

# Transformative treatment

Biovotec's Ralf Schmidt tells Portal about the eggshell membrane-based wound dressing set to transform the treatment of hard to heal and chronic wounds

**O**slo-based biotech firm Biovotec has recently been awarded a coveted phase II SME Instrument grant from the European Commission's research and innovation framework programme Horizon 2020. The two-year, €1.3m award will be invested in the collaborative project BIOcURE, which will see the company work closely alongside Irish specialty wound healing manufacturer Finesse Medical to bring to market a new, dissolvable wound dressing which has the potential to accelerate healing rates, slash healthcare costs, and improve the quality of life of the millions of people across Europe affected by chronic wounds.

## What is it?

The product is a low-cost alternative to current bovine collagen-derived wound care dressings, which are often too costly and therefore limited in use. It was developed based on a novel biomaterial derived from eggshell membrane (ESM), a thin, protein-rich lining which protects the egg and its chick during development and which exhibits a number of functionalities similar to the extracellular matrix of human skin, a key component in the wound healing process.

The membrane is taken from waste eggshells, which have been discarded within the egg production industry, purified and ground into a powder before incorporation into a wound dressing. The finished product takes the form of a thin, dissolvable film, similar



*Tissue Engineering 2D Matrix, dissolvable film containing activated egg shell membrane*

to a transparent blister plaster, which can be applied directly to the wound and covered by a secondary dressing, a format which makes it easy to apply and allows for greater flexibility in terms of size. Crucially, the film can be used in combination with all existing secondary dressings, be they foams or bandages.

## How does it work?

It works by attacking the so-called 'vicious cycle' of delayed wound healing, a perpetual state characterised by inflammation, excess protease production and tissue degradation. Three distinct properties help ESM to break the wound out of this cycle and kick-start the healing process. Firstly, it is anti-inflammatory, meaning it reduces the inflammation response; secondly, it has an MMP (matrix metalloprotease)-binding function, which reduces the MMPs in the wound – a key risk factor in delayed wound healing and, thirdly, it promotes granulation tissue formation.

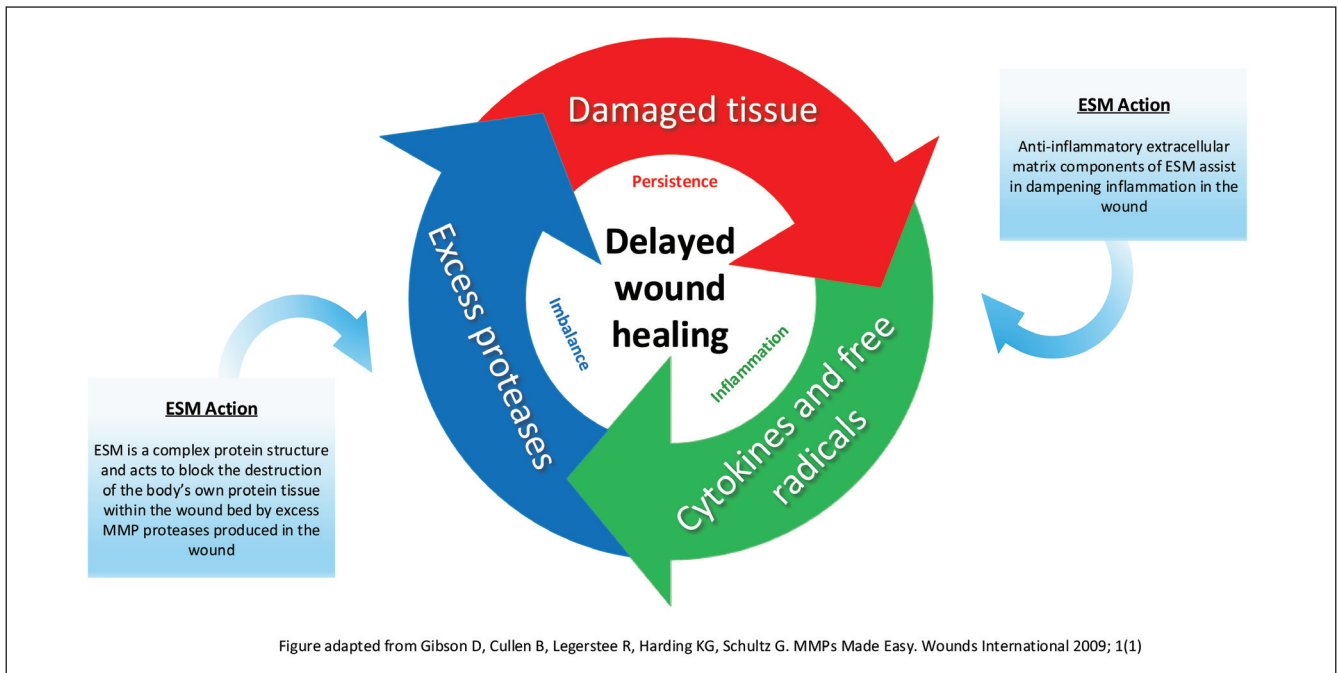
## What will it treat?

The product will hopefully be fit for use on a variety of wounds, including bed or pressure sores – skin ulcerations which occur when sustained pressure interrupts the blood supply to a particular part of the body, often due to poor mobility – and diabetes-related wounds such as foot ulcers, which are estimated to affect some 25% of people with diabetes.<sup>1</sup>

Biovotec's primary focus, however, is venous leg ulcers, a chronic open sore caused by venous insufficiency of the leg. The most common of all leg ulcerations, venous ulcers today affect approximately 1% of the population and some 3% of people over 80, an incidence which is set to rise significantly as the world's elderly population continues to grow.<sup>2</sup>

## How much will it cost?

With increasing prevalence, of course, comes escalating expense: in the UK alone, venous leg ulcers are estimated to cost anywhere between £168m (~€199m) and £198m each year,<sup>3</sup> which represents an ever-significant burden on already over-stretched healthcare resources. Reducing the price per patient, without compromising on care, will naturally be vital, and it is this cost effectiveness which Biovotec believes sets the ESM film apart: Biovotec aims to market its product at a price significantly lower than many of the biological wound treatments currently available on the EU market.



*ESM can break the vicious circle based on our in vitro and in vivo models*

There are a lot of wound care products out there, all of which claim different functionalities, but the bottom line is: price matters. Most biological or advanced wound care treatments actually come at a very high cost, which often means that they just aren't used. That's why our aim with BIOCURE is to combine these unique biological functionalities with a very competitive price.

**What's next?**

Biovotec has already demonstrated the effectiveness of its ESM dressing in pre-clinical studies; now its focus is on production scale-up and commercialisation. With this in mind, Biovotec has built up its supply chain with Finesse Medical. Safety studies are underway to support clinical trials in Europe which are expected to commence in 2017. We already enjoy a good collaboration with our lead investigator in Bradford Royal Infirmary, Mr Kevin Mercer, who is a vascular surgeon with a strong research interest in wound care. We also work very closely with Professor Peter Vowden and his team at NIHR WoundTec HTC, whose mission is to facilitate and fast-track the development of innovative, cost effective medical devices for wound care which will improve the lives of patients in the UK National Health Service.

The first clinical trials will involve between 40 and 50 patients with venous leg ulcers, who will be treated at Bradford and two other hospital sites in Great Britain.

Biovotec is optimistic that the trials' outcome will successfully secure a CE mark for EU market approval, after which we will look to expand into trials for use of the product beyond venous leg ulcers while building up our commercial base. At the same time, the company hopes to begin discussions with other established players in the wound healing industry to see

whether the film can be combined with their products – the aim being that a price-competitive and cost efficient product can be brought to market in 2018 or, as we call it at Biovotec, the 'year of commercialisation'.

Naturally, then, Biovotec has some way to go before its BIOCURE dressing can be successfully put to use in wound care clinics across Europe, but with Horizon 2020's backing, a proven technology, and a global market estimated at some USD \$3bn (~€2.7bn), it nonetheless looks set to firmly cement its place as a European leader in the ever-evolving world of hard to heal and chronic wound care, bringing significant benefits to patients, taxpayers and healthcare professionals.

**References**

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