

T-Skin Staplers are Faster on Long Skin Slice Closure Surgery: a case study

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How to cite this article: Andi Asadul Islam¹, Juliani Ibrahim^{2*}, Venansius R.Kurniawan³, Akhmad Edwin Indra⁴ et. al. T-Skin Staplers are Faster on Long Skin Slice Closure Surgery: a case study International Journal of Contemporary Surgery 2023;11(2).

Abstract:

Introduction: A T-Skin stapler is a type of skin staple commonly used in the closure of surgical wounds on skin slices. Quick and accurate treatment of patients is required. However, there is still limited research comparing the handling speed of the tool with other skin staples.

Method: We used a T-Skin stapler that is built of sterile grade 317 L medical metal with code SS1 and the surgical thread type T-Silk no. 330 with code S21. We created numerous portions in goat experimental animals that were aged over 2-3 years and weighed more than 20.5-26 kg after randomly inflicting gout on animals with surgical incision wounds (10 cm).

Result: The T-Skin stapler and surgical threads had comparable results with respect to wound closure, but the T-Skin stapler was faster in all steps observed. A comparison of the speed of surgical wounds with a stapler was found to be 6.3 times faster than using sutures with surgical threads. The time used to remove the staples was an average of 92.4 seconds, while the time taken for thread removal was 110.6 seconds.

Conclusion: The T-Skin stapler and surgical threads had comparable results with respect to wound closure; however, the T-Skin stapler was faster in all steps observed.

Keywords: T Skin staplers, surgical wound, animals research

Introduction

The most common adverse event affecting patient safety globally is healthcare-associated infections (HAI), which patients acquire while receiving care [1]. One of the most frequent issues in daily practice or in the emergency room is wounds, whether open wounds or closed wounds. One of the abilities a general practitioner needs to have is the ability to

handle wounds. Quick healing with ideal aesthetic results and functioning is the fundamental objective of wound treatment.

This objective is accomplished by enhancing trauma and infection avoidance efforts and by creating the ideal environment for wound healing. Therefore, any surgical or traumatic wound that heals with the secondary goal of healing rather than the primary intention of healing

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is considered an acute wound. An acute wound is anticipated to proceed through the stages of typical healing, leading to the wound's closure ².

Management wounds on the closure of surgical wounds is mostly done by suturing surgical wounds using surgical needles and threads. While in long surgical wounds and with the covid-19 pandemic, the doctor who operated wanted the operation to be done by more quickly but still safe. Various studies have shown that the use of in closing surgical wounds will be faster but still safe. Triton Manufacture as a national company strongly supports by Government Regulation of the Republic of Indonesia No.14 of 2015 in related main development plan in for National industrial development for 2015-2035 and Presidential Instruction of the Republic of Indonesia no.6 of 2016 concerning the Acceleration of the development of the pharmaceutical and Medical Device Industry.

Therefore, to substitute imported S-Skin stapler products that are widely used in Indonesia. The ingredients and methods of production and storage of T-SKIN STAPLER are products that have been circulating and used in Indonesia. On this basis, the results of the T-SKIN STAPLER clinical trial will be the same as the results of other skin product clinical trials. Likewise, the results of the clinical evaluation from T-SKIN STAPLER are the same as the results of the evaluation of the use of other skin staplers. Since there is no distribution permit yet, the evaluation of the use of T-SKIN STAPLER in humans, therefore, comparison material will be carried out on the animals trial. The T-SKIN STAPLER product is an effective technique to promote wound healing and integration of skin grafts and synthetic leather equivalents. Furthermore, the use of T-SKIN STAPLER would be provided to a wide community that choosing this product would give to academicians or clinical practitioners that using T-SKIN STAPLER would be more efficient time and more valuable. Therefore, the objectives of this evaluation will provide evidence that which works faster on surgical wound closure between wearing a skin stapler or wearing surgical thread stitches and which is safer for both methods between wearing a skin stapler or wearing surgical thread sutures as well as how the animal treats whether it does not feel soreness or pain at the time of removal of staples from the scar.

Material and Methods

Research sample

The study population is surgical wounds in animals the surgical incision wounds were made in several parts in goat experimental animals, the number of goats that will get

treatment according to World Health Organization (WHO) standards is 7 heads ¹. Ethical approval was not considered necessary, this is a case report involving animals. Although no identical model animals were sampled, however, they met all aspects of the course of the disease or structure in humans or other animals.

T- Skin stapler

The T-Skin stapler product under investigation is a novel formulation containing a blend of natural and synthetic ingredient that act to promote coagulation and support wound healing. The composition includes a proprietary blend is made of sterile grade 317 L medical metal, code SS1, so it is hoped that there will be no infection or more irritation in the closed surgical wound. Thus it is expected that wound healing occurs naturally in normal times. The surgical thread used to cover the skin is a surgical thread that is of good quality in the market and is widely used so far, namely T-Silk no. 330 code S21. Prior research has demonstrated the efficacy of similar products in reducing bleeding and promoting wound healing in animal models ³.

Case Presentation

Evaluation of the use of skin staplers involved seven (7) animals of goats aged over 2-3 years weighing more than 20.5-26 kg. Each goat is randomly numbered, namely from number 1 to number 7. The activity was carried out by 6 neurosurgery residents, and anaesthesiologist nurses supervised by the head of the Trauma Commission of IKABI (Makassar Division). The study was conducted in accordance with Animal Welfare Act and the Guide for the Care and Use of Laboratory Animals. Ethical clearance is not required in this case but this experimental animal research still applies to the experimental animals properly.

The activity began in goat number 1 by premeditating SA 2 ample +Diazepam 1 ample administered intramuscularly. Furthermore, under general anesthesia with the administration of Ketamine 0.5 mg/kg BB. Maintenance Diazepam 1 amp + Ketamine 1 cc dilution 10 cc after decreased consciousness the area to be sliced is shaved so that there is no more hair on it (on the right abdomen and left abdomen, as well as on the inside of the right thigh and left thigh) after being shaved clean, then given a betadine disinfectant. The incision begins on the right abdominal part 10 cm long. After the incision is completed and there is no more bleeding, the installation of the stapler begins. After the installation of the T-SKIN STAPLER continued with the closure with the suture of the T-Silk surgical thread on the other side.

Furthermore, the right thigh is closed by using a T-SKIN

STAPLER and the left thigh with T-silk thread stitching. The installation of the stapler in this way is carried out subsequently on all goats the time used in the use of staplers and surgical thread sutures will be recorded on form 1 and the results of the souvenir will be seen in appendix 1. Table 3.1

All samples or all seven goats were evaluated against the density of the meeting between the two ends of the wound skin that were met with the use of staples and threads. The speed of time used in the use of staples and threads, safety in terms of the reaction of skin tissue in wounds and the appearance of staples that have been removed after use. The 6th and 7th goat specialties will be observed specifically to ensure that if there is inflammation, it does not come from processes and materials (staplers and threads) but as an extension of the animal's environment and behavior that is difficult to control. Evaluation on the seven goats was carried out on the first day of closure, the fifth day and the 14th day (healing). The picture of the wound that has been covered (day 1) both by T-SKIN STAPLER, and by the T-Silk thread is visible as figure 3.1.) On the fifth day the condition of the scars both with the T-Stapler and with the T-Silk was observed. The observation results look like the attached picture of figure 3.1.

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On the 10th day both staples and threads used to remove the wound, removed or retracted. The time used to revoke is seen in the appendix table 3.2. The healing condition of the wound that has been removed both the thread and the staples are seen in figure 3.1. The results of the assessment of the occurrence of discomfort at the time of revocation, there was no visible screaming or struggling movement in all goats. Seen in figure 1. The entirety of the 140 staples that have been removed, are viewed one after another against the shape of length, diameter and color. Seen in the appendix of Table 4. The primary endpoint was time to hemostasis, as well as secondary endpoints including wound closure, inflammation, and infection Result

The result of the study demonstrated that the T-SKIN STAPLER product was highly effective in promoting haemostatic and wound healing recommended Table 3.1 shows the length of time it takes to close a 10 cm long wedge wound with the number of staples and stitches of 10 staples each and 10 stitches haemostatics for each of the 10 locations is 5413 seconds for threads and 865 seconds for staples, the average time used by 1 location (10 cm) is 54.3 seconds for threads and 86.5 seconds for staples. The comparison of the speed of surgical wounds with a stapler is very meaningful 6.3 times faster than using sutures with surgical threads, which is 86.3:541.3

Table 1. Length of time used to isolate 10 staples and 10 stitches on a 10-cm-long skin slice (in minutes and seconds)

Goat No	Abdomen		Thigh	
	Stapler	Sutures	Stapler	Thread
Goat No.1	2 minutes 26 seconds (146 seconds)	9 minutes 42 seconds (582 seconds)	2 minutes 26 seconds (146 seconds)	2 minutes 26 seconds (146 seconds)
Goat No.2	0 minute 48 seconds (48 seconds)	9 minutes 27 seconds (567 seconds)	2 minutes 26 seconds (146 seconds)	2 minutes 26 seconds (146 seconds)
Goat No.3	1 minutes 24 seconds (84 seconds)	7 minutes 34 seconds (454 seconds)	2 minutes 26 seconds (146 seconds)	2 minutes 26 seconds (146 seconds)
Goat No.4	1 minutes 26 seconds (86 seconds)	8 minutes 52 seconds (532 seconds)	2 minutes 26 seconds (146 seconds)	2 minutes 26 seconds (146 seconds)
Goat No.5	1 minutes 15 seconds (75 seconds)	8 minutes 0 seconds (146 seconds)	2 minutes 26 seconds (146 seconds)	2 minutes 26 seconds (146 seconds)
Total	439 seconds	2615 seconds	426 seconds	2798 seconds

The condition of the wound when it is finished closing, it appears that both those covered with staples and those covered with threads look all tightly closed, nothing else is open gaps, as shown in figure 3.1.

Observations on the fifth day showed hermetically sealed scars on the use of staples, as well as on the use of threads. In general, the appearance of wound closure with staples is better or tighter than that of scars covered with thread as seen in Appendix 2 of Figure 3.1.

Observation on the tenth day to see if the staples used remain attached, nothing is released and still functions to

tighten the two peripheral skins of the wound. No wounds appear to be gaping.

Observations on the tenth day were also to evaluate the length of time used to remove staples and threads, the presence of comfort disturbances at the time of removal of one thread after another and staples, as well as the laying of staplers that had been removed. The time used to remove the staples is an average of 92.4 seconds. The average time taken in thread removal is 110.6 seconds as seen in table attachment 3.2

Table 2. Length of time used to replug 10 staples and 10 stitches on a 10-cm- long slice of skin (in minutes and seconds)

Goat Number	Abdomen		Thigh	
	Stapler	Sutures	Stapler	Thread
Goat No.1	3 minutes 22 seconds (202 seconds)	91minutes 40 seconds (100 seconds)	1 minutes 49 seconds (109 seconds)	2 minutes 11 seconds (131 seconds)
Goat No.2	1 minute 39 seconds (99 seconds)	2 minutes 22 seconds (142 seconds)	1 minutes 58 seconds (118 seconds)	1 minutes 54 seconds (114 seconds)
Goat No.3	0 minutes 56 seconds (56 seconds)	1 minutes 24 seconds (64 seconds)	1 minutes 32 seconds (92 seconds)	2 minutes 1 seconds (121 seconds)
Goat No.4	0 minutes 55 seconds (55 seconds)	1 minutes 10 seconds (70 seconds)	1 minutes 20 seconds (80 seconds)	2 minutes 20 seconds (140 seconds)
Goat No.5	0 minutes 44 seconds (44 seconds)	1 minutes 34 seconds (94 seconds)	1 minutes 09 seconds (69 seconds)	1minutes 50 seconds (110 seconds)
Total	456 seconds	2615 seconds	468 seconds	616 seconds

The time required at the removal of the stapler is 456 seconds +468 seconds = 924 seconds. The time taken at thread removal is 490 seconds + 618 seconds = 1106 seconds.

It is noticed that the time required for the removal of the stapler is shorter (924 seconds) than the time required for the removal of the thread (1106 seconds). The average time taken in a stapler pull is $924 \text{ seconds} / 10 = 92.4 \text{ seconds}$, faster than the average time taken in thread removal is $1106 \text{ seconds} / 10 = 110.6 \text{ seconds}$.

Observations about the presence of comfort/pain disturbances

at the time of revocation are not visible any struggling movements and shout that indicate pain in the removal of each staple, as written in Table 1.

In Figure 1. there are also no signs of rejection or tissue reaction either, to the stapler or the thread. The safety of using staples assessed from tissues macroscopically is seen in Figure 1. Surgical wounds that have been removed staples and threads appear to have their skin fused, no parts are red, sore or secrete fluid when the scar is pressed.

Table 3. The presence of movement or pressure at the time of the removal of staples and threads

Goat No.	Abdomen		Thigh	
	Stapler	Sutures	Stapler	Thread
Goat No.1	None	None	None	None
Goat No.2	None	None	None	None
Goat No.3	None	None	None	None
Goat No.4	None	None	None	None
Goat No.5	None	None	None	None

Table 4. Changes in the Shape, Length, Diameter, and Color of Staples Removed from Wounds That Have Been Closed in Goats 1-7

Staples in Goat	Changes from T-SKINSTAPLER to the Standard			
	Shape	Length	Shape	Length
Goat No.1	None	None	None	None
Goat No.2	None	None	None	None
Goat No.3	None	None	None	None
Goat No.4	None	None	None	None
Goat No.5	None	None	None	None
Goat No.6	None	None	None	None
Goat No.7	None	None	None	None

The condition of the scars on day 14 appears to have mostly healed with mostly invisible stitches. There are several locations where the stitch marks remain the blood clot points that have dried up. This is seen in Figure 1.

Diagram 1: Comparison of the number of wounds that have healed tightly closed using a stapler and those that use surgical thread sutures

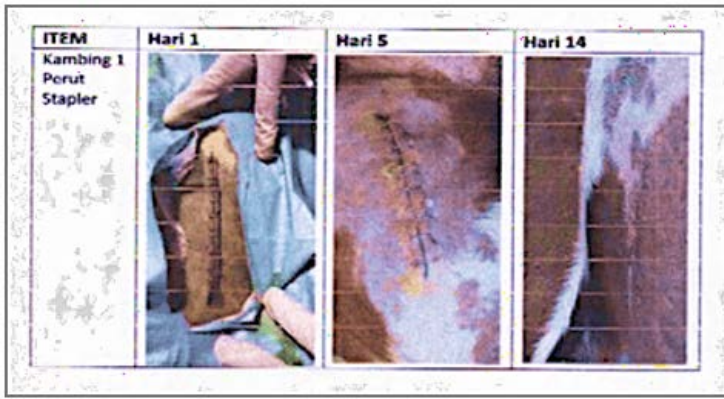
Goat No	Perfectly Healed	
	Stapler	Thread
Goat 1 Thigh		There are still 5 traces of yam
Goat 1 Abdomen		There are still 2 traces of yam
Goat 2 Thigh		There are still 3 traces of yam
Goat 2 Abdomen		There is still dried blood
Goat 3 Thigh		
Goat 3 Abdomen		There are still traces of yam
Goat 4 Thigh		
Goat 4 Abdomen	There are still 2 stitch marks	There is still dried blood
Goat 5 Thigh		
Goat 5 Abdomen	There is still dried blood	There are still stitch marks
Goat 6 Thigh		
Goat 6 Abdomen		
Goat 7 Thigh		
Goat 7 Stomach		
	Green; it has healed clean and evenly.	Yellow: There are still parts with a virgin point.

Figure 1. The condition of the wound after it is covered with a stapler and thread on the first day (I) of day 5 (five) and day 14 (fourteen (the wound is expected to heal).

To more clearly see the healing of the wound on day 14 between the Stapler and the Thread Stitching technique depicted in Diagram 1.

Appendix 1. Comparison of the number of wounds that have healed tightly closed using a stapler and those that use surgical thread sutures

Goat No. 1 Abdomen stapler in day 1, day 5 and day 14

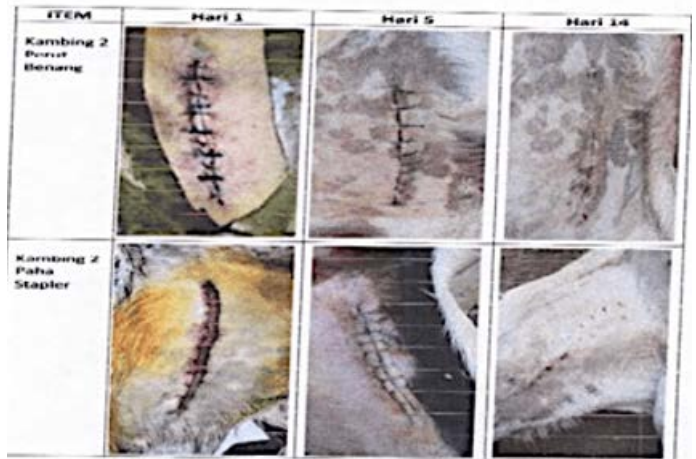


Goat No. 1 Comparison between Abdomen by stapler and thread



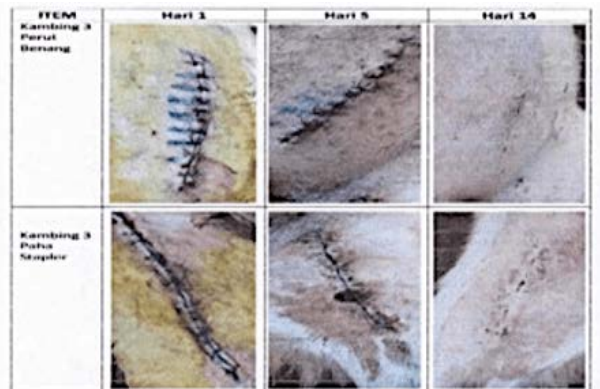
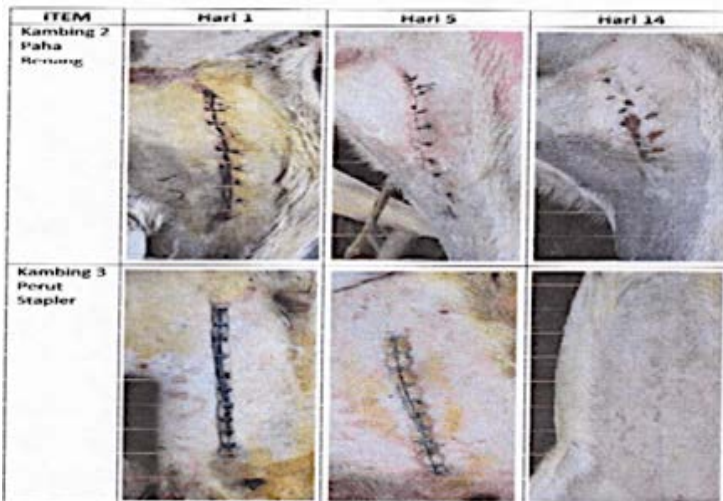
Goat No. 1 and 2. Comparison between thigh by thread and abdomen by stapler and thread in day 1, day 5 and day 14

Goat No 2. Comparison between abdomen by thread and thigh by stapler in day, day 5 and day 14

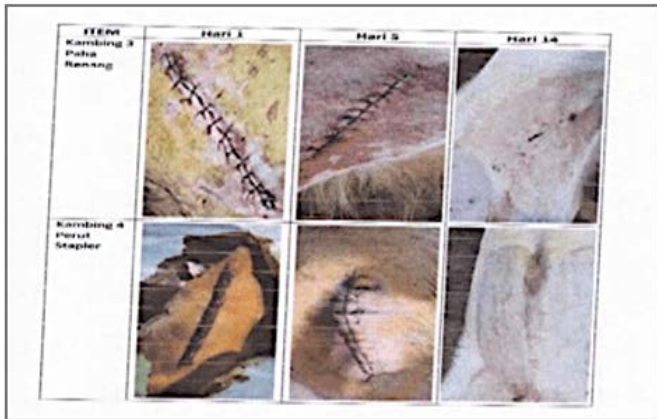


Goat No 2 and 3. Comparison between thigh by thread and abdomen by stapler in day 1, day 5 and day 14

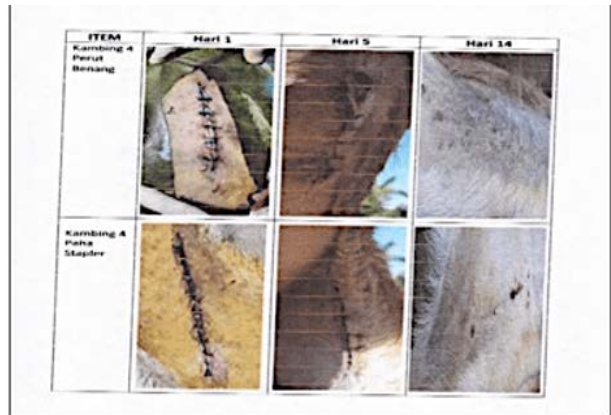
Goat No 3. Comparison between thigh by thread and abdomen by stapler in day 1, day 5 and day 14



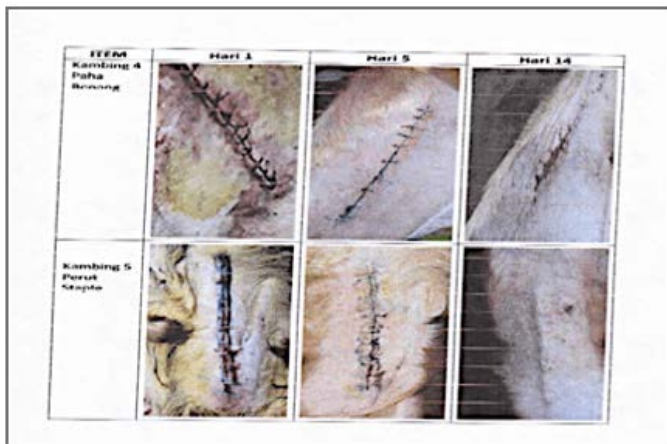
Goat No 3 and 4. Comparison between thigh by thread and abdomen by stapler in day 1, day 5 and day 14



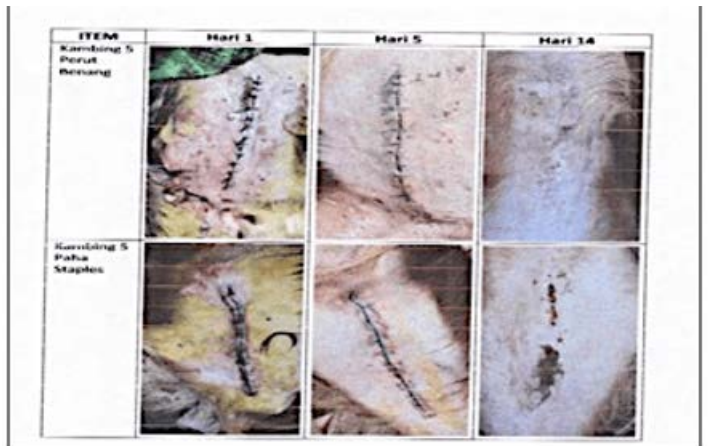
Goat No 4 and 4. Comparison between abdomen by thread and thigh by stapler in day 1, day 5 and day 14



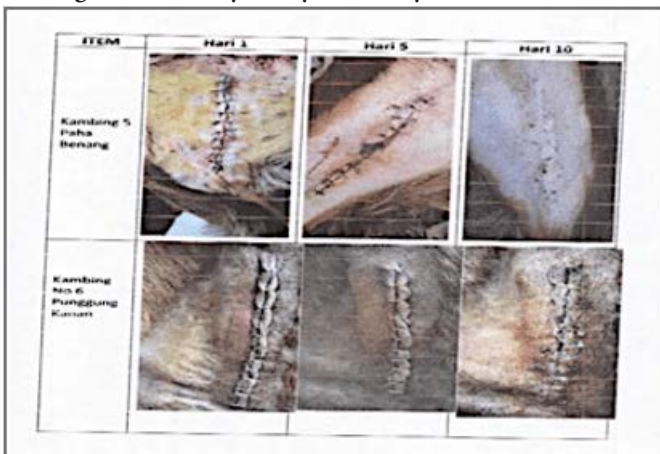
Goat No 4 and 5. Comparison between thigh by thread and abdomen by stapler day 1, day 5 and day 14



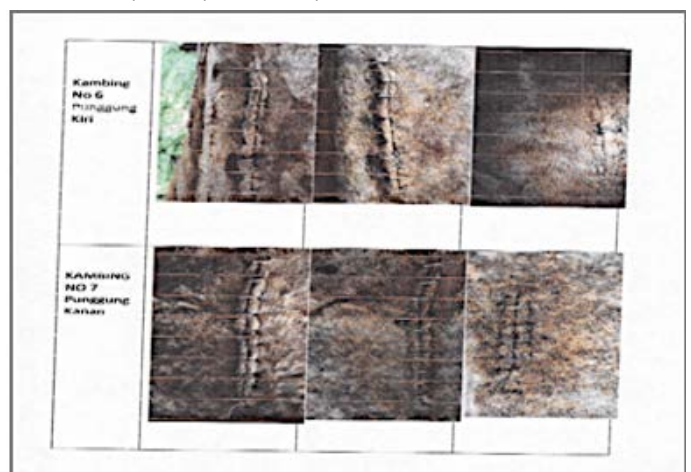
Goat No 5. Comparison between abdomen by thread and thigh by stapler in day 1, day 5 and day 14

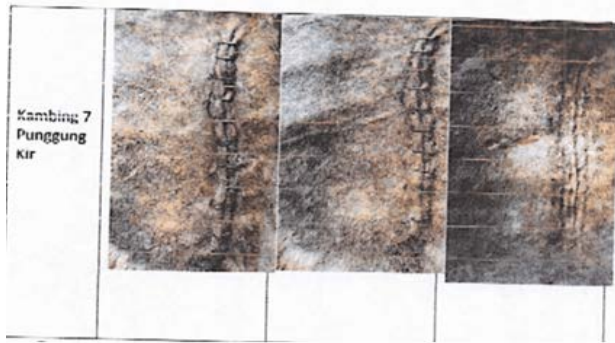


Goat No 5 and 6. Comparison between thigh by thread and right back in day 1, day 5 and day 14



Goat No 6 and 7. Comparison between left back and right back in day 1, day 5 and day 14



Goat No.7. left back in day 1, day 5 and day 14**Discussion**

The use of experimental animals in biological research is while still enforcing animals in a humane manner while still avoiding inappropriate or excessive use of experimental animals and referring to the international guiding principles for biomedical research involving animals 4. Including planned to alleviate or eliminate the suffering of experimental animals should be specifically mentioned and detailed in the research protocol important in ethics prevention and elimination of pain caused by research and medical treatment of experimental animals is an element of animal use 5. Although animals cannot yet be completely replaced, it's important that researches maximize refinement and reduction. This is a significant issue since the demand for hospital beds is leading to an increase in the rate of early patient discharges from hospitals following major surgeries. Moreover, in pandemic condition health services strongly effort to prevent nosocomial infection. This Finding suggest that T-SKIN STAPLER product has significant potential for use in surgical setting to reduce bleeding and promote wound healing. Future research should focus on optimizing the product formulation and delivery, as well as conducting larger scale clinical trials to evaluate it's safety and efficacy in human subject. Overall, these results represents an important step forward in the development of new haemostatics agent for use in surgical practice.

Conclusion

The time used to close the surgical wound is 6.3 times faster in the stapler compared to the surgical thread suture. Healing with a stapler seems faster and neater compared to healing at thread stitches. There is not even a visible reaction of tissue rejection to the stapler (changes in the tissue and in the material) and there is no noticeable discomfort at the time of removal/ removal. The time used to open the staples from the wound is faster than the time used in the removal of the thread, but the difference is not significant.

Conflict of Interest: The author declares there is no conflict of interest

Source of Funding: This project was funded through PT. Triton Manufactures

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