

Human Reticular Acellular Dermal Matrix in the Healing of Chronic Diabetic Foot Ulcerations That Have Failed Standard Conservative Treatment: A Retrospective Crossover Study

Wounds: June, 2016

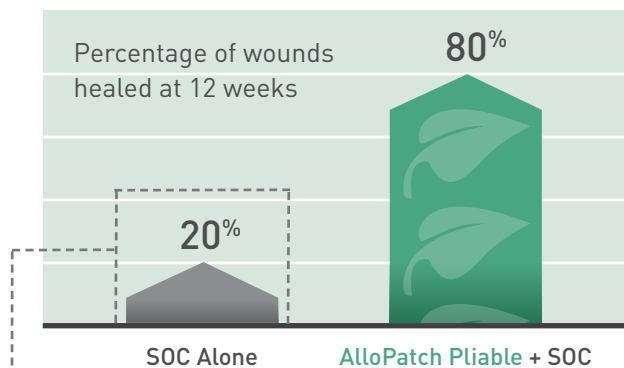
Charles M. Zelen, DPM | Dennis P. Orgill, MD, PhD | Thomas E. Serena, MD | Robert D. Galiano, MD, FACS | Marissa J. Carter, PhD, MA
Lawrence A. DiDomenico, DPM | Jarrod P. Kaufman, MD | Jennifer Keller, DPM | Nathan J. Young, DPM | William W. Li, MD

After a successful randomized, multi-center, prospective study, evaluating the effectiveness of AlloPatch Pliable in healing chronic diabetic foot ulcerations, AlloPatch Pliable was put back to the test. Sixteen patients enrolled in the SOC arm of the original study failed to heal using standard of care (SOC) alone. Of the 16 failed cases, 12 patients met eligibility requirements to join a crossover study and to receive weekly treatments of AlloPatch Pliable to determine if healing could be achieved and, if so, how quickly.

At the conclusion of the crossover study, AlloPatch Pliable was shown to be an effective option for patients who had failed to heal with SOC treatments alone. These results validate the use of AlloPatch Pliable as an adjunct to healing in even the most difficult wounds.

More research, more healing

Original Prospective Clinical Study



Retrospective Crossover Clinical Study

83% of patients in the study achieved complete wound healing, including a ~70% reduction in wound size in the first week alone.

SOC Alone (n=20)



■ Wounds Healed ■ Wounds Failed to Heal

Zelen CM, et al. *Int Wound J.* 2016 Apr 12; DOI: 10.1111/iwj.12600

12 of 16 eligible for crossover study

AlloPatch Pliable + SOC (n=12)



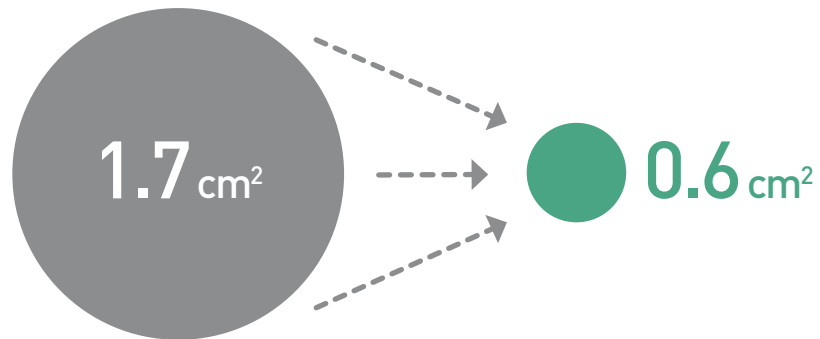
■ Wounds Healed ■ Wounds Failed to Heal

Zelen, et al *Wounds.* Epub 2016 November 21.

Significantly more healing – almost immediately

~70%
wound reduction
after just
1 treatment

Average Wound Area Reduction after 1 treatment of
AlloPatch® Pliable + SOC



Complete healing in less time – at a low cost

Mean Healing Time of

21 days

Mean cost to closure

\$800

Number of Weeks to Closure
AlloPatch® Pliable + SOC



The Wound Clinic Difference:

With a variety of graft sizes available within the Medicare bundled payment, AlloPatch Pliable is exceptionally cost effective. Now clinicians have access to one of the highest quality, lowest cost to closure grafts. The best care is now available for everyone.

Heal wounds in a fraction of the time, at a fraction of the cost.^{1, 2, 3}

¹ Paulos, M. & Papadopoulos, D. Poster presented at Diabetic Limb Salvage Conference, September 22-24, 2011, Washington, DC.

² Zelen CM, et al. *Int Wound J.* 2016 Apr;13(2):272-82.

³ Zelen CM, et al. *Int Wound J.* 2016 Apr 12, DOI: 10.1111/iwj.12600