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

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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 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
<table>
<thead>
<tr>
<th>Clinical Description</th>
<th>Ulcer Duration</th>
<th>Ulcer Type &amp; Location</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Case 1. Diabetic, age 56</strong></td>
<td>Unknown duration</td>
<td>Diabetic ulcers</td>
</tr>
<tr>
<td>Alcoholic, poor nutrition</td>
<td></td>
<td>Left 4(^{th}) toe (established), base of Right foot (early)</td>
</tr>
<tr>
<td><strong>Case 2. Quadriplegic, age 43</strong></td>
<td>2 years</td>
<td>Stage 4 pressure ulcer</td>
</tr>
<tr>
<td>diabetic, smoker</td>
<td></td>
<td>Right greater trochanter</td>
</tr>
<tr>
<td><strong>Case 3. Quadriplegic, age 35</strong></td>
<td>1 month</td>
<td>Stage 4 pressure ulcer</td>
</tr>
<tr>
<td>smoker</td>
<td></td>
<td>Right buttock</td>
</tr>
<tr>
<td><strong>Case 4. Venous ulcers</strong></td>
<td>Several Months</td>
<td>Chronic venous ulcer</td>
</tr>
<tr>
<td>(duration 38 yrs), age 75, intellectually impaired</td>
<td></td>
<td>Left shin</td>
</tr>
<tr>
<td><strong>Case 5. Leukocytoclastic vasculitis</strong></td>
<td>Usually 8 months</td>
<td>Multiple vasculitic ulcers</td>
</tr>
<tr>
<td>(duration &gt; 6 yrs), age 60, morbid obesity, Hypertension</td>
<td></td>
<td>Both legs</td>
</tr>
</tbody>
</table>
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
Healing mainly from the central skin flap growth
<table>
<thead>
<tr>
<th>Case</th>
<th>Change in Wound Surface Area (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Case 1: Diabetic</td>
<td></td>
</tr>
<tr>
<td>- Left 4(^{th}) toe</td>
<td>82</td>
</tr>
<tr>
<td>- Base of right foot</td>
<td>78</td>
</tr>
<tr>
<td>Case 2: Quadriplegic</td>
<td>55</td>
</tr>
<tr>
<td>- Right greater trochanter</td>
<td></td>
</tr>
<tr>
<td>Case 3: Quadriplegic</td>
<td>74</td>
</tr>
<tr>
<td>- Right buttock</td>
<td></td>
</tr>
<tr>
<td>Case 4: Venous ulcer</td>
<td>35</td>
</tr>
<tr>
<td>- Left shin</td>
<td></td>
</tr>
<tr>
<td>Case 5: Leukocytoclastic vasculitis</td>
<td>40</td>
</tr>
<tr>
<td>- Right shin</td>
<td></td>
</tr>
</tbody>
</table>
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