Institution: Queen's University Belfast

Unit of Assessment: 3a Pharmacy

Title of case study: 'Cohesive Paste™': A Product with Enhanced Comfort and Skin Protection for Stoma Patients

1. Summary of the impact (indicative maximum 100 words)

In the UK approximately 100, 000 people have a stoma, an artificial opening in the bowel that is used to divert the flow of exudate prior to subsequent external collection. Stoma exudate is a corrosive fluid, which varies in pH and enzyme content. Therefore, it is important that the stoma seal adhesive paste operates successfully within a diverse range of physiological conditions. The novel stoma adhesive developed by Jones and colleagues through KTP funded research in the School of Pharmacy was launched by Eakin as *Cohesive Paste*™ and is now sold in 26 countries, with sales of more than £1M to date.

2. Underpinning research (indicative maximum 500 words)

The design of a stoma adhesive paste that possesses optimal clinical performance is not trivial. Such systems are required to offer bioadhesion to and retention at the applied site despite undergoing dilution following exposure to stoma exudate, a liquid of diverse chemical properties. Dilution of conventional systems frequently results in a loss of rheological and hence adhesive properties. Furthermore, the performance of currently available systems is often compromised by evaporation of the solvent phase in use, with subsequent detrimental effects on their rheological properties and retention.

The underpinning research for this project in the School of Pharmacy lay in the work by Jones (Chair in Biomaterials Science) and colleagues in the School on bio(muco)adhesion and bioadhesive formulations, and on biomaterials and medical devices. 'Bioadhesion' refers to adhesion to a biological surface, often a moist surface (sometimes termed 'mucoadhesion'). From 1995-2008, overall grant awards for bioadhesion and biomaterials research to Jones and colleagues were £1.8M in total, from UK Research Councils (EPSRC, BBSRC, £469k) and the medical devices/healthcare industries, with government (£1.3M). An early focus was on developing a system to deliver antibiotics into the periodontal cavity, where the challenges were (i) adhesion to a moist epithelial surface and (ii) retention of the delivery system in the presence of a continuous flow of aqueous exudate from the periodontal cavity. The research led to a range of publications[1-5] studying the fundamental rheological behaviour of bioadhesive (mucoadhesive) polymer systems, including their rheological properties, which were crucial to adhesive performance and ability to absorb exudate. The work was extended over this period to the design of moisture-activated bioadhesive platforms (polymeric systems that only become adhesive following absorption of water) designed as implants and/or drug delivery systems, the interaction of fluids with biomaterials and the subsequent effects on the biomaterial system[6].

The experience gained from research on periodontal disease and bioadhesion proved highly relevant to a similar problem of adhesion of stoma seals (a biomaterial construction) in a moist environment, where a continuous low-level flow of exudate is also present. Effective adhesion to a wet surface under these conditions, where the skin/epithelium is sometimes damaged, is particularly challenging. Conventional adhesives (e.g. pressure-sensitive adhesives) are unsuitable for damaged skin and typically fail in a wet environment. If over-wetted (e.g., in situations where the surface is continually moistened by a flow of aqueous fluid), bioadhesives can lose adhesion as a slippy mucilage is formed. Thus, seeking to overcome these challenges, three successive KTP schemes were established by TG Eakin Ltd, a leading UK manufacturer of stoma products, with Jones and colleagues in the School of Pharmacy. The schemes, between 1999 and 2007, were worth £377k in research funding and developed the earlier periodontal adhesive system and related biomaterials research into a novel stomacare adhesive that provides effective adherence to

the stoma/skin bed in the presence of exudate from the stoma. In so doing, this system optimised the contact between the stoma bag and the patient, and decreased the incidence of skin irritation and breakdown.

3. References to the research (indicative maximum of six references)

1. JONES, D.S., WOOLFSON, A.D., BROWN, A.F., COULTER, W.A., McCLELLAND, C. & IRWIN, C.R. 2000. Design, characterisation and preliminary clinical evaluation of a novel, mucoadhesive topical formulation containing tetracycline for the treatment of periodontal disease. *Journal of Controlled Release* **67** 357–368.
2. JONES, D.S., BROWN, A.F., WOOLFSON, A.D., DENNIS, A.C., MATCHETT, L.J. & BELL, S.E.J. 2000. Examination of the physical state of chlorhexidine within viscoelastic, bioadhesive semi-solids using Raman spectroscopy. *Journal of Pharmaceutical Sciences* **89 (5)** 563 - 571.
3. JONES, D.S., BROWN, A.F. & WOOLFSON, A.D. 2001. Rheological characterisation of bioadhesive, anti-microbial, semi-solids designed for the treatment of periodontal diseases: Transient and dynamic viscoelastic and continuous shear analysis. *Journal of Pharmaceutical Sciences* **90 (12)** 1978 – 1990.
4. JONES, D.S., MULDOON, B.C.O., WOOLFSON, A.D. & SANDERSON, F.D. 2007. An examination of the rheological and mucoadhesive properties of poly(acrylic acid) organogels designed as platforms for local drug delivery to the oral cavity. *Journal of Pharmaceutical Sciences* **96** 2632-2646.
5. JONES, D.S., WOOLFSON, A.D. & BROWN, A.F. 1998. Viscoelastic properties of bioadhesive, chlorhexidine-containing semi-solids for topical application to the oropharynx. *Pharmaceutical Research* **15** 1131 – 1136.
6. ANDREWS, G.P. & JONES, D.S, 2006. Rheological characterization of bioadhesive binary polymeric systems designed as platforms for drug delivery implants. *Biomacromolecules,* **7** 899-906.

Grant Awards (KTP Schemes with Eakin Ltd)
(i) 1999-01: £87000 (ii) 2001-03: £139,000 (iii) 2005-07: £151,000

4. Details of the impact (indicative maximum 750 words)

This case study describes the impact of research on bioadhesion and biomaterials in the School of Pharmacy, QUB, which resulted in a new product, Cohesive Paste™, being launched commercially by a leading stoma care company. Unlike competitors, Cohesive Paste™ offers patients an alcohol-free, 'no sting' formulation particularly suitable for use on damaged, excoriated skin. Now sold in 26 countries, Cohesive™ was launched[a] commercially in October 2007, with sales building from 2008 onwards to more than £1M to date. Importantly, the product allowed the company to provide a complete range of stomacare products (seals, pouches, adhesive etc.) under the 'Cohesive' brand.

Operations for certain bowel conditions, e.g., inflammatory bowel disease or cancers of the bowel, frequently involve the formation of a stoma, an artificial opening in the bowel to either temporarily or permanently divert the flow of faeces (ileostomy or a colostomy). Unfortunately, a complication associated with stomas is leakage of the bowel contents that, amongst other issues, e.g., prolapse, hernia, results in high patient morbidity. The overall incidence of such complications ranges from 21-70%. Leakage from the stoma is associated with pronounced skin irritation and breakdown. Cooperative funding from DTI and TG Eakin Ltd (a manufacturer of stoma products sold worldwide) via a Knowledge Transfer Partnership (KTP Scheme) led Jones and colleagues in the School of Pharmacy at Queen's University Belfast to develop a novel bioadhesive product to address the problems of leakage from the stoma.

Cohesive Paste™ is composed of a hydrophobic viscoelastic matrix into which a range of hydrophilic bioadhesive polymers of defined cross-link density and particle size is mechanically dispersed. Upon contact with exudate, the product, based on the earlier periodontal and related studies, is designed to control ingress of fluid into the adhesive, to undergo swelling and to offer enhanced adhesion to the site of attachment, thereby increasing wear time of the stoma device. Furthermore, the hydrophilic components form a gel layer that interact with the components of exudate and prevent these from contacting and damaging the skin/stoma interface. The design of the novel stoma adhesive involved complex rheological characterisation of viscoelastic and bioadhesive properties using the experience and knowledge gained in earlier underpinning research.

The impact is on the expansion of the company (sales and profitability) and, importantly, on stoma patients, who benefit from the use of the product through a decreased incidence of skin irritation and breakdown[c]. A nurse testimonial[d] states that '*The Eakin Cohesive Paste™ also increases the wear time of Eakin Wound Pouches by adding extra security and protecting the skin from faecal fluid contamination. This technique works well on both fistula and wound management. The paste does not break down over prolonged use, expanding the wear time of wound pouches to 5-7 days. The paste is easily removed when changing pouches and does not leave a residue on the skin'.*

In 2007, the KTP scheme[e] between Eakin and the School of Pharmacy, which resulted in 'Cohesive Paste™', won a KTP Award[f] from the Technology Strategy Board. Indicating the commercial impact, the company said that they considered the partnership to have been 'an enormous success in developing an entirely new product'. Cohesive Paste™ is now sold in some 26 countries with sales of more than £1M to date[g]. Confirming the beneficial impact on patients and healthcare professionals, in November 2010 TG Eakin Ltd received the Gold Prize[h] in the 'Continence and Stoma Care' category of the 'Nursing Times Product Awards' in London for the '*highly innovative Cohesive Paste™*' which, the judges felt, '*transformed patient care, helping healthcare professionals work efficiently*'.

5. Sources to corroborate the impact (indicative maximum of 10 references)

(a) *Launch of Cohesive Paste*
http://www.eakin.eu/DatabaseDocs/nlr_41873120_issue_3.pdf

(b) *Brochure for Cohesive Paste*
http://www.eakin.eu/productdetails/3135/5/cohesive_paste.aspx

(c) *Presentation of clinical trial data*
http://www.eakin.eu/casestudies/81/introducing_a_novel_product_for_the_protection_of_peristomal_skin.aspx

(d) *Nurse Testimonial on use of Cohesive Paste*

(www.eakin.eu/DatabaseDocs/prd_61094092_nurse_testimonial.pdf)

e) *Confirmation of KTP funding to Jones et al and of the Eakin partnership*
Head of KTP and Business Networks, Research and Enterprise Directorate,
Queen's University Belfast

(f) *Confirmation of KTP Award to Jones for Cohesive Paste development)*
http://info.ktponline.org.uk/content/libraryMaterial/2007Awards.pdf

(g) *Marketing Data on Cohesive Paste*
International Marketing Executive, TG Eakin Limited

(h) *Confirmation of Nursing Times Award for Cohesive Paste*
http://www.eakin.eu/awards.aspx