

The risk seems to outweigh the benefits of using "Human tissue for human wound". Intact human allograft tissue rich in **Elastin** is not appropriate for human wound treatments. Elastin is not an ideal matrix compared to biocompatible native Type-I collagen.

1. Risk of Carcinogenicity:

All tissue derived intact membranes from amnion (Amniofix, Epifix, Amnioexcel, Xwrap), placenta (Grafix), umbilical cord (Cellesta Cord), pericardium (Architect from Equine), urinary bladder (Cytal from Porcine), intestinal wall (Oasis from porcine SIS) and even skin (Kerecis from fish, EZ Derm from porcine, Apligraf from human) do possess at least 15% elastin (w/w). The peptides (Elastokines) derived during the process of disintegration by an enzyme (Elastase) may all be carcinogenic [1] and could cause various pathological conditions including emphysema, chronic obstructive pulmonary disease, atherosclerosis, metabolic syndrome, etc. [2]. There is no successful elastin based biomaterial available until now for tissue replacement/repair applications.

2. Less biocompatibility:

Most biomolecules in intact tissue derived membranes are incompatible compared to Type-I collagen matrix. For example, only some proteins are proven to be immunologically safe based on the amino acid sequence homology with the host tissue proteins. Too many isoforms [3] of Elastin could cause incompatibility.

3. Living cells from placental membrane may cause adverse response:

Incorporation of third person's tissue cells as a tissue regenerative scaffold are detrimental [4] for the treatment of wounds and it could cause Graft-versus-host disease [5]. The genome makeup of fibroblast differs between individuals and thus, fibroblast of one person will not express similar proteins in another person. Several company products failed while using fibroblast of a third person in their matrices to function as a universal tissue regenerative cell system.

Reference:

1.https://www.nature.com/articles/s41467-020-18794-x

2.https://www.tandfonline.com/doi/full/10.1080/10409238.2020.1768208#:~:text=The%20destruction%20of%20elastin%20 and,atherosclerosis%2C%20metabolic%20syndrome%20and%20cancer.

- 3. https://en.wikipedia.org/wiki/Elastin#:~:text=Elastin%20is%20a%20key%20protein,it%20is%20poked%20or%20pinched.
- 4. https://pubmed.ncbi.nlm.nih.gov/18971876/
- 5. https://www.lls.org/treatment/types-of-treatment/stem-cell-transplantation/graft-versus-host-disease