CHAPTER **42**

AMNIOX

Jeremy M. Thomas, DPM

INTRODUCTION

Human Amniotic Membrane and Umbilical Cord (hAMUC) are fetal tissues that are clinically proven to have innate regenerative properties that can be preserved and transplanted to other environments. These tissues comprise unique proteins, cytokines and growth factors in the extracellular matrix that have been shown to modulate inflammation, reducing adhesion and scar formation while encouraging regenerative healing (1-7).

Amniox is a cryopreserved form of human Amniotic Membrane and Umbilical Cord (hAMUC). Amniox Medical's proprietary CryoTek preservation process retains the relevant natural structural and biologic characteristics of the hAMUC tissue while devitalizing the cell activity to eliminate the possibility of graft rejection (8). It was first introduced in ocular application in 1997. The product was approved by the FDA in 2011 for foot and ankle use.

There are two types of tissue that can be utilized to supplement repair in the foot and ankle. Clarix Cord 1K is used as a surgical covering, wrap, or barrier. The Clarix form of Amniox can be utilized during foot and ankle surgery to decrease scar formation or augment the healing of tendon repairs. Neox Flo wound matrix is used as a wound covering for dermal ulcers or defects. Both the Neox and the Clarix come in multiple sizes and can be modified to fit the wound or overlying area. The Amniox tissue can be sutured in place if desired with an absorbable tissue. The tissue will absorb over 30 days from the time of application.

PROCEDURE

This relatively new product was introduced to me in the summer of 2014. It was presented to me as an option to decrease both healing time in ulcers and decrease postsurgical scar tissue. At the time of writing this article, my use with the product has been limited. However, the purpose is to introduce the product and provide preliminary results.

I have used Amniox 5 times. I have only used the Clarix Cord 1K thus far. To date I have performed 3 Cheilectomies, 1 bunion, and 1 soft tissue mass excision with Amniox as a supplement to the procedure. Prior to the procedure, the local Amniox representative is contacted to bring the product for the case selected. What I have done thus far is have the Clarix Cord opened and placed in saline at the start of the procedure. A 2 X 2 centimeter size has been used. Care was taken to perform anatomical dissection and then the procedure performed. After flushing the surgical site with cold saline, the graft was placed on a sterile towel next to the operative site. Using a previously non-used sterile forceps and iris scissor, the tissue was cut to fit the area directly under the deep fascia. If there is a technical portion of application it is cutting the tissue to fit the area that will allow for deep fascia closure without buckling or extrusion through the sutured deep fascia. If Amniox was for tendon augmentation, then the tissue would need to be cut to fit both the length and diameter of the tendon. However, tendon augmentation with Amniox has not been utilized thus far by the author.

The tissue can be laid in place and left without suture to absorb. The tissue can also be sutured with Vicryl for proper placement and to avoid migration during deep fascial closure. Use of a nonabsorbable suture would not be recommended due to the absorption of Clarix Cord over the span of the month. I have not attempted to suture the tissue in place in the procedures performed and have elected to cut it and lay it over the desired location. The layers of anatomical dissection were then closed using a Vicryl suture. Of the cases performed, the deep fascia was closed over the Amniox Clarix Cord first. A wet to dry sterile dressing was applied and the appropriate postoperative course commenced with partial weightbearing.

PRELIMINARY RESULTS

The postoperative course has extended for these 5 patients over the span of 3 months and the results thus far have been positive. I have had no postoperative complications and the 5 patients are walking without discomfort. The range of motion of the affected joint has been within normal limits for the level of surgery preformed and without pain. Now as stated above, the product was introduced to me as a scar reducing property. There has not been enough time to properly evaluate this within the 5 surgical patients. My goal over the next year is to utilize the graft in as many different cases as possible. Results will be gathered both pre- and postoperatively. Some of the findings will include range of motion, pain levels, complications and time to complete recovery based on the procedure performed. Of all the factors to examine, the most difficult one will be scar tissue formation. Scar tissue is an inevitable conclusion to any surgery. Being able to distinguish whether it is better or worse with Amniox or any tissue would be a challenge. My goal over the next year is to not only report findings, but

to compare these findings to cases performed in prior years without the use of Amniox.

In conclusion, I intended to introduce the reader to the product. This is not an endorsement for the product. There have been limited studies on the use of the product and the ones I have seen have been supported by Amniox Medical. *Please note that I am not being reimbursed by anyone for the writing of this chapter or any upcoming findings that are collected. I provide it to the reader only for educational purposes.*

REFERENCES

1. He H, Li W, Chen SY, Zhang S, Chen YT, Hayashida Y, et al. Suppression of activation and induction of apoptosis in RAW264.7 cells by amniotic membrane extract. Invest Ophthalmol Vis Sci 2008;49:4468-75.
2. He H, Li W, Tseng DY, Zhang S, Chen SY, Day AJ, et al. Biochemical characterization and function of complexes formed by hyaluronan and the heavy chains of inter-alpha-inhibitor purified from extracts of human amniotic membrane. J Biol Chem 2009;284:20136-46.
3. Li W, He H, Kawakita T, Espana EM, Tseng SC. Amniotic membrane induces apoptosis of interferon-gamma activated macrophages in vitro. Exp Eye Res 2006;82:282-92.
4. Park WC, Tseng SC. Modulation of acute inflammation and keratocyte death by suturing, blood, and amniotic membrane in PRK. Invest Ophthalmol Vis Sci 2000;41:2906-14
5. TissueTech. Data on file.
6. Tseng SC, Li DQ, Ma X. Suppression of transforming growth factor-beta isoforms, TGF-beta receptor type II, and myofibroblast differentiation in cultured human corneal and limbal fibroblasts by amniotic membrane matrix. J Cell Physiol 1999179:325-35.
7. Wang MX, Gray TB, Park WC. Reduction in corneal haze and apoptosis by amniotic membrane matrix in excimer laser photoablation in rabbits. J Cataract Refract Surg 2001;27:310-9.
8. Tan EK, et al. Submitted to Tissue Eng.