EVALUATION OF SKINLINK™, AN EFFECTIVE NEW APPROACH TO THE CLOSURE OF CUTS AND LACERATIONS.

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SkinLink™ is manufactured and distributed in the UK by Medlogic Global Ltd.

Introduction

Fast and efficient wound closure is a major concern for emergency healthcare personnel, especially as cuts and lacerations are frequent reasons for consultation to the Emergency Room (ER). A number of approaches can be used to close these common wounds; however, the current trend is to use non-invasive methods that are less painful and less traumatic than conventional sutures. Nowadays, closure strips and surgical glues are in popular use, but both methods have their limitations. Closure strips have limited long term adhesion and glues are more suitable for very short wounds having little tension.

SkinLink™ Anchored Skin Closures (**SkinLink™**, Biogentis/Medlogic Global Ltd in the UK) is a non-invasive and painless method of skin closure, which combines the advantages of both closure strips and surgical glues, without their disadvantages. **SkinLink™** is quick and easy to apply, needs no anesthesia, is water-resistant and provides
good cosmetic outcome. **SkinLink™** is the only skin closure innovation developed in the last three decades and is now commercially available in Canada and the UK and will soon be launched in the USA.

Note: UK Packaging is different to that shown above.

Objective

- To evaluate the efficacy of **SkinLink™** in closing cuts and lacerations.
- To assess physician and patient satisfaction with **SkinLink™** as a method of wound closure.
- To evaluate the level of pain upon wound closure.
- To evaluate adverse reaction within one month.

Patients Inclusion Criteria

- Traumatic wound in the head and neck region (12 hours duration) or elsewhere (6 hours duration).
- Laceration normally requiring sutures of 4-0 or less.
- Minimum age : 3 months.
- Legal consent from patient or legal guardian.

Exclusion criteria

- Contaminated or infected wound.
- Crush injury.
- Laceration.
- Laceration with loss of tissue or surrounding abrasion.
- Puncture wound or bite.
- Contamination in or around wound after cleaning (e.g. grease).
- Laceration in selected sites :
- Areas of high hair density (e.g. scalp)
- Genital or perineal area
- Mucous membranes
- Active dermatological disease in the area of the wound
- Potential lack of availability for follow-up
- Regular sport activities during the period of treatment

Methods

- Case analysis of 30 patients admitted to the emergency ward and/ or medical clinic settings.
- Upon admission, wounds were cleansed using standard clinical methods.
- **SkinLink™** was applied according to the package insert. If necessary, wounds were closed with deep dermal sutures prior to skin closure with **SkinLink™**
- Photographs of the wound were taken at presentation, after closure with **SkinLink™**, and at follow-up after 10 days and 1 month.

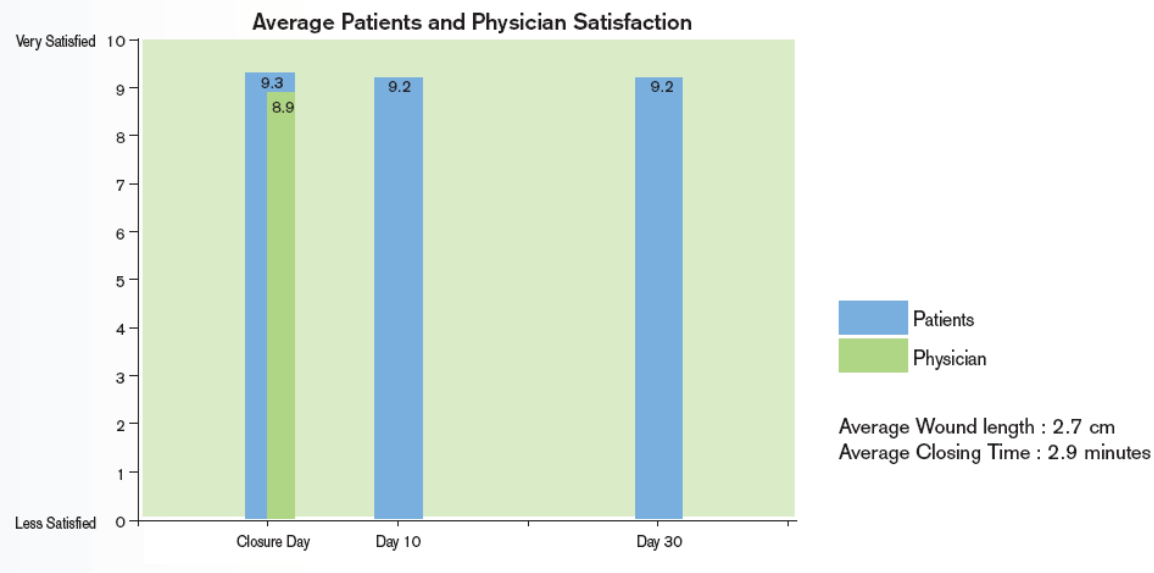
- Patient and physician satisfaction with this new method of closure were documented using visual analog scales at closure time and also at each follow-up for patients.

Visual Analog Scales

- Scales consist of 10 cm lines, scoring for satisfaction and pain. The left terminus of the line represents “very unsatisfied” or “unbearable pain”, the right terminus represents “very satisfied” or “no pain.” For young children, the left and right ends of the pain scale were illustrated with a sad and happy face, respectively. Patients were asked only to fill out the pain scale at the time of application. Parents were asked to provide answers for very young children.
- Upon wound closure and at follow-up time points, patients and physicians were asked to score their level of satisfaction with the SkinLink treatment by placing an “X” along the line at the appropriate place.

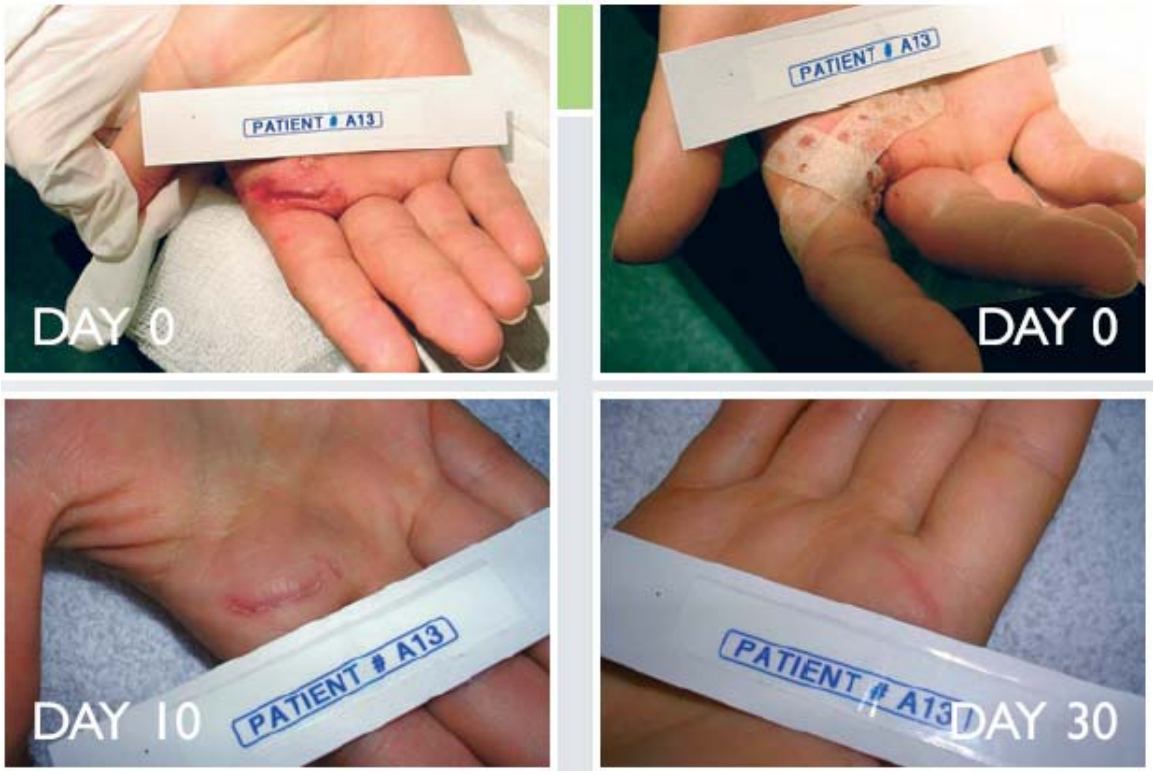
Results

- Preliminary results are reported here on 24 patients; study is ongoing.
- Distribution of wounds are : Head and neck 13, Superior limbs 7, Inferior limbs 3 and Trunk 1.
- The average length of wounds treated with **SkinLink™** was 2.7 cm.
- The average skin closure time with **SkinLink™** was 2.9 minutes (compared to 13 minutes for stiches, as reported in the medical literature.)
- On a scale of 1 to 10, initial patient satisfaction with the SkinLink™ method of wound closure was 9.3, while physician satisfaction was 8.9.
- At 10 days follow-up, overall patient satisfaction was 9.2
- At one-month follow-up, overall patient satisfaction was 9.2



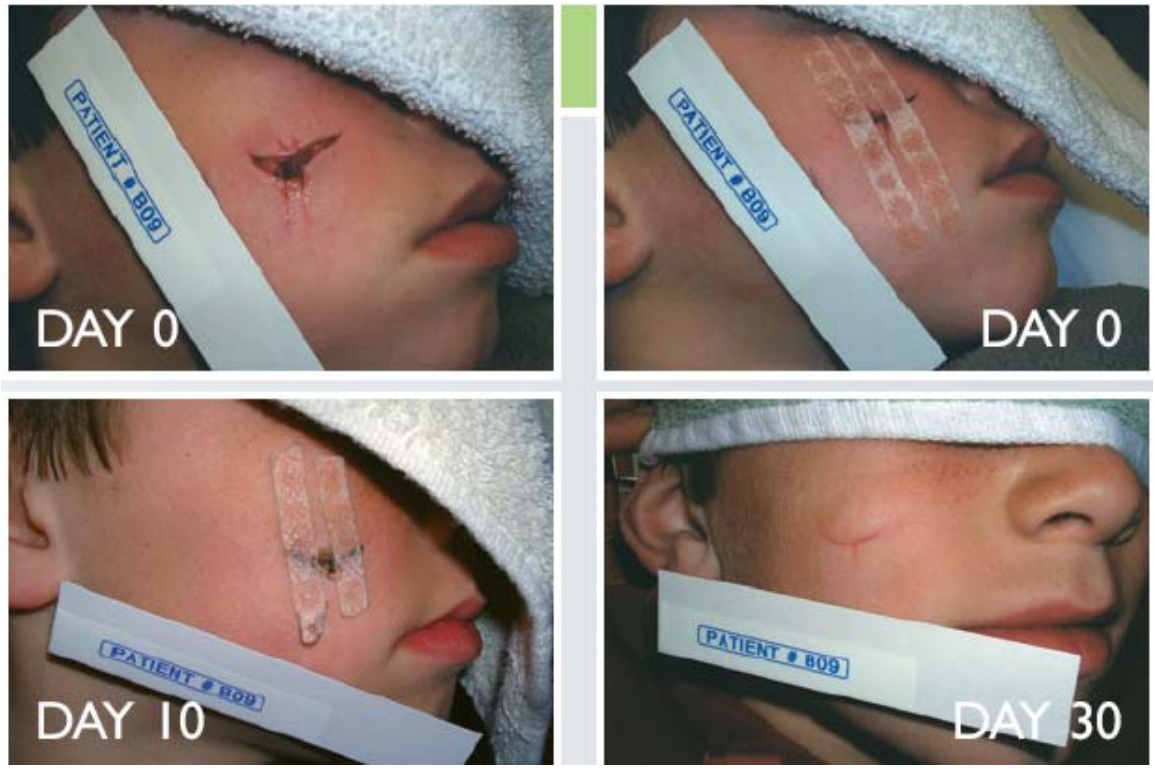
Patient A13

- Woman, 30 years old
- Laceration right hand at the second metacarpal due to broken glass
- Irrigation required, no anesthesia
- Wound 3 cm long
- Closure time 5 minutes
- Patient did not want sutures (fear of needles), extremely satisfied.



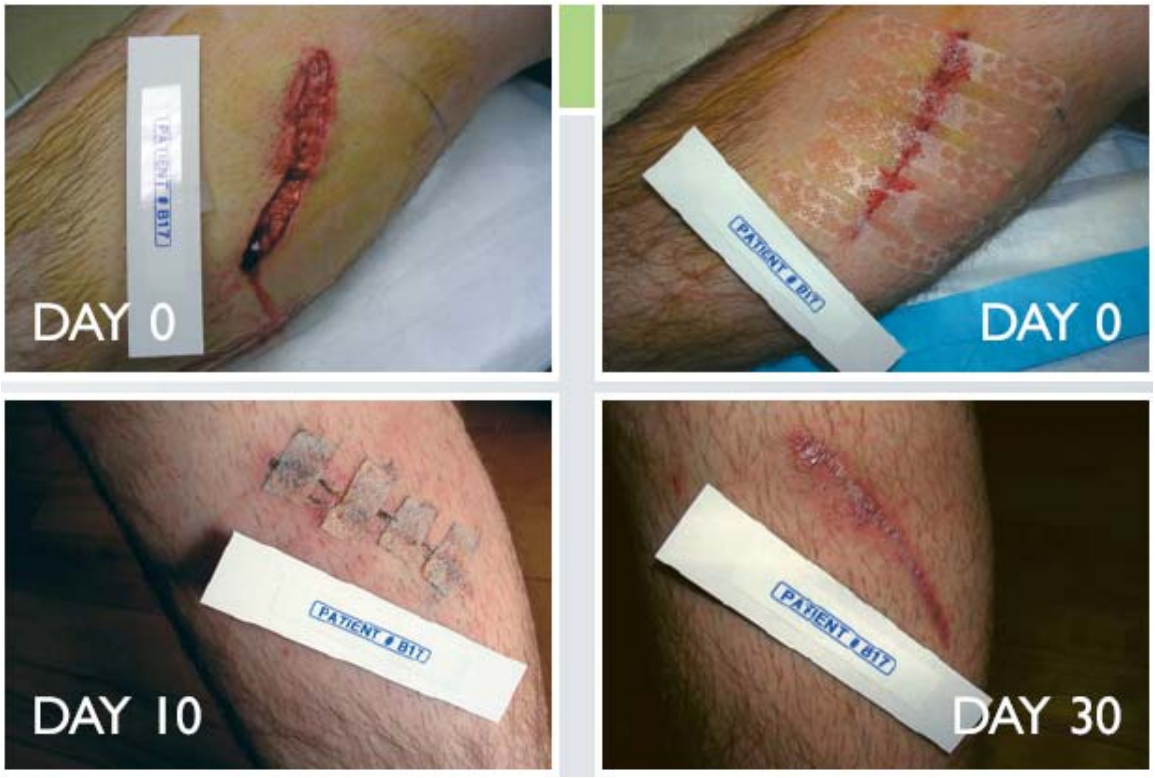
Patient B09

- Male child, 6 years old
- Shallow elliptic laceration to right cheek due to ice skate
- No anesthesia nor irrigation
- Wound 2.4 cm long
- Closure time 3 minutes
- Patient/parents skeptic of procedure, extremely happy with final result.



Patient B17

- Male 15 years old
- Deep laceration to right leg due to glass; required deep dermal sutures
- Anesthesia for deep sutures required, not skin, irrigation required
- Wound 7.7 cm long
- Closure time 5 minutes
- Patient thought this was “cool”.



Patient B18

- Woman, 88 years old
- Fell on right elbow; paper thin skin
- No anesthesia or irrigation
- Wound 3.8 cm long
- Closure time 3 minutes
- Patient really satisfied with result.