A Comparison of Two Antimicrobial Dressings

A Randomized Prospective Trial Comparing PVA Foam with Two Organic Pigments to a Silver Based Wound Dressing

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Pioneering Advancements in PVA Technology

Method: A randomized prospective clinical trial of patients with lower extremity wounds.

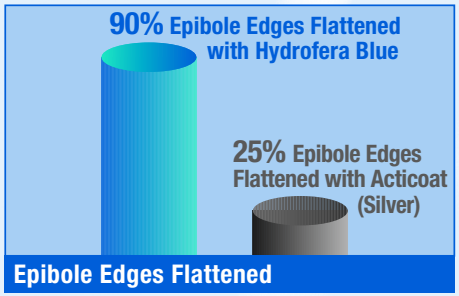
Patient Demographic: 40 patients with lower extremity wounds: 20 placed on Hydrofera Blue, 20 placed on Acticoat (either Burn Dressing or Absorbent).

Results: The PVA foam had average days to healing of 67 days while the Silver dressing had average days to healing of 75 days. The PVA foam had an 88% pain reduction within the first 72 hours and the Silver dressing had a 40% pain reduction in the first 72 hours. The edges flattened in 90% of the patients on the PVA foam and in only 25% of the patients on the Silver dressing. Both products were equally effective in reducing the bioload. There was edema reduction (without the use of compression) in 80% of the PVA foam and 60% with the silver dressing. There was no maceration of the surrounding tissue with the PVA foam and 30% of the patients using the silver dressing had surrounding tissue maceration. The cost of the PVA foam with the two organic pigments is roughly $6.60 per 4x4 sheet and the Silver dressings for a 4"x4" dressing are $15.00 to $30.00 depending on the absorbency.

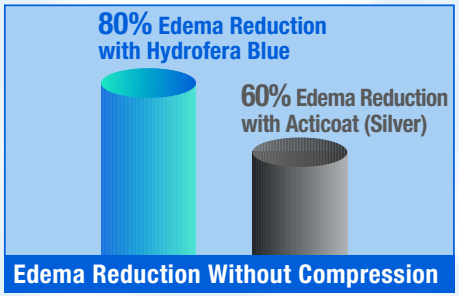
Conclusion: If you are looking at days to healing only, both products will work, however if any of the concurrent issues stated above are of concern the PVA foam with the two organic pigments provided a better outcome.

85 yr. old female. Wound for 1 yr. prior to participating in study. Seen by 6 surgeons and tried multiple treatments to heal wound unsuccessfully. **Began Hydrofera Blue 11/15/04. Healed 1/20/05. Total Healing time: 9.5 Wks.**

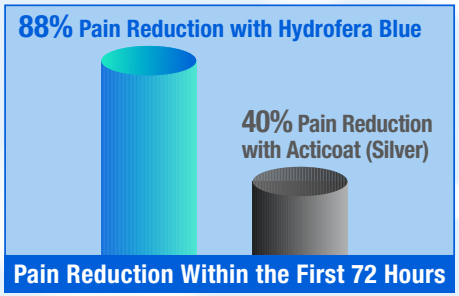
35 yr. old Male. Traumatic injury motorcycle accident left an open wound for three yrs. Due to severity of pain associated with wound patient opted for amputation. Amputation opened up and created another wound. **Began using Hydrofera Blue 9/10/04. Healed 10/22/04. Total Healing Time: 6 wks.**



Graph reflects the percentage of Epibole edges that flattened within the first 2 weeks of use without compression.

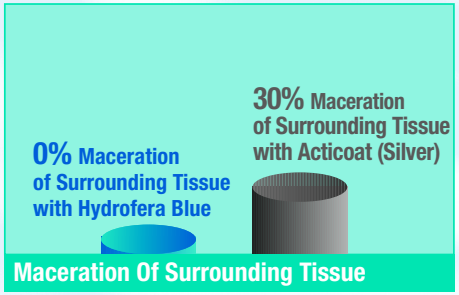


Graph reflects the percentage of edema reduction within the first 2 weeks without the use of compression.

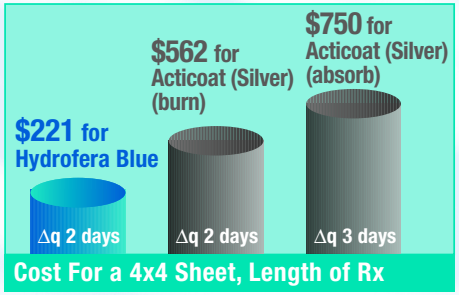


Graph reflects average pain reduction among the total number of patients. Study utilized the numeric pain scale from 0 to 10.

Graph reflects the average days to healing among study participants in each category.



Graph depicts the maceration of surrounding tissue secondary to drainage throughout the course of treatment.



Graph reflects the cost for a 4" x 4" sheet of product for duration of treatment. On average Hydrofera Blue cost 60-71% less than Acticoat. It should also be noted that Hydrofera Blue is reimbursed by Medicare and Medicaid.

Polymer Matrix Composition

Hydrofera Blue™

{ PVA sponge } + { Methylene Blue and Gentian Violet }

A Simple, Safe, and Effective Moist Wound Dressing, to take on the most Difficult Wounds

Study Criteria

The primary goal of the study was to document (in a controlled fashion with clearly defined documentation) the effectiveness of Hydrofera Blue as compared to that of a silver dressing. Each subject should be afflicted with a lower extremity wound that requires ongoing treatment. Noted shall be: number of wounds, size, depth, location, pain level as noted using the numeric pain scale) and inflammation.

Inclusion Criteria:
Each subject should be afflicted with a lower extremity wound that requires ongoing treatment.

Exclusion Criteria:
Any medical condition that should confuse the results of the study such as poor nutritional status.

Study Criteria

1) Pain Reduction
2) Days to Healing
3) Cost
4) Epibole Edges
5) Edema Reduction
6) Maceration
7) Infection Control