

Flaminal; A Clinical Trial to assess the efficacy of use in Partial Thickness Burns.



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Introduction

Flaminal was originally developed to manage bio-burden and promote wound healing in chronic wounds. It was found to use a complex of enzymes to destroy the bacterial cell wall whilst not damaging healthy tissue. The RNSH experience with chronic wound healing found Flaminal was able to make a positive impact on wound progression and healing times.

These studies led the team to investigate the use of this product to manage Partial Thickness Burn injuries, considering that the product reduced bio-burden whilst not interfering with the Healing Wound.

Prior Flaminal



16 days after Flaminal



Chronic Wound Healing – Previously treated with Silver products – 16 days post Flaminal dressing regime. Patient with CRF with Calciflax

Method

Patients were invited to participate in the study at the 48hr mark post burn injury, once it was determined by clinical assessment that the patient had a Partial Thickness Burn wound as characterised by blistering, pink denuded skin, and rapid capillary return over the burn area. All patients agreeing to participate signed a consent form and were given education regarding the product by the Burns/Plastics CNC.

Once patients were enrolled they were dressed with a thick layer of Flaminal (+2mm) to the entire burn surface area. The area was then sealed with a single layer of paraffin gauze (Jelonet). The secondary dressing would consist of soft padding (Webriil) and either a retentive stocking or crepe.

The dressing would be changed 3 times a week until the burn wound was healed or the product deemed no longer appropriate for use on that particular burn patient.

Burn wound re-epithelialisation (healing) was determined by clinical review of the patient by the Burn CNC and at least one other senior burn clinician, usually the Burns/Plastics Registrar or Burns Fellow.

All information was maintained on a simple evaluation sheet. See below;

Flaminal Trial Questionnaire:

Type of wound:

Previous Wound regimes:

Appearance of Wound:

Photos taken:

Date Flaminal commenced:

Date Flaminal ceased:

Rationale for ceasing product:

Report on wound progress:

Aim

The aim of this study was to investigate Flaminal as a viable alternative in the management of Partial Thickness Burns.

Many dressings including silver applications, hydrofibers, and hydrocolloids are used in the management of Partial Thickness Burns, all will assist in the wound healing process. The idea of this study was to assess whether Flaminal could provide comparable outcomes in terms of wound re-epithelialisation, pain reduction, and number of dressing changes.

Results

Flaminal has so far been trialled on 8 burn patients. The age range was 2 years to 58 years. The range of Partial Thickness burn size was 2% to 15% TBSA (mean 5.5%). In 7 out of 8 patients entered into the trial, wound re-epithelialisation (healing) was achieved in 7 to 11 days with a mean of 8.6 days. The one patient who did not meet this criteria was shown to have a deeper dermal injury and was withdrawn from the trial.

The patient withdrawn from the trial was grafted. The application of Flaminal pre-operatively did not adversely affect graft outcome or bio-burden in the wound per se.

All patients reported a dramatic reduction in pain whilst the dressing was in-situ, this included the patient who was treated with Flaminal prior to grafting. We used the Numerical Rating Scale to measure pain intensity. All 8 patients reported pain scores of 7 to 9 (mean 7.7) the 2 patients who were 2 & 3 years of age were assessed using the Numerical Faces Rating Scale. Once Flaminal had been applied, the patients rating of pain intensity decreased significantly with pain scores of 2 to 3 (mean 2.4).

All patients found the product comfortable whilst in-situ. Staff applying the product found it slightly more labour intensive than other standard therapies. This was mainly in relation to ensuring even application of the product whilst ensuring recommended thickness. The product was easy to remove, although it did leave a gel like residue at the wound interface – this was easily removed with gauze and caused no harm to the wound surface. On average more dressings were required to achieve wound healing 2 to 4 (mean 3) when compared to silver based regimes where wound healing can be achieved with 1 to 3 dressing changes (mean 2.1).

Discussion

The initial results from using Flaminal for this short trial have been encouraging. The major revelation was the effect the product had on patients pain intensity. Several examples emerged that not only reduced a patient's pain but their length of stay. One in particular a 14y.o. boy with Partial Thickness leg burns was unable to walk because of pain, after the application of Flaminal and encouragement of Physiotherapy the patient left hospital 48hrs later fully ambulant and with little to no pain.

Flaminal was found to be slightly more labour intensive than other burn dressings. This was mainly due to users not being conversant with the application of the Flaminal gel at a thickness the company recommends. This issue would be easily overcome with user experience and further training.

In all cases the outcome of wound re-epithelialisation occurred in acceptable timeframes as compared with traditional burn dressings. There was no evidence of delayed wound healing as a result of using Flaminal on a Burn wound. This was also the case for all the Chronic non-burn wounds the product has been previously trialled on.

Recommendations

- That further clinical trials on a greater scale are undertaken to substantiate these initial findings.
- Aspen Medical finalize a pricing policy in order that Cost Benefit Analysis can be undertaken in comparison with other market products.
- The analgesic effects of Flaminal be further investigated.
- Flaminal be considered as an adjunct analgesic in painful partial thickness burns if further investigations report the same analgesic effect.
- That Flaminal be added to the formulary of products available for Partial Thickness burns if further investigations substantiate initial findings.

Acknowledgements

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- Aspen Pharmicare for providing the Flaminal required to undertake this initial trial.



Right lower leg Partial Thickness burn, Healed with Flaminal in 11 days.