

# Early Findings from the Observational Longitudinal Study of Ostomy Consumers

Renee Malandrino MSN RN CWOCN, Ginger D. Salvadalena PhD RN CWOCN, Michael Riemer MS, Sally J. Urwin BS CCDM CCRC  
Hollister Incorporated, Libertyville, Illinois

## Introduction:

Longitudinal cohort studies are not often conducted in stoma care, but they offer benefits over cross-sectional designs. Some benefits include the ability to follow subjects over time and to identify sequences of events which may help establish possible cause and effect (Caruana et al, 2015).

The purpose of this global study is to better understand the perspectives and experiences of individuals with stomas to identify patterns and trends. The data reflect real world experiences reported monthly over time. This study has been in process for over one year and enrollment is currently expanding to multiple countries, including Canada, with a goal of enrolling 600 persons for five years of data collection.

## Study Objective:

The primary objective of this study is to assess the longitudinal impact of ostomy product use on stoma related cost of care, resource utilization, quality of life, peristomal skin health, overall ostomy product satisfaction and other factors.

## Method:

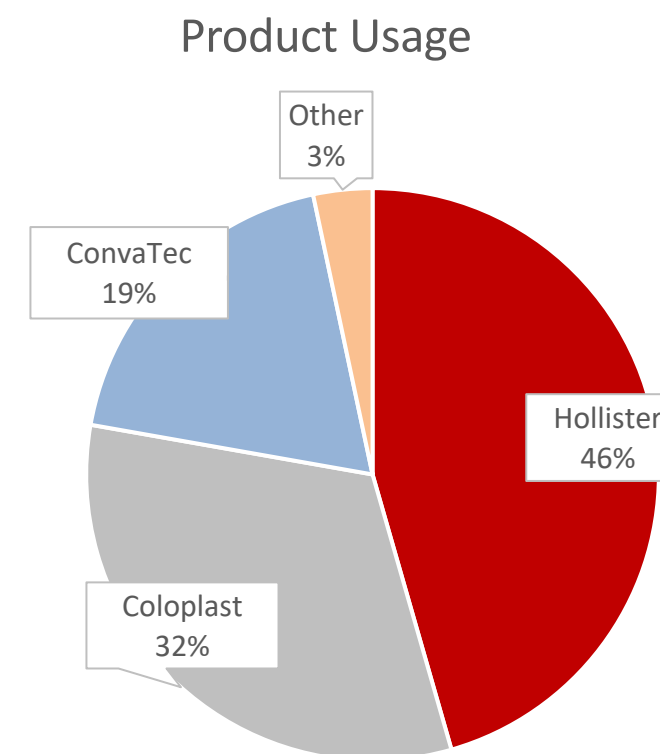
Study participants or their home caregivers complete electronic surveys on a monthly basis. All survey data is collected electronically through a Title 21 CRF Part 11 compliant system.

The survey covers a wide variety of topics including product usage, ostomy care habits, peristomal skin health, healthcare utilization, quality of life and level of social support. The surveys are currently available in English, French Canadian and Spanish languages (depending on the country). The study has received ethics approval in the US and Canada.

## Early Results (n=70):

After the first seventeen months of data collection the retention rate is 93%. Using the Emotional/Informational subscale of the Rand MOS social support survey, the average score suggests the individuals have adequate social support and self-reported quality of life is high.

Characteristic	n	%
Gender		
Male	28	40%
Female	42	60%
Stoma Type		
Ileostomy	40	57%
Colostomy	24	34%
Urostomy	6	9%
Stoma in Fold or Crease		
Yes	12	17%
No	58	83%
Stoma Height		
Raised	52	74%
Flush	16	23%
Recessed	2	3%
Hernia near your Stoma		
Yes	26	37%
No	41	59%
I don't know	3	4%



## Rand MOS Social Support Survey

n	Mean	STD	Min	Max
56	4.0	1.22	1	5

## Self-Reported Quality of Life (0 to 100 scale)

n	Mean	STD	Min	Max
64	83.6	17.10	3	100

## Conclusion:

The results from this longitudinal study provide insights which have implications for ostomy management and education, clinical practice and product innovations. Early findings, such as a high retention rate, indicate a willingness of participants to share candidly their experiences and opinions. Through this unique study partnership, we gain a better understanding of the ever-changing lives of those who live with an ostomy.

## References:

Caruana, E. J., Roman, M., Hernández-Sánchez, J., & Solli, P. (2015). Longitudinal studies. *Journal of thoracic disease*, 7(11), E537–E540. <https://doi.org/10.3978/j.issn.2072-1439.2015.10.63>

The study is posted on ClinicalTrials.gov (NCT03715179), Observational Study of Ostomy Consumers

Disclosure: Study sponsored by Hollister Incorporated

JOIN US IN RECRUITING CANADIAN PARTICIPANTS:

Contact Hillary Marhoefer at Hollister Incorporated to learn more about how you can help us recruit for this study: [hillary.marhoefer@hollister.com](mailto:hillary.marhoefer@hollister.com)