User assessment of a

NEW POUCHING SYSTEM

designed for discretion and concealment

Introduction:

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.

The Ostomy Comprehensive Health and Life Assessment survey of 4,097 North American, United Kingdom and Italian¹ ostomates, found that 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 necessitated by the need for discretion as pouches protrude from the abdomen as they fill with effluent and in some cases balloon due to flatus. Because of this new ostomy products must consider the issue of discretion as important as other issues such as comfort and ease of use, and insure that this is incorporated into the design. Fifteen percent of the participants were using a Dansac product prior to the evaluation. The remainders were using products from other manufacturers, the majority of them being Colopast Sensura and Assura users.

Results:

One hundred eighty-four people, seventy-seven males (41.9%) and one hundred seven females (58.2%), participated in the evaluation. Most participants described their lifestyle as moderatively active (63.6%), the rest described their lifestyle as either very active (32.1%) or not active (4.4%). Most stomas were round, 21% reported skin or fat folds around the stoma and 27% reported having a hernia or a protrusion.

The intent, when developing the new pouching system described here was to improve pouch discretion, comfort and ease of positioning. The new pouch and wafer design provides a low headspace, off centered starter hole, new filter technology and a re-designed integrated closure as features intended to improve discretion and comfort, as well as enabling the users' greater freedom to choose clothes and activities that reflect their lifestyle. To assess the success of the new pouching system design a product evaluation was conducted. The product evaluation also assessed quality of life issues. The purpose of the Nordic product evaluation was to provide nurses with new knowledge into patient QOL and to give end-users an opportunity to wear the new pouches and assess the changes made to design and function.

Method:

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This was a multi-site, unblinded, historical controlled assessment a new 1 piece closed pouch.² Participants were users of any current marketed regular size, cut-to-fit or pre- cut closed pouch.

Each participant was provided with 15 sample products to wear according to their normal habit. Participants recorded wear time, peristomal skin conditions and reasons for changing the pouch at each pouch change. In addition, they provided an overall assessment of pouch features and were asked to make a comparison to the pouch they normally use when all 15 pouches had been used.³

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The overwhelming reason for changing the pouch was "routine" (80.1%).

The great performance of the filter, combined with the low headspace and the new design, may have contributed to the response of 88,9% being neutral or positive to the fact that Novalife was less noticeable under clothing than their current pouch, and that in 92,3% of pouch wearings the users were satisfied that the pouch design met its intended purpose; to be less noticeable under clothing.

The product performs well when taking the new oval shaped, off centered skin barrier into consideration. The pouches were well accepted with approximately 88% or greater of the wear occasions being rated as being neutral or positive for the attributes such as wear time (88.9%), lifting of flange (84.2% positive) and security (82,4% positive and neutral). Approximately 89% of participants stated they never experienced any leakage of stool or effluent onto the peristomal skin when wearing the new pouch (Graph 1-6).

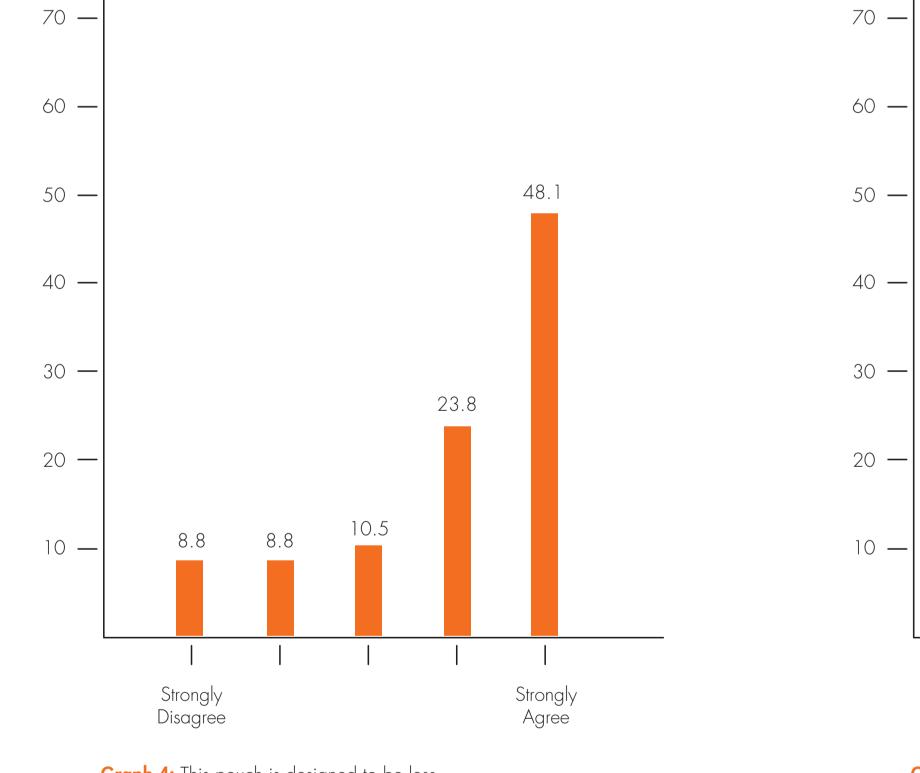
Summary:

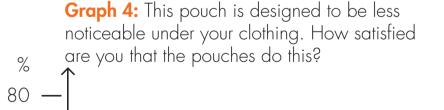
The Ostomy Comprehensive Health and Life Assessment survey provided evidence that discretion of an ostomy pouching system is an important consideration for the comfort and quality of life of a person with an ostomy. Thus the new NovaLife pouching system has been developed to address the specific needs of discretion, and thereby improve self-confidence and quality of life. The evidence is conclusive; the new NovaLife closed pouch is an exceptional performer.

	Graph 1: The skin barrier on this pouch is secure whilst wearing it:		Graph 2: Did the flange lift from the skin?
) —	-	% 80 –	

Graph 3: Did you experience leakage whilst wearing these pouches? % 80 —↑

NovaLife Wear Diary





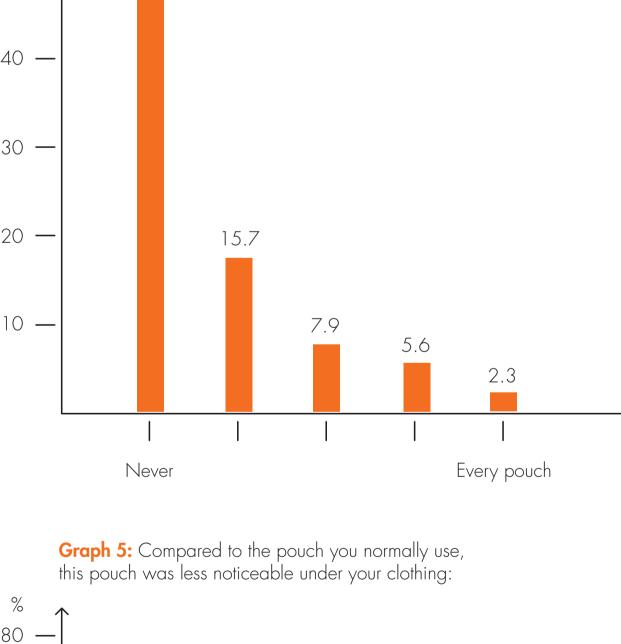


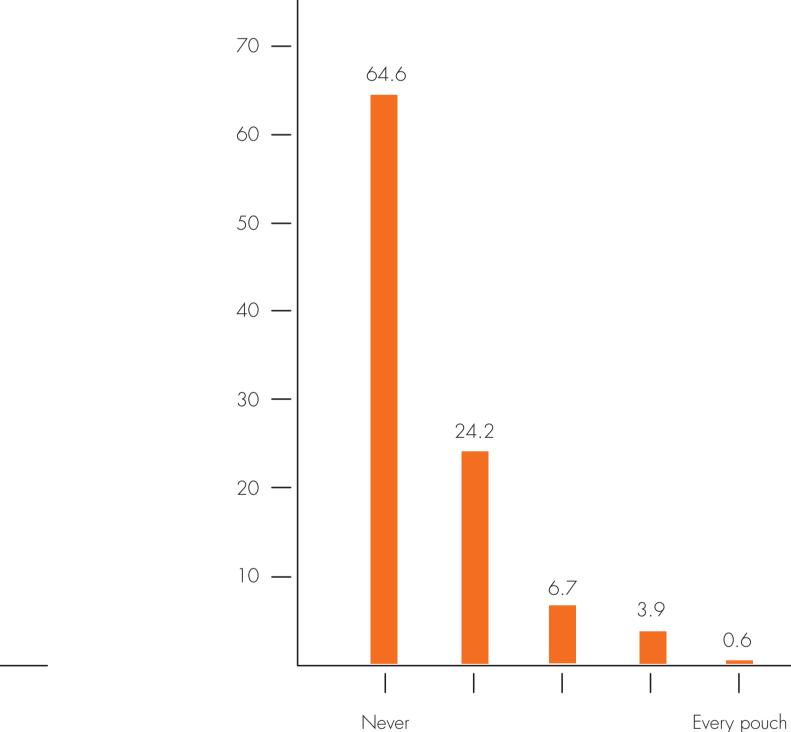




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Pouch Number	Date Applied	Time Applied	Skin Condition (Circle one)	Date Removed	Time Removed	Reason (Circle one)	Skin Condition (Circle one)
	dd/mm/yyyy	hh:mm	1) clear, no problem 2) pink 3) red and shiny 4) red and moist 5) very red and weeping	dd/mm/yyyy	hh:mm Circle either am or pm	 routine flange was leaking skin irritation smell / odour pouch was leaking filter was clogged other: (please explain) 	1) clear, no pro 2) pink 3) red and shin 4) red and moi 5) very red and
1	//	: am/pm	1 2 3 4 5	//	: am/pm	1 2 3 4 5 6 7	1 2 3 4
2	//	: am/pm	1 2 3 4 5	//	: am/pm	1 2 3 4 5 6 7	123
3	//	: am/pm	1 2 3 4 5	//	: am/pm	1 2 3 4 5 6 7	123
4	/	: am/pm	1 2 3 4 5	//	: am/pm	1 2 3 4 5 6 7	1 2 3
5	//	: am/pm	1 2 3 4 5	//	: am/pm	1 2 3 4 5 6 7	123
6	//	: am/pm	1 2 3 4 5	//	: am/pm	1 2 3 4 5 6 7	123.
7	//	: am/pm	1 2 3 4 5	//	: am/pm	1 2 3 4 5 6 7	123.
8	/	: am/pm	1 2 3 4 5	//	: am/pm	1 2 3 4 5 6 7	123.
9	//	: am/pm	1 2 3 4 5	//	: am/pm	1 2 3 4 5 6 7	123.
10	/	: am/pm	1 2 3 4 5	//	: am/pm	1 2 3 4 5 6 7	1 2 3 4
11	//	: am/pm	1 2 3 4 5	//	: am/pm	1 2 3 4 5 6 7	1 2 3 4
12	//	: am/pm	1 2 3 4 5	//	: am/pm	1 2 3 4 5 6 7	1 2 3 4
13	//	: am/pm	1 2 3 4 5	//	: am/pm	1 2 3 4 5 6 7	1 2 3 4
14	//	: am/pm	1 2 3 4 5	//	: am/pm	1 2 3 4 5 6 7	1 2 3 4
15	//	: am/pm	1 2 3 4 5	//	: am/pm	1 2 3 4 5 6 7	1 2 3 4

Graph 6: The wear time of this pouch is acceptable:

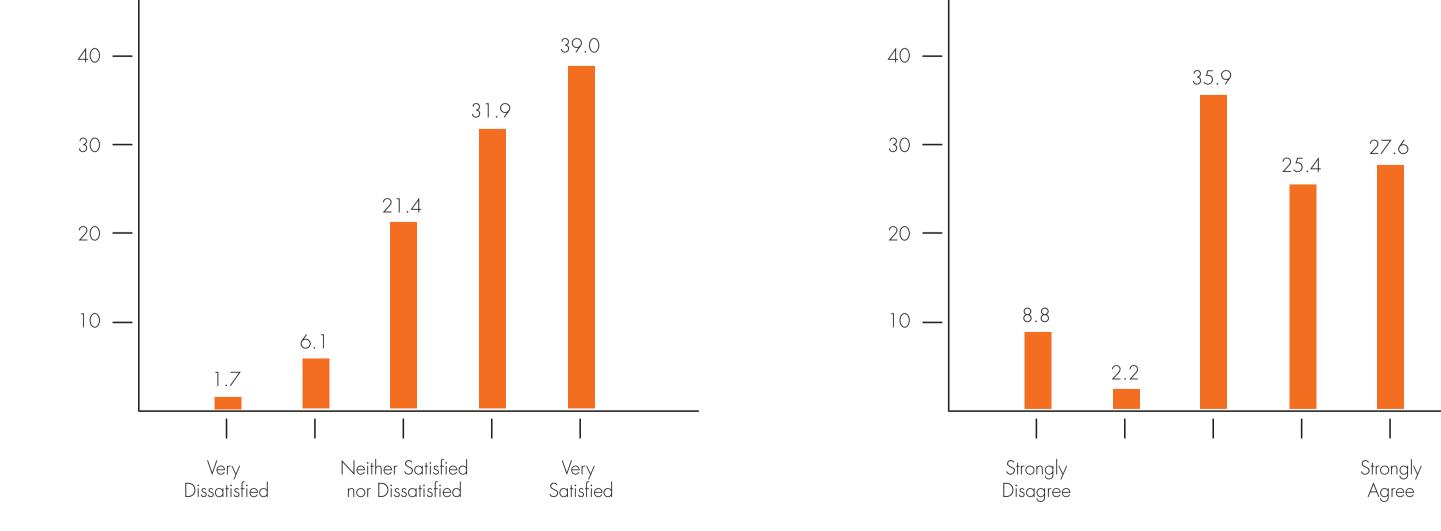
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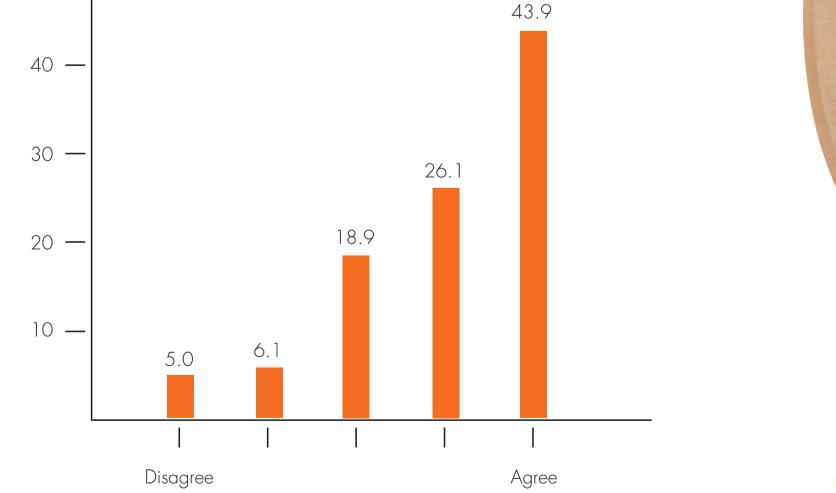
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The NEW pouching system – discretion and concealment

References:

The Ostomy Comprehensive Health and Life Assessment, Dansac A/S, Fredensborg, Denmark.
 The pouch tested is Dansac NovaLife Closed.
 NovaLife Nordic Assessment, Dansac A/S, Fredensborg, Denmark.

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