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# Accelerated Healing of Diabetic and Venous Ulcers with Adjunctive Dehydrated Human Amniotic Membrane: A Real-World Retrospective Cohort Study from a Single-Provider Practice

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## Abstract

**Aim**: To examine whether incorporation of Sanoplast®, a dehydrated human acellular amniotic membrane (DHAAM), as a topical adjunct to standard wound dressing improves healing of diabetic and venous ulcers in a real-world setting of a single-physician practice.

**Results:** The area of DHAAM-treated wounds reduced to 60%, 47%, and 34% relative to their original size after the first three applications, respectively. Thus, a 50% reduction in wound area was achieved after two applications of DHAAM, compared to the "Standard of care" (SOC) group, which reached a 50% reduction after seven wound dressing applications. Overall, 69% of wounds treated per protocol with Sanoplast® DHAAM completely healed within 12 weeks of treatment compared to 47% in the SOC group. The median closure time for the DHAAM group (9.0 weeks) was less than SOC (13.3 weeks) and the probability of wound closure increased (Hazard Ratio = 1.9; 95% CI: 0.9–4.1).

**Conclusion:** Dehydrated human acellular amniotic membrane was found to be a safe and easy-to-use wound dressing that accelerates wound healing in lower appendage wounds in patients with comorbidities associated with reduced wound healing (diabetes, smoking, advanced age).

## Keywords
Wound healing; Dehydrated human acellular amniotic membrane; Diabetic foot ulcer; Real world evidence; Biologic wound dressing.

## Introduction
Diabetes mellitus is a global health epidemic, with over 500 million individuals affected worldwide. One of the most debilitating complications of diabetes is the development of chronic, non-healing wounds, particularly diabetic foot ulcers. These ulcers affect approximately 15% of diabetic patients and are a leading cause of lower limb amputations, with mortality rates exceeding those of many cancers.

Despite advances in wound care, diabetic foot ulcers remain notoriously difficult to treat due to underlying pathophysiological factors such as neuropathy, poor circulation, and an impaired inflammatory response. Standard treatment approaches are often ineffective, causing reduced quality of life, morbidity, prolonged hospitalizations, and increased healthcare costs. As a result, there is an urgent need for new wound care approaches that can accelerate wound closure and reduce complications.

Human placenta-sourced therapeutics are gaining increasing recognition for their benefits in the treatment of hard-to-heal wounds, including diabetic ulcers [1]. Randomized controlled clinical trials investigating the effect of dehydrated human amnion or amnion-chorion membrane as part of the wound dressing have shown tendency promote faster healing and complete closure of chronic wounds, such as diabetic foot ulcers and venous leg ulcers, compared to standard of care alone [2,3,4,5].

To our knowledge, this retrospective cohort study is the first to report on the therapeutic efficacy of dehydrated human amniotic acellular membrane (DHAAM) in the treatment of lower appendage wounds (diabetic and venous ulcers) in real-world settings.

## Methods
### Study type
This is a retrospective analysis of real-world clinical wound care data collected by a single physician in the practice of treating lower appendage wounds. All the wounds in this report were treated and dressed by Mitchell Pearce under the supervision of Dr. Christopher Bowlin at multiple locations in the State of Tennessee during the 07/2023 - 05/2025 period.

### Ethics and patient consent
All patients provided written informed consent prior to participation in this study. The consent process involved a detailed explanation of the study purpose, procedures, potential risks, benefits, and alternative treatment options for wound management using human placental allografts. Patients were informed of

their right to withdraw from study at any time without affecting their standard of care. The study protocol, including the informed consent process, and conducted in accordance with the principles of the Declaration of Helsinki.

### DHAAM manufacturing

Sanoplast® is a dry sterile sheet of extracellular matrix manufactured by BioXTek from dehydrated decellularized human amniotic membranes. The size of the sheet ranges from 2x2 to 10x20cm in and 20-50mm in thickness. The sheet can by 1-ply or 2-ply in thickness. Amniotic membrane is obtained from donated placental tissue recovered by a non-profit birth tissue procurement agency after informed consent and screening for healthy mothers scheduled for elective Caesarian deliveries. During processing, the amniotic membrane layer is physically separated from the placenta, washed, decellularized, dehydrated and terminally sterilized by irradiation.

## Wound dressing protocol

Prescribed wound treatment aimed for weekly changing of the bandage. During each visit, a wound site was first debrided with a 15-blade scalpel to remove any hyperkeratosis from the surrounding edges. The wound bed was then debrided with a curette to reveal healthy bleeding granular tissue. A single sheet of Sanoplast® DHAAM wound cover (either 1-ply or 2-ply) was applied directly to the wound bed with any overlying edges of the graft folded inwards over the wound. On top of that, an AdapticTM non-adhering dressing was applied, followed by multiple layers of gauze as well as a rolled gauze wrap and an ACETM bandage for compression. Wounds in the SOC group received the same treatment, but without the application of DHAAM.

## Wound scoring

During each clinical visit, each wound intended to be treated with DHAAM was photographed and scored for size by "Tissue Analytics", wound imaging and analysis software that was granted Breakthrough Device Status by the U.S. Food & Drug Administration in 2022.

Measurements of wounds in SOC cohort were taken using a disposable measuring device to calculate length and width in centimeters at the largest sections of the wound. The wound area was calculated by multiplying the width and length measurements. Change in wound area for both cohorts was calculated as % of the wound size on first visit, using (Day X / Day 1) x 100 formula. For all the wounds, a wound was considered healed when it was re-epithelialized and was fully granular with no open areas.

## Statistical analysis

Patient records were evaluated for adherence to the treatment regimen. Patients who skipped three consecutive weeks or more were censored from the analysis due to non-adherence to the treatment regimen.

Statistical analysis was performed using GraphPad Prism 10 software, version 10.5.0. All continuous variables were tested for normality using the Shapiro–Wilk test. Continuous variables with normal distribution are reported as means ± SEM and compared using Welch's unpaired t-test, which does not assume equal SDs. A p-value $< 0.05$ was considered indicative of statistical significance.

Non-normally distributed continuous variables are reported as medians with interquartile ranges (IQR) and analyzed using non-parametric tests (Mann-Whitney test and Kolmogorov-Smirnov test). Contingency tables comparing DHAAM and SOC groups in categorical variables were compared using Fisher's exact and Chi-square tests, where appropriate. Time-to-healing data was plotted as Kaplan Meier graphs. Kaplan-Meier graphs of DHAAM and SOC were compared using the Mantel-Cox test. The p-value results of statistical tests are reported in the same tables as the data.

## Results

### Patient demographics

We analyzed the admission records of 45 patients. The wounds of 21 patients were treated with the standard of care protocol described in Methods, while wound care of 24 patients used the same protocol for wound care and dressing changes, but included DHAAM (Sanoplast®). Baseline patient demographic and health data are summarized in Table 1. The mean age was 62 ± 2 years in the DHAAM group and 63 ± 3 years in the SOC group (p = 0.73). The sex distribution was similar between groups (male: 71% DHAAM vs. 76% SOC; p = 0.75) as well as the incidence of smoking habit (current: 21% DHAAM vs 10% SOC; p = 0.53). The main difference was in the incidence of type 2 diabetes: it was more prevalent in the DHAAM group (92%) compared to the SOC group (57%) (p = 0.06).

| | DHAAM | SOC | *p* value |
|---|---|---|---|
| Patients, n | 24 | 21 | |
| Patient age, years | | | 0.73[t] |
| Mean ± SE | 62 ± 2 | 63 ± 3 | |
| Range | 46-84 | 39-89 | |
| Sex | | | 0.75[F] |
| Male | 71% | 76% | |
| Female | 29% | 24% | |
| Type 2 diabetes | 92% | 57% | 0.06[F] |
| Smoking status | | | 0.53[F] |
| Current | 21% | 10% | |
| Former | 17% | 29% | |
| No, never | 63% | 48% | |

**Table 1:** Baseline demographic variables.

### Wound characteristics at baseline

Treatment records of 51 wounds were analyzed in this study: 30 in the DHAAM group and 21 in the SOC group (Table 2). The majority of wounds in each group were diabetic ulcers (80% in DHAM, 67% SOC group), followed by venous ulcers and traumatic wounds. There was no statistically significant difference in wound etiology between the two groups (p = 0.23). Assigned Wagner grades were distributed similarly across groups (p = 0.15), each consisting mostly of Wagner grade 1 and grade 2 wounds. The most notable difference between the two groups of wounds was in baseline wound age: as a group, DHAAM-treated wounds were significantly older (median 77, IQR 27-244 "days old") than wounds in the SOC group (median 10, IQR 4-31 "days old"). This difference in baseline wound age between two cohorts was highly significant (p = 0.0002).


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Wounds that remain open for more than 12 weeks are considered chronic and have poor prognosis for healing due to overt dysregulation of the normal wound healing process. Only 12% of the SOC group were older than 12 weeks at the time of first treatment by the current medical provider. In contrast, 43% of wounds in DHAAM cohort were older than 12 weeks at first treatment. The difference was statistically significant (p = 0.012) (Table 2, Supplemental Figure 1).

| | DHAAM | SOC | p value |
|---|---|---|---|
| Wounds, n | 30 | 21 | |
| Wound etiology | | | 0.23[F] |
| Diabetic ulcer | 80% | 67% | |
| Venous ulcer | 13% | 10% | |
| Trauma | 7% | 24% | |
| Wound duration at 1st application, days | | | 0.0002[M-W] |
| Median | 77 | 10 | |
| IQR | 27 - 244 | 4 - 31 | |
| % of chronic[#] wounds | 43% | 10% | 0.01[F] |
| Wound grade, Wagner | | | 0.15[F] |
| Grade 1 | 67% | 71% | |
| Grade 2 | 33% | 19% | |
| Grade 3 | 0% | 10% | |
| Wound area at baseline ($cm^2$) | | | |
| Median | 2.4 | 2.0 | N/A* |
| IQR | 1.0 - 4.4 | 0.3 - 6.0 | |

F = Fisher's exact, Matt-Whitney test

* = does not apply as wound area was not measured by the same method

[#] wounds older than 12 weeks at the start of treatment

**Table 2:** Wound baseline characteristics.

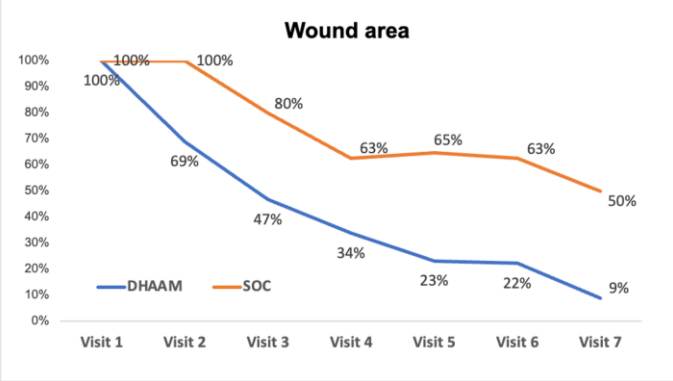


**Figure 1**: Wound area at each in-clinic visit (and dressing application) relative to the initial size.

## Wound healing outcomes

Wound healing efficacy criteria evaluated were: wound area change after each dressing application, incidence of wound closure at 12 weeks, and time to healing (Table 3).


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| | DHAAM | SOC | p values | |
|---|---|---|---|---|
| | | | M-W | K-S |
| Wound area[#] relative to initial visit, median (IQR) % | | | | |
| after 1 application | 69 (49 - 88) | 100 (90 - 100) | *0.001* | *0.000* |
| after 2 applications | 47 (31 - 66) | 80 (29 - 100) | *0.018* | *0.008* |
| after 3 applications | 34 (15 - 54) | 63 (12 - 100) | *0.029* | *0.011* |
| % of wounds healed at 12 weeks | | | | |
| per protocol* | 69 (16/23) | 47 (9/19) | 0.14[F] | |
| intended to treat | 53 (16/30) | 43 (9/21) | 0.57[F] | |
| Kaplan-Meier curve analysis | | | | |
| Median closure time, weeks | 9.0 | 13.3 | *0.08*[M-C] | |
| A/B Hazard Ratio[M-H] (95% CI) | 1.9 (0.9 - 4.1) | | *0.08*[M-C] | |

M-W, Matt-Whitney; K-S, Kolmogorov-Smirnov; X, Chi square; K-M, Kaplan-Meier; M-C, Mantel-Cox; M-H, Mantel-Haenszel

[#]includes area all the available wound area measurements regardless of the outcome

*Calculations do not include unhealed wounds that discontinued treatment prior to 12 weeks

**Table 3** Treatment outcomes.

## Wound area reduction

Wounds treated with DHAAM demonstrated a more accelerated rate of closure than those receiving standard of care as observed by the reduction in wound area (Table 3, Figure 1). The median wound area, expressed as a percentage relative to the area at the initial visit, was consistently lower in the DHAAM group compared to the SOC group across all time points. After one visit, the DHAAM group showed a median wound area of 69% (IQR: 49–88) compared to 100% (IQR: 90–100) in the SOC group (p = 0.001, Mann–Whitney; p = 0.0001, Kolmogorov–Smirnov). After two visits, the median wound area was 47% (IQR: 31–66) in the DHAAM group versus 80% (IQR: 29–100) in the SOC group (p = 0.018, Mann–Whitney; p = 0.008, Kolmogorov–Smirnov). After the third visit, the DHAAM group maintained a lower median wound area of 34% (IQR: 15–54) compared to 63% (IQR: 10–100) in the SOC group (p = 0.029, Mann–Whitney; p = 0.011, Kolmogorov–Smirnov). These results suggest a more pronounced and earlier reduction in wound size in the DHAM-treated wounds compared to SOC.

## Number of dressing applications to reach 50% reduction in wound area

As a group, wounds treated with DHAAM showed a fast progressive reduction in wound area reaching 50% after only two office visits (i.e. after only two dressings with DHAAM) (Figure 1). In contrast, the SOC group reached the 50% area reduction after seven in-office dressing changes.

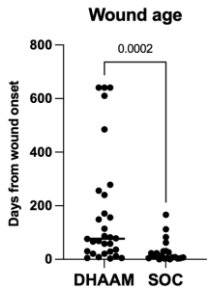


**Figure S1:** Wound age at the time of first dressing. Line represents median. Comparison by Mann-Whitney non-parametric test.


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### Incidence of wound closure at 12 weeks

Of the patients who adhered to regular in-office visits for wound dressing changes no less than three times per month, 70% (16/23) achieved complete closure in the DHAAM group in comparison to 47% (9/19) healing in the SOC group within the 12 weeks. This difference did not reach statistical significance (p = 0.14, Chi-square test). In the intention-to-treat analysis that included all wounds, the proportion of closed wounds was 53% (16/30) in the DHAAM group versus 43% (9/21) in the SOC group (p = 0.57) within the 12 weeks.

### Time to complete wound closure

The initial and last dates of each wound's office visit and wound status (healed, 1 vs non-healed, 0) at the 12 weeks mark after initial visit were plotted into the Kaplan-Meier graphs to visualize and compare probabilities of wound closure over time (Figure 2).

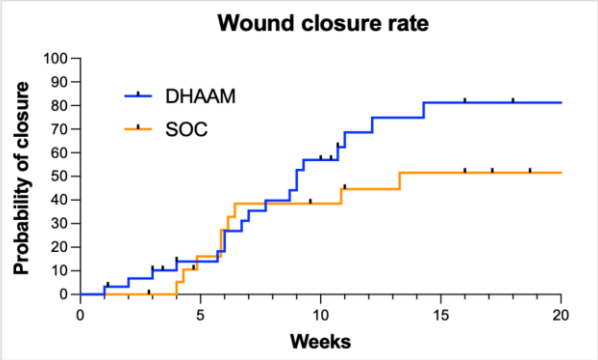


**Figure 2:** Kaplan-Meier graph of wound closure rate over time.

Kaplan-Meier analysis demonstrated a faster wound closure rate in the DHAAM group compared to the standard of care: median time to complete wound closure was 9 versus 13 weeks in the DHAAM versus SOC group, accordingly (p = 0.086, Log-rank Mann–Cox test) (Table 3). The hazard ratio was 1.9 (95% CI: 0.9–4.1, indicating that wounds treated with DHAAM were almost twice as likely to close compared to those receiving standard care. Although the difference did not reach the statistical significance threshold of 0.05, the model predicted an improved trend of healing for the DHAAM group.

### Adverse events

None of the patients whose wound care included DHAAM experienced treatment-related adverse events.

## Discussion

### Would healing efficacy

In this retrospective cohort study of real-world clinical records of lower appendage wound care in elderly (mostly diabetic) patients under single-physician care, we observed that wounds whose care included topical application of Sanoplast® DHAAM in each dressing change show a more accelerated rate of wound area reduction, especially in the first four weeks, than wounds treated by the same physician using the same wound care and dressing change protocols but without the DHAAM. The observed rapid rate of wound area declines in the DHAAM-treated group (30% reduction in wound area after one DHAAM application, 50% reduction in wound area after two applications) is comparable to other retrospective

studies investigating the use of DHAM as an adjunct therapy in hard to heal wounds [1,6]. Surrogate outcomes, defined as 50% or 80% wound area reduction, are excellent predictors of ultimate wound healing. Particularly, changes in wound size over the first 4 weeks of care can be used to successfully predict which wounds will heal at 3 and 6 months [7,8,9].

The observed incidence of complete wound closure within 12 weeks in the DHAAM group (69% "per protocol", 53% overall) is comparable to published results of prospective randomized controlled trials investigating human amnion and amnion-chorion membrane as a topical cover in the treatment of diabetic ulcers and venous leg ulcers [5,10,11,6]. While the difference in incidence of wound closure between DHAAM and SOC groups (69 vs 47%) didn't reach statistical significance (p=0.14 Fisher's exact test), it may be due to unequally distributed cofounding variables in favor of the SOC cohort: diabetes diagnosis and wound age (see “Limitations of the study”).

All the efficacy criteria result in the DHAAM cohort (incidence of closure at 12 weeks, HR ratio of the probability of closure, and median time to closure) matched very closely to the results of a randomized controlled clinical trial of hypothermically stored amniotic membrane for use in diabetic foot ulcers [6]. We interpret this to mean that dehydration does not have a negative impact on the bioactivity of the human amniotic membrane; and that Sanoplast® dehydrated amniotic membrane supports diabetic ulcer healing comparably to the hypothermically stored (wet) membrane. In contrast to RCTs, this study demonstrates the therapeutic efficacy of HDAAM in a real-world setting, with less than perfect patient compliance with prescribed treatments (weekly clinic visits for dressing changes, off-loading, compression).

## Limitations of the study

This study is limited by differential bias against the DHAAM cohort due to baseline differences in comorbidities between the two groups. The DHAAM cohort had a higher proportion of patients with type 2 diabetes and a higher proportion of chronic wounds (defined as wounds open for more than 12 weeks) compared to the SOC group. Both of these variables (diabetes and chronic wound status) are well-established risk factors associated with impaired wound healing and poor prognosis for closure [12,13]. As a result, the DHAAM cohort had a greater burden of baseline risk factors predictive of poor healing outcomes than SOC cohort, which introduced bias into the interpretation of comparative outcomes. Therefore, we conclude that the observed improvement in wound healing in DHAAM cohort relative to SOC underestimates the true therapeutic benefit of adjunctive DHAAM.

Another well-known variable in wound healing is initial wound size: larger diabetic foot ulcers require significantly more time to heal than smaller ones [13]. We could not directly compare wound area between the two cohorts as it was measured by different methods: DHAAM – treated wounds were measured via image-based digital planimetry, while SOC–treated wounds manually with a ruler. Estimation of wound area by multiplying the longest length and width introduces a systematic positive bias that tends to overestimate the actual wound area, as it includes areas that are not actually part of the wound, especially in wounds with jagged or non-uniform edges. In contrast, digital planimetry (from image analysis) traces the exact wound border and provides a more accurate measurement that is usually

smaller than what is estimated by manual measurement. Thus, while median and IQR measurements appear similar between the two cohorts, the SOC cohort wound area measurements are likely to be overestimated, which may introduce yet another positive bias in favor of wound healing in the SOC group relative to DHAAM cohort.

### Convenience of the DHAAM use as an adjunctive to wound care

Sanoplast® DHAAM membrane was noted for its ease of use due to its thin, pliable, and biodegradable structure, application of which does not require suturing or subsequent removal. Single-use individually-packaged DHAAM wound cover is sterile, does not require cold chain for transport and storage, and has a long shelf life, making it a convenient and relatively cost-effective wound care option for wound care specialists.

### Safety

We have not observed any adverse events associated with the use of Sanoplast® products. This is consistent with other studies, where the use of human amniotic membrane in treating diabetic foot ulcers has been shown to be safe, with no significant difference in adverse events between the HAM and control groups [5,14].

The presence of cellular debris in an ECM scaffold, device, or allograft elicits an inflammatory immune response in the recipient and is associated with poor downstream tissue remodeling [15,16,17,18]. Manufacturing of Sanoplast® from human amniotic membrane tissue includes a proprietary decellularization process. By eliminating cellular components from amniotic tissue, this processing step reduces the risk of an adverse inflammatory immune response and poor remodeling, while preserving the biochemical and structural properties of the extracellular matrix that promote wound healing.

### Cost-effectiveness

The cost-effectiveness of incorporating dHAM into wound care of elderly and/or diabetic patients becomes particularly evident when considering the high costs associated with diabetic foot complications. Economic evaluation by [19], demonstrated that early use of dehydrated human amnion/chorion membrane (dHACM) allografts in the treatment of diabetic foot ulcers is both clinically and economically advantageous. In a large Medicare claims-based model incorporating over 1.2 million ulcer episodes, early initiation of dHACM resulted in an average gain of 0.013 quality-adjusted life years (QALYs) and a cost savings of $3,674 per patient within one year. Over a five-year horizon, the treatment yielded a net monetary benefit of $9,726 per patient at a willingness-to-pay threshold of $100,000 per QALY, confirming its strong cost-effectiveness from a U.S. payer perspective.

## Conclusion

Retrospective evaluation of real-world clinical patient records of a single physician practice on the use of DHAAM products (Sanoplast®) in the treatment of lower appendage wounds of predominantly diabetic foot ulcer etiology revealed that topical application of these products into standard wound care dressing was supportive of faster wound healing than the standard treatment without the DHAAM. Implementing Sanoplast® into wound care of diabetic patients could lead to reduced patient morbidity, reduced burden on Medicare, and improved patient quality of life.

### Funding information

The study was conducted as a retrospective analysis of real-world clinical data, and no funding was received from BioXTek for this research. Dr. Christopher Bowlin and Mitchell Pearce declare no third-party funding. Dr. Morsci is a paid consultant for BioXTek, the manufacturer of Sanoplast®, the dehydrated human acellular amniotic membrane products evaluated in this study.

### Conflict of interest statement

Dr. Christopher Bowlin declares no financial or non-financial conflicts of interest related to the products evaluated in this study or the manufacturer of these products. Mitchell Pearce declares no conflicts of interest.

Dr. Morsci is an independent consultant for BioXTek, the manufacturer of Sanoplast®. To mitigate potential bias, Dr. Morsci's role was limited to data analysis and manuscript preparation, while study design, clinical data collection and patient treatment performed independently by Mitchell Pearce under the supervision of Dr. Christopher Bowlin.

All authors have critically reviewed the manuscript to ensure objectivity and transparency in reporting the findings.

### Data availability statement

The data that support the findings of this study are available on request from the corresponding author.

### Ethical conduct of research

The authors state that they have followed the principles outlined in the Declaration of Helsinki for all human investigations. In addition, for all subjects participating in this study, informed consent has been obtained prior to any study procedures being performed.

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