

When Nothing Else Works: Proposal for an Unfair Wound Product Evaluation

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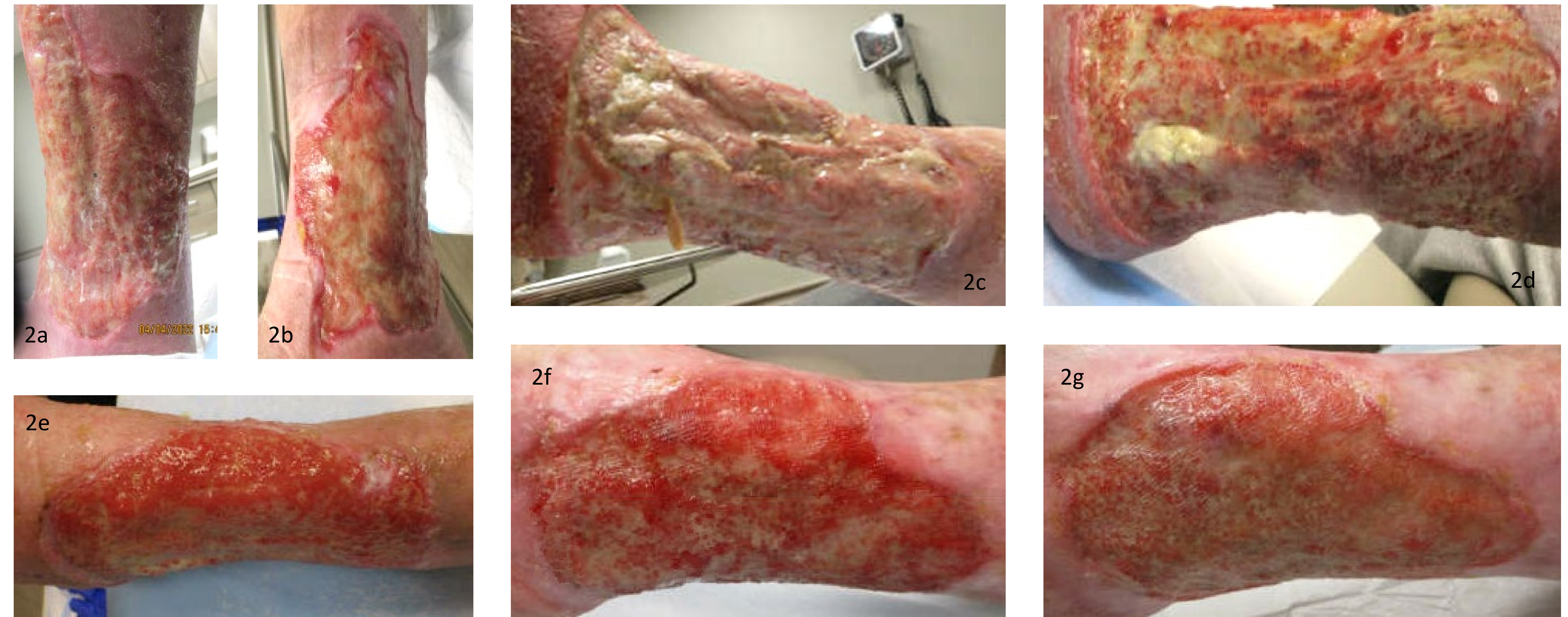
Introduction

When evaluating a new wound product or therapy it is best practice to try it on a variety of typical wounds, thereby giving a fair representation of its effectiveness in the real world. The reality is, however, that new products are usually tried on the wounds that have us at our wits end. And while it's not exactly fair to judge new therapies based on the most challenging wounds, these are the patients most in need of effective therapies. Therefore, we will dispense with pretense and outline our admittedly unfair plan for the evaluation of a unique topical oxygen device in wounds that have stubbornly resisted all other treatments.

Topical oxygen therapy has been shown to increase tissue oxygenation and sustain it over time, resulting in reduced infection, improved angiogenesis, and the formation of higher tensile strength collagen during wound healing.¹⁻³ Cyclical pressurized topical oxygen therapy (CPTOT)* combines high concentration oxygen delivery with therapeutic level cyclical compression, which gives the added benefit of edema reduction and improved wound bed perfusion, while allowing more efficient oxygen diffusion, nutrient exchange, and removal of inflammatory factors. Because pressures are cyclical, CPTOT can be used safely in patients with compromised vascular status.

Methods

We proposed to evaluate CPTOT on difficult and atypical wounds that had not healed, despite standard of care, advanced modalities and all our best efforts. Patients/caregivers were trained to deliver CPTOT independently, at home, according to the manufacturer's instructions. Retrospectively, information regarding wound progression, and wound-related pain was gathered. Because these are atypical wounds, patients served as their own controls, and pre-treatment vs. post-treatment healing trajectories are compared.



Results

Case 1: 68-year-old male in good health other than significant peripheral vascular disease, who presented with a right medial calf wound, present for 3 years since undergoing vascular surgery complicated by surgical site infection.

1a. Initial Visit: Poor pulses present. Sent for x-rays which were negative and requested previous vascular studies. Exam of wound with visible tendon and muscle, no S/S of infection.

- Wound measurement: 15 x 13 x 1.0 cm

1b. One month: Debrided with SonicOne, Utilizing moist wound (silver gel). Had attempted mild edema management with tubular bandage but patient unable to tolerate.

- Wound measurement: 14.6 x 11.5 x 1.0 cm

1c. Two months: Tissue somewhat improved but no epithelialization. Using hydrogel along wound edges to prevent drying and Ca alginate to wound bed daily.

- Wound measurement: 14 x 11 x 1.0 cm

1d. 3 Weeks After Starting CPTOT: Wound edges epithelializing.

- Wound measurement: 13.5 x 10.7 x 1.0 cm

1e. Month 3 of CPTOT: Improved wound bed vascularity and significant epithelial advancement. Decreased inflammation.

- Wound measurement: 12 x 8.5 x 0.5 cm

1f. Month 5 of CPTOT: Continued epithelial advancement and improvement wound bed vascularity.

- Wound measurement: 11 x 8 x 0.3

Case 2: 60-year-old female with HTN, smoking, asthma, and depression, who presented with a left lower leg wound that reportedly started when she cut her leg shaving 5 years prior and failed to heal. She had no previous history of compression, and her leg was well perfused with triphasic pedal pulses.

2a. Initial Visit:

- Wound measurement: 15 x 13 x 0.5 cm
- Circumference (edema) measurements: foot 25 cm, ankle 25 cm, calf 35 cm

2b. Day 4: Circumference measurements: foot 25, ankle 24, calf 33

2c. Over the ensuing months, the ulcer was getting marginally smaller with topical dressings and treatments altered to meet the changing needs of the wound. She was biopsied on several occasions with no malignancy, but tissue changes consistent with PG. She had multiple courses of culture driven antibiotics. She was treated with tapering doses of prednisone which were marginally successful and was ultimately treated with Cyclosporin which she tolerated initially then began to have increasingly severe side effects. Due to inability to tolerate opioids, her pain was managed with Naproxen, Venlafaxine and Gabapentin. At the patient's request, her clinic visits were decreased, and home care continued with dressing changes and compression. Her leg continued to deteriorate despite local care and frequent ultrasound debridements (with no pathology noted). The size of her wound didn't change as much as the quality of her tissue. She continued to smoke despite counseling to the contrary. Her wounds became much worse, larger and with necrosis. She was sent to the ED and was given a dose of dalbavancin and continued on oral doxycycline for MRSA infection but not admitted.

2d. 1 Year: Wounds had improved somewhat but the patient was

getting more depressed and decided to stop taking all medications. She was counseled and admitted for physical and mental health. 2 weeks prior to this we had received approval for TWO2 therapy.

- Wound measurement: 19 x 18 x 0.5 cm with exposed tendon

2e. 3 Weeks After Starting CPTOT: Using therapy 1-2 times daily. Marked improvement in wound bed vascularity. Using absorptive dressings over contact layer.

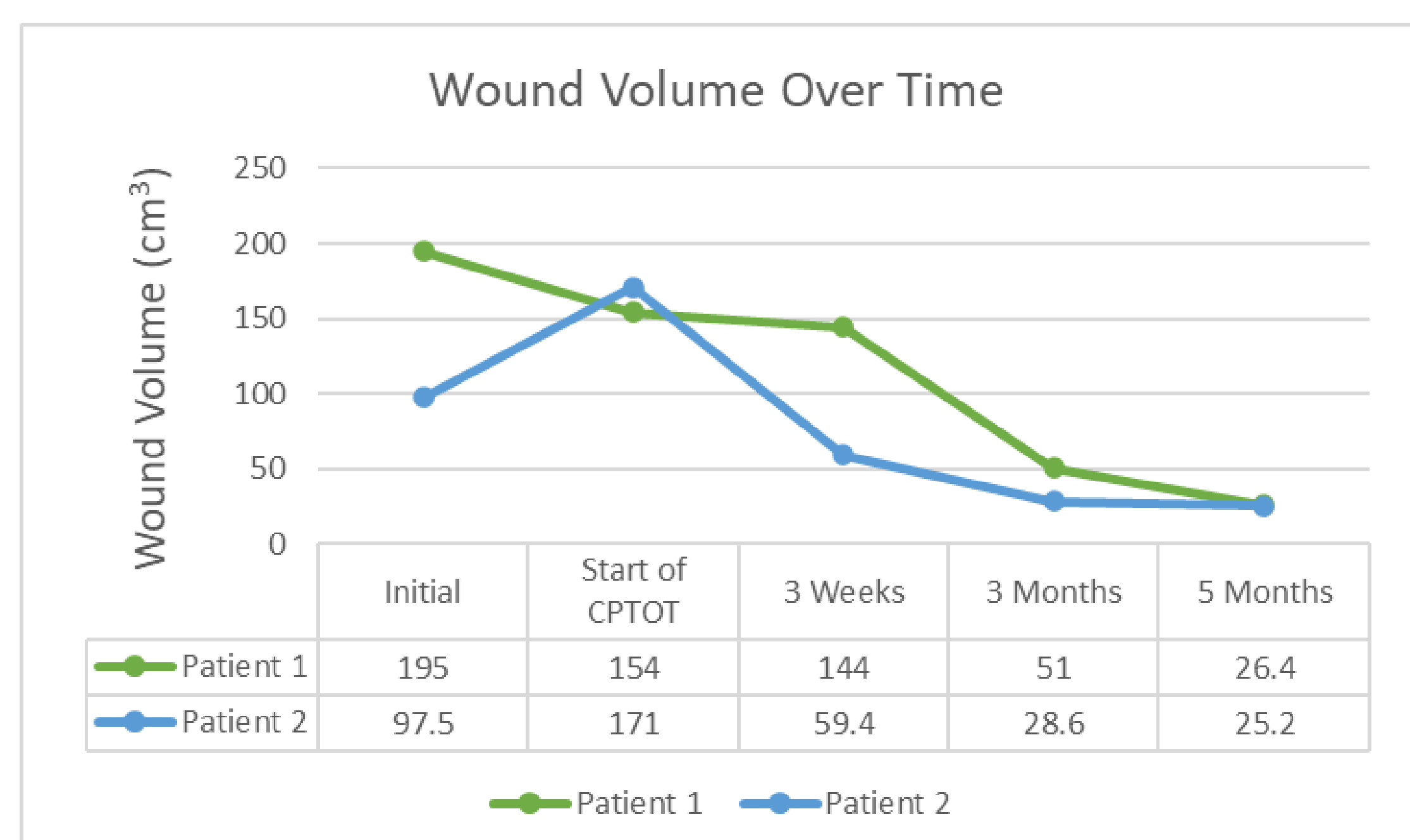
- Wound measurement: 19.3 x 15.4 x 0.2 cm

2f. Month 3 of CPTOT: Wound measurement: 13 x 11 x 0.2 cm

2g. Month 5 of CPTOT: Wound measurement: 12.7 x 9.9 x 0.2 cm

Conclusion

CPTOT was effective in decreasing pain, improving wound bed vascularity, improving pain and positively shifting the healing trajectory of two extremely challenging wounds.



References

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