DEVELOPMENT OF *IN VITRO* PERFORMANCE TESTS AND EVALUATION OF NONABSORBABLE SURGICAL SUTURES

BY

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DEVELOPMENT OF IN VITRO PERFORMANCE TESTS AND EVALUATION OF NONABSORBABLE SURGICAL SUTURES

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Abstract

There have been reports suggesting that polypropylene (PP) monofilament sutures are associated with mechanical failure. In order to overcome the problem, a new monofilament suture made from polyvinylidene fluoride (PVDF) under the trade name of Teflene® has been developed. Few studies have measured the *in vitro* properties of Teflene® sutures, and those that have, have been limited to a few tensile properties of the straight suture such as tensile strength, elongation and creep behavior.

The *in vitro* performance properties of Teflene® sutures were evaluated and compared with those of commercial sutures made from polypropylene (PP) such as Prolene®, new Surgilene® and old Surgilene®, and polyester (PET) such as Ethibond® and Ti-Cron® in four sizes (2-0, 3-0, 4-0, and 5-0). The performance properties of sutures included both the physical properties of straight sutures such as suture diameter, tensile strength, elongation, surface roughness, coefficient of friction, bending stiffness and tissue drag; and knot characteristics such as knot pull strength, knot run-down, knot snug-down, and knot security. Existing standard test methods and testing instruments were used if available to measure certain suture properties such as diameter, tensile strength, knot pull strength, and some physical properties. The researcher had to develop the other test methods and accessory devices needed to perform the tests for measuring tissue drag, knot run-down, knot snug-down, and knot security.

From the test results, Teflene® sutures were found in general to possess equivalent characteristics to those of existing commercial sutures, but also some differences were observed, such as greater elongation and less knot run-down. These differences may give

them an unique handling performance especially in terms of making a knot and sliding it into position at the time of handling, and causing less damage to adjacent tissue when suturing.

Table of Contents

Page

List of Tables

Page

List of Figures

Page

CHAPTER I

INTRODUCTION

A nonabsorbable surgical suture is a flexible strand of material, in either monofilament or multifilament form and used for ligating blood vessels and approximating tissues together. Its diameter and tensile strength vary with its size designation, which is defined within specific limits by American and European standards. It is called "nonabsorbable" because it retains its strength *in vivo* longer than two to three months (Chu & Moncrief, 1983).

Nonabsorbable surgical sutures have been made from a variety of synthetic and natural materials. The Egyptians used linen as a suture material as far back as 2000 B.C.; catgut and silk dominated the suture market until the 1930's. Synthetic fibres such as nylon and polyester have been used as suture materials since the 1950's. Synthetic sutures have demonstrated less tissue reaction than natural materials (Stone, 1988). A monofilament suture has minimum surface and therefore has minimal tissue reaction. On the other hand, a multifilament suture has a better handling performance because it is easier to manipulate.

Synthetic polymer filaments, such as polyamide (PA), polyester (PET) and polyolefin have been successful as nonabsorbable surgical sutures because of their excellent performance properties, namely, tensile strength, flexibility and ease of manipulation. However, these polymeric filaments do not possess the ideal frictional properties required in surgery. Most sutures are coated with a lubricant, such as silicone or Teflon®, to reduce tissue drag and optimise knot characteristics.

Problem Statement

In recent years, there have been reports suggesting that polypropylene monofilament sutures are associated with suture mechanical failure (Urban, 1994). With a view to overcoming the problem, Péters Laboratoire Pharmaceutique, a French pharmaceutical company, has developed a new monofilament suture from polyvinylidene fluoride (PVDF), which has been subjected to a special treatment to modify its crystalline form and level of crystallinity. This suture has been marketed under the trade name of Teflene® in North America. One of the aspects of this study was to evaluate the performance properties of these Teflene® sutures. However, existing standard test methods and testing instruments for measuring the performance properties of sutures are limited to suture diameter, tensile strength, knot pull strength and certain physical properties. They do not include the measurement of physical properties of straight sutures such as surface roughness, coefficient of friction, tissue drag and various knot characteristics.

Purposes of the Study

The first purpose of the study was to evaluate *in vitro* the newly developed Teflene® suture, and compare its performance properties with several well known commercial sutures made from polypropylene (PP) and polyester (PET).

The second purpose of the study was to compare the performance properties of new Surgilene® suture with those of old Surgilene® suture. The new Surgilene® suture,

which was introduced on the market recently with a revised polymeric formulation, is going to replace the old Surgilene® suture which has been on the market for several years.

The third purpose of this study was to develop a set of reliable test methods, to design and build suitable accessory devices to be fixed on an Instron universal tester, so as to evaluate those suture performance properties which were not covered by present standard test methods, such as tissue drag, knot run-down, knot snug-down and knot security.

Hypotheses

In order to serve the purposes of the evaluation of Teflene® sutures and of the comparison of the new and old Surgilene® sutures, seven hypotheses were proposed.

Hypothesis 1: There is no difference in the performance properties between different brands of sutures.

Hypothesis 2: There is no difference in the performance properties between different sizes of sutures.

Hypothesis 3: There is no difference in the performance properties between different brands and sizes of sutures.

Hypothesis 4: For size 2-0 sutures, there is no difference in the performance properties between:

a) Teflene® and the other monofilament sutures;

b) Teflene® and the braided sutures;

c) new Surgilene® and old Surgilene® sutures.

Hypothesis 5: For size 3-0 suture, there is no difference in the performance properties between:

a) Teflene® and the other monofilament sutures;

b) Teflene® and the braided sutures;

c) new Surgilene® and old Surgilene® sutures.

Hypothesis 6: For size 4-0 suture, there is no difference in the performance properties between:

a) Teflene® and the other monofilament sutures;

b) Teflene® and the braided sutures;

c) new Surgilene® and old Surgilene® sutures.

Hypothesis 7: For size 5-0 suture, there is no difference in the performance properties between:

a) Teflene® and the other monofilament sutures;

b) Teflene® and the braided sutures;

c) new Surgilene® and old Surgilene® sutures.

Definitions

In this study, the performance properties of sutures include both the physical properties of straight sutures such as suture diameter, tensile strength, elongation, surface roughness, coefficient of friction, bending stiffness and tissue drag; and their knot characteristics such as knot pull strength, knot run-down, knot snug-down, and knot

security. The conceptual definitions of performance properties are presented in this section.

1. Tensile strength is the maximum resistance of a suture to deformation when subjected to tension by an external applied force.

2. Elongation is an extension or increase in length of a suture deformation when subjected to tension by an external applied force.

3. Surface roughness is a surface character and represents the unevenness of a suture's surface. It is also called surface rugosity.

4. Coefficient of friction is a frictional property that is needed to maintain uniform relative motion between two contacting surfaces to the perpendicular force holding them in contact.

5. Bending stiffness is the resistance of a suture to bending. It is also called flexibility or flexural rigidity.

6. Tissue drag represents the average force of resistance experienced by a suture when it is pulled through tissue with a uniform motion.

7. Knot pull strength is the breaking force applied to both ends of a knotted suture during a tensile test carried to rupture.

8. Knot run-down is a force required to advance the first throw of a knot.

9. Knot snug-down is a force required to displace or move a completed knot prior to reaching its final position.

10. Knot security is the breaking force applied to a knotted suture from inside the suture loop. It indicates the ability of a suture knot to stay in its pre-determined place under increasing tension from inside the loop.

Suture Samples

The recently developed Teflene® monofilament suture, three other monofilament sutures, Prolene®, new Surgilene® and old Surgilene® as well as two braided sutures, Ethibond® and Ti-Cron®, were investigated in this study. For each brand of suture, four different sizes, 2-0, 3-0, 4-0 and 5-0, were tested (Table 1).

Limitations

Since the suture samples for this study have been obtained from the suppliers, the sampling of different batches has not been controlled by the researcher. In other words, the sampling technique has not been randomized. Because the suture knots for the tests were tied manually, this introduced some variability in the shape and tension of each knot.

Table 1

Suture Samples

Brand	Polymer	Structure	Coating	Manufacture
Teflene®	Polyvinylidene fluoride (PVDF)	Monofilament	Uncoated	Péters Laboratoire Pharmaceutique, France
Prolene®	Polypropylene (PP)	Monofilament	Uncoated	Ethicon
Surgilene® (New)	Polypropylene (PP)	Monofilament	Uncoated	Davis & Geck
Surgilene® (Old)	Polypropylene (PP)	Monofilament	Uncoated	Davis & Geck
Ethibond®	Polyester (PET)	Braided	Coated with polybutylate	Ethicon
Ti-Cron®	Polyester (PET)	Braided	Coated with silicone	Davis & Geck

CHAPTER 2

LITERATURE REVIEW

This chapter presents a review of the literature on three related topics: nonabsorbable sutures in general, the performance properties of sutures, and the Teflene® suture in particular. A summary is provided at the end of the chapter.

Nonabsorbable Sutures

Sutures are probably the material most frequently implanted in humans. The properties of an ideal suture include ease of handling, minimum tissue reaction, adequate tensile strength and knot security. Sutures that lose their entire tensile strength within two to three months are called absorbable sutures; whereas those that retain their strength longer than two to three months are called nonabsorbable sutures (Chu, 1983).

Nonabsorbable Suture Materials

Nonabsorbable sutures may be in either monofilament or multifilament form and should be suitably resistant to deterioration when exposed to the action of living mammalian tissue. The individual filaments of a multifilament suture may be combined by spinning, twisting, or braiding. The diameter and tensile strength of a suture should correspond to the size designation indicated on the label and should fall within the prescribed limits designated by the US Pharmacopeia. Sutures may be impregnated or treated with a suitable coating, softening or antimicrobial agent (USP, 1990).

Nonabsorbable sutures have been made from synthetic and non-synthetic (natural) materials. Table 2 shows examples of commercial nonabsorbable sutures and their chemical compositions (Casey & Lewis, 1986).

Classes of Nonabsorbable Sutures

According to US Pharmacopeia, nonabsorbable sutures are classified into the following three groups:

1. Class I Suture - These contain silk or synthetic fibres. If a coating is present, it does not significantly affect the suture's thickness. All sutures tested in this study fall in Class I.
2. Class II Suture - These include cotton or linen fibres or coated natural or synthetic fibres, in which the coating significantly affects their thickness, but does not contribute significantly to their strength.
3. Class III Suture - These include only those made from monofilament or multifilament metal wire (USP, 1990).

Table 2
Suture Materials

Material	Composition	Brand	Structure	Coating
Synthetic				
Nylons				
Nylon 66	$[-NH(CH_2)_6NHCO(CH_2)_4CO-]$	Surgilon®	braided	Silicone
		Dermalon®	Mono-filament	
Nylon 6	$[-NH(CH_2)_5CO-]$	Nurolon®	Braided	Wax
		Ethilon®	Mono-filament	
Polyesters				
Poly(butylene terephthalate)	$[-O(CH_2)_4OCOC_6H_4CO-]$	Miralene	Mono-filament	
Poly(ethylene terephthalate)	$[-O(CH_2)_2OCOC_6H_4CO-]$	Ethibond®	Braided	Poly-butylate
		Ethiflex®	Braided	Teflon®
		Ti-Cron®	Braided	Silicone
		Mirafil®	Mono-filament	
Poly[Poly(tetra-methylene ether) tereph-thalate-co-tetramethylene terephthalate)]	$[-O(CH_2)_4OCOC_6H_4CO-]_{84}$ $[-O(CH_2CH_2CH_2-CH_2O-)_n$ $COC_6H_4CO-]_{16}$	Novafil®	Mono-filament	
Polyolefins				
Polypropylene (PP)	$[-CH_2CH(CH_3)-]$	Prolene®	Mono-filament	
		Surgilene®	Mono-filament	
Polyfluorocarbon				
Polyvinylidene fluoride(PVDF)	$[-CH_2-CF_2-]$	Teflene®	Mono-filament	
Non-synthetic				
Silk	Protein	Dermal®	Multi-filament	Wax
				Wax
Cotton	Cellulose		Staple	
Linen	Cellulose		Staple	
Metal	Stainless steel		Mono-filament	

Suture Size

Two standards are currently used to describe the size of sutures: US Pharmacopeia (USP) and European Pharmacopeia (EP). The former is more commonly used in North America including Canada (Table 3). In general, the diameters of commercial sutures are at the upper end of the limits specified by USP. This may assume that manufacturers want to maximize the sutures' physical properties (Kusy & Whitley, 1983).

Table 3

Nonabsorbable Suture Size and Diameter Classification

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	1.00	1.099
9	11	1.100	1.199
10	12	1.200	1.299

Performance Properties of Sutures

This section presents reviews in three respects: the significance of performance properties of sutures, measurements of performance properties of sutures, and test conditions and sample sizes.

Significance of Performance Properties of Sutures

The surgeons' acceptance of sutures is governed by sutures' performance properties, which include the physical properties of the straight sutures as well as their knot characteristics. The tensile strength of straight sutures and the knot pull strength of sutures are basic tensile characteristics. The strength of a knotted suture must be sufficient to maintain tissue approximation during a sufficient period of time to allow complete healing to occur. The average knot pull strength of a suture is not less than the minimum requirement specified by USP in Table 4 (USP, 1990).

Surface roughness and coefficient of friction are characteristics of the suture's surface. The type of suture structure, material and coating, and the tension applied to it will also influence the value of its coefficient of friction. Braided sutures usually have higher surface roughness values than do monofilament sutures. Uncoated sutures usually have higher coefficients of friction than coated sutures (Gupta, 1985). A suture with a rough surface can injure tissues when suturing, but offers better knot run-down. It is

Table 4

Knot Pull Strength Specification

Size Codes	USP Gauge No. EP Size Codes(mm)	Limits on Average Knot Pull Tensile Strength (kgf) Class I (Min.)	Class II (Min.)	Class III (Min.)
12-0	0.01	0.001		0.002
11-0	0.1	0.006	0.005	0.02
10-0	0.2	0.019	0.014	0.06
9-0	0.3	0.043	0.029	0.07
8-0	0.4	0.06	0.04	0.11
7-0	0.5	0.11	0.06	0.16
6-0	0.7	0.20	0.11	0.27
5-0	1	0.40	0.23	0.54
4-0	1.5	0.60	0.46	0.82
3-0	2	0.96	0.66	1.36
2-0	3	1.44	1.02	1.80
0	3.5	2.16	1.45	3.40
1	4	2.72	1.81	4.76
2	5	3.52	2.54	5.90
3 & 4	6	4.88	3.68	9.11
5	7	6.16		11.4
6	8	7.28		13.6
7	9	9.04		15.9
8	10			18.2
9	11			20.5
10	12			22.8

therefore important that a suture has an appropriate balance of surface roughness and coefficient of friction. Bending stiffness, flexibility or flexural rigidity is the resistance of a suture to bending, and it is a parameter that significantly influences the performance properties of a suture. In particular, it can be used to predict a suture's handling performance (Chu & Kizil, 1989). It provides a relative index of the ease of making a knot and indicates how readily a knot will move or open under stress. It is easier to form

a knot using a suture with low stiffness, while a stiffer suture offers more resistance in making a knot and is more prone to opening under strain.

Tissue drag represents an aspect of the ease of suturing and is determined by measuring the average force required to pull the suture through biological tissue. It is believed to be influenced by the suture's surface characteristics and stiffness (Planck, 1990).

During an operation it is important that surgeons find it easy to form and place a knot. It is equally important that the suture has good knot security, so that the knot will keep its place without opening or moving. A stiffer suture has higher knot run-down, knot snug-down and lower knot security, so it is harder to manipulate and form a knot, and once formed, the knot slides open more easily. A suture with a high coefficient of friction has better knot security, but it also has higher tissue drag and can injure adjacent tissue during suturing.

Knot run-down is determined by the force required to advance the first throw of a knot so that it can be placed correctly prior to making the second and subsequent throws. The ease of knot run-down is believed to depend on suture stiffness and surface characteristics (Planck, 1990).

Knot security, or knot holding capacity, indicates the ability of a suture knot to stay in its pre-determined place under increasing tension from inside the loop. It is determined by measuring the maximum force required to cause the knot to break open. It equally is thought to depend on suture stiffness and surface characteristics (Planck, 1990).

Measurements of Performance Properties of Sutures

Many studies have been done in measuring the performance properties of sutures *in vitro*. Table 5 shows a summary of references in the literature which describe measurements of the physical properties of straight sutures. Table 6 shows a summary of references which describe measurements of knot characteristics. Standard test methods are also presented in these two tables if they exist. However, the standard test methods are restricted only to suture diameter, tensile strength, bending stiffness and knot pull strength. As Tables 5 and 6 clearly show, there are no standard test methods for many suture performance properties such as surface roughness, coefficient of friction, tissue drag, knot run-down, knot snug-down, and knot security.

Table 5

Summary of Measurements of Physical Properties of Straight Sutures

Property	Standard Method	Researcher	Measurement	Instrument
Diameter	USP		Measure the diameter at three points along a suture corresponding to one-fourth, one-half, and three-fourths of its length.	Mechanical thickness gauge of dead weight type
		Rodeheaver, 1987	Measure the diameter.	Linear vernier microscope and video microscope
		Plank, 1990	Measure the diameter.	Diameter tester (with automatic scanning and data processing)
Tensile strength (& elongation)	ASTM D2256-90		Measure the breaking load (the maximum force applied to a suture to rupture) and elongation (the ratio of the extension of a suture to its initial length prior to stretching).	Tensile testing machine of CRE type (Constant Rate of Elongation)
		Fraunhofer,1988	Measure the breaking load and elongation.	Unite-O-Matic tensometer
		Rodeheaver, 1981	Measure the breaking load and elongation.	Instron
Surface roughness	Not available.		Not available.	Not available.
		Planck, 1990	Measure the up and down motion of a sensory foot in contact with the surface of a moving suture.	Hommel roughness tester

Table 5 (continued)
Summary of Measurements of Physical Properties of Straight Sutures

Property	Standard Method	Researcher	Measurement	Instrument
Coefficient of friction	Not available.		Not available.	Not available.
		Rodeheaver, 1983	Measure the force required to pull a suture across a second suture at a right angle.	Instron
		Gupta, 1985	Measure the force required to advance a certain number of throws along the suture.	Instron
Bending stiffness	ASTM D1388-64		Measure the heart loop length of a suture, then calculate the bending stiffness.	Heart loop tester.
		Chu & Kizil, 1989	Measure the force required to bend a suture to a fixed angle.	Table V-5 stiffness tester
		Planck, 1990	No detail was given.	A new stiffness tester (no detail as given)
		Cohan, 1985	Measure the number of turns required before a vertically held weighted suture starts to rotate(Torsional stiffness).	
Tissue Drag	Not available.		Not available.	Not available.
		Planck, 1990	Measure the force required to pull a suture through a polyurethane membrane.	Instron

Table 6

Summary of Measurements of Knot Characteristics of Sutures

Property	Standard Method	Researcher	Measurement	Instrument
Knot pull strength	USP 1990		Measure the force required to break a suture tied into a surgeon's knot.	Incline Plane Tester of CRL type (Constant Rate of Load)
		Cohan, 1985	Same as above	Instron
Knot run-down	Not available.		Not available.	Not available.
		Zimmer, 1991	Measure the force required to advance the first throw of a knot.	Instron
Knot snug-down	Not available.		Not available.	Not available.
		Planck, 1990	Measure the force required to move a surgeon's knot along the suture.	Instron
Knot Security	Not available.		Not available.	Not available.
		Stone, 1986	Measure the force required to cause a knot to break open.	Instron

Test Conditions and Sample Sizes

The US Pharmacopeia has specified the conditions and sample size for testing sutures. However, different researchers have used different pre-conditioning, test conditions and sample sizes (Table 7).

Table 7

Test Conditions and Sample Size

Researcher	Pre-conditioning & Test Conditions	Sample Size
USP, 1990	Sample must be tested promptly after removal from its container.	10
Chu, 1983	Samples were stored at standard conditions for 24 hours prior to testing. Temperature: 21.0±1.0°C, Relative Humidity: 65±2%.	5
Rodeheaver, 1987	In wet condition, samples were immersed in 0.9% saline solution at 22°C for 15 minutes prior to testing.	Not specified.
Stone, 1986	Not specified.	4

Teflene® Sutures

Teflene® sutures are recently developed product, and little literature has been published related to their medical or clinical use. Urban (1994) has studied its physical, chemical, and biological properties and has found that Teflene® sutures have similar breaking strengths but higher elongation than their polypropylene counterparts such as

Prolene®. It is believed that this is because Teflene® in the form of a suture has a higher level of crystallinity than polypropylene. Teflene® sutures have proven to provide good handling, excellent biocompatibility and a minimal cellular and tissue response *in vivo* (Laroche et al., in press). However, the physical properties that were measured in these studies were limited to few tensile properties such as tensile strength, elongation and creep behaviour of straight sutures. No tests of bending stiffness, knotting or surface characteristics were attempted by previous researchers.

Summary

After reviewing the literature, this researcher has made the following four observations:

1. The present standard test methods for sutures are limited to suture diameter, tensile strength and a few other performance properties. Standard test methods for other important performance properties such as tissue drag, knot pull-down, knot snug-down and knot security do not exist.

2. Many studies to evaluate the behaviours of sutures have been performed and described by previous researchers. However, much attention has been paid to a few properties such as tensile strength and knot pull strength, and less to surface roughness, coefficient of friction, bending stiffness, tissue drag and the various knot characteristics. While Planck (1990) has mentioned some tests for measuring these performance properties, he described neither the test methods nor the test devices in detail, so it is not possible to repeat his work and obtain accurate, reliable and valid results.

3. The surface roughness and coefficient of friction of sutures have been measured by several researchers using different instruments. However, the Kawabata Evaluation System (KES), a modern, powerful and suitable instrument, has to the best of the researcher's knowledge not been used by researchers to date. Consequently, it is believed that the KES might be an important instrument in measuring these performance properties of sutures.

4. Previous *in vitro* studies on Teflene® sutures have not completely evaluated the sutures' performance, especially their handling behaviour, which involves both physical properties and knot characteristics.

CHAPTER 3

METHOD

This chapter describes the tests performed and instruments used in this study, including the Instron universal tester, the accessories needed for each test method, the specimen preparation and manipulation, the test methods, and the test conditions.

Calibration and Selection of Accessories for Instron Universal Tester

Most tests to measure suture performance properties involve using a constant-rate-of-extension (CRE) type tensile tester, such as an Instron universal tester. A CRE type Instron universal tester (Model 4206) was used for this study.

Calibration

To ensure the measurements were accurate, the Instron universal tester was calibrated to meet the specifications established by ASTM. For example, the pulling clamp of the tester was checked to ensure that it moved at a uniform rate, and the force measuring mechanism (load cell) was confirmed to move a negligible distance with increasing force less than 0.13 mm(ASTM D76-93).

Selection of Load Cell, Yarn Grips, Gauge Length and Crosshead Speed

The selection of a load cell was the first step in preparing for a tensile test. The capacity of the load cell was chosen so that the expected maximum force fell within 10 to 90% of the load cell's capacity (ASTM D76-93).

The selection of yarn grips depends upon the tensile strength of the test specimen. Pneumatic yarn grips were mounted so that the pulling axis of the testing machine coincided with the central axis of a properly mounted specimen. With their flat metal gripping faces and polished guide horns, these grips provided the required restraint, precluded slippage, and minimised specimen failure in the clamped areas (ASTM D76-93).

The gauge length used for a tensile test is the initial distance the suture travels between the grips. It was used as the basis for calculating the percent elongation. Commonly used gauge lengths for yarns lie in a range from 100 to 250 mm, with larger gauge length being preferred, were possible, because of their increased sensitivity and accuracy for measuring of the elongation (Instron Co., 1984). A gauge length of 150 mm was used throughout this study.

The selection of a crosshead speed (the rate of elongation) depends upon the material being tested and the type of test. When the breaking elongation of a specimen lies between 8% and 100% of the initial length, the crosshead speed should be 60% of the initial gauge length (ASTM D2101-82). A crosshead speed of 90 mm/min, i.e. a strain rate of 60%/min, was used throughout this study.

According to the specifications of the Model 4206 Instron tester used in this study, the accuracy of the load weight system at analogue output was ±1% of the reading to 1/50

of load cell capacity. The repeatability of the position measurement was ±0.05 mm, and the crosshead speed accuracy ±2%. These specifications fell well within the limits stipulated by ASTM D76-93.

Preparation and Manipulation of Suture Specimens

It was essential to handle the suture specimens during testing with care. In particular it was important to avoid introducing any change in twist level or any stretching of the suture while removing it from the package and mounting it in the instrument. During testing on the Instron tester, first one end of the suture specimen was secured in the top grips. Then the other end was placed between the other grips and a 5±1 mN/tex (0.5 gf/tex) pre-tension load was applied prior to closing the bottom grips. This pre-tensioning load is considered sufficient to remove any slack or kinks from most sutures without appreciable stretching. Any touching of the portion of the suture between the grips with bare hands was avoided (ASTM D2256-90).

A so-called jaw (grip) break is any break that occurs within 3 mm of a distance of the jaws and which results in a value that is 20% or more below the average breaking force of all the other specimens. The results from any jaw breaks, or from any incidents where there was suture slippage in the grips or other faulty operation that gave a result 20% below the average breaking force were discarded as required by the standard method (ASTM D2256-90).

Test Methods

A summary of the suture tests performed, the test methods followed, and the instruments used in this study are listed in Table 8. The list covers all the performance properties, and includes descriptions of the tests for both the physical properties of straight sutures and the knot characteristics.

Physical Properties of Straight Sutures

The following physical properties of straight sutures were tested, they included suture diameter, tensile strength and elongation, surface roughness and coefficient of friction, bending stiffness, and tissue drag.

Suture diameter. The suture diameter was measured following the method described in the US Pharmacopoeia. A dead-weight, mechanical thickness gauge, equipped with a direct-reading dial and graduated to 0.02 mm was used. The presser foot was 28.6 mm in diameter. The total weight applied to the specimen was 473 g. Three measurements were made at three points corresponding roughly to one-fourth, one-half, and three-fourths of the suture's length. To measure braided size 2-0 sutures (Ethibond® and Ti-Cron®), three measurements were performed before and after rotating the suture through an angle of 90°.

Table 8

Summary of Suture Tests

Performance Property	Test Method	Instrument	Customized Device
Physical Property			
Diameter	USP	Mechanical thickness gauge of dead weight type.	Not needed.
Tensile strength (& Elongation)	ASTM D2256-90	Instron	Not needed.
Surface roughness & Coefficient of friction	Kawabata KES-FB4 manual.	Kawabata KES-FB4 surface tester	Not needed.
Bending stiffness	ASTM D1388-64 (Heart loop test)	Heart loop tester	Not needed.
Tissue drag	A test method was developed by the researcher.	Instron	A special device was designed and built by the researcher.
Knot characteristics			
Knot pull strength	USP	Instron	Not needed.
Knot run-down	A test method was developed by the researcher.	Instron	A special device was designed and built by the researcher.
Knot snug-down	A test method was developed by the researcher.	Instron	A special device was designed and built by the researcher.
Knot security	A test method was developed by the researcher.	Instron	A special device was design and built by the researcher.

Ten strands of each size and brand of sutures were measured and the average diameter was calculated to determine whether or not it fell within the tolerance prescribed in USP.

Tensile strength and elongation. The tensile strength and elongation of sutures were measured following ASTM D2256-90. Tensile strength is the breaking force applied to a specimen in a test. An Instron universal tester (Model 4206) fitted with pneumatic yarn grips was used to measure the breaking force and the elongation at break. The breaking force was the maximum force applied to the suture specimen during a tensile test carried to rupture. The elongation was determined as the ratio of the extension of the specimen to the length of the material prior to stretching, i.e. initial gauge length. The tester was operated at a crosshead speed of 90 mm/min, with a 100 kg capacity CTM load cell, and a gauge length of 150 mm. Ten specimens of each size and brand of suture were tested and the average tensile strength and elongation calculated for each.

Surface roughness and coefficient of friction. A Kawabata Evaluation System (KES) FB4 surface tester was used to measure the surface roughness and the coefficient of friction. A surface sensory foot and a frictional sensory foot were employed to determine these two properties in sequence. For each test, a separate specimen was traversed at a constant rate of 1 mm/sec under a tension applied by a dead weight of 50 g. The vertical displacement pattern for surface roughness was recorded and values of surface roughness were calculated by computer. The horizontal frictional force between the moving suture specimen and fixed sensory foot was recorded continuously over a

distance of 2 cm, and the mean coefficient of friction was also calculated and displayed by the computer. Ten strands of each size and brand of suture were measured and the means of surface roughness and coefficient of friction calculated for each.

Bending stiffness. Static bending stiffness was measured by following the ASTM D1388-64 (Reapproved 1975) heart loop test. The length for each specimen was 25 cm. The two ends of the specimen were clamped together, and the specimen was allowed to hang vertically under its own weight to form a heart shaped loop. The loop length (from the top edges of the clamps to the base of the loop) was measured, and the bending length was obtained from the table provided by ASTM D1388-64. The following equation was used to measure the bending stiffness in terms of flexural rigidity.

$$G = W \times c^3$$

Where G = flexural rigidity in g·cm,

W = weight per unit area in g/cm^2,

c = bending length in cm.

Ten strands of each size and brand of suture were measured and the average bend stiffness calculated for each.

Tissue drag. In order to measure tissue drag, a special device was designed and constructed for fitting to an Instron universal tester (Fig. 1). Instead of using fresh or fixed biological tissue, whose thickness and structure are highly variable, the test method used a tissue simulant made of an expanded polyurethane membrane of standard thickness

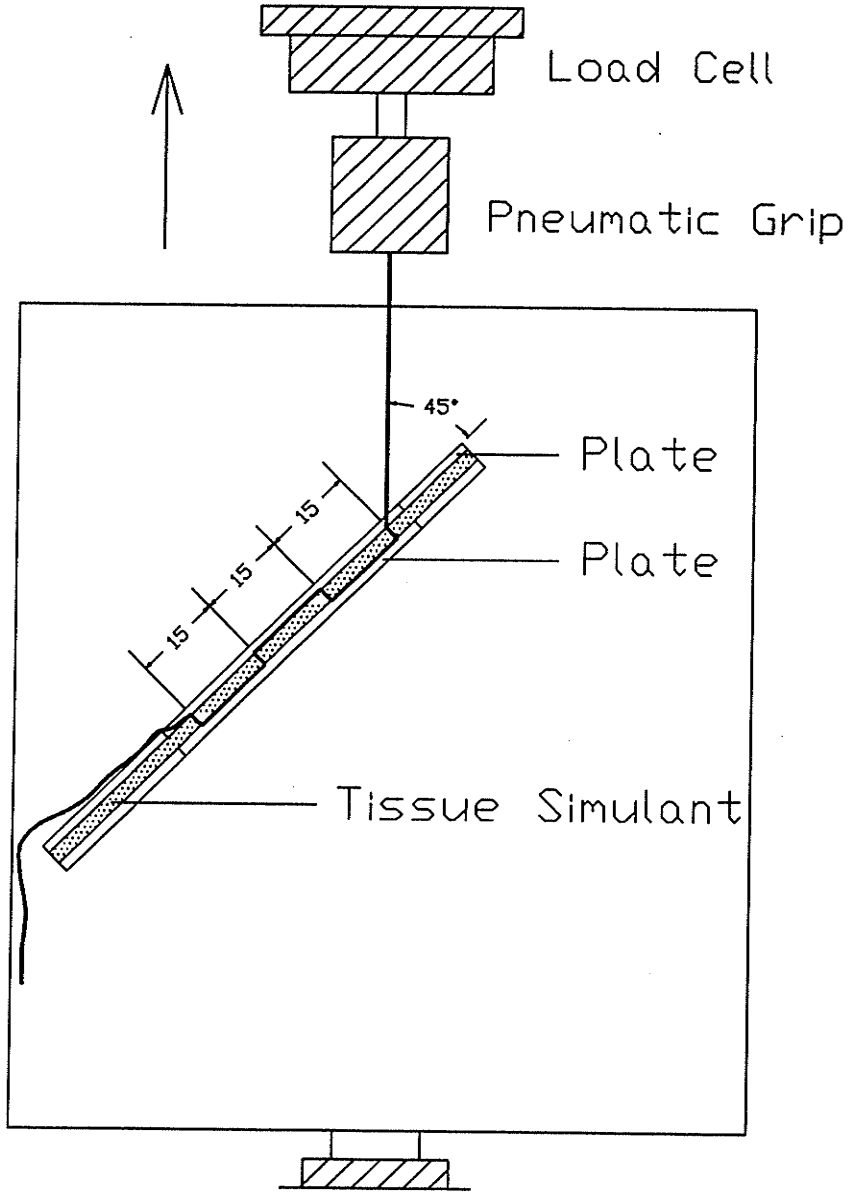

Figure 1. Tissue drag device.

(Vileda, supplied by Yom SA, France). With the needle attached to the suture, each suture was passed four times through the tissue simulant, which was mounted rigidly on a frame at 45° with respect to the suture axis below the crosshead. The four stitching holes in the urethane membrane were in a straight line 15 mm apart and the initial gauge length was 40 mm. The Instron load cell recorded the force required to pull 300 mm of suture through the urethane membrane at a crosshead speed of 300 mm/min by a chart recorder. Ten repeat tests were performed under both wet and dry conditions and the average tissue drag in each condition was calculated according to the load-displacement chart recorded for each specimen.

Knot Characteristics of Sutures

The following knot characteristics of sutures were tested. They included knot pull strength, knot run-down, knot snug-down and knot security.

Knot pull strength. The average knot pull strength of the sutures was determined using the standard test method described in the US Pharmacopoeia. However, instead of an Incline Plane Tester, an Instron universal constant rate of extension (CRE) tester was used and operated at a constant crosshead speed of 90 mm/min, with a load cell of 100 kg capacity and an initial gauge length of 150 mm. Each sample was tied into a standard surgeon's knot (2=1) (Fig. 2). The first throw was made with the suture wound around a piece of flexible rubber tubing of 6.5 mm inside diameter and 1.6 mm wall thickness. The second throw completed the compound knot prior to removing the tubing. The two ends

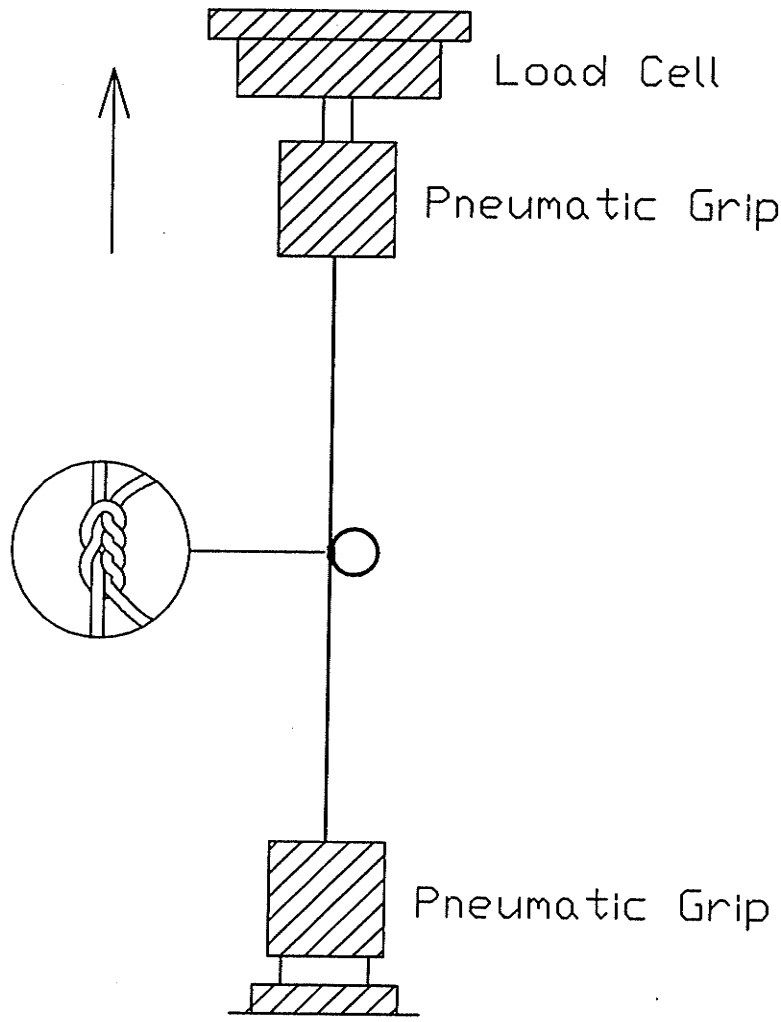

Figure 2. Knot pull device.

of the suture were held in pneumatic clamps with the knot approximately midway between the clamps. Ten strands of each brand and size of suture were tested and the average knot-pull strength was calculated for each.

Knot run-down. A special device was designed, constructed and fitted to an Instron universal tester to measure the knot run-down force (Fig. 3). The device permitted the suture to be loaded with dead weights of 10 g each and the force required to move the first throw of a square knot or a granny knot a distance of 100 mm was recorded on a chart recorder. The Instron was operated with a load cell of 2 kg capacity and an initial gauge length of 150 mm, at a crosshead speed of 90 mm/min. Ten strands of each size and brand of suture were measured and the average calculated according to the load-displacement chart recorded for each specimen.

Knot snug-down. In order to measure the knot snug-down force for a suture, a special device was developed and fitted to Instron universal tester (Fig. 4). The suture was tied into a granny knot (2=1) which was placed between two pins 15 mm in diameter. The upper pin represented the thumb of the surgeon who moved the knot by pressing on it. The two free ends were clamped between the pneumatic yarn grips. The force required to displace the completed knot prior to reaching its final position was recorded on a chart recorder. The tester was operated with a CTM load cell of 2 kg capacity at a crosshead speed of 90 mm/min over a distance of 100 mm. Ten strands of each size and brand of suture were tested and the average knot snug-down force calculated according to the load-displacement chart. In the event that the knot tightened instead of moving, the

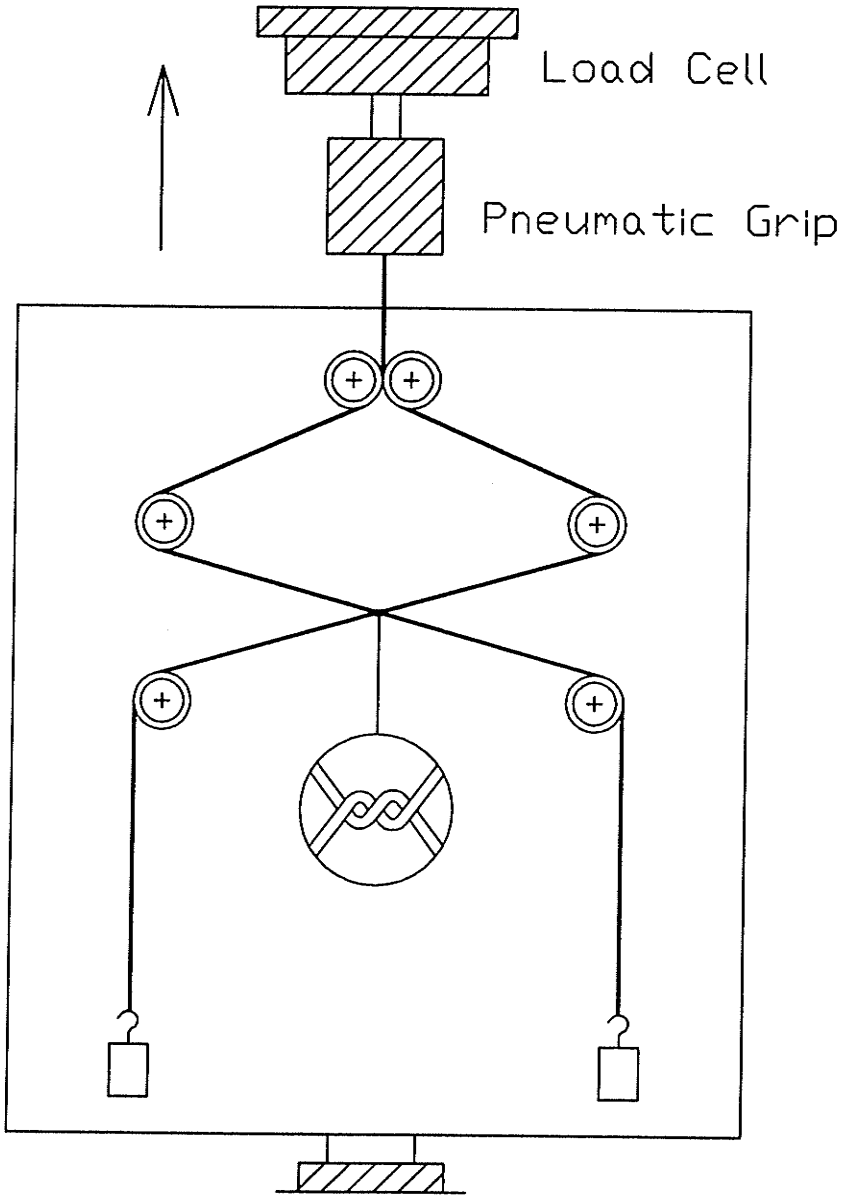

Figure 3. Knot run-down device.

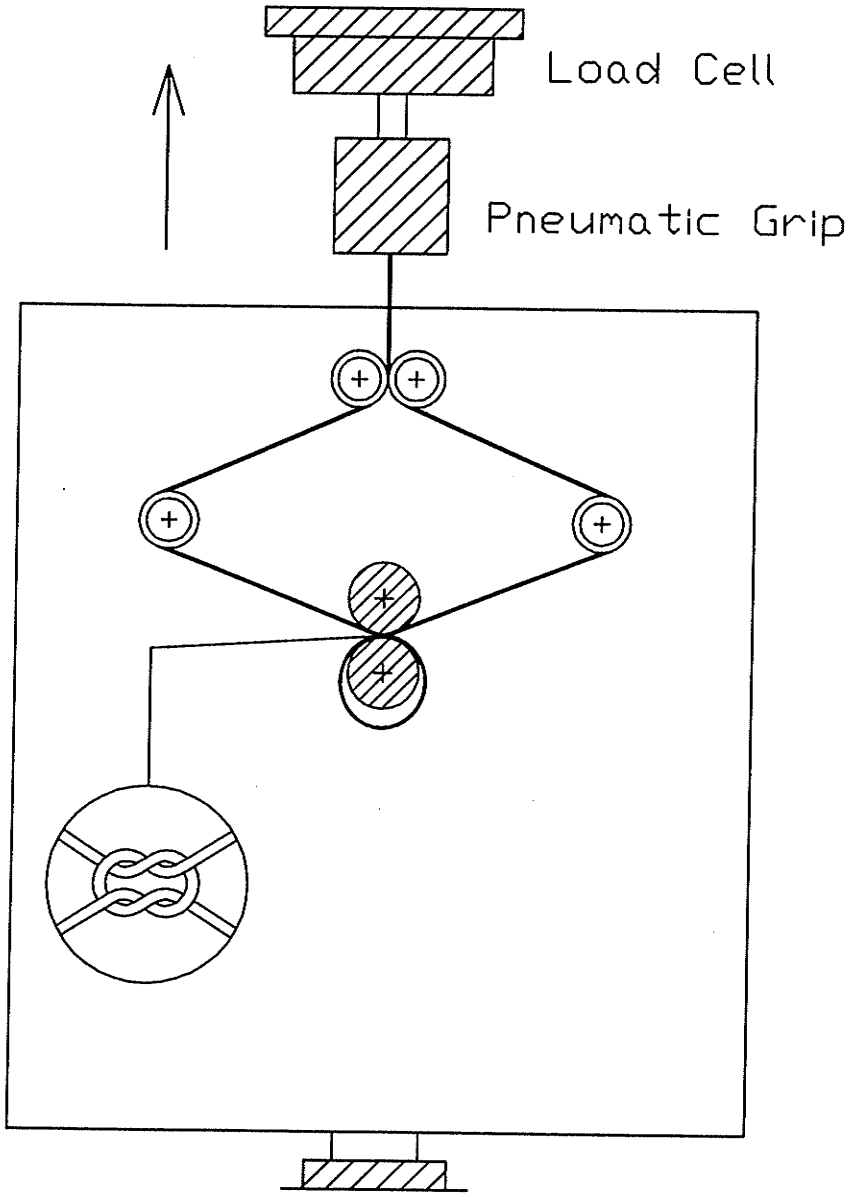

Figure 4. Knot snug-down device.

force would reach the capacity of the load cell, the test would automatically be stopped and a value of zero knot snug-down was recorded.

Knot security. A device was developed and fitted to the Instron universal tester for performing the knot security test (Fig. 5). In order to ensure that the knot failed and broke open during the test, and did not slide open, two brands of knots were used on different sutures. A knot consisting of a granny knot followed by a square knot (1x1x1=1) was tied on the monofilament sutures, while a knot consisting of two continuous square knots (1=1=1=1) was used with the braided sutures. These knots were used to make and place a loop of suture around two pins 15 mm in diameter and the knot ears were cut to 5 mm in length. A CTM load cell of 100 kg capacity, and an initial gauge length of 10 mm (the distance between the two pins) were used for the test. The two pins were forced apart at a crosshead speed of 90 mm/min. Ten specimens were tested for each size and brand of suture, and the average knot security force was calculated for each.

In the knot security test a bursting force is applied inside the suture loop. This applies a tensile force at the patient's side of the knot and causes the knot to break open. It is different from knot-pull strength, since the latter test applies a tensile force at the physician's side of the knot (i.e. the side of the knot with ears), and causes the knot to tighten.

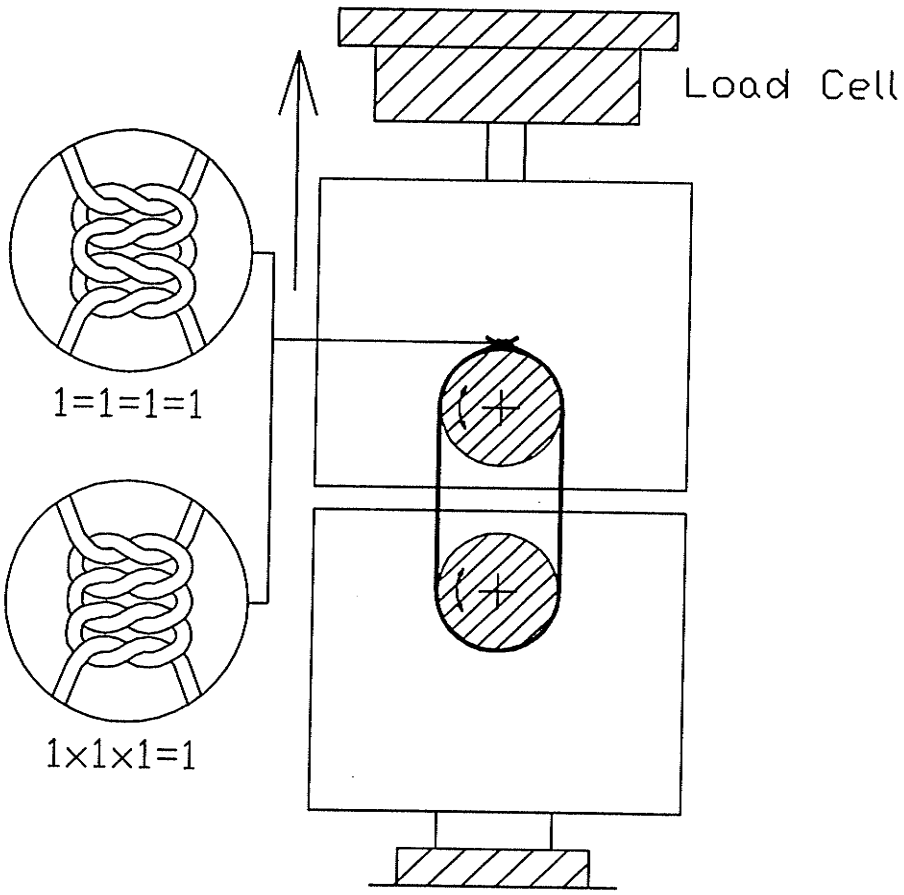

Figure 5. Knot security device.

Testing Conditions

Except for the wet tissue drag test, all samples were tested promptly after removal from their containers (USP, 1990). The wet sample used to measure tissue drag was prepared by immersing the suture in 0.9% saline solution for 5 minutes at 22°C prior to testing. All tests were performed under standard conditions of 21° ± 1°C, and 65% ± 2% relative humidity.

CHAPTER IV

RESULTS AND DISCUSSION

This chapter presents the test results of the performance properties of the sutures, describes the data analysis including the hypothesis testing and the correlation analysis, and discusses the reliability of the customized test methods and accessory devices,.

Performance Properties of Sutures

The first purpose of the study was to evaluate Teflene® sutures, and compare their performance properties with other monofilament, as well as braided sutures. The second purpose of the study was to compare the performance properties of a New Surgilene® suture with the Old Surgilene® suture. The results of performance property tests are presented and discussed in this section. They include suture diameter, tensile strength and elongation, surface roughness and coefficient of friction, bending stiffness, tissue drag, knot pull strength, knot run-down, knot snug-down, and knot security.

Suture Diameter

The results of suture diameter for each size and brand of suture are summarized in Table 9 and shown in Figure 6. The average diameter of each size of Prolene®, New Surgilene®, and Old Surgilene® suture falls within the range prescribed in the USP. The average diameter of size 2-0 and 5-0 of Teflene® suture, size 2-0, 3-0 and 5-0 of Ethibond® suture, and size 2-0, 4-0 and 5-0 of Ti-Cron® suture also fall within the range.

However, the average diameters of size 3-0 and 4-0 Teflene suture are 10% and 4% larger than the maximum diameter required by the USP respectively. In addition, the average diameter of size 4-0 Ethibond® suture is 0.5% larger than the maximum diameter, and the average diameter of size 3-0 Ti-Cron® suture is 2% smaller than the minimum diameter required by the USP.

Table 9

Diameters of Sutures

	Diameter (mean ± S.D.) (mm)			
	Size 2-0 (N=10)	Size 3-0 (N=10)	Size 4-0 (N=10)	Size 5-0 (N=10)
Monofilament				
Teflene®	0.302 ± 0.005	0.274 ± 0.004	0.207 ± 0.003	0.145 ± 0.003
Prolene®	0.311 ± 0.005	0.246 ± 0.006	0.185 ± 0.002	0.134 ± 0.002
New Surgilene®	0.332 ± 0.007	0.240 ± 0.009	0.193 ± 0.004	0.143 ± 0.004
Old Surgilene®	0.331 ± 0.009	0.243 ± 0.004	0.199 ± 0.002	0.142 ± 0.005
Braided				
Ethibond®	0.325 ± 0.002	0.231 ± 0.007	0.200 ± 0.009	0.133 ± 0.009
Ti-Cron®	0.306 ± 0.003	0.196 ± 0.008	0.155 ± 0.003	0.123 ± 0.005
USP Prescribed Range for Average Diameters (mm)	0.300-0.339	0.200-0.249	0.150-0.199	0.100-0.149

In general, the diameters of sutures, especially smaller size sutures, are at the upper end of the USP limits. It is believed that the reason for this is because manufacturers want to maximize the sutures' mechanical properties (Kusy & Whitley, 1983). In contrast the diameter of the 2-0 size Teflene® suture is not only at the lower end of the USP range,

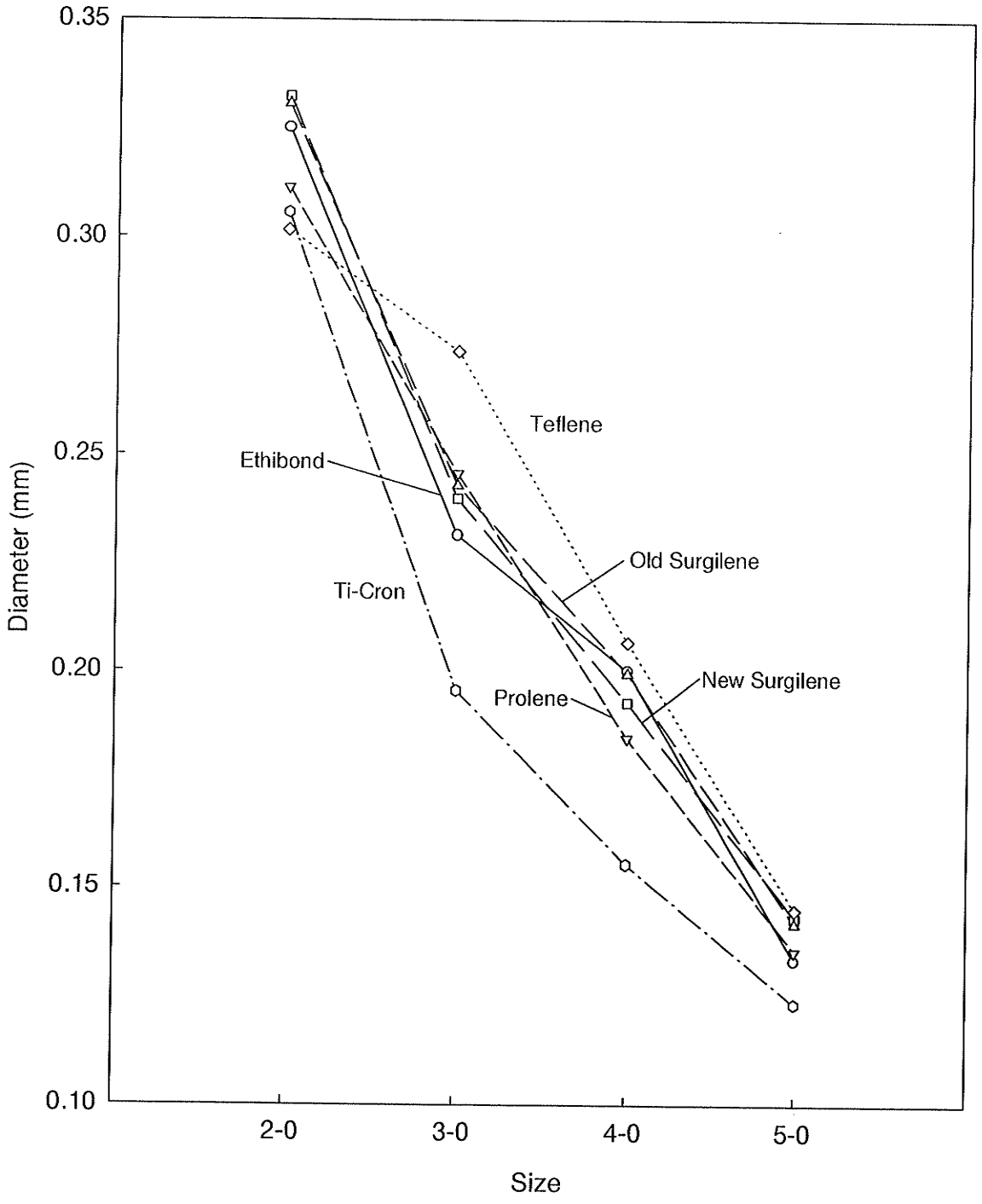

Figure 6. Diameter by size.

but also is the finest of all the sutures tested. As will be seen later this has implications for the tensile strength, knot pull strength and knot security values for the size 2-0 Teflene®.

Tensile Strength and Elongation

The average tensile strength of each size and brand of suture is presented in Table 10. As anticipated, the tensile strength is directly related to the suture diameter. Braided sutures have a higher tensile strength than monofilament sutures. Figure 7 shows that the tensile strengths of Teflene® and the other three monofilament sutures are very similar for sizes 3-0, 4-0 and 5-0. However, the 2-0 size Teflene® is much weaker than all the other 2-0 sutures tested (Figure 7). This is primarily due to its finer diameter.

Table 10

Tensile Strength of Sutures

	Tensile Strength (mean ± S.D.) (N)			
	Size 2-0	Size 3-0	Size 4-0	Size 5-0
	(N=10)	(N=10)	(N=10)	(N=10)
Monofilament				
Teflene®	26.1 ± 1.2	21.7 ± 1.4	14.5 ± 0.4	8.1 ± 0.5
Prolene®	39.2 ± 2.5	22.5 ± 3.8	15.7 ± 0.8	8.5 ± 0.7
New Surgilene®	40.9 ± 4.4	24.0 ± 0.6	16.8 ± 0.4	9.8 ± 0.7
Old Surgilene®	39.8 ± 5.8	23.8 ± 1.7	14.6 ± 1.2	7.4 ± 0.8
Braided				
Ethibond®	44.2 ± 1.7	30.9 ± 1.4	21.9 ± 0.8	9.4 ± 0.9
Ti-Cron®	54.7 ± 4.9	30.2 ± 1.5	21.9 ± 0.8	10.8 ± 0.7

The average elongation of each size and brand of suture is summarized in Table 11. A wide range of elongation was observed (Figure 8). Monofilament sutures have

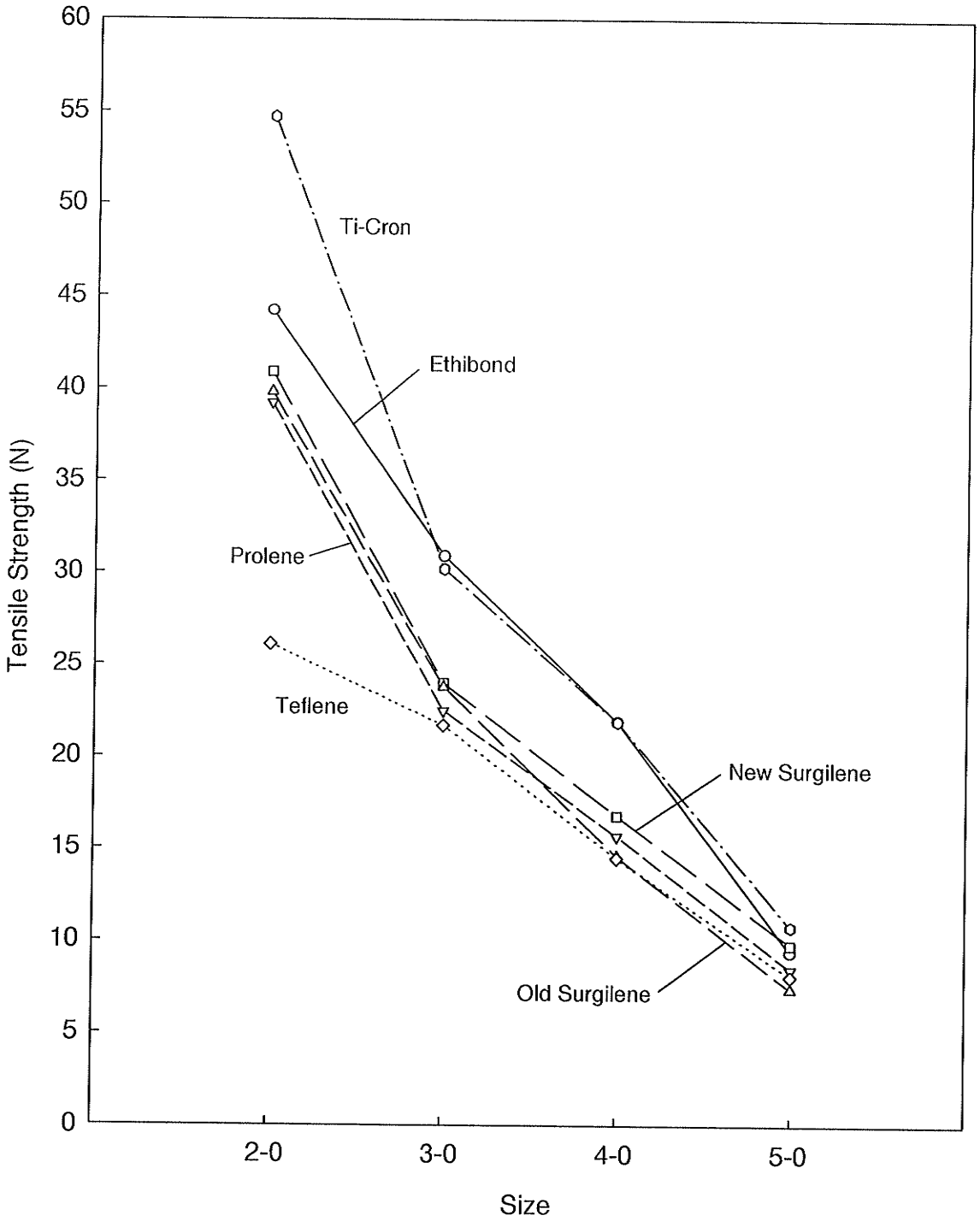

Figure 7. Tensile strength by size.

higher elongation (26-61%) than braided sutures (11-21%). Teflene® has the highest elongation among all the sutures tested. Its elongation is about 50% higher than that of the other three monofilament sutures. This result is consistent with the findings reported previously by Urban (1994). Elongation does not appear to be diameter dependent.

Table 11

Elongation of Sutures

	Elongation (mean ± S.D.) (%)			
	Size 2-0 (N=10)	Size 3-0 (N=10)	Size 4-0 (N=10)	Size 5-0 (N=10)
Monofilament				
Teflene®	61.1 ± 6.0	53.4 ± 2.5	55.5 ± 4.2	49.4 ± 6.9
Prolene®	38.1 ± 4.6	31.8 ±11.0	38.3 ± 5.3	33.0 ± 5.8
New Surgilene®	30.3 ± 7.3	43.7 ± 6.2	40.4 ± 3.2	29.5 ± 4.7
Old Surgilene®	28.3 ± 9.0	33.7 ± 5.6	26.5 ± 2.7	29.1 ± 4.4
Braided				
Ethibond®	11.3 ± 0.7	13.4 ± 2.2	12.3 ± 1.3	10.8 ± 1.3
Ti-Cron®	16.5 ± 0.8	13.8 ± 0.8	12.6 ± 0.5	20.7 ± 3.6

Surface Roughness and Coefficient of Friction

The average values for surface roughness of each size and brand of suture are summarized in Table 12. It is evident that for all sizes, Teflene® and the other monofilament sutures, Prolene®, New Surgilene® and Old Surgilene®, have very low and nearly identical surface roughness (Figure 9). On the other hand, the braided sutures such as Ethibond® and Ti-Cron® have three to twelve times greater surface roughness than the monofilaments. This result may be explained by the uneven topography of the braided structure.

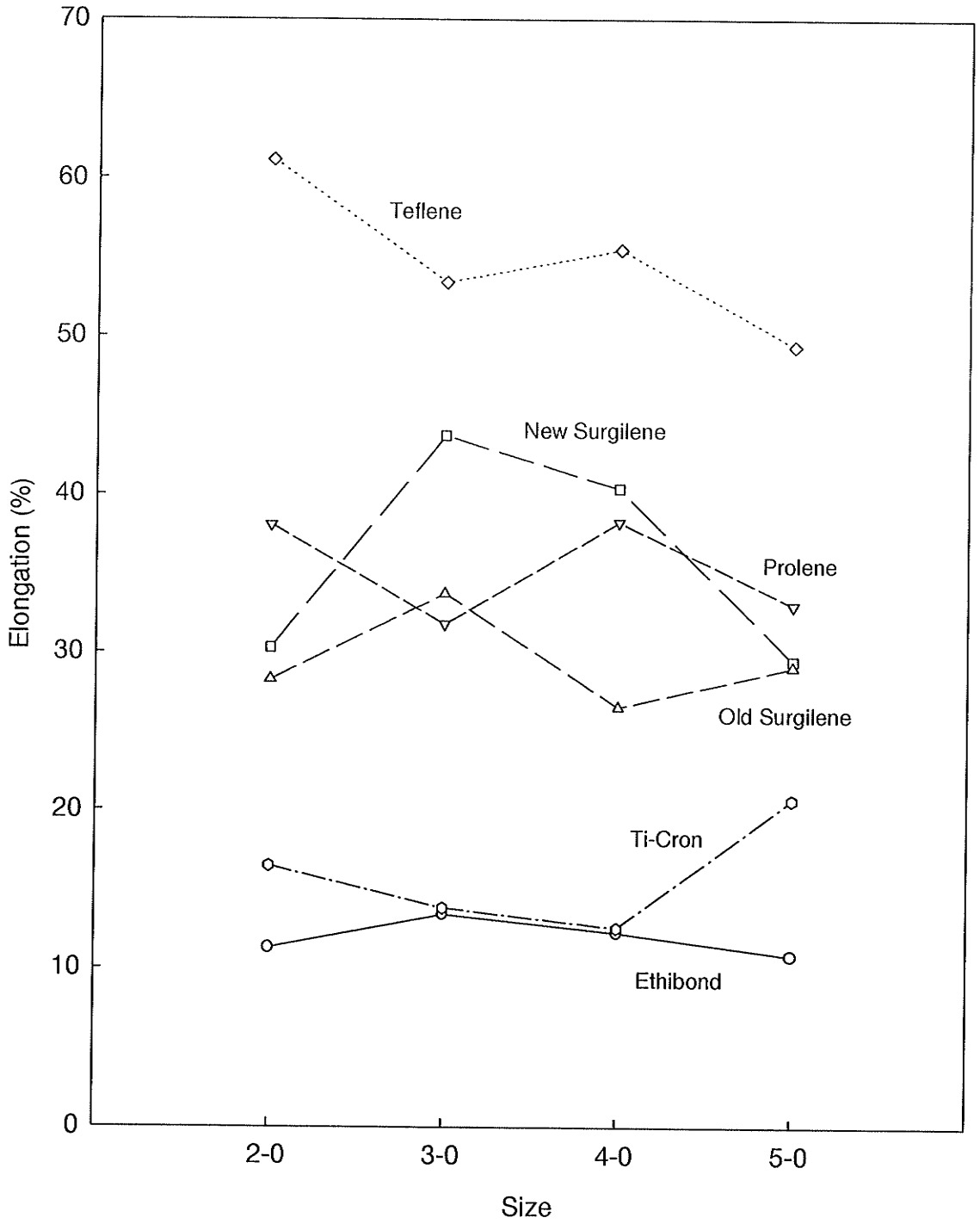

Figure 8. Elongation by size.

The average coefficient of friction for each size and brand of suture are presented in Table 13. The results of coefficient of friction vary from suture to suture, and do not appear to be size dependent (Figure 10). The Teflene® sutures have a low or the lowest coefficient of friction, compared to the other sutures.

Table 12

Surface Roughness of Sutures

	Surface Roughness (mean ± S.D.) (micro)			
	Size 2-0	Size 3-0	Size 4-0	Size 5-0
	(N=10)	(N=10)	(N=10)	(N=10)
Monofilament				
Teflene®	0.15 ± 0.05	0.18 ± 0.06	0.14 ± 0.02	0.14 ± 0.03
Prolene®	0.18 ± 0.06	0.15 ± 0.05	0.13 ± 0.03	0.12 ± 0.01
New Surgilene®	0.13 ± 0.01	0.12 ± 0.01	0.13 ± 0.02	0.12 ± 0.01
Old Surgilene®	0.12 ± 0.01	0.12 ± 0.01	0.12 ± 0.01	0.12 ± 0.01
Braided				
Ethibond®	1.75 ± 0.67	0.72 ± 0.39	1.07 ± 0.20	0.86 ± 0.16
Ti-Cron®	1.62 ± 0.65	0.46 ± 0.29	1.05 ± 0.48	0.97 ± 0.09

Table 13

Coefficient of Friction of Sutures

	Coefficient of Friction (mean ± S.D.)			
	Size 2-0	Size 3-0	Size 4-0	Size 5-0
	(N=10)	(N=10)	(N=10)	(N=10)
Monofilament				
Teflene®	1.00 ± 0.14	1.01 ± 0.11	1.04 ± 0.14	1.24 ± 0.18
Prolene®	1.53 ± 0.13	1.41 ± 0.10	1.44 ± 0.08	1.66 ± 0.24
New Surgilene®	1.27 ± 0.15	0.99 ± 0.27	1.26 ± 0.08	1.18 ± 0.13
Old Surgilene®	1.15 ± 0.24	1.06 ± 0.11	0.83 ± 0.08	1.33 ± 0.17
Braided				
Ethibond®	1.57 ± 0.21	1.16 ± 0.20	1.20 ± 0.12	1.47 ± 0.23
Ti-Cron®	1.39 ± 0.22	1.09 ± 0.16	1.44 ± 0.18	1.46 ± 0.20

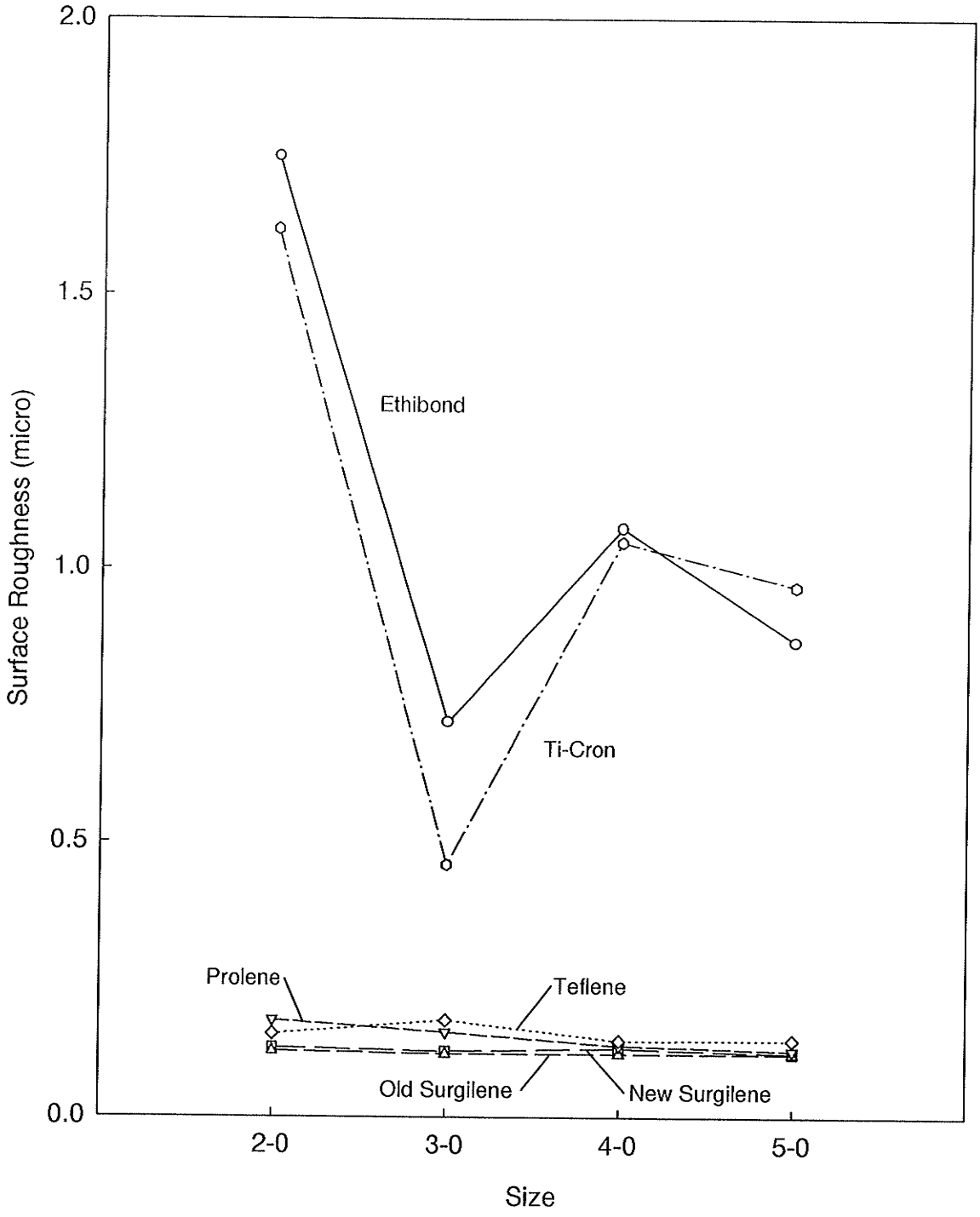

Figure 9. Surface roughness by size.

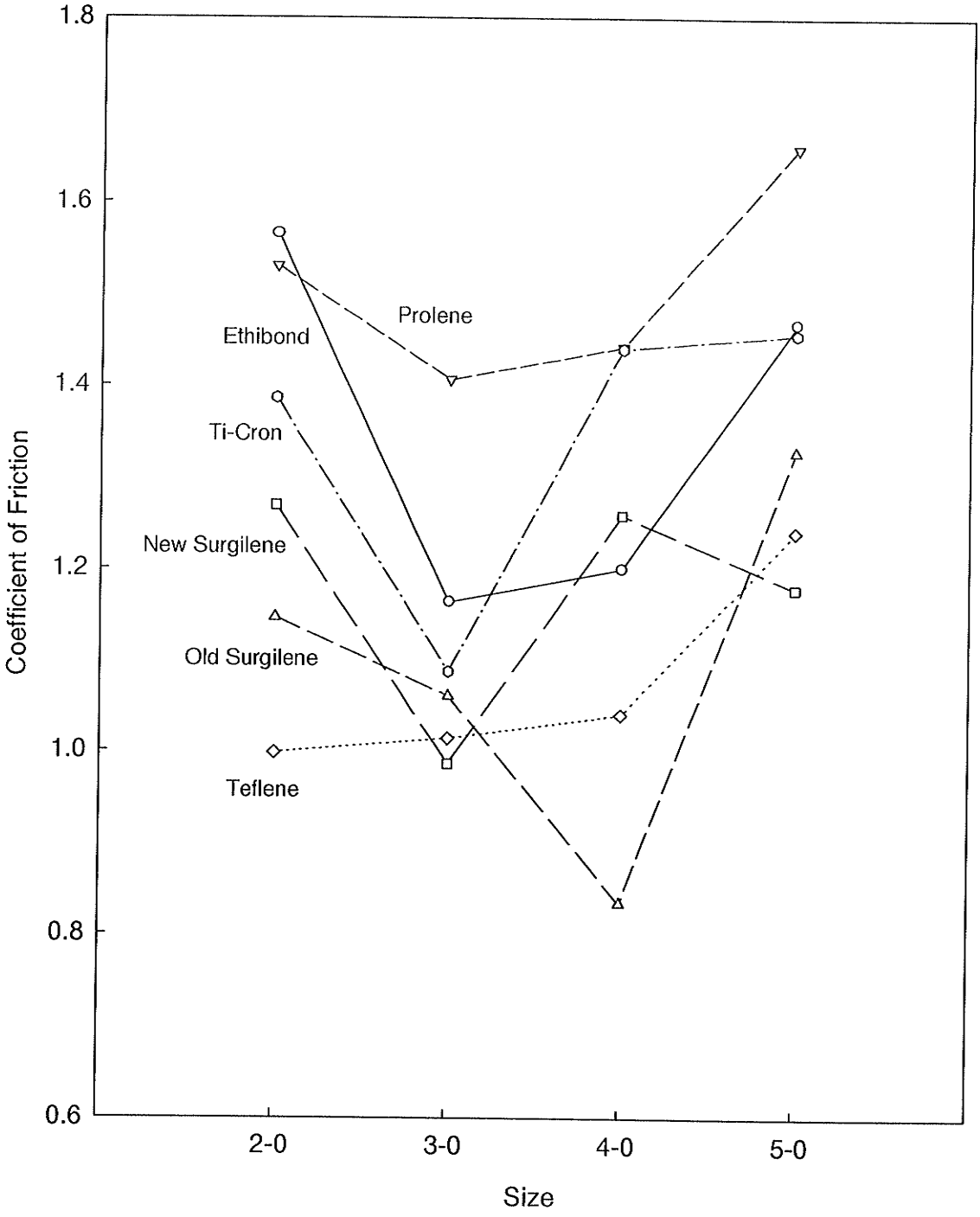

Figure 10. Coefficient of friction by size.

Bending Stiffness

The average bending stiffness of each size and brand of suture is shown in Table 14. Teflene® has by far the highest bending stiffness amongst all the sutures tested, while the other three monofilament sutures, Prolene®, New Surgilene® and Old Surgilene®, have similar and much lower bending stiffness values (Figure 11). It seems that the bending stiffness of monofilament sutures appears to be size dependent, being directly related to suture diameter. This result is consistent with the findings reported by Chu and Kizil (1989).

Table 14

Bending Stiffness of Sutures

	Bending Stiffness (mean ± S.D.) (g·cm)			
	Size 2-0	Size 3-0	Size 4-0	Size 5-0
	(N=10)	(N=10)	(N=10)	(N=10)
Monofilament				
Teflene®	2.48 ± 0.35	2.05 ± 0.28	1.57 ± 0.16	1.51 ± 0.16
Prolene®	1.28 ± 0.05	0.92 ± 0.14	0.71 ± 0.07	0.57 ± 0.04
New Surgilene®	1.27 ± 0.15	1.09 ± 0.13	0.78 ± 0.07	0.56 ± 0.06
Old Surgilene®	1.74 ± 0.45	1.14 ± 0.08	0.89 ± 0.06	0.64 ± 0.05
Braided				
Ethibond®	0.58 ± 0.09	0.95 ± 0.13	0.54 ± 0.08	0.48 ± 0.10
Ti-Cron®	1.68 ± 0.11	1.03 ± 0.09	1.28 ± 0.13	0.53 ± 0.13

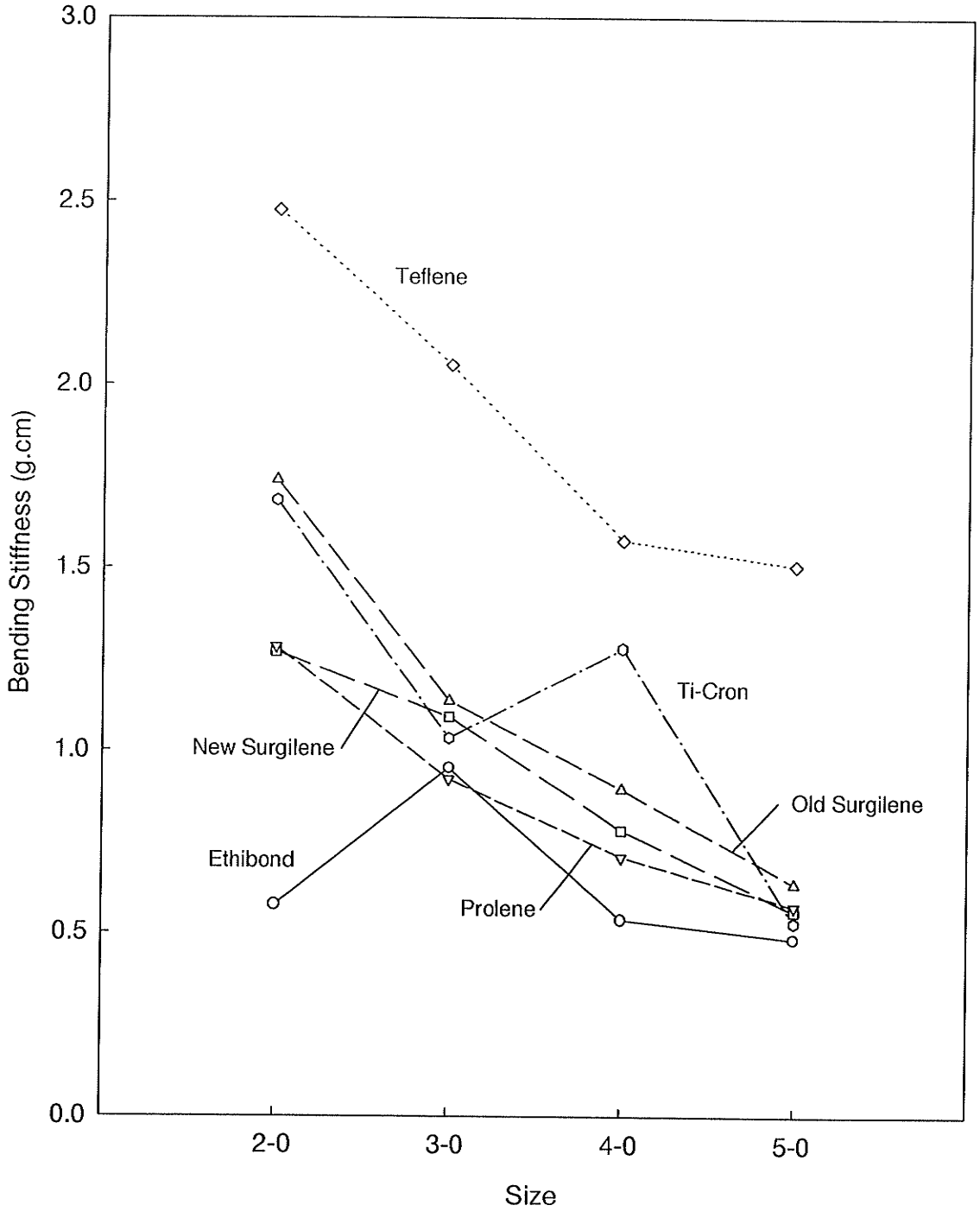

Figure 11. Bending stiffness by size.

Tissue Drag

The average tissue drag of each size and brand of suture in the dry condition is summarized in Table 15. The results for the Teflene® sutures fall within the range of the other monofilament sutures and are similar to Old Surgilene® for size 3-0, 4-0 and 5-0 (Figure 12). Dry tissue drag does not appear to be size dependent. Prolene® has a much higher dry tissue drag than all the other sutures tested.

Table 15

Tissue Drag in Dry Condition of Sutures

	Tissue Drag in Dry Condition (mean ± S.D.) (N)			
	Size 2-0	Size 3-0	Size 4-0	Size 5-0
	(N=10)	(N=10)	(N=10)	(N=10)
Monofilament				
Teflene®	1.61 ± 0.24	1.27 ± 0.35	1.34 ± 0.19	1.23 ± 0.36
Prolene®	1.87 ± 0.38	3.03 ± 0.50	2.72 ± 0.59	1.72 ± 0.27
New Surgilene®	1.05 ± 0.10	0.76 ± 0.06	0.52 ± 0.06	0.66 ± 0.05
Old Surgilene®	1.21 ± 0.34	1.31 ± 0.36	1.51 ± 0.20	1.20 ± 0.14
Braided				
Ethibond®	0.62 ± 0.14	1.36 ± 0.08	1.38 ± 0.15	1.14 ± 0.12
Ti-Cron®	0.91 ± 0.10	0.52 ± 0.02	0.55 ± 0.15	0.17 ± 0.12

The average tissue drag for each size and brand of suture in the wet condition is shown in Table 16. Comparing Figure 13 with Figure 12, which were drawn in the same scale, it is obvious that the wet tissue drag is lower than the dry tissue drag for the same suture. In general, the results of tissue drag in the wet condition are less than those in the dry condition. This is particularly evident for Prolene® sutures which are often wetted out

in the operation room in order to improve their dry characteristics (R. P. Guzman, personal communication, June 9, 1995). This improvement is believed to be due to the effect of lubrication by the water. Like the performance in the dry condition, the wet tissue drag of Teflene® falls within the range defined by the other monofilament sutures, and is similar to that of Old Surgilene® (Figure 13). Tissue drag in the wet condition also does not appear to be size dependent.

Table 16

Tissue Drag in Wet Condition of Sutures

	Tissue Drag in Wet Condition (mean ± S.D.) (N)			
	Size 2-0	Size 3-0	Size 4-0	Size 5-0
	(N=10)	(N=10)	(N=10)	(N=10)
Monofilament				
Teflene®	0.65 ± 0.08	0.66 ± 0.12	0.59 ± 0.12	0.49 ± 0.06
Prolene®	0.43 ± 0.05	0.84 ± 0.15	0.66 ± 0.18	0.60 ± 0.16
New Surgilene®	0.56 ± 0.04	0.42 ± 0.03	0.50 ± 0.02	0.34 ± 0.01
Old Surgilene®	0.84 ± 0.14	0.58 ± 0.10	0.54 ± 0.09	0.46 ± 0.08
Braided				
Ethibond®	0.29 ± 0.06	0.81 ± 0.14	0.88 ± 0.18	0.68 ± 0.17
Ti-Cron®	0.92 ± 0.19	0.69 ± 0.07	0.69 ± 0.08	0.60 ± 0.14

Knot Pull Strength

The average knot pull strength of each size and brand of suture is shown in Table 17. The average knot pull strength for Teflene® and all the other sutures tested is well above the minimum limits specified by the USP. Size 3-0, 4-0, and 5-0 Teflene® sutures have similar knot pull strengths as the other brands, but the size 2-0 is weaker than the

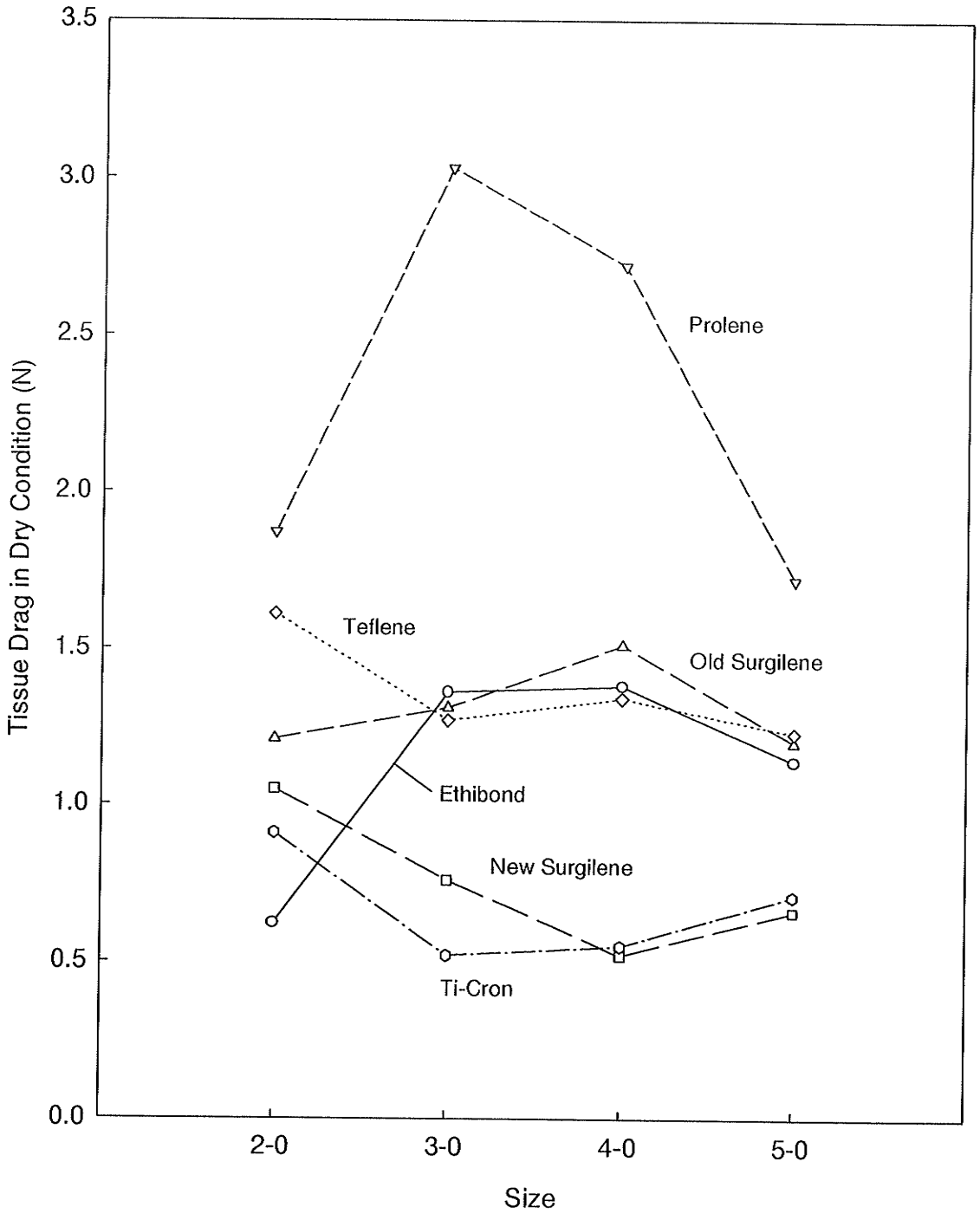

Figure 12. Tissue drag in dry condition by size.

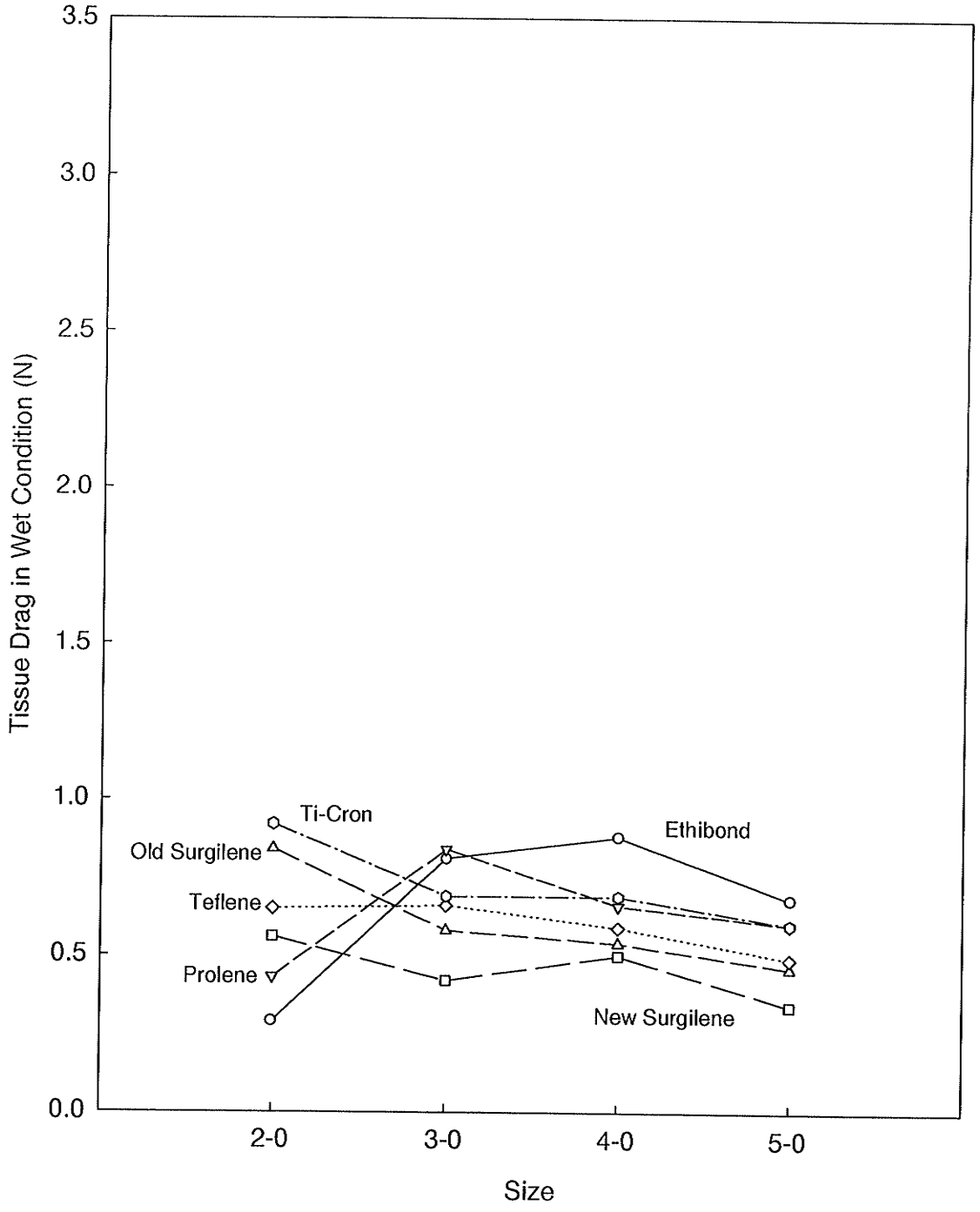

Figure 13. Tissue drag in wet condition by size.

others (Figure 14). This is most likely due in part to its finer diameter. As anticipated, the knot pull strength for each brand increases directly with the suture diameter.

Table 17

Knot Pull Strength of Sutures

	Knot Pull Strength (mean ± S.D.) (N)			
	Size 2-0	Size 3-0	Size 4-0	Size 5-0
	(N=10)	(N=10)	(N=10)	(N=10)
Monofilament				
Teflene®	20.4 ± 1.4	17.6 ± 0.8	11.0 ± 0.7	6.2 ± 0.2
Prolene®	26.1 ± 4.1	16.5 ± 1.2	10.1 ± 0.6	6.4 ± 0.6
New Surgilene®	25.9 ± 1.7	16.2 ± 1.4	10.7 ± 0.7	6.0 ± 0.7
Old Surgilene®	27.1 ± 1.5	16.1 ± 0.5	9.7 ± 0.8	6.6 ± 0.6
Braided				
Ethibond®	24.6 ± 1.7	16.9 ± 1.4	11.3 ± 0.9	6.1 ± 0.5
Ti-Cron®	25.3 ± 1.0	15.0 ± 1.0	11.8 ± 2.6	7.1 ± 0.5
USP Prescribed the Minimum for Average Knot Pull Strength (N)	14.1	9.4	5.9	3.9

Knot Run-Down

The average knot run-down of each size and brand of suture is shown in Table 18. The knot run-down of Teflene® appears to be much lower than those of the other three monofilament sutures, Prolene®, New Surgilene® and Old Surgilene®, and in fact is similar to those of the two braided sutures, Ethibond® and Ti-Cron® (Figure 15). There does not appear to be an obvious explanation for this unexpected result. The knot run-down of monofilament sutures seems to be size dependent, being directly related to suture diameter.

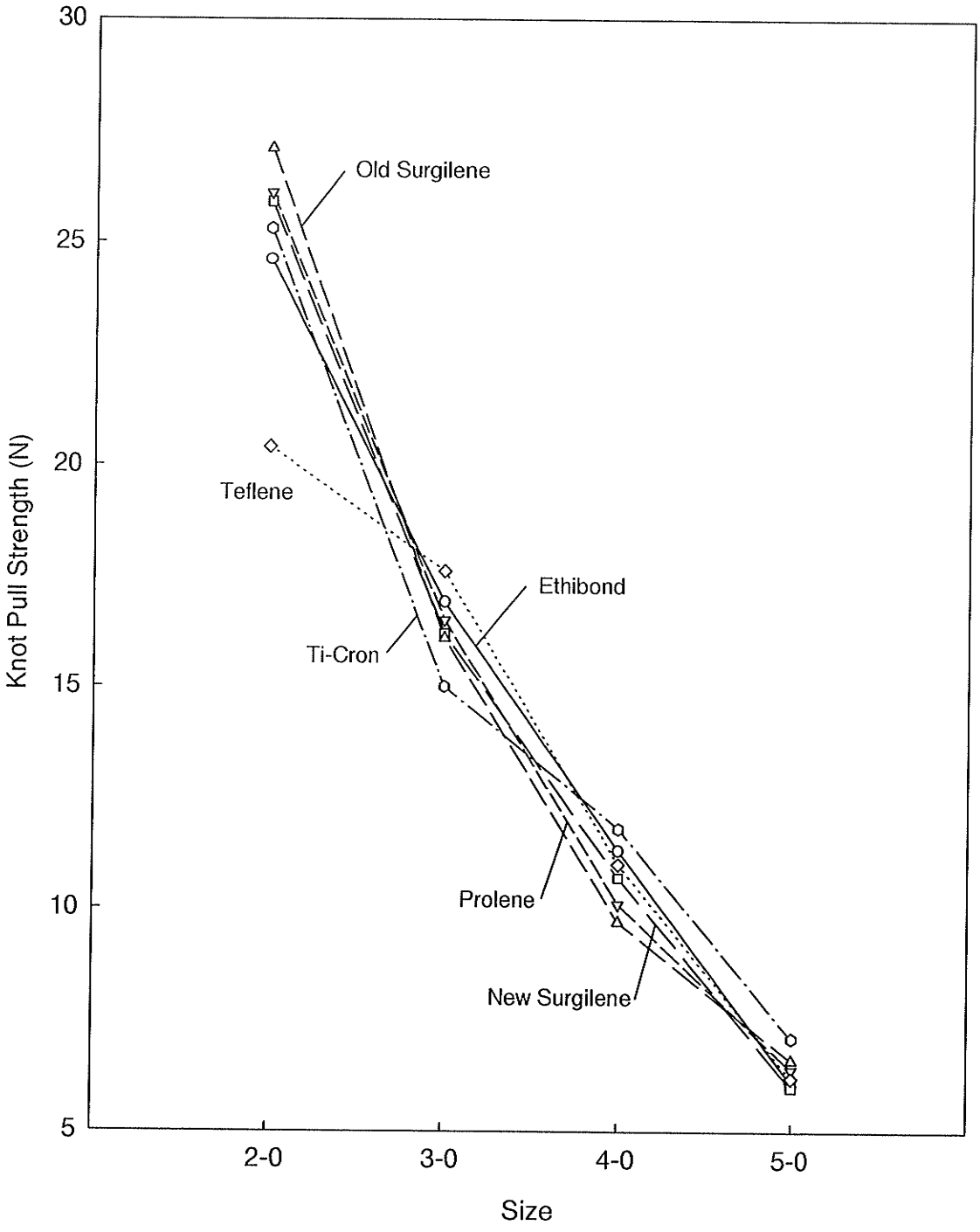

Figure 14. Knot pull strength by size.

Table 18

Knot Run-Down of Sutures

	Knot Run-Down (mean ± S.D.) (N)			
	Size 2-0	Size 3-0	Size 4-0	Size 5-0
	(N=10)	(N=10)	(N=10)	(N=10)
Monofilament				
Teflene®	0.60 ± 0.04	0.58 ± 0.04	0.57 ± 0.01	0.55 ± 0.02
Prolene®	0.81 ± 0.03	0.78 ± 0.03	0.75 ± 0.02	0.72 ± 0.01
New Surgilene®	0.86 ± 0.07	0.73 ± 0.02	0.71 ± 0.11	0.69 ± 0.02
Old Surgilene®	0.83 ± 0.03	0.71 ± 0.03	0.72 ± 0.03	0.67 ± 0.01
Braided				
Ethibond®	0.60 ± 0.02	0.59 ± 0.01	0.60 ± 0.02	0.60 ± 0.03
Ti-Cron®	0.64 ± 0.03	0.56 ± 0.02	0.63 ± 0.02	0.64 ± 0.01

Knot Snug-Down

The researcher observed during the knot snug-down testing of the monofilament sutures that the knot was totally immobile. The granny knot tightened, rather than moved, making it impossible to measure the knot snug-down. The average knot snug-down of each size of braided suture is presented in Table 19. The knot snug-down of braided sutures does appear to be size dependent, being directly related to suture diameter (Figure 16).

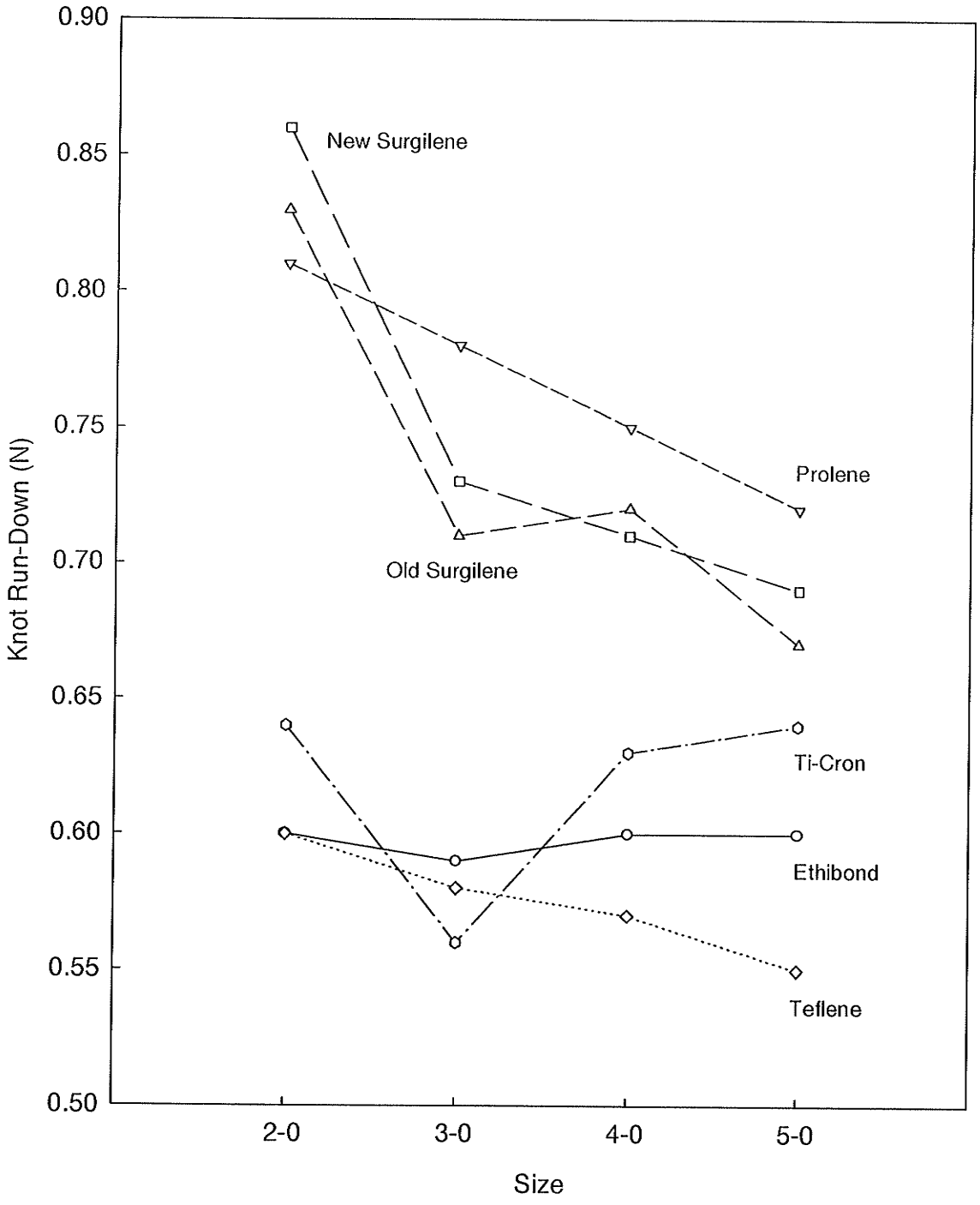

Figure 15. Knot run-down by size.

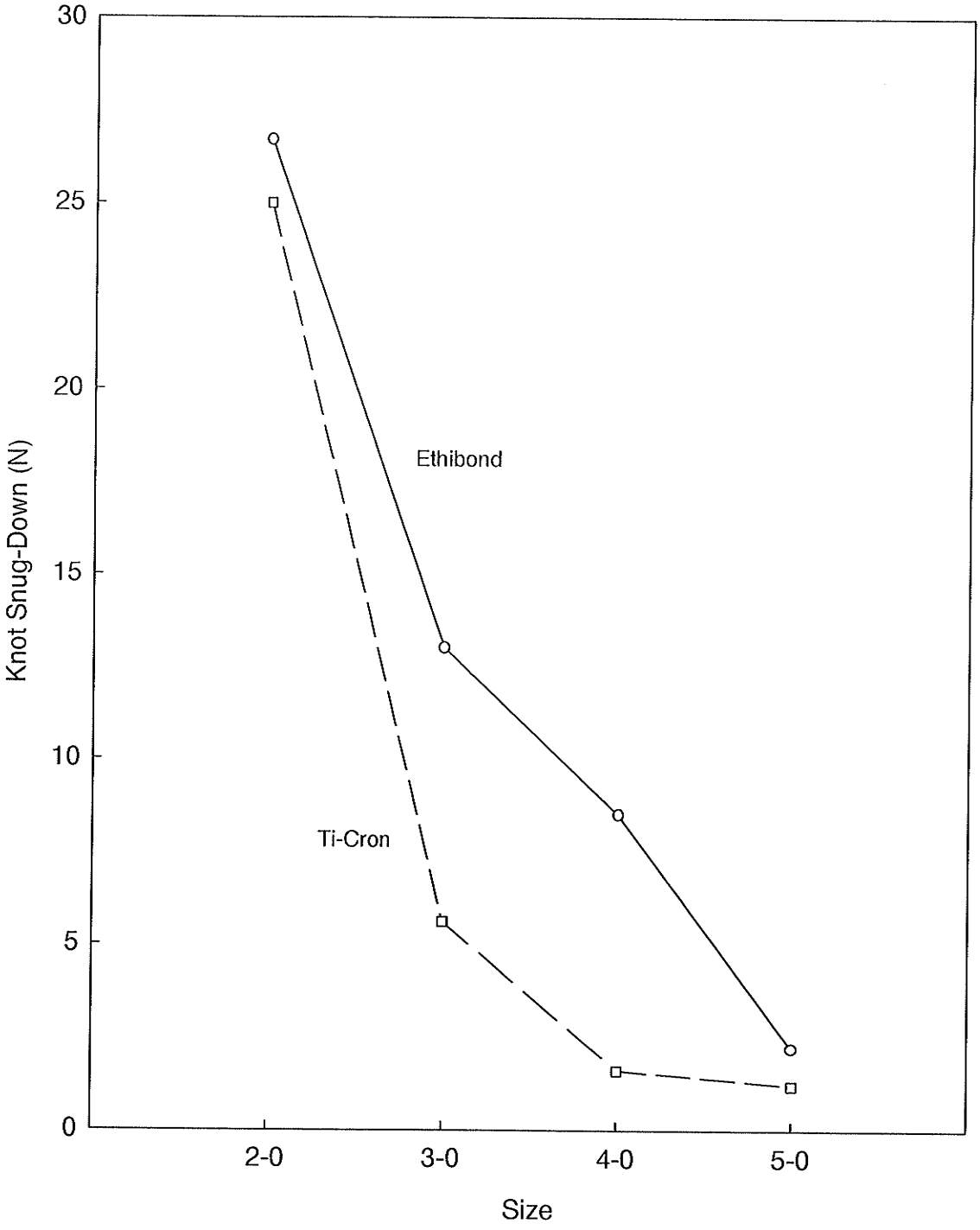

Figure 16. Knot snug-down by size.

Table 19

Knot Snug-Down of Sutures

	Knot Snug-Down (mean ± S.D.) (N)			
	Size 2-0	Size 3-0	Size 4-0	Size 5-0
	(N=10)	(N=10)	(N=10)	(N=10)
Braided				
Ethibond®	26.7 ± 3.9	13.0 ± 3.4	8.5 ± 3.3	2.2 ± 0.7
Ti-Cron®	25.0 ± 4.3	5.6 ± 2.0	1.6 ± 0.3	1.2 ± 0.4

Knot Security

The average knot security of each size and brand of suture is summarized in Table 20. Teflene® and the other sutures of size 3-0, 4-0 and 5-0 have similar values for knot security, but the value for the 2-0 size Teflene® is lower than for the other brands (Figure 17). This is likely to be due in part to its finer diameter. As anticipated, knot security appears to be size dependent, increasing directly with suture diameter.

Table 20

Knot Security of Sutures

	Knot Security (mean ± S.D.) (N)			
	Size 2-0	Size 3-0	Size 4-0	Size 5-0
	(N=10)	(N=10)	(N=10)	(N=10)
Monofilament				
Teflene®	38.1 ± 5.6	29.2 ± 3.3	18.1 ± 1.5	10.8 ± 1.1
Prolene®	50.6 ± 6.5	26.9 ± 3.5	18.6 ± 3.6	11.3 ± 1.3
New Surgilene®	49.1 ± 8.5	29.0 ± 4.2	20.0 ± 2.6	11.7 ± 1.1
Old Surgilene®	50.3 ± 8.0	29.1 ± 3.1	19.4 ± 2.7	10.6 ± 1.3
Braided				
Ethibond®	44.4 ± 3.3	33.8 ± 3.1	21.4 ± 2.6	12.1 ± 1.4
Ti-Cron®	52.5 ± 2.7	25.4 ± 1.9	18.5 ± 2.1	12.7 ± 1.0

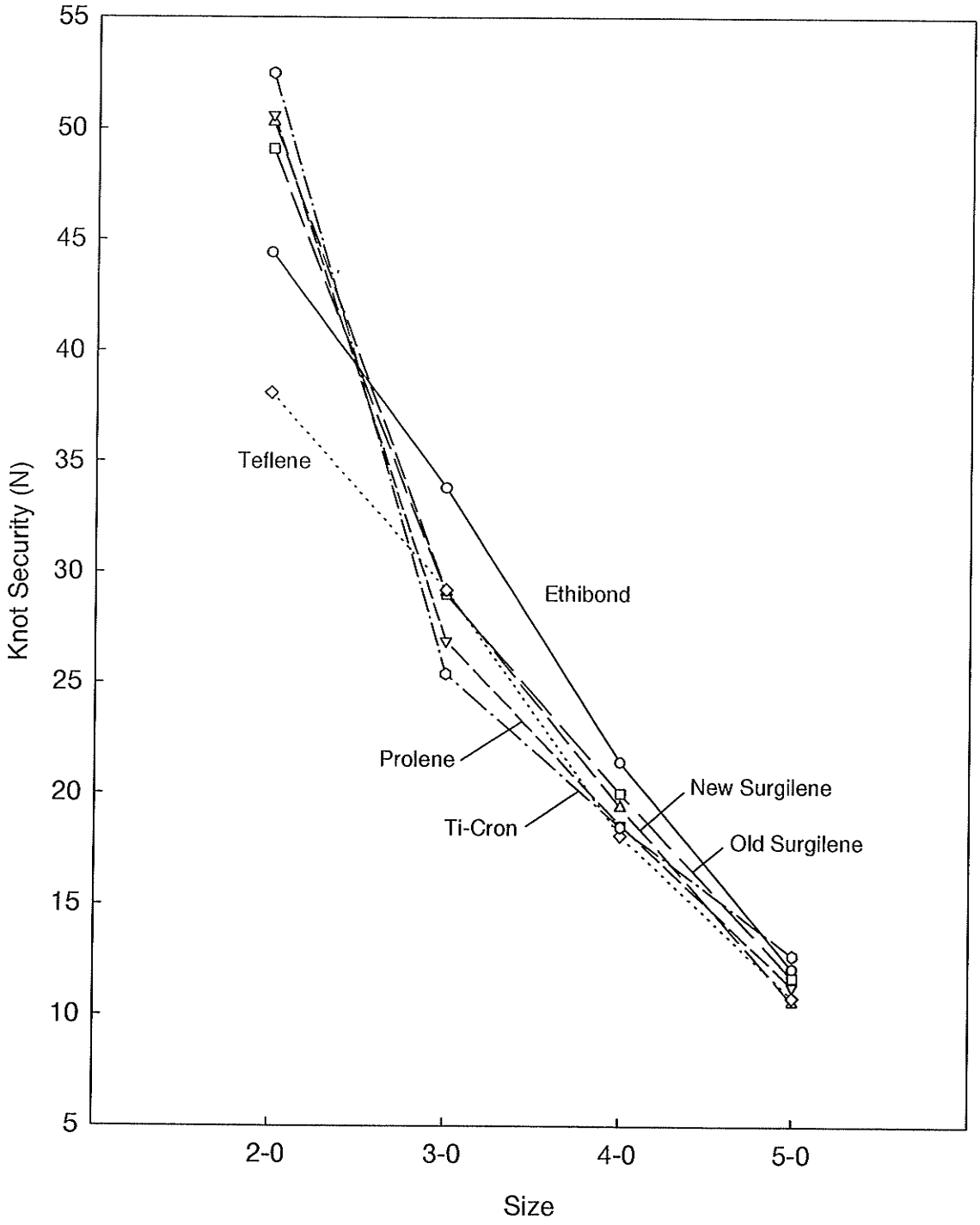

Figure 17. Knot security by size.

Hypothesis Testing

This section presents the results of hypothesis testing. A 0.05 level of significance was used for all the hypotheses. Hypotheses were tested using analysis of variance.

Three assumptions have to be met in order for data to be suitable for an analysis of variance (Anova): (i) the observations are independent; (ii) the observations are sampled from a normal distribution; and (iii) the groups have equal variances. The first and third assumptions have been met in this study. A test for normality was performed on the data set of each property. The data sets for diameter and knot run-down were found to have a normal distribution. The other data sets were transformed by conversion to a natural logarithm, resulting in normal distributions. Therefore, all three assumptions were met.

Two-way Analysis of Variance

The three hypotheses tested are:

Hypothesis 1: There is no difference in the performance properties between different brands of sutures.

Hypothesis 2: There is no difference in the performance properties between different sizes of sutures.

Hypothesis 3: There is no difference in the performance properties between different brands and sizes of sutures.

To test these three hypotheses, a two-way analysis of variance test was conducted on the means of each property of each size and brand of suture so as to determine whether

the size, the brand, and their interaction influenced each property. The results are listed in Table 21.

Hypothesis 1 was rejected for all properties except knot pull strength. Sutures of different brands are significantly different for all the properties tested except knot pull strength. Hypothesis 2 was rejected for all properties except elongation. Sutures of different sizes are significantly different for all the properties tested except elongation. Also, Hypothesis 3 was rejected for all properties. The interaction effects between brand and size means that sutures of different brands and sizes are significantly different for all the properties tested. These results are not surprising, since with such a large amount of data (six brands, four sizes, thirteen properties and 312 means from a total of 3120 measurements), there is a wide variation of values in the Anova test when all the data are pooled together. In fact, the Anova test only gives a general overview, indicating that most of the means are different. It does not describe which mean value for a particular property of a specified brand and size of suture differs from which. Therefore, further analysis of variance of the means for each specific brand and size of suture was conducted so as to reveal such comparisons.

Table 21

Two-Way Analysis of Variance Results for Brand and Size

Performance Properties	p-Value		
	Brand	Size	Brand*Size
Diameter	0.0001	0.0001	0.0001
Tensile strength	0.0001	0.0001	0.0001
Elongation	0.0001	0.2312	0.0001
Bending stiffness	0.0001	0.0001	0.0001
Coefficient of friction	0.0001	0.0001	0.0001
Surface roughness	0.0001	0.0001	0.0001
Tissue drag (dry)	0.0001	0.0001	0.0001
Tissue drag (wet)	0.0001	0.0076	0.0001
Knot pull strength	0.5473	0.0001	0.0001
Knot run-down	0.0001	0.0001	0.0001
Knot snug-down	0.0001	0.0001	0.0001
Knot security	0.0021	0.0001	0.0001

Contrast Analysis of Variance

In order to serve the first and the second purposes of this study, i.e. the evaluation and comparison of Teflene® sutures with the other monofilament and braided sutures, and the comparison of New Surgilene® and Old Surgilene®, several contrast analyses of variance were performed for the means of each performance property of each size of suture. The comparisons were mainly conducted in three groups: (i) Teflene® vs. the other monofilament sutures, namely Prolene®, new Surgilene® and old Surgilene®; (ii) Teflene® vs. braided sutures, namely Ethibond® and Ti-Cron®; and (iii) New Surgilene® vs. Old Surgilene® sutures. The surface roughness was excluded from these contrast analyses of variance. Because the mean values for surface roughness of the monofilament sutures are much lower than those of braided sutures (Figure 9), this may have resulted in

a large amount of variability in the analysis.

The four parallel hypotheses were tested, one for each suture size.

Hypothesis 4: For size 2-0 sutures, there is no difference in the performance properties between:

a) Teflene® and the other monofilament sutures;

b) Teflene® and the braided sutures;

c) New Surgilene® and Old Surgilene® sutures.

Hypothesis 5: For size 3-0 suture, there is no difference in the performance properties between:

a) Teflene® and the other monofilament sutures;

b) Teflene® and the braided sutures;

c) New Surgilene® and Old Surgilene® sutures.

Hypothesis 6: For size 4-0 suture, there is no difference in the performance properties between:

a) Teflene® and the other monofilament sutures;

b) Teflene® and the braided sutures;

c) New Surgilene® and Old Surgilene® sutures.

Hypothesis 7: For size 5-0 suture, there is no difference in the performance properties between:

a) Teflene® and the other monofilament sutures;

b) Teflene® and the braided sutures;

c) New Surgilene® and Old Surgilene® sutures.

The results of the hypothesis testing are summarized in Tables 22, 23, 24 and 25.

Table 22

Contrast Analysis of Variance Results for Size 2-0 Sutures

Performance Properties	p-Value		
	Teflene® vs. the Other Monofilament Sutures	Teflene® vs. the Braided Sutures	New Surgilene® vs. Old Surgilene®
Diameter	0.0000	0.0000	0.4867
Tensile strength	0.0000	0.0000	0.6045
Elongation	0.0001	0.0000	0.5200
Bending stiffness	0.0000	0.0000	0.0000
Coefficient of friction	0.0004	0.0000	0.4705
Tissue drag (dry)	0.0076	0.0000	0.1813
Tissue drag (wet)	0.1178	0.0040	0.0000
Knot pull strength	0.0000	0.0000	0.2425
Knot run-down	0.0000	0.1534	0.0761
Knot security	0.0000	0.0000	0.6843

Table 23

Contrast Analysis of Variance Results for Size 3-0 Sutures

Performance Properties	p-Value		
	Teflene® vs. the Other Monofilament Sutures	Teflene® vs. the Braided Sutures	New Surgilene® vs. Old Surgilene®
Diameter	0.0000	0.0000	0.3074
Tensile strength	0.0231	0.0000	0.7776
Elongation	0.0001	0.0000	0.0029
Bending stiffness	0.0000	0.0000	0.4195
Coefficient of friction	0.2329	0.2516	0.1772
Tissue drag (dry)	0.0308	0.0000	0.0000
Tissue drag (wet)	0.1522	0.0358	0.0009
Knot pull strength	0.0028	0.0003	0.8907
Knot run-down	0.0000	0.7650	0.1052
Knot security	0.4177	0.8857	0.8686

Table 24

Contrast Analysis of Variance Results for Size 4-0 Sutures

Performance Properties	p-Value		
	Teflene® vs. the Other Monofilament Sutures	Teflene® vs. the Braided Sutures	New Surgilene® vs. Old Surgilene®
Diameter	0.0000	0.0000	0.0015
Tensile strength	0.0000	0.0000	0.0000
Elongation	0.0001	0.0000	0.0000
Bending stiffness	0.0000	0.0000	0.0070
Coefficient of friction	0.0074	0.0000	0.0000
Tissue drag (dry)	0.5125	0.0000	0.0000
Tissue drag (wet)	0.5916	0.0002	0.3999
Knot pull strength	0.0278	0.3564	0.3940
Knot run-down	0.0000	0.0000	0.1230
Knot security	0.2690	0.0975	0.6427

Table 25

Contrast Analysis of Variance Results for Size 5-0 Sutures

Performance Properties	p-Value		
	Teflene® vs. the Other Monofilament Sutures	Teflene® vs. the Braided Sutures	New Surgilene® vs. Old Surgilene®
Diameter	0.0143	0.0000	0.5492
Tensile strength	0.1761	0.0000	0.0000
Elongation	0.0001	0.0000	0.8572
Bending stiffness	0.0000	0.0000	0.0573
Coefficient of friction	0.0455	0.0037	0.0665
Tissue drag (dry)	0.2007	0.0000	0.0000
Tissue drag (wet)	0.2772	0.0016	0.0045
Knot pull strength	0.0642	0.3025	0.0123
Knot run-down	0.0000	0.0000	0.0028
Knot security	0.3187	0.0010	0.0384

Teflene® vs. the other monofilament sutures. Table 26 presents a summary of the contrast analyses of variance. For size 2-0 sutures, Hypothesis 4 was rejected for all the performance properties except for wet tissue drag. Size 2-0 Teflene® suture is different from the other monofilament sutures in all respects except for its wet tissue drag. For size 3-0 sutures, Hypothesis 5 was not rejected for several performance properties such as tensile strength, coefficient of friction, tissue drag (dry and wet), and knot security. In other words, the size 3-0 Teflene® suture is similar to the other monofilament sutures in terms of these properties. For size 4-0 sutures, Hypothesis 6 was not rejected for certain performance properties such as tissue drag (dry and wet), knot pull strength, and knot security. This means that these properties of size 4-0 Teflene® suture are similar to those of the other monofilament sutures. For size 5-0 sutures, Hypothesis 7 was not rejected for all performance properties except elongation, bending stiffness, and knot run-down. This means, that size 5-0 Teflene® suture is similar to the other monofilament sutures except in terms of elongation, bending stiffness, and knot run-down, which are different.

Table 26

Summary of Contrast Analysis of Variance Results

Performance Properties	Teflene® vs. the Other Monofilament Sutures				Teflene® vs. the Braided Sutures				New Surgilene® vs. Old Surgilene®			
	Size				Size				Size			
	2-0	3-0	4-0	5-0	2-0	3-0	4-0	5-0	2-0	3-0	4-0	5-0
Diameter	S	S	S		S	S	S	S			S	
Tensile strength	S		S		S	S	S	S			S	S
Elongation	S	S	S	S	S	S	S	S		S	S	
Bending stiffness	S	S	S	S	S	S	S	S	S		S	
Coefficient of friction	S		S		S		S	S			S	
Tissue drag (dry)	S				S	S	S	S		S	S	S
Tissue drag (wet)					S		S	S	S	S		S
Knot pull strength	S	S			S	S						S
Knot run-down	S	S	S	S			S	S				S
Knot security	S				S			S				

Note. S = Means are statistically different at the 0.017 level of significance (0.05/3=0.017, by Bonferroni method) .

Teflene vs. the braided sutures. For size 2-0 sutures, Hypothesis 4 was rejected for all the performance properties except for knot run-down. This means that size 2-0 Teflene® suture is different from the braided sutures tested in all respects except for knot run-down. For size 3-0 sutures, Hypothesis 5 was not rejected for several performance properties such as the coefficient of friction, wet tissue drag, knot run-down, and knot security. This means that these performance properties of size 3-0 Teflene® suture are similar to those for braided sutures. For size 4-0 sutures, Hypothesis 6 was not rejected for only two performance properties, namely knot pull strength and knot security. This indicates that the size 4-0 Teflene® suture is similar to the braided sutures with respect to these two performance properties. Lastly, for size 5-0 sutures, Hypothesis 7 was rejected

for all performance properties except for knot pull strength, indicating that the size 5-0 Teflene® suture differs from the braided sutures in all respects except for knot pull strength (Table 26).

New Surgilene® vs. Old Surgilene®. For size 2-0 sutures, Hypothesis 4 was not rejected for any of the performance properties except bending stiffness and wet tissue drag. From this it is concluded that size 2-0 new Surgilene® suture is similar to Old Surgilene® in all respects except for bending stiffness and wet tissue drag. For size 3-0 sutures, Hypothesis 5 was not rejected for any of the performance properties except elongation and dry and wet tissue drag. The size 3-0 New Surgilene® suture is therefore similar to Old Surgilene® in terms of all its performance properties except elongation and dry and wet tissue drag. For size 4-0 sutures, Hypothesis 6 was not rejected for wet tissue drag, knot pull strength, knot run-down, and knot security, which means that the size 4-0 New Surgilene® suture has a number of similar properties to Old Surgilene® including wet tissue drag, knot pull strength, knot run-down and knot security. For size 5-0 sutures, Hypothesis 7 was not rejected for any of the performance properties except for tensile strength, dry and wet tissue drag, knot pull strength and knot run-down. The size 5-0 New Surgilene® suture is similar to Old Surgilene® with respect to all performance properties except for these five (Table 26).

Correlation Analysis

In order to understand the relationship between the various performance properties of sutures, two sets of correlation coefficient analysis were conducted, one for all the sutures tested and the other for monofilament sutures only. This section describes and explains the results of these analyses.

Table 27 presents a summary of the linear correlation coefficients between performance properties for the monofilament sutures tested.

1. As expected, tensile properties such as tensile strength, knot pull strength and knot security are strongly positively correlated with diameter and strongly correlated with each other. The correlation coefficient values between these properties are from 0.954 to 0.975 (Table 27). This is consistent with the results that these tensile properties are size dependent.

2. Bending stiffness is positively correlated with some knot characteristics such as knot pull strength and knot security and suture diameter. Their correlation coefficients are around 0.6, which indicated that they are not strong. These results may be explained by the fact that bending stiffness is known to be closely correlated to suture diameter which was used in the calculation during the heart loop test method.

3. Knot run-down is negatively correlated with elongation and the correlation coefficient is 0.556, which is not strong.

Table 28 presents a summary of the linear correlation coefficients between performance properties for all the sutures tested, which include the monofilament and the braided sutures. The results are to those in Table 27.

1. Similar to the results in Table 27, tensile properties such as tensile strength, knot pull strength and knot security are strongly positively correlated with diameter and strongly correlated with each other. The correlation coefficients between these properties lie between 0.876 and 0.955 (Table 28).

2. Knot characteristics, such as knot pull strength and knot security, are positively correlated with bending stiffness. The coefficients range from 0.523 to 0.567, which shows that the correlations are not strong.

3. Knot snug-down of the braided sutures is strongly positively correlated with diameter and certain tensile properties such as tensile strength, knot pull strength and knot security. The correlation coefficients range from 0.848 to 0.939. Because knots made with monofilament sutures do not move, they do not give any knot snug-down results. These results, therefore, represent the findings from only two brands of braided sutures.

Table 27

Correlation Coefficients of Performance Properties for the Monofilament Sutures

Properties	Diameter	Tensile strength	Elongation	Bending stiffness	Coefficient of friction	Surface roughness	Tissue drag (dry)	Tissue drag (wet)	Knot pull strength	Knot run-down	Knot security
	(N=160)	(N=160)	(N=160)	(N=160)	(N=160)	(N=160)	(N=160)	(N=160)	(N=160)	(N=160)	(N=160)
Diameter	1.000 (0.000)	0.954 (0.000)	0.071 (0.370)	0.669 (0.000)	-0.178 (0.025)	0.260 (0.001)	0.116 (0.146)	0.361 (0.000)	0.975 (0.000)	0.425 (0.000)	0.955 (0.000)
Tensile strength		1.000	0.082 (0.300)	0.539 (0.000)	-0.134 (0.091)	0.196 (0.013)	0.094 (0.239)	0.324 (0.000)	0.959 (0.000)	0.539 (0.000)	0.950 (0.000)
Elongation			1.000	0.486 (0.000)	-0.162 (0.041)	0.229 (0.004)	-0.019 (0.811)	0.029 (0.717)	0.071 (0.373)	-0.556 (0.000)	0.021 (0.794)
Bending stiffness				1.000	-0.320 (0.000)	0.358 (0.000)	0.068 (0.392)	0.328 (0.000)	0.631 (0.000)	-0.269 (0.001)	0.590 (0.000)
Coefficient of friction					1.000	0.029 (0.713)	0.251 (0.001)	-0.031 (0.699)	-0.139 (0.080)	0.203 (0.010)	-0.169 (0.033)
Surface roughness						1.000	0.234 (0.003)	0.113 (0.154)	0.258 (0.001)	-0.115 (0.147)	0.242 (0.002)
Tissue drag(dry)							1.000	0.427 (0.000)	0.146 (0.066)	0.097 (0.224)	0.098 (0.216)
Tissue drag(wet)								1.000	0.373 (0.000)	0.099 (0.211)	0.304 (0.000)
Knot pull strength									1.000	0.444 (0.000)	0.955 (0.000)
Knot run-down										1.000	0.480 (0.000)

Note. Figures in parentheses are values of significance probability.

Table 28

Correlation Coefficients of Performance Properties for the Monofilament and Braided Sutures

Properties	Diameter	Tensile strength	Elongation	Bending stiffness	Coefficient of friction	Surface roughness	Tissue drag (dry)	Tissue drag (wet)	Knot pull strength	Knot run-down	Knot snug-down	Knot security
	(N=240)	(N=240)	(N=240)	(N=240)	(N=240)	(N=240)	(N=240)	(N=240)	(N=240)	(N=240)	(N=80)	(N=240)
Diameter	1.000 (0.000)	0.876 (0.000)	-0.115 (0.075)	0.553 (0.000)	-0.142 (0.028)	0.019 (0.765)	-0.120 (0.063)	0.052 (0.420)	0.948 (0.000)	0.339 (0.000)	0.939 (0.000)	0.936 (0.000)
Tensile strength		1.000	-0.171 (0.008)	0.448 (0.000)	-0.070 (0.281)	0.284 (0.000)	-0.077 (0.232)	0.199 (0.002)	0.941 (0.000)	0.224 (0.001)	0.848 (0.000)	0.935 (0.000)
Elongation			1.000	0.459 (0.000)	-0.263 (0.000)	-0.755 (0.000)	0.331 (0.000)	-0.167 (0.009)	0.037 (0.954)	0.230 (0.000)	-0.197 (0.080)	-0.041 (0.525)
Bending stiffness				1.000	-0.318 (0.000)	-0.252 (0.000)	0.106 (0.101)	0.227 (0.000)	0.567 (0.000)	-0.013 (0.843)	0.266 (0.017)	0.523 (0.000)
Coefficient of friction					1.000	0.289 (0.000)	0.037 (0.566)	-0.028 (0.664)	-0.116 (0.073)	0.054 (0.409)	-0.116 (0.308)	-0.123 (0.057)
Surface roughness						1.000	-0.347 (0.000)	0.179 (0.005)	0.109 (0.091)	0.441 (0.000)	0.315 (0.004)	0.143 (0.027)
Tissue drag(dry)							1.000	0.237 (0.000)	0.046 (0.478)	0.265 (0.000)	0.211 (0.060)	0.035 (0.585)
Tissue drag(wet)								1.000	0.147 (0.023)	-0.064 (0.319)	-0.156 (0.167)	0.145 (0.025)
Knot pull strength									1.000	0.288 (0.000)	0.860 (0.000)	0.955 (0.000)
Knot run-down										1.000	-0.189 (0.093)	0.298 (0.000)
Knot snug-down											1.000	0.901 (0.000)

Note. Figures in parentheses are values of significance probability.

The Reliability of Customized Test Methods and Accessory Devices

The third purpose of the study was to develop a set of reliable test methods and accessory devices to evaluate those performance properties of sutures which were not covered by standard test methods. In this study, four customized test methods were developed, and accordingly, four sets of customized accessory devices were designed and attached to an Instron tester, so as to perform tissue drag, knot run-down, knot snug-down, and knot security tests. The data from repeated tests on different specimens taken at random gave a normal distribution as stated in the hypothesis testing section of this chapter. In addition, the results of these four properties are consistent with those of other related properties which were obtained by using standard test methods and equipment. For example, the results of knot security for each size and brand of suture obtained by using the customized test method and device are closely correlated with the results of tensile strength obtained by using the standard test method and equipment. The correlation coefficient is 0.975 (Table 27). It therefore appears that the customized test methods and devices are reliable.

CHAPTER V

SUMMARY, CONCLUSION, AND IMPLICATION

In this chapter, the researcher summarizes this study; draws conclusions from the analysis, and discusses the implications for further study.

Summary

There have been reports suggesting that polypropylene (PP) monofilament sutures are associated with mechanical failure. In order to overcome this problem, a new monofilament suture made from polyvinylidene fluoride (PVDF) under the trade name of Teflene® has been developed. Few studies have measured the *in vitro* properties of Teflene® sutures, and they have been limited to determining the tensile properties of the straight sutures such as tensile strength, elongation and creep behaviour. The first purpose of this study was to evaluate *in vitro* Teflene® sutures, and compare their performance properties with commercial sutures made from polypropylene (PP) such as monofilament sutures Prolene®, new Surgilene® and old Surgilene®, and polyester (PET) such as braided sutures Ethibond® and Ti-Cron®. In addition to an evaluation of Teflene® sutures, the second purpose of this study was to compare a new Surgilene® suture, which was introduced on the market recently with a revised polymeric formulation, with the old Surgilene® suture, which has been on the market for several years. Existing standard test methods and testing instruments for measuring the performance properties of sutures are restricted to suture diameter, tensile strength, and knot pull strength. The measurements

of physical properties of straight sutures such as surface roughness, coefficient of friction, tissue drag and various knot characteristics are not covered. Therefore, the third purpose of this study was to develop four reliable test methods so as to evaluate tissue drag, knot run-down knot snug-down and knot security. This has involved the design and building of suitable accessory devices to be fixed on an Instron universal tester.

The *in vitro* performance properties were measured on suture samples representing six different brands in four sizes (2-0, 3-0, 4-0, and 5-0). The performance properties of sutures included both the physical properties of straight sutures such as suture diameter, tensile strength, elongation, surface roughness, coefficient of friction, bending stiffness and tissue drag; and knot characteristics such as knot pull strength, knot run-down, knot snug-down, and knot security. Existing standard test methods and testing instruments were used to measure suture properties of diameter, tensile strength, knot pull strength, and some physical properties. An Instron tester and a Kawabata Evaluation System (KES) were used to perform these tests. The researcher developed four sets of test methods and accessory devices needed to measure tissue drag, knot run-down, knot snug-down, and knot security.

The data were tested to confirm their normality so that further statistical analysis could be performed using analysis of variance, contrast analysis of variance, and correlation analysis. One objective was to compare each property of Teflene® suture with the other three monofilament sutures, and with the two braided sutures. Secondly, it was necessary to compare each property of the new Surgilene® sutures with the old Surgilene®

sutures. Lastly, a correlation coefficient analysis was conducted for all properties of sutures in order to determine the linear associations among these properties.

Conclusions

The Evaluation of Teflene® Sutures

The *in vitro* evaluations of Teflene® and other sutures generated the following results.

1. Diameter. The diameters of existing commercial sutures do not always fall within the limits specified by the USP. In particular, the diameters of size 3-0 and 4-0 Teflene® sutures are slightly larger than the limits specified by the US Pharmacopoeia (10% and 4% respectively). In contrast, the diameter of size 2-0 Teflene® suture is not only at the lower end of the limits, but also the finest of all the sutures tested.

2. Tensile strength and elongation. Teflene® sutures have similar tensile strength to the other monofilament sutures, and have at least 50% higher elongation than the other monofilament sutures.

3. Surface roughness and coefficient of friction. There is no significant difference between Teflene® and the other monofilament sutures in terms of surface roughness and coefficient of friction. The braided sutures have surface roughness values three to twelve times higher than those of the monofilament sutures.

4. Bending stiffness. Teflene® sutures have the highest values for bending stiffness among all the monofilament and braided sutures tested.

5. Tissue drag. Teflene® sutures have a similar level of tissue drag in both dry and wet condition to the other monofilament sutures. New Surgilene® has less tissue drag than the old Surgilene® in both dry and wet conditions.

6. Knot pull strength. Teflene® and all the other sutures meet the requirement specified by the USP.

7. Knot run-down. The knot run-down of Teflene® sutures is less than that of the other monofilament sutures and similar to that of the braided sutures.

8. Knot snug-down. Because of the immobility of the knot, it is not possible to measure the knot snug-down for Teflene® and the other monofilament sutures. The braided sutures Ethibond® and Ti-Cron® have similar values for knot snug-down.

9. Knot security. and the other monofilament sutures have similar knot security.

From these test results, it appears that in general the small sizes (3-0, 4-0 and 5-0) Teflene® sutures possess equivalent characteristics to those of existing commercial sutures. But at the same time it has some different features, such as greater elongation and lower knot run-down. From a clinical perspective, these results mean that Teflene® sutures will likely be easier to manipulate, especially in terms of making a knot and sliding it into position at the time of handing, and will cause less damage to adjacent tissue when suturing. The greater elongation of the Teflene® sutures means that once a knot is tightened, the knot will stay in place with less of a tendency to move or untie itself. A distinguish feature of the size 2-0 Teflene® suture is its finest diameter compared to the other sutures tested. This property limits its tensile strength, knot pull strength and knot security performance in comparison to the other monofilament sutures. A diameter of

about 0.37 mm, rather than 0.30 mm, would be required for size 2-0 Teflene® suture, should a tensile strength of about 40 N, similar to the other monofilaments, be desired.

The Comparison of New Surgilene® and Old Surgilene® Sutures

New Surgilene® sutures are similar to old Surgilene® in most of their properties such as tensile strength, elongation, bending stiffness, coefficient of friction, surface roughness, knot pull strength, knot run-down and knot security. On the other hand, new Surgilene® sutures have at least 50% lower tissue drag both in dry and wet conditions than old Surgilene®.

Correlations Between Performance Properties

The tensile properties such as tensile strength, knot pull strength and knot security are strongly positively correlated with diameter and strongly correlated with each other. This is consistent with the test results that these tensile properties are size dependent. Bending stiffness is positively correlated with suture diameter and some knot characteristics such as knot pull strength and knot security. These correlations are not strong. Knot run-down of monofilament sutures is negatively correlated with elongation and the correlations are not strong. Knot snug-down of the braided sutures is strongly positively correlated with diameter and certain tensile properties such as tensile strength, knot pull strength and knot security.

The Customized Test Methods and Accessory Devices

Four sets of test methods and accessory devices, which were attached to an Instron tester so as to measure tissue drag, knot run-down, knot snug-down, and knot security, were developed in this study. The results show that these test methods and accessory devices are reliable in three respects. First, each specimen tested gave a unique measurement and for each size and brand of suture, the distribution of measurements was normal. Second, the results for similar properties, such as tensile strength, knot pull strength and knot security, were consistent with each other. Lastly, the tests have good repeatability.

Implications for Further Study

In this project, only the *in vitro* performance properties of Teflene® and the other sutures were studied. Because sutures are materials that are implanted in humans, the relationship between their *in vitro* performance properties and *in vivo* performance properties needs to be understood. Further studies are recommended to clarify such relationships.

The bending stiffness of sutures was measured in this study using that static heart loop test. A more detailed understanding of the bending properties of sutures could be obtained by measuring the dynamic stiffness of sutures using a Kawabata Evaluation System (KES) FB2 pure bending tester. In this way, the curvature of bending could be recorded at different rates of loading and the bending rigidity and hysteresis of the bending moment calculated by computer.

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