A randomized controlled trial to assess the performance and safety of a novel Ostomy Ring (Osto Ring™) to improve ileostomy and colostomy management

Eugene Yen, MD, K. Agnes Brugger BSN, RN

Background and Significance:

Ostomy surgery refers to a surgical procedure in which part of the intestine is removed and the intestinal contents are rerouted through the abdominal wall via a stoma (http://www.niddk.nih.gov/health-information/health-topics/digestive-diseases/ostomy-surgery-bowel/Pages/ez.aspx). This type of surgery results in the patients utilizing an external pouch, a plastic bag affixed around the stoma on the abdominal skin to collect the waste. Depending on the reason for the surgery, stomas may be temporary or permanent.

It was estimated in 2012 that there are 1 million people in the United States and Canada living with ostomies, with an additional 100,000 new ostomies created per year in the United States. (Mitchell KA, Rawl SM, Schmidt CM, et al. Demographic, clinical, and quality of life variables related to embarrassment in veterans living with an intestinal stoma. J Wound Ostomy Continence Nurs. 2007;34(5):524-532).

The quality of life for patients who undergo this type of surgery is significantly affected. It is an adjustment for a patient to psychologically understand that his or her body will no longer perform a bodily function "normally". The patient needs to learn new skills such as how to correctly apply the pouching system, adjust wear time, and learn how and when to empty the pouch and remember to check the pouch seal to detect any signs of leakage. These new skills take time to learn and one of the greatest challenges is to find the best pouching system that can provide a consistent wear time to prevent leakage, embarrassment and peristomal skin issues.

A new device has been created with the aim of improving wear time and decreasing problems with leakage. The Osto Ring™ (GoDuRn LLC, 9722 Oak Pass Rd., Beverly Hills, CA 90210) is a novel and proprietary add-on modifier to the Hollister 2 piece New Image pouching system that creates a more secure seal between the patient's peristomal skin and the skin barrier, and therefore reduces the risk of leakage.

We hypothesize that the addition of the Osto-Ring™ will reduce leakage from the stoma appliance and may also increase the length of time needed between pouch changes. Currently, the mean ostomy pouch wear time in the United States is 5.2 days (Richbourg L, Fellows J, Arroyave WD. Ostomy pouch wear time in the United States. J Wound Ostomy Continence Nurs. 2008 Sep-Oct;35(5):504-8), and out-of-pocket costs can be as high as $30 with each pouching system change which translates to a yearly cost of close to $3000. Longer wear time would therefore translate into needing fewer ostomy bags and less money spent on ostomy supplies.

Overall Objective:

The primary objective of this pre-market study is to assess the safety and performance of the Osto Ring™ as it relates to the pouching system wear time and degree of leakage.

Research Design:

Study population: 30 adult subjects who have had an ileostomy or colostomy for at least 6 months, who currently use the Hollister New Image 2 piece pouching system acting as their own controls, will use their standard 2 piece New Image Hollister pouching system without the Osto Ring™ for 28 days. On Day 29 subjects will be switched to the Osto-Ring regimen until day 56. Patients will be evaluated in person at Day 0 and approximately Days 28, 56, and 75 (within business days and scheduling convenience).

The Osto-Ring for this study is being supplied by GoDuRn, LCC, and provided to subjects free of charge.

During the standard of care visit to the health care provider, subjects will be evaluated to confirm that they meet the criteria for participating in this study.

Study Design:

Day 0-27

Visit One

- **Subject will wear their standard of care Hollister 2 piece New Image pouching system for 28 days.**
    - At the first visit they will remove their pouching system to allow the investigator to assess their skin (research staff will take photo) using the Ostomy Skin Tool Reference Guide [See appendix B]
    - They will be given and asked to fill out the Quality of Life Questionnaire [See appendix C]
    - They will be given Ostomy Evaluation Record [See appendix A] and asked to complete this at every pouching system change. (And take photos of the skin site and adhesive side of the ostomy flange.)

Day 28-55

Visit Two

- **Subjects will now wear their standard of care Hollister 2 piece New Image pouching system with the Osto-Ring for the next 28 days.**
    - At the first visit they will remove their pouching system to allow the investigator to assess their skin using the Ostomy Skin Tool Reference Guide [see appendix B] (photo taken)
    - They will be fitted for the proper Osto-Ring size and given a belt.
    - They will be given and asked to fill out the Quality of Life Questionnaire [See appendix C]
    - They will be given 2 questionnaires and asked to complete them at every pouching system change. Subject will take photograph at each stoma change
        - Ostomy Evaluation Record [See appendix A]
        - Osto Ring Evaluation Record [See appendix D]

Day 56

Visit Three

Patients will decide if they want to continue using the Osto-Ring™ with their standard of care pouching system.

- Their pouching system will be removed and will have a skin assessment by the investigator using the Ostomy Skin Tool Reference Guide, Appendix B.

- They will be asked how they are doing and to report any side effects they may have experienced even if they do not think it is related to the Osto-Ring™.
- They will be asked to complete :
  - The Ostomy Quality of Life Questionnaire

If they felt that the Osto Ring was helpful, subjects will be asked to extend the wear of their devices by 1-4 days per their experience (if possible). Photographs will be taken at each stoma change of the skin and the adhesive side of the flange.

Day 75
Visit Four
At this last visit, patients can decide to have their Osto Ring removed or continue using it if they like.

All four of the clinic visits are considered research-related, along with completion of questionnaires and peristomal skin assessment.

During this study, Dr. Yen and his research team will collect information about the patients for the purposes of this research. This includes their name, telephone number, medical record number, initials, date of birth, medical, surgical and medication history, date of study entry, dates of study procedures and results of tests and procedures done as part of the study.

To calculate the study sample size, data from prior studies and expert opinion was used for power analysis since this device uses a novel approach to increase wear time. The mean wear time for ileostomy pouches in the United States is 5.01 +/- 2.25 days (Richbourg L, Fellows J, Arroyave WD. Ostomy pouch wear time in the United States. J Wound Ostomy Continence Nurs. 2008 Sep-Oct;35(5):504-8). An increase of wear time by 25% to 6.26 days is beneficial for patient care. We determined the effect size to be 0.56 assuming that the pool standard deviation is similar to the study cited above. Using a paired t-test with a significance level of 0.05 and power of 0.8, 27 patients are needed for this study.

All patients will be recruited from the NorthShore University HealthSystem IBD center and General Surgery Clinics. Evaluation and management for any stoma related questions, concerns or assessments may also be provided by our IBD center team. Results of the study will not be made available to the sponsor or anyone with a perceived or actual conflict of interest (eg actual/potential financial relationship) until the statistical analysis has been independently completed.

Inclusion Criteria:
Subjects interested in participating in the clinical investigation must comply with the following criteria:

1. Are at least 18 years of age and have full legal capacity
2. Have had an end or loop ileostomy or colostomy for at least 6 months.
3. Have used a Hollister 2 piece New Image pouching system for at least 8 weeks
4. Able to provide informed consent
5. Have a stoma with a diameter of 57mm or less

6. Change their pouching system at least two times in seven days

Exclusion Criteria:
Subjects complying with the following criteria must be excluded from participation in the clinical investigation:

1. Unable to give informed consent.
2. Are pregnant or currently breastfeeding.
3. In the last 2 months has received or is currently receiving, chemotherapy or radiation therapy.
4. In the last month has received or is currently receiving systemic or local steroid treatment in the peristomal area.
5. Currently suffering from severe peristomal skin problems such as peristomal pyoderma, abscess.
6. Currently suffering from a peristomal hernia.
7. Known hypersensitivity toward any of the test product (Osto Ring™ is made of surgical grade stainless steel)
8. In the last 30 days has participated or is currently participating in a clinical study
9. Assessed with an ostomy skin tool score of ≥3

Primary Outcomes:
Performance Efficacy:
To evaluate the Osto Ring™ for pouching system wear time, and degree of leakage in subjects when using the Osto Ring™ as compared to when not using the Osto-Ring™

- Integrity of the adhesive side of the flange (photos)
- Wear Time:
    - Total time pouching system worn will be calculated by the Ostomy Evaluation Record. This is defined as the difference between the dates and times the appliance is changed. (Appendix A)
- Leakage:
    - Degree of leakage at time of pouching system changes will be measured using line item from Ostomy Evaluation Record (Appendix A)

Secondary Outcomes:
1. The condition of the peristomal skin and stoma (Appendix B)
2. The number and frequency of adverse events
3. The subjects' quality of life using the Stoma Quality of Life (QoL) questionnaire (Appendix C)
4. Subject Ease of Use (ease of application, pain level with application, comfort, convenience of use) will be assessed using Likert scale: 1 = poor, 2 = satisfactory 3= very good, 4= excellent (Appendix D)

Analysis plan:

All means and frequencies will be compared between the groups with the Osto Ring™ versus the group without it and will be controlled for the order in which a subject used the Osto Ring.

- Wear Time:
    - Mean days in between pouching system changes
- Leakage:
    - Frequency of any degree of leakage at pouching system changes
    - Frequency of much leakage at time of pouching system change
- Skin condition:
    - % of patients with moderate to severe skin conditions at time of each WOC nurse or physician study visit
    - Mean % of time with moderate to severe skin conditions throughout the 4 week interval at every WOC nurse or physician study visit
- Quality of Life:
    - Mean quality of life scores
- Time per Ostomy Care Session
    - Mean minutes spent during ostomy care session
- Ease of Use
- Mean % of time ease of use reported as very good or excellent by subject , Satisfaction and Confidence
    - Mean satisfaction and confidence scores
- Device Recommendation
    - % of subjects reporting they strongly agree to recommend the device to others

We will compare the baseline characteristics of the two groups. Continuous variables will be compared with the paired *t* test, and categorical variables were compared with the Fisher exact test. Each item on the ostomy evaluation record form will be individually reported.

Safety Assessments and Termination Guidelines

WOC nurses will perform skin assessments at key times. Patients are to be told that they must mention any deviation from their baseline ostomy pouching system changing routine. Failure to do so will result in a protocol violation. Patients receiving an Ostomy Skin Tool score of ≥3 without a known cause will be withdrawn from the study.

Any patient suffering an allergic reaction to either product (the standards New Image Hollister appliance or Osto Ring) or suspected of having an adverse reaction of any kind as determined by the patient and/or the ostomy will be removed from the trial, return for clinical assessment as indicated and return to their standard stoma care appliance.

The data safety monitoring committee will consist of Drs Eugene Yen and Joseph Muldoon, who will review any unanticipated adverse events and have the authority to stop the trial at any time if any safety concerns are raised.

Osto-Ring™ Risks

Side effects may include:

- allergic reaction to the ring,
- worsening of the peristomal skin condition, or
- prolonged time needed in changing the ostomy pouching device.

2-piece New Image Hollister Pouching System

The 2 piece New Image Hollister Pouching System is standard of care. Concerns regarding this system will be handled by the regular physician. However, all concerns will be addressed.

Appendix A

OSTOMY EVALUATION RECORD

ID Number: _____ Date: _____
Number of days since last Change: _____

Please respond to each of the following items describing your experience in between pouching system changes. One Ostomy Evaluation Record should accompany EACH Ostomy Change

1. What was your average wear time (time between placing the pouching system on and taking it off) _(days)_____

2. Did you notice any skin damage around your stoma, redness and open areas? Yes or No

3. Did you note any odor from the ostomy between appliance changes?
☐No odor ☐Slight odor
(Skip to Question 3) ☐Strong odor

4. How bothersome did you consider the odor?

☐Not at all bothersome

☐Slightly bothersome
☐Moderately bothersome
☐Severely bothersome
☐Extremely bothersome

5. Did you encounter leakage and if so how much?

☐No leakage (Skip to Question 7)
☐Slight leakage
☐Much leakage

How many days was the pouching system in place before you noted leakage? _____

6. How bothersome did you consider the leakage?

☐Not at all bothersome
☐Slightly bothersome
☐Moderately bothersome
☐Severely bothersome
☐Extremely bothersome

7. Was your social freedom limited by your ostomy?

☐Not limited at all
☐Slightly limited
☐Greatly limited

Somewhat unaccepting
☐Very unaccepting

8. How convenient was your ostomy care?

☐Very convenient
☐Somewhat convenient
☐Neutral
☐Somewhat inconvenient
☐Very inconvenient

8. How satisfied were you with your ostomy care?

☐Very satisfied
☐Somewhat satisfied
☐Neutral
☐Somewhat dissatisfied
☐Very dissatisfied
☐Somewhat dissatisfied
☐Very dissatisfied

Appendix B

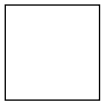
The Ostomy Skin Tool is a standardized and validated measuring instrument for assessing the extent and severity of peristomal skin change in terms of discoloration (D), erosion (E), and tissue overgrowth (T) (DET). (Martins L et al; Br J Nurs. 2010 Aug 12-Sep 8;19(15):960, 932-4) Ostomy Skin Tool used with written permission from Coloplast, Minneapolis, MN.

Date:_____ Subject ID_____

Discoloration

Area of Discoloration (1-3)

If area is 0,
then severity must be 0



Severity of Discoloration (1-2) ☐

Erosion

Area of Erosion (1-3) ☐

If area is 0
then severity must be 0

Severity of Erosion (1-2) ☐

Tissue Overgrowth

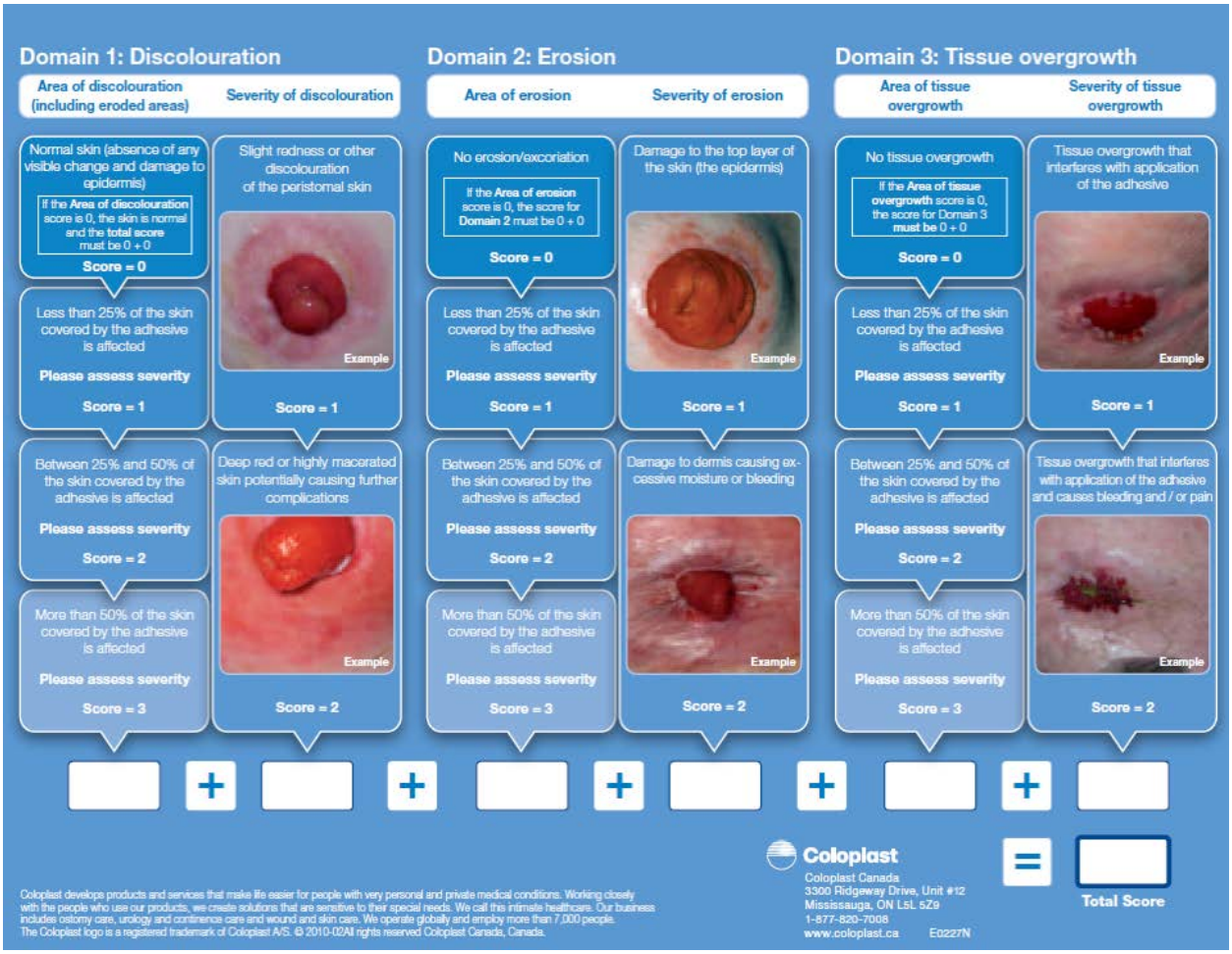
Area of tissue overgrowth (1-3) ☐

If area is 0
then severity must be 0

Severity of tissue overgrowth (1-2) ☐

Total ☐

OSTOMY SKIN TOOL REFERENCE GUIDE



Ostomy Skin Tool used with written permission from Coloplast, Minneapolis, MN.

Appendix C

Ostomy Quality of Life Questionnaire

1. **I feel the need to know where the nearest toilet is**

Always	Sometimes	Rarely	Not At All
①	②	③	④

2. **I become anxious when the pouch is full**

Always	Sometimes	Rarely	Not At All
①	②	③	④

3. **I feel tired during the day**

Always	Sometimes	Rarely	Not At All
①	②	③	④

4. **I am afraid of meeting new people**

Always	Sometimes	Rarely	Not At All
①	②	③	④

5. **It is difficult to hide the fact that I wear a pouch**

Always	Sometimes	Rarely	Not At All
①	②	③	④

6. **My stoma makes it difficult for me to be with other people**

Always	Sometimes	Rarely	Not At All
①	②	③	④

7. **I sleep badly during the night**

Always	Sometimes	Rarely	Not At All
①	②	③	④

8. **I feel lonely even when I am with other people**

Always	Sometimes	Rarely	Not At All
①	②	③	④

9. I need to rest during the day

Always	Sometimes	Rarely	Not At All
①	②	③	④

10. I worry that my condition is a burden to people close to me

Always	Sometimes	Rarely	Not At All
①	②	③	④

11. I avoid close physical contact with my friends

Always	Sometimes	Rarely	Not At All
①	②	③	④

12. I worry that my family feel awkward around me

Always	Sometimes	Rarely	Not At All
①	②	③	④

13. I feel embarrassed about my body because of my stoma

Always	Sometimes	Rarely	Not At All
①	②	③	④

14. It would be difficult for me to stay away from home overnight

Always	Sometimes	Rarely	Not At All
①	②	③	④

15. I worry that the pouch rustles

Always	Sometimes	Rarely	Not At All
①	②	③	④

16. I worry that the pouch may smell

Always	Sometimes	Rarely	Not At All
①	②	③	④

17. My stoma makes me feel sexually unattractive

Always	Sometimes	Rarely	Not At All
①	②	③	④

18. I worry about noises from the stoma

Always	Sometimes	Rarely	Not At All
①	②	③	④

19. I worry that the pouch will loosen

Always	Sometimes	Rarely	Not At All
①	②	③	④

20. My stoma pouch limits the choice of clothes that I can wear

Always	Sometimes	Rarely	Not At All
①	②	③	④

Appendix D

1. Osto-Ring™ Evaluation Record

very easy	somewhat easy	neutral	somewhat difficult	very difficult
5	4	3	2	1

2. Satisfaction with Osto Ring™

Poor	Satisfactory	Very Good	Excellent
①	②	③	④

3. Confidence with Osto Ring™

Poor	Satisfactory	Very Good	Excellent
①	②	③	④

4. Problems with Osto Ring™

None	Few	Several	Many
①	②	③	④

Please specify any problems: _____

5. Comfort of Osto Ring™ felt

very comfortable	somewhat comfortable	neutral	somewhat uncomfortable	very uncomfortable
5	4	3	2	1

I would highly recommend the Osto Ring™ to others

Strongly Agree	Agree	Neither	Disagree	Strongly Disagree
①	②	③	④	⑤

6. Have you changed your pouching system in any way?

Yes	No
☐	☐

7. Is there anything else that you would like to tell us about the Osto Ring™ device?

_____

_____

_____

_____

_____

_____