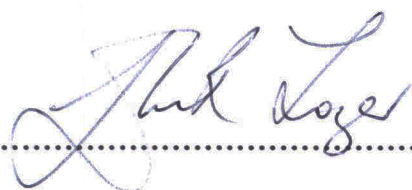


# Case Reports

## OPAL Products

### Treatment of Partial Thickness Burns

Prepared by: Dr Lyn Tozer  
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Date: 3 March 2010



**Datapharm Australia**

# OPAL Products

## Case Reports – Burns Treatment

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**Professor Dr Geoffrey Mitchell, MBBS PhD FRACGP FChPM, serves as medical advisor to Phoenix Eagle.** Geoff has been involved in general practice education and research for over twenty years. In 2009 he was appointed Professor of Primary Care Research in the Discipline of General Practice at the School of Medicine at the University of Queensland and is the recipient of an Australian Government Primary Health Care Senior Research Fellowship for the period 2007-2010. Since 1996 Geoff has combined clinical and academic practice and maintains a general practice in Ipswich, Australia.

Geoff has dual specialist qualifications in general practice and palliative medicine, and was awarded a PhD for work on the use of case conferences as a means of involving and improving the skills of general practitioners in the palliative care setting.

Geoff has been instrumental in the production of the first national guidelines for palliative care (Therapeutic Guidelines: Palliative Care), and research into the promoters and inhibitors of general practitioners maintaining involvement in palliative care. This work has informed national policy in promoting general practice involvement in palliative care. He is also researching evidence-based treatments for clinical problems in palliative care, notably using single patient (n-of-1) trial methodology.

Geoff is a member of the NHMRC Expert advisory group rewriting clinical guidelines for ADHD and is a member of the Palliative Medicines working group for the Department of Health and Ageing. He has acted as a medical advisor to the Queensland Health Rights Commission.

**Dr Lynette Tozer, MBBS MHA was appointed by Phoenix Eagle to collate information and author case reports of users of OPAL products.** Lyn has been Medical Director at **Datapharm Australia Pty Ltd** since 2005 where she has oversight of medical writing and pharmacovigilance.

Lyn graduated in medicine from the University of Sydney and spent several years in general practice. In the early 1980s she wrote for a medical encyclopaedia explaining medical concepts to the lay public. In 1994 Lyn joined Datapharm as Medical Services Manager having responsibility for clinical trial management and oversight of monitoring services.

In 2008 Lyn completed a general practice retraining course through the University of Sydney (SIGPET) to enhance clinical skills and to improve knowledge of current clinical protocols and therapeutics. She is a member of the Australasian Medical Writers Association (AMWA).

# OPAL Products

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### SUMMARY

Between 2003 and 2010, eleven individuals with ready access to OPALA or OPAL001 cream or filtrate or Optiderma gel, used these products to treat accidental burns. Two others (the inventor and a medical practitioner) used themselves as subjects to self-test OPAL001 filtrate to treat self-inflicted burns.

Between 2008 and 2010, information on eleven subjects, eight females and three males, aged 43 to 85 years, was gathered by personal interview, questionnaire and follow-up telephone interview. All had sustained partial thickness burns to upper limbs during food preparation (boiling water, hot oil and hot cooking implements) or other household activity. All OPAL products used had been refrigerated up to the time of application. Four subjects applied OPAL immediately, five within five minutes, one within 20 minutes and one at about 30 minutes. Seven used the cream formulation (30% w/w filtrate in aqueous cream base), one the filtrate and two the gel formulation (Optiderma). Most used multiple applications on the same day and once or twice daily thereafter. Three subjects applied the product only once, immediately or within minutes of the burn.

Prior to treatment two subjects described the pain as mild, four as moderate and five as severe or extreme. With the exception of one subject who delayed application for 30 minutes, all experienced substantial relief of pain following the first application of OPAL. For four this was immediate and for four it took from 15 to 30 minutes. Nine subjects reported improved condition of the burn area from immediately to within hours of application and all subjects reported that their experience of relief was faster than expected. For most the burn did not behave as they expected, with no progression to blistering or obvious burn damage to the skin. One subject who blistered reported that this did not progress as expected but became reattached to subcutaneous tissue. In almost all cases erythema resolved quickly.

Additional information was provided by the inventor and a medical practitioner who conducted self-testing by immersing one or two fingers in oil heated to 160°C for up to 10 seconds prior to applying OPAL001 filtrate at 16°C. Both reported immediate pain relief on immersion in the filtrate and no tissue damage was observed on video or when the fingers of the doctor were examined by another independent medical practitioner<sup>^</sup>.

There appears to be a strong relationship between the application of OPAL products, relief of pain and limitation of tissue damage. The mechanisms that reverse damage from thermal injury require further studies of OPAL products in the treatment of partial thickness burns.

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<sup>^</sup>Geoffrey Mitchell, Professor of Primary Care Research, University of Queensland School of Medicine.

# OPAL Products

## Case Reports – Burns Treatment

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### **Case Report: ID 01**

#### **Incident**

In December 2006, this 56 year old female sustained a burn to the dorsal aspect of her left hand between the thumb and forefinger when boiling water spilled from a kettle. The burn was mild in severity and the level of pain was described as moderate. OPALA cream was applied to the burn immediately.

#### **Outcome**

Immediately following application of OPALA the level of pain was unaffected but relief was reported to occur gradually over minutes (different from this participant's previous experience of burns). The associated erythema subsided within 10 to 15 minutes. OPALA cream was applied twice daily for 5 days and no other treatments were used. The speed of change to the burn area was described as gradual over hours or days. The participant noted that skin in the burn area did not become dry or hardened and healing was complete in one week which was faster than she expected. She reported no side effects of the treatment and considered the OPALA product to be helpful.

### **Case Report: ID 02**

#### **Incident**

In 2006 this 43 year old female sustained a burn to two fingertips on her right hand when she touched a roasting pan while removing toast from the oven. The burn was mild in severity and the level of pain was also described as mild (rated as 5-6/10). OPAL001 cream was applied to the burn immediately.

#### **Outcome**

Application caused stinging which lasted about five minutes. Immediately following application of OPAL001, pain decreased to 3/10 and it was noted that pain was reduced by continued rubbing of the cream into the burn area. OPAL001 was reapplied after five minutes and pain rated as 0-1/10. The burned skin initially went white but did not progress to blistering as the participant expected and the speed of change to the burn area was described as occurring over minutes. No other treatments were used and healing was complete in four days which was faster than the participant expected. She reported no side effects of the treatment and considered the OPAL001 product to be helpful. This participant referred to OPAL001 cream as the "miracle" cream and noted that the product used was over four years old.

# OPAL Products

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### **Case Report: ID 03**

#### **Incident**

In 2005 this 44 year old male sustained a burn when hot oil splashed onto the fingers and palm of one hand as he was cleaning a BBQ plate. The burn was severe and the level of pain was described as extreme. OPALA cream was applied to the burn after approximately 20 minutes (5-30 minutes).

#### **Outcome**

Immediately following application of OPALA the pain was described as mild and within minutes the pain was gone. The erythema surrounding the blisters faded within two hours and the blisters went white. Pain relief was reported to occur gradually over minutes (different from this participant's previous experience of burns). He applied OPALA cream a second time within an hour of the burn and noted that the colour of the burned skin changed after each application. No other treatments were used, the blisters became smaller and the burn was healed in four days which was faster than the participant expected. He reported no side effects of the treatment and considered the OPALA product to be helpful. This participant used OPALA cream on several occasions to treat burns caused by welding, open flame, stovetop and dry ice. In each case there was rapid and lasting pain relief. He noted that for pain relief took longer to occur with the dry ice burn (three hours).

### **Case Report: ID 04**

#### **Incident**

In 2003 this 56 year old female sustained a burn to the middle two fingers of her right hand when she accidentally dipped them into hot cooking oil. The burn was moderate in severity and the level of pain was also described as moderate. OPALA cream was applied to the burn within five minutes.

#### **Outcome**

Immediately following application of OPALA the pain was described as mild and blistering which had begun did not develop further. Erythema and swelling resolved very quickly and complete healing was reported after four to five hours which was faster than she had expected. OPALA was applied the cream to the burn area only once. The participant reported no side effects of the treatment and considered the OPALA product to be helpful. This participant was an employee of Phoenix Eagle but had not previously used OPAL products.

# OPAL Products

## Case Reports – Burns Treatment

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### **Case Report: ID 05**

#### **Incident**

This male participant sustained a burn to the inside of one arm and hand while cooking. The burn was severe and the level of pain was described as extreme. OPALA cream was applied to the burn within five minutes.

#### **Outcome**

Following application of OPALA there was immediate relief of pain which was then described as mild. Pain relief was reported to occur gradually over minutes (different from this participant's previous experience of burns) and OPALA was applied repeatedly every hour for three to five hours and then at one later time. No other treatments were used and there were no side effects of the treatment. The participant considered the OPALA product to be helpful.

### **Case Report: ID 06**

#### **Incident**

This female participant sustained a burn to the fingers of one hand covering an area of 1 cm<sup>2</sup> on the little finger and 2-3 cm<sup>2</sup> on the other fingers. The burn was severe and the level of pain was described as extreme. The participant initially applied ice to the burn for 20 minutes and then OPAL001 filtrate was applied about 30 minutes after the burn occurred.

#### **Outcome**

Immediately following application of OPAL001 there was no change to the level of pain which remained severe. The pain gradually diminished over two days (different from this participant's previous experience of burns) and OPAL001 was used daily after the first application. Skin of blistered areas appeared to reattach to subcutaneous tissue and healing was described as more rapid than expected. She reported no side effects of the treatment and considered the OPALA product to be helpful.

# OPAL Products

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### **Case Report: ID 07**

#### **Incident**

In July 2007, this 59 year old female sustained a steam burn to the inner aspect of her right forearm while using a rice cooker. The burn was moderate in severity and the level of pain was described as moderate. OPAL001 cream was applied to the burn within five minutes.

#### **Outcome**

While the outline of the area could still be seen, no blistering occurred and the participant experienced immediate relief of pain following the initial application of OPAL001. She reapplied the OPAL001 cream daily and reported completed healing after 12 days despite having injured the area by scraping it on a metal object two days after the burn occurred. No other treatments were used and healing was faster than the participant expected. She reported no side effects of the treatment and considered the OPALA product to be helpful.

### **Case Report: ID 08**

#### **Incident**

In October 2009, this 53 year old male sustained a burn when he lifted a very hot, heavy cast iron frying pan so that all the weight and heat was concentrated at the base of the right index finger. The burn was described as moderate in severity and the pain as intense. The burn area was immediately placed under cold running water for a couple of minutes prior to the application of OPAL (as Optiderma gel formulation) to the area.

#### **Outcome**

The burn area remained painful and stung more immediately following application of the OPAL gel and this lasted for approximately 15 minutes. The pain then subsided and OPAL was reapplied twice daily for the next three days. The burn area was initially erythematous and on the second day the epidermis in the burn area was white but no blister formed. This whitened skin was removed and the skin underneath appeared normal. The burn healed more quickly than expected, in approximately three days, without scarring. He reported the stinging as a side effect of the treatment and considered the OPAL product to be helpful.

# OPAL Products

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### **Case Report: ID 09**

#### **Incident**

In 2009, this 46 year old female sustained an oil burn to the hand while cooking. The burn and the degree of pain were both described as moderate. OPAL (as Optiderma gel formulation) was applied to the burn immediately.

#### **Outcome**

The burn area remained painful and stung more immediately following application of the OPAL gel and after 30 minutes she washed the gel away. The pain was gone after 30 minutes to 2 hours and the burn did not develop into a blister. After healing there is no visible scarring or any sign of the burn having been present. The burn healed more quickly than expected. She reported the stinging as a side effect of the treatment and considered the OPAL gel to be helpful.

### **Case Report: ID 10**

#### **Incident**

In December 2009, this 58 year old female sustained a burn to the inner aspect of her left forearm approximately 4 cm in length after leaning on a heated towel rail. It was a mild burn and the pain was mild however it was apparent that a blister was beginning to form almost immediately. OPALA cream (refrigerated) was applied to the burn within five minutes.

#### **Outcome**

It took approximately 15 minutes for the pain to subside and it was gone completely by 30 minutes. She reapplied the cream twice more on the day of the incident and once the following day. Although the erythema remained for a few days the blister never developed. The participant's watchband rubbed one end of the burn site however complete healing was achieved in approximately three weeks. There was no skin breakdown and no scarring. Notably, there was also no increased pigmentation at the burn site which had been the participant's previous experience following burns. She reported no side effects of the treatment and considered the OPALA product to be helpful.



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### **Case Report: ID 11**

#### **Incident**

On 13 January 2010, this 85 year old female sustained a burn to the inner aspect of her forearm while reaching into a hot oven. The oven shelf caused a linear burn approximately 8 cm in length. The burn was described as moderate and the degree of pain as severe. OPALA cream was applied immediately, directly from the refrigerator.

#### **Outcome**

The participant experienced immediate relief of pain following application of the cream. The expected blistering did not occur and she did not reapply the cream. No other treatment was used. After two days there remained a faint pink mark, healing proceeded faster than expected and was complete in seven days. She reported no side effects of the treatment and considered the OPALA product to be helpful.

# OPAL Products

## Case Reports – Burns Treatment

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### **OPAL 001 self testing demonstration**

The inventor of OPAL products has repeatedly conducted demonstrations by immersing two of his fingertips (index and middle) into hot cooking oil at greater than 160°C. He delays for about two minutes following withdrawal of the fingers from the oil prior to immersion of the index finger into OPAL001 filtrate at approximately 20°C. The middle finger remains untreated. This has been recorded on video, showing the treated finger recovering rapidly while expected tissue damage (redness and blistering) occurs in the untreated finger. Pain relief in the treated finger is reported to be almost immediate while the untreated finger is described as being extremely painful.

This demonstration was observed by a medical practitioner who repeated the process with himself as the subject. He placed the tip of his left index finger into hot cooking oil (approximately 160°C) for two consecutive intervals. The pain this caused was described as intense. There was a delay of five minutes prior to immersing the finger in OPAL001 filtrate at approximately 16°C. He described an immediate cooling sensation and reduced pain after thirty seconds. He was pain free and no evidence of tissue damage was observed one minute after immersion in the OPAL filtrate. After 24 hours there was no sign of tissue damage when the finger was examined by another independent medical practitioner<sup>^</sup>.

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<sup>^</sup>Geoffrey Mitchell, Professor of Primary Care Research, University of Queensland School of Medicine.