ABSTRACT

HUANG, YIHAN. A Comparison of the Properties and Performance of Polyvinylidene Fluoride and Polypropylene Barbed Sutures in Tendon Repair. (Under the direction of Dr. Martin W. King).

Barbed sutures are able to penetrate and anchor the surrounding tissues with their projected barbs, which means there is no need to tie a knot. They have attracted more attention and have been introduced into the surgeon’s armamentarium for their specific advantages over traditional knotted sutures, but have never been used in tenorrhaphy. Polypropylene (PP) barbed sutures have been widely used, but there are an increasing number of reports indicating dissatisfaction with polypropylene monofilament sutures because of their thrombogenic properties and long-term mechanical failure. Polyvinylidene fluoride (PVDF) has been identified as an alternative monofilament suture material for polypropylene. The goal of this study was to evaluate the properties and anchoring performance of PVDF barbed sutures compared with PP barbed sutures in tendon repair. Size 2-0 PVDF and PP barbed sutures were fabricated using a manual barb cutting machine, and porcine patellar tendons were repaired using these size 2-0 barbed sutures and a cross-locked cruciate suturing technique. In addition, size 2-0 and 3-0 non-barbed PDVF and PP sutures were also included as the controls to the study using a similar cross-locked cruciate suturing technique with knots. The geometries of a single barb were observed and the tensile properties of the sutures were measured. Further, the ex vivo biomechanical properties were also evaluated via a suture/tissue pull-out test, which measured the maximum pull-out force and the 2-mm-gap formation force. In conclusion, the results proved the hypothesis that barbed polyvinylidene fluoride sutures provide improved mechanical properties and a better tissue anchoring ability compared to barbed polypropylene sutures when used to repair porcine tendon tissue.
A Comparison of the Properties and Performance of Polyvinylidene Fluoride and Polypropylene Barbed Sutures in Tendon Repair

by
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A thesis submitted to the Graduate Faculty of North Carolina State University in partial fulfillment of the requirements for the degree of Master of Science

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To my parents and family for their support, encouragement and love through my entire time pursuing the degree of Master of Science
BIOGRAPHY

Yihan Huang was born in Hangzhou, Zhejiang, China on August 19th, 1994. She entered the College of Textiles, Donghua University, Shanghai, China in the same year as she graduated from Yuhang High School, Hangzhou, Zhejiang, China in June 2012. While at Donghua University, she was the captain of the School Women’s Basketball Team from 2013 to 2015. During her undergraduate study, Yihan worked with Dr. Jing Gao on the preparation of silica sol and its superhydrophobic application on wool-polyester fabrics, and she graduated with a Bachelor of Science with a major in Functional Materials (Biomedical Textile Material and Technology) in July 2016.

In 2015, during the third year of her undergraduate degree, she got the opportunity to pursue a Master of Science degree in Textile Engineering abroad through the Global Training Initiative exchange program between Donghua University and North Carolina State University. Her thesis research works on barbed sutures has been completed under the guidance of Dr. Martin W. King.
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TABLE OF CONTENTS

LIST OF TABLES ................................................................................................................... viii

LIST OF FIGURES .................................................................................................................. ix

CHAPTER 1 INTRODUCTION ................................................................................................. 1

1.1 Introduction ....................................................................................................................... 1

1.2 Background ....................................................................................................................... 2

1.3 Problem statements .......................................................................................................... 3

1.4 Goals and Objectives ....................................................................................................... 3

1.5 Limitations ....................................................................................................................... 5

CHAPTER 2 LITERATURE REVIEW ....................................................................................... 6

2.1 Introduction of surgical sutures ....................................................................................... 6

2.1.1 Wound closure ........................................................................................................... 6

2.1.2 Materials .................................................................................................................... 6

2.1.3 Size ............................................................................................................................. 8

2.1.4 Attached needles ....................................................................................................... 10

2.1.5 Functional sutures ..................................................................................................... 10

2.2 Introduction of barbed sutures ....................................................................................... 12

2.2.1 The history of barbed sutures ................................................................................. 13

2.2.2 Market of barbed sutures ......................................................................................... 14

2.2.3 Single barb geometry design ................................................................................... 15

2.2.4 Selection of sutures for different applications ......................................................... 16
2.2.5 Applications ........................................................................................................ 18
2.2.6 The anchoring performance of barbed sutures ..................................................... 20
2.3 Polyvinylidene fluoride and polypropylene ............................................................ 21
  2.3.1 Structure, physical and chemical properties ....................................................... 21
  2.3.2 Comparison between PVDF and PP sutures ......................................................... 25
2.4 Tendon repair ........................................................................................................... 32
  2.4.1 Tendon ................................................................................................................ 32
  2.4.2 Tendon repair ....................................................................................................... 33

CHAPTER 3 MATERIALS AND METHODS .................................................................... 40
  3.1 Materials ................................................................................................................ 40
    3.1.1 Surgical sutures ................................................................................................. 40
    3.1.2 Tendon tissue samples ...................................................................................... 40
  3.2 Methods .................................................................................................................. 42
    3.2.1 Fabrication of barbed surgical sutures ............................................................... 42
    3.2.2 Microscopic analysis ......................................................................................... 44
    3.2.3 Tensile test ....................................................................................................... 44
    3.2.4 Tendon repair ................................................................................................... 45
    3.2.5 Tissue/suture pull-out test ............................................................................... 47
    3.2.6 Statistical analysis ............................................................................................ 49

CHAPTER 4 RESULTS AND DISCUSSION .................................................................. 50
  4.1 Measurement of suture and barb geometries ......................................................... 50
4.1.1 Measurement of suture diameter ................................................................. 50
4.1.2 Measurement of barb geometries ................................................................. 52
4.2 Results of tensile testing .................................................................................. 55
  4.2.1 Ultimate tensile force .................................................................................. 56
  4.2.2 Elongation at break ...................................................................................... 60
  4.2.3 Stiffness or initial modulus ......................................................................... 61
4.3 Results of suture/tissue pullout test ................................................................. 64
  4.3.1 Maximum pullout force ................................................................................ 64
  4.3.2 Two mm gap formation force .................................................................... 66
  4.3.3 Failure mode ................................................................................................ 69

CHAPTER 5 CONCLUSIONS AND FUTURE WORK ................................................. 71
  5.1 Conclusion ...................................................................................................... 71
  5.2 Limitations of the current study ..................................................................... 72
  5.3 Future work .................................................................................................... 72
### LIST OF TABLES

- Table 2-1 USP and EP Size Codes and Corresponding Diameters ........................................ 9
- Table 3-1 Specific parameters of attached needles for tendon repair .................................. 43
- Table 4-1 Diameters of sutures .................................................................................................. 50
- Table 4-2 Parameters of barb geometries .................................................................................. 52
- Table 4-3 Tensile Properties of sutures ..................................................................................... 55
- Table 4-4: Percentage loss compared with 2-0 non-barbed sutures ........................................ 60
- Table 4-5: Maximum suture/tissue pullout force and 2-mm-gap formation force for the 6 groups .................................................................................................................................................. 64
- Table 4-6 Modes of failure ........................................................................................................ 69
LIST OF FIGURES

Figure 2-1: Geometry of a single barb ................................................................. 16
Figure 2-2: Polyvinylidene fluoride ................................................................. 21
Figure 2-3: Polypropylene ........................................................................... 24
Figure 2-4: Ultimate breaking force for different sizes of virgin PVDF and polypropylene sutures ................................................................. 26
Figure 2-5: Extension at breaking for different sizes of virgin PVDF and polypropylene sutures ........................................................................... 26
Figure 2-6: Tensile creep properties of 5-0 and 6-0 PVDF and polypropylene sutures ........ 27
Figure 2-7: Experimental creep curves of PVDF and PP monofilaments ................. 28
Figure 2-8: Scanning electron photomicrographs of retrieved and cleaned 6-0 polyvinylidene fluoride (left) and 6-0 polypropylene (right) sutures showing the surface morphology after implantation for 1 year ........................................................................ 29
Figure 2-9: Scanning electron photomicrographs of retrieved and cleaned 6-0 polyvinylidene fluoride (left) and 6-0 polypropylene (right) sutures showing the surface morphology after implantation for 2 years ........................................................................ 30
Figure 2-10: The residual tensile strength of PVDF and polypropylene sutures during 7 years of exposure to hydrolytic conditions ......................................................... 31
Figure 3-1: PVDF and PP surgical sutures ......................................................... 40
Figure 3-2: Porcine leg (a) Before dissection; (b) After dissection ...................... 41
Figure 3-3: Patellar tendon (a) Before transection; (b) After transection ............... 41
Figure 3-4: Barb cutting machine ........................................................................................................42
Figure 3-7: Barbed suture mounted on the Instron test machine .........................................................45
Figure 3-8: Cross-locked cruciate suturing technique ........................................................................46
Figure 3-9: Modified cross-locked cruciate suturing technique ........................................................46
Figure 3-10: Patellar tendon after repair with (a) monofilament suture; (b) barbed suture .... 47
Figure 3-11: A High-definition video camera was set 25 cm away from the Instron Universal
Testing Machine ..................................................................................................................................48
Figure 4-1: Comparison of the diameter of commercial sutures with their target ranges ..... 51
Figure 4-2: (a) Comparison of the cut angle of the fabricated barbed sutures with their target
value; (b) Comparison of the cut depth of the fabricated barbed sutures with their target
value ..................................................................................................................................................53
Figure 4-3: Microscopic images of a single barb on the suture’s surface for (a) 2-0 PVDF
barbed suture; (b) 2-0 PP barbed suture ..........................................................................................54
Figure 4-4: (a) Comparison of the ultimate tensile force of PVDF and PP monofilament
barbed and non-barbed sutures; (b) The results of ANOVA analysis for the ultimate
tensile force of PVDF and PP monofilament barbed and non-barbed sutures ...................... 57
Figure 4-5: (a) Reduction in cross-sectional area of barbed sutures; (b) Reduction in cross-
sectional area between 2-0 and 3-0 monofilament sutures ......................................................... 58
Figure 4-6: Comparison of elongation at break of PVDF and PP barbed and non-barbed
sutures ..................................................................................................................................................61
Figure 4-7: (a) Comparison of the stiffness or initial modulus of PVDF and PP barbed and non-barbed sutures; (b) The results of ANOVA analysis for the stiffness or initial modulus of PVDF and PP barbed and non-barbed sutures...................................................... 62

Figure 4-8: (a) Comparison of the maximum suture/tissue pullout force for the PVDF and PP barbed and non-barbed sutures; (b) The results of ANOVA analysis for the maximum suture/tissue pullout force for the PVDF and PP barbed and non-barbed sutures........ 65

Figure 4-9: (a) Comparison of the 2-mm-gap formation force for the PVDF and PP barbed and non-barbed sutures; (b) Results of ANOVA analysis for the 2-mm-gap formation force of the PVDF and PP barbed and non-barbed sutures................................................. 67

Figure 4-10: Comparison of the failure modes of PVDF and PP monofilament barbed and non-barbed sutures.......................................................... 70
CHAPTER 1 INTRODUCTION

1.1 Introduction

Surgical sutures have been used worldwide for wound closure for many centuries. In evaluating their performance there have been plenty of theoretical \textit{in vitro} studies, animal tests and human trials. And from among the many different types, materials and sizes of sutures, the barbed suture, as an innovative type of suture, has been developed over the last 20 years and was approved by US Food and Drug Administration (FDA) in 2004 for clinical use in the USA. With its projected barbs, this type of suture is able to penetrate and anchor the surrounding tissues, which means there is no need to tie a knot. Over the last 12 years, barbed sutures have attracted more attention and have been introduced into the surgeon’s armamentarium for their specific advantages over traditional knotted sutures. In particular, they are being widely used in cosmetic and plastic surgery, and in other types of surgery that are space-limited, such as laparoscopic surgery and less invasive obstetric and gynecological surgeries.

The \textit{in vitro} suture/tissue pull-out test is the most appropriate method to undertake an initial evaluation of the anchoring performance of barbed surgical sutures with their surrounding tissue before committing to an \textit{in vivo} trial.

In this study the scope and application for using barbed surgical sutures for other types of surgery has been evaluated. In particular, the question of whether or not a barbed suture would be suitable to use in orthopedic surgery for the repair of torn and injured tendons and ligaments has been addressed, and this thesis reports the findings of an initial study in which porcine patellar tendon tissues were repaired with barbed and non-barbed surgical sutures.
1.2 Background

In a recent report produced by Transparency Market Research it was indicated that the global surgical suture market holds an incremental opportunity of US$5,080 million from 2017 to 2025 with a compound annual growth rate (CAGR) of 3.9% over the same period. In terms of product type, the global market for surgical sutures has been segmented into two main categories: absorbable sutures and non-absorbable sutures. Non-absorbable sutures are essential in long-term treatments and required in specific fields like cardiovascular surgeries. This segment accounted for about 40% of global market share and is expected to keep this position over the same period. Non-absorbable suture materials include, but are not limited to, polypropylene, polyester, nylon, and stainless steels. Surgical polypropylene sutures alone accounted for more than US$300 million on the global market in 2016.

As non-absorbable sutures, both polypropylene (PP) and polyvinylidene fluoride (PVDF) sutures are indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures. Compared with the mature market of polypropylene surgical sutures, there are a few companies produce polyvinylidene fluoride sutures. Only one product from a British company to date has received approval from the United States Food and Drug Administration (FDA) for distribution and sales in the USA. Clearly the market is still at an early beginning stage.
1.3 Problem statements

Polypropylene barbed sutures have been used widely for skin closure, cardiovascular, ophthalmic, general closure, orthopedics, plastic and microsurgeries, soft tissue approximation and ligation. But there are an increasing number of reports indicating dissatisfaction with polypropylene monofilament sutures because of their thrombogenic properties and long term mechanical failure (Urban et al. 145-156). Polyvinylidene fluoride (PVDF), has been identified as an alternative monofilament suture material that has the potential to replace polypropylene. Mechanically, it has been shown to have a similar tensile breaking strength and a higher extension at break compared to polypropylene. When tested for long term creep, PVDF has less delayed and permanent deformation compared with polypropylene surgical sutures (Urban et al. 145-156). However, up until now, no-one has considered barbing PVDF sutures, and no surgeon or researcher has measured the anchoring performance of polyvinylidene fluoride barbed sutures in tendon tissues. So these are the primary goals of this research study.

1.4 Goals and Objectives

The overall goal of this study was to evaluate the anchoring performance of different types of knotless barbed sutures in repairing tendon tissue using polyvinylidene fluoride size 2-0 and polypropylene size 2-0 surgical sutures. Tensile tests and suture/tissue pullout tests using both barbed and non-barbed sutures were designed and performed to see whether polyvinylidene fluoride can provide an equivalent or significant improvement in mechanical properties and anchoring performance compared to polypropylene sutures. The main hypothesis of this study
was that barbed polyvinylidene fluoride sutures provide improved mechanical properties and better tissue anchoring ability than barbed polypropylene sutures when used to repair porcine tendon tissue.

With the guidance of this overall goal, six specific objectives were identified as follows:

1. To fabricate barbed polypropylene and polyvinylidene fluoride sutures using an existing manual barb cutting machine.
2. To dissect porcine hind legs and to transect the patellar tendon tissue at the middle point.
3. To measure the mechanical tensile properties of polypropylene and polyvinylidene fluoride sutures, and to determine whether the type of suture material, suture size and presence of barbs influences the tensile properties.
4. To compare the configuration and morphology of polypropylene and polyvinylidene fluoride barbed sutures, and to determine whether the type of suture material influences the barb’s appearance.
5. To determine the highest pullout force and 2-mm-gap formation force in porcine tendon tissues repaired with different types of suture material, suture sizes and with or without the presence of barbs.
6. To determine the mode of failure in suture/tissue pullout test, and to determine whether the type of suture material, suture size and the presence of barbs will have an impact on failure mode.
1.5 Limitations

1. The barbing procedure for making the barbed sutures used in this study was performed manually.

2. Due to the limited supply of porcine patellar tendons, the sample size for each group was limited to 10 specimens.

3. All the tendon repair procedures and the tying of knots in this study were performed by the researcher, who was trained, but who was not a professional experienced surgeon.

4. A video recording of each suture/tissue pullout test was initiated manually so as to determine the time and displacement of each test by synchronizing the camera with the output from the load cell of the mechanical tester.
CHAPTER 2 LITERATURE REVIEW

2.1 Introduction of surgical sutures

2.1.1 Wound closure

Surgical sutures are a medical device used to hold body tissues together after an injury or surgery, and they have been used for millennia. They are classified by the US Food and Drug Administration (FDA) as either a Class II or a Class III device. They always involve one or two needles with an attached, or swaged, length of thread.

Clips, adhesive tapes, surgical sutures, staples, surgical zippers, adhesives and laser tissue bonding are all used as cutaneous wound closure materials. It is well recognized that among these alternative candidates, surgical sutures have been the most common and extensively used method as an effective and critical component of surgery and trauma management. Surgical sutures are used to hasten the process of wound closure and healing by holding injured, damaged or incised tissues together (Dennis et al. 1544-1559).

2.1.2 Materials

Sutures can be classified as having either a natural or synthetic origin, made from either an absorbable or nonabsorbable material, and having either a monofilament or a multifilament structure. Suture materials are defined as absorbable or nonabsorbable suture materials based on their engineered and anticipated ability to be absorbed by the body (Dennis et al. 1544-1559). Absorbable sutures degrade by means of an enzymolytic or hydrolytic mechanism; which means that either enzymes catalyze the degradation or water molecules penetrate into
the polymer structure and breakdown the polymer by chain scission. On the other hand, nonabsorbable or permanent sutures are not broken down, digested or removed naturally from the body (Dennis et al. 1544-1559).

Wound closure using a suture material was first recorded in human history on Egyptian scrolls dating back to 3,500 BC (Al-Mubarak and Al-Haddab 178-188). A wide range of different suture materials have been used in the past for medical purposes, and some of them are still used today. Natural suture materials include, but are not limited to, linen, cotton, silk and human and animal hair. Then in the 1900’s surgeons started using gold and silver wires as suture materials (Black 619-623).

External nonabsorbable sutures usually require removal after healing, which is inconvenient for both the patient and surgeon. So this created the need for absorbable sutures. In 1806, Philip Syng Physick invented an absorbable suture made from buckskin. This represented the start of today’s modern suturing technique (Luck et al. 137-142). The perfect suture should be nonelectrolytic, nonangiogenic, noncarcinogenic, nonallergenic, and avoid bacterial colonization and also, should have easy handling characteristics (Greenberg and Clark 146-158). The choice of suture material depends on a variety of factors, such as the number of tissue layers involved in the wound closure, the desired tension across the wound, the depth of suture placement, the expected time of suture removal, and the preferred level of inflammatory reaction (Dennis et al. 1544-1559). The first synthetic polymeric suture was created in the 1930’s, and since then research has focused on the invention of synthetic absorbable sutures. With the synthesis of polyglycolic acid by Frazza and Schmitt in 1970, Dexon® braided
multifilament suture was the first commercial synthetic absorbable suture to be developed, tested and approved for surgical use. Other nonabsorbable synthetic suture materials, such as polypropylene and nylon, have proven themselves to be sufficiently strong and biocompatible to be preferred over natural polymers such as silk. And over the last 45 years, various synthetic biomaterials have been synthesized, such as polydioxanone and polyglycolide-co-e-caprolactone, so that suture materials with a range of different absorption rates have been developed (Greenberg & Clark 146-158).

### 2.1.3 Size

As mentioned above, there are various criteria used to classify suture materials, such as whether they are natural or synthetic, absorbable or nonabsorbable, monofilament or multifilament. However, there is another category of suture classification, and that is suture size. There are currently 2 standards used to describe the size of suture materials: The United States Pharmacopoeia (USP) and the European Pharmacopoeia (EP). In North America, the USP is more commonly used. Table 1 summarizes the USP and EP standards for both collagen sutures and synthetic sutures. Because in the past the finest suture was a silk Size 0 suture, and with the advancement of even finer synthetic sutures, the USP standard now uses 2 numerals (such as 2-0 and 10-0) to classify sutures finer than Size 0. This means that the higher the first number, the smaller the suture diameter.
Table 2-1 USP and EP Size Codes and Corresponding Diameters

<table>
<thead>
<tr>
<th>Collagen Suture</th>
<th>Synthetic Suture</th>
<th>Limited on Average Diameter (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>USP Size Code</td>
<td>USP Size Code</td>
<td>EP Size Code</td>
</tr>
<tr>
<td>8-0</td>
<td>0.4</td>
<td>0.04</td>
</tr>
<tr>
<td>8-0</td>
<td>7-0</td>
<td>0.5</td>
</tr>
<tr>
<td>7-0</td>
<td>6-0</td>
<td>0.7</td>
</tr>
<tr>
<td>6-0</td>
<td>5-0</td>
<td>1</td>
</tr>
<tr>
<td>5-0</td>
<td>4-0</td>
<td>1.5</td>
</tr>
<tr>
<td>4-0</td>
<td>3-0</td>
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<td>0</td>
<td>3.5</td>
</tr>
<tr>
<td>0</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>1</td>
<td>2</td>
<td>5</td>
</tr>
</tbody>
</table>
2.1.4 Attached needles

The barbed sutures available on the market invariably have one or two needles attached. There are straight, half-curved (also known as ski) and curved needles, and the curved needles have various shapes: 1/4 circle, 3/8 circle, 1/2 circle, 5/8 circle and a compound curve. The needles with a 3/8 circle and 1/2 circle are widely used in modern surgical procedures.

And the attached needles also have various types of pointed tips to facilitate insertion into different tissues. The pointed tips include, but are not limited to, taper point, taper cutting, ball point, cutting edge, diamond point, thin line, and lancet point. The taper point, taper cutting, and diamond point are more commonly used with barbed sutures.

The needle diameter is not the main concern when using conventional sutures, but it should be selected carefully when using barbed sutures. The thinner the surgical needle, the smaller the insertion hole, and the better the barb engagement will be with the surrounding tissue. On the other hand, the needle diameter should be wide enough to make a hole to hold the suture in place. Therefore, an ideal ratio of needle diameter to barbed suture diameter needs to be less than 3:1 for both straight needles and curved needles. In fact, 2:1 or less is preferred, and according to a recent patent, the ratio of 1.8:1 or less is the best (Patent Application Publication and Leung).

2.1.5 Functional sutures

Because there is no single suture material that is able to meet all types of surgical and medical requirements, there has been increased interest in recent years in functional sutures with
additional properties, such as those incorporating antimicrobial agents, like silver, and bioactive molecules like DNA, proteins, growth factors, antibodies and drugs (Dennis et al. 1544-1559). Infections caused by bacterial attachment and proliferation on the surface of sutures are a primary concern during reconstructive procedures and when implanting biomedical devices, because they increase the risk of morbidity and mortality (Costerton, Stewart, and Greenberg 1318-1322).

There are two main ways to modify sutures so as to achieve antimicrobial behavior; one is to coat the suture with an antimicrobial agent like chitin, and the other is to treat the suture with silver nanoparticles. By being able to release a drug at a specific site postoperatively, it has long been predicted that this will reduce infections at surgical sites and facilitate wound healing. Now this can be achieved by using drug-eluting sutures. Drug-eluting sutures can be created by a number of different methods, such as dip-coating the suture in the active agent, chemical grafting onto the surface, or by electrospinning (Dennis et al. 1544-1559). However, the concentration, release rate and potency of the drug is difficult to control while maintaining the required mechanical properties of the suture.

Sutures coated with growth factors or stem cells, like some biodegradable scaffolds, have the ability to deliver needed active components to targeted sites. In addition to adding a coating, by seeding stem cells on the suture’s surface, it is possible to intensify the tissue regeneration and promote rapid healing at the injured site (Guyette et al. 809-818). There are a number of advantages of incorporating stem cells and/or growth factors with suture materials, which can then serve as a carrier in heart surgery or tendon repair. The rate of healing is accelerated with
improvement in tendon repair strength, and greater resistance to gap formation (Dennis et al. 1544-1559).

An electronic suture is another kind of functional suture that has been invented as a result of recent developments in materials technology. These sutures have the ability to monitor, sense, and actuate typical biological responses locally in the body. The most common electronic suture is the suture with the capacity to measure and maintain the ideal temperature with a microheater, which can improve the healing response (Kim et al. 3263-3268). Sutures with different sensors are also being used to monitor and control the pH level as well as the amount of exudate, bacteria, oxygen and enzymes present in a wound (Dargaville et al. 30-42).

2.2 Introduction of barbed sutures

Barbed sutures are sutures having multiple barbs projecting from their surface and pointing parallel to each other in one direction. This allows the suture to be passed through tissue in one direction, but to resist removal in the opposite direction. Since the barbs grasp the surrounding tissue, there is no need for tying a knot, making it easier for surgeons who can save suturing time during surgery. Also without a knot, the stresses between the suture and the surrounding tissue are more evenly distributed along the length of the suture which facilitates the healing process.
2.2.1 The history of barbed sutures

The idea of using barbed sutures in medical applications was first described in the 1950’s, but the first US patent for barbed sutures was granted to Dr. John Alcamo in 1964 (Surgical Suture). In Dr. Alcamo’s description, the suture could be made from a fiber, filament, or thread, with a surface which was not smooth. Instead the surface was roughened, and the diameter of the suture was not uniform. The roughened part might have raised projections, depressions, or teeth, which was the part of the suture that prevented it from slipping when inserted into incisions or wounds. However, all his designs of barbs were unidirectional, which required the surgeon to “double back” to secure the closure. (SURGICAL SUTURE; Ruff 6S)

Bidirectional barbed sutures came into existence due to the inconvenience of surgeons having to “double back” with the unidirectional barbed sutures. Three years after the first patent of a barbed suture, Dr. Alan McKenzie was granted a UK patent for a bidirectional barbed suture made of nylon, which at that time had to be used in the form of two sutures inserted in a cruciate pattern.

Then in 1993 Dr. Gregory Ruff applied for two essential patents; one involving the fabrication of unidirectional barbed sutures, and the other relates to bidirectional barbed sutures. These two types of barbed sutures were inspired by porcupines’ quills. The single-directional barbed suture had a cannula that shielded the barbs, and the bidirectional barbed suture had needles at both ends. These patents were granted in 1994 and 2001, respectively. (Ruff 6S)
2.2.2 Market of barbed sutures

Currently there are several commercial barbed sutures on the market, which have been designed for aesthetic and plastic surgery and approved by the US FDA over the last 20 years. These include the unidirectional absorbable Silhouette midface suture invented by Dr Nicanor Isse in 2006, the bidirectional nonabsorbable Woffles thread produced by Kolster MeThods Inc., the unidirectional absorbable V-Loc barbed suture made and distributed by Covidien Inc. and the bidirectional absorbable Quill knotless devices, such as the Quill PDO and the Quill Monoderm.

In 2004, the Quill unidirectional nonabsorbable barbed suture with a swaged needle was approved by the FDA for midface suspension. It relied on a 2-0 polypropylene suture. And in October 2004, one month after the unidirectional barbed suture was approved, the bidirectional absorbable barbed suture made from polydioxanone with a curved needle on each end, was licensed for wound closure.

In 2009, Covidien Limited received their initial approval for an absorbable wound closure device made of polyglycolide-co-L-lactide, and the next year, they were allowed to market their absorbable “V-Loc” barbed suture made from the same polyglycolide-co-L-lactide and a nonabsorbable “V-Loc” polyethylene terephthalate knotless device.

Each of these devices have their own advantages and disadvantages (Paul 31S).

At the present time, the most widely used barbed sutures for aesthetic and plastic surgery is the Quill Monoderm device manufactured and distributed by Angiotech Pharmaceuticals Inc. Quill Monoderm is made from the absorbable polyglycolide-co-e-caprolactone polymer and is
designed for placement within the mid-dermis. It has a faster rate of absorption than the same sized Quill PDO product. Jeffrey et al. compared the biomechanical wound strength and the rate of healing between a 4-0 V-Loc 90 wound closure device, a 3-0 Quill Monoderm and a 4-0 Quill Biosyn barbed suture in an in vivo porcine model. By performing mechanical in vitro tests and histological analysis postoperatively at Days 0, 3, 10, and 21, it was found that the V-Loc 90 device gave a minimal inflammatory response throughout the study, the Biosyn had significantly stronger biomechanical wound strength during the early postoperative period, and the only significant difference in mechanical performance between the V-Loc 90 device and the Quill Monoderm was on postoperative Day 21 (Zaruby et al. 232-240).

2.2.3 Single barb geometry design

The literature reports that various barb designs are needed for different surgical applications, and the variables, such as the preferred disposition and configuration of barbs along the body of the suture, depends on the type of tissue, such as skin or tendon, that the suture is closing. The disposition of the barbs may be staggered, cut in one or multiple spirals, overlapping or random. And the configuration of the barbs includes the angle of spirality $\alpha$, the barb cut angle $\beta$, the barb cut depth, the barb cut length (Figure 2-1) and the interbarb cut distance (Ingle and King 302-309; (12) Patent Application Publication and Leung).
2.2.4 Selection of sutures for different applications

In the years since Dr. Alcamo first received his US patent on barbed sutures in 1964, the use of barbed sutures in medical applications has exploded, with tens of thousands of operations and surgical procedures now employing this technology.

As well as requiring a suture to have high tensile strength, a minimal inflammatory response to the surgical procedure and the implanted device is also essential. Obviously, the degree of the inflammatory reaction is directly related to the total volume of the knots incorporated along the suture line. As a result, surgeons prefer to use a suture that has a small knot size or even to eliminate the knots altogether while maintaining the wound holding strength of the suture line (Greenberg and Goldman 107-115).

In the case of laparoscopic surgery, knot tying is much more difficult since the space is limited and the knots are invariably weaker than those tied by hand or robotically. Thus, using knotless sutures could securely close a wound in less time, with less cost, and less aggravation.
Various factors need to be taken into account when selecting the material and size of suture for a specific wound closure application, including the tissue characteristics, the tensile strength, reactivity, absorption rates, and handling properties. Surgeons should also consider the type of tissue and physiologic milieu into which the suture is being inserted.

The most routine procedures in obstetric and gynecologic surgery include perineal repair, rectus fascia reapproximation, uterine reapproximation and vaginal cuff closure. There has been evidence to show that synthetic absorbable suture materials, such as fast-absorbing polyglactin 910, are more suitable for perineal repair because of the limited inflammatory tissue response and reduced postpartum pain compared with collagen sutures such as chromic catgut. On the other hand, one of the most essential requirements for sutures used in rectus fascia reapproximation is their relatively longer tensile strength retention time. So polydioxanone or polyglyconate sutures are preferred material choices for this kind of surgery.

In comparison with the previously mentioned procedures, vaginal cuff closure requires surgeons to consider both long term strength requirements as well as the possible sources of irritation and bacterial contamination. Multifilament polyglycolic acid based sutures, monofilament polydioxanone and monofilament polyglyconate are candidates of choice (Greenberg and Clark 146-158).
2.2.5 Applications

2.2.5.1 Wound closure

Nicole et al. compared the performance of a 3-0 V-Loc 90 absorbable knotless device and a 3-0 Biosyn synthetic absorbable monofilament suture for single layer, appositional gastrotomy and enterotomy closure in 14 adult dogs. The bursting strength was found to be similar for these two sutures, and there was a significant reduction in the jejunum closure time when using the knotless barbed suture, but not when closing the stomach or colon. Similar results were achieved by Jeffrey et al. when they compared the burst pressure following wound closure with a 3-0 V-Loc 180 device and a 3-0 Maxon barbed suture for single-layer enterotomy closure in a canine model (Miller, Zaruby, and Kaminskaya 107-111; Ehrhart et al. 210-216). Megan et al. evaluated the maximum load to failure and the type of failure mode of a 2-0 V-Loc 180 absorbable wound closure device and a 2-0 standard polyglyconate knotted suture for diaphragmatic herniorrhaphy in 32 female Beagle dogs. They found that the 2-0 barbed polyglyconate V-Loc sutures were equivalent to the 2-0 polyglyconate standard sutures since there was no statistical difference in maximum load to failure between using the knotless suture and the standard knotted suture (Templeton et al. 65-69).

2.2.5.2 Tissue approximation and fixation

During the last decade, barbed sutures are being used more widely for tissue approximation and fixation across multiple specialties including plastic, aesthetic, gynecologic, orthopedic, and gastrointestinal surgery (Nguyen et al. 764-769).
Since the first report of surgical facial rejuvenation published in the early 1900’s, the application of barbed sutures for tissue suspension has become more popular in recent years. This includes procedures such as bladder suspension, uterine suspension, upper lid ptosis correction and a number of other plastic surgical procedures. Over the last 20 years since the introduction of barbed sutures, all these techniques have been shown to reduce stress relaxation compared to using traditional surgical sutures, since the skin is held under tension at two points. But this issue can be readily solved when using bidirectional barbed sutures, which are able to redistribute the retention forces along the suture line. In this way we have found that the tissue will be compressed in one direction while there is no tension placed in the other direction (Paul 31S; Villa et al. 108e).

Starting from the year 2000, conventional surgical sutures began to be used to correct facial paralysis and midface volume enhancement by elevating the malar fat pads through facial soft tissue suspension. However, the most commonly used nonbarbed sutures for correction of facial paralysis have unsatisfactory outcomes for long-term follow-up, and have caused a series of complications with increased morbidity and recovery times (Villa et al. 108e). On the other hand, since 2001 barbed sutures made from absorbable and nonabsorbable materials have experienced increasingly successful long-term prognoses in aesthetic plastic surgery either with barbs facing in one direction or with bidirectional devices. The absorbable materials include PDO and Monoderm, while the nonabsorbable materials include both nylon and polypropylene. It was Dr. Marlen Sulamanidze who in 2001 was the first to propose using bidirectional barbed sutures to suspend facial skin tissue using an Aptos thread which was
made of polypropylene and designed to be used in freely mobile tissue. However, the Aptos threads have not been accepted and used widely because of ptosis relapse and other unexpected results, which led to modifications to the Aptos threads, in the needle design, and the placement technique (Sulamanidze and Sulamanidze 7).

Another approach using barbed sutures for midface suspension called “Contour Threads” and marketed by Surgical Specialties was developed by Dr. Gregory Ruff and approved by the US FDA in 2005. The sutures were also made of polypropylene, but different from the Aptos threads, because the Contour Thread device was unidirectional and the arrangement of the barbs was designed in a helical design similar to DNA. This enabled the suture to be fixed at the proximal end to nonmobile structures such as the deep temporal fascia and the mastoid fascia. Nevertheless, this knotless suture encountered complications in maintaining soft tissue elevation over the long term and other problems because of the position of the suture material in the dermis and the fact that the suture did not absorb (Paul 31S; Ruff 16S).

2.2.6 The anchoring performance of barbed sutures

The anchoring performance and tissue holding capacity of a barbed suture depend on the mechanical properties of the surrounding tissue. This means that the optimal design for a barbed suture, such as the geometric shape, frequency, alignment and sequence, will vary with the type of tissue it approximates, like skin, tendon, and fatty tissue (Ingle and King 302-309). In 2009, Ingle et al explored the effect of the barb cut angle and cut depth on the tensile and tissue anchoring properties of a single barbed suture in skin and tendon tissues, and found that
with an increase of cut depth, the effective cross-sectional area of the suture decrease, causing a decrease in peak tensile load and peak elongation.

Ingle et al also performed finite element analysis to simulate the effect of cut angle and cut depth on the displacement of a barb under point loading. They also simulated a single barbed suture/tissue pull out test, comparing different barb geometries when the sutures were surrounded by either skin or tendon tissue. The results showed that a higher cut angle or a longer cut depth or length results in a more flexible barb, and this leads to a wider impact on the surrounding tissue. It was concluded that more flexible barbs used in skin tissue can offer better mechanical anchoring performance, while in tendon repair, stiffer barbs are preferred (Ingle, King, and Zikry 879-886).

2.3 Polyvinylidene fluoride and polypropylene

2.3.1 Structure, physical and chemical properties

2.3.1.1 Polyvinylidene fluoride

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Figure 2-2: Polyvinylidene fluoride

In general, the outstanding mechanical strength, as well as the chemical resistance and thermal stability, are determined primarily by the high degree of polymer crystallinity. Polyvinylidene fluoride consists of a repeating unit of \(-\text{CH}_2\text{-CF}_2\) \(-\), and it is because of the spatial
arrangement of CH2 and CF2 groups along the polymer chain that the PVDF has a unique crystalline structure (Liu et al. 1-27). There are at least five distinct phases of crystalline forms in PVDF: \( \alpha \) (form I), \( \beta \) (form II), \( \gamma \) (form III), \( \delta \) (from IV), and \( \varepsilon \) (form V). These different crystal polymorphs are formed depend on their processing conditions, and are classified by three different chain conformations; namely, all-trans (TTTT) planar zigzag for \( \beta \)-phase, TGTG’ for \( \alpha \) and \( \delta \) phases, and T3GT3G’ for \( \gamma \) and \( \varepsilon \) phases (Zheng et al. 2159-2162). Among these five phases, \( \alpha \) and \( \varepsilon \) phases are non-polar phases, while \( \beta \), \( \gamma \), and \( \delta \) phases are polar phases. The \( \beta \)-phase is the most essential polymorph of PVDF for its superior piezoelectric, pyroelectric and ferroelectric properties, while form I (\( \alpha \)-phase) is the most common and stable isomer for PVDF. It is important to understand the variables that will affect the crystallization of PVDF in order to obtain the specific desired phase. The crystallization of PVDF is dependent on a number of factors including molecular weight, molecular weight distribution, polymerisation method, thermal history and cooling rate (Liu et al. 1-27). Crystallization of melted PVDF at atmospheric pressure produces the \( \alpha \)-phase, but quenching from the melt will generate \( \beta \)-phase PVDF. If, however, crystallization is from solution, then you will obtain the \( \gamma \)-phase PVDF (Schilling et al. 269-275; Nakagawa and Ishida 2153-2171). There have been various techniques developed to make the transitions between the different crystalline phases (Prest Jr and Luca 5042-5047). To convert the non-polar \( \alpha \)-phase to the polar \( \beta \)-phase, the most common approach is to include thermal treatment, mechanical stretching, an application of high pressure, or a strong electric field (Zheng et al. 2159-2162).
The glass transition temperature (Tg) of PVDF is about -35 °C, and it has been reported that neither oxidation nor degradation reactions will occur when porous PVDF is exposed continuously to environmental temperatures between -80 to 300°F (-62 to 149°C).

The high level of crystallinity of PVDF provides it with superior mechanical strength, as well as stiffness, toughness and creep resistant properties. On the other hand, a reduction in crystallinity will result in greater flexibility of PVDF filaments, and in general, a reduction in end use operating temperatures (Humphrey and Amin-Sanayei).

On account of the high electronegativity of fluorine atoms, there is a high dissociation energy of the C-F bond, which provides such fluoropolymers with outstanding stability and superior chemical resistance (Liu et al. 1-27).

PVDF retains its integrity in most chemicals and solvents such as acids and alkalis, and will not be affected when exposed to sunlight or other sources of ultraviolet radiation. PDVF has also been approved for use in nuclear radiation environments where it can survive without extensive degradation (Humphrey and Amin-Sanayei).
2.3.1.2 Polypropylene

![Polypropylene structure](image)

Figure 2-3: Polypropylene

Like polyvinylidene fluoride, the superior properties of polypropylene largely depend on its high level of crystallinity (Quynn et al. 166-173). It is well known that there are three kinds of polypropylene classified by the orientation of the CH3 groups: isotactic polypropylene, atactic polypropylene and syndiotactic polypropylene. In isotactic polypropylene, the CH3 groups are oriented on one side of the carbon backbone, in atactic polypropylene, the CH3 groups are oriented randomly on either side, and in syndiotactic polypropylene, the CH3 groups are oriented on alternate sides of the backbone chain. Different orientations of the CH3 groups provide polypropylene with different levels of crystallinity. The higher degree of crystallinity makes isotactic and syndiotactic polypropylene stiffer and more resistant to creep than atactic polypropylene.

The density of polypropylene lies between 0.895 and 0.92 g/cm³. By adding fillers, one can manipulate the relative amounts of crystalline and amorphous regions within the polymer. Polypropylene is normally tough and flexible, especially when copolymerized with ethylene. Polypropylene also has superior resistance to fatigue.

Polypropylene is resistant to most acids and alkalis. It is also resistant to various organic solvents below 176°F (80°C). It can be used at higher temperatures depending on the heating
2.3.2 Comparison between PVDF and PP sutures

2.3.2.1 Mechanical properties

Polypropylene barbed sutures have been used widely as for skin closure, cardiovascular, ophthalmic, general surgery, orthopedics, plastic, aesthetic and micro-surgeries when the procedure requires soft tissue approximation or ligation. At the same time, there are reports expressing dissatisfaction with polypropylene monofilament sutures because of their thrombogenicity and because of mechanical failure (Urban et al. 145-156). In order for polyvinylidene fluoride to be considered as an alternative suture material for polypropylene, it should have at least a similar mechanical performance to polypropylene. Urban et al. performed a series of tests to study the morphology, thermal characteristics, tensile properties, mechanical creep and resistance to iatrogenic trauma for both PP and PVDF. The mechanical test results showed that both materials had similar breaking strengths (Fig. 2-4). The PVDF sutures had higher extension at break (Fig. 2-5) with less delayed extension when tested for tensile creep (Fig. 2-6) (Urban et al. 145-156).
Figure 2-4: Ultimate breaking force for different sizes of virgin PVDF and polypropylene sutures (Urban et al. 145-156)

Figure 2-5: Extension at breaking for different sizes of virgin PVDF and polypropylene sutures (Urban et al. 145-156)
Rashid et al. compared the mechanical properties of 2-0 barbed and non-barbed polypropylene sutures. Each suture was tied with a surgeon’s knot and tested on a tensile mechanical tester until failure. The tensile strength measured for the 2-0 polypropylene barbed suture was about 40 N, which was about midway between that of the 2-0 and 3-0 non-barbed sutures. The elongation at break was closest to that of the 3-0 non-barbed suture, while the stiffness was higher than that of any of the knotted sutures (Rashid et al. 869-872).

Polypropylene and polyvinylidene fluoride are both thermoplastic, non-absorbable materials, but they have different crystalline forms and different levels of crystallinity. Thus some researchers draw parallels between the mechanical properties and in vivo behavior of polypropylene and polyvinylidene fluoride monofilament sutures.

Wada et al. compared the mechanical properties of 5-0 polyvinylidene fluoride and polypropylene monofilaments for flexor tendon repair. It appears that there was no significant
difference in tensile strength and elongation at break for polyvinylidene fluoride and polypropylene, but the mean knot pull strength of PVDF sutures was much greater. And according to their creep test, they arrived at the conclusion that PVDF monofilament sutures had better creep resistance than polypropylene because polyvinylidene fluoride sutures remained more dimensionally stable and less prone to creep during the whole test, even though they stretched more during the first 30 minutes. And based on the results of their ex vivo biomechanical test, it was apparent that PVDF sutures had superior biomechanical properties when used in tenorrhaphy, with both a higher gap formation force and an ultimate breaking force (Wada et al. 212-216). Wang et al. obtained similar conclusions when they compared the creep behavior and elasticity of polyvinylidene fluoride and polypropylene monofilament sutures and hernia meshes in both the wale and course directions (Figure 2-7) (Wang and Zhang 1558-1566).

Figure 2-7: Experimental creep curves of PVDF and PP monofilaments (Wang and Zhang 1558-1566)
2.3.2.2 Biocompatibility and biostability

Biocompatibility is the property of a material that makes it compatible with living tissue. Biocompatibility means that it will not produce a toxic or immunological response when exposed to the body or bodily fluids. Biostability is the ability of a material to keep its dimensional, physical, and chemical properties after implanted in living tissue. These are two extremely important properties that are expected for any long-term implant.

![Figure 2-8: Scanning electron photomicrographs of retrieved and cleaned 6-0 polyvinylidene fluoride (left) and 6-0 polypropylene (right) sutures showing the surface morphology after implantation for 1 year (Mary et al. 199-206).](image-url)
Figure 2-9: Scanning electron photomicrographs of retrieved and cleaned 6-0 polyvinylidene fluoride (left) and 6-0 polypropylene (right) sutures showing the surface morphology after implantation for 2 years (Mary et al. 199-206).

Mary et al. evaluated these two crucial properties of polyvinylidene fluoride and polypropylene sutures used in vascular surgery by monitoring their in vivo behavior, and found that they experienced a similar healing process and had almost the same healing characteristics. Using infra-red spectroscopy, they both experienced a temporary increase in carbonyl group absorption, which might have been due to the inflammatory response during the first few months in vivo. But after 1 and 2 years in vivo, polyvinylidene fluoride showed better biostability than polypropylene because there was no evidence that PVDF experienced surface cracking, while polypropylene did (Figure 2-8 and Figure 2-9) (Mary et al. 199-206).

Laroche et al. found that the tensile strength of both PVDF and polypropylene sutures experienced some decrease when exposed to hydrolytic conditions, but the polypropylene
monofilament lost strength more rapidly between 2 to 7 years’ post-implantation (Figure 2-10) (Laroche et al. 1190-1199).

Polyvinylidene fluoride also showed great biocompatibility and tissue integration when compared with five other commercial suture materials, including non-absorbable polyester (PET) and polytetrafluoroethylene (ePTFE) and absorbable poliglecaprone (PGCL), polydioxanone (PDO) and polyglactin (PGLA) surgical sutures. Of all six materials tested, after 21 days in vivo, the PVDF sutures had the smallest size of foreign body granuloma and the smallest comet tail-like infiltrate (CTI) length. These observations confirmed PVDF’s excellent biocompatibility and its ability to produce type I and type III collagen between 3 and 21 days which led to rapid tissue integration (Lambertz et al. 1-11).
2.4 Tendon repair

2.4.1 Tendon

A tendon or sinew is a tough band of fibrous connective tissue that connects muscle to bone. This connection enables the tendons to regulate forces between muscle tissues during movement, so that the body remains stable.

A large portion of the tendon matrix is composed of collagen, which makes up 60–85% of the dry weight of the tendon. Approximately 95% of this is type I collagen, while the rest are types III, V, XII and XIV collagen. Because of this collagen-rich structure, tendon tissue has a high tensile strength. However, there is also a non-collagenous matrix in a tendon tissue, and it has been demonstrated that this component is age-related, and is likely to affect tendon resistance to injury (Thorpe et al. 248-259).

Tendons act as biological springs that can stretch elastically storing and releasing energy during movement, and also regulating the muscle mechanical performance. (Maganaris et al. 307–313). Dr. Yamada measured the tensile properties of human tendinous tissue, and found the average ultimate tensile strength for calcaneal tendon was about 5.4 kg/mm$^2$ for adults, and it was greatest in the 10 to 59 age period when compared to the ultimate tensile strength in different age groups. The tensile strength in the 0 to 9 and 60-69 age group is 95% and that in the 70-79 age group is 78% of the strength in the 10 to 59 age group (Hiroshi Yamada, 99-100).

Dr. O’Brien measured the mechanical properties of the patellar tendon in adults and children, and found that the maximal patellar tendon force was 5453±307 N for men, 3877±307 N for women, 2017±170 N for boys and 2169±182 N for girls. He also calculated the stiffness and
the Young’s modulus. In his research, stiffness and Young’s modulus were greater in adults than in children, but there was no significant difference between men and women, or boys and girls (O’Brien, Thomas D., et al. 1190-1195).

There are two main kinds of tendons classified by their function. One is a positional tendon, such as in the fingers, which help maintain the hand’s position when writing and holding, and the other is an energy storing tendon. This kind of tendon provides mobility and movement, and is involved in storing energy efficiently. When a tendon ruptures, it needs surgical treatment, or it will result in a systemic disease such as rheumatoid arthritis and lead to corticosteroid use (Kearns and Singh). It is well known that traumatic tendon laceration is a common problem encountered by hand surgeons the world over.

2.4.2 Tendon repair

2.4.2.1 Techniques

Strickland has claimed that the ideal tendon repair should have the following characteristics (Strickland 214-235):

(1) Easy suture placement
(2) Secured knots
(3) Smooth end-to-end tendon apposition
(4) Minimal gaping to no gaping at the repair site
(5) Avoid injury to tendon vasculature
(6) Have sufficient strength for early active postoperative motion.

With the use of multiple suture strands crossing the repair site, the tenorrhaphy should be strong enough to guarantee postoperative motion. Currently, 4-strand repairs are the “minimum” number of core strands needed for early movement. Cruciate repairs are one of the most commonly used suturing techniques in tenorrhaphy, and various researchers have shown that the cross-lock cruciate configuration is biomechanically the most suitable choice for tendon repair, since it optimizes the gap formation force, as well as the maximum load to failure (Chauhan, Palmer, and Merrell 1846-1853).

2.4.2.2 Maximum load to failure and gap formation force

When reviewing the literature for biomechanical measures, almost every article refers to the maximum tensile load to failure. This is a key property because it indicates how large a force the repaired tissue can support during early active motion. It is important that the barbed suture is able to tolerate both the repair procedure and any post-surgical physical rehabilitation therapy. The in vitro experimental data is usually obtained with a suture/tissue pullout test. (Ingle and King 302-309)

Gap formation represents the clinical quality of the repair and the anchoring strength of the suture material. From a clinical point of view, if the gap at the repaired site grows to a distance greater than 2mm, then the tendon has lost its function and the repair is considered a failure (Zeplin et al. 16-20; Nayak et al. 1355-1362).
2.4.2.3 Tendon repair with non-barbed sutures

The repair of a severed tendon should be strong enough to tolerate the force of 40-50 N, which is the tensile force generated during early active motion. The strength required to support such a load largely depends on the biomechanics of the sutures used in the tenorrhaphy repair (Clemente et al. 251-257). Thus, it is essential to explore the biomechanical properties of barbed sutures which are being designed and used in this study for tendon repair.

There has been much evolution in the clinical repair techniques over recent years, like increasing the number of crossing strands at the repair site, and the evolution of epitendinous repair, so as to meet the higher strength requirement of tenorrhaphy.

With the use of conventional surgical sutures, the surgeon is expected to tie secure knots at the end of the repair, which can be challenging, especially when the space is limited. Also, knots are potentially the weakest points in a conventional tendon repair, since they will reduce the maximum holding capacity of the suture by accommodating a variety of applied loads including tensile, bending, rotational, shear and compression forces to the suture in and close to the knot. In fact, reductions in the tensile strength of knotted sutures from 35% to 95%, have been reported depending on the type of knot and the suture material. In addition, the region of active flexion may also be affected because of the enlargement of the cross-sectional area with the presence of the knot. On the other hand, tying knots may introduce the potential for human error and inter-user variability (Greenberg and Goldman 107-115). Recently, knotless sutures have gained more attention because they have certain advantages over traditional knotted sutures (Ingle and King 302-309).
2.4.2.4 Repaired using barbed sutures

Soon after Dr. John Alcamo received his first patent for a barbed suture in 1964, McKenzie proposed the idea in 1967 of using barbed sutures to repair lacerated tendons of the hand (McKenzie 440-447). Although there is little information available regarding the safety, efficacy, longevity or complications encountered when used for tendon repair, the use of barbed sutures in tenorrhaphy has attracted much attention theoretical and clinical attention over the last forty years (Shah, Rowlands, and Au 6-15).

Joyce et al. found that a 2-0 barbed polybutester V-Loc suture could withstand a similar tensile force to a 3-0 non-barbed polypropylene suture before rupture in a fresh porcine flexor tendon. However, the 2-0 barbed suture needed a greater force then the non-barbed polypropylene control in order to form a 2-mm-gap (p<0.05) (Joyce et al. 40-45).

Sato et al. chose a 4-0 V-Loc barbed sutures and a 4-0 Maxon non-barbed suture to repair the digitorum profundus tendons of pigs using a two-strand modified Kirchmayr-Kessler technique. Both barbed and non-barbed sutures were made from polyglyconate resorbable polymer. Following biomechanical testing and statistical analysis, it was concluded that the barbed sutures were more suitable for tendon repair because the V-Loc barbed suture showed a significantly greater ultimate tensile strength and a significantly higher 1-mm-gap formation force. (Sato et al. 1421-1424)

Clemente et al. invented a new 4-strand barbed suture technique, and made comparisons between a 2-0 polypropylene Quill SRS barbed suture and a 2-0 polydioxanone (PDO) Quill
SRS barbed suture with this new technique, and a modified Kessler technique using a 3-0 Prolene® polypropylene conventional non-barbed suture control. They monitored the breaking force, the 2-mm-gap formation force, the maximum load to failure, the mode of failure, and the cross-sectional area of the repair site. This new suturing technique exhibited better resistance to failure and required a higher force to form a 2-mm gap when compared to the traditional Kessler technique. On the other hand, the Quill SRS PDO suture demonstrated significantly superior biomechanical properties in providing a successful tenorrhaphy repair (Clemente et al. 251-257). Other researchers have arrived at similar conclusions that knotless barbed sutures provide equivalent or even higher strength combined with reduced repair site cross-sectional area compared with traditional tenorrhaphy techniques (Lin et al. 315-319; Jordan et al. 72; Parikh, Davison, and Higgins 1551-1558; McClellan et al. 327E). This evidence suggests that barbed sutures have an advantage over conventional sutures in tendon repair, and therefore should be a considerable alternative strategy for surgeons to choose.

However, on the other hand, there are several published articles that report that knotless barbed sutures exhibit a weaker biomechanical performance than traditional sutures. Zeplin et al. published a paper in 2010 in which they evaluated the tensile strength of a 3-0 non-barbed polydioxanone suture and a 3-0 unidirectional V-Loc barbed suture in the repair of human flexor digitorum tendons with both a 2-strand and a 4-strand Kirchmayr-Kessler technique. After statistical analysis, they found that the barbed suture repair had significantly lower tensile strength than the knotted suture group, when using either the 2-strand technique or the 4-strand technique (Zeplin et al. 446-449).
Similarly, Duffy et al. evaluated the performance and resistance to gap formation of a non-absorbable barbed suture, compared with a non-barbed suture made from the same polypropylene material. Although the barbed suture required a greater force to form a 2mm gap, the maximum load to failure for the non-barbed polypropylene suture was significantly higher than that of the V-Loc barbed suture (D. J. Duffy; R. P. Main et al.). Philip et al. undertook a study that considered the physiological conditions so as to get a more accurate prediction of the in vivo performance. They compared a size 3-0 PDO non-barbed suture with a size 3-0 V-Loc unidirectional barbed suture using a 4-strand Kirchmayr-Kessler suture technique to repair a human flexor digitorum tendon, followed by the application of both mechanical linear and cyclical loading. The average results for the tensile force required to form a >3 mm gap showed that there was no significant difference in the tensile force after linear and cyclical loading between the polydioxane conventional suture and the barbed glycolic-carbonate suture (p> 0.05). In addition, the cyclical fatigue stresses did not lead to a reduction in the gap formation force (Zeplin et al. 16-20).

Nayak et al. also performed cyclic loading to identify the 1-mm-gap formation force of zone II flexor tendons after operating with a 4-strand Kessler repair technique using a 2-0 Quill SRS barbed suture and comparing it with a 3-0 braided polyester/ultra high molecular weight polyethylene composite traditional suture. There was a significant difference in the force required to form 1-mm-gap between the barbed suture and the traditional braided suture. The 1-mm-gap formation force with the barbed suture was significantly greater, which points to the
potential advantage of using a barbed suture for tenorrhaphy once the appropriate suturing technique has been established (Nayak et al. 1355-1362).
CHAPTER 3 MATERIALS AND METHODS

3.1 Materials

3.1.1 Surgical sutures

Two different types of surgical sutures in two different sizes (Figure 3-1) used in this study were obtained from G. Krahmer GmbH in Buchholz, Germany.

![Figure 3-1: PVDF and PP surgical sutures](image)

3.1.2 Tendon tissue samples

Sixty (30 pairs) porcine knees from 30 3-4-year female pigs with an average weight of 561 lbs. (423-716 lbs.) were harvested from the City Packing Company through Neese Country Sausage, Inc. in Burlington, NC. They were dissected in the Biomechanics Laboratory in the Biomedical Engineering Department at North Carolina State University (Figure 3-2). The section of each tendon corresponding to the patellar tendon in the pig was identified, and the
center point of this area was marked, shown in Figure 3-3(a). A scalpel was used to carefully create a defect in the middle of each tendon (Figure 3-3(b)). Each tendon was randomly assigned to one of six different groups (n=10). After dissection, the tendons were stored at 20°F in the freezer.

Figure 3-2: Porcine leg (a) Before dissection; (b) After dissection

Figure 3-3: Patellar tendon (a) Before transection; (b) After transection
3.2 Methods

3.2.1 Fabrication of barbed surgical sutures

Using a pair of scissors, 50 cm lengths of each type of suture were cut for tensile testing, and 70 cm lengths were cut for tendon repair. Then a special barb cutting machine (Figure 3-4) donated by Quill Medical was used to fabricate and cut barbed sutures on the PVDF and PP cut monofilaments.

![Barb cutting machine](image)

Figure 3-4: Barb cutting machine

The pair of clamping mechanisms, Part No. 1, was used to hold the suture at both ends and provided tension when the sample was mounted on the device, so as to make sure the suture remained straight when the barbs were cut. Once the suture sample was mounted on the cutting machine, Part No. 2 (red rubber faced downward) was placed on the base, and the screws (Part No.3) were rotated to fix the suture sample completely in the groove. Parts No. 4 and No.5 were placed on top of Part No. 2, and a new scalpel was used (Part No. 6) to cut the barbs in
two directions. The number of barbs, the angle of the blades, and the distance between the blades were fixed. There were three different numbers of dots (1, 2 and 3 dots) on Parts No. 1, No. 4, and No. 5, respectively. The dots on Parts No. 1, No. 4 and No. 5 (in the red square, Figure 3-4) were kept the same for each cutting, so as to make sure the barbs were distributed uniformly in a straight line along the length of the suture.

The two barb sections were cut in opposite directions, 8 cm on each side with a 2 mm gap in the middle. There was a 17 cm non barbed section at the two ends of the sutures for tensile testing.

After fabrication, there was 16 cm on each side with 2 mm gap in the middle, as well as a 19 cm non barbed section at the two ends of the sutures for tendon repair. Then all the sutures for tendon repair were swaged with needles at both ends. The details of the surgical sutures and the attached needles used for the different groups are listed in Table 3-1.

Table 3-1 Specific parameters of attached needles for tendon repair

<table>
<thead>
<tr>
<th>Size</th>
<th>Needle</th>
<th>Shape</th>
<th>Point type</th>
<th>Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-0</td>
<td></td>
<td>3/8 Circle</td>
<td>Diamond</td>
<td>22</td>
</tr>
<tr>
<td>3-0</td>
<td></td>
<td>1/2 Circle</td>
<td>Diamond</td>
<td>20</td>
</tr>
</tbody>
</table>
3.2.2 Microscopic analysis

The morphology of the barbed sutures before testing was viewed using an optical microscope (Nikon Corp, Tokyo, Japan) at a magnification of 20x. The images were captured by a Tucsen camera and subsequently analyzed using IS Capture professional imaging software. The geometric dimensions were measured in terms of the suture diameter, cut depth and cut angle.

3.2.3 Tensile test

The tensile properties of both barbed and non barbed sutures were tested on an Instron Universal Testing Machine (Instron Corp, Canton, MA) using test method ASTM D3822. The two ends of the monofilament sutures and barbed sutures were mounted in the two clamps of the test machine. For barbed sutures, the barbed section was mounted in the middle of the gauge length (Figure 3-7).

The load cell capacity was 100 N, the preload was 2 N, the gauge length was 20 cm, and the cross-head speed was 300 mm/min. The ambient temperature and relative humidity (RH) were 70 °F and 65 % respectively.

The ultimate tensile force was measured as the breaking force (Newtons, N), the displacement at failure (mm) and the time measured by the transducer were transferred to a connected computer and were collated and analyzed by an Instron software program (Instron Corp, Canton, MA).
3.2.4 Tendon repair

All tendons were thawed at room temperature for 24 hours before surgical repair was performed. All the repairs were undertaken by the single operator (YH) using a 4-strand cross-locked cruciate suturing technique (Figure 3-8) or a 4-strand modified cross-locked cruciate suturing technique (Figure 3-9) using both the original monofilament and barbed surgical sutures. Each suture was used to repair one porcine patellar tendon.
The starting point was placed in the center of the lacerated site of the tendon, and a 5-mm wide cross locked anchor was made at the point of a 15-mm-long purchase. Then, a cross-locked anchor was made in the same fashion at the opposite side of the tendon. After making 4 cross-locked anchors bisymmetrically, the monofilament suture was tied using a surgeon’s knot. For barbed sutures, the 2-mm-long non barbed gap was placed in the center of one thread at the repair site, and the first 2 cross-locked anchors were made using barbed suture in one direction,
and the other 2 cross-locked anchors were made using the barbed suture with the barbs in the opposite direction. After making all 4 cross-locked anchors, the barbed sutures were locked at a point 10-mm away from the repair site.

![Figure 3-10](image1.png)

Figure 3-10: Patellar tendon after repair with (a) monofilament suture; (b) barbed suture

### 3.2.5 Tissue/suture pull-out test

The anchoring performance of PVDF and PP barbed sutures in porcine patellar tendon tissue were evaluated by means of measuring the maximum load, the force required to generate a 2-mm gap, and the mode of failure. The maximum load occurred before the suture failed, and the failure was defined as the point at which the suture broke or pulled through the tendon tissue. The 2-mm-gap formation force represents the required load to produce a defect at the repair site and is therefore interpreted to correspond to a clinical failure. (1)

The proximal end of each tendon was then mounted individually in a stainless steel clamp and fixed to the mobile arm of the tensile test machine (Instron Corp, Canton, MA). The distal end
of each tendon was mounted in the other custom clamp and fixed to the base of the Instron test machine.

Uniaxial testing was performed using a 2000 N load cell. A caliper (millimeter scale) was placed adjacent to the tendon to monitor gap formation at the repair site during testing. Gap formation was recorded with a high-definition video camera (Canon VIXIA HF R62, Canon Inc., Tokyo, Japan) that was manually synchronized with the load cell’s output (Figure 3-11). The repaired samples were preloaded at a tension of 2 N and stressed at a rate of 10 mm/min. Then, after pre-tensioning, a tensile force was applied at a rate of 20 mm/min until failure. The ambient temperature and relative humidity (RH) were 70 °F and 65 % respectively.

Figure 3-11: A High-definition video camera was set 25 cm away from the Instron Universal Testing Machine

The ultimate tensile force, which was the breaking force (Newton, N), the displacement (mm) at the failure point, and the time during the uniaxial tension test measured by the transducer
were transferred to a connected computer and were collated and analyzed with an Instron software program (Instron Corp, Canton, MA).

After the testing, the video images were analyzed frame-by-frame by Image J software (National Institutes of Health, Bethesda, MD) to determine the force (N) when the 2-mm gap formed and the repair officially failed.

3.2.6 Statistical analysis

The results of the continuous variables were described using mean ± SD, and the means were compared using ANOVA and the Student’s t-test. All analyses were performed using JMP Pro13 (SAS Institute, Cary, NC). A p-value no more than 0.05 was considered statistically significant.
CHAPTER 4 RESULTS AND DISCUSSION

4.1 Measurement of suture and barb geometries

4.1.1 Measurement of suture diameter

The results of microscopic analysis of the suture diameter are shown in Table 4-1.

Table 4-1 Diameters of sutures

<table>
<thead>
<tr>
<th>Group</th>
<th>Suture Diameter (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PVDF 2-0 NB</td>
<td>0.319±0.003</td>
</tr>
<tr>
<td>PVDF 3-0 NB</td>
<td>0.232±0.003</td>
</tr>
<tr>
<td>PP 2-0 NB</td>
<td>0.317±0.002</td>
</tr>
<tr>
<td>PP 3-0 NB</td>
<td>0.244±0.002</td>
</tr>
</tbody>
</table>

According to the United States Pharmacopoeia (USP) the average diameter of 3-0 synthetic sutures should be between 0.20-0.249 mm, and that of 2-0 synthetic sutures should be within the limits of 0.30-0.339 mm.

In order to compare the diameters more clearly, the data in Table 4-1 was converted into a bar chart shown in Figure 4-1. The target diameter range of size 3-0 sutures is marked with blue lines, while that of size 2-0 sutures is marked with red lines.
According to the bar chart, it’s easy to tell that the diameters of commercial sutures meet the requirements of the US Pharmacopeia.

Figure 4-1: Comparison of the diameter of commercial sutures with their target ranges

Error bar = standard deviation
4.1.2 Measurement of barb geometries

The results of microscopic analysis of the barb geometries are shown in Table 4-2.

The barb geometries were set at a cut angle of 165° and a cut depth of 20%. In order to compare the cut angle and cut depth with the target value more clearly, the data in Table 4-2 was converted into a bar chart in Figure 4-2. The target value is marked with a red line.

Table 4-2 Parameters of barb geometries

<table>
<thead>
<tr>
<th>Group</th>
<th>Cut Angle (°)</th>
<th>CV(%)</th>
<th>Cut Depth (%)</th>
<th>CV(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PVDF 2-0 B</td>
<td>167.2±3.1</td>
<td>1.9</td>
<td>21.1±3.1</td>
<td>14.0</td>
</tr>
<tr>
<td>PP 2-0 B</td>
<td>165.9±1.7</td>
<td>1.0</td>
<td>22.4±2.4</td>
<td>10.5</td>
</tr>
</tbody>
</table>
Figure 4-2: (a) Comparison of the cut angle of the fabricated barbed sutures with their target value; (b) Comparison of the cut depth of the fabricated barbed sutures with their target value
By comparing the measured cut angle and cut depth of the fabricated barbed sutures with their target values in Figure 4-2, it can be seen that the dimensions of the fabricated barbed sutures are close to their proposed values. The coefficient of variation (CV) for the cut angles of the fabricated barbed sutures are close to 1% and those for cut depth are close to 10%. A higher CV value means greater variability of individual measurements around the mean. The higher CV for the cut depth may have resulted from the changing of the cutting blade position with the changing of the suture specimen, since all the barbs were cut by hand. The CV for the cut angle remained near to 1%. This is a low level, which suggests a reproducible value due to the blades being fixed in the cutter assembly which kept the angle of all the blades constant.

Microscopic images of a single barb on the suture’s surface were captured and are shown in Figure 4-3.

![Microscopic images of a single barb](image)

(a) 2-0 PVDF barbed suture; (b) 2-0 PP barbed suture

The single barbs on the PVDF and PP barbed sutures show different shapes, reflecting the different degree of bending of the barbs. It is evident from Figure 4-3 that the barb on the PP suture bends backward more than the barb on the PVDF suture. A higher degree of bending
may cause the PP suture to bend or peel differently from the PVDF suture when inserted into surrounding tissue.

### 4.2 Results of tensile testing

The results of tensile testing in terms of ultimate tensile force, elongation at break and initial modulus or stiffness are shown in Table 4-3.

<table>
<thead>
<tr>
<th>Group</th>
<th>Ultimate tensile force (N)</th>
<th>Elongation at break (%)</th>
<th>Stiffness / Initial modulus (GPa)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PVDF 2-0 NB</td>
<td>38.0 ± 1.8</td>
<td>67.0 ± 2.2</td>
<td>0.36 ± 0.01</td>
</tr>
<tr>
<td>PVDF 2-0 B</td>
<td>22.2 ± 2.6</td>
<td>29.7 ± 3.1</td>
<td>0.31 ± 0.05</td>
</tr>
<tr>
<td>PVDF 3-0 NB</td>
<td>22.5 ± 0.6</td>
<td>61.9 ± 3.2</td>
<td>0.23 ± 0.01</td>
</tr>
<tr>
<td>PP 2-0 NB</td>
<td>34.4 ± 1.6</td>
<td>61.2 ± 2.6</td>
<td>0.33 ± 0.02</td>
</tr>
<tr>
<td>PP 2-0 B</td>
<td>14.3 ± 2.2</td>
<td>21.5 ± 1.5</td>
<td>0.36 ± 0.06</td>
</tr>
<tr>
<td>PP 3-0 NB</td>
<td>18.2 ± 1.3</td>
<td>62.5 ± 4.0</td>
<td>0.18 ± 0.02</td>
</tr>
</tbody>
</table>
4.2.1 Ultimate tensile force

In order to compare the average ultimate tensile force for the 6 groups more clearly, the data in Table 4-3 was converted into a bar chart in Figure 4-4. ANOVA analysis was done to compare the differences between these groups, the results are shown in Figure 4-4. From Figure 4-4, it is evident that the ultimate tensile force for the PVDF sutures is generally stronger than those PP sutures with the same size. According to the ANOVA analysis result, the ultimate tensile force of the 2-0 PVDF barbed suture is equivalent to that of 3-0 PVDF nonbarbed suture, which were 22.2±2.6 N and 22.5±0.6 N respectively. On the other hand, there is a significant decrease when comparing the 2-0 PP barbed suture with a 14.3±2.2 N ultimate tensile force compared with the 3-0 PP non-barbed sutures, and its 18.2±1.3 N ultimate tensile value. Of particular note is that the superior ultimate tensile force of the 2-0 PVDF barbed suture exceeds that of the 2-0 PP barbed suture. This demonstrates that one of the hypotheses is true, namely that barbed PVDF sutures provide improved mechanical properties compared to barbed PP suture.

The ultimate tensile force of 2-0 PP barbed sutures was similar to the results Rashid got, that needing about 40 N to break the 2-0 PP barbed sutures during the tensile test (Rashid et al. 869-872).
Figure 4-4: (a) Comparison of the ultimate tensile force of PVDF and PP monofilament barbed and non-barbed sutures; (b) The results of ANOVA analysis for the ultimate tensile force of PVDF and PP monofilament barbed and non-barbed sutures
Figure 4-5: (a) Reduction in cross-sectional area of barbed sutures; (b) Reduction in cross-sectional area between 2-0 and 3-0 monofilament sutures
In Figure 4-5 (a): O stands for the center of the circle, R stands for the radius of the circle, and \( d \) stands for the cut depth.

\( S_R \) is the area of the circle, \( S_T \) is the area of the triangle OAB, \( S_s \) is the area of the sector OADB, \( s_B \) is the area of each black segment in the figure.

\[
\theta = \arccos \frac{OC}{OA} = \arccos \frac{OD - d}{OA} = \arccos \frac{R - d}{R}
\]

\[
S_s = \frac{2\theta}{2\pi} \times S_R = \frac{2\theta}{2\pi} \times \pi R^2 = \theta R^2
\]

\[
S_T = \frac{AB \times OC}{2} = \frac{2 \times AC \times OC}{2} = \sqrt{O^2 - OC^2} \times OC = \sqrt{R^2 - (R - d)^2} \times (R - d)
\]

\[
S_B = S_s - S_T = R^2 \arccos \frac{R - d}{R} - \sqrt{R^2 - (R - d)^2} \times (R - d)
\]

\[
\text{% reduction in cross-sectional area of barbed suture} = \frac{3 \times S_B}{S_R} \times 100\%
\]

In Figure 4-5 (b): R stands for the radius of 2-0 monofilament suture, and \( r \) stands for the radius of 3-0 monofilament suture.

\( S_{2-0} \) is the cross-sectional area of the 2-0 monofilament suture, \( S_{3-0} \) is the cross-sectional area of the 3-0 monofilament suture.

\[
\text{% reduction in cross-sectional area of the monofilament suture} = \frac{S_{2-0} - S_{3-0}}{S_{2-0}} \times 100\%
\]

\[
= \frac{\pi R^2 - \pi r^2}{\pi R^2} \times 100\% = \frac{R^2 - r^2}{R^2} \times 100\%
\]

According to the equations above, the results of reduction in cross-sectional area of the barbed suture compared to the non-barbed suture are shown in Table 4-4. This table also shows the percentage loss in ultimate tensile force between the different types of sutures.
Table 4-4: Percentage loss compared with 2-0 non-barbed sutures

<table>
<thead>
<tr>
<th>Group</th>
<th>Percentage loss in cross-sectional area</th>
<th>Percentage loss in ultimate tensile force</th>
</tr>
</thead>
<tbody>
<tr>
<td>PVDF 2-0 B</td>
<td>45.8%</td>
<td>41.6%</td>
</tr>
<tr>
<td>PVDF 3-0 NB</td>
<td>47.1%</td>
<td>40.8%</td>
</tr>
<tr>
<td>PP 2-0 B</td>
<td>50.2%</td>
<td>58.3%</td>
</tr>
<tr>
<td>PP 3-0 NB</td>
<td>40.8%</td>
<td>47.0%</td>
</tr>
</tbody>
</table>

The values for percentage loss in ultimate tensile force for all the 2-0 barbed and 3-0 non-barbed sutures are close to the percentage loss in cross-sectional area compared with their 2-0 non-barbed suture made from the same material. From this observation, we can conclude that both polyvinylidene fluoride and polypropylene monofilaments are homogenous, and the loss in ultimate tensile force is solely due to a reduction in the effective cross-sectional area of the suture.

4.2.2 Elongation at break

In order to show the comparison for the elongation at break of the 6 groups more clearly, the data in Table 4-3 was converted into a bar chart in Figure 4-6.
The elongation at break decreased significantly when the sutures were barbed. Since the elongation at break of the 2-0 and 3-0 non-barbed PVDF sutures were 67.0±2.2% and 61.9±3.2% respectively, and those for the 2-0 and 3-0 PP non-barbed sutures were 61.2±2.6% and 62.5±4.0% respectively. After barbing the elongation at break fell to a value between 20 and 30%, and the suture size did not appear to have a major effect on the elongation at break of the suture.

4.2.3 Stiffness or initial modulus

In order to compare the stiffness or the initial modulus of the 6 groups more clearly, the data in Table 4-3 was converted into a bar chart in Figure 4-7. ANOVA analysis was performed to compare the differences among these groups, and the results are shown in Figure 4-7.
Figure 4-7: (a) Comparison of the stiffness or initial modulus of PVDF and PP barbed and non-barbed sutures; (b) The results of ANOVA analysis for the stiffness or initial modulus of PVDF and PP barbed and non-barbed sutures.
Stiffness or the initial tensile modulus refers to the rigidity of an object, and its ability to resist deformation in response to an applied force. The values of 0.23±0.01 and 0.18±0.02 GPa are the average measured stiffness of the 3-0 non-barbed sutures made from PVDF and PP respectively. They are significantly lower values than the stiffness of the 2-0 barbed and non-barbed sutures, which are all higher than 0.30 GPa. While comparing the two suture materials, the PVDF non-barbed suture showed a higher resistance to the applied force. According to the ANOVA analysis results, no significant change in stiffness or initial modulus was observed as a result of the barbing process. While the 2-0 PVDF barbed suture had a lower stiffness than the 2-0 PVDF non-barbed suture, the 2-0 PP barbed suture had a similar stiffness to the 2-0 PP non-barbed suture.
4.3 Results of suture/tissue pullout test

Table 4-5: Maximum suture/tissue pullout force and 2-mm-gap formation force for the 6 groups

<table>
<thead>
<tr>
<th>Group</th>
<th>Maximum Pullout Force (N)</th>
<th>2-mm-gap Formation Force (N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PVDF 2-0 NB</td>
<td>1045.0 ± 11.4</td>
<td>24.7 ± 7.8</td>
</tr>
<tr>
<td>PVDF 2-0 B</td>
<td>71.8 ± 11.8</td>
<td>28.9 ± 6.4</td>
</tr>
<tr>
<td>PVDF 3-0 NB</td>
<td>58.9 ± 11.2</td>
<td>14.1 ± 3.2</td>
</tr>
<tr>
<td>PP 2-0 NB</td>
<td>102.9 ± 18.2</td>
<td>19.6 ± 4.0</td>
</tr>
<tr>
<td>PP 2-0 B</td>
<td>58.8 ± 7.7</td>
<td>25.3 ± 4.7</td>
</tr>
<tr>
<td>PP 3-0 NB</td>
<td>64.9 ± 6.8</td>
<td>18.2 ± 4.7</td>
</tr>
</tbody>
</table>

4.3.1 Maximum pullout force

In order to compare the maximum suture/tissue pullout force between the 6 groups of samples more clearly, the data in Table 4-5 was converted into a bar chart in Figure 4-8. ANOVA analysis was performed to compare the differences among these groups, and the results are illustrated in Figure 4-8.
Figure 4-8: (a) Comparison of the maximum suture/tissue pullout force for the PVDF and PP barbed and non-barbed sutures; (b) The results of ANOVA analysis for the maximum suture/tissue pullout force for the PVDF and PP barbed and non-barbed sutures.
According to the bar chart and ANOVA analysis results, there are no significant differences in suture/tissue pullout force between the non-barbed PVDF and PP monofilament sutures for each suture size. The force required to cause suture failure during the suture/tissue pullout test decreased significantly from the 2-0 non-barbed suture, with a force of more than 100 N, to either the 2-0 barbed or the 3-0 non-barbed suture, which were less than 75 N. This observation is consistent with the ultimate tensile force results measured during the tensile tests. Thus, we can draw the conclusion that a reduction in the suture’s cross-sectional area, either by selecting a smaller size suture, or by cutting barbs on the surface, will result in a decrease of the mechanical properties of the suture.

When comparing the barbed size 2-0 sutures, the PVDF suture required a force of 71.8±11.8 N to either break the suture or pull it out of the tissue, whereas the PP suture needed only 58.8±7.7 N of force. This difference is similar to the comparison for ultimate tensile force between the non-barbed PVDF and PP monofilament sutures. Clearly, the higher the maximum suture/tissue pullout force, the more successful the barbed suture is in anchoring the tendon tissue and providing a superior anchoring performance.

### 4.3.2 Two mm gap formation force

In order to compare the 2-mm-gap formation force of 6 groups more clearly, the data in Table 4-5 was converted into a bar chart (Figure 4-9). ANOVA statistical analysis was performed to compare the differences between the groups. The results are presented in Figure 4-9.
Figure 4-9: (a) Comparison of the 2-mm-gap formation force for the PVDF and PP barbed and non-barbed sutures; (b) Results of ANOVA analysis for the 2-mm-gap formation force of the PVDF and PP barbed and non-barbed sutures
The average 2-mm-gap formation force of the PVDF and PP size 2-0 barbed sutures was 28.9±6.4 N and 25.3±4.7 N respectively. These values are higher than those of the size 2-0 and 3-0 non-barbed sutures made from the same material. This is due to the fact that the barbs fabricated on the surface of the monofilament sutures anchored the tendon tissue, preventing the suture from slipping or being pulled out by an applied force in the opposite direction to suture insertion. The barbed sutures used in this study were bi-directional, so the sutures could not be easily pulled out in either direction.

Although there was no significant difference in the average 2-mm-gap formation force between the PP and PVDF barbed size 2-0 sutures, by viewing the microscopic images of a single barb on the PVDF and PP sutures, the degree of barb bending by the two materials was different. The ease of bending of the PP barb was greater than for the PVDF barb, which means that the PP barbs are easier to bend or peel backward. Combined with the greater maximum suture/tissue pullout force achieved by the PVDF barbed suture, it is now possible to conclude that barbed polyvinylidene fluoride suture provides better tissue anchoring than polypropylene when used to repair porcine tendon tissue.

Gap formation at the repair site has been associated with the formation of adhesions as a common and serve complication after tendon repair for it will affect motion recovery and may prolong the tendon healing process. It also plays an important role as an indication to determine clinical failure. (Vanhees, Matthias et al. 56–61) The results of 2-mm-gap formation force indicated the attractive possibility of using PVDF barbed sutures in tendon repair.
### 4.3.3 Failure mode

Table 4-6 Modes of failure

<table>
<thead>
<tr>
<th>Group</th>
<th>Mode of failure</th>
<th>Knot Broke</th>
<th>Suture Rupture</th>
<th>Tissue Tear</th>
</tr>
</thead>
<tbody>
<tr>
<td>PVDF 2-0 NB</td>
<td>Knot Broke</td>
<td>8</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Suture Rupture</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Tissue Tear</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PVDF 2-0 B</td>
<td>Knot Broke</td>
<td></td>
<td>10</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Suture Rupture</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Tissue Tear</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PVDF 3-0 NB</td>
<td>Knot Broke</td>
<td>8</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Suture Rupture</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Tissue Tear</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PP 2-0 NB</td>
<td>Knot Broke</td>
<td>9</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Suture Rupture</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Tissue Tear</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PP 2-0 B</td>
<td>Knot Broke</td>
<td></td>
<td>10</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Suture Rupture</td>
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<tr>
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<td>Tissue Tear</td>
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<td>PP 3-0 NB</td>
<td>Knot Broke</td>
<td>8</td>
<td>2</td>
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<td></td>
<td>Suture Rupture</td>
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<td>Tissue Tear</td>
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During the suture/tissue pullout test, the monofilament barbed and non-barbed sutures failed in different ways. Most of the non-barbed knotted sutures broke at or near the knot. It’s understandable that the knot is potentially the weakest point for non-barbed monofilament sutures used in tendon repair. This is because the suture material at the knot is exposed to multiple forces, including bending, torsion, compression, shear as well as tension.

In a few instance the tissues tore prior to knot failure. This may have been due to the porcine leg tissue being partially damaged during dissection. The operator was not experienced, and was given limited instruction about how to dissect the patellar tendon tissue. In view of the limited number of porcine legs available, a small number of the tendon tissues were slightly damaged, leading to a small number of tendon tears during the suture/tissue pullout test.

Suture breakage was the only reason why the barbed sutures failed during the suture/tissue pullout test. After cutting the barbs, the cross-sectional area that supported the applied tensile load decreased, causing the mechanical properties of the suture to decline. Hence the remaining and narrowest part of the suture caused by the barbing procedure is the weakest point and is where the suture breaks.
CHAPTER 5 CONCLUSIONS AND FUTURE WORK

5.1 Conclusion

With the overall goal to evaluate the anchoring performance of polyvinylidene fluoride and polypropylene knotless barbed sutures in repairing tendon tissue, this study has found the following seven conclusions:

1. Barbed polypropylene and polyvinylidene fluoride sutures were fabricated successfully with the desired geometry and uniformity using the existing barb cutting machine.

2. This study demonstrated for the first time that PVDF sutures can be barbed, and used for effective tendon repair.

3. Separate and complete porcine patellar tendons were harvested by dissecting porcine hind legs without causing trauma or damage to the tendon tissue.

4. Polyvinylidene fluoride sutures show superior mechanical properties in terms of higher ultimate tensile force and stiffness. These tensile properties were reduced by decreasing the suture diameter, and by the fabrication of multiple barbs along.

5. The type of suture material influenced the behavior of the barb when responding to the applied load from surrounding tissue. The barbs on the polypropylene suture surface bent backward more than those of the polyvinylidene fluoride suture.

6. The highest pull-out force was achieved by the 2-0 polyvinylidene fluoride non-barbed suture, while the 2-0 polyvinylidene fluoride barbed suture required the most force to form the 2-mm gap in the suture/tissue pullout test. By using a larger size, the suture will give a superior mechanical performance in repairing tendon tissue. And barbs showed excellent
anchoring performance in terms of reaching a higher gap formation force.

7. All the barbed sutures failed because the suture broke, whereas most of the non-barbed sutures failed at a point near the knot. The mode of failure is related to the presence of the barbs, and is not related to the suture size or the type of suture material.

5.2 Limitations of the current study

The existing barb cutting machine was able to provide the desired geometry and uniformity of barbs, but the barbing procedure used in this study was still performed manually. The sample size of both tensile test and suture/tissue test could have been larger to make the results and conclusion more precise and convincing. Repairing tendons and tying knots at the end of surgery completed by a professional experienced surgeon would have made the research more clinically significant, reliable and relevant. The use of software designed to connect the video camera to the computer on the mechanical testing machine, would have enabled the video recording of the suture/tissue pullout test to be more closely synchronized with the load cell’s output, and so improve the accuracy of the test results.

5.3 Future work

Future work should focus on the improvement of the barb cutting machine to increase barbing efficiency and reliability. In addition, the influence of the ratio of the suture and needle
diameters on the performance and properties of repaired tendon tissue should be investigate so as to determine the suitable and optimal ratio for tendon repair.

The long-term in vitro and in vivo mechanical properties and anchoring performance of both barbed and non-barbed sutures made from these two materials need further study to demonstrate the clinical advantages of polyvinylidene fluoride barbed sutures over traditional PP and PVDF sutures. First an in vivo animal trial is necessary and essential to demonstrate the possibility to use polyvinylidene fluoride barbed sutures for clinical tendon repair.
REFERENCES


