Xennovate Medical
Innovation to Reality™

TECHNICAL BRIEF

August 2008

TECHNICAL BRIEF: ABSORPTION STUDY OF COMPETITIVE HYDROCOLLOID FORMULATIONS

Using Xennovate's standard test protocols for absorption and adhesion, the three standard formulations available were analyzed in the lab and the data summarized below.

August 2ØØ8

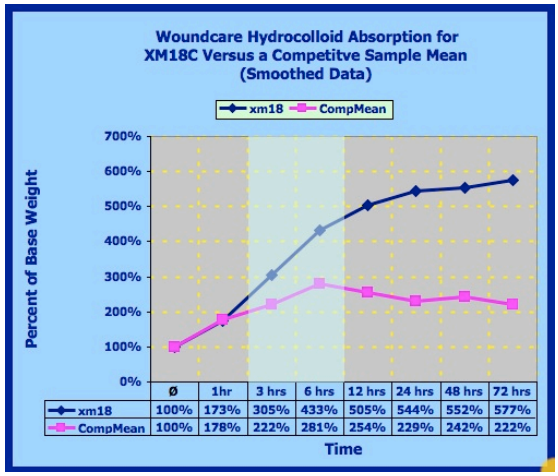
Preface

Several analytical studies were undertaken by Xennovate Medical LLC in early 2006 to validate the wound dressing application advantages the Company believes its xm18 has over key competitors in the moist wound healing hydrocolloid skin barrier market segment. This report explains the studies and validates the occlusive, moisture absorption advantages held by Xennovate Medical's xm18 formulation versus the competitors studied. Our premise is that long lasting, or continual, absorption is a good thing for the EndUser's skin, and our formula was created with this in mind. As our objective was to highlight xm18 and not to denigrate the competition, we have chosen to blind the competitive brands for this publication by coding them with a key held internally. Separately, then, we have aggregated all of the competitive samples and created a mean value ("CompMean") for all the competitive samples to compare to our xm18. Our success can be seen in the chart nearby comparing the performance of xm18 directly to a competitive aggregate ("CompMean") of the studied samples. The disaggregated competitive data can be found on page two.

Study Results

The most meaningful comparisons are made against the collective competitive averages ("CompMean"); see data and charts nearby. From the data representing the percent by weight absorbed, we can see that the y35 sample exceeds xm18's absorptive capacity in the first 12 hours, but begins falling shortly thereafter; this is not practical in the clinical setting.

The key word here is* falling*, because that performance clearly represents a breakdown in

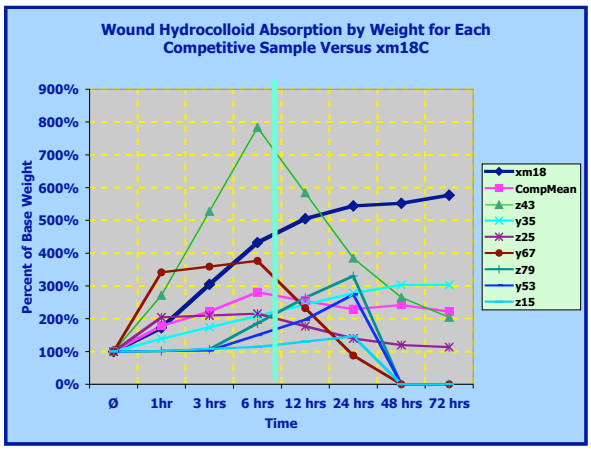


	Ø	1hr	3 hrs	6 hrs	12 hrs	24 hrs	48 hrs	72 hrs
xm18	100%	173%	305%	433%	505%	544%	552%	577%
CompMean	100%	178%	222%	281%	254%	229%	242%	222%

the sample. Breakdown means that absorbent components of the hydrocolloid are dissolving and are potentially retained in the wound. From the medical literature, we know that histologic evaluations of apparently healed wounds in humans and animals have indicated deep-seated foreign body reactions and granulomata formations[2,3] even when using Duoderm CGF (Convatec) and Restore (Hollister), Hollister's Restore being the worst in the Chakravarthy study; their compounds demonstrated a definite delay in wound closure.[1] [These are direct references found in the footed articles]

Virtually every sample other than xm18, except z15, reaches a peak and then begins falling within the 72-hour period under observation. Of course, z15 has totally disintegrated within 24

hours (as have three other samples), so it is not a real exception, after all.



Study Conclusion

As you will find upon review of the data and results, Xennovate Medical's xm18 wins this competitive comparison hands down. At the end of 72 hours, with the samples totally submersed in saline solution, only xm18 has not dissolved and, in fact, continues absorbing; its absorptive uptake at 72-hours is twice the next closest competitive sample. All but one of the competitive samples has broken down completely, thereby running the risk of absorption by the wound of harmful hydrocolloid components, which "… may cause deep-seated, unresolved

Samples utilized for this study included...

- ✓ Bertek's Hydrocol®
- ✓ Convatec's DuoDerm Signal®
- ✓ CVS & Meijer (Private branded OTC outlets)
- ✓ Dr. Scholl's Spenco®
- ✓ Dumex' Primacol®
- ✓ Euromed's Sure Skin® II
- ✓ Hollister's Restore® CX

Procedure for Hyrdocolloid Wound Dressing Absorption Study

A test sample of each hydrocolloid under study was created. The samples were all two inches by two inches. Their thickness was a function of what the respective companies market, so you will find that the initial weights of the samples will differ. Xennovate Medical promotes the use of its wound hydrocolloid at a thickness of 15 mils (0.381 mm) versus the industry standard of 20+ mils (~1/2 mm) because it provides a lower cost to our customers based on weight and a lower profile to the EndUser, while lasting as long or longer than competitive brands. This study validates this marketing claim.

Each 2x2 sample was then attached on one side to a 4x4 sheet of Mylar, if a backing film was not already present, to maintain the integrity of the sample for as long as possible and for weighing it. Once the samples were prepared, they were subjected to full immersion (a rigorous test compared to actual applications) in a 0.9% normal saline solution for up to a maximum of 72 hours. The samples were removed from the saline bath periodically and weighed, until they were no longer viable due to complete disintegration into the wet bath. The researcher captured and recorded the weight in grams of each sample as indicated. Subsequently, the weight at each time period was divided by the initial weight of the sample to enable rational comparisons across the data. The data for both curves has been smoothed (blue data points), where data points were missing, using a simple adjacent mean calculation.

REFERENCES

1 D.Chakravarthy, Evaluation of three new hydrocolloid dressings: Retention of dressing integrity and biodegradability of absorbent components attenuate inflammation" J Biomedical Materials Res, Vol.28, 1165-1173 (1994)

2 P. Rosseau and R.M. Niecestro, "Comparison of the physiochemical properties of various hydrocolloid dressings," Wounds, 3, 43-48 (1991)

3 M.D. Leek and Y.M. Barlow, "Tissue reactions induced by hydrocolloid wound dressings," J. Anat., 180, 545-551 (1992)