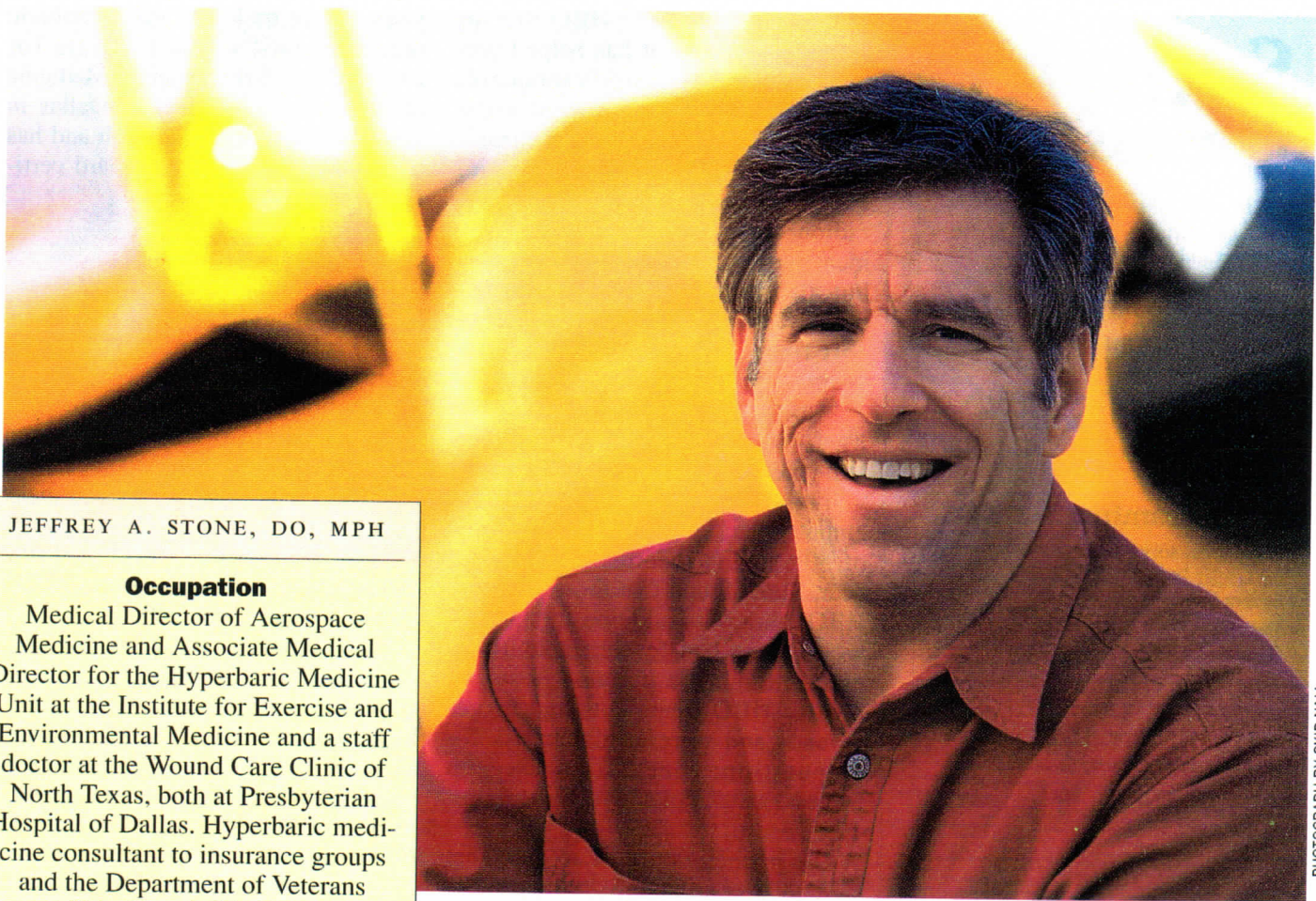


## The Pressure's On



PHOTOGRAPH BY SKIP NALL

JEFFREY A. STONE, DO, MPH

### Occupation

Medical Director of Aerospace Medicine and Associate Medical Director for the Hyperbaric Medicine Unit at the Institute for Exercise and Environmental Medicine and a staff doctor at the Wound Care Clinic of North Texas, both at Presbyterian Hospital of Dallas. Hyperbaric medicine consultant to insurance groups and the Department of Veterans Affairs Hospital in Dallas.

### Professional Focus

Studying the effect of hyperbaric oxygen therapy on diabetic wounds.

### Outside Interests

Stone is an airplane pilot and a scuba diver. He loves classical music and plays the French horn. He's been married for 12 years and has two sons, David and Daniel.

### Research Funding

American Diabetes Association  
Clinical Research Grant

**In his free time, Jeff Stone goes to great heights in this 1931 German training plane (model 131E, Bucker Jungnann). In his research, he goes to great depths to help people with diabetic foot wounds.**

**H**ave you ever gone hiking high in the mountains? You might have noticed that the higher up you went, the more you struggled for oxygen. That's because at higher altitudes there's less atmospheric pressure, and therefore, less oxygen. When you hiked down the mountain, your breathing got easier because the air was more concentrated and contained more oxygen.

You might ask yourself what any

of this has to do with diabetes. Jeffrey Stone, DO, MPH, would say "a lot." Especially for people with diabetic wounds.

Stone works with people who have chronic foot wounds, that is, wounds that have gone unhealed for more than two months. Many of the people Stone sees have diabetes. On average, the wounds of his patients with diabetes have been present for 11.8 months,

*continued on page 60*





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and some have been there for years.

Stone thinks that hyperbaric oxygen (HBO) therapy can help these wounds heal. During HBO therapy, a patient breathes oxygen at increased atmospheric pressure.

Doctors have used HBO therapy for over 40 years. It has helped people recover from carbon monoxide poisoning, decompression sickness after diving accidents, and chronic bone infections. More recently, it's been used for people with soft tissue radionecrosis (when radiation treatment for cancer kills the cancer cells but also kills the good tissues and blood vessels), failing skin grafts, and soft-tissue infections. Now Stone wants to add foot ulcers to that list.

"I believe that HBO therapy, when used with standard foot care on certain types of chronic diabetic wounds, will result in faster healing and fewer amputations," Stone says. In a review of 501 patient records, reported last year, Stone found that those who had HBO therapy in addition to standard wound care had fewer amputations, even though the people chosen to receive HBO treatments had bigger wounds and were at higher risk for amputation. (See "High Oxygen Saves Feet," *Forecast*, September 1995, p. 30.)

Other doctors aren't so sure that HBO helps, so Stone is setting out to prove that it does. In a study of over 100 people with foot ulcers, Stone will see if HBO therapy increases the number of wounds that heal, helps wounds to heal more quickly, and reduces the number of amputations.

Stone is well prepared for this study because he has had years of experience with HBO therapy. After medical school, Stone earned a master of public health degree from Harvard. He completed a residency in aerospace medicine and a fellowship in hyperbaric medicine at the U.S. Air Force School of Aerospace Medicine at Brooks Air Force Base, San Antonio. He was then named chief of

the Department of Aviation and Hyperbaric Medicine at the United States Army Aeromedical Center in Fort Rucker, Ala., where he developed the Army's hyperbaric medicine program. He ran that program for two years before he joined the hyperbaric medicine unit at the Institute for Exercise and Environmental Medicine at Presbyterian Hospital of Dallas in 1992, where he does research and has a clinical practice. He is board certified in aerospace medicine.

### Starved For Oxygen

To Stone, HBO therapy seems tailor-made for treating certain foot ulcers. "HBO is based on precise physiological principles," he says.

The body needs oxygen to heal itself. White blood cells need oxygen to fight infections, and tissues need oxygen to repair themselves and make new blood vessels. Without enough oxygen, wounds don't heal, and that can lead to amputations—some 50,000 a year in people with diabetes.

Unfortunately, some people with diabetes have a hard time getting enough oxygen to foot ulcers. They have poor circulation because the large arteries in their legs and feet have "hardened." Hardened arteries are narrower than healthy arteries, and blood moves through them more slowly. Poor circulation slows down healing because wounds don't get enough oxygen. Such wounds are called ischemic ulcers.

Even when the blockages in these large arteries are cleared, some diabetic wounds don't heal. It appears that the affected area still isn't getting an adequate flow of blood.

Stone thinks HBO therapy will help people with ischemic ulcers because HBO helps oxygen get to the wounded area.

In Stone's study, patients will go into an HBO chamber. The atmospheric pressure will be increased, and the subjects will breathe pure oxygen. The effect: Their tissues will get 15 to 18



times the normal amount of oxygen. This extra oxygen, asserts Stone, will help certain ischemic ulcers heal.

### A Researcher With A Bias

"I'm a strong proponent of hyperbaric therapy when it's used appropriately," says Stone. His enthusiasm makes him a biased researcher. But most researchers are. They start experiments expecting certain results.

Biases could lead to problems because researchers might unconsciously fix the results. For example, Stone might inadvertently assign people with smaller ulcers to get HBO treatments and assign people with large, hard-to-heal ulcers to the non-HBO (control) group. If the HBO group does better, would it be because of the HBO therapy or because they had smaller wounds?

The people in the study might also be biased. For example, a patient might strongly believe that HBO treatments will help and is enthusiastic and hopeful when he finds that he's part of

*continued on page 62*

### Total Pressure

At sea level, the pressure of the atmosphere is 760 millimeters of mercury (mmHg), which is 1 atmospheric absolute (ATA) pressure. That's how much force is pushing down on us.

Air is made up of different gases, and the total pressure of the air equals the sum of the pressures of each of the gases. Air is 21 percent oxygen, so the partial pressure of oxygen in air is 21 percent of 760 mmHg, or 160 mmHg.

When the pressure of the atmosphere is increased to 2 ATAs, the total pressure is twice 760 mmHg, or 1,520 mmHg. The pressure of oxygen is 21 percent of 1,520, or 319 mmHg. So even breathing air at 2 ATAs will increase the amount of oxygen you get. But it will also

increase the amount of other gases you breathe, such as nitrogen, which can make you sick if you breathe too much of it.

The people in the HBO group in Stone's study will breathe 100 percent oxygen at 2.4 ATAs (the same pressure found at 45 feet below sea level) so they'll receive 1,824 mmHg of oxygen, or about 11 times the amount of oxygen they'd get breathing regular air.

The pressure doesn't only affect the amount of oxygen going into the lungs. The pressure on the body forces more oxygen to move from the blood into the cells of tissues. When a person breathes 100 percent oxygen at 2.4 ATAs, tissues receive 15 to 18 times the amount of oxygen they'd get if the person were just sitting in a room breathing regular air.

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\* See International Dental Journal "Xylitol and its effects on dental caries" Volume 45 Number 1 (Supplement 1) February 1995 Entire issue.  
\* See Dental Dialogue "Xylitol Symposium At University of Michigan", January 27, 1988.  
\* See "The Xylitol Advantage Beyond Brushing, Flossing, Fluoride." Dr. John Peldyak, January 1996.

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the treatment group. His ulcer heals quickly. But was it because of the HBO or because of the patient's enthusiasm and hope?

Previous studies of HBO therapy have indicated that it works, but there has been controversy surrounding them because of their biases. In some, researchers chose which patients got HBO treatments. Some subjects knew they were getting HBO therapy. This may have affected the results, which is part of the reason that some people feel that HBO has not been proven to be effective.

To protect the results of a study from biases, better-designed studies are "double-blinded"—neither the study subjects nor the researchers know who is getting the experimental treatment.

Stone's study is double-blinded. Subjects will be randomly assigned to the HBO or control group. All of the subjects have "treatments" in a pressurized hyperbaric chamber, but some people will breathe 100 percent oxygen (the real treatment) and some will breathe only the amount of oxygen in regular air.

**Not Only Oxygen**

People in the study will be over the

age of 21, have either type I or type II diabetes, and have had non-healing diabetic wounds for at least two months. All of the patients will receive a regimen of standard wound care. If patients have a correctable blockage of blood vessels, they'll have procedures done to correct the blockage before they enter the study. Any infected bone will be removed. Patients will be helped to get their blood glucose levels close to normal. They'll be encouraged to stop smoking, to eat a healthy diet, lose weight if needed, and do exercises that won't put weight on the feet with the wounds.

Stone emphasizes that HBO can't take the place of any of these standard therapies. "HBO is not a cure-all," he says, "and it's not even the first treatment that should be tried. Many ulcers will do fine without HBO treatments. But some still won't heal. Then, hyperbaric oxygen therapy should be tried. But it still needs to be used as an adjunct to standard foot care."

While continuing with standard wound therapy, each patient will be assigned to either the HBO group or the control group. People in the HBO group will sit in the HBO chamber, and the atmospheric pressure will be increased to what a diver would feel

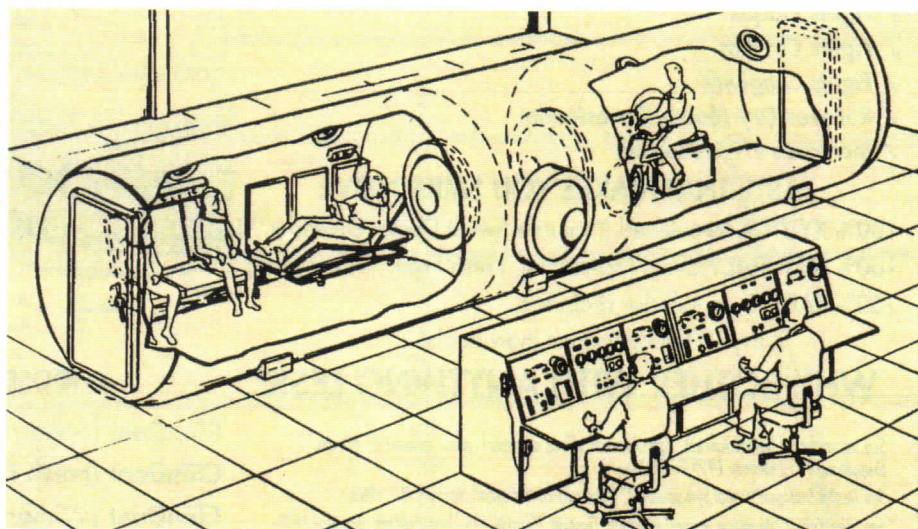


ILLUSTRATION BY COURTESY OF PRESBYTERIAN HOSPITAL OF DALLAS

**Atmospheric pressure in this \$2 million chamber can go from the equivalent of 200 feet below sea level to the equivalent of an altitude of 100,000 feet.**



45 feet below sea level. (Stone sometimes refers to treatments as "dives.") They will feel pressure changes in their ears, as they would in a plane that's landing. They'll breathe 100 percent oxygen for two 45-minute sessions, with a 5-minute air break in between. They'll use masks or hoods to breathe pure oxygen.

People in the control group will also go into the chamber, and the chamber will be pressurized. In contrast to the HBO group, the control group will breathe the amount of oxygen they'd get in regular air. They'll get 15 minutes of 100 percent oxygen before returning to air pressure at sea level, which will reduce their risk of

decompression sickness to near zero.

While in the chamber, people can read, listen to the radio, or watch videos. The chamber is monitored on the outside by people using advanced controls and computer systems, and there's always a health care professional in the chamber. "I go in every few weeks," says Stone. "It's quiet. I don't bring my beeper. I get to talk to the patients, or just read."

All patients will have a maximum of 40 treatments during a period of about eight weeks while still getting standard wound therapy. Stone will assess the wound sites every week. If after 40 treatments a patient's wound does not show significant healing,

Stone will see whether the patient was in the control or the HBO group. If the patient was in the control group, the patient will be taken out of the study and offered HBO treatments.

Stone will follow up with patients for one year after the therapy. He will look at how many patients needed amputations, the number of wounds that healed completely, and how long it took the wounds to heal. Stone will also examine the records to see if certain types of people or wounds did especially well with HBO therapy.

If Stone can prove that HBO therapy works, there may be a new standard of care for people with diabetic foot wounds. —STACEY N. WAGES

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