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Validity of parameters in static linear testing of flexor tendon repair

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ABSTRACT

To study the biomechanical properties of flexor tendon repairs, static tensile testing is commonly used because of its simplicity. However, cyclic testing resembles the physiological loading more closely. The aim of the present study is to assess how the biomechanical competence of repaired flexor tendons under cyclic testing relates to specific parameters derived from static tensile testing. Twenty repaired porcine flexor tendons were subjected to static tensile testing. Additional 35 specimens were tested cyclically with randomly assigned peak load for each specimen. Calculated risks of repair failure during repetitive loading were determined for mean of each statically derived parameter serving as a peak load. Furthermore, we developed a novel objective method to determine the critical load, which is a parameter predicting the survival of the repair in cyclic testing. The mean of statically derived yield load equalled the mean of critical load, justifying its role as a valid surrogate for critical load. However, regarding mean of any determined parameter as a clinically safe threshold is arbitrary due to the natural variation among samples. Until the universal performance of yield load is verified, we recommend employing cyclically derived critical load as primary parameter when comparing different methods of flexor tendon repair.

1. Introduction

Flexor tendon repair must be biomechanically adequate to withstand the method of rehabilitation used postoperatively (Tang, 2006). The postoperative rehabilitation regimens after flexor tendon repair range from passive movements (Duran and Houser, 1975) to early active flexion of the fingers (Elliot et al., 1994; Small et al., 1989). The trend has been towards early active protocols that increase excursion of the tendons but also the force applied to the repair. The tendon repair strength needed to withstand early active motion is not exactly known.

Traditionally, biomechanical properties of tendon repairs have been studied using static tensile testing until the failure of the repair (Pruitt et al., 1991). Static testing protocols follow general material science tensile testing principles allowing the determination of elongation, yield load, and ultimate load. However, a repaired tendon is not homogenous material. Because of the interaction between the tendon and the suture, the interpretation of elastic and plastic regions from the load-deformation curve is probably not as reliable as in homogenous materials. Ultimate force is often reached long after the repair has already gapped beyond clinically acceptable limits. Therefore, it has been suggested that instead of ultimate force, the yield force should be used for comparison of different repairs (Viinikainen et al., 2004). On the other hand, based on the gapping studies in animals, different gap forces have also been used to evaluate the strength of repairs (Momose et al., 2001). Currently, there is no consensus, which parameter derived from the static testing is clinically relevant.

In postoperative active rehabilitation programs, tendons are subjected to repetitive motion exercises. Therefore, it has been proposed, that cyclic testing enables the determination of the competence of the repaired tendon in a more physiologic way than static testing (Gibbons et al., 2009; Pruitt et al., 1991; Sanders et al., 1997). Cyclic loading has been shown to lead gapping between the tendon ends at lower loads than static loading (Pruitt et al., 1991; Viinikainen et al., 2009) and to decrease the ultimate strength of the repaired tendon (Gibbons et al., 2009). Cyclic testing would probably yield clinically more relevant mechanical property but currently there are no reliable standardized methods to determine biomechanical properties in cyclic testing. The aim of the present study was to assess the relationship between the parameters of repaired flexor tendons in static testing and the

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tendency to fail in cyclical loading. Based on the cyclic testing results, we also developed an objective method to determine an applicable parameter: the critical load, representing the load where irreversible deformations start predisposing the tendon repair to disruption.

2. Materials and methods

2.1. Samples

A total of 55 porcine flexor digitorum profundus II (FDP-II) tendons were used in this study. Fresh frozen pig hind-leg trotters were obtained from the abattoir. The ratio of males and females could not be retraced. Before surgery the trotters were thawed to room temperature, the tendons were dissected and the dimensions were measured using a caliber. Cross sectional areas of the tendons were calculated ($A = \pi^* ab$, in which a is the semi-minor and b the semi major axes). Each tendon was cut with a surgical scalpel and repaired. The repair was performed using two Pennington modified Kessler sutures (Pennington, 1979) with 4–0 braided polyester (Ethibond Excel, Ethicon, San Lorenzo, PR, US) as core suture and was completed with nine-purchase over-and-over peripheral repair with 6–0 polyamide (Ethilon, Ethicon, San Lorenzo, PR, US) (Fig. 1). The specimens were kept moist in saline-soaked gauzes, except when measured. Approval of ethical board was not needed for this study because no living animals were involved.

2.2. Biomechanical testing

Biomechanical testing of the specimens was performed using a materials testing machine (LR 5 K Lloyd Instruments Ltd, Hampshire, UK) connected to a computer with software (Nexygen, Lloyd Materials Testing, Ametek, Inc, Berwyn, PA, US). Of a total of 55 samples, randomly selected group of 20 repaired tendons were subjected to static tensile testing, and a group of 35 for cyclic testing.

2.3. Static tensile testing

Twenty repaired tendons were secured to the testing machine with clamps 30 mm apart from each other, and linear tensile loading was subjected to the specimen until the breakage of the repair. A preload of 0.5 N was used. Velocity of the loading was 20 mm/min. Ultimate load and the yield load were determined from the load-deformation curve. The yield load was determined with a 0.1 mm offset method (Lotz et al., 1998). The biomechanical testing was filmed using two diametrically placed cameras (Canon EOS 550D and Canon EOS M, Tokyo, JP) to enable the evaluation of gap formation (1 and 2 mm partial and total gapping loads) and failure mode. The gap was considered to be partial when the maximum opening of the repair site reached certain measurement (1 or 2 mm). On the other hand, the gap was considered to be total when the minimum opening of the repair site was more than the measurement (1 or 2 mm). The video recordings were independently interpreted by two authors to determine the gapping loads and the mean of their interpretations was considered legitimate. The interrater coefficient of variation was determined.

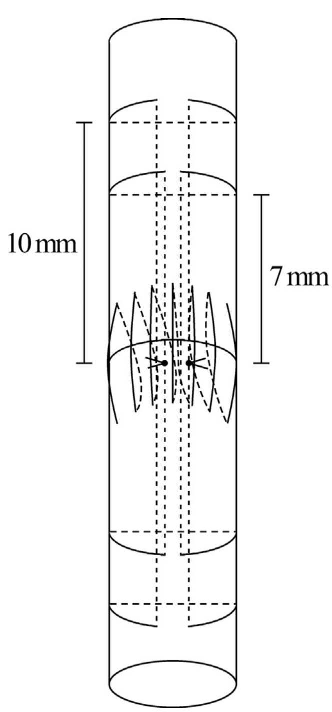

Fig. 1. A schematic illustration of the repair method.

2.4. Cyclic testing

Thirty-five repaired tendons were loaded in a cyclic manner using the same set-up, machine, and video recording as for static tensile testing. Maximum cycle count was 500. The velocity of loading was 300 mm/min. The base load was 0 N in all tests. The peak load was randomly adjusted for each specimen so that the group of 35 samples would cover the whole range of loads both under and over the yield load (from 17.0 N to 61.9 N) derived from static tensile testing pilot study. Each specimen was tested using constant peak load; the tendon either sustained all 500 cycles after which the testing ended or the repair disrupted during the testing.

Maximum likelihood estimation (MLE) is often used to estimate parameters of statistical model. Let θ be a vector that includes parameters of likelihood function and $x = x_1, x_2, \ldots, x_n$ be an observed sample. The likelihood of parameters θ with observations x equals the probability of observations x with parameter values θ: $\mathcal{L}(\theta|x) = P(x|\theta)$. For independent and identically distributed observations, the joint probability of observations x is product of the probabilities. Thus, for a continuous probability distribution $\mathcal{L}(\theta|x) = \prod_{i=1}^{n} f_\theta(x_i)$, in which f_θ is probability density function with parameters θ. The best likelihood is obtained by maximizing this result.

We used MLE to estimate the probability of failure for cyclically loaded specimens (Fig. 2A and D). Let $I_f(i)$ be an indicator function in which i is an index of an observation. The value of the indicator function is 1, if specimen failures, and value 0, if specimen sustains all 500 cycles. For convenience, let us call these two possible outcomes success (0) and failure (1).

Let $p_\theta(x)$ be the probability of failure, in which x is peak load used in cyclic tests and θ includes parameters of the probability distribution. If load x_i corresponds to observation i, probability of failure is $p_\theta(x_i)$ and probability of success is $1 - p_\theta(x_i)$. Utilizing the indicator function, the probability is $|p_\theta(x_i) + I_f(i) - 1|$ in both cases. So, the function to be maximized is $\prod_{i=1}^{n} |p_\theta(x_i) + I_f(i) - 1|$.

For simplicity, it is assumed that the cyclic peak load by which the repaired tendon barely sustains 500 cycles is normally distributed. Strictly, it is possible that the sample would present a double peak distribution, since sample most likely consists of tendons from both sexes. The probability of failure at given peak load equals the probability that the load which the tendon repair withstands is less than the load used. Thus, the probability of failure is obtained from cumulative distribution function of the normal distribution: $p_{\mu,\sigma}(x) = \frac{1}{2}\left[1 + \mathrm{erf}\left(\frac{x-\mu}{\sqrt{2\sigma^2}}\right)\right]$, in which parameters to estimate are expectation value μ and standard deviation σ.

The estimate parameters were assessed by computer software (MATLAB R2015b, MathWorks, Natick, MA, US). The steepest slope of the curve represents the average point where irreversible plastic changes begin to cumulate (coined to the critical load). However, it does not take into account the biological variation among samples and subsequent clinically safe threshold of loading. Due to the assumption of normal distribution, the risk of repair failure at theoretical critical load is 50%. Point $p_{\mu,\sigma}(-2\sigma)$ that is twice the standard deviation under mean of the critical load is coined to the safe load. It takes into account the effect of variation within the sample, and can be regarded as a more clinically relevant parameter than the critical load.

2.5. Analysis

The individual risk of repair failure for each statically derived parameter (ultimate load, yield load, and 1 mm and 2 mm partial and total gapping loads) to be used as a peak load of repetitive loading is judged from the estimate curve: $probabilityoffailure(\%) = y_1 * 100\%$, where y_1 represents the probability to failure (y-axis) at the point where load (x-axis) equals the mean of each statically derived parameter (Fig. 2B and C). The probabilities are related to the total variation within the present sample.

To rule out the possible confounding effect of caliber differences between specimens, Pearson's correlation coefficient was used for determination of the correlation between statically derived parameters and cross-sectional area, and unpaired T-test was used to compare cross sectional areas of the statically and cyclically tested tendons. Also, unpaired T-test was used to compare critical load of cyclically tested tendons to ultimate load, yield load and gapping loads of statically tested tendons. An alpha level of 0.05 was considered significant.

3. Results

The mean cross-sectional area of the repaired tendons was 5.8 (SD 1.2) mm^2. Ultimate loads of statically tested tendons were not related to cross-sectional areas of the tendons ($R = 0.130$,