

CLINICAL EVIDENCE BOOKLET

– a compilation of clinical evidence and real life testimonials

Introduction:

Evidence based nursing, or EBN, is a form of clinical practice that emphasizes research findings to manage the health problems of a patient. It allows the clinical practitioner to assess current research findings, and other information, for the purpose of providing more informative clinical decision making. As stated by Sackett, et al, it is "integrating of best research evidence with clinical expertise, and patient values to achieve the best possible patient management"¹. EBN contributes to a better understanding of a patient's condition, as well as the effectiveness of treatment methods. The booklet described here is one process to achieve this.

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.

The findings presented in this booklet are based on one of today's most extensive Quality of Life studies undertaken in the USA, UK and Italy², as well as findings from a multi site, unblinded, historically controlled observational study of a new product line within ostomy care.

Discussion:

For people living with a stoma, there is a psychological challenge to having to empty the contents of the bowel or bladder into a pouching system attached to their abdomen. There is also the challenge of discretion that is, not having others aware that you have a pouch, which requires a change in clothing style. By continually focusing on the needs and requirements of our customers - and by asking and listening- we have become more and more aware of the quality of life wants and needs of those we manufacture products for. Among these needs discretion is a top priority. Why? The data has shown us that most persons with a stoma occasionally or more often worry that someone will notice the pouch under their clothing. Indeed, the results of the recently conducted and extensive Ostomy Comprehensive Health and Life Assessment (OCHLA) study (n=4097), confirmed what we already suspected. The study found 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 OCHLA study spurred us on - we concentrated our efforts on finding ways to optimize pouch design and create a game changer that would help solve the customer needs identified.

The new Clinical Evidence Booklet cites:

Two white papers:

- The evolution of Ostomy pouches
- Novalife white paper

Three Novalife posters:

- Pouch Discretion and concealment
- The Challenges of Conducting Clinical Research
- User Assessment of a New Pouching System

Three Quality of Life abstracts

- Sexual Intimacy
- Poor Body Image
- Social Isolation

+ Real stories from people with a stoma

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

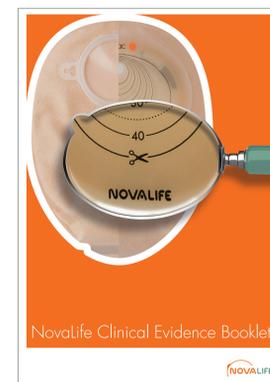


Table 1: How often do you worry about people noticing the pouch under your clothing?

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

Table 2: If an ostomy appliance is easily concealed under clothing, how important is this to you?

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



The NEW pouching system
– discretion and concealment



Helene,
Stoma since 1998

References:

- 1) Sackett, Straus, Richardson, Rosenberg, & Haynes, Evidence Based Medicine, BMJ Publishing, 2003, p. 3.
- 2) The Ostomy Comprehensive Health and Life Assessment, Dansac A/S, Fredensborg, Denmark.
- 3) The new ostomy pouches described in the Clinical Evidence Booklet are Dansac: Novalife Closed & Open.

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