

VOLUME TWO

Evidence of
innovation





“
**I FEEL MORE
CONFIDENT.”**

Helen, UK

Uses Aurum® Xtra flushable pouches

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SPECIALISING IN THE DESIGN, DEVELOPMENT AND MANUFACTURE OF GROUND BREAKING MEDICAL INNOVATIONS



2018 marked the 30th anniversary of Welland Medical, an award winning British manufacturing company.

2018 was an exciting year for us as we celebrated our 30th year in business. It was back in 1988 when Welland Medical's journey as a British manufacturer of stoma care appliances commenced and now 30 years on, we are one of the leading ostomy brands in the UK and worldwide. Renowned for manufacturing ground breaking stoma care solutions, Welland Medical has come on leaps and bounds from our humble beginnings in Billingshurst, West Sussex.

Working closely with healthcare professionals, patients and care organisations over the years has allowed us to become pioneers in innovation, seeing ground breaking solutions introduced to the market. In 1996 and 2003 Welland Medical became firmly established as leaders in innovation; launching the world's first, award winning, flushable colostomy pouch and flange extenders respectively.

To date, we continue to bring to market revolutionary products, with the introduction of the world's thinnest, most conformable and discreet flange extender, UltraFrame® and the first mouldable solution, Curvex (now branded Aurum® Profile) specifically designed to conform to body curves, such as a parastomal hernia.

Our forward thinking, commitment to innovation and continuous improvement has seen a huge investment in research and development over many years, transforming the company from a workforce of 15, manufacturing products using manual processes to a dedicated team of over 200 employees with the latest technological advancements in design and automated manufacturing at our fingertips.

Awarded Investors in People status in 2002, Welland Medical has gone on to achieve the much sought after Gold and Champion accreditations and has become well-respected in the local community for our commitment to employees.

Our 30-year transition from a small local business to a multi-million-pound company manufacturing products for worldwide distribution has been exciting for all involved. Longest serving employee Helen Gilbert, HR Manager at Welland Medical, has been with the company since the beginning. Reflecting on the last 30 years Helen commented: "Being involved in Welland's incredible journey has been a truly inspiring experience and one which I am very proud to have been part of".

With sales increasing, new products in the pipeline and more machinery on order, the future of stoma care looks bright.

“IT'S LIKE HAVING
A NEW LIFE.”

Denise, UK

Uses Aurum® Xtra flushable pouches

“We are proud to have built a successful and innovative business in Manor Royal which has provided us with the environment and skills to prosper into a medical brand that is recognised worldwide.”

Chris Primett,

Managing Director at Welland Medical



OSTOMY CHALLENGES

PARASTOMAL HERNIA PREVALENCE AND COMPLICATIONS

78% A parastomal hernia develops in up to 78% of patients with a stoma...

It typically occurs within
2 YEARS
of ostomy creation, but may develop as long as **20 or 30 years** after surgery⁽¹⁾.

Difficulty with maintaining a seal between the ostomy appliance and the stoma is secondary to periodic peristomal bulging⁽²⁾.

As a result...

leakage around the stoma appliance may be frequent, resulting in significant peristomal dermatitis and difficulty concealing the ostomy under clothing. Skin irritation is more prevalent with ileostomies and urostomies due to their respective effluent⁽³⁾.

QUALITY OF LIFE⁽⁴⁾

Peristomal skin complications can cause a wide range of signs and symptoms, which can lead to:

- > **DISCOMFORT**
- > **PAIN**
- > **POOR SELF-IMAGE**
- > **SOCIAL ISOLATION**
- > **IMPAIRED QUALITY OF LIFE**

STUDY

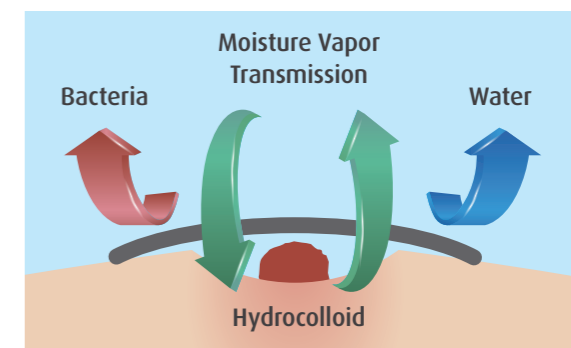
HYPERFLEX® A NATURAL BASED HYDROCOLLOID ADHESIVE

Dr Arash Moavenian, Head of Research and Innovation

Our Hyperflex® hydrocolloid adhesive containing Manuka honey is made using five food grade ingredients. Containing no additives, preservatives or tackifiers, this skin friendly formulation is designed especially for ostomates and their skin.

INTRODUCTION

In Ostomy, the primary use of the adhesive flange is to attach a pouch to the abdomen around the stoma. The challenge is to optimise the formulation of the adhesive and the structure of the flange to give a balance of good skin adhesion, moisture vapour transmission, pouch support and protection without compromising the surface or structure of the skin around the stoma. Though the Hyperflex® hydrocolloid flange acts as an adhesive it also is capable of absorbing fluids without losing its adhesion.



AIMS

The Hyperflex® hydrocolloid adhesive containing Manuka honey provides the following functions:

- Maintains correct humidity at the skin-flange interface while removing excess exudates through absorption
- Maintains the pH range of normal skin
- Permits the exchange of gases while maintaining a barrier layer to the external environment
- Is biocompatible and does not provoke any reaction through the prolonged contact with skin tissue

- Provides sufficient adhesion to the surface of the skin so that the pouch and contents can be supported, but when required, be removed without trauma
- Ensuring the risk of irritation and damage is significantly reduced

The objective of this appraisal is to demonstrate the specific features of the Hyperflex® hydrocolloid adhesive containing Manuka honey that contribute to it being an effective, secure, biocompatible, skin friendly adhesive utilised in the management of stoma care.



SCAN
FOR MORE
INFORMATION

MATERIALS AND METHODS



CMC

Carboxymethyl Cellulose (CMC) is derived from cellulose from cotton linters and is made water-swellaable by introducing carboxymethyl groups along the cellulose chain, which makes hydration possible. CMC is known for its excellent water retaining capacity and swells at a fast rate providing instant wet adhesion and instant tack for the Hyperflex® hydrocolloid adhesive.



Gelatine

Gelatine is a natural water soluble functional polymer that is manufactured from purified protein obtained by partial acid hydrolysis (type A) or by partial alkaline hydrolysis (type B) of collagen or a mixture of the two processes. The chemical structure of gelatine is what makes it water soluble and form gels that are strong, flexible and transparent with a positive binding action. Gelatine is responsible for prolonged hydration in the Hyperflex® hydrocolloid adhesive.



Manuka Honey

The Hyperflex® hydrocolloid adhesive contains UMF®16+ Manuka honey, a natural product that comes from the Manuka tree ("Leptospermum scoparium") indigenous to New Zealand.

The properties of highly graded Manuka honey are:

- Unique Manuka Factor (UMF) – a much higher concentration of natural antibacterial compound called methylglyoxal (MGO)
- a lowering of pH – inhibits microbial growth and releases more oxygen to tissue
- high sugar content – results in high binding of water preventing bacterial growth and reducing oedema
- glucose oxidase – results in the production of hydrogen peroxide contributing to antimicrobial efficacy



Pectin

The Hyperflex® hydrocolloid adhesive contains pectin that is obtained from citrus fruit peels e.g. lemons and limes and is extremely versatile because of its excellent gelling abilities. Pectin is a preferred hydrocolloid because of its skin friendliness and it assists in re-establishing the skin's "acid mantle", it absorbs moisture, provides wet adhesion, and hydrates and swells at a relatively slow rate, thus impeding breakdown of the Hyperflex® hydrocolloid adhesive.



Polyisobutylene

Polyisobutylene (PIB) a clear linear polymer of medium molecular weight is used as the base polymer in the Hyperflex® hydrocolloid adhesive and is manufactured by polymerising isobutylene.

As PIB is a polymer that relies mainly on molecular chain entanglement for cohesive strength the Hyperflex® hydrocolloid adhesive formulated with PIB is

characterised by its high degree of flexibility and tack. PIB also adds unique property profiles to the Hyperflex® hydrocolloid adhesive -

- Excellent barrier to moisture
- Permanent tackiness
- Odourless
- High take up of hydrocolloid powders & additives
- Elasticity over a wide temperature range

RESULTS

An independent account by Thanassis Pavlopoulos, Sales Supervisor

Patient: Male, 5, temporary ileostomy since 2011 (Megacolon)

Source: Thanassis Pavlopoulos, Sales Supervisor, GCP Medical, Greece

Problem: Negative skin reaction

Treatment: Aurum® with Manuka honey 1 piece ileostomy pouch and WBF® Spray

Diagnosis and treatment:

Panos underwent surgery for Megacolon and a temporary ileostomy was formed when he was 2 years old. Panos, now 5 years old, was very active before his surgery and continued to be so after but he didn't understand why he had to wear a pouch. The pouch he was wearing only stayed on his skin for a few hours at a time. This resulted in extended and painful dermatitis around his stoma (Figure 1).

Due to the dermatitis, Panos was reluctant to wear a pouch. This made changing his pouch, which was required 6 or 7 times a day, very difficult for his parents. His parents informed their doctor and GCP Medical S.A were contacted. I was sent to visit the family and suggested using an Aurum® 1 piece ileostomy pouch.

Eosin solution was used for approximately 2½ weeks and thereafter WBF® Spray was used between pouch changes. Within the first month of starting this routine the wear time of each pouch had increased up to 12 hours. Welland Medical Adhesive Remover Spray and Wipes were used to minimise any pain.

Outcome and follow up:

After 2 months of this routine the dermatitis had improved and the wear time increased to just less than 24 hours (Figure 2). Panos' family only have to spend a few minutes a day taking care of his stoma. He can play and be active without consequences and his parents have gained more confidence in helping and supporting him live with his stoma.



CONCLUSIONS

The Hyperflex® hydrocolloid adhesive containing Manuka honey is an effective solution in the maintenance of peristomal skin health and a number of factors contribute to this:

- The adhesive flange is manufactured in different thicknesses and sizes to handle different wear times and fluid amounts depending on the size and type of pouch
- All ingredients are food grade which have a history of contact with mucosal skin
- Polyisobutylene contains a chemically saturated aliphatic carbon-carbon backbone (very stable polymer thus requires no stabiliser additive which can

cause irritation to some users)

- The formulation contains few components so that, statistically, few skin reactions can be expected
- The flange maintains optimum skin moisture by absorbing excess fluids and reducing the amount of skin maceration
- The presence of pectin assists in re-establishing the skin's "acid mantle", eliminating or preventing dry and irritated skin
- Incorporation of Manuka honey enhances the skin friendly properties due to the unique properties of Manuka honey

MANUKA HONEY, NATURE'S GOLDEN SOLUTION FOR SORE SKIN

Manuka honey is a pure and natural ingredient made from the nectar of the Manuka flower found in New Zealand.

Renowned for its antibacterial and anti-inflammatory properties, the use of honey for the treatment of wounds can be traced back to the ancient Egyptians.

Produced by honeybees feeding on the flower of the Manuka bush (*Leptospermum Scoparium*), Manuka honey is now widely recognised as one of the world's most unique forms of honey. Containing characteristics known to kill bacteria, suppress inflammation and stimulate the growth of cells, the introduction of Manuka honey in to our skin friendly Hyperflex® hydrocolloid adhesive helps to promote healthy skin around the stoma.

Highly regarded for its natural antibacterial properties, Manuka honey contains a unique list of components including methylglyoxal (MGO). This key component originates from the nectar of the flowers found on the Manuka bush. The level of MGO found in the honey is linked to the antibacterial and antiviral activity the honey contains. The 16+ UMF® Manuka honey added to our hydrocolloid-based adhesive contains high levels of MGO and builds on the natural hydrocolloid formulation we have been using successfully for over three decades.



PURE AND NATURAL

Manuka honey is made only from nectar



ONE OF A KIND

Manuka honey's unique therapeutic properties help to promote healthy skin



TRIED AND TESTED

The use of honey for treating wounds dates back to the ancient Egyptians



KIND TO SKIN

Our Hyperflex® hydrocolloid with Manuka honey is kind to even the most vulnerable skin



A COMPLETE SOLUTION

Available as a one or two-piece, Profile, Convex and flushable in a range of sizes





PROVEN BY OSTOMATES



“**MY SKIN CONDITION
IS MUCH BETTER
AROUND MY STOMA.**”

Mr H, UK
Uses Aurum® 2

“**I HAD NO LEAKS AND
IT WAS SOFT AGAINST
MY SKIN.**”

Mrs E.M, UK
Uses Aurum®

“**I FIND IT VERY EASY TO
USE AND MUCH BETTER
FOR MY SKIN.**”

Mrs M.C, UK
Uses Aurum® Xtra

DID YOU KNOW?



I fly approx. 77,200kms to
gather the nectar needed
to produce a litre of honey



**77,200
KM**

I need to visit around
4,000,000
flowers to make 1kg of honey



KG



I visit
55-100
flowers during any one
flight from the hive



1 Teaspoon

In my lifetime I
produce a maximum
of 1 teaspoon of honey

STUDY

THE EVOLUTION OF A UNIQUE POUCH SOLUTION FOR OSTOMATES WITH A PARASTOMAL HERNIA

Dr Arash Moavenian, Head of Research and Innovation

Quality of life for ostomy patients can often be adversely affected by the development of a parastomal hernia (PH) and/or peristomal irregularities (PI) and this frequently presents a difficult challenge for stoma care nurses.

INTRODUCTION

PIs tend to occur at the side of or immediately adjacent to the stoma and are quite a common adverse effect following stoma construction. PHs are difficult to diagnose as patients are not educated enough about the incidences and are often mis-diagnosed as a loss of muscle tone.

In the case of PIs the stoma may present as a sunken abdominal defect with creasing of the surrounding skin as it is drawn in because of tension.

Stoma appliance dysfunction and leakage represents a complication requiring surgical intervention, but if patients have no or mild symptoms, surgical repair is avoided and a nonsurgical method of management is preferred.

METHOD

2001 The first version of a pouch with a soft, mouldable flange, which provides a secure seal around complex body contours and can be inverted for use with PH was launched in 2001.

It was ideally suited to patients who suffer from peristomal recesses caused by post-operative weight gain or loss, uneven peristomal skin, moats, dips and/or scar tissue around the stoma site, patients who suffer from poor dexterity issues and who find it difficult to apply accessories such as flange extenders, washers and/or stoma pastes or for patients who just suffer from general leakage issues associated with standard flat flanged products.

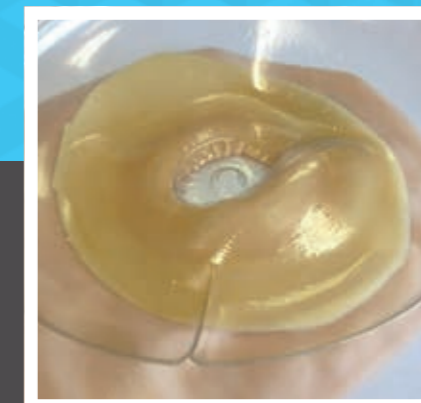
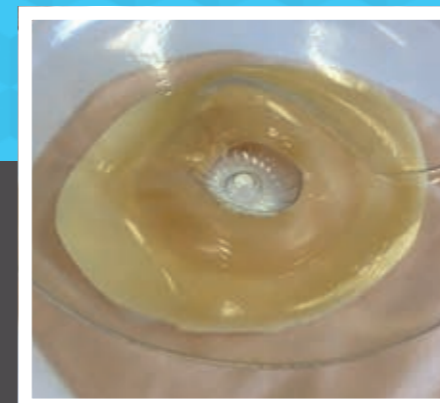
The images below demonstrate the mouldability of this flange over a representational model of a parastomal hernia.

As demonstrated the flange can adapt to uneven skin surfaces, recesses or protrusions around the stoma site.

2012 Brought new pouch aesthetics, more ergonomic hydrocolloid flange and pouch shapes, split softback and the addition of integrated belt loops and further innovations were made in 2017.

2017 A range of pouches with a soft and mouldable flange containing Manuka honey in the hydrocolloid as well as new pouch aesthetics, additional pouch sizes and the introduction of a larger flange size (60mm) was launched. This range is recommended for parastomal hernias, uneven skin dips, moats or scar tissue surrounding the stoma or a stoma positioned in a crease or skin fold or for ostomates who have poor dexterity and find it difficult to use washers or pastes and provides a secure seal around complex body contours where a flat flange is not suitable.

In pre-launch evaluations 18 participants tried the new 60mm flanged product and the results shown demonstrate how evaluators found the new product as an alternative to their current pouch.



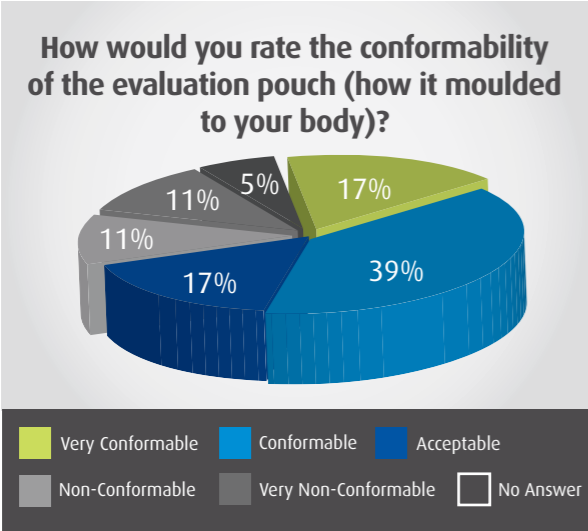
Aurum® Profile
conforming to
hernia replica.



RESULTS

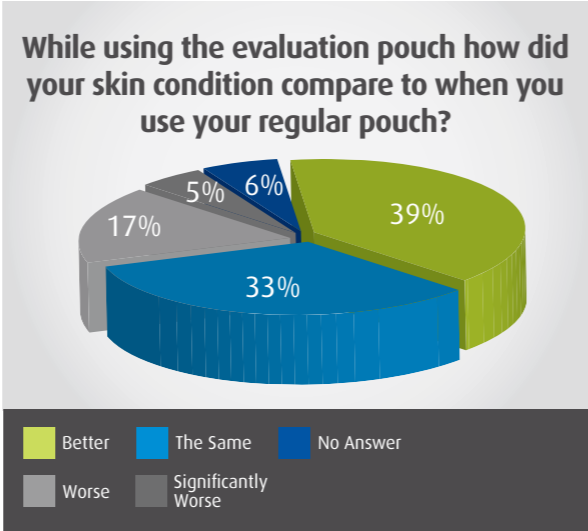
Conformability

56% of evaluators said they found the evaluation pouch to be conformable or very conformable



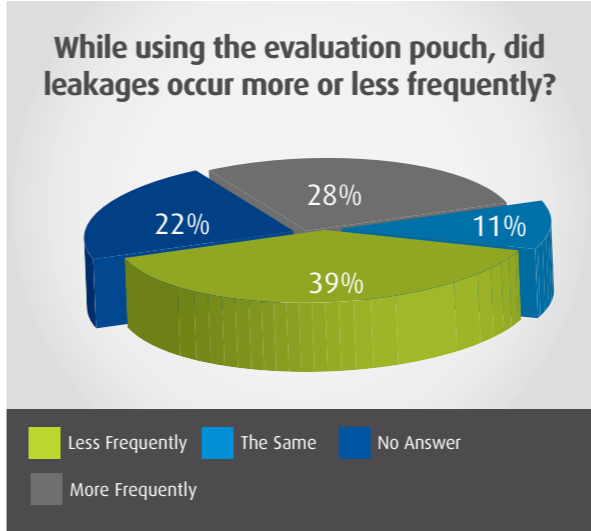
Skin Condition

72% of evaluators said their skin condition was the same or better



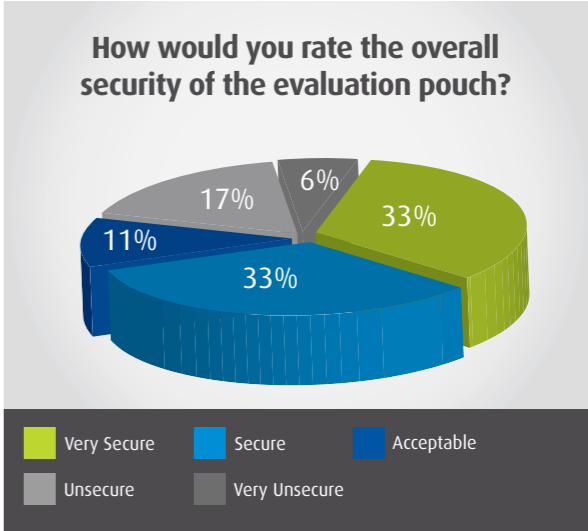
Leakage

39% of evaluators said they experienced leakage less frequently or much less frequently



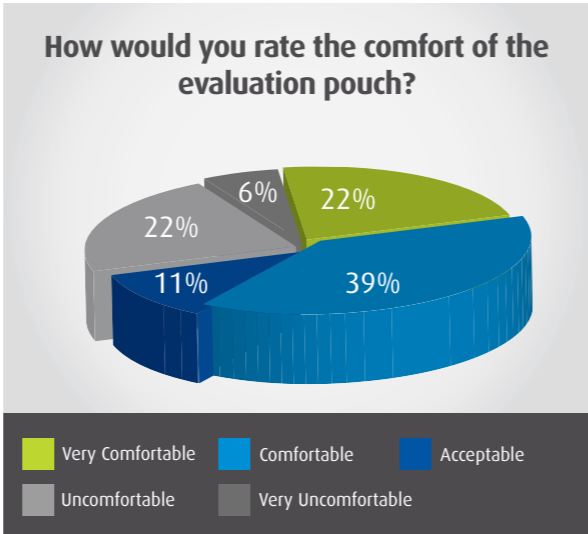
Overall Security

66% of evaluators said they found the evaluation pouch to be secure or very secure



Comfort

61% of evaluators said they found the evaluation pouch to be comfortable or very comfortable



CONCLUSIONS

Each ostomate has a unique body profile and it is important that a variety of products are available for use so that everyone may find the right product to suit their individual needs. This range of pouches is the first to specifically target PHs in this way and this evaluation focused on the feedback of ostomates with PHs in varying sizes and shapes. This was the first time these ostomates had used this range and it is clear that while the larger flange suited some ostomates' needs well, it was not perfect for all participants.

Based on the feedback received, it is clear that the pouch with the soft, mouldable flange with Manuka honey incorporated into the hydrocolloid flange has, for the majority of participants, had a positive effect on the condition of their peristomal skin. These participants provided positive feedback with regards to the frequency of leakage as well as the conformability, comfort and security experienced, demonstrating a simple solution in the management of stomas for ostomates with PHs and PIs.

CLINICAL STUDY

CAUSES, PREVENTION, THERAPY PARASTOMAL HERNIAS

by Dr Marius Passon and Bernd Ginsberg



Dr Marius Passon

Dr Marius Passon is Senior Physician for General, Vascular and Visceral Surgery at the Diakonie Hospital Bethesda in Freudenberg, Germany, Specialist in Phlebology and Proctology and a managing director of CFMI.

Bernd Ginsberg

Bernd Ginsberg is a Stoma Therapist and Managing Director of Wegimed GmbH, Bernd Ginsberg GmbH and CFMI Consultants for Medical Interests GmbH in Siegen, Germany.



Hernias are among the most common complications following the creation of a stoma. In many cases, they cause a care problem, pain and digestive irregularities, potentially culminating in a prolapse and ileus.

CAUSES

In order to surgically create a stoma, it is necessary to cut through the layers of the abdominal wall. The hole in the abdominal wall remains – even if a small hole was originally selected – in order to ensure that the stoma functions smoothly. Due to the varying pressure in the abdomen, the hole in the abdominal wall is also under a lot of strain on a sustained basis. For this reason, it is sensible to introduce hernia prevention at an early stage.

PREVENTION

Patients should be informed about hernia prevention following surgery: Coughing, sneezing and lifting loads increase the pressure in the abdomen. Counterpressure must be applied in these instances. In some cases, it is sufficient to press firmly against the abdominal wall with two hands.

USE OF STOMA BELTS

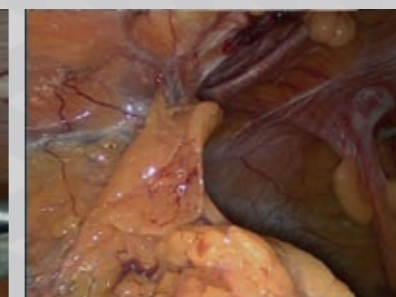
In the case of pronounced hernias, the use of made-to-measure belts should be considered, as these ensure optimum pressure distribution and stability. All hernia belts must be applied lying down to prevent incarceration. Ready-made stoma belts should be flexible, easy to apply and should have a suitable stoma opening. Stoma belts are usually reimbursed by the health insurance companies. There are individual lump-sum contracts in which stoma belts are included in the monthly lump sum.

Welland Aurum® Profile pouches cover the hernia bulge with no creasing

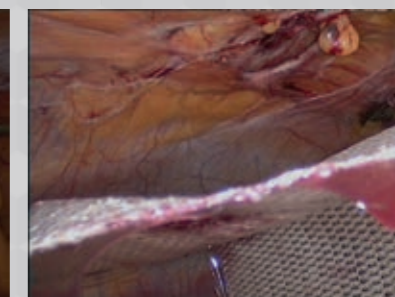
Exposing the hernia



Minimally invasive removal of adhesions



Placement of the mesh



Therapy

In terms of conservative therapy, special stoma care systems are also available to the user in addition to the use of stoma belts. Soft, mouldable adhesive substances adapt to the irregularities and protrusions of the abdominal wall. These products cover the hernia bulge with no creasing. In this way, odours and leakage of excrement are almost completely eliminated. An additional component to mention is Manuka honey, which is categorised as skin protection.

Modern aids allow many patients with small hernias to live a safe life, enabling them to manage their stoma care on a daily basis.

Stoma care becomes a problem if there is an adverse increase in the size of the hernia and therefore a deformation of the abdominal wall. Factors that promote rapid growth of a hernia are excess weight, lung disease or a poorly created stoma.

Surgical procedures

Surgical treatment of parastomal hernias should be carried out by experienced surgeons only. A conventional open or laparoscopic minimally invasive technique may be selected. The patient's anatomical configuration will determine which procedure is used on the patient in line with the concept of tailored hernia surgery.

Below are two examples:

- With the minimally invasive method, the meshes are fitted into the abdominal cavity. Very often, the adhesions have to be removed in advance. For this technique, a mesh is positioned around the stoma
- The other mesh is applied around the supplying section of the colon, which is realigned. The blood supply to the stoma must be monitored during surgery

For the open procedure, the preparation takes place externally; the hole is reduced, and the mesh is positioned outside of the abdomen. It may be necessary to reposition the stoma.

Current studies show that when a stoma is first created, the implantation of the mesh is conducive to reinforcing the abdominal wall to help prevent a hernia.

In many cases, parastomal hernias require an interdisciplinary intervention. Prevention by means of early patient education is indispensable. The selection of appropriate, customised aids as well as the care provided by specialists and stoma therapists are essential for those affected.

CASE STUDY

Aurum® Profile with Manuka honey urostomy pouch

A clinical account by Nelleke van de Vliert, Nursing Consultant

Patient

Female, 80, urostomy

Source

Nelleke van de Vliert, Nursing Consultant, Welland Nederland, The Netherlands

Problem

Red, moist and painful skin due to frequent leakage. Parastomal hernia

Solution

Aurum® Profile with Manuka honey 1 piece urostomy pouch, Hyperseal® Washers with Manuka honey and WBF® Barrier Wipes

DIAGNOSIS AND TREATMENT

Welland Service Team (WST) was approached by a hospital nurse for help. They had a patient with an urostomy who experienced a lot of leakage and had severe moist, red and painful skin. To clearly identify the problem I visited the patient at her residence.

Data held on file.
The views and opinions expressed in this article are those of the source and do not necessarily reflect the views and opinions of Welland Medical.

DIAGNOSIS AND TREATMENT

During the home visit on 29-01-2018 I observed the patient had moist and red skin due to contact with urine (Figure 1). The patient had a lot of problems with leakage, which was likely caused by the urostomy being situated in a skin fold, especially when she is sitting. The patient was using a 1 piece flat urostomy pouch of a competitor. Also the patient has a parastomal hernia.

The next step was to inform the patient what the cause of the problem was, namely leakage, caused due to the fact that the urostomy was situated in a skin fold, with the result of urine being in contact with the patient's skin almost 24/7.

The 1 piece flat urostomy pouch was replaced by an Aurum Profile urostomy pouch. The pouch was changed twice a day. Aurum Profile was chosen because the patient has a parastomal hernia and the stoma is situated in a skin fold, especially when patient is sitting down. The stoma tends to retract to skin level. Aurum

Profile was chosen to enable the skin to heal and recover. Also Hyperseal Washers with Manuka honey were applied. The skin was protected by WBF Barrier Wipes.

Both the patient and home care team were educated as to the best techniques to use for her stoma care routine.

The appointment was made to evaluate the process in 7 days.



Figure 1

HOME VISIT 05-02-2018

Leakage has almost disappeared with a few exceptions (Figure 2). Skin is slowly beginning to recover and isn't as painful. Also the skin is less moist. The patient continues to use Aurum Profile with Manuka honey urostomy pouches, Hyperseal Washers with Manuka honey and WBF Barrier Wipes.



Figure 2

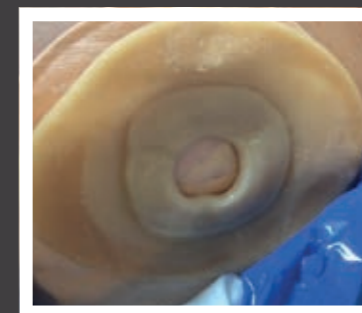


Figure 3

HOME VISIT 19-02-2018

The patient's skin is no longer moist and her skin is healing well (Figure 3). Leakage has disappeared and pain is gone. The patient continues to use Aurum Profile urostomy pouches, Hyperseal Washers with Manuka honey and WBF Barrier Wipes.

OUTCOME AND FOLLOW UP

The patient is well and comfortable with Welland Aurum Profile. Aurum has had a positive healing influence on damaged skin in a short space of time. The leakage has stopped with the use of Profile.

CASE STUDY

Pyoderma gangrenosum and the effects of Manuka honey

A clinical account by Katy Martin-Skurr, Nursing Consultant

Patient

Female, 56, Crohn's disease

Source

Katy Martin-Skurr, Nursing Consultant, Omnigon, New Zealand

Problem

Pyoderma gangrenosum, parastomal hernia

Solution

Aurum® Profile with Manuka honey, Aurum® Convex with Manuka honey and HyperSeal® Washers with Manuka honey

INTRODUCTION

The use of medicinal honey in wound healing is well documented in ancient times by both Greek and Egyptian healers. With the discovery of antibiotics in the 1930s use of these traditional wound healing products waned. In recent times the appearance of antibiotic resistant bacteria has seen a resurgence of interest in more traditional non pharmaceutical wound healing treatments.

This case study will present the care of Hilary who was admitted with an acute exacerbation of Crohn's disease and went on to develop pyoderma gangrenosum.

Hilary has consented to the use of her information for this presentation. All names used are pseudonyms.

WHO IS HILARY?

Hilary is a 56 year old Caucasian women who presented acutely with a known history of Crohn's disease. On presentation she was nutritionally compromised weighing 45kg, she was dehydrated with abdominal distention, pellagic, experiencing severe abdominal pain and had malodorous diarrhoea.

Hilary acknowledged that her health had been deteriorating for some time.

Medications on admission included Prednisone, Azathioprine, Pentaza and Allopurinol.

Hilary is a heavy smoker with an intake of 3-4 standard alcoholic drinks per day. She lives with her supportive husband Bruce. They have two adult children who live locally.

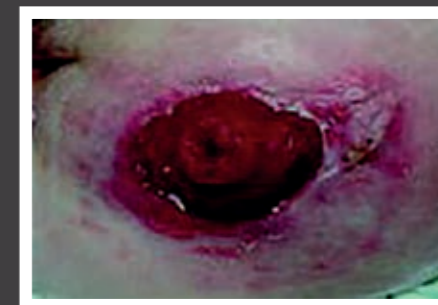


Fig 1. Hilary's ulcerated lesion

SURGICAL TREATMENT

Hilary's condition on admission was critical and she was immediately prepared for surgery. A CT scan confirmed air in her abdomen and the likelihood of perforation.

Surgical Procedure

- Subtotal colectomy with formation of an end ileostomy and mucous fistula

A mucous fistula is formed to allow the expulsion of gas and mucous from the distal non-functioning end of the colon post resection. Hilary's mucous fistula was formed due to concern that her remaining rectal stump may break down causing abdominal sepsis.

Hilary spent 14 days in the high dependency unit on total parental nutrition and potassium replacements. She was discharged 24 days after admission with nutritional supplements.

While Hilary initially struggled with the psychological adjustment needed to manage life with a stoma I had no specific concerns for her on discharge.

Hilary's very thin body habitus had contributed to significant creases across the parastomal plane however these had been successfully managed with a competitor pouch and seal.

While Hilary's initial recovery had been un-eventful this was not to continue.

Second Admission

On review in her home four weeks post-surgery and in her first week of discharge Hilary was found to be cachexic with further weight loss. Now weighing 37kg, she was hypotensive 88/40, severely dehydrated and at risk of renal impairment.

It was apparent that once again Hilary had not taken any affirmative action regarding her deteriorating health. She was immediately re-admitted to hospital and found to have an oesophageal ulcer. After re-hydration and the initiation of omeprazole therapy and with further dietary input she was again discharged.

During this admission it was noted that Hilary had developed an ulcerative lesion by her stoma. (see Fig 1)

Third Admission

Review in the stomal therapy clinic at 10 weeks post-surgery revealed that Hilary was again acutely unwell. She had severe abdominal pain which she rated as 10/10, was again hypotensive and dehydrated. In spite of all advice Hilary had again neglected her deteriorating health. A CT scan revealed multiple intra-abdominal abscesses in the right iliac fossa, and the pyloric and retro splenic regions. After conservative treatment with antibiotics Hilary was again discharged.



Fig 2. Pyoderma gangrenosum

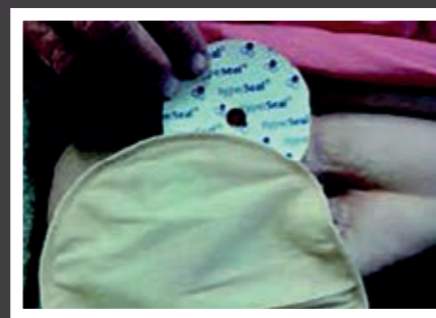


Fig 3. Use of Welland Manuka honey seal and Aurum Convex pouch



Fig 4. Healing



Fig 5. Pyoderma gangrenosum healed

PYODERMA GANGRENOSUM

The ulcerated lesions around Hilary's ileostomy were diagnosed as Pyoderma gangrenosum.

Pyoderma gangrenosum (PG) is a rarely occurring, destructive, neutrophilic dermatosis condition with distinctive clinical characteristics. Lyon et al ⁽¹⁾ reported an incidence of 0.6% occurrence in practice or 1 per 100,000 people. Typically PG affects young to middle aged adults with a slight predominance in females. In 50% of cases PG will be associated with a systemic disorder such as inflammatory bowel disease, rheumatoid arthritis and some haematological conditions ^(1, 2).

PG effects the legs, buttocks and abdomen, however it effects a peristomal skin area far more commonly.

The majority of patients with PG will have an ileostomy as opposed to any other type of stoma ⁽¹⁾. It has been suggested that the unique environment around an ileostomy and the repeated trauma involved in pouch removal lays the foundation for the opportunistic development of parastomal pyoderma gangrenosum (PPG).

While the ethology of PPG is unknown the clinical presentation follows a typical pathway:

- A painful pustule which rapidly ulcerates
- Extremely painful ulcers which have a bluish colouring (see Fig 2)
- Undermining and ragged edges

Surgery is contraindicated in the management of PPG as it usually results, not in healing but in enlargement of the ulcerated area.

The non-healing ulceration of PPG has a significant morbidity for stoma management. Morbidity from pain, discomfort, bleeding and exudate impairs pouch adhesion causing leaks and diminished quality of life.

Once resolved PPG generally results in the formation of scar tissue which can be problematic for future pouching.

Hilary's PPG was initially treated with a competitor powder, a Welland HyperSeal washer with Manuka honey and a Welland Aurum Convex with Manuka honey pouch (see Fig 3). The rationale for this product selection was to achieve healing of the PPG ulcers with the Manuka honey. (See Manuka honey)

Hilary's PPG healed rapidly and has not recurred (see Fig 4 & 5). Prior to the use of the Welland pouches Hilary was changing her pouch daily. Her sense of security has improved and she now has a leak free two day wear time.

When Hilary developed a parastomal hernia we moved to one of the new Welland Profile with Manuka honey pouches. The flexibility of the Welland Profile flange easily moulded over Hilary's hernia and gave a secure fit while still giving the benefits of Manuka honey for wound healing.



**SCAN
FOR MORE
INFORMATION**

MANUKA HONEY AND WOUND HEALING

Manuka honey has several actions which contribute to wound healing.

Antibacterial Action

Manuka honey has high concentrations of the antibacterial compound methylglyoxal (MGO) ⁽⁵⁾. This has been reported to effectively inhibit the growth of up to 60 types of bacteria including both aerobes and anaerobes either gram positive or negative ⁽⁴⁾. Included in the list of 60 bacteria inhibited by Manuka honey are MRSA, E coli, Salmonella and Staph aureus. Unlike other honeys the antibacterial properties of Manuka honey are both heat and light stable.

A consequence of Manuka honey's antibacterial action is the effect of deodorising offensive wound odours created by bacteria ⁽⁵⁾.

Moist Wound Healing

Honey is hygroscopic drawing moisture from the environment and dehydrating bacteria to prevent growth. The high sugar content of honey osmotically draws fluid to a wound facilitating a moist wound healing environment. A moist wound healing environment facilitates easy dressing removal preventing future trauma and pain.

pH Management

Wounds which are bacteria colonised, and ileostomy output share the feature of having a high skin damaging alkaline pH of 7 or above. With a low pH in the range of 3 Manuka honey has an acidification effect which neutralises alkaline damage to the skin.

Wound Pain

Most wound pain results from exposure of nerve endings to the prostaglandins which are produced as a result of the inflammatory process and from the pressure created by oedema of the wound. Manuka honey's anti-inflammatory and osmotic actions reduce the wound swelling and therefore the pain from a wound.

CONCLUSION

My experience with Hilary and the use of a pouch with Manuka honey incorporated into the hydrocolloid flange in the healing of her PPG has led me to consider the use of Manuka honey as both a prevention and a treatment for stomal skin damage. I believe that the use of Manuka honey pouches in the healing of pyodermal lesions is worthy of further investigation.

STUDY

LIFE EXPERIENCES ME AND MY PARASTOMAL HERNIA

Moira Evans, RGN, Product Development Clinical Lead, CliniMed Ltd

The study was initiated following my attendance at the 2015 ASCN parastomal hernia study day, and forms part of my Nursing & Midwifery Council (NMC) reflective practice. The study aim was to gather patient experiences of what it means to them to lead a productive life whilst managing their stoma and parastomal hernia.

METHOD

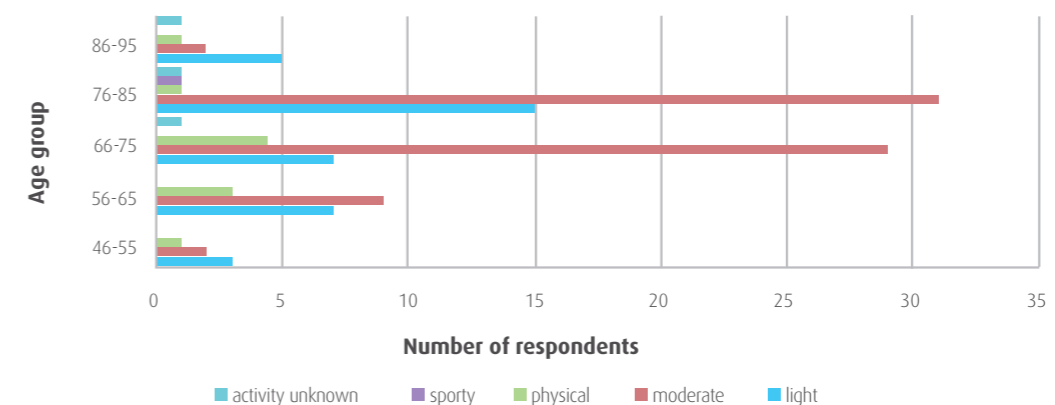
127 ostomate's postal survey responses have been analysed, providing us with a ratio of male 53: female 47. The survey found that in addition to the routine use of drainable pouches by ileostomates, this type of pouch was used by colostomates with a more liquid output. The analysis shows that 49% respondents used a drainable pouch, whilst 45% used a closed pouch leaving 6% as urostomates.

1 HOW I FEEL EVERYDAY

Each respondent was asked to score their daily activity level, they could choose one of four descriptions; light, moderate, physical or sporty. This is represented in the graph against the

grouped ages. We can see that the largest group were respondents aged 76-85 who considered their daily activity level to be moderate (24% of all the respondents n=31).

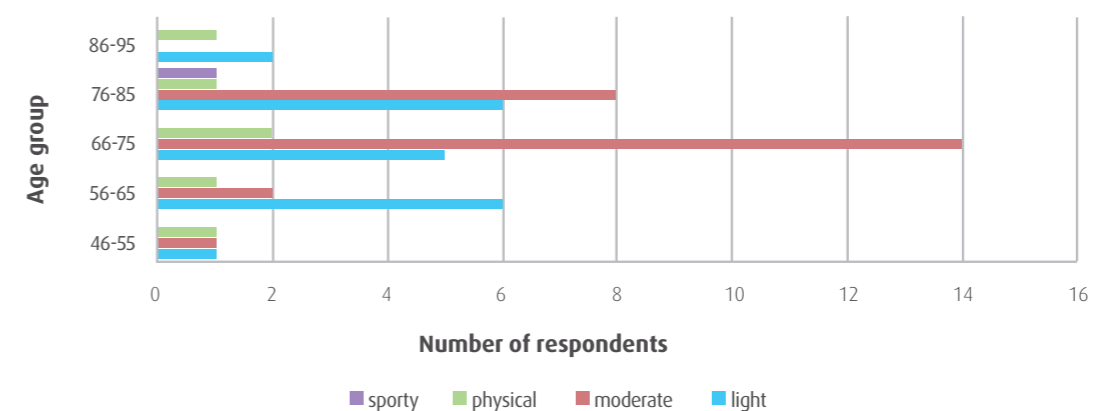
Patients by activity level and age (n=127) group



The wide age range provides us with a broad insight into the levels of pain experienced across the activity and age groups. The largest group experiencing pain

was in the 66-75 year group who described their activity level as moderate, represented as (11% respondents n=14).

Number of patients experiencing parastomal hernia pain - by age and activity level (n=52)

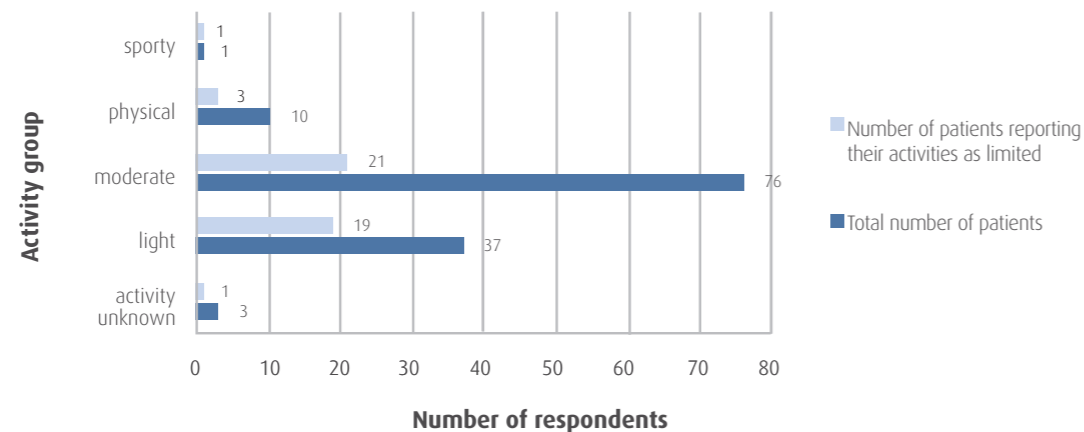


2 WHAT I CAN DO EVERYDAY

The survey asked whether the individual felt that their activities were limited by the presence of their

parastomal hernia. Of the 127 total respondents, 45 reported that they felt their activities were limited by their hernia.

Current activity levels and whether they are limited by the parastomal hernia

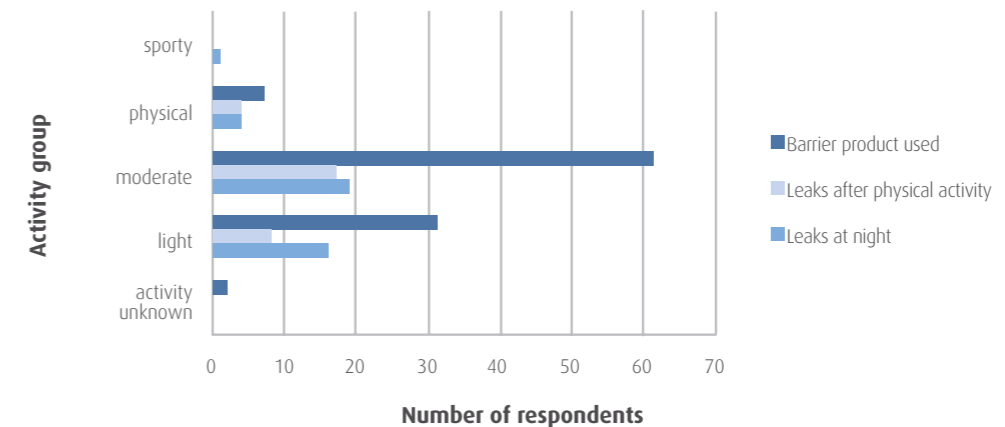


4 HOW MY HERNIA BEHAVES AND HOW I PROTECT MY PERISTOMAL SKIN

Cronin (2016) explains how the use of an accessory can support the ostomate to gain independence through the reduction of continuing skin problems associated

with effluent leakage onto the skin. The importance of maintaining skin integrity using silicone barrier products to protect the skin is discussed. Effluent leakage onto the skin causes chemical irritation to the epidermal and dermal layers of the skin, known as moisture associated skin damage. In our survey, we report that 78% (n=99) of respondents use a barrier product to protect their peristomal skin.

When my stoma pouch leaks and how I protect my skin



3 HOW I SUPPORT MY STOMA

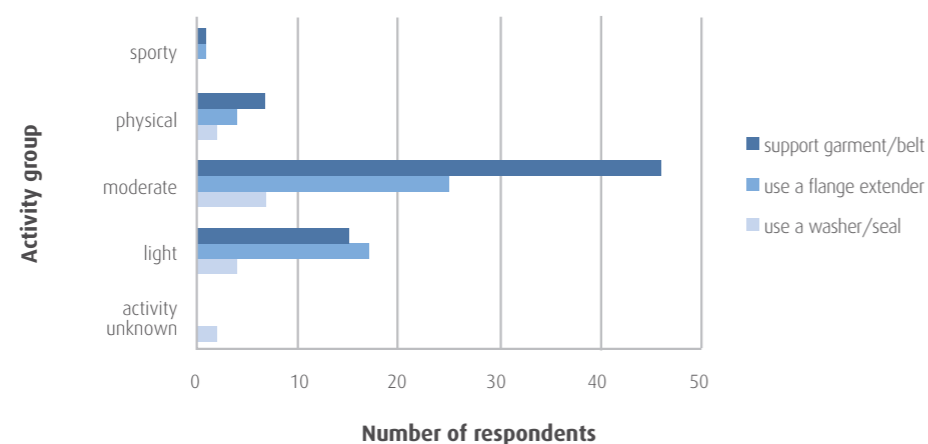
The ASCN National Stoma Care Clinical Guidelines (2016), Parastomal Hernia Management suggests that each patient has a personalised plan to minimise complications; accessories may be used as part of this plan.

Burch and Sica (2005) describe that patients may choose to wear a support garment to give the abdominal muscles greater support during certain activities. The graph below shows how the survey respondents use these grouped by their activity level.

Black (2016) states that many stoma patients use flange extenders to increase the seal between the skin and stoma flange in order to remain with their current product, with the overall aim of reducing leakage and thereby preventing skin complications. This survey demonstrates that flange extenders are used by 37% (n=47) of our respondents.

The moderate activity group have the highest use of a support garment/belt, flange extenders and washer/seals. Some respondents use more than one accessory product.

The accessories I use to support my parastomal hernia



CONCLUSION AND LEARNING OBJECTIVES

Within this survey, patients shared their experiences of living life with their parastomal hernia, describing how they managed and which accessory products helped them to pursue the level of activity that they aspire to. By sharing "what it means to me" experiences, we are able to review these from a nursing perspective and the impact upon patient's lives:

• It is a cause of pain and discomfort to 48% (n=61) of the respondents

• The highest users of a support garment/belt were the moderate activity level group, collectively representing 66% (n=84) of the users of these accessories

• 31% (n=39) of the respondents suffer with night time leaks

• 35% (n=44) of respondents report that their level of activity is limited by the presence of their parastomal hernia



CASE STUDY

Aurum® Convex with Manuka honey ileostomy pouch

A clinical account by Inge Florie, Nursing Consultant

Patient

Female, 50, Ileostomy

Source

Inge Florie, Nursing Consultant, Welland Nederland, The Netherlands

Problem

Red and painful skin due to frequent output leakage

Solution

Aurum® Convex with Manuka honey 1 piece ileostomy pouch and HyperSeal® Washers with Manuka honey

DIAGNOSIS AND TREATMENT

Welland Service Team (WST) was directly approached by the patient for help. This patient with an Ileostomy had a lot of problems with leakage. So much so that she became socially isolated. The patient has also had psychological problems for some time. After speaking on the phone for a while, patient was offered a home visit to clearly identify the problem. The patient gladly took the offer, so I visited her at home.

Data held on file.

The views and opinions expressed in this article are those of the source and do not necessarily reflect the views and opinions of Welland Medical.

HOME VISIT 11-05-2018

During the visit I observed the patient had painful, irritated red skin due to direct contact with output (Figure 1). The patient had a lot of problems with leakage, probably caused by the stoma being tilted on the right side, the right side being lower than the left. The stoma is wide (45 mm from left to right).

What contributed to the problem was the fact that the stoma care was sometimes neglected due to personal problems. The patient was using a 1 piece flat Ileostomy pouch of a competitor and also indicated that she needs help in her daily routine.

The next step was to inform the patient what the cause of the problem was. There was a combined problem; the tilted stoma which is the cause of the leakage in combination with the fact that the stoma care is sometimes somewhat neglected due to personal reasons.

The flat 1 piece Ileostomy pouch was replaced by an Aurum Convex 1 piece Ileostomy pouch. The pouch was changed twice a day. In this case the right side of the Ileostomy tends to retract to skin level. Convex was chosen because the Ileostomy is tilted on the right side and needs help to protrude. Welland Aurum with Manuka honey was specifically chosen to enable the skin to heal and recover. Also HyperSeal Washers with Manuka honey were applied in the form of a half ring on the right side of the stoma.

The patient is well instructed with regard to the specific stoma care. It has also been agreed that a member of the WST will regularly evaluate with the patient and that she can always contact the them.

Furthermore, the patient is working on a counselling trajectory with a physio, dietician, psychologist etc. to work on her personal problems.

HOME VISIT 16-06-2018

Leakage has almost disappeared with a few exceptions. Skin is slowly beginning to recover and isn't painful anymore (Figure 2). The patient continues the use of Aurum Convex 1 Piece ileostomy pouch and HyperSeal Washers with Manuka honey.

The patient has worked hard on her wellbeing and is much more structured. Stoma care is carried out much more consistently.

HOME VISIT 18-09-2018

The patient is doing well. Skin is recovering well (Figure 3). No more leakage except for a few exceptions. Stoma care is carried out more carefully. Continue the use of Aurum Convex 1 Piece ileostomy pouch and HyperSeal Washers with Manuka honey.

She has lost weight and is busy with rehabilitation. She still finds it difficult to find a certain rhythm. Still needs guidance.



Figure 1



Figure 2

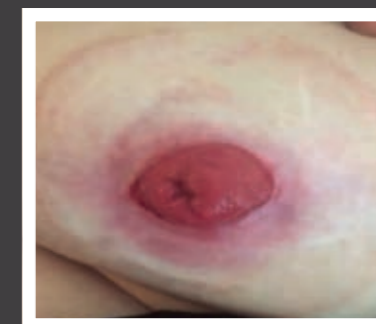


Figure 3

OUTCOME AND FOLLOW UP

The patient is comfortable with Welland Aurum Convex 1 piece ileostomy pouch. Welland Aurum has had a positive healing influence on damaged skin. The leakage has now stopped with the continued use of Aurum Convex.

“
**I CAN DO ANYTHING I LIKE,
WHICH IS SOMETHING
THAT I COULD NOT DO
PREVIOUSLY BEFORE USING
THE FLUSHABLE POUCH.”**

Michel, UK

Uses Aurum® Xtra flushable pouches



STUDY

THE EVOLUTION OF A TOILET DISPOSABLE COLOSTOMY POUCH

Dr Arash Moavenian, Head of Research and Innovation

Perhaps the greatest adjustment colostomates must go through, is the deviation from what is considered “normal” toilet behaviour.

INTRODUCTION

The formation of a stoma has a huge impact on their lives and, in some cases, it's one that is never fully adjusted to. For over 20 years, Welland Medical's Flushable range of colostomy pouches has aimed to restore that sense of normality, with each evolution bringing further improvements to the user experience and quality of life.

Impact

Flair Xtra®

Flair Active® Xtra

Aurum® Xtra

1996

2004

2009

2015

TIMELINE OF FLUSHABLE INNOVATION

1996

The flushable range of products was first launched in 1996, with an innovative answer to a number of important questions. Materials that were sensitive to certain environments and bacteria were being developed, and whilst they were well suited to the task of collecting an ostomates waste, they did not offer the same odour barrier properties that Welland Medical's multi-layer bag film did. The award winning 'bag within a bag' was born.

With the outer bag providing all the benefits of a standard colostomy bag – including odour protection and filtration – the inner bag could make use of innovative materials that would enable it to be flushed down the toilet.

By tearing the bag along a circular tear path, the outer bag, which remains unsoiled during the wear, could be removed and simply disposed of in the household waste, leaving behind the flushable liner still attached to the colostomate's abdomen.

Once removed, the liner together with the hydrocolloid flange could be placed directly in the toilet. The lightweight tissue on the outside of the liner which gave the bag some of its mechanical strength when dry, begins to weaken and break away, leaving the film unsupported and reducing its strength.

The colostomate could then flush the liner away, along with any anxieties about what to do with a soiled bag.





2004

2004 brought new pouch aesthetics, a more ergonomic hydrocolloid flange shape and an improved tear-seal, offering an easier tear separation. The asymmetric flange offered increased adhesion where it was needed most; at the “3” and “9” o’clock positions, giving colostomates an increased sense of security.

2009

In 2009, a further innovation made use of smart materials and processes, and replaced the tear separation with a smooth peel action. The Peel Seal technology, allowed the inner and outer bags to be hermetically sealed during use of the bag, and then, via an easily accessible tab at the top of the bag, be smoothly peeled apart. This innovation also brought a new backing material to the hydrocolloid flange, which was more breathable and conformed better to the peristomal area.

2015

Most recently, the flushable range became a part of the Aurum® family. With Manuka honey incorporated into the hydrocolloid flange to help promote skin health, and another redesign of pouch and flange shape, brought the technology, function and pouch aesthetics in line with the changing landscape of the colostomy market. The Aurum range also brings more choice, with a mini bag introduced to complement the midi and maxi options already available.

An extension of the Peel Seal technology also now enables the colostomate to remove the hydrocolloid flange from the inner liner and either flush separately or place in the bin, to offer more choice surrounding the pouch changing process.

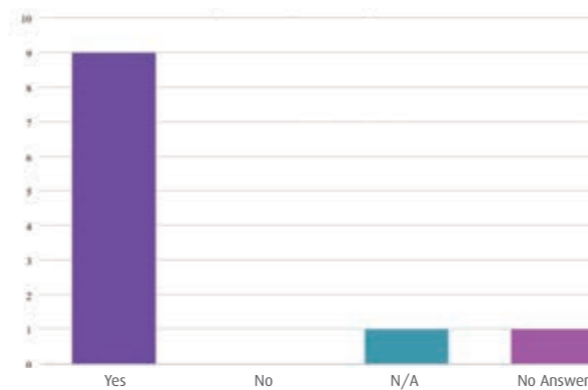


**SCAN
FOR MORE
INFORMATION**

RESULTS

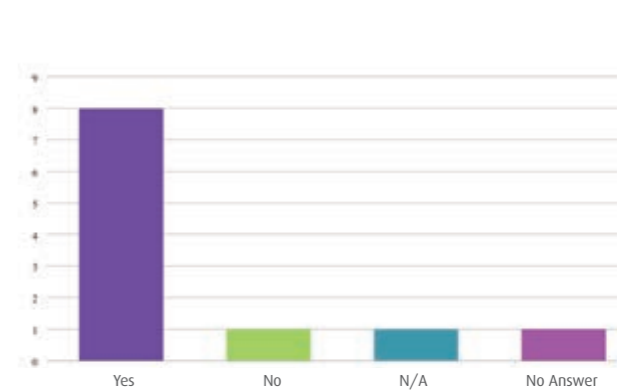
A selection of results from the ‘International comparison of the relative impact of pouch features on ostomates lifestyles’ trial are shown here to illustrate the improved levels of quality of life experienced by the patients when using the flushable pouch throughout the world.

Does wearing a flushable pouch make you feel more confident?



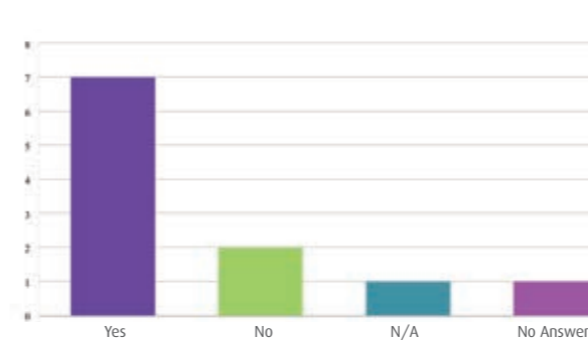
82% of ostomates felt more confident when using a flushable pouch

Has wearing a flushable pouch made overnight stays, holidays and travel easier?



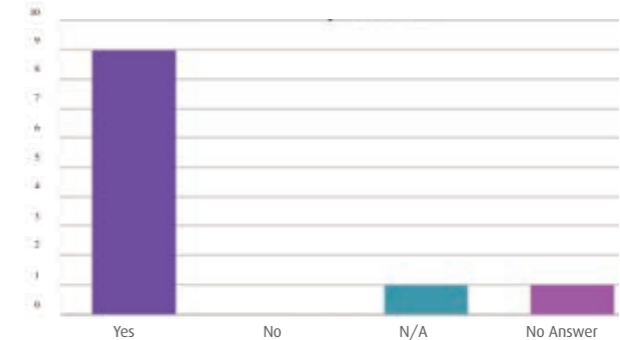
73% of ostomates felt that wearing a flushable pouch made overnight stays, holidays and travel easier

Are you more confident when socialising and participating in hobbies?



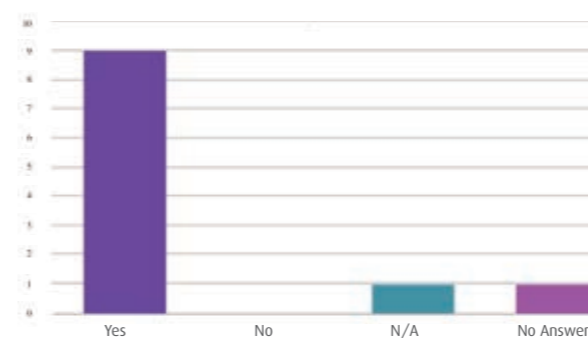
64% of ostomates felt more confident when socialising and participating in hobbies

Do you find changing the flushable pouch an easy procedure?



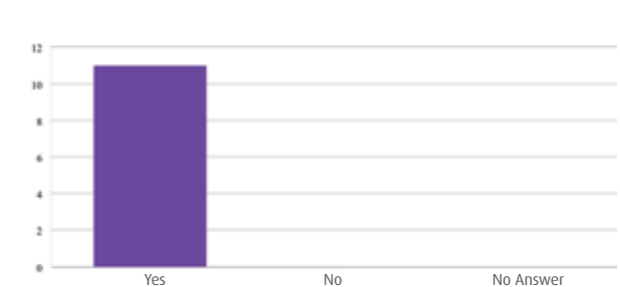
82% of ostomates found changing the flushable pouch quick and easy

Do you find changing the flushable pouch a quick procedure?



82% of ostomates found changing the flushable pouch a quick procedure

Would you say that the flushable pouch has improved your overall quality of life?



100% of ostomates felt the flushable pouch improved their overall quality of life

STUDY

THE FLUSHABLE GENERATION

Moira Evans, RGN, Product Development Clinical Lead, CliniMed Ltd

“Before using the flushable I was cautious at first but using them I was confident and felt more of a human being and more hygienic, I gained in confidence and freedom, just excellent. In most gentlemen’s toilets there are no waste bins, I just flush the bag, put the rest in my pocket and find the first litter bin and pop it in and have no worries. Freedom is not being tied to finding disabled toilets.”

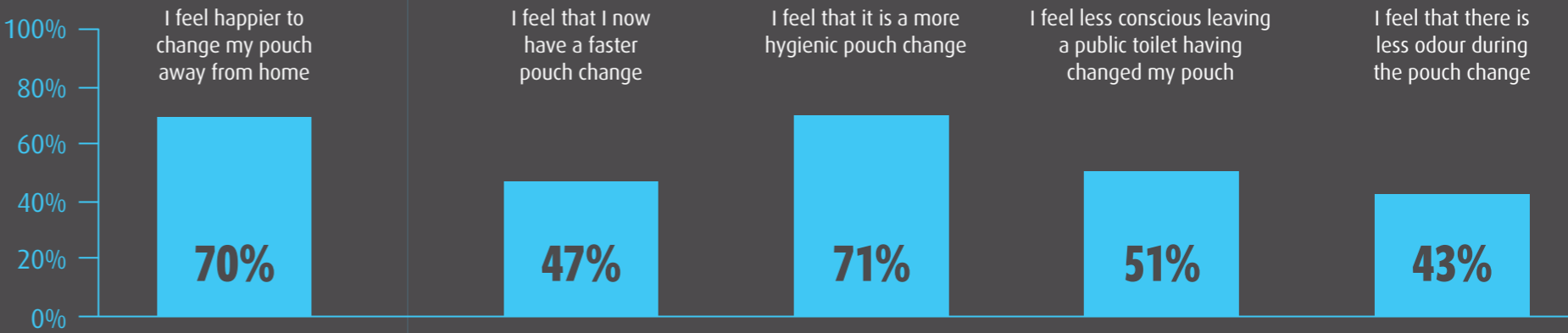
Mr C, Lancashire, UK

40

AIM

Following the introduction of flushable colostomy stoma pouches over 20 years ago; a survey was undertaken with 530 colostomates, to identify whether the product innovation continues to offer practical and lifestyle support and enhances quality of life.

From the responses received from patients using a flushable pouch for more than 6 months: The respondents were asked whether they agreed with the following statements:



41

METHOD

A postal survey was devised and patients who had routinely been using one of the flushable pouches for a period of 6 months or more were invited to participate.

RESULTS

The collective results support enhanced quality of life and lifestyle highlighting the views of the colostomate.

“You don’t have to worry about leaving a bag in a bin; I feel more confident going to an event, activities and visiting. It gives me more confidence.”

Miss K, Devon, UK

“

Before using the flushable pouches, I would decline sociable events, i.e. lunches, dinner and weddings; not knowing how I would dispose of the pouch if it was necessary. All of that has gone, as flushable pouches have changed the way of living, they are so convenient and easier to use.”

Mrs M, Derbyshire, UK

“

I do things that any other people do, most times I just feel normal. It is much easier to change, better when away from home, easier to dispose of.”

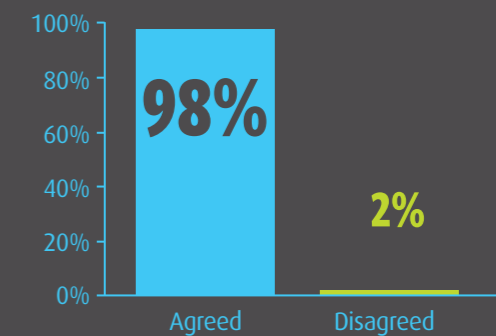
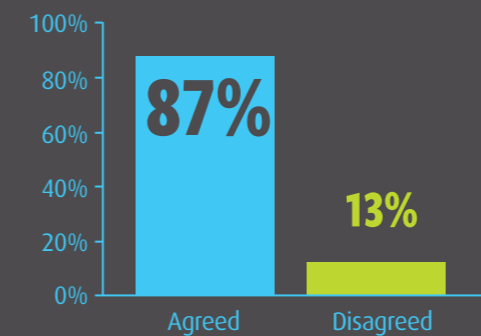
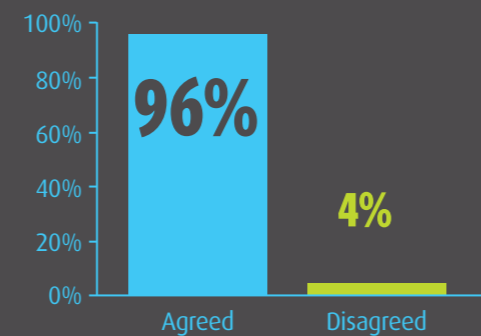
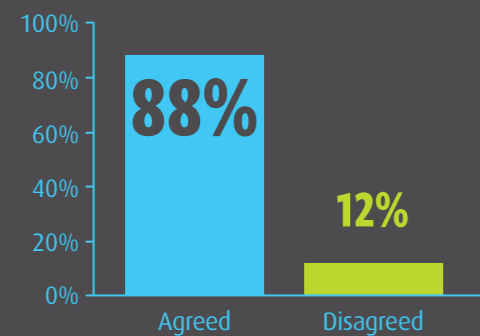
Mrs H, Warwickshire, UK

I have more confidence to do the things that I want to do, since using my flushable pouch:

Using a stoma pouch which can then be flushed down the toilet makes the whole process seem more normal:

Using my flushable pouch has given me greater freedom to enjoy life:

By using a flushable pouch, I feel that I am actively helping to support our environment by reducing landfill:



CONCLUSION

As confidence in the use of flushable pouches continues to grow for both patients and nurses alike, this 530 patient study suggests that this product innovation has changed how colostomates feel about themselves and has enhanced their quality of life as they live with their stoma.

VICKY'S STORY

FLUSHABLE FREEDOM

We Know That For Some People,
Having Surgery That Leads To A
Stoma Can Be Life-Changing.

Coming to terms with living with a colostomy can be extremely difficult to deal with and many people say they feel a loss of confidence and freedom to live their lives how they want to.

But what if it didn't have to be that way? For many people, finding the right colostomy pouch that best meets their needs can turn their lives around and help them find a way to regain their confidence and sense of freedom, or even to start a new chapter in their lives.

Our sister company and UK distributor, CliniMed, have been travelling around the country, getting to know some of the people who use our flushable colostomy pouches and have been asking them "What does using a flushable pouch mean to you?" They had the pleasure of meeting a fantastic group of people who all kindly agreed to be filmed so that they could share their stories with you.

“
**I JUST WISH
MORE PEOPLE
KNEW ABOUT
THEM.**”

As a former flight attendant married to a former pilot, Vicki still loves to travel and see the world. At first she found it very difficult adjusting to life with a colostomy, but since using the Aurum® Xtra colostomy pouch she hasn't looked back.



SCAN
TO WATCH
VICKY'S STORY

Aurum® Xtra is branded Aura® Flushable in the UK.

DENISE'S STORY

FLUSHABLE FREEDOM

Since using Aurum® Xtra Denise is now able to enjoy the freedom to do what she loves most, such as visiting French restaurants with her husband.

She definitely doesn't let her colostomy stop her living the life she chooses and believes in a can-do attitude and making the most of life.

“
**IT'S LIKE
HAVING A
NEW LIFE.**”



SCAN
TO WATCH
DENISE'S STORY



TREVOR'S STORY

FLUSHABLE FREEDOM

Trevor is a keen sailor who spends part of each year travelling on his boat, enjoying the warmer weather of Northern Spain.

Trevor is a former trustee of Colostomy UK and is keen to help other colostomates find a sense of freedom and confidence by using the Aurum® Xtra colostomy pouch.

To hear more ostomates share their flushable story, you can find more via the 'Freedom to be' page www.flushablefreedom.co.uk (Only UK residents can order samples from this website).

“
**I FEEL
HUMAN
AGAIN!**”



SCAN
TO WATCH
TREVOR'S STORY





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Acknowledgment: I would like to thank all of the stoma patients who took part. The testimonial statements provided by:- Ms S, Berkshire (1), Mrs M, Derbyshire (2), Mrs R, South Wales (3), Mrs H, Warwickshire (4), Mrs C, Berkshire (5), Mr C, Lancashire (6), Miss K, Devon (7) and Mr B, Lincolnshire (8). Poster presented at the ECET Conference in Berlin, June 2017.

In memory of Barrie Mills 1948 – 2018

Barrie Mills had worked for Welland Medical for nearly 23 years as a Design Engineer. In that time Barrie made an enormous contribution to the company and in particular to the design and development of new products. Many of our most successful products including Convex, Curvex, belt loops and 2 piece have Barrie's unique stamp on them. Barrie had a long history of working in stoma care and took huge passion

in designing solutions for both people with a stoma and nurses alike. This clearly shone through when he was in front of them demonstrating a new unique idea that he had been working on.

For Barrie, Welland Medical was his life. He loved the job, he loved the people and he loved the products. He will be greatly missed.

“
**BE AN INNOVATOR,
NOT AN IMITATOR.**”

Audrey Carballo



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