

# The Use of 2.5% Sodium Hyaluronate Wound Gel

## to Promote Wound Healing for Patients with Diabetic Foot Ulcers (DFUs) and Lower Leg Ulcers (LLUs) in Community Settings by a Certified Wound Ostomy Continence Nurse (CWOCN)

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### Background

- Reducing health care costs has been acknowledged as a global issue.
- “Every 30 seconds a lower limb is lost due to diabetes somewhere in the world”.**
- 50% patients with leg ulcers had a leg ulcer history 5 to 10 years; 30% > 10 years.
- Treatment costs increases when the duration of treatment, and product use increase.
- Early identification of difficult-to-heal wounds and targeted use of advanced wound care products should be considered whenever possible (Vowden 2011).

### 2.5% Sodium Hyaluronate Wound Gel

Has been used for management of lower leg ulcers, pressure ulcers, diabetic foot ulcers, and surgical wounds (Reece & Quiring, 2002; Woo, et al 2005).

### Method (Study period: May – November 2016)

This prospective, self-controlled non-randomized clinical case series study was conducted to evaluate the efficacy of 2.5% sodium hyaluronate wound gel for community patients with DFUs or LLUs in out-patient clinic settings by assessing:

- The healing rates by comparing the changes of wound size and time to heal
- The incidence of complications

### Inclusive Criteria

- Wounds that failed to reduce size by 30% after treatment for 4 weeks
- DFU: of wound size <10 cm<sup>2</sup>; have been off-loaded with most appropriate offload device, Total Contact Cast (TCC), Poor Man TCC, iTCC, etc.
- LLUs of wound size <100 cm<sup>2</sup>
- Patient with LLUs that have been on 20 mmHg or more compression therapy

### Study Protocol (Weekly wound gel treatment till wound closed or a max. 27 weeks)

- Sharp or mechanical wound debridement by the Principal Investigator, a CWOCN
- Applied wound gel liberally to wound base and margins
- Maintained moisture/bacterial balance with bacterial binding dressings to
- Continued with appropriate offload (DFUs) or compression (LLUs)

**Results: 33 patients recruited; 20 patients completed the study (10 DFU (50%); 10 LLUs (50%):**

- 8 patients (40%): wounds closed**
- 9 patients (45%): wounds improved
- 3 patients (15%): wound status undetermined
- Mean Home Care Nurse treatment days before PI treatment: 195 days
- Mean PI treatment days before wound gel treatment: 193 days
- Mean wound gel weekly applications 15 weeks (105 days)

### Implications:

- The results supported the use of the wound gel to supplement standard wound treatment for patients with DFUs or LLUs.
- To provide stronger evidence, further studies with a larger sampling size with follow up assessments in 3, 6 and 12 months to evaluate the recurrence rates is recommended.

Case 1				Case 2					
August 5, 2015 6 cm x 4.2 cm = 25.4 cm <sup>2</sup>	May 25, 2016 1 <sup>st</sup> wound gel on 290 days PI treatment 4 cm x 2.4 cm = 9.6 cm <sup>2</sup>	July 14, 2016 4 <sup>th</sup> week wound gel 3 cm x 2.5 cm = 7.5 cm <sup>2</sup>	Nov 30, 2016 20 <sup>th</sup> week wound gel <b>Wound Closing</b> 1.5 cm x 0.7 cm = 1.05 cm <sup>2</sup>	March 14, 2016 1 <sup>st</sup> PI Treatment 0.4 cm x 0.3 cm = 0.12 cm <sup>2</sup> 0.3 cm deep with undermining	May 31, 2016 Wound infected requiring IV antibiotics 2.1 cm x 1 cm = 2.1 cm <sup>2</sup>	July 26, 2016 3 <sup>rd</sup> TCC Offloader + 1 <sup>st</sup> wound gel 2 cm x 1.5 cm = 3 cm <sup>2</sup>	Aug 16, 2016 6 <sup>th</sup> TCC Offloader + 4 <sup>th</sup> wound gel 1.3 cm x 1.2 cm = 1.56 cm <sup>2</sup>	Nov 14, 2016 After 13 <sup>th</sup> wound gel + TCC Poor Man <b>Wound Closed</b>	
Case 3					Case 6				
Aug 25, 2016 TCC Poor Man + 1 <sup>st</sup> Wound gel 1 cm x 0.5 cm = 0.5 cm <sup>2</sup> (0.5 cm deep with undermining 0.5 cm 12 – 12 o'clock)	September 22, 2016 3 <sup>rd</sup> TCC Offloader + 2 <sup>nd</sup> Wound Gel 1 cm x 1 cm = 1 cm <sup>2</sup> Deep sinus 3 cm @ 9 o'clock	Sept 29, 2016 4 <sup>th</sup> TCC Offloader + 3 <sup>rd</sup> Wound Gel 0.5 cm x 0.8 cm = 0.5 cm <sup>2</sup> Deep sinus 2.5 cm @ 9 o'clock	Oct 17, 2016 5 <sup>th</sup> TCC Offloader + 5 <sup>th</sup> Wound Gel 1.5 cm x 0.5 cm = 0.75 cm <sup>2</sup> Sinus 0.3 cm @ 9 o'clock	Nov 7, 2016 After 7 <sup>th</sup> TCC Offloader and 7 <sup>th</sup> Wound Gel <b>Wound closed</b>	August 1, 2015 1 <sup>st</sup> PI Treatment Bacterial Binding dressings started 1.5 cm x 0.9 cm = 1.35 cm <sup>2</sup>	Dec 22, 2015 11 <sup>th</sup> PI Treatment 2 cm x 1 cm = 2 cm <sup>2</sup>	May 6, 2016 1 <sup>st</sup> IPM Wound Gel (Post 27 <sup>th</sup> 250 days PI treatment) Deep Small Wound 0.9 cm x 0.6 cm = 0.54 cm <sup>2</sup> (0.4 cm deep)	June 24, 2016 8 <sup>th</sup> Wound Gel Wound size ↑ Depth ↓ <b>100% granulation</b> 1 cm x 0.8 cm = 0.8 cm <sup>2</sup> (0.2 cm deep)	Nov 4, 2016 Post 22 <sup>nd</sup> Wound Gel Patient was discharged after <b>Wound Closed on Sept 30, 2016</b>

### References:

- Reece, et al. (2002) Hyaluronic acid in an ionic polymer gel matrix helps create an optimal environment for ulcer healing. Poster presentation, SAWC Conference, Apr 2002.
- Sibbald et al (2011). Special Consideration in Wound Bed Preparation. *Advances in Skin and Wound Care*, Sept 2011, pp. 425–436
- Vowden (2011). Hard-to-heal Wounds Made Easy. *Wounds International* 2011; 2(4), pp. 1 – 6. <http://woundsinternational.com>

### Disclaimer

- This study was unfunded. The vendor provided the 2.5% sodium hyaluronate wound gel for 20 selected patients for product evaluation.
- The trade name of this 2.5% sodium hyaluronate wound gel is GlycoBioSciences Inc. IPM™ Wound Gel Bio.