

Prospective Pilot Study: Results from a prospective clinical trial involving **20 patients with 23 wounds** shows that Continuous Diffusion of Oxygen (CDO) therapy to **dramatically reduce pain in a short time frame**. The study was **published in Wound Central** in September of 2018¹. This pilot prospective study had open inclusion criteria to allow the researchers to target painful wounds that responded to CDO. The research was conducted by Advanced Wound Consultants (AWC) in Chicago, IL.

“I’ve Lost My Fear”

This **patient quote was a favorite for the researchers**. The patient was a Spanish speaking woman who was very hard of hearing and had her son translate for her. She was fearful of nursing visits since she had come to associate the visits with the pain of wound debridement and dressing changes. Even touching the dressing was extremely painful. After 3 days of treatment, at the first dressing change, when asked about her pain levels, her son translated “I have lost my fear” – the pain had gone away hours after applying CDO and she was no longer fearful of the nurse or the treatment.

The study consisted of treating 23 wounds in 20 different patients. Two of the patients had multiple wounds and requested CDO for treatment of the other wounds because of the pain relief. Wounds were chronic in nature and had been under the researchers care for at least a month prior to initiating CDO on their wounds. All had been treated with a variety of therapies, ranging from advanced dressings to antibiotics to negative pressure wound therapy. The age of the wounds ranged from 40 to 330 days old at the time of CDO application. Patient age ranged from 33 to 98 years old at the start of CDO therapy. The wound size ranged from under 1.0 cm² to 117 cm². **Median baseline was 8 on a scale of 10**. 65% of the patients were female.

Summary of Most Significant Results by Adding Oxygen Continuously:

- **The application of CDO therapy resulted in dramatic pain relief in a majority of the patients by the first follow-up visit: over half the patients experienced at least a 75% reduction in pain**
- **All patients experienced pain relief after having CDO applied**
- **Pain relief was not dependent on wound closure: patients who had no wound closure, or their wounds become larger, in the first week experienced pain relief similar to those who did have wound closure**
- **Patients requested CDO therapy on other wounds for pain relief as a result of their experience with pain relief on the first wound**
- **CDO therapy works very well on wounds with mixed etiology, recurrent wounds (wounds with recidivism), recalcitrant wounds, stalled wounds where local perfusion is suspect, surgical incisions and toe amputations**
- **CDO therapy should be considered strongly as an option for achieving effective pain relief and lessen the need for prescription pain medication**

Summary from Abstract: This was a pilot prospective study of the experience with Continuous Diffusion of Oxygen (CDO) therapy to monitor pain reduction and wound healing outcomes in an outpatient setting for the treatment of chronic ulcers. CDO was found to not only be an effective therapy to heal wounds, yet also yielded impressive pain relief. Most (91%) patients reported noticeable pain relief by the first visit, with the majority becoming pain-free within the first week. All patients experienced pain relief regardless of wound closure rates. We found it to work very well on a wide variety of wounds, including those with mixed etiology, recurrent wounds, recalcitrant wounds, stalled wounds where local perfusion is suspect, surgical incisions and toe amputations. In general, we experienced the majority of wounds healing in 4-5 weeks. From this study, CDO appears to work very well at reducing wound pain. Given the current issues with oversubscriptions of pain medicines and the associated dependencies that arise from the use of strong, addictive pain killers such as opioids, CDO therapy should be considered strongly as an option for providing effective pain relief and positive outcomes for wound healing.

Study Setup

The researchers were allowed to enroll patients with chronic, very painful wounds. Wound type was not specified so that the clinicians could adjust and target enrolling wound types that appeared to respond better to CDO therapy. The results were analyzed by 4 groupings:

- Pain Relief & Full Closure – patients had both complete pain relief (0 of 10) and full closure
- Pain Relief & Closure – patients had complete pain relief (0 of 10) and significant wound closure until non-compliance with CDO therapy
- Pain Relief & Limited Closure – patients who experienced both complete pain relief (0 of 10) and limited ($\leq 30\%$) wound closure
- Limited or No Pain Relief or Closure – patients who experienced limited ($\leq 30\%$) or no pain relief and wound closure

Results

- 83% of patients experienced significant closure overall
 - 57% closed completely (all of these patients were compliant with CDO therapy)
 - closed in 51 days (mean) with a mean wound age of 135 days
 - largest wound to close was 55 cm², base pain 10, pain went to 0 even though wound initially expanded 37% before proceeding to close
 - Remainder were on a trajectory to heal until non-compliance was noted (wounds closed 53-93%)
 - Largest was 117 cm², base pain 10, no pain (0) at first follow-up
- In wounds that generally did not close overall (17%), pain relief was dramatic
 - 75% were pain free (0/1) by the first follow-up visit (from a median base pain of 8)
 - Median closure was only 5% for this group in this timeframe
- Wounds that got larger or stayed the same size during the first week had greater pain relief
 - 44% were pain free at first visit, vs. 39% for all wounds
- One patient was treated for 3 different wounds and experienced pain relief every time

Discussion

Overall, 83% experienced significant or full closure. Of this group, all of the wounds that experienced partial closure were on a trajectory to heal until the patient became non-compliant with the CDO therapy. These wounds were pain free and had closed between 53% and 93% (median of 85%) when the patient became non-compliant. The common reasons for non-compliance were: 1) the wound was healing, and 2) the wound was no longer painful, so why carry the system around?

Patients reported increases in pain associated with CDO stopping. One patient stated that the previous night she felt pain at approximately 1:00 AM and upon inspection realized the tubing from the OxySpur dressing had become disconnected. She stated that she was pain free until then and her pain had increased to 6 after the oxygen was not being delivered.

Even in wounds that did not respond to CDO therapy with significant progress on wound closure, the patients experienced complete pain relief upon application of CDO therapy. Three of the four wounds were pain free (0 or 1) by the first follow-up visit (median of 5 days) from a median baseline pain of 8. In this timeframe, the median closure rate was only 5%.

Reference:

1. Bowen J, Ingersoll MS, Carlson R. Effect of CDO on Pain in Treatment of Chronic Wounds, Wound Central, 2(4) 2018-09, 186-195