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Original Article

Suture Retention Strength of Expanded Polytetrafluoroethylene (ePTFE) Graft

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Our meticulous investigation of ePTFE graft breakage when a wire placed at the edge of an ePTFE graft was pulled, revealed that, depending on the breakage pattern, a break starts much earlier than the peak suture retention strength, which is the current international indicator for anastomotic-site break strength. Furthermore, the breakage patterns differ based on the thickness of the wire and the fiber direction of the ePTFE graft. Based on these findings, we advocate measuring the peak suture retention strength using 0.10-mm sutures and a standardized wire thickness in order to assess the anastomotic retention strength of ePTFE grafts.

Key words: ePTFE, suture retention strength, anastomotic strength

Anastomotic strength is one of the physical properties of conventional grafts, and it is measured in terms of suture retention strength (a wire placed in a graft is pulled, and the peak force measured during the pulling process up to breakage is determined) in accordance with the provisions of the American National Standards Institute/Association for the Advancement of Medical Instrumentation (ANSI/AAMI) [1]. However, there are no set standards for wire material, wire thickness and needle size when measuring the suture retention strength. Therefore, there is a certain degree of confusion when measuring anastomotic strength. Basically, the breakage patterns and stress-strain curves of Dacron grafts are also believed to be different from those of ePTFE grafts, and the measurement of anastomotic strength based on suture retention strength developed for Dacron grafts may not be suitable for ePTFE grafts. Previously we investigated changes in the anastomotic strength of expanded ePTFE grafts [2] in this study we investigated techniques for accurately measuring anastomotic strength, a key surgical parameter, by analyzing the breakage patterns of ePTFE anastomotic sites and stress-strain curves.

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Materials and Methods

Materials. Impra grafts (Impra, Tempe, AZ, USA) with a 4-mm internal diameter, standard wall (wall thickness: 0.6 mm), 2-cm length and 30-μm internodal distance were prepared.

Measurements. With each prepared graft, a

pinhole was made by placing a 0.4-mm round needle perpendicularly to the longitudinal axis of the graft at a point 3 mm from the edge. To minimize the effects of suture materials on stress-strain curves, steel wires of 5 different thicknesses were used (diameters of 0.07, 0.10, 0.13, 0.15 and 0.20 mm; Asahi Intecc Co., Ltd., Nagoya Japan). These steel wires were passed through the pinhole to form a loop and were then fixed to the tensile testing machine (EZ test, Shimazu, Kyoto, Japan), such that the distance from the grip was 15 cm. The 5-mm edge of the graft contralateral to the pinhole was fixed to the grip on the inferior side of the testing machine. The steel wire was pulled at a rate of 10 cm/min until the graft was completely torn (Fig. 1). For each tensile test, a stress-strain curve was drawn using the image analysis software installed in the computer (Factory SHIKIBU 2000). The entire process of graft breakage was captured using a digital camcorder (Sony PC-120) to record the graft breakage pattern, break-

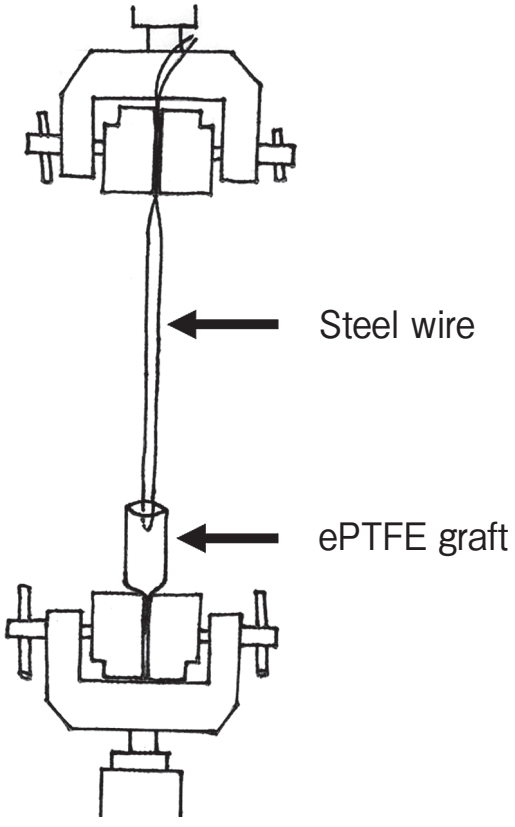


Fig. 1 Schema of the testing method of suture retention strength.

starting point and break end point. From each stress-strain curve, the break-starting strength and suture retention strength were calculated by playing the video backward from the break end point. Among tensile tests, the break-starting strength, suture retention strength and stress-strain curve were compared. Stress-strain curves were plotted at 1/20-sec intervals. Still video images could be checked at 1/30-sec intervals. All tensile tests were conducted at room temperature in a dry environment.

Suture retention strength: A stress-strain curve was prepared for each breakage process, and suture retention strength was defined as the peak strength during the process.

Break-starting strength: From each video clip, the instance when a longitudinal cut or horizontal tear could be macroscopically confirmed on the graft wall was ascertained and plotted on the stress-strain curve, and the tensile strength at this point of time was determined from the stress-strain curve drawn using the software that came with the testing machine.

Scanning electron microscopy. After each tensile test, all grafts were cut along the longitudinal axis to expose the internal surface. Each graft was fixed using glue-stick tape to a special aluminum stub and subjected to gold spraying. Using an electron microscope (HITACHI Scanning Electron Microscope Model S-2300, Japan), the site of graft breakage was observed with 25-kV accelerating voltage.

Statistical analysis. For each steel wire thickness, 10 tensile tests were conducted. All measurements were expressed as means ± standard deviation. Continuous data were analyzed by either unpaired Student's t test or one-way analysis of variance (ANOVA), while Scheffe's F test was used as needed. The level of significance was set at $p < 0.05$. Statistical analyses were conducted using StatView for Windows Version 5.0 (SAS Institute Inc., Cary, NC, USA).

Results

Breakage patterns. Breakage patterns were classified into the following 3 types: longitudinal cutting; circumferential tearing; and mixed patterns.

1. Longitudinal cutting pattern (Fig. 2A)

In this breakage pattern, there is no circumferential graft tear, but there is a sharp cut in the longitu-

dinal direction. The point in time when a longitudinal cut began forming matched the suture-retention strength of the stress-strain curve, and after reaching the suture retention strength, 3 declines were observed on the stress-strain curve. The first decline was steep; it indicated the instant when the longitudinal cut began to form. The second decline was gradual; it indicated the process by which the cut advanced longitudinally. The third decline was again steep and reached the zero point (the point when graft breakage ended).

2. Circumferential tearing pattern (Fig. 2B and C)

In this pattern, there is no longitudinal cut, and only circumferential tears are observed. After reaching the suture retention strength, 2 declines were observed on the stress-strain curve. The first decline was gradual and indicated the process by which the graft was being torn circumferentially. The second decline was steep and reached the zero point (the point when graft breakage ended). Of the 3 patterns of breakage, the suture retention strength of this pattern was the greatest.

3. Mixed pattern (Fig. 2D)

In this breakage pattern, a circumferential tear was seen first, followed by a longitudinal cut. In addition, the point in time when the longitudinal cut began forming matched the suture retention strength of the stress-strain curve, and after reaching the suture retention strength, 3 declines were seen on the stress-strain curve. The first decline was steep, and it indicated the instant when the longitudinal cut began to form. The slope of the first decline was the same as that of the longitudinal cutting pattern. The second decline was gradual and indicated the process by which the cut advanced longitudinally. However, on the stress-strain curve, the greater the suture retention strength, the steeper the decline when compared to the longitudinal cutting pattern. The third decline was again steep and reached the zero point (the point when the graft breakage ended).

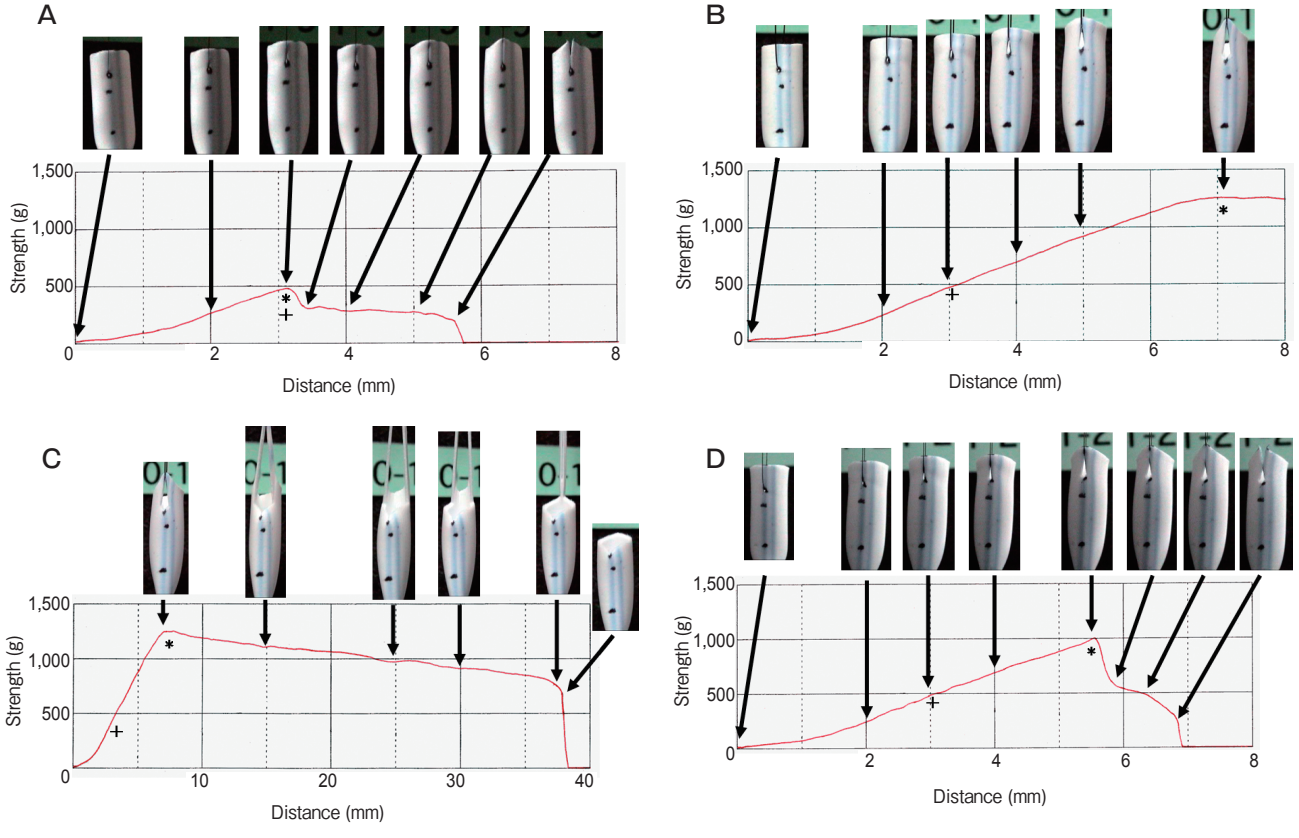


Fig. 2 Stress-strain curve and photographs of the breakage of ePTFE graft in the longitudinal cutting pattern (A), the circumferential tearing pattern from zero point to the point of peak strength (B) and from the zero point to the end point of the breakage (C), and the mixed pattern (D). *, Peak strength (suture retention strength); +, Break-starting strength.

In the circumferential tearing and mixed patterns, a circumferential tear was seen before reaching the suture retention strength. During the period from the initial formation of a circumferential tear to the time the suture retention strength was reached, circumferential tearing and longitudinal elongation of the graft wall were concurrently observed. The point of the suture retention strength on the stress-strain curve was the point in time when the longitudinal elongation of the graft wall ended. The stress-strain curves for the 3 breakage patterns were plotted on the same coordinate axis (Fig. 3), and the stress-strain curve from the zero point to the suture retention strength for the longitudinal cutting pattern was the same as that for the other 2 patterns. For the circumferential tearing and mixed patterns, the stress-strain curve from the zero point to the suture retention strength was the same.

Measurements. As shown in Fig. 4, the longitudinal cutting pattern tended to be seen more often with tensile tests using narrow steel wires, while the circumferential tearing pattern tended to be seen more often with tensile tests using thick steel wires. Irrespective of the steel wire thickness, the suture retention strength of the longitudinal cutting pattern was significantly different from that of the other 2 breakage patterns (Fig. 5). From plotting the suture retention strength and break-starting strength for 50

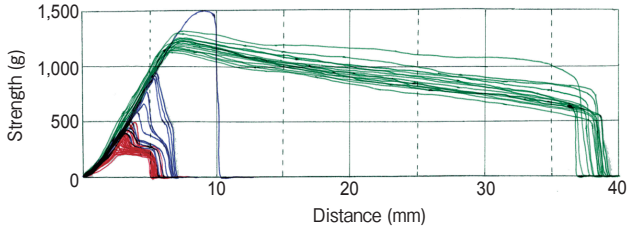


Fig. 3 Typical stress-strain curves of longitudinal cutting pattern (red), mixed pattern (blue) and circumferential tearing pattern (green) were shown on the same coordinate axes.

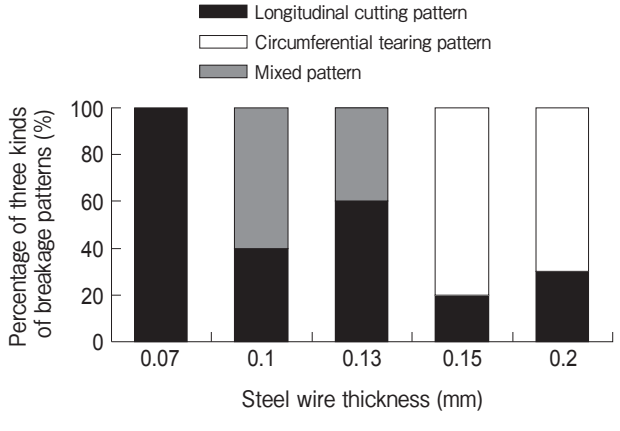


Fig. 4 Percentage of 3 kinds of breakage patterns in relation to thickness of steel wire thickness.

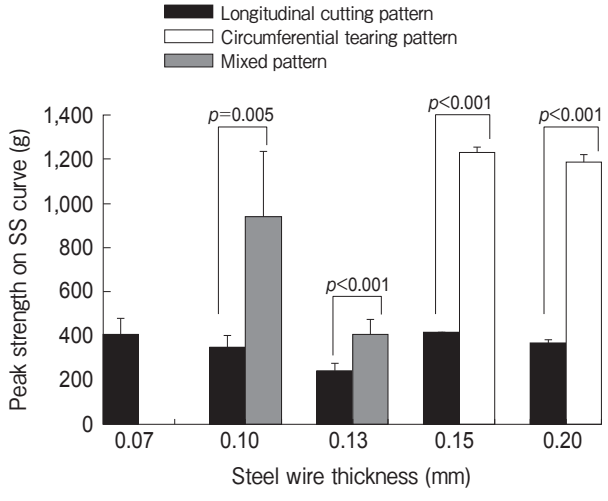


Fig. 5 Average peak strength (suture retention strength) of 3 kinds of breakage patterns in relation to steel wire thickness. Error bars represent one standard deviation of the mean.

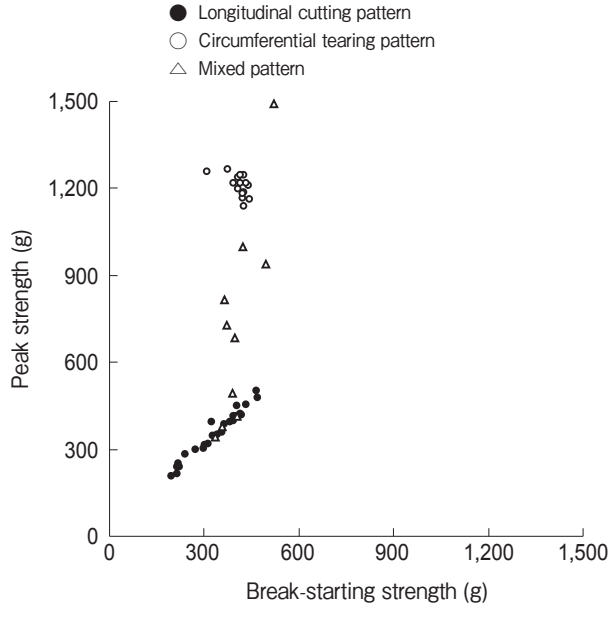


Fig. 6 Relation between peak strength (suture retention strength) and break-starting strength.

tensile tests using 5 steel wire thicknesses (0.07-0.20 mm) on the same coordinate axes (Fig. 6), it was clear that there were 2 groups: in one group, the suture retention strength and break-starting strength were mostly comparable, while in the other group, the suture retention strength was clearly greater than the break-starting strength. For the longitudinal cutting pattern, there were no statistically significant differences between break-starting strength and suture retention strength (Fig. 7). The break-starting strength for the circumferential tearing and mixed patterns tended to be greater than that for the longitudinal cutting pattern (Fig. 8). Significant differences were seen in the break-starting strength of the longitudinal cutting pattern with respect to the steel wire thickness, but not with the circumferential tearing and mixed patterns (Fig. 9).

Scanning electron microscopy. When scanning electron microscopy was performed in order to observe longitudinal graft cuts, longitudinal breakage of node bundles was seen, and when examining circumferential graft tears, tears in the internodal fibers were observed (Fig. 10A and B).

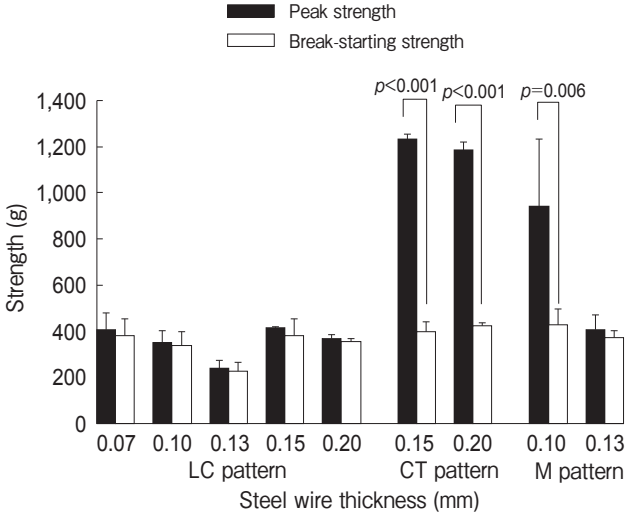


Fig. 7 Average peak strength (suture retention strength) and break-starting strength in 3 kinds of breakage patterns in relation to steel wire thicknesses. Error bars represent one standard deviation of the mean. LC pattern, longitudinal cutting pattern; CT pattern, circumferential tearing pattern; M pattern, mixed pattern.

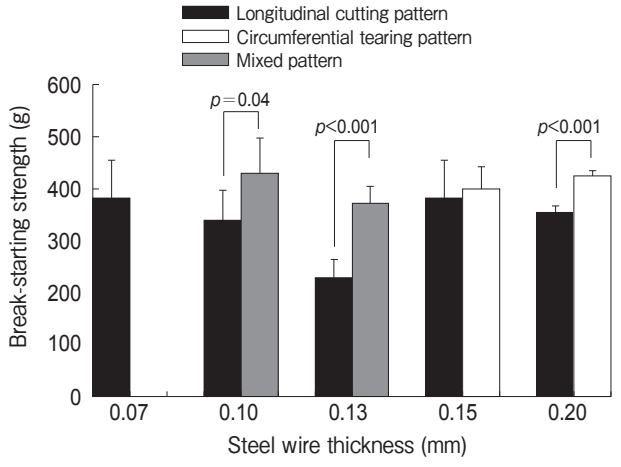


Fig. 8 Average break-starting strength of 3 kinds of breakage patterns in relation to steel wire thicknesses. Error bars represent one standard deviation of the mean.

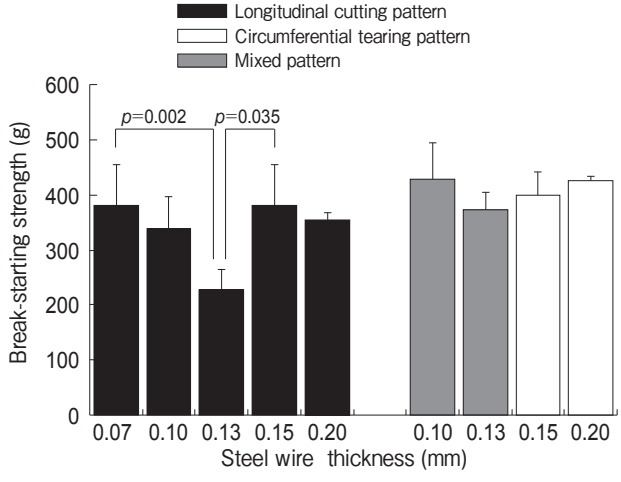


Fig. 9 Average break-starting strength of 3 kinds of breakage patterns in relation to steel wire thicknesses. Error bars represent one standard deviation of the mean.

Discussion

With regard to the strength of native vessel-graft anastomosis, there have been many reports on biological hemodynamic problems [3-5], graft and vessel compliance mismatch [6] arteriosclerosis and arterial degeneration [7-9] and suture material problems [10]. The results have indicated that most graft anastomosis failures are due to vascular fragility [11-12]. However, there have been several reports

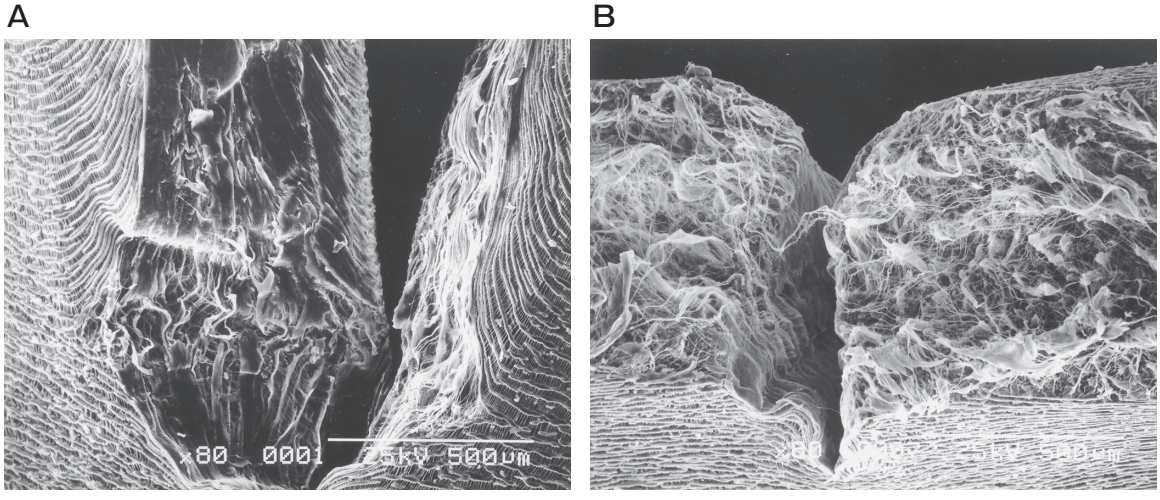


Fig. 10 Scanning electron micrograph of internal luminal surface of ePTFE graft. **A**, longitudinal cutting pattern; **B**, circumferential tearing pattern.

of ePTFE graft breakage without any vessel damage [13–15], and we believe that it is necessary to closely investigate the graft wall strength at the contact between the ePTFE grafts and sutures. The present study investigated graft wall strength at the contact between the graft and the suture.

Like tensile strength and bursting strength, suture retention strength is one of the indicators for graft anastomotic strength established by ANSI/AAMI [1], and it is an important indicator for attaining sales licenses for grafts. According to ANSI/AAMI [1], suture retention strength is measured in 2 ways: the straight-across procedure and the oblique procedure. With the straight-across procedure, a graft is cut longitudinally in order to make a sheet, and a wire is placed at one edge to conduct a tensile test. With the oblique procedure, the graft is cut at a 45-degree angle along the long axis, and a tensile test is conducted at 4 points including the heel and toe of the cutoff stump. With these procedures, ANSI/AAMI states that a wire that is strong enough to avoid breakage should be placed 2 mm from the graft edge and pulled at a rate of 50-200 mm/min, and that its thickness must be recorded. Currently, manufacturers measure and assess anastomotic strength using their own methods. We believe that suture retention strength is affected by numerous unregulated factors, such as needle thickness and shape and suture material and thickness. We prepared an experimental system to reproduce a state similar to that in which grafts are used for patients. In other words, using a tube graft, a circular hole was made exactly 3 mm from the edge, and a steel wire was inserted through the hole. In clinical settings, polypropylene sutures are used for vascular anastomosis, but because polypropylene stretches when pulled, the dynamic strength of the anastomotic sites of grafts cannot be measured, making an accurate stress-strain curve impossible. Subsequently, we selected steel wires. Five thicknesses corresponding to the thickness of common sutures in vascular surgery were selected: 0.07, 0.10, 0.13, 0.15 and 0.20 mm.

Through the present study, we noted the following points: first, as reported previously, the patterns of graft breakage could be roughly classified into 3 groups (longitudinal cutting pattern, circumferential tearing pattern and mixed pattern); second, suture thickness impacted breakage patterns; third, when a circumferential tear was seen in a graft, the break-starting strength did not match the suture retention strength; and fourth, the stress-strain curve from zero to the point when a longitudinal cut began forming for the longitudinal cutting pattern (*i.e.*, the time-point for suture retention strength) was the same as the other 2 breakage patterns, and for the circumferential tearing and mixed patterns, the stress-strain curve from zero to the point in time when a longitudinal cut began forming (*i.e.*, the timepoint for suture retention strength) was the same. The results showed that break-starting strengths could be classified into 2

groups: longitudinal cutting break-starting strength; and circumferential tearing break-starting strength. Finally, it was clarified that the circumferential tearing break-starting strength was less likely to be affected by suture thickness.

The above findings suggest that breakage patterns are determined based on the balance between circumferential tearing and longitudinal cutting break-starting strengths at the site of wire placement in the graft wall. We believe that the longitudinal cutting pattern is seen when the longitudinal cutting break-starting strength is smaller than the circumferential tearing break-starting strength, while the circumferential tearing and mixed patterns are seen when the circumferential tearing break-starting strength is smaller than the longitudinal cutting break-starting strength. Furthermore, the mixed pattern is observed when the longitudinal cutting break-starting strength is smaller than the circumferential tearing break-starting strength during the pulling process, while the circumferential tearing pattern is seen when the circumferential tearing break-starting strength remains smaller than the longitudinal cutting break-starting strength throughout the pulling process.

Artificial wall thickness, internodal distance, nodal width, interfiber distance and fiber width are measured by electron microscopy as an indicator to assess ePTFE grafts [16]. Electron microscopy showed nodal tears in the longitudinal direction of grafts at the site of longitudinal cuts and tears in the internodal fibers at the site of circumferential tears. These results suggest that longitudinal cutting break-starting strength is mostly affected by node strength and that the circumferential tearing break-starting strength is mostly affected by fiber strength. Because the wall structure of ePTFE grafts is not uniform, even if the same ePTFE graft is used, the above-mentioned electron microscopic assessment items of the ePTFE graft wall vary depending on the wire placement site. The strength of the internodal fibers, *i.e.*, the circumferential tearing break-starting strength, is less likely to be affected by various factors, such as graft wall structure, suture thickness, and distance from graft edge to wire placement site. On the other hand, the strength of all nodes located between the graft edge and wire placement site, *i.e.*, the longitudinal cutting break-starting strength, is more likely to be affected by the above-mentioned factors (graft wall structure, suture thickness, and distance from graft edge to wire placement site). In the present study, the frequency of circumferential tearing tended to be high when a thick wire was used. If this tendency is true, the observation of both the longitudinal cutting pattern and circumferential tearing pattern in the tensile tests using same-thickness wire would indicate a mixed pattern. However, mixed patterns were not observed in the tensile tests of 0.15- or 0.20-mm steel wires. In our preliminary study, the pinholes were examined using an electron microscope, and the forms were made uniform without extreme longitudinal cutting and circumferential tearing. The reason why longitudinal cutting patterns were observed and mixed patterns were not may be that longitudinal tearing at the pinhole site occurred when a steel wire was passed through it. In the present study, significant differences were seen in the longitudinal cutting break-starting strength among the 5 steel wire thicknesses, but the correlation between steel wire thickness and longitudinal cutting break-starting strength could not be clarified. Rather, these statistical differences were believed to be due to differences in graft wall structures at the wire placement site and measurement errors for the distance between the graft edge and wire placement site.

In the present study, the frequency of circumferential tearing was high when a thick wire was used, and the suture retention strength tended to be high. However, at this time, a break had already occurred. Therefore, from the viewpoint of anastomotic strength measurement, it is meaningless to use a thick wire. As the wall structure of ePTFE, which is widely used as a graft material, is unique, tensile tests show both longitudinal cuts and circumferential tears. Because a circumferential graft tear indicates a high suture retention strength, when assessing and comparing anastomotic strength, 0.10-mm sutures should be used. As 0.10-mm sutures are generally used during surgery, the results of such research would be clinically meaningful.

After reporting these data to affiliated associations, we plan to propose that wire thickness should be standardized when measuring suture retention strength as an objective indicator of the strength of ePTFE anastomotic sites.

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