

## ***Limb Salvage Effects Of HBO Validated***

### *Randomized Prospective Clinical Trial Demonstrates HBO's Effectiveness in Treatment of Severe Prevalently Ischemic Diabetic Foot Ulcers*

For the diabetic patient, foot ulcers and the frequently associated sequelae of sepsis and amputation are common complications of the disease. The etiology of the diabetic foot ulcer is multifactorial. For those patients who have primarily neuropathic lesions such as the classical mal perforans ulcer from repetitive painless trauma the prognosis is good. These ulcers usually have little ischemia and the defect frequently heals with aggressive wound management and unweighting. For those patients with predominately ischemic ulcers the prognosis is poor as both healing and the ability to fight infection are compromised.

Over the past decade the clinical evidence to support the use of hyperbaric oxygen for the management of selected diabetic wounds has been increasing. The mechanisms of oxygen enhancement of wound healing depend on the hydroxylation of procollagen. The hydroxylation is necessary for polymerization and cross-linkage of procollagen strands and the transport of collagen molecules to the extracellular space. Collagen deposition, must precede the development of new capillaries and is proportional to tissue oxygen tension through out and beyond the physiological range. The process proceeds at half the maximal rate at 20mmHg and at 90% of the maximal rate of 200 mmHg. Cell replication also requires oxygen; fibroblast and vascular endothelial cells replicate most rapidly at 40mmHg.

Several different investigators have reported increased limb salvage rates using hyperbaric oxygen therapy where vascular surgery is not an option. Baroni et al. (1987) reported a significant reduction in amputation rates for those patients receiving HBO versus cohort patients who did not. Sixteen of 18 patients in the treated group healed while only one of ten in the control group healed. The amputation rate in the controls was 40% versus 12.5% in the hyperbaric group ( $p < 0.001$ ). Oriani (1990) reported a prospective trial of HBO for the management of diabetic foot wounds (Wagner class 3 or greater) and found an amputation rate of only 5% for the HBO group in contrast to 33% for those patients who did not receive HBO. With the exception of HBO therapy there were no significant differences between the groups relating to age, glycemic control, nephropathy, neuropathy, and a variety of other variables. Doctor et al. (1992) also showed the benefit of hyperbaric oxygen therapy in the infected diabetic foot. Ten percent of the hyperbaric oxygen treated group underwent major amputations versus 43% in the control group. While these studies were performed in a prospective format and they must be interpreted with some caution due to the lack of randomization which is characteristic of most studies addressing therapeutic interventions for the diabetic foot. As an outcome measure, the limb was considered to be salvaged when the plantar support was preserved and the ulcer healed despite minor amputations (toe or forefoot), and the limb was considered lost when a major amputation (below of above the knee) had been effected. The decision to carry out a major amputation was made the consultant surgeon who was blinded to the randomized process and therefore was unaware whether the patient was in the HBO or control group.

Sixty-eight diabetic patients were consecutively admitted into the study. Three patients in the hyperbaric group had major amputations: two below the knee and one above the knee. In the control group, 11 patients (33%) received major amputation: 7 below the knee and 4 above the knee. The difference was significant at the 0.016 level. It was also observed that the transcutaneous oxygen tension in the dorsum of the foot was significantly increased in subjects treated with hyperbaric oxygen therapy:  $14.0 \pm 11.8$  mmHg in the HBO group versus  $5.0 \pm 5.4$  mmHg in the control group ( $p = 0.0002$ ). The presence of higher transcutaneous oxygen values among the HBO patients is important because it implies a greater vascular density. Such an increase in capillary vascularity would give more durability to the recovered tissue compared to the control patients. In summary, the authors concluded that hyperbaric oxygen therapy in conjunction with traditional therapies, effectively decreases major amputations in diabetic patients with severe ischemic foot ulcers.

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