



## Clinical Evidence Surrounding Skin Health

### Edge/Environment

#### **Puracol Plus**

**Cole W. The use of collagen dressings to prepare the wound bed prior to the use of amniotic membrane allografts. Presented at the Clinical Symposium on Advances in Skin & Wound Care and the Symposium on Advanced Wound Care, Fall. New Orleans, LA & Las Vegas, NV. September 2015. (Ask your Medline representative for a copy of this poster, LIT067WC)**

The purpose of this evaluation was to test the hypothesis that better wound bed preparation with a Puracol Plus would promote healing in wounds thus decreasing the need or number of dehydrated human amnion chorion membrane allograft (dHACM) applications. Puracol Plus was applied on thirteen patients, 8 presenting with diabetic foot ulcers and 5 with venous leg ulcers from various outpatient wound centers or a long term acute care facility. There was an average total wound area decrease of 56% with an average weekly decrease of 14% with Puracol Plus alone, and six patients' wounds closed without use of the dHACM. The average decrease in volume was 79% with a 26% weekly wound volume reduction. For the rest, all their wounds closed within a matter of weeks once the dHACM was applied. Overall, all wounds except one were put on a healing trajectory.

**Shah SV, Chakravarthy D. Evaluation of a Bovine 100% Native Collagen for the Treatment of Chronic Wounds. *J Wound Ostomy Continence Nurs.* 2015;42(3):226-234.**

**Abstract:** <http://www.ncbi.nlm.nih.gov/pubmed/25945821>

**Purpose:** This 20 patient case series describes the use of a bovine-derived, 100% native, type I collagen dressing in patients with chronic and persistent wounds.

**Conclusion:** Following a change in chronic wound care regimen from conservative treatment and/or the use of submucosal intestinal matrix, oxidized regenerated cellulose/collagen matrix, or skin substitute to include a bovine-derived, 100% native, type I collagen dressing, an 83.3% (15 out of 18 patients) wound closure rate was achieved. Two patients were excluded from the data set analysis because they received additional intervention outside the parameters described in this multiple-case series.

#### **Puracol Plus Ag+**

**Joyner M. The use of native collagen wound dressing in the management of full thickness wounds caused by pyoderma gangrenosum. Presented at the Clinical Symposium on Advances in Skin & Wound Care; Orlando, FL; October 2013. (Ask your Medline representative for a copy of this poster, LIT920)**

Pyoderma gangrenosum presents with large, painful sores on the skin particularly in the lower extremities that tend to increase in size with additional trauma, such as aggressive debridement. Part of the treatment for pyoderma gangrenosum requires an immunosuppressant, steroids, which may slow wound healing, and atraumatic or easily removable dressings for wound management. Due to its biodegradable properties and conformability, a native collagen dressing (Puracol Plus Ag+) was selected. Over the course of six months, three patients with pyoderma gangrenosum received steroid treatments and the native collagen dressing. Since the dressing is biodegradable, dressing changes were not required, so trauma that could have been encountered with



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other non-biodegradable or adherent dressings was avoided.

### **Hyalomatrix**

**Carpenter S, Brabham R, Shaffett T, Hunt R, Flanagan B. Successful Healing of Complex Wounds using an Esterified Hyaluronic Acid Matrix. Presented at the Symposium on Advanced Wound Care, Fall; Las Vegas, NV; September 2015. (Ask your Medline representative for a copy of this poster, LIT059WC)**

The purpose of this case series is to describe the use of Hyalomatrix in three patients with full thickness wounds, including a diabetic foot ulcer, trauma wound and a surgical wound, to help generate vascularized tissue and neo-epithelialization all the way to complete epithelialization. Hyalomatrix was reapplied every 2-3 weeks until wounds were completely covered by newly formed epithelial tissue. The average initial wound size ranged from 6.7 - 12.8 cm<sup>2</sup>, and all wounds had complete epithelialization within 21-60 days after 1-4 applications. This case series demonstrates the successful epithelialization of complex wounds using adequate wound bed preparation and Hyalomatrix. In stalled chronic wounds, the matrix was assimilated with surrounding viable tissue, building granulation tissue and neoepithelialization.

**Schneider HP, Landsman AS. Esterified Hyaluronic Acid Matrix Promotes Formation of Granulation Tissue and Facilitates Wound Closure. Presented at the Symposium on Advanced Wound Care, Fall; Las Vegas, NV; September 2015. (Ask your Medline representative for a copy of this poster, LIT061WC)**

Six chronic diabetic foot ulcers and three chronic venous leg ulcers were treated with Hyalomatrix. Over a 12 week period, an increase from 46% to 91% granulation tissue across the wound bed was observed, along with four of the nine of the wounds closing. There was a very steady decrease in wound size with time across all wounds, and by week 12, the average wound size among those wounds not closed was 0.78cm<sup>2</sup>, compared to an initial wound size of 7.93cm<sup>2</sup>. There was a clear trend where granulation tissue was continuously forming, at the expense of fibrous and necrotic tissue. Based on this small sample set, Hyalomatrix was beneficial for treating difficult chronic wounds, as it provided scaffold for the formulation of granulation tissue resulting in reconstruction of the dermal tissue to achieve wound closure.

**Shah S, Saleh P. The Use of an Esterified Hyaluronic Acid Containing Bilayer Matrix in Healing of Chronic and Stalled Wounds, an Outpatient Experience. Presented at the Symposium on Advanced Wound Care, Fall; Las Vegas, NV; September 2015. (Ask your Medline representative for a copy of this poster, LIT057WC)**

In this study, Hyalomatrix was applied on six patients with a variety of chronic wounds (DFU, pressure, venous, surgical and vasculitic) that had failed to close with standard therapy for greater than 30 days. The use of Hyalomatrix resulted in re-epithelialization with a good safety profile and patient satisfaction. In all cases, the patients tolerated the dressing application and removal. All wounds had improved granulation without slough or bioburden, and in most cases, Hyalomatrix was used to close the wound after appropriate wound bed preparation.

**Vlad LG, Gumus T, Molnar JA. The Use of an Esterified Hyaluronic Acid Three-Dimensional Scaffold for Treating Chronic Wounds. Presented at the Symposium on Advanced Wound Care, Fall; Las Vegas, NV;**



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**September 2015. (Ask your Medline representative for a copy of this poster, LIT060WC)**

The purpose of this case series is to evaluate clinical usefulness of Hyalomatrix in three patients with recalcitrant lower extremity wounds. Patient 1 with a recalcitrant diabetic foot/leg ulcer closed after two applications in eight weeks. Patient 2 with a venous ulcer had a 25% decrease in wound size at week 4. Patient 3 refractory venous ulceration was healed in 4 weeks after a single application, after this wound had been refractory for the prior 3-4 months. Overall, Hyalomatrix useful for treatment regimen of recalcitrant lower extremity wounds and promoted healthier vascularized tissue and an improved wound bed.

**Shannon S, Bauerle T, Rayborn A, Wale A, Shannon T. Esterified Hyaluronic Acid Scaffold\*: A Testing Sample. Presented at the Clinical Symposium on Advances in Skin & Wound Care. New Orleans, LA. September 2015. (Ask your Medline representative for a copy of this poster, LIT074WC)**

Hyalomatrix was trialed on five patients with varying wound types, including diabetic foot ulcers, a venous ulcer, a surgical wound and a burn. Hyalomatrix was removed in 1 to 3 weeks with fresh reapplications performed in two cases to further the beneficial effect. Upon final removal, the wound beds were suitably closed incorporating either surgical flaps or autologous grafts. All patients maintained durable wound closure. Hyalomatrix provided an environment conducive to wound healing so that varying study subjects, including non-compliant subjects, could be taken to wound closure in a timely fashion.

**Sherman R. Harnessing a Bridge Esterified Hyaluronic Acid Scaffold Dressing to Enhance the ECM to Advance the Healing of Diabetic Wounds. Presented at the Clinical Symposium on Advances in Skin & Wound Care and the Symposium on Advanced Wound Care, Fall. New Orleans, LA & Las Vegas, NV. September 2015. (Ask your Medline representative for a copy of this poster, LIT058WC)**

The objective of this study was to improve the quality of the ECM in 10 diabetic surgical ulcers with Hyalomatrix. After applications of HYAFF scaffold, a noticeable improvement was seen in the wound beds which had healthier tissue. This bilayered HYAFF scaffold was effective in managing wounds through the inflammation phase towards granulation. Further effectiveness studies are warranted.

**Milne C. The Use of a Novel Hyaluronic Acid Based Dressing in the Management of Difficult Chronic Wounds. Presented at the Symposium on Advanced Wound Care, Spring; San Antonio, TX; May 2015. (Ask your Medline representative for a copy of this poster, LIT043WC)**

The purpose of this case series was to evaluate Hyalomatrix in three patients with various co-morbidities and difficult chronic wounds. In the weeks prior to the application of Hyalomatrix, cases 1 and 2 received weekly serial debridement, but case 3 refused debridement. Hyalomatrix was applied per manufacturer's recommendations. Hyalomatrix successfully managed difficult to treat wounds of an average of 12 months duration, range of four to 18 months. The wounds of cases 2 and 3 closed after three to four applications, respectively, in an average of 5.15 weeks and have remained closed. Patient 1's wound, after lacking microvascularization and with a low ABI, finally had a healthy, red wound base with three applications. The wound also decreased in volume by 22% and by 33% in area. Hyalomatrix was found to be a particularly viable option for patients who do not qualify for traditional wound care products due to insurance or product



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approval restrictions.

**Branigan M, Wu S. Outcomes of a Biologically Derived Hyaluronic Acid Wound Dressing in Treatment of Chronic Lower Extremity Wounds. Presented at the Symposium on Advanced Wound Care, Spring; San Antonio, TX; May 2015.**

The purpose of this study was to evaluate the outcomes of chronic lower extremity wounds treated with Hyalomatrix that acts as a scaffold for cellular invasion and capillary growth. Ten consecutive patients with twelve chronic lower extremity ulcers, 100% male, aged  $57.5 \pm 7.3$  years were selected. Seven of the 10 patients have diabetes, and the mean duration of wounds was  $9.44 \pm 8.2$  months. All patients received surgical debridement for their wounds and were placed on therapy consisting of weekly to every other week applications of Hyalomatrix with weekly non-adherent and moisture-retentive dressing until complete epithelialization. In total, 91.7% of wounds measuring a mean  $2.08 \pm 1.2$  cm<sup>2</sup> healed in the 20-week evaluation period. Of those that healed, healing took place in a mean  $8.6 \pm 2.7$  weeks.

**Livingston M, Chakravarthy D, Roman M. Evaluation of the Use of a Hyaluronic Acid Based Wound Dressing with a Silicone Fluid Transfer Dressing. Presented at the Symposium on Advanced Wound Care, Spring; San Antonio, TX; May 2015. (Ask your Medline representative for a copy of this poster, LIT041WC)**

Hyalomatrix was evaluated on nine patients with chronic or non-healing wounds of mixed etiologies, separated into Group A and Group B. The chronic non-healing wound group (A), of on average 2.2 month duration, had an 89% surface area closure rate with Hyalomatrix. Chronic non-healing wounds in patients with complex secondary wound etiologies (group B), of an average 5 month duration, had a 44% surface area closure rate. Two significant variables in the outcomes of this patient group would be the complex patient etiologies along with a shorter average application time of the dressing at 2 weeks versus just short of 4 weeks in the other. The author discusses the need for longer application times or multiple applications of the HA-based wound dressing for complex etiology patients.

**Livingston M, Chakravarthy D, Roman M. Nine Patient Evaluation of a Hyaluronic Acid-Based Wound Dressing. Presented at the National Pressure Ulcer Advisory Panel's Conference; Orlando, FL. February 2015. (Ask your Medline representative for a copy of this poster, LIT035WC)**

Hyalomatrix was evaluated on nine patients with chronic or non-healing wounds of mixed etiologies. Versatel One was used to secure Hyalomatrix. At the endpoint of this nine patient cohort, there was an average 68.90% reduction in wound area. For all nine patients, the total initial wound area was 26.32 cm<sup>2</sup> and total final wound area was 8.59 cm<sup>2</sup>, which gives a total wound area reduction of 67.36%. No adverse reaction to Hyalomatrix was observed. At the endpoint of this six patient cohort, there was an average 63.5% reduction in wound area. The total initial wound area was 19.08 cm<sup>2</sup> and total final wound area was 5.23 cm<sup>2</sup>, which gives a total wound area reduction of 72.6%. Following a single application, or two for patient 3 because Hyalomatrix was pulled up, there was a significant decrease in wound size ( $p = 0.009$ ). The wounds of patients 7 and 9 closed completely following the first application, and the wounds of patients 3 and 4 had almost achieved complete closure. No adverse reaction to the HA-based wound dressing was observed.



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**Huddleston L, Montoya L. The Use of a Hyaluronic Acid Based Matrix in the Management of Extremely Recalcitrant Wounds. Presented at the Symposium on Advanced Wound Care, Fall; Las Vegas, NV; October 2014. (Ask your Medline representative for a copy of this poster, LIT015WC)**

In many wound centers, recalcitrant wounds that refuse to heal following a plethora of increasingly expensive treatment modalities frustrate clinicians. When those treatment options are exhausted, the wound is managed palliatively, often with a poor prognosis and outcomes including amputation. A new treatment modality involved the use of an HA-based wound dressing (Hyalomatrix) was trialed on four of the most challenging non-healing wounds present at this wound center. The wounds had been open for 4-28 months prior to the application of HA-based wound dressing. Cases 1 and 2 achieved full wound closure in 9.9 and 7 weeks respectively with 10.1% and 14.3% wound size reduction per week. Case 3 achieved a 59.4% decrease in wound volume after 8 weeks of treatment with 7.4% total wound size reduction per week. Case 4 achieved a 45.6% decrease in wound volume after 9 weeks of treatment with 5.1% total wound size reduction per week. A healing response in 50% of the group chosen, and at least an initial healing response in the remaining, was deemed clinically significant, given the patients chosen had wounds that were not responding to many of the prior treatments.

**Livingston M, Chakravarthy D, Roman M. Evaluation of the use of a hyaluronic acid based wound dressing with a silicone fluid transfer dressing. Presented at the Clinical Symposium on Advances in Skin & Wound Care; Las Vegas, NV; September 2014. (Ask your Medline representative for a copy of this poster, LIT003WC)**

To examine the use of a novel HA-based wound dressing (Hyalomatrix), the product was evaluated on six patients with recalcitrant wounds. A non-adherent silicone transfer dressing (Versatel One) was used to ensure that the HA-based wound dressing and corresponding new growth of epithelial tissue remained intact during the dressing change process associated with the periodic removal of a secondary dressing was also used. At the endpoint of this six patient cohort, there was an average 63.5% reduction in wound area. The total initial wound area was 19.08 cm<sup>2</sup> and total final wound area was 5.23 cm<sup>2</sup>, which gives a total wound area reduction of 72.6%. No adverse reaction to the HA-based wound dressing was observed. For all patients, the silicone transfer dressing effectively maintained the HA matrix in place, and it did not damage epithelialized tissue on removal.

**Vaienti L, Marchesi A, Palitta G, Gazzola R, Parodi PC, Leone F. Limb Trauma: the use of an advanced wound care device in the treatment of full-thickness wounds. *Strat Traum Limb Recon.* 2013;8:111-115. Open access: full article publically available online:**

[http://download.springer.com/static/pdf/992/art%253A10.1007%252Fs11751-013-0165-8.pdf?auth66=1418664588\\_02215a23dbef96b4b44aeffef63d9401&ext=.pdf](http://download.springer.com/static/pdf/992/art%253A10.1007%252Fs11751-013-0165-8.pdf?auth66=1418664588_02215a23dbef96b4b44aeffef63d9401&ext=.pdf)

**Purpose:** The purpose of this 15 patient observational case series was to evaluate the clinical efficacy and safety of Hyalomatrix on dermal reconstruction in full thickness traumatic wound defects.

**Conclusion:** All patients went on to successful repair, and the mean average time to complete healing was 26.8 days.



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**Motolese A, Vignati F, Brambilla R, Cerati M, Passi A. Interaction between a regenerative matrix and wound bed in nonhealing ulcers: results with 16 cases.** Biomed Res Int. 2013; 2013:849321. **Abstract:** <http://www.ncbi.nlm.nih.gov/pubmed/23971047>

**Purpose:** The purpose of this 16 patient case series was to evaluate the use of a Hyalomatrix grafting for reconstructive surgery of venous leg ulcers.

**Conclusion:** Four patients did not require the epidermal graft since they showed a quick and satisfying reepithelialization. The combination of wound bed preparation with application of Hyalomatrix can be a useful approach for treatment of partial thickness ulcers.

### **Revitalon**

**Lullove EJ. Use of Revitalon, an Amniotic Tissue Derivative in Complex Lower Extremity Wounds. Presented at the Symposium on Advanced Wound Care, Spring; Orlando, FL; April 2014. (Ask your Medline representative for a copy of this poster, LIT359R)**

Revitalon is a human allograft that consists of a dehydrated composite of amniotic and chorionic membrane that can be used as a wound covering. The membrane consists of endogenous growth factors and cytokines. The purpose of the study was to evaluate the use of Revitalon, an amniotic placental membrane tissue whose uniqueness lies in the fact that it is processed aseptically and contains both the amnion and the chorion components of the amniotic membrane, on difficult to heal wounds on the lower extremity. It is to be noted that the presence of severe vascular compromise, active or latent infection, or uncontrolled infection at the wound site may compromise the usefulness of the tissue. A convenience sample of 5 patients with wounds associated with surgery, diabetes, and peripheral arterial disease was chosen, whose wounds were managed with single or repeated applications of a human amniotic membrane derived allograft. In 4 of the 5 cases, the wounds progressed to the process of natural healing and led to full closure following one application. If the wound volume is not reducing at an appreciable rate, a second application is recommended. Wound closure times were 14, 15, 42, 63, and 113 days for the five patients, in increasing order of healing time.

These publications were presented at various wound care conferences to share research and clinical results within a scientific community. The information is intended for healthcare professionals in the US only. It is provided for informational purposes and is not intended to replace a discussion with a healthcare provider. All decisions regarding patient care must be made with a healthcare provider and consider the unique characteristics of each patient.

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