

NovaLife Clinical Evidence Booklet



Contents

1	Introduction	page 4
2	Ostomy Pouches White Paper	page 6
3	Dansac Novalife White Paper	page 10
4	Novalife Posters	
	Pouch Discretion and Concealment	page 18
	The Challenges of Conducting Clinical Research	page 22
	User Assessment of a New Pouching System	page 26
5	QoL Abstracts	
	Sexual Intimacy	page 30
	Poor Body Image	page 34
	Social Isolation	page 38
6	Real People – Real Life	page 42
7	Afterword	page 54

Quality of life needs expressed by users inspired us to optimize pouch design and to create a new game changer – Novalife.



1 Welcome to Novalife Clinical Evidence Booklet

Ostomy surgery is a life altering surgery. While the benefits to the health of the person that has undergone the surgery is self-evident – it saves lives and frees people from debilitating diseases – the physical presence of the effect of the surgery, the stoma and its maintenance, can be a difficult obstacle to overcome.

For people living with a stoma, it is not only a psychological challenge to have to empty the contents of the bowel or bladder into a pouching system attached to their abdomen, but the appliance itself is not exactly a discrete item and often requires a change in clothing style.

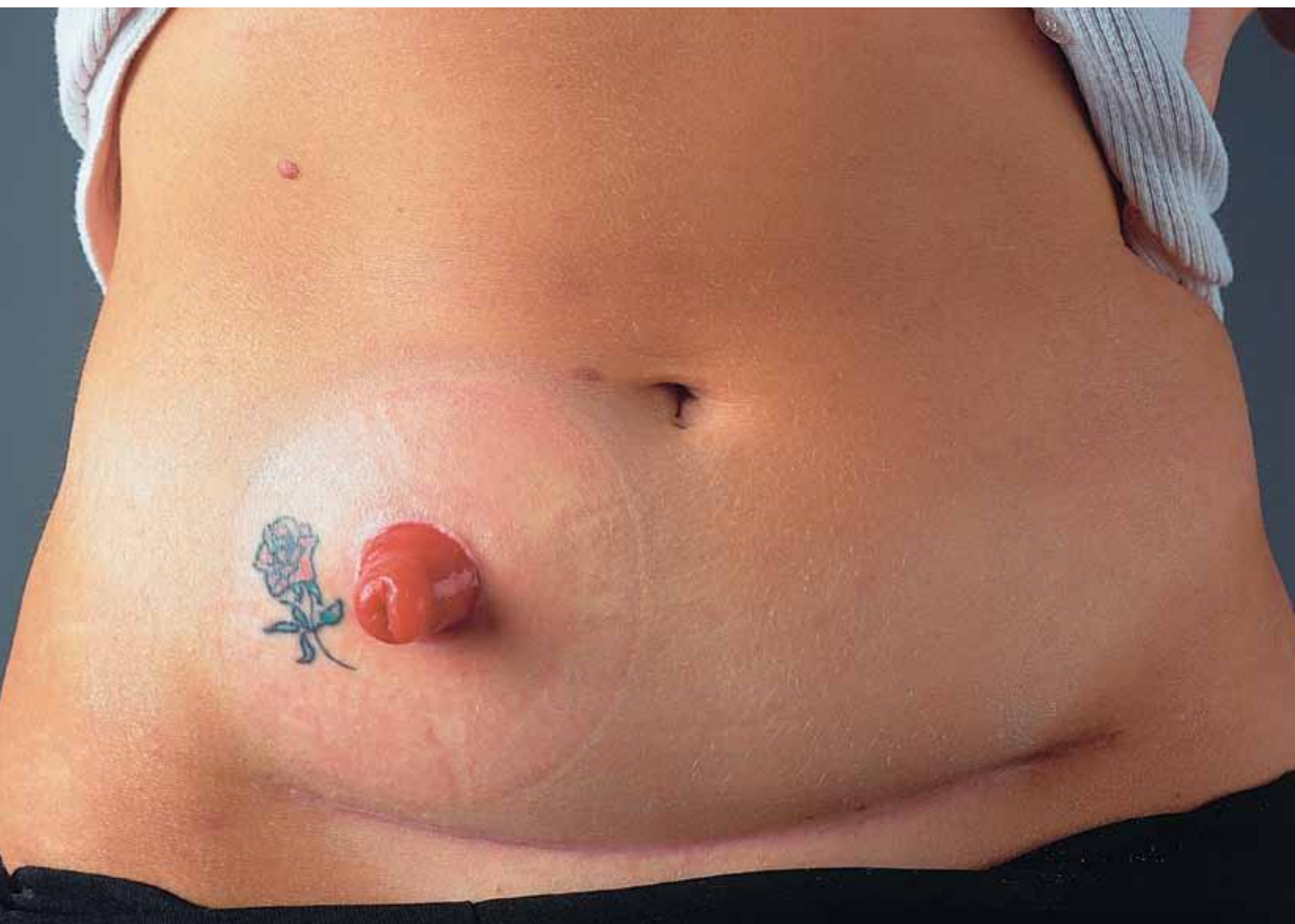
At Dansac we have always been focused on the needs and requirements of our customers – and by asking and listening we have become more and more aware of their quality of life needs. Among these needs, discretion has top priority; all persons with a stoma occasionally or more often worry that someone will notice the pouch under their clothing. Indeed, the results of a recently conducted and extensive QoL study (n=4097), confirmed what we already suspected. For example, the study showed that over 88% of the users cited stated that an appliance, easily concealed under their clothing, is important to them.

As with most any consumer product design, there are incremental improvements and there are giant leaps or game changers. For decades ostomy pouches have improved gradually, with small incremental steps at a time. Our findings and preliminary results from the QoL study spurred us on – we concentrated our efforts on finding ways to optimize pouch design and create a game changer that would help solve these customer needs. So we thought carefully about the details of the design, the form and the function of the new pouches. The result is Novalife, a giant leap and game changer, with a design that reshapes and redefines everything that has gone before.

The Novalife Clinical Evidence Booklet presents some of the clinical evidence and real life testimonials that have influenced the creation of Novalife.



The pouch we see today was born of trial and error.



2 Ostomy Pouches White Paper /1

Ostomy pouches: Evolution makes way for a revolution

As with any consumer product, the design of ostomy pouches has changed over time. Even though the purpose of a stoma pouch has remained for decades – to contain faeces or urine – the pouch we see today was born of trial and error, with each iteration the result of efforts to get closer to delivering a product that best meets customer needs.

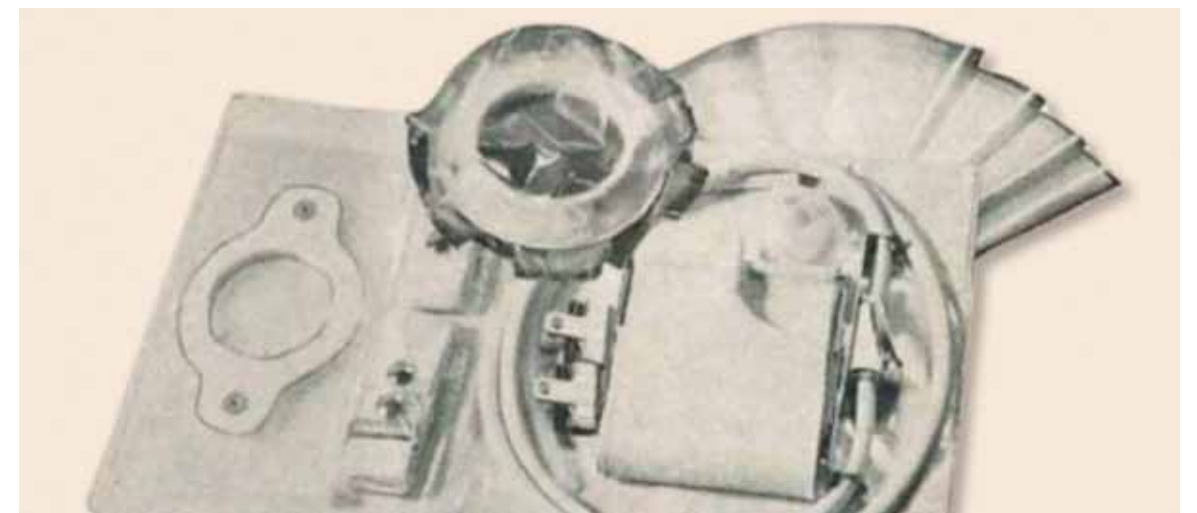
Students of design know that for most consumer products there is a natural progression of gradual improvements to design and function punctuated by the occasional “big leap” or revolution. For ostomy pouches, necessity has driven remarkable design advances.

Early ostomy pouches: form closely matches function

To understand how the natural progression of design applies to ostomy pouches, one could go back to the early years of ostomy surgery, such as 1707, when German surgeon Lorenz Heister suggested the necessity to wear tin or silver pipe or cloths placed on a stoma to receive the excrement. However, a more recent history – since the 1940s – clearly shows how initially the form of an ostomy pouch closely matched its function.

Permanent rubber pouches, or the Koenig-Rutzen pouch, introduced in 1920, continued through the 1940s as the standard for collecting and containing faeces or urine. These heavy and bulky appliances were glued to the body with a latex suspension; while these collection devices could be rinsed and cleaned, over time the odour of output permeated the rubber material. In 1957, the first fully disposable pouch with zinc oxide backing entered the marketplace.

1920



This revolutionised the management of an ostomy. The use of plastics and films became more prominent in consumer products, including stoma pouches, which made them less bulky than rubber, but did little for odour prevention or noise. The design of these pouches demonstrated the roots of the material used: the poly-vinylidene dichloride (PVDC) was originally developed to keep meats and cheese fresh.

User friendly materials and more ergonomic designs

For the following few decades, the natural progression of improvements to ostomy pouch design largely centered on the materials used. Karaya pouches were introduced in 1964, using the sap from a certain species of tree to deliver a more natural barrier that could mould to people's bodies while protecting the skin. In the 1970s, manufacturers

1964



explored combinations of vinyl layers for improved odour prevention and sound suppression. At this time designers began to explore with moderate success more bell-shaped pouches to reduce ballooning from gases released with output and to ease draining for drainable products. During this decade, new hydrocolloid skin-friendly barriers were developed for increased flexibility, security and comfort, as well as two-piece products with locking flanges for increased discretion.

Moving toward a more universal design

These incremental improvements showed how medical device manufacturers were beginning to more clearly understand the quality of life needs of ostomates. Yet it wasn't until the 1990s that manufacturers began to deliver pouches that made it much less apparent to others that the user was wearing an appliance. The tapered skin barrier was launched in 1992 and helped deliver greater discretion and improve adhesion.

1971



Up to this point, the shape of ostomy pouches was primarily symmetrical. When placed on the body, the appliance was still clearly about function, with integration with the body secondary. That changed with the introduction of anatomical pouches. These pouches were the first step to fit to the contours of the groin area. However, users of drainable pouches still endured the long "tail" of the drainable area, even as integrated closure systems were developed during the next decade.

Manufacturers had focused much effort to address odour suppression through the pouch material itself; their experiments with various filter technologies were met with mixed success because most filters of the time were ineffective if they became wet. That changed with the introduction of integrated filters. However, the filters remained somewhat problematic because their weight often caused the tops of pouches to flap over, creating a more noticeable bulk under a user's clothing.

Reaching Universal Design

Students of product design understand that the paradigm of Universal Design, or a design usable for as many people as possible regardless of other factors, is a game changer. Incremental improvements to ostomy pouch design continued through the early 21st century, with manufacturers exploring novel film structures and integrated closure systems. Then Dansac created one of the industry's giant leaps with its Novalife pouching system. The pouch's teardrop shape truly helps deliver on the promise of anatomical pouches not realised in the late 1990s. The streamlined shape is

1992



designed to integrate better with the groin area of the body and is much less noticeable to others. Yet its compact shape belies its capacity.

The barrier of the Novalife pouch is a game changer. For decades, users of cut-to-fit barriers were accustomed to the placement of starter holes and cutting areas. The starter hole was placed in the center of the barrier with concentric circles defining cutting ranges. After 2000, some manufacturers began using concentric ovals on barriers to define cutting areas, which made the job of cutting to specific stoma needs much easier.

Today, the barrier on the Novalife pouch applies the best practice of oval cutting guides, but takes the cut-to-fit barrier to a new level: the starter hole is no longer at the center of the barrier; rather it is toward the top. What does this mean for the user? When the hole for the stoma is at the top of the barrier/pouch, there is much less "headspace," meaning material above the stoma. That means the pouch sits lower on the body, below the belt line for most ostomates, and that makes a pouch much less noticeable. The placement of the starter hole also means there's more barrier with adhesive to connect to the body at the points where leakage is likely to occur. Stoma care nurses have long known that the positions of 3, 6, and 9 o'clock on a barrier are points where leakage is most likely to occur. With the revolutionary placement of the starter hole on the Novalife product, there's more material and more adhesive to help reduce the risk of leakage.

The bane of many drainable pouch users – the omnipresent "tail" – is no longer an issue with the Novalife pouch. The tail folds up neatly through a unique integrated closure so that the drainable pouch actually looks and feels like a closed pouch. Even though the system's integrated filter delivers a new level of odour control, it is the placement on the pouch that is the revolution. The lateral placement of the filter means much less bulk because the pouch top no longer tends to fold over.

As with most any consumer product design, there are incremental improvements, and there are giant leaps or game changers. For decades ostomy pouches improved gradually. As manufacturers became more acutely aware of user quality of life needs, they modified their products. As Dansac A/S continued to reach out to consumers they looked for a way to universalize pouch design, to create a game changer. That giant leap is Novalife.

1998



2010



2011



58% stated they had changed the style of clothing they wore to accommodate the pouching system.



3

Dansac Novalife White Paper /1

Authors

Vigdis Hannestad, Global Clinical Services Manager.
Thomas Nichols, Principal Clinical Research Statistician.

Introduction

Ostomy surgery is a life altering surgery. While the benefits to the health of the person that has undergone the surgery is self-evident – it saves lives and frees people from debilitating diseases – the physical presence of the effect of the surgery, that is, the stoma and its maintenance can be a difficult obstacle to overcome. The stoma must empty the contents of the bowel or bladder into a pouching system attached to the abdomen of the ostomate. The pouching system comprised of a pouch and a skin barrier for attachment to the abdomen is not a discrete item, often requiring the ostomate to change clothing styles to accommodate the pouching system. In fact, in the Ostomy Comprehensive Health and Life Assessment survey of 4,097 North American, United Kingdom and Italian¹ ostomates, 58% stated they had changed the style of clothing they wore to accommodate the pouching system. This is done to keep people from noticing they are wearing a pouch and is necessitated by the need for discretion as pouches protrude from the abdomen when they fill with effluent and in some cases balloon due to flatus. (Flatus gases enter the pouch through the stoma and expand the volume of the pouch, much like blowing up a balloon. If a filter does not work as intended, pouch ballooning becomes a problem when the volume of gases in the pouch distends the pouch to the extent that it is easily visible underneath the user's clothing).

As two ostomates recently said:

“The wafer sticks out more forming a bulge in my clothing. Gas in the pouch adds to the problem.

“Pouch concealment is probably one of the most difficult issues to deal with for colostomy patients. Loose fitting/blousier clothes, wearing your shirts or tops on the outside instead of tucked into your trousers are the only good ways to keep your pouch from being noticed. I happen to be one who has almost continuous discharge because I have very little colon left. This makes concealment even more difficult.

Often ostomates describe a loss of identity, dignity, privacy and independence following ostomy surgery. This is most likely due to a compromised confidence in themselves. When living with a stoma, there are two main factors at stake; convenience and dignity. Convenience should be understood as something which provides ease and comfort to habits and practice. Dignity on the other hand is more complicated. People with stomas lose the ability to control their bowels; a pouching system is a continual reminder of this, which is often equated as a loss of dignity and the fear of being stigmatized by people and society.

In this White Paper we will use findings from a recent large QoL study undertaken in US, UK and Italy as well as findings from a multi site, unblinded, historically controlled observational study of the new Novalife 1 piece Open and Closed products when discussing around this topic.

Background

Appliance discretion is more than just product concealment; it is also the ability to unobtrusively function during daily activities. The new generation of ostomy products are intended to improve upon discretion and comfort. Pouch visibility is a key component of discretion as ostomates may be concerned that the ostomy pouch is apparent to others. A recent study (Table 1) indicates that as many as 56% of ostomates occasionally or always will worry about the pouch being noticeable to others.

From childhood we are taught and rewarded to control bowel and bladder functions. When faced with the reality of a stoma, ostomates have a long and difficult journey ahead to overcome the stigma of non-control so rigidly enforced in early life. It is not uncommon for someone who has undergone ostomy surgery to be self-conscious of the fact that they are an ostomate; to have lost control of their bodily functions, and to worry that this will be revealed to others if it is noticed that they are wearing a pouch.

As stated, approximately 56% of ostomates occasionally, or more often worry about this issue, with more than 19% always worrying about it. The impact of this for the ostomate is found by associating this concern with quality of life issues that could be affected when discretion is compromised, e.g., the possibility of increased social isolation.

Table1: How often do you worry about people noticing the pouch under your clothing?

	Never	Occasionally		Always	
	1	2	3	4	5
N	1240	528	1086	383	780
%	30.87	13.14	27.04	9.53	19.42

Table 2: Worrying about people noticing the pouch under clothing and...

	N. America		United Kingdom		Italy	
	r	p-value	r	p-value	r	p-value
– feeling alone and friendless	-0.34	0.001	-0.31	0.001	-0.28	0.001
– relating to others	-0.39	0.001	-0.32	0.001	-0.29	0.001
– feeling isolated from others	-0.37	0.001	-0.37	0.001	-0.25	0.001
– feeling separate from others	-0.38	0.001	-0.40	0.001	-0.30	0.001

Table 3: If an ostomy appliance is easily concealed under clothing, how important is this to you?

	Frequency	%	Cumulative
Very important	1347	60.73	
Important	613	27.64	88.37
Neither important nor unimportant	173	7.80	7.80
Unimportant	58	2.61	
Very unimportant	27	1.22	3.83

When the issue of the pouch being noticed under clothing is associated with the quality of life issue of social isolation² a statistically significant correlation is found; r= -0.39, p=0.001. The isolation attributes that are most closely aligned with appliance concealment are shown in Table 2.

Thus, as the worry about others noticing the pouch under clothing increases, there is a statistically significant associated decrease in social connectivity. Confirmation of this can be found when the ostomates are further queried as to how important the issue of appliance concealment is to them. The data from the Ostomy Comprehensive Health and Life Assessment is conclusive. Over 88% of the ostomates in

the study stated that an appliance, easily concealed under their clothing, is important to them (Table 3). From this, it is easy to see that an ostomy appliance designed to be easily concealed is an integral component of discretion; a sought after quality of life necessity for the ostomate.

As said before, appliance discretion is more than product concealment; it is also the ability to unobtrusively function during daily activities. Having a stoma can affect everyday activities that most people take for granted. As an example, the survey found that approximately 16% of all ostomates consider their stoma as representing a disability, 33% of all ostomates have had to change their work habits (approximately 10% had to change occupations), and 23% of UK and Italian ostomates no longer stay away from home overnight since their surgery. Findings from a multi-centre cross-sectional study (N 86) that evaluated the relationship between colostomy pouch change and disposal practices and the patient's psychological wellbeing found that 50% felt that their body was out of their control and 33% reported avoiding social and leisure activities.³

The new generation of ostomy products are intended to improve discretion, comfort and easy positioning.

To this end, Dansac A/S has constructed a redesigned pouching system to offer the ostomate improved product discretion and product function. The redesigned pouch has lower headspace, an off centered starter hole and a superior efficiency filter. Product intention is to improve discretion and comfort as well as enable the ostomate greater freedom to choose clothes and activities that reflect their lifestyle.

Methods
1: QoL

The survey instrument used in the QoL study is the Hollister Ostomy Comprehensive Health and Life Assessment. It is a validated and reliable instrument containing 113 questions assessing pre and post surgical health and life status. Internal consistency is set to Cronbach's alpha not less than 0.82.

This is a self reported assessment of health status, marital status, occupational status, sexual and social wellbeing, emotional status, family life, and overall contentment with life. The database consists of 4,097 adult colostomates, ileostomates, and urostomates geographically dispersed throughout North America, the United Kingdom and Italy.

2: Product

A prospective, unblinded, historically controlled observational study of a one-piece pouch with enrollment targeted to complete with a minimum of 140 subjects (70 evaluating open pouches and 70 evaluating closed pouches). The study received a waiver of review by the NHS REC and was conducted in accordance with basic ethical principles including informed consent and respect for the confidentiality of participants. Each participant satisfied the inclusion and exclusion criteria and provided signed informed consent prior to enrollment.

Closed pouches / Cell 1:

73 subjects (cell 1) who were currently using the Dansac Nova 1 Closed product (closed control), were enrolled in order to detect a 15% difference in product performance between test device and historical control (alpha=0.05, beta=0.20). Subjects were to be at least two months post-operative and have a peristomal skin irritation score of 2 or less in order to be enrolled. Current users of pre-sized or convex products were excluded from the study.

73 demographic profiles and 926 subject assessments were available for analysis. 31 males (42.5%) and 42 females (57.5%), participated in the study. A large proportion of the participants reported using their current system for either less than one year (34.2%) or from one to five years (54.8%) with a lesser proportion reporting that they had been using their current system for more than five years (11.0%). Most participants described their lifestyle as moderately active (65.8%), the rest described their lifestyle as either very active (21.9%) or not active (12.3%). Most stomas were reported as being either flush (64.4%) or protruding (30.1%) with a small proportion reported as recessed (5.5%). Subjects reported a median 25 months (IQR: 12 to 52 months) since their original ostomy surgery.

Open pouches / Cell 2:

The drainable participants (cell 2) were users of current regular size, cut-to-fit Dansac Nova 1 drainable pouches (drainable control) who assessed the Novalife 1 Open pouches. A total of 76 subjects were enrolled (completed informed consent and were assigned a subject number) in the drainable cell and 75 had evaluable data. One male subject discontinued prior to applying the first pouch therefore there was no data to collect. All data collected from the 75 subjects who trialed the product were included in the data analysis.

Of the 75 who participated in the open pouch cell, 38 subjects were male (50.67%) and 37 were female (49.33%). The average age was 56.71 years (S.D. 16.17 years; range 20 – 85 years). The average time after surgery was 39.80 months (S.D. 54.78). The average weight was 74.71 kg (SD 13.78; range 45 – 114) and the average height was 169.17 cm (SD 9.21; range 143 – 188). There were 6 subjects who dropped out of the study, no reported adverse events, and 12 subjects deviated from the protocol by either wearing their current pouch during the study or wearing the test product more than 8 days. The 6 subjects who discontinued their participation in the study attributed product failure as their reason for discontinuing the study. There were no reports of skin or stoma irritation attributable to the use of the test pouches.

Each subject was provided one box of test product which contained either 15 closed pouches (cell 1) or 8 open pouches (cell 2) for each subject to wear consecutively. Subjects were instructed to wear the test devices according to their normal habit. Subjects recorded wear time and their assessment of relevant characteristics for each pouch. In addition, they provided an assessment in comparison to the pouch they normally use (control). Individual participation was for 8 days or until the test product had been used up, whichever came first. The study was comprised of 2 visits, an enrollment visit and a completion visit and a phone call at approximately day 4.

Assessments of wear time, leakage (barrier failure), filter performance, comfort and discretion was also obtained.

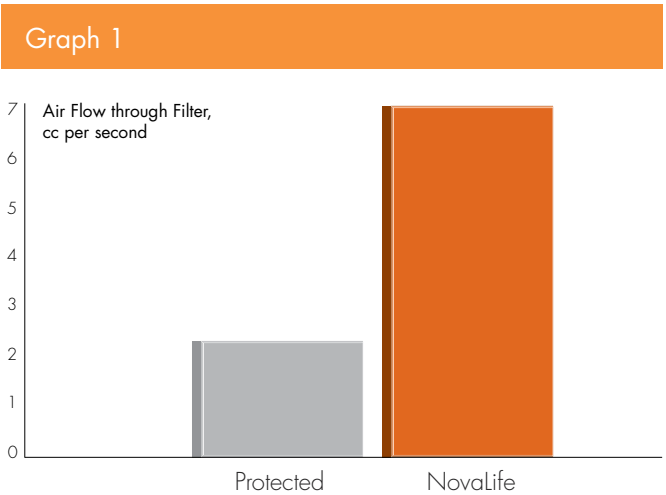
Results
Ballooning

When pouch ballooning was assessed (cell 1), almost half (47%) of respondents stated there was less ballooning than with the pouch they normally use.

Ballooning can result in effluent leakage if the flange to abdomen seal is compromised. Leakage is not only embarrassing but can contribute to peristomal skin disorders. There is a large variation in the volume and composition of flatus produced by individuals. The main constituents of flatus gases are produced by metabolic activity (e.g., hydrogen, carbon dioxide and methane) and by swallowing of air (nitrogen, oxygen). Variations among individuals in the amount of flatus produced depend on their diets, the nature of the microorganisms in their intestinal tract and the amount of air they swallow. Research shows that odour is in the top

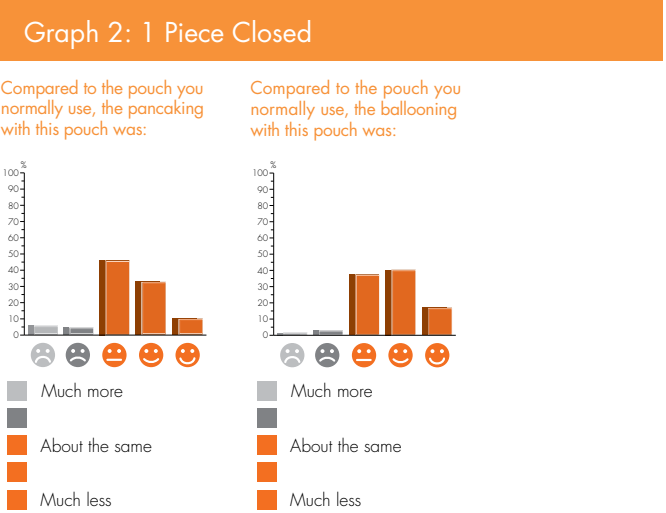
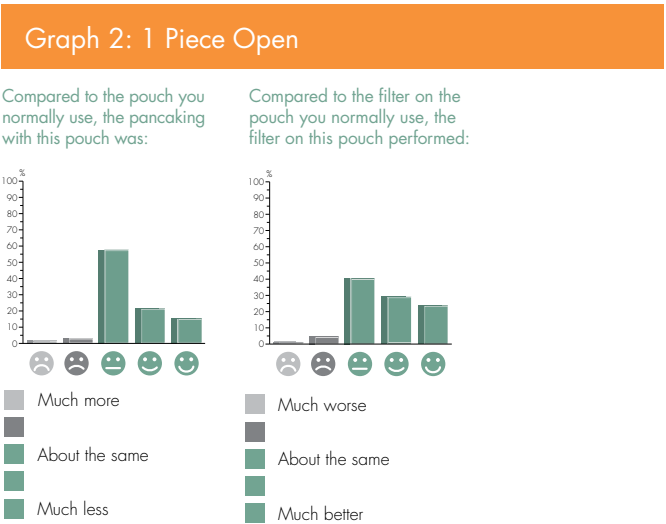
3 of an ostomate’s concerns.^{4,5} It is therefore essential that the pouch filter must be able to accommodate the wide range of gas volumes and allow the gases to exit the pouch.

The airflow rate through the filter is more than doubled for the new Novalife filter compared to the previous generation of filter technology (Graph 1).



Filter performance /Discretion

The superiority of the filter, combined with the low headspace and the new design, may have contributed to the response that in 71% of pouch wearings, under a variety of conditions, study subjects were satisfied that the pouch design met its intended purpose; to be less noticeable under clothing, and that in 72% of all wearings study subjects agreed that it was less noticeable than their current pouch (Graph 2).



Discretion

Table 4: 1 Piece Open

This pouch was designed to be less noticeable under your clothing. How satisfied are you that this pouch does this?

Response	n	%
1. Very dissatisfied	2	0.4
2.	7	1.4
3. Neither satisfied nor dissatisfied	139	27.6
4.	208	41.4
5. Very satisfied	147	29.2
Total	503	

The filter on the new Novalife products employs an advanced membrane material, the GORETM Medical Membrane. The microporous structure of this material provides a membrane that is very “breathable”, allowing rapid airflow. The Novalife filter design also uses a larger membrane surface area than is typically found on pouch filters. Combining a large surface area with a high porosity membrane material provides a substantially higher level of airflow through the filter package.

As mentioned earlier, discretion is also the ability to unobtrusively function during daily activities. When the

Table 5: 1 Piece Open

Compared to the pouch you normally use, this pouch was less noticeable under your clothing.

Response	n	%
1. Disagree	4	0.8
2.	10	2.0
3.	129	25.6
4.	197	39.2
5. Agree	163	32.4
Total	503	

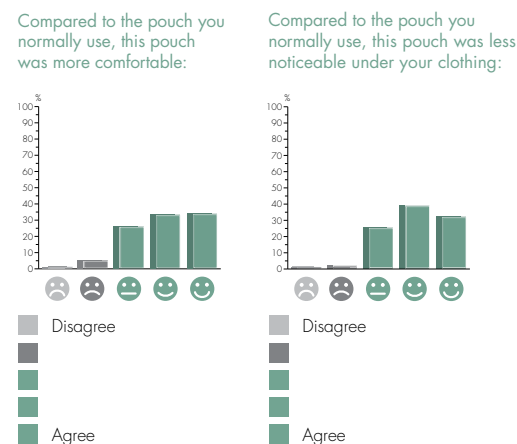
respondents in the study were queried as to environments that they felt comfortable wearing the new pouch in (Under which situations did the new pouch help you feel more comfortable), 35 of 73 (48%) responded “at work”, 34 of 73 (46.6%) responded “at a friend’s home”, 35 of 73 (48%) responded “at other public events”, and 15 of 73 responded “during intimate moments”. Please note that respondents were asked to select all that apply, therefore multiple responses are possible. Thus, the newly designed pouch also demonstrated to provide discretion during varied daily activities (Graph 3).

Wear time considerations

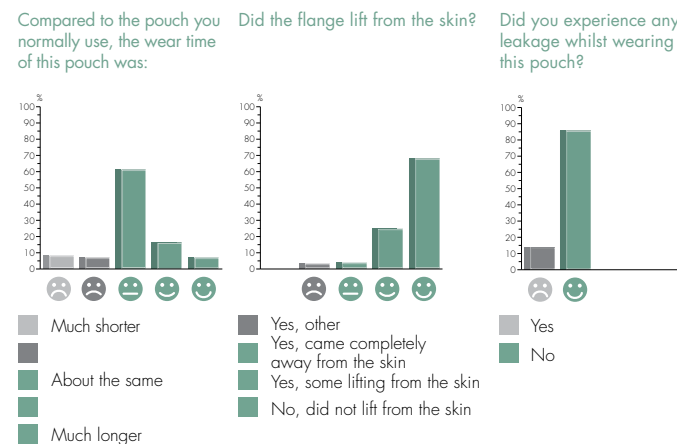
From childhood we are taught and rewarded to control bowel and bladder functions. When faced with the reality of a stoma, ostomates have a long and difficult journey ahead to overcome the stigma of non-control so rigidly enforced in early life. It is not uncommon for someone that has undergone ostomy surgery to be self-conscious of the fact that they are an ostomate; to have lost control of their bodily functions, and to worry that this will be revealed to others if it is noticed that they are wearing a pouch. If experiencing leakage of stool or urine this is a severe setback to quality of life and trust in the product.

The product performs well when taking wear time, lifting of flange or barrier rolling into consideration. The new pouches were well accepted with approximately 85% or greater of the wear occasions being rated as being neutral or positive for the attributes such as cutting/application, wear time and security (Graph 4).

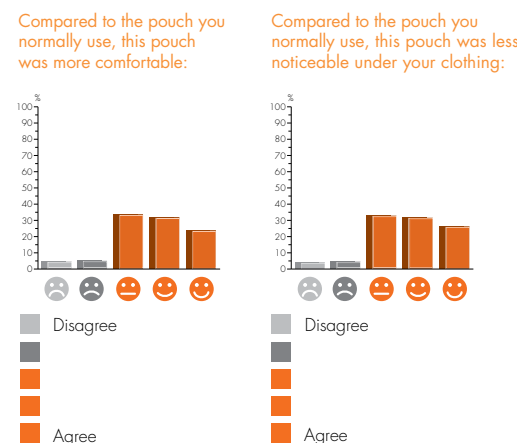
Graph 3: 1 Piece Open



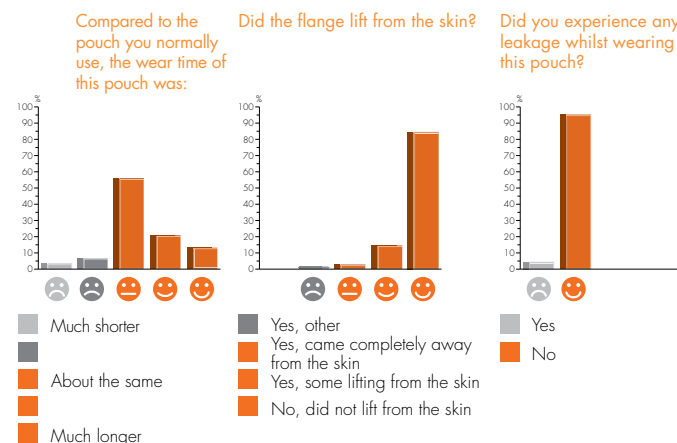
Graph 4: 1 Piece Open



Graph 3: 1 Piece Closed



Graph 4: 1 Piece Closed



Conclusions

As stated many times before in this White Paper, having a stoma can affect everyday activities that most people take for granted. Compounding this issue is the ostomy pouching system which the ostomate must adapt or adjust his or her life around to accommodate. Of great importance to this process of adjustment is discretion, in which adjustment means finding methods of concealment of the appliance, or trying to be inconspicuous during changing and disposal of the appliance.³

There are several studies which form the basis of our understanding of the psychological, social, cultural and economic effects of living with a stoma. The Ostomy Comprehensive Health and Life Assessment has shown there are cross-cultural common effects of living with a stoma, but not all people react similarly when confronted with a life altering surgery. Some studies have focused on the various stages of patient acceptance and highlight some of the challenges which many ostomates face when dealing with a stoma, limitations which are sometimes imposed by the ostomate themselves.^{2,6,7}

In an article in Evidence-Based Nursing in 2004 Rozmovits and Ziebland⁸ talk about how patients with colorectal

cancer expressed a loss of adulthood related to a loss of professional and sexual identity, dignity, privacy, independence, and ability to socialize. Loss of dignity, privacy, and independence, was a sub theme described by 22 patients who had temporary or permanent stomas. The unpredictability of bowels affected job performance and fundamental aspects of socially expected adult identity.

We must constantly remind ourselves that the ostomate is not a static entity, but rather a person with a dynamic mix of biological, social, and other life impacting needs. We must keep in mind that the post surgical recovery of the ostomate is not just a matter of maintaining the stoma and peristomal environment. While this is of great importance and impacts the person significantly, to concentrate on only this is to deny the holistic patient and the multitude of bio-psycho-socio interactions that are dynamically represented in the post surgical recovery.⁹ Being one of the top global manufacturers of ostomy appliances, we have dedicated ourselves to develop and produce first class ostomy appliances to meet the need of today's ostomates.

The Ostomy Comprehensive Health and Life Assessment survey provided considerable evidence that discretion of an ostomy pouching system is an important consideration for the comfort and quality of life of a person with an ostomy. In fact, the inspiration for the development of the new Dansac Novalife pouching system came from the survey which employed the voice of the ostomate in critical issues, and an innovative method of interpreting this voice. Thus the new Novalife pouching system has been developed to address the specific needs of discretion, and thereby improve self-confidence and quality of life. The novel design incorporates a reduced headspace, offset starter hole in the barrier, improved filter and a improved closure system in the drainable version. In the multi site, unblinded, historically controlled assessment that has been performed in UK the new Novalife pouches were well accepted with the majority of the subjects. The new pouches were well accepted with approximately 85% or greater of the wear occasions being rated as being neutral or positive for the attributes such as cutting/application, wear time, security, filter performance and comfort.

The new Novalife pouches improved discretion and comfort as well as enabled the ostomate greater freedom to choose clothes and activities that reflect their lifestyle. 72% of study subjects were satisfied that the pouch design met its intended purpose; to be less noticeable under clothing, and 76%

agreed that it was less noticeable than their current pouch. The Novalife pouching system offers the ostomate increased function and discretion; two sought after commodities in the pursuit of self-confidence and quality of life.

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Often ostomates describe a loss of identity, dignity, privacy and independence following ostomy surgery.



4 Pouch Discretion and Concealment. Importance for the ostomate and products to meet their needs /1

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Authors

Patricia Black, Hillingdon Hospital, Uxbridge, UK.
Caroline Rudoni, St. George's Hospital, London, UK.
Teresa Williams, Milton Keynes General Hospital, Milton Keynes, UK.
Ann Edwards, Castle Hill Hospital, Cottingham, UK.
Jane Cox, King's Mill Hospital, Sutton-in-Ashfield, UK.
Julie Hemmingway, The Leeds General Infirmary, Leeds, UK.
Jo Pragnell, The John Radcliffe Hospital, Oxford, UK.
Thom Nichols, Hollister Incorporated, Libertyville, IL USA.
Vigdis Hannestad, Dansac A/S, Fredensborg, Denmark.

Introduction

Often ostomates describe a loss of identity, dignity, privacy and independence following ostomy surgery. This is most likely due to a compromised confidence in themselves. When living with a stoma, there are two main factors at stake; convenience and dignity. Convenience should be understood as something which provides ease and comfort to habits and practice. Dignity on the other hand is more complicated. People with stomas lose the ability to control their bowels; a pouching system is a continual reminder of this, which is often equated as a loss of dignity and the fear of being stigmatized by people and society.

Appliance discretion is more than product concealment; it is also the ability to unobtrusively function during daily activities. The new generation ostomy products are intended to improve upon discretion and comfort. Pouch visibility is a key component of discretion as ostomates may be concerned that the ostomy pouch is apparent to others. A recent study¹ indicates that as many as 54% of ostomates occasionally or always worry about the pouch being noticeable to others.

Methods

A multi site, unblinded, historically controlled observational study of a new 1-piece product was performed.² 73 subjects who were currently using a 1-piece product, were enrolled in order to detect a 15% difference in product performance between test device and historical control ($\alpha=0.05$, $\beta=0.20$).

The study received a waiver of review by the NHS REC and was conducted in accordance with basic ethical principles including informed consent and respect for the confidentiality of participants. Each participant satisfied the inclusion and exclusion criteria and provided signed informed consent prior to enrollment. Individual participation was for one

week or upon using 15 closed pouches, whichever came first. Participants were asked to complete a usage diary for each pouch worn.

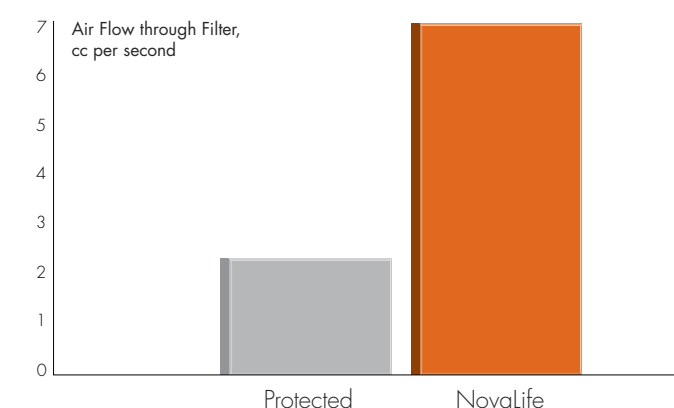
Results and Discussion

Ostomy surgery is a life altering surgery. While the benefits to the health of the person that has undergone the surgery are self-evident – it saves lives and frees people from debilitating diseases – the physical presence of the effect of the surgery, that is, the stoma and its maintenance can be a difficult obstacle to overcome. When faced with the reality of a stoma, ostomates have a long and difficult journey ahead to overcome the stigma of non-control so rigidly enforced in early life. It is not uncommon for someone that has undergone ostomy surgery to be self-conscious of the fact that they are an ostomate; to have lost control of their bodily functions, and to worry that this will be revealed to others if it is noticed that they are wearing a pouch. To this end, and necessitated by the need for discretion it is common for ostomates to change clothing styles to accommodate the pouching system; pouches protrude from the abdomen when they fill with effluent, and balloon due to flatus.

A newly designed pouch with lower headspace, an off centered starter hole and an improved filter was assessed. Product intention with the new design is to improve discretion and comfort, as well as enable the ostomate greater freedom to choose clothes and activities that reflect their lifestyle.

Integral to the pouch design and the issue of discretion is the performance of the improved filter. The airflow rate through the filter is more than doubled for with this new filter compared to the previous generation of filter technology (Graph 1).

Graph 1



4

Pouch Discretion and Concealment.
Importance for the ostomate and products to meet their needs /2

The superiority of the filter, combined with the low headspace and the new design, may have contributed to the response that in 71% of pouch wearings, under a variety of conditions, study subjects were satisfied that the pouch design met its intended purpose; to be less noticeable under clothing, and that in 72% of all wearings study subjects agreed that it was less noticeable than their current pouch. This is shown in Graph 2 and 3.

Discretion

Additionally, 72% of study subjects were satisfied that the pouch design met its intended purpose; to be less noticeable under clothing, and 76% agreed that it was less noticeable than their current pouch.

Discretion is also the ability to unobtrusively function during daily activities. When the respondents in the study were queried as to environments that they felt comfortable wearing the new pouch in (Under which situations did the new pouch help you feel more comfortable), 35 of 73 (48%) responded “at work”, 34 of 73 (46.6%) responded “at a friends home”, 35 of 73 (48%)³ responded “at other public events”, and 15 of 73 responded “during intimate moments”.

Conclusion:

Having a stoma can affect everyday activities that most people take for granted. Adjusting to a stoma involves concealment of the appliance and consideration of what is involved during changing and disposal of the appliance.

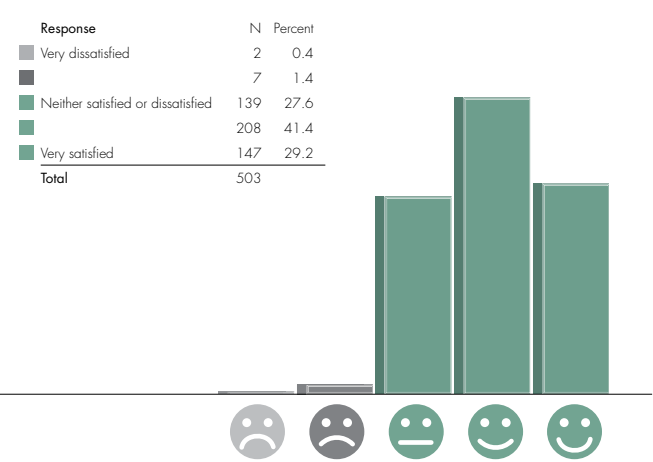
The study finds that the new pouches were well accepted by the majority of subjects. With the additional benefit of improved discretion the newly designed pouches may positively impact self-confidence and quality of life of those with ostomies.

Footnotes

- 1) Hollister Ostomy Comprehensive Health and Life Assessment, Hollister Incorporated, Libertyville, Illinois, USA.
- 2) The tested pouch is the Dansac Novalife 1 Open.
- 3) Respondents were asked to select all that apply, therefore multiple responses are possible. Thus, the newly designed pouch has also demonstrated to provide discretion during varied daily activities.

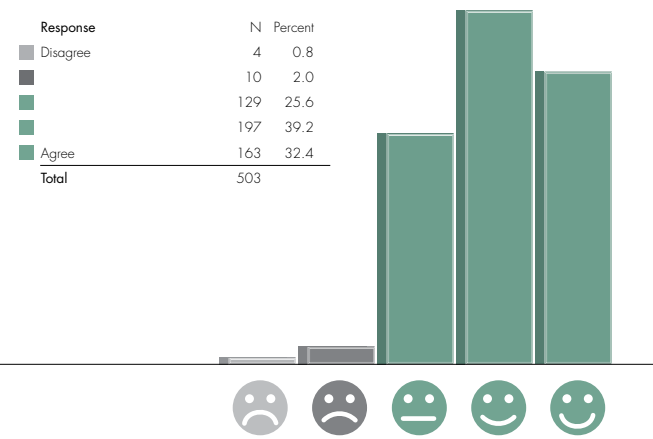
Graph 2: 1 Piece Open

This pouch was designed to be less noticeable under your clothing. How satisfied are you that this pouch does this?



Graph 3: 1 Piece Open

Compared to the pouch you normally use, this pouch was less noticeable under your clothing.



Acknowledgement

St. George's Hospital, London, UK
Caroline Rudoni
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Hillingdon Hospital, Uxbridge, UK
Pat Black

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Jane Cox
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Nurses are well positioned to undertake research studies due to their clinical skills and access to patients.



The Challenges of Conducting Clinical Research: The Investigators Perspective /1

First published in June 2010 at the WOCN/WCET Congress, Phoenix, Arizona, USA.

Authors

Jane Cox, King's Mill Hospital, Sutton-in-Ashfield, UK.
Teresa Williams, Milton Keynes General Hospital, Milton Keynes, UK.
Julie Hemmingway, The Leeds General Infirmary, Leeds, UK.
Ann Edwards, Castle Hill Hospital, Cottingham, UK.
Stacy Schroeder, Hollister Inc., Libertyville, IL USA.

Introduction

As new drugs/devices are developed and the demands for evidence based care increase, the need for qualified nurses to serve as investigators in clinical trials will likewise grow. Some nurses have extensive experience serving as investigators for various types of clinical research; however, many nurses have limited to no experience in this area. Those who have participated as investigators for clinical research have a unique insight into challenges provided by the various types of research study. Nurse investigators who participated as site investigators in a recent clinical trial were asked to share their perspective.

Objective

To share the experience and insight gained by participating as a site investigator for a clinical trial and to educate ETs and WOC nurses on the challenges encountered and opportunities presented.

Methods

A recent industry-sponsored multi-site medical device research study was conducted in the United Kingdom. Many of the nurse investigators for this study had experience with case studies and/or product evaluations but had limited experience with clinical trials. The challenges they discovered, the impact this type of research had on their subject care, and what they gained from the experience was obtained through interviews.

Summary

Investigators who participated in this study were interested in conducting clinical research to expand their knowledge of research for advancement of their professional practice and to improve quality of life for their patients. Most investigators had no experience with conducting a clinical research study in their institution. Some had experience with product placement trials but most of their exposure to clinical research was through coursework. As with most clinical trials, these investigators had enthusiastic expectations for enrollment which resulted in several sites not meeting their recruitment goals or reduced the goals prior to or during the study.

"The time spent was enormously rewarding."

"The study itself... overall was an enjoyable experience."

"There is also a degree of commitment and staying power required to see the project finished."

Limited time was the most common challenge amongst study staff, which was compounded with a large amount of study paperwork, difficulty locating patients that qualified for the study, long approval periods for institutional legal or ethics departments and communication challenges between site (UK) and sponsor (US) time zones. Several investigators felt that there was a steep learning curve to start the study, while a few felt that startup was relatively easy. All investigators

4

The Challenges of Conducting Clinical Research: The Investigators Perspective /2

found that collecting the study information from subjects was challenging and demanded a significant amount of time. Investigators felt that hospitals could provide more local support so that "critical reflexivity is both nurtured and valued". Some investigators also felt that the sponsor should provide a study day to review the study and meet with potential patients. Investigators reported gaining a better understanding of the research process, ethics and those responsible for research related processes at their institutions.

These investigators proposed recommendations for other new investigators as:

- Gain a clear understanding of the expectations and limitations of the project and each investigator.
- Establish a good understanding of the study methodology.
- Identify a designated clinical study area.
- Ensure good rapport with patients/clients.
- Consider advertisements for subject recruitment.
- Keep in mind that many patients may have changed products in the community.
- Don't underestimate the amount of time the study will take.
- Clearly explain what the sponsor requires on data collection tools to all subjects.

There is also a degree of commitment and staying power required to see the project finished.

While clinical research is challenging and time consuming, especially for new investigators, a majority of investigators found their time and effort towards the larger project goal to be rewarding. Investigators also greatly value the experience they gained and look forward to applying their lessons learned for future research studies.

Conclusion

Nurses are well positioned to undertake research studies due to their clinical skills and access to patients. However, nurses undertaking this research felt that they needed more clinical research education. To better prepare nurses for the challenges of clinical research, formal and informal training need to be provided; along with a more structured support

system in the hospital and recognition of the value research provides. These changes may increase nurse participation in clinical studies resulting in improved patient care and evidence based practice due to the results of these studies.

Footnotes

The tested pouches in this clinical study are the Dansac Novalife 1 Closed and Open.

Acknowledgements

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"We have gained invaluable knowledge and skills in clinical research which we can take forward to future studies."

"It helps me keep abreast with new developments in the field."

"The largest challenge... was time constraints and the ability to manage several tasks at once, not only within the research project but our own clinical practice."

"We have enjoyed undertaking this challenge and as a team have heightened our profile in different areas within the organization."

With the additional benefit of improved discretion, the new pouch should improve self-confidence and quality of life.



User Assessment of a New Pouching System Designed to Improve Discretion and Confidence / 1

First published in June 2010 at the WOCN/WCET Congress, Phoenix, Arizona, USA.

Authors

Caroline Rudoni, St. George's Hospital, London, UK.
Jane Cox, King's Mill Hospital, Sutton-in-Ashfield, UK.
Teresa Williams, Milton Keynes General Hospital, Milton Keynes, UK.
Ann Edwards, Castle Hill Hospital, Cottingham, UK.
Julie Hemmingway, The Leeds General Infirmary, Leeds, UK.
Patricia Black, Hillingdon Hospital, Uxbridge, UK.
Jo Pragnell, The John Radcliffe Hospital, Oxford, UK.
Richard Murahata, Hollister Inc., Libertyville, IL USA.
Stacy Schroeder, Hollister Inc., Libertyville, IL USA.
Michael Riemer, Hollister Inc., Libertyville, IL USA.

Introduction

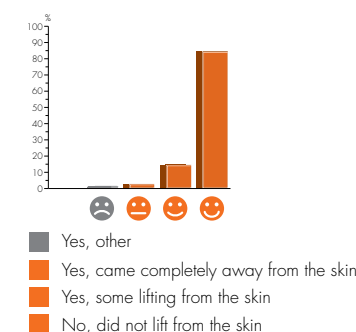
There is considerable evidence that discretion of an ostomy pouching system is an important consideration for the comfort and quality of life of a person with an ostomy. A new pouching system has been developed to address this specific need, and thereby improve their self-confidence and quality of life. The novel design incorporates a reduced headspace, offset starter hole in the barrier, improved filter and improved closure system in drainable version. When engaged, the closure system provides a profile similar to that of the closed pouch. While providing these improvements, it is critical that the basic function of the pouching system not be compromised. The discretion and confidence benefits are addressed in the poster "Pouch Discretion and Concealment". The assessment of core attributes is reported here.

1 Piece Closed

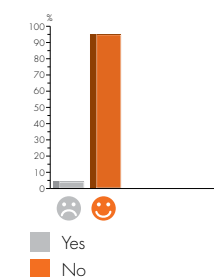
Compared to the pouch you normally use, the wear time of this pouch was:



Did the flange lift from the skin?



Did you experience any leakage whilst wearing this pouch?

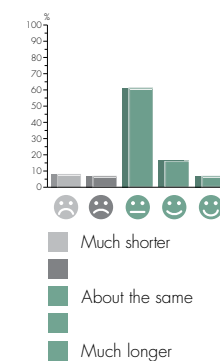


Compared to the pouch you normally use, the pancaking with this pouch was:

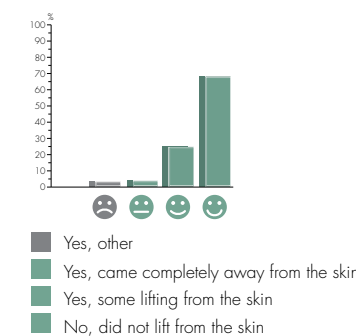


1 Piece Open

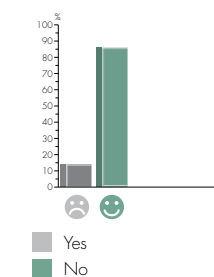
Compared to the pouch you normally use, the wear time of this pouch was:



Did the flange lift from the skin?



Did you experience any leakage whilst wearing this pouch?



Compared to the pouch you normally use, the pancaking with this pouch was:



4

User Assessment of a New Pouching System Designed to Improve Discretion and Confidence /2

Methods

This study was a prospective, unblinded, historically controlled observational study of a one-piece pouch with enrollment targeted to complete with a minimum of 140 subjects (70 evaluating open pouches and 70 evaluating closed pouches). The study received a waiver of review by the NHS REC and was conducted in accordance with basic ethical principles including informed consent and respect for the confidentiality of participants. Each participant satisfied the inclusion and exclusion criteria and provided signed informed consent prior to enrollment. Individual participation was for one week or upon using either 15 closed pouches or 8 open pouches whichever came first. Participants were asked to complete a usage diary for each pouch worn.

Conclusion

The new pouches were well accepted with approximately 85% or greater of the wear occasions being rated as being neutral or positive for the attributes such as cutting/application, wear time, security, ease of draining, filter performance and comfort. With the additional benefit of improved discretion, the new pouch should improve self-confidence and quality of life of those with ostomies while continuing to satisfy the core attributes.

Footnotes

The pouches in this clinical study are Dansac Novalife 1 Closed and Open.

Acknowledgements

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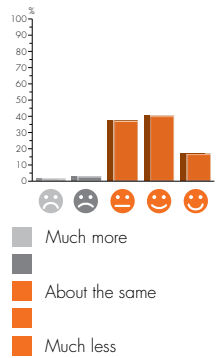
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1 Piece Closed

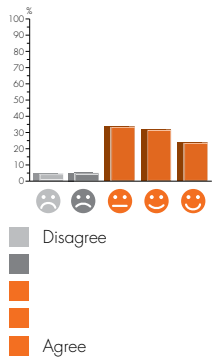
Compared to the pouch you normally use, the ballooning with this pouch was:



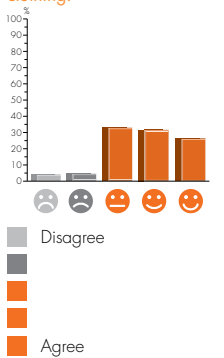
Compared to the filter on the pouch you normally use, the filter on this pouch performed:



Compared to the pouch you normally use, this pouch was more comfortable:

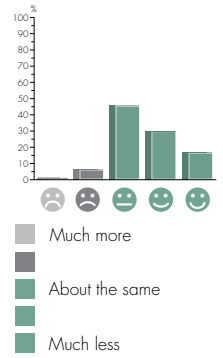


Compared to the pouch you normally use, this pouch was less noticeable under your clothing:

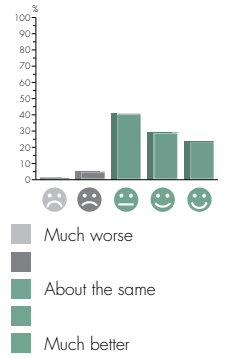


1 Piece Open

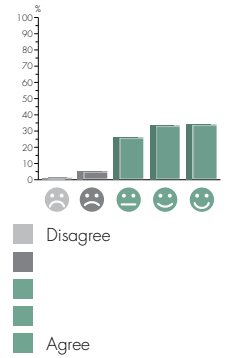
Compared to the pouch you normally use, the ballooning with this pouch was:



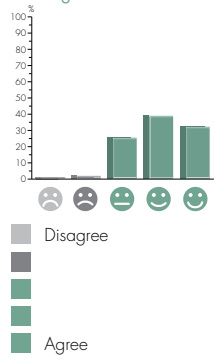
Compared to the filter on the pouch you normally use, the filter on this pouch performed:



Compared to the pouch you normally use, this pouch was more comfortable:



Compared to the pouch you normally use, this pouch was less noticeable under your clothing:



The desire for sexual intimacy is described as a biological force and a cognitive experience.



5 Age and Gender Related Prevalence of the Desire for Sexual Intimacy in an Ostomy Population /1

First published in June 2010 at the WOCN/WCET Congress, Phoenix, Arizona, USA.

Authors

Thom Nichols, MS, MBA, Michael Riemer, MS.
Hollister Incorporated, Libertyville, Illinois, USA.

Introduction

The desire for sexual intimacy is described as a biological force and a cognitive experience.¹ Collectively, experts agree that it is a condition not necessarily reflected in an individual's actions. Within a population, strong or normal sexual desires for intimacy are associated with mixtures of emotion that are contextual; ranging from positive to negative. What is known is that desire for sexual intimacy decreases as a population ages, and can differ by gender. This study investigates age and gender-related prevalence of the desire for sexual intimacy in a population of adult ostomates (over the age of 18) from North America and the United Kingdom (n = 2,721).

Methods

The data is derived from the Ostomy Comprehensive Health and Life Assessment²; a validated and reliable survey distributed in North America and the United Kingdom. The instrument is a self-reported, multi-item survey querying major facets of the lives of persons having undergone ostomy surgery. The survey instrument consisting of 113 items has been assessed for construct and content validity, and overall reliability (Cronbach's Alpha = 0.84) of item-related responses.

The study is not a clinical investigation as outlined in 21 CFR, Part 56, nor is it subject to provisions as outlined in 21 CFR, Part 56:101, 102, and 103. It falls in compliance with 45 CFR, Part 46:101, b(2) governing IRB review. Additionally, NHS Research Ethics Service of the United Kingdom finds that the research presented here is not a clinical investigation and therefore ethical review was not necessary under the guidance of the NHS Research Ethics Committee. The confidentiality of all respondents was assured, and no identifying data was incorporated into the database.

Results and Discussion

Decreases in sexual desire associated with aging are commonly linked to lower levels of testosterone. However, there is no known minimal level of testosterone necessary to promote sexual desire. Decrease in sexual desire is also influenced by factors such as gender (reported to be more prominent in women than in men³), health, emotional status, and environment. While it was not the intent of this study

to determine the impact that a stoma has on sexual desire, it was the intent to demonstrate prevalence in the general population of ostomates. To this end, survey respondents were asked a series of questions related to affection, sexual activity, and desire for sexual intimacy. The data discussed in this report are concerned with the self-reported response to the current desire for sexual intimacy (n = 2,599).

The survey indicates 54% of ostomates consider their desire for sexual intimacy to be weak or non-existent. However, this does not consider age or gender influence. Age and gender are shown to be factors in the decrease in desire for sexual intimacy: ranging from 14% weak or no desire in males less than 45 years old to 86% weak or no desire in females 75 years of age or older. See Table 1. The age related correlation for males is $r = 0.36$, and for females is $r = 0.39$. A comparison between males and females indicates that for age groups within the study, males are significantly less likely to self-report weak or no desire for sexual intimacy. This observation appears independent of stoma type. See Tables 2 through 4.

Conclusions

Attempts to quantify desire for sexual intimacy in a population of those that have undergone a life-changing event, such as ostomy surgery, must not only consider the psycho-socio aspects of the surgery, but also must consider the effects of gender and age as covariates. While it may be convenient to excuse decreasing sexual desire in an ostomate population as a result of the many emotional and physical manifestations of having a stoma, the fact is that in an older or aging population, sexual desire decreases.

References

1. Delamater JD and Sill M. Sexual Desire in Later Life. The Journal of Sex Research. 2005; 42 (2).
2. The Hollister Ostomy Comprehensive Health and Life Assessment, Hollister Incorporated, Libertyville, Illinois, USA.
3. Meston C. Aging and Women's Sexuality. The Sexual Psychophysiology Laboratory. University of Texas at Austin. 2009.

Financial assistance/disclosure

The support of Hollister Incorporated for this clinical presentation is gratefully acknowledged.

5

Age and Gender Related Prevalence of the
Desire for Sexual Intimacy in an Ostomy Population /2

Table 1: Desire for sexual intimacy by age and gender

Age Categories (Years)	≤44		45-64		65-74		≥75	
	Male	Female	Male	Female	Male	Female	Male	Female
n=	119	217	520	671	366	259	257	190
Desire (Strong/normal)	85.7%	60.8%	63.5%	39.6%	53.0%	29.7%	31.5%	14.2%
Non-desire (Weak/no desire)	14.3%	39.2%	36.5%	60.4%	47.0%	70.3%	68.5%	85.8%

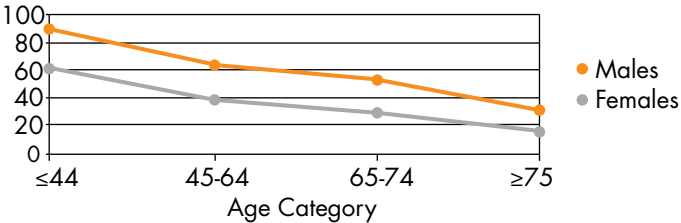


Table 2: Desire for sexual intimacy by age and gender for those with colostomies

Age Categories (Years)	≤44		45-64		65-74		≥75	
	Male	Female	Male	Female	Male	Female	Male	Female
Colostomy								
Males: n = 451 Females: n = 449								
Desire (Strong/normal)	71.0%	69.8%	60.1%	30.6%	48.9%	23.9%	25.0%	18.7%
Non-desire (Weak/no desire)	29.0%	30.2%	39.9%	69.4%	51.1%	76.1%	75.0%	81.3%

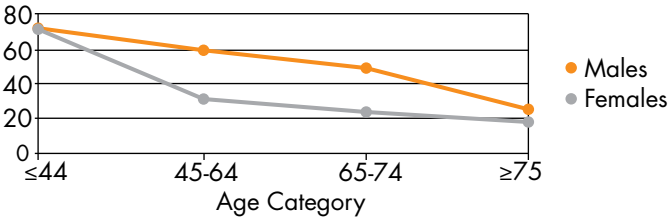


Table 3: Desire for sexual intimacy by age and gender for those with ileostomies

Age Categories (Years)	≤44		45-64		65-74		≥75	
	Male	Female	Male	Female	Male	Female	Male	Female
Ileostomy								
Males: n = 566 Females: n = 712								
Desire (Strong/normal)	91.1%	60.4%	66.8%	47.9%	61.7%	35.8%	33.3%	11.2%
Non-desire (Weak/no desire)	8.9%	39.6%	33.2%	52.1%	38.3%	64.2%	66.7%	88.8%

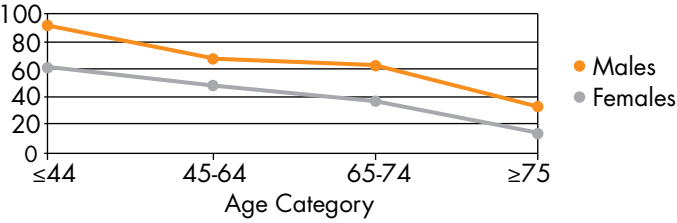
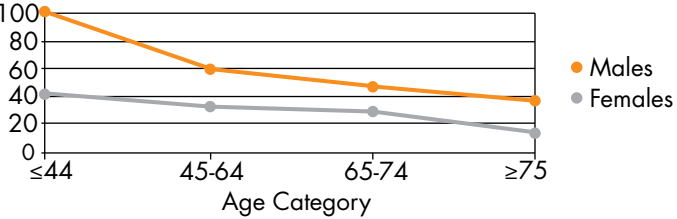


Table 4: Desire for sexual intimacy by age and gender for those with urostomies

Age Categories (Years)	≤44		45-64		65-74		≥75	
	Male	Female	Male	Female	Male	Female	Male	Female
Urostomy								
Males: n = 213 Females: n = 143								
Desire (Strong/normal)	100%	40.0%	57.9%	32.2%	48.0%	28.2%	36.8%	13.3%
Non-desire (Weak/no desire)	0%	60.0%	42.1%	67.8%	52.0%	71.8%	63.2%	86.7%



21% associate poor body image with the stoma changing their appearance.



5

The Prevalence of Poor Body Image in an Ostomy Population /1

First published in June 2010 at the WOCN/WCET Congress, Phoenix, Arizona, USA.

Authors
Thom Nichols, MS, MBA, Michael Riemer, MS.
Hollister Incorporated, Libertyville, Illinois, USA.

Introduction
Traumatic surgeries resulting in altered body appearance, such as ostomy surgery, have been demonstrated to affect the quality of life of those that have undergone such surgery.¹ However, it would be a mistake to assume that all who have undergone ostomy surgery have poor body image. This study investigates the prevalence of poor body image associated with ostomy surgery in a sample of people with ostomies in North America and the United Kingdom (n = 2,693).

Methods
The data is derived from the Ostomy Comprehensive Health and Life Assessment;² a validated and reliable survey distributed in North America and the United Kingdom. The instrument is a self-reported, multi-item survey querying major facets of the lives of persons having undergone ostomy surgery. The survey instrument consisting of 113 items has been assessed for construct and content validity,

and overall reliability (Cronbach's Alpha = 0.84) of item-related responses. The study is not a clinical investigation as outlined in 21 CFR, Part 56, nor is it subject to provisions as outlined in 21 CFR, Part 56:101, 102, and 103. It falls in compliance with 45 CFR, Part 46:101, b(2) governing IRB review. Additionally, NHS Research Ethics Service of the United Kingdom finds that the research presented here is not a clinical investigation and therefore ethical review was not necessary under the guidance of the NHS Research Ethics Committee. The confidentiality of all respondents was assured, and no identifying data was incorporated into the database.

Results and Discussion
The survey asks two body-imaging questions of the ostomates. Cross-tabulating these questions offers insight into the perception of body image by the ostomate. Approximately 17% of the respondents associate poor body image with stoma disfigurement, while 21% associate poor body image with the stoma changing their appearance. Approximately 36% associate a non-negative body image perception with the stoma having no effect on appearance. This is shown in Table 1.

Table 1: Body image perception

	When I stand in front of a mirror, I think my stoma has...			
	Changed my appearance	Disfigured me	Has had no effect on the way I look	Total
I like the way I look	31 1.2%	7 0.3%	111 4.1%	149 5.6%
I do not like the way I look	561 20.8%	462 17.2%	186 6.9%	1,209 44.9%
What I see, I am OK with	406 15.1%	83 3.1%	846 31.4%	1,335 49.6%
Total	998 37.1%	552 20.5%	1,143 42.4%	2,693 100%

5

The Prevalence of Poor Body Image in an Ostomy Population /2

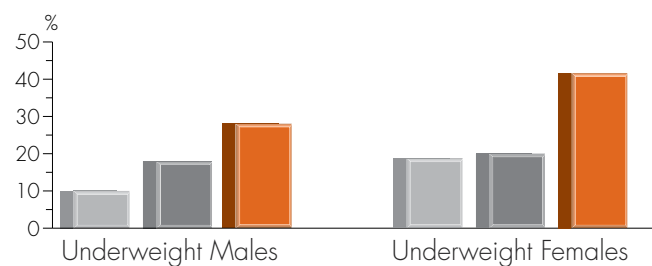
However, negative association categories must be considered with respect to body mass index (BMI) and gender. See [Graph 1-3](#). For those within normal BMI ranges, as defined by the World Health Organization (WHO),³ no differences in negative perception are noted between genders. However, for non-normal BMI ranges statistically significant differences in negative perceptions are noted between genders raising the possibility that body image perception in this population may be confounded with BMI.

Conclusions
The published literature contains numerous articles on body image perception in an ostomy population. However, this may be the first time that prevalence is documented in a study sufficiently large enough to isolate significant variance components. The study indicates that attempts to quantify poor body image, as a result of stoma surgery, must consider the gender of the respondent and control for BMI. For study respondents within the normal BMI range, there were no gender differences noted for negative body image perceptions. However, for those outside of normal BMI, females indicated a greater propensity to associate the stoma with a negative body image.

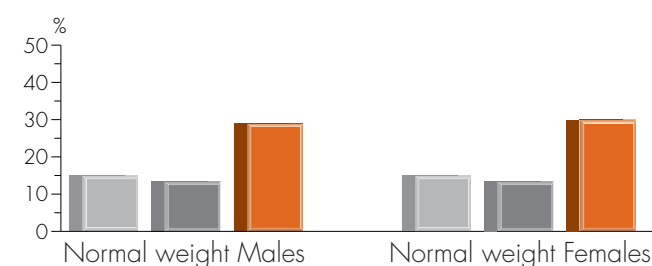
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 2. The Hollister Ostomy Comprehensive Health and Life Assessment, Hollister Incorporated, Libertyville, Illinois, USA.
 3. http://apps.who.int/bmi/index.jsp?introPage=intro_3.html.

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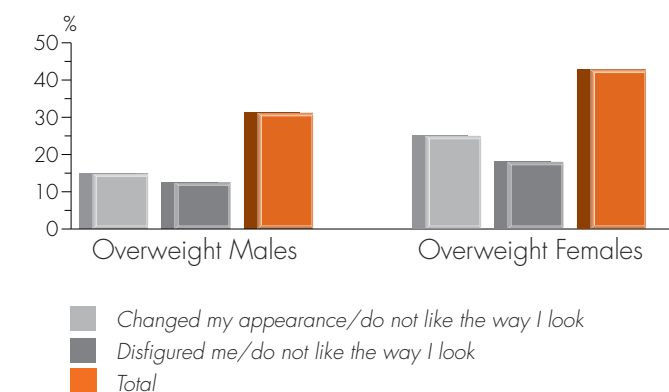
Graph 1
Underweight respondents and negative body image. Comparison of males and females. Chi sq = 3.94, p = 0.0472



Graph 2
Normal weight range respondents and negative body image. Comparison of males and females. Chi sq = 0.1153, p = 0.7342.



Graph 3
Overweight respondents and negative body image. Comparison of males and females. Chi sq = 30.879, p < 0.0001



Social isolation is not uncommon in a population that has undergone life-altering surgery.



5

The Prevalence of Social Isolation in an Ostomy Population /1

First published in June 2010 at the WOCN/WCET Congress, Phoenix, Arizona, USA.

Authors
Thom Nichols, MS, MBA, Michael Riemer, MS,
Hollister Incorporated, Libertyville, Illinois, USA.

Introduction
Social isolation is not uncommon in a population that has undergone life-altering surgery. The extent to which social isolation is permanent may influence physical and mental well-being. This study investigates social isolation prevalence in the general population of people with ostomies in North America and the United Kingdom (n = 2,068).

Methods
The data is derived from the Ostomy Comprehensive Health and Life Assessment¹; a validated and reliable survey distributed in North America and the United Kingdom. The instrument is a self-reported, multi-item survey querying major facets of the lives of persons having undergone ostomy surgery. The survey instrument consisting of 113 items has been assessed for construct and content validity, and overall reliability (Cronbach's Alpha = 0.84) of item related responses. Social isolation is derived using Hawthorne's Friendship Scale; a validated and reliable index of social isolation.² The study is not a clinical investigation as outlined in 21 CFR, Part 56, nor is it subject to provisions as outlined in 21 CFR, Part 56:101, 102, and 103. It falls in compliance with 45 CFR, Part 46:101, b(2) governing IRB review. Additionally, NHS Research Ethics Service of the United Kingdom finds that the research presented here

is not a clinical investigation and therefore ethical review was not necessary under the guidance of the NHS Research Ethics Committee. The confidentiality of all respondents was assured, and no identifying data was incorporated into the database.

Results and Discussion
Social isolation, as indexed by Hawthorne ranges from "very socially isolated" to "very socially connected". 20% of study subjects demonstrate low levels of social support, or being very socially isolated. For those 24 months or less post surgery, 21% demonstrate this. Of those more than 24 months post surgery, 19% are so categorized. Overall, no significant differences are noted in the isolation index for those less than 24 months post surgery, or those greater. However, when categorized by geographic location, North American respondents indicated 24% of those less than 24 months post surgery as having low levels, or being very socially isolated, compared with 16% of those greater than 24 months post surgery (p = 0.0031). For United Kingdom respondents, this is 17% and 21% respectively (no significant difference). The data indicates that social isolation can occur in those with immediate social support networks available. For males 24 months or less post surgery and indicated as very socially isolated or isolated/low levels of support, only 16% indicated living alone. For males greater than 24 months post surgery this is 41%. For females 24 months or less post surgery and indicated as very socially isolated or isolated/low levels of social support, 26% indicate living alone. For females greater than 24 months post surgery this is 42% (Table 1-3).

Table 1: Isolation

Time from surgery:	Total		Less than or equal to 24 months		Greater than 24 months	
	n	%	n	%	n	%
Isolation scale:						
Very socially isolated	166	8.0	60	9.4	87	7.1
Isolated or low levels of social support	254	12.3	73	11.5	143	11.8
Some social support	294	14.2	94	14.8	167	13.7
Socially connected	464	22.4	148	23.2	252	20.7
Very socially connected	890	43.0	262	41.1	568	46.7

5

The Prevalence of Social Isolation in an Ostomy Population /2

Table 2: Social isolation in males

Time from surgery:	Less than or equal to 24 months		Greater than 24 months	
	n	%	n	%
Isolation scale:				
Very socially isolated	26	8.8	37	6.5
Isolated or low levels of social support	25	8.4	65	11.5
Some social support	38	12.8	69	12.2
Socially connected	66	22.2	115	20.3
Very socially connected	142	47.8	280	49.5

Table 3: Social isolation in females

Time from surgery:	Less than or equal to 24 months		Greater than 24 months	
	n	%	n	%
Isolation scale:				
Very socially isolated	24	10.0	47	7.3
Isolated or low levels of social support	48	14.2	77	12.0
Some social support	56	16.5	97	15.2
Socially connected	82	24.2	135	21.1
Very socially connected	119	35.1	284	44.4

Conclusions
Social isolation in a population that has undergone life-altering surgery can impact mental and physical health. The extent that it occurs in the ostomy population is not well documented. This study finds that it occurs in approximately 20% of all people with ostomies. This may be the first time that the prevalence of social isolation in this population has been documented in a large study.

References

1. The Hollister Ostomy Comprehensive Health and Life Assessment, Hollister Incorporated, Libertyville, Illinois, USA.
2. Hawthorne G. Measuring social isolation in older adults: development and initial validation of the friendship scale. Soc Indic Res. 2006;77: 521-548.

Financial assistance/disclosure
The support of Hollister Incorporated for this clinical presentation is gratefully acknowledged.



*Individual needs, lifestyle,
work, social environments and
physical challenges.*

6 Real People – Real Life /1

Real life. Real needs. Real people

At Dansac, we are dedicated to helping people living with a stoma overcome the physical, social and psychological repercussions of getting a stoma.

To understand what the priorities are for someone attaching a stoma pouch to their abdomen, one of our primary tasks is to listen – to the experience and the needs of people living with a stoma.

Individual needs, lifestyle, work, social environments and physical challenges – all of these aspects are translated into the design and development of products.

Discretion, comfort, security – a question of dignity

By having a continuous and open dialogue with people living with a stoma and stoma care professionals, we are able to dedicate our efforts to the fundamental issues and concerns experienced by both parties.

The results of interviews, studies and clinical research have given us a clear picture of the needs and requirements for a pouch. It must be discreet, comfortable, convenient and easy to use, without compromising security, skin-friendliness, odour and noise control.

These are the principles that have influenced the creation of our newest generation of 1 and 2 piece open and closed pouches – Novalife – a unique pouch that encompasses both form and function to overcome concerns such as discretion, convenience, comfort and security.

Real stories

In this chapter we give the word to some people who are willing to share their very personal stories and experiences – the reason for surgery and how they have overcome this, and what they expect from a product to be able to live a full life.



Different lifestyles
– individual needs.



6 Real People – Real Life /2



“ I would not be alive today without the stoma...

*Eiichiro, Colostomy since 2009
Read more about Eiichiro: page 46*



“ The stoma gives me much more freedom...

*Nathalie, Ileostomy since 2009
Read more about Nathalie: page 48*



“ The stoma is no hindrance to my life...

*Scott, Ileostomy since 2006
Read more about Scott: page 50*



“ Having a stoma doesn't hold me back in any way...

*Heidi, Ileostomy since 2002
Read more about Heidi: page 52*

Eiichiro

Colostomy since 2009

60 years old

Country:
Japan

Occupation:
Flight mechanic (now retired)

Leisure time:
Repairing radios, bicycle riding



6 Real People – Real Life /3

“I would not be alive today without the stoma...”

I would not be alive today without the stoma

In April 2009 I was diagnosed with rectal cancer. The doctor informed me that the treatment was surgery and maybe a stoma. I did not receive any brochures or any other information about what a stoma is and how to take care of it. The day before the surgery my abdomen was marked where the stoma was to be placed, in case it was necessary to create one. I woke up after surgery without a stoma and that was a relief, however I did not feel well and X-rays showed that there was a leakage between the two intestines that had been stitched together. I had a very bad infection in my abdomen and did not feel well at all, so during the night I had to go through acute surgery and woke up with a stoma. I have never had any problems accepting this and one of the reasons is that I know I would not have been alive today without the stoma.

My skin is very sensitive

I think that my acceptance made it easier for me to take care of the stoma after surgery. I had no difficulties with looking at the stoma or taking care of it. I found it very difficult to cut the barrier, but that was just a matter of practicing.

After discharge I went to the stoma outpatient clinic, and the stoma care specialist showed me different pouches. I tried approximately 10 different pouches before deciding on a Dansac pouch. My skin is very sensitive due to the chemotherapy, and it is important for me to have a very skin-friendly barrier, which I have found with a Dansac barrier.

It was difficult for my wife and son

I am married and have two adult children. It was difficult for my wife that I was ill, but it was the cancer that she was afraid of. When I was first diagnosed at the hospital my son drove me home in his car. I told him about the cancer diagnosis and he was so shocked that he could not speak and had to park the car. My son and I have a very close relationship and he was so afraid that he would lose me. He moved into our house, so that he could help my wife and I when I came home from hospital. He has accepted the situation now and it is nice to have him around.

I would like to travel again

I am retired now, but I used to be a flight mechanic. It was an interesting job that I enjoyed very much. Because of my work, I received a lot of cheap flight tickets and I have visited many different places in Japan and I have been to Europe several times. I would very much like to go again, but I need to get in better shape first. I have lost 10 kilos after surgery

and chemotherapy. I am now trying to gain weight. As a flight mechanic I love to repair things and one of my hobbies is to repair radios. I feel relaxed when working with the radios and hearing nice music like jazz and popular music.

Exercise is so important for my health

Before I got sick I did a lot of exercise which is so important for my health and I rode my road racer about 50-80 kilometres every Saturday. After having my stoma I found it much more difficult because the pouch is in the way. I have tried the new Dansac Novalife, and for the first time I was able to ride the bike and not feel the pouch. It was amazing.

The doctors do not have my cancer under control, but it is important for me to write my story and have my pictures taken because I hope it can help other people in the same situation. I hope that my story will show that you can live a normal life with a stoma. Be open about it and do not be afraid to tell people about your situation.

Nathalie

Ileostomy since 2009

33 years old

Country:
The Netherlands

Occupation:
Consultant (Public Employment Services)

Leisure time:
Has recently had her first child



6 Real People – Real Life /4

“The stoma gives me much more freedom...”

I did everything to avoid surgery

I was diagnosed with Ulcerative Colitis in 2002. I was on medication all the time and still I wasn't in good health. The doctors mentioned surgery and stoma several times, but I did everything to avoid it.

One of the reasons that I did not want a stoma was that I have had eczema for many years and I was worried that it would be a problem and get worse in the area where the pouch is attached. Fortunately this is not a problem when using Dansac's very skin friendly wafer and I have never had any problems.

I use a 1-piece system because I want an appliance that is as discreet as possible.

I got my stoma while I was pregnant

When I was 18 weeks pregnant I was so ill that there was no other solution than to have my colon removed and to have a stoma. At the time all I could think about was the baby inside me and I was more concerned with her health than with me having a stoma.

When I woke up from the anaesthetic the obstetrician was by my side like an angel and all I wanted was to hear that my baby was doing fine. She removed the cover and I saw the stoma, the pouch and the big wound dressing. Seeing it was fine, I was expecting it would be there, but it was much more important for me to know that my baby was all right; and she was.

While I was in hospital my focus was on the baby. I took care of the stoma and it was not a problem. It was not until I came home and saw myself in a mirror that I realised the change my body had been through; the stoma and the scar. It took me a couple of weeks to accept, but I was feeling much better and wasn't ill for the first time since I was diagnosed which helped me a lot.

The stoma gives me much more freedom

Suddenly I experienced a freedom I had not had for a very long time. Before the operation my radius of movement was very short because I had to find toilets all the time. Now I can go out of the house without knowing where to find a toilet. The doctors have told me about the possibility of having an ileo pouch operation, but I have no intention of having one. My husband keeps telling me to keep the stoma, because it gives us much more freedom. Now when we are going somewhere, I am the one waiting for him.

I have just gone back to my old job where I work as a consultant in Public Employment Services. I am in close contact with many people every day and I often visit people in their home. Of course it is important to me that I can rely on my pouch and that no one can see or smell anything. I only once had a problem, driving a car after an appointment. My seatbelt was pressing on the stoma and I experienced a leakage. After this I have learnt to settle the seatbelt higher up.

My health is better than it has been for many years

After giving birth to a little baby girl in November, my health is better than it has been for many years. I really enjoy life and our daughter. Having a baby sometimes means that you have to ignore your own needs and I just don't have time to fiddle around with my pouch between nappy changes and feeding my baby. I am not always able to spend a lot of time on myself and often a visit to the restroom has to be done very quickly. At these moments it means a lot that the pouching system is very easy to use.

I got my stoma while I was pregnant, which means that I have not tried to wear my normal clothes after getting the stoma. Now 6 months after the birth I still find it difficult to hide my pouch beneath the waistband, so I still buy pregnancy trousers. I try to buy other clothes as I would like to find a new style.

Scott

Ileostomy since 2006

35 years old

Country:
United Kingdom

Occupation:
Policeman

Leisure time:
Sports



6 Real People – Real Life /5 “The stoma is no hindrance to my life...”

I would not have a stoma!

I have always lived a very active life with lots of physical activities, and I have always been healthy.

In August 2006 I got abdominal pain and diarrhoea, and I felt very weak. My doctor treated me for a bowel infection. The week after it got worse, and I had periods with pain where I laid crouching on the toilet floor. When I was admitted to hospital some weeks later, I had lost a lot of weight, from 80 to 55 kg. I was so weak that I could not do anything. The stoma care nurse came several times to talk to me and site the stoma, but every time I sent her away – I was not going to have a stoma! I had been searching on the internet, and what I saw and read about gave me the impression of a life that I could not adopt a positive attitude to.

After a couple of days the doctor came and said that it was a matter of life or death if I didn't get an operation. Together with the stoma care nurse we found the right place for my stoma – it was important for me that I could still wear my uniform as a policeman. When I woke up I was feeling so bad and thought: “I am dying now”, but the surgeon came and told me the operation had been successful.

My wife was fantastic

My wife, whom I have been together with for 5 years, was at the hospital every day, and she has been a fantastic support. Initially I did not want to look at the stoma, but one day she insisted on being by my side when my stoma pouch was changed. I looked at her, and she did not show any kind of discomfort and that helped me so much.

After discharge from hospital, I was so weak that I needed help just to take a shower. I was very determined in my rehabilitation and had set a goal for every week. The first week I started my training by walking one block, the week after two blocks and so on. I must admit that there were days when I could not pull myself together, but my wife was there and she made sure that I got out of the house.

Sports is a part of my life

I have always been dedicated to sports, and I wanted to get back in shape.

When I was in hospital I read about a fireman who had a stoma, and it did not have any effect on neither his private life nor his working life. I compared myself with him because I have a similar job, working as a policeman in a SWAT

team, and I did not want to change anything about that. I enjoy my job and have been working like this for 6 years. It is a physically demanding job, and I needed to get back to my old shape.

I returned to work after 3 months, and a year after surgery I participated in a competition between the SWAT team and the parachute troops. We had to run 10 miles with full equipment (15 kg), and I came in before 5 of my colleagues and was very satisfied with my performance. I made a mistake by not calculating that without the large bowel I needed more fluid and salt, so when I reached the finish line I had cramps in my legs.

Helping others

I do my exercises every day in a park nearby together with our big dog. I run and do 10 press-ups at each bench on the route. One day a woman stood staring at me, and I asked her if she needed any help, but she just wanted to know how I could manage my training. I told her that she could do the same, but she said no, she had a stoma. “So do I” and I had to show her, otherwise she would not believe me. We had a nice talk and I still meet her. Now she is doing power-walking.

As said before, it helped me a lot to read about the fireman who easily could manage his job after getting a stoma. I would have liked to talk to a person like that when I was at the hospital, so now I frequently visit patients and talk with them about living a life with a stoma.

No limits

Like the limitations I got on food, I was also told that I could not do my fitness like before, because heavy weights do not go well with my stoma. I have nicely and quietly increased the intensity of my training, and now I do my training just like before my operation. I think it is very important that you do not give yourself limitations, but set goals and reach them without pushing yourself too hard.

In November 2008 I got married to Sadie, and we now have a very healthy baby boy called Harley who was born in August 2009.

I have been offered to get my stoma reversed, but I have a very good life and the stoma is no hindrance to my life and to our lifestyle. I know what I have now and I have no problems what so ever, so I do not think I will have the reverse operation.

Heidi

Ileostomy since 2002

41 years old

Country:
United Kingdom

Occupation:
Artist and painter

Leisure time:
Travelling & family



Real People – Real Life /6

“Having a stoma doesn’t hold me back in any way...”

I could barely walk

I was diagnosed with Crohn’s disease when I was 16 years old, after a terrible year of exhaustion, pain, vomiting, and diarrhoea and weight loss. I was extremely weak and weighed under six stone. I couldn’t eat, and would even wretch at the smell of food. It felt as if someone was continuously twisting a knife in my abdomen. I could barely walk, had to crawl up the stairs on all fours and when touched even lightly, it felt as if I were being punched.

Within a week of starting college that September, I was admitted to hospital for an emergency operation to remove one third of my colon – and to finally receive a diagnosis and medication.

I did not want to suffer any more

Despite prolonged periods of illness and immense pain, I travelled extensively throughout my twenties, determined to live life to the full. Sometimes I would need to be hospitalised whilst away from home. I met and married my husband in Hong Kong. In 2002, after having settled back in England and endured two terrible pregnancies, and produced two beautiful children, I found myself with worsening health. I had started to become ill again and was now suffering from incontinence as well as pain and diarrhoea, and was admitted to hospital with a total blockage in the remaining section of my colon. It was then that I was first introduced to a stoma nurse. She explained that I would soon need to start thinking about the possibility of having an ileostomy, and as she talked, I knew that I wanted it sooner, rather than later – I did not want to suffer any more. I made the decision that day to have elected surgery, in order to try to stave off further disease and suffering.

I’d had several surgeries before my stoma surgery, but the night before this operation I had an odd feeling, and before giving my approval to the surgeon, I asked him if something could go wrong. He told me that I would be fine and that I did not want to know about the complications. The operation went well – I was fine in the recovery room – but all was not well, and shortly after I was projectile vomiting bile. Later that evening my intestine had completely “collapsed”. It was four months before it even started to work again. After six weeks without food, I had lost a lot of weight and I was given intravenous nutrition, but it was six months, a second ileostomy operation, and septicæmia from my feed tube, seizures and MRSA before I was finally able to leave the hospital for good.

For me art is an incredibly good form of therapy

After being discharged from hospital, I started to paint, and was given a place on a Foundation course – a year after my initial stoma surgery. I soon found that art is an incredibly good form of therapy, and before long I found that my memories and trauma were seeping, and then pouring through into my work.

People seem to have difficulties with talking about stomas

Both before and after my surgery I found that people seem to have difficulties with talking about stomas, it is still very much a taboo. I would love to break away at this taboo and I believe that I can start doing this by showing my art work. I paint and make sculptures, based on my experiences of both the illness and of having a stoma and I hope that they will help to bring about public awareness of people with a stoma. We are all different and I am not suggesting that we should all go around showing our stoma pouches, but I believe that people with a stoma should not be embarrassed or ashamed by their condition, and this can be helped with broader awareness.

Ever since I’ve had my stoma, I have lived life to the full, as I did before, but without the restrictions of my illness; I go scuba-diving and horse riding and we travel to different places around the world. Last year we spent a month holidaying in Mozambique, diving with manta rays and swimming with wild dolphins! I think it is very important to think of yourself as a normal and healthy person. Of course, I have days where I don’t feel great, but I tell myself that I am fine and that I’m just having what I call a “Crohn’sy” day.

Having a stoma does not hold me back in any way

My main expectation of a pouch is that it should be comfortable and secure; I should be able to forget about it and get on with my life. As, like me, my stoma is incredibly active and changeable, I need a flexible pouch system that allows my body to move freely and lets me put my energies into thinking about life, as opposed to worrying about leaks and discomfort. Most of the time, I don’t even think about myself as having a stoma, my pouch is discreet and I am able to wear most of the clothes that I would have worn before the operation, with a few minor changes. I use a two piece system and I change the pouch every morning after having my shower, because I like to have a new pouch each day. But I have to say that having a stoma, and all that is associated with it has become second nature to me, and doesn’t hold me back in any way.

There is always room for improvement.

7 Afterword

With the Novalife Clinical Evidence Booklet, we hope to have given you not only a great deal of relevant and interesting information, but also a good idea of how we develop and refine our products.

The findings in this booklet are based on one of today's most extensive QoL studies undertaken in the USA, UK and Italy, as well as findings from a multi site, unblinded, historically controlled observational study of the new Novalife 1 piece Open and Closed products.

One of our cornerstones has always been to listen to the needs of people living with a stoma and stoma care professionals. By exploring individual needs, lifestyle, work, social environments and physical challenges and by having a continuous and open dialogue, we can dedicate our efforts into developing unique products and educational services that can make life with a stoma more comfortable, more discreet, more secure – more liveable.

Our educational portfolio is probably the most comprehensive on the market. With Novalife, we have reached a milestone in product development and hopefully created the best stoma appliance, for now...

Nevertheless, there is always room for improvement, so we will continue to evolve and dedicate ourselves to what we do best: stoma care.

www.dansac.com

