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Development of Medical Shark Skin Forceps: Improved Grasping Power and Easy Manipulation

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ABSTRACT

Background and Objectives: Important safety requirements for forceps used in surgical procedures are the ability to stably grasp fine tissue and to cause minimal tissue damage. Shark skin has the structural feature of circumpolar scales, which increase the frictional force of the scales by roughening their surface. We have developed and patented medical forceps with a shark skin pattern placed on the tip surfaces. The aim of this study was to examine the safety and efficacy of the shark skin forceps compared with existing forceps, both fundamentally and clinically.

Methods: To evaluate gripping power and usability, we compared bead transfer times for each forceps type. Grasping force and frictional force were measured quantitatively and compared among the types. To evaluate safety, we performed pathological examination of lung and urethral tissue after grasping, in an animal experiment. Subjective assessment of user experience was then performed using a questionnaire.

Results: In the dry lab assessment, transfer time was fastest using the shark skin forceps (34 s vs 61 s and 62 s, $p < 0.05$). Frictional force values were highest for the shark skin forceps ($p < 0.05$). In the animal experiment, there was no difference in pathological tissue damage to lung or ureter tissues among the forceps types after grasping. The questionnaire responses indicated advantages of the shark skin forceps in terms of ease of grasping membranes and lower degree of grasp failure.

Conclusion: Forceps with shark skin on the tips showed greater stability of tissue grasping and equivalent safety compared with existing forceps.

Key Words: General surgery, Medical forceps, Shark skin.

INTRODUCTION

In surgical procedures, the slightest error can cause major bleeding leading to postoperative complications and mortality, especially when dissection is performed around blood vessels.[1–3] Accordingly, forceps that can grasp fine tissue stably, do not slip, and cause minimal tissue damage are crucial for ensuring safety. Weight and design optimization are also important to prevent fatigue in the surgeon after long hours of surgery, as well as ease of gripping the forceps when wearing surgical gloves. Various forceps have been designed with these requirements in mind and are currently used in clinical practice (e.g. Aesculap®; B Braun, Tokyo, Japan and Scanlan®; Scanlan International, Minnesota, USA). Nevertheless, it is common for surgeons to experience difficulty in intraoperative grasping that results in bleeding.

Shark skin is composed of circumpolar scales that are arranged in an orderly fashion similar to sharp teeth, with fine protrusions and V-shaped grooves.[4,5] This structure reduces water resistance and has been used in swimwear design.[6] Conversely, the presence of small protruding structures on the dairy scale has been reported to increase the frictional force of the scale by roughening its surface.[7,8] We considered that this feature could be applied to the development of an ideal forceps. Accordingly, we have designed and patented a medical forceps that has a shark skin pattern on the tips (Tanaka Medical Instruments, Japan),

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developed in the Medical-Engineering Hybrid Professional Development Program at the Nagasaki University Graduate School of Biomedical Sciences.

The aim of the study was to examine the safety and efficacy of the shark skin forceps compared to existing forceps, both fundamentally and clinically.

METHODS

Development of the Shark Skin Forceps

We have applied a design that is a biomimicry of shark skin. It is known that the inherent structure of shark skin reduces fluid resistance in one direction but increases it in the opposite direction.[9] We exploited this structure to increase resistance by placing such a structure on the tips and handle of the forceps (Tanaka Medical Instruments, Japan, Patent No. 6310051). We then evaluated the function of shark skin forceps in comparison with forceps already in clinical use: Aesculap® (standard, nontraumatic, FB 404R) and Scanlan® (DeBakey, flat handle, 4004-50). All three types are of the same standard (stainless steel, 2-mm tip, 24 cm in length) (**Figure 1**).

Bead Transfer Test

To evaluate the gripping power and usability of the shark skin forceps compared with two other forceps, we performed a dry lab trial, as described in a previous report.[10] Three beads were placed in a recessed plate on the left side of the participant, who was instructed to transfer all beads individually to a plate on their right side, and then immediately return all three beads individually to the left plate. The time taken to complete this task was recorded. If any beads dropped off a plate, they were returned to the original plate by hand. There were 30 participants in the experiment: 24 physicians (15 surgeons and 9 postgraduate clinical residents) and 6 medical students (age range, 23–53 years, 21 males and 9 females). The participants performed this operation twice for each of the three forceps types, in the order Aesculap®, Scanlan®, and shark skin forceps.

Frictional Force Measurement

We have previously reported a testing device developed to measure forceps function (**Figure 2a**).[11] A hydraulic-driven system (HDS) based on syringes and syringe pumps is used for driving the left–right symmetrical lever linkage system of the device. A simple real-time feedback control system was built to remotely control the bars of the operating tweezers and monitor the forces on the jaws. A second HDS was then used to pull or push the tweezer operating system (**Figure 2a**) or the target (**Figure 2a**), and thus generate relative movement between the jaws and the target. Using this device, we measured frictional force at the tips of each type of forceps when grasping a 5-mm-thick resin sheet (Hitohada®; Exseal Co., Ltd., Gifu, Japan) (**Figure 2b**), with the tweezer tips extending 5 mm into the sheet at the start point. We set the input load position 20 mm in front of the center of gravity of the tweezers. We measured the

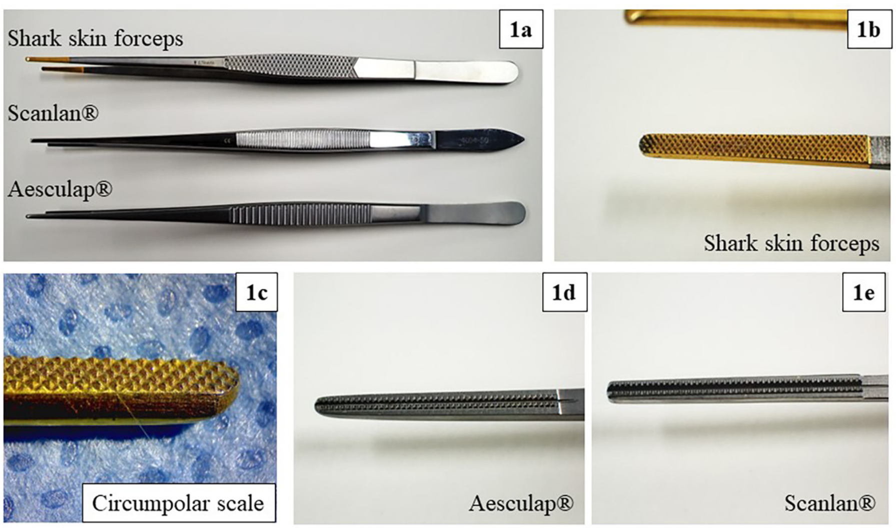

Figure 1. A) Photograph of three forceps, **B**) Forceps tips of the shark skin forceps, **C**) Circumpolar scale of shark skin forceps, **D**) Aesculap®, **E**) Scanlan®.

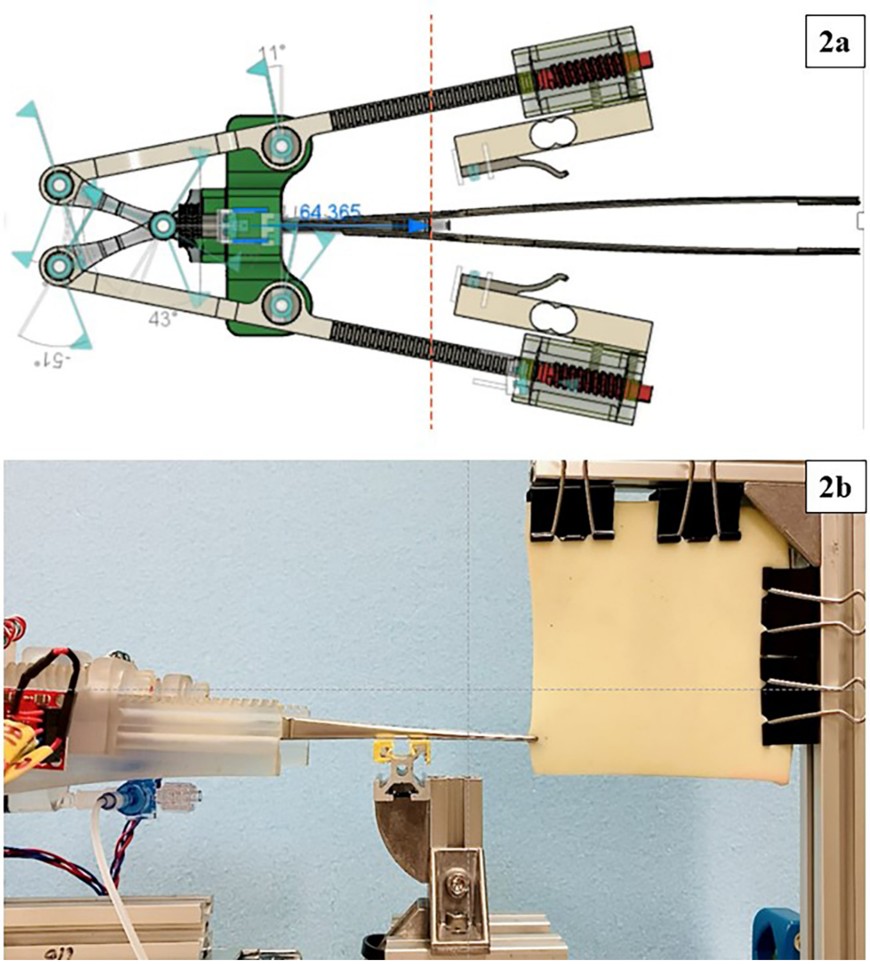

Figure 2. A) Diagram of device used to measure constant holding force and **B**) Photograph of the experimental setup.

holding force of each forceps type at forces of each of 300 gf (2.94 N) and 350 gf (3.43 N) during movement (by dragging on the target sheet or the holding area) in the horizontal direction. Each measurement was repeated ten times. The same method was used to measure frictional force in the vertical direction. After extraction of the frictional force values during the change from static to dynamic friction, the ratio of frictional force to holding force was calculated for each type of forceps and compared among types, as decided in consultation with an engineer.[11]

Animal Experiment

We assessed the safety of the forceps in a wet lab experiment using pigs. The experiment was performed in strict accordance with the recommendations in the Guide for the Care and Use of Laboratory Animals of the National Institutes of Health. The study protocol was approved by the Institutional Animal Care and Use Committee of Nagasaki University (Approval No. 1710181416). Under general anesthesia by intramuscular injection of 0.1 mL/kg ketamine and inhalation of 2% isoflurane, the animal was placed on a surgical table, and intubated and artificially ventilated. Eight surgeons performed surgery and completed questionnaires on the use of each forceps.

To check safety, each surgeon used the forceps to grasp lung tissue (**Figure 3a**) and ureter (**Figure 3b**). We then checked for air leaks in the areas of lung that had been grasped (**Figure 3c**), and pathologically evaluated sections of ureter that had been grasped (**Figure 4**).

Subjective Assessment by Questionnaire

Following the animal experiment, each research participant filled out a questionnaire regarding their experience

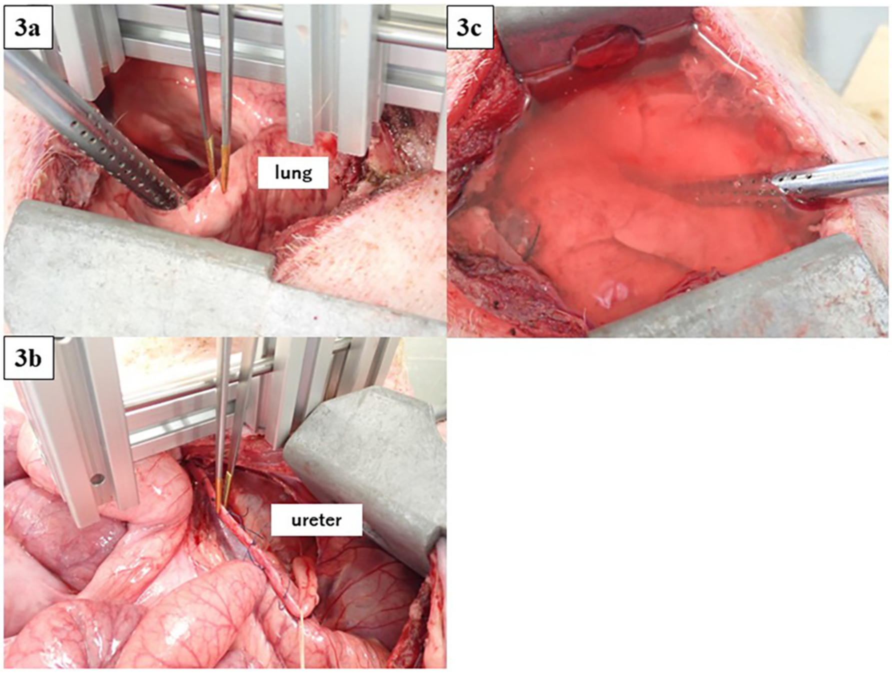

Figure 3. Animal experiment in which **A**) Lung Tissue and **B**) Ureter were grasped by each forceps type. **C**) An air leak test was performed after grasping lung tissue. No air leak was observed.

using the forceps. The questionnaire items evaluated the following: ease of grip, appropriate weight, ease of grasping organs, ease of grasping membranes (pleura, vascular sheath, etc.), degree of blood adhesion, and degree of organ injury due to grasping. Responses were scored using a Likert scale as follows: 5, 'very satisfied'; 4, 'satisfied'; 3, 'neutral'; 2, 'dissatisfied'; and 1, 'very dissatisfied'.

Statistical Analysis

Data are reported as the mean ± standard deviation. Comparisons between groups were performed using the Wilcoxon signed rank test and t test. Values of $P < 0.05$ were considered statistically significant. ANOVA was used for multiple comparisons. All statistical analyses were performed using JMP PRO (version 15; SAS Institute Inc., Cary, NC).

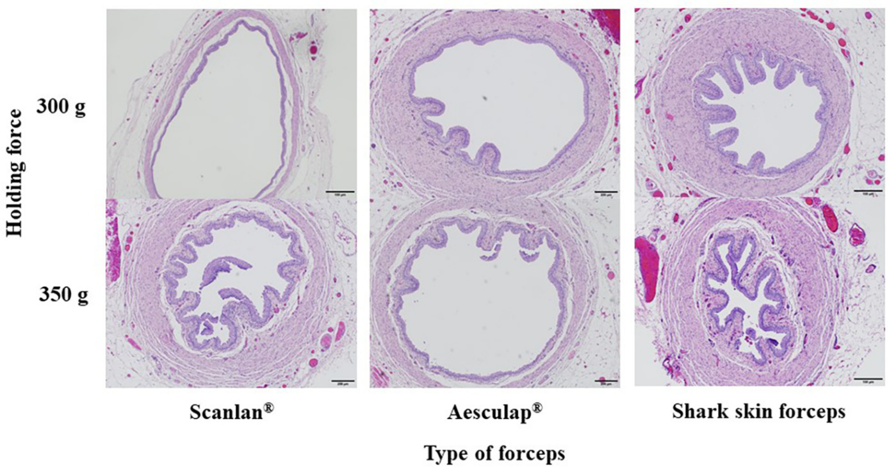

Figure 4. Pathological findings in urethral tissue after grasp. The degree of damage was similar among the three forceps.

RESULTS

Bead Transfer Test

The overall time required to transfer all beads was significantly shorter using the shark skin forceps (34.3 ± 6.2 s) compared with Aesculap® (61.7 ± 13.4 s) and Scanlan® (62.3 ± 14.4 s) ($P < 0.05$) (**Figure 5**). The same trend was observed for both the physicians and medical students.

Frictional Force Measurement

For horizontal frictional force, the median ratio of frictional force to holding force was significantly higher using the shark skin forceps than using Scanlan® and Aesculap® (0.60, 0.43, and 0.38, respectively; $P < 0.05$) (**Figure 6a**). For vertical frictional force, the ratio was 0.38 for the shark skin forceps, 0.36 for Scanlan®, and 0.26 for Aesculap®. The ratio was significantly higher for shark skin forceps than for Aesculap® (**Figure 6b**).

Animal Experiment

No air leakage due to tissue damage was observed in any pig lung tissue after grasping, for any of the three forceps. Pathological examination of the ureters after grasping showed no obvious differences in tissue damage among the three forceps.

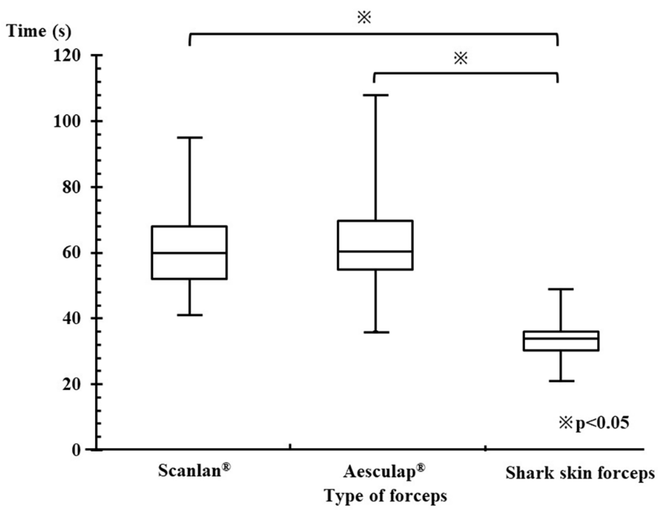

Figure 5. Mean bead transfer times in the dry lab assessment. Bead transfer time was the shortest using the shark skin forceps ($P < .05$).

Subjective Assessment of the Animal Experiment by Questionnaire

The **Table 1** lists the results of the questionnaire. Mean scores for the shark skin forceps, Aesculap® and Scanlan® were 4.00, 3.50, and 3.88, respectively, for "Ease of gripping the handle of the forceps"; 3.88, 3.38, and 3.50, respectively, for "Appropriate weight of the forceps"; 4.38, 3.88, and 3.88, respectively, for "Ease of grasping organs; 4.38, 3.63, and 4.63, respectively, for "Ease of grasping membranes; 3.25, 3.13, and 2.63, respectively, for "Degree of failure of grasping organ"; and 3.88, 3.63, and 3.63, respectively, for "Acceptable level of blood adherence".

The shark skin forceps scored significantly higher than Aesculap® for "Ease of grasping membranes" ($P = 0.046$) and significantly higher than Scanlan® for "Degree of failure of grasping organ" ($P = 0.035$).

DISCUSSION

In this study, we examined the efficacy and safety of newly developed shark skin forceps in comparison with two types of existing forceps. In the basic experiments, the shark skin forceps was stronger than the existing forceps in terms of horizontal and frictional force. Damage to grasped tissue was similar between the shark skin forceps and existing forceps. In addition, participants in the clinical experiments rated the shark skin forceps highest in terms of ease of use and safety.

Intraoperative complications associated with surgical operations are known to lead to major postoperative problems.[1–3] Ranucci et al. investigated independent risk factors for surgery-related mortality in cardiac surgery.[2] They reported thrombo-embolic complications, infections, and surgical reoperation as major complications associated with major bleeding, and multivariate analysis identified major bleeding as an independent prognostic factor of operative mortality. Therefore, stable and easy-to-use forceps is very important for ensuring safety during surgery and for preventing postoperative complications. Aesculap® and Scanlan® are the main forceps used in real-world clinical practice. These forceps have a groove with a fixed width at the tip to enable stable tissue grasping. However, the tissue grasp can be weak or slippery and cannot always be held properly due to insufficient local frictional force. In this study, we developed a novel forceps equipped with a shark skin structure. Shark skin is covered with dermal dentin, termed denticles.[4,5,12], and this concept has been applied to swimming suits and

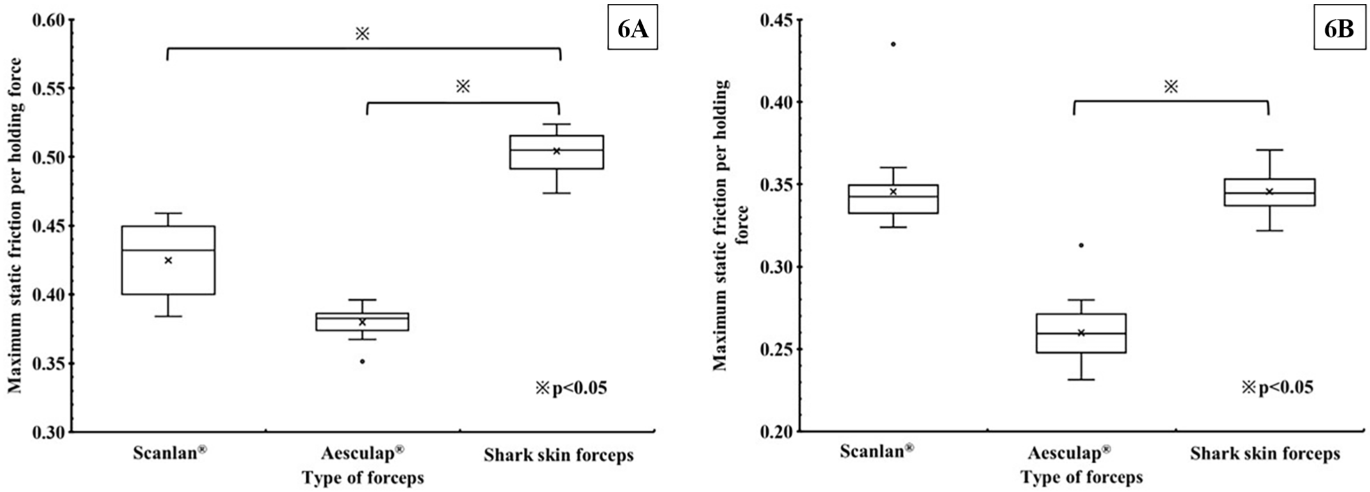

Figure 6. Ratio of frictional force to holding force in the **A**) Horizontal And **B**) Vertical directions. The shark skin forceps produced the highest force in both the horizontal and vertical directions ($P < .05$).

aircraft projects for the purpose of reducing frictional resistance.[6] In contrast, shark skin exhibits high frictional anisotropy due to the arrangement of inclined denticles, which has been used in research to improve the efficiency of robot locomotion and in applications such as sword grips and grinders. We attempted to employ this feature in the design of a nonslippery forceps.[13] In basic experiments, we compared frictional force between the shark skin forceps and two existing forceps and found high frictional force in both horizontal and vertical movements with the shark skin forceps.

Errors can occur during prolonged surgery due to loss of the surgeon's grip strength because of fatigue and a loss of grasping power due to tissue fluid adhesion and poor glove adhesion. Accordingly, forceps should be light and easily gripped. The shark skin forceps used in the present study weighed 55.1 g, which is similar to the weights of Aesculap® (62.1 g) and Scanlan® (54.4 g). With regard to comfort, the shark skin structure was also applied to the grip area of the handle to make it more comfortable to hold. The questionnaire survey showed that the shark skin forceps were more satisfactory than the other types with respect to weight and ease of holding.

It has also been reported that stress injury from grasping of tissue can cause bleeding, adhesions, and decreased bowel motility.[14–16] Therefore, forceps that enable tissue

Table 1.
Survey of the Animal Experiment for Assessing Efficacy of Forceps

Questionnaire	Shark Skin Forceps	Aesculap®	Scanlan®	*p*-value (Shark Skin Forceps vs. Aesculap®)	*p*-value (Shark Skin Forceps vs. Scanlan®)
Ease of gripping the handle of the forceps	4.00	3.50	3.88	0.248	0.769
Appropriate forceps weight	3.88	3.38	3.50	0.275	0.410
Ease of grasping organs (lungs, stomach, etc.)	4.38	3.88	3.88	0.228	0.228
Ease of grasping membranes (pleura, vascular sheath, etc.)	4.38	3.63	4.63	0.046	0.541
Degree of failure of grasping organ	3.25	3.13	2.63	0.293	0.035
Acceptable level of blood adherence	3.88	3.63	3.63	0.580	0.580

Data are reported as the mean values.
Responses were scored using a Likert scale as follows: 5, 'very satisfied'; 4, 'satisfied'; 3, 'neutral'; 2, 'dissatisfied'; 1, 'very dissatisfied'.

to be grasped accurately and for a shorter duration should minimize tissue damage. In the present investigation, we evaluated whether accurate grasping due to the shark skin structure contributed to shorter tissue grasping times. To ensure universality of the evaluation, we included a wide range of participants (from students to experienced surgeons) in the experiments. In the task of moving multiple beads with forceps, bead transfer time was significantly shorter with the shark skin forceps than with the other forceps.

The forceps currently in clinical use became available after safety verification (data not available). In the present study, we verified the safety of each forceps by evaluating the degree of pathological contusion in pig ureter after grasping by forceps (**Figure 4**). To avoid human bias, we also performed a quantitative evaluation of mechanical holding strength. Tissue contusion was comparable between the shark skin forceps and other two forceps, which suggests that the shark skin forceps can be used as safely as the existing forceps.

Surgical instruments are subject to wear and tear with repeated use. It has been reported that worn surgical instruments can cause damage to the body that requires reoperation.[17,18] Furthermore, the sterilization and reuse of surgical instruments can lead to biofilm formation that is associated with device-related infection.[19,20] It has been reported that the structure of shark skin protects against external stimuli and reduces mechanical wear.[12] Furthermore, the structure of shark skin can prevent the attachment of bacteria and reduce biofilm formation.[7,8] These features were exploited in the present application of a shark skin structure to the tip and handle of the newly designed forceps, with the aim of developing an ideal instrument that is mechanically and chemically safe.

There are several limitations to this study. First, we performed basic experiments on a small number of animals, and further testing is necessary to reach a final conclusion regarding the efficacy of the new forceps. In addition, there may be some information bias associated with the questionnaire survey. Second, the data presented in this study are preliminary rather than actual surgical data. In the future, it will be necessary to construct clinical trials that can be linked to actual clinical practice.

We are currently developing shark skin forceps for use in minimally invasive surgery and examining their performance and ease of use for participants with different levels of experience and training. The shark skin forceps may be useful in minimally invasive surgeries in the future.

CONCLUSION

Despite the limitations of the study, the shark skin forceps shows promise as an effective and stable instrument for grasping tissue, and has equivalent safety to that of existing forceps.

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