THE TREATMENT OF VASCULAR ULCERS WITH ALKALISED FRUIT EXTRACT

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Background:

Arterial ulcers are difficult to treat without reversing the underlying vascular insufficiency. In many patients this is not possible, necessitating standard wound healing methods of treating infection, removing necrotic tissue and keeping the surface moist, clean and clear of slough.

A new product has been developed for treating chronic wounds not responding to normal treatment. The active composition comprises a filtrate extracted from papaw that has been alkalised by the addition of sodium bicarbonate to the heated pulp. This composition has been named OPAL A. Fltrates derived from other fruits and vegetables subject to the same alkalisation process appear to have similar therapeutic properties.

A number of chronic wounds, including venous, diabetic and pressure ulcers, have been treated successfully with OPAL A and with OPAL001 which is a 10:1 mixture of the OPAL filtrates derived from papaw and peach. Creams have been produced from the OPAL A and OPAL001 filtrates by mixing 30% by weight of one or other of the filtrates into an aqueous cream base. The treatment regimen consists of daily application of the undiluted filtrate directly in or on the wound and of the cream to the skin around the wound, or, in the case of a wound in a lower limb, to the whole limb from the knee to the feet and toes.

Three cases of the OPAL treatment of ulcers arising from arterial insufficiency are presented.

Case 1. 86 yr female, generalisedarteriopathy.

This lady has had multiple strokes and is completely immobile and dependent on others for all care.

In 2007, she developed ulcers over the interphalangeal joints of both second toes in separate incidents. The first of these was to the toe on her right foot, which did not heal despite intensive treatment with antibiotics and daily dressings. The second incident occurred in cold weather several months later, when ulcers developed in marginally viable skin on the first and second toes of the left foot. In both cases the second toe IP joint was breached by the ulcer floor. The right IP joint subluxed, and had to be cleaned and reduced.

Treatment with OPAL001 was commenced for both wounds. In both instances, healing commenced quickly, with substantial closure of the wound in the first instance. Thereafter healing was slower, but steady progress was made to full healing in approximately four months.

This lady subsequently developed a large squamous cell carcinoma on the left temple which required excision and full thickness skin grafting in early 2008. The graft took, but the superficial layers of skin were ischaemic. Some parts of the graft were non-viable and ulcerated. OPAL001 treatment was commenced. Non-viable areas became demarcated, and the remaining graft was much more viable, at one week. The wound healed completely in three months.

Left Toes

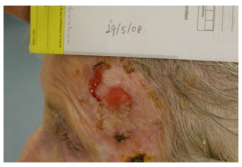
Baseline

Two weeks

Six weeks

Left Temple

Baseline


Five Weeks

Eight weeks

Case 2. 84 year male, thrombangiitis obliterans, alcoholism

This man has had thromboangiitisobliterans since his 40s, and a previous right lumbar sympthectomy. He had chronic vascular insufficiency of the left leg at the time of first contact consultation in mid-2008. He was an alcoholic who lived in a boarding house, neglecting himself badly. He had lost the toenail of the left fourth toe, and the nail bed had become infected. The entire toe was swollen and inflamed, but there was no evidence of osteomyelitis on X-ray. He was treated with regular dressings and antibiotics for many months, with no improvement. There was one admission to hospital for treatment of the foot with intravenous antibiotics. In addition, he had a lumbar sympathectomy three months before commencing the OPAL treatment. He was admitted to a residential care facility one month before OPAL treatment commenced where his diet and care of the ulcer improved, but there was no change in the ulcer's appearance.

Treatment with OPAL A was commenced in December 2008. After eight days (one day after the photo of 16 Dec 08) , and in spite of the toe appearing to have improved, the whole toe broke down to reveal necrotic phalanges. There was clearly very severe underlying ischaemia of the whole foot. He was admitted to hospital where the fourth toe, and subsequently his remaining three small toes were amputated. Two months later, this surgical wound, which broke down, has not healed. He remains under the care of the local hospital. It is not clear whether OPAL had a part to play in this patient's deterioration, but the underlying ischaemia was almost certainly the main cause.

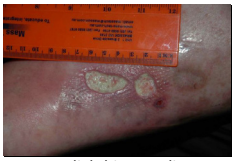
Baseline

One week.

Case 3 60 year Male – Leucocytoclasticvasculitis and morbid obesity

This man developed multiple painful leg ulcers, over the six years to 2006 when he was first treated with OPAL001. He was diagnosed with leucocytoclasticvasculitis, and the ulcers were in effect local areas of severely ischaemic skin. The ulcers were very painful and took an average of eight months to heal.

This was an early case, and the application of OPAL differed to the cases above. Daily application of OPAL001 to the skin at the edge of each wound and in the wound cavity appeared to shorten the healing time by half. In addition the ulcers ceased to be painful. The patient subsequently used OPAL001 cream prophylactically on the skin of his lower limbs, and the number of new ulcers has reduced to almost zero.


L medial shin: Baseline

Eight weeks

Sixteen weeks -healed

Disclosure:
Phoenix Eagle, the manufacturer of OPAL skin products, provided OPAL products to these patients free of charge. A/Prof Mitchell is paid as a consultant to provide independent medical advice and review cases. Prof Woodward is a member of the company's scientific advisory committee.

Discussion

Arterial insufficiency causes ulcers that are difficult to heal and are often intractable. In the cases discussed above normal treatment had failed to promote healing. The alkalised fruit extracts appear to improve microvascular circulation in ischaemic, but not necrotic, tissue and to promote healing at the rate expected in healthy skin.

Towards the end of 2009, the company owning the IP, for which patents have been granted in a number of countries, elected to treat OPAL A as the product to be more rigorously studied and trialled. The healing of seemingly intractable non-arterial ulcers using OPAL A and the rate of healing appears to not be different than when OPAL001 is used.

An RCT is required to assess the safety and efficacy of the OPAL filtrates more rigorously . Such a trial is planned for the second half of 2009 on venous and pressure ulcers for which Professor Woodward is the principal investigator.

Scientific studies have been undertaken to identify the active agents and the mechanism of action, and the results to date have suggested the direction of future scientific studies.