Amputation Date Cancelled Due to the Use of Transdermal, Sustained Oxygen Therapy in the Healing of a Diabetic Foot Ulcer with Osteomyelitis

Claire Wilson, RN, BSN, CWON[1], Scott Hirsh, D.P.M.[2], Alan Hirsh, M.D.[3]

[1]Cleveland Clinic Health System, Cleveland, OH; [2]Private Practice, Mayfield Heights, OH; [3]University Hospital Health System, Cleveland, OH

Introduction

Approximately 6 million Americans suffer from chronic open wounds that can lead to the development of osteomyelitis and sometimes require amputation.[1] The cost of care for diabetic and ischemic ulcers is extremely high. Nationwide, chronic wound care represents nearly $20 billion in health care costs.[2] Hypoxemia caused by disrupted vasculature is a key component in the pathophysiology of chronic wounds. Recent works by Hunt & others have created a new understanding of oxygen in wound healing.[3] Phagocytes and nearly every cell in the wound microenvironment possess a special enzyme to convert oxygen to Reactive Oxygen Species (ROS). These ROS contribute as cellular messengers to promote redox dependant processes including cytokine activity, angiogenesis, cell mobility and extra cellular matrix production. This view differs sharply with the traditional view that oxygen radicals were toxic to tissue. In a more refined view, it is believed that ROS may act as a signaling mediator in a wide variety of cellular responses.

Work by Babior showed that high concentration of ROS led to extensive bacterial killing.[4] This is mediated by an explosive production of super-oxide ions by cell specific NADPH oxidases found in leukocytes and macrophages. These enzymes have maximal effectiveness at higher than normal levels of oxygen. Thus, oxygen can be seen as having a strong antibiotic effect on wound healing.

Methods

EpiFLO^{SD}, an FDA cleared therapy device, manufactured by Ogenix Corporation, is a wound closure device that provides transdermal sustained oxygen therapy at a flow rate of 3ml/hr, 24 hours a day, 7 days a week. The disposable device is used in conjunction with conventional occlusive dressings currently on the market. Animal studies show that wounds treated with EpiFLO^{SD} therapy have a significant increase in re-epithelialization, collagen development, granulation, glycosaminoglycans and other collagen precursors in the treated wound.[5]

References

1. Frykberg RG, Armstrong DG, Giurini J, et al. Diabetic foot disorders: a clinical practice guideline. American College of Foot and Ankle Surgeons. J. Foot Ankle Surg 2000; 39 (5 Suppl): S1-60.

2. Harding KG, Morris HL, Patel GK. Science, medicine and the future: healing chronic wounds. BMJ 2002; 324 (7330):160-3

3. Hunt TK, Hussain Z, Sen CK. Give me ROS or give me death. Pressure 2001; 30:10-11

4. Babior BM, Oxygen-dependent microbial killing by phagocytes. N Engl J Med 1978; 298:659-68

5. Said HK, Mustoe, T, et al. American College of Surgeons Clinical Congress, Oct 2002 and article accepted for publication in the Archives of Surgery

Case Study

History- a 77 year old physically active male with a history of IDDM and arterial insufficiency presented with a neuropathic ulcer with osteomyelitis on the medial aspect of the right first metatarsal head. The ulcer had been present for more than 47 days and had been treated with a wet-to-dry gauze dressing. Additionally, he received Augmentin 875mg BIDx 19 days. There had been no improvement. The patient had a prior history of two toe amputations on the same foot due to ulcers with osteomyelitis. A below the knee amputation was scheduled. Mediations included: NOVOLIN 70/30, Norpace, Diovan, Plavix, Digitek.

Assessment

The wound measured 2.5cm x 2.5cm x 1.0cm. The wound bed had exposed bone and contained dusky pink, gray tissue. The wound border was circumscribed with a 0.5cm area of thick, yellow callus. The wound drainage was scant, clear and odorless. The patient did not experience any pain. The bone scan was positive for osteomyelitis, C-reactive protein was 1.44mcg/dl and the sed rate was 37mm.

Goals of Therapy

1. Heal the osteomyelitis without amputation
2. Close the wound
3. Protect the area from pressure
4. Provide a simple, easy to change bandage system
5. Permit the patient to continue with his active lifestyle

Conclusion

Transdermal, sustained oxygen therapy was effective in the treatment and closure of a diabetic foot wound with osteomyelitis. We were successful in achieving our goals of avoiding the amputation, healing the osteomyelitis, closing the wound and keeping it closed, protecting the area from pressure, providing the patient with a safe, effective, simple to use technology that permitted the patient to remain physically active during the treatment period.

Week 2

Week 5

Week 15

Protocol

On 9/26/04, the wound was debrided and cleansed. An EpiFLO^{SD} therapy cannula was placed directly into the wound bed. The cannula was then covered by an Aquacell Ag ® dressing and covered with an occlusive, clear film dressing. The EpiFLO^{SD} device pumped 3ml of > 99% pure oxygen into the wound bed, 24 hours a day, 7 days a week. The dressing was changed when the Aquacell Ag® had become saturated. The frequency of the dressing changes varied from 1-2 days throughout the treatment period. The patient was followed by home health nurses two times a week for the first few weeks of treatment to ensure that the patient's wife would be able to properly assess the wound and change the dressing as needed.

The patient was also fitted with a special off loading healing sandal. Activities of daily living were able to be continued and enjoyed. The patient remained on oral antibiotic therapy throughout the EpiFLO^{SD} therapy period. By week 2 the wound bed was red and granulating. Patient reported feeling a tingling sensation in his foot and leg for the first time in many years. By week 15 (1/12/05) the wound closed. His CRP was less than 0.3 mcg/dl and his sed rate was 14 mm. The patient's serum markers, including C-reactive protein and sed rate indicate that he is free of infection. The wound has remained closed.

Device Application

Use of EpiFLO^{SD} when compression is not required

Step One:

Place the sterile cannula near the edge of the wound bed.

Step Two:

Cover the wound with an occlusive dressing.

Step Three:

Secure EpiFLO^{SD} in place with tape or in a pocket.

Use of EpiFLO^{SD} with compression for venous stasis ulcers

Step One:

Place the sterile cannula beneath an occlusive wound dressing near the edge of the wound bed.

Step Two:

A protective gauze wrap is carefully wrapped around the leg. Care is taken not to kink the catheter.

Step Three:

A Profore ® compression dressing is secured to the leg. Again, care is taken not to kink the catheter.

Step Four:

The Profore ® dressing is covered with a protective bandage and EpiFLO^{SD} is secured into place with tape.