

## ประสิทธิผลการใช้อุปกรณ์ครอบป้องกันทวารเทียมยื่นยาวและไส้เลื่อนข้างทวารเทียม Effectiveness of a stoma protector for prevention of stomal prolapse and parastomal hernia

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### บทคัดย่อ

**วัตถุประสงค์** เพื่อทดสอบประสิทธิภาพของอุปกรณ์ครอบป้องกันทวารเทียม (SP stoma protector) ในการป้องกันภาวะทวารเทียมยื่นยาวและไส้เลื่อนข้างทวารเทียม

**วัสดุและวิธีการ:** เป็นวิจัยกึ่งทดลอง (แบบศึกษากลุ่มเดียว วัดก่อนและหลัง) โดยใช้อุปกรณ์ครอบป้องกันทวารเทียมต้นแบบซึ่งประกอบด้วย ตัวครอบทวารเทียม และเข็มขัดผ้า ในผู้ป่วย 16 ราย ที่มีภาวะทวารเทียมยื่นยาว เก็บข้อมูลที่โรงพยาบาลมหาวิทยาลัยในภาคใต้ ตั้งแต่ มกราคม 2563 ถึง พฤษภาคม 2564 ภาวะทวารเทียมยื่นยาวและไส้เลื่อนข้างทวารเทียมได้รับการประเมินสองครั้งเพื่อเปรียบเทียบประสิทธิภาพ โดยประเมินก่อนที่จะใช้อุปกรณ์ครอบป้องกันทวารเทียมที่คลินิกศัลยกรรม และมีการติดตามผลการใช้ทางโทรศัพท์หลังการใช้ 2-3 วัน

**ผลการวิจัย** กลุ่มตัวอย่าง 16 ราย อายุระหว่าง 8-83 ปี (มัธยฐาน 59) ส่วนใหญ่ได้รับการวินิจฉัยว่าเป็นมะเร็งลำไส้ใหญ่ (ร้อยละ 87.5) และมีทวารเทียมแบบลำไส้ไม่ถูกตัดขาดจากกัน (loop stoma) ร้อยละ 81.3 (ในจำนวนนี้ร้อยละ 43.8 มีดัชนีมวลกายมากกว่า 23) ได้รับการผ่าตัดฉุกเฉินร้อยละ 37.5 และมากกว่าครึ่งมีภาวะทวารเทียมยื่นยาวหลังการผ่าตัดน้อยกว่า 90 วัน (ร้อยละ 62.5) หลังจากใช้อุปกรณ์ครอบป้องกันทวารเทียมพบว่า สามารถป้องกันการเกิดภาวะทวารเทียมยื่นยาวและไส้เลื่อนข้างทวารเทียมได้ทุกราย นอกจากนี้กลุ่มตัวอย่างยังรู้สึกพึงพอใจในด้านการออกแบบด้วยค่ามัธยฐานคะแนนสูงสุดคือ 10 คะแนน รองลงมาคือ ใช้งานง่ายและมีคุณภาพ รวมทั้งรู้สึกสุขสบาย (มัธยฐาน = 8.5)

**สรุป:** อุปกรณ์ครอบป้องกันทวารเทียมมีประสิทธิภาพในการป้องกันภาวะทวารเทียมยื่นยาวและไส้เลื่อนข้างทวารเทียม แม้ใช้ในช่วงเวลาสั้น ใช้งานง่ายและไม่มีผลเสีย แต่การปรับปรุงต่อไปต้องใช้วัสดุที่มีความแข็งแรงทนทานมากขึ้น

**คำสำคัญ:** อุปกรณ์ครอบป้องกันทวารเทียม ทวารเทียมยื่นยาว ไส้เลื่อนข้างทวารเทียม

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## Abstract

**Objective:** To investigate the effectiveness of a SP stoma protector to prevent stomal prolapse and parastomal hernia.

**Material and Methods:** A quasi- experimental design, ( one group, pre- posttest of an intervention group), using a prototype SP stoma protector consisting of a stoma shield and belt, in 16 patients who had stomal prolapse. Data were collected at the university hospital, in Southern Thailand; from January 2020 to May 2021. The stomal prolapse and parastomal hernias were assessed twice, to compare their effectiveness, before using the SP stoma protector at the clinic, and again after a few days follow-up via telephone.

**Results:** The sixteen participants, ages ranging from 8-83 years old (median age being 59), were mainly diagnosed with colorectal cancer (87.5 %) and had a loop stoma (81.3. %). From this, 43.8% of them had a BMI > 23, had received emergency surgery (37.5 %), and had a prolapse after surgery  $\leq$  90 days (62.5 %). After using the SP stoma protector, it was demonstrated that it could prevent the occurrence of stoma prolapse and parastomal hernia. The participants also felt satisfied with the design, with the highest median score =10, followed by the easy to use and quality; including, that it felt comfortable (median score =8.5).

**Conclusion:** The “SP stoma protector” was effective in preventing stomal prolapse and parastomal hernia when applied in the short term. Although, it is easy to use and had no adverse effects, the material might require a higher grade of material for further improvement.

**Keywords:** stoma protector, stomal prolapse, parastomal hernia

## Introduction

A stoma is an opening of the intestine in the abdominal wall, for eliminating feces or urine from the body. In Thailand, new cases with a stoma have been increasing as of 2014. As of the last report, from February 28, 2017, there has been about 3.5 % from the total of 54,493 cases (National Health Security Office, 2016). Ostomates usually use a wafer and pouch to cover the stoma, which is attached to the abdomen to collect effluent. Ostomates can

perform daily activities similar to normal people, unless there are complications. Post stoma complications, affecting lifestyle and quality of life, are stomal prolapse and parastomal hernia. The incidence rates of these complications were 12% and 61.7%, respectively. The risk of having a stoma are increased over time; especially, when the ostomate has either weakness in the abdominal wall (e.g., those who are older adults, are obese or have thick abdominal

walls), or have high intra-abdominal pressure (e.g., severe coughing, frequent sneezing, or forced urination). Both conditions were found in ostomates who had a colostomy rather than a ileostomy (Malik, Lee, Harikrishnan, 2018). A previous study showed that those who had a transverse loop colostomy in particular were found to have a higher risk of prolapse; accounting for 7- 26% (Murken, Bleier, 2019), due to a large opening in the abdominal wall. In addition, more than 50% of ostomates with stomal prolapse had a parastomal hernia (Kim, Kumar, 2006).

While stomal prolapse or parastomal hernia occurs in the early period, it may drop back or return into the abdominal cavity by itself. However, it affects body image, daily activities and self- care for ostomates, because of difficulty with maintaining an appliance (Krishnamurty, Blatnik, Mutch, 2017). One way to prevent, or maintain

conservative treatment, is by using a tight belt over the abdominal wall opening (the hole at the rectus abdominis muscles). This can lead ostomates to feel discomfort from tightening of the abdomen; thus, causing most patients to reject the belt. As a result, the bowel protrudes longer, or the abdomen spacing is bigger. A protruding bowel can sometimes become swollen until the point where it cannot drop back into the abdomen (figure 1). This may cause friction with the appliance, leading to stoma injury. In addition, the physician can sometimes spend up to more than 4 hours to reduce a prolapsed stoma (figure 2), if the bowel protrusion is more swollen; this may cause ischemia and necrotic tissue (Butler, 2009). This then requires further, intensive treatment and a higher cost of care for repair; including, other expenses for hospitalization.



*Figure 1 swelling protrude bowel*

The “Stoma protector”, a device for preventing stomal prolapse, has been



*Figure 2 stomal prolapse reduction*

produced and patented in the last 20 years (Biesenbach, 2000; Cesare, 1954; Whealin,

1991). However, there are still limitations for its use in terms of material durability and difficulty in cleansing. New or similar products have currently not been found, nor imported into Thailand. This may be due to rare cases of stomal prolapse, and the high cost of the device. Therefore, the researcher team invented the: “*SP stoma protector*”, by using conventional plastic materials to cover the outside of the pouch. Although, it is not of a high medical grade, it had low allergic reactions. The channel, at the lower end of the domes shield, is to allow the stool to flow into the pouch easily; this is for protection from leakage and pancaking. The ostomates were confident that it was difficult for leakage to occur.

It requires the use of a belt, so as to apply appropriate pressure to the

abdomen, and to tighten the openings in the abdominal wall to prevent parastomal hernia after the stomal prolapse is reduced (figure 3). A parastomal hernia may lead to easy leakage, peristomal skin problems from effluent ( chemical) irritation or mechanical injury (due to the frequency of pouch changes) (figure 4). Stomal prolapse and parastomal hernia prevention was aimed to be achieved as well as feeling comfortable when being used, without complications from compression. So, a soft fabric belt was used to maintain its shape and breathability.



Figure 3 parastomal hernia after reduced stomal prolapse.

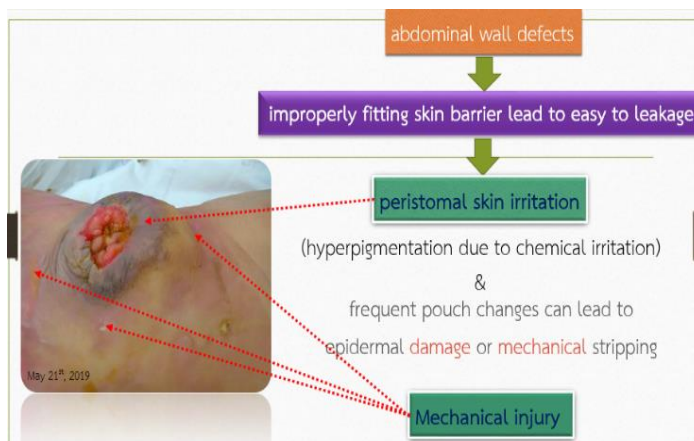


Figure 4 impact of parastomal hernia

## Material and Method;

A quasi-experimental (one group, pre-posttest) design was conducted in 16 patients who had stomal prolapse, and visited at either the outpatient of surgical department or admitted at surgical wards where the first author worked as an advanced practice nurse (APN), at one university hospital, Southern Thailand; during January 2020 to May 2021. A prototype “SP stoma protector” was licensed by Prince of Songkla University (PSU), and the study protocol was approved

by The Human Ethics Committee of the Faculty of Medicine, PSU (REC 63-029-15-7). Conceptual research & development (Wongkhan, 2017) consisted of 7 steps: 1) Review & analyze problems and conceptual/theory of innovation 2) Design & produce a “SP stoma protector” prototype 3) A trial in a small sample 4) Prototype development 5) Trial in a large sample 6) Improve the quality of the prototype 7) Quasi- experimental design research to investigate the effectiveness of the “SP stoma protector” to prevent stomal prolapse and parastomal hernia at the same time, and then solve defects and publicize. (figure 5).

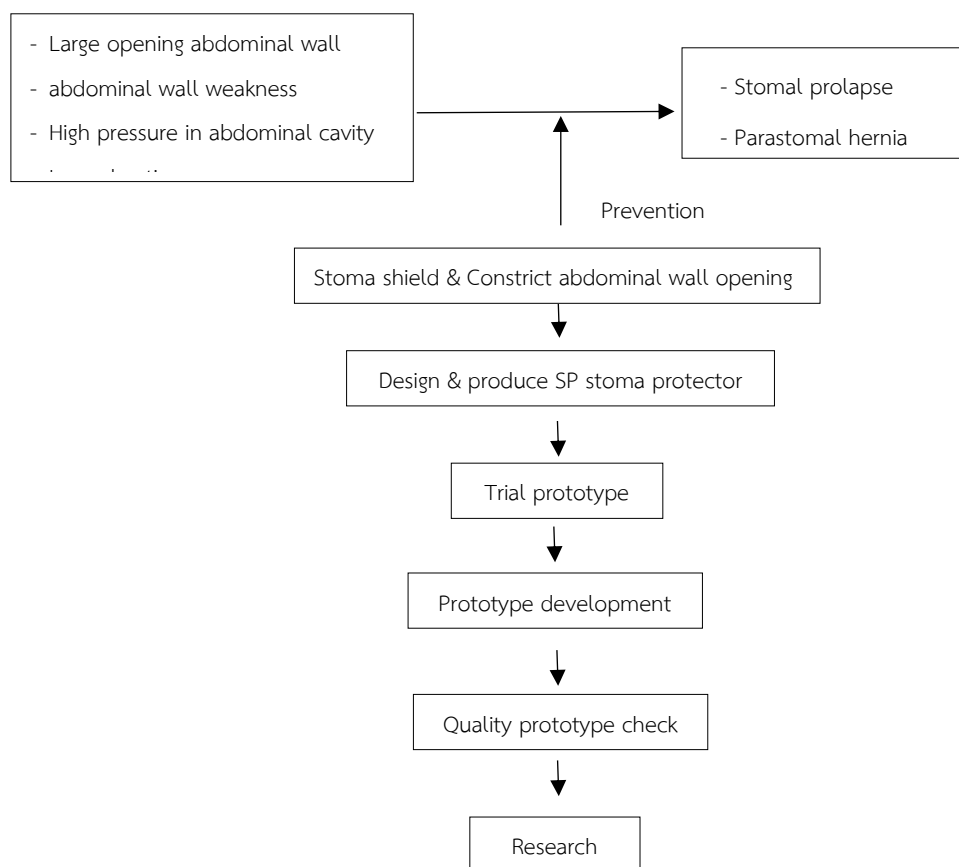


Figure 5 Conceptual research & development

### Inclusion criteria

size of the stoma being more than 4 centimeters, with or without parastomal hernia.

### Exclusion criteria

stomal prolapse cannot be reduced, due to high intra-abdominal pressure from ascites, advanced cancer or diseases etc. Diameter of the wafer was less than 57 millimeters.

### Research tool

The “SP stoma protector” consisted of a **stoma shield**, with the base of the plastic material being round in shape, with a diameter of 57 mm. The outside has a trapezium shape, formed by a 3D printing machine, for preventing bowel protrusion, and a **fabric belt** for constricting the opening of the abdominal wall (figure 5). It is designed to fit comfortably on the abdomen, exerting gentle pressure on the adhesive wafer, while maintaining a better seal for a longer wearing time. This reduces the number of times of changing the wafer, which can result in healthy skin.



Figure 5 “SP stoma protector” instruction

**Participants;** a new invention design calculated from the formula (Wayne, 1995, Ngamjarus, Chongsuvivatwong, 2014)

$$n = \frac{z_{1-\frac{\alpha}{2}}^2 p(1-p)}{d^2}$$

$Z_{1-\frac{\alpha}{2}}$  = 95% confidence level = 1.96, P = the researchers expected that it could help reduce the incidence of stomal prolapse by more than 80% = 0.8, D = experimental Error, 20% = 0.2, N=16)

## Data Collection

Clinical data were retrieved from medical records. Demographic data were recorded at the clinic before using the “SP stoma protector”, and monitored the outcomes after using it by a telephone call to the participants within a few days, by the research assistance.

**Collection tool;** the short form of a questionnaire for participants’ satisfaction (score 0-10, 0 was no satisfaction and 10 was the highest level of satisfaction) was used. It had four questions, namely: quality/outcome, easy to use, designs, comfortable, and satisfaction. The additional item was assessed in regards to any adverse effects;

such as, parastomal hernia after using, skin irritation, allergy and pressure injury.

## Results

Sixteen participants, ages ranging from 8-83 years old (median age was 59), who were mainly diagnosed with colorectal cancer (87.5%), and having a loop stoma (81.3. %) were enrolled in the study. From these, 43.8% of them had a BMI > 23, had received emergency surgery (37.5 %) and had a prolapse after surgery ≤ 90 days (62.5 %). Median level of being uncomfortable & anxiety with stomal prolapse before using the “SP stoma protector” was 6.5. (Table 1)

**Table 1** Demographic and Medical Data (N=16)

Variables	N	%	Variables	N	%
Median of age 59 (min-max; 8-83 years)			Loop Ileostomy	1	6.3
8 - 20	1	6.3	Loop Colostomy	12	75.0
21 – 40	0	0	End colostomy	3	18.8
41-60	8	50.0	surgery    Emergency	6	37.5
61- 80	4	25	Elective	10	62.5
≥ 81	3	18.8			
Gender; Female	5	31.3	Prolapse with parastomal hernia	6	37.5
Male	11	68.8	without parastomal hernia	10	62.5
BMI *ped 1			Median of duration after surgery 70 days (Min-Max=4-207 days)		
≤ 18.4	3*	18.8	4-30 days	4	25.0
18.5 – 22.9	6	37.5	31-90 days	6	37.5
≥ 23	7	43.8	>90 days	6	37.5
Colorectal cancer	14	87.5	Median of level of uncomfortable & anxiety before using the device 6.5 (Min-Max=2-10 score)		
Non-colorectal cancer	2	12.5			

After using the “SP stoma protector”, it could prevent the occurrence of stoma prolapse and parastomal hernia. The researchers evaluated the outcome after usage, by a follow up visit via telephone. It was found that the stomal prolapse and parastomal hernia had disappeared after using the “SP stoma protector” continuously

during the daytime. Some used it when they went outside, partly due to feeling worried or being afraid of a returning stomal prolapse. The participants also felt satisfied with the design; with the highest median score =10, followed by easy to use (median score = 9.5) and quality (median score =9.0); including feeling comfortable (median score =8.5). (Table 2)

**Table 2** SP stoma protector effectiveness (N=16)

Variables (incidence)	N	%	Variables (score)	Median	Min-Max	range
Prevent stomal prolapse	16	100	- Level of satisfaction for quality	9.0	7-10	3
Parastomal hernia post using	0	0	- Level of easy to use the device	9.5	5-10	5
allergy	0	0	- Level of satisfaction for designs	10	8-10	2
Itching	1	6.3	- Level of comfortable	8.5	6-10	4
Pressure injury	0	0				

One participant had the lowest level of uncomfortable & anxiety scores, because her stoma was just protruding at only 4 centimeters, and it could flow back into the abdomen cavity. However, in some cases, the stoma was swollen, causing pain and stomal injury. As a result, they were afraid to eat and conduct daily living activities, and the children do not want to go to school and stopped studying.

This study found that the “SP stoma protector” was able to prevent stomal prolapse in all cases. There were no adverse events (pressure injury or allergy); with only 1 case

who had itching. The median score of comfortable level was lowest, because of compression from the belt; which is also required to be very tight to reduce the opening via the abdominal muscles. However, 37.5% of the participants gave it a full score (10/10). In addition, about half of the participants gave the full satisfaction score regarding quality (43.75%), easy to use and design of device 50% and 62.5%, respectively.

Some of the participants reflected on their use of the "SP stoma protector" all the time in daily activities for one week, as



it improved their stoma's large protrusion. They reported the advantage of using it in terms of temporary usage when going out, as the prolapse was reduced and to gain confidence. After using, they reported no pain in the abdomen anymore. They were able to eat well, and felt confidence in doing more daily activities without any stress. In addition, the participants who were children felt confident and happy to go to school.

Although, the participants felt mostly satisfied with the device being used in daily life, some problems were found. Firstly, the wing of the stoma shield was the weakest point to be broken. Secondly, the width of the shield did not fit with the size of the flange. Thirdly, the elastic belt was difficult to adjust for size to fit around the body. Some suggestions from the participants were; material durability; particularly at the wing, and a better belt design for easily fitting with the waistline.

## Discussion

To date, people with a stoma have lived with an appliance collecting stool or urine, and some may encounter a stomal prolapse. Stomal prolapse have often been found in those who are obese. Similar to this study, 43.8 % of the participants had a BMI > 23 (23.5-29.1), and 37.5 % of this group had a stomal prolapse

with parastomal hernia. According to the study of Kim & Kumar (2006) Stomal prolapse can cause both physical and mental stress, and leads to inconvenience in the patients' life as well as affecting their quality of life. As a consequence, every effort has been made for reducing complications. The "SP stoma protector" can prevent the occurrence of stomal prolapse, because of its shield; a dome shaped guard against bowel large protrusion. In addition, the plastic materials make it lightweight; although it is thick is still prevents stoma injury from friction.

A tight-fitting belt constricts the opening of the abdominal wall, preventing part of the bowel to protrude under the skin beside a stoma that is called a "parastomal hernia". This study found the participants initially used it all the time and then occasionally used for a short period, due to its tightness and a feeling of being uncomfortable when used all the time. Although, the comfort score was lower than other aspects, some advantages of the "SP stoma protector" were shown, as it is a product made from inflexible materials, which do not deteriorate quickly, so it can be used and reused for a long time. The features of the "SP stoma protector" were like that of a support garment. When comparing with other studies, in which an elastic binder was often used to prevent stomal prolapse & parastomal hernia, the

patients reflected on their experience as to its quick deterioration, resulting in decreasing of the tightness of the abdomen, as a disadvantage. In this study, the “SP stoma protector” was able to prevent a stomal prolapse as well as prevent parastomal hernia and stomal injury. Ostomates used the device, as it helped increase their confidence in engaging in strenuous physical activities. The “SP stoma protector” gave them reassuring confidence, was comfortable as well as helping them to distract from their stoma (Hubbard, Taylor, Munro, et al, 2019).

The cause of stomal prolapse in this study, was 68.75% (11/16 cases) from abdominal wall weakness, due to advanced age ( $\geq 61$  years) 43.75% and obesity (BMI  $>23$ ) 43.75% (7/16 cases). Another cause was from a large opening in the abdominal wall after surgery, from having undergone a loop stoma and emergency surgery. In the cases of intestinal obstruction, the colon was swollen and the stoma was edematous, requiring resizing overtime. This caused a high risk for prolapse, more so than in usual cases.

In this study 37.5% (6/16 cases) had stomal prolapse with parastomal hernia, and 83.33% of these (5/6 patients) were older adults ( $\geq 60$  years) with obesity (BMI  $>23$ ). Therefore, the “SP stoma protector” was used to tighten the abdominal wall openings, which were helpful for prevention of

stomal prolapse and parastomal hernia. This was done without having to tighten the abdomen as much as a cotton belt, because the stoma shield is already a preventive tool for stomal prolapse, and also prevents stoma injury from daily activities; including exercise.

The disadvantage of the “SP stoma protector” is the wing of the shield, which is strong enough, but was brittle partly due to the material being made from a 3-dimension printer. This defect should be corrected in the next production. In this study, the initial idea to solve the participants' problems was using a cloth belt over it, which would be a further trial in the future.

## Conclusion

The “SP stoma protector” was effective in preventing a stomal prolapse, and parastomal hernia in the short term. It is easy to use, with no adverse effects being evident. However, it requires improvement related to the plastic materials used for the stoma shield, so as to be more durable.

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Intellectual Property Office, Prince of Songkla University (IPOP).

## Conflict of interest

The authors declare no conflict of interest.

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