## Monograph

## The Clinical Case for Use of Hyperbaric Oxygen Therapy in the Treatment of Diabetic Wounds

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Non-healing wounds of the diabetic foot are considered one of the most significant complications of diabetes, representing a major worldwide medical, social, and economic burden that greatly affects patient quality of life. Approximately 25.8 million Americans—one in every 12—are diabetic, and the disease is causing widespread disability and death at an epidemic pace, according to the Centers for Disease Control and Prevention.<sup>1</sup>



Although diabetes can ravage the body in many ways, non-healing ulcers on the feet and lower legs are common outward manifestations of the disease. Also, diabetics often suffer from nerve damage in their feet and legs, allowing small wounds or irritations to develop unnoticed. Given the abnormalities of the microvasculature and other side effects of diabetes, these wounds take a long time to heal and require a specialized treatment approach for proper healing.

As many as 15% of diabetic patients will eventually develop foot ulcers2 and recurrence within five years is 70%.<sup>3</sup> If not aggressively treated, these wounds can lead to amputation, and it is estimated that every 30 seconds a lower limb is amputated because of a diabetic wound.<sup>4</sup> Amputation often triggers a downward spiral of declining quality of life, frequently leading to disability and death. In fact, less than one-third of diabetic amputees will live longer than five years—a survival rate equivalent to that of many cancers.<sup>5,6</sup>

Many of these lower extremity amputations can be prevented through an interdisciplinary approach to treatment involving a variety of therapies and techniques, including debridement, dressing selection, offloading, and patient education. When wounds persist, a specialized and holistic approach is required for healing. Systemic hyperbaric oxygen therapy (HBOT) has been used to assist wound healing for more than 40 years. HBOT involves the systemic delivery of oxygen through pressurized chambers. Best known as an antidote for the "bends" (decompression illness), HBOT is also a proven method to advance wound healing.<sup>7</sup>

In 2012 alone, Healogics<sup>™</sup> effectively utilized more than 415,000 HBOT treatments.<sup>8</sup> These treatments helped to reduce swelling, fight infection, build new blood vessels, and ultimately produce healthy tissue. Essentially, HBOT helps to heal the wound from the inside out. During HBOT, patients are monitored for the increased concentration of oxygen in the blood near the wound. If the oxygen level is higher, the therapy is most likely beneficial to the patient. A typical course of treatment involves about 90 minutes per day in a specialized chamber, five days per week, over a four -to-six-week period.

## A Study of the Effectiveness of HBOT

Several randomized, controlled trials have demonstrated the benefit of systemic HBOT for wound healing.<sup>9-14</sup> In 1996, a randomized controlled study of 68 patients referred for amputation was conducted by Faglia et al.<sup>11</sup> The results were as follows:

Half of the participants received aggressive HBOT while the other half did not.<sup>11</sup> The study, later used by CMS to approve HBOT for reimbursement, showed that for those who did receive HBOT, only three out of 35 patients required amputation. For those who did not receive the treatment, 11 of the 33 resulted in the affected limbs being amputated.<sup>11</sup> Medicare reimburses HBOT, and the American Diabetes Association agrees that it is a beneficial advanced therapy in certain diabetic ischemic wounds.<sup>15</sup>

More recent outcome data (2007) from the largest retrospective study of patients with diabetic foot ulcers with critical limb ischemia conducted by Fife et al showed that of 1,006 patients who received HBOT at one of five participating centers, 73.8% experienced improvement (wound granulated or healed).<sup>16</sup> Given the high cost of amputation and rehabilitation, in both economic and emotional terms, these data suggest that HBOT is an important advanced therapy to heal lower-extremity lesions, especially those with a Wagner Grade 3 or above.

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