

Amniotic Tissue: Making Waves, Fixing Smiles

By Daniel Knowlton



Regenerative medicine: it's a hot spot of research and development in almost every medical field. In medicine, finding ways to help the body heal itself is continuously aiding or, in some cases, replacing implants and devices made of metal and plastic. To find one of the best healers in the human body for dentistry, Robert Tofe, president of Snoasis Medical, looked back to one of the first tissues of life, to find a source for his regenerative product line; the placenta. As it turns out, this often discarded tissue has the potential to protect and heal the body long after its time spent protecting a baby during pregnancy.

Mr. Tofe is leading the way in developing uses for this technology. He's using amnion tissue, the inner most lining of the placental sac, to heal tissue in the oral cavity, called mucosal tissue. "What makes amnion

so special?" asks Mr. Tofe. "The basement membrane, the part cells travel on, closely mimics the basement membrane of oral mucosal tissue. It has a high concentration of laminin-5, which is found in the basement membrane of both of these types of tissue; laminin-5 is the primary cellular adhesion factor for gingival epithelial cells."

Mr. Tofe, however, is not the first to discover the healing properties of amnion. The first recorded clinical use of amnion tissue was in the early 1900s, when physicians began using it on patients with burns or ulcerated skin conditions. Fast forward to 2009, and we finally have the research and scientific know-how to develop widely available amnion tissue based medical products.

Probably the first "aha" moment for clinicians occurred early on when,

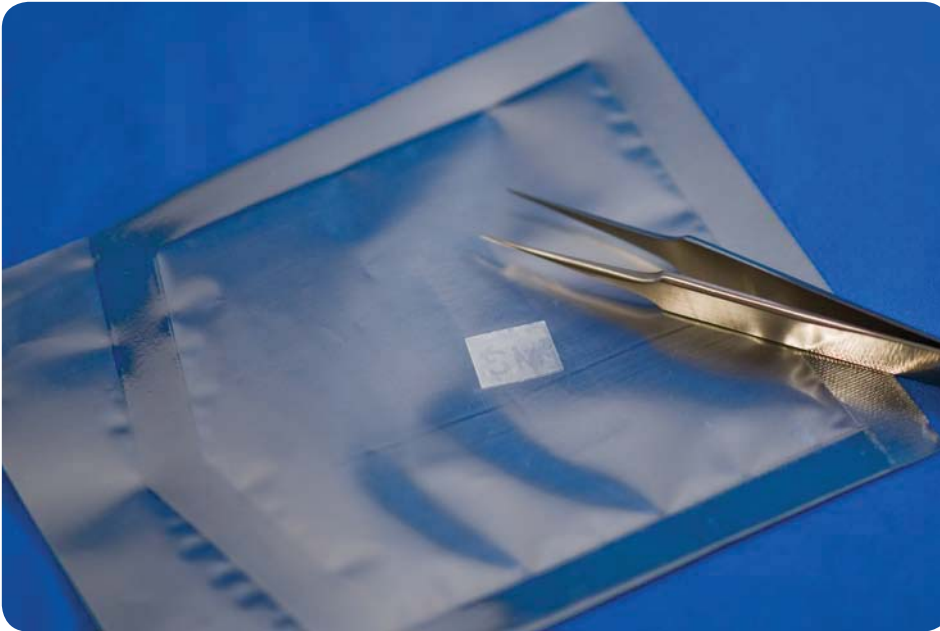
as was published in the *American Journal of Surgical Research* in the 1930's, human amnion membrane was found to be transplantable from one person to another, without fear of the host rejecting the transplant. "One really exciting aspect of amnion," explains Mr. Tofe "is that it is immunoprivileged. Placental tissue, including amnion, does not exhibit a class II antigen. For example, if you took a piece of my tissue and transplanted it into your body, it would exhibit an immune response and

possibly graft rejection. With amnion, you don't get that. The placenta serves as a barrier that protects the baby from the mother during its term in the womb."

"In fact, since the first recorded publication of its use in 1910, I've never seen mention of an immune response to amnion tissue - fresh, frozen or processed."

Fixing Smiles

So what does Robert Tofe use this wonder tissue to treat? Gingival recession. This condition occurs when the gums recede; exposing a tooth's root, causing sensitivity and pain. "There are basically only two treatments," says Mr. Tofe. "Dental surgeons can harvest a piece of tissue from the roof of the mouth, known as the palate; however, this is not very



BioCover allograft

fun for the patient. In those cases, the surgeon has to make an incision to expose the tooth's root and then use that piece of the patient's palate to suture over the defect. But, wait, there's still more. The surgeon must then bring the original flap of tissue back over the wound site and suture that in place."

So the surgeon has to create a new wound, suture twice and worry about all the extra pain and infection potential. Before Tofe and Snoasis, the dental surgeon's only alternative to the cut twice and suture twice approach was to use donated (from cadavers) allograft dermis tissue.

"Cadaveric tissues are difficult to use," says Mr. Tofe. "Among the reported problems with cadaveric skin is that early healing associated with its use is often less than ideal. Specifically, physicians have reported that cadaveric skin can be discolored, have a foul smell and if the

membrane becomes exposed, it can get infected. The use of dermis tissue does not eliminate all of the pain. Once placed, patient's gum tissue is stretched over this bulky material and sutured into place, causing discomfort and local trauma."

Now comes a third option from Snoasis and Robert Tofe. BioCover is the product's brand name and it is processed, dehydrated allograft of amnion tissue for use in treating gingival recession. "Our material is very thin, which is actually better suited than allograft dermis (much thicker) for oral surgery," says Mr. Tofe. "Surgeons can put BioCover onto the surgical site dry. The natural moisture in the wound allows the amnion membrane to self adhere to the exposed root surface and proximal bone."

"The clinician does not need sutures to secure BioCover in place which actually eliminates the most technical

step of the surgery. I've heard so many doctors say, 'Oh, it's so easy!' and it can reduce surgery time by 50% to 80%."

The tissue donations, which eventually turn into sealed packages of BioCover, originate from a completely different kind of operation. "We get our amnion tissue from consenting mothers who undergo elective cesarean section surgery," says Mr. Tofe. "A procurement agency retrieves the tissue and delivers it to processing, where it is cleaned, dried, fused, embossed and terminally sterilized." Snoasis embosses each BioCover product with the company initials, SM, in order to help clinicians identify the basement side of the allograft. "Another benefit," adds Mr. Tofe, "is that BioCover is stored at room temperature and has a five-year shelf life."

Although Snoasis has only been selling BioCover for seven weeks, this short amount of time has been long enough to see patient's sporting pain-free smiles. "The early healing is phenomenal. Patients usually take ibuprofen for 24 hours, and after that they're fine. They can return to their lives. They can't brush that spot for two weeks, obviously, but they aren't in pain. It hurts to harvest palatal tissue. With our product, the clinician simply makes the incisions, covers the defect with BioCover, and closes it."

The Road to Commercialization

The product and the procedure may seem simple and straightforward, but the path Robert Tofe took to start Snoasis and develop BioCover had its share of twists and turns. He began building the company in February,

2007, by investing a good deal of his time and money. Mr. Tofe took it upon himself to begin research of the placenta by looking online. "I've done a lot with Google," he says. Robert's father, Andrew Tofe, Ph.D., a man who found both CeraMed and CeraPedics, called Surgical Biologics, through a Google search. "They had actually started down the path of amnion research in the dental field. They were about three or four months ahead of me, and they already had prototypes. At first, it seemed like I had a competitor."

These two budding companies, however, met face-to-face and eventually decided to combine forces. In November 2007, "we agreed in principal to work with one another," says Mr. Tofe. "Then it took us to July of 2008 to complete the deal. It was a long negotiation, but now we have a wonderful arrangement. Snoasis owns the exclusive dental rights to their intellectual property and all current and future products. Surgical Biologics, including improvements originating from Snoasis, owns the exclusive rights for all non-dental

applications. I think this arrangement enables a high level of cooperation. Surgical Biologics is a phenomenal partner."

It did, however, take some convincing on Mr. Tofe's part to bring the two companies together. "I knew this was going to work. I remember thinking that this could be huge. Surgical Biologics wanted to find a big corporate partner, and I told them that if they go with Snoasis, we would out perform any of the large dental implant companies." Why? "The

Sometimes the answer to better patient outcomes is simple



The human mind
may have designed it,
but the human body
provided the
natural biological
solution.



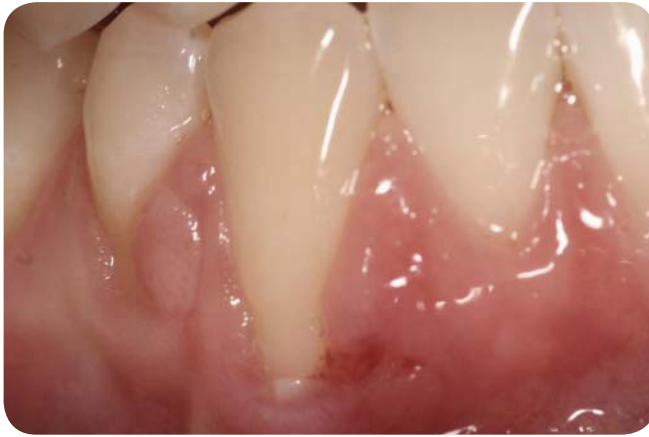
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Gingival recession, prior to treatment.



Gingival recession, after treatment with the BioCover allograft.

larger companies focus on implants and as history has showed over and over again, they do a poor job at marketing hardware and regenerative products.”

It also helps that, despite being at the young age of 34, Mr. Tofe has had many years of experience in the field. “I spent a number of years in dentistry. My dad founded CeraMed, a dental bone substitutes in the late 1980s; I started working there when I was 15. I stayed all the way until I was 26, but when my dad started CeraPedics, an orthopedic bone substitutes company in 2002, I jumped ship and became his fourth employee. That was a hell of a ride.” However, after CeraPedics secured a \$14.5 million of venture capital, Mr. Tofe decided to use what he had learned over the years and created his own company. “I’ve got four employees, and this is all really new. Periodontists are the scientists of the dental community, so they are skeptical. But I never worry. Snoasis has an incredible products and I’m

excited to share my love for our amnion based tissue products with others.”

To ensure the safety associated with the use of this product, BioCover is procured and processed according to standards established by the United States Food and Drug Administration (FDA) and The American Association of Tissue Banks (AATB). An additional assurance of safety is achieved by terminally sterilizing each membrane.

The Future of Amniotic Tissue

Mr. Tofe hopes that the benefits of this novel allograft from living donors, reduced surgery time, improved patient outcomes, and an affordable price tag, may be just enough to convince the skeptics.

“In dentistry, a product has to work. It has to be easy to use, and it has to be economical; there is very little third party reimbursement. BioCover delivers on all counts.”

Mr. Tofe has certainly set himself up to achieve his simple goal of “building the number one dental regenerative products company.”

As for the future of this technology, amnion tissue has many potential uses across the field of medicine. Mr. Tofe has two other amniotic tissue products currently in clinical trials: another product to treat gingival recession and a membrane barrier for guided bone and guided tissue regeneration. “I believe this technology has tremendous potential wherever there is mucosal tissue” says Mr. Tofe. But for now, Robert Tofe is content to use the placenta as basis for helping dental professionals improve outcomes. “I don’t have to take the world. I’ll just take dentistry.”

