Alginate Product Range
Evidence Based Case Studies

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Case Studies 2012

Healthy peristomal skin is an essential aspect in the quality of life as an ostomist and yet recent studies have highlighted that peristomal skin complications are significant (Herlufsen et al 2006, Williams et al 2010). Literature has shown that of those people with stomas, approximately one third of colostomy patients and over two thirds of ileostomy and urostomy patients experience peristomal skin problems (Lyon et al 2000). The United Ostomy Association conducted a survey in 2000 and found that peristomal skin complications were the most common reason patients visited a Wound Ostomy Continence nursing service (Rolstad, Erwin-Toth 2004).

One of the goals of good stoma management is to maintain healthy peristomal skin to the point where there should be no difference between the peristomal skin and the surrounding abdominal skin (Williams et al 2010). However the peristomal skin is extremely vulnerable and once damaged can be hard to treat, particularly with the problem of having to affix a skin barrier adhesive (Thompson et al 2011).

Alginates are quite abundant in nature although all commercial alginates are produced from marine brown algae (seaweed) (Woo-Ram 2007). Alginates made their first big impression in wound care in the 1980’s as dressings for split skin donor sites. A study comparing the use of alginates and paraffin gauze on the donor sites had to be abandoned by Attwood (1989) as there was consistently better healing under the alginates (Heenan 2007).

It is not fully understood why alginate actively promotes healing. Alginates are biocompatible, hydrophilic (water loving) and biodegradable (Woo-Ram et al 2009). Once a gel has been formed via ion exchange between the alginate and the wound, the wound secretions and bacterial contamination are minimised which promotes wound healing (Timmons 2009). It is also known that alginate dressings can exert bioactivity which may modulate cell function and thus influence the healing process (Thomas et al 2000).

Alginates are quite abundant in nature although all commercial alginates are produced from marine brown algae (seaweed) (Woo-Ram 2007). Alginates made their first big impression in wound care in the 1980’s as dressings for split skin donor sites. A study comparing the use of alginates and paraffin gauze on the donor sites had to be abandoned by Attwood (1989) as there was consistently better healing under the alginates (Heenan 2007).

The alginate wafer (Oakmed Ltd, UK) has been designed to incorporate alginates in the ostomy pouch wafer so that it can actively help with the healing of any sensitive, sore excoriated peristomal skin.

The following case studies are a great testament to the healing power of alginates and the improvement in patient quality of life and cost savings in resources and clinical time.
Case Study One by David Greenwood, Stoma Care Nurse Specialist, Macclesfield District General

Patient History
The patient is a 78 year old female who was involved in a road traffic collision in mid 2010 from which she suffered abdominal injuries including a perforated small bowel and transverse colon. Both were repaired surgically, but the transverse colon became ischaemic and was subsequently resected with formation of an end colostomy in the right upper quadrant and mucous fistula in the left upper quadrant.

What the patient said:

“I feel so much more confident in this pouch, I can finally go shopping and visit my family”

The pouch is much more comfortable and reliable

“My skin feels much less sore and I no longer live with the constant discomfort I did previously”

It’s marvellous

Observations on referral
The patient was initially in ICU and was referred to the Stoma Care Nurses (SCNs) for management of the stoma and mucous fistula. The patient was transferred to a surgical ward and initially recovered well, adapted to their stoma management, requiring minimal input from the SCN.

The patient became unwell with a wound infection and the wound eventually dehisced to leave a large open abdominal wound. After several days a loop of bowel was identified at the superior aspect of the wound preventing the use of VAC therapy. This subsequently developed into an enterocutaneous fistula and has since functioned as the stoma. Following this, the colostomy has remained minimally active.

Complications or problems being experienced
Initial complication was management of a large open abdominal wound incorporating a high output enterocutaneous fistula.

As the wound reduced and ultimately healed, the fistula remains and continues to function as a jejunostomy. Situated within an area of scar tissue, the enterocutaneous fistula is within a large skin dip, the surrounding skin is exceptionally uneven and fragile. This results in a ‘para-stomal’ area which is liable to ‘breaking down’, becoming sore and excoriated and is difficult to successfully adhere any products to the skin or to achieve a sufficient wear time.

Maximum wear time achieved was approximately 24 hours, the average was 6-12 hours. The outcome of this was that the patient became effectively housebound, suffered constantly from sore excoriated skin and became almost entirely dependent upon family and carers.

Community visits
The patient was seen on a daily basis by the SCNs as an in-patient and subsequently on a regular basis in the community. She continues to be seen every 2-3 weeks to assist with management of her stoma and fistula and to support her carers.
Conclusion

The patient has found that the Oakmed Options Soft Convex Alginate SCA45-4120KV ileostomy pouch has been significantly more reliable than any other product trialled. It has shown appreciably improved wear time and comfort. The skin surrounding her fistula remains susceptible to damage from stomal effluent but the occurrence of this is greatly reduced and this has undoubtedly been due to the Oakmed Soft Convex Alginate pouch.

Cost Analysis over 1 week

Patient was changing pouch on average every 12 hours (sometimes as often as 6 hourly)

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<th>Cost</th>
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<tbody>
<tr>
<td>Average convex product</td>
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<td>£54.60</td>
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<tr>
<td>Average seal</td>
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<td>£23.80</td>
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<tr>
<td>Average paste</td>
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Using Oakmed Alginate soft convex – Patient changing pouch every 24 hours (could be 72hrs)

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<th>Item</th>
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<th>Save</th>
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</thead>
<tbody>
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<tr>
<td>Total</td>
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</tr>
</tbody>
</table>

Saving approximately £48.65 a week

Treatment

A number of alternative products had been used, approximately 20 different types, from various manufacturers, all with hydrocolloid flanges. Most had been convex and all had been used with an adhesive seal, paste or a combination of both.

I introduced the Oakmed Options Soft Convex Alginate pouch, the SCA45-4120KV, I re-visited the patient and found that she was continuing to use the product and reporting vastly improved reliability, comfort and wear time. The pouch I initially applied lasted for 72 hours and subsequently for between 24 and 72 hours.

On review of the pouch it was intact, the skin around her fistula was markedly improved than on any previous visit, displaying less discolouration and soreness. She is also able to leave the house for short periods, with family support for the first time in more than 12 months.

Outcome

The patient continues to use the Oakmed SCA45-4120KV and remains very happy with it. She reports improved skin condition around the fistula and a wear time of up to 72 hours although she opts to change the pouch every 24 hours, which naturally results in improved confidence and she is now beginning to return to a more normal lifestyle.

When visiting her at home, she now answers the door to me herself, and is able to participate in light household tasks and is regularly leaving the house for outpatients appointments as well as shopping. She is even attending family gatherings, an activity which she had considered unthinkable 3 months ago.
Case Study Two

**Patient History**

This patient is 68 years old. She had surgery on her back in 1980 which affected her nervous system and left her incontinent. She has a loop colostomy.

The patient does not take any medication which may affect skin healing in any way. She is in good health otherwise.

She has had sore skin for approximately one year. Problems with leakage made the skin ulcerate and become macerated and wet.

She has tried lots of different products, including various convex pouches and different accessories in an effort to solve her skin problem, none of which really solved her issues.

She did have some success with an alginate based wound dressing which led us to think of the Oakmed alginate pouches for their skin healing and moisture absorption qualities.

**Observations on referral**

On examination the patient’s skin was raw and excoriated. Area of raw skin measuring 4cm by 2½cm, (see week 1).

The patient has a dip in the nine-o’clock position. This lady also complains of pancaking and is fearful of leaks which affects her mood.

**Complications or problems being experienced**

The patient complains of being sore and uncomfortable most of the time.

She was changing the pouch four to five times a day because pouches will not stick on to macerated skin and are therefore leaking.
There is formation of granulation tissue, epithelialisation and contraction of the surface area of raw excoriated skin. The skin healing process was virtually complete after three weeks and was initiated in less than five days.

Case Study Two
by Sarah Taylor, Stoma Nurse Specialist, University of Coventry and Warwickshire Hospital

Macerated skin decreased by over 20% after just 7 days

The patient does still manage to go out and really tries not to let it stop her living her life.

The patient attends the Stoma Clinic regularly for her sore skin and leakage problems.

Treatment
We chose the Oakmed Alginate Connect 2 two piece pouch AJH0015 (flange) with JH610 (closed pouch). No accessories were used.

Outcome
After one week the area of macerated skin had decreased by 20-25%. After a further two weeks the area of macerated skin had decreased by 85% (see week 3).

After 21 days macerated skin had decreased by 85%
Each patient was individually assessed and was found to have peri-stomal excoriation due to irritant dermatitis. This inflammation of the skin is typically manifested by erythema, redness, burning and scaling of the skin. It may also lead to blistering. It is reported to be a non-specific response of the skin to direct chemical damage (Lyon C, Smith A, Griffiths C, 2000).

In this situation, the chemical damage was due to the corrosive nature of faecal liquid from leaking pouches due to a flush recessed stoma. Peri-stomal skin problems create a unique challenge to stoma care nurses because certain topical ointments and creams can be very oily. Therefore the application of these products affects the adhesion of any stoma pouch unless the healing agent is integral with the pouch, such as the alginate within Oakmed pouches. Algines are naturally occurring substances, used extensively in the wound care field and are proven to initiate skin healing and absorb moisture.

Decreased hospital stays require patients to have intensive education regarding peri-stomal issues, which can also be a challenge for the stoma care nurse and patient concerned. It could be argued that peri-stomal complications can be prevented with timely, optimal pre and post surgery skin care and the appropriate selection of a suitable pouch.
Patient History, Treatment and Outcome.

Both case study participants underwent emergency surgery, which involved the removal of the whole of their large bowel (colon), and the formation of an ileostomy. Due to the acute nature of the surgery, both patients were not sited pre-operatively for stoma formation. This unfortunately resulted in inappropriately placed stomas by the surgeon and also stomas that became very flat and recessed at the abdominal surface. This caused frequent appliance leakages, resulting in sore peri-stomal skin.

On assessment the peri-stomal excoriation was evident due to the chemical damage of liquid faecal matter. Initial treatment by the ward nursing staff was skin barrier protection, hydrocolloid seals and flange retention strips. After two days the appliances continued to leak and a referral was made to myself. I entered the individuals, after assessment, into the trial of alginate pouches and assessed their effectiveness.

The loss of peri-stomal skin integrity affects the persons entire well-being, confidence and quality of life. Sore skin leads to appliance leakages, pain, embarrassment and a complete interruption to their socioeconomic health. The cost of treating peri-stomal soreness is high.

The objective of this evaluation case study was to assess the effectiveness of Oakmed alginate pouches in the following categories, of which I have added a 7th dimensional assessment criteria. I felt this was significant on behalf of the participants (and reported by). In addition to the objectives set by Oakmed.

1. Nature of the peri-stomal skin at the commencement of the study
2. Evidence of healing of the peri-stomal skin
3. Reduction of the surface area of sore, excoriated peri-stomal skin
4. Reduction in pain and discomfort at pouch changes
5. Evidence of absorption of moisture
6. Reduction in the need for accessories
7. Effect on the individual's mental, physical, psychological and emotional well-being/health

Both patients were then commenced on Oakmed Alginate soft convex drainable, SCA45-4120KV.

Following four days of the application of the Oakmed pouch, dermatological improvement of the peri-stomal surface was significant. By day 4, a complete resolution of pain, discomfort and leakages were apparent. Both patients had become depressed from not only the affects of acute surgery but the additional indignity of appliance leakage and sore, painful skin.

By day ten, both peri-stomal areas were completely healed. Both patients expressed their relief of no further episodes of discomfort, pain, soreness and embarrassment. A noticeable increase was observed in their general well-being, confidence and morale.

The additional benefits of cost reduction were also evident as we no longer required the use of ostomy belts, skin protection barrier films or flange retention strips. The patients appliance wear time also increased, with less pouch changes: from five times per day to every three days.

Observations

Dermatological improvement of the peri-stomal surface was significant after 4 days.

No pain or soreness after 10 days.

Wear time increased from 5 times per day to every 3 days after 10 days.
Patient History

This patient is a 24 year old male who had a panproctocolectomy in 2009 for Crohn’s disease. At this present time the patient is not taking any medications and agrees to take part in this case study. He was using a Hydrocolloid one piece appliance but in his words had tried “everything”. He had in fact tried about five different types of pouch but his skin had been sore for months. He had a dermatological referral and had been re-educated to correct the method of his stoma management as he had flitted from one product to another and had also tried many types of accessories.

Observations on referral

This patient was self-referred for advice. On inspection the ileostomy appeared slightly proud to the skin, sloughy and slight ulceration was noted on aperture. The peri-stomal skin appeared excoriated and red with some bleeding points noted.

His stoma had been situated high at his own request and he reported constant leakage which was causing his skin excoriation. He had no panicking or template problems but reported that his skin was incredibly itchy and as a result he had been suffering from a lack of sleep and so had become very tired.

When asked to score his pain from one to ten, ten being the worst he said ten on occasions and seven at other times.

He was often in the stoma clinic with his problems, at least once a week for a twenty minute appointment. He preferred this to community visits.

Treatment

He was advised by the Clinical Nurse Specialist to use a pouch from the Oakmed range of alginate pouches with their skin healing and moisture absorption properties. The range includes one piece flat, closed and drainable pouches, two piece flat pouches and soft convex drainable pouches.

The product chosen was AV-4120k (flat flange drainable pouch).
The patient's skin had visibly improved within just 5 days and was well on its way to being completely healed. The patient reported that his pain score (1-10, ten being the worst) had reduced from 7-10 to 4.

Improvements
The patient was seen on day five to repeat the photographs. The peri-stomal skin appeared less excoriated and not as red. The patient reported less itching and no leakage. Evidence is seen on the photographs of a marked reduction of surface area of sore peri-stomal skin and evidence of a reduction in the amount of moisture present.

Outcome
The patient reported how pleased he is with his new product and how well his peri-stomal skin is responding. He now attends clinic less and for a reduced time, his visits are down to ten minutes maximum.

He reports his quality of life is much improved and his pain score from one to ten (ten being the worst) has reduced to four. He also reports that his sleep pattern is much improved and he is less tired.

He has booked a summer holiday.
Patient History

This patient, aged 42, was admitted for ileo-anal pouch surgery. He already had an ileostomy following sub-total colectomy for ulcerative colitis.

Not on any medication which would affect skin healing properties.

No known allergies.
Observations on referral

On admission a bright red adhesive shaped erythema was noted, excoriated in places, showing sensitivity to his current adhesive.

The patient said it had been like this for a while and he had started to have problems with the pouch adhering to his skin which in turn led to an increased number of pouch changes.

The area was described as, ‘not painful but uncomfortable.’

There were no obvious signs of leakage or any other reason for sore skin i.e. template size, dips or creases in the skin, position of the stoma.

Complications or problems being experienced

The patient said his skin had been like this for a while getting gradually worse and was causing him discomfort, his pouches weren’t sticking properly.

Treatment

We chose Oakmed Alginate drainable flat pouch AV-4120k as product of choice because of the skin healing properties of the alginate within the adhesive.

We have used this alginate product in our department previously on problem skin and had some excellent results.

This pouch was applied immediately after surgery and initially was left in-situ but was changed every other day at a later post-op stage.

No accessories were used with the product.

Improvements

No leaks were experienced with the alginate product.

The patient said “it felt a lot more comfortable within a couple of days”.

The area of erythema reduced in size after one week. The skin was dull red rather than inflamed.

Outcome

After a period of two weeks there was no residual inflammation left. Some patchy red areas within the excoriated area were returning to normal.

The patient continues to use the alginate drainable pouch successfully rather than his previous appliance, changing the pouch on alternate days.

Conclusion

The patient’s skin was healed successfully within a 14 day period.

No accessories were needed in addition to the alginate pouches.

The cost was for the pouches only.

The patient remains happy with his pouch.
Skin problems are common among patients with a stoma. Patients may develop a skin problem for a variety of reasons, many of which are beyond their control. This can result in a real reduction in quality of life as patients feel that they are not in control.

The main outcomes assessed in these case studies were resolution of sore peristomal skin, patient quality of life, reduction in amount of product and accessories required to solve the peristomal skin problem and reduction in time required with the Stoma Care Nurse Specialist.

In this cohort the patients all found their quality of life had improved as the leaks were resolved and sore peristomal skin was healed. There was no need for any accessories while using the alginate products whereas a number had been used previously. The number of bag changes also dramatically reduced. This represented a significant cost saving in each case.

The sore peristomal skin, which had been a problem for many months for a couple of patients, was showing signs of healing within a few days, and was healed for three of the patients by day 10. The fourth patient had seen 85% healing in her wound. The patient who had the fistula, which had formed a jejunostomy found her skin improved within a few days but full wound healing was reached at 4 months. The output of the jejunostomy was managed well with this pouch.

The resolution of these problems while using the alginate product resulted in the reduction of the amount of clinic time required from the Stoma Care Nurses with these patients.

The Oakmed alginate product was successful in its outcomes of increasing patient quality of life, reducing the need for extra products and accessories, initiating wound healing and reducing the amount of time required by the Stoma Care Nurses.

Further in depth study would be required to test conclusively how effective the alginate product is compared to others in the arena of wound healing but the Oakmed alginate products may represent a significant cost effective treatment of sore peristomal skin.
# Acknowledgements
Thank you to all those patients and healthcare professionals who have been involved.

David Greenwood, Stoma Care Nurse Specialist, Macclesfield District General
Sarah Taylor, Stoma Nurse Specialist, University of Coventry and Warwickshire Hospital
Julie Hemingway, Nurse Specialist Manager, Colorectal Nursing Team, St James University Hospital, Leeds
Jane Gascoigne, Colorectal/Stoma Care Nurse Specialist, The Alexandra Hospital, Redditch
Lesley Verrill and Gillian Powell, Stoma Care Clinical Nurse Specialists, York Teaching Hospital, NHS Foundation Trust

Oakmed are constantly seeking to improve patient’s lives by developing technically advanced products. This ongoing process of product evaluation and development includes validation of the efficiency and effectiveness of our products. If you would like to be part of the development process please contact your Territory Manager.

## Products

### Alginate

<table>
<thead>
<tr>
<th>Products</th>
<th>Closed Pouches</th>
<th>Drainable Pouches</th>
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<tbody>
<tr>
<td><em>Option</em></td>
<td><em>Colostomy Alginate</em></td>
<td><em>Colostomy Plus Alginate</em></td>
</tr>
<tr>
<td>Hole Size</td>
<td>Packs of 30</td>
<td>Packs of 30</td>
</tr>
<tr>
<td>Cut to fit 20mm - 60mm</td>
<td>Window</td>
<td>Window</td>
</tr>
<tr>
<td>25mm</td>
<td>A-0320K</td>
<td>A-0420K</td>
</tr>
<tr>
<td>30mm</td>
<td>A-0330K</td>
<td>A-0430K</td>
</tr>
<tr>
<td>35mm</td>
<td>A-0335K</td>
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### Soft Convex

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<th>Drainable Pouches</th>
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<tr>
<td><em>Option</em></td>
<td><em>Colostomy Soft Convex Alginate</em></td>
<td><em>Midi Ileostomy Soft Convex Alginate</em></td>
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<tr>
<td>Cut to fit 20mm to 24mm</td>
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<td>Window</td>
</tr>
<tr>
<td>25mm</td>
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<td>SCA25-0420K</td>
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<td>SCA25-0440K</td>
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### Connect 2

- A wafer size is selected and then the bag size is chosen. The wafers come in packs 10 and the bags in packs of 30.

#### Wafers

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<td><em>Connect 2 Skin Wafers</em></td>
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</tr>
<tr>
<td>15mm - 45mm</td>
<td>AJH0015</td>
</tr>
<tr>
<td>Pre cut to 20mm</td>
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<td>AJH0040</td>
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<td>Pre cut to 45mm</td>
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#### Closed Pouch

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<td><em>Option</em></td>
<td><em>Colostomy Mini Pouch</em></td>
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<td>Hole Size</td>
<td>Window</td>
</tr>
<tr>
<td>Fits up to 45mm Stoma</td>
<td>Window</td>
</tr>
<tr>
<td>JH520</td>
<td>JH500</td>
</tr>
<tr>
<td>JH510</td>
<td>Window, filter and soft cover to both sides</td>
</tr>
<tr>
<td>AJH0015</td>
<td>AJH0020</td>
</tr>
<tr>
<td>AJH0025</td>
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</tr>
<tr>
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<td>AJH0040</td>
</tr>
<tr>
<td>AJH0045</td>
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### Drainable Pouches Clip / Integral soft tie closure

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<td><em>Connect 2 Mini Ileostomy</em></td>
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<tr>
<td>Fits up to 45mm Stoma</td>
<td>Window</td>
</tr>
<tr>
<td>JH120</td>
<td>JH100</td>
</tr>
<tr>
<td>JH110</td>
<td>Window, filter and soft cover to both sides</td>
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<tr>
<td>AJH0015</td>
<td>AJH0020</td>
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<td>AJH0025</td>
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<td>AJH0035</td>
<td>AJH0040</td>
</tr>
<tr>
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