

## CELLULAR AND/OR TISSUE BASED PRODUCTS FOR WOUNDS 2015 BIBLIOGRAPHY

### Alloderm® Regenerative Tissue Matrix

Desman E, Bartow W, Anderson LH. Human Skin Allograft for Patients With Diabetic Foot Ulcers, Venous Leg Ulcers, or Surgical/Traumatic Wounds: A Retrospective, Descriptive Study. *Ostomy Wound Management*. 2015; 61 (7): 16-21.

Sinha UK, Shih C, Chang K, Rice DH. Use of AlloDerm for coverage of radial forearm free flap donor site. *Laryngoscope*. 2002 Feb; 112(2):230-4. PubMed PMID: 11889375.

### Amnioexcel

Lintzeris, D, et al. Use of a Dehydrated Amniotic Membrane Allograft on Lower Extremity Ulcers in Patients with Challenging Wounds: A Retrospective case Series. *Ostomy Wound Management*. 2015;61(10):29-36.

### Apligraf®

Alvarez OM, Fahey CB, Auletta MJ, Fernández-Obregón A. A novel treatment for venous leg ulcers. *J Foot Ankle Surg*. 1998 Jul-Aug; 37(4):319-24. PubMed PMID: 9710785.

Brem H, Balledux J, Sukkarieh T, Carson P, Falanga V. Healing of venous ulcers of long duration with a bilayered living skin substitute: results from a general surgery and dermatology department. *Dermatol Surg*. 2001 Nov; 27(11):915-9. PubMed PMID: 11737123.

Donohue KG, Carson P, Iriondo M, Zhou L, Saap L, Gibson K, Falanga V. Safety and efficacy of a bilayered skin construct in full-thickness surgical wounds. *J Dermatol*. 2005 Aug; 32(8):626-31. PubMed PMID: 16334861.

Edmonds M; European and Australian Apligraf Diabetic Foot Ulcer Study Group. Apligraf in the treatment of neuropathic diabetic foot ulcers. *Int J Low Extrem Wounds*. 2009 Mar; 8(1):11-8. Epub 2009 Feb 3. PubMed PMID: 19189997.

Eaglstein WH, Alvarez OM, Auletta M, Leffel D, Rogers GS, Zitelli JA, Norris JE, Thomas I, Iriondo M, Fewkes J, Hardin-Young J, Duff RG, Sabolinski ML. Acute excisional wounds treated with a tissue-engineered skin (Apligraf). *Dermatol Surg*. 1999 Mar; 25(3):195-201. PubMed PMID: 10193966.

Falanga V, Margolis D, Alvarez O, et al. Rapid healing of venous ulcers and lack of clinical rejection with an allogeneic cultured human skin equivalent. *Arch Dermatol*. 1998; 134:293-300.

Falanga V, Saap LJ, Ozonoff A. Wound bed score and its correlation with healing of chronic wounds. *Dermatol Ther*. 2006 Nov-Dec; 19(6):383-90. PubMed PMID: 17199681.

Gohari S, Gambla C, Healey M, Spaulding G, Gordon KB, Swan J, Cook B, West DP, Lapiere JC. Evaluation of tissue-engineered skin (human skin substitute) and secondary intention healing in the treatment of full thickness wounds after Mohs micrographic or excisional surgery. *Dermatol Surg*. 2002 Dec; 28(12):1107-14; discussion 1114. PubMed PMID: 12472488.

Griffiths M, Ojeh N, Livingstone R, Price R, Navsaria H. Survival of Apligraf in acute human wounds. *Tissue Eng*. 2004 Jul-Aug; 10(7-8):1180-95. PubMed PMID: 15363174.

Kuhn C, Angehrn F. Use of high-resolution ultrasound to monitor the healing of leg ulcers: a prospective single-center study. *Skin Res Technol*. 2009 May; 15(2):161-7. PubMed PMID: 19622125.

Schonfeld WH, Villa KF, Fastenau JM, Mazonson PD, Falanga V. An economic assessment of Apligraf (Graftskin) for the treatment of hard-to-heal venous leg ulcers. *Wound repair and regeneration*, 2000; 8: 251-257.

Veves A, Falanga V, Armstrong DG, Sabolinski ML; Apligraf Diabetic Foot Ulcer Study. Graftskin, a human skin equivalent, is effective in the management of noninfected neuropathic diabetic foot ulcers: a prospective randomized multicenter clinical trial. *Diabetes Care*. 2001 Feb; 24(2):290-5. PubMed PMID: 11213881.

Waymack P, Duff RG, Sabolinski M. The effect of a tissue engineered bilayered living skin analog, over meshed split-thickness autografts on the healing of excised burn wounds. The Apligraf Burn Study Group. *Burns*. 2000 Nov; 26(7):609-19. PubMed PMID: 10925183.

Zaulyanov, Larissa, Kirsner Robert S. "A review of a bi-layered living cell treatment (Apligraf®) in the treatment of venous leg ulcers and diabetic foot ulcers". *Clinical Interventions in Aging*: 2007;2 (1):93-98. \*\*

## **Biovance**

Bhatia, M., et al., The mechanism of cell interaction and response on decellularized human amniotic membrane: Complications in wound healing. *Wounds*, 2007. **19**: p. 207-217.

Letendre, S., et al., Pilot trial of biovance collagen-based wound covering for diabetic ulcers. *Adv Skin Wound Care*, 2009. 22(4): p. 161-

Mahmoudi-Rad, M., et al., Acellular amniotic membrane: an appropriate scaffold for fibroblast proliferation. *Clin Exp Dermatol*, 2013. **38**(6): p. 646-51

Smiehl JM, Treadwell T, Hahn HD, Hermans MH. Real World Experience With a Decellularized Dehydrated Human Amniotic Membrane Allograft. *Wounds*. 2015;27(6):158-169.

## **DermACELL<sup>AWM</sup>.**

Bertasi G., et. al. Use of a novel acellular dermal matrix allograft to treat complex trauma wound: a case study. *Int. J. Burns Trauma.* 2014;4(2):62-65.

Chen, S., Tzeng, Y., Wang, C. Case Report: Treatment of a severe burn with DermACELL, an acellular dermal matrix. *Int. J. Burns Trauma.* 2012; 2160-2026.

Mulder, G. Tissue augmentation and replacement of heel fat pad with a decellularized sterile human dermal matrix. *Wounds.* 2012;24(7):185-189.

Roussalis, J. Case Study: Treatment of a scalp wound with exposed frontal bone using DermACELL<sup>®</sup> AWM. *Int. J. Burns Trauma.* 2014;4(2):49-52.

Yonehiro, L., Burleson, G., MD, et. al. Use of New Acellular Dermal Matrix for Treatment of Non-Healing Wounds in the Lower Extremities of Patients with Diabetes. *Wounds.* 2013;25(12):340-344

## **Dermagraft<sup>®</sup> Human Fibroblast-Derived Dermal Substitute**

Browne AC, Vearncombe M, Sibbald RG. High bacterial load in asymptomatic diabetic patients with neurotrophic ulcers retards wound healing after application of Dermagraft. *Ostomy Wound Manage.* 2001 Oct; 47(10):44-9. PubMed PMID: 11890078.

Gentzkow GD, Iwasaki SD, Hershon KS, Mengel M, Prendergast JJ, Ricotta JJ, Steed DP, Lipkin S. Use of dermagraft, a cultured human dermis, to treat diabetic foot ulcers. *Diabetes Care.* 1996 Apr; 19(4):350-4. PubMed PMID: 8729158.

Grey JE, Lowe G, Bale S, Harding KG. The use of cultured dermis in the treatment of diabetic foot ulcers. *J Wound Care.* 1998 Jul; 7(7):324-5. PubMed PMID: 9791355.

Marston WA, Hanft J, Norwood P, Pollak R; Dermagraft Diabetic Foot Ulcer Study Group. The efficacy and safety of Dermagraft in improving the healing of chronic diabetic foot ulcers: results of a prospective randomized trial. *Diabetes Care.* 2003 Jun; 26(6):1701-5. PubMed PMID: 12766097.

Naughton G, Mansbridge J, Gentzkow G. A metabolically active human dermal replacement for the treatment of diabetic foot ulcers. *Artif Organs.* 1997 Nov; 21(11):1203-10. PubMed PMID: 9384327.

Newton DJ, Khan F, Belch JJ, Mitchell MR, Leese GP. Blood flow changes in diabetic foot ulcers treated with dermal replacement therapy. *J Foot Ankle Surg.* 2002; 41:233-237

Purdue GF. Dermagraft-TC pivotal efficacy and safety study. *J Burn Care Rehabil.* 1997 Jan-Feb; 18(1 Pt 2):S13-4. PubMed PMID: 9063802. (NOTE: Off-Label Use.)

Warriner RA 3rd, Cardinal M; TIDE Investigators. Human fibroblast-derived dermal substitute: results from a treatment investigational device exemption (TIDE) study in diabetic foot ulcers. *Adv Skin Wound Care.* 2011 Jul; 24(7):306-11. PubMed PMID: 21685733.

### **Epifix \*\***

Zelen CM, Gould L, Serena TE, et al. A Prospective, Randomised, Controlled, Multi-Centre Comparative Effectiveness Study of Healing Using Dehydrated Human Amnion/Chorion Membrane Allograft, Bioengineered Skin Substitute, or Standard of Care for Treatment of Chronic Diabetic Lower Extremity Ulcers. *International Wound Journal*. 2014: 1-7.

### **Grafix \*\***

Gordon NM, Maxson S, Hoffman JK. Biologically enhanced healing of the rotator cuff. *Orthopedics*, 2012 Jun; 35(6): 498-504. PubMed PMID: 22691639.

Lavery LA, Fulmer J, Shebetka KA, et al. The efficacy and safety of Grafix® for the treatment of chronic diabetic foot ulcers: results of a multicentre, controlled, randomised, blinded, clinical trial. *Int Wound J*. 2014;11:554–560. \*\*

### **Graftjacket®**

Brigido SA. The use of an acellular dermal regenerative tissue matrix in the treatment of lower extremity wounds: a prospective 16-week pilot study. *Int Wound J*. 2006 Sep; 3(3):181-7. PubMed PMID: 16984575.

Brigido SA, Boc SF, Lopez RC. Effective management of major lower extremity wounds using an acellular regenerative tissue matrix: a pilot study. *Orthopedics*. 2004 Jan; 27(1 Suppl):s145-9. PubMed PMID: 14763548.

Martin BR, Sangalang M, Wu S, Armstrong DG. Outcomes of allogenic acellular matrix therapy in treatment of diabetic foot wounds: an initial experience. *Int Wound J*. 2005 Jun; 2(2):161-5. PubMed PMID: 16722865.

Reyzelman A, Crews RT, Moore JC, Moore L, Mukker JS, Offutt S, Tallis A, Turner WB, Vayser D, Winters C, Armstrong DG. Clinical effectiveness of an acellular dermal regenerative tissue matrix compared to standard wound management in healing diabetic foot ulcers: a prospective, randomised, multicentre study. *Int Wound J*. 2009 Jun; 6(3):196-208. Epub 2009 Apr 2. PubMed PMID: 19368581

Winters CL, Brigido SA, Liden BA, Simmons M, Hartman JF, Wright ML. A multicenter study involving the use of a human acellular dermal regenerative tissue matrix for the treatment of diabetic lower extremity wounds. *Adv Skin Wound Care*. 2008 Aug; 21(8):375-81. PubMed PMID: 18679086.

### **Graftjacket® XPress**

Brigido SA, Schwartz E, McCarroll R, Hardin-Young J. Use of an acellular flowable dermal replacement scaffold on lower extremity sinus tract wounds: a retrospective series. *Foot Ankle Spec*. 2009 Apr; 2(2):67-72. PubMed PMID: 19825754.

### **Hyalomatrix Bi-layered Wound Dressing**

Faga A, Nicoletti G, Brenta F, Scevola S, Abatangelo G, Brun P. Hyaluronic acid three-dimensional scaffold for surgical revision of retracting scars: a human experimental study. *Int Wound J*. 2012 May 28. doi: 10.1111/j.1742-481X.2012.00981.x. [Epub ahead of print] PubMed PMID: 22630331.

Gravante G, Sorge R, Merone A, Tamisani AM, Di Lonardo A, Scalise A, Doneddu G, Melandri D, Stracuzzi G, Onesti MG, Cerulli P, Pinn R, Esposito G. Hyalomatrix PA in burn care practice: results from a national retrospective survey, 2005 to 2006. *Ann Plast Surg*. 2010 Jan; 64(1):69-79. PubMed PMID: 20010411.

Gravante G, Delogu D, Giordan N, Morano G, Montone A, Esposito G. The use of Hyalomatrix PA in the treatment of deep partial-thickness burns. *J Burn Care Res*. 2007 Mar-Apr; 28(2):269-74. PubMed PMID: 17351444.

### **Integra® Dermal Regeneration Template**

Cuadra A, Correa G, Roa R, Piñeros JL, Norambuena H, Searle S, Las Heras R, Calderón W. Functional results of burned hands treated with Integra®. *J Plast Reconstr Aesthet Surg*. 2012 Feb; 65(2):228-34. Epub 2011 Oct 29. PubMed PMID: 22041337.

Dantzer E, Braye FM. Reconstructive surgery using an artificial dermis (Integra): results with 39 grafts. *Br J Plast Surg*. 2001 Dec; 54(8):659-64. PubMed PMID: 11728107.

Frame JD, Still J, Lakhel-LeCoadou A, Carstens MH, Lorenz C, Orlet H, Spence R, Berger AC, Dantzer E, Burd A. Use of dermal regeneration template in contracture release procedures: a multicenter evaluation. *Plast Reconstr Surg*. 2004 Apr 15; 113(5):1330-8. PubMed PMID: 15060344.

Khan MA, Ali SN, Farid M, Pancholi M, Rayatt S, Yap LH. Use of dermal regeneration template (Integra) for reconstruction of full-thickness complex oncologic scalp defects. *J Craniofac Surg*. 2010 May; 21(3):905-9. PubMed PMID: 20485078.

### **Integra® Bilayer Matrix Wound Dressing**

Shores JT, Hiersche M, Gabriel A, Gupta S. Tendon coverage using an artificial skin substitute. *J Plast Reconstr Aesthet Surg*. 2012; 65:1544-1550. PubMed PMID: 22721977.

### **Integra® Dermal Regeneration Template**

Branski LK, Herndon DN, Pereira C, Mlcak RP, Celis MM, Lee JO, Sanford AP, Norbury WB, Zhang XJ, Jeschke MG. Longitudinal assessment of Integra in primary burn management: a randomized pediatric clinical trial. *Crit Care Med*. 2007 Nov; 35(11):2615-23. PubMed PMID: 17828040.

Heimbach DM, Warden GD, Luterman A, Jordan MH, Ozobia N, Ryan CM, Voigt DW, Hickerson WL, Saffle JR, DeClement FA, Sheridan RL, Dimick AR. Multicenter post approval clinical trial of Integra dermal regeneration template for burn treatment. *J Burn Care Rehabil.* 2003 Jan-Feb; 24(1):42-8. PubMed PMID: 12543990.

## **Neox**

Chua *et al.*, 2014. An Open Label Prospective Pilot Study to Evaluate the Efficacy of Cryopreserved Amniotic Tissue Grafts for Chronic Non-healing Ulcers. *WOUNDS 2014;26(5): E30-E38.*

Caputo, 2014. Pilot Study to Examine the Efficacy of Umbilical Cord\* Matrix for Limb Salvage Therapy in Chronic Ulcer Patients with Osteomyelitis. *Society for Advance Wound Care, Orlando, FL, April 24-27. Accepted Abstract and invited podium presentation.*

Couture 2015. Cryopreserved NEOX CORD 1K in the Treatment of Wounds with Varying Etiologies and Co-Morbidities. *American Podiatric Medical Association, Orlando, FL, July 23-26, 2015.*

Caputo *et al.*, 2015. A single-center, retrospective study of NEOX CORD 1K for patients suffering with complex diabetic foot ulcers complicated by underlying osteomyelitis. *Wound Repair and Regeneration, submitted.*

Couture, 2015. A single-center, retrospective study of NEOX® CORD 1K for wound healing in patients suffering from chronic wounds of the foot and ankle DFUs/Grade I/II. *Wound Repair and Regeneration, In preparation.*

Raphael, 2015. Novel Surgical Technique for Treating Chronic Ulcers Utilizing Cryopreserved Umbilical Cord (UC). *Society for Advanced Wound Care, San Antonio, TX, April 27-May 3.*

Swan, J., Use of Cryopreserved, Particulate Human Amniotic Membrane and Umbilical Cord (AM/UC) Tissue: A Case Series Study for Application in the Healing of Chronic Wounds. *Surg Technol Int, 2014. 25: p. 73-8.*

## **Oasis® Wound Matrix**

Barendse-Hofmann MG, van Doorn LP, Oskam J, Steenvoorde P. Extracellular matrix prevents split-skin grafting in selected cases. *J Wound Care.* 2007; 16:455-458.

Cazell SM, Lange DL, Dickerson JE, Slade HB. The Management of Diabetic Foot Ulcers with Porcine Small Intestine Submucosa Tri-Layer Matrix. *Adv. Wound Care.* 2015 [epub]

Landsman A, Roukis T, DeFronzo D, Agnew P, Petranto D, Surprenant M; Living Cells or Collagen Matrix: Which Is More Beneficial in the Treatment of Diabetic Foot Ulcers? *Wounds* 2008 May; 20(5):111-116.

Mostow EN, Haraway GD, Dalsing M, Hodde JP, King D; OASIS Venus Ulcer Study Group. Effectiveness of an extracellular matrix graft (OASIS Wound Matrix) in the treatment of chronic leg ulcers: a randomized clinical trial. *J Vasc Surg.* 2005 May; 41(5):837-43. PubMed PMID: 15886669.

Niezgoda JA, Van Gils CC, Frykberg RG, Hodde JP. Randomized clinical trial comparing OASIS Wound Matrix to Regranex Gel for diabetic ulcers. *Adv Skin Wound Care.* 2005 Jun; 18(5 Pt 1):258-66. PubMed PMID: 15942317.

O'Donnell T, Lau J. A systematic review of randomized controlled trials of wound dressings for chronic venous ulcer. *J Vas Sur.* 2006 Nov; 44 (5): 1118-25. (NOTE: Not an RCT, but as a systematic review, it is the highest level of evidence literature can provide.)

Rando T. Use of a biological extracellular matrix wound therapy to heal complex, chronic wounds. *Journal of Wound Care* 2009; 18:70-74.

Romanelli M, Dini V, Bertone M, Barbanera S, Brilli C. OASIS wound matrix versus Hyaloskin in the treatment of difficult-to-heal wounds of mixed arterial/venous aetiology. *Int Wound J.* 2007 Mar; 4(1):3-7. PubMed PMID: 17425543.

Romanelli M, Dini V, Bertone MS. Randomized comparison of OASIS wound matrix versus moist wound dressing in the treatment of difficult-to-heal wounds of mixed arterial/venous etiology. *Adv Skin Wound Care.* 2010 Jan; 23(1):34-8. PubMed PMID: 20101114.

### **Primatrix™ Dermal Repair Matrix**

Lullove E. Acellular fetal bovine dermal matrix in the treatment of nonhealing wounds in patients with complex comorbidities (Retrospective study). *J Am Podiatr Med Assoc.* 2012 May-Jun; 102(3):233-9. PubMed PMID: 22659766.

Karr JC. Retrospective comparison of diabetic foot ulcer and venous stasis ulcer healing outcome between a dermal repair scaffold (PriMatrix) and a bilayered living cell therapy (Apligraf). *Adv Skin Wound Care.* 2011 Mar; 24(3):119-25. PubMed PMID: 21326023.

Kavros SJ. Acellular fetal bovine dermal matrix for treatment of chronic ulcerations of the midfoot associated with charcot neuroarthropathy. *Foot Ankle Spec.* 2012 Aug; 5(4):230-4. Epub 2012 Jun 19. PubMed PMID: 22715495.

Neill J, James KS, Lineaweaver W. Utilizing biologic assimilation of bovine fetal collagen in staged skin grafting. *Ann Plast Surg.* 2012 68: 451-456.

Strauss NH and Brietstein RJ. Fetal dermal repair scaffold in the treatment of difficult-to-heal complex wounds. *Wounds.* 2012Nov; 24(11):327-334.

### **TalyMed® Advanced Matrix**

Hankin CS, Knispel J, Lopes M, Bronstone A, Maus E. Clinical and cost efficacy of advanced wound care matrices for venous ulcers. *J Manag Care Pharm.* 2012 Jun; 18(5):375-84. PubMed PMID: 22663170.

Kelechi TJ, Mueller M, Hankin CS, Bronstone A, Samies J, Bonham PA. A randomized, investigator-blinded, controlled pilot study to evaluate the safety and efficacy of a poly-N-acetyl glucosamine-derived membrane material in patients with venous leg ulcers. *J Am Acad Dermatol.* 2012 Jun; 66(6):e209-15. Epub 2011 May 26. PubMed PMID: 21620515.

### **Theraskin®**

Bundy, et al. Cryopreserved Allograft as an Alternative Option for Closure of Diabetic Foot Ulcers. *Podiatry Management* 2013: 131-136

DiDomenico L, Emch KJ, Landsman AR, Landsman AS. A Prospective Comparison of Diabetic Foot Ulcers Treated With Either a Cryopreserved Skin Allograft or a Bioengineered Skin Substitute. *Wounds* 2011 July; 23(7):184-189.

Landsman AS, Cook J, Cook E, Landsman AR, Garrett P, Yoon J, Kirkwood A, Desman E. A retrospective clinical study of 188 consecutive patients to examine the effectiveness of a biologically active cryopreserved human skin allograft (TheraSkin®) on the treatment of diabetic foot ulcers and venous leg ulcers. *Foot Ankle Spec.* 2011 Feb; 4(1):29-41. Epub 2010 Dec 6. PubMed PMID: 21135263.

Sanders, et.al. Analysis of a Prospective, Multicenter Randomized Controlled Clinical Trial Comparing a Bioengineered Skin Substitute to a Human Skin Allograft. *Ostomy Wound Management.* 2014(Sept); 60(9):26-38)

### **Unite Biomatrix \*\***

Alexander JH, Yeager DA, Stern DS, et al. Equine Pericardium as a Biological Covering for the Treatment of Diabetic Foot Wounds: A Prospective Study. *Journal of the American Podiatric Medical Association.* 2012; 102(5):352-357

\*\* Studies published in various AB MAC LCDs for CTPs. The manufacturer of these products is not a member of the Alliance of Wound Care Stakeholders or Coalition of Wound Care Manufacturers and therefore the information has not been verified.