Registry Report / Clinical Case Series Review
TransCu O₂®

EO₂ Concepts®
innovative wound healing
Patient Outcomes with TransCu O$_2$®

- 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 O₂®

- Over 945 verified patients have been, or were currently receiving, Continuous Diffusion of Oxygen (CDO) therapy with the TransCu O₂® (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.)
## EO₂ Registry Outcomes

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

<table>
<thead>
<tr>
<th>Time</th>
<th>Prior to CDO</th>
<th>CDO</th>
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<tbody>
<tr>
<td>60</td>
<td>$9,100</td>
<td>$2,600</td>
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<tr>
<td>39</td>
<td></td>
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Day 0 – Wound Size 3.0 x 2.6 cm

Day 39 – Full Closure of Wound

(090910JM - Courtesy of Dr. S. Nicholas Desai, DPM, FACFAS, Chief, Department of Surgery, Memorial Hermann Sugar Land, Texas)
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

Prior to CDO

<table>
<thead>
<tr>
<th>Time</th>
<th>Cost</th>
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<tr>
<td>152</td>
<td>$21,683</td>
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CDO

<table>
<thead>
<tr>
<th>Time</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>81</td>
<td>$8,640</td>
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</table>

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

<table>
<thead>
<tr>
<th>Time</th>
<th>Cost</th>
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<tr>
<td>&gt;120</td>
<td>$9,800</td>
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<tr>
<td>47</td>
<td>$3,100</td>
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</table>

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

<table>
<thead>
<tr>
<th>Time</th>
<th>Cost</th>
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</thead>
<tbody>
<tr>
<td>&gt;60</td>
<td>&gt;$1,440</td>
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</table>

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

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

Day 2 – First Dressing Change, Wound Draining

Day 7 – Full Closure of Wound

(090923VL - Courtesy of Dr. S. Nicholas Desai, DPM, FACFAS, Chief, Department of Surgery, Memorial Hermann Sugar Land, Texas)
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

Day 0 – Initiation of 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

Day 0 – Initiation of CDO
Day 111 – Wound Closed

(100827MM - Pictures courtesy of Dr. Sarsfield, MD, FRCSC, Covenant Wound Care Center, Waterloo, Iowa and Vince Jenness, BS, RRT, CWCMS)
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

Day 0 – Initiation of CDO therapy
Day 33 – Wound completely closed

(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

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

(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

(100827KK - Pictures courtesy of Dr. Sarsfield, MD, FRCSC, Covenant Wound Care Center, Waterloo, Iowa and Vince Jenness, BS, RRT, CWCM)
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

(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

(121017LG - Pictures courtesy of Dr. Melanie Eubanks, DPM, Gastonia, NC)
VGM Case Study: Patient #1

- 43 year old, Caucasian female with venous insufficiency, post phlebitic 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.

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

(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

(Treating Physician: Dr. Patrick Edwards | Wound Nurse: Lillian Rodriquez, RN)
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.

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

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

(Attending Physician: Dr. Patrick Edwards | Wound Nurse: Mary Uhe RN)
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)