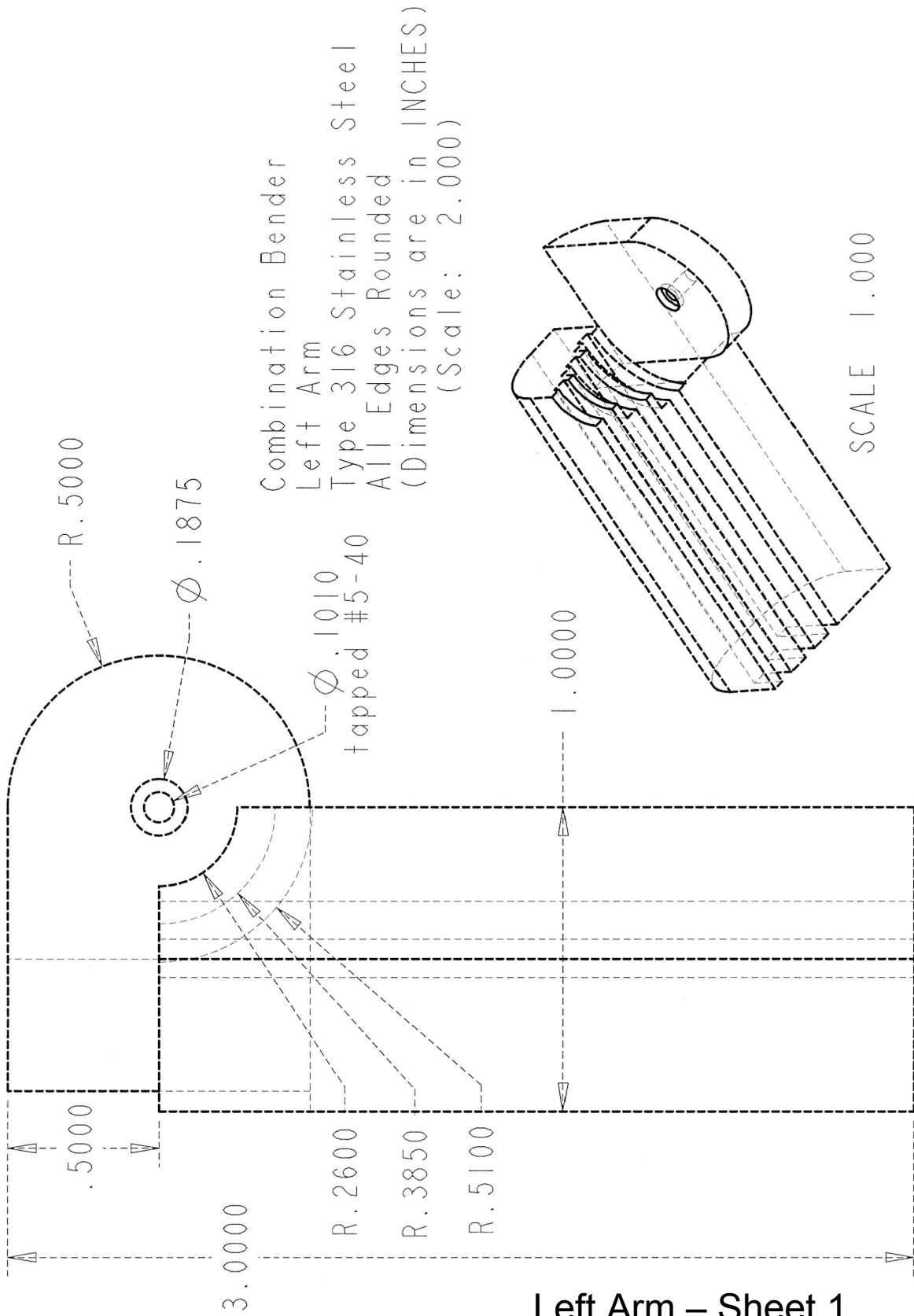
Sheet 1



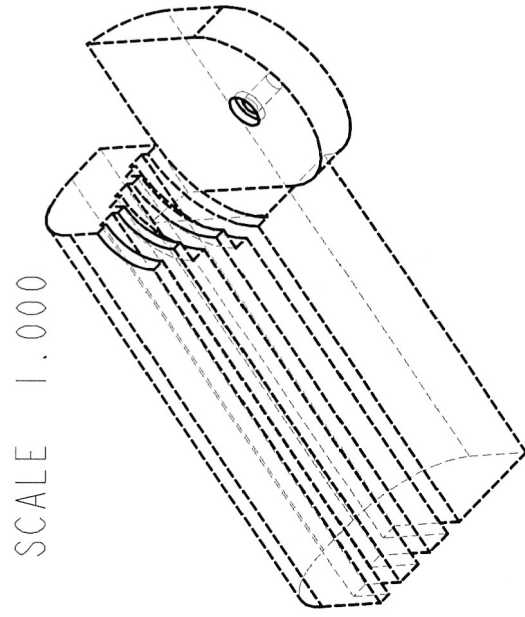
Sheet 2



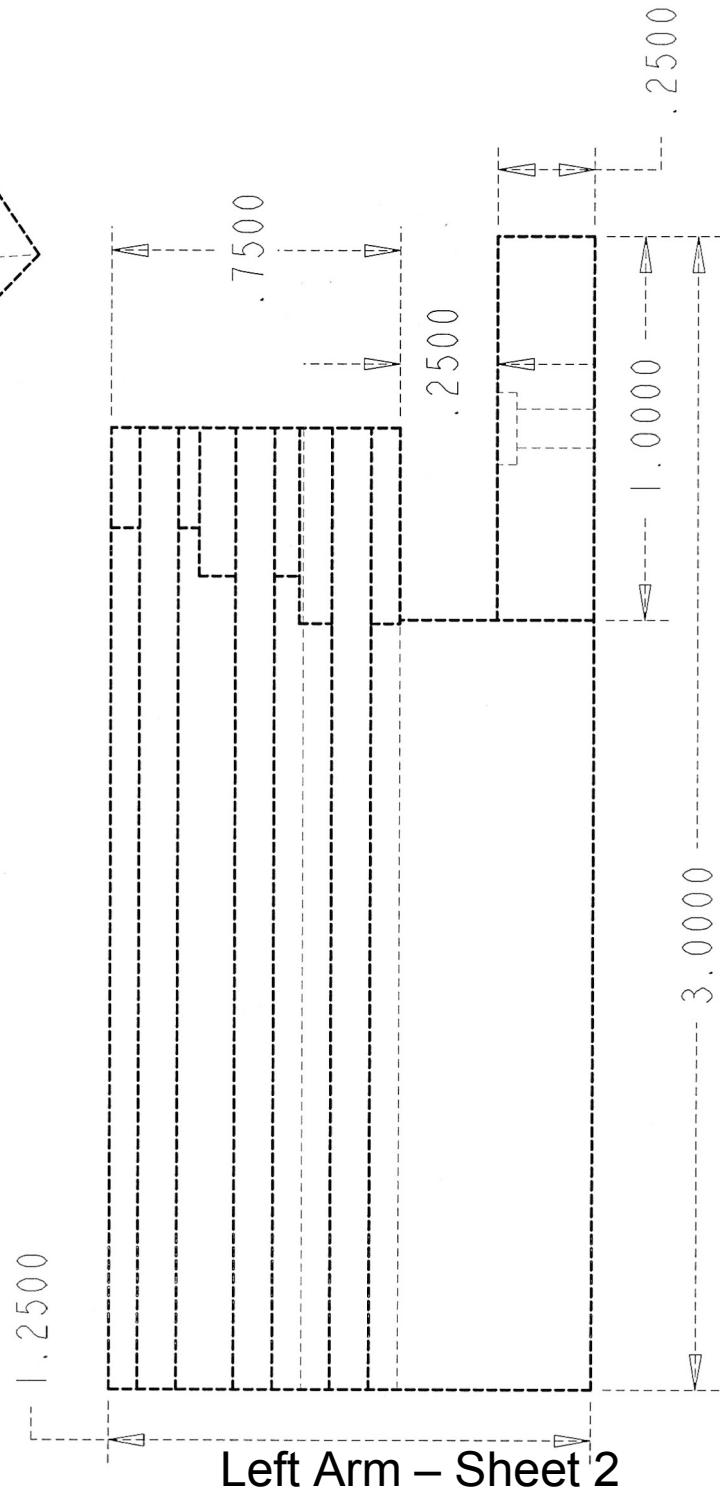
Left Arm



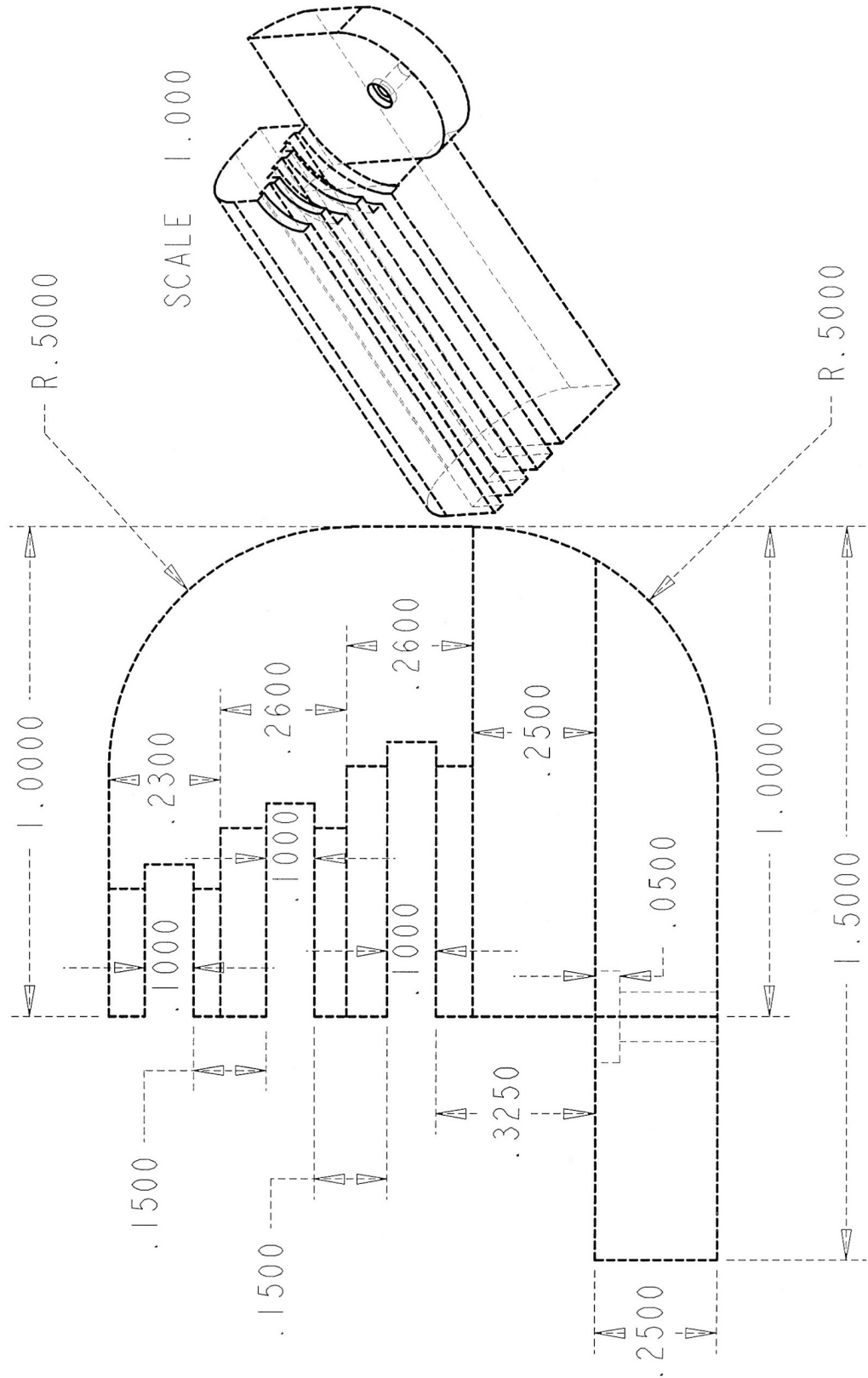
Left Arm – Sheet 1



Combination Bender - Left Arm
 Type 316 Stainless Steel
 All Edges Rounded
 (Dimensions are in INCHES)
 (Scale: 2.000)



Combination Bender - Left Arm
 Type 316 Stainless Steel
 All Edges Rounded
 (Dimensions are in INCHES)
 (Scale: 3.000)



Left Arm – Sheet 3

Vita

William James Hurst

William Hurst was born in Chicago, Illinois on August 3, 1971. After completion of his high school diploma, he enlisted in the United States Navy on July 13, 1989. During his naval career, he completed the Navy's Nuclear Power Training program and was selected to be a power plant operations instructor at the age of eighteen. He then transferred to the U.S.S. Atlanta (SSN-712), where he completed a six-year tour receiving numerous decorations including the Navy and Marine Corps Achievement Medal. After completion of his eight years of military service, he attended the College of DuPage in Glen Ellyn, Illinois, where he received an Associates in Engineering Science Degree with high honors. William then attended the University of Illinois at Chicago where he received a Bachelors of Science Degree in Bioengineering with highest college honors. He then attended the Virginia Polytechnic Institute and State University in Blacksburg, Virginia, where he received a Masters of Science Degree in Mechanical Engineering. He is a member of several professional and honors societies including: American Society of Biomechanics, American Society of Mechanical Engineering, Society of Automotive Engineering, Tau Beta Pi Engineering Honors Society, Golden Key Honors Society, and Phi Theta Kappa Honors Society. In the summer of 2003, William will assume the position of Laboratory Manager at the Liu Ping Laboratory for Functional Tissue Engineering Research Laboratory, in the Department of Biomedical Engineering at Columbia University in New York City.

William is a loyal husband to his wife Deirdre and a dedicated father to his son Liam. William enjoys motorcycling and is currently a member of the American Motorcyclist Association and Harley Owners Group.

For further information, he may be contacted through his mother at the following address:

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William James Hurst
