H
uman amniotic membrane allografts have been used in surgical procedures for more than 100 years. Known to decrease inflammation, reduce scar tissue formation, and support soft tissue regeneration, dehydrated human amniotic membrane allografts also have been proven to reduce wound-closure time, overall cost to treat wounds, and scarring. Clinicians who have gone through basic training for chronic wound management are all taught that lower extremity compression is the “gold standard” for management of ulcers caused by chronic venous insufficiency, as long as there is no co-existing arterial disease significant enough to prevent the use of compression therapy.

ROLE OF AMNIOTIC MEMBRANE
Human amniotic membrane is non-immunogenic, non-vascular tissue comprising the innermost layer of the placenta (the amnion and the chorion). Composed of a single layer of epithelial cells, a basement membrane, and an avascular connective tissue matrix, amniotic membrane contains extracellular matrix (including collagen and laminins), cell-signaling proteins (such as cytokines), and growth factors that are essential to the healing process. Amniotic membrane layers also consist of epithelium cells (lining of hollow organs and glands that protect or enclose); a thick, compact layer (composed of reticular fibers); and a fibroblast layer. The membrane also contains cell-anchoring collagen types IV, V, and VII — structural proteins that are essential for wound healing.

In vitro testing confirms presence of essential soft tissue growth factors and cytokines in human amniotic membrane allografts. Growth factors bind to the extracellular matrix and are released into surrounding tissue, providing a continual release of growth factors during the tissue regeneration process.

Unlike many of the xenografts and composite dermal substitutes on the market today, dehydrated human amniotic membrane allografts may be used in a wide variety of applications that can reduce the need to carry products in inventory. Wound healing applications for dehydrated amniotic membrane include acute and chronic full- and partial-thickness wounds such as diabetic foot ulcers, venous leg ulcers, arterial ulcers, pressure ulcers, post-surgical or post traumatic wounds, wound dehiscence, burn injuries, acute suture line repairs, and subcutaneous wound tunnel repair. With a variety of sizes available, the waste typically realized with other grafts is reduced significantly. Many diabetic foot ulcers may be less than 4 sq cm, so sizing options are important.

IMPROVING HEALING TIME
In 2007, Surgical Biologics (Kennesaw, GA) developed the PURION® process for the use of dehydrated amniotic membrane as an allograft. First utilized in ophthalmic surgery (there have been more than 45,000 implants to date without any adverse events associated with dehydrated amniotic membrane), amniotic membrane has been utilized more recently as a potent facilitator of wound healing in various fields, including lower extremity ulcers, ophthalmological surgery, burns, gynecologic surgery, orthopedics, and a variety of other applications.1-7

The process works by safely and gently separating the placental tissues. The various layers of the amniotic membrane are cleaned and reassembled with minimal manipulation of the tissue to maintain the structure. The tissue is then dehydrated to preserve the elements that are key to healing, with no chemicals being utilized. Dehydrated human amniotic membrane has a shelf life of five years and may be micronized to create a powder configuration to be used as topical powder or injectable solution. The final product may be stored at room temperature and is regulated by the FDA under section 361 of the Public Health Service Act as Human Cells, Tissues, & Cellular and Tissue Products. Placentas are recovered only by scheduled Caesarean section procedures, and each donation is subject to FDA compliant screening criteria and blood testing.

Among other benefits, the PURION process allows tissue to be dehydrated and sterilized, producing an easy-to-use graft. To date, 100,000 allografts have been distributed for human implantation in various surgical applications, and a number of recent studies have demonstrated the clinical cost effectiveness of using dehydrated human amniotic membrane allografts. One prospective, stratified, randomized, comparative, parallel group, single-center clinical trial compared the proportion of diabetic foot ulcers completely healed by use of dehydrated amniotic membrane graft (Epi-Fix®, MiMedx Group Inc., Kennesaw, GA) every other week, plus standard of care (SOC) versus a SOC protocol of advanced wound care dressings in patients living with a nonhealing diabetic foot ulcer with adequate arterial perfusion. Following surgical debridement, all patients underwent weekly dressing chang-
es and the graft was applied under a non-adherent dressing. In the EpiFix group, 92 percent of patients healed completely in 6 weeks compared to 8% of the SOC group.

**SCAR TISSUE REDUCTION**

Dehydrated human amniotic membrane allografts help reduce scarring, as demonstrated in a retrospective study9 that reviewed the use of amnion-based allograft membrane to prevent post-operative scarring between the tendon, peritendonous structures, and overlying skin. Patients were evaluated at an average of 1.7 years post-surgery. Of 14 patients, 86 percent were clear of scarring around the surgery site and 93 percent were scar-free at the tendon-repair site. Of the patients with signs of scar tissue, the effects were reported as “mild” or “moderate.” The findings were statistically significant with p=0.012.

**COST EFFECTIVENESS**

Abrams, et al, tracked 20 patients who failed to have at least 50% closure within four weeks and treated the group with an evidence-based approach and dehydrated human amniotic membrane allograft in lieu of previously used skin substitute. Patients were assigned based on risk into high-risk and low-risk categories. Patients were cared for based on traditional wound care principles including debridement, offloading, infection control, and maintenance of a moist wound environment. Those considered low risk — defined as those with a new ulcer, no infection, palpable pulse, ankle brachial index (ABI) >0.8, and having received advanced therapies after four weeks if wounds did not decrease in size by 50% (but with wounds failing to close by 50% in four weeks) — and patients considered moderate-to-high risk — defined as those with documented renal disease, previous history of ulcer or amputation, elevated HgbA1c, ulcer duration of >30 days, ABI <0.8, and no local signs of infection — were treated with dehydrated human amniotic membrane allografts. By using the PURION-processed dehydrated human amniotic membrane allograft, the clinic realized a 42% reduction in cost, 50% reduction in time to closure, and all patients achieved full closure.10

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**References**


