2.5% Sodium Hyaluronate Wound Gel Study Cases

Case 1 – Patient with Lower Leg Ulcer Not Responding to Compression

This patient was a 50-year old male patient with nonhealing right lower leg since January 2014. He was referred to HCN with standard wound care and compression therapy ulcer started on April 24, 2015. When his lower leg ulcer failed to improve despite adequate compression therapy (30 – 40 mmHg) and standard wound care, HCN referred patient to the Complex Wound Care and was first treated by the PI on August 5, 2015.

The PI taught the patient how to change his dressings with the bacterial binding dressings weekly to maintain bacterial and moisture balance. High compression therapy with a 2-layer compression stockings were applied persistently by the patient.

The ulcer status improved initially with reduction in size but wound progress was stalled after a few months. On May 25, 2016, the patient consented to the 2.5% sodium hyaluronate wound gel to his treatment protocol.

The lower leg had 22% size reduction after 3rd week of wound gel treatment; and 90% size reduction after 19th wound gel treatment on November 30, 2016.

Case 1

			
August 5, 2015 6 cm x 4.2 cm = 25.4 cm²	**May 25, 2016** 1st wound gel on 290 days PI treatment 4 cm x 2.4 cm = 9.6 cm²	**July 14, 2016** 4th week wound gel 3 cm x 2.5 cm = 7.5 cm²	**Nov 30, 2016** 20th week wound gel 1.5 cm x 0.7 cm = 1.05 cm²

Case 2 – Patient with Infected DFU

The patient is a 55-year male patient with right a DFU on the lateral 5th metatarsal. He was admitted to HCN for standard wound care since December 3, 2014. HCN referred the patient to the Complex Wound Clinic in March 2014.

The patient was first treated by the PI on March 14, 2016. The DFU was covered with 100% yellow slough. The size of the wound was small but deep with undermining (0.4 cm long; 0.3 cm wide, 0.3 cm deep; undermining 0.3 cm from 9 0'clock to 6 0'clock). The PI initiated weekly application of bacterial binding dressings to maintain bacterial and moisture balance. The PI also applied TCC Poor Man to provide additional offload.

His DFU was infected on May 31, 2016 requiring intravenous antibiotics treatment. As soon as the infection was under controlled, the PI started treating the patient with TCC Offloader, the gold standard for DFU treatment, on June 24, 2016.

With the DFU progressed only slowly, the patient consented for the 2.5% sodium hyaluronate wound gel study on July 26, 2016 with the goal to close his DFU as soon as possible. Wound healing continued to progress steadily. The DFU had reduced 50% after 3rd wound gel treatment.

The PI discontinued TCC offloader treatment with application of TCC Poor Man instead on October 3, 2016. The DFU continued to improve and eventually was closed on November 14, 2016 after 13th wound gel applications.

Case 2

				
March 14, 2016 1st PI Treatment 0.4 cm x 0.3 cm = 0.12 cm² 0.3 cm deep with undermining	**May 31, 2016** Wound infected requiring IV antibiotics 2.1 cm x 1 cm = 2.1 cm²	**July 26, 2016** 3rd TCC Offloader + 1st wound gel 2 cm x 1.5 cm = 3 cm²	**Aug 16, 2016** 6th TCC Offloader + 4th wound gel 1.3 cm x 1.2 cm = 1.56 cm²	**Nov 14, 2016** Wound Closed after 13th wound gel + TCC Poor Man

Case 3 – Patient with Left Foot DFU with 3 cm deep sinus tract)

The patient was a 59-year old male with a left foot plantar DFU over 5th metatarsal. He was referred to HCN on April 22, 2016 for standard wound care with a small piece of adhesive felt applied for offload. The DFU was small but was 100% yellow slough with deep undermining 0.5 cm all around. HCN referred the patient to the Complex Wound Clinic with first treatment by the PI on July 3, 2016.

The PI initiated weekly application of bacterial binding dressings to maintain bacterial and moisture balance on August 25, 2016. The PI also applied TCC Poor Man to provide additional offload. With slow progression and persistent deep undermining and no granulation, the PI recommended application of gold standard TCC offloader on September 8, 2016.

On September 15, 2016, the patient signed the 2.5% sodium hyaluronate wound gel study informed consent with the first wound gel applied by PI afterward. During the next clinic visit on September 22, 2016, the PI found a thick skin blister from medial side of the DFU to dorsal lateral side of left foot. After deroofing the thick blister with all dead skin removed, a hypergranulated open ulcer was exposed at midfoot area below 4th metatarsal. When probing the deep undermining of left foot DFU, the new lesion was found to be connected to the undermining area. The DFU was 1 cm long, 1 cm wide, 1 cm deep; sinus 3 cm 9 o'clock. The PI continued with the same treatment protocol with bacterial binding dressings, application of the second 2.5% sodium hyaluronate wound gel wound gel treatment, and TCC Offloader.

The DFU improved significantly next week on September 29 2016 with wound size reduced to 0.5 cm long, 0.8 cm wide, 0.5 cm deep; and the sinus was reduced to 2.5 cm @ 9 o'clock.

The DFU continued to improve with steady size reduction and increased granulation with weekly application of the same treatment. Eventually, the PI discontinued TCC offloader treatment with application of TCC Poor Man instead on October 4, 2016. The HCN applied the same treatment protocol and TCC Poor Man the next week when the PI was on vacation.

The DFU continued to improve and eventually closed on November 7, 2016 after 7th 2.5% sodium hyaluronate wound gel applications and 7th TCC Offloader applications.

Case 3

				
Aug 25, 2016 TCC Poor Man + 1st Wound gel 1 cm x 0.5 cm = 0.5 cm² (0.5 cm deep with undermining 0.5 cm 12 – 12 o'clock)	**September 22,** 2016 3rd TCC Offloader + 2nd Wound Gel 1 cm x 1 cm = 1 cm² Deep sinus 3 cm @ 9 o'clock	**Sept 29, 2016** 4th TCC Offloader + 3rd Wound Gel 0.5 cm x 0.8 cm = 0.5 cm² Deep sinus 2.5 cm @ 9 o'clock	**Oct 17, 2016** 5th TCC Offloader + 5th Wound Gel 1.5 cm x 0.5 cm = .0.75 cm² Sinus 0.3 cm @ 9 o'clock	**Nov 7, 2016** Wound closed after 7th TCC Offloader and 7th Wound Gel

Case 4 – Right Foot Plantar DFU

This 59-year patient was referred to the Complex Wound Clinic by HCN in July 2016 for bilateral plantar 5th metatarsal DFU when his bilateral DFU deteriorated overtime. He was referred to HCN on April 22, 2016 for standard wound care with a small piece of adhesive felt applied for offload.

The PI started treating the right DFU with TCC Offloader and the left DFU with TCC Poor Man on August 25, 2016. Based on the promising results of the Wound Gel treatment, the PI discussed the Wound Gel study with the patient when started TCC treatment. The patient consented and Wound Gel treatment was started on August 25, 2016.

The right foot plantar DFU healing progressed with more than 50% size reduction in 2 weeks. On the other hand, the left foot DFU deteriorated even with the same treatment protocol except that TCC Poor Man was applied to the left foot DFU. The PI decided to start treating the right foot DFU with TCC Poor Man and the left foot DFU with TCC Offloader on September 8, 2016.

The right foot DFU was closed on November 7, 2016 after 10th Wound Gel treatment.

Case 5

				
Aug 25, 2016 1st TCC Offloader 1st Wound Gel 2 cm x 1.5 cm = 3.75 cm² (0.2 cm deep)	**Sept 2, 2016** 2nd TCC Offloader 2nd Wound Gel 2 cm x 1.5 cm = 3 cm² (0.2 cm deep)	**Sept 8, 2016** Discontinued after 2nd TCC Offloader 1st TCC Poor Man 3rd Wound Gel 1.5 cm x 1 cm = 1.5 cm² (0.1 cm deep)	**Oct 24, 2016** TCC Poor Man 2nd 9th Wound Gel 0.2 cm x 0.2 cm = 0.04 cm² (0.1 cm deep)	**Nov 7, 2016** Wound Closed after 10th Wound Gel

Case 5 – Patient with Lower Leg Ulcer Likely Pyoderma Gangrenosum (PG)

This patient was a 58-year old woman with a history of Lupus. Patient has this chronic nonhealing left lower leg ulcer for 3 years after sustaining a traumatic injury to the left lower leg 3 years ago, during when she accidentally hit her left lower leg against the car door when getting out of the car.

The patient was treated at the hospital wound clinic for 1 year before being referred to the HCN in July 2015. She was readmitted to the hospital for rapid wound deterioration when the HCN applied an antiseptic dressing that had been known useful for Pyoderma Gangrenosum (PG). She was readmitted to the HCN for wound care on Oct 11, 2015.

The patient was referred by the HCN to the Complex Wound Clinic and was first treated by the PI on Nov 9, 2015. The left lower leg ulcer was very painful, with presence of hypergranulation, and purplish wound edges. With a medical history of Lupus, and history of rapid deterioration after trauma, the PI treated the ulcer as PG. Sharp wound debridement was not done due to pathergy nature of PG. The PI initiated weekly application of bacterial binding dressings to maintain bacterial and moisture balance. The patient continued wearing high compression stockings persistently.

The lower leg responded to the treatment initially for the first couple months. However, wound healing was stalled with the ulcer started to increase in size slowly in April 2016. With success in closing other patients with suspected PG, the PI recommended the patient trialing daily application of topical 2% Dilantin on June 17, 2016. However, her lower leg ulcer continued to deteriorate slowly in the next 15 weeks.

With deterioration of the wound status, the PI recommended the patient trialing the wound gel treatment on September 30, 2016. Patient consented and the first wound gel was started on September 30, 2016. With application of the wound gel, her lower leg ulcer reduced in size slowly.

At the end of this study on November 30, 2016, the patient's LLU had reduced more than 40% in size with 100% granulation.

Case 5

				
Nov 25, 2015 1st PI Treatment Bacterial Binding dressings 8 cm x 7.9 cm = 63.2 cm²	**June 17, 2016** 1st daily 2% Dilantin Treatment 7 cm x 3 cm = 21 cm²	**Sept 30, 2016** Post 15th week daily 2% Dilantin 1st Wound Gel 7 cm x 5 cm = 35 cm²	**Nov 18, 2016** 8th Wound Gel 100% Granulation 7 cm x 5 cm = 35 cm²	**Nov 30, 2016** 10th Wound Gel 100% Granulation 7 cm x 3 cm 21 cm²

Case 6 – Patient with Chronic Right Foot Dorsal Ulcer with Intolerance to Compression

The patient was a 58-year old patient. She stated she had an eczema spot on the top of her right foot that was itchy, she scratched it and it became ulcerated and infected. After 144 days of HCN treatment since April 2, 2015, patient was referred to the Complex Wound Clinic in August 2015.

The PI first treated patient on August 5, 2015. Standard lower leg wound treatment with regular sharp wound debridement and bacterial binding dressings were initiated. Patient was taught to change her dressing every 5 – 7 days with follow up treatments every 2 – 3 weeks. Prescriptions for compression stockings were given but the patient could not tolerate any type of compressions with rashes developed. Therefore, the patient was encouraged to perform ankle-flexi joint exercise a few times throughout the day instead.

Despite standard treatment with regular sharp wound debridement, the patient's right foot ulcer deteriorated overtime the next few months. Fortunately, with persistent best practice the right foot dorsal ulcer eventually started to progress but very slowly in January 2016.

The PI discussed the Wound Gel study with the patient in May 2016. The patient consented with in 1st Wound Gel treatment was started on May 6, 2016 when the wound was small but relatively deep (0.9 cm long, 0.6 cm wide and 0.4 cm deep).

Wound healing progressed steadily with weekly Wound Gel treatment added to the established treatment protocol. Initially, the wound size increased slightly but the depth was reducing.

Eventually, the ulcer was closed on September 30, 2016. The PI continued treating the patient weekly till patient was discharged on November 4, 2016 because she was afraid that her wound would reopened.

Case 6

				
August 1, 2015 1st PI Treatment with Bacterial Binding dressings started 1.5 cm x 0.9 cm = 1.35 cm²	**Dec 22, 2015** 11th PI Treatment 2 cm x 1 cm = 2 cm²	**May 6, 2016** 1st IPM Wound Gel (Post 27th 250 days PI treatment); wound was small but deep 0.9 cm x 0.6 cm = 0.54 cm² (0.4 cm deep)	**June 24, 2016** 8th Wound Gel Wound size increased but depth has reduced wit 100% granulation 1 cm x 0.8cm = 0.8 cm² (0.2 cm deep)	**Nov 4, 2016** Post 22nd Wound Gel Patient was discharged after wound closed on Sept 30, 2016

Case 7 – Patient with Plantar 2nd Metatarsal DFU Post Transmetatarsal amputations

This 67-year patient was referred to the Complex Wound Clinic by HCN on Oct 16, 2015 for Total Contact Cast (TCC) treatment.

The patient had been treated by a Surgical Podiatrist since 2014 with multiple HCN admissions. When the left foot plantar DFU post Transmetatarsal amputation, the Surgical Podiatrist recommended the patient to have a below knee amputation. As last resort before consenting for a below knee amputation, the patient consented for TCC treatment when he returned from vacation in January 2016.

The PI started treating the patient with weekly sharp wound debridement and bacterial binding dressings in addition to application of TCC Poor Man (adhesive felt with a horse-shoe hole underneath the DFU) for offload on Feb 15, 2016. The patient was wearing a cast boot for offload. However, the DFU healing only progressed very slowly.

The PI discussed the Wound Gel study with the patient in May 2016. The patient consented with the Wound Gel study; the 1st Wound Gel treatment was applied on May 16, 2016. With the addition of the 2.5% sodium hyaluronate wound gel to the established treatment protocol, the DFU was observed to have increased granulation and size reduction overtime.

The patient was quite active in his personal life. As a result, the TCC Poor Man did not provide adequate offload as evidenced by the TCC Poor Man being very worn out each week. Therefore, the PI initiated TCC Offloader on July 13, 2016.

With adequate offload, weekly callus paring by the PI, and continuation of Wound Gel application, the plantar DFU was closed on October 26, 2016.

Case 7

				
Feb 15, 2016 1st PI Treatment 1st TCC Poor Man + Bacterial Binding dressings 1.5 cm x 1 cm = 1.5 cm² (0.4 cm deep)	**May 16, 2016** 1st Wound Gel + TCC Poor Man + Bacterial Binding dressings 1.2 cm x 1 cm = 1.2 cm² (0.4 cm deep)	**July 13, 2016** 6th Wound Gel + 1st TCC Offloader + Bacterial Binding dressings 1 cm x 0.8 cm = 0.8 cm² (0.3 cm deep)	**Aug 22, 2016** 7th TCC Cutimed (day 40) + 12th Wound Gel 0.8 cm x 0.4 cm = 0.32 cm² (0.2 cm deep)	**Oct 26, 2016** Post 18th Wound Gel + Post 11th TCC Cutimed (day 75) Patient Discharged to Wound Closure

Case 8 – Recurrent Left Lower Leg Ulcer for more than 70 years since age of 9

This 80-year patient has this recurrent left lower leg ulcer for more than 70 years since age of 9 after a traumatic injury. He had been self-managing this chronic wounds with multiple systemic and topical antibiotics ordered by his family doctor for years. He was referred to the Complex Wound Clinic by Infectious Disease Specialist after a recurrent Osteomyelitis in August 2015.

The PI first treated patient on August 26, 2015. Standard lower leg ulcer treatment with regular sharp wound debridement and bacterial binding dressings were initiated. The patient was taught to change her dressing every 5 – 7 days with regular HCN treatment in between PI treatments every 2 – 3 weeks.

Prescriptions for high compression stockings were given but the patient was reluctant to wear compression stockings with adequate compression till February 2016 when his lower leg ulcer progressed very slowly.

Wound healing progressed slowly despite continuation of standard lower leg ulcer treatment including regular sharp wound debridement and weekly bacterial binding dressings. With such a long wound history and the patient's advancing age, wound healing was definitely a challenge.

The PI discussed the use of Wound Gel with the patient. The patient consented for the Wound Gel study; the first Wound Gel treatment was started on May 12, 2016. The 2.5% sodium hyaluronate wound gel was applied weekly in addition to standard wound treatment by the PI.

After a total of 23 weekly applications, his lower leg ulcer had reduced in size by 20% only at the end of the study on November 30, 2016.

Case 8

				
Aug 26, 2015 1st PI Treatment Bacterial Binding dressings 5 cm x 3 = 15 cm² (0.3 cm deep)	**Nov 4, 2016** 7th PI Treatment Bacterial Binding dressings + Subadequate Compression 4 cm x 3 cm = 12 cm² (0.3 cm deep)	**May 12, 2016** 28th PI Treatment 1st Wound Gel 5 cm x 2.5 cm = 12.5 cm² (0.3 cm deep	**Aug 26, 2016** 40th PI Treatment 12th Wound Gel 5.2 cm x 2 cm = 11 cm² (0.3 cm deep)	**Nov 30, 2016** 49th PI Treatment 23th Wound Gel 4 cm x 2.5 cm = 10 cm² (0.3 cm deep

Case 9 – Patient with Chronic Right Lower Leg Ulcer without Compression Therapy

This 73-year patient was referred to the Complex Wound Clinic by HCN in April 2015 for non-healing left lower leg ulcer. She had been under HCN since June 11, 2014. The ulcer started when she scratched a dry itchy area in May 2014. She had similar ulcers in the past. The patient was treated by a Dermatologist specialized in chronic wound management a few times with no progress.

The PI first treated patient on April 24, 2015. Standard lower leg ulcer treatment with sharp wound debridement and bacterial binding dressings were initiated. The patient was taught to change her dressing every 5 – 7 days with regular HCN treatment in between PI treatments every 2 – 3 weeks.

Prescriptions for moderate compression stockings were given to the patient. However, the patient's lower leg was so small that she could not be fitted into any readily available compression garment. The patient was reluctant to pay for customized made stockings. Therefore, the patient was encouraged to perform ankle-flexi joint exercise a few times throughout the day instead.

Wound healing progressed very slowly despite continuation of standard lower leg ulcer treatment including regular sharp wound debridement and weekly bacterial binding dressings. The PI discussed the Wound Gel study with the patient in May 2016. The patient consented with in 1st Wound Gel treatment was started on May 13, 2016. The 2.5% sodium hyaluronate wound gel was applied weekly in addition to standard wound treatment by the PI. With addition of weekly Wound Gel treatment, the lower leg ulcer progressed steadily.

After 16th weekly application, her lower leg ulcer had reduced in size by 90% on August 26, 2016. At that time, the patient requested to be discharged to self-management with regular HCN treatment because she did not want to drive to the Complex Wound Clinic any more. With the support of the HCN, the patient continued applying Wound Gel weekly.

The HCN reported that the patient's lower leg ulcer was closed in October 2016. Unfortunately, the patient continued sustaining minor traumatic injury or having itchy skin lesions that led to skin breakdown from time to time.

Case 9

				
April 24, 2015 1st PI Treatment Bacterial Binding dressings 14.5 cm x 9 cm = 130.5 cm² (0.2 cm deep)	**Dec 28, 2015 2016** 26th PI Treatment Treatment 2.7 cm x 2.7 cm = 7.29 cm² (0.2 cm deep)	**May 13, 2016** 40th PI Treatment 1st Wound Gel 4 cm x 1 cm = 4 cm² (0.1 cm deep)	**July 22, 2016** 45th PI Treatment 11th Wound Gel 1 cm x 0.8 cm = 0.8 cm² (0.1 cm deep)	**Aug 26, 2016** 49th PI Treatment 16th Wound Gel Discharged to HCN 0.8 cm x 0.5 cm = 0.4 cm² (0.1 cm deep)

Case 10 – Patient with Right Heel DFU post 4th and 5th Metatarsal Amputations

This 53-year patient was referred to the Complex Wound Clinic by HCN in February 2016 for TCC treatment to treat his slow healing right heel DFU. The patient had his right 4th and 5th metatarsal amputated due to previous history of DFU infection. After the surgery, his right foot became so deformed that his heel is bearing most of his body weight during weight bearing. Offloading the heel became a challenge.

The patient noticed his right heel was sored with blistering after working long hour outdoor at home on a hot summer day. Eventually the blistered area became ulcerated and infected. The patient has been under HCN since April 23, 2015.

The PI started treating the patient with TCC offloader on July 21, 2016. With consideration of the promising Wound Get treatment since the start of the study, the PI discussed the use of the Wound Gel with the patient on August 4, 2016. After the patient signed the consent form, the PI began applying the Wound Gel weekly on August 4, 2016.

With the application of TCC offloader, the bacterial binding dressings and weekly Wound Gel, the right heel DFU healing progressed overtime. The patient was satisfied with the wound healing rates.

Although this right heel DFU was not closed yet, the right heel DFU has reduced by 95% at the end of the study on November 29, 2016.

Case 10				
				
July 21, 2015 1st PI Treatment 1st TCC Offloader + Bacterial Binding dressings 3.8 cm x 3 cm = 11.8 cm² (0.2 cm deep)	**Aug 4, 2016** 3rd PI Treatment 1st Wound Gel + 3rd TCC Offloader day 14 4 cm x 2.8 cm = 11.2 cm² (0.2 cm deep)	**Sept 22, 2016** 11th PI Treatment 11th Wound Gel + 9th TCC Offloader day 63 2.5 cm x 1.5 cm = 3.75 cm² (0.2 cm deep)	**Nov 7, 2016** 18th PI Treatment 16th Wound Gel + 17th TCC Offloader day 96 1.5 cm x 0.7 cm = 1.05 cm² (0.2 cm deep)	**Nov 29, 2016** 21th PI Treatment 18th Wound Gel + 19th TCC Offloader day 118 1 cm x 0.5 cm = 0.5 cm² (0.1 cm deep)

Case 11 – Patient with Left Foot DFU that Failed to Heal Post Skin Graft

This 66-year patient was referred to the Complex Wound Clinic by the HCN in December 2014 for left foot ulcer that failed to close after revascularization and two failed skin grafts. Wound healing was further complicated with venous stasis as evidence by gross edema of his left lower leg, toes and foot. With the patient living by himself, optimizing his blood sugar control and nutrition could be challenging to promote wound healing.

The patient had a right below knee amputation; and his left 3rd, 4th and 5th toes were amputated too. His surgeon had already warned him about left below knee amputation. He was very worried that if his foot ulcer further deteriorated, his left foot would may need to be amputated.

The PI first treated patient on December 17, 2014. The left foot ulcer was large (10 cm x 9 cm) extending from the mid-lateral plantar to mid-lateral dorsal of the foot. Standard lower leg and DFU treatment with sharp wound debridement, modified compression for venous stasis, and bacterial binding dressings were initiated. The dressings had been changed every 2 – 3 days by HCN in between PI weekly treatments since then.

The left foot DFU progressed slowly but steadily over time. Unfortunately, the patient was admitted to the hospital several times due to acute cardiac assaults. His wound healing process was interrupted each time when the patient was admitted to acute care.

With consideration of the promising 2.5% sodium hyaluronate wound gel treatment since the start of the study, the PI discussed the use of the Wound Gel with the patient in August 2016. After the patient signed the consent form, the PI began applying the Wound Gel weekly on August 5, 2016.

The patient was satisfied with the wound healing rates. On September 30, 2016, the foot ulcer was only 9.72 cm², a 50% size reduction since the start of the Wound Gel on August 5, 2016. Unfortunately, the patient was admitted to the hospital. On October 31, 2016, his wound deteriorated with the size increased to 13.5 cm², a 30% size increase just after 3 weeks of hospitalization. Fortunately, with restarting standard lower leg and DFU and application of the Wound Gel weekly, the foot ulcer healing progressed again. From a follow up assessment on December 16, 2016, the foot ulcer was only 10.5 cm², a 25% size reduction in 6 weeks since October 31, 2016.

Case 11

					
Dec 17, 2014 1st PI Treatment Bacterial Binding dressings 10 cm x 9 = 90 cm² (0.1 cm deep)	**Dec 18, 2016** 25th PI Treatment 8.5 cm x 8.5 cm = 72.25 cm² (0.1 cm deep)	**Aug 5, 2016** 51st PI Treatment 1st Wound Gel 7.8 cm x 2.4 cm = 18.72 cm² (0.1 cm deep)	**Sept 30, 2016** 59th PI Treatment 9th Wound Gel (foot ulcer reduced by 50% since Wound Gel started) 5.4 cm x 1.8 cm = 9.72 cm² (0.1 cm deep)	**Oct 31, 2016** 60th PI Treatment 10th Wound Gel (wound deteriorated post hospitalization) 7.5 cm x 1.8 cm = 13.5 cm² (0.2 cm deep)	**Dec 16, 2016** 65th PI Treatment 15th Wound Gel (foot ulcer reduced by 25% 6-week post hospitalization) 7 cm x 1.5 cm = 10.5 cm² (0.2 cm deep)

Case 12 – Patient with Left midfoot plantar DFU with 4th & 5th Toe Amputations and Charcot Deformity

This 55-year patient was referred to the Complex Wound Clinic by HCN in June 2016 for his recurrent right midfoot plantar DFU with Charcot deformity. The patient has been admitted to HCN since May 17, 2016. He has multiple hospitalizations and HCN referrals for recurrent DFU. The patient already had his left 4th and 5th toes amputated because of previous infected DFU. He really wanted to heal this plantar DFU as he did not want to have his foot amputated. HCN started negative pressure wound therapy on May 30, 2016 but wound healing progress remained slow even though the patient was wearing a cast boot for offload.

The PI first treated patient on July 20, 2016. Based on the size, location, and Charcot deformity, the PI recommended TCC Offloader in addition to application of bacterial binding dressings. The patient consented and 1st TCC Offloader was started on July 20, 2016.

Based on the promising results of the Wound Gel treatment, the PI discussed the Wound Gel study with the patient in August 10, 2016. The patient consented with the study to see if addition of the Wound Gel would accelerate wound healing.

With the application of TCC offloader, the bacterial binding dressings and weekly Wound Gel, the right foot DFU healing progressed overtime. Over the course of the study, his midfoot plantar DFU progressed steadily.

At the end of the study on November 30, 2016 the DFU was only 1 cm², a 80% size reduction since the start of the Wound Gel on August 10, 2016.

Case 12

				
July 20, 2015 1st TCC Offloader day 0 5 cm x 4.3 cm = 21.5 cm² (2.5 cm deep, undermining 1.5 cm 9 – 12 o'clock)	**Aug 10, 2016** 4th TCC Cutimed day 21 + 1st Wound Gel 5 cm x 2.5 cm = 12.5 cm² (1 cm deep, undermining 1 cm @10 – 6 o'clock)	**Sept 29, 2016** 4th TCC Cutimed day 21 + 1st Wound Gel 3 cm x 1.5 cm = 4.5 cm² (0.5 cm deep; no undermining)	**Nov 7, 2016** 4th TCC Cutimed day 21 + 1st Wound Gel 1.8 cm x 1 cm = 1.8 cm² (0.5 cm deep, no undermining)	**Nov 30, 2016** 4th TCC Cutimed day 21 + 1st Wound Gel 2 cm x 0.5 cm = 1 cm² (0.5 cm deep, no undermining)

Case 13 – Patient with Recurrent Right Foot DFU on Midfoot Medial Side

This 78-year patient was referred to the Complex Wound Clinic by the patient's Podiatrist in June 2016 for a nonhealing right foot plantar on midfoot medial side.

The patient has had multiple HCN admissions for the same wound since Oct 22, 2014 before he had the right foot DFU repaired by a Surgical Podiatrist in November 2014. Unfortunately, the surgical site dehisced in December 2014. The same Surgical Podiatrist surgically repaired the DFU in February 2015 but the surgical site dehisced again immediate post-surgery. The DFU was finally closed in December 2015 after the patient had a skin graft by another Surgeon. Unfortunately, the patient was readmitted to HCN on May 29, 2016 when his plantar midfoot DFU with Charcot deformity grew callous. When the local Podiatrist debrided the callus, the area was found to be ulcerated.

The PI first treated patient on July 27, 2016. Standard DFU treatment with sharp wound debridement, bacterial binding dressings, and TCC Poor Man were initiated. The PI then began treating the patient weekly. Based on the promising results of the Wound Gel treatment, the PI discussed the Wound Gel study with the patient in August 12, 2016. The patient consented with the study to see if addition of the Wound Gel would accelerate wound healing.

With the application of TCC Poor Man, bacterial binding dressings and weekly Wound Gel, the right foot DFU healing progressed steadily overtime. The DFU had reduced in size by more than 90% after nine Wound Gel applications on October 21, 2016. Unfortunately, he was admitted to acute care when his right 5th toe was gangrened the next day.

The patient was discharged from the hospital after the Vascular Surgeon had revascularized his right foot surgically on December 1, 2016. When the PI reassessed the patient on December 2, 2016, this right foot DFU was found to be closed.

Case 13				
				
July 27, 2015 1st TCC Poor Man Day 0 + Bacterial Binding dressings 1.9 cm x 1.4 cm = 2.66 cm² (0.3 cm deep, sinus tract 1 cm at 5 o'clock)	**Aug 12, 2016** TCC Poor Man Day 1st Wound Gel 1.8 cm x 1.3 cm = 2.34 cm² (0.2 cm deep, sinus tract 0.3 cm at 5 o'clock)	**Sept 2, 2016** TCC Poor Man 4th Wound Gel 1.5 cm x 1.3 cm = 1.95 cm² (0.2 cm deep, no sinus)	**Oct 21, 2016** TCC Poor Man 10th Wound Gel 1 cm x 0.6 cm = 0.6 cm² (0.1 cm deep)	**Dec 2, 2016** Patient was admitted to acute care Oct 22 – Nov 22, 2916 Wound Closed

Case 14 – Patient with Recurrent Right Foot Plantar 1st Metatarsal DFU

This 81-year patient was referred to the Complex Wound Clinic by HCN in July 2015 for nonhealing right foot 1st and 3rd metatarsals DFU. The patient stated that she developed theses 2 wounds in February 2015 because her right foot became deformed after right 2nd, 3rd and 4th toes amputation in November 2013. The amputations were warranted when her right 2nd toe was severely infected with sepsis. The patient has been under the care of HCN since March 17, 2015.

The PI first treated patient on August 19, 2015 with standard DFU treatment with sharp wound debridement, bacterial binding dressings, and TCC Poor Man initiated. Both the 3rd and 1st metatarsal DFUs were closed on Dec 22, 2015 but the 1st metatarsal DFU reopened on December 31, 2015 with gradual deterioration over time despite continuation of standard DFU treatment.

The PI discussed the Wound Gel study with the patient in August 2016. The patient consented and the first Wound Gel treatment was applied on August 18, 2016. With the application of TCC Poor Man, bacterial binding dressings and weekly Wound Gel, the right foot 1st metatarsal DFU healing progressed overtime.

At the end of the study on November 30, 2016, he DFU was only 0.18 cm², a 90% size reduction since the start of the Wound Gel study on August 18, 2016.

Case 14

					
Aug 19, 2015 1st TCC Poor Man Day 0 0.5 cm x 0.5 cm = 0.25 cm² (0.2 cm deep)	**Dec 22, 2015** TCC Poor Man Discontinued When Wound Closed	**Dec 31, 2015** 1st Metatarsal DFU reopened TCC Poor Man Restarted 0.5 cm x 0.4 cm = 0.2 cm² (0.2 cm deep)	**Aug 18, 2016** TCC Poor Man Day 1st Wound Gel 1.4 cm x 1.4 cm = 1.96 cm² (0.2 cm deep)	**Oct 27, 2016** 60th PI Treatment 10th Wound Gel 0.6 cm x 0.4 cm = 0.24 cm² (0.2 cm deep)	**Nov 30, 2016** 65th PI Treatment 15th Wound Gel 0.6 cm x 0.3 cm = 0.18 cm² (0.2 cm deep)

Case 15 – Patient with Recurrent Deep Left Foot Plantar DFU that Probed to Bone

This 81-year patient was referred to the Complex Wound Clinic by Infectious Disease Specialist in August 2016 for TCC treatment for recurrent left foot plantar DFU. The patient had a right foot plantar DFU treated by the PI with TCC in March 2014. The right foot DFU was closed in May 2014 with no recurrence.

The patient was readmitted to HCN on July 17, 2015 when he developed a left foot plantar 1st metatarsal DFU. He was discharged to wound closure in Aug 2015 but was readmitted in 2 weeks on Sept 17, 2015 when the left DFU blistered and reopened. The patient later discharged himself from HCN when he chose to have his left foot plantar DFU treated by his podiatrist.

The left DFU was eventually closed but after a 2-month vacation in Europe in the summer, client's left foot plantar 1st metatarsal reopened. He had his recurrent left foot DFU treated by his Podiatrist but within days he was admitted to acute care for sepsis when he was critically ill requiring IV antibiotics. He was readmitted to HCN on Aug 11, 2016 for wound treatment.

The PI first treated patient on August 31, 2015. The left foot 1st metatarsal DFU was deep and probe to bone. The PI recommended TCC offloader in addition to standard DFU treatment with sharp wound debridement and bacterial binding dressings. However, the patient refused TCC offloader after one application even though his DFU had significant improvement in just a few days. The patient stated his gait was unsteady with the TCC Offloader. He used a cane but he did not want to use a walker to improve gait stability.

Based on the promising results of the Wound Gel treatment, the PI discussed the Wound Gel study with the patient in September 1, 2016 when TCC treatment was initiated. The patient consented with the study to see if addition of the Wound Gel would accelerate wound healing.

Over the course of the study, his midfoot plantar DFU progressed steadily. However, at the end of the study, the depth of the DFU was found to have increased on December 1, 2016. It was beyond the scope of the study period for the PI to continue treating the patient.

Case 15

				
Aug 31, 2016 1st TCC Offloader 1st Wound Gel Bacterial Binding dressings 2 cm x 2 cm = cm² (1 cm deep probe to bone)	**Sept 8, 2016** Discontinued TCC offloader 1st TCC Poor Man 2nd Wound Gel 1.5 cm x 1.4 cm = 2.1 cm² (0.5 cm probe to bone)	**Oct 17, 2016** 6th TCC Poor Man 7th Wound Gel 1 cm x 0.8 cm = 0.8 cm² (0.3 cm deep)	**Nov 7, 2016** 9th TCC Poor Man 10th Wound Gel 0.6 cm x 0.4 cm = 0.24 cm² (0.3 cm deep)	**Dec 1, 2016** 12th TCC Poor Man 13th Wound Gel 0.4 cm x 0.3 cm = 0.12 cm² (1 cm deep probe to bone)

Case 16 – Patient with Infectious Right Lower Leg Ulcer Post Failed Skin Graft

This 49-year patient was referred to the Complex Wound Clinic initially by Infectious Disease Specialist (ID Specialist) in November 2015. The patient had been treated by the by ID Specialist after she was admitted to hospital for cellulitis on May 20, 2015. She had been under the care of HCN since Oct 1, 2015.

The patient cancelled her initial Complex Wound Clinic appointment in Nov 2015 when she consented for skin graft. She was told by the ID Specialist that surgical intervention was the only option to close her wound**.** However, the patient was upset with the result of the surgical debridement and skin grafts. Her lower leg ulcer became a deep cave after the surgery. She asked the Plastic Surgeon to remove the skin graft but was declined. Unfortunately, the skin graft failed to close her lower leg ulcer. The patient then asked to be referred to the Complex Wound Clinic again.

The PI first treated patient on January 6, 2015. Standard lower leg ulcer treatment with sharp wound debridement, bacterial binding dressings, and compression therapy were initiated. The patient was taught to self-manger her wound in between HCN and Complex Wound Clinic follow up visits. Wound healing progressed over time with standard lower leg ulcer treatment but it failed to close completely.

The PI discussed the use of Wound Gel on September 21, 2016. Final wound closure was achieved on October 19, 2016 after 4th Wound Gel application.

Case 16

				
Jan 6, 2016 1st PI Treatment Bacterial Binding dressings 6.6 cm x 3.2 cm 21.12 = cm² (1.8 cm deep)	**March 2, 2016** 1st Wound Gel Treatment 5.3 cm x 3.1 cm = 16.43 cm² (1 cm deep)	**May 25, 2016** 28th PI Treatment 4 cm x 0.5 cm = 2 cm² (0.2 cm deep)	**Sept 21, 2016** 28th PI Treatment 1st Wound Gel 1cm x 1 cm = 1 cm² (0.1 cm deep)	**Oct 19, 2016** 28th PI Treatment Wound Closed after 4th Wound Gel

Case 17 – Patient with Recurrent Right Heel DFU post Failed Skin Graft

This 64-year patient was referred to the Complex Wound Clinic by the ID Specialist in May 2016 for recurrent of recently closed right heel DFU. Client has multiple HCN admissions for the same DFU with the most readmission on Oct 6, 2015.

The patient was previously treated by the PI for the same right heel DFU with TCC Offloader weekly from Feb 9, 2016 to April 11, 2016 when the right heel DFU was closed after 10th TCC Offloader. The PI then referred the patient to HCN to reassess his newly closed DFU for another week.

Unfortunately, the right heel DFU reopened with a large thick blister just in less than 2 weeks. His right heel DFU deteriorated rapidly with deep wound infection requiring IV antibiotics. He was admitted to acute care for revascularization in July 2016. While he was in the hospital, the Vascular Surgeon attempted to close his right heel DFU with skin graft. The patient and his family were worried about amputation and wanted the PI to treat him with TCC Offloader again.

The PI started the patient with TCC Offloader treatment on August 11, 2016 when the skin graft failed to close his right heel DFU. Patient's medical status was stable with regular hemodialysis but optimizing his medical and nutritional status could be challenging. With consideration of the size of the DFU, frailty of the patient and high risk for recurrence, the PI discussed the Wound Gel study with the patient in September 2016. The patient consented and the first Wound Gel treatment was applied on September 22, 2016.

With TCC Offloader and Wound Gel treatment, the right heel DFU healing progressed steadily over the course of treatment. Although the right heel DFU was not closed at the end of the study on November 30, 2016, the size of the ulcer was only d to 4.1 cm², a 40% size reduction, since the start of Wound Gel study on September 22, 2016.

Case 17				
				
Aug 11, 2015 1st TCC Offloader + Bacterial Binding dressings 4.5 cm x 4.2 cm = 18.9 cm² (0.2 cm deep)	**Sept 22, 2016** 7th TCC Offloader 1st Wound Gel 3 cm x 2.5 cm = 7.5 cm² (0.2 cm deep)	**Oct 4, 2016** 9th TCC Offloader + 4th Wound Gel 2.5 cm x 1.8 cm = 4.5 cm² (0.2 cm deep)	**Nov 24, 2016** 13th TCC Offloader + 8th Wound Gel 3 cm x 1.5 cm = 4.5 cm² (0.1 cm deep)	**Nov 30, 2016** 14th TCC Offloader + 9th Wound Gel 2.6 cm x 1.4 cm = 4.1 cm² (0.1 cm deep)

Case 18 – Patient with Recurrent Left Lower Leg Ulcer

This 48-year patient was referred to the Complex Wound Clinic by her family doctor in September 2016 for recurrent nonhealing left lower leg ulcer. Client has history of Deep Vein Thrombosis (DVT). She was treated by Complex Wound Clinic team once on Jan 13, 2016 when her left lower leg ulcer recurred. The lower leg ulcer was healed shortly afterward.

The patient's left lower leg reopened spontaneously again in September 2016 despite adhering to everything advised by the HCN to reduce the risk for recurrence, including wearing compression stockings consistently; exercise to lose weight.

With consideration of the patient's high risk for recurrence, the PI discussed the Wound Gel study with the patient during the first treatment on October 3, 2016. The patient consented and the first Wound Gel treatment was started on October 3, 2016.

With continuation of standard wound treatment and persistent compression therapy, and weekly Wound Gel treatment, the left lower leg ulcer progressed steadily over the course of treatment.

Although the right heel DFU was not closed at the end of the study on November 30, 2016, the size of the ulcer was only d to 0.4 cm², a 90% size reduction, since the start of Wound Gel study on October 3, 2016

Case 18

				
Oct 3, 2016 1st PI Treatment 1st Wound Gel + Bacterial Binding dressings + Compression Therapy 2 cm x 1.2 cm = 2.4 cm² (0.2 cm deep)	**Oct 19, 2016** 2nd PI Treatment 4th Wound Gel + Bacterial Binding dressings + Compression Therapy 2 cm x 1 cm = 2 cm² (0.1 cm deep)	**Nov 2, 2016** 4th PI Treatment 6th Wound Gel + Bacterial Binding dressings + Compression Therapy 1.4 cm x 0.8 cm = 1.12 cm² (0.1 cm deep)	**Nov 16, 2016** 5th PI Treatment 8th Wound Gel + Bacterial Binding dressings + Compression Therapy 1 cm x 0.3 cm = 0.3 cm² (0.1 cm deep)	**Nov 30, 2016** 7th PI Treatment 10th Wound Gel + Bacterial Binding dressings + Compression Therapy 0.8 cm x 0.5 cm = 0.4 cm² (0.1 cm deep)

Case 19 – Patient with Atypical Right Lower Leg Ulcer related to Protein C Deficiency

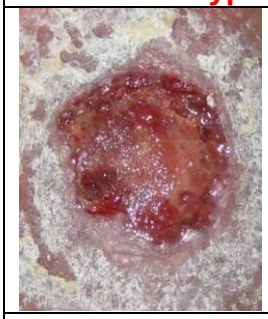
This 42-year patient has medical History of Protein C Deficiency, a Genetic Blood Clot Disorder disease. The patient needs to take anti-coagulant medications with dosage regulation from time to time as needed. The patient was referred to the Complex Wound Clinic by HCN in December 2014 for a chronic nonhealing right lower leg ulcer. She has been treated by HCN since June 1, 2014. Her lower leg ulcer deteriorated slowly overtime despite standard wound treatment by HCN, and having increased her protein intake; and wearing high compression stockings persistently.

The PI first treated patient on December 17, 2014. Standard lower leg treatment with sharp wound debridement and bacterial binding dressings were initiated. The PI began treating the patient weekly since then. Despite best practice with trial of varied advanced wound care products, including topical collagen wound products, and electrical pulse stimulation device, her lower leg ulcer continued to increase in size slowly overtime.

Wound biopsy was done by a dermatologist in April 2016. The biopsy had ruled out malignancy but there was no definite conclusion of the wound etiology. The PI discussed the Wound Gel study with the patient in July 2016. The patient consented with in 1st Wound Gel treatment was started on July 14, 2016.

At the end of the Wound Gel study on November 30, 2016, the size of the wound had slightly increased. However, the wound bed appeared to have slight increased granulation. Also, the wound edges had advanced slightly with epithelialization at 3 – 6 o'clock area.

Case 19 – Atypical lower leg ulcer not responding to Wound Gel treatment

				
Dec 17, 2014 1st PI Treatment Bacterial Binding dressings 3 cm x 3 cm = 9 cm² (0.2 cm deep)	**Dec 31, 2015** 50th PI Treatment 2.1 cm x 2.1 cm = 4.41 cm² (0.2 cm deep)	**July 14, 2016** 72th PI Treatment 1st Wound Gel 4.5 cm x 4.5 cm = 20.25 cm² (0.2 cm deep)	**Sept 22, 2016** 82th PI Treatment 11th Wound Gel 4.5 cm x 4.5 cm = 20.25 cm² (0.2 cm deep)	**Nov 30, 2016** 91th PI Treatment 10th Wound Gel 5 cm x 4.3 cm = 21.5 cm² (0.2 cm deep)

Case 20 – Patient with Right Lower Leg Arterial Ulcer

This 83-year patient was referred to the Complex Wound Clinic by HCN in May 2016 for chronic right lower leg arterial located at lateral malleolus. The patient has been admitted to HCN since July 10, 2016.

The patient was previously referred to the Complex Wound Clinic in April 2015 for the same wound. He was discharged to HCN in July 2015 when his ulcers were determined to be arterial requiring vascular intervention before healing was possible. The patient requested to be referred to the Complex Wound Care team again when he was determined not a candidate for revascularization.

The attending surgeon debrided the wound and prescribed topical Misopoo 0.0024% + 5% Phenytoin ointment and Nifedifine gel twice daily on May 18, 2016. When the ulcer did not respond to this treatment, the patient consented for the Wound Gel treatment on August 3, 2016 as the last resort. The PI began applying the Wound Gel weekly in addition to standard wound treatment on August 3, 2016.

Unfortunately, the lower leg failed to progress and continued to deteriorate overtime. At the end of the Wound Gel study on November 30, 2016, the lower leg ulcer had increased in size and was still covered with 100% nonviable tissues.

Case 20 – Arterial lower leg ulcer not responding to Wound Gel treatment

				
May 18, 2016 1st PI Treatment Bacterial Binding dressings 2.3 cm x 2.2 cm = 5.06 cm² (0.3 cm deep)	**June 18, 2016** 2nd PI Treatment 2.3 cm x 2.2 cm = 5.06 cm² (0.3 cm deep	**Aug 3, 2016** 3rd PI Treatment 1st Wound Gel 3 cm x 2.5 cm = 7.5 cm² (0.3 cm deep)	**Sept 30, 2016** 8th PI Treatment 10th Wound Gel 5 cm x 2.5 cm = 12.5 cm² (0.3 cm deep)	**Nov 30, 2016** 14th PI Treatment 19th Wound Gel 4 cm x 3 cm = 12 cm² (0.3 cm deep)