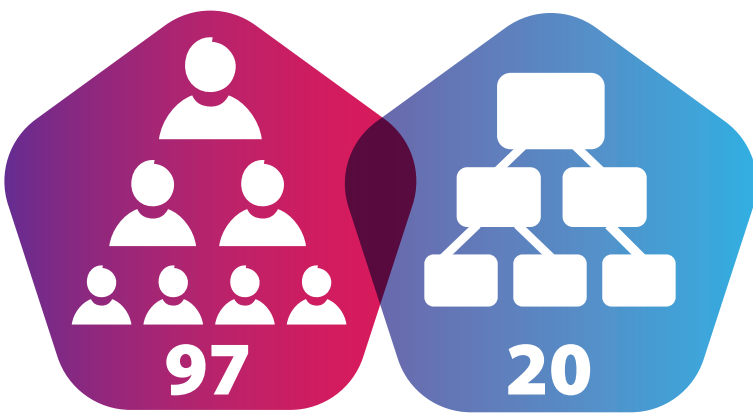




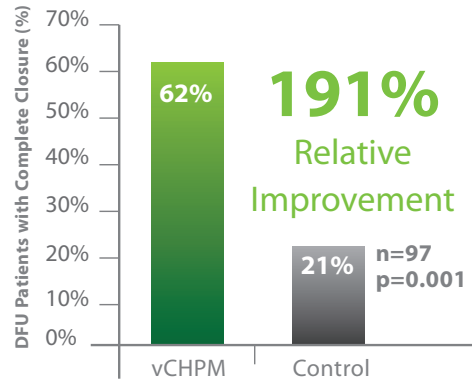
- A chronic ulcer will often develop severe complications such as infection which can lead to **hospitalization** or **amputation**, due to a significant tissue destruction and loss of normal foot function(1). Thus, one of the momentous **goals** of wound care which brings the benefits of the patient and minimizes the cost burden on our health-care system, is to reduce the need for amputation and hospitalization and to provide a treatment, leading to a **fast** and **durable wound closure**(1).

The Efficacy and Safety of vCHPM for the Treatment of Chronic Diabetic Foot Ulcers: Results of a Multi-Centre, Controlled, Randomized, Blinded Clinical Trial.



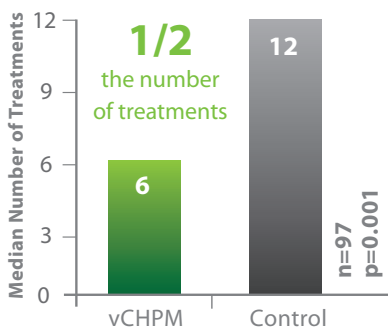
- The treatment was administered with vCHPM (n=50) or standard care (n=47). Standard care included surgical debridement, off-loading, and non-adherent dressings. A 12-week open-label crossover treatment phase was offered to patients in the control group who failed in the treatment with standard care.

The primary endpoint was complete wound closure in chronic diabetic foot ulcers by 12 weeks.

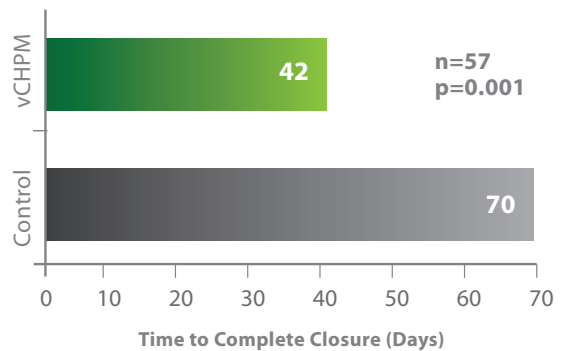


- Relative improvement 3 times greater than other wound therapies which have been used in multi-center randomized controlled trials (2).

vCHPM is shown to achieve full closure with 1/2 the treatment, in nearly 1/2 the time.

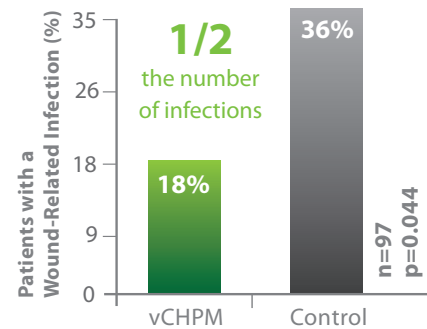
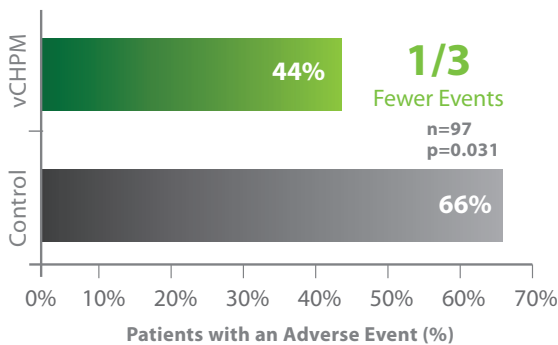


- More patients experienced a %50 or greater reduction in wound size at Day 28 with vCHPM vs standard care (%62 vs %40.4, p=0.035)



- **Demonstrated durability of wound closure**
%82 of wounds treated with vCHPM closed by Week 12 remained closed throughout 12-week follow-up phase

Patients experience $\frac{1}{3}$ fewer adverse events and $\frac{1}{2}$ the number of infections as those treated as standard of care



- Complex DFUs with exposed tendon or bone remain a challenge. They are more susceptible to complications such as infection and **amputation** and require treatments that promote rapid development of granulation tissue and, ultimately, re-epithelialization. This is the results of a prospective, multicenter, open-label, and single-arm **clinical trial** to establish clinical outcomes when vCHPM is applied weekly to complex DFUs with exposed deep structures.

27 patients completed the study:

- ▶ Primary endpoint: 100% wound granulation by week 16,
- ▶ %96.3 of patients in a mean of 6.8 weeks showed complete wound granulation.
- ▶ Complete wound closure occurred in 59.3% (mean 9.1 weeks).
- ▶ The 4-week percent area reduction was 54.3%.
- ▶ There were no product-related adverse events.

So it is considered that vCHPM is a safe and effective option for the successful management of complex wounds with exposed tendon and bone that typically are excluded from randomized controlled clinical trials (1).

Cost Analysis

- The average 1 year per patient medical cost of DFUs is estimated at **28,000\$**. Patients who fail to heal with traditional standard care are at risk for chronic ulcers or limb loss, with the average cost of major amputations approaching **19,000\$** per patient per admission(3).



Only with applying 3 Amniosin™ dressings after 5 weeks in a patient with DFUs in Khorshid Hospital, Isfahan

References:

- Frykberg RG, Gibbons GW, Walters JL, Wukich DK, Milstein FC. A prospective, multicentre, open-label, single-arm clinical trial for treatment of chronic complex diabetic foot wounds with exposed tendon and/or bone: positive clinical outcomes of viable cryopreserved human placental membrane. *International wound journal*. 2017;14(3):569-77.
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- Haugh AM, Witt JG, Hauch A, Darden M, Parker G, Ellsworth WA, et al. Amnion Membrane in Diabetic Foot Wounds: A Meta-analysis. *Plastic and Reconstructive Surgery Global Open*. 2017;5(4):e1302.