

Potential treatment for the hard to heal

The first clinical trial for many years of an Australian-made wound healing product is underway at the Austin Hospital in Melbourne. Kate McDonald spoke to the director of the trial, Associate Professor Michael Woodward, and looks at the science behind the product.

It may sound on first hearing as the spiel of a snake-oil salesman, but the story behind the development of a new Australian product designed to promote wound healing is a compelling one. Using an extract derived from paw paw fruit, an Australian company called Phoenix Eagle has developed a new product, OPAL A, that could very well revolutionise wound healing and wound care itself in this country.

The story is an unusual one to say the least, but in the company's favour is the quality of the people it has managed to get on board. Not only does it have local and international specialists as advisors, but it has managed to recruit one of Australia's best known wound management experts, Associate Professor Michael Woodward of the University of Melbourne's School of Medicine and past-president of the Australian Wound Management Association (AWMA), to run its early phase clinical trial at the Heidelberg



Michael Woodward: looking for evidence..

Repat, based at the Austin Hospital.

Woodward himself admits to being a bit sceptical about the story when he first heard it, but having witnessed some remarkable results after the product was used to treat pressure ulcers at Perth's Quadriplegic Centre, he has come on board.

"I think that whenever anybody says this vegetable extract does miraculous things, the first reaction of a doctor is to be a little bit doubtful," he says. "That's not because we are all in the pockets of the pharmaceutical industry and only believe in expensive drugs, it's just because many claims have been made about foods and vitamins in the past which have not been proven once they've been subjected to the light of evidence."

Woodward is now looking for the evidence for OPAL A, running a blinded, randomised, placebo-controlled trial of the product in people with hard to heal venous and pressure ulcers. The candidates will receive either a placebo or a treatment with OPAL A filtrate, applied directly to the wound, as well as a 30 per cent-strength cream applied to the surrounding area.

Only those who are not responding to regular therapy will be recruited, Woodward says. "We don't want a new product that is no better than what we have already got," he says.

"For that reason we have everybody treated for four weeks with regular therapy and then at the end of that four week period they only get into the study proper if their ulcer hasn't healed by 25 per cent of the surface area.

"The good thing, if it turns out to be effective, is that it is a totally Australian invention which most people will feel comfortable with," Woodward says.

Patented process

The story behind the product's discovery is, as mentioned, a compelling and slightly unusual one. The inventor, Tom McArthur, has no scientific training to speak of but has been responsible for a number of inventions in his time. According to Phoenix Eagle's managing director, Mark Richardson, McArthur has been interested in the therapeutic properties of fruits and vegetables for years. His interest was strongly reinforced when he was in the British army based in Malaya in the 1950s.

He spent many years experimenting, and finally came up with a way to extract a filtrate from the pulp of the fruit by heating it and adding sodium bicarbonate.

Many different fruits and vegetables can be used in this process but paw paw looks the most promising at the moment. The company

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took out a global patent application on the process, the products derived from the process and the uses of these products, and has filed this application in the major global markets.

It was the cosmetic applications which first sparked McArthur's interest, but the more important application, for the healing of chronic wounds, came about by chance. McArthur began to treat an acquaintance who had an ulcerous toe that had become necrotic and had been scheduled for amputation, having already lost three others. The treatment, which has been video-recorded, was successful and the patient kept his toe.

Another patient, confined to a wheelchair and suffering from a large ulcer on his hip and a hard scar on his buttock, was also successfully treated.

Then, Richardson received a phone call from the director of nursing at the Quadriplegic Centre in WA, where the



product was unexpectedly being trialled by one of the nursing staff, with excellent results.

Things were starting to look very interesting indeed, Richardson says. The idea was initially to manufacture the product for cosmetic uses, but its quite excellent – albeit anecdotal – results in chronic wounds showed that it should be taken a little more seriously. So, Geoff Mitchell, a general practitioner, palliative care specialist and professor of medicine at the University of Queensland in Ipswich, was asked to take a look.

“The inventor treated patients on an informal basis and then they started keeping records, which included taking photographs of the treatment process as time went on,” Mitchell says. “They asked me to be an independent observer and to correlate what these people had observed with medical records, hospital records and nursing service records so that we could have a credible story that would be accepted by the profession.”

Mitchell presented five cases, which he was not involved in, at the AWMA conference in Darwin two years ago, and at the recent AWMA 2010 conference in Perth, presented the results of seven more that he had treated personally. “They were all chronically unwell patients but with different

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causes of their disease,” Mitchell says.

“The product has only been used on people where normal treatments have been trialled and failed. We were at the point where the patients had had the best that is on offer and none of the various standard treatments had worked, so we tried something that might.”

The results were quite excellent, with significant wound healing – properly documented and photographed – in most cases. There was one adverse event, resulting in the amputation of a toe which had appeared to be marginally viable before treatment with OPAL A had commenced.

Mitchell was introduced by the company to Dr Fraser Russell, a biochemical pharmacologist from the University of the Sunshine Coast at Sippy Downs, who is investigating the possible modes of action of the filtrate.

While the scientific explanation of the therapeutic properties is as yet poorly understood, there are several possible modes of action, Russell says. One he is

investigating is the product’s anti-oxidant properties and another is the inhibition of a pro-inflammatory pathway involving the 5-lipoxygenase enzyme.

Whatever the mode or modes of action, OPAL A does seem to be working. Phoenix Eagle has contracted Dr Lyn Tozer, the medical director of clinical trial specialist company Datapharm Australia, to collect and document the medical and anecdotal evidence including evidence for the healing of superficial and partial thickness burns. Datapharm is managing the clinical trial on behalf of the company, and is working closely with Michael Woodward and his team at Austin Health.

In the meantime, the clinical trial is still recruiting. Woodward is looking for patients in the Melbourne region with hard to heal venous leg ulcers or pressure ulcers who have not responded to other treatments. For more information, contact the wound clinic’s research nurse, Kristin Cooper, on 03 9496 4232. **HA**



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