Placenta Tissues
What is available, What do we know and How can we utilize for our patients?

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AOFAS SPECIALTY DAY
March 5, 2016

Placental Tissue Products

• Commercially available
• Biologically active
• Derived from consensually donated placenta obtained from cesarean section deliveries

Different Combinations of Tissue

• Amniotic membrane alone
• Amnion and chorion
• Amniotic membrane with umbilical cord

Different Formulations

• Amniotic tissue as a sheet
• Amniotic fluid extract
• Morselized / micronized amniotic membrane suspensions

Why consider its use

• Well suited when tissue regeneration modulation is the goal
  o Decrease inflammation
  o bioburden
  o cell senescence
  o growth factor deficiency
  o increased levels of proteases
How does it work?
- directs tissue healing towards regeneration and away from scarring and inflammation

Published uses in Foot and ankle:
- soft tissue modulation for tendon repair / tendinosis
- wound care
- articular cartilage, hallux rigidus
- plantar fasciitis

**Annotated Bibliography for Placenta Tissue Uses in Foot and Ankle**

**Plantar Fasciitis (3)**

Study looked at PalinGen SportFLOW (AM-AF). 44 patients that failed 6 months of nonop Achilles/PF pain treatment. Injected this material and followed patients for 12 weeks. Conclusion: significant pain reduction

The aim of this pilot study was to investigate the use of c-hAM in comparison to corticosteroid injection. They specifically evaluated c-hAM’s short-term safety and effect on patient outcomes. 24 patients with PF. 14 pts in control group (Depo-Medrol) and 9 pts in study group (c-hAM). Followed pts at 6 wks, then again at 12 wks. Offered a second injection to pts at the 6 wk mark (3 pts in each group received this second injection). In the 1 injection group, shoe fit score and general health score were significantly greater in the control group. In the 2 injection group, foot pain score was significantly greater at the 18 wk mark in the study group. VAS
scores showed no difference between the control and study groups; however, there appeared to be a dose-dependent effect in the c-hAM study group. So in summary, this paper demonstrates that c-hAM is safe and at least comparable to corticosteroids, and secondly, its lays some foundation on the dose-dependent effect of placental tissues.

Zelen CM, Poka A, Andrews J. Prospective, randomized, blinded, comparative study of injectable micronized dehydrated amniotic/chorionic membrane allograft for plantar fasciitis—a feasibility study. Foot Ankle Int. 2013;34(10):1332-1339. This study is the first IRB approved randomized, prospective single center clinical trial which examined the efficacy of a single injection of micronized dehydrated human amniotic/chorionic membrane (mDHACM) for refractory chronic plantar fasciitis. 45 pts (3 groups of 15). Patients were randomized into 1 of 3 groups: (1) standard care, plus 2 injections (2 cc of 0.5% Marcaine plain, then 1.25 cc sterile 0.9% saline) (controls), (2) standard care, plus 2 injections (2 cc of 0.5% Marcaine plain, then 0.5 cc of mDHACM injectable) (0.5 cc mDHACM group), or (3) standard care, plus 2 injections (2 cc of 0.5% Marcaine plain, then 1.25 cc of mDHACM injectable) (1.25 cc mDHACM group). Total of 8 wks of f/u with weekly f/u visits through 6 wks. controls continued to report moderate to severe pain throughout the 8-week study period, while those receiving mDHACM reported a significant reduction of pain from very severe at baseline to within the mild to moderate range at 1 week and reported continuing reduction in pain over the study period. Pain reduction from baseline appears similar for the mDHACM groups. They prescribed Tramadol 50mg for pain associated with the injection. No statistical difference in AOFAS scores between the 2 groups that received mDHACM. While patients receiving treatment were blinded to their group assignment the investigator performing the injection and follow-up was aware of the treatment group, thus may have been biased as to study outcome. No difference was identified between the 2 groups that received mDHACM; however, the sample size was small and thus, a larger sample size is needed to determine if a difference exists among the 2 groups.
Retrospective chart review that looked at 124 patients in which AM/UC tissue was used. Minimum f/u was 120 days. Clinical outcomes of interest were postop infections, delayed or nonhealing wounds, adverse surgical site reactions, and repeat surgery for formal I&D. Most common surgical use was in Achilles and peroneal tendon repairs. Other uses were in Brostrom/peroneal tenosynovectomy as well as PTT repairs. 19 complications recorded which lead to an complication rate of 15%; however, 7 of the 19 complications were wound-related problems which lead to an overall complication rate of 5% (7/124). Of those 7 wound-related problems, 2 needed formal I&D, thus, demonstrating a reoperation rate of 1.6% (2/124). Historical rates of wound infection are between 2-5%, so the present study’s evaluation of wound infections with use of AM/UC tissue is less than the historical data. Conclusion: use of amniotic tissue use in foot and surgery is safe with a decreasing trend in overall complication rates compared to historical rates.

Wounds (∞)

They looked at 20 diabetic foot wounds. Injected gAM-AF solution into the margins of the wound (within 0.5 cm from the wound edge) at the 12, 3, 6, & 9 o’clock position and did this at 14 to 21 day intervals. Tegaderm dressing for 3 days after each injection followed by standard wet-to-dry dressing changes until the next injection. 18 of 20 wounds (90%) healed during the 12-week observation period. No wounds progressed to amputation. Limitations of the study include not comparing to other therapeutic modalities and comparing it to historical controls.

Hallux Rigidus (1)


**Topical Reviews:**


Reviews the biological mechanisms of action of placental tissues. Clinical literature review focuses mostly on LE ulcers


Good general review.

**Basic Science:**


Prospectively compared histological, histochemical, matrix protein content, and biological activity properties of fresh and cryopreserved human amniotic membrane tissue. Histological and histochemical properties were similar. There was a significant loss of total protein and a trend toward significant loss of albumen in
the AM samples but not Amniochorionic samples. Hyaluronic acid content and molecular size distribution was preserved. Biological assays of macrophage viability and TGF-Beta 1 suppression were the same.

**Diabetic foot ulcers:**
