# Treatment of a sacral pressure ulcer and extensive hyperkeratosis with OPAL A filtrate and cream: A case study

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### **Abstract**

OPAL A, derived from the pawpaw fruit, is a promising treatment for chronic skin ulcers. We report the case of a 75-year-old man with paraplegia who presented with a chronic sacral pressure ulcer and extensive hyperkeratosis on his buttocks. After two weeks of treatment with OPAL A filtrate and cream and ongoing bed rest, the ulcer showed evidence of healing and there was a marked reduction in the hyperkeratotic coverage. Five weeks later, the condition of the ulcer was further improved, but the wound was not fully closed. The hyperkeratosis had disappeared. The patient was discharged and continued OPAL A treatment at home. Follow-up examination 24 days after discharge revealed the ulcer to be in good condition, with granulation tissue present on the surface of the ulcer. Hyperkeratosis remained absent and the skin surrounding the ulcer appeared healthy. Although further studies are clearly needed, the encouraging results in this patient contribute to the increasing evidence base justifying rigorous clinical trials of OPAL A for chronic skin ulcers.

Keywords: cream, filtrate, hyperkeratosis, OPAL A, sacral pressure ulcer.

## Introduction

Chronic skin ulcers (including pressure and venous ulcers) affect more than 270,000 Australians and are associated with a significant financial burden<sup>1-3</sup>. Standard care for chronic skin ulcers consists primarily of specialised dressings and compression therapies, in addition to other interventions (as necessary) such as the use of pressure redistribution support surfaces, patient repositioning, oral nutritional support and antimicrobial therapy<sup>4</sup>. Although newer treatments are available, these treatments either have notable side effects or are not conclusively superior to standard care<sup>5,6</sup>.

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OPAL A (Phoenix Eagle Company Pty Ltd, Hillarys, Western Australia), derived from the inner flesh of pawpaw (*Carica papaya*) fruit, is a promising treatment for chronic ulcers. In a previously published case series of 11 patients with chronic pressure ulcers, daily topical treatment with OPAL001, a product containing 91% OPAL A, was reported to be associated with rapid (one to 14 weeks) healing of 9/11 ulcers<sup>7</sup>. Notably, three of these ulcers had been present for more than 12 months<sup>7</sup>. The mechanism of action of OPAL A is currently under investigation, but may involve inhibition of proinflammatory responses, antioxidant effects, and/or vasorelaxation<sup>8</sup>.

Here, we describe a patient with paraplegia who had a chronic sacral pressure ulcer and extensive surrounding hyperkeratosis and was treated with OPAL A filtrate and cream.

# Case presentation

The patient, a 75-year-old man with paraplegia (T7/8), was admitted to the Quadriplegic Centre (Shenton Park, Western Australia) for respite care on 23 November 2009 and was found to have a sacral pressure ulcer and extensive surrounding hyperkeratosis on his buttocks. The patient lived at home with his wife, used an electric wheelchair for mobility and spent considerable time sitting in his wheelchair or in bed. He was an ex-smoker, with a history of ischaemic heart disease

(1993), for which he received a coronary artery bypass in 1995 and ongoing antihypertensive and antihyperlipidaemic medication. The patient had a five-year history of non-insulin dependent diabetes, which was managed by antidiabetic medication and lifestyle modification. Other notable features included regular epistaxis, neurogenic and spasmodic pain, partial hearing loss, and allergies to sulfamethoxazole/ trimethoprim and penicillin. In consultation with a general practitioner and dermatologist, the condition on his buttocks had been diagnosed as psoriasis and he had received over two years of ongoing treatment with Waxes ointment (tincture of benzoin and sulphur). The patient had no obvious cognitive or behavioural problems on admission, his vital signs were normal (temperature, 36°C; blood pressure, 116/63 mmHg; respiratory rate, 18 breaths per minute; pulse rate, 78 beats per minute), and oxygen saturation was 90%. The patient was found to be anaemic and vitamin D deficient.

# **Investigations**

On 25 November 2009, the patient was transferred to the Royal Perth Hospital for a plastic surgery consultation on the sacral pressure ulcer. At this time, biopsies of the keratotic material surrounding the ulcer were taken from the lower, middle and upper regions of the patient's left buttock.

The middle and upper biopsies were similar, with no viable epidermis or dermis, or evidence of inflammation, fungal elements or malignancy. Anucleate keratotic debris was present and several bacterial colonies were isolated. The lower biopsies revealed variable hypergranulosis, irregular psoriasiform hyperplasia, and superficial dermal fibrosis extending vertically to the dermal papillae. There was no evidence of epidermal thinning, epidermal or dermal inflammation, malignancy, or fungal elements. Keratinocytes were typical in appearance. The lower biopsies had characteristics consistent with a diagnosis of lichen simplex chronicus.

The patient remained at the Royal Perth Hospital for two days before being transferred back to the Quadriplegic Centre, where he was placed on an air mattress and regularly rotated from side to side.

#### **Treatment**

Treatment with OPAL A products (Phoenix Eagle Company Pty Ltd, Hillarys, Western Australia) was started on 1 December 2009 (Figure 1.1). OPAL A filtrate (0.5 ml) was applied daily, directly on the ulcer using ribbon gauze before the ulcer was covered with non-adherent Telfa dressing. OPAL A cream was applied to the tissue surrounding the

pressure ulcer and 2 cm beyond the area of hyperkeratosis. The patient remained in bed (on an air mattress, with side-to-side rotation) while receiving OPAL A treatment, but was allowed access to the bathroom.

# Outcome and follow-up

After two weeks of OPAL A treatment, the ulcer showed evidence of healing and the hyperkeratosis had diminished markedly (Figure 1.2). The ulcer and hyperkeratosis continued to improve with ongoing OPAL A treatment (Figures 1.3–1.5). The patient requested to be discharged on 5 January 2010 and was given OPAL A cream, but not OPAL A filtrate, for use at home. Plastic surgery was not considered a necessary treatment option at this time. The patient was advised to continue bed rest until the ulcer had healed. Regular home follow-up examinations were performed by the Quadriplegic Centre community clinical nurse after the patient was discharged.

The condition of the ulcer continued to improve (21 January 2010, Figure 1.6) after the patient was discharged from the Quadriplegic Centre. However, on 27 January 2010, the condition of the ulcer had worsened. The patient was provided with OPALA filtrate and the appropriate application procedure was demonstrated to his wife. The patient was reexamined on 29 January 2010, at which time the ulcer appeared larger, but no deeper, than during the previous week. There was no necrotic tissue in or around the ulcer, nor was there evidence of slough or exudate. Granulation tissue was evident on the surface of the ulcer, the skin surrounding the ulcer appeared healthy and the hyperkeratosis had not reappeared. The patient was advised to continue daily treatment with OPAL A filtrate and cream and to avoid exerting pressure on the affected area.

The patient was readmitted to the Quadriplegic Centre on 10 June 2010 for respite care. Examination at this time revealed that the hyperkeratosis had not reappeared, but that the pressure ulcer had not healed. The patient reported that he had only been using OPAL A cream, but not the filtrate, and that the ulcer was currently being dressed using an antimicrobial barrier dressing. As the patient was not consistently using OPAL A cream and filtrate, supply of these products was withdrawn.

#### Discussion

The chronic sacral pressure ulcer and surrounding hyperkeratosis highlighted in this case study were the result of the patient sitting for extended periods of time. The patient also had a history of cardiovascular disease and



Figure 1. Sequential photographs of the patient's sacral pressure ulcer and buttocks before treatment (1.1), during treatment with OPAL A filtrate and cream at the Quadriplegic Centre (1.2–1.5), and during treatment with OPAL A cream at home (1.6). (1.1) Photograph taken on 1 December 2009. Note the extensive hyperkeratosis on the patient's buttocks surrounding the sacral pressure ulcer. (1.2) Photograph taken on 14 December 2009. (1.3) Photograph taken on 21 December 2009. (1.4) Photograph taken on 29 December 2009. (1.5) Photograph taken on 4 January 2010. (1.6) Photograph taken on 21 January 2010.

non–insulin dependent diabetes, which may have played an underlying role in the formation and/or persistence of the ulcer and hyperkeratosis (later diagnosed as lichen simplex chronicus). Before being admitted to the Quadriplegic Centre, the patient had been diagnosed with psoriasis and had received ineffective treatment for over two years.

The patient's ulcer and hyperkeratosis rapidly improved after the start of treatment with OPAL A filtrate and cream and ongoing bed rest on an air mattress with side-to-side rotation. After four weeks of treatment, the ulcer was obviously smaller than before the start of treatment with OPAL A filtrate and cream. Further evidence of wound healing included skin growth at the margins of the wound and granulation tissue formation on the surface of the ulcer. Notably, the hyperkeratosis/lichen simplex chronicus had completely disappeared after four weeks of treatment.

Upon discharge from the Quadriplegic Centre, the patient continued treatment with OPAL A cream, but spent considerable time in a sitting position rather than maintaining strict bed rest. As a result, the condition of the patient's ulcer ultimately deteriorated, although the hyperkeratosis did not reappear. At this time, the patient was provided with OPAL A filtrate for ongoing treatment in combination with OPAL A cream. Only OPAL A cream was initially supplied for ongoing home-based treatment to reduce the burden of ulcer management for the patient's wife. Unfortunately, the patient did not continue consistent treatment with OPAL A filtrate and cream or maintain bed rest; hence, the effectiveness of wound management from approximately four weeks after discharge from the Quadriplegic Centre is unclear.

In summary, this case study highlights the combined benefits of bed rest and OPAL A filtrate and cream for the treatment of a chronic pressure ulcer and surrounding hyperkeratosis, both of which had been unsuccessfully treated in the past. The encouraging results obtained for this patient in a clinical practice setting contribute to the increasing clinical evidence base for OPAL A. Well-designed, larger clinical trials are warranted to investigate the use of OPAL A in chronic skin ulcers.

# Acknowledgements

The authors acknowledge the independent medical writing assistance provided by Luke Carey, PhD, and Serina Stretton, PhD, of ProScribe Medical Communications (www.proscribe.com.au), funded from an unrestricted financial grant from Phoenix Eagle Pty Ltd. ProScribe's services complied with international guidelines for Good Publication Practice (GPP2).

Phoenix Eagle Pty Ltd provided OPAL A supplies to the Quadriplegic Centre.

Both authors participated in the interpretation, drafting, revision and final approval of the case study.

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