Retrospective Analysis of Two Biologic Wound Dressings: Bilayered Skin Substitute versus Porcine Submucosa

D. Isaac Bazan, DPM, 1,2, Laura A. Escobedo, DPM, 1,2, Jakob C. Thorud, DPM, 1,2, Daniel C. Jupiter, PhD 3, Christopher G. Browning, DPM, 1,3, Donald M. Lynch, DPM, 1,3

1Scott & White Healthcare, Temple, TX; 2Texas A&M Health Science Center, Temple, TX; 3Preventive Medicine and Community Health, University of Texas Medical Branch, Galveston, TX

Purpose
To compare 12 week diabetic foot ulceration healing rates of bilayered skin substitute and porcine small intestine submucosa.

Methodology
A retrospective chart review of diabetic patients with diabetic foot ulcerations using an Apligraf or an Oasis centered protocol was completed. Strict inclusion and exclusion criteria were established (Table 1). The two protocol groups were compared in terms of demographic age, gender, race, and comorbidities, as well as disease specific variables. These variables were also compared between those who achieved healing at 12 weeks and those who did not. All comparisons were done using t-tests or chi-squared/Fisher’s exact tests, as appropriate. A multivariate logistic regression model for healing at 12 weeks was built. The impact of demographic covariates and treatment group on time to healing was assessed using Cox regression.

Results
Forty-seven patients met inclusion/exclusion criteria and were included in the study. Of these patients, 29 followed the Apligraf centered protocol and 18 followed the Oasis centered protocol. Demographic data can be seen in Tables 2 and 3. The treatment groups differed only in terms of side of operation (Apligraf had 55.17% right side surgery, while Oasis had 83.33% right side surgery, chi-squared p-value 0.048) and albumin (Apligraf 3.06g/-0.81 and Oasis 3.45g/-0.51, t-test p-value 0.05).

In Cox regression only treatment group was significant (p-value 0.0079), with median time to healing with Apligraf being 123 days, and median time to healing with Oasis being 36 days. The hazard ratio for healing in favor of Oasis was 2.57 (95% CI 1.31 – 5.06). HbA1C and albumin were also included in the multivariate Cox regression we subsequently built. Only treatment protocol achieved significance in the model, with a hazard ratio of 2.48 (95% CI 1.25-5.13) in favor of Oasis.

Analysis and Discussion
In this retrospective review there was no significant difference in healing rate at 12 weeks between the two protocol groups. However, survival analysis showed that the Oasis centered protocol achieved faster healing times. Overall, healing at 12 weeks occurred in 35 of 47 patients (74.5%) and 44 of 47 patients (74.5%). Other studies have 12 week healing rates of 49% in Oasis [3] and 51% [1] to 56% [8] in Apligraf, in diabetic foot ulcerations. This difference is likely due to our strict inclusion and exclusion criteria. Many patients were excluded from the current study due to PVD, Charcot, antibiotics, or deeper ulcerations. This would select for patients with more favorable outcomes.

Conclusion
DFUs continue to be a difficult medical problem to treat and a financial burden on the healthcare system. This study looked at two biological wound dressings. Although neither graft was found to be superior in terms of healing DFUs, Oasis was found to have an advantage in terms of healing time.

References
8. Chappell, S., The longevi

Table 3: Inclusion and Exclusion Criteria

<table>
<thead>
<tr>
<th>Inclusion Criteria</th>
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<tbody>
<tr>
<td>Full thickness neumaphysitis</td>
<td>Patients with active infection</td>
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<tr>
<td>DFUs 14 weeks duration</td>
<td>Patients currently on antibiotics</td>
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<tr>
<td>DFUs that have not responded to conventional ulcer therapy</td>
<td>Patients with allergies to porcine or porcine material</td>
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<td>DFUs with a University of Texas HSCSA Grade 3A (Fig. 1)</td>
<td>Patients with burn wounds</td>
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<td>Previous application of我院枝条stripped tissue replacement</td>
<td>Patients with a diagnosis of Charcot arthropathy</td>
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<td>One or more palpable pedal pulses or an ABI of less than 0.55</td>
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<tr>
<td>Recorded off-loading</td>
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In terms of healing at 12 weeks, 35 of 47 patients (74.5%) healed. Nineteen of 29 (65.5%) on Apligraf healed, whereas 16 of 18 (88.89%) on Oasis healed (Fisher’s exact p-value 0.09). Albumin level among those who healed had a mean of 3.63+/-.55, as compared to those who did not heal (2.78+/-1, t-test p-value 0.078). No other variables reached the significance level required to be entered into the multivariate logistic model. Neither variable was significant in the multivariate model.