Please note: These studies may involve findings that exceed the claims currently cleared by the FDA for the product. Bravida Medical is not intending to make performance claims about its product. The intent is to disseminate the scientific literature on these products. We encourage you to read these studies to understand the strengths and limitations of the data. For some claims, Bravida is seeking to broaden the indications with the FDA in the future using data, such as these studies, to provide the substantiation.



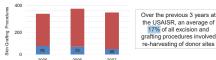
### Comparison of SilverIon<sup>®</sup> Dressing to Xeroform<sup>™</sup> Gauze in the Treatment of Skin Graft Donor Site Wounds



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## Introduction

Availability of autogenous skin is central in management of burn wounds. Larger burns require frequent re-harvesting of donor autograft to achieve complete wound coverage.



- Xeroform gauze (Tyco Healthcare Group, Mansfield, MA) is the standard skin graft donor site dressing at many burn centers although many products have been proposed as an improvement on this basic method.
- Silverlon (Argentum, Willowbrook, IL) is a silver impregnated wound dressing which is widely used in the treatment of partial thickness burns. We hypothesized that Silverlon would improve wound healing and decrease pain when compared to Xeroform.

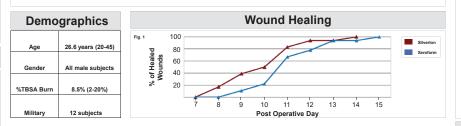
### Methods

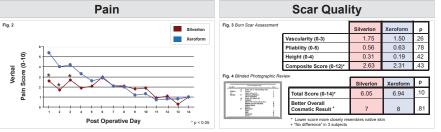
- We conducted a prospective, randomized, patient controlled study comparing the rate of re-epithelielization, pain, and cost of donor site wounds treated with Xeroform or Silverlon.
- From December 2005 March 2007, all patients admitted to the USAISR Burn Unit were screened for enrollment.
- Exclusion Criteria
- 1. Age < 18 years 2. TBSA > 30% burn
- Critical illness requiring mechanical ventilation or vasoactive medications
- Premorbid major medical problems or medications affecting wound healing
- 5. Unavailability of two anterior, symmetrically located donor sites, not previously harvested
- 6. Inability of subject to consent
- 7. Pregnancy
- Eligible patients had symmetrically paired donor sites harvested by the same surgeon using a standardized technique.
- Subjects received both the control (Xeroform) and study (SilverIon) dressings, randomized to each donor site.
- > Wounds were assessed daily for healing, pain, and inflammation.
- Additional data was collected on cost and nursing time, outpatient scar quality, and cosmetic appearance by blinded comparison of digital photographs.
- Wilcoxon Signed-Rank Test or Paired T Test were used to measure differences for each endpoint in the two groups.

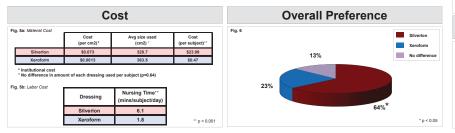
# Results

#### > Eighteen subjects completed the study.

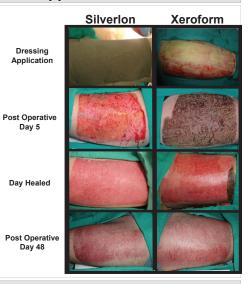
- The average time to wound healing was decreased with Silverlon, 10.2 ± 1.63 days (mean ± SD) compared to Xeroform, 11.4 ± 1.57 days (p<0.05). (Fig. 1)</p>
- Pain scores were significantly lower on the Silverlon side on post operative days 1-3 (Fig. 2) Overall pain scores were significantly lower with Silverlon (2.04) compared to Xeroform (2.66) as well (p<0.05).
- There were no differences with inflammation indices or infection rates between the two dressings. At the time of outpatient follow-up (mean post operative day 48), scar quality was similar as determined by Burn Scar Assessment Score (Fig. 3) and by an independent and blinded reviewer (Fig. 4).
- Material and labor costs were higher for the Silverlon dressing. (Fig. 5)
- > Subjects preferred the Silverlon dressing or had no preference of one dressing over the other 77% of the time.







### Appearance of Wound



## Conclusion

- Split thickness donor site wounds treated with Silverlon healed significantly faster than those treated with Xeroform, albeit at greater monetary costs.
- Silverlon also provided better initial post operative and overall analgesia with respect to donor site pain. Subjects preferred the Silverlon dressing the majority of the time.
- Because of the frequency of serial excision and grafting procedures in large burns and necessity of rapid donor site healing while minimizing discomfort to the patient, Silverlon appears to be a superior dressing compared to Xeroform in achieving these goals.

## References

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