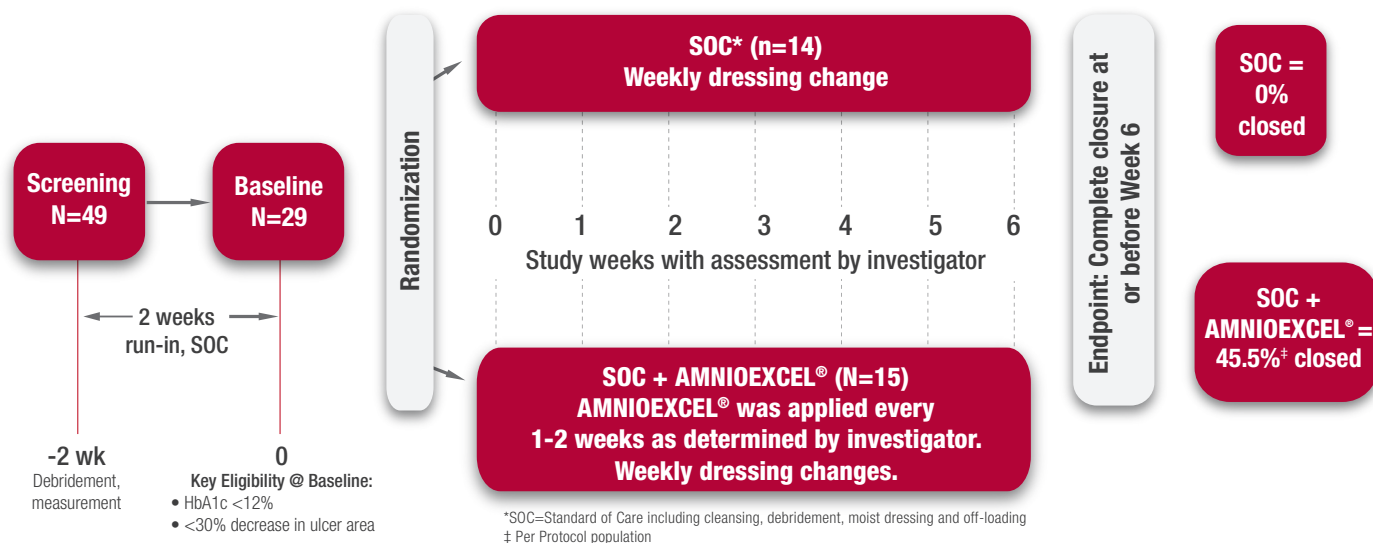




See *WOUNDS*,  
March 2016, for full article

## Multicenter RCT demonstrates AMNIOEXCEL® + SOC significantly increases closure of chronic DFUs



Clinicaltrials.gov #NCT02209051

This prospective, multicenter, randomized, controlled clinical trial (RCT) with standardized ulcer care and off-loading incorporated a 2 week run-in period. Despite a short 6-week study period, AMNIOEXCEL® + SOC achieved significantly greater (p=0.008) ulcer closure rates over SOC alone.

### A Prospective, Randomized, Multicenter and Controlled Evaluation of the Use of Dehydrated Amniotic Membrane Allograft (DAMA) compared to Standard of Care for the Closure of Chronic Diabetic Foot Ulcers.

Snyder RJ, Shimozaki K, Tallis A, Kerzner M, Reyzelman A, Lintzeris D, Bell D, Rutan RL, and Rosenblum B

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#### In this trial:

- Stratified randomization yielded a statistically balanced demographic and wound characteristic distribution between groups
- Endpoint of complete ulcer closure objectively adjudicated with photographs and ulcer tracings
- Comparable adverse event profile between groups
- Both the Intent to Treat (all randomized subjects) and the Per Protocol (all completing the study) populations demonstrated statistically significantly greater ulcer closure rates with the addition of AMNIOEXCEL® to the standard of care regimen.

AMNIOEXCEL® Amniotic Allograft Membrane is a novel human placental-based tissue product. The membrane forms a protective covering over the wound while providing the key components found in human amnion including an intact ECM (extracellular matrix), cytokines and other growth factors. The dehydrated membrane is easy to store and use and helps provide the optimal environment to repair, reconstruct and replace wound tissue.



AMNIOTIC ALLOGRAFT MEMBRANE  
**AMNIOEXCEL®**



www.amnioexcel.com or call 800.445.7627