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# Registry Report / Clinical Case Series Review TransCu O<sub>2</sub><sup>®</sup>

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***EO<sub>2</sub> Concepts***<sup>®</sup>  
*innovative wound healing*

# Patient Outcomes with TransCu O<sub>2</sub>®



- Chronic wounds treated successfully thus far include:
  - Venous stasis ulcers
  - Pressure ulcers
  - Diabetic foot ulcers
  - Gangrenous ulcers
  - Wound bed preparation for skin grafting
  - Full and split thickness skin grafts
  - Radiation burns
  - Dehiscent surgical wounds
  - Diabetic amputation wounds
- Majority of wounds treated with CDO have been unresponsive to other therapies, such as:
  - Moist wound therapy (MWT)
  - Hyperbaric oxygen therapy (HBOT)
  - Negative pressure wound therapy (NPWT)
  - Skin grafting
  - Antibiotics

# Patient Outcomes with TransCu O<sub>2</sub>®



- Over 945 verified patients have been, or were currently receiving, Continuous Diffusion of Oxygen (CDO) therapy with the TransCu O<sub>2</sub>® (Nov 2015)
- Statistics based on data for over 699 compliant patients for which we have final verified outcomes
- Overall rate of compliance was 89%
- **Overall success rate was 74%**
- These outcomes are very significant since most wounds treated *were unresponsive to other advanced therapies*
- Age of wounds prior to treatment
  - Range from several days to over 20 years
  - Average age of wound prior to start of CDO therapy is **359 days (~12 mo.)**
- Time to achieve successful outcome
  - Average is **59 days (~2 mo.)**



# EO<sub>2</sub> Registry Outcomes



	Overall	Diabetic Foot Ulcers	Venous Ulcers	Pressure Ulcers	Surgical Wounds	All Other Wounds
Total Number of Verified Patients	945	240	143	204	137	221
Number of Verified, Compliant Patients	624	179	103	139	100	103
Success Rate (Compliant Only)	74%	77%	70%	71%	79%	73%
Avg. Patient Age, years	67	66	70	68	64	67
Avg. Wound Age Before CDO, days	359	362	426	420	276	267
Avg. CDO Therapy Time to Success, days	59	64	80	59	56	43
Percent Compliance	89%	89%	89%	90%	92%	87%





# Case Study: Diabetic Foot Ulcer



- 64 year old Hispanic male with non-healing diabetic ankle ulceration
- Age of wound greater than 2 months (>60 days)
- Previous therapies include: 20 sessions of hyperbaric oxygen therapy (HBOT): estimated cost \$9,100 with no noted improvement
- Full closure achieved with CDO at 3 ml/hr by 39 days for \$2,600



Day 0 – Wound Size 3.0 x 2.6 cm



Day 39 – Full Closure of Wound





# Case Study: Diabetic Non-Healing

- 65 year old Caucasian male with non-healing diabetic wound
- Age of wound greater than 4 years
- Previous therapies include: 5 months of VAC NPWT: actual cost \$21,683 with home health (HH)
- Full closure achieved with CDO at 3 ml/hr by 81 days for \$8,640 with HH



Day 0 – Wound Size 1.7 x 1.2 x 0.5 cm



Day 81 – Full Closure of Wound



(120522JW - Courtesy of Dr. R. Levine, MD, Cos Cob, CT)



# Case Study: Venous Stasis Ulcer

- 89 year old female with chronic non-healing venous stasis ulcer on right leg
- History of: diabetes type II, PVD, vascular disease, femoral & renal stenosis...
- Previous therapies include: 4 months (> 120 days) of negative pressure wound therapy (NPWT): estimated cost \$9,800
- Full closure achieved with CDO at 10 ml/hr by 47 days (~ 1 ½ mos) for \$3,100

Prior to CDO	Time	>120	47	CDO
Cost		\$9,800	\$3,100	

Day 2 – First Dressing Change



Day 47 – Full Closure of Wound



(091114FS - Courtesy Cindy S. Bailey RN, BSN, WCC, Genesis Medical, Indianapolis, Indiana)





# Case Study: Dehisced Surgical Wound

- 63 year old Caucasian male with diabetes and osteomyelitis has a dehisced amputation wound open greater than 60 days
- Previous therapies include: intravenous and oral antibiotics, two weeks of negative pressure wound therapy (NPWT), \$1440 without antibiotics
- Full closure achieved with CDO at 4ml/hr by 22 days for \$1460

Prior to CDO	Time	>60	22	CDO
	Cost	>\$1,440	\$1460	

Day 0 – First Dressing Change



Day 22 – Full Closure of Wound



(101029RB - Pictures courtesy of Dr. Jason C. Zeigler, DPM, Winston-Salem, North Carolina and Jennifer Carter, MSA)



# Case Study: Toe Pressure Ulcer



- Diabetic female with non-healing pressure ulcer on great toe for greater than two months (>60 days)
- Unresponsive to moist wound therapy (MWT)
- Full closure achieved in 8 days with CDO at 3 ml/hr as an adjunctive therapy to MWT

Time



>60 Prior to CDO  
CDO

Day 2 – First Visit and Dressing Change



Day 8 – Full Closure of Wound



(090914VL - Courtesy of Dr. S. Nicholas Desai, DPM, FACFAS, Chief, Department of Surgery, Memorial Hermann Sugar Land, Texas)



# Case Study: Shin Ulcer



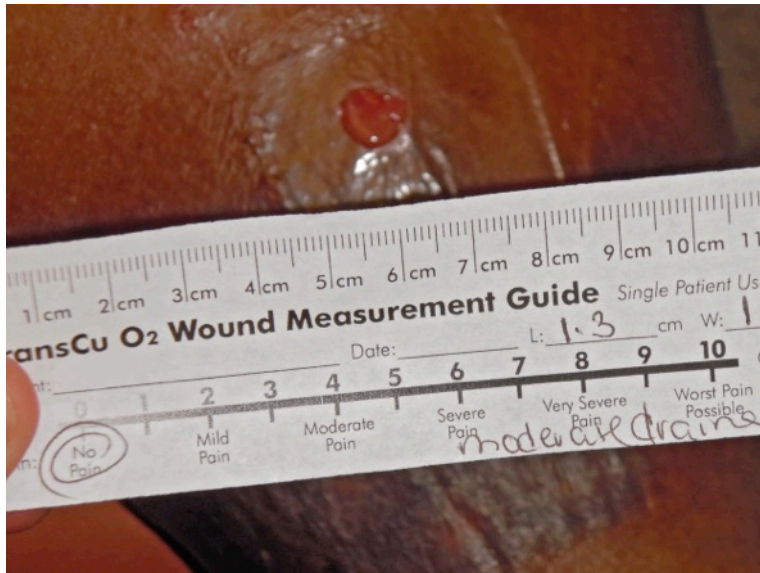
- Diabetic female with non-healing shin ulcer for several months (> 60 days) with moderate drainage
- Unresponsive to moist wound therapy (MWT)
- Full closure achieved with CDO at 3 ml/hr in 7 days, at which point complete re-epithelialization had occurred (wound closed) & wound was no longer draining

Time

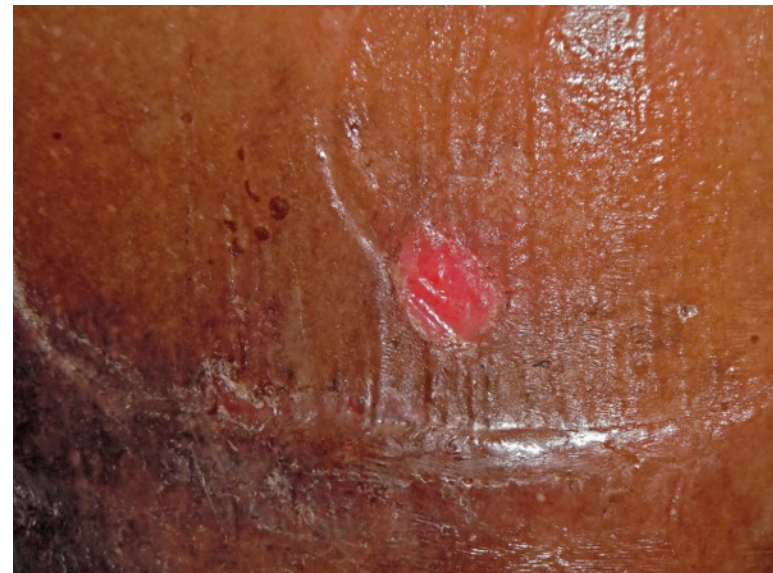


>60 Prior to CDO  
CDO

Day 2 – First Dressing Change, Wound Draining



Day 7 – Full Closure of Wound





# Case Study: Venous Stasis Ulcer



- 89 year old Caucasian female with a chronic venous stasis ulcer resulting from an unknown cause, open over three years (>1,095 days)
- Comorbidities: poor circulation in both legs
- Previous therapies include: Aquacel® AG, Calcium Alginate, Santyl® Collagenase, Medihoney™ patches, Silvercel®, and Xeroform™
- Full closure achieved with CDO at 10 ml/hr by 72 days

Time 72

Day 0 – Initiation of CDO



1095

Prior to CDO  
CDO

Day 72 – Full Closure of Wound



(110523GP - Pictures courtesy of Dr. Franklin Steele, MD, Valdese, North Carolina and Dawn Burk, Resp-I-Care)

# Case Study: Surgical Wound



- 59 year old Caucasian female with a non-healing surgical wound originating secondary to a motor vehicle accident, open greater than 455 days
- Previous therapies include: *GRAFTJACKET*®, negative pressure wound therapy (NPWT) and moist wound therapy (MWT)
- Full closure, evidenced by complete re-epithelialization, achieved with CDO by 111 days

Time



>455 Prior to CDO  
CDO

Day 0 – Initiation of CDO

Day 111 – Wound Closed





# Case Study: Skin Ulceration



- 86 year old Caucasian female with leg ulcer on the lower left tibia which has persisted approximately 90 days
- Comorbidities: congestive heart disease, hypertension, cerebrovascular accident, coronary artery disease, arthritis and depression
- Previous therapies include: moist wound therapy (MWT)
- Full closure achieved with CDO at 3 ml/hr by 33 days



(101108MR - Pictures courtesy of Dr. Doug Curran, MD, Athens, Texas and Jon Pugh, Healthline)

# Case Study: Pressure Ulcer



- 50 year old Caucasian female with a pressure ulcer, open for 90 days, ulcer has progressively gotten larger, deeper, more malodorous, fibrotic, and necrotic
- Comorbidities: diabetes, diabetic retinopathy & peripheral neuropathy...
- Previous therapies include: multiple debridements, local wound care with various wound care products, and an attempt at primary closure
- Full closure achieved with CDO by 55 days

Time



90

Prior to CDO  
CDO

Day 0 – Initiation of CDO



Day 55 – Full Closure of Wound



(100809WP - Pictures courtesy of Dr. Christine Salcher, DPM, Sherman, Texas and Amyee McAlister, Healthline)

# Case Study: Skin Graft



- Female with deep ulcer on right foot
- Patient has already had partial amputation of left foot from similar condition
- Patient received a split thickness skin graft
- CDO applied at 10 ml/hr for 9 days with two-part absorbent foam layer and occlusive dressing to ensure take of graft
- Graft continued to full closure

Day 0 – Start of Treatment, Deep Pressure Ulcer



Day 14 – Split Thickness Graft Healing



(091109ER - Courtesy of Dr. S. Nicholas Desai, DPM, FACFAS, Chief, Department of Surgery, Memorial Hermann Sugar Land, Texas)





# Case Study: Toe Amputation

- Female with amputation of toes on right foot
- Previous unsuccessful therapies include: negative pressure wound therapy (NPWT) for ~2 months
- Patient received a split thickness skin graft on the amputation
- CDO at 10 ml/hr with oxygen cannula placed above a non-adherent dressing and covered with a foam dressing for 14 days to ensure graft survival/take
- Graft went on to full closure

Day 0 – CDO started with Split Thickness Skin Graft



Day 14 – CDO stopped, continued to full healing



(091116LH - Courtesy of Dr. Thomas Shannon, MD, Houston, Texas and Kim Sims, South Texas Medical Supply, Tomball, Texas)

# Case Study: BKA Buerger's Disease



- 33 year old Caucasian male with right below-knee amputation several years ago, developed pressure ulcer over 10 months ago from prosthetic limb
- Has Buerger's Disease (thromboangiitis obliterans) and history of smoking
- Previous therapies include: multiple courses of intravenous antibiotics and two full-thickness skin grafts
- Wound treated with CDO at 10 ml/hr for 14 days to prepare wound bed, then another week after placement of full-thickness skin graft, healed at ~100 days

Day 0 - Wound After Debridement



Day 14 - Wound After 14 Days CDO



(100204BI - Courtesy of Dr. Thomas Shannon, MD, Houston, Texas and Kim Sims, South Texas Medical Supply, Tomball, Texas)



# Case Study: Groin Wound



- 61 year old Caucasian female with a groin wound secondary to pseudo aneurysm that was infected, age of wound 65 days
- Previous therapies include: *GRAFTJACKET*®, negative pressure wound therapy (NPWT) and moist wound therapy (MWT)
- Full closure to sufficient wound re-epithelialization achieved with CDO by 25 days, wound then allowed to heal completely with conventional dressings

Day 0 – Initiation of CDO



Day 25 – Wound Re-epithelialized



# Case Study: Surgical Wound



- 51 year old Caucasian male with a non-healing surgical wound resulting from amputation and open debridement of the ulcerative lesion, open 91 days
- Comorbidities: arterial disease, diabetes, obesity, smoker, heart disease (CHF)
- Previous therapies include: soaks and topical dressings, including Neosporin®, Bactroban and Silvadene Cream
- Full closure achieved with CDO at 4 ml/hr by 91 days

Day 0 – Initiation of CDO



Day 91 – Full Closure of Wound



(100805RM - Pictures courtesy of Dr. Urukalo, DPM, Austin, Texas and Jo Tiller, Healthline)

# Case Study: Pressure Ulcer



- 77 year old Caucasian male with a pressure ulcer, caused by patients knee immobilizer, on the right heel for 13 days
- Comorbidities: heart disease, diabetes
- Full closure achieved with CDO at 3 ml/hr by 48 days

Day 3 – Cannula track visible



Day 48 – Wound completely closed



(100901JW - Pictures courtesy of Dr. Mark Kuper, DO, Fort Worth, Texas and Kathy Foster, Healthline)



# Case Study: Diabetic Foot Ulcer



- 61 year old Caucasian male with a diabetic ulcer on the left ankle for over 45 days
- Comorbidities: chronic obstructive pulmonary disease, diabetes
- Previous therapies include: conventional wound care interventions
- Full closure achieved with CDO at 3 ml/hr by 98 days

Day 0 – Initiation of CDO, mild pain



Day 57 – Healthy healing wound, no pain



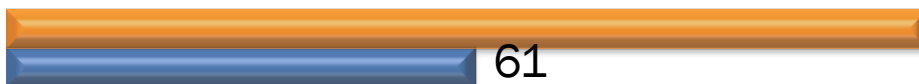
(100831AB - Pictures courtesy of Jill Pridgen, Physician Assistant - Certified)

# Case Study: Diabetic Foot Ulcer



- 86 year old Caucasian male with a non-healing diabetic foot ulcer resulting from diabetes, open 120 days
- Comorbidities: diabetes, heart disease, marginal circulation, pain in legs & feet
- Previous therapies include: Medihoney™, MaxOrb® and Unna Boot (hyperbaric oxygen therapy recommended, yet not pursued due to distance for patient)
- Full closure achieved with CDO at 7 ml/hr by 61 days

Time



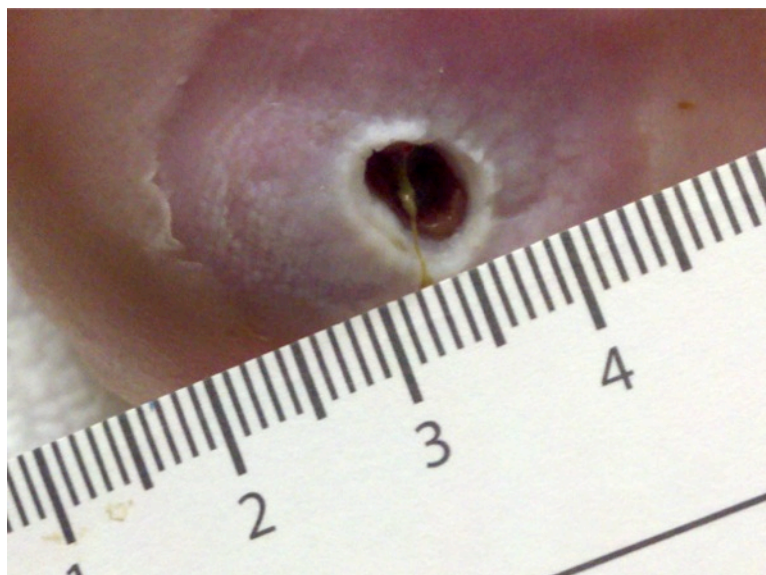
120

Prior to CDO

CDO

Day 0 – Initiation of CDO

Followup – Day 135 (74 days after closure)



(110323HH - Pictures courtesy of Dr. Franklin Steele, MD, Valdese, North Carolina and Buffy Lamb, Resp-I-Care)



# Case Study: Diabetic Foot Ulcer



- 54 year old female with a non-healing diabetic foot ulcer, open 90 days
- Comorbidities: diabetes mellitus and peripheral neuropathy
- Previous therapies include: Negative Pressure Wound Therapy and collagen matrix dressings
- Wound responded quickly to CDO: >70% area decrease by day 32 of treatment
- Full closure achieved with CDO at 10 ml/hr by 153 days

Day 0 – Initiation of CDO, 2.7 x 4.2 x 0.5 cm



Followup – Post-closure



(120914CW - Pictures courtesy of Dr. Melanie Eubanks, DPM, Gastonia, NC)

# Case Study: Diabetic Foot Ulcer



- 71 year old male with a chronic diabetic foot ulcer, open 395 days
- Comorbidities: diabetic neuropathy, left lower extremity amputation, Charcot arthropathy, on dialysis for kidney failure, was at risk for amputation
- Previous therapies include: hydrofibers and collagens, as well as IV antibiotics
- Wound responded quickly to CDO: 85% area decrease by day 29 of treatment
- Full closure achieved with CDO at 4 ml/hr by 62 days

Time

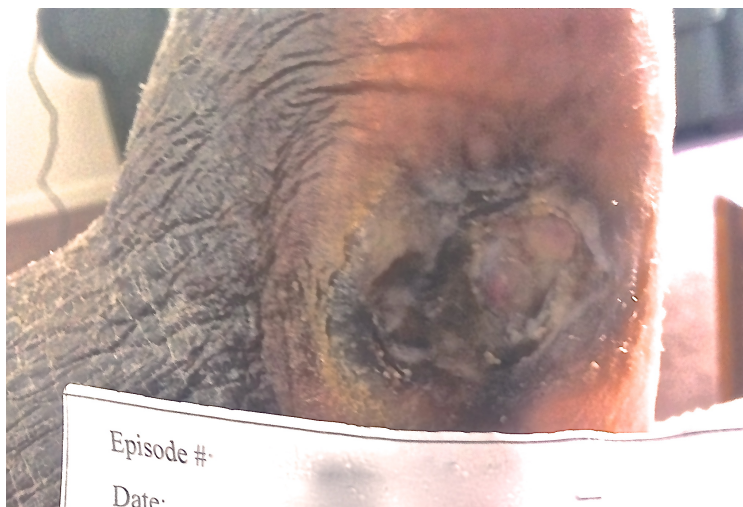


395

Prior to CDO  
CDO

Day 0 – Initiation of CDO, 2.2 x 2.5 x 0.1 cm

Day 62 – Full closure





# VGM Case Study: Patient #1



- 43 year old, Caucasian female with venous insufficiency, post phlebotic syndrome, and Lupus.
- Age of wound greater than 2.5 years. (> 913 days)
- Other Therapies: Compression, Multiple failure with advance moist wound therapy, multiple courses of antibiotics.

Time

28

>913

Prior to  
CDO

Time on  
CDO

Day 0- Wound size 1.1 x 1.4 x 0.0 cm



Day 28- Wound healed



(Treating physician: Dr. Gerald Sarsfield)

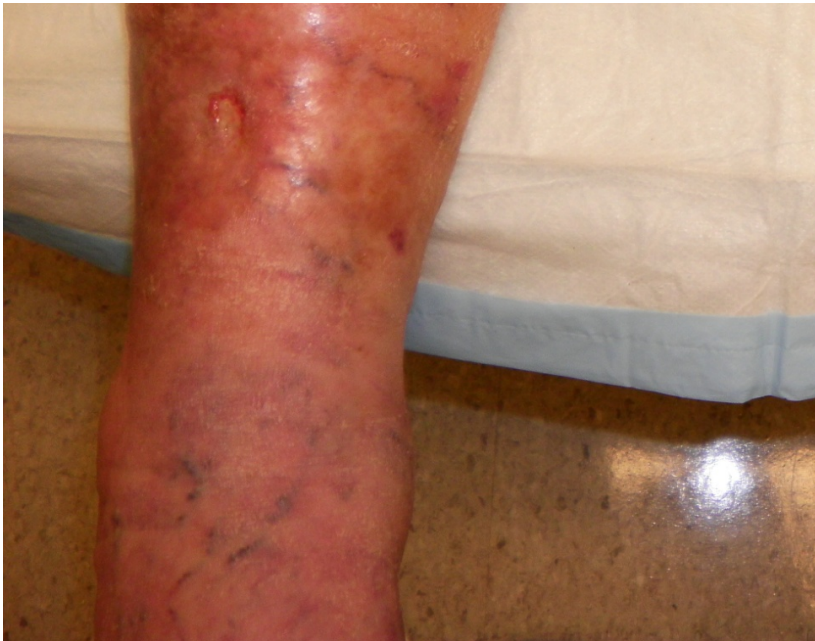
# VGM Case Study: Patient #4



- 83 year old Caucasian female with non healing pretibial wound
- Age of wound prior to CDO: > 90 days
- Other Therapies: Advanced moist wound therapy. Not a HBO candidate
- Wound reached full closure after 34 days of CDO treatment



Start of CDO- Wound size 1.0 x 1.0 X 0.1



Day 34 of CDO- Wound Healed



(Treating Physician: Dr. Gerald Sarsfield)





# VGM Case Study: Patient #5



- 86 year old Caucasian female with history of lower extremity ulcers, peripheral vascular disease, venous insufficiency, and diet controlled diabetes mellitus. Hospitalized several times for lower extremity ulcers.
- Other treatments included: Antibiotics, advanced moist wound therapy.
- Age of wound prior to CDO: > 90 days
- Nurse and Physician left CDO in place until scab fell off
- Patient treated for 141 days

Start of CDO- Wound size 4.1 x 2.2 x 0.0



Day 141- Wound healed

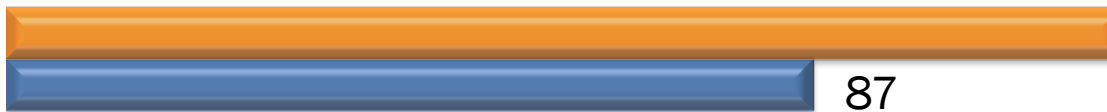


# VGM Case Study: Patient #6



- 76 year old Caucasian female with a non-healing coccyx wound.
- Age of the wound prior to CDO: 120 days
- Other therapies tried: Advance moist wound therapy
- Initial measurements: 1.9 x 0.6 x 0.8
- Wound healed in 73 days. Left on patient 14 extra days to strengthen new epithelium. 87 days total treatment time.

Time



120

87

Prior to  
CDO  
Time on  
CDO

Day 42- Wound size 0.8 x 0.4 x 0.3  
Undermining 0.2 @ 6 o'clock



Day 73- Wound healed



(Treating Physician: Dr. Marc Miller | Wound Nurse: Melody Thomas, RN WCC)



# VGM Case Study: Patient #7



- 84 year old Caucasian female with chronic cellulitis with an ulcer on right medial malleolus.
- Age of wound prior to CDO: > 60 days.
- Other therapies: Advanced moist wound therapy. She is being treated with multiple antibiotics and was hospitalized.
- Days of treatment with CDO: 34 days



Prior to  
CDO  
Time on  
CDO

Start of CDO: Wound size 4.5 x 1.5 x < 0.1



Day 34- Wound Healed



(Treating Physician: Dr Andrew Cope)

# VGM Case Study: Patient #8



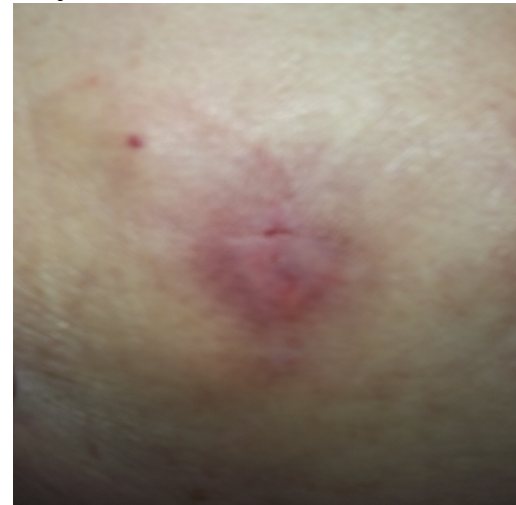
- 83 year old Caucasian female with a history of COPD, pneumonia and compression deformity of thoracic vertebra. She has a pressure ulcer on the spine at approximately T3-T4.
- Age of wound prior to CDO: >1 yr.
- Days of CDO: 56 days



Start of CDO- Wound size 1.0 x 0.5 x 0.1



Day 56- Wound healed



# Patient #9

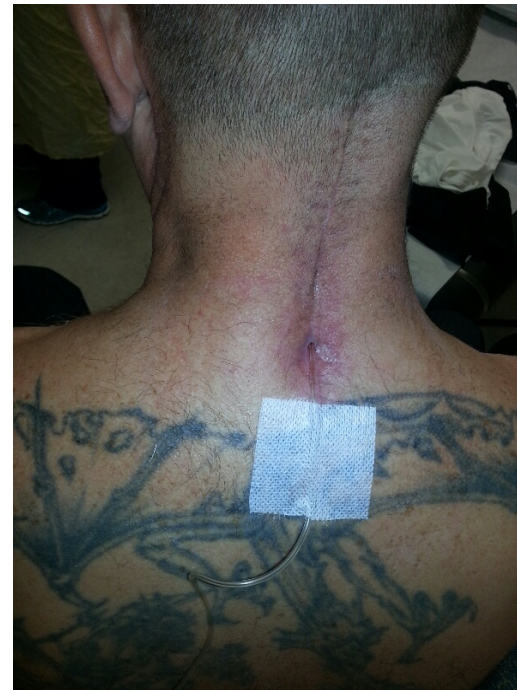


- 50 year old Caucasian male, post laminectomy surgical wound due to staff infection. Past medical history includes posterior cervical bilateral laminectomy C3-C4.
- Age of wound prior to CDO: 64 days
- Previous therapies attempted: surgical debridement, weekly wound management.

Day 0- Wound size: 0.3cm x 0.3 cm x 6 cm  
Tunneling at 12 o'clock



Day 20- Wound closed



(Treating physician – Dr. G. Sarsfield, MD)