Article published online: 2024-07-26

In Vitro Evaluation of Flexural Strength of Different Skin Staples

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VCOT Open 2024;7:e103–e107.

Abstract

Objective The aim of the study was to assess the flexural deformation strength of various brands of skin staples postfiring, and to compare the distance and alignment of the staple tips.

Study Design In this experimental *in vitro* study, nine types of commercially available skin staples were tested. Following firing, six staples of each type were mounted on a material testing machine. Mechanical properties of staples were evaluated under uniaxial loading test, which translated to the bending of the staple for determination of flexural deformation strength. Staples were evaluated for tip alignment and distance between pointed tips.

Results Maximum force to flexural deformation was greater for Precise (29.633 ± 7.8421 N), than Proximate (16.200 ± 1.1541 N; $p = 0.000$), Henry Schein (23.383 ± 5.2282 N; $p = 0.011$), Weck Visistat (24.329 ± 1.0372 N; $p = 0.025$), Appose (18.133 ± 1.2675 N; $p = 0.000$), Manipler (14.067 ± 3.7393 N; $p = 0.000$), and Leukoclip (22.288 ± 1.6915 N; $p = 0.002$) but was not different from Gima (27.483 ± 6.5637 N; $p = 0.370$) and Advan (27.283 ± 2.8708 N; $p = 0.327$) Precise, Appose, and Advan fired staples had their pointed tips met, whereas Manipler, Leukoclip, Gima, Henry Schein, Proximate, and Weck Visistat showed a gap between pointed tips. Proximate staples also showed malalignment between their pointed tips.

Conclusion The flexural deformation strength of skin staples manufactured by Precise, Gima, and Advan was between 29 and 27 N and thus significantly superior to the other six staple types tested.

Keywords
- bioengineering
- biomechanics
- soft-tissue surgery
- skin and soft-tissue reconstruction
- wound management

Introduction

The present study contributes to the existing body of knowledge by providing an analysis of the mechanical properties of skin staples, which could potentially lead to improvements in soft tissue and skin closure.

Surgical skin staples are the most commonly used staples in small animal surgery and are considered the fastest and most cost-effective method for closing long skin incisions.[1–4] Apart from skin closure, skin staples have been used for closing flaps, securing skin grafts, drains, dressings, or tubes,

received December 10, 2023
accepted after revision June 16, 2024

DOI https://doi.org/10.1055/s-0044-1788577.
ISSN 2625-2325.

closing enterotomies and gastrotomies, and performing intestinal anastomoses, gastropexies, and subcutaneous and fascial closures.[5–13]

Skin staplers of many different types are used for staple application into tissues. Staples come in two sizes: regular (4.8–6.1 mm) and wide (6.5–7.0 mm).[5] Each staple is composed of a cross-member that is placed perpendicular to the incision, two limbs that penetrate the skin, and after the firing through a stapler, two pointed tips that are bending beneath the skin parallel to the cross-member.[5] When fired, the stapler anvil crimps the cross-member at two sites bringing the limbs together and usually forming a rectangular or arcuate (triangular) configuration allowing for proper good skin apposition.[1,5] Disadvantages of skin staples may include eversion of skin edges and rotation in mobile regions or thin skin.[1–3,14] Patient movement can create or enhance distraction forces on the wound.[2,3]

Staple instability and pivoting may occur when thin skin wounds are undergoing translational forces such as in the groin, axillary, or ventral abdominal regions; staples rotate up to 90 degrees, perpendicular to the margins of the skin, becoming thereby inefficient.[1,2] Consequently, dehiscence may occur due to the skin stretching through a gap created between the pointed staple limbs. The use of metallic staples, absorbable subcutaneous staples, and polyglactin 910 sutures has been evaluated for closure of skin incisions in eight experimental pigs.[14] Skin incisions closed with metal staples in one pig showed partial dehiscence in the center of the incision as four metal staples had been pulled out of the skin edges.[14]

Previously, skin staplers of six manufacturers including Autosuture (United States Surgical Corporation, United States), Appose (Sherwood-Davis & Geck, United States), Precise (3M Medical – Surgical Division, United States), Proximate (Ethicon, Inc, United States), Reflex (Richard-Allan Medical, United States), and Weck Visistat (Edward Weck & Co, United States) were tested on canine cadavers[3]; it was found that all staplers except Proximate performed well on *in vitro* skin closures.[3] It was assumed that regional skin mobility may induce flexural or bending forces that might lead to failure of formed staples and subsequent complications in wound healing. No studies evaluating the flexural strength of different skin staples after firing have been published.

The purpose of the present study was to evaluate the flexural deformation strength of various staples postfiring and to compare the distance and alignment of the staple tips providing insights into the mechanical resilience of different staple types. We hypothesized that some staples may exhibit superior flexural strength characteristics compared with other staples.

Materials and Methods

Using a material testing equipment, the flexural strength of different staple brands postfiring was evaluated. Commercially available wide skin staples from nine different manufacturers were tested. These included AD (Advan, Ningbo Advan Electrical Co Ltd, China), AP (Appose, Covidien, United States), MAN (Manipler, B. Braun Surgical SA, Spain), GIM (Gima, Ningbo Advan Electrical Co Ltd, China), LK (Leukoclip, Smith & Nephew Medical Ltd, England), PRE (Precise, 3M Health Care, United States), PX (Proximate, Ethicon Endo-Surgery, United States), HS (Henry Schein, United States), and VIS (Weck Visistat, Teleflex, United States). For the evaluation of flexural strength, one stapler of each type was fired, and six configured staples from each stapler were collected. Each staple was then mounted sequentially in an Electroforce 3550 materials testing machine (TA Instruments, United States). This was done by attaching the upper and lower limbs of the construct to the upper and lower hooks in the middle of their limb's length. The testing machine was set at a speed of 2 mm/min, and maximum force was applied until the first flexural deformation occurred, which was recorded as a failure (►**Fig. 1**). For the evaluation of staple tip alignment, and distance between the pointed tips, two staplers of each type were fired six times. The fired staples were photographed and examined under 4× magnification. All testing and examinations were performed by the same investigator.

Statistical Analysis

Statistical analysis was performed using commercial software (IBM Statistics SPSS 27, United States). Data were evaluated for normality using the Shapiro–Wilk *W* test.

Fig. 1 Photograph of a fired stapler attached to the materials testing machine for evaluation. The upper and lower hooks of the machine are mounted at the level of the limbs of the staple. The first flexural deformation that occurred was recorded as a failure.

Analysis of variance was used to compare the differences of mean maximum force to flexural deformation among groups. Data were expressed as a mean ± standard deviation. A *p* value less than 0.05 was considered significant.

Results

The maximum force to flexural deformation was greater for PRE (29.633 ± 7.8421 N), GIM (27.483 ± 6.5637 N), and AD (27.283 ± 2.8708 N) than that for VIS (24.329 ± 1.0372 N), HS (23.383 ± 5.2282 N), LK (22.288 ± 1.6915 N), AP (18.133 ± 1.2675 N), PX (16.200 ± 1.1541 N), and MAN (14.067 ± 3.7393 N).

The force-displacement curves of the staples AD, AP, GIM, LK, PX, and HS displayed four phases: an initial increase in flexural deformation, a decrease, another increase, and a final decrease. In contrast, the staples from MAN and VIS showed five phases: an increase in flexural deformation, a decrease, a plateau, another increase, and a final decrease. The curve for the PRE included an increase, followed by a decrease, a plateau, and a final decrease. These load-displacement curves translate the uniaxial displacement of the staples' two ends to bending, representing the flexural strength of the nine different staples (►**Fig. 2**).

The PRE, AP, and AD staples fired had their pointed tips met, whereas MAN, LK, GIM, HS, PX, and VIS showed a gap between pointed tips before applying any force. PX staples also showed malalignment between their pointed tips, whereas all the other staples had their pointed tips well aligned before applying any force.

Discussion

The study meant to contribute to the existing knowledge on staple characteristics by providing an analysis of the mechanical properties of skin staples; findings might help choose the most appropriate staple materials for improvements in soft tissue and skin closure.

The skin staplers tested were those most commonly used in small animal practices in Greece. Some types of staplers lock their pointed tips in proximity, whereas a gap between their tips is evident in others.[1] This gap between the tips may also allow increased postoperative tissue swelling with less vascular compromise,[1] and this may be seen as an advantage. This increased gap may also enhance a trend for staple rotation up to 90 degrees during increased skin tension.[1] Metallic staples and skin sutures have been used for closure of subdermal plexus flaps in 97 clinical dogs.[6] Wound dehiscence was observed in 35% of all dogs in this study. However, the sample size of dogs in this study was insufficient to determine whether the skin closure method influences the incidence of dehiscence. However, in another experimental study in 10 dogs, the use of metallic staples, tissue glue, and intradermal sutures has been assessed for closure of skin incisions. Wound dehiscence was observed in one dog and staple loss was noted in another three dogs

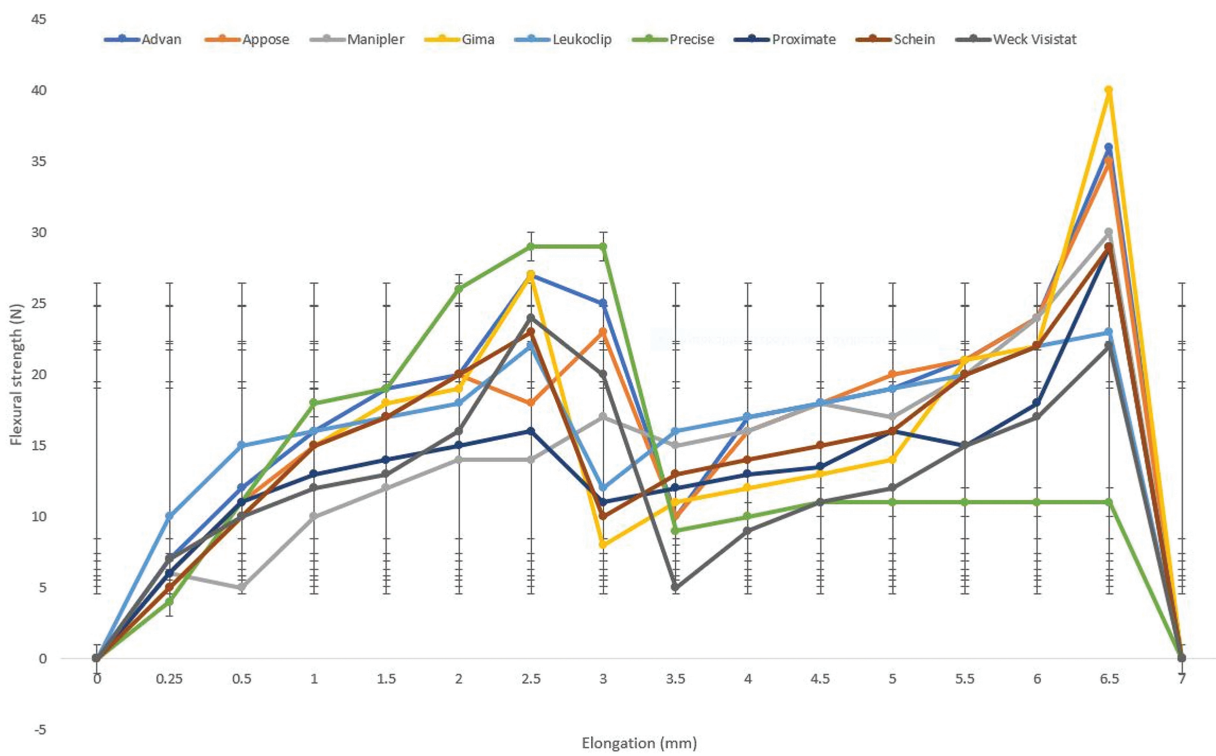

Fig. 2 Load displacement curves of nine different staples underwent flexural strength bending. Data were shown as mean ± standard deviation (SD).

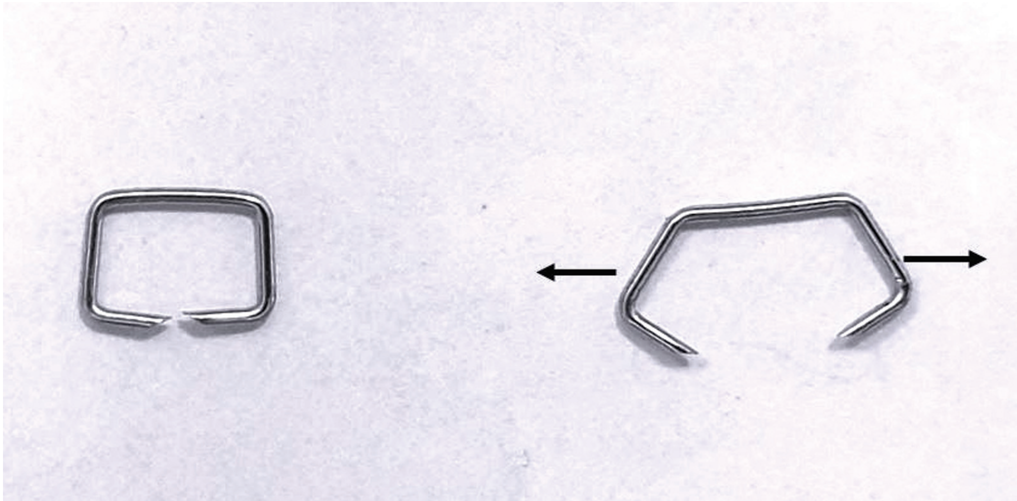

Fig. 3 A formed staple postfiring (left) underwent flexural or bending forces that might lead to failure (right).

with metal staples.[4] An *ex vivo* study in cadaveric tissues evaluated the holding power of different skin staples that were placed in skin incisions followed by rubbing the closed incisions to mimic body movement; it was found that among others Appose staples were rated the highest, showing no rotation; Weck Visistat staples rotated in less than 10%, Precise rotated in 25%, and Proximate showed 50% rotation under similar *ex vivo* conditions.[3] In our study, AP and PRE staples were found to close completely without gapping tips, assuming that they would exhibit less tendency to rotate than the other staple types such as Proximate, which we found malaligned.

The nonopening of the limbs of the formed staple ensures its secure fixation, less rotation, and good apposition of skin edges as local skin mobility, body movements, and increased incisional tension may result in the deformation of the formed staple. When staple deformation occurs, it can be assumed that the secure fixation of the staples was reduced and that rotational movements became more likely, resulting in incorrect apposition of the edges and impairment of wound healing (►**Fig. 3**). Reasons for staple rotation may include staple placement too high or loosely failing to be engaged properly in the skin, not placing the staple in the center of the incision line, improper apposition of the incision, or leaving a gap at the incision edges. The mechanical strength of a stapled wound depends rather on the summary of the resilience of several staples and rarely on the failure of one single staple. PRE, GIM, and AD staples in our study showed greater force to flexural deformation than the other staple types. In a recent *ex vivo* canine study, the tensile strength of simple interrupted, cruciate intradermal, and subdermal suture patterns used for closure of skin incisions was compared. The simple interrupted and cruciate patterns exhibited significantly higher mean tensile strength at skin-edge separation and suture-line failure than the intradermal and subdermal patterns.[15] Although no reliable comparisons can be made between these findings and those of our study, the maximum force of flexural deformation of ours was less than the tensile strength of external or internal suture patterns.

This experimental setup study presented here has limitations: one is the creation of flexural deformation by a force applied in a single direction only; in a clinical setting, forces are acting over time at different angles and directions. Another is bending and/or closure of staples will be different when fired into tissues as compared with just firing “into air.” These *ex vivo* experimental results cannot be easily applied to real situations, and our experimental setup was unable to test the theory that staples rotate instead of opening up.

Conclusions

Using material testing equipment, the study objective was to evaluate different staple types in terms of flexural deformation strength and determine the distance and alignment of the staple pointed tips. Staples manufactured by PRE, GIM, and AD were more resilient to flexural deformation than those of the AP, MAN, VIS, LK, PX, and HS types. The PRE, AP, and AD staples, when fired, had their pointed tips closed, whereas the MAN, LK, GIM, HS, PX, and VIS staples showed a gap between pointed tips. PX-type staples also showed malalignment between their tips, whereas all the other staples had a complete alignment of their pointed tips. Based on these observations, the PRE, GIM, and AD staples yielded more resilience to deformity in one direction than the other staple types.

Author Contributions
All the authors contributed to the conceptualization, methodology, investigation, and original draft preparation (writing). I.S. was responsible for the statistics. M.T., A.A., N.M., and L.G.P. were responsible for reviewing and editing of the manuscript. All the authors have read and agreed to the published version of the manuscript.

Funding
None.

Conflict of Interest
None declared.

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