

GrafixPL PRIME in the Management of Chronic Wounds: A Prospective Case Series¹

GP19004/REV00

Study design

- Prospective, open-label, single-center case series on GrafixPL PRIME in the management of chronic wounds in 11 patients treated for up to 12 weeks
- Primary endpoint: Proportion of patients who achieved complete wound closure at the end of treatment

Patient demographics

- Comorbidities included, but were not limited to, hypertension (54%), diabetes (54%), and deep vein thrombosis (18%)
- All patients had previously failed ≥ 4 weeks of SOC
- 54% of patients had previously failed one or more advanced wound therapies (EpiFix, Apligraf, &/or V.A.C.)

Wound characteristics

- 5 DFUs, 5 VLU, 1 pressure ulcer
- Wound area at baseline (mean): 6.2 cm²
- Wound duration prior to study (mean): **17.8 months**

EpiFix is a trademark of MiMedx Group, Inc. Apligraf is a trademark of Novartis. V.A.C. is a trademark of KCI.

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Reference:

1. Reyzelman AM et al. Wounds 2019;31(4):97–102.

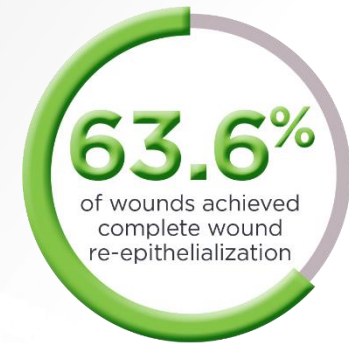
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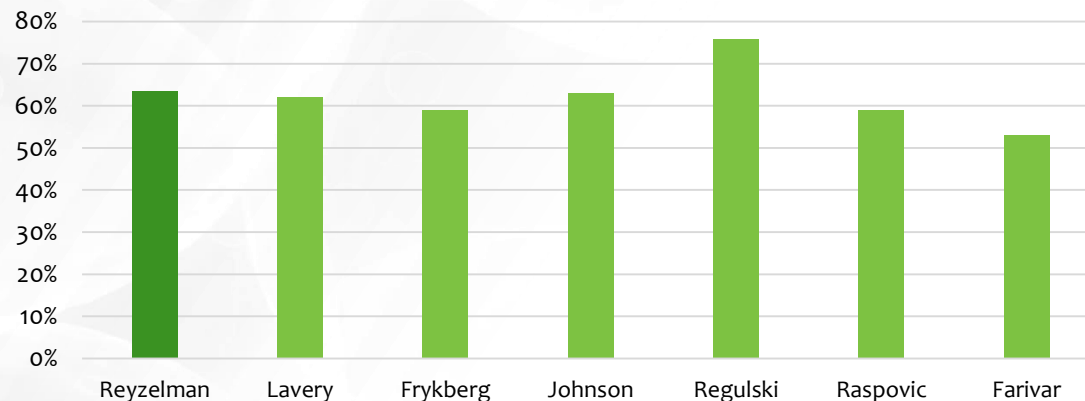
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Study outcomes

- Complete wound closure: **63.6%**
 - **Consistent with closure rates reported with Grafix**
 - Suggests clinical equivalence between lyopreserved and cryopreserved formulations
- Time to closure (mean): 47.1 days
- Number of graft applications (mean): 6 grafts
- No adverse events



Proportion of Patients Who Achieved Closure with GrafixPL¹ and Grafix²⁻⁷



Reference:

1. Reyzelman AM et al. Wounds 2019;31(4):97–102. 2. Lavery LA et al. Int Wound J. 2014; 11(5): 554–560. 3. Frykberg RG et al. Int Wound J. 2016; doi: 10.1111/iwj.12649. 4. Johnson E et al. Wound Repair Regen. 2016; doi: 10.1111/wrr.12503. 5. Regulski M et al. Ostomy Wound Manage. 2013; 59(12): 38–43. 6. Raspovic KM et al. Wound Repair Regen. 2018 Apr 23. doi: 10.1111/wrr.12635. 7. Farivar BS et al. Journal of Vascular Surgery: Venous and Lymphatic Disorders. 2019; <https://doi.org/10.1016/j.jvsv.2018.09.016>: 1–6, published by Elsevier Inc.

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