

Alkalised fruit extract as a potential treatment for chronic ulcers – a case series

Geoffrey Mitchell*

Thomas McArthur**

Karin Hollerbach***

Mark Richardson**



*University of Queensland



**Phoenix Eagle Company Pty Ltd



***Taku Group

Chronic skin ulcers

- **Common**
 - 6.5 million chronic ulcers per year from venous stasis, diabetes, or pressure ulceration in US (Singer, 1999)
- **Costly**
 - 1 billion UK pounds per year (Harding, 1998)
- **Serious**
 - Leads to:
 - Chronic infection (cellulitis)
 - Amputation (especially diabetics)
 - Social isolation (quadriplegics)
(from prolonged bed rest)

Principles of standard care

- Debridement
- Infection control
- Moist clean environment
- Pressure bandaging for lower limb ulceration

The OPAL Process

- Pulped pawpaw / pulped peach
- Filtrates extracted from pulps prepared according to the OPAL Process
 - Involves heat and alkalinisation
- Filtrates mixed together and preservative added
- Product named OPAL001

Ulcer treatment

- Ulcer treatment evolved to:
 - Filtrate - applied to wound
 - Filtrate in ointment base - applied to skin around and proximal to wound
 - Daily application of both

Initial observations

- Inventor (McArthur) experimented with fruit extracts, processing them in different ways, hoping to identify therapeutic effects
 - Tried various extracts informally on a range of conditions
- After the OPAL Process was developed, one person used it on a chronic leg ulcer to see if it would work
 - Rapid improvement noted
- Word of mouth: Further patients with chronic ulcers tried the treatment with positive results

Independent assessment of cases

- Clinical academic (Mitchell) retained to provide independent evaluation of clinical cases
- Reviewed the first five consecutive cases where comprehensive records available
- Each patient (n = 5 males) interviewed
- Reviewed case records from patient's GPs, nursing services where involved and clinical photographs
- All cases reviewed retrospectively

Clinical Description	Ulcer Duration	Ulcer Type & Location
Case 1. Diabetic , age 56 Alcoholic, poor nutrition	Unknown duration	Diabetic ulcers Left 4 th toe (established), base of Right foot (early)
Case 2. Quadriplegic , age 43, diabetic, smoker	2 years	Stage 4 pressure ulcer Right greater trochanter
Case 3. Quadriplegic , age 35, smoker	1 month	Stage 4 pressure ulcer Right buttock
Case 4. Venous ulcers (duration 38 yrs), age 75, intellectually impaired	Several Months	Chronic venous ulcer Left shin
Case 5. Leukocytoclastic vasculitis , (duration > 6 yrs), age 60, morbid obesity, Hypertension	Usually 8 months	Multiple vasculitic ulcers Both legs



Case 1: Diabetic ulcer Left 4th toe

- Three toes previously amputated

← At presentation

Note deep necrosis centrally, superficial ulcer, severely distorted nail

← 1 week

Healing of superficial areas



← 4 weeks

Healing progressing rapidly

Nail lifted off



← 6 weeks

All but the central part healed

Case 3: Quadriplegic

Ulcer from ill-fitting seat cover

← Baseline + 3 weeks (1st photo)

Rim of granulation visible

Infection and odour gone



← 5 weeks

Continued closure





← 9 weeks
Before
debriding



← 9 weeks
After
debriding



← 5 months



← 6 - 7 months

(Approx – no date on photo)

Wound fully healed



Case 4: Chronic venous ulcer

Left shin (7x4 cm)

← At presentation



← 1 week

Note slough debrided,
improved skin
appearance



← 6 weeks

Healing mainly from
the central skin flap
growth



← 12 weeks

Changes in area - baseline to 6 weeks

Case	Change in Wound Surface Area (%)
Case 1: Diabetic	
- Left 4 th toe	82
- Base of right foot	78
Case 2: Quadriplegic	55
- Right greater trochanter	
Case 3: Quadriplegic	74
- Right buttock	
Case 4: Venous ulcer	35
- Left shin	
Case 5: Leukocytoclastic vasculitis	40
- Right shin	

Adverse events

- Slight stinging in one patient
 - Transient
- Nil other adverse events

Possible mechanisms

- Improved micro-circulation
- Proteolytic action to remove slough
- Stimulation of skin growth factors
- Possible anti-bacterial action

Work in progress

- Assay of OPAL001 Filtrate to identify active compound(s)
- Development of a bio-assay
- Clinical trial to establish safety and efficacy
- Further testing to optimise formulation and dosage
- Working towards regulatory approval