PGY-2

**Critical Review Form**

**Therapy**

[Gimbel NS, Kapetansky DI, Weissman F, Pinkus HK. A study of epithelization in blistered burns. AMA Arch Surg. 1957;74(5):800-803.](http://pmid.us/13410367)

**Objective: “To discover such differences in epithelization as may depend upon whether the blisters are aspirated, unroofed, or allowed to remain intact.” (p 800)**

**Methods: An unspecified number of medical students (presumably volunteers) had controlled burns made in a horizontal row below their umbilicus after lidocaine anesthesia. The investigators used a heated copper wire to produce 12-16 small burns in a horizontal row. In the first two experiments each subject received 6 burns with 20-seconds contact at 62º C and another 6 with 45-seconds contact. Then two burns were left intact for the duration, two were aspirated (at what point-in-time?), and two were unroofed at 24 hours. Half of the wounds of each type were biopsied on day 5 and the other half on day 14. In the third and last experiment, subjects had 16 burns at 61º C with six left intact for the duration, five unroofed at 24 hours, and another five unroofed at 48 hours. Half the wounds of each type were biopsied on day 5 and the other half on day 8. No primary or secondary outcomes are stated,** [**power calculation**](http://pmid.us/8015121) **proposed, or statistical analysis plan described.**

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| **Critical Review Form: Therapy** | |
| Guide | Comments |
| **Are the results valid?** | |
| **Did experimental and control groups being the study with a similar prognosis?** | |
| Were patients randomized? | No randomization occurred. |
| Was allocation concealed? Was it possible to subvert the randomization to ensure a patient would be “randomized” to a particular group? | Yes, since patients were not randomized and were aware of the duration of burn injury applied. |
| Were patients analyzed in the groups to which they were randomized? | Yes. |
| Were patients in the treatment and control groups similar with respect to known prognostic factors? | No treatment or control groups. |
| **Did experimental and control groups retain a similar prognosis after the study started?** | |
| Were patients aware of group allocation? | Yes, since no randomization or blinding. |
| Were clinicians aware of group allocation? | No clinicians involved in this experimental design. |
| Were outcome assessors aware of group allocation? | Yes, the investigators were presumably the outcome assessors. |
| Was follow-up complete? | No lost to follow-up reported. |
| **What are the results?** | |
| How large was the treatment effect? | * Intact blisters were larger than aspirated or unroofed blisters on average, but this was not statistically significant. * Intact blisters in the 20-second and 45-second burn all healed completely at 14 days. Neither aspirated nor unroofed blisters consistently healed at 14 days. * The biopsy specimens indicate a relatively thicker epithelium at the wound periphery which becomes less prominent over the 14-days of wound healing. |
| How precise was the estimate of the treatment effect? (i.e. what 95% CIs were associated with the results?) | No [confidence intervals](https://www.cmaj.ca/content/171/6/611.long) are presented. |
| **How can I apply the results to patient care?** | |
| Were the study patients similar to my patient? | No, because they are presumably young and healthy without immunocompromising disorders. And the burns were controlled. |
| Were all clinically important outcomes considered? | No. Assessments of pain control and infection rates would also be important, as well as patient satisfaction with wound appearance. |
| Are the likely treatment benefits worth the potential harm and costs? | Uncertain based on this study because of the artificial experiment design, lack of randomization or control, inadequate contemplation of outcomes, and uncertain patient demographics. |

**Limitations:**

1. **Non-randomized, artificial experimental design so** [**multiple biases**](http://pmid.us/447779) **possible and therefore only hypothesis generating.**
2. **No demographics of the student subjects (and uncertain consent or IRB approval) which could hide variables that confound wound healing (immunocompromised status) and limit** [**external validity**](http://pmid.us/15639683)**.**
3. **No description of** [**who assessed “healing”**](http://pmid.us/17332104) **using what criteria.**
4. **No** [**sample size**](http://pmid.us/12954688) **assumptions so potentially** [**under-powered**](http://pmid.us/12117401)**.**
5. **No** [**statistical analysis**](http://pmid.us/18175191) **plan.**
6. **Important outcomes neglected (wound healing, pain control, infection rates).**

**Bottom Line:**

**Minor burn blisters occur as the epidermis separates from the dermis. Most minor burn blisters resolve spontaneously within 12-days as atmospheric water loss exceeds dermal fluid diffusion as epithelium regenerates between the healing dermis and epidermis. This 63-year-old study provides histological evidence of epidermal healing and hypothesis-generating proof that neither aspiration nor unroofing of burn blisters is preferred to leaving the blister intact.**