Temporal changes in the tensile strength of ultra-high-molecular-weight polyethylene cable embedded in muscle tissue

INTRODUCTION
Sublaminar wiring for posterior spinal fixation remains a very popular technique. Since then many materials have been used for this method such as cables made from stainless steel or titanium instead of traditional monofilament stainless steel wires and favorable clinical outcomes have been reported. However, complications of nerve damage within the spinal canal due to compression by the metal wires and cables have also been reported. We have used ultra-high-molecular-weight (UHMW) polyethylene material, Tekmilon tape, instead of metal materials to allow safe sublaminar wiring with fewer complications. Tekmilon tape is more flexible than conventional metal materials, we could place it more safely under the vertebral arch when performing sublaminar wiring. We have demonstrated that the initial strength of Tekmilon tape is equivalent to metal wires and cables in our previous study. However, in clinical use, the strength of Tekmilon tape must be maintained until bone union has occurred to enhance stabilization of the spine. Therefore, temporal changes in the strength of Tekmilon tape in the body should be clarified.

MATERIAL AND METHODS
Ethylene oxide gas-sterilized UHMW polyethylene tape of width 3 mm (NCS3 Tekmilon tape; Alfresa Pharma, Osaka, Japan) and UHMW polyethylene suture, USP suture size 1 (11EW Tekmilon suture; Alfresa Pharma) (Fig. 1) were provided by Alfresa Inc. Male Japanese white rabbits (age, 10 weeks) were used in this study under the animal care guidelines of our institution. Each experimental group consisted of ten rabbits for the embedding period of 1, 3, 6, and 12 months. The samples were embedded into the bilateral paravertebral muscles of a rabbit and were carefully removed without any damage at the end of each period. Sequential straight tensile strength of ten Tekmilon tapes and ten Tekmilon sutures were measured using Tensilon RTC 1250-A (A&D Company Limited, Tokyo, Japan) with a device distance of 50 mm and crosshead speed of 100 mm/min. For the remaining ten samples, a knot was made at the center of each sample and sequential knot-pull tensile strength was measured in the same manner.

Statistical analyses were performed by one-way analysis of variance (ANOVA) with Dunnett's multiple comparison of means test. A p-value of less than 0.05 was considered significant.

RESULTS
Mean initial straight tensile strength for Tekmilon tape (month 0) was 626N ± 27 (standard deviation), compared with 483N ± 61 at 12 months. Mean initial knot-pull tensile strength for Tekmilon tape (month 0) was 345N ± 33, compared with 345N ± 33 at 12 months. Mean initial straight tensile strength for Tekmilon suture (month 0) was 385N ± 25, compared with 106N ± 12 months. Mean initial knot-pull tensile strength for Tekmilon suture (month 0) was 141N ± 81, compared with 81N ± 12 months (Table 1). Compared with initial strength at month 0 (100%), straight tensile strength for Tekmilon tape was 92% at 6 months and 77% at 12 months, whereas Tekmilon suture was dramatically decreased 39% at 6 months and 28% at 12 months. The degree of decrease in strength was significantly smaller for Tekmilon tape than for Tekmilon suture (Fig. 2 A and B). Mean knot-pull tensile strength for Tekmilon tape was 104% at 6 months and 100% at 12 months, compared with Tekmilon suture, which was 71% at 6 months and 57% at 12 months (Fig. 2 C and D). There were no significant strength change in the Knot-pull tensile strength for Tekmilon tape between 0, 6, and 12 months (P<0.05), but a significant difference was observed in all other groups (P<0.05).

DISCUSSION
The present study demonstrates that the initial strength of Tekmilon tape in muscle tissue was maintained over time. These results suggest that temporal changes in the tensile strength of Tekmilon tape are negligible over long time periods. Moreover, since single knot is clinically relevant, it is very important that the knot-pull tensile strength was maintained over a 12-month period. The results also demonstrate the difference of temporal changes between Tekmilon tape and Tekmilon suture. The tensile strength of Tekmilon tape was better maintained than Tekmilon suture when embedded in muscle tissue for a period of 12 months, suggesting that the type of weaving could cause temporal differences of these materials in vivo.

In conclusion, Tekmilon tape maintains sufficient strength in vivo until bone union has occurred. It is useful for sublaminar wiring instead of metal materials.

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