

wound healing perspectives®

A CLINICAL PATHWAY TO SUCCESS

VOLUME 2 NO. 2 WINTER 2005

→ OSTEORADIONECROSIS

A PUBLICATION OF NATIONAL HEALING CORPORATION

Caring for wounds we can't see

Unlike more typical chronic wounds, radiation injuries are usually not as visible nor do they require the same type of topical management. Some of the most problematic wounds are those which occur in previously irradiated tissue. A simple biopsy or tooth extraction can create a wounding incident that puts an extreme metabolic and vascular demand on compromised tissue. Without proper treatment, this can have devastating impact. *The wounds that occur in the irradiated tissue constitute one of the clearest indications for hyperbaric oxygen treatment to prevent and manage problem wounds.*

Radiation creates injury to soft tissue and bone which then leads to *hypovascular, hypocellular, and hypoxic tissue*. This causes the tissue to breakdown and non-healing wounds. As time passes after radiation treatment the tissue integrity worsens, creating a pathology that is more at risk for osteoradionecrosis five years after radiation versus one year. These patients require intense comprehensive wound management. Intractable pain, nutritional deficiencies, pathologic fractures, and oral and cutaneous fistulas are just some of the complications they frequently face. The multidisciplinary approach to wound management that we provide in our centers is of extreme benefit to this unique group of patients.



Katy Rowland
SVP Clinical Services
National Healing Corporation

Causes and incidence of radiation injuries

The National Cancer Institute reports that the incidence of cancer in the United States stabilized between 1995 and 2002, but still about a million people get cancer each year, according to the American Cancer Society (ACS). The ACS goes on to estimate that millions more people are living with the effects of cancer or have been cured.

The ACS lists radiation therapy as one of the most common cancer treatments and states that it is used in more than half of all cancer cases, such as head and neck cancers, prostate cancer, and breast cancer. There are two types of radiation injury: acute dermatitis frequently sets in early and is treated conservatively with balms and ointments, but serious radiation complications can occur in up to 5% of those patients receiving therapeutic radiation requiring more advanced care. (Feldmeier, 2002)

Following initial tumor



THE NATIONAL CANCER INSTITUTE REPORTS THAT THE INCIDENCE OF CANCER IN THE UNITED STATES STABILIZED BETWEEN 1995 AND 2002.

radiation, blood vessels degenerate. This progressive process continues throughout the patient's life and blood supply continues to diminish.

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Hyperbaric oxygen chambers



The Sechrist 3200 monoplace hyperbaric oxygen chamber is the most common HBO chamber used in many National Healing Wound Centers.

This HBO chamber is designed for use in clinical environments requiring critical care support. The chamber has specially designed ports that allow for respiratory support, IV lines, electrical monitoring, transcutaneous oxygen monitoring, patient air-breaks, and non-invasive blood pressure monitoring.

The Model 3200 chamber was designed with safety in mind. The chamber and stretcher are grounded. A patient grounding strap is provided. An emergency vent system can

(continued on page 3)

Osteoradionecrosis

Osteoradionecrosis (ORN) is simply defined as “exposed bone in a field of radiation that has failed to heal either spontaneously or with treatment for at least six months.” (Johnson, et al, 1994) Both the soft tissue and underlying bone are involved. The soft tissue wound is an “ulcerative loss of overlying mucosa or skin that exposes the bone beneath.” The bone is not viable and may or may not show osteolysis. ORN is most commonly found in the mouth.

Following irradiation, the tissue becomes hypovascular, hypocellular, and hypoxic. The tissue then begins to break down either spontaneously or as a result of trauma. Ultimately, the area becomes a non-healing wound, where the metabolic demands surpass the body’s ability to provide for them.

Microorganisms begin to impact the surface of the exposed bone in the mouth. These factors combine to make ORN a problem of wound healing rather than of infection – closely related to a diabetic ulcer

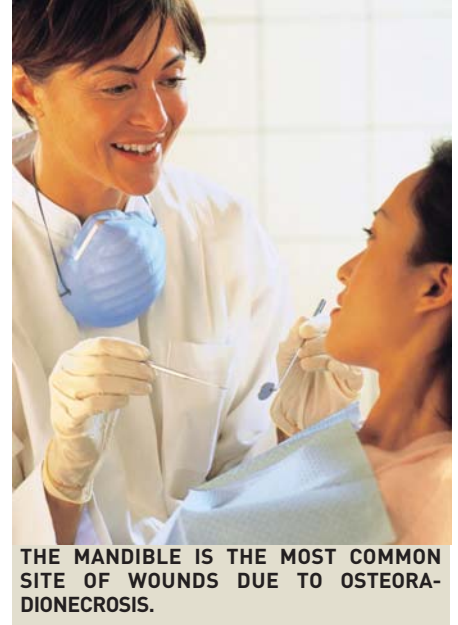
of the lower extremities. (Marx, 1983)

The mandible is the most common site of these wounds primarily because the bone is poorly vascularized due to its density, but also because teeth are present. Since radiation is successfully used to treat many types of head and neck cancer caused by tobacco use, the area is also a common site of irradiation.

Risk factors for ORN include the following:

- inadequate post-dental extraction healing time before radiation therapy;
- traumatic extractions within irradiated bone;
- alcohol and tobacco abuse; and
- nutritional factors. (Stofka, 1993)

ORN can occur at any time after a patient receives radiation therapy to the head or neck. The risk increases with time because the degenerative process is ongoing.



THE MANDIBLE IS THE MOST COMMON SITE OF WOUNDS DUE TO OSTEORADIONECROSIS.

Complications that result from ORN include intractable pain, trismus, nutritional deficiencies due to the inability to ingest food, pathologic fractures, oral and cutaneous fistulas, and the loss of large areas of soft tissue and bone. Drug dependency is also a frequent challenge for these patients. Patients suffer the psychological stigma of severe facial deformities and having a non-healing wound. They also often lose time from work and family. (Johnson, et al, 1994) ■

ULTIMATELY, THE AREA BECOMES A NON-HEALING WOUND, WHERE THE METABOLIC DEMANDS SURPASS THE BODY’S ABILITY TO PROVIDE FOR THEM.



Given the pain, debilitation, and expense involved in treating ORN, any prevention opportunity should be seized. Patients considering radiation therapy of the head or neck should consider a pre-radiation dental consultation to optimize

Preventing Osteoradionecrosis

oral health and prevent dental work after the radiation treatment.

Prophylactic HBO is necessary when post-irradiation dental care involving trauma to the mandible is needed. **Marx's suggested protocol for prevention therapy is 20 pre-surgical HBO treatments followed by 10 post-surgical treatments.**

Feldmeier's systematic review (2002) includes

three published reports (two case series and one randomized controlled trial) that suggest HBO prevents mandibular osteoradionecrosis (ORN). There was a collective incidence of ORN in 4.5% of patients who received HBO as part of their therapy. ORN occurred in 29.9% of patients in the single control group that Marx tracked. ■

HBO HAS NOT BEEN FOUND TO INCREASE THE RISK OF CANCER RECURRENCE OR PROGRESSION FOR PATIENTS WHO ARE BEING TREATED FOR RADIATION INJURIES. (FELDMEIER, ET AL, 1994)

Causes and incidence of radiation injuries *(continued from page 1)*

In the event of even minor trauma, healing is impaired due to this is-chemic change in tissue. These problems are often discovered long after the radiation therapy is complete – sometimes several years later. The most common sites of radiation injuries are the head, neck, genitourinary area, and bowel. Unresolved serious delayed radiation injuries cause death under certain circumstances,

and certainly decrease quality of life in most instances. (Feldmeier, 2002)

The methodology of treating radiation injuries has changed dramatically over time. It was once believed that irradiated tissue will gradually revascularize and improve with time. This caused physicians to delay reconstruction and tooth extractions to take advantage of these

changes. It is now known that delaying treatment longer than six months will lead to serious complications such as soft tissue and bone necrosis due to decreased vascularity, less tissue perfusion, and more fibrosis. Decreased tissue perfusion can lead to a greater risk for healing complications. ■

Hyperbaric oxygen chambers

(continued from page 2)

depressurize the chamber in 60 seconds or less. Each chamber has a patient-activated call system in addition to continuous audio monitoring via the two-way communication system.

All Wound Healing Center clinical staff are specially trained at the National Healing Institute's Wound Care and Hyperbaric Oxygen course in the theory and practice of using HBO chambers. Contact your Wound Healing Center today to arrange a tour of the center. ■

The Marx Protocol for ORN therapy

Evaluating the quality of irradiated bone



X-ray and computed tomography (CT) are useful to detect localized osteolytic processes. MRI is better to view inflammation in soft tissues and tumor infiltration in bone. Selective angiography of the craniofacial arteries can give information about local vascularity. (Granström, 1992) ■

*Robert E. Marx, DDS, is chief of oral and maxillo-facial surgery at the University of Miami School of Medicine. He developed the **Marx Protocol**, the standard of care to prevent and treat ORN, in 1983. His current clinical interests are benign and malignant tumor surgery and reconstructive surgery. His current research interests are cancer research, wound healing, and growth factors.*

- **Stage I:** all patients with ORN receive 30 HBO treatments at 2.4 ATA for 90 minutes each. Wound care is maintained and antibiotics are usually discontinued. The wound is re-evaluated after 30 treatments. If improvement is shown (amount of exposed bone decreases, re-sorption, spontaneous sequestration, or softening of exposed bone), the patient receives 10 more treatments. If there is no response, the patient proceeds to stage II as a non-responder.
- **Stage II:** Local surgical debridement is completed to identify patients with superficial bone involvement who don't need jaw resection. All necrotic bone is removed to a base of bleeding bone with minimal periosteal

reflection. If healing progresses well, 10 more treatments are completed. If the wound breaks down, the patient is advanced to stage III as a non-responder.

with ORN. Combining all of the reported cases provides a total of 371 cases of mandibular ORN.

Improvement was reported in 83.6% or 310 cases.

HBO TREATED TISSUES CAN OFTEN GO ON TO HEAL SPONTANEOUSLY. (KINDWALL, 1992)

- **Stage III:** The patient undergoes a transoral partial jaw resection. The margins of the resection are determined by the presence of bleeding bone at the time of surgery. Any reconstruction that is needed to repair tissue deficiencies or fistulas should be performed at this time. HBO is immediately continued for 10 postoperative treatments. Prosthetic rehabilitation can begin 3 months after the reconstruction is complete. Soft tissue surgery can be performed one month after fixation removal. *(Patients with pathologic fractures, fistulas, or radiographic evidence of osteolysis to the inferior border begin at stage III.)*

Feldmeier points out that "although resolution would be a better endpoint, hyperbaric oxygen was not combined with aggressive extirpation of necrotic bone or with surgical reconstruction of bony discontinuity, especially in the earlier reports."

Studies carried out at the hyperbaric unit at the US Air Force School of Aerospace Medicine demonstrate that the pO₂ in the radiated area will rise to approximately 80% of normal after 18 to 30 treatments. It plateaus at this level, but this is sufficient to make surgery and even grafting in the radiated area possible. (Kindwall, 1992) ■

A systematic review of the literature by Feldmeier (2002) found 13 reports on the use of HBO in treating patients

HBO Therapy:

Does it promote growth or recurrence of malignancy?

For some time, practitioners of hyperbaric medicine have had concerns that HBO therapy could lead to proliferation of malignant cells and angiogenesis in a malignant tumor in much the same way it works on nonhealing wounds. Since cellular and vascular proliferation are promoted by HBO in a healing wound, one might assume that it would have the same effect in a tumor. This line of reasoning is indeed understandable at first glance, but it fails to recognize important differences between the complex physiology of

strongly suggest no more than a neutral effect of HBO on tumor growth. In fact some studies suggest a negative impact of HBO on malignant progression or formation. For angiogenesis, similarities in wound healing and cancer are striking but significant differences were found including the relative importance of angiogenic factors and the process of cessation of angiogenesis. Tumors that grow in hypoxic environments are more prone to metastases and more lethal to the patient. They are also more likely to mutate toward resistant genotypes.

THE PHYSIOLOGY OF HEALING IS DIFFERENT FROM THAT OF MALIGNANCY. (FELDMEIER, 2003)

wound healing and the equally complex and unique pathophysiology of malignant transformation, tumor growth, and metastases.

A recent study by Feldmeier, et al, (2003) reviews clinical reports, animal studies, and cell cultures including existing mechanisms whereby HBO would have carcinogenic effects. The process of angiogenesis in wound healing and in cancer growth were compared and contrasted. ***In vitro, in vivo, and clinical studies***

The study also included 15 clinical reports which analyze the effects of hyperbaric oxygen on recurrence or metastases in patients exposed to HBO. The 15 studies involved a total of 72 patients with recurrent or progressive cancer (including those in the control group). Destruction of the primary tumor was consistently improved in the hyperbaric group compared to the air controls. Often, this improvement in local control did not translate into a survival advantage

for the patients.

Feldmeier et al point out that while 3 clinical publications entailing 72 patients suggest a possible cancer or metastases promoting effect, large numbers of mostly controlled studies including over 3,000 patients enrolled in trials designed to investigate hyperbaric oxygen as a radiosensitizer demonstrate either a neutral or cancer inhibitory effect.

According to the authors, the force of the clinical experience fails to support concerns that HBO enhances malignant growth. Patients for whom HBO treatments are likely to be useful for the treatment of radiation injuries should not have this therapy denied to them because of concerns that HBO might cause a higher likelihood of tumor recurrence or metastases. ■

Treating osteoradionecrosis

Extraction of teeth in the previously radiated jaw accounts for 89% of all trauma-induced cases of mandibular radionecrosis. Today's typical course of treatment for ORN is based on the concept that Marx presented in 1983. This treatment is designed to support the injured living tissue and surgically remove the non-living tissue. Wound repair can then proceed to resolve the disease. (Johnson, et al, 1994) When teeth must be extracted due to radiation caries, subsequent mandibular radionecrosis can be avoided in 92% of cases by following the ***Marx Protocol*** to add HBO to the treatment plan. The patient's response or lack thereof to HBO is the main indicator for surgery. When the physician can differentiate the dead bone from merely compromised bone, the dead bone can be surgically resected. One study completed in the 1970s that didn't use HBO or surgery found that 92% of patients (41/45) were non-responders. ■

Questions and answers with

Indications for HBO



Medicare has approved reimbursement for HBO therapy when the following diagnoses are made:

- Actinomycosis
- Acute carbon monoxide intoxication
- Acute peripheral arterial insufficiency
- Acute traumatic peripheral ischemia
- Chronic refractory osteomyelitis
- Crush injuries and suture (reattachments) of severed limbs
- Cyanide poisoning
- Decompression illness
- Diabetic wounds of the lower extremities
- Gas embolism
- Gas gangrene
- Osteoradionecrosis
- Preparation and preservation of compromised skin grafts with prior history of graft failure
- Progressive necrotizing infections
- Soft tissue radiation injury ■

Robert Bartlett, MD, FACEP, CIME, UHM, is the Corporate Medical Director for Hyperbaric Oxygen Therapy at National Healing Corporation.

He is board-certified in both hyperbaric and emergency medicine. He is also a Certified Independent Medical Examiner and a Diving Medical Officer with the National Oceanic and Atmospheric Administration. Dr. Bartlett has over 15 years of wound care experience and considerable management experience through the creation and direction of several health care companies and one health care foundation.

Dr. Bartlett is a member of the executive committee of the Undersea and Hyperbaric Medical Society. He serves on the executive committee of the American College of Hyperbaric Medicine and is the lead author and editor-in-chief of the Hyperbaric Medicine Board Exam for the organization.

Dr. Bartlett is an associate professor of surgery at the Medical University of South Carolina and an associate professor of pharmacy at the University of South Carolina. He is a magna cum laude graduate of the University of South Alabama School of Medicine. His research

interests include oxygen dynamics and knowledge engineering. Dr. Bartlett is based in Columbia, South Carolina. He can be reached at rbartlett@nationalhealing.com.

Q: Why should we use HBO on radiation patients?

A: There are no alternative therapies that correct the problems these patients have. Narcotics and antidepressants have been used to control the pain associated with these injuries with limited success and significant side effects, including drug addiction. HBO is the only therapy that reverses the effects of radiation on healthy tissue.

Q: What is the problem with radiation injury?

A: Radiation is designed to kill tumor cells; however, the secondary effect is an injury to blood vessels which leaves the tissue hypoxic with a limited ability to recover from daily trauma or surgical procedures.

Q: How does HBO help?

A: HBO has been demonstrated in all tissues to date to induce angiogenesis and restore capillary density and oxygen values to 80% of normal.

Q: What groups of radiation patients should we consider HBO for?

A: The classic indication for HBO has been tooth extraction for patients with prior radiation therapy. Since that time, treatment guidelines have been expanded to include soft tissue injury to pelvic organs as the second most common area. Specifically, these are patients who have received radiation to treat GYN, prostate, and colon cancers. The most common presentations are hematuria, bladder spasms, proctalgia, and rectal bleeding.

Q: What are the common complications of operating in irradiated tissue?

A: Dehiscence, infection, and delayed healing.

Q: How would HBO be used to reduce surgical complications?

A: Patients receive a pre-operative prep of one month of therapy during which time the angiogenesis effect occurs. Following surgery the patient receives one to two weeks of treatment because the tissue will always have some residual disease.

h Dr. Bartlett



Q: Are there any drug interactions with HBO?

A: Patients who are receiving chemotherapy must have a thorough review by a hyperbaric physician as there are some drugs that may have adverse effects. Three drugs to specifically watch for are cisplatin, bleomycin, and adriamycin.

Q: Do you need a biopsy to substantiate the diagnosis of radiation injury?

A: A biopsy is often desirable; however, it may

not always be practical. It is important that the differential diagnosis has excluded other possible causes prior to referral.

Q: Is there a relationship between HBO and tumor growth?

A: No.

Q: Is there a relationship between HBO and tumor recurrence?

A: No, however, it should be kept in mind that all cancer patients have a higher baseline risk of recurrence with the

primary tumor as well as an increased risk for secondary cancer types.

Q: Can HBO be used for pain management in these radiation patients?

A: Yes, if there is reasonable confidence that pain is due to radiation injury and not recurring cancer or other causes. ■

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working with hyperbaric oxygen

Hyperbaric physicians take no chances with patients in these circumstances:

- Untreated pneumothorax
- History of spontaneous pneumothorax
- Recent use of cisplatin or adriamycin for chemotherapy
- Any use of bleomycin for chemotherapy
- Current use of disulfiram (Antabuse) if your patient needs >1 treatment

Common side effects from HBO therapy are:

- Idiosyncratic cataract growth
- Transient deterioration of far vision as near vision improves. Effect is commonly noticed after 30 treatments. Vision generally returns to baseline after 2-3 months.
- Paresthesia, tingling of the fingertips, can be noticed after 30 treatments. Effect disappears about one month after completing treatment.

Inherent risks are barotraumas, transient visual changes, and oxygen seizures. The Wound Healing Center has policies and procedures in place to limit these risks while providing the highest quality care. ■

QUESTIONS OR COMMENTS?

Contact Heather Cicero at
1.888.332.0202 or
hcicero@nationalhealing.com.

Wound Healing Perspectives

STAFF

James E. Patrick, CEO
Laura McMullen, Editor
Erica Cheeks, Writer
Heather Cicero, Layout Design
Lorraine Alt, Proofreader

CLINICAL ADVISORS

Katy Rowland, RN, MBA
SVP of Clinical Services
Craig L. Broussard, PhD, RN, CSN
Regional Director, Clinical Services
Trisha Carlson, MSN, MBA, RN, CWCN
Regional Director, Clinical Services
Robert Bartlett, MD, FACEP, CIME, UHM
Corporate Medical Director, HBO

IMAGES

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HBO is a cost-effective treatment for ORN

Marx began to study the cost-effectiveness of combining HBO and surgery known as the **Marx Protocol** in treating ORN in 1984. This table shows that cost analysis in 1991 dollars. *The combination of HBO and surgery has a 100% resolution rate and holds costs to less than one-quarter that of surgery alone and half that of HBO alone.*

TREATMENT	NUMBER OF PATIENTS	AVERAGE ONE YEAR COSTS	AVERAGE TOTAL COSTS	RESOLUTION RATE
NON-HBO	116	\$47,000	\$162,000	10%
HBO WITHOUT SURGERY	88	\$40,000	\$83,000	18%
MARX-UM PROTOCOL	492	\$49,000	\$49,000	100%
MARX-UM PROTOCOL USED IN PRIVATE PRACTICE	112	\$45,000	\$45,000	100%

UM = UNIVERSITY OF MIAMI

COST ANALYSIS OF 300 CASES OF OSTEORADIONECROSIS IN US DOLLARS (JANUARY 1, 1991), JOHNSON, ET AL, 1994. UPDATED APRIL 2004 IN A PRESENTATION IN BOYNTON BEACH, FL.

SYMPTOMS OF RADIATION INJURIES

Osteoradionecrosis: Dental caries requiring extraction, non-healing wound in oral cavity (usually from dental extractions), non-healing wound under jaw.

Radiation cystitis: Urinary frequency, urgency, nocturia, gross hematuria, pain.

Radiation proctitis: Diarrhea, rectal bleeding, tenesmus, abdominal pain, constipation, pain.

