TEXTILE PROSTHESIS FOR VASCULAR APPLICATIONS

Except where reference is made to the work of others, the work described in this thesis is my own or was done in collaboration with my advisory committee.

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TEXTILE PROSTHESIS FOR VASCULAR APPLICATIONS

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TEXTILE PROSTHESIS FOR VASCULAR APPLICATIONS

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Swagat Appasaheb Irsale, son of Mr. and Mrs. Appasaheb K. Irsale, was born on February 6, 1978, in Ichalkaranji, India. He graduated with a Bachelors degree in Man-Made Textile Engineering from Textile and Engineering Institute, India in April 1999. He completed his Master of Textile in Textile Technology from Textile and Engineering Institute, India in August 2002. He joined graduate program in Textile Engineering at Auburn University to work towards the degree of Master of Science in Fall 2002.

THESIS ABSTRACT

TEXTILE PROSTHESIS FOR VASCULAR APPLICATIONS

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Master of Science, May 14, 2004

(Master of Textile, Textile Technology, India, August 2002)

(Bachelor of Textile, Man-Made Textile Technology, India, April 1999)

120 TYPED PAGES

Directed by Dr. Sabit Adanur

The goal of this study was to develop a whole new class of implantable endoluminal prosthesis for biomedical applications based on advanced textile technology. The most likely initial application is in the field of arterial circulation. In this study a prototype endovascular textile prosthesis was developed consisting of integrated sealing and reinforcing component. The prosthesis had inherent advantage of reducing concentration of mechanical stress, which will be responsible for the device failure.

Basic fabric forming methods such as braiding and narrow weaving were explored for bio-medical textile applications. The specific application of this endovascular textile prosthesis would be primarily in human blood vessels to combat Coronary Artery Disease (CAD). The current study strictly focuses on prototype manufacturing of 'textile stent' to be used as substitute for commercially available metal stents in near future. The developed prototype textile stent is an integrated braided and

seamless tubular narrow woven fabric assembly. The braided structure acts as reinforcing component and narrow woven seamless tubular fabric tightly covering it, acts as sealing component. Various braided structures to be used as reinforcing component were made with 1100 denier polyester monofilament yarn and tested for compression resistance on Instron materials tester. The variables studied were braid diameter, braid angle and heat set time. All variables and their interactions have statistically significant effect on compression resistance properties of braided structures. The seamless tubular fabric to be used as sealing component was manufactured on narrow loom with 150 denier polyester multifilament yarn used in both warp and weft directions. Another seamless tubular fabric was manufactured with nylon-lycra elastic yarn in weft direction. The tubular elastic fabric facilitated integration of braided and narrow woven seamless tubular structures in the prototype textile stent. Monofilament was used in reinforcing component of the prototype due to its stiffness and multifilament for sealing component as it will be easy to control porosity of sealing component in future textile stent structures.

A prototype of bifurcated stent was also developed for abdominal aortic aneurysm application. The prototype bifurcated stent was manufactured on Wardwell composite braiding machine with 1100 denier polyester monofilament yarn.

DISCLAIMER

The author makes no representation, promise, express or imply warranty concerning the suitability of 'prototype textile stents' for implantation in any living organism. These prototypes were strictly developed for this specific research study and the results and applications are valid and limited only to this study. The results do not approve or endorse the implantation of such prototype textile stents devices. The author has no control over the information given in the references and can't be held responsible for their content and authenticity.

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Style manual or journal used for proceedings,

Computer software used Microsoft Word and Microsoft Excel

Textile Research Journal

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CHAPTER 1

INTRODUCTION

1.1 Introduction to Medical Textiles

Textiles have always been a part of healthcare industry. Recently their applications have started going beyond usual wound care products, plasters, clothing, bedding, etc. With the latest innovations in textile technology, a wide variety of woven, nonwoven and knitted forms of textiles are increasingly creating their own platform into a variety of fields including bio-medical, surgical, and healthcare. Medical textiles come under technical textile category. Technical textiles is a US$ 60 billion market worldwide where medical textiles constitute around 8 % of it. Owing to greater application in medicine, there has been a significant rise in consumption of medical textiles in the last decade. In 1990, the consumption of technical textiles was around 7844 mega ton, which included 958 mega ton of medical textiles; in 2000 the figures were 11327 mega ton and 1374 mega ton, respectively. The industry experts expect these figures to reach 13688 mega ton and 1652 mega ton, respectively by 2005 [1].

By 2005, hygiene and medical textiles valued at US$ 4.1 billion predicted to account for almost 12% of global technical textile market [2]. Tissue engineering, which complies with textile structures to be implanted, has emerged as very promising for

developing many innovative applications in medicine viz. dental implants, bone grafting, breast repairing, ear-nose-throat applications, cosmetic surgery, etc. With greater co-ordination among experts from textile and healthcare industry, we could see a greater number of textile-based products used in medicine and health care industry in the near future. One of the main reasons for many parts of world not producing enough technical or medical textiles is a very high duty on import of its machinery coupled with the need of a high monetary investment. This will automatically result in higher demand for U.S. made biomedical textile products from all over world in the near future.

Medical textiles include but not limited to bandages, sponges, dressings, tapes, bed linens, under pads, bedpan covers, dental bibs, drapes, wraps, packs, blood oxygenerators, kidney dialyzers, instrument pads, orthopedic pads, hospital curtains, sterile packaging, etc. With the advent of textile technology, textile structures have also found their own place in implantable devices.

The term biomaterials is defined as materials that are used in contact with tissue , blood, cells, proteins and any other living substance. Biomaterials include metals, ceramics, polymers, natural fibers and their composites [3]. Textile endovascular prosthetic devices are defined as the textile biomaterials implanted inside arteries or blood vessels to keep vessel lumen open for longer time.

Medical textiles can be classified in three major categories as surgical products, extra corporeal devices and health care and hygiene products. The surgical products are again classified into implantable and non-implantable products. The classification of medical textiles is shown in Figure 1.1 [3].

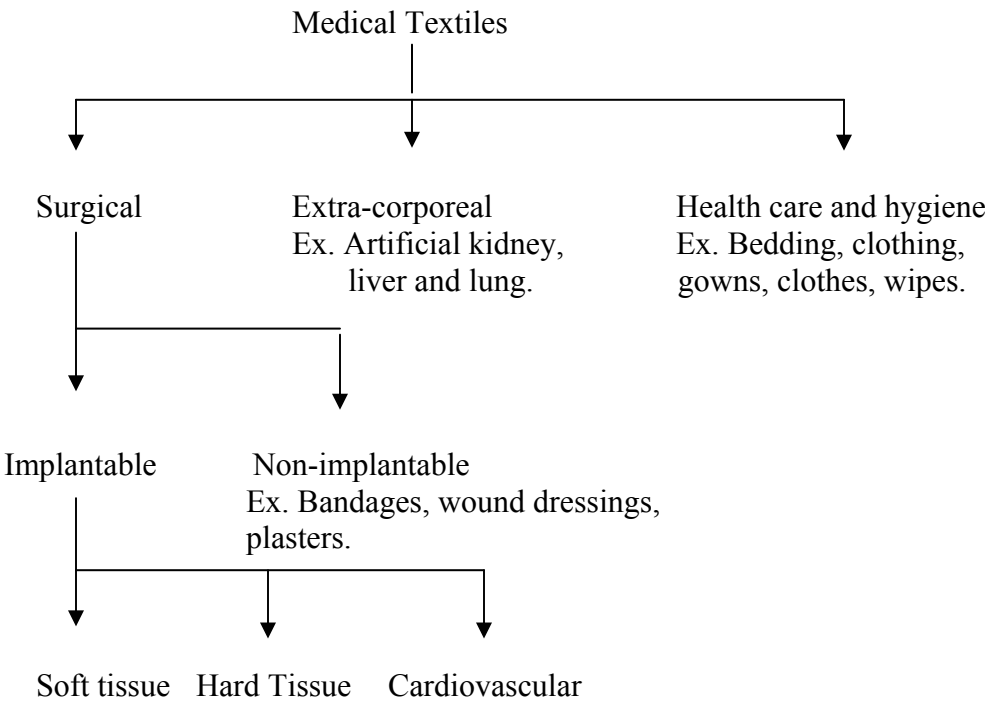

Figure1.1: Classification of medical textiles.

1.2 Textile Structures in Biomedical and Healthcare Industry

The first appearance of textile structures as biomedical material was a suture thread used for wound closings for more than 4000 years ago. Later, fiber forming polymers, woven structures, braids and nonwoven structures also started showing up in textile based medical and healthcare products. The present applications of textiles in biomedical field include their use in products ranging from gowns and wound dressings to sophisticated arterial and skin grafts. Textile materials such as fibers, yarns and fabrics have been explored as potential raw materials for usage in innovative as well as day to day biomedical textile products. Gupta [4] discussed various polymers, fibers and related textile structures used in medicine. He mentioned applications of nonwoven fabrics in wipes, sponges, dressings and gowns made directly from fibers by needle felting,

hydroentangling or bonding process. Sutures and arterial grafts are generally made from expanded Polytetrafluoroethylene (ePTFE). Braided materials are often treated with biodegradable (polylactic acid) or non-biodegradable (Teflon®) coating to reduce their capillarity.

Other biomedical applications of polymers involve implants and functions which do not have direct blood contact. In these applications problem of long term blood compatibility is not nearly as important. Nevertheless, these applications also have specific requirements associated with them. Gebelein and Koblitz [5] described the polymers for wound dressings and mentioned that artificial skin must have flexibility and permeability properties of natural skin and also be able to maintain these features for long term applications. The polymers must be capable of matching colors of skin at site and should not undergo discoloration on exposure to light, heat or everyday environment. A wound dressing or a temporary skin replacement, on the other hand must permit healing of sub dermal tissue.

Ulrich et al. [6] mentioned several applications of polyurethane elastomers, which can be divided into polyesters and polyethers. The authors mentioned successful use of polyurethane products in biomedical applications such as catheters, blood bags, solution containers, stoppers, endotracheal tubes, gas therapy tubing and heart assist devices. The authors also mentioned that heart assist devices formulated from polyurethane elastomer have shown longest survival in calves. Their flex endurance, wear resistance and vascular acceptability have made segmented polyurethane elastomers material of choice for heart assist pumps. Improvements in methods for characterization of polyurethane elastomers have produced superior materials and research related to these would be continued to

produce improved non-clotting polyurethane implants for blood vessels, nerves, bile ducts, and ureter and bladder repairs.

1.3 General Requirements of Textiles for Biomedical Applications

All materials to be used as medical textiles can be classified depending on whether they are natural or synthetic, biodegradable or non-biodegradable. All textile materials used in biomedical applications must be non-toxic, non-allergic, non-carcinogenic, and able to be sterilized without imparting any change in physical or chemical characteristics. The major requirements for biomedical polymers are non-toxicity (e.g. non-pyrogenicity, non-allergic response and non-carcinogenesis), ability to be sterilized (radiation, ethylene oxide gas, dry heating, autoclave), optimum mechanical properties (strength, elasticity and durability) and biocompatibility (bioinert, bioactive). A major concern with artificial implants is the reaction body will have towards implant.

Textile structures are widely used in biomedical engineering, especially as implantable devices. The first function of textiles as implantable material is the replacement of tissue. When no natural tissue is available or new tissue does not have the required properties like stability, extensibility or when penetration of tissue would not allow the device to function over long time, replacement function is necessary. Other function is to support the tissue, where textile structure reinforces new tissue, which penetrates pores of textile. For vascular grafts woven or knitted fabrics, for ligament prosthesis braids, woven structures, or warp knits and for tendon replacement braids or twisted yarn bundles are used. For any implantation, porosity and pore size of implant are the most important properties. These properties have great influence on in vivo behavior

of a textile implant. The in vivo behavior depends on interaction between product (material properties, textile structure, and manufacturing process) and body (environment around textile structure, and immune reaction of body). The surface chemistry and homogeneity of product are also important with regard to reaction of body [3].

Although it depends on specific application, in general, biomedical requirements for a satisfactory artificial implant may be stated as follows:

- A suitable artificial surface for cells to adhere and grow easily.
- Optimum porosity, which will allow tissues to grow and encapsulate the implant.
- Fiber diameter, in general, smaller than cell diameter for their adherence.
- Biodegradable or biostable depending on application.
- Non-toxic, where fiber, polymer or fabrication techniques must be non-toxic and fibers should be free from contaminations.

1.4 Textiles as Vascular Replacement and Endovascular Implants

Shumacker and King [7] were among the first to use textile structures as arterial substitutes. They implanted nylon tubes as substitute to defected arteries in humans. Considerable loss of blood occurred through those nylon arterial grafts; however, it became evident that it would be advantageous to render nylon tube impervious to blood. Then this objective was accomplished by placing a thin sheet of non-reactive polythene between two sheets of nylon and ironing the material with an iron temperature adjusted to wool setting. The low melting point of polythene as compared to high melting point of nylon was utilized to fuse together three sheets. In all six patients grafts functioned well.

A good aortic pathway has been re-established in all six cases. In all of them graft was sutured without difficulty. The authors concluded that plastic materials could be successfully used as aortic substitutes and advantages observed were low cost, easy availability, easy and quick manufacture, easy sterilization by autoclave, good tensile properties, easy suturability at the ends of vessels, and ability to be harvested before implantation.

Many researchers studied the application of textile materials as endovascular implants in humans. Dake et al. [8] studied the effect of transluminally placed endovascular stent grafts as an alternative to surgical repair like bypass. A total of 13 patients were selected and observed for a period of 24 months. Each endovascular stent graft was custom designed and had a self-expanding stainless steel stent covered with a woven Dacron®-polyester graft. The objective of this study was to evaluate feasibility, safety and effectiveness of stent grafts for treating descending thoracic aortic aneurysm. The results showed successful endovascular placement of stent graft prosthesis in all patients. Complete thrombosis of thoracic aortic aneurysm surrounding stent graft was observed in 12 patients and partial in one patient. There were no deaths or instances of paraplegia, stroke, distal immobilization or infection after an average follow up of 11 months. Thus these preliminary results demonstrated textile endovascular stent graft as a safe and successful alternative in highly selected patients. However the authors recommended careful long-term evaluation of this method.

1.5 Coronary Occlusion

The coronary blood vessels sometimes become occluded as a result of blood clots or other abnormalities that plug lumen of vessels. The vessels may get slowly and progressively occluded over a period of years.

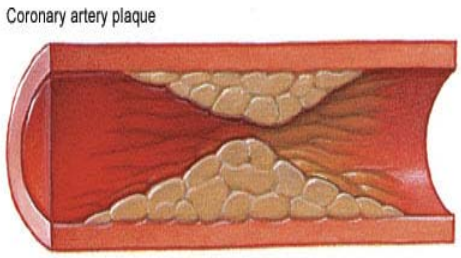

Figure 1.2: Coronary artery plaque www.mayohealth.org Access date: June 18, 2003

The most obvious cause of coronary occlusion is thrombosis resulting from atherosclerosis. Guyton [9] summarized the process of atherosclerosis as follows:

"In various diseases affecting lipid metabolism and also in old age, lipids containing mainly cholesterol and cholesterol salts get deposited beneath intima of major arteries. These deposits become calcified over a period of years and considerable fibrous tissue invades wall of these degenerating arteries as shown in Figure 1.2. These deposits are called as plaques. The plaques are generally gradual deposits of fat, cholesterol, calcium, and other cellular sludge from blood. Furthermore, atherosclerosis plaques occasionally break through intima of blood vessels and protrude into lumen. The presence of such rough surface inside vessel initiates clotting process. When a small clot is developed, platelets become entrapped and cause more clot to develop until vessel is plugged, or clot breaks away and plugs a smaller vessel further downstream. This mechanism causes more vessels to occlude. If blood flow to cardiac muscle is diminished

beyond a critical level, the muscle not only becomes non-functional, but also actually begins to die. Procedure of death of muscle fiber begins with about 1 hour of total ischaemia and completes in 4-5 hours".

1.6 Coronary Artery Disease

Coronary artery disease is the most common type of heart disease causing from atherosclerosis- the gradual build up of plaques inside blood vessels. Plaques both narrow and harden the arteries. This progressive narrowing and hardening of arteries over time is called as atherosclerosis. Atherosclerosis is a type of arteriosclerosis, which consists of various artery disorders. Plaques alone can significantly cause blockage of arteries. They can also become fragile and rupture, forming blood clots at the site or in further vascular stream of the body. These plaques actually narrow the artery so less blood flows through artery and ultimately to heart muscle. The reduced blood flow to heart muscle causes chest pain called as angina. A sudden complete blockage of arteries can also lead to heart attack. The coronary artery disease develops gradually, slowly and silently over decades. Generally it goes virtually unnoticed until it produces a heart attack. Coronary artery disease often occurs due to high levels of low-density lipoprotein (LDL) - so called as bad cholesterol- in blood. High blood cholesterol of this kind can be an inherited problem, but it is also a byproduct of poor health habits like eating high fat food. High blood pressure and smoking also contributes to atherosclerosis. Thus major risk factors for this disease include family history of heart disease, high blood cholesterol, high blood pressure, diabetes, smoking, and physical inactivity. Drugs and surgical techniques can repair narrowed coronary arteries, but best long-term solution is to make life style changes that can control risk factors related to coronary artery disease [9, 10].

1.7 Coronary Angioplasty – Opening Clogged Arteries

Angioplasty is a procedure to widen (dilate) a blocked artery. Angioplasty is originated from word angina, which means chest pain due to inadequate supply of blood to heart muscle. Angioplasty is also known as Coronary artery balloon dilation, Balloon Angioplasty, and Percutaneous Transluminal Coronary Angioplasty (PTCA).

In Figure 1.3, the term PRE means before angioplasty and the arrow shows the exact location of blockage. The size of artery looks small, this means artery has blocked and due to atherosclerosis it has become hard and narrow.

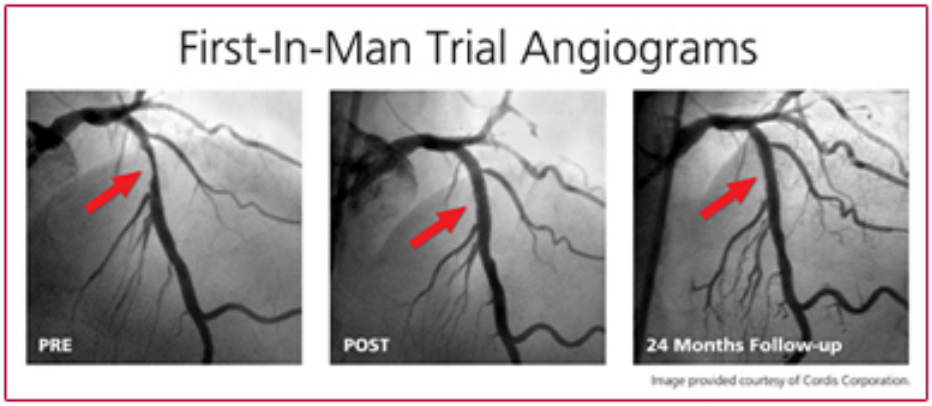

Figure 1.3: Angiogram showing arterial plaque and artery blockage.

Cordis endovascular photo library.

http://www.cordisendovascular.com/photo5.asp?photo Access date: June 18, 2003.

The procedure of balloon angioplasty is as shown in Figure 1.4.

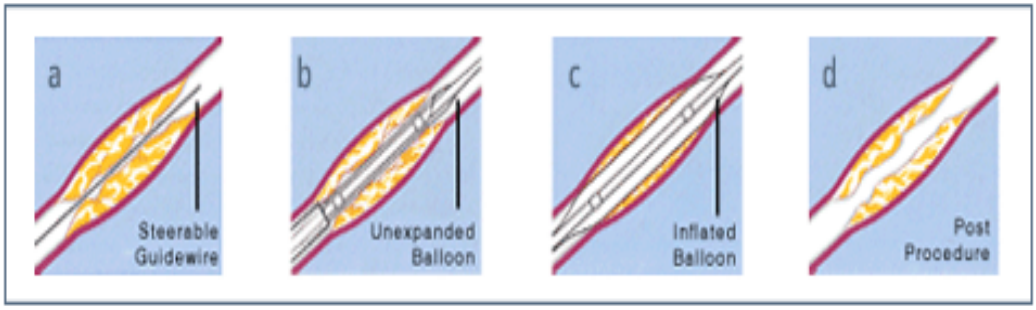

Figure 1.4: Balloon angioplasty procedure.

http://www.cypherusa.com/patient/treating_cad_options.jhtml Access date: June 17, 2003.

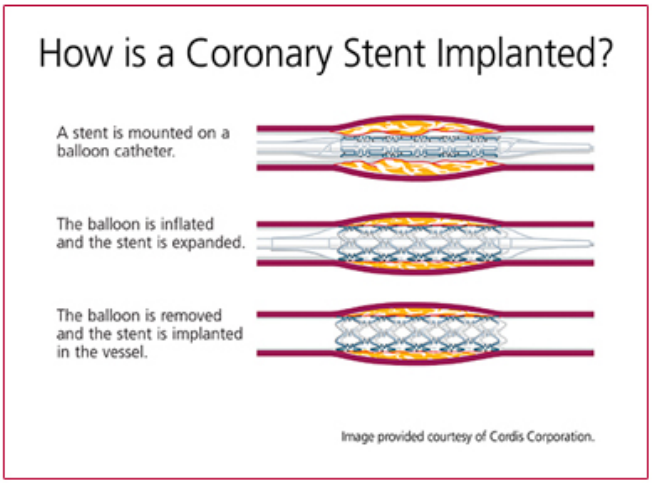

Figure 1.5: Balloon angioplasty with stent implantation.

Cordis endovascular photo library.

http://www.cordisendovascular.com/photo5.asp?photo Access date: June 18, 2003.

The more modified version is balloon angioplasty with stent. In this procedure once artery is opened by balloon, a stent is placed inside artery to act as scaffold to help keep artery open after angioplasty [9, 10]. When balloon is inflated, stent expands and locks itself inside the artery as shown in Figure 1.5. During angioplasty stent implantation is an optional procedure.

Stents do not completely eliminate reblockages from developing or causing artery to renarrow (restenosis). However stents reduce likelihood of renarrowing by about 50 percent. The recurrence of stenosis (blockage) after corrective surgery is called as restenosis.

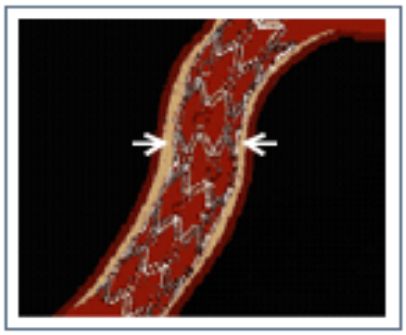

Figure 1.6: Angiogram of artery treated with stent.

http://www.cypherusa.com/patient/treating_cad_options.jhtml Access date: June 17, 2003.

Figure 1.6 shows angiogram of an open artery implanted with stent. These kinds of angiograms are taken periodically so as to check if artery is open or not. Generally occlusion of arteries is expressed in percentage.

1.8 Coronary Bypass Surgery

The main disadvantage of coronary angioplasty is that it does not eliminate the cause of artery blockage or remove defected artery itself. So arteries, which are stented, may become narrow again in the future, if lifestyle changes are not made after balloon angioplasty. Figure 1.7 shows an artery before, during and 12 months after stent implantation. The rightmost figure shows occluded artery after stenting. The plaque build up on the periphery of artery is clearly visible.

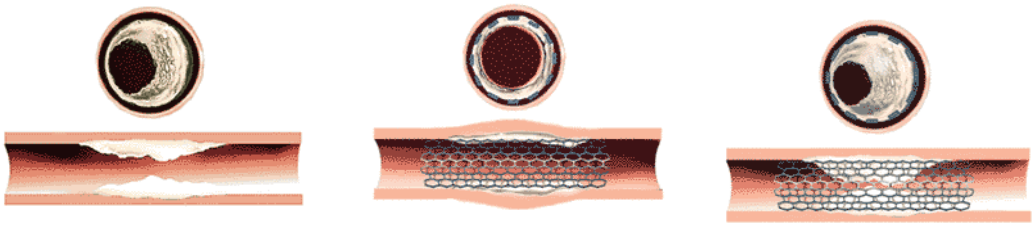

Figure 1.7: Artery before, during and after stent implantation.

www.mplsheart.com/pages/ NewsArticle.asp?ID=2 Access date: June 18, 2003.

When a passage of coronary artery is repeatedly clogged or multiple arteries are repeatedly blocked or left main coronary artery is severely blocked, a new route has to be created for blood. This is done by taking arteries or veins from other parts of body – called grafts- and using them to reroute blood by bypassing clogged artery. Graft segments are generally generated from saphenous vein, which runs just beneath the surface of leg. This surgery is called as Coronary Artery Bypass Grafting (CABG). The heart after bypass surgery is as shown in Figure 1.8. This is an open-heart surgery [9, 10].

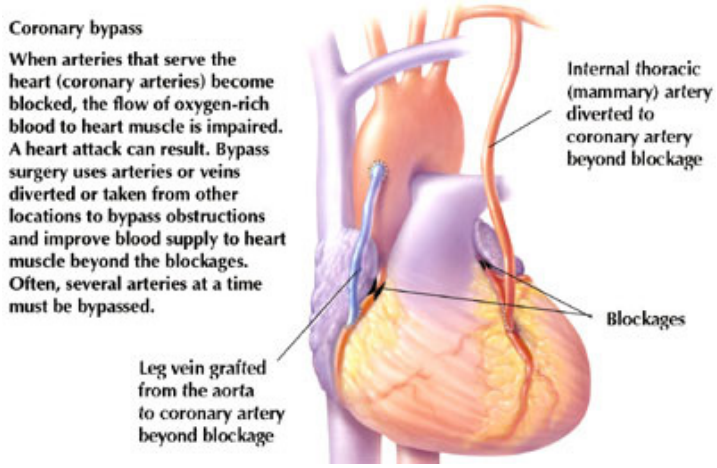

Figure 1.8: Coronary bypass surgery.

www.mayohealth.org Access date: June 18, 2003.

Please refer Appendix C (page 113) for key terms and their meanings.

CHAPTER 2

LITERATURE REVIEW

2.1 Introduction to Stents

Various definitions of stent are as follows:

"Stent is defined as an optional endovascular mechanical scaffold, implanted during balloon angioplasty to keep artery lumen maximum open for longer time" [10].

"Stent is a device placed in a body structure (such as a blood vessel or gastrointestinal tract) to provide support and keep the structure open" [11].

"Stent is a tube made of metal or plastic that is inserted into a vessel or passage to keep it open and prevent closure due to a stricture or external compression" [12].

Advantages of using stent in balloon angioplasty:

- Stents provide fixation through columnar strength or proximal anchoring or by both and also improve clinical outcome by treating acute and threatened vessels which are near to closure.
- Stents are easy to use compared to atherectomy and laser devices.
- Stents provide improved and less invasive outcome in most complex lesions.
- Compared to only balloon angioplasty, stents improve long term clinical and angiographic outcomes.
- Stents provide a much more predictable and acute angiographic outcome.

The success of stent therapy depends mainly on stent design, types of underlying lesions to be treated, state of sclerotic disease, and lesion length. While using a stent one must also consider a more complex medical treatment including minimizing the effect of risk factors such as smoking, hypertension, hypercholesterolemia, diabetes and hyper coagulability. Out of all other alternative methods, only balloon angioplasty is found to be most successful. For femoral popliteal arteries, after balloon angioplasty the patency rates range from 40-70%, where as iliac results ranged up to 90%. Technical success in these cases mostly depends on the type of lesion. Treatment of short (< 2cm), concentric, and non calcified restenosis has shown 70% patency for over 5 years, but it is clear that therapy of short occlusions observed to be less successful. Alternative recanalization technique like hottip laser, rotax catheter and laser angioplasty have nearly abandoned [13].

Before stent implantation information will be required about each aneurysm or site where stent is to be implanted. The knowledge of length and diameter of cuff, length of aneurysm, tortuous curves if there are any, and size and morphology of artery is very important. Accurate preoperative balloon sizing is of critical importance while using a balloon expandable stent because a stent once dilated becomes of fixed diameter.

Requirements of ideal textile stent:

- The textile stent must have all basic properties such as porosity and compliance depending on patient's history and implantation site requirements. The biomedical properties of stents especially depend on stent's surface chemistry, surface energy and surface texture, both at the time of implantation and after

prolonged time of implantation. For a textile surface to be biocompatible it should have minimum surface area, low surface potential and no impurities.

- The fabric structure must be blood impermeable but tissue permeable so as to form well anchored neointimal lining.
- The textile stent must maintain vascular luminal diameter > 80% of normal lumen diameter, avoiding thrombosis, spasms and all kinds of other complications.
- The textile stent must adhere securely to atherosclerotic scuff. Any movement can cause significant arterial damage.
- The expansion ratio of stent and fabric covering it must be large enough to allow the stent to fill aortic lumen. The textile stent must be flexible enough to fit in a delivery system and able to travel through tortuous and angulated path inside arteries or stenotic regions.
- The fabric must be thin enough to be inserted inside delivery system and strong enough to withstand arterial pressure without excessive dilatation.
- The textile stent must compress plaque against arterial wall, control elastic recoil of media after dilatation, and prevent intimal dissections.
- The textile stent must have the ability to resist successive compressive loading. There should not be any change in physical or chemical properties of textile stent due to blood flow, blood pressure and even balloon dilatation. It must be immune to fatigue. The textile stent must be visible in imaging equipments like MRI after implantation inside the body.

- The stent must have excellent suturablity, and sutures must be stable. The structure of stent must be user friendly so as to facilitate transport, handling and storage. The textile stent must be available in all sizes and at reasonable cost.
- The textile stent must be approved by U.S. Food and Drugs Administration [14].

2.2 Types and Functions of Stents

Percutaneous endovascular stenting is defined as a non-surgical method, in which a stent-metal meshwork device- is percutaneously placed into vascular lumen for protecting vessel against abrupt closure, maintaining blood flow of vessel and preventing late restenosis of vessel. The efficiency of stenting depends on intrinsic and spontaneous expansive force of stent, diameter of recipient vessel, intrinsic pressure of vascular wall itself and dilating ability and diameter of balloon used for stent delivery. After implantation stent is covered by proliferation of cells of intimal layer and gets embedded in vessel wall. The rapid endothelialization results in a smooth and regular lumen at stented site, which improves blood flow in stented lumen and prevents possibility of stenosis or thrombosis. Stents can be divided into three major types such as coil stents, self-expandable stents and balloon expandable stents. A coil stent is composed of coiled stainless steel wire mounted co-axially over a guide wire, which is positioned with a pusher catheter and then implanted into artery. The inherent disadvantage of this is significant narrowing of stented lumen and small diameter of tubular coils with high rate of thrombosis. Self-expanding stent group consists of self expanding spirals (Mass stent), self expanding zigzag stent (Gianturco stent) and wall stent (Medinvent stent). Balloon expandable stents include Palmaz stent and Strecker stent, which are most common and popular for implantation in humans. Palmaz stent is a stainless steel tube with parallel

rows of staggered rectangular slots etched in its wall. For deployment, stent is coaxially mounted onto an angioplasty balloon catheter, and then manually crimped up to target size by an assembly advancing over the guide wire. The newest type of balloon expandable stent is Strecker stent (tantalum stent). Strecker stent is a flexible and interwoven mesh made up of a pliable, elastic and highly radio-opaque tantalum wire. It is wrapped tightly around an angioplasty balloon catheter [15].

2.3 Background and History of Vascular Implants and Stenting

Voorhees et al. [16] first explored application of textile materials as implants by using vinyon N cloth tubes for bridging arterial defects in 15 dogs. The prosthesis was made from 37 denier yarn, 144 × 90 strands per square inch, vinyon N cloth. The cloth was folded and stitched longitudinally to form tubes of desired length and diameter. All prostheses were sterilized by boiling prior to use. Out of 15 dogs, 8 have been sacrificed, 3 died from causes other than failure of prosthesis and 4 lived well. In 4 of these the tubes were patent and without significant mural thrombi. Foreign body reaction about vinyon N cloth was completely absent. Fibroblasts growing into and through interstices of cloth were observed throughout the cloth section. The longest postoperative follow-up period was 153 days and shortest was 24 hours. The authors concluded that porous vinyon N cloth tubes can be used as arterial prosthesis in abdominal aorta of dogs.

Hufnagel and Rabil [17] followed the study done by Voorhees and co-workers with a study of implantation of number of plastic materials in an attempt to evaluate usefulness of these materials and find materials which avoid disadvantages of vinyon. The authors investigated polymers of acrylonitrile (Orlon®), varying forms of nylon,

Orlon® coated with silicone, Dacron® and glass fiber. These materials were selected on the basis of their physical properties. For prostheses applications cloth was made into a tube by sewing it into a tubular form. The ends of tube were slightly flared and then turned back as a cuff. The tubes were sewn by hand and a double suture line was used. The tubes were 4-10 cm in length and 5-12 mm in diameter. When implanted in abdominal aorta of dogs, tubes from 5-7 mm in diameter showed 90% patency over a period of 1 year. No disruption of graft or aneurysm was observed at suture line. The authors concluded that their study showed uniform patency in vessels down to size of abdominal aorta of dogs. Encouraged by this success authors implanted 15 orlon prostheses in humans to replace abdominal aortic bifurcation in case of aneurysm and chronic occlusion. The authors found all prostheses patent for a follow up period of 16 months with no complications of haemorrhage or aneurysm formation. Thus authors concluded that Orlon® prostheses could be used as replacement of aortic bifurcation, iliac arteries and femoral arteries in humans.

Following these positive results Wesolowiski et al. [18] carried a three year study involving over 350 growing pigs and dogs using 37 different synthetic fabrics. The object was to establish specifications for ideal synthetic vascular material. The synthetic materials tested involve 1 vinyon N, 2 nylon, 2 Orlon®-acrylic, 15 Dacron®-polyester, 11 Teflon®, 2 ivalon, 2 glass and 2 lead fabric samples. The authors suggested that ideal synthetic vascular graft material must be non-toxic, non allergic, durable and must not show any deterioration on prolonged implantation. The graft material must have certain desirable physical properties. The authors concluded that implantation porosity of grafts should be less than 50 ml of water per minute per square cm of graft wall at a pressure

equivalent of 120 mm Hg. Calcification inside grafts could be avoided if porosity of material was greater than 5000 ml of water per minute per square cm of fabric with a pressure head of 120 mm of Hg.

2.4 Success with Stenting

Transluminally placed endovascular stent grafts (TPEGs) represent a new concept in vascular surgery, integrating principles of standard prosthetic grafting with endovascular techniques. The first published study on stent implantation in humans was by Sigwart et al. [19]. The object of this study was to develop an intravascular mechanical support with the aim of preventing restenosis and sudden closure of diseased arteries after angioplasty. The endoprosthesis developed for the support consisted of a self expandable stainless steel mesh that can be implanted non-surgically in coronary or peripheral arteries. 24 coronary stents were implanted in 19 patients who presented with coronary artery restenosis in 17 cases, abrupt closure after transluminal angioplasty in 4 cases and deterioration of coronary bypass graft in 3 cases. The aim of authors was to deal with problems of balloon angioplasty such as acute occlusion and late restenosis. The stent was woven from a surgical grade stainless steel alloy formulated according to specifications of International Standards Organization. The stent was geometrically stable, pliable and self expanding. Follow up in all patients continued for 9 months, which showed no further evidence of restenosis within stented segment. Thus the authors concluded that stents offered a useful way to prevent occlusion and restenosis after transluminal angioplasty.

The object of the study conducted by Bonn et al. [20] was to assess safety and efficacy of Palmaz balloon expandable vascular stent and its effect on results of

percutaneous transluminal angioplasty. The authors also reviewed technical aspects of stent implantation such as angiographic and haemodynamic effects and early clinical response. The authors discussed potential indications for stent placement and its role in relation to conventional Percutaneous Transluminal Angioplasty (PTA). In this study 35 Palmaz balloon expandable intraluminal stents (Johnson and Johnson, NJ) were percutaneously placed in 23 limbs in 19 patients. Technical success was achieved in placement of 34 of 35 stents. The Palmaz stent was effectively dilated and maintained patency of all 37 lesions in 19 patients. The authors concluded that stent placement was effective and did not significantly increase complication rate of conventional iliac PTA.

Rees et al. [21] implanted 21 Palmaz balloon expandable intraluminal stents (Johnson and Johnson Interventional systems, Warren, NJ) in 12 patients who underwent recanalization and stenting of iliac occlusions. In this study, percutaneous transluminal angioplasty has been extended by placement of a balloon expandable intraluminal stent across diseased arterial segment as a means to oppose elastic recoil of recanalized segment. After implantation repeat evaluations were obtained at 2 weeks, 1 month, and at 3, 6, 9, and 12 months. This allowed measurement of luminal diameter and calculation of neointimal thickness. Follow up clinical and non-invasive laboratory findings indicated that all stents were patent. The authors concluded that their early experience suggested important role of stents in management of iliac occlusions. However the authors suggested further investigational research as patient population in their study was very small.

The purpose of the study conducted by Marin et al. [22] was to perform a preliminary histopathologic analysis of explanted human endovascular stented grafts

implanted in patients treated for occlusive disease. Over a 16 months period, 26 endovascular stents were placed in 21 patients with limb threatening ischaemia caused by femoral artery occlusive disease. During the follow up period 7 months after grafting a portion of endovascular graft with surrounding artery was explanted. Specimens of 5 other endovascular grafts were obtained during surgical revision for graft stenosis after 3 and 6 weeks and for outflow artery restenosis after 3, 5 and 6 months. The stent grafts were composed of 6 mm PTFE grafts. A Palmaz balloon expandable stent (P 294, Johnson and Johnson Interventional systems, Warren, NJ) was sutured to each graft with 4 CV-6 Gore Tex® sutures. Three weeks after implantation of transluminally placed endovascular grafts, the graft tissue specimens were encased on both internal and external surfaces by organizing thrombus. After 6 weeks, grafts showed firm attachment between native arterial wall and external surface of graft. The luminal surface of graft was observed to be covered with neointima composed of a thin fibrous tissue base and an overlying cell monomer. After 3 months neointima was observed to be well developed. The specimens examined between 3 and 7 months showed well-incorporated external surface of graft. In one failing graft specimen, which was explanted 3 months after grafting, a significant stenosis was found. The graft demonstrated marked neointimal thickening over 15 mm grafted segments. From these observations authors concluded that the healing of PTFE endovascular stented grafts in humans demonstrated limited plaque hyperplasia and presence of endothelial cells on luminal surface. The authors also noted that it was unclear whether that was a unique manifestation of healing of prosthetic grafts inserted within the walls of arteries or not.

The purpose of the study conducted by Jaegere et al. [23] was to review immediate and long-term results of intracoronary stenting reported in literature and reflect future developments. The data reported in this paper was originated from a wide variety of patients. It was considered that high implantation success rate does not apply to general population referred for coronary intervention, since it was clinical practice to select patients on the basis of their suitability for stent implantation. The advantages of metals in stents over other materials were their high long-term integrity, relatively low profile and small surface area. Also most metals found to be electropositive and thus thrombogenic because blood particles are negatively charged. The authors discussed their results as follows:

> It is clear that stent implantation results in significant further improvement in stenosis geometry compared with balloon angioplasty. There is a greater than 1 mm increase in minimal luminal diameter with stent implantation, compared with less than 1mm following balloon angioplasty. Stent implantation results in a residual diameter stenosis of less than 20 % with normalization of calculated resistances to flow and pressure to drop across the stenosis. The immediate changes in stenosis geometry do not differ between self-expanding and balloon expandable devices. At follow-up, however, loss in minimal luminal diameter following stent implantation is considerably greater than in patients following balloon angioplasty. Despite this larger loss, the minimal luminal diameter at follow up in patients after stent implantation is greater than those who underwent balloon angioplasty. Both animal studies and pathologic and angiographic observations have shown independently that degree of neointimal

thickening is related to severity of vessel wall injury. The use of multiple stents has identified as a risk factor for restenosis.

The objective of the study conducted by Mitchell et al. [24] was to investigate the feasibility and efficacy of stent grafting for treatment of descending thoracic aorta aneurysms. For this study, 103 patients underwent endovascular repair of their thoracic aortic aneurysm with self expanding Z stents covered by a woven Dacron®-polyester tube graft (Meadox- Boston Scientific, Boston, MA) between July 1992 to November 1997. A custom fabricated stent graft, oversized by 10-15% compared with CT-scan determined diameters, was then positioned optimally and deployed. The average stent graft diameter was 3.5 cm and average length was 10.5 cm. Primary success was defined as achieving aneurysm exclusion during first treatment session and before stent follow up CT scan and secondary success as an endoleak subsequently treated successfully. Follow up averaged 22 months, and was 100 % complete. Complete aneurysm thrombosis was achieved in 86 patients and early morbidity was observed in 9 +/- 3% patients. The authors concluded that results were satisfactory. The authors also suggested that mortality and morbidity might have been associated with high risk character of patient population.

Hennersdorf et al. [25] reported percutaneous coronary transluminal angioplasty in a 67 year old patient in his left anterior descending artery in February 1993 with a residual stenosis of 30%. In June 1993, a repeated percutaneous coronary angioplasty was necessary for high grade symptomatic restenosis. Finally in October 1993 a combined excimer-laser and balloon angioplasty was performed after development of a second restenosis. A 3.0mm Palmaz-Schatz stent with a length of 14 mm was implanted with a 3 mm balloon catheter at a maximal inflation pressure of 12 atmospheres. The coronary

angiography performed after 6 months showed a good long-term result without restenosis; a coronary artery aneurysm was no longer detectable. The authors concluded that coronary aneurysms could be treated effectively and permanently by implantation of a stent.

The objective of the study done by Sambeek et al. [26] was to investigate the preliminary use of endovascular stent grafts for treatment of femoropopliteal artery aneurysm. Ten patients with an aneurysm of femoropopliteal artery referred for endovascular treatment were investigated. The series consisted of patients with a true aneurysm of superficial femoral artery (n=2); a true aneurysm of popliteal artery (n=4); an aneurismal dilation of a biograft bypass (n=2); a false aneurysm of superficial femoral aneurysm (n=1); and a false aneurysm of a composite bypass (n=1). In 8 of 10 patients, the stent graft was composed of one or more Palmaz stents sutured to an ePTFE tube graft; in other two patients a venous covering was used in combination with Palmaz stents. The procedure was guided by angiography and intravascular ultrasound. The results showed that endovascular stent grafting of aneurysms of femoropopliteal artery was a feasible but experimental procedure, and should be restricted to a selected group of patients.

Lupattelli et al. [27] evaluated the efficacy of percutaneous transluminal angioplasty and subsequent Strecker stent implantation for treatment of chronic iliac artery occlusions. A total of 39 patients were subjected to this procedure. The occluded vessels were catheterized, dilated and subjected to stenting in all patients. The Strecker stent was introduced percutaneously, positioned at the level of stenosis and expanded by inflating balloon. The stent consisted of a tubular network of loosely connected tantalum

wire loops having diameter of 0.1 mm. The length of occlusion varied from 4.5 to 10.5 cm and lesions were located in common iliac arteries (25), external iliac arteries (10) and in combination of both (4). After stenting procedure, 37 out of 39 patients showed a statistically significant improvement in clinical symptoms, while in 2 patients a complete occlusion resulted due to long dissection not covered by the stent in one case and stent misplacement in other case. At 6 months follow up, 89.7% patency was observed. The authors concluded that Strecker stent could be successfully implanted in addition to percutaneous transluminal angioplasty (PTA) to treat iliac arteries.

The purpose of the study conducted by Wirthlin et al. [28] was to review the experience with hybrid aortic stent grafts and compare outcomes of hybrid grafts to standard grafts in an attempt to define role of hybrid grafts in endovascular treatment of abdominal aortic aneurysms (endoAAA). Endografts were classified as hybrid, if components from more than one type of stent graft were used and standard if constructed only from one stent graft type. Hybrid grafts were classified as ‘anticipated’, if surgeon stated in operative report the need for additional graft was expected and all others were classified as ‘unanticipated’. One objective of this study was to compare anticipated grafts with unanticipated ones based on type of intraoperative endoleak and supplemental components used to create a hybrid. The outcomes of hybrid grafts were compared to those of standard grafts and significance was defined as p value < 0.05 using Fisher’s exact test. During the study period, 145 endoAAA repairs were performed. The authors concluded that, outcomes for all categories were similar for hybrid versus standard grafts: technical success (93 versus 99%), conversion to open AAA (7.1 versus 2.3%), vascular complications (7.1 versus 7.6%), systematic complications (21 versus 11%), endoleak (15

versus 14%) and rupture (0 versus 0%). The authors also concluded that the short-term safety and effectiveness of hybrid grafts was similar to those of standard grafts. They suggested that combining of these grafts might improve the ability of grafts to treat complex iliac aneurysm diseases. The authors also suggested the need to determine long-term effectiveness of hybrid grafts.

Schalij et al. [29] implanted 119 Micro stent II (MS-XLs) in 102 patients (average age= 62.83 years). Nineteen stents (16%) were implanted in saphenous vein graft and 100 (84%) were implanted in native coronary arteries. The objective of the study was to evaluate in vivo results of long Micro stent II (MS-XL). Twenty five patients (25%) were treated because of acute myocardial infraction, thirty (29%) for unstable angina, and 47 (46%) because of stable angina. Eighty six de novo lesions (84%) and sixteen restenotic lesions (16%) were treated. The results showed that 116 MS-XLs were implanted successfully. The minimum lumen diameter increased from 0.5 +/- 0.5 mm before to 2.7 +/- 0.5 mm after stent implantation. The acute gain was 2.2 +/- 0.4 mm. Early clinical events (< 4 weeks) include death in 3 (3%), sub acute stent thrombosis in 1 (1%), non Q wave infraction in 2 (2%), CABG in 1 (1%) and vascular complications in 2 (2%). Late clinical events (> 6 months) include acute myocardial infraction in 5 (5%), reintervention in 6 (6%) and CABG in 1 (1%). The procedural success rate was 88%. Authors concluded that stenting of long lesions with MS-XLs stent was successful but associated with an acceptable complication rate.

The objective of the study conducted by Formichi et al. [30] was to validate ease of deployment and in vivo healing performance of nitinol-polyester self expanding stent graft using a canine thoracic aortic aneurysm model. Arterial aneurysms were surgically

treated in 8 dogs by sewing polyester patch onto anterior side of thoracic aorta. Nitinol polyester self expanding stent grafts were implanted transluminally via femoral route and deployed at the site of throracic aneurysm. Aneurysm exclusion and endograft patency were accessed by angiography after implantation and before animal sacrifice at scheduled periods ranging from 1 week to 3 months. The explanted specimens were examined with MRI. Seven out of eight stent grafts were implanted successfully; a bend occurred within anuerysmal sac in 1 dog. At the time of explantation, all devices were structurally intact and well positioned. No exacerbated inflammatory reaction due to either nitinol wires or polyester sleeves was observed after 3 months of implantation. The authors concluded that nitinol-polyester self expanding stent graft demonstrated effective exclusion of thoracic aneurysms with a satisfactory healing response and no excessive tissue or inflammatory reactions.

2.5 Complications with Stents and Stenting

Lampmann [31] suggested stenting in superficial femoral artery to be controversial treatment in case of occlusive diseases. He argued as, although results of percutaneous treatment especially in hunter canal region were moderate, balloon angioplasty has potential to become an established technique. Many investigators tried to improve their results with additional stenting of superficial femoral arteries after inappropriate results of balloon angioplasty or stenting. After using graft materials with stents, results in literature were not as consistent as they should be. The author strongly recommended not performing stenting on a routine basis unless main issue of extensive intimal hyperplasia was cured.

Restenosis is a major drawback of coronary angioplasty. Stents are the only less invasive means of reducing incidence of restenosis. Unfortunately, intra-stent restenosis still occurs in 20-30% cases following prosthesis implantation. Neointimal proliferation (NIP), composed of smooth muscle cells and extra cellular matrix, is one of the major mechanisms of intra stent restenosis. The endothelial cell (EC), acting as interfaces and transducers of biomechanical and humoral stimuli, is one of the major factors promoting NIP. Generally three distinct phenomena lead to NIP:

- The expansion of stent wires at the time of implantation can result in severe vascular trauma, which leads to NIP.
- Stent implantation induces complex interactions between blood components and metal structure of prosthesis. The material roughness of stent surface can affect adsorption of plasma proteins, which may lead to NIP.
- The stent implanted may alter coronary flow and induce changes in pressure distribution, flow velocity and streamline. These changes result in local modification of mechanical stress exerted on EC.

These changes also cause in applying various shear stresses on EC. Also when EC proliferation increases dangerously, they are subjected to weak shear stress. Thus restenosis develops preferentially in areas where endothelium is exposed to a low and oscillating stress. EC reacts to low shear stress by releasing adenosine di and tri phosphate to induce macroscopic platelet aggregation. Also when EC are subjected to a strong wall shear stress, amount of nitric acid secreted increases significantly leading to an inhibition of EC growth. Thus morphology and functions of EC are connected to local

wall shear stress which ultimately leads to NIP. Zones with high EC proliferation are localized at sites of low Wall Shear Stress (WSS), as strong shear leads to cell migration. Thus stimulation of endothelial cells by arterial WSS plays a central role in restenosis [32].

Cwikiel [33] described the origin of restenosis as follows:

> Percutaneous transluminal angioplasty or insertions of stents cause injury to vessel wall followed by healing process. This process can result in restenosis, caused by intimal hyperplasia and a remodeling of artery, also called as chronic spasm. Development of restenosis is more frequent after treatment of long stenosis and occlusions, while best results are obtained after treatment of short stenosis. The lumen diameter of treated artery is important and generally inversely proportional to frequency of significant stenosis. While stent implantation, both stenotic segment of artery and also normal artery adjacent to it is dilated. The entire dilated segment is denuded of endothelium and about 20% of smooth muscle cells in media are damaged. The circumferential stretching of artery wall can cause disruption of internal elastic membrane and also of media. Originating from plaque, intimal dissection can occur, and severity of injury correlates to degree of subsequent intimal hyperplasia. The atherosclerotic plaque intrudes into wall of artery and can also cause fracture. Immediately after stent implantation, its surface will be covered by a strongly adherent monolayer of proteins in about 5 seconds. After 1 minute surface is uniformly coated by five layers of proteins, predominantly fibrinogen. The holes between stent wires are filled with thrombus composed of fibrin, platelets, and white and red blood cells. The amount of adherent platelets and leukocytes increases during first few hours after stent implantation. The primary response of vessel wall is exactly similar to

events described above with proliferation and migration of smooth muscle cells and formation of neointima. The thrombus formed between stent wires is successively replaced by proliferating neointima. This initial hyperplasia can cause restenosis in lumen or at edges of stent. Endothelialization starts immediately after the procedure and will continue until stent and stented segment of artery are covered by immature endothelium, which takes approximately 3-4 weeks.

The objective of the study carried by King et al. [34] was to characterize changes in microstructure of polyethylene terephthalate biotextiles retrieved from patients after 2 to 16 years in vivo. This study used thermal analysis, FTIR spectroscopy, and vapor phase dyeing techniques for characterization. The authors from their previous study demonstrated that once implanted, the fibers swell and absorb a variety of biological species in addition to producing various monomer and oligomer fragments. The authors were particularly interested in knowing whether this swelling behavior significantly changes microstructure of fibers and changes occur throughout diameter and/or on surface. The authors used random stratified sampling and retrieved arterial prostheses. Each explant was photographed and a pathological examination of luminal surface was done by routine histology and SEM. The current study pointed out a complex model in which slow biodegradation of polyester fibers in vivo indicated a multi step process. After fiber swelling, molecular chain scission has commenced and an increasing proportion of amorphous material near fiber surface appeared to be lost. The microcrystalline structure could then be reorganized through growth of larger crystalline regions at the expense of smaller ones and amorphous regions. The resulting ‘annealed’

structure would likely to offer improved resistance to further degradation and showed why kinetics of chain scission was not linear but follow a logarithmic decay mode.

The object of the study conducted by Guidoin et al. [35] was to examine structure and healing characteristics of chronically implanted stentor endografts which were explanted due to migration, endoleak, and thrombosis or aneurysm expansion. Also goals were to ascertain cause of mechanical failures that contribute to complications mentioned above and assess physical and chemical stability of endograft materials and structures involved in device construction. Special attention was given to nitinol's chemical stability as it was used as stent material. All endovascular prostheses were first generation modular stentor devices manufactured by MiniTec (LaCiotat, France) with thin woven tubular polyester covering sewn along its longitudinal side. The metallic tubular frame was composed of several zigzag nitinol elements held together with polypropylene monofilament sutures. The endovascular devices were provided to Quebec Biomaterials Institute by surgeons participating in EUROSTAR program. Structural modifications in metal components were examined using radiography, endoscopy and Magnetic Resonance Imaging (MRI). Specimens taken from components of stent grafts were examined histologically and with SEM to assess healing behavior. Physical and chemical stability of nitinol and polyester woven grafts was evaluated using SEM and electron spectroscopy was used for chemical analysis. SEM of the polypropylene sutures showed evidence of surface deterioration characterized by uniformly spaced circumferential cracking, peeling and flaking of polymer material in outermost surface layer. The textile structure showed evidence of yarn shifting and distortion and tendency towards yarn damage and filament breakage. The authors concluded that these phenomena could lead

to hole formation in the structure, which in turn would cause blood leakage and progressive growth of aneurysm and finally its rupture. Holes and openings in structure were also created by yarn damage and filament breakage. The broken filaments were the result of 2 distinct phenomena such as abrasion of explant over certain defined regions, which suggested movement between fabric structure and arterial wall and puncturing action or impact of a sharp surface against fabric. SEM of nitinol wires revealed corrosion on surface of wires. Corrosion marks were observed on numerous zigzag elements.

The objective of the study conducted by Riepe et al. [36] was to examine durability of Stentor and Vanguard endovascular devices in human implants. A total of 34 devices, 25 Stentor (MiniTec, Bahamas) and 9 Vanguard (Boston Scientific, USA) have been examined. The mean duration of these grafts implantation was 29.8 +/- 16 months, samples ranging implantation time from 1 to 64 months. The grafts were explanted due to endoleak (26 cases) and occlusion (5 cases). In 2 cases the cause of explant was unknown. These Stentor and Vanguard devices have an internal self-expanding nitinol stent covered with approximately 0.16 mm thin woven polyester fabric on outside. The stent was composed of zigzag shaped wire spirals. The spirals were held together by approximately 0.09 mm thick polypropylene ligatures. All explanted grafts were examined by Scanning Electron Microscopy (SEM). The polyester covering of grafts showed two types of damage, visible by naked eye. Seventeen Stentor devices showed up to 1 mm wide gaps along sutured seam. Eighteen explants showed isolated holes in fabric due to wear between metal frames. All examined polypropylene ligatures connecting the stent showed signs of wear. The main damage to ligatures was observed

as kinks in graft and between body middle rings and upper ring. SEM showed signs of corrosion on nitinol wires. Authors classified nitinol's wire corrosion in 4 types as small circular or oval pits (100%), bizarre or map shaped craters (68%), large surface deficiencies (14%), and wire fractures (32%). The authors concluded that missing fixation of stent frames resulted in a loss of stability, allowing stent frames to slip over one another, leading to kinking and longitudinal shortening of graft. This was also the source of damage to the fabric. Creases in polyester fabric between moving frames, caused fractures in textile cover. Another important conclusion was that corrosion of stent wires surely was an indicator of wire fractures.

Briguori et al. [37] compared early and late outcome of patients with complex coronary lesions in small vessels (< 3mm) treated with traditional coronary angioplasty (angioplasty group) with elective stent implantation (stent group). Angioplasty group (n=97) and stent group (n=112) were comparable for all clinical and angiographic characteristics. All patients in 2 groups had angiographic follow up. Major adverse cardiac events and restenosis rate were evaluated. No patients in 2 groups experienced in hospital death or bypass surgery. Myocardial infraction occurred in four patients in angioplasty group and in seven patients in stent group. Long term major adverse cardiac events were not different in two groups. Target lesion revascularization rate was 33% in angiography group and 34% in stent group. The authors concluded that compared to balloon angioplasty elective stent implantation in small vessels with complex lesions did not improve early or late outcomes.

Babalik et al. [38] reported stenting in left popliteal artery. The mentioned 48 year old patient was diagnosed with coronary artery disease in two vessels; a severe stenosis in

proximal segment of left popliteal artery and 50% narrowing of right popliteal artery. Self-expandable (Angiomed Memotherm stent; C.R. Bard Inc, GA, USA) stent was first implanted. Repeat angiography showed repeat covering of lesion with stenosis, so another stent was implanted overlapping the first stent. The length of overlapping was approximately 1.8 cm determined by comparing balloon diameter with second stent diameter. There were no complications related to angioplasty procedure. Six months after the initial procedure, repeat angiography showed that the stent in left popliteal artery had completely fractured at the point of overlap. Late stent failure, mainly restenosis was attributed to intimal hyperplasia, which was also considered to be mechanism of stent failure in most cases with peripheral artery disease.

Sullivan et al. [39] evaluated vascular wall response to superficial injury, without Internal Elastic Lamina-IEL rupture after balloon angioplasty and intravascular stent placement in porcine arteries. The effect of stent strut geometry on degree of vessel injury and early restenosis were also determined. In this study balloon expandable stainless steel stents were placed into iliac arteries of 10 swines. A Palmaz stent with rectangular struts and smooth corners, was randomly assigned to iliac arteries (group 1), and a novel stent which was designed and manufactured in laboratory with thicker struts and sharper corners which specifically induce larger wall stress concentrations, was placed in contra lateral iliac artery. Intravascular ultrasound was used in all deployments to ensure accurate balloon sizing and avoid stent over expansion or deep vascular injury. The results of this study showed that there was no correlation between the amount of medial compression (short of IEL rupture) and degree of restenosis and neointimal hyperplasia. This observation held true for both Palmaz and novel stents. The most

interesting finding of this study was the difference in intimal response between arteries with intact and ruptured IEL. Arteries with ruptured IEL showed a dramatic increase in neointimal hyperplasia when compared with IEL intact arteries, regardless of degree of medial compression. Once IEL was fractured, there was a 10-fold increase in neointimal response. Stent strut geometry might, however be a significant factor causing IEL fracture. Six of total 10 novel stents caused fracture and only 30% Palmaz did same in this case. The authors concluded that this might be function of overall strut thickness, strut geometry or both. Thus to avoid restenosis and myointimal hyperplasia, intact IEL has to be maintained. Alteration of stent strut height and geometry did not significantly affect restenosis and development of myointimal hyperplasia in arteries with superficial injury. The authors also concluded that, stent strut profile might increase local vessel wall stress concentrations, leading to IEL rupture and an exaggerated response to injury.

The purpose of the study conducted by Caldwell et al. [40] was to determine vascular response to balloon angioplasty and deployment of endovascular stents. Sinclair mini swine of ages 5-6 months were used as animal models. Standard sterile surgical procedures were used and 3161 SS Palmaz stents (Johnson and Johnson, Interventional Systems Co.) of appropriate sizes were implanted in internal and external iliac arteries of 9 animals. Balloon angioplasty was performed in both internal and external iliac arteries of 2 animals. All animals were euthansized 90 days after surgical procedure. The mean iliac diameters were measured with IVUS (Intravascular Ultrasound) before implantation, after stenting and at euthanasia. The results of this study showed that both balloon angioplasty and stent placement led to IEL loss of integrity. Cell proliferation occurred as indicated by an increase in presence of proteoglycans (PGs). No clear correlation was

observed between cell proliferation (PGs) and presence of calcium, but it was clear that IEL damage was associated with presence of calcification. More calcium was observed in stented arteries. The authors also concluded that increase in calcium content around stent struts could be stimulated by presence of stress concentrations within tissue or due to result of biological response aimed at redistributing stresses at this region of high stress concentration.

The objective of the study conducted by Riepe et al. [41] was to understand the cause and propose a mechanism for frame dislocation in endovascular stent grafts. The authors studied 5 tube grafts explanted due to secondary distal leakage, 15-21 months after implantation. One bifurcated graft was removed during emergency after aortic rupture caused by secondary leakage. A second bifurcated graft was harvested from a patient with thrombotic occlusion in one limb. The inside of grafts was observed endoscopically. The stent was inspected after removal of fabric. The broken ligatures of those stents were counted and examined by scanning electron microscope. The strength of fabric was tested by probe puncture test. Authors found that 17-44% of stent ligatures of body middle were loose. The knots were found to be intact. The degradation of polyester textile was not observed. The authors also observed multiple holes along suture line of woven polyester fabric tube. The authors concluded that continuous movement of grafted aorta and inside blood impose permanent stress to stent frame and also on polyester fabric resulting in morphological changes in body middle ring of grafts. Authors also recommended differentiating between ability of stent wires to slip diagonally within intact ligatures and stent wire dislocation due to fracture of ligature.

The study conducted by Maintz et al. [42] reported three cases of venous obstruction of subclavian vein treated with placement of wall stent. In case 1 (26-year old woman) a 10 mm wall stent was implanted across stenosis after Percutaneous Transluminal Angioplasty (PTA) with 10 mm balloon. In case 2 (30-year old woman) balloon angioplasty with 12 mm balloon was performed. In case 3 (29-year old woman) after PTA with 10 mm balloon, a 12 mm diameter wall stent was implanted. The results in all three patients showed rethrombosis due to stent failure, two involving stent fragmentation and one showing stent collapse. The reason for stent occlusion or restenosis was excessive proliferation of neo-intima. Twenty-two months after implantation of wall stent, a high-grade restenosis was developed in case 2, due to stent compression along longitudinal axis and this led to stent damage. In case 1, the patient was free of symptoms for the first two years. Then the stent fragmented, necessitating complicated surgery. In case 3, the stent failed after just 9 months, but without surgical intervention. The authors concluded that, a subclavian vein thrombosis justified stenting only if PTA alone fails.

Berkalp et al. [43] described coronary angiographic and intravascular ultrasound evaluation of late coronary artery aneurysm after percutaneous balloon angioplasty and stent implantation. A 46-year old patient was treated with percutaneous balloon angioplasty with stent implantation. The patient was treated with percutaneous balloon angioplasty in right coronary artery. After one and half years he was readmitted because of unstable angina. Angiography at this stage showed total occlusion of right coronary artery and aneurysm was observed where balloon angioplasty had done. Again balloon angioplasty was performed with 0.014 inch standard guide wire and occlusion site was

dilated with a 3 mm balloon catheter. Four months later no loss of intimal diameter was observed and angiography revealed no difference in diameter of true aneurysm. In second case angiography in a 47-year old woman showed 95% stenosis in right coronary artery. The vessel was dilated by balloon angioplasty and a NIR stent was implanted. Angiography after 4 months revealed that stent location was patent but had an aneurysmic dilation at the proximal edge of the stent. In aneurysmatic portion the vessel wall had a thin atherosclerotic plaque, which showed fibrous structure in border of normal vessel. The repeated coronary angiography 3 months later demonstrated no enlargement in pseudo-aneurysm dimensions.

2.6 Developments in Stents

Giessen et al. [44] investigated angiographic patency and histologically compared neointimal hyperplasia of coated and uncoated self expanding, stainless steel mesh stents (Wallstent, Schneider, Switzerland) implanted in normal coronary arteries of three groups of 8 pigs each. The authors concluded that an anticoagulant treatment of Acenocoumarol or BioGold polymer coating protected against early thrombotic occlusion with stainless steel self-expanding stents implanted in normal coronary arteries of pigs. Neointimal hyperplasia was not affected by these preventive measures against stent thrombosis and extent of it was limited in all groups.

Baldus et al. [45] reported a 78-year old patient who underwent angioplasty in two lesions in different artocoronary bypass grafts, whereas one lesion was treated by conventional stent, and two adjacent lesions in a second bypass graft were treated by two newly designed stents with a PTFE membrane between two layers of stent struts. The

authors concluded that PTFE membrane covered stents might reduce restenosis as compared to conventional stents in venous bypass grafts.

Peng et al. [46] reviewed the developments in polymer related stents mainly deployed in coronary arteries, which included polymer coated stents, biostable stents and biodegradable stents. Some efforts have been made to coat metallic stents with polymers using different methods so as to diminish their thrombogenic properties. A nylon mesh, Gianturco self-expanding metallic stent, was developed by Yoshioka. Roeren reported a Palmax-silicone stent which was coated with a medical grade silicone polymer. DeScheerder studied amphiphilic polyurethane coated, stainless steel, slotted tube, and balloon expandable stents implanted in porcine coronary arteries. Drug-eluting polymer coating was reported by Sheath. He concluded that coated stents accumulate less thrombus and tended to have better patency. Schwartz developed a tantalum stent coated with a natural polymer, fibrin. The author also mentioned advantages of fully polymer stents as proven compatibility with blood, customized strength and surface properties, and easy incorporation of drugs inside them. The function of biostable polymers designed by Murphy was to maintain luminal integrity in a similar manner as that of metallic stents. Van Der Giessen studied self expanding braided mesh stent made of PET for percutaneous coronary artery implantation. However hysteresis like behavior was noticed and attributed partly to braided construction and partly to a feature of polymer material itself. Agrawal reported a bioabsorbable intravascular stent made of poly L-lactic acid, which functioned to remain in situ for a predicted period of time, keeping vessel wall patent and then degrading to non-toxic substances.

Topol and Surruys [47] described custom-designed stents especially manufactured for bifurcation lesions, side branches, ostial lesions, and aneurysms. The authors also mentioned stainless steel stents, made radioactive by ion bombardment in a cyclotron and emitted both β-radiation and γ-radiation from the radionuclide.

Heparin coated stents were shown to be effective in reducing thrombosis in rabbit peripheral vessels and in porcine coronary arteries. Johnson and Johnson has heparin coated Palmaz-Schatz stent on which heparin is end linked to stent surface with a patented Carmeda coating technology. Also in case of Wiktor heparin coated stent (Hepamed coating) and Jostent (Caroline heparin coating), heparin is randomly attached on the stent surface [47].

The CYPHER Sirolimus drug eluting coronary stent consists of a proven antiproliferative drug, called Sirolimus®, a controlled release polymer, and a closed stent delivery platform. Upon placement, Sirolimus® elutes into vessel wall and impedes process of neointimal hyperplasia, thereby reducing in stent restenosis significantly. The goal of this drug eluting stent is to provide a safe, efficacious drug on a platform, which allows uniform vessel wall coverage. The drug blocks smooth muscle cell proliferation and allows natural healing. When implanted in 45 patients, CYPHER stent achieved sustained reduction in neointimal hyperplasia for up to 2 years of follow up [48].

CHAPTER 3

DESIGN, MANUFACTURING AND TESTING OF STENTS

3.1 Materials and Machines

3.1.1 Materials

- 1100 and 2440 denier polyester monofilament and 150 denier polyester multifilament (50 individual filaments) yarn.
- 6.3 mm (0.25 inch), 12.7 mm (0.5 inch), 19 mm (0.75 inch), and 25.4 mm (1 inch) round hollow copper tubes as mandrels.
- 150 denier nylon-lycra elastic yarn (nylon = 85.23 %, lycra = 14.77 %).
- Plasticryl M-30 used for cold sizing the polyester multifilament warp.

3.1.2 Machines Used for Manufacturing

- Wardwell composite braiding machine with 64 spindles and vertical track plate was used for braiding. The spool movement was in maypole fashion and direction of braid formation was horizontal. The machine is shown in Figure 3.1.

Figure 3.1: Wardwell Braiding machine.

- Wardwell quill winding machine, with unique facility to adjust to any length of spools, was used for quill winding. The traverse length and speed were also easily adjustable to facilitate proper winding.
- West Point-USA mini sizing machine.
- Jakob-Muller narrow fabric needle loom as shown in Figure 3.2.

Figure 3.2: Jakob-Muller fabric needle loom.

- Oven with automatic temperature control (Despatch Oven Company).
- Uster Tensorapid 3.
- Instron materials tester, Model 1122.

All machines were available in Auburn University, Textile Engineering.

3.2 Experimental Work

3.2.1 Manufacturing of Braided Structures Used as Reinforcing Component of Prototype Textile Stents

The yarns selected were 1100 and 2440 denier polyester monofilaments. The thread strength, knot strength and loop strength of both yarns were tested on Uster Tensorapid 3. ASTM method D3217 (Standard test method for breaking tenacity of man-made textile fibers in loop or knot configurations), was followed. The yarn samples were then heat set for 1 hour at seven different temperatures: 200, 240, 280, 320, 360, 400, and 440˚ F. Again thread strength, knot strength and loop strength of all these yarn samples were tested on Uster Tensorapid 3.

Depending on the results of tensorapid tests the optimum temperature for further experimentation was chosen as 182 ˚C (360 ˚F). Also depending on the strength results of both yarns, the best yarn was selected and used for manufacturing of further braided structures to be used as reinforcing component of prototype textile stent. The selected yarn was then wound on spools of Wardwell braiding machine. Wardwell quill winding machine has a unique facility to adjust to any length and size of spools. The traverse length can also be set easily. Proper tension was maintained while winding yarn so as to minimize unwinding tension variation. Formation of ballooning was avoided. Optimum speed was chosen for quill winding. Winding tension was adjusted so as to get well built packages. Out of all spools prepared, 64 fault and breakage free spools were selected for braiding.

The spools were mounted on the Wardwell braiding machine and the yarns were threaded through the respective guides. Then all yarns were pulled forward and passed

through former ring. All these yarns were then fixed on a long base mandrel with a tape. Four different diameter mandrels 6.3 mm (0.25 inch), 12.7 mm (0.5 inch), 19 mm (0.75 inch), and 25.4 mm (1 inch) were used to manufacture braided structures. These four mandrels slide on the long base mandrel. All the braided structures were manufactured on movable outer mandrels. The speed of spools and traverse of yarn carrier were varied and adjusted to manufacture samples of required braid angle on these mandrels. This was done by trial and error and by measuring braid angle with 'a' dial as shown in Figure 3.3. Horngears were adjusted to manufacture 2/2 regular braid.

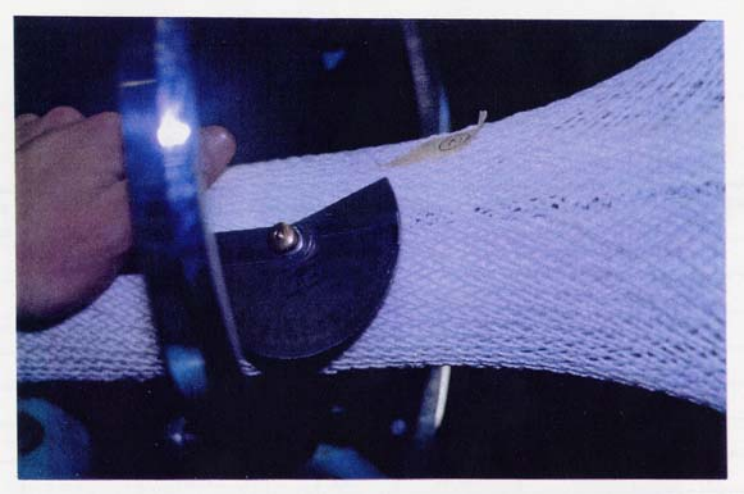

Figure 3.3: 'a' dial for measuring braid angles [Klein, J., 1999]

For each mandrel diameter, braided structures were manufactured for four different braid angles: 30˚, 45˚, 60˚, and 75˚ (braid angle = 2α). Seven braid structures of each respective braid diameter and braid angle were heatset at seven different heat set times: 0, 20, 40, 60, 80, 100, and 120 minutes. The braided structures were heatset in oven at a predetermined temperature for different heatset times as mentioned earlier. The braided structures were heatset on mandrels so as to maintain their structural integrity.

All heatset braided structures were then tested for their compression resistance on Instron materials tester.

3.2.2 Manufacturing of Seamless Narrow Woven Tubular Fabrics to be Used as Sealing Component of Prototype Textile Stents

150 denier polyester multifilament yarn was selected for narrow weaving as warp. To manufacture tubular fabric, 150 denier polyester multifilament yarn packages were mounted on warping machine creel; the yarns were passed and threaded through the respective guides and leasing reed. The warp sheet was tied to already available sheet of yarns so as to avoid rethreading of new warp threads throughout the sizing machine path. 4% solution of cold size (plasticryl M-30) was prepared and used for sizing warp yarns. The squeeze roller pressure was 1.5×10^4 Kg/m^2. The speed of sizing machine was 6.3 m/min. The % of size applied was low because the primary function of the size was to reduce fraying of individual filaments and the secondary function was to add strength to filament yarns. Fraying of filaments might cause breaking of individual filaments in a yarn or lead to formation of balls (nep like locked structures). These balls might afterwards lead to warp yarn breakage. Therefore a low % size was preferred for sizing warp yarns. Higher % size might have made the warp too stiff. The number of yarns in sized warp sheet was 100. The warp sheet was dried with drying cylinders. Around 100 meters of sized warp was wound on narrow beam. Two sets of 100 warp ends were wound on narrow beam side by side, so the total number of warp ends on the beam was 200.

The sized warp beam was then mounted on the narrow loom and pattern chain was prepared to manufacture tubular fabric. The weave repeat for tubular fabric was 4

pick repeat as shown in Figure 3.4, where U stands for upper shed and L stands for lower shed. The weave in each shed was plain weave. Thus the fabric was with two plain surfaces with no interlacement between them except at edges, hence forming a tubular fabric. The harness draft was straight. Each dent of the reed had 4 warp ends. The pattern chain was prepared and mounted on the machine. Electric drop wires were used for all warp ends as stop motions.

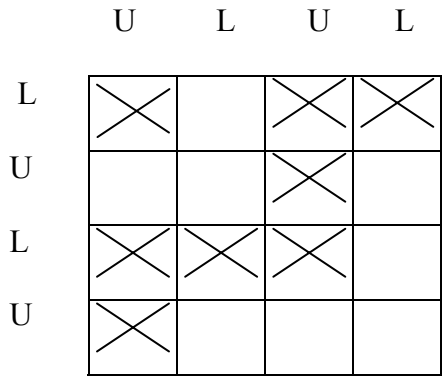

Figure 3.4: Weave for tubular fabric.

The same 150 denier polyester multifilament yarn was used as weft. Care was taken to manufacture sufficient fault free fabric.

After this, the weft was changed to nylon-lycra elastic yarn. Care was taken so that elastic yarn was placed as weft in tubular fabric without extension. Full extensibility of elastic yarn was utilized by inserting them without extension. Tubular seamless fabrics were then tested for mechanical properties. The properties of tubular fabrics were compared statistically. The different fabrics were as shown in Figure 3.5.

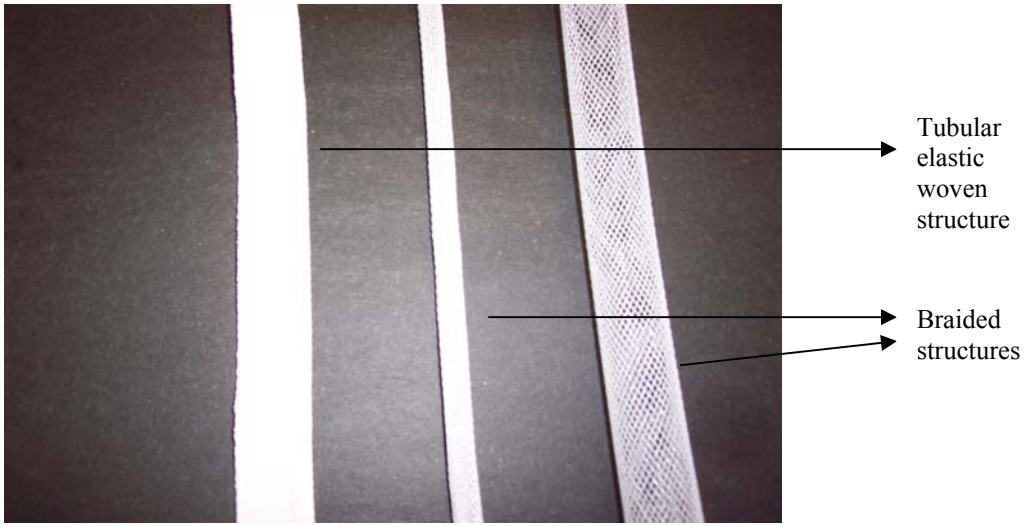

Figure 3.5: Braided and tubular elastic woven samples.

3.2.3 Manufacturing of Bifurcated Braided Structures to be used as Endografts

Bifurcated braided structures can be explored for their application in abdominal aortic aneurysms implantation in humans. Researchers have proved successful application of bifurcated stents for treatment of abdominal aortic aneurysm. These kind of bifurcated endovascular stent grafts offer great potential for reduced morbidity, mortality and hospital stay because of minimally invasive endovascular placement through catheters. Most abdominal aortic aneurysms extend into one or both iliac arteries. Therefore bifurcated endovascular stent grafts are designed consisting of proximal aortic trunk divided into two distinct lumens or sockets to receive two smaller diameter leg (iliac) components as shown in Figure 3.6. Wilson et al. [49] implanted Didcott self-expanding braided wire stents, which were integrally attached to porous spun polycarbonate urethane liners. Successful implantation of these bifurcated grafts was observed in 9 of 11 dogs.

Figure 3.6: In-vivo application of bifurcated stent graft in humans.

http://www.uphs.upenn.edu/surgery/clin/vasc/abaneur.html Access date: October 10, 2003.

Figure 3.7: Commercially available bifurcated stent grafts.

Tex Heart Inst J. 2000; 27 (2): 128–135.

Figure 3.7 shows commercially available bifurcated stent graft. All commercially available bifurcated stent grafts are made up of metal or combination of metal and textiles. In this study a prototype of textile bifurcated stent was manufactured. The textile bifurcated stent was manufactured on 64 spindle Wardwell braiding machine. The

prototype consisted of one legged braided structure divided further into two legs as shown in Figure 3.8. Figure 3.9 shows wooden dismantled mandrel used for braiding bifurcated textile stent.

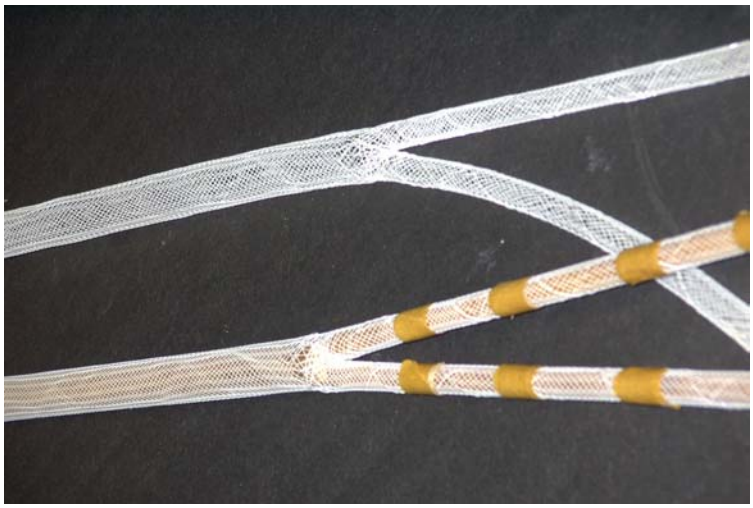

Figure 3.8: Prototype bifurcated stent (sample with tapes is method A and without tapes is method B).

Figure 3.9: Dismantled wooden mandrel used for braiding bifurcated stent

First, braided structure with 64 spools was manufactured. Then, without breaking any yarns, half of the spools on one side of the machine were taken off. The remaining 32

spools on the machine were rearranged such that they could be able to braid the exact same structure as required without missing any interlacement. This type of arrangement of spools is as shown in Figure 3.10. The figure shows only 32 yarns braiding.

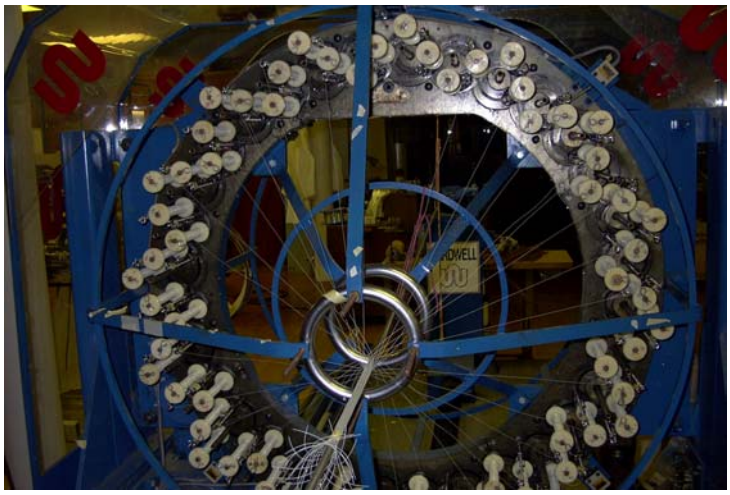

Figure 3.10: Arrangement of spools on Wardwell braiding machine showing 32 out of 64 yarns actually braiding.

With 32 spools on the machine, one leg of Y shaped structure was manufactured and then remaining 32 spools were mounted on machine. The first set of 32 spools was taken off the machine. The other leg was manufactured with remaining set of 32 spools. The position of spools was carefully maintained and monitored for proper interlacement of yarns while braiding each leg. The design used for bifurcated braided structures was 2/2 braid. Care was taken such that there were no entanglements in yarns while they were off the creel. Two sets of yarns- one on and the other off the machine- were changed flawlessly after braiding one leg, without disturbing other yarns or unnecessarily extending them. This was called as method A. In method B, apart from selecting 32 yarns from one side of the machine, yarns were selected from all four quadrants. Each quadrant contributed eight yarns selected so that they would braid exactly same as 32 yarns

selected in method A. Bifurcated structures were heatset on mandrels so as to maintain their structural integrity. Both samples were analyzed for tactile properties.

3.3 Testing Methods

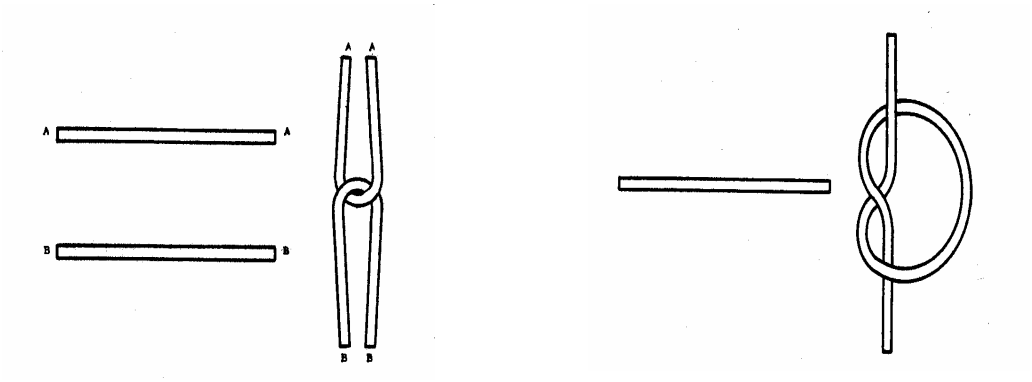

Figure 3.11: Loop and knot test for monofilament yarns.

The loop and knot test samples are as shown in Figure 3.11 as they are mounted in tensorapid jaws. The monofilament yarn must make a loop or knot within the jaws of tensorapid. Care was taken such that the portion of yarn having a loop or knot gets tested for loop and knot strength. For all yarn samples, the same method was followed to make loop or knot in the yarn.

The test method used is the "Standard test method for breaking tenacity of man-made textile fibers in loop or knot configurations- ASTM D 3217-95". As far as the behavior of monofilament yarns is concerned, it is similar to those of individual man-made fibers. Therefore the ASTM test method D 3217-95 [58] used for man-made fibers was resembled to monofilament yarns and used for knot and loop testing of all monofilament yarns in this study.

3.3.1 Testing of Reinforcing Braided Component of Prototype Textile Stent

Figure 3.12: Top and bottom plain surfaces.

Figure 3.13: Adjustment of both jaws for specific diameter.

Figure 3.14: End-point of the test.

The experimental arrangement on Instron materials tester is as shown in Figures 3.12 - 3.14. The stationary upper jaw was modified with a plain surface attached to it. The lower jaw was kept movable. The level of lower jaw was elevated as shown in Figure 3.12. The elevated surface of lower jaw was also flat. The Instron materials tester was adjusted for respected sample parameters such that the distance between two flat surfaces was optimum for different diameter samples as shown in Figure 3.13. With this

arrangement, it was possible to have variable gauge lengths (GLs) for four different diameter structures. As the test started, the lower jaw moved upwards and compressed the braided structure. A specific distance between upper and lower jaw was decided as the end point of the test as shown in Figure 3.14. The 'test end' distance between upper and lower jaw was kept the same for all compression tests of different diameter samples. The detail readings of compression resistance of braided samples are given in Appendix A.

3.3.2 Testing of the Tubular Fabrics to be Used as Sealing Component

The sealing component of the prototype textile stent was manufactured with two different weft yarns. Sealing component samples were tubular narrow woven seamless structures. The first weft yarn was 150 denier polyester multifilament and other was nylon-lycra blend elastic yarn. Samples manufactured with both weft yarns were tested on Instron materials tester for their mechanical properties. The samples were tested in both machine and cross machine directions.

Figure 3.15: Experimental arrangement for tubular woven samples on Instron (machine direction)

Figure 3.16: Experimental arrangement for tubular woven samples on Instron (cross-machine direction)

The gauge length for sample testing was 76.2 mm (3 inches) for machine direction and 3.2 mm (0.125 inch) for cross machine direction. Values of maximum load and maximum % strain were recorded and statistical analysis was carried out.

3.4 Statistical Analysis

The output of inferential statistical analysis consists of two basic types of information: a single estimate of population parameter and an interval estimate or a range of population parameter. In order to present these types of estimates, we must have some information about population and be able to specify extent of confidence that we will have in estimates produced. With regards to the first requirement, we can obtain information about population from a representative sample drawn from population, or from historical data describing population. The extent of confidence is a risk we take, which will depend on many factors that are primarily driven by nature of the characteristic variable considered and population variability. In practice, role of inferential statistics is best illustrated in decision making situations such as:

- When actual value of a certain characteristic or a design parameter is questioned.
- When values of a certain characteristics of two populations are compared.

These applications are commonly handled using the so called ‘test of hypotheses’. A hypothesis test is a contention based on preliminary observation of what appears to be facts, which may or may not be true. The test of hypothesis compares the contention with collected facts. If these facts are shown to agree with contention, the contention is retained, which means that the hypothesis is accepted. If contention and facts do not agree, the contention is discarded, that means hypothesis is rejected [50].

For example, we may assume that the new yarn has better strength than the old one. To test this contention, the new yarn is tested for strength properties. In this case, a test of hypothesis may be stated as:

H_o: μ new = μ current.

H_1: μ new ≠ μ current.

where H_o is called as null hypothesis and H_1 is called as alternative hypothesis.

A design of experiment is a procedure in which predetermined and purposeful changes are made in some inputs of process and corresponding changes in output are determined. In general, there are three main objectives of design of experiments:

- To evaluate the effect of certain factors on a particular response variable.
- To determine factor levels at which output or response variable is at its optimum level (maximum, minimum or exact target).
- To develop a relationship between the number of factor variables and response variables that can assist experimental settings in future.

The simplest type of design of experiment is the "one-factor at a time approach". In this approach, only one factor is allowed to vary and other factors are kept constant. Thus, response variable is examined only at different levels of one factor. But the current study has three different factors such as braid angle, braid diameter and heatset time; therefore, this type of design can not be applied. Therefore the factorial design is selected.

Factorial design is a procedure in which each complete trial or replication of experiment at all possible combinations of levels of the factors are examined. If only two levels are used for each factor, the experiment will involve the following number of experimental combinations:

Number of experimental combinations = $(\text{levels})^{\text{factors}} = (2)^2 = 4$.

If three levels of each factor are used, the number of experimental combinations will rise to 8. Thus as the number of factors and number of levels increase, the number of experimental combinations will also increase. This presents a new challenge because of time and resources limitation in conducting an experiment. In addition we often need to use many replicates of each experimental combination to minimize sampling or experimental errors.

During the design of an experiment, first, all factors that supposed to have effect on response variable are listed. The idea of showing all possible factors is that during the experiment, factors that are not considered in the study should be kept constant at values which are approximately optimum. In addition, the results of experiment should be reported in association only with those factor levels that were kept constant during the experiment [50].

The current study has three variables such as braid angle, braid diameter and heatset time. Braid angle and braid diameter each has four different levels and heatset time has seven different levels. Thus the experimental design will be,

Number of experimental combinations = $(\text{levels})^{\text{factors}} = (4)^2\,(7)^1 = 112$.

All other factors must be held constant during the experiment and only these three factors should be varied. In this case, the braided structures were manufactured by changing combination of all these three factors. After manufacturing the braided samples, compression resistance was tested for all structures. Therefore, compression resistance result was the response variable. In this case the response variable was measurable and related to the objective of the study.

In this study, two-factor full factorial design was used. Out of three variables, two were considered as variables at a time and the third was kept constant. This two-factor design will provide information about linear and their interaction effects. In design of experiments, the main effect is a term that describes a measure for comparison of responses at each level of a factor averaged over all levels of other factors in the experiment. Interaction is defined as the term describing a measure for differential comparison of responses for each level of a factor at each of several levels of one or more other factors [50]. For example, one level of braid angle was kept constant and braid diameter and heatset times were considered as variables. Then main effect gave the influence of braid diameter and heatset time on compression resistance properties of braided structures and the interaction effect gave combined or interaction effect of both braid diameter and heat set time on compression resistance of braided structures. But it should be noted that these statistical analysis results were valid only for the specific experimental arrangement and for specific levels, not for overall or general levels.

Analysis of Variance (ANOVA) is a powerful analytical technique that can be used in many engineering and manufacturing applications. This technique is very useful in revealing important information particularly in interpreting experimental outcomes and in determining the influence of some factors on other processing parameters. After calculation of ANOVA results it is very important to interpret those results correctly.

Table 3.1: Example of two-way ANOVA output in EXCEL.

ANOVA

Source of Variation	*SS*	*df*	*MS*	*F*	*P-value*	*F crit*
Sample	17727181	3	5909060	197.6835	1.4E-44	2.685645
Columns	9892895	6	1648816	55.15999	3.4E-31	2.180563
Interaction	5147317	18	285962	9.566662	2E-15	1.696666
Within	3347850	112	29891.52			
Total	36115242	139				

A typical ANOVA output of EXCEL is as shown in Table 3.1. The ‘df’ in the ANOVA table means degrees of freedom, which is the number of values in final calculation of a statistic that are free to vary. In the above example, the Sample row shows the value of degrees of freedom as 3. This means that only three values out of all values are allowed to deviate from mean, hence called as degrees of freedom.

Excel displays values of F-statistic and F critical (F critical = F crit). In order to analyze the results, the values of F and F critical have to be compared. The P-value indicates the probability of Type I error associated with our decision to accept null hypothesis. The values in the Sample row give effect of variable in row on response. The values in the Column row give effect of variable in column on response. The values in the Interaction row give combined effect of both variables on response. In the above example the Sample, Column and Interaction F values are greater than F critical. The values of p for all are very little, practically equal to zero. Therefore we can not accept null hypothesis. In this case we can conclude that both variables and their interaction effects on response are statistically significant.

The current study also included the manufacturing of sealing component of prototype textile stent. The sealing component was manufactured as tubular narrow woven seamless structures. The design of statistics followed was one way ANOVA. Only weft has changed so the type of weft yarn was taken as variable and mechanical properties measured on Instron were taken as response. Typical output of one way ANOVA is shown in Table 3.2.

Table 3.2: Example of one-way ANOVA output in EXCEL.

ANOVA

Source of Variation	*SS*	*Df*	*MS*	*F*	*P-value*	*F crit*
Between Groups	3772.918	1	3772.918	1.729426	0.224926	5.317645
Within Groups	17452.81	8	2181.601			
Total	21225.72	9				

CHAPTER 4

RESULTS AND DISCUSSION

4.1 Selection of Polyester as Biocompatible Material

Many researchers have worked and proved biocompatibility of polyester in vascular prostheses. Important work was done by King et al. [51] in which he described the current manufacturing techniques and provided detailed information about a wide variety of polyester filaments, yarns and fabrics used in commercial biomedical devices. He mentioned polyester as the most preferred fiber for manufacturing vascular prosthesis because of its biocompatibility and availability in yarn form in a wide range of linear densities and filament counts. Hence polyester was selected as material for developing prototype endovascular textile prosthesis.

4.2 Selection of Yarn for Braided Structures to be Used as Reinforcing Component in Prototype Textile Stent

The tensile, knot and loop strengths of 1100 and 2440 denier monofilament yarns are as shown in Figure 4.1. It is clear from Figure 4.1 that tensile, knot and loop strengths of 1100 denier yarn are more than those of 2440 denier yarn. This is because 1100 denier monofilament was drawn at a higher ratio while manufacturing than that of 2440 denier, having better molecular orientation in the yarn axis. Another important point is the higher flexibility of 1100 denier yarn over 2440 denier yarn, because flexibility is proportional to fourth power of diameter and 1100 denier yarn has lesser diameter than that of 2440 denier. Bailey [52] mentioned the first and foremost requirement of stent as flexibility, so

as to allow it to travel through tortuous vascular path. Bailey also defined characteristics of ideal stent as flexible, trackable, non-thrombogenic, allowing limited intimal hyperplasia, visible on fluoroscopy, high radial strength when expanded, circumferential coverage, low biocompatible profile and minimal hydrodynamic effects. Thus it was clear that the yarn selected must be sufficiently flexible for its application as endovascular stents. Plank et al. [53] studied the application of textile materials in implantation. For vascular grafts woven or knitted fabrics, for ligament prosthesis braids, wovens, or warp knits and for tendon replacement braids or twisted yarn bundles were used. He concluded flexibility as a basic requirement for textile vascular implants. Phoenix [54] studied the mechanical response of tubular braided structures and proved that structure of tubular braids was similar to twisted yarns since individual strands travel in helical paths as individual fibers do in twisted yarn. He studied the mechanical properties of diamond braided structures and resembled them to regular and hercules braided structures. He also concluded that high strength yarns ultimately gave high strength braided structures.

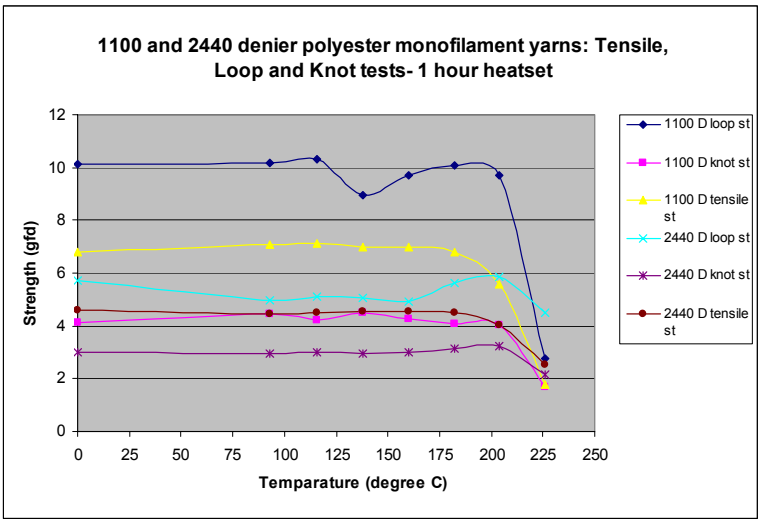

Figure 4.1: Tensile, knot and loop tests of the yarns used.

In Figure 4.1, each sample was heatset for 60 minutes. It is also clear from the graph that all three strengths of 1100 denier yarn were greater than those of respective 2440 denier yarn. Thus depending on these experimental results and reference from literature mentioned above, it was concluded that 1100 denier monofilament yarn has better strength and flexibility than 2440 denier, which are the most basic requirements of vascular implants. As a result, 1100 denier monofilament yarn was selected as the best yarn and used for further development of braided reinforcing component of the prototype textile stent structures.

4.3 Selection of Best Heatset Time for Braided Structures

After selecting the 1100 denier yarn as the best yarn, the best heatset time was determined. For this purpose the 1100 denier yarn was heatset at different heatset times and at various temperatures. Then the strengths were measured on Uster tensorapid.

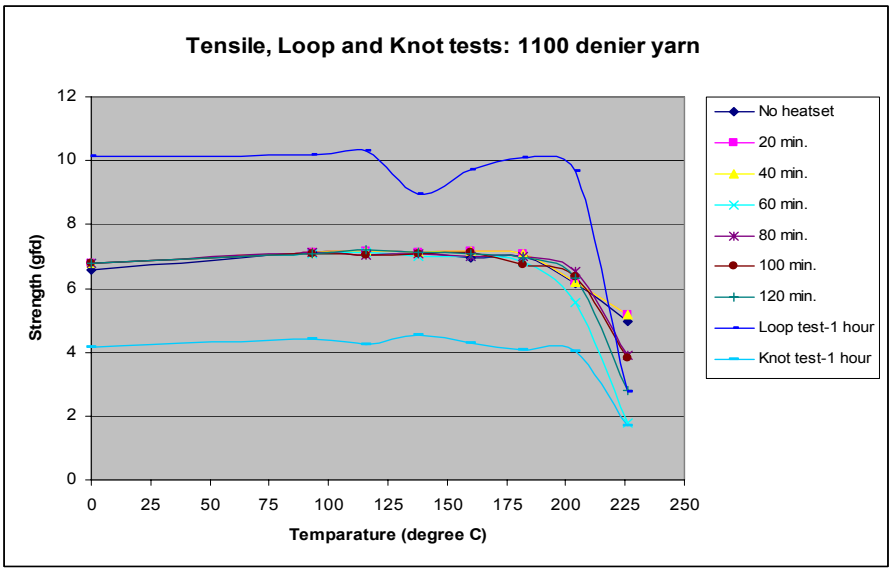

Figure 4.2: Strength results for 1100 denier yarn at different heatset times and at different temperatures.

The tensile, knot and loop strength results of 1100 denier at 8 different heatset temperatures and 7 different heatset times are as shown in Figure 4.2. There was significant drop in all three types of strengths after 204 ˚C (400 ˚F). Cook [55] studied the effect of temperature on polyester. He mentioned that polyester has an excellent resistance to prolonged exposure at elevated temperatures below its softening point, and this characteristic has proven very important in many of its industrial applications.

His comments were as follows:

"Polyester yarns as supplied by manufacturer are usually heat sensitive and shrinks when heated in water or air. Generally polymer materials are stabilized to heat. One method is to shrink the material to stable its dimensions either by steaming or by subjecting to dry heat under certain conditions, which allow free relaxation. One of the most important properties of polyester fibers is their ability to take on a permanent set when shaped at high temperature. During heat setting, further crystallization of polyester takes place, resulting in an increase in stiffness".

Booth [56] also commented on the effect of heat setting on polyester as,

"Polyester is most thermally stable of all synthetic fibers. Like all thermoplastic fibers its tenacity decreases and elongation increases with increase in temperature. At 180 ˚C it retains around half of its original tenacity. On cooling at 20 ˚C (68 ˚F), its tenacity returns to almost initial value. At –50 ˚C strength of polyester increases by 35-40 % and elongation decreases correspondingly. The working temperature limits for polyester range from –70 to 175 ˚C. At 240-248 ˚C, fiber looses all its strength, while destruction of crystalline structure begins at about 235 ˚C (455 ˚F). The fiber sticks at 205 ˚C and melts at 250 ˚C. Safe ironing temperature for polyester is 135 ˚C".

In Figure 4.2 consistent results were observed for all three strengths from 0 to 182 ˚C (360 ˚F). It was clear that after 204 ˚C (400 ˚F) all three strengths have shown significant drop.

Figure 4.3: Degradation of braided sample at 226 ˚C (440 ˚F).

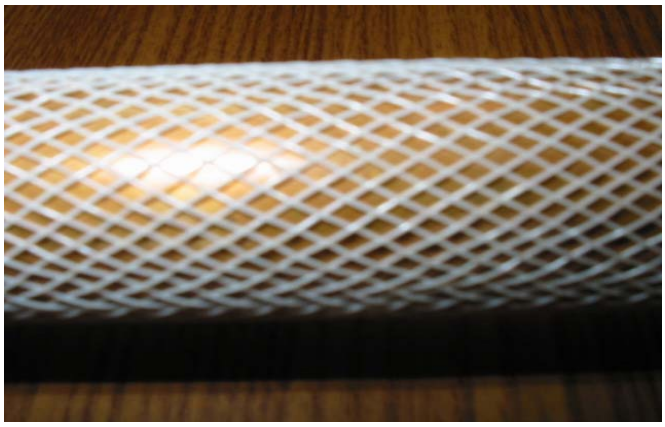

Figure 4.4: Braided structure heatset at 182 ˚C (360 ˚F).

Figure 4.3 shows the degradation of polyester monofilament yarn at 226 ˚C (440 ˚F), heatset for 60 minutes when made into braided structures. Therefore 226 ˚C (440 ˚F) was not the right temperature to heatset any future structures. Figure 4.4 shows the braided structure heatset at 182 ˚C (360 ˚F). The structure was found to be well intact at this temperature. Also from Figure 4.2 it was clear that temperature up to 182 ˚C (360 ˚F) did not have significant effect on yarn strength, and therefore ultimately not on braided

structure properties. Thus 182 ˚C (360 ˚F) was selected as the optimum temperature to heat set all future braided structures.

4.4 Analysis of Compression Resistance Results of Braided Structures Used as Reinforcing Component in Prototype Textile Stent

4.4.1 Effect of Braid Angle and Heatset Time on Compression Resistance by Keeping Braid Diameter Constant

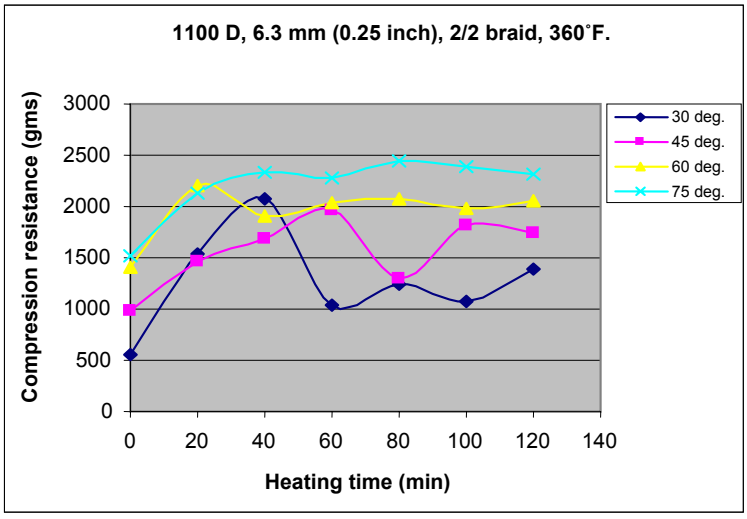

Figure 4.5: Effect of braid angle and heatset time on compression resistance- 6.3 mm (0.25 inch) braid diameter

Figure 4.5 shows the effect of braid angle and heatset time on the compression resistance of braided structures of 6.3 mm (0.25 inch) diameter. For all four braid angles less compression resistance was observed for non heatset sample (0 minutes heat set). For statistical analysis, braid angle and heatset time were variables and braid diameter was kept constant as 6.3 mm (0.25 inch). The results of ANOVA are as shown in Table 4.1.

Table 4.1: Two-way ANOVA results for 6.3 mm (0.25 inch) braided structures.

6.3 mm (0.25 inch) sample, Sample = braid angle with 4 levels.

Column = Heat set times 7 levels.

ANOVA

Source of Variation	*SS*	*df*	*MS*	*F*	*P-value*	*F crit*
Sample	17727181	3	5909060	197.6835	1.4E-44	2.685645
Columns	9892895	6	1648816	55.15999	3.4E-31	2.180563
Interaction	5147317	18	285962	9.566662	2E-15	1.696666
Within	3347850	112	29891.52			
Total	36115242	139				

The Table shows that the values of F are greater than the values of Fcritical for Sample, Column and Interaction. Also for all these three, the value of p was very low. Therefore there was a low chance of accepting that there was no effect of these two variables on response. It was clear that there was significant effect of braid angle (Sample) and heatset time (Column) on compression resistance of 6.3 mm (0.25 inch) braided structures. The analysis also shows significant effect of interaction of both factors on compression resistance properties of 6.3 mm (0.25 inch) braided structures.

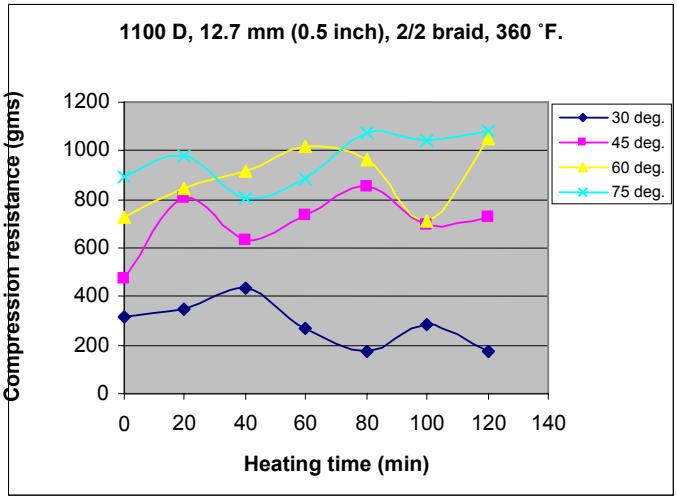

Figure 4.6: Effect of braid angle and heatset time on compression resistance- 12.7 mm (0.5 inch) braid diameter

Figure 4.6 shows the effect of braid angle and heatset time on compression resistance of braided structures of 12.7 mm (0.5 inch) diameter. Among all four braid angles less compression resistance was observed for 30˚ braid angle samples. In the statistical analysis, braid angle and heatset time were variables and braid diameter was kept constant as 12.7 mm (0.5 inch). The results of ANOVA are as shown in Table 4.2.

Table 4.2: Two-way ANOVA results for 12.7 mm (0.5 inch) braided structures.

12.7 mm (0.5 inch) sample, Sample = braid angle with 4 levels.

Column = Heat set times 7 levels.

ANOVA

Source of Variation	*SS*	*df*	*MS*	*F*	*P-value*	*F crit*
Sample	9741236	3	3247079	1076.809	2.1E-82	2.685645
Columns	379897.4	6	63316.23	20.99717	2.2E-16	2.180563
Interaction	1227335	18	68185.25	22.61186	3.3E-29	1.696666
Within	337732	112	3015.464			
Total	11686200	139				

The Table shows that the values of F are greater than the values of Fcritical for Sample, Column and Interaction. Also for all these three, the value of p was very low. Therefore there is a low chance of accepting that there was no effect of these two variables on response. It was clear that there was significant effect of braid angle (Sample) and heatset time (Column) on compression resistance of 12.7 mm (0.5 inch) braided structures. The analysis also shows significant effect of interaction of both factors on compression resistance properties of 12.7 mm (0.5 inch) braided structures.

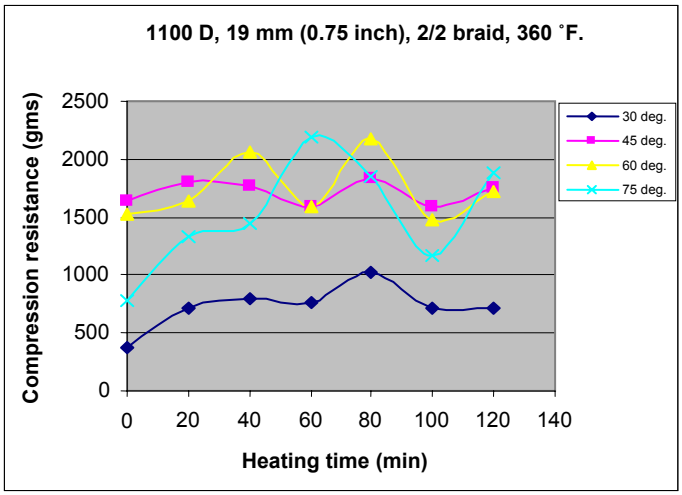

Figure 4.7: Effect of braid angle and heatset time on compression resistance- 19 mm (0.75 inch) braid diameter

Figure 4.7 shows the effect of braid angle and heatset time on compression resistance of braided structures of 19 mm (0.75 inch) diameter. Out of four braid angles, less compression resistance was observed for 30˚ samples. For the statistical analysis, the variables were braid angle and heat set time and braid diameter was kept constant as 19 mm (0.75 inch). The results of ANOVA are as shown in Table 4.3.

Table 4.3: Two-way ANOVA results for 19 mm (0.75 inch) braided structures.

19 mm (0.75 inch) sample, Sample = braid angle with 4 levels.

Column = Heat set times 7 levels.

ANOVA

Source of Variation	*SS*	*df*	*MS*	*F*	*P-value*	*F crit*
Sample	23839806	3	7946602	144.4371	2.4E-38	2.685645
Columns	5439810	6	906634.9	16.47896	1.5E-13	2.180563
Interaction	5120983	18	284499.1	5.171044	1.9E-08	1.696666
Within	6161985	112	55017.72			
Total	40562584	139				

The Table shows that the values of F are greater than the values of Fcritical for Sample, Column and Interaction. Also for all these three, the value of p was very low. There was a low chance of accepting that there was no effect of these two variables on response. It was clear that there was significant effect of braid angle (Sample) and heatset time (Column) on compression resistance of 19 mm (0.75 inch) braided structures. The analysis also shows significant effect of interaction of both factors on compression resistance properties of 19 mm (0.75 inch) braided structures.

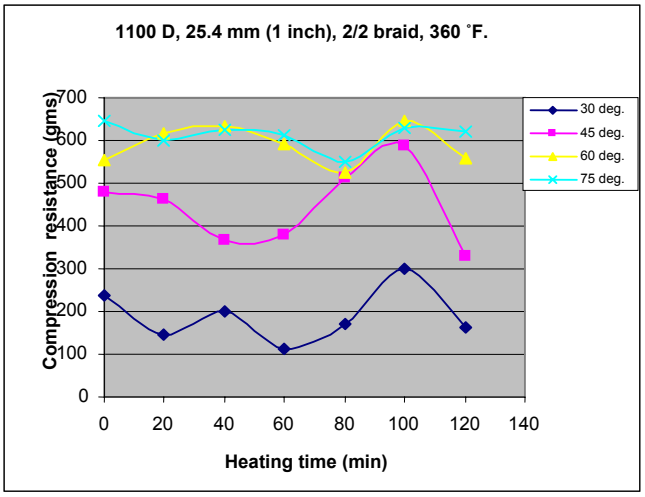

Figure 4.8: Effect of braid angle and heatset time on compression resistance- 25.4 mm (1 inch) braid diameter

Figure 4.8 shows the effect of braid angle and heatset time on compression resistance of braided structures of 25.4 mm (1 inch) diameter. Out of all four braid angles, less compression resistance was observed for 30˚ samples. In the statistical analysis, the variables were braid angle and heatset time and braid diameter was kept constant as 25.4 mm (1 inch). The results of ANOVA are as shown in Table 4.4.

Table 4.4: Two-way ANOVA results for 25.4mm (1 inch) braided structures.

25.4 mm (1 inch) sample, Sample = braid angle with 4 levels.

Column = Heat set times 7 levels.

ANOVA

Source of Variation	*SS*	*df*	*MS*	*F*	*P-value*	*F crit*
Sample	3942063	3	1314021	1329.841	2.3E-87	2.685645
Columns	209313.4	6	34885.56	35.30557	1.1E-23	2.180563
Interaction	253936.3	18	14107.57	14.27742	2.6E-21	1.696666
Within	110667.6	112	988.1036			
Total	4515980	139				

The Table shows that the values of F are greater than the values of Fcritical for Sample, Column and Interaction. Also for all these three, the value of p was very low. There was a low chance of accepting that there was no effect of these two variables on response. It was clear that there was significant effect of braid angle (Sample) and heat set time (Column) on compression resistance of 25.4 mm (1 inch) braided structures. The analysis also shows significant effect of interaction of both factors on compression resistance properties of 25.4 mm (1 inch) braided structures.

Thus it can be concluded that for all four braid diameters the effect of braid angle and heatset time was statistically significant. The interaction effect of both factors was also found to be statistically significant. Another important point is that all these results and statements are valid only for specific variables and their specific levels as mentioned in the study. The yarn denier, weave and heatset temperature were constant for all structures.

4.4.2 Discussion on Compression Resistance Results by Keeping Braid Diameter Constant

The objective of the study conducted by Riepe et al. [57] was to investigate whether repeated cycles of standard, hospital-performed autoclave resterilization affected physical properties of polyester vascular grafts or not. In this case two different types of polyester vascular grafts were tested. One was 20 mm DeBakey soft woven Dacron® vascular prosthesis (Bard, USA) and the other was a 16 mm woven double velour Dacron graft (Meadox, USA). On both grafts 0, 1, 5, 10, and 20 cycles of autoclave sterilization were performed. These samples also underwent probe puncture testing; longitudinal filament burst testing as well as examination by Scanning Electron Microscope (SEM) and Fourier Transformed Infrared Spectroscopy (FTIR). The sterilization was performed at 134 ˚C and at 240 kPa (2.4 bar) steam pressure for 6 min. Every sterilization cycle took approximately 40 min. The grafts were weighed on highly accurate scales. Tactile testing was performed by 3 surgeons, all having high experience with polyester vascular grafts. Probe puncture testing was performed on complete graft wall. Tactile testing results revealed a change of feeling with increasing cycles of sterilization. Weighing showed no weight gain, indicating no water binding to polyester molecules during all cycles. There was no change of strength of polyester graft seen by probe puncture or by individual filament burst testing. SEM showed no change of surface of single filaments up to 10,000 X magnifications. In infrared spectroscopy no significant increase of polyester molecule chain scission by hydrolysis was seen. The authors also pointed out that even if the results of their study showed no measurable changes in material, they did not know whether frequent sterilization accelerated in vivo degeneration process or not. They also

pointed out that repeated sterilization increased risk of contamination of grafts. Thus the authors studied the effect of repeated cycles of autoclave resterilization on vascular graft properties. This effect of repeated resterilization was resembled to the effect of heatset time on prototype textile stents in this study and from these results it was concluded that there was statistically significant effect of heat set time on compression resistance properties of reinforcing component of prototype textile stents.

4.4.3 Effect of Heatset Time and Braid Diameter on Compression Resistance by Keeping Braid Angle Constant

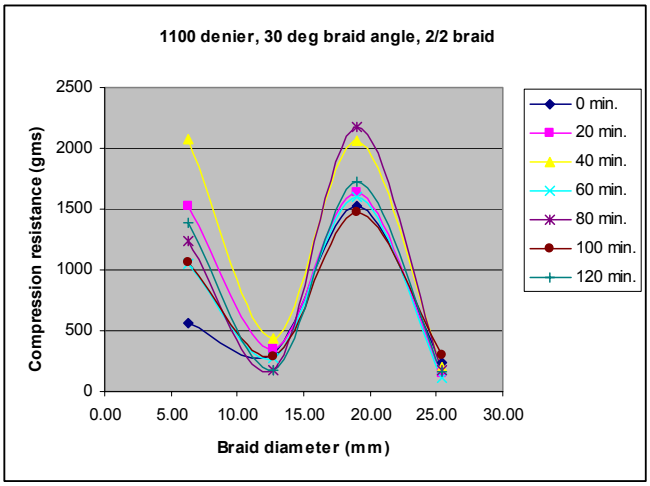

Figure 4.9: Effect of braid diameter and heatset time on compression resistance (30˚ braid angle).

Figure 4.9 shows the effect of braid diameter and heatset time on compression resistance of braided structures of 30˚ braid angle. It is also clear that, 19 mm braid diameter structures showed higher compression resistance at 30˚ braid angle at all heatset times. So it is concluded that these structures needed to be heatset for lesser time than the range of heatset times selected here. In the statistical analysis, the variables were braid diameter and heatset time and braid angle was kept constant as 30˚. The results of ANOVA are as shown in Table 4.5.

Table 4.5: Two-way ANOVA results for 30˚ braid angle structures.

30° braid angle, Sample = braid diameter with 4 levels.

Column = Heat set times 7 levels.

ANOVA *Source of Variation*	*SS*	*df*	*MS*	*F*	*P-value*	*F crit*
Sample	60498074	3	20166025	920.8185	9.96E-79	2.685645
Columns	3513388	6	585564.6	26.73798	1.42E-19	2.180563
Interaction	5613765	18	311875.8	14.24084	2.89E-21	1.696666
Within	2452812	112	21900.11			
Total	72078039	139				

The Table shows that the values of F are greater than the values of Fcritical for Sample, Column and Interaction. For all these three, the value of p was very low. It was clear that there is significant effect of braid diameter (Sample) and heatset time (Column) on compression resistance of 30˚ braid angle structures. The analysis also shows significant effect of interaction of both factors on compression resistance properties of 30˚ braid angle structures.

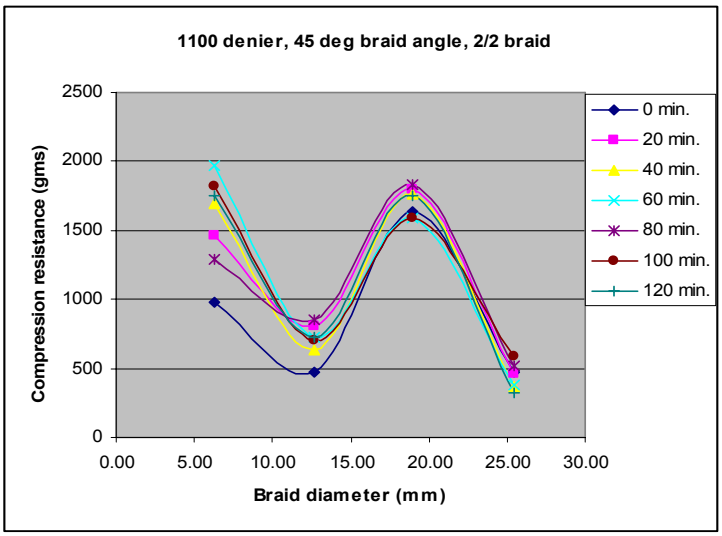

Figure 4.10: Effect of braid diameter and heatset time on compression resistance (45˚ braid angle).

Figure 4.10 shows the effect of braid diameter and heatset time on compression resistance of braided structures of 45˚ braid angle. In case of 45˚ braid structures also the compression resistance values observed for 19 mm were higher than those of 6.3 mm and 12.7 mm structures. For all heatset times similar trend was observed in this case. So it can be concluded that 19 mm braid diameter structures have higher inherent compression resistance or these structures can be heatset for lesser time than other ones so as to get equal magnitude of compression resistance. In the statistical analysis, the variables were braid diameter and heatset time; braid angle was kept constant as 45˚. The results of ANOVA were as shown in Table 4.6.

Table 4.6: Two-way ANOVA results for 45˚ braid angle structures.

45° braid angle, Sample = braid diameter with 4 levels.

Column = Heat set times 7 levels.

ANOVA

Source of Variation	*SS*	*df*	*MS*	*F*	*P-value*	*F crit*
Sample	41086557	3	13695519	925.4522	7.6E-79	2.685645
Columns	1114760	6	185793.3	12.55467	8.71E-11	2.180563
Interaction	3394636	18	188590.9	12.74372	1.55E-19	1.696666
Within	1657458	112	14798.73			
Total	47253410	139				

The Table shows that the values of F are greater than the values of Fcritical for Sample, Column and Interaction. For all these three, the value of p was very low. There was a low chance of accepting that there was no effect of two variables selected on response. It was clear that there was significant effect of braid diameter (Sample) and heatset time (Column) on compression resistance of 45˚ braid angle structures. The analysis also showed significant effect of interaction of both factors on compression resistance properties of 45˚ braid angle structures.

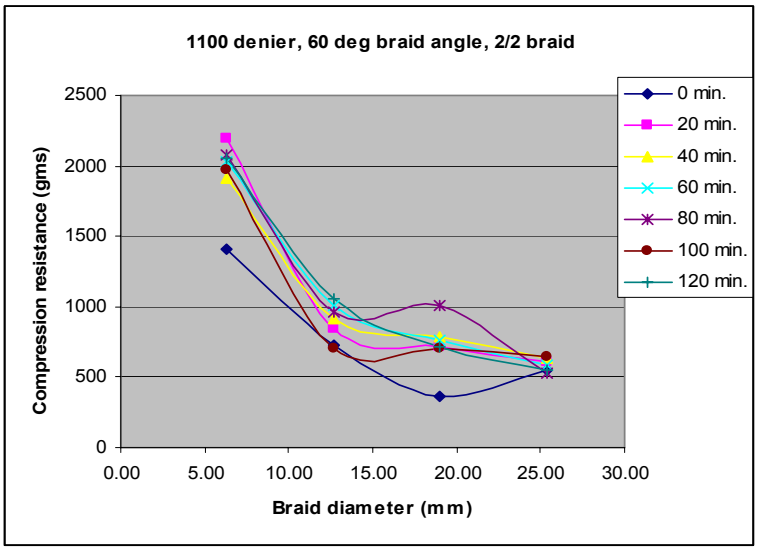

Figure 4.11: Effect of braid diameter and heat set time on compression resistance (60˚ braid angle).

Figure 4.11 shows the effect of braid diameter and heatset time on compression resistance of braided structures of 60˚ braid angle. For all heatset times the trend for change in compression resistance was observed to be similar. In the statistical analysis the variables were braid diameter and heatset time; braid angle was kept constant as 60˚. The results of ANOVA are as shown in Table 4.7.

Table 4.7: Two-way ANOVA results for 60˚ braid angle structures.

60° braid angle, Sample = braid diameter with 4 levels.

Column = Heat set times 7 levels.

ANOVA

Source of Variation	*SS*	*df*	*MS*	*F*	*P-value*	*F crit*
Sample	40436407	3	13478802	582.0575	4.01E-68	2.685645
Columns	1931013	6	321835.4	13.89787	9.23E-12	2.180563
Interaction	1687903	18	93772.36	4.049388	2.1E-06	1.696666
Within	2593603	112	23157.17			
Total	46648925	139				

The Table shows that the values of F are greater than the values of Fcritical for Sample, Column and Interaction. For all these three, the value of p was very low. There was a low chance of accepting that there was no effect of these two variables on response. It was clear that there was significant effect of braid diameter (Sample) and heatset time (Column) on compression resistance of 60˚ braid angle structures. The analysis also showed significant effect of interaction of both factors on compression resistance properties of 60˚ braid angle structures.

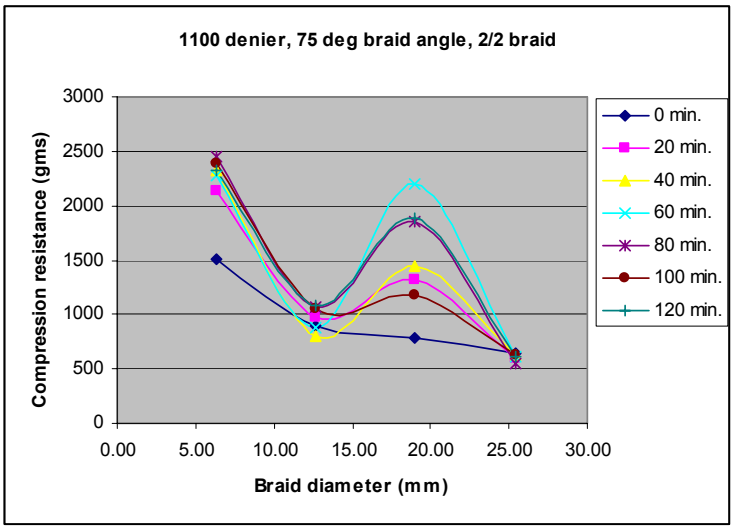

Figure 4.12: Effect of braid diameter and heat set time on compression resistance (75˚ braid angle).

Figure 4.12 shows the effect of braid diameter and heatset time on compression resistance of braided structures of 75˚ braid angle. Except 0 minutes, for all the other heatset times, the trend for change in compression resistance was observed to be similar. In the statistical analysis, the variables were braid diameter and heatset time; the braid angle was kept constant as 75˚. The results of ANOVA are as shown in Table 4.8.

Table 4.8: Two-way ANOVA results for 75˚ braid angle structures.

75° braid angle, Sample = braid diameter with 4 levels.

Column = Heat set times 7 levels.

ANOVA

Source of Variation	*SS*	*Df*	*MS*	*F*	*P-value*	*F crit*
Sample	50482708	3	16827569	579.1267	5.23E-68	2.685645
Columns	4273267	6	712211.1	24.511	2.2E-18	2.180563
Interaction	6142756	18	341264.2	11.74473	2.59E-18	1.696666
Within	3254362	112	29056.8			
Total	64153092	139				

The Table shows that the values of F are greater than the values of Fcritical for Sample, Column and Interaction. For all these three, the value of p was very low. There was a low chance of accepting that there was no effect of these two variables selected on response. It was clear that there was significant effect of braid diameter (Sample) and heatset time (Column) on compression resistance of 75˚ braid angle structures. The analysis also showed significant effect of interaction of both factors on compression resistance properties of 75˚ braid angle structures.

It can be concluded that for all 4 braid angles, the effect of braid diameter and heatset time was statistically significant. The interaction effect of both factors was also found to be statistically significant. Another important point is that all these results are valid only for specific variables and their specific levels. The yarn denier, weave and heatset temperature were constant for all structures. As far as this study was concerned, the 6.3mm and 12.7 mm diameter structures were for implantation in humans and 19mm and 25.4 mm diameter structures were for implantation in animals. All graphs and tables will provide useful guidelines to future commercial manufacturing of textile stents.

4.4.4 Effect of Braid Angle and Braid Diameter on Compression Resistance by Keeping Heatset Time Constant

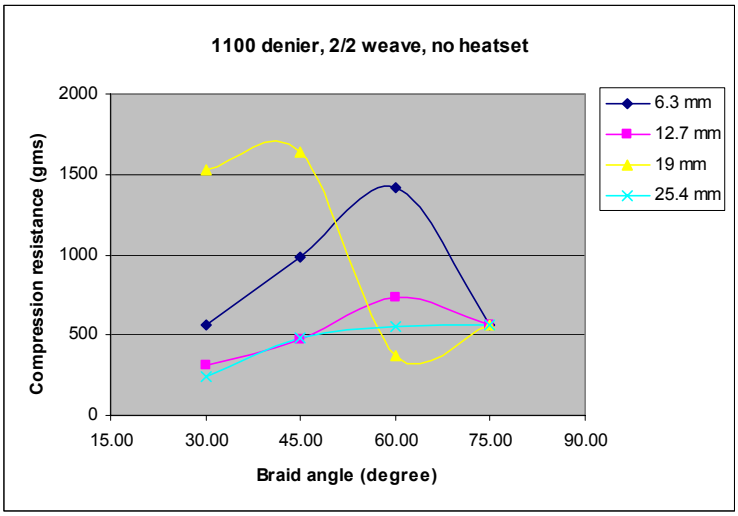

Figure 4.13: Effect of braid angle and braid diameter on compression resistance (without heatset).

Figure 4.13 shows the effect of braid angle and braid diameter on compression resistance of braided structures without heatset. Only 25.4 mm (1 inch) structures showed increase in compression resistance as the braid angle increased. In the statistical analysis, the variables were braid diameter and braid angle; heatset time was kept constant as 0 minutes. The results of ANOVA are as shown in Table 4.9.

Table 4.9: Two-way ANOVA results for no heatset braided structures

0 minutes heatset, Sample = braid angle with 4 levels.

Column = braid diameter 4 levels.

ANOVA

Source of Variation	*SS*	*Df*	*MS*	*F*	*P-value*	*F crit*
Sample	1062110	3	354036.5	12.76004	1.24E-06	2.748195
Columns	6370834	3	2123611	76.53831	3.87E-21	2.748195
Interaction	8766292	9	974032.5	35.10567	1.91E-21	2.029793
Within	1775727	64	27745.73			
Total	17974962	79				

The Table shows that the values of F are greater than the values of Fcritical for Sample, Column and Interaction. For all these three, the value of p was very low. There was a low chance of accepting that there was no effect of these two variables selected on response. It was clear that there was significant effect of braid angle (Sample) and braid diameter (Column) on compression resistance of braided structures with no heatset. The analysis also showed significant effect of interaction of both factors on compression resistance properties of braided structures with no heatset.

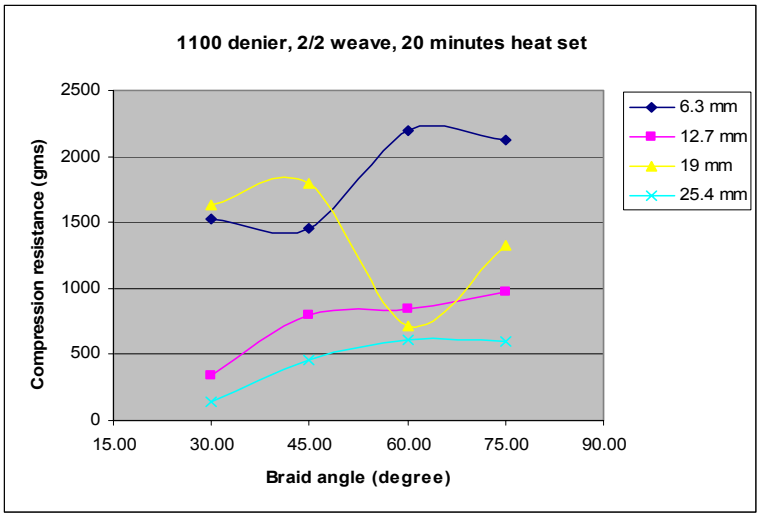

Figure 4.14: Effect of braid angle and braid diameter on compression resistance (20 minutes heatset).

Figure 4.14 shows the effect of braid angle and braid diameter on compression resistance of braided structures, heatset for 20 minutes. It should be noted that these results were only related to samples heatset for 20 minutes. All braid diameters except 19 mm (0.75 inch) showed increase in compression resistance as braid angle was increased. In the statistical analysis, the variables were braid diameter and braid angle; the heatset time was kept constant as 20 minutes. The results of ANOVA are as shown in Table 4.10.

Table 4.10: Two-way ANOVA results for 20 minutes heatset braided structures. 20 minutes heat set, Sample = braid angle with 4 levels.

Column = braid diameter 4 levels.

ANOVA

Source of Variation	*SS*	*Df*	*MS*	*F*	*P-value*	*F crit*
Sample	1215440	3	405146.6	19.05546	6.08E-09	2.748195
Columns	22956551	3	7652184	359.9088	5.36E-40	2.748195
Interaction	6312535	9	701392.7	32.98894	9.54E-21	2.029793
Within	1360733	64	21261.45			
Total	31845258	79				

Table 4.10 shows that the values of F are greater than the values of Fcritical for Sample, Column and Interaction. For all these three, the value of p was very low. There was a low chance of accepting that there was no effect of these two variables selected on response. It was clear that there was significant effect of braid angle (Sample) and braid diameter (Column) on compression resistance of braided structures heatset for 20 minutes. The analysis also showed significant effect of interaction of both factors on compression resistance properties of braided structures heat set for 20 minutes.

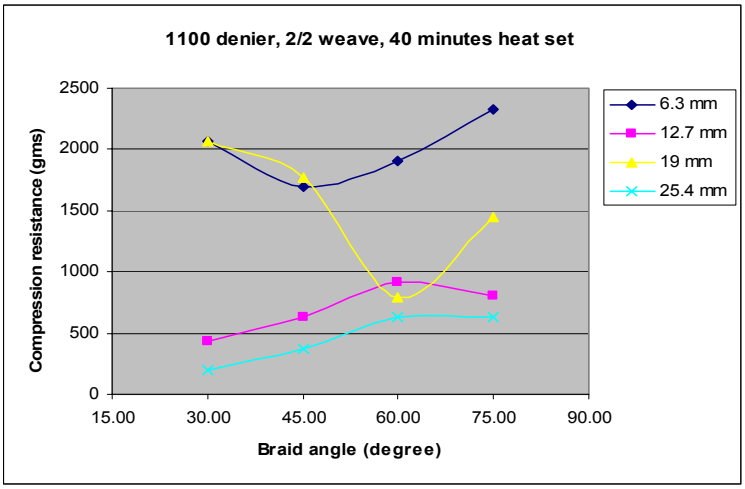

Figure 4.15: Effect of braid angle and braid diameter on compression resistance (40 minutes heatset).

Figure 4.15 shows the effect of braid angle and braid diameter on compression resistance of braided structures, heatset for 40 minutes. Samples of 12.7 mm (0.5 inch) and 25.4 mm (1 inch) diameter showed increase in compression resistance as the braid angle increased. In the statistical analysis, the variables were braid diameter and braid angle; heat set time was kept constant as 40 minutes. The results of ANOVA are as shown in Table 4.11.

Table 4.11: Two-way ANOVA results for 40 minutes heatset braided structures.

40 minutes heat set, Sample = braid angle with 4 levels.

Column = braid diameter 4 levels.

ANOVA

Source of Variation	*SS*	*df*	*MS*	*F*	*P-value*	*F crit*
Sample	655047.5	3	218349.2	9.88408	1.92E-05	2.748195
Columns	30813148	3	10271049	464.9428	2.24E-43	2.748195
Interaction	6255705	9	695078.3	31.46433	3.21E-20	2.029793
Within	1413824	64	22090.99			
Total	39137724	79				

Table 4.11 shows that the values of F are greater than the values of Fcritical for Sample, Column and Interaction. For all these three, the value of p was very low. There was a low chance of accepting that there was no effect of these two variables selected on response. It was clear that there was significant effect of braid angle (Sample) and braid diameter (Column) on compression resistance of braided structures heatset for 40 minutes. Thus the analysis showed significant effect of interaction of both factors on compression resistance properties of braided structures heat set for 40 minutes.

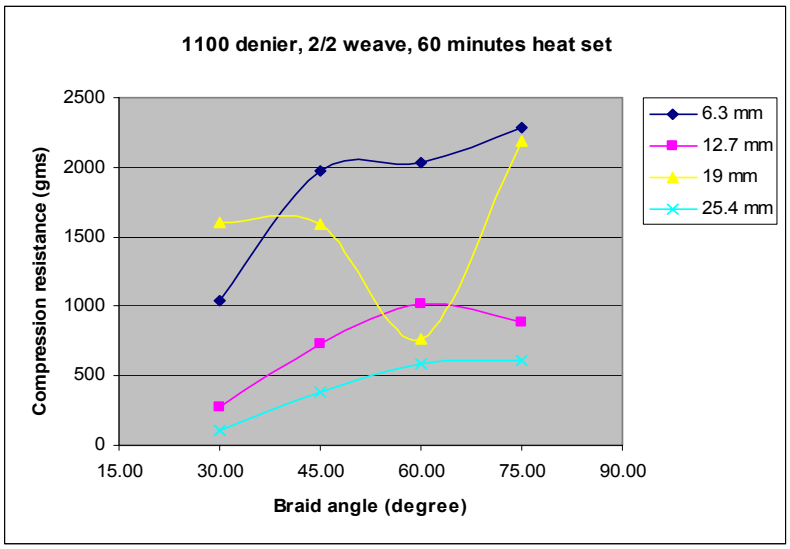

Figure 4.16: Effect of braid angle and braid diameter on compression resistance (60 minutes heatset).

Figure 4.16 shows the effect of braid angle and braid diameter on compression resistance of braided structures, heatset for 60 minutes. Samples of 6.3 mm (0.25 inch) and 25.4 mm (1 inch) diameter showed increase in compression resistance force as the braid angle increased. In the statistical analysis, variables taken were braid diameter and braid angle; heatset time was kept constant as 60 minutes. The results of ANOVA are as shown in Table 4.12.

Table 4.12: Two-way ANOVA results for 60 minutes heatset braided structures.

60 minutes heat set, Sample = braid angle with 4 levels.

Column = braid diameter 4 levels.

ANOVA

Source of Variation	*SS*	*df*	*MS*	*F*	*P-value*	*F crit*
Sample	5453303	3	1817768	148.3367	9.21E-29	2.748195
Columns	26393424	3	8797808	717.9342	3.41E-49	2.748195
Interaction	6516948	9	724105.3	59.08971	1.36E-27	2.029793
Within	784277.6	64	12254.34			
Total	39147951	79				

The Table shows that the values of F are greater than the values of Fcritical for Sample, Column and Interaction. For all these three, the value of p was very low. There was a low chance of accepting that there was no effect of these two variables on response. It was clear that there was significant effect of braid angle (Sample) and braid diameter (Column) on compression resistance of braided structures heatset for 60 minutes. The analysis also showed significant effect of interaction of both factors on compression resistance properties of braided structures heatset for 60 minutes.

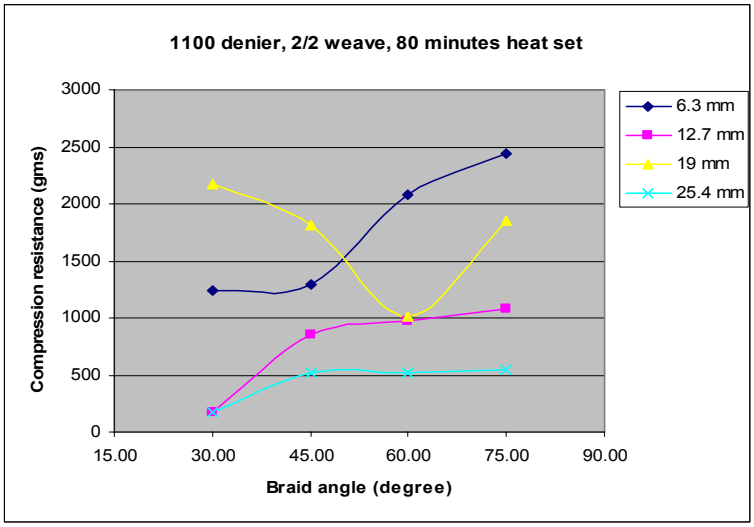

Figure 4.17: Effect of braid angle and braid diameter on compression resistance (80 minutes heatset).

Figure 4.17 shows the effect of braid angle and braid diameter on compression resistance of braided structures, heatset for 80 minutes. Samples of 6.3 mm (0.25 inch), 12.7 mm (0.5 inch) and 25.4 mm (1 inch) diameter showed increase in compression resistance force as the braid angle increased. In the statistical analysis, the variables were braid diameter and braid angle; the heatset time was kept constant as 80 minutes. The results of ANOVA are as shown in Table 4.13.

Table 4.13: Two-way ANOVA results for 80 minutes heatset braided structures.

80 minutes heat set, Sample = braid angle with 4 levels.

Column = braid diameter 4 levels.

ANOVA

Source of Variation	*SS*	*df*	*MS*	*F*	*P-value*	*F crit*
Sample	3054323	3	1018108	41.49322	5.16E-15	2.748195
Columns	26832417	3	8944139	364.5205	3.65E-40	2.748195
Interaction	8831802	9	981311.4	39.99358	6.14E-23	2.029793
Within	1570350	64	24536.73			
Total	40288893	79				

The Table shows that the values of F are greater than the values of Fcritical for Sample, Column and Interaction. For all these three, the value of p was very low. There was a low chance of accepting that there was no effect of these two variables selected on response. It was clear that there was significant effect of braid angle (Sample) and braid diameter (Column) on compression resistance of braided structures heatset for 80 minutes. The analysis also showed significant effect of interaction of both factors on compression resistance properties of braided structures heatset for 80 minutes.

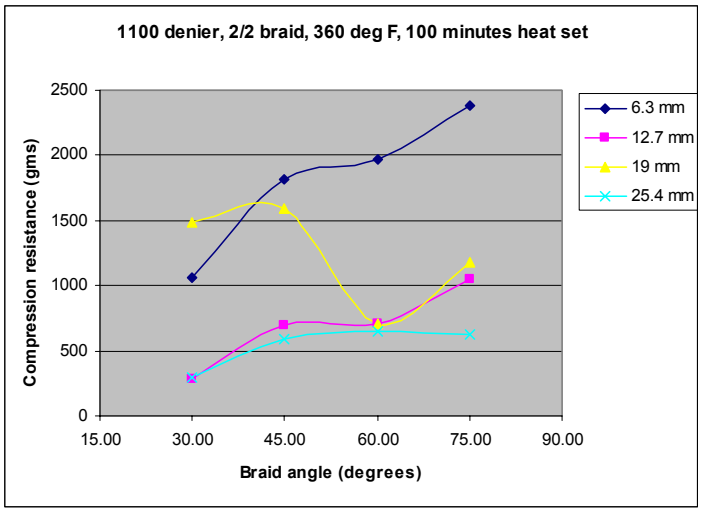

Figure 4.18: Effect of braid angle and braid diameter on compression resistance (100 minutes heatset).

Figure 4.18 shows the effect of braid angle and braid diameter on compression resistance of braided structures, heatset for 100 minutes. Samples of 6.3 mm (0.25 inch), 12.7 mm (0.5 inch) and 25.4 mm (1 inch) diameter showed increase in compression resistance as the braid angle increased. In the statistical analysis, the variables were braid diameter and braid angle; the heatset time was kept constant as 100 minutes. The results of ANOVA were as shown in Table 4.14.

Table 4.14: Two-way ANOVA results for 100 minutes heatset braided structures.
100 minutes heat set, Sample = braid angle with 4 levels.
Column = braid diameter 4 levels.

ANOVA

Source of Variation	*SS*	*df*	*MS*	*F*	*P-value*	*F crit*
Sample	3048285	3	1016095	44.23533	1.33E-15	2.748195
Columns	20102445	3	6700815	291.7176	2.92E-37	2.748195
Interaction	5648690	9	627632.2	27.32374	1.11E-18	2.029793
Within	1470094	64	22970.21			
Total	30269513	79				

The Table shows that the values of F are greater than the values of Fcritical for Sample, Column and Interaction. For all these three, the value of p was very low. There was a low chance of accepting that there was no effect of these two variables on response. It was clear that there was significant effect of braid angle (Sample) and braid diameter (Column) on compression resistance of braided structures heatset for 100 minutes. The analysis also showed significant effect of interaction of both factors on compression resistance properties of braided structures heatset for 100 minutes.

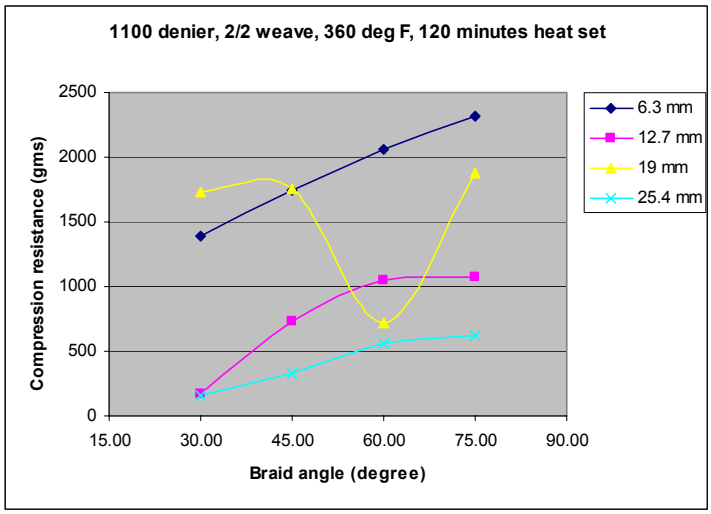

Figure 4.19: Effect of braid angle and braid diameter on compression resistance (120 minutes heatset)

Figure 4.19 shows the effect of braid angle and braid diameter on compression resistance of braided structures, heatset for 120 minutes. Samples of 6.3 mm (0.25 inch), 12.7 mm (0.5 inch) and 25.4 mm (1 inch) diameter showed increase in compression resistance as the braid angle increased. In the statistical analysis, the variables were braid diameter and braid angle; the heatset time was kept constant as 120 minutes. The results of ANOVA are as shown in Table 4.15.

Table 4.15: Two-way ANOVA results for 120 minutes heatset braided structures.

120 minutes heat set, Sample = braid angle with 4 levels.

Column = braid diameter 4 levels.

ANOVA

Source of Variation	*SS*	*df*	*MS*	*F*	*P-value*	*F crit*
Sample	3829305	3	1276435	51.0145	5.82E-17	2.748195
Columns	27174330	3	9058110	362.0199	4.49E-40	2.748195
Interaction	6331315	9	703479.5	28.11553	5.45E-19	2.029793
Within	1601346	64	25021.02			
Total	38936296	79				

The Table shows that the values of F are greater than the values of Fcritical for Sample, Column and Interaction. For all these three, the value of p was very low. There was a low chance of accepting that there was no effect of these 2 variables on response. It was clear that there was significant effect of braid angle (Sample) and braid diameter (Column) on compression resistance of braided structures heat set for 120 minutes. The analysis also showed significant effect of interaction of both factors on compression resistance properties of braided structures heat set for 120 minutes.

4.4.5 Discussion on Compression Resistance Results by Keeping Heatset Time Constant

Edwards and Tapp [58] studied the performance of smooth and straight grafts. Tubes of three sizes were used clinically in bridging iliac, femoral and popliteal artery defects. Braided nylon tubes having inside diameter of 6.1, 7.7 and 9.4 mm were used. A total of 14 patients have received 15 nylon grafts in peripheral vessels. Various concentrations of formic acid were used and best mixture of formic acid into water was found to make the tube grafts smooth for suturing and handling. The aim in using formic acid was to produce a vascular graft tube with the required degree of stiffness for suturing. The early results in 10 consecutive patients with artery replacement were encouraging. The grafts showed very thin smooth inner lining without any evidence of calcium deposition even after 1 year of implantation. Very high thrombosis was observed in stiff straight grafts. The authors concluded that flexible braided nylon tubes treated with formic acid could be successfully used as artery replacements. Thus flexibility of textile stents is the most important property. The results of our work showed that the flexibility of prototype textile stent depends on flexibility of the reinforcing component which is a braided structure. Moreover, it is clear that the flexibility of braided structures

depends on the braid angle and braid diameter. The results of compression resistance presented in this study can be used as guidelines for manufacturing of future commercial braided structures to be used as reinforcing component for textile stents.

4.5 Prediction of Compression Resistance of Braided Structures

This study involved four levels of braid angle- 30°, 45°, 60°, and 75°, four levels of braid diameter- 6.3 mm (0.25 inch), 12.7 mm (0.5 inch), 19 mm (0.75 inch), and 25.4 mm (1 inch), and seven levels of heatset time- 0, 20, 40, 60, 80, 100, and 120 minutes. The statistical analysis results showed that individual effects of each factor as well as interaction effects of any two factors on compression resistance were significant. The study was limited only to those specific levels of each factor as mentioned earlier. As far as providing guidelines to commercial manufacturing of braided structures to be used as reinforcing component in textile stents is concerned, the study must provide guidelines for each and every possible value of braid angle, braid diameter and heatset time. The 3-D graphs provided in this study certainly led towards these manufacturing guidelines. The 3-D graphs were drawn with braid angle and heatset time against compression resistance. All graphs were drawn with respect to braid diameters. The stents are also commercially sold and manufactured depending on their diameter and length. Therefore, it was convenient to predict the compression resistance of textile stents depending on their diameters.

Figure 4.20 shows the compression resistance results for 25.4 mm (1 inch) diameter braided structures. The plot showed significant increase in compression resistance as the braid angle was increased from 30° to 75°. With the help of this graph it

is possible to predict compression resistance of braided structure for any braid angle between 30° to 75° and heatset time between 0 to 120 minutes.

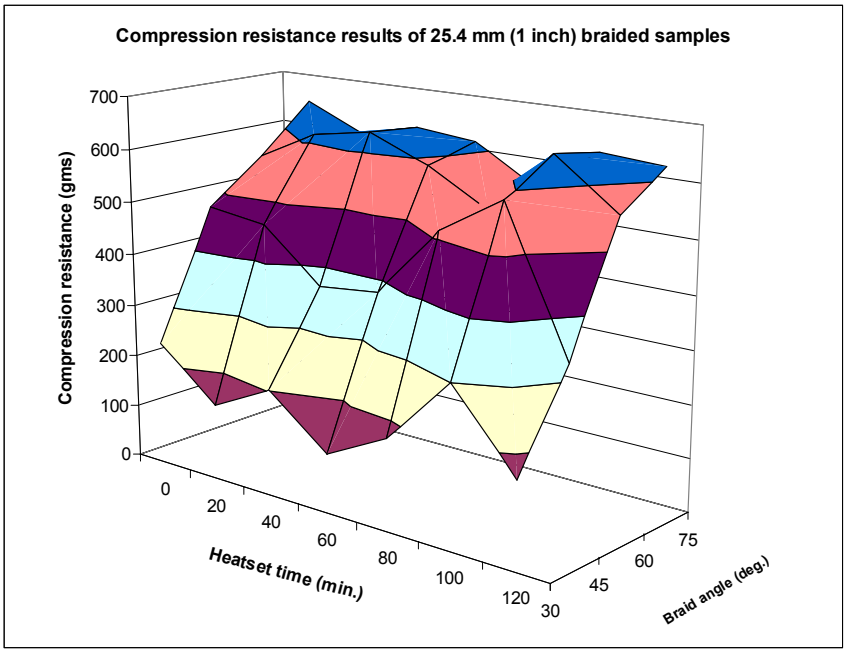

Figure 4.20: 3-D plot for prediction of compression resistance of 25.4 mm (1 inch) braided samples.

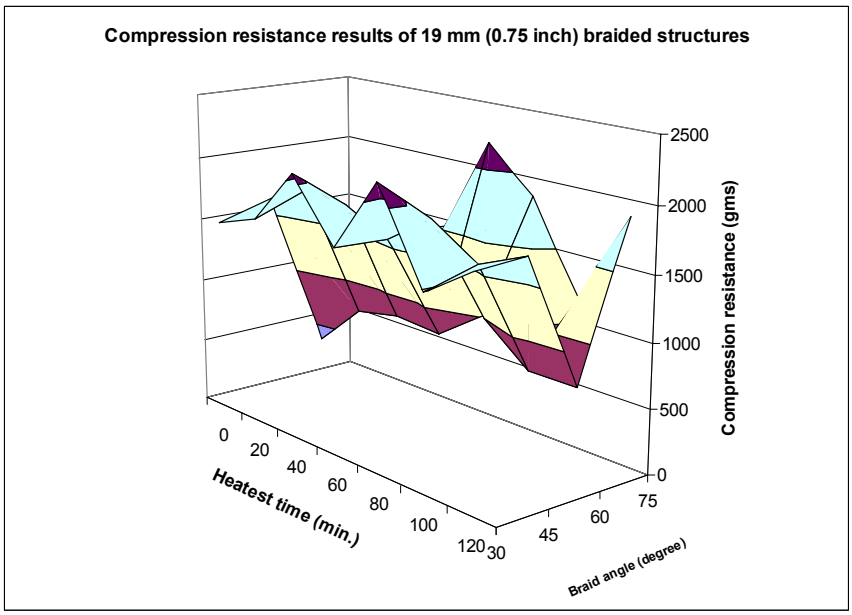

Figure 4.21: 3-D plot for prediction of compression resistance of 19 mm (0.75 inch) braided samples.

For 19 mm (0.75 inch) braid diameter, 30° and 75° braid angle structures showed maximum and 60° braid angle structures showed minimum values of compression resistance for all heatset time values (Figure 4.21). No specific trend was observed as far as the heatset time is concerned. In fact, the trend observed for 19 mm (0.75 inch) braided structures was interesting. There was no increase in compression resistance as the braid angle was increased, as observed in other samples. So it was concluded that 19 mm (0.75 inch) braided structures were unstable even after heat setting at different levels as mentioned. Due to this instability the compression resistance values observed for 60° braid angle structures were less than the others, which was the most striking point of these graphs.

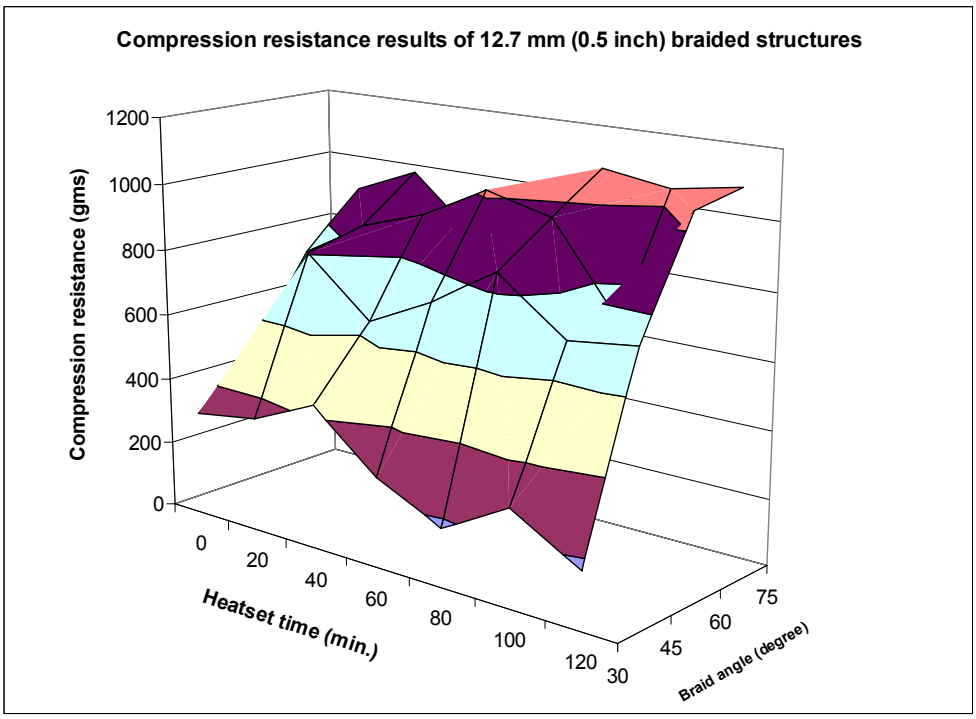

Figure 4.22: 3-D plot for prediction of compression resistance of 12.7 mm (0.5 inch) braided structures.

Figure 4.22 shows 3-D plot of compression resistance values of 12.7 mm (0.5 inch) braided structures obtained from the current study. The surface clearly shows an increase in compression resistance values as the braid angle was increased; but no significant trend was observed for heatset time at all different braid angles.

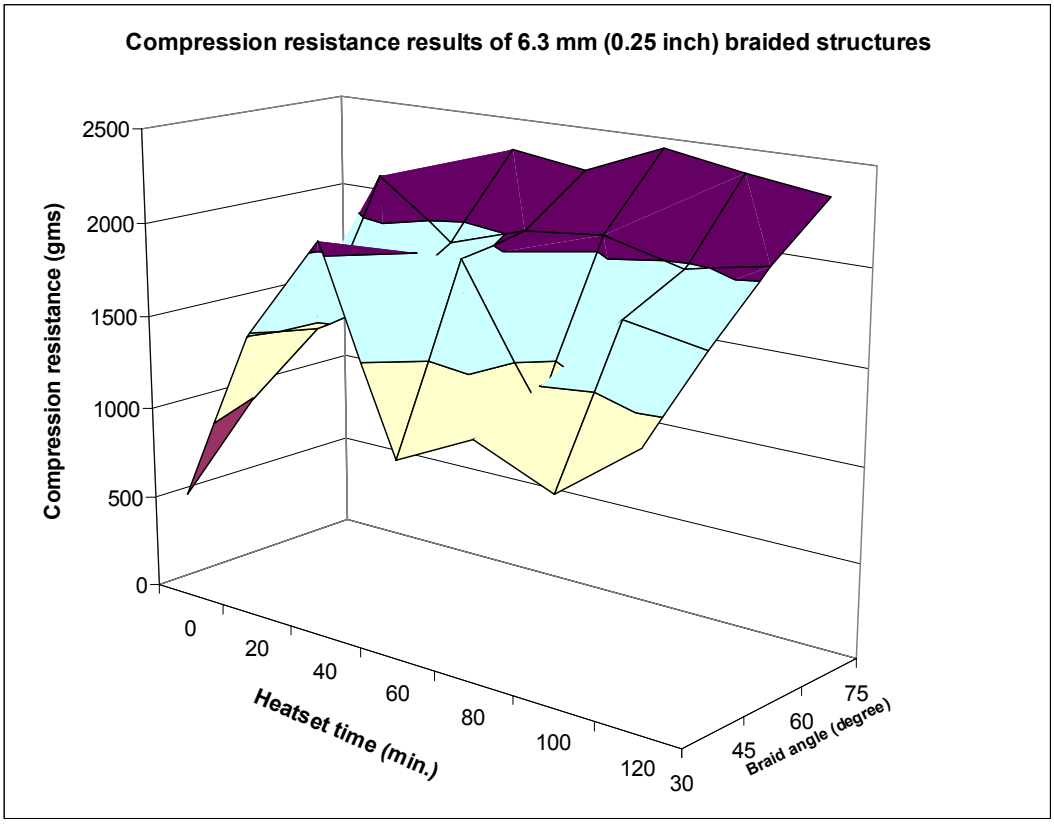

Figure 4.23: 3-D plot for prediction of compression resistance of 6.3 mm (0.25 inch) braided samples.

Figure 4.23 shows 3-D plot of compression resistance results of 6.3 mm (0.25 inch) braided structures obtained from this study. Except for 20 minutes heatset time, the compression resistance values were increased as the braid angle was increased. In this graph 30° braid angle structures heatset at 20 minutes showed higher compression

resistance than 45° and 60° structures heatset at 20 minutes. Therefore, it was concluded that at 20 minutes heatset, 45° and 60° braid angle structures were not stable. They needed more heatset to make them stable. Those structures showed lower values of compression resistance than the stable ones.

Thus these 3-D surfaces provide a useful guideline for manufacturing of different diameter braided structures to be used as reinforcing component.

4.6 Analysis of Properties of Tubular Narrow Woven Seamless Elastic and Non-elastic Fabrics Used as Sealing Component in Prototype Textile Stent

4.6.1 Results for Mechanical Properties of Sealing Component

Tables 4.16 and 4.17 show one way ANOVA test results for load at break of sealing component tested on Instron in both machine and cross-machine directions.

Table 4.16: One way ANOVA results for load at break, machine direction sample testing.

ANOVA

Source of Variation	*SS*	*df*	*MS*	*F*	*P-value*	*F crit*
Between Groups	3772.918	1	3772.918	1.729426	0.224926	5.317645
Within Groups	17452.81	8	2181.601			
Total	21225.72	9				

Table 4.17: One way ANOVA results for load at break, cross-machine direction sample testing.

ANOVA

Source of Variation	*SS*	*df*	*MS*	*F*	*P-value*	*F crit*
Between Groups	1058.573	1	1058.573	1.138937	0.317021	5.317645
Within Groups	7435.518	8	929.4397			
Total	8494.091	9				

In both cases it was clear that the value of Fcritical (Fcrit) was greater than Fcalculated (F). Also in both cases the values of P (P-value) was considerably high, 22% and 31%, respectively. This clearly proved that the null hypothesis must be accepted and there was no effect of change in weft from 150 denier multifilament to elastic yarn on load at break of sealing component of textile stent when tested in both machine and cross-machine directions.

Table 4.18: One way ANOVA results for % strain at break, machine direction sample testing.

ANOVA

Source of Variation	*SS*	*df*	*MS*	*F*	*P-value*	*F crit*
Between Groups	144.7042	1	144.7042	23.64061	0.001252	5.317645
Within Groups	48.968	8	6.121			
Total	193.6722	9				

Table 4.19: One way ANOVA results for % strain at break, cross-machine direction sample testing.

ANOVA

Source of Variation	*SS*	*df*	*MS*	*F*	*P-value*	*F crit*
Between Groups	2445.001	1	2445.001	104.7974	7.12E-06	5.317645
Within Groups	186.646	8	23.33075			
Total	2631.647	9				

Tables 4.18 and 4.19 show one way ANOVA results for % strain at break of sealing component of textile stent for both machine and cross machine directions. For both tests the values of F were greater than the respective values of Fcritical. It was clear that there was a significant effect of change of weft on % strain when tested in both directions. The detail readings of load at break and % strain are given in Appendix B (Page 112).

4.6.2 Discussion on Mechanical Properties of Elastic Seamless Tubular Fabrics

The objective of the study conducted by Riepe et al. [59] was to examine the durability of Stentor and Vanguard endovascular devices in human implants. A total of 34 devices, 25 Stentor (MiniTec, Bahamas) and 9 Vanguard (Bosten Scientific, USA) have been examined. The mean duration of these grafts implantation was 29.8 +/- 16 months. These Stentor and Vanguard devices have an internal self-expanding nitinol stent covered with approximately 0.16 mm thin, woven polyester fabric on outside. The stent was composed of zigzag shaped wire spirals. The spirals were held together by approximately 0.09 mm thick polypropylene ligatures. All explanted grafts were examined by scanning electron microscopy. The polyester covering of grafts showed two types of damage, visible by naked eye. Seventeen stentor devices showed up to 1 mm wide gaps along the sutured seam. Eighteen explants showed isolated holes in the fabric due to wear between metal frames. All of the examined polypropylene ligatures connecting the stent showed signs of wear. The main damage to ligatures was observed as kinks in the graft and between body middle rings and upper ring. The authors concluded that the missing fixation of stent frames resulted in a loss of stability, allowing the stent frames to slip over one another, leading to kinking and longitudinal shortening of graft. This was also the source of damage to fabric. Creases in polyester fabric between moving frames, caused fractures in textile cover. Another important conclusion was that corrosion of the stent wires surely was an indicator of wire fractures. Thus authors mentioned in-vivo complications due to metal stent fracture or slippage. Therefore continuous braided structures were selected in the current study as the reinforcing component of prototype textile stent where monofilaments gave rigidity to

textile stent and braided structures provided continuity expected to avoid possible fracture of stent body frames. The sufficient flexibility of braided structures will also facilitate their in-vivo performance.

Whittlesey et al. [60] evaluated 14 different elastic and inelastic fabrics for their implantation application as arteries. The 14 different fabrics were nylon tricot, nylon knit, nylon mil, orlon tricot, vinyon N, stehli, nylon knit II, nylon braid, USCI heavy, nylon crimped seamless, electrabraid, USCI medium nylon, B-H Dacron and B-H helanca. 74 adult mongrel dogs have been subjected to replacement of a portion of either thoracic or abdominal aorta by synthetic fabric sleeves. The results showed seamless sleeves to serve more satisfactorily than hand fashioned tubular conduits. Tightly braided seamless nylon tube of coarse yarn was found to be unsatisfactory because of great difficulty encountered in suturing it. Crimped braided nylon tubes were found to be somewhat resistant to passage of suture needles. Elastic synthetic fabric seamless tubes were found to be most satisfactory. Thus the authors concluded that the seamless tubes offered the greatest potential for clinically acceptable vascular prosthesis. The prototype textile stent in the current study had a sealing component which is tubular woven seamless structure, so as to eliminate all complications related to suture failure, seam slippage, hole formation in seams, suture degradation etc, as mentioned in the literature.

The objective of the study conducted by Salzmann et al. [61] was to investigate the authenticity of the hypothesis that balloon dilatation of stent grafts would alter the physical structure of prosthetic graft material. For this study non compliant angioplasty balloons, to dilate expanded polytetrafluoroethylene (ePTFE) a material commonly used for endovascular stent grafts, were used. The maximum outer diameter (inflated balloon

within the lumen) and the recoiled outer diameter (balloon removed) of two types of ePTFE were measured to compare material recoil. The ePTFE used were of 3 mm inside diameter and of 4 mm standard wall diameter. The internodal distance was 30 μm. After balloon dilatation, ePTFE samples were scanned by scanning electron microscope (SEM). The parameters measured were wall thickness, internodal distance, nodal width, interfiber distance and fiber width. The results showed that, following primary dilatation, both types of ePTFE recoiled approximately 20% regardless of inflated balloon diameter. SEM analysis also revealed variation in internodal distance and significant difference in wall thickness, nodal thickness, and interfiber distance. The authors concluded that data supported the hypothesis that balloon dilatation altered structure of ePTFE.

This problem of changes in structural properties of stents due to balloon dilatation as mentioned or due to residual stresses in arteries can be rectified with adding some elasticity to the stents. The prototype textile stent developed in the current study had inherent advantage of elasticity as its sealing component was composed of elastic yarn in weft direction. Also prototype textile stent has a seamless sealing component so there will not be any seam slippages or suture breaks at seams. Due to elasticity the sealing component will firmly adhere to reinforcing braided component facilitating in-vivo performance of the textile stent.

4.7 Discussion on Method of Manufacturing of Bifurcated Stent

Method A sample showed better tactile properties than method B sample. Braided structure is a tubular structure and as it divides into two legs it must have distinct and intact structure. Method A sample had distinct splitting of 64 yarns on both sides of original structure, which afterwards divided into 2 legs. Therefore Method A sample showed better interlacement at joint of single structure and bifurcated legs than Method B sample.

CHAPTER 5

CONCLUSIONS

The current study focuses on prototype manufacturing of integrated braided and narrow woven tubular seamless structure to be used as stent for endovascular application in humans. The prototype was fully manufactured with textile materials.

The conclusions of current study are as follows:

- All components of the prototype 'braided and seamless narrow woven stent' were manufactured with the available machinery.
- The graphs of compression resistance provided guidelines for manufacturing of reinforcing component (braided) of prototype textile stent.
- High compression resistance value of braided reinforcing component showed better tactile properties.
- Braid angle, braid diameter and heat set time of braided structures have statistically significant effect on compression resistance.
- Interaction effect of any two of three variables on compression resistance was also statistically significant.
- Elastic seamless narrow fabrics showed better integrity to braided structures than non-elastic ones.

- Change in weft from non-elastic to elastic has statistically significant effect on % strain of narrow fabrics when tested in both machine and cross-machine directions on Instron.
- Change in weft from non-elastic to elastic has no statistically significant effect on load at break of narrow fabrics when tested in both machine and cross-machine directions on Instron.
- Manufacturing of bifurcated braided structure for application as endografts in humans was feasible with the existing machinery.
- Bifurcated stent sample manufactured by Method A showed better interlacement and tactile properties than Method B sample.
- The integrated braided and tubular seamless woven fabric assembly (textile stent) has potential to eliminate defects in commercially available stents due to biocompatibility of material and integrity and flexibility of the structure.

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APPENDICES

A. Readings for Compression Resistance of Braided Structures

For statistical analysis the arrangement of readings was changed. The following tables include all individual readings of compression resistance of braided structures. The unit of measurement of compression resistance was grams. The data is taken from Excel worksheet used for ANOVA analysis.

		0	20	40	60	80	100	120
1/4 inch	30 deg.	533	1666	1897	1029	999	1105	1247
1/4 inch	30 deg.	674	1642	1900	898	1441	935	1534
1/4 inch	30 deg.	478	1409	2170	966	1129	956	1615
1/4 inch	30 deg.	668	1607	2215	1264	1487	1192	1201
1/4 inch	30 deg.	464	1322	2167	1064	1141	1147	1345
1/4 inch	45 deg.	905	1360	1866	1864	1216	1462	1518
1/4 inch	45 deg.	939	1477	1368	1927	1456	1914	1833
1/4 inch	45 deg.	997	1676	1829	2083	1072	1737	1710
1/4 inch	45 deg.	1039	1435	1438	1901	1353	2052	1816
1/4 inch	45 deg.	1030	1355	1954	2068	1344	1920	1805
1/4 inch	60 deg	1305	2405	1866	2176	1792	1755	1940
1/4 inch	60 deg	1483	2336	1968	2057	1909	2180	2050
1/4 inch	60 deg	1483	2515	1642	1897	2031	1875	2291
1/4 inch	60 deg	1427	1960	1972	1822	2114	2181	2144
1/4 inch	60 deg	1374	1782	2094	2206	2523	1882	1864
1/4 inch	75 deg.	1485	2087	2460	2405	2507	2519	2260
1/4 inch	75 deg.	1703	2426	2528	2160	2456	2175	2232
1/4 inch	75 deg.	1515	1929	2217	2477	2543	2345	2092
1/4 inch	75 deg.	1445	2099	2190	2241	2546	2435	2528
1/4 inch	75 deg.	1407	2107	2253	2118	2176	2427	2499

		0	20	40	60	80	100	120
1/2 inch	30 deg.	331	357	482	258	168	331	226
1/2 inch	30 deg.	320	337	457	272	188	293	158
1/2 inch	30 deg.	326	350	437	257	168	269	166
1/2 inch	30 deg.	306	328	395	258	160	273	143
1/2 inch	30 deg.	285	346	399	307	188	275	161
1/2 inch	45 deg.	460	793	593	734	939	739	648
1/2 inch	45 deg.	475	783	610	695	808	686	727
1/2 inch	45 deg.	467	828	653	711	863	701	811
1/2 inch	45 deg.	473	850	646	759	862	650	690
1/2 inch	45 deg.	488	759	651	756	794	716	760
1/2 inch	60 deg	726	749	953	898	900	761	1163
1/2 inch	60 deg	720	790	886	1084	1012	713	1055
1/2 inch	60 deg	738	848	899	1054	1012	682	979
1/2 inch	60 deg	724	983	924	1001	965	688	1039
1/2 inch	60 deg	739	856	904	1038	946	688	1021
1/2 inch	75 deg.	870	1045	770	830	992	817	1053
1/2 inch	75 deg.	1060	1003	847	863	1135	1020	1064
1/2 inch	75 deg.	878	943	768	886	981	1149	968
1/2 inch	75 deg.	847	918	878	917	1153	1095	1129
1/2 inch	75 deg.	826	972	780	908	1108	1143	1182

		0	20	40	60	80	100	120
3/4 inch	30 deg.	2021	1487	1761	1599	2246	1642	1655
3/4 inch	30 deg.	2142	1579	2338	1609	2277	1209	1719
3/4 inch	30 deg.	1237	1686	2182	1581	2380	1325	1787
3/4 inch	30 deg.	1106	1729	2129	1636	2144	1434	1640
3/4 inch	30 deg.	1114	1698	1927	1572	1799	1791	1836
3/4 inch	45 deg.	1456	1938	1780	1443	1738	1515	2052
3/4 inch	45 deg.	1623	1641	1530	1407	1772	1456	2007
3/4 inch	45 deg.	1694	1844	1599	1625	1899	1654	1739
3/4 inch	45 deg.	1632	1794	1862	1617	1777	1608	1529
3/4 inch	45 deg.	1788	1774	2068	1856	1962	1742	1442
3/4 inch	60 deg	401	457	611	416	1017	1235	1062
3/4 inch	60 deg	406	762	909	796	1062	610	719
3/4 inch	60 deg	232	940	702	817	1274	361	795
3/4 inch	60 deg	434	721	875	846	931	470	640
3/4 inch	60 deg	373	711	856	937	792	875	352
3/4 inch	75 deg.	690	1883	1721	1978	1644	932	1753
3/4 inch	75 deg.	433	1121	1614	2112	1685	1184	1883
3/4 inch	75 deg.	1337	1270	1094	2439	1525	1206	1574
3/4 inch	75 deg.	788	1218	1173	2173	2091	1126	1727
3/4 inch	75 deg.	666	1128	1614	2259	2319	1422	2457

		0	20	40	60	80	100	120
1 inch	30 deg.	254	136	195	111	165	302	185
1 inch	30 deg.	253	134	196	112	173	329	161
1 inch	30 deg.	192	143	208	110	157	256	161
1 inch	30 deg.	242	151	205	101	170	324	149
1 inch	30 deg.	250	159	207	124	194	290	154
1 inch	45 deg.	462	404	339	313	463	579	316
1 inch	45 deg.	496	438	356	402	499	609	337
1 inch	45 deg.	497	506	405	443	540	577	336
1 inch	45 deg.	493	491	368	336	495	598	327
1 inch	45 deg.	442	477	369	406	575	573	322
1 inch	60 deg	581	561	691	567	493	598	558
1 inch	60 deg	550	627	651	600	529	631	556
1 inch	60 deg	570	615	561	600	558	687	570
1 inch	60 deg	528	649	655	550	562	629	560
1 inch	60 deg	549	622	615	634	490	688	540
1 inch	75 deg.	563	637	641	614	518	593	532
1 inch	75 deg.	657	598	625	621	521	632	590
1 inch	75 deg.	691	605	633	612	581	626	660
1 inch	75 deg.	638	591	612	597	606	669	662
1 inch	75 deg.	683	557	619	623	510	618	656

B. Readings for Mechanical Properties of Narrow Tubular Seamless Fabrics

Load at break, machine direction					
	y1	y2	y3	y4	y5
Non-elastic	168.7	153.2	227.2	165	145.6
Elastic	167	151.9	152.3	30.66	163.6

% strain at break, machine direction					
	y1	y2	y3	y4	y5
Non-elastic	21.3	25.96	22.66	20.8	22.3
Elastic	30.86	27.1	28.4	34.6	30.1

% strain at break, cross machine direction					
	y1	y2	y3	y4	y5
Non-elastic	7.8	8.367	10.5	13.667	17.167
Elastic	37.833	39.667	43.833	52	40.533

load at break, cross machine direction					
	y1	y2	y3	y4	y5
Non-elastic	81.5	100.7	41.61	9.799	8.268
Elastic	38.66	36.19	13.4	20.35	30.39

y1, y2, y3, y4, and y5 indicate readings of 5 tests.

C. Related Keywords and Their Meanings

Reference: **http://cancerweb.ncl.ac.uk/omd/**

Anastomosis : An opening created between two normally separate organs by surgical, traumatic or pathological means

Anatomy : Study of the structure of the body and relationship between its parts

Anesthesia : Loss of normal sensation or feeling

Aneurysm : A sac formed by the dilatation of the wall of an artery, vein or heart

Angina : A disease, which repeatedly causes sudden strong pains in the chest because blood-containing oxygen is prevented from reaching the heart muscle by blocked arteries

Angiogram : A diagnostic procedure which visualizes blood vessels following introduction of a contrast material into the artery

Angiography : A technique used to take images of arteries or veins inside the human body

Angioplasty : An operational method to remove blockage from an artery of a person who has angina

Aortic bodies : Small clusters of chemoreceptive and supporting cells located near the aortic arch, pulmonary arteries, and coronary arteries

Artery : Thick tubes that carry blood from heart to other parts of the body

Atherosclerosis : The progressive narrowing and hardening of the arteries over time

Blood : A circulating tissue composed of a fluid portion (plasma) with suspended formed elements (red blood cells, white blood cells, platelets)

Calcification : The process in which organic tissue becomes hard by deposition of calcium salts within its substance

Carotid artery : An artery located in the front of neck that carried blood from heart to brain

Catheter : A tubular, flexible surgical instrument which can be inserted inside the arteries or veins for various purposes

Cholesterol : A fatlike steroid alcohol found in animal fats and oils, in bile, blood, brain tissue, milk, yolk of egg, myelin sheaths of nerve fibers, the liver, kidneys and adrenal glands

Clotting : Coagulation of blood

Compliance : A physical quality of yielding to pressure or force without disruption, or an expression of the measure of the ability to do so

Computed Tomography : A special radiographic technique that uses a computer to assimilate multiple X-ray images into a 2 dimensional cross-sectional image

Contour :

1. The outline of a part; the surface configuration

2. In dentistry, to restore the normal outlines of a broken tooth or create the external shape or form of a prosthesis

Coronary : An extremely dangerous medical condition in which the flow of blood to the heart is blocked by a blood clot

Coronary : Relating to the arteries that supply blood to the muscles of the heart

Dilatation : The condition, as of an orifice or tubular structure, of being dilated or stretched beyond the normal dimensions

Embolism : Sudden blockage of an artery by a clot or foreign material which has been brought to site by blood current

Euthanasia : The act or practice of putting the people or animals to death suffering from incurable conditions or diseases

Femoral : Pertaining to the femur or thigh

Fluoroscope : A fluoroscope is an imaging device that uses X-rays to view internal body structures on a screen

Graft : Portion of a lesion in the body

Grafting : The procedure of inserting or implanting a portion of lesion in the body

Haemorrhage : The escape of blood from the vessels, bleeding

Haemostasis : The arrest of bleeding, either by the physiological properties of vasoconstriction and coagulation or by surgical means

Haemostatic : Of or relating to stagnation of the blood or serving to arrest haemorrhage or a medicine or application to arrest haemorrhage

Harvesting : The growth medium upon which an experimental population of cells or microorganisms can be grown and analyzed

Histology : The study of cells and tissue on microscopic level

Humour : A normal functioning fluid or semi fluid of the body

Humoral : Relating to, proceeding from or involving a bodily humour

Hyperplasia : The abnormal multiplication or increase in the number of cells of a tissue

Hyperplastic : Of or pertaining to hyperplasia

Iliac : Pertaining to or in the region of ilium, or dorsal bone of the pelvis

Implantation : The insertion or grafting of living, biological, inert or radioactive material into the body

Indentation : The act of indenting or state of being indented

Indented : Cut in the edge or inequalities, like jagged or notched teeth

Inflammation : A localized protective response elicited by injury or destruction of tissues, which serves to destroy or dilute both the injurious agent and the injured tissue

Infra- : A position below the part denoted by the word to which it is joined

Intimal : Relating to the intima or inner coat of a vessel

Invasive : Involving puncture or incision of the skin for insertion of an instrument or foreign material into the body

In vitro : Biological processes or reactions happening outside the body in artificial conditions, often in a test tube

In vivo : Inside the living body

Ischaemia : A low oxygen state usually occurs due to obstruction of the arterial blood supply or inadequate blood flow leading to hypoxia in the tissue

Lesion : Any pathological or traumatic discontinuity of tissue or loss of function of a part

Magnetic Resonance Imaging : A special imaging technique used to image internal stuctures of the body

Morbidity : A diseased condition or state or the incidence of a disease

Mortality : The death rate

Neo- : A prefix meaning new, recent

Neoformation : Formation of neoplasia or neoplasm or process of regeneration or a regenerated tissue or part

Neoplasia : Literally new growth, usually refers to abnormal new growth same as tumour, which may be benign or malignant

Obliteration : Blotting out, especially by filling of a natural space or lumen by fibrosis or inflammation

Orthotopic : In the normal or usual position

Paraplegia : Paralysis of legs and lower part of the body

Patency : The state of being freely open, especially referred to lumens of arteries and veins

Physiology : The study of how living organisms function

Polysaccharide : Polymers of (arbitrarily) more than about ten monosaccharide residues linked glycosidically in branched or unbranched chains

Popliteal : Of or pertaining to the ham; in the region of the ham, or behind the knee joint

Prognosis : A forecast of the probable outcome of an attack or disease

Proliferative inflammation : An inflammatory reaction in which the distinguishing feature is an actual increase in the number of tissue cells

Prosthesis : An artificial substitute used for a missing body part or organ

Protein : Any of a group of complex organic compounds which contain carbon, hydrogen, oxygen, nitrogen and usually sulphur, the characteristic element being nitrogen and which are widely distributed in plants and animals

Proteoglycan : A high molecular weight complex of protein and polysaccharide

Radiopaque : A radiopaque substance will be highlighted (appear white) on a plain X-ray

Renal : Pertaining to the kidney

Restenosis : Recurrence of stenosis after corrective surgery on the heart valve; renarrowing of a structure (usually a coronary artery) following the removal or reduction of a previous narrowing

Saphenous vein : The vein which drains the foot and leg

Stenosis : Narrowing of a duct or canal

Stent : A tube made of metal or plastic that is inserted into a vessel or passage to keep the lumen open and prevent closure due to a stricture or external compression

Stricture : A narrowing, especially of a tube or canal, due to scar tissue or tumour

Strut : In general, any piece of a frame which resists thrust or pressure in the direction of its own length

Symptoms : Manifestation of disease and pathological conditions which may occur in various diseases

Thrombosis : The formation, development or presence of thrombus

Thrombus : An aggregation of blood factors, primarily platelets and fibrin with entrapment of cellular elements, frequently causing vascular obstruction at the point of its formation

Topology : The method for assisting the memory by associating the thing or subject to some place for remembering the thing