

Impact case study (REF3b)

Institution: University of Bolton
Unit of Assessment: 15 - General Engineering
Title of case study: Preventive Measures and Enhanced Health, Hygiene and Quality of Life of the Wider Community
1. Summary of the impact (indicative maximum 100 words)

A novel pressure-relieving technology has been developed to enhance the quality of life of a range of people. This has enabled the development firstly of a novel compression therapy system for the prevention and treatment of venous leg ulcers especially for middle-aged and older communities as well as having the potential for huge savings to the NHS. Secondly, is a unique pressure-relieving cushion to reduce pressure sores with specific applications for wheelchair users. Baltex Ltd, UK are successfully producing both commercially. An exclusive agreement has been signed with a global medical device company, BSN Medical for marketing the single-layer bandage.

2. Underpinning research (indicative maximum 500 words)
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2.1. Medical Devices for Wound Management (refs 1 to 5)

It was established from the earlier research funded by the former UK DTI that a novel compression system is essential to address the problems associated with the multilayer compression system for the treatment of venous leg ulcers. The principal problems include uneven pressure distribution and an ineffective compression profile, which are considered to be critical because high pressure can damage the venous and arterial systems on the limb and the beneficial effect is not attainable if the compression system provides too low a pressure.

In the UK alone about 1% of the adult population suffers from venous ulceration and the cost to the NHS for the treatment is about £650million per annum. EPSRC acknowledged the significance of further research in this area and awarded a grant to Dr S.Rajendran (PI) and Professor S.C.Anand (CI) for designing and developing a single-layer compression therapy system during 2005 - 2009. A 3-dimensional single-layer bandage was developed and it possessed all the desirable attributes and sustained graduated pressure of the current four layer bandage system, offering financial and technological benefits to the NHS and other allied establishments in the world.

Results from the associated project funded by NWDA/EPSRC (2005 – 2008) paved the way for developing a unique odour/volatile adsorbent wound dressing by making use of the natural polysaccharides in aloe vera. It should be stressed that the currently available activated carbon charcoal, odour-adsorbent dressing possesses some undesirable characteristics besides environmental concerns and therefore the situation demanded a need to develop an alternative to activated carbon charcoal-containing dressings. Under the leadership of Professor Anand, the team in which Dr Rajendran was a co-investigator has developed a novel dressing that meets most of the requirements of an ideal wound dressing in addition to odour adsorption and antimicrobial properties.

2.2. Pressure Relieving Cushion (ref 6)

This development has risen directly from the three-dimensional single-layer venous leg ulcer bandage, because high localised pressures experienced by patients' having confined mobility, including wheelchair users, can cause venous leg ulcers. Based on our improved understanding on the need to reduce localised pressure and the associated textile structure developments which have enabled this to be achieved, a novel pressure-relieving cushion has been developed and fully characterised (2009-2013) for the treatment and management of pressure sores and other diseases suffered by the wheelchair patients. Baltex Ltd, UK are currently marketing the cushion

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throughout the Europe and other countries. Professor Anand is the Principal Investigator and Dr Rajendran is the Co-investigator.

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

1. G.Lee, S.Rajendran and S.C.Anand, Novel single layer compression bandage system for the treatment of chronic venous leg ulcers, *British J Nursing*, 18, 15, S4-S18 (2009).
2. G.Lee, S.C.Anand and S.Rajendran, Are Biopolymers Potential Deodourising Agents in Wound Management? *Journal of Wound Care*, 18, July, 290-295(2009).
3. S.Rajendran, S.C.Anand and G.Lee, A Novel Single Layer 3D Spacer Bandage for Venous Leg Ulcer Management, *Wounds UK*, Harrogate, 10 – 11 November 2008.
4. S.C.Anand and S.Rajendran, Development of 3-Dimensional structures for Venous Leg Ulcer Management, *Fiber Med* 11, International Conference on Medical and Healthcare Devices, Tampere, Finland, 28-30 June 2011.
5. S.Rajendran, S.C.Anand and C.Wood, Pressure Actuator, UK Patent: GB 1012671.2, 28 July 2010.
6. S.C.Anand, C.Wood and B.McArdle, Cushioning Fabrics, UK Patent: GB 1306094.2, 04 April 2013.

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

The underpinning research described in this report has impacted significantly on the lives of a range of people by enhancing the hygiene and patient care through prevention and treatment. The venous leg ulcer research is highly significant mainly because it enhances the quality of life of middle-aged and older people to boost the cost saving for the NHS, which is crucial in the current economic climate. The novel single-layer bandage replaces the standard four layer system.

The leg ulcer takes a long time to heal which can cause distress to patients and also the treatment cost is high to the NHS. About 1% of the adult population suffers from active ulceration during their lifetime. The prevalence of venous leg ulcer increases with age, from 1% within the adult population to 3.6% in the over 65 age group. The total cost to the NHS for venous leg ulcer treatment is about £650 million per annum, which is 1-2% of the total healthcare expenditure. Cost per patient has recently been estimated to be between £1200 and £1400. The annual cost for treating venous leg ulceration in the USA is between \$1.9 billion and \$2.5 billion and in Western Europe it is 1% of the total annual healthcare budget.

It has been well established that compression therapy by making use of compression bandages is the 'Gold Standard' for the treatment and prevention of venous leg ulcer as there is no medication or surgery to cure the ulcer. In the UK, a multilayer system (four layer bandaging system) is widely used whilst in Europe a two layer regime is popular.

With the above background, it is stressed that the impact and benefits accrued from Bolton's venous leg ulcer research are enormous both nationally and worldwide and are highly significant. The market revenues are expected to increase significantly after the launch of the novel 3D single-layer bandage because it offers cost-effective single-layer therapy, which would replace the current practice of multilayer bandage systems with enhanced functional properties for treating venous leg ulcers. Current competitors provide a multilayer compression system and not a single company currently offers a single-layer compression system. The research is considered to be revolutionary because currently no 3D single-layer bandage has been listed in the 'Drug Tariff' for use in the UK. The novel compression regime is also much lighter, comfortable and can be laundered up to 50 times.

Since the commercial exploitation of novel compression therapy deals with people's healthcare, the ultimate beneficiaries would be middle-aged and elderly patients particularly women who are more prone to developing venous leg ulcers. It is anticipated that patients would feel utmost

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comfort by having a single-layer bandage system, instead of multilayer bandages, on their limbs. It should be noted that the bandages stay on the limb for several weeks or months because a typical venous leg ulcer is a chronic condition which takes a long time to heal. In contrast to the 3D single-layer regimen, four layer regimes are bulky and cause discomfort to patients because they are too cumbersome.

Additional benefits to patients with single-layer bandages over multilayer bandages are: a) they are highly breathable; b) they provide good resilience and cushioning effects due to the 3D cell structure; and c) offering simplicity of application. Nurses, doctors and other hospital staff will also receive benefits through increased understanding of innovations and novel practices accruing as a direct result of this single-layer therapy. The novel single-layer 3D bandage would subsequently reduce leg ulcer healing times as well as nursing time and thus offers financial and technological benefits to the NHS and private hospitals. In contrast to a single-layer system, the four layer system consumes considerable nursing time. The current multilayer bandages are manufactured by using different technologies and equipment and the cost involved is high. In contrast, the novel single-layer 3D bandage is manufactured using only one machine and the production cost is comparatively low. Considering savings in the material and production costs, in the nursing time and in the time to heal the ulcers, it is estimated that a total saving of around £60 million per annum would be realised upon the successful launch of the single-layer compression therapy. The environmental aspects of this novel product are also extremely crucial. The increased use of the single-layer bandage, in contrast to four layer bandages, will enable the establishment of a much improved and efficient mode of clinical and medical waste disposal and will result in a safer and cleaner environment. Other direct beneficiaries include fibre manufacturers, medical textile product manufacturers, supply chains, and of course medical and scientific communities in the UK and worldwide. All these measures would ultimately boost the UK economy. A patent has been applied for and licensed to Baltex Ltd, UK who have successfully produced the commercial product and an exclusive agreement has been signed with a global medical device company, BSN Medical for marketing the single-layer bandage worldwide. The outcomes of the research will pave the way for developing future products for the treatment of varicose veins and DVT. It is forecast by Baltex Ltd, UK that a revenue of £100,000 in 2013 and £1.0 million after three years would be achieved.

Underpinning the above research, Dr Rajendran was invited for presentation meetings in India and this yielded the academic collaboration with The South India Textile Research Association (SITRA) and PSG College of Technology (PSGT) in India. The University has signed a Memorandum of Understanding with SITRA in January 2010 which extends until July 2015. This facilitates further collaborative research in healthcare sector in the UK and India. An international conference highlighting the healthcare and hygiene was organised jointly with PSGT in July 2010.

The sales projections for pressure relieving cushion for the treatment and management of pressure sores and other diseases suffered by the wheel chair patients would be £40,000 in the first year (2013) and £5.0 million in five years.

Some of other impact indicators include 10 refereed publications, 15 conference presentations, 8 book chapters, 4 patents and career development of 6 researchers.

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

1. <http://gow.epsrc.ac.uk/NGBOViewGrant.aspx?GrantRef=EP/C538196/1>
2. The Bolton News, 8 November 2011.
3. Parliament Report, Research and Development Work Relating to Assistive Technology 2008-09, Report Presented to Parliament by the Department of Health, July 2009, Page 23.
4. BBC Radio Manchester, Business Hour Interview, 5th April 2011.
5. S.Rajendran, The Future of Medical Fibres and Biomaterials for Healthcare and Hygiene Market, Hohenstein Future Textile Symposium - Successful Strategies for the World

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- Markets: How to get in the Growing Health Market with Innovative Products, Hohenstein, Germany, 19 February, 2008.
6. S.Rajendran, Innovative Medical Fibres and Textile Medical Devices for Healthcare and Hygiene, EKOTEKS Symposium, Istanbul, Turkey, 12 March, 2008.
 7. S.Rajendran and S.C.Anand, Insight into the Development of a Novel Single Layer Bandaging Regime for the Treatment of Venous Leg Ulcers, 86th Textile Institute's World Conference, Hong Kong, 18 – 20 November 2008.
 8. S.Rajendran, S.C.Anand and G.Lee, Novel 3D Single-layer Compression Bandage System for the Treatment of Venous Leg Ulcers, The Bolton Research Forum in Health and Social care, Bolton, 30 June 2009.
 9. S.Rajendran, S.C.Anand and A.Afifi, A Novel Concept for Designing a Single Layer Compression Bandage System for the Treatment of Venous Leg Ulcers, Ambience 08, Boras, Sweden, 2 -3 June 2008.
 10. S.C.Anand, Development of 3-Dimensional Structures for Venous Leg Ulcer Management, 3rd World Conference on 3-D Structures and their Applications, Wuhan, China, 20-21 April, 2011.