COMPARATIVE STUDY OF KNOT PERFORMANCE AND EASE OF MANIPULATION OF MONOFILAMENT AND BRAIDED SUTURES FOR ARTHROSCOPIC APPLICATIONS

BY

XIAOLI LI

A Thesis

Submitted to the Faculty of Graduate Studies

In Partial Fulfillment of the Requirements for the Degree of

MASTER OF SCIENCE

Department of Clothing and Textiles

University of Manitoba

Winnipeg, Manitoba

The author has granted a non-exclusive licence allowing the National Library of Canada to reproduce, loan, distribute or sell copies of this thesis in microform, paper or electronic formats.

The author retains ownership of the copyright in this thesis. Neither the thesis nor substantial extracts from it may be printed or otherwise reproduced without the author's permission.

L'auteur a accordé une licence non exclusive permettant à la Bibliothèque nationale du Canada de reproduire, prêter, distribuer ou vendre des copies de cette thèse sous la forme de microfiche/film, de reproduction sur papier ou sur format électronique.

L'auteur conserve la propriété du droit d'auteur qui protège cette thèse. Ni la thèse ni des extraits substantiels de celle-ci ne doivent être imprimés ou autrement reproduits sans son autorisation.

Canadä

THE UNIVERSITY OF MANITOBA

FACULTY OF GRADUATE STUDIES
****
COPYRIGHT PERMISSION PAGE

Comparative Study of Knot Performance and Ease of Manipulation of
Monofilament and Braided Sutures for Arthroscopic Applications

BY

Xiaoli Li

A Thesis/Practicum submitted to the Faculty of Graduate Studies of The University

of Manitoba in partial fulfillment of the requirements of the degree

of

Master of Science

XIAOLI LI © 2000

TABLE OF CONTENTS

Page

Acknowledgements

I wish to express my deep appreciation to my major adviser Dr. Martin W. King, for his inspiring and constructive guidance and supervision throughout the study.

I also wish to give my special thanks to other members of the graduate committee: Dr. Peter MacDonald, for his valuable time and advice; Dr. Jose A. Gonzalez for his advice and help; Dr. Randy Guzman, for his time and advice. In addition, I wish to thank Dr. John Bracken, for his help with technical terms.

I would like to thank in particular Dr. Dennis Murphy, for his constructive statistical ideas and assistance; Dr. Hansheng Xie, for his time and assistance in statistical analysis. I also would like to thank Sergio Mejia and Bob Talbot, for their technical assistance with SEM imaging and photography.

I wish to give my special thanks to Dr. Nelma Fetterman, Head of the Department of Clothing and Textiles, for her understanding and encouragement, as well as to the professors, staffs and fellow students in the department, who gave me support and friendship during my time in Canada.

Finally, I wish to express my deep thanks to my husband, for his support, love and sacrifice throughout my studies at the university and to my family, for their support.

ABSTRACT

Recent studies have indicated that absorbable monofilament suture materials currently

used for arthroscopic surgery, such as poly (p-dioxanone) (PDS®) and poly (glycolide

trimethylenecarbonate) (Maxon), show unsatisfactory knot slippage and elongation, even

when tested under low cyclic loads. Such inferior knot performance can lead to dehiscence

and failure of interventions such as shoulder cuff repair. Consequently, the primary

objective of this study is to determine whether alternative monofilament sutures, such as

poly (glycolidetrimethylenecarbonate-co-dioxanone) (Biosyn®) and polypropylene

(Prolene®) or braided poly (ethylene terephthalate), i.e. polyester (Surgidac®), provide

superior knot performance and equivalent ease of manipulation to the existing absorbable

PDS® suture.

An in vitro experiment was designed in which both Duncan and Snyder knotted loops

were tied from four different suture materials: PDS®, Biosyn®, Prolene® and Surgidac®,

using a standard arthroscopic knot pusher (Sixth Finger) and an Arthrex® practice box.

The ease of manipulation was evaluated by measuring the time required to tie the knots,

and the knot performance was assessed by performing first a cyclic fatigue test, and then a

tensile loop pull test to failure under saline using an Instron® Universal tester. Among the

criteria for evaluating the mechanical performance of the knotted loop were the loop

elongation at 30N of applied force, the force required to extend the loop by 6% (3mm),

called the loop holding capacity, as well as the knot security and maximum elongation at

failure. The results were analyzed statistically by two-way analysis of variance in order to

identify significant differences between the dependent variables.

Improvements in knot performance were observed by using Prolene® monofilament and Surgidac® braided sutures instead of PDS® sutures. Superior loop elongation and loop holding capacity values were obtained for these alternative materials, particularly when tied in a Snyder knot. Similar, but less dramatic improvements were found with the Duncan knot, which was invariably associated with greater knot slippage and knot failure due to slippage. In comparison, the Snyder knot failed more frequently due to suture breakage in or near the knot. Biosyn® knots gave no improvement over PDS®, due to the ease of elongation of the Biosyn® sutures at comparatively low loads. Difficulties were encountered in advancing the half-hitch throws of the braided poly (ethylene terephthalate) sutures (Surgidac®) down the cannula, which resulted in longer knotting times than for the current PDS® monofilament sutures.

In conclusion, only the polypropylene monofilament (Prolene®) suture was found to give superior knot performance and equivalent ease of manipulation to the current poly(p-dioxanone) (PDS®) suture. Furthermore, while both the Duncan and Snyder knots took similar knotting times to tie and install arthroscopically, the Snyder knot was invariably associated with superior knot performance, with less loop elongation and less frequent knot slippage than the Duncan knot. Further studies are recommended to optimize the coating to be applied to poly (ethylene terephthalate) braided sutures which will improve their surface frictional properties and so reduce their knotting times to levels equivalent to those for PDS® sutures.

List of Tables

List of Figures

CHAPTER 1

INTRODUCTION

A suture is a threadlike strand of material, either natural or synthetic in origin (Chu, 1983), which functions primarily to maintain wound closure and to promote wound healing during the time after surgery when the wound is most vulnerable to dehiscence. The ideal suture is one that possesses a number of important characteristics, including easy handling, the ability to form a secure knot, high tensile strength and acceptable biocompatibility (Moy, 1992; Hong, 1998).

Optimum tissue apposition is achieved when the knotted suture loop is secure and is tied with the appropriate suture material. A secure surgical knot is the fastening made by entangling one or more strands of a suture, so that when tension is applied to the suture it causes an increased contact pressure and tightening of the component parts of the knot. The ideal surgical knot is one that requires the fewest components; that is, the smallest number of turns and throws so as to achieve high strength and security. This is because the knot itself is the weakest part in any knotted loop (Chu, 1983).

In the clinical situation, the surgeon must choose which type of suture and which type of knot will be most appropriate for a specific task. For example, to repair shoulder instability, arthroscopic surgery is commonly performed. In this case, it is important that the length and tightness of the suture loop remain constant following surgery, because an elongation or loose suture loop will cause loss of tissue apposition (Mishra, 1997). Recognizing that some clinical failures are due to the elongation of an arthroscopically

tied knot, it is important for surgeons who use this surgical approach to select a type of suture material and a type of knot that will provide high tensile strength, low elongation and minimal knot slippage.

Problem Statement

In arthroscopic surgery, it is important to have good knot security to ensure optimal tissue apposition for healing. Arthroscopic stabilization can be achieved when the suture knot remains secure and the length of the suture loop remains constant. Recent studies have indicated that current suture materials, such as monofilaments made from poly (p-dioxanone) (PDS®) and poly (glycolidetrimethylenecarbonate) (Maxon®) show knot slippage and elongation even when tested under low cyclic loads (Mishra, 1997; Loutzenheiser, 1995). Consequently the demand for alternative suture materials for arthroscopic surgery remains.

Objectives of the Study

With a view to resolving this problem, another type of resorbable suture, made from a glycolide copolymer (Biosyn®), and two types of nonabsorbable sutures, namely a braided poly (ethylene terephthalate) or polyester (Surgidac®) and a polypropylene monofilament (Prolene®), were chosen to be evaluated as alternative materials for arthroscopic surgery.

2

The objectives of this study were:

1) To compare the knot performance and ease of manipulation of the alternative monofilament sutures (Biosyn® and Prolene®) with that of the commonly used arthroscopic material (PDS®).

2) To compare the knot performance and ease of manipulation of polyester braided sutures (Surgidac®) with that of the commonly used arthroscopic material (PDS®).

3) To determine whether or not the independent variables, such as type of knot, type of suture, affect the dependent variables, namely the knot performance and ease of manipulation.

4) To determine whether or not correlations exist between the various dependent variables in terms of the knot performance and ease of manipulation.

Null Hypotheses

H_{01}: There is no difference in knot performance and ease of manipulation between types of knot.

H_{02}: There is no difference in knot performance and ease of manipulation between the types of suture.

H_{03}: There is no interaction between type of knot and type of suture in knot performance and ease of manipulation.

H_{04}: For each type of knot, there is no difference in knot performance and ease of manipulation among different types of suture.

H_{05}: For the Duncan knot, there is no difference in knot performance and ease of manipulation among different types of sutures.

H_{06}: For the Snyder knot, there is no difference in knot performance and ease of manipulation among different types of sutures.

H_{07}: There is no correlation between any two of the dependent variables, namely the knot performance and ease of manipulation.

Definitions

1. Loop elongation is defined as the average maximum displacement or growth in length of a knotted suture loop at a peak load under cyclic loading.

2. Knot elongation is defined as the difference between the loop elongation and suture elongation at a peak load under cyclic loading.

3. Number of cycles is defined as the number of cycles during cyclic loading when the displacement or growth of a suture loop reaches 3 mm (i.e. 6% of the initial loop circumference). This degree of displacement or growth in the loop is considered to correspond to clinical failure.

4. Loop holding capacity is defined as the maximum force that results in a displacement or growth in length of 3 mm (6%) in a knotted suture loop that is originally 5cm in circumference. This corresponds to the maximum force that a suture loop can support at the moment of clinical failure.

4

5. <u>Knot security</u> is defined as the maximum force applied to the inside of the suture loop that either causes the suture to break and the knot remains intact or causes the knot to slip completely off the end of the suture.

6. <u>Maximum elongation</u> is defined as the maximum displacement of a knotted suture loop when the suture breaks and the knot remains intact.

7. <u>Ease of manipulation</u> is defined as the average time required to complete the tying of a particular type of knot.

Limitations

The suture samples for this study were supplied by the manufacturers. The sample selection relied on the availability of suture materials supplied. In other words, the suture samples were not randomly selected from the total population available.

The experimental knots used in this study were tied by the investigator. The reliability of the investigator's knot tying ability was evaluated by comparing it with that of an experienced surgeon during a preliminary experiment which is reported in the Appendix.

CHAPTER 2

LITERATURE REVIEW

This literature review includes six topics: 1) sutures, 2) surgical knots, 3) knot performance of suture materials, 4) ease of manipulation and knot tying of suture materials, 5) a review of sutures and surgical knots for arthroscopic applications, and 6) a summary of observations.

Sutures

Suture Materials

A suture is a length of threadlike material used to close a surgical wound or incision, or to approximate the edges of a tissue injury or defect. The suture is usually drawn through the tissue near the edges of the wound with a needle and then tied so as to draw the edges together (Casey, 1986). The ideal suture is one that meets all requirements for a particular application. Some of the most important characteristics include ease of handling, ability to form a secure knot, high tensile strength and acceptable biocompatibility (Moy, 1992; Hong, 1998).

There are two basic types of suture materials: absorbable and nonabsorbable. Absorbable sutures are those that lose their entire tensile strength within two to three months following implantation. Nonabsorbable sutures are those that retain their strength for periods longer than three months *in vivo* (Chu, 1983).

6

Sutures are made from a wide variety of polymeric and metallic materials. The polymers can be either of natural or synthetic origin. The only nonpolymeric suture material in common use is stainless steel (Casey, 1986).

Suture materials are made with different structures or physical configurations. The monofilament type consists of a single continuous filament usually with a circular cross-section. Multifilament sutures consist of many fine filaments, which are either twisted or braided together. To reduce the surface friction and to protect the fine filaments during handling, most multifilament sutures receive a surface treatment or coating (Chu, 1983)

The following two tables list the chemical and structural properties of various commercial sutures that are or have been available in North America (Chu, 1983; Casey, 1986).

Suture Sizes

Two standard systems are currently used to describe the size of sutures: the US Pharmacopoeia (USP) and the European Pharmacopoeia (EP). These size systems are further divided into three subsystems; one for collagen, one for absorbable synthetic, and the last for nonabsorbable synthetic sutures. Tables 3, 4 and 5 show the suture size code and the limits of average diameter for these three subclassifications.

7

Table 1

Absorbable Sutures

Polymer Material	Chemical Composition	Brand Name	Suture Structure	Surface Treatment
Catgut	Protein - Plain &Chromic	Catgut or Surgical	Twisted	
Reconstituted collagen	Protein - Plain &Chromic	Collagen	Twisted	
Poly(glycolide-co trimethylene carbonate)	$[-OCH_2CO-]_{67}$ $[OCH_2CH_2CH_2OCO-]_{33}$	Maxon	Mono	-
Polyglycolic acid	$[-OCH_2CO_2CO-]$	Dexon Dexon Plus	Braided Mono	- Yes
Poly(glycolide-co lactide)	$[-OCH_2CO_2CH_2CO-]_{90}$ $[OCH(CH_3)CO_2CH (CH_3)-CO-]_{10}$	Vicryl	Braided	With & without an absorbable coating
Poly(dioxanone)	$[-OCH_2CH_2-OCH_2CO-]$	PDS	Mono	-
Poly(glycolide-co-trimethylene carborate-co-dioxanone)	$[-OCH_2CO-]_{60}$ $[OCH_2CH_2CH_2OCO-]_{26}$ $[-OCH_2CH_2-OCH_2CO-]_{14}$	Biosyn	Mono	-

8

Table 2

Nonabsorbable Sutures

Polymer Material	Chemical Composition	Brand Name	Suture Structure	Surface Treatment
Silk	Protein	Surgical Dermal	Braided Twisted	Tru-Permanizing
		Virgin silk	Twisted	-
		Silk	Braided	Silicone
		Silk	Braided	Paraffin wax
Cotton	Cellulose	Surgical Cotton	Twisted	-
Linen	Cellulose	Linen	Twisted	Wax

Polyesters

Polymer Material	Chemical Composition	Brand Name	Suture Structure	Surface Treatment
Poly(ethylene terephthalate)	$[-O(CH_2)_2OCOC_6H_4CO-]$	Surgidac	Braided	Poly(butylene adipate)
		Ethibond	Braided	Polybutylate
		Mersilene	Braided	-
		Ethiflex	Braided	Teflon
		Dacron	Braided	-
		Ti-cron	Braided	Silicone
		Silky	Braided	Teflonized
		polydek	Braided	Teflonized
		Sterilene	Braided	Teflonized
		Tevdek	Braided	Teflonized
		Astralen Mirafil	Mono	-
Poly(butylene terephthalate)	$[-O(CH_2)_4OCOC_6H_4CO-]$	Polydek	Braided	Teflon
		Miralene	Mono	-
Poly[poly (tetramethylene-ether)terephthalate]	$[-(CH_2)_4OCOC_6H_4CO]_{84}$ $[-O(CH_2CH_2CH_2CH_2O-)$ $_nCOC_6H_4CO-]_{16}$	Novafil	Mono	-

Polymer Material	Chemical Composition	Brand Name	Suture Structure	Surface Treatment
Polyamide Nylon 6	$[-NH(CH_2)_5CO-]$	Ethilon	Mono	-
		Nurolon	Braided	Yes
		Supramin	Core-sheath	-
		Perlon	Core-sheath	-
Nylon 66	$[-NH(CH_2)_6NHCO$ $(CH)_4CO-]$	Ethilon	Mono	-
		Nurolon	Braided	Wax
		Surgilon	Braided	Silicone
		Dermalon	Mono	-
Polyolefins Polypropylene	$[-CH_2CH(CH_3)-]$	Prolene	Mono	-
		Surgilene	Mono	-
Polyethylene	$[-CH_2-]$		Mono	-
Polyvinylidene fluoride	$[-CH_2-CF_2-]$	Teflene	Mono	-
Stainless steel		Surgical stainless Steel Flexon	Mono & Twisted Mono & Twisted	- -

10

Table 3

Sizes of Collagen Sutures

USP Size Codes	USP Gauge No. EP Size Codes (mm)	Limits on average diameter (mm) Min	Max.
9-0	0.4	0.040	0.049
8-0	0.5	0.050	0.069
7-0	0.7	0.070	0.099
6-0	1	0.10	0.149
5-0	1.5	0.15	0.199
4-0	2	0.20	0.249
3-0	3	0.30	0.339
2-0	3.5	0.35	0.399
0	4	0.40	0.499
1	5	0.50	0.599
2	6	0.60	0.699
3	7	0.70	0.799
4	8	0.80	0.899

Table 4

Sizes Absorbable Synthetic Sutures

USP Size Codes	USP Gauge No. EP Size Codes (mm)	Limits on average diameter (mm) Min	Max.
12-0	0.01	0.001	0.009
11-0	0.1	0.010	0.019
10.0	0.2	0.020	0.029
9-0	0.3	0.030	0.039
8-0	0.4	0.04	0.049
7-0	0.5	0.050	0.069
6-0	0.7	0.070	0.099
5-0	1	0.10	0.149
4-0	1.5	0.15	0.199
3-0	2	0.20	0.249
2-0	3	0.30	0.339
0	3.5	0.35	0.399
1	4	0.40	0.499
2	5	0.50	0.599
3 & 4	6	0.60	0.699
5	7	0.70	0.799

Table 5

Sizes of Nonabsorbable Synthetic Sutures

USP Size Codes	USP Gauge No. EP Size Codes (mm)	Limits on average diameter (mm)	
		Min	Max.
12-0	0.01	0.001	0.009
11-0	0.1	0.010	0.019
10-0	0.2	0.020	0.029
9-0	0.3	0.030	0.039
8-0	0.4	0.040	0.049
7-0	0.5	0.050	0.069
6-0	0.7	0.070	0.099
5-0	1	0.10	0.149
4-0	1.5	0.15	0.199
3-0	2	0.20	0.249
2-0	3	0.30	0.339
0	3.5	0.35	0.399
1	4	0.40	0.499
2	5	0.50	0.599
3&4	6	0.60	0.699
5	7	0.70	0.799
6	8	0.80	0.899
7	9	0.90	0.999
8	10	1.0	1.099
9	11	1.100	1.199
10	12	1.200	1.299

Surgical Knots

Parts of a Knot

There are six terms commonly used to describe the component parts of traditional flat square knots and half-hitch sliding knots.

1. A " knot " is composed of two or more throws (Dinsmore, 1995).

2. A "throw" refers to each of the specific number of steps or layers in a knot (Dinsmore, 1995).

3. "Flat throw" describes the type of throw when the thread moves from one side of the knot (A) to the opposite side (B) (Trimbos, 1986) (Figure 1).

4. "Sliding throw" describes the type of throw when the thread enters and leaves the knot on the same side (A or B) (Trimbos, 1986) (Figure 1).
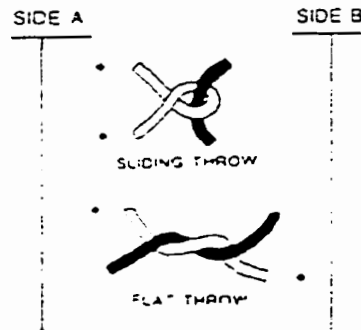
Figure 1. Configuration of flat and sliding throws (Trimbos, 1986).

5. "Post" is the straight thread in a sliding knot around which the second thread is tied (Dinsmore, 1995).

6. " Turn" refers to the number of twists in a given throw. It is used to describe both flat throw and half- hitch sliding knots (Dinsmore, 1995).

Knot Code

There are two standardized nomenclatures. One, which describes flat square knots, was introduced by Tera in 1976. The other describes half-hitch sliding knots. It was developed by Trimbos in 1986, and appears to be an extension of Tera's nomenclature for flat knots (Dinsmore, 1995).

The knot code using Tera's nomenclature indicates the number of turns in each throw, the number of throws in the flat square knot, and the relationship between successive throws. Arabic numbers are used to indicate the number of turns in each throw. The relationship between successive throws is indicated by the symbols "= "and "x". The "="symbol shows that the thread in successive throws enters and leaves the knot in the same direction. An example of this type of knot is the basic square knot described as "1=1". This code shows that the knot has two throws, one turn in each throw and the threads in the two throws are in the same direction. The symbol "x" shows that the threads pass crosswise between successive throws, such as in the basic granny knot, represented by "1x1". This code indicates that the knot has two throws, one turn in each throw, and that the two threads pass crosswise between the throws (Tera, 1976).

In Trimbos's nomenclature instead of using an Arabic number to represent the number of turns, an "S" is used to indicate each sliding throw. The relationship between

successive sliding throws and the post around which they are tied is indicated by symbols " = ", " x ", " // " and " # ". The symbol "=" means that successive throws pass around the same post in the same direction, while symbol "x" means that successive throws pass around the same post, but in the opposite direction. The symbol "//" means that the same sliding throws are tied alternately around different posts, whereas "#" means that successive sliding throws have both opposite directions and are tied around different posts (Trimbos, 1986).

Types of Surgical Knots

There are two main categories of surgical knots. One category is for flat throw square knots and the other is for sliding knots.

Square knots

The "square knot" is defined as a surgical knot which comprises at least two flat throws. Depending on the relationship between successive throws, square knots can be divided into parallel knots and crossed knots. Parallel knots are those in which the thread enters and leaves the knot in the same direction. If the threads are crossed, then the knot is referred to as a crossed knot (Tera, 1976). Examples of these knots and knot codes are presented in Figure 2.

(a)

Basic square knot (reef knot)

$1 = 1$

(b)

Granny knot

1×1

(c)

Surgeon's knot (friction knot)

2×1

(d)

Double throw knot

$2 = 2$
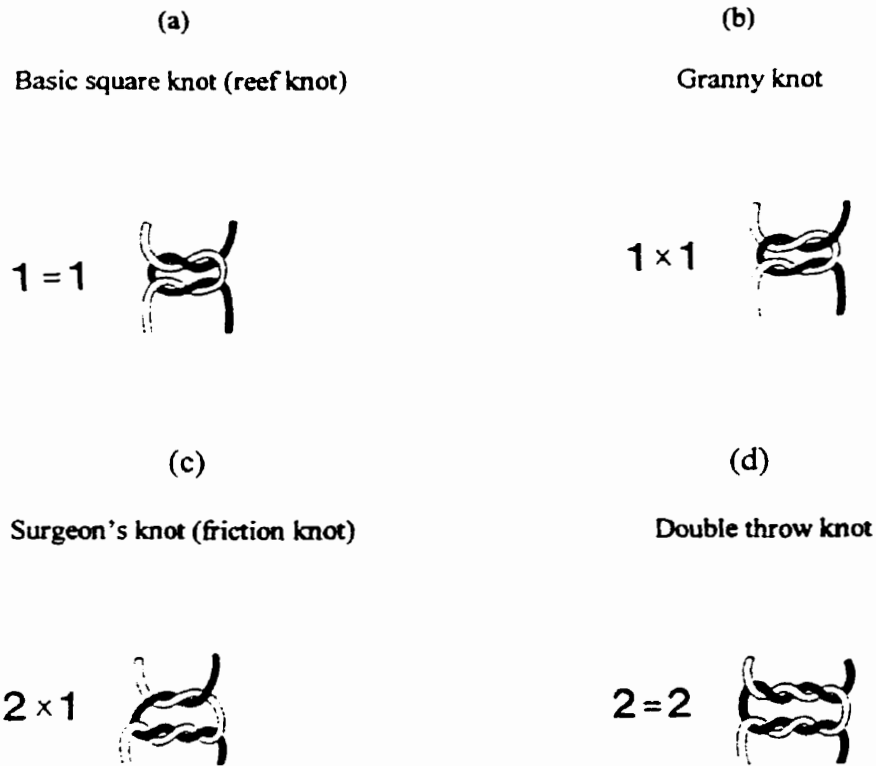
Figure 2. Examples of square knots and codes (Tera, 1976).

Sliding knots

Sliding knots consist of at least two sliding throws. Each sliding throw has either a clockwise or a counter-clockwise direction around the adjacent post. Sliding knots can be divided into two groups. One group is called half-hitch knots, which are derived from flat throw square knots and the other group is called slip knots. These are extracorporeal knots that are tied at a distance from their ultimate position and then pushed or "snugged" into place by means of endoscopic instruments (Trimbos, 1986; Pasic, 1995; Sweeney, 1996). Examples of these knots and knot codes are presented in Figure 3.

Half-hitch Knot

S=S   SXS   SXS#SXS

Slip Knot

Figure 3. Examples of sliding knots (Dinsmore, 1995; Shimi, 1994; Mishra, 1997).

Knot Performance of Suture Materials

When using the term knot performance of a suture material, one is inevitably

referring to a number of different mechanical properties of the knotted loop. These

include loop elongation, loop holding capacity, knot security, and maximum elongation.

Loop Elongation

Loop elongation refers to the maximum displacement or growth in the length of a

knotted loop at a peak load under cyclic loading. (Mishra, 1997). A suture loop that is

loose will cause loss of tissue apposition no matter how tightly the knot is tied (Burkhart, 1998).

Cyclic fatigue testing is relevant to arthroscopic clinical practice. After surgical repair of the rotator cuff in the shoulder, for example, the suture line is likely to be loaded repetitively by low forces at slow rates due to muscular activity, joint mobility, therapy, or even clinical examination before healing is complete (Loutzenheiser, 1995). A previous *in vitro* study has demonstrated that PDS® monofilament sutures show significant loop elongation under the application of a cyclic load of low magnitude, which could place such a surgical repair at risk (Loutzenheiser, 1995).

Loop Holding Capacity

Loop holding capacity refers to the maximum force that produces a displacement or growth of 3 mm in the length of a knotted suture loop. This threshold has been used by several investigators who found that in the clinical situation this amount of displacement results in loss of tissue apposition (Loutzenheiser, 1995; James, 1992; Batra, 1992).

Knot Security

Knot security is a measure of the strength of a knot. It refers to the maximum load the knotted loop is able to support prior to breaking (fracture) or complete slippage (Loutzenheiser, 1995). Previous studies have shown that loop holding capacity and knot security are influenced by the type of knot, the knot configuration, the type of suture material, the size and coating of the suture, as well as the technique used for knot tying (Magilligan, 1974; Van Rijssel, 1990; James, 1992).

18

Maximum Elongation

Maximum elongation refers to the maximum displacement of a stressed knotted suture loop, either when the suture breaks and the knot remains intact, or when the knot slips completely off the end of the suture. In a previous study it was shown that for PDS® sutures the maximum elongation was greater than 5mm regardless of which knot configuration was tested. This degree of loop displacement is well beyond the 3 mm limit assumed to represent clinical failure by loss of tissue apposition (Loutzenheiser, 1995).

Ease of Manipulation and Knot Tying of Suture Materials

The terms ease of manipulation and ease of handling refer to an important characteristic for the ideal suture (Moy, 1992). Surgeons evaluate the handling characteristics of sutures by constructing knots using manual and instrument tying techniques. The surgeon naturally prefers a suture that permits a throw to be easily advanced to the wound edges, so the ultimate closure of the wound can be easily visualized (Faulkner, 1996). To determine the ease of manipulation one can measure the average time required to complete the tying of a particular type of knot.

In endoscopic surgery, the main concern is in reducing operating time. Time and motion principles can be applied so as to shorten the operating time. This can be accomplished through tight choreography of movements, employing the ergonomic principle of economy of motion and flawless technique (Szabo, 1994).

With a view to shorten operating time, Szabo (1994) presented the principles and techniques of needle loading, handling, and driving as well as describing in detail the

series of movements involved in tying an intracorporeal half-hitch sliding knot. In 1997, Hanna (1997) studied the influence of direction of view, target-to-endoscope distance and the manipulation angle on endoscopic knot tying. It was found that a 60^0 manipulation angle gave a shorter time than other angles. Even though many knots are made and knot tying consumes a substantial part of the duration of virtually all surgical procedures (Van-Rijssel, 1990), no study of the influence of the type of knot and the suture material on the operating time appears to have been undertaken to date.

Review of Sutures and Surgical Knots for Arthroscopic Application

Arthroscopic Suture Materials

Two types of suture materials are commonly recommended for use in arthroscopic shoulder stabilization and meniscal repair. They are the PDS® monofilament absorbable suture and the braided polyester nonabsorbable suture (Mishra, 1997). Recent studies have indicated that sutures, such as monofilaments made from poly (p-dioxanone) (PDS®) and poly (glycolidetrimethylenecarbonate) (Maxon), show knot slippage and elongation even when tested under low cyclic loads (Mishra, 1997; Loutzenheiser 1995). In contrast, knots tied with braided nonabsorbable polyester (Ticron) sutures tended to fail by suture breakage (Mishra, 1997).

Most surgeons use suture sizes No. 0, 1, or 2 for the shoulder stabilization procedures. In most of the previous studies, size No. 1 was used (Mishra, 1997; Burkhart, 1998; Loutzenheiser, 1995).

20

Arthroscopic Surgical Knots

Arthroscopic assisted knot tying commonly consists of an initial sliding knot followed by a series of half hitches.

Arthroscopic knot code

The codes used to describe arthroscopic knots include two parts, which are connected with an equal sign "=". The first part is the abbreviation of the initial slip knot, and the second part is the code for half-hitches. In the following example: "DL=S#S#S" indicates that the initial Duncan loop is followed by three half-hitches with switching posts and reversing directions between successive throws (Loutzenheiser, 1995).

Arthroscopic knots

Four types of sliding knot configurations have been used in previous studies (Mishra, 1997; Burkhart, 1998; Loutzenheiser, 1995). They are the Overhand loop, Duncan loop, Roeder knot and Snyder knot (See Figure 4).

The Snyder knot was found to have relatively smaller loop elongation and greater loop holding capacity than the other knots when tied with Maxon and Ticron sutures (Mishra, 1997). The Duncan loop plus three half-hitches with post switching and reversing throws showed the least loop elongation and the best loop holding capacity for PDS® sutures (Loutzenheiser, 1995).
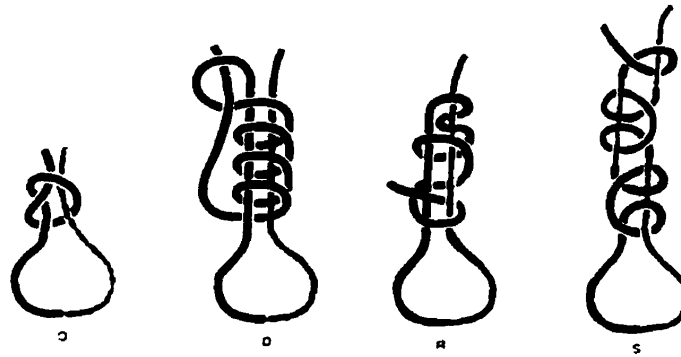
Figure 4. Arthroscopic knots. O = Overhand loop, D = Duncan loop, R = Roeder knot, S = Snyder knot. The Overhand loop, Duncan loop and Roeder knot were all followed by three half-hitches with post switching and reversing direction between each throw (Mishra, 1997).

Knot Tying Techniques and Instruments.

Arthroscopic knots, such as the Duncan loop, are tied extracorporeally and pushed down cannula to the site of surgery. Arthroscopic knot tying is difficult and time consuming. Some arthroscopic procedures may fail due to the fact that the knots are poorly tied (Sweeney, 1996). Obviously knots must be tight and must not slip. Several specific knot tying techniques have been recommended, including the use of a knot pusher to tie a square knot, a Duncan loop, alternating half-hitches and a Snyder knot (Fischer, 1995).

Knot pushers are commonly used to move or "snug" a knot or a throw down a cannula to the surgical site. To do this, there are four types of knot pushers: slotted, single hole, double hole, and the mechanical spreader (Fischer, 1995). It has been found that the double hole knot pusher, such as the Surgeon's Sixth Finger®, is able to maintain higher tension on the suture during tying and manipulation which leads to knots tied with

22

significantly tighter suture loops than obtained with a standard single-hole knot pusher (Burkhart, 1998).

Observations

In summarizing this review of the literature there appear to be five major observations.

1) It has been reported that suture materials in current use, such as PDS®, show high levels of elongation under low loads, even during cyclic loading. Few studies reported on the performance of alternative suture materials.

2) Of all the various types of knots used in arthroscopic surgery, two types of knots, the Duncan and the Snyder knots. show better knot security and appear to be more suitable for arthroscopic applications.

3) The Surgeon's Sixth Finger® knot pusher is able to maintain better loop elongation and higher tension on the suture than a single-hole knot pusher.

4) While the literature has identified two of the requirements for an ideal suture to be its ease of manipulation, and its ability to form a secure knot, no studies have been found on the ease of manipulation for arthroscopic surgery. Previous studies have measured knot performance related to arthroscopic surgery in terms of loop elongation, loop holding capacity. number of cycles, knot security and maximum elongation.

5) No standard test methods were found for measuring any of these properties.

CHAPTER 3

MATERIALS AND METHODS

Variables

<u>Independent variables</u>

1) Type of knot

   There were two types of knot: 1) the Duncan loop plus three half-hitches with

   reversing post and switching throws called the Duncan knot, and 2) the Snyder knot.

2) Type of suture

   The four types of suture material were 1) poly (p-dioxanone) (PDS®), 2)

   poly(glycolidetrimethylene-carbonate-co-dioxanone) (Biosyn®), 3) polypropylene

   (Prolene®), and 4) poly (ethylene terephthate) or polyester (Surgidac®).

<u>Dependent Variables</u>

1) Knot performance characteristics:

   a) Loop elongation

   b) Knot elongation

   c) Loop holding capacity

   d) Number of cycles

   e) Knot security

   f) Maximum elongation

2) Ease of manipulation

   a) Knotting time

Specimen Preparation

<u>Suture Materials</u>

As well as testing poly (p-dioxanone) (PDS®) monofilament sutures, three additional sutures were selected (Figure 5). They were all size 1 and had a length of at least 90cm. These sutures were chosen because they were commercially available in size 1 and in a length of at least 90cm, which is the minimum length required for using the Surgeon's Sixth Finger® knot pusher. The chemical name and physical characteristics of the sutures are presented in Table 6. In addition, scanning electron microscope (SEM) images of these four types of sutures were recorded and digitized.

Scanning electron microscopy was performed on a Cambridge Instruments Stereoscan 120 instrument, and the images were captured and digitized with an IBAS Konstron Electronic image analyzer with accompanying software. After making sure there was good conduction between the specimen and the aluminum stub with graphite paint, the mounted specimens were coated with gold/palladium in an Edwards Model 5150B sputter coater.

Figure 6 shows the SEM image of the surface of a PDS® suture. Figure 7 shows the surface of a Biosyn® suture, Figure 8 a Prolene®, and Figure 9 is a SEM micrograph of a Surgidac® suture.
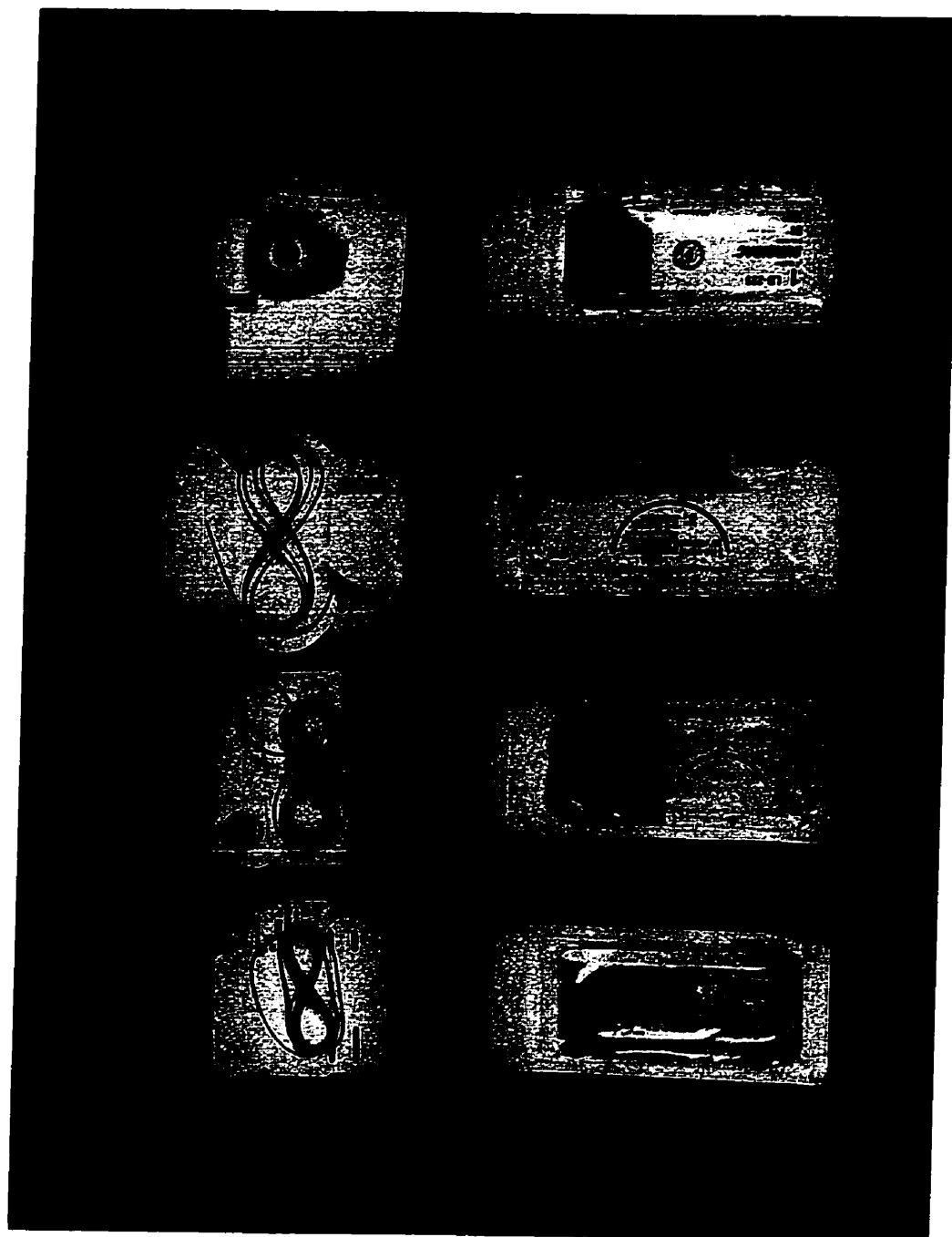
Figure 5. Sutures for the study
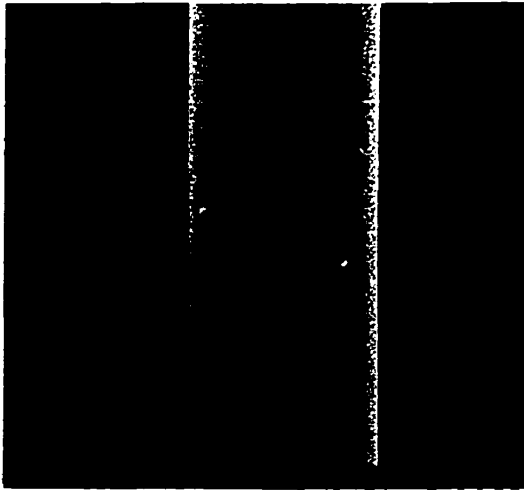
Figure 6. SEM image of a PDS® suture
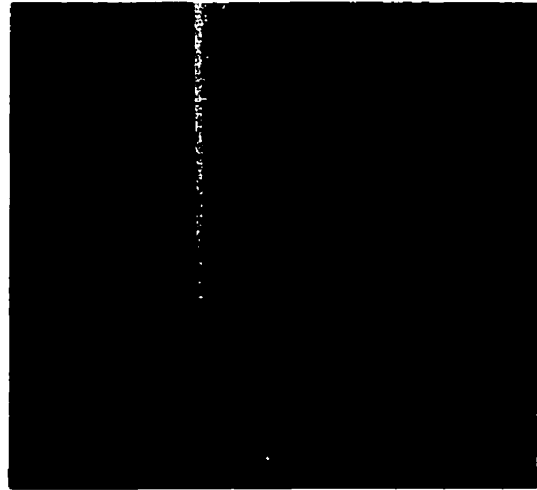
Figure 7. SEM image of a Biosyn® suture
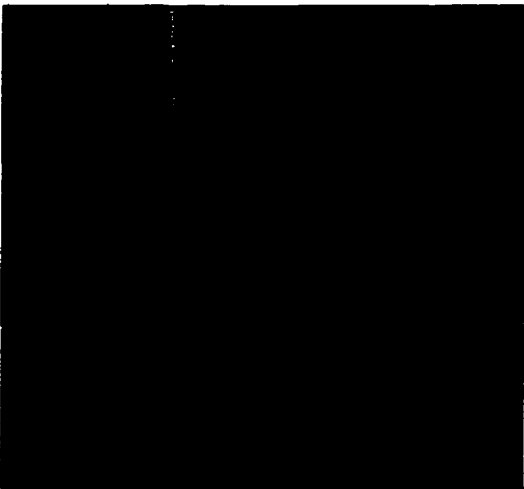
Figure 8. SEM image of a Prolene® suture
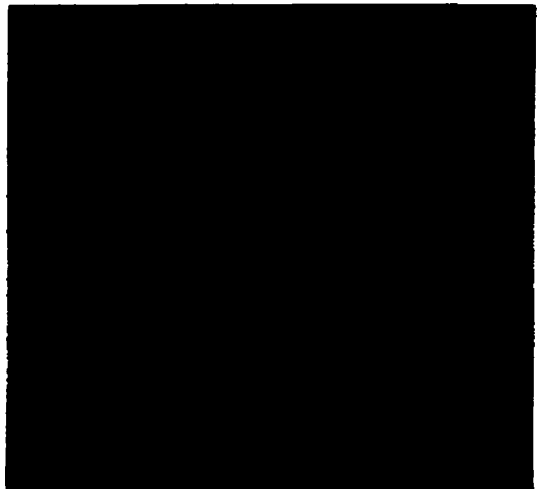
Figure 9. SEM image of a Surgidac® suture

27

Table 6

Sutures Selected for the Study

Brand Name	Polymer Material	Suture Structure	Coating	Manufacturer
PDS®	Poly(dioxanone)	Mono	None	Ethicon
Biosyn®	Poly(glycolide-co-trimethylenecarbonate-co-dioxanone)	Mono	None	USSC
Prolene®	Polypropylene	Mono	None	Ethicon
Surgidac®	Poly(ethylene terephthalate)	Braided	Poly(butylene adipate)	USSC

Types of Knots

Two types of knots were assessed. They are referred to as the Duncan knot and the Snyder knot (Figure 10). They were chosen since previous studies has shown them to provide the best knot security (Mishra, 1997).

1) The Duncan loop plus three half-hitches with post switching and reversal of the loop direction were added to secure the Duncan knot. This knot is commonly used in arthroscopic surgery, because it is considered to be the best sliding knot configuration (Louzenheiser, 1995; Fischer, 1995). The code for this knot configuration is DL=S#S#S (Figure 11)

2) The Snyder knot is also commonly used in arthroscopic surgery (Fischer, 1995). The knot code is SXS#SXS#S (Mishra, 1997) (Figure 11).
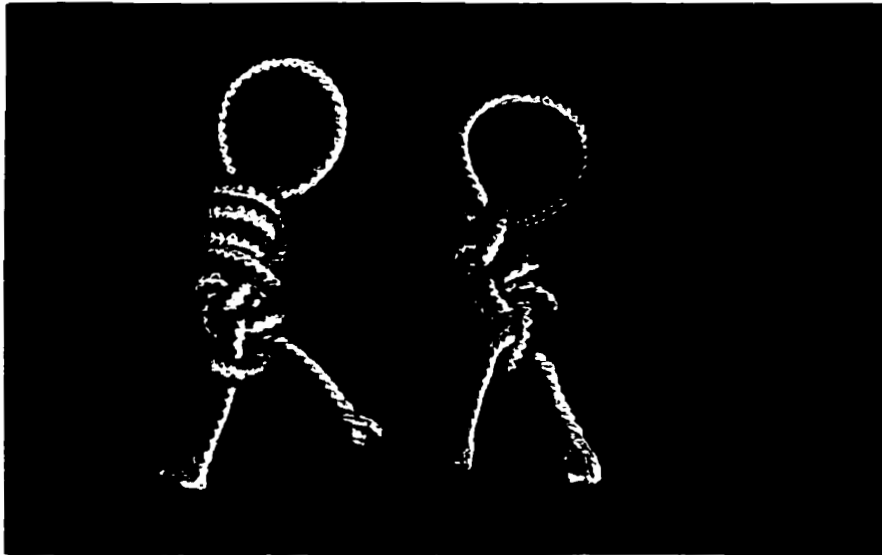
Figure 10. Photographs of the Duncan knot (left) and Snyder knot (right)
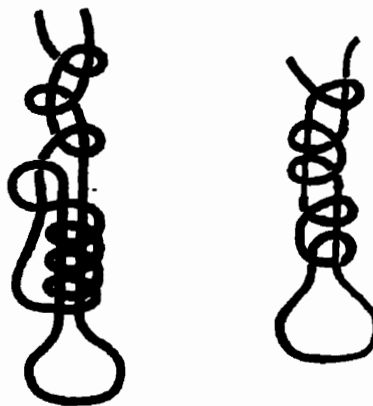
Figure 11. Configuration of the Duncan loop plus three half-hitches (left) (Loutzenheiser, 1995) and the Snyder knot (right) (Mishra, 1997).

Knot Tying Techniques

The instrument used was the Surgeon's Sixth Finger® knot pusher with suture passer (Arthrex®, Naples, FL) (Figure 12). This instrument is recommended by Burkhart for rotator cuff repair (Burkhart, 1998). Eugene Wolf's hangman knot tying technique as described by Snyder was used for tying the Duncan knot and the Snyder knot (Fischer, 1995). The knots were tied by the investigator in a simulation of arthroscopic knot tying. They were tied around a 1.6 cm diameter rigid plastic rod (5 cm circumference) made from polytetrafluoroethylene (Teflon) with a low friction surface (Figure 13) and mounted in an " Arthrex® wooden shoulder" arthroscopy practice box (Naples, FL) (Figure 14). The knot loop and additional throws were formed outside a 7 mm diameter cannula, and then moved down the cannula using the Sixth Finger knot pusher (Figure 15). Knots were tied in a standard atmosphere ($21\pm1°C$ and $65 \pm 2\%$ relative humidity). After tying, the knots were carefully removed from the rod and tested immediately.

Number of Specimens

The number of knot specimens tested for each type of suture and each type of knot was estimated from a preliminary trial. The maximum coefficient of variation v among the important properties loop elongation and loop holding capacity for different combinations of suture and knot was found in the trial to be 9%. The number of specimens required to generate a standard error no greater than 5% of the mean (E) from which the highest coefficient of variation generated among different combinations was given by: $N = (v/E)^2 = (9/5)^2 = 3.24 = 4$ specimens (Canadian General Standards Board, 1987)
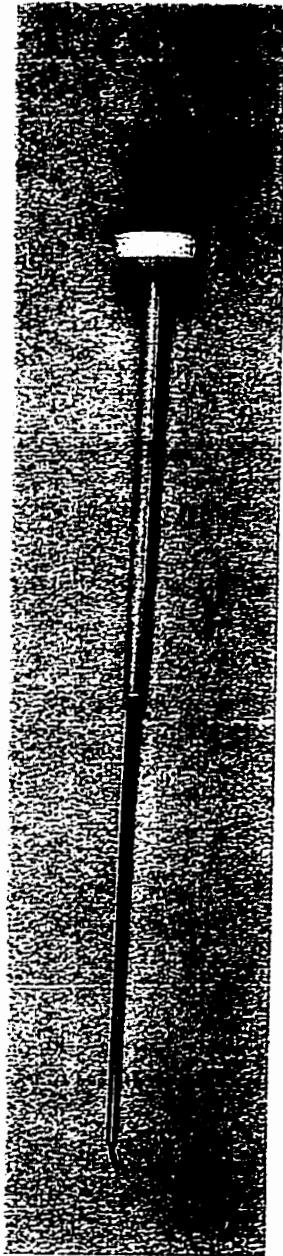
Figure 13. The rod

Figure 12. The Surgeon's Sixth . finger knot pusher.
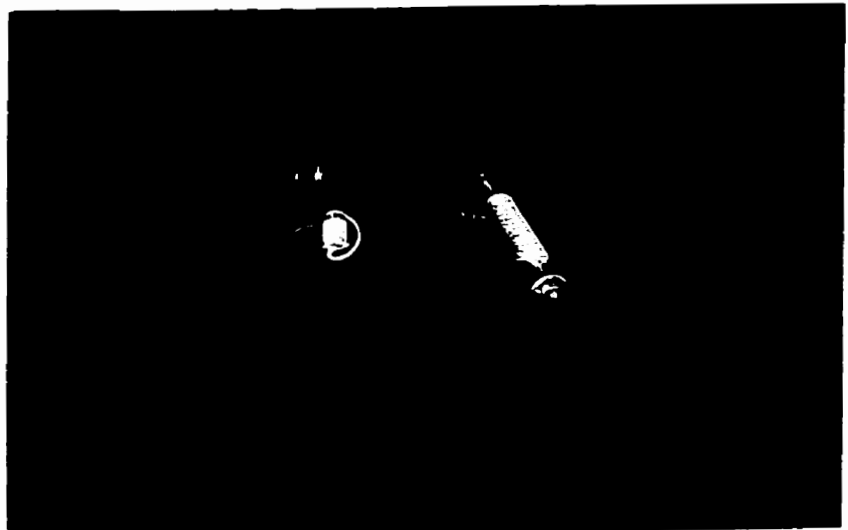
Figure14. The Arthrex wooden shoulder arthroscopy practice box

Figure 15. Knot tying using the instruments for this study, showing sliding a throw down the cannula

However, other properties, such as knot security and maximum elongation generated from the same combination of sutures and knots gave higher coefficients of variation. Therefore a larger sample size was needed to reduce the variation among these properties. As a compromise, a sample size of 10 was selected for this study. A sample size of 10 was also used in Loutzenheiser's study (1995).

Sampling

Eighty knot specimens were tied around 16 Teflon rods. Five knots of different sutures were tied around each rod. A random selection was used to determine the order of knot tying and the type of suture used for each plastic rod. The 16 groups of knots were tied following the order generated by random selection.

Validation of Knot Tying Technique

In order to validate the results of this study for the knots tied by the investigator, it was necessary to compare the knot performance and ease of manipulation for knots tied by the investigator with those tied by an experienced arthroscopic surgeon. The results of this preliminary experiment are shown in the Appendix.

Test Methods

There is no USP standard test method for making measurements of loop elongation under cyclic loading. A test method used previously by researchers for testing this

33

property is called the loop method. It was reported by Loutzenheiser (1995) and Mishra (1997) and has been adapted for use in this study.

Testing Apparatus

An Instron® Universal Tester, TM Model (Instron®, Canton, MA) was used. It was fitted with a CTM load cell with a 1000 N capacity and an environmental tank to allow testing under liquid conditions. The Tester has been retrofitted with a computer system (Hewlett Packard 4540 CEL) (VACS Ltd., Brampton, ON) to provide control of the crosshead motion and real-time acquisition of the applied load, strain rate, and displacement data (Figure 16). Two specially designed hooks were clamped between the flat polished metal faced pneumatic jaws on the Instron® so as to allow the knotted suture loop to be placed around them and then stressed (Figure 17).

Testing Conditions

To simulate the arthroscopic environment, testing was performed in Tris buffered (pH 7.6) saline in the environmental tank at 21^0C. This was to simulate the physiological liquid environment (Mishra, 1997).

Principles of the Test Method

Mechanical loading of the knotted suture loop occurred by moving the two hooks apart. Cyclic loading and strength testing were performed in two consecutive stages on the same knotted loop. During cyclic loading the loop displacement was measured after each cycle. During ultimate loading the applied force at 3 mm loop displacement and at

Figure 16 . Computer controlled Instron® Universal tester system
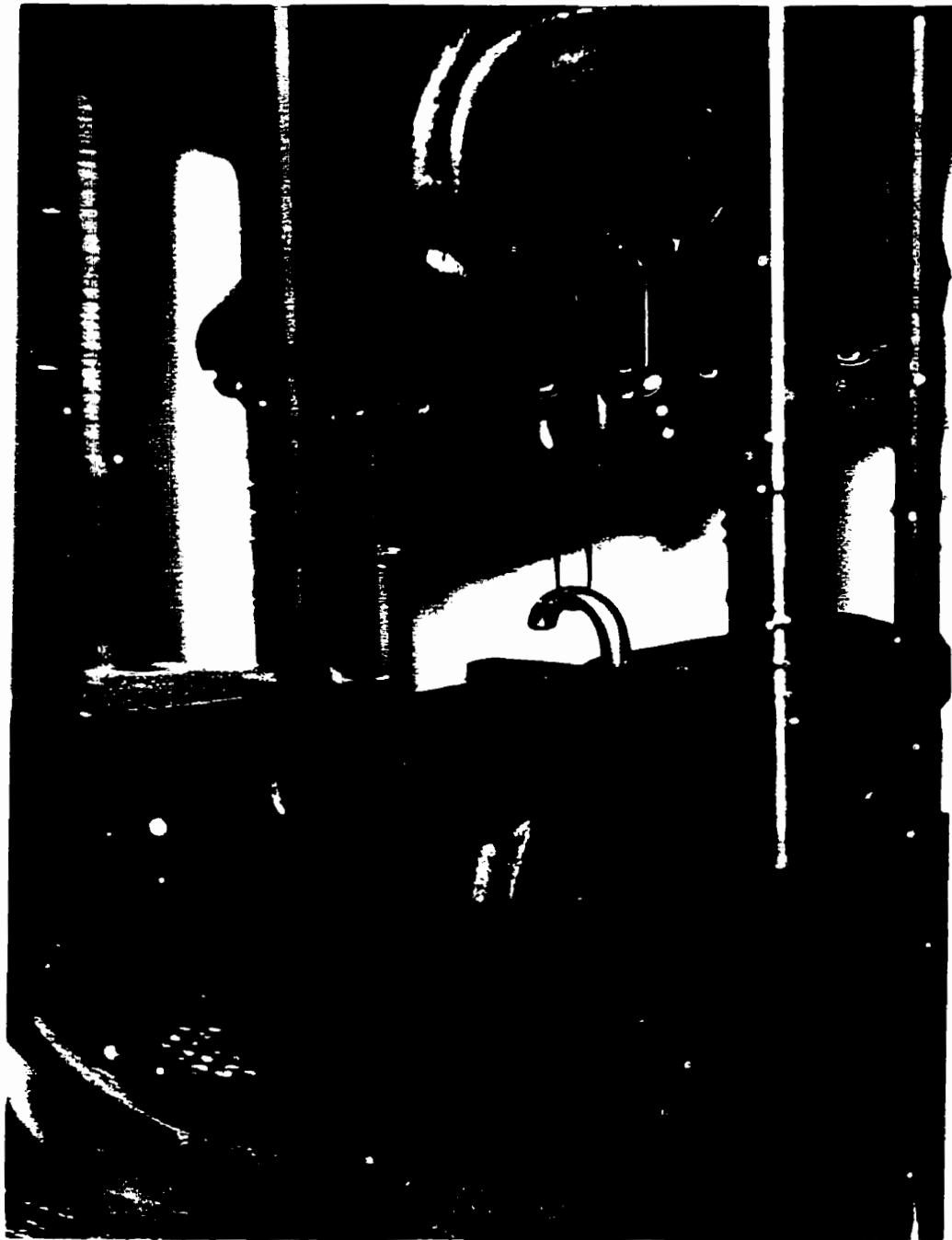
Figure 17. A knotted loop being stressed between the two hooks in the environmental tank filled with saline solution

failure were measured together with the displacement or maximum elongation at the ultimate failure point (Mishra, 1997; Loutzenheiser, 1995).

Test Procedure for Loop Elongation under Fatigue Testing (Cyclic Loading)

Loop elongation was defined as the average maximum displacement of a knotted suture loop at the peak load during cyclic loading (Loutzenheiser, 1995).

1. A 7 N preload was applied at a strain rate of 40 mm/min to remove any initial slack and provide a zeroed reference point for the knotted loop.

2. After the preload was reached, a strain rate of 12 mm/min was applied in a linear ramp to a load of 30 N. The maximum displacement with respect to the zeroed position was recorded at the peak load (30 N) for each cycle up to a total of 10 cycles. In addition, the number of cycles when the knotted loop reached or exceeded 3 mm extension was recorded.

This 30 N peak load was selected because it is consistent with the maximum magnitude of force applied clinically during laxity tests as described in previous experiments (Loutzenheiser, 1995).

Test Procedure for Knot Elongation and Suture Elongation (Cyclic Loading)

Knot elongation is defined as the difference between maximum suture elongation and maximum loop elongation under cyclic loading.

In order to obtain the knot elongation for the eight combinations of knots and sutures, the suture elongation was determined for the four types of sutures. The length of the straight suture specimens tested was 10 cm and they were selected at random from boxes

of sutures supplied by the manufacturer. Ten specimens were tested for each type of suture.

The test procedure for suture elongation was adapted from the standard single thread test procedure for sutures (USP, 1995). The following changes were made. The first was that yarn clamps were used for holding the specimen in the Instron® instead of the flat pneumatic jaws. The second was that the specimens were immersed in saline solution for one minute before testing and then tested immediately on removal instead of performing the test in saline in the environmental tank. Thirdly, the testing speed was two times that used for loop testing. The speed for the preload was 80 mm/min, and for cyclic loading was 24 mm/min. Also, the cyclic loading was from 3.5 N to 15 N, which was half that used for the knotted loop testing (7 N to 30 N). Because the length of the straight suture specimen (10 cm) was two times that of the knotted loop (5 cm), these changes in testing conditions ensured that the straight suture experienced the same strain rate and same applied load as the looped specimens.

Test Procedure for Loop Holding Capacity and Knot Security Under Ultimate Loading

Loop holding capacity was defined as the maximum force that results in a displacement of 3 mm of the knotted suture loop.

Knot security was defined as the maximum force applied to the inside of the suture loop that, either causes the suture to break and the knot to remain intact, or causes the knot to slip completely off the end of the suture (Louzenheiser, 1995).

After cyclic loading, each knot was tested for knot security and knot holding capacity by pulling to failure at a rate of 75 mm/min. The applied force at 3 mm loop displacement was recorded, if applicable, as well as the maximum force and maximum elongation.

Test for Ease of Manipulation

The time required to complete the tying of each knot was measured by viewing a replay taken by a video camera. The average time was then calculated for each set of 10 knots. In addition, any problems associated with the knot tying procedure were observed and recorded.

A video camera was used during the knot tying procedure to record the movement of the investigator's hands and the instruments. During the replay of these videos, a stopwatch was used to record the time required to complete each knot.

CHAPTER 4

RESULTS AND DISCUSSION

This chapter presents the results from knot performance testing and from measuring the ease of manipulation of the sutures. In addition, the results of hypothesis testing are presented, and the meaning of the experimental data is discussed.

Knot Performance and Ease of Manipulation of Sutures

As indicated in Chapter 1, the objectives of the study were to compare the knot performance and ease of manipulation of different types and groups of suture materials. The knot performance was measured in terms of loop elongation, knot elongation, loop holding capacity, knot security, and maximum elongation at break. Ease of manipulation was assessed in terms of the time required to tie each type of knot and suture combination.

The methods used for testing the knotted suture loops, as described in Chapter 3, were carried out without any difficulties.

Number of Cycles to Reach 3 mm Loop Elongation

A typical load-time curve for the ten cycles of fatigue testing is presented in Figure 18. At the same time, 10 pairs of load-elongation data were obtained. The average

number of cycles required during cyclic loading for the loop specimen to elongate by 3

mm are given in Table 7.
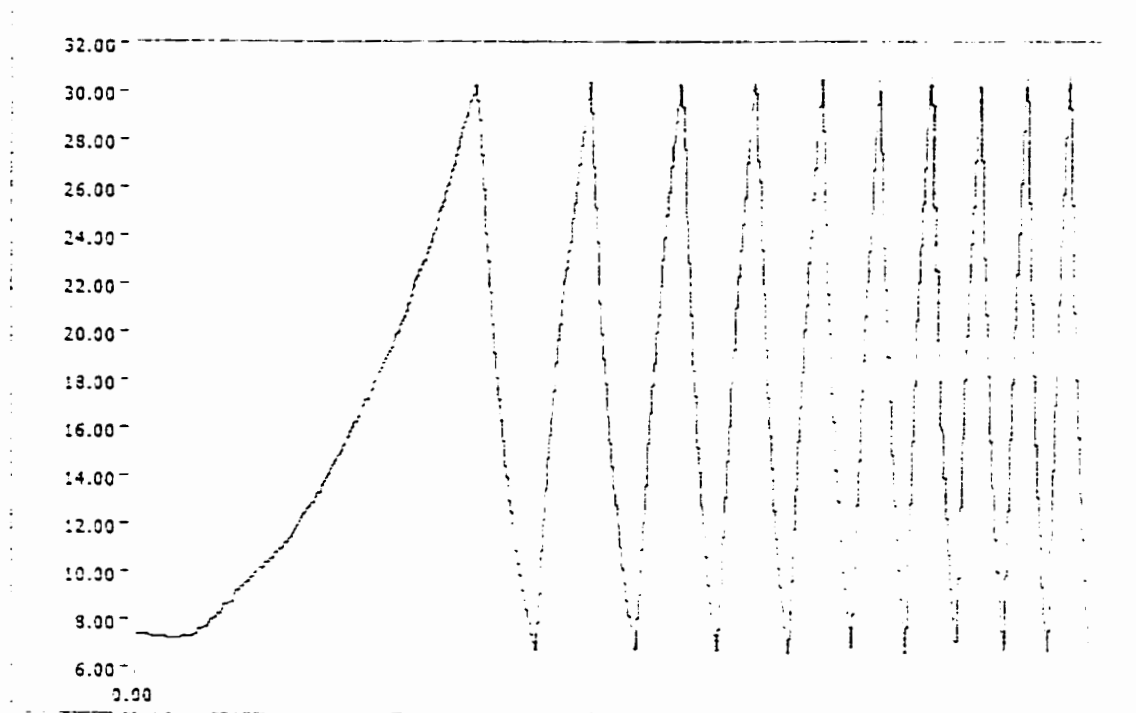
Figure 18. A load-time curve for the ten cycles of fatigue testing of a Biosyn® Duncan loop. Load in N.

Table 7

Number of Cycles to Reach 3 mm Loop Elongation

	Average Number of Cycles	
Suture	Duncan	Snyder
PDS®	1	2
Biosyn®	1	1
Prolene®	6	>10
Surgidac®	>10	>10

This indicates that only the Surgidac® suture in both knotted configurations and the Prolene® Snyder knots were able to resist elongation of 3 mm during the cyclic fatigue test. These data also indicate the ease with which both the Biosyn® and PDS® sutures can elongate at relatively low applied loads.

Loop Elongation at 30 N

Loop elongation has previously been defined as the average maximum displacement or growth in length of a knotted suture loop at 30 N peak load under cyclic loading. The test results of loop elongation of the eight types of sutures are presented in Table 8 and Figure 19.

Table 8

Results of Loop Elongation at 30 N

| Suture | Loop Elongation (mean±SD) (mm) | |
	Duncan	Snyder
PDS®	4.2±0.3	3.5±0.3
Biosyn®	5.3±0.5	4.8±0.3
Prolene®	3.3±0.4	2.7±0.5
Surgidac®	1.6±0.4	1.2±0.2

Table 8 shows that the average loop elongation of the Surgidac®/Duncan and

Surgidac®/Snyder knots is less than 3 mm after 10 loading cycles. The average loop

elongation of the Prolene® suture with either type of knot is approximately 3 mm. In

contrast, the loop elongation of the PDS® and Biosyn® sutures with either type of knot is

in excess of 3 mm after 10 loading cycles.

Figure 19 is a strip plot of all the observations of loop elongation. The eight clusters

of points represent the distribution of loop elongation for the eight types of suture/knot

combinations. It is evident that the observed values for loop elongation fall into eight

narrow distributions, which makes it easy to identify the differences between the different

suture materials. For either type of knot, Biosyn® has the greatest loop elongation,

followed by PDS®, Prolene® and Surgidac®. Generally speaking, the Duncan knots

appear to have marginally greater loop elongation than the Snyder knots when tied with

the same type of suture.
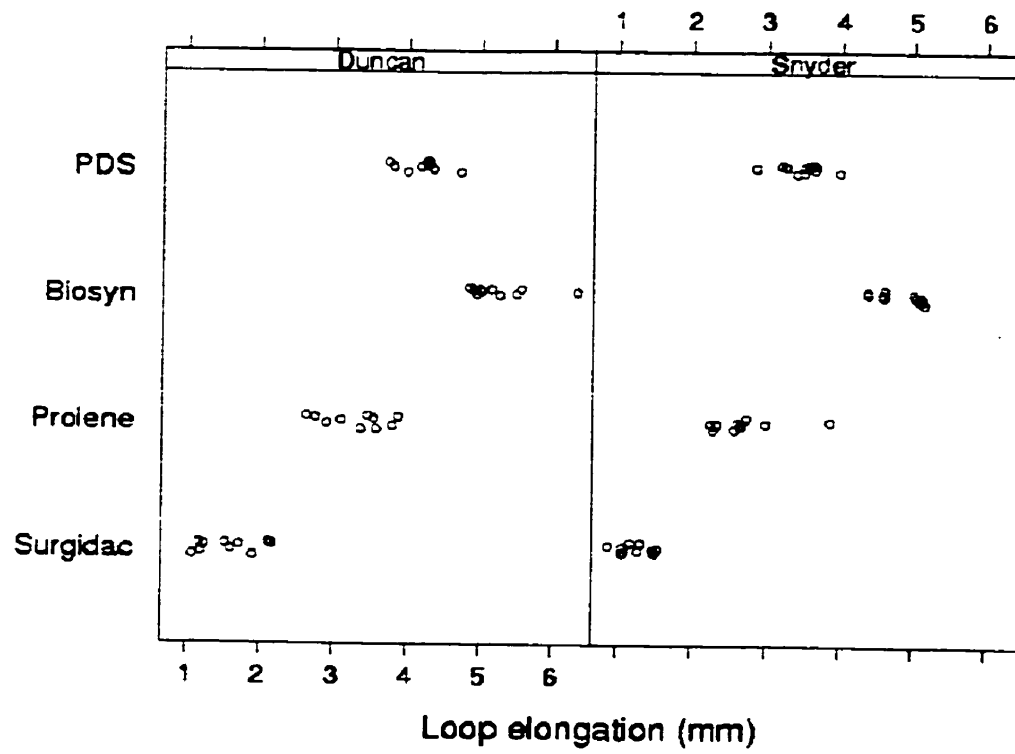
Figure 19. Loop elongation

This result is consistent with those reported by Mishra (1997), who showed that Duncan knots appear to have greater loop elongation than Snyder knots when tied with Maxon and Ticron. It is of interest to note that Loutzenheiser reported a mean loop elongation at 30 N for a pusher tied Duncan knot of only 1.8 mm when tested under similar cyclic fatigue conditions (Louzenheiser, 1995). The value is lower than the one reported here, which may be explained by the fact that Loutzenheiser tested his knots in the dry state, or because the precise test conditions for loading his looped specimens were different from those in this study.

Knot Elongation and Suture Elongation at 30 N

Knot elongation is defined as the difference between the loop elongation and the average suture elongation at 30 N peak load under cyclic loading, and as such represents that part of loop elongation that is due to slippage within the knot rather than stretching of the suture material. Experimental values for knot elongation were obtained by subtracting the maximum suture elongation at 30 N during cyclic loading from the observed loop elongation for each specimen, and then averaging the difference for each suture/knot group.

Table 9 and Figure 20 present the test results of knot elongation for each type of knotted suture loop. In addition, Table 9 presents the average suture elongation results

Table 9

Results of Knot Elongation and Suture Elongation at 30 N

Suture	Knot Elongation (mean±SD)(mm)		Suture Elongation at 30 N (mean±SD)(mm)
	Duncan	Snyder	
PDS®	1.8 ±0.3	1.1 ±0.3	2.4± 0.1
Biosyn®	1.0±0.5	0.5±0.3	4.3± 0.1
Prolene®	1.6±0.4	1.0±0.5	1.7± 0.1
Surgidac®	1.2±0.4	0.9±0.2	0.4± 0.0

for the four types of sutures. It should be noticed that the values of knot elongation presented may be underestimated due to the different stress conditions experienced by the sutures used for measuring knot elongation and suture elongation. The main difference is that the suture specimens for knot elongation were stressed during the knot tying procedure as each throw was made and manoeuvred into position down the cannula. This did not happen to the suture specimens used for measuring suture elongation which were tested without any prestressing. This may have resulted in an overestimate of suture elongation, which, in turn, may have resulted in an underestimate of knot elongation.
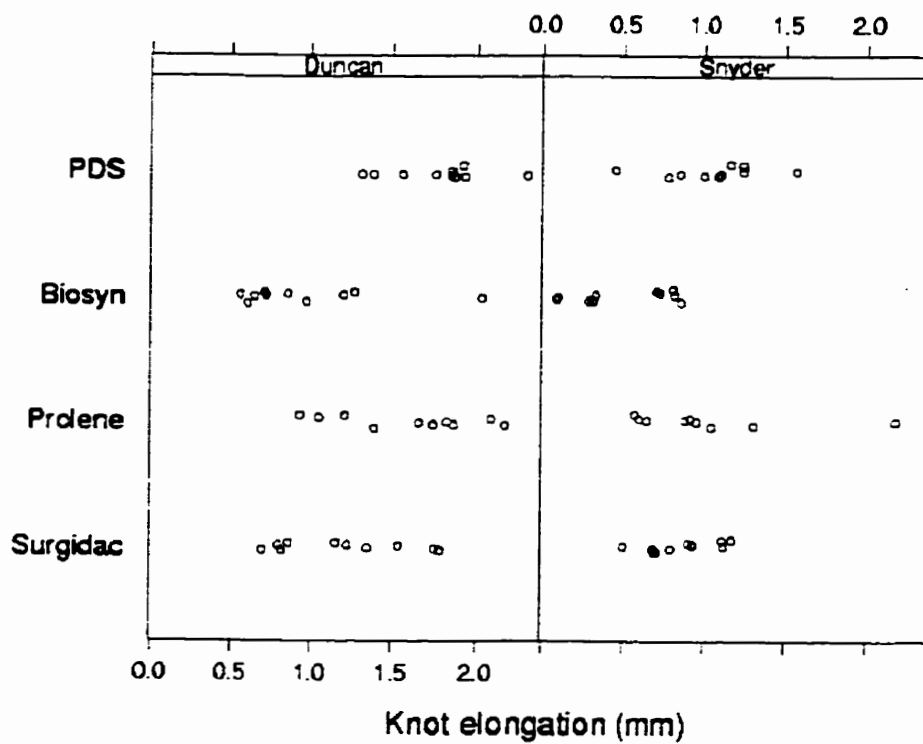
Figure 20. Knot elongation

Figure 20 shows the distributions of observed knot elongation values for the different suture/knot groups.

In general, the distinct differences in performance between the four suture types, as observed with loop elongation, are not evident. Even though the knot elongation for the Biosyn® knots appears to be marginally less than for the other three sutures, this difference may not be significant. This suggests that the main reason for the observed differences between the sutures for loop elongation was due mainly to differences in the amount the suture materials stretched rather than differences in knot slippage or tightening.

Again, as with loop elongation, there is a tendency for the Snyder knots to be associated with less knot elongation than the Duncan knots. If this difference is significant, it may merely be a reflection on the fact that there is less suture material to stretch in a Snyder compared to a Duncan knot.

Loop Holding Capacity

Loop holding capacity is defined as the maximum force that results in a 3 mm (6%) displacement or growth in a knotted suture loop that is originally 5 cm in circumference. This corresponds to the maximum force that a suture loop can support at the moment of clinical failure. Table 10 and Figure 21 present the test results for loop holding capacity.

Table 10

	Loop Holding Capacity (mean±SD) (N)	
Suture	Duncan	Snyder
PDS®	20.1±1.4	21.7±1.0
Biosyn®	22.6±1.1	24.5±1.5
Prolene®	23.7±4.4	27.1±1.9
Surgidac®	33.1±2.4	36.5±2.3

Table 10 shows that the mean values for loop holding capacity of the Snyder knots

are greater than those for the Duncan knots. This result is consistent with the findings

reported by Mishra (1997), who also showed that Snyder knots tied with polyester

braided (Ticron) and polyglycolide monofilament (Maxon) sutures have a greater loop

holding capacity than Duncan knots. Furthermore, the braided polyester suture,

Surgidac®, has a significantly superior loop holding capacity relative to the 3

monofilament sutures regardless of the type of knot tied. Mishra (1997) also

demonstrated that polyester braided sutures have greater loop holding capacity than

absorbable monofilament sutures, such as Maxon.

Figure 21 shows that the results of loop holding capacity for both types of knot

generally fall within a relatively narrow distribution for each type of suture. It also

confirms the higher loop holding capacity for the Surgidac® sutures, and gives an

indication that the capacity of Prolene® may be higher than Biosyn®, which in turn may

be higher than PDS®.
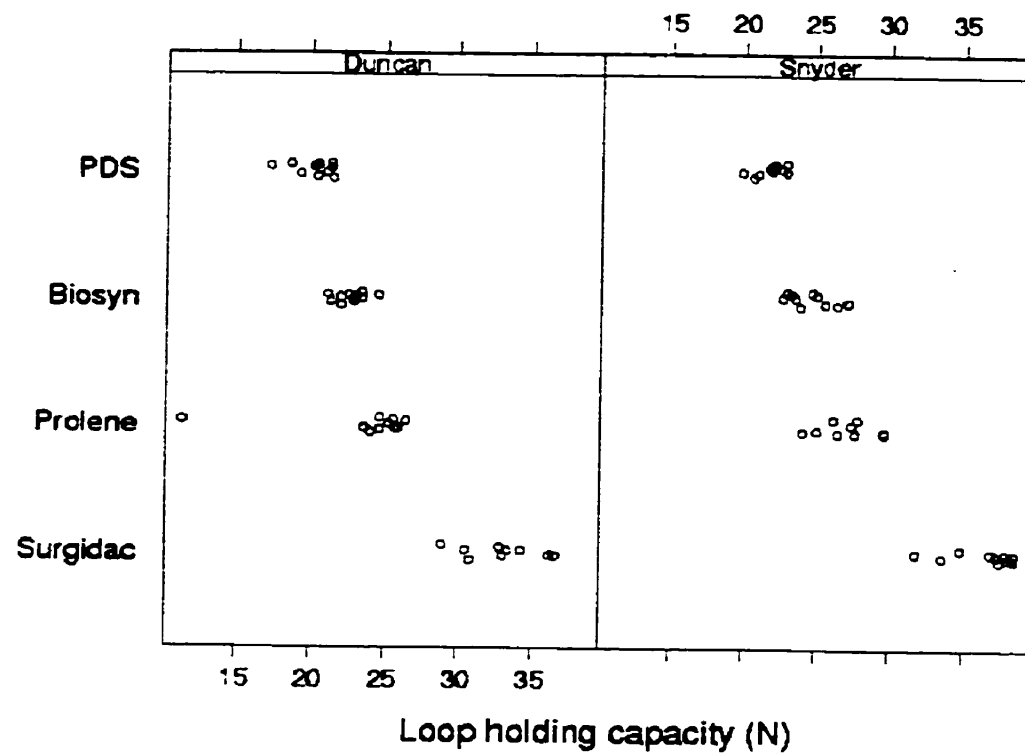
Figure 21. Loop holding capacity

50

Knot Security

Knot security is defined as the maximum force applied to the inside of the suture loop that either causes the suture to break and the knot to remain intact, or causes the knot to slip completely off the end of the suture. A typical load-time curve obtained from an ultimate loading test is given in Figure 22. The test results of knot security for the eight types of knotted suture loops are presented in Table 11 and Figure 23.
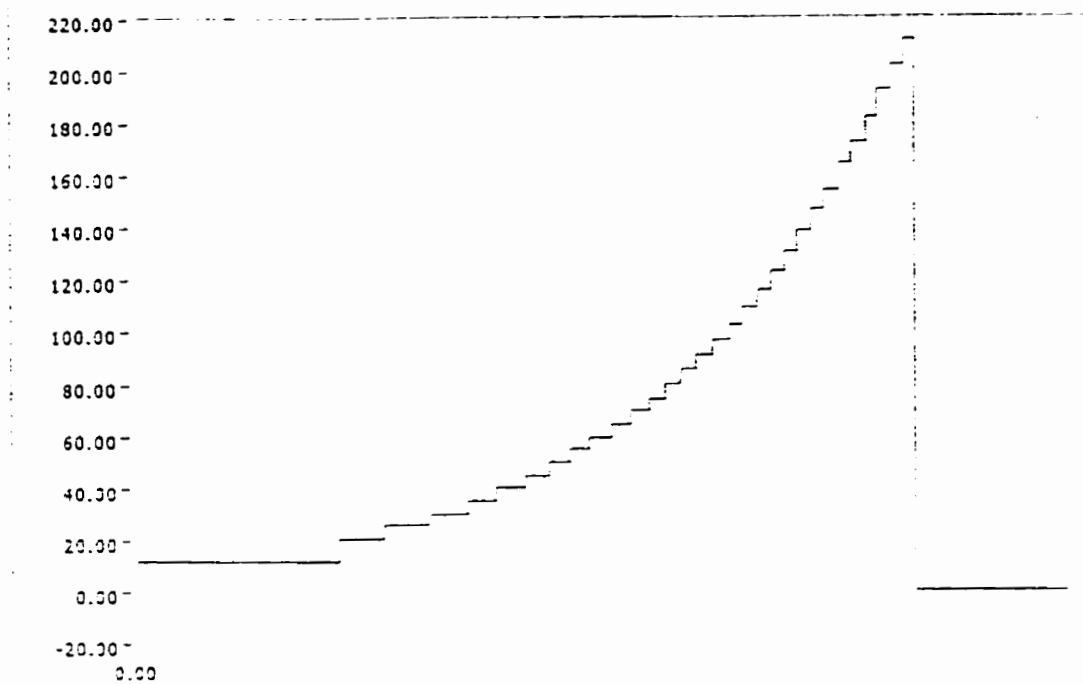
Figure 22. A load-time curve for the ultimate loading test of a Biosyn®/Snyder loop. Load in N.

Table 11

Results of Knot Security

Suture	Knot Security (mean±SD) (N)	
	Duncan	Snyder
PDS®	70.0±12.4	66.5±7.5
Biosny®	66.2±14.4	89.0±16.0
Prolene®	56.3±14.9	59.8±5.6
Surgidac®	65.3±15.3	74.2±12.1

Table 11 suggests that the highest average knot security values were achieved by tying Snyder knots with Biosyn® and Surgidac® sutures, but that similar differences were not found when the same sutures were tied in Duncan knots. By referring to Figure 23 it can be seen that the knot security values for each of the eight types of knotted suture loops formed a wide distribution range. This is particularly true for all four Duncan knots. Consequently, the differences in mean values listed in Table 11 may not be significant. These results support the previous observations made in Mishra's study (1997). He showed that the Snyder knot had superior knot security to the Duncan knot when tied with braided polyester Ticron sutures, but no such difference was observed with absorbable monofilament Maxon sutures.
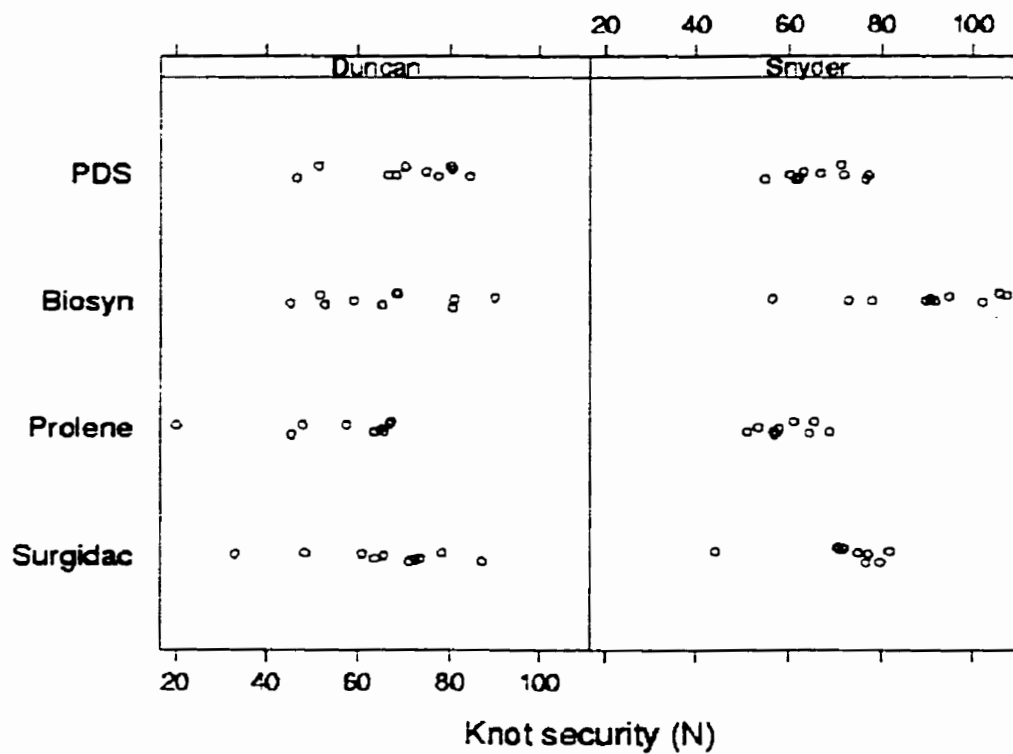
Figure 23. Knot security

Maximum Elongation

Maximum elongation is defined as the maximum displacement of a knotted suture loop when the suture breaks and the knot remains intact. The test results for maximum elongation are presented in Table 12 and Figure 24.

Table 12

Results of Maximum Elongation

Suture	Maximum Elongation at Loop Failure (mm)	
	Duncan	Snyder
PDS®	23.3±5.0	17.8±2.1
Biosyn®	14.6±2.9	14.5±1.6
Prolene®	14.1±5.0	12.8±2.6
Surgidac®	9.8±4.2	8.3±1.9

The average values listed in Table 12 suggest that for both types of knots, PDS® sutures give the highest elongation at failure, and that Surgidac® sutures give the lowest. Furthermore, there is a tendency for the average maximum elongation of the Duncan knots to be greater than that for the Snyder knots.

Figure 24, however, shows that within each suture/knot group there is a relatively wide distribution of maximum elongation values and that the Duncan knots appear to be more variable (i.e. less consistent) than the Snyder knots. The observed maximum elongations for all types of knotted suture loops were far beyond 3 mm. Therefore, maximum elongation is considered to be a less useful indicator for evaluating the knot performance of sutures for arthroscopic surgery.
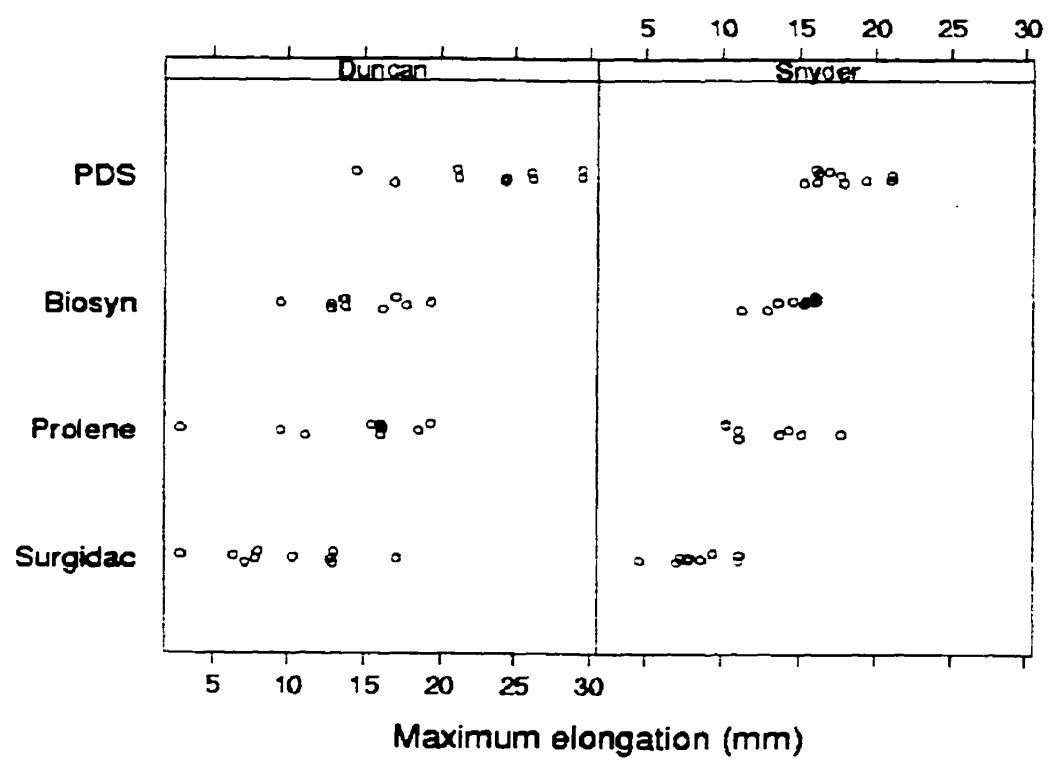
Figure 24. Maximum elongation

Mechanisms of Loop Failure

After mechanical testing the suture residues were analyzed and several observations were made by scanning electron microscopy (SEM) using the procedure described in Chapter 3. It was found that the suture loops failed in one of two different ways. One was by the knot slipping; the other was by the suture breaking. More detailed observations showed that suture breakage could occur at different locations within the suture loop, such as 1) in the knot, 2) near the knot, or 3) in the loop. Table 13 lists the mechanism and frequency of each type of failure for the eight groups of knotted suture loops.

Table 13

Results of Suture Loop Failure

Suture	Duncan		Snyder	
PDS®	Break in knot	(8/10)	Break near knot	(9/10)
	Slip	(2/10)	Slip	(1/10)
Biosyn®	Break in knot	(5/10)	Break near knot	(6/10)
	Slip	(5/10)	Break and knot untied	(3/10)
			Break in loop	(1/10)
Prolene®	Break in loop	(5/10)	Break near knot	(7/10)
	Break in knot	(2/10)	Break in loop	(3/10)
	Slip	(3/10)		
Surgidac®	Break	(1/10)	Break near knot	(8/10)
	Slip	(9/10)	Break in knot	(1/10)
			Slip	(1/10)

From the data it is noticed that the Duncan knot was more likely to fail either by suture breaking in the knot for monofilament sutures or by knot slippage for braided

sutures. On the other hand, the Snyder knot was more likely to fail by suture fracture near, rather than in, the knot.

Most of the PDS® knotted loops failed because the suture broke. The main difference between the Duncan and Snyder knots was that, for Duncan loops, the PDS® suture broke in the knot (Figure 25), while for the Snyder loop it broke near the knot (Figure 26). In both cases, longitudinal cracks were observed on the curved external surfaces where the bent PDS® suture was under maximum tensile stress (Figure 27). Half the Biosyn® sutures tied in a Duncan knot failed by suture fracture; the other half by knot slippage. Figure 28 shows an example of a Duncan knot where the suture broke in the knot. The fracture morphology of the broken suture suggests a brittle tensile failure mechanism (Figure 29) (Hearle, 1989). All the Biosyn® sutures tied in a Snyder knot failed by suture breakage, mostly near the knot (Figure 30). Most of the Prolene® knots also failed by suture fracture. The Duncan knots failed more frequently because the suture broke in the loop, whereas the Snyder knots were more prone to the suture breaking near the knot (Figure 31). In all cases of Prolene® suture breakage, the fracture morphology suggested a tensile failure mechanism associated with longitudinal cracking and axial splitting (Figure 31 & 32) (Hearle, 1989). For the Surgidac® sutures the Duncan knots failed almost exclusively by slippage, whereas most of the Snyder knots failed by suture fracture near the knot (Figure 33).
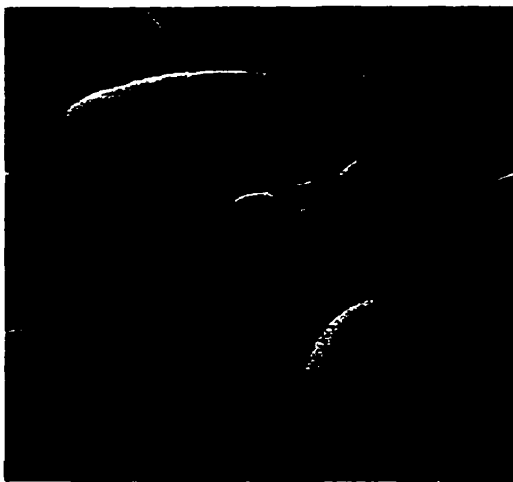
Figure 25. SEM micrograph of a broken PDS® Duncan knot showing the fracture end in the knot (arrow).

Figure 26. SEM micrograph of a broken PDS® tied in a Snyder knot showing the fracture end near the knot (arrow) and surface cracking in the knot.

Figure 27. SEM micrograph of a broken PDS® Duncan knot showing cracks on the curved external surface of the bent suture.

58

Figure 28. SEM micrograph of a broken Biosyn® Duncan knot showing the fractured end in the knot (arrow) and a suture surface free from damage or distortion.
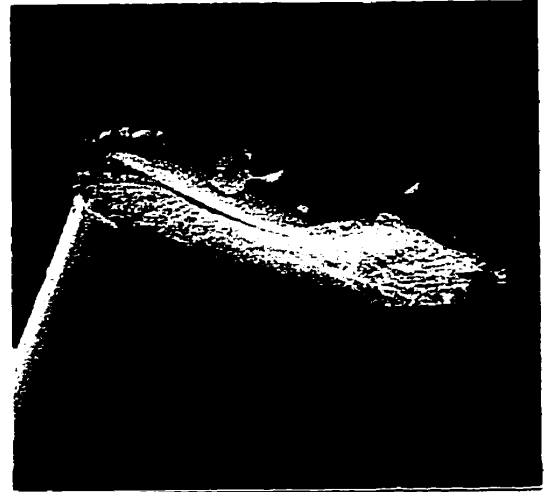
Figure 29. SEM micrograph showing the fracture plane of a broken Biosyn® suture tied in a Duncan knot suggesting brittle tensile failure.

Figure 30. SEM micrograph of a broken Biosyn® Snyder knot showing the fracture end near the knot and a suture surface free from damage and distortion.

Figure 31. SEM micrograph of a broken Prolene® Snyder knot showing the fracture end near the knot with axial splitting (arrow) and a flattened cross-sectional shape in the knot.

Figure 32. SEM micrograph of a broken Prolene® Snyder knot showing longitudinal cracking and axial splitting.
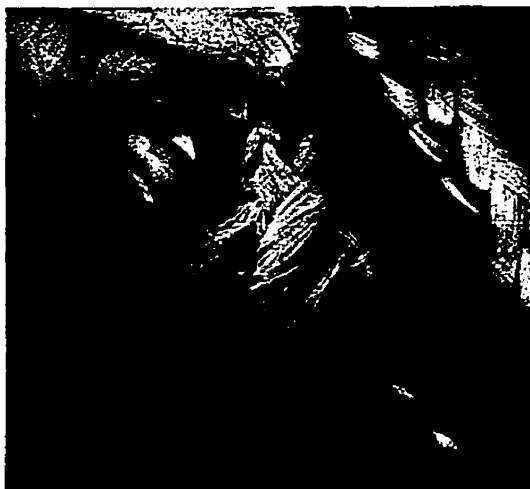
Figure 33. SEM micrograph of a broken Surgidac® suture showing suture fracture near the Snyder knot.

Ease of Manipulation

Ease of manipulation is defined as the average time required to complete the tying of a particular type of knot. The test results are presented in Table 14 and Figure 34.

Table 14

Knotting Time Required for Tying Each Type of Knot

Suture	Knotting Time (mean+SD) (second)	
	Duncan	Snyder
PDS®	113±7	116±10
Biosny	120±8	119±10
Prolene	123±6	113±8
Surgidac	129±18	145±22

The tying of the knots used in this study was accomplished without major difficulties. The following three observations were made with respect to the ease of knot tying. 1) The PDS® and Biosyn® sutures were relatively easy to manipulate and tie in both types of knots. 2) There were no problems in tying Prolene® sutures in a Duncan knot, but when tying the Snyder knot, there were occasions when it was difficult to slide down the first half-hitch throw. Such difficulties, however, did not translate into longer total tying times for the Prolene®/Snyder knots listed in Table 14. 3) More severe difficulties were encountered when attempting to slide down the half-hitch throws of the Surgidac® sutures when tying both types of knots. This was because it was necessary to push the half hitch throws down the Sixth Finger in a slack condition and then eliminate

the excess suture at the bottom of the cannula by tightening once the throw was in place. This resulted in longer knotting times for both types of knots.

Figure 34 shows that the knotting time distributions appear to be marginally wider for the Snyder group compared to the Duncan group of knots. In addition, the Surgidac® suture appears to have a wider distribution of times compared to the three monofilament sutures regardless of the type of knot tied. This is no doubt related to the problem mentioned previously in which the half-hitch throws were difficult to advance down the cannula. In contrast, the PDS® suture appeared to require the shortest time to tie the Duncan knot.

In order to determine whether or not the differences identified in Tables 8-12 and Table 14 are significant, it was necessary to undertake a statistical analysis of the data. This is discussed in the next section.
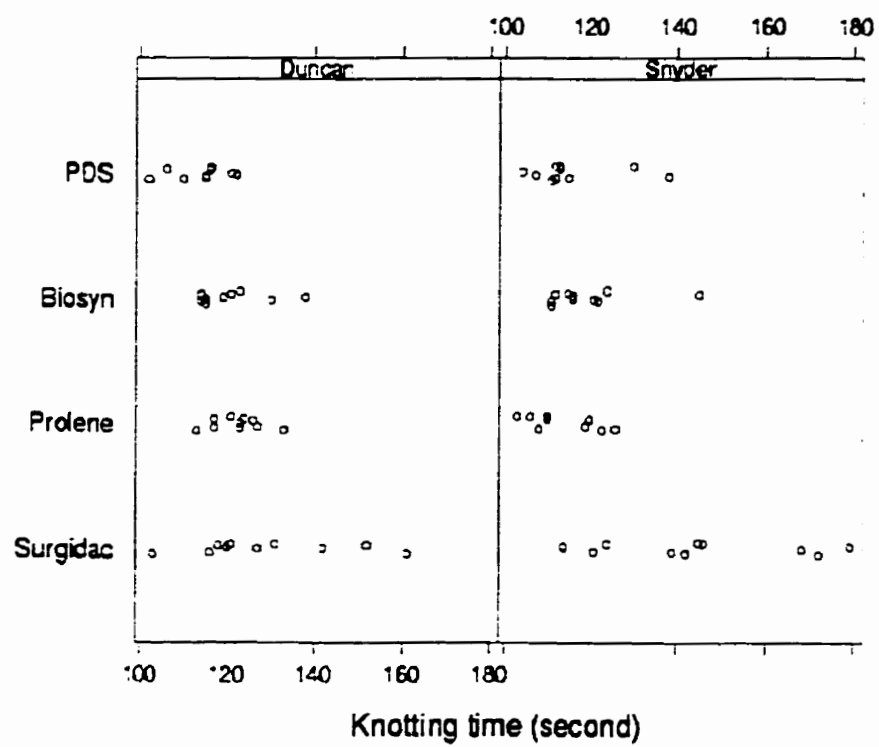
Figure 34. Knotting time

Hypothesis Testing

Since the objective of hypothesis testing was to compare the means of different dependent variables that may have been influenced by the two independent variables, i.e. suture type and knot type, a two-way analysis of variance was selected for the initial analysis of the data.

Normality Test

In order to use two-way analysis of variance, conventionally three assumptions should be satisfied:

1) the samples are independent

2) the observations examined follow a normal distribution

3) the groups have similar variances.

The normality of the observations was verified by plotting the residuals in normal quantile plots. The results are presented in Figure 35. It shows that, except for a few outliers, loop elongation, knot elongation, and loop holding capacity approximately fit a straight line relationship, which means that these residuals correspond approximately to normal distributions. In contrast, the residuals for knot security, maximum elongation and knotting time did not fit a straight line relationship well, which means that they were not normally distributed. The equality of group variances was verified by means of a Levene's test.
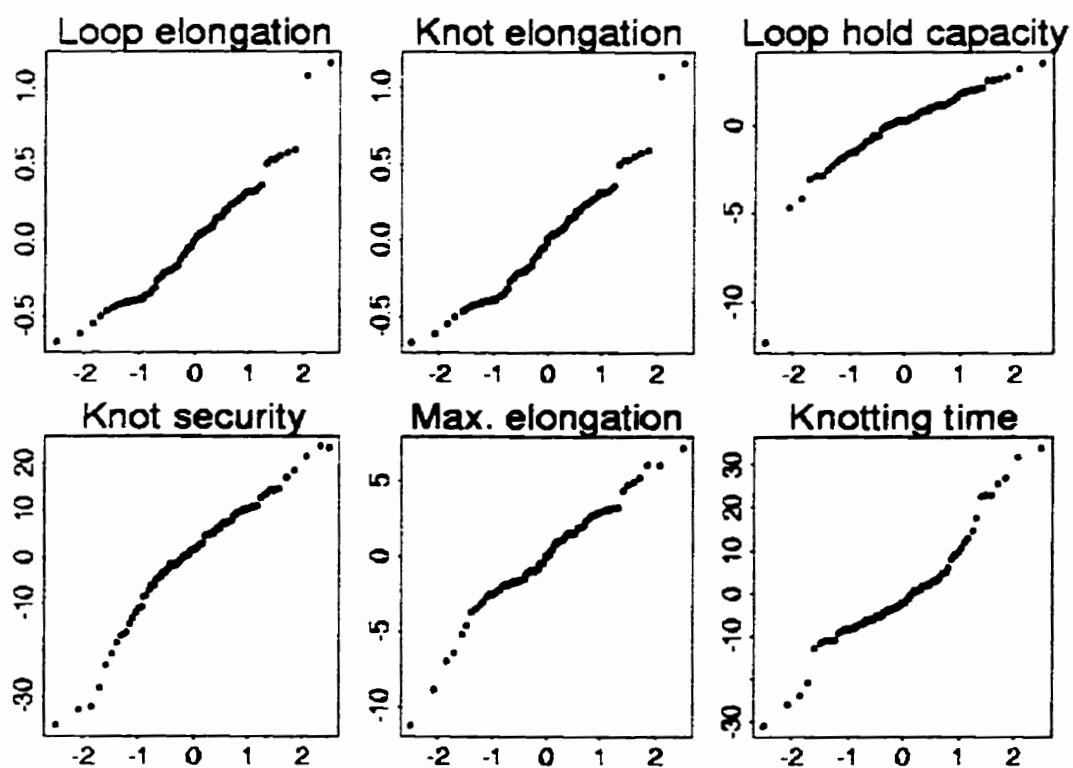
Figure 35. Normal quantile plot

Table 15

Results of Levene's Test of Variance Homogeneity

Properties	p-values
Loop elongation	0.4984
Knot elongation	0.4984
Loop holding capacity	0.2042
Knot security	0.2956
Maximum elongation	0.0051
Knotting time	0.0019

The results in Table 15 show that loop elongation, knot elongation, loop holding capacity, and knot security had equivalent variances among the eight groups. In contrast, on account of their small p-values, maximum elongation and knotting time had unequal variances between the groups.

The results of the normality and group variance tests showed that loop elongation, knot elongation, and loop holding capacity met the three assumptions. Therefore a two-way analysis of variance was conducted on these three variables. On the other hand, knot security, maximum elongation and knotting time did not meet the normality and/or the variance assumptions. However, according to Yandell (1997), normality is the least important assumption and moderate lack of normality is not a serious problem for the testing of group means. He also indicated that unequal variances do not cause appreciable problems when comparing means. Therefore, a two-way analysis of variance was also conducted on knot security, maximum elongation and knotting time.

The following section presents the results of the hypothesis testing, which was conducted using two-way analysis of variance and a correlation coefficient analysis. The significance level of $p < 0.05$ was taken throughout the statistical analysis.

Two-way Analysis of Variance

Hypothesis H_{01}: There is no difference in knot performance and ease of manipulation between types of knot.

Hypothesis H_{02}: There is no difference in knot performance and ease of manipulation between types of suture.

Hypothesis H_{03}: There is no interaction between the type of knot and type of suture in knot performance and ease of manipulation.

In order to test these three null hypotheses, two-way analysis of variance was used to determine whether the type of knot, the type of suture and their interaction influenced the loop elongation, knot elongation, loop holding capacity, knot security, maximum elongation and knotting time required to tie each type of knot. The results are presented in Table 16.

Table 16

Results of Two-way Analysis of Variance

Properties	p-values		
	Knot	Suture	Knot*Suture
Loop elongation	0.0001	0.0001	0.3916
Knot elongation	0.0001	0.0001	0.3916
Loop holding capacity	0.0001	0.0001	0.4380
Knot security	0.0119	0.0001	0.0128
Maximum elongation	0.0072	0.0001	0.0758
Knotting time	0.3769	0.0001	0.0253

Hypothesis H_{01} was rejected for all performance properties except knotting time. This means that significant differences were found between the two types of knots for loop elongation, knot elongation, loop holding capacity, knot security and maximum elongation, but no significant difference was found in knotting time between the two types of knots.

Hypothesis H_{02} was rejected for all the performance properties measured. In other words, significant differences were observed among the different types of sutures for all properties.

Hypothesis H_{03} was not rejected for loop elongation, knot elongation, loop holding capacity and maximum elongation and rejected for knot security and knotting time. This means that there were no interactions between the type of knot and the type of suture for loop elongation, knot elongation, loop holding capacity and maximum elongation. But as indicated in the interaction plots of Figure 36, where the Snyder and Duncan curves intersect, interactions between the type of knot and the type of suture were observed for knot security and the time required to tie the knots. It should be remembered that this means that the interaction between the type of knot and the type of suture occurred only when the applied load reached the failure point of the suture loop. At lower loads, there may or may not have been an interaction between the two independent variables.

Contrast Analysis of Variance

The results from the two-way analysis of variance indicated that significant differences were observed between most of the mean values. However they have not
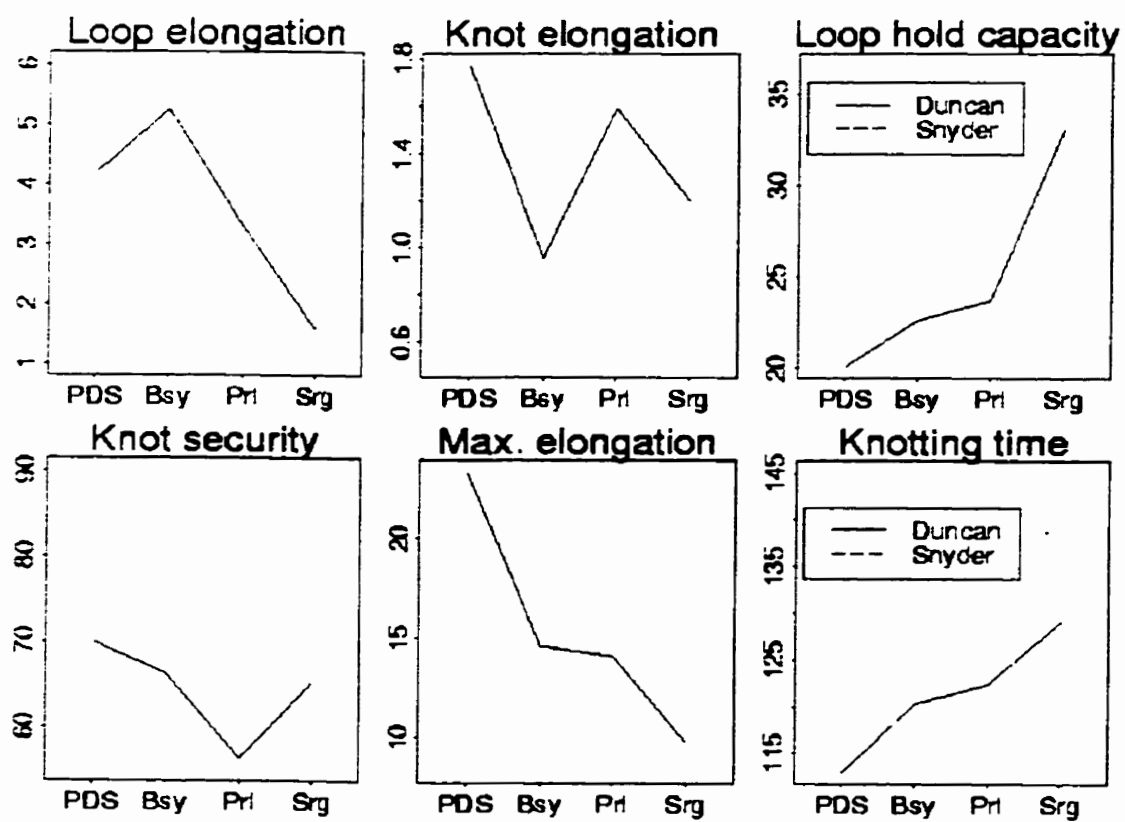
Figure 36. Interactions among type of knot and type of suture.
Bsy = Biosyn®, Prl = Prolene®, Srg = Surgidac®.

identified which specific pairs of means were significantly different. Therefore, contrast analysis was conducted to determine which specific pairs were significantly different for each of the variables that measured knot performance and ease of manipulation.

Hypothesis H_{04}: There is no difference in knot performance and ease of manipulation between:

a) the braided and monofilament sutures

b) PDS® and Biosyn®

c) PDS® and Prolene®

d) PDS® and Surgidac®

e) Biosyn® and Prolene®

f) Surgidac® and Biosyn®

g) Surgidac® and Prolene®

Table 17 shows the results of contrast analysis of variance between the different sutures when the data for both types of knots were combined.

Table 17

<u>Results of Contrast Analysis of Variance for Both Types of Knots</u>

Properties	p-values						
	Braided vs Mono	PDS® vs Biosyn®	PDS® vs Prolene®	PDS® vs Surgidac®	Biosyn® vs Prolene®	Surgidac® vs Biosyn®	Surgidac® vs Prolene®
Loop elongation	0.0001	0.0001	0.0001	0.0001	0.0001	0.0001	0.0001
Knot elongation	0.2461	0.0001	0.3784	0.0022	0.0001	0.0114	0.0273
Loop holding capacity	0.0001	0.0003	0.0001	0.0001	0.0124	0.0001	0.0001
Knot security	0.7861	0.0222	0.0133	0.8858	0.0001	0.0315	0.0091
Maximum elongation	0.0001	0.0001	0.0001	0.0001	0.3180	0.0001	0.0001
Knotting time	0.0001	0.1594	0.3265	0.0001	0.6796	0.0001	0.0001

1) Braided vs Monofilament

For braided and monofilament sutures, Hypothesis H_{04} was rejected for loop

elongation, loop holding capacity, maximum elongation and knotting time, but not

rejected for knot elongation and knot security. This means that significant differences

were observed between the braided and monofilament sutures for loop elongation,

loop holding capacity, maximum elongation and knotting time, but not for knot

elongation and knot security.

2) PDS® vs Biosyn®, Prolene® and Surgidac®

For PDS® and Biosyn®, Hypothesis H_{04} was rejected for loop elongation, knot

elongation, loop holding capacity, knot security and maximum elongation, but not

rejected for knotting time. This indicates that there were significant mean differences

for loop elongation, knot elongation, loop holding capacity, knot security and

maximum elongation, but not in knotting time. For PDS® and Prolene®, Hypothesis

H_{04} was rejected for loop elongation, loop holding capacity, knot security and

maximum elongation, and accepted for knot elongation and knotting time. From this, it

71

is inferred that significant differences were observed in loop elongation, loop holding capacity, knot security and maximum elongation, but not in knot elongation and knotting time. For PDS® and Surgidac®, Hypothesis H_{04} was rejected for loop elongation, knot elongation, loop holding capacity, maximum elongation and knotting time, but not rejected for knot security. This means that there were significant differences in loop elongation, knot elongation, loop holding capacity, maximum elongation and knotting time, but not in knot security.

3) Biosyn® vs Prolene®

For Biosyn® and Prolene®, Hypothesis H_{04} was rejected for loop elongation, knot elongation, loop holding capacity and knot security, and accepted for maximum elongation and knotting time. This indicates that there were significant differences between Biosyn® and Prolene® in loop elongation, knot elongation, loop holding capacity and knot security, but no significant differences were evident in maximum elongation and knotting time.

4) Surgidac® vs Biosyn® and Prolene®

For Surgidac® and Biosyn® and for Surgidac® and Prolene®, Hypothesis H_{04} was rejected for all the properties measured, which means that Biosyn® and Prolene® were found to be significantly different from Surgidac® for all the dependent variables.

Hypothesis H$_{05}$: For the Duncan knot, there is no difference in knot performance and ease

of manipulation between:

a) the braided and monofilament sutures

b) PDS® and Biosyn®

c) PDS® and Prolene®

d) PDS® and Surgidac®

e) Biosyn® and Prolene®

f) Surgidac® and Biosyn®

g) Surgidac® and Prolene®

Table 18 presents the results of contrast analysis of variance between different types

of sutures when tied in the Duncan knot.

Table 18

Results of Contrast Analysis of Variance for the Duncan Knot

Properties	p-values						
	Braided vs Mono	PDS® vs Biosyn®	PDS® vs Prolene®	PDS® vs Surgidac®	Biosyn® vs Prolene®	Surgidac® vs Biosyn®	Surgidac® vs Prolene®
Loop elongation	0.0001	0.0001	0.0001	0.0001	0.0001	0.0001	0.0001
Knot elongation	0.0819	0.0001	0.2888	0.0010	0.0003	0.1473	0.0211
Loop holding capacity	0.0001	0.0149	0.0006	0.0001	0.2751	0.0001	0.0001
Knot security	0.8053	0.5084	0.0185	0.4133	0.0853	0.8748	0.1169
Maximum elongation	0.0001	0.0001	0.0001	0.0001	0.7379	0.0023	0.0061
Knotting time	0.0230	0.1882	0.0924	0.0048	0.7072	0.1185	0.2329

1) Braided vs Monofilament

For braided and monofilament sutures, Hypothesis H$_{05}$ was rejected for loop

elongation, loop holding capacity, maximum elongation and knotting time, but not

rejected for knot elongation and knot security. This means that significant differences

were found between the braided and monofilament sutures in terms of loop elongation, loop holding capacity, maximum elongation and knotting time, but not for knot elongation and knot security.

2) PDS® vs Biosyn®, Prolene® and Surgidac®

For PDS® and Biosyn®, Hypothesis H_{05} was rejected for loop elongation, knot elongation, loop holding capacity and maximum elongation, and but was not rejected for knot security and knotting time. This means that loop elongation, knot elongation, loop holding capacity and maximum elongation were found to be significantly different, but not in the case of knot security and knotting time. For PDS® and Prolene®, Hypothesis H_{05} was rejected for loop elongation, loop holding capacity, knot security and maximum elongation, but was not rejected for knot elongation and knotting time. This means that significant differences were found for loop elongation, loop holding capacity, knot security and maximum elongation, but not for knot elongation and knotting time. For PDS® and Surgidac®, Hypothesis H_{05} was rejected for all properties except knot security, which means that significant differences were found between PDS® and Surgidac® in terms of loop elongation, knot elongation, loop holding capacity, maximum elongation and knotting time, but not with knot security.

3) Biosyn® vs Prolene®

For Biosyn® and Prolene®, Hypothesis H_{05} was rejected for loop elongation and knot elongation but was not rejected for loop holding capacity, knot security, maximum elongation and knotting time. This means that the only significant differences observed between Biosyn® and Prolene® were in terms of loop elongation and knot

elongation, whereas no differences were found in loop holding capacity, knot security, maximum elongation and knotting time.

4) Surgidac® vs Biosyn® and Prolene®

For Surgidac® and Biosyn®, Hypothesis H_{05} was rejected for loop elongation, loop holding capacity and maximum elongation, but not rejected for knot elongation, knot security and knotting time. This means that significant differences were observed between Surgidac® and Biosyn® for loop elongation, loop holding capacity and maximum elongation, but not for knot elongation, knot security and knotting time. For Surgidac® and Prolene®, Hypothesis H_{05} was rejected for loop elongation, knot elongation, loop holding capacity and maximum elongation, but not rejected for knot security and knotting time. This means that significant differences were found between Surgidac® and Prolene® for loop elongation, knot elongation, loop holding capacity and maximum elongation, but not for knot security and knotting time.

Hypothesis H_{06}: For the Snyder knot, there is no difference in knot performance and ease of manipulation between:

a) the braided and monofilament sutures

b) PDS® and Biosyn®

c) PDS® and Prolene®

d) PDS® and Surgidac®

e) Biosyn® and Prolene®

f) Surgidac® and Biosyn®

g) Surgidac® and Prolene®

Table 19 shows the results of contrast analysis between the different types of sutures when tied in a Snyder knot.

Table 19

Contrast Analysis of Variance for the Snyder Knot

Properties	p-values						
	Braided vs Mono	PDS® vs Biosyn®	PDS® vs Prolene®	PDS® vs Surgidac®	Biosyn® vs Prolene®	Surgidac® vs Biosyn®	Surgidac® vs Prolene®
Loop elongation	0.0001	0.0001	0.0128	0.0001	0.0001	0.0001	0.0001
Knot elongation	0.9155	0.0016	0.8446	0.2861	0.0037	0.0304	0.3986
Loop holding capacity	0.0001	0.0060	0.0001	0.0001	0.0144	0.0001	0.0001
Knot security	0.8906	0.0002	0.2350	0.3080	0.0001	0.0044	0.0313
Maximum elongation	0.0001	0.0343	0.0022	0.0001	0.2854	0.0001	0.0054
Knotting time	0.0001	0.4972	0.7791	0.0001	0.3475	0.0001	0.0001

1) Braided vs Monofilament

For braided and monofilament sutures, Hypothesis H_{06} was rejected for loop elongation, loop holding capacity, maximum elongation and knotting time, but not rejected for knot elongation and knot security. This means that there were significant differences between the braided and monofilament sutures in terms of loop elongation, loop holding capacity, maximum elongation and knotting time, but not for knot elongation and knot security.

2) PDS® vs Biosyn®, Prolene® and Surgidac®

For PDS® and Biosyn®, Hypothesis H_{06} was rejected for all the knot performance variables, except for knotting time. This means that significant differences were found between PDS® and Biosyn® for all the knot performance variables, but not in terms of knotting time. For PDS® and Prolene®, Hypothesis H_{06} was rejected for loop elongation, loop holding capacity and maximum elongation, but not rejected for knot elongation, knot security and knotting time. This means that significant differences

were observed between PDS® and Prolene® for loop elongation, loop holding capacity and maximum elongation, but not for knot elongation, knot security and knotting time. For PDS® and Surgidac®, Hypothesis H_{06} was rejected for loop elongation, loop holding capacity, maximum elongation and knotting time, but not rejected for knot elongation and knot security. This indicates that significant difference between PDS® and Surgidac® were found with respect to loop elongation, loop holding capacity maximum elongation and knotting time, but not for knot elongation and knot security.

3) Biosyn® vs Prolene®

For Biosyn® and Prolene®, Hypothesis H_{06} was rejected for loop elongation, knot elongation, loop holding capacity and knot security, but it was not rejected for maximum elongation and knotting time. This indicates that significant differences were found between Biosyn® and Prolene® for loop elongation, knot elongation, loop holding capacity and knot security, but not for maximum elongation and knotting time.

4) Surgidac® vs Biosyn® and Prolene®

For Surgidac® and Biosyn®, Hypothesis H_{06} was rejected for all the properties measured, which means that significant differences were found between Surgidac® and Biosyn® for all six variables. For Surgidac® and Prolene®, Hypothesis H_{06} was rejected for loop elongation, loop holding capacity, knot security, maximum elongation and knotting time, but not rejected for knot elongation. This means that significant differences were found between the Surgidac® and Prolene® results for all variables except knot elongation.

Correlation Analysis

In order to find out whether any linear associations existed between any two of the dependent variables, Pearson's correlation analysis was conducted.

Table 20 gives the summary of the correlation coefficients obtained between pairs of dependent variables when the data from all the knot and suture groups were entered into the model. Figure 37 provides a visual representation of the same data by giving a correlation plot of each pair of dependent variables.

Table 20

Matrix of Correlation Coefficients (R) among Dependent Variables

Properties	Loop Elongation	Knot Elongation	Loop Holding Capacity	Knot Security	Maximum Elongation	Knotting Time
Loop elongation	1.0000	0.1297	-0.8020	0.1666	0.5393	-0.4245
Knot elongation	0.1297	1.0000	-0.3236	-0.3069	0.3883	-0.1247
Loop holding capacity	-0.8020	-0.3236	1.0000	0.0702	-0.6391	0.5585
Knot security	0.1666	-0.3069	0.0702	1.0000	0.4097	0.0108
Maximum elongation	0.5393	0.3883	-0.6391	0.4097	1.0000	-0.4515
Knotting time	-0.4245	-0.1247	0.5585	0.0108	-0.4515	1.0000

The correlation coefficient between loop elongation and loop holding capacity is −0.8020, which indicates a strong, negative correlation. However, it can be seen in Figure 37 that the relationship is only linear above an initial loop holding capacity threshold. The correlation coefficient between loop elongation and maximum elongation is 0.5393, which indicates that the correlation is moderate and positive. The correlation between loop elongation and knotting time is −0.4245, indicating a moderate, negative correlation. The other correlations between loop elongation with knot elongation and knot security are both weak. The absolute values of the correlation coefficients between knot

elongation and the other variables range from 0.1247 to 0.3883, indicating that these correlations are weak.

Loop holding capacity is positively correlated with knotting time and negatively correlated with loop elongation and maximum elongation. The correlation coefficient with loop elongation is high at −0.8020, showing a strong relationship. With knotting time it is 0.5585, and with maximum elongation it is −0.6391, which correspond to moderately strong correlations. No correlation appears to exist between loop holding capacity and knot security. The correlation coefficient between knot security and maximum elongation is 0.4097, which shows a moderate positive correlation between these two properties. Maximum elongation is negatively correlated with loop holding capacity and knotting time, and positively correlated with loop elongation and knot security. All these correlations are only of moderate strength.
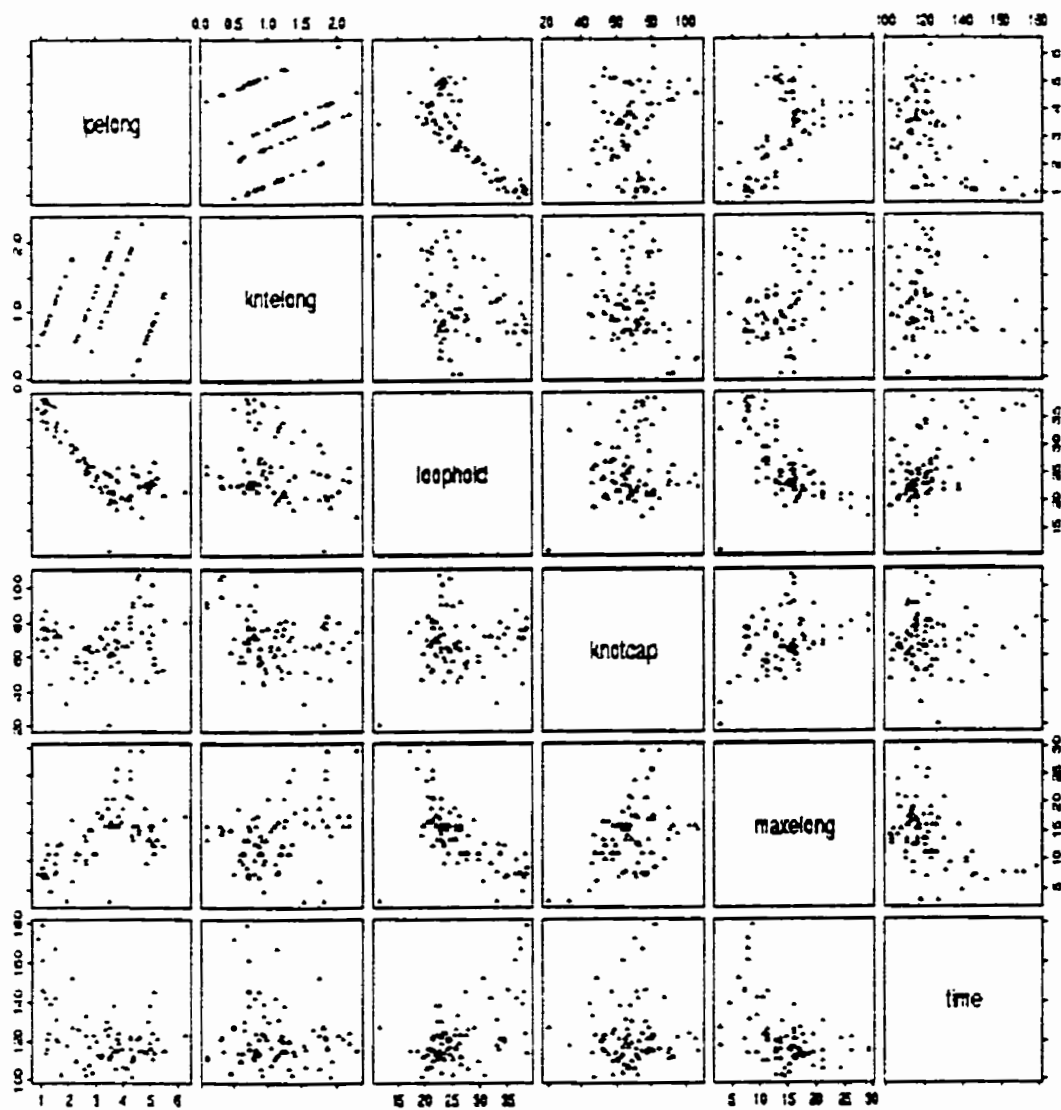
Figure 37. Scatterplot matrices among pairs of dependent variables. Lpelong = loop elongation, kntelong = knot elongation, loophod = loop holding capacity, knotcap = knot security, maxelong = maximum elongation, time = knotting time.

CHAPTER 5

CONCLUSIONS AND IMPLICATIONS

This chapter includes a number of general and specific conclusions as well as a discussion of the implications for future studies.

General Conclusion

The purpose of the study was to find alternative suture materials for arthroscopic surgery that would provide both improved knot performance and maintain ease of manipulation of the current PDS® monofilament suture materials.

This study has shown that improvements in knot performance have been achieved by using Prolene® and Surgidac® sutures instead of PDS® monofilaments. Loop elongation values after 10 cycles of standard wet fatigue testing are smaller and less than the critical 3 mm criterion when polyester braided (Surgidac®) sutures are used in either a Snyder or a Duncan knot configuration, or when monofilament polypropylene (Prolene®) sutures are used in a Snyder knot.

Similar improvements over PDS® have been observed in the loop holding capacity of Surgidac® polyester braided and polypropylene monofilament sutures. This means, for example, that a Surgidac® polyester suture tied in a Snyder knot will support a 37 N force compared to PDS®'s 22 N before the knotted loop extends or grows by 6% (3 mm). Prolene® monofilament also provides some improvement with 27 N loop holding

81

capacity. Similar and consistent, but less dramatic, improvements have been found with the use of Duncan knots. Biosyn® monofilament sutures, because of their low tensile modulus and ease of stretching at low applied loads, do not offer any improvement over PDS® in terms of loop elongation for either type of knot.

In terms of ease of manipulation, no significant differences in knotting times were found for the alternative monofilament sutures, Biosyn® and Prolene®, when compared to the PDS® suture using both knot configurations. In contrast, it took considerably more time to prepare the knots from polyester braided Surgidac® sutures because of the difficulty in advancing the half hitch throws down to the cannula.

From this evidence it is concluded that polypropylene monofilament sutures with superior knot performance and equivalent ease of manipulation may have clinical advantages over PDS® in certain arthroscopic procedures. This is not the case for the braided polyester suture, which, in spite of superior mechanical properties, was found to be more difficult to handle and manipulate using arthroscopic techniques.

Specific Conclusions and Recommendations

1. Effect of Independent Variables

   a) Type of knot

   The results of the two-way analysis of variance showed that the type of knot had an effect on all the knot performance properties, but no effect on the ease of manipulation in terms of knotting time.

b) Type of suture

The type of suture had an effect on both the knot performance and the ease of manipulation (knotting time), regardless of the type of knot.

c) Interactions

The interaction between the type of knot and the type of suture was not found for loop elongation, knot elongation, loop holding capacity, and maximum elongation. However, interactions were observed for knot security and knotting time.

2. Braided vs Monofilament Sutures

The braided suture, Surgidac®, was found to be superior to the three monofilament sutures in terms of knot performance, and poorer in terms of ease of manipulation.

3. PDS® vs Biosyn®, Prolene®, and Surgidac®

a) PDS® vs Biosyn®

In general, Biosyn® did not show superior knot performance compared to PDS® due to its larger loop elongation. Even though it had better knot elongation, loop holding capacity, and a significantly greater knot security, the greater loop elongation would result in a potentially higher risk of surgical failures, which means that this type of suture cannot be recommended for arthroscopic surgery.

b) PDS® vs Prolene®

In general, Prolene® showed superior loop elongation, knot elongation and loop holding capacity for both types of knot. However its knot security when tied in a Duncan knot was disappointing, whereas its knot security in a Snyder knot was equivalent to that of PDS®. As a result Prolene® has been found to have superior

knot performance for arthroscopic applications when tied in a Snyder, but not a Duncan knot.

c) PDS® vs Surgidac®

It is evident when reviewing the knot performance results that Surgidac® had superior loop elongation and loop holding capacity as well as equivalent knot security compared to PDS® for both types of knot. However, its significantly longer and more variable knotting times mean that it has inferior ease of manipulation when compared to PDS® sutures, and as such, it cannot be recommended for arthroscopic surgery.

4. Biosyn® vs Prolene®

In general, the Biosyn® suture demonstrated inferior loop elongation, knot elongation and loop holding capacity compared to Prolene®. Because of this, and in spite of its superior knot security performance, Biosyn® cannot be recommended for arthroscopic surgery.

5. Surgidac® vs Biosyn® and Prolene®

In comparison with Biosyn®, Surgidac® was superior in terms of loop elongation and loop holding capacity for both types of knot. For the Duncan knot it had equivalent knot security, and for the Snyder knot it showed inferior knot security. In a similar comparison with Prolene®, Surgidac® was found to be superior to Prolene® in terms of loop elongation and loop holding capacity. This was because Surgidac® has limited extensibility and does not elongate as the monofilament sutures as Biosyn® and

Prolene® do under low loads. On the other hand, Surgidac® sutures were difficult to manipulate and their knotting times were significantly longer than those measured for Biosyn® and Prolene® monofilaments.

6. <u>Correlation between Dependent Variables</u>

The correlation matrix shows whether a linear relationship existed between pairs of dependent variables. The following conclusions were obtained based on the correlation matrix.

a) Correlation between knot elongation and loop elongation.

Knot elongation was found to have a very weak correlation with loop elongation. This means that knot elongation is not dependent on loop elongation. In other words, knot elongation appears to be more strongly dependent on suture elongation, i.e. the elongation of suture under 30 N load.

b) Correlation between loop elongation and loop holding capacity

Loop elongation had a strong negative correlation with loop holding capacity, which means that the smaller the loop elongation, the greater the loop holding capacity above a certain threshold value. The reason for this is that loop elongation is strongly dependent on suture elongation; the greater the suture elongation, the greater the loop elongation and the smaller the force required to reach a given elongation. Since loop holding capacity is the load required to reach 3 mm elongation for the suture loop, it means that 3 mm elongation was reached at a smaller load.

c) Correlation between knot security and other properties

The test results did not show any strong correlation between knot security and the other properties in the study. This is not surprising, since the performance of the suture knot at maximum loading is dependent on many variables, only some of which are knot dependent. For example, by observing the fracture residues by SEM, it was found that the failure mechanism of knotted sutures depends to a great extent on the polymer structure and the suture properties as well as the knot characteristics.

d) Correlation between maximum elongation and other properties

The maximum elongation had moderate, negative correlation with loop holding capacity. This can be explained in terms of the earlier discussion for loop elongation, since the same basic principles apply.

e) Correlation between knotting time and other properties

The correlations between knotting time and the other properties were either weak or moderate in strength.

Implications for Future Study

The evaluation of suture materials for arthroscopic surgery in this study was based on two important criteria: 1) knot performance and 2) ease of manipulation. From the test results, it is evident that the knot performance alone did not provide enough information about the suitability of the sutures for arthroscopic surgery. It has therefore been essential to take both criteria into consideration.

For example, this study has shown that the polyester braided Surgidac® suture has a significantly better knot performance than monofilament sutures. However, because of the considerable difficulty encountered in sliding the half-hitch throws down the cannula, it took much longer to tie the knot. Since the ease of sliding is related to the surface frictional characteristics of the suture, it is recommended that other braided polyester sutures with different surface coatings and alternate frictional properties be investigated in an attempt to solve this problem.

One of the observations made while tying the knots for this study was that it was sometimes difficult to advance the first half-hitch throw of the Prolene® sutures when tying a Snyder knot. The same difficulty was not encountered during subsequent throws or when tying a Duncan knot, and so this observation did not translate into longer knotting times for the Prolene® Snyder knots. An explanation of this phenomenon may be at that when the Prolene® sutures cross at a large angle there is more surface friction than when the two strands lie almost parallel to each other. Further studies on the frictional properties of sutures crossing at different angles may clarify this problem and lead to more efficient arthroscopic techniques in the future.

The results from this study have also indicated a need for greater understanding of the manipulation process associated with arthroscopic techniques. Ergonomic studies on the optimum movements required for the forming, moving, placing and timing of each throw in a compound knot would be helpful in improving the efficiency of such surgical techniques.

The SEM observations of the fractured residues in this study identified different failure mechanisms for the sutures in different knotted configurations. Some appeared to

fail due to brittle tensile loading, while others failed due to an axial splitting mechanism. Further studies are needed to understand the relative importance of these competing mechanisms, so that the knot security properties of sutures can be modeled and predicted for a range of different types of knot.

REFERENCES

Batra, E. K., Franz, D. A., Towler, M. A., Rodeheaver, G. T., Thacker, J. G., Zimmer, C. A., & Edlich, R. F. (1992). Influence of emergency physician's tying technique on knot security. Journal of Emergency Medicine, 10, 309-316.

Burkhart, S. S., Wirth, M. A., Simonick, M., Salem, D., Lanctot, D., & Athanasiou, K. (1998). Technical Note: Loop security as a determinant of tissue fixation security. The Journal of Arthroscopic and Related Surgery, 14, 773-776.

Canadian General Standards Board. (1987). Textile test methods: Precision and accuracy of measurements (CAN/CGSB-4.2-No 1-M87), Ottawa, Canada.

Casey, D. J., & Lewis, O. G. (1986). Bulk characterization of biomaterials: Absorbable and nonabsorbable sutures. Handbook of Biomaterials Evaluation: Scientific, Technical, and Clinical Testing of Implant Materials. (pp. 86-94). New York, NY: Macmillan.

Chu, C. C. (1983). Survey of clinically important wound closure biomaterials. Biocompatible Polymers, Metals, and Composites. (pp. 477-523). Lancaster, PA: Technomic.

Dinsmore, R. C. (1995). Understanding surgical knot security: A proposal to standardize the literature. Journal of the American College of Surgeons, 180, 689-699.

Faulkner, B. C., Gear, A. J. L., Hellewell, T. B., Mazzarese, P. M., Watkins, F. H., & Edlich, R. F. (1996). Biomechanical performance of a braided absorbable suture. Journal of Long Term Effects of Medical Implants, 6, 169-179.

Fischer, S. P. (1995). Arthroscopic knot-tying. Proceeding of Arthroscopy Association of North America Annual Meeting (pp. 180-193).

Hanna, G. B., Shimi, S., & Cuschieri, A. (1997). Influence of direction of view, target-to-endoscope distance and manipulation angle on endoscopic knot tying. British Journal of Surgery, 84, 1460-1464.

Hearle, J. W. S., Lomas, B., Cooke, W. D., & Duerden, I. J. (1989). Fiber Failure and Wear of Materials: an Atlas of Fracture, Fatigue, and Durability, (pp. 33-39, 54-59). England, West Sussex: Ellis Horwood Ltd.

Hong, T., King, M. W., Michielsen, S., Cheung, L. W. K., Mary, C., Guzman, R., & Guidoin, R. (1998). Development of in vitro performance tests and evaluation of nonabsorbable surgical sutures for cardiovascular surgery. ASAIO Journal, 44, 776-785.

James, J. D., Wu, M. M., Batra, E. K., Rodeheaver, G. T., & Edlich, R. F. (1992). Technical considerations in manual and instrument tying techniques. Journal of Emergency Medicine, 10, 469-480.

Loutzenheiser, T. D., Harryman, D. T., Yung, S. W., France, M. P., & Sidles, J. A. (1995). Optimizing arthroscopic knots. The Journal of Arthroscopic and Related Surgery, 11, 199-206.

Magilligan, D. J., & DeWeese, J. A. (1974). Knot security and synthetic suture materials. The American Journal of Surgery, 127, 355-358.

Mishra, D. K., Cannon, W. D., Lucas, D. J., & Belzer, J. P. (1997). Elongation of arthroscopically tied knots. American Journal of Sports Medicine, 25, 113-117.

Moy, R. L., Waldman, B., & Hein, D. W. (1992). A review of sutures and suturing techniques. Journal of Dermatologic Surgery and Oncology, 18, 785-795.

Pasic, R., Levine, R.L. (1995). Laparoscopic suturing and ligation techniques. The Journal of the American Association of Gynecologic Laparoscopists, 3, 67-79.

Shimi, S. M., Lirici, M, Velpen, G.V., Cuschieri, A. (1994). Comparative study of the holding strength of slipknots using absorbable and nonabsorbable ligature materials. Surgical Endoscopy, 8, 1285-1291.

Sweeney, H. J. (1996). Knot tying. Proceeding of Arthroscopy Association of North America Annual Meeting. (pp. 176-177).

Szabo, Z., Hunter, J., Berci, G., Sackier, J., & Cuschieri, A. (1994). Analysis of surgical movements during suturing in laparoscopy. Endoscopic Surgery and Allied Technologies, 2, 55-61.

Tera, H., & Aberg, C. (1976). Tensile strengths of twelve types of knot employed in surgery, using different suture materials. Acta Chirurgica Scandinavica, 142, 1-7.

Trimbos, J. B., Van-Rijssel, E. J. C., & Klopper, P. J. (1986). Performance of sliding knots in monofilament and multifilament suture material. Obstetrics and Gynecology, 68, 425-430.

United States Pharmacopeia, The National Formulary, USP 23, NF 18. United States Pharmacopeial Convention, Inc. Rockville, MD. 1995.

Van-Rijssel, E. J., Trimbos, J. B., & Booster, M. H. (1990). Mechanical performance of square knots and sliding knots in surgery: comparative study. American Journal of Obstetrics and Gynecology, 162, 93-97.

Yandell, B.S. (1997). Practical Data Analysis for Designed Experiments (1st Ed.). New York, NY: Chapman & Hall.

APPENDIX

Preliminary Experiment

PRELIMINARY EXPERIMENT

Objective

The objective of the preliminary experiment was to evaluate the investigator's knot tying ability. The effectiveness of the investigator's knot tying technique was evaluated by comparing the knot performance and ease of manipulation of knots tied by the investigator with those tied by an experienced arthroscopic surgeon.

Method

The experiment involved the tying and evaluation of Snyder knots using size 1 PDS® sutures. The knots were tied using the same Arthrex® wooden practice box and the same type of Sixth Finger® knot pusher as described in Chapter 3.

The knot tying procedure for both persons was recorded with a video camera. Before starting the experiment, the whole knot tying procedure was reviewed to make sure that both persons tied exactly the same type of knot. After knot tying, the knots were stored in a dessicator for the same period of time. Eight knots tied by each person were tested on an Instron® Universal tester fitted with an environmental tank filled with buffered saline using the same protocol as described in Chapter 3.

Following the tying procedure, the recorded videos were reviewed and the length of time required to complete each knot was measured using a stopwatch. This enabled the average knotting time to be calculated for each person.

Results and Discussion

The test results are presented in the following table.

Table 21

Results of Snyder Knots Tied for Preliminary Test (mean+SD)

Properties	Surgeon (n=8)	Investigator (n=8)
Loop elongation (mm)	5.9±2.8	3.6±1.4
Loop holding capacity (N)	22.3±1.3	19.2±4.1
Knot security (N)	50.5±18.0	56.8±21.7
Maximum elongation (mm)	15.8±6.4	15.4±7.2
Knotting time (Second)	126 ±24	140 ±13

Null Hypothesis: There is no difference between the knots tied by the surgeon and those tied by the investigator in terms of knot performance, i.e. loop elongation, loop holding capacity, knot security and maximum elongation, and with respect to ease of manipulation, i.e. knotting time.

The normality and equality of the variances for each property were verified by plotting the data in normal quantile plots, and by using the Levene's test. Because the knot performance data failed to meet the assumptions of a two sample t-test, the Wilcoxon Rank sum test was conducted to analyze the results for loop elongation, loop holding capacity, knot security and maximum elongation. The knotting time data was analyzed by means of a Student t-test, and the p-values generated are listed in Table 22. The significance level at which the hypothesis was rejected was defined by $p < 0.05$.

Table 22

<u>Results of Statistical Analysis</u>

Properties	p-value
Loop elongation	0.0460
Loop holding capacity	0.0615
Knot security	0.5995
Maximum elongation	0.7525
Knotting time	0.1772

In view of the fact that all the calculated p-values were either equivalent to or greater than 0.05, the null hypothesis was not rejected for all five properties. This means that no differences were observed in knot performance or ease of manipulation between the knots tied by the surgeon and those tied by the investigator.

Conclusion

The statistical analysis showed that there was no significant difference between the knots tied by the surgeon and those tied by the investigator.