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Application of static fatigue testing to the behavior of absorbable sutures

J.L. Prati, D.H. Kim, M.J. Matthewson*

Department of Materials Science and Engineering, Rutgers, The State University of New Jersey, 607 Taylor Road, Piscataway, NJ 08854-8065, USA

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A B S T R A C T

Absorbable sutures, since their conception, have become the dominant method for surgical wound closure and are constantly being improved. However, despite their years of service, not all aspects of their performance are fully understood. In particular, suture absorption is usually characterized by immersing the suture in a model *in vitro* environment under zero stress followed by measurement of the residual tensile strength as a function of immersion time. When in use, absorbable sutures are exposed to mechanical stress, which may affect the absorption rate; however, this phenomenon has not been adequately studied. The present work reports results of static fatigue tests in which the suture material is subjected to a mechanical load while immersed in a controlled environment and the time to fracture is measured as a function of the applied load. This approach is proved a viable method for obtaining a more detailed evaluation of absorbable suture performance.

1. Introduction

The development of absorbable sutures was an innovation to wound closure technology due to the fact that surgically inserted sutures could be absorbed after their purpose is fulfilled without the need for their physical removal. However, the ability of the suture to be absorbed results in a decrease in its tensile strength over time and therefore an understanding of the kinetics of strength degradation is useful. Current methods for studying this phenomenon include both *in vivo* (Bezwada et al., 1995) and *in vitro* (Mäkelä et al., 2002) studies. Specifically, the customary method used by manufacturers for *in vitro* testing consists of immersing the sutures in a test environment under zero stress for a set time and then removing them for dynamic tensile testing to determine the residual strength. In this case, the suture only encounters tensile stress during dynamic testing. In contrast, sutures are exposed to some stress postoperatively which will affect the degradation rate. Deng et al. (2005) attempted to evaluate the effect of static forces on degradation by applying relatively small loads (0.2–0.8 N) during submersion in solution. However, they still relied on dynamic testing to generate the strength data; thus, it is not a true static measurement (by “static” in this context we mean a static applied force).

In vivo testing more closely approximates the conditions of usage in practice. However, the *in vivo* environment is not fully controlled and the actual conditions of, for example, stress in the sutures, are unknown. This becomes more challenging with fluctuation in individual anatomical stresses. For example, models estimate that vascular surgery around the aorta could be subjected to stresses anywhere from 120 to 450 kPa for abdominal aortic aneurisms; (Raghavan et al., 2000) but other applications are unlikely to lead to such high stresses. In addition, *in vivo* studies utilize surgical knots, which are stress concentrators and will also strongly affect failure.

This paper describes a method that determines time to fracture of a suture as a function of static applied load using a static tensile technique. Fractured ends of selected specimens were examined using an optical microscope.

1.1. Materials

Coated VICRYL® (polyglactin 910) suture (J885G; ETHICON, Somerville, NJ, USA), was chosen for this study as representative of a typical braided suture material. The samples were USP size 3-0 gauge (0.2 mm diameter), undyed, and braided. VICRYL® ligatures (Ligapak) were used because they are longer than sutures but are identical to VICRYL® sutures except that the latter have a needle attached. For convenience, the specimens will continue to be referred to as sutures.

VICRYL® is an absorbable, FDA-approved co-polymer composed of 90% glycolide and 10% L-lactide. The specifications provided by the manufacturer suggest total absorption within 56–70 days while retaining at least 50% of its initial tensile strength at the end of the third week and 25% at the end of the fourth (Ethicon Product Catalog, 2015).

1.2. Experimental methods

The tensile static fatigue testing used an instrument that was

* Corresponding author.
E-mail address: mjohnm@fracture.rutgers.edu (M.J. Matthewson).

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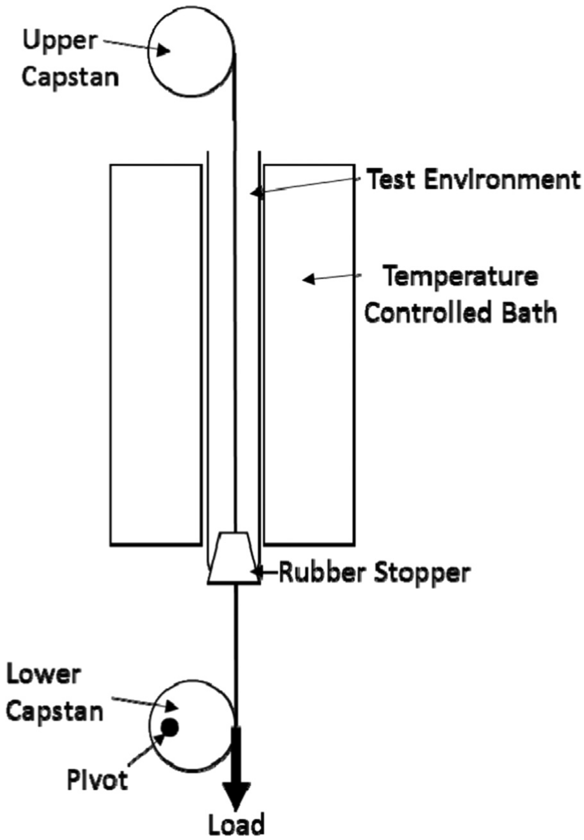

Fig. 1. Schematic of the equipment used for static fatigue testing.

originally designed for static testing of glass optical fibers and is shown schematically in Fig. 1 (Matthewson and Kurkjian, 1987). The sutures were gripped by wrapping twice around rubber coated capstans and taping down the ends. This avoids stress concentrations caused by, for example, knotting the sample. A series of predetermined loads in the range 4–34 N were applied using dead weights. The braided suture is made up of 338 fibers with an approximate diameter of 43 µm each, so each newton of load corresponds to a nominal stress of approximately 2 MPa in the individual fibers. During absorption the fibers thin so that the actual stress in them is unknown. We therefore will describe all results in terms of the applied load instead of the nominal applied stress.

The suture was threaded through a tapered rubber stopper at the bottom of a tube filled with the test environment: an isotonic (0.9%) saline solution. The tube is a sliding fit in a temperature bath so the suture supports the weight of the test solution, tube, stopper, the lower capstan, and the additional load applied to the lower capstan by dead weights; all were accounted for when recording the total applied load. The tube was contained inside a temperature-controlled water jacket maintained at 36–37 °C, representative of body temperature. The saline solution was added using a hypodermic needle through the rubber stopper at the bottom of the test environment to prevent air pockets.

While the top capstan was stationary, the vertical position of the bottom capstan was adjustable to compensate for elongation of the suture by creep. The lower capstan is on a pivot and rotates downwards when the suture breaks, activating a timer stop switch. Only data from samples that fractured in the test environment were used for evaluation; any suture that failed outside the test environment was not included in the data analysis. Selected fiber ends were examined using a Keyence optical microscope VHX-5000 with a high-resolution zoom lens (VH-Z500R/Z500T).

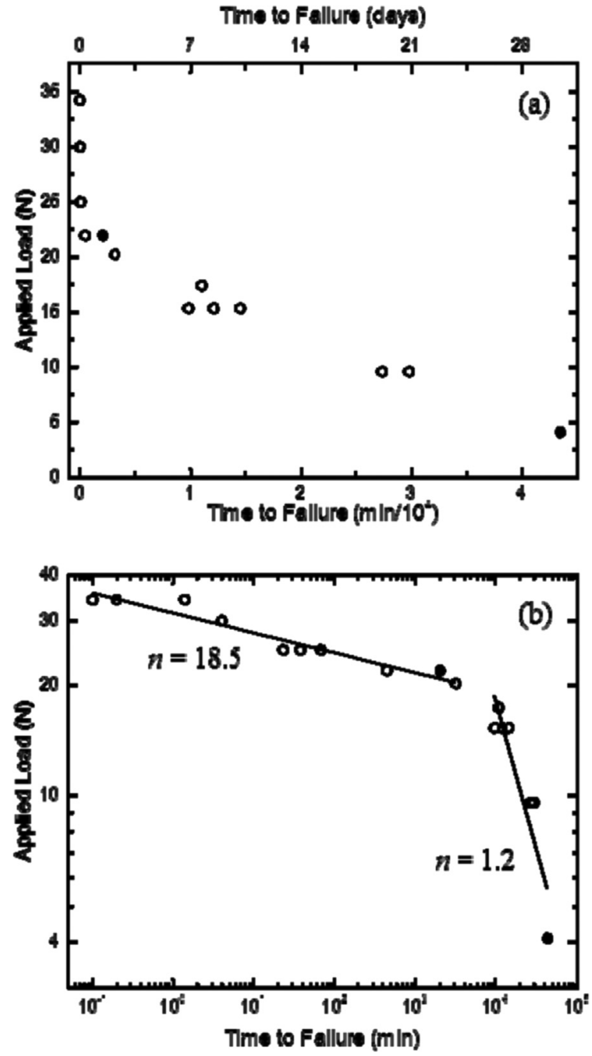

Fig. 2. Data from static fatigue testing on VICRYL® sutures; (a) uses linear axis scales while (b) uses logarithmic axes. The filled points represent the samples that were selected for optical microscopy.

2. Results and discussion

The results for the time to failure as a function of applied load are shown in Fig. 2. The horizontal axes are time despite it being the dependent variable because this is a widely used convention. At a load of 34 N, the time to fracture was within two minutes. This is consistent with the value of 38.4 N for the instantaneous breaking strength of nominally identical 3-0 VICRYL® sutures as determined using dynamic methods (Naleway et al., 2015). In Fig. 2(a) with a linear time scale, the data appear bilinear with a steep fall at short times and a gradual decrease in time to failure with decreasing load suggesting two mechanistic regimes. Extrapolating to the instantaneous failure load results in "strength retention" values (strength normalized to the initial instantaneous strength) that is consistent with the manufacturer's specifications for strength degradation over time (Ethicon Product Catalog, 2015). Fig. 2(b) shows a log-log plot of the data that better represents the bilinear behavior. Such data are often represented by empirical power laws relating the time to failure, t_f, to the applied load, P:

$$t_f = AP^n$$

where A is a pre-exponent and n is the power which describes the sensitivity of t_f, to the applied load – the value of n controls the degradation rate and hence the eventual lifetime. The trend lines fitted to the two regions in Fig. 2(b) give values of $n = 18.5$ in the high load

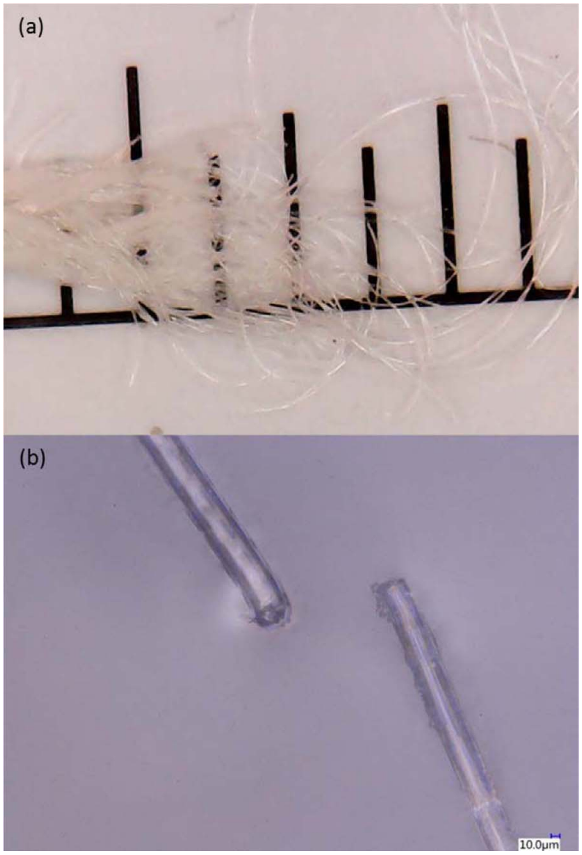

Fig. 3. Optical micrographs of a broken suture end which failed under a load of 22 N after 1.4 days. (a) low magnification (scale marks are 0.5 mm apart) showing fraying of the suture braid, and (b) higher magnification showing the ends of two fibers. Fiber ends show minimal necking.

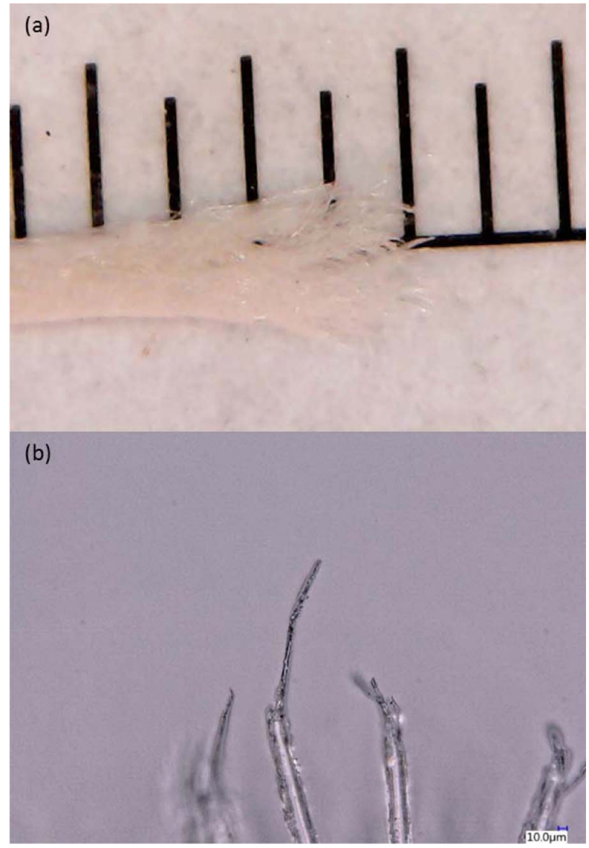

Fig. 4. Optical micrographs of a broken suture end which failed under a load of 4.1 N after 30.1 days. (a) low magnification (scale marks are 0.5 mm apart) showing minimal fraying of the suture braid, and (b) higher magnification showing the ends of individual fibers which exhibit significant necking.

region and 1.2 in the low load region. The high value of n in the high load region shows that as the applied load is reduced below the "instantaneous" strength of the suture, the time to failure increases rapidly. In contrast, in the low load region the lifetime does not extend rapidly as the load is reduced; it is likely that over the longer time involved in the low load measurements, the corrosion of the suture by the environment is controlling the failure. However, the failure time does still depend on the load and this has an important practical implication; any stress in the suture post surgery will accelerate absorption to some extent.

In the high stress region of Fig. 2(b), the time to failure, although stress dependent, is short and suggests less sensitivity to environmental degradation. This is supported by the observation that a suture tested in air failed in 0.2 min under a load of 34 N.

The broken ends of two samples were examined with an optical microscope (filled points in Fig. 2. Fig. 3(a)) shows that for the high load break, the individual fibers comprising the braid failed at varying points along the length of the suture. This leads to fiber pullout and fraying of the end. At higher magnification, Fig. 3(b) suggests a brittle fracture mechanism which is consistent with high strain-rate failures (Kinloch and Young, 1995).

Fig. 4 shows a sample that failed after 30 days at a relatively low load of 4.1 N. The fracture positions of individual fibers are much closer together than in Fig. 3(a) and fiber pullout was greatly reduced compared to the high load sample. At higher magnification Fig. 4(b) shows necking and more ductile failure of the fiber. This shows a clear change in failure mechanism from apparently brittle at high load to apparently ductile at low load. Comparison of Figs. 3(b) and 4(b) shows fiber diameters of 43 and 30 μm (away from the severely necked regions), respectively and shows that considerable thinning has been caused by extended immersion in the test environment.

3. Conclusions

Experiments on a particular suture material (VICRYL®) have shown the effectiveness of using a static testing method to study the absorption/failure behavior of sutures under a constant applied load. Although the measurements described here are preliminary in nature and were only intended to validate the static fatigue test method, they do show intriguing and significant results worthy of further study. A change in failure mechanism was observed where at high applied loads the failures appear brittle and are controlled primarily by the applied stress, while at lower loads, the failures are more ductile in nature and are controlled more by the test environment. However, in the low load regime, it is found that the time to failure does decrease with increasing static load which suggests that the absorption time for the sutures when used in practice will depend on the residual stress left in them as the wound heals. This phenomenon cannot be studied using standard dynamic testing methods used by suture manufacturers, but the static method described here is ideally suited for that purpose.

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