Part III

Robust Engineering: Mechanical Applications

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Taguchi's Quality Engineering Handbook. Genichi Taguchi, Subir Chowdhury and Yuin Wu

CASE 23

Biomechanical Comparison of Flexor Tendon Repairs

Abstract: The aim of this study was to determine the optimal method for flexor tendon repair. We used the Taguchi method of analysis to identify the strongest and most consistent repair.The optimum combination of variables was determined by the Taguchi method to be the augmented Becker technique. Five tendons repaired with the optimized combination were then tested and compared to the set of tendons repaired initially using the standard modified Kessler technique. The strength of the flexor tendon repair improved from an average of 17 N to 128 N with a standard deviation improving from 17% of the mean to 4% of the mean. Stiffness of the optimized repair technique improved from an average of 4.6 N/mm to 16.2 N/mm.

1. Introduction

Flexor tendon repair continues to evolve. Despite years of research by many investigators, the optimum suture technique remains elusive. As our understanding of tendon healing and biomechanics advances, new goals are set for ultimate motion. Historically, treatment involved delayed primary tendon grafting. Currently, primary repair is done followed by a postoperative active extension–passive flexion protocol [13]. There is now a trend toward primary repair followed by early *active* flexion, which aims to improve final results [24].

The premise is that early active flexion reduces adhesions and improves the ultimate range of motion and function [6]. Toward that end, investigators have tried to determine the strongest method of tendon repair [5,8,14,19,27,28,31]. Because of the many variables investigated, the various testing methods used, and the different focus of each study, a review of the literature does not provide the optimum combination of factors for the best repair technique.

The purpose of our experiment was to identify the factors that have the greatest effect on outcome variation and to determine the value of the factors that result in the most consistent outcomes Thus, the first goal of our study was to determine a method for tendon repair that provides greater strength combined with less outcome variability. To accomplish this, we used the Taguchi method of experimental design and analysis [16].

There are many examples in the medical field where the optimum method or process has not yet been determined because of the number of variables and the inherent limitations in patients of material for study. The second goal of our study was to evaluate the Taguchi method for future medical applications.

2. Materials and Methods

Material for Study

Flexor tendons were harvested from seven fresh-frozen human hands. Flexor pollicis longus, as well as index, middle, and ring finger flexor digitorum superficialis and flexor digitorum profundus tendons were each divided transversely into two sections of equal length. Comparison of proximal and distal sections have shown no substantial difference in tendon diameter or stiffness characteristics [3]. A total of 14 flexor tendon specimens were available per hand for testing. Tendon size is not under the control of the surgeon and was considered extraneous (so-called *noise*) according to the Taguchi method.

Static Testing

After each specific tendon repair, specimens were mounted in a servohydraulic mechanical testing machine (Instron, Canton, Massachusetts) for tension testing to failure. A jig was specially designed to grip the tendon ends so that minimal slippage would occur. The gripper was first tested with whole tendons and noted to withstand tensile loads of more than 1000 N before slippage was identified visually. Elongation was produced at a constant speed of 0.33 mm/s. A preload of 2.0 N was applied prior to testing to remove slack in the system. Ultimate strength was determined by the peak load recorded.

Real-time recording was made using an x–y plot for displacement–load analysis. This revealed that the initial portion of each curve was linear. Stiffness was determined by the slope of this initial curve. The load was determined at 2.0 mm displacement, and the result was divided by 2.0 to yield a stiffness of newtons per millimeter. We recognize that cross-head displacement for stiffness only provides an estimate of the true gap. During specimen testing we noted that the overwhelming majority of displacement was from the relatively weak and compliant repair. Increased stiffness is therefore reflective of less gap formation.

Variables under Study

Five control factors were studied: core tendon repair technique, core suture type, core suture size, epitenon technique, and distance from the repair site for core suture placement (Table 1).

Eight techniques of core tendon repair were examined, as shown in Figure 1: modified Kessler 1, consisting of a two-strand repair with a single knot within the repair site; modified Kessler 2, consisting of a two-strand repair with an epitenon-first repair with the core suture knot away from the repair site; Tsuge, consisting of a two-strand repair with a single knot outside the repair site; Tajima, consisting of a two-strand repair with two knots within the repair site; Lee, consisting of four-strand repair with two knots within the repair site; double modified Kessler, consisting of a four-strand repair with the modified Kessler method repeated: a single suture with one knot outside the repair site being used to produce the four-strand core repair; augmented Becker, consisting of a four-strand with two knots outside the repair site; and Savage, consisting of a six-strand repair with a single knot within the repair site.

Table 1
Summary of factors under study

Control Factor	Levels[a]
Core suture technique	Modified Kessler 1 (MK1) Modified Kessler 2 (MK2) Double modified Kessler (Dbl. MK) Savage Lee Tsuge Tajima Augmented Becker (Aug. Beck)
Core suture material	Ethillon, Nurolon, Prolene, Mersilene
Core suture size	4-0, 3-0
Epitenon suture technique	None, volar only, simple, cross-stitch (cross)
Suture distance from cut edge (cm)	0.5, 1.0

[a] Modified Kessler 1, two-strand repair with a single knot within the repair site; modified Kessler 2, epitenon-first two-strand repair with a single knot outside the repair site; Lee, double-loop locking four-strand repair with two knots within the repair site; savage, six-strand repair with a single knot within the repair site; Tsuge, two-strand repair with a single knot outside the repair site; augmented Becker, four-strand repair with two knots outside the repair site; double modified Kessler, four-strand repair with a single not outside the repair site; Tajima, modified Kessler grasp with two knots within the repair site.

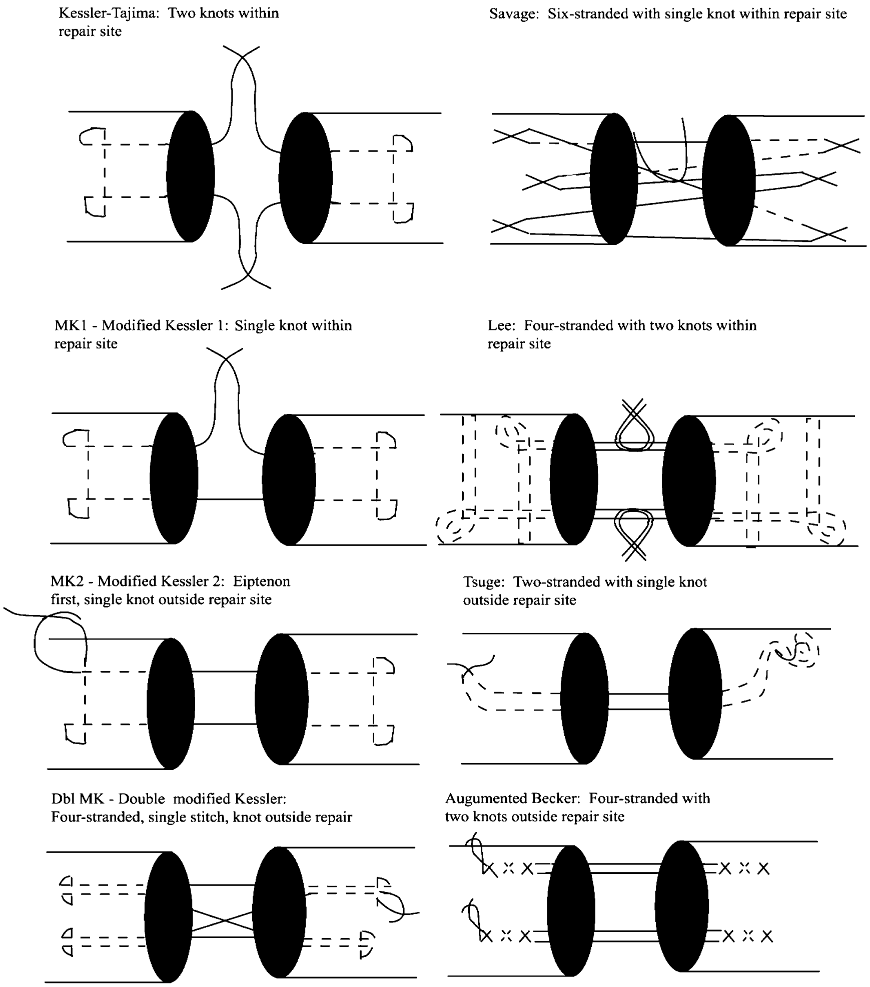

Figure 1
Eight repair techniques

Four core suture materials were examined: monofilament nylon (Ethilon), braided nylon (Nurolon), polypropylene monofilament (Prolene), and braided polyester (Mersilene) (Ethicon, Inc., Somerville, New Jersey). Two core suture sizes were examined: 4-0 and 3-0. Four epitenon techniques were examined: no epitenon, volar only, simple, and crossed. Suture distances of 0.5 and 1.0 cm were examined. (This refers to the distance from the repair site to the entry or exit and the transverse course of the core suture.)

All knots were three-throw square knots. All repairs were done by a single surgeon. All modified Kessler techniques used the locking-loop modification described by Pennington [17].

Experimental Design: Taguchi Method

The set of 16 experiments (Table 2) was repeated four times, for a total of 64 experiments. Within each set of 16 experiments, the order was randomized. In this case, 64 experiments gave a minimum

Table 2
Test matrix

No.	Suture Type	Epitenon	Technique	Core Size	Suture Distance (cm)
1	Ethilon	None	MK1	4-0	0.5
2	Ethilon	Volar	MK2	3-0	1.0
3	Nurolon	None	Lee	3-0	1.0
4	Nurolon	Volar	Savage	4-0	0.5
5	Nurolon	Simple	MK2	4-0	0.5
6	Nurolon	Cross	MK1	3-0	1.0
7	Ethilon	Simple	Savage	3-0	1.0
8	Ethilon	Cross	Lee	4-0	0.5
9	Prolene	None	Tsuge	4-0	1.0
10	Prolene	Volar	Aug. Becker	3-0	0.5
11	Mersilene	None	Dbl. MK	3-0	0.5
12	Mersilene	Volar	Tajima	4-0	1.0
13	Mersilene	Simple	Aug. Becker	4-0	1.0
14	Mersilene	Cross	Tsuge	3-0	0.5
15	Prolene	Simple	Tajima	3-0	0.5
16	Prolene	Cross	Dbl. MK	4-0	1.0

of eight repetitions of any particular variable. For example, the modified Kessler 1 technique was performed eight times, the Ethilon core was used 16 times, and the 4-0 suture was tested 32 times.

Initial and Confirmation Runs

To validate the method, the initial and the optimum repair techniques were compared. Initially, a set of eight flexor tendons was repaired using a standard method: a modified Kessler technique using a 4-0 Ethilon core suture placed 0.5 cm from the lacerated ends and a simple epitenon stitch with 6-0 Ethilon. At the completion of the 64 experiments, the optimum combination was determined using the Taguchi method. A set of five flexor tendons with this predicted optimum combination was then tested. The resulting mean and standard deviation were compared to the initial standard method to show the improvement that was obtained.

3. Results

SN Ratio

Traditional statistical methods use the mean to compare results. Using the standard deviation, one may then determine whether the difference between two groups is significant. With the Taguchi method, one uses a different statistic, the signal-to-noise (SN) ratio, to compare results.

In the Taguchi method, variables under study are divided into factors that either can be controlled (control factors) or factors which either cannot be controlled or are too expensive to control (noise factors). The greater the effect of the noise, the greater the inconsistency. The goal of the Taguchi method is to choose control factors that produce not only the desired result (such as stronger) but also to direct a process that is less sensitive to noise. Although noise cannot be eliminated, the effect of noise can be minimized. This produces a result that is not only stronger but is also less variable. Calculation of the SN ratio takes into account not only the mean but also the variation from one result to the next. Therefore, we can think of SN ratio analysis as being two-dimensional as opposed to regular analysis being only one-dimensional [16].

When the experimental goal is to maximize the outcome variable, the SN ratio in decibels is

$$\text{SN ratio} = -10 \log^{10} \frac{1/y_1^2 + \cdots + 1/y_n^2}{n}$$

where y is the strength or stiffness of each of the n repetitions of the experiments (here n was 4). The SN ratio is, in a sense, a combination of the mean and the variance. Mathematically, the ratio increases as the individual values become larger. Improved consistency or decreased variability between values also increases the ratio.

The SN ratios for tensile strength and stiffness for each of the 16 experimental combinations, with n equal to 4, were calculated (Table 3). We next calculated the SN ratios of each of the individual components of the five control factors. The values of these SN ratios are simply the average of the signal-to-noise ratios of all experiments containing that particular control factor component (Table 4). For example, the SN ratio for tensile strength considering the control factor suture and the component Ethilon is (Table 3, rows 1, 2, 7, 8)

$$\text{SN ratio for Ethilon} + \tfrac{1}{4}(25.8 + 30.4 + 37.2 + 31.2) + 31.2 \text{ dB}$$

Results Using the Taguchi Method

Strength and stiffness were related only indirectly. Correlating the SN ratios of strength to those of stiffness yields a Pearson correlation coefficient of 0.51 ($p = 0.022$). This suggests that only about one-half of the variation in stiffness could be predicted by the strength. A higher ultimate strength therefore did not necessarily correlate with greater stiffness. Ultimate strength often occurred at more than 8.0 mm of displacement, whereas determination of stiffness was within the initial 2.0 mm of displacement. Diao et al. [3] also looked at strength and stiffness after tendon repair. Their group of tendons repaired with deep peripheral sutures failed catastrophically at 4 mm of displacement. Their group repaired with superficial peripheral sutures failed gradually by a pattern of breaking and unwinding at 16 mm of displacement. Based on the biology of tendon healing, we would predict that a strong repair that allows a gap of 8 mm would not be successful. The performance of the repair should therefore be judged by studying both the strength and the stiffness.

A comparison of two SN ratios is less intuitive than a comparison of two means. Using the following formula, one may correlate decibel difference with percent difference:

$$\text{percent change in value} = (10^{x/20} - 1)(100)$$

where x is the change in SN ratio (in decibels). For example, a 1-dB difference in strength between factors is equivalent to a 12% difference in strength. A 10.0-dB difference is equivalent to a 215% difference.

Suture Technique

Of all the variables studied, suture technique had the greatest effect on both strength (change in ratio = 10.5 dB, maximum = 36.6 dB) and stiffness of the repair (change in ratio = 5.9 dB, maximum = 16.2 dB) (Table 4).

Core Suture

The SN ratios for the various core suture materials were similar, with the exception of Nurolon (Table 4). Several of the repairs with Nurolon failed because the knot untied. This did not occur with any of the other sutures. Three-throw square knots were useed throughout the study; four throws would be unrealistic given the bulk of the knot. This led to occasional low values, as reflected in the low SN ratio.

Epitenon

Moderate improvement with epitenon repair was obtained compared to no epitenon repair. Simple epitenon was 31.2 dB − 28.7 dB = 2.5 dB better than no epitenon repair (Table 4). This is approximately $10^{2.5/20}$ or 33% stronger.

Table 3
Tensile strength, stiffness, and SN ratios

	Suture Type	Epitenon	Technique	Core	Suture Distance (cm)	Tensile Strength for Each Repetition (N)				Stiffness for Each Repetition (N/mm)				Signal-to-Noise Ratio for 4 Repetitions (dB)	
						TS1	TS2	TS3	TS4	Stiff1	Stiff2	Stiff3	Stiff4	SN TS	SN Stiff
1	Ethilon	None	MK1	4-0	0.5	19	16	21	26	1.75	2.40	2.57	2.05	25.8	6.5
2	Ethilon	Volar	MK2	3-0	1.0	34	32	36	32	4.51	4.55	2.53	3.78	30.4	10.9
3	Nurolon	None	Lee	3-0	1.0	26	16	49	48	4.81	4.81	4.72	4.51	28.1	13.5
4	Nurolon	Volar	Savage	4-0	0.5	52	50	46	26	5.71	9.51	5.20	3.95	31.7	14.5
5	Nurolon	Simple	MK2	4-0	0.5	13	18	22	22	5.50	6.88	2.96	3.95	24.8	12.4
6	Nurolon	Cross	MK1	3-0	1.0	21	15	24	37	6.06	7.18	3.99	4.55	26.3	14.0
7	Ethilon	Simple	Savage	3-0	1.0	95	88	59	65	2.74	4.77	3.73	4.59	37.2	11.3
8	Ethilon	Cross	Lee	4-0	0.5	38	44	29	39	4.37	4.98	6.23	5.93	31.2	14.4
9	Prolene	None	Tsuge	4-0	1.0	21	19	25	24	2.48	2.66	2.01	2.53	27.0	7.5
10	Prolene	Volar	Aug. Becker	3-0	0.5	72	80	67	90	7.83	7.57	5.67	5.93	37.6	16.3
11	Mersilene	None	Dbl. MK	3-0	0.5	39	45	58	73	7.14	6.88	5.93	7.14	33.9	16.5
12	Mersilene	Volar	Tajima	4-0	1.0	14	27	27	25	5.24	4.64	6.66	3.52	26.3	13.3
13	Mersilene	Simple	Aug. Becker	4-0	1.0	53	70	66	60	5.89	7.65	5.28	7.22	35.7	16.0
14	Mersilene	Cross	Tsuge	3-0	0.5	21	33	20	21	7.14	7.5	7.78	8.82	27.0	17.8
15	Prolene	Simple	Tajima	3-0	0.5	21	26	27	19	8.86	6.49	3.35	5.84	27.1	14.1
16	Prolene	Cross	Dbl. MK	4-0	1.0	31	49	46	46	6.62	6.66	8.34	4.21	32.2	15.4

Table 4
SN ratios for strength and stiffness (dB)

	SN Ratio	
	Strength	**Stiffness**
I. Technique		
MK1	26.1	10.3
Taijima	26.7	13.9
Tsuge	27.0	12.7
MK2	27.6	11.7
Lee	29.7	14.0
Dbl MK	33.0	16.0
Savage	34.4	12.9
Aug. Becker	36.6	16.2
II. Core suture		
Nurolon	27.7	13.6
Mersilene	30.7	15.9
Prolene	30.9	13.3
Ethilon	31.1	10.8
III. Core size		
4-0	29.3	12.5
3-0	31.0	14.3
IV. Epitenon		
None	28.7	11.0
Cross	29.2	15.4
Simple	31.2	13.5
Volar	31.5	13.8
V. Suture distance (cm)		
0.5	29.9	14.1
1.0	30.4	12.7

Core Suture Size

The 3-0 Mersilene suture improved strength 1.7 dB compared to 4-0 Mersilene (31.0 dB − 29.3 dB). The stiffness improved by 1.8 dB (Table 4).

Suture Distance

Suture distance for core suture placement from the cut edge had the least effect on strength and stiffness of any variable tested. The failure mode of the core suture for repair at 0.5 cm showed more failures from suture pullout than from breakage. In repairs at 1.0 cm, only four of 32 (13%) repairs failed by pullout. With repairs at 0.5 cm, 11 of 32 (34%) failed by pullout. Pullout of the core suture is in a sense a premature failure in that the suture pulled out of the tendon before the suture itself failed. The SN ratio shows that a smaller suture distance gives greater stiffness, an intuitively apparent result.

Optimum Combination of Factors

In choosing the optimum combination of factors, both strength and stiffness were considered. The optimum combination of variables was found to be an augmented Becker technique using 3-0 Mersilene core suture placed 0.75 cm from the cut edge with volar epitenon suture. As anticipated, this exact combination had not actually been tested in the Taguchi array. A set of tendons was then repaired with this optimized combination to confirm the results of the Taguchi analysis.

The results of the optimum combination tested confirmed the results predicted to be accurate. The initial standard combination was compared to the optimum combination, both predicted and tested (Table 5). Included are values for strength and stiffness. The low values for the series are given along with the percent decrease from the mean.

4. Discussion

The goal of flexor tendon repair is restoration of full motion of the finger. Historically, repair was followed by postoperative immobilization [10,11]. Healing of flexor tendons was thought to occur via an extrinsic process mediated by the flexor sheath [18]. This was logically thought to require immobilization of the tendon with necessary adhesion formation. Final motion of the digit was, not surprisingly, limited. Studies by Lundborg and Rank [12] and Gelberman et al. [6] provide evidence that the flexor tendon has an intrinsic repair capability. This revision of the understanding of the healing process gave impetus to the need to study postoperative motion protocols.

In a study of canine tendon healing, Gelberman et al. [6] found that tendon healing could occur without adhesion formation. In addition, mobilized tendons healed more rapidly than immobilized repairs and had greater ultimate strength [6]. In a clinical study, Kleinert et al. [9], using postoperative active extension and passive flexion, produced substantially improved results. In a subsequent clinical study, Strickland et al. [25] confirmed the benefits

Table 5
Comparison of standard and optimum combinations of variables

	Standard Method	Optimum Combination	
		Predicted	Tested
Mean tensile strength (N)	17.2 ± 2.9	94	128 ± 5.6
Low value (difference from mean)	13.1 (24%)		121 (5%)
Mean stiffness (N/mm)	4.6 ± 1.0	10	16.2 ± 5.8
SN ratio (dB)			
Tensile strength	24.4	40	42.1
Stiffness	12.7	20	22.8

of postoperative light-active rehabilitation after a four-strand core suture repair in zone II flexor tendon lacerations. The light-active mobilized group yielded 76% (19 of 25) excellent and good results. This was in comparison to 56% (14 of 25) excellent and good results compared to a previously reported group treated with passive motion after a two-strand core suture repair.

Prior to the healing tendon sharing the load, active flexion places increased demand on the repair. Currently, popular techniques are not sufficiently strong to withstand the forces associated with mobilization. Many factors have been studied to create a stronger repair. Most studies have focused on various core suture techniques [7,14,28,31]; some have investigated core suture materials [8,28,29] or epitenon techniques [15,29]. Comparisons and conclusions are difficult because these studies have involved a variety of tendon models (dog, rabbit, chicken, human), different size sutures for the same techniques, different techniques for testing, and have been both in vivo and in vitro studies.

Some investigators have focused on gap formation [1,22,23]. Logic dictates that a gap at the repair site will fill with fibrous tissue and lead to an inferior repair with regard to strength, stiffness, and tendon length. This will present clinically as decreased total active motion and an increased rupture rate. In a prospective clinical study using radiopaque markers, Seradge [22], found a direct correlation between the amount of elongation at the repair site and the incidence of secondary tenolysis. In contrast, Silfverskiold et al. [23] found only a weak correlation between elongation and final interphalangeal joint motion.

Small and Colville [24] reported results of a prospective clinical study that used an early active flexion protocol in 98 patients. Using the modified Kessler technique with 4-0 Ethilon or 4-0 Monofil core suture and 6-0 Prolene epitenon suture, they had excellent or good results in 77% (90 of 117) of digits, but noted dehiscence in 9.4% (11 of 117) of digits. Cullen et al. [2] noted a rupture rate of 6.5% (two of 31) of digits. They used a modified Kessler technique using 3-0 Tycron core and 6-0 Prolene epitenon stitches.

To interpret expected demands on a tendon repair, it is important to examine the forces that the tendon may generate. Schuind et al. [21] measured in vivo forces using a specially designed device during carpal tunnel release. They found forces of up to 8.8 N in passive mobilization, up to 34.3 N in active unresisted finger motion, and up to 117 N in tip pinch. One would predict that in a digit with edema, forces even higher than 34.3 N may be generated in an early active motion protocol.

These studies on early active motion are encouraging [20]. They provide evidence that motion is improved following early active flexion. However, the higher rupture rate reflects the large load that is placed on the relatively weak repair.

Optimum Variables

In determining the optimum combination for repair, both strength and stiffness were considered

(Table 4). For each variable, such as technique or suture material, the ideal choice would be the variable that gives the maximum value for both strength and stiffness. When the maximums did not coincide, a rationale was provided for choosing the optimum variable.

For technique, the augmented Becker was chosen because it yielded the highest ratio for both strength and stiffness. For core suture type, Mersilene was chosen since it performed nearly the highest for strength and clearly the highest for stiffness; prolene would be the second choice. For suture size, 3-0 yielded both the highest strength and the highest stiffness; volar epitenon was chosen since strength was considered to be more important than stiffness. Distance from the end was the only continuous variable, and 0.75 cm was chosen to optimize both strength and stiffness. One may choose a combination of variables other than the optimum combination determined, but a confirmation experiment should be done for that combination to avoid the effect of unexpected interactions.

Suture technique was the most important variable studied (Table 4). As might be predicted, the two-strand techniques gave the lowest values. The six-strand Savage technique did not perform as well as expected. This may have resulted from the inability of each suture across the repair to share the load evenly. This would lead to earlier-than-expected failure because of overload on any one suture.

Schuind et al. [21] estimated the maximum force expected during active flexion to be 34.3 N. Substituting this value into the formula gives a value of 30.7 dB. This is an estimate of the minimum SN ratio required for tendon repair. None of the two-strand techniques was able to achieve this level (Table 4). An SN ratio of more than 31.0 dB was reached for both the double modified Kessler and the augmented Becker (Table 4). Both of these repair techniques should be strong enough to withstand early active flexion. In our opinion, the six-strand Savage technique is too difficult and time consuming to be widely accepted by surgeons.

Taking into account both strength and stiffness, Mersilene would be the first choice and Prolene the second choice (Table 4). Techniques that require suturing into as opposed to across or down the tendon fibers require more handling of the tendon. Braided suture has more friction and tends to deform the tendon more than monofilament suture. Technical considerations may therefore lead to the choice of Prolene. Ethilon would have been chosen if strength alone was used for selection. Ethilon performed poorly with respect to stiffness and therefore is not the optimum choice when considering overall repair performance.

Increasing the core suture size substantially improved both strength and stiffness (Table 4), but not as much as would have been predicted from the material properties alone. Ethicon, Inc. [4] reports a suture strength for 4-0 Mersilene of 13.0 N and for 3-0 Mersilene of 18.0 N. This reflects an improvement in strength of 38% in going from 4-0 to 3-0 Mersilene. The Taguchi method showed that the 3-0 core suture improved strength 1.7 dB compared with 4-0 core suture (31.0 dB − 29.3 dB). This translated into a difference of approximately 22%.

Injury to flexor tendons outside zone II would certainly be better repaired with the large suture [26]. In zone II lacerations, additional studies would have to be made to evaluate the gliding characteristics before the 3-0 suture could be recommended because of the added bulk. There is a clinical precedent for using this size suture in zone II injuries. Cullen et al. [2] report on their results of early active motion in zone II repairs using 3-0 Tycron modified Kessler technique. They had 77% (24 of 31 digits) excellent or good results with a rupture rate of 6.5% (two of 31 digits).

The addition of a simple epitenon suture has been shown in previous studies to have an impact on strength [15,29]. Volar epitenon was chosen to test the clinical situation where suturing only the volar epitenon is technically feasible. Simple epitenon repair was chosen over volar only because performance was similar mechanically and the biology of tendon healing suggests that unexposed tendon leads to less scar production [30]. Simple epitenon was stronger than no epitenon by 2.5 dB, or approximately 33%. Wade et al. [29] found that adding a peripheral 6-0 polypropylene stitch improved strength by 12.7 N, with an ultimate strength of 31.3 N, a difference of 41%. The results here agree with Wade et al. that a peripheral stitch adds substantial strength to the repair.

Comparing modified Kessler 1 (core suture first) to modified Kessler 2 (epitenon suture first) repairs, the SN ratio for strength improved from 26.1 dB to 27.6 dB, respectively. This translates to an expected improvement in strength of $10^{1.5/20}$, or 19% improvement by suturing the epitenon first. This correlated well with the study by Papandrea et al. [15] using 26 matched canine tendons. They found an improvement of 22% when performing epitenon first repair using 4-0 braided polyester core suture and 6-0 braided polyester epitenon suture.

Standard versus Optimum Combination

The Taguchi method was used to identify a stronger and less variable repair method. The confirmation experiment determines whether the Taguchi method of study was accurate. Variation may be measured by the standard deviation, but in the spirit of attaining quality, the minimum result is also important. It is the occasional low value that is associated with the occasional failure.

The optimal flexor tendon repair improved in strength from 17.0 N to 128 N, with a low value going from 24% below the mean to 5% below the mean (Table 5). Anticipating stress on a repair of up to 35 N during unopposed active flexion, a repair that can resist 128 N of tension with minimal variation should give the surgeon enough confidence to begin an early postoperative active flexion protocol.

The increase in stiffness from 4.6 N/mm to 16.2 N/mm substantially reduces the gap under physiologic load. With the standard combination, a load of 34.0 N would exceed the expected strength of the repair, but if the repair remained intact, a gap of 7.4 mm is predicted. With the optimum combination, a maximum gap 2.1 mm is expected at 34.0 N of load.

Taguchi Method

The Taguchi method differs from traditional statistical methods by its focus on identifying a solution that is, in this instance, both a stronger and a less variable method of repair. The parameter used for optimization is the SN ratio, in which a low value is more heavily penalized by the formula used than a high value is rewarded. In other words, it is the low values that are associated with failure. Not only does the SN ratio help reduce variability, but it does so by identifying control factors that lead to those low values. The Taguchi method identifies which factors provide the greatest contribution to variation and determines those settings or values that result in the least variability. However, the method does not allow easy analysis of interactions between factors.

The optimum technique for a flexor tendon repair shown in this study still may not satisfy many surgeons. It may, for example, be unacceptable because of time or effort to perform the augmented Becker technique. One may in fact decide that any four-strand repair technique is either technically unappealing, injurious to the tendon, or both. Inspection of the signal-to-noise ratio graph, however, allows one to realize that the two-strand techniques are simply too weak to allow for a reliable early active motion protocol. The clinical series by Small and Colville [24] and Cullen et al. [2] both used a two-strand repair technique followed by early active flexion. Small reported 77% (90 of 117 digits) excellent or good results with a dehiscence rate of 9.4% (11 of 117 digits). Cullen reported 77% (24 of 31 digits) excellent or good results with a rupture rate of 6.5% (two of 31 digits). The Taguchi method suggests that by using the optimum combination, a better range of motion and a smaller rupture rate are possible. The results show that only a four-strand technique is strong enough to perform immediate active flexion rehabilitation reliably.

References

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