

Institution: University of St Andrews



Unit of Assessment: UoA 09: Physics

Title of case study: Commercialisation of wearable light sources for improved treatment of acne and skin cancer

Period when the underpinning research was undertaken: 2000 - 31 December 2020

Details of staff conducting the underpinning research from the submitting unit:

| Name(s): | Role(s) (e.g. job title): | Period(s) employed by submitting HEI: |
|-------------------|----------------------------------|--|
| Ifor D. W. Samuel | Professor | 01 August 2000 - present |

Period when the claimed impact occurred: 01 August 2013 – 31 July 2020

Is this case study continued from a case study submitted in 2014? N

Section B

1. Summary of the impact

Research in optoelectronics by Prof. Samuel has led to the development of wearable light sources for medical applications which have been brought to market by the spin-out company Ambicare Health Ltd. The Lustre family of products provides a treatment for acne and is sold over the counter in 200 Boots stores, online mainly via Amazon and through skin clinics in the UK. The Ambulight family of products provides a simple and cost effective way of treating many skin cancers by photodynamic therapy and is used in hospitals and skin clinics in the UK, EU and Australia. Lustre and Ambulight have regulatory approval throughout the EU and in Australia and Lustre is approved in the USA by the FDA.



Ambicare Health Ltd.'s 'Lustre Solo' wearable light source for acne treatment exploits our optoelectronics research.

These devices bring economic benefits to the UK through Ambicare Health Ltd. which, since August 2013, has sold approximately 4,000 Lustre units worth GBP1,000,000 at end retail value and to its distributor Spirit Health Group which, in the same time period, sold more than 7,650 Ambulight light sources for skin cancer treatment worth GBP750,000.

Importantly, the Lustre and Ambulight products also bring healthcare benefits by providing effective, convenient and comfortable treatment to patients suffering from these widespread conditions. The skin cancer treatment is very popular with patients as it avoids the need for surgery, is convenient to use, does not require specialised equipment, and yields good cosmetic outcomes. The acne products enable simple and effective treatment at home. More than 10,000 people (acne and skin cancer patients) have benefited from these treatments. The pioneering nature of the work has been recognised by an award from the International Photodynamic Association.

2. Underpinning research

Acne affects most people (approximately 90%) during their lives and if severe or prolonged can have serious adverse effects not only on skin, but also on self-image and the ability to socialise. It is well known that sunlight can help, but it is not consistently available, leading to a need for a convenient, compact and portable light source for acne treatment.

Skin cancer is a serious and growing problem affecting between 10% and 15% of the UK population, 40% of the US population and 75% of the Australian population in their lifetimes. The most common treatment is surgical excision but this leaves a scar and carries a risk of infection. For many non-melanoma skin cancers, photodynamic therapy (PDT) is an effective treatment in which a light sensitive cream is applied to the skin and activated by an external light source. PDT normally requires specialised light sources available in only a small number of hospitals, limiting its availability, a problem which is overcome with our invention.

Research in optoelectronics has been a major activity in St Andrews for many years. In 2000, Prof. Samuel set up the Organic Semiconductor Centre to advance multidisciplinary research including organic semiconductor optoelectronics and organic light-emitting diodes (OLEDs). OLEDs are compact visible light sources which can be flexible. They consist of thin layers of organic semiconductors in between suitable contacts, and so enable very unusual light sources to be made that are thin and emit uniformly over an area. Further attractive features are that the light-emitting material can be deposited onto a substrate from solution, enabling simple fabrication of devices, and the colour can be tuned by suitable choice of emitter. The group's research on OLED materials and devices led to solution-processed OLEDs with world-record efficiency [R1], [R2]. The availability of such efficient and bright devices enabled new applications to be considered, especially beyond the field of displays which was the focus of most researchers at the time.

In the treatment of skin cancer using PDT, a photosensitiser cream is applied to the lesion to be treated which is metabolised by the tumour. The photosensitiser, when illuminated by a powerful light source (often a laser), causes targeted cell death, destroying the tumour. This procedure gives a very good cosmetic outcome but requires spending a day at the hospital and can be painful. The need for specialised equipment means that relatively few centres (7 in Scotland) are able to offer this treatment. A discussion with Prof. Ferguson at Ninewells Hospital in 2001 led to the idea of using a wearable (and disposable) light source based on flexible sheet OLEDs instead of the current bulky and expensive hospital-based light sources. A patent on this invention was filed late in 2001 [R3] and an alternative implementation filed in 2006 [R4].

In subsequent research, wearable light sources suitable for medical use were made in St Andrews and evaluated at Ninewells Hospital. The concept of an ambulatory light source for medical and cosmetic purposes was implemented using both organic and inorganic light-emitting diodes [R4]. The former gives a more compact light source and more uniform illumination; the latter is easier to manufacture in a conventional electronics factory. After initial clinical evaluation [R5], the OLED device was successfully used in a pilot trial that showed equivalent effectiveness and much-reduced pain in the treatment of skin cancer than conventional laser-based PDT [R6]. This was the critical research result that enabled Ambicare to raise substantial money to commercialise wearable light sources.

3. References to the research

R1, R2, R5 & R6 are papers published in internationally recognised peer reviewed journals. R3 & R4 are granted patents.

- R1. J.P.J. Markham, S-C. Lo, S.W. Magennis, P.L. Burn and I.D.W. Samuel, "High efficiency green phosphorescence from spin-coated single-layer dendrimer light-emitting diodes", *Applied Physics Letters* 80, p. 2645, (2002). DOI: [10.1063/1.1469218](https://doi.org/10.1063/1.1469218)
- R2. S.C. Lo, N.A.H. Male, J.P.J. Markham, S.W. Magennis, P.L. Burn, O.V. Salata and I.D.W. Samuel, "Green phosphorescent dendrimer for light-emitting diodes", *Advanced Materials*, 14, p. 975 (2002). DOI: [10.1002/1521-4095\(20020705\)14:13/14<975::AID-ADMA975>3.0.CO;2-D](https://doi.org/10.1002/1521-4095(20020705)14:13/14<975::AID-ADMA975>3.0.CO;2-D)
- R3. Samuel, I and Ferguson, J. "Therapeutic light-emitting device", International patent publication WO03043697, Priority 17/11/2001 and associated applications. <https://patents.google.com/patent/WO2003043697>
- R4. Samuel, I. Ferguson, J. and Mcneill, A. "Light emitting device for use in therapeutic and/or cosmetic treatment", International patent publication WO2007125336, Priority 27/04/2006 and associated applications. <https://patents.google.com/patent/WO2003043697>
- R5. H. Moseley, J.W. Allen, S. Ibbotson, A. Lesar, A. McNeill, M.A. Camacho-Lopez, I.D.W.

Samuel, W. Sibbett and J. Ferguson, "Ambulatory photodynamic therapy: a new concept in delivering photodynamic therapy", *British Journal of Dermatology*, 154, p. 747 (2006). DOI: [10.1111/j.1365-2133.2006.07145.x](https://doi.org/10.1111/j.1365-2133.2006.07145.x)

- R6. S.K. Attili, A. Lesar, A. McNeill, M. Camacho-Lopez, H. Moseley, S. Ibbotson, I.D.W. Samuel and J. Ferguson, "An open pilot study of ambulatory photodynamic therapy using a wearable low-irradiance organic light-emitting diode light source in the treatment of nonmelanoma skin cancer", *British Journal of Dermatology*, 161, p.170 (2009). DOI: [10.1111/j.1365-2133.2009.09096.x](https://doi.org/10.1111/j.1365-2133.2009.09096.x)

4. Details of the impact

Commercialisation of wearable light sources based on our OLED research has led to both healthcare and economic impact. Regulatory approvals have been achieved in the EU, Australia and the USA. Since August 2013, sales of acne treatment products by Ambicare Health Ltd. were worth GBP1,000,000 at end retail value, and those of light sources for skin cancer treatment, distributed by Spirit Health Group, totalled GBP750,000. During the same time, more than 10,000 people (patients) in the UK, EU and Australia have benefited from convenient and effective treatment of acne and skin cancer.

From Research to Products and Regulatory Approval Across the World

Our research on OLEDs, including flexible substrates and device fabrication capabilities as described in section 2 provided the opportunity to make compact wearable light sources for skin cancer treatment. To realise this vision, we applied for and received a Proof of Concept grant from Scottish Enterprise (between 2002 and 2004) to make a demonstrator device whose initial evaluation was conducted at Ninewells Hospital in 2005. Further support from Scottish Enterprise led to the fabrication of additional devices in St Andrews which were used in a pilot trial in 2007 demonstrating the potential of OLEDs for the photodynamic therapy of skin cancer [R6].

To enable the above research to be widely used, the prototype research devices outlined above needed to be developed into a form suitable for regulatory approval and manufacture. The regulatory approval of a medical device is a major task requiring extensive design and testing to appropriate standards and so is both expensive and time consuming. To address this, a spin-out company, Ambicare Health Ltd., based in Livingston was formed and GBP2,000,000 of venture capital was raised at the start of 2008. The results of the pilot trial [R6] were essential to enable this fundraising. This investment funded the development of the first ambulatory skin cancer and acne products, following the ISO13485 standards for medical devices.

Since August 2013, Ambicare has successfully developed and launched a range of improved products based on market feedback [S1]. These are:

- 'Ambulight Multi' – a multi-headed skin cancer device with recyclable power supply that enables more skin cancer lesions to be treated at once, and reduces treatment cost
- 'Lustre Pro' – a high-intensity version of the wearable acne treatment for use in skin cancer clinics
- 'Lustre Solo' – a device in which the power supply and light source are integrated into a single lightweight wearable unit to treat acne.

Ambulight and Lustre devices have both received **regulatory approval** as medical devices for sale throughout **Europe** and have been approved by the **Australian** Therapeutic Goods Administration. Lustre gained FDA approval for over the counter sales in the **USA** in 2014 [S1, S2].



Ambicare products: Ambulight PDT (left), Lustre Pro (middle) and Lustre Solo (right).

The main benefits are economic and in healthcare, and each of these should be considered in connection with both acne and skin cancer treatment.

Sales and distribution of Ambicare products bring economic impact to two UK SMEs

The Lustre products for acne treatment have been sold, mainly in the UK, through skin clinics, online through various websites including Amazon, and most significantly through 200 Boots stores. **Ambicare Health Ltd. has sold approximately 4,000 Lustre devices at an average selling price exceeding GBP200 with an associated turnover since August 2013 of approximately GBP1,000,000** at end retail value [S1]. Ambulight has been sold for skin cancer treatment in the UK, EU and Australia. Ambicare's distributor for the skin cancer treatment, Leicester-based **Spirit Health Group, has sold over 7,650 Ambulight light sources with a total revenue of GBP750,000 to 18 centres in the UK and 33 centres in Australia.** Additionally, Spirit Health Group has supplied a further 2,500 light sources to a distributor in the Netherlands [S3].

Ambicare products deliver improved healthcare to over 10,000 people (patients) worldwide

The Lustre and Ambulight products have provided innovative, convenient and effective treatment to **more than 10,000 people (acne and skin cancer patients) in the UK, EU and Australia,** based on the sales figures above. We believe this is a very significant benefit that is even greater than the economic benefits outlined above.

Lustre provides a very convenient and effective way of treating acne which otherwise can have a very serious effect on the lives of people. It is easy to underestimate the effects of acne. Whilst some acne in teenage years is a 'rite of passage', the lives of many people are severely affected by acne, affecting their self-esteem, and inclination to interact with others, and making them desperate to find a solution.

With more than 4,000 units sold, Lustre is bringing significant healthcare benefits to many acne sufferers for whom **the product not only successfully treats their acne but as a consequence also improves their self-esteem and confidence.** Of the many reviews left by users on **Boots.com and Amazon.com, 90% of the users have given 4* or 5* ratings** [S1].

Many positive reviews are posted on the product website with such testimonials as:

"After years of every treatment...[Lustre] really was the final attempt for me to clear up my ugly and painful skin... My skin [is now] completely spot free and I am more happy and confident than ever!"

"we have been struggling with [my son's] acne for a year now and were literally desperate ... acne has taken away a happy confident boy ... [Using Lustre] breakouts [are] clearing up quicker and scarring is fading...Well worth every penny spent..", "I have used the Lustre for the past 4 years to treat hormone and stress-related acne flare ups and have always been really happy with the results....the Lustre Solo is a game changer" and *"My daughter has used the Solo every day now....she is happier and more positive"* [S4, highlighted text].

Lustre Pro used for 1 hour/day for 12 weeks
Courtesy of Jane Marsh (RGN) Skin Health Spa, London



The benefits to skin cancer patients from using Ambulight Multi are that a light-based treatment is much gentler than surgery, gives a better cosmetic outcome and is more convenient for the patient. As the light source is wearable and allows the patient to move around, the treatment is much more comfortable than current photodynamic therapy which requires the patient to lie still under a fixed, intense light source in a hospital. Additionally, **Ambulight is more convenient for hospital staff as patients need less supervision than for conventional PDT.**

The Ambulight device brings “*many benefits to patient care*” according to a Consultant in Oral and Maxillofacial Surgery at King’s College Hospital, London who, as of May 2020, has treated approximately 20 people (skin cancer patients) with it. She explains: “*patients found it less painful than using conventional light sources. They did not need pain relief to be administered*” plus “*the treatment was effective with a good cosmetic outcome and the patients liked being able to move around during treatment.*”. Confirming the benefits to staff she said: “*I found it convenient to use because it did not need continuous supervision by a nurse*”. [S5]. She also explains another aspect of its importance, which is to severely ill patients: “*We have many transplant patients and patients on other immunosuppressive therapy. The patients often have multiple lesions. These patients benefit from the greater convenience and reduced pain [which] are particularly important for them.*” [S5].

The benefits are also described by the Head of Photobiology at Ninewells Hospital, Dundee: “*over the past three years we have conducted a randomised controlled trial comparing ambulatory PDT using the Ambulight device with conventional PDT in 50 [people] patients. The results of the study showed that ambulatory PDT was extremely well tolerated, with very low pain scores and was as effective as conventional PDT, with high levels of patient satisfaction. Using this approach, patients can undertake treatment themselves at home and less time is spent at the hospital, with less time of medical staff needed to supervise the patients.*” [S6, April 2020].

The CEO of Spirit Health Group explains the novelty offered by the technology: “*I was very interested in the Ambulight device ... because it was so different from existing skin cancer treatments ... I could see immediately that [it] would enable treatment to be taken to the patient rather than the other way round, and bring many benefits to both the patient and the healthcare system. Although wearable devices for fitness monitoring are commonplace today, the development of wearable medical devices in the treatment of cancer is much rarer and Ambulight is a breakthrough*” [S3].

He goes on to confirm the number of patients to have benefitted from their sales of Ambulight in the UK and Australia: “*Each light source treats one lesion, and most patients have either one or two lesions, so we estimate that 7,650 lesions have been treated on approximately 6,767 [people] patients.*”. He quoted patient feedback including: “*having suffered from cancer more than once it was great to be able to have treatment on multiple sites at once in a community clinic rather than a hospital*” and “*it was much less painful than previous treatment with a large lamp*”. He concludes: “*I hope this gives a clear idea of how Ambulight has transformed skin cancer treatment*” [S3].

Ambulight has been used successfully across the world, and its international recognition and transformational potential has been recognised by the **award of the Clinical Research Excellence Prize of the International Photodynamic Association** to Prof. Samuel and Dr Ibbotson for “*pioneering work on ambulatory photodynamic therapy*” [S7]. Its benefits are summarised by the Consultant and Reader at King’s College Hospital “*In conclusion, I believe Ambulight PDT is a major step forward for PDT because it enables effective and convenient treatment of common skin cancers and is very popular with patients.*” [S5].

5. Sources to corroborate the impact

- S1. Letter from CEO of Ambicare Health Ltd., pp.1-3 (31/03/2020)
- S2. Lustre PRO Light System, FDA 510k approval number 143713, (29/12/2014)
<http://510k.medevnet.com/applications/index.cfm?id=K143713>
- S3. Letter from CEO of Spirit Health Group Ltd., pp.1-2 (09/06/2020)
- S4. Customer reviews from <https://www.lustreclearskin.com/reviews/> pp.1, 3, 4, 18 (20/02/2020)
- S5. Letter from Reader and Consultant at King’s College Hospital, London, pp.1-2 (13/05/2020)
- S6. Letter from Head of Dermatology, Ninewells Hospital, Dundee, pp.1-2 (06/04/2020)
- S7. Letter from President of International Photodynamic Association, p.2 (25/06/2019)