Disclosures:

National PI of Multi-Center DFU Trial, MiMedx.
Classification of Osteomyelitis:

- Acute osteomyelitis
  - Is a suppurative infection of bone or bone marrow
  - Typically accompanied by
    - Surrounding edema
    - Vascular congestion
    - Small vessel thrombosis

Refractory Osteomyelitis

Classification of Osteomyelitis:

- **Chronic Refractory Osteomyelitis**
  - Results when a nidus of infected dead bone remains accompanied by a surrounding ischemic soft tissue envelope and a chronic clinical course
  - Acute osteomyelitis in a compromised host or location
Classification of Osteomyelitis – Orthopedics View:

- Cierny-Mader Staging System
  - Anatomic Type
    - Stage 1: Medullary osteomyelitis
    - Stage 2: Superficial osteomyelitis
    - Stage 3: Localized osteomyelitis
    - Stage 4: Diffuse osteomyelitis

ABSTRACT

Introduction: Open fractures with significant soft tissue injury are associated with high rates of complications, such as non-union, infection, chronic pain and disability. Complications often require further inpatient care, and in many cases, multiple operations and prolonged rehabilitation. Use of hyperbaric oxygen therapy as an adjunct to standard orthopaedic trauma care has the potential to reduce the complications of musculoskeletal injury and thus improve outcomes. Two previous randomised trials have suggested some

Strengths and limitations of this study

- A prospective, randomised study with blinded outcome scoring.
- Open-label design with standard trauma care as the control.
- Multiple centres involved from a variety of countries.
- Very slow recruitment.
- Target enrolment reduced from initial plans.
Hyperbaric Oxygen in Lower Limb Trauma (HOLLTT):

- International, multicenter, randomized, open-label, clinical trial

- Inclusion criteria:
  - Suffered trauma with an acute open fracture of the tibia
  - Severe soft tissue injury (Gustilo grade 3)
  - High risk of injury-related complications
  - Located at trauma hospital with hyperbaric facilities.

- Within 48 h of injury starting 12 sessions of hyperbaric oxygen

- Primary outcome measure is the incidence of acute complications of the open fracture wound at 14 days.

- Short-term outcome measures include amputation, need for fasciotomy, time until wound closure, breakdown of closed wounds, time until definitive orthopedic fixation, number of operative procedures.
Classification of Soft Tissue Injuries (derived from Gustillo):

- **Type I**
  - wound < 1 cm

- **Type II**
  - 1-10cm

- **Type III A**
  - > 10 cm, high energy
  - adequate tissue for coverage
  - includes segmental / comminuted fractures even if wound <10cm
  - farm injuries are automatically Gustillo III

- **Type IIIB**
  - extensive periosteal stripping and requires free soft tissue transfer
  - contamination

- **Type IIIC**
  - vascular injury requiring vascular repair
  - contamination
Hyperbaric Oxygen in Lower Limb Trauma (HOLLT):

- Pending Publication

- High complication rates:
  - Non-union
  - Post-operative Infection (> 30%)
  - Amputations
  - Chronic pain

- Preliminary data may suggest a reduction in amputations in those receiving HBO₂ therapy within 48 hours of injury.
Hyperbaric Oxygen in Management of Crush Injuries:

- Randomized double-blind placebo-controlled trial
- 36 patients with an acute open fracture of the tibia with severe soft tissue injury (Gustilo grade 3) and high risk of injury-related complications
  - Treated within 24 hours after surgery
  - 100% O₂ at 2.5 ATA for 90 min BID x 6 days (HBO₂ group n=18)
  - 21% O₂ at 1.1 ATA for 90 min BID x 6 days (Placebo group n=18)
Hyperbaric Oxygen in Management of Crush Injuries:

- Complete healing observed (p < 0.01):
  - 17 out of 18 in the HBO$_2$ group
  - 10 out of 18 in the placebo group

- New surgical procedure performed (p<0.05):
  - 1 out of 18 in the HBO$_2$ group
  - 6 out of 18 in the placebo group
Classification of Osteomyelitis:

- Chronic Refractory Osteomyelitis
- CMS

Chronic osteomyelitis is classified as *refractory* when it has failed to respond to a combination of definitive surgical debridement and a period of 4 weeks of appropriate antibiotic therapy.
Osteomyelitis Treatment Protocol:

“Appropriate therapy” includes:

- Aggressive Antibiotics
  - Typically 42 days (6 weeks)
  - Antibiotics should be culture-directed
  - Oral vs. IV (PICC) for outpatient management

- Aggressive Surgical Debridement
  - Remove infected/dead bone, as well as involved hardware if possible

- Educate on dietary needs
  - e.g., malnutrition (protein), vitamin D, Vitamin C, Vitamin A, Zinc

- Address comorbidities
  - e.g., diabetes, venous insufficiency, smoking cessation, renal/liver failure

- Vascular evaluation/intervention if indicated
Osteomyelitis Treatment Protocol:

- HBO$_2$ as adjunctive therapy
  - Treat at 2.0 to 2.4 ATA once or twice daily
  - Oxygen administered 90 to 120 minutes per session
  - Treatment range: 30 to 40
  - May require up to 60 treatments “within a 12 month period” to achieve sustained therapeutic benefit
Osteomyelitis Treatment Protocol: CMS Proposed Changes

- HBO₂ therapy restrictions:
  - DFU Wagner Grade 3 or greater will be allowed no more than 40 treatments (90-120 minutes daily) without documentation of improvement. Maximum of 60 treatments/12 months.
    - Wound volume or surface area is expected to measurably diminish over 30 days of wound care with adjunctive HBO₂ therapy.
  - Prior Authorization trial between 3 regions recently revealed racial bias:
    - Michigan and Illinois increased their denial rates by about 15%, but New Jersey increased by 50% under the same trial conditions, and it was in a distinctly African American population.
HBO₂ therapy is not considered medically necessary for:

- Treatment of osteomyelitis of small, solid exposed bones of the forefoot and fingers
  - Metatarsal head
  - Phalanges
  - Sesamoid

- Effectively treated with debridement and receive minimal benefit from HBO₂ therapy due to limited perfusion.

Both these studies have significant shortcomings:

- Inclusion of Wagner grade 2 DFUs in 46 out of 103 (45%) subjects available for end point adjudication.¹

- Margolis cohort study² included Wagner 2 DFUs in 54.3% of the HBO₂ group that also showed no benefit of HBO₂.

  - Including a substantial cohort of patients with Wagner grade 2 DFUs that do not even meet the indications set by both the Undersea & Hyperbaric Medical Society or CMS unavoidably biases the study’s conclusion toward the absence of benefit from HBO₂ therapy.

---


Other significant shortcomings:

- Study’s use of photographic adjudication whether a limb “met the criteria for amputation” rather than the use of actual amputation rates as an outcome measure.¹
  - The fact that there may be patients who “met the criteria for major amputation” but who went on to heal undermines the conclusions of this study.


Other significant shortcomings:

- Dataset also did not distinguish “major” amputations (e.g., below or above the knee) from “minor” amputations (e.g., toe or partial foot).
  - Patients whose ambulation was preserved with a partial foot or toe amputation were still considered hyperbaric failures.


A clinical practice guideline for the use of hyperbaric oxygen therapy in the treatment of diabetic foot ulcers

CPG Authors: Enoch T. Huang, Jaleh Mansouri, M. Hassan Murad, Warren S. Joseph, Michael B. Strauss, William Tettelbach, Eugene R. Worth

UHMS CPG Oversight Committee: Enoch T. Huang, John Feldmeier, Ken LeDez, Phi-Nga Jeannie Le, Jaleh Mansouri, Richard Moon, M. Hassan Murad

CORRESPONDING AUTHOR: Dr. Enoch T. Huang — enoch.huang@mac.com

ABSTRACT

BACKGROUND: The role of hyperbaric oxygen (HBO₂) for the treatment of diabetic foot ulcers (DFUs) has been examined in the medical literature for decades. There are more systematic reviews of the HBO₂/DFU literature than there have been randomized controlled trials (RCTs), but none of these reviews has resulted in a clinical practice guideline (CPG) that clinicians, patients and policy-makers can use to guide decision-making in everyday practice.

METHODS: The Undersea and Hyperbaric Medical Society (UHMS), following the methodology of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) Working Group, undertook this systematic review of the HBO₂ literature in order to rate the quality of evidence and generate practice recommendations for the treatment of DFUs. We selected four clinical questions for review regarding the role of HBO₂ in the treatment of DFUs and analyzed the literature using patient populations based on Wagner wound classification and age of the wound (i.e., acute post-operative wound vs. non-healing wound of 30 or more days). Major amputation and incomplete healing were selected as critical outcomes of interest.

RESULTS: This analysis showed that HBO₂ is beneficial in preventing amputation and promoting complete healing in patients with Wagner Grade 3 or greater DFUs who have just undergone surgical debridement of the foot as well as in patients with Wagner Grade 3 or greater DFUs that have shown no significant improvement after 30 or more days of treatment. In patients with Wagner Grade 2 or lower DFUs, there was inadequate evidence to justify the use of HBO₂ as an adjunctive treatment.

CONCLUSIONS: Clinicians, patients, and policy-makers should engage in shared decision-making and consider HBO₂ as an adjunctive treatment of DFUs that fit the criteria outlined in this guideline. The current body of evidence provides a moderate level of evidence supporting the use of HBO₂ for DFUs. Future research should be directed at improving methods for patient selection, testing various treatment protocols and improving our confidence in the existing estimates.
Exhaustive HBO₂ therapy systematic review to develop the UHMS clinical practice guidelines for the diabetic foot:

- Analyzing 9 RCTs

- > 20 observational studies

- Using GRADE criteria
Elements of GRADE

- Clear separation between quality of evidence and strength of recommendations
- Explicit evaluation of the importance of outcomes
- Explicit and comprehensive criteria for downgrading and upgrading the quality of evidence rating
- Transparent system of moving from evidence to recommendations
Elements of GRADE

- The GRADE approach specifically assesses:
  - Methodological flaws within the component studies
  - Consistency of results across different studies
  - Generalizability of research results to the wider patient base
  - How effective the treatments have been shown to be
Organizations that use GRADE


### Table 1. Features of wound grading systems

<table>
<thead>
<tr>
<th>Grading Classification</th>
<th>Grade Tier</th>
<th>Grading System</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Classic Wagner</strong></td>
<td><strong>Grade 0</strong></td>
<td>no open lesion, may have healed lesions</td>
</tr>
<tr>
<td>Grading System</td>
<td></td>
<td><strong>Grade 1</strong> superficial ulcer without penetration to deeper layers</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Grade 2</strong> deeper ulcer, reaching tendon, bone, or joint capsule</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Grade 3</strong> deeper tissues are involved, and there is abscess, osteomyelitis, or tendonitis</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Grade 4</strong> there is gangrene of some part of the toe, toes, and/or forefoot</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Grade 5</strong> gangrene involves the whole foot or enough of the foot that no local procedures are possible and BKA is indicated</td>
</tr>
<tr>
<td><strong>University of Texas</strong></td>
<td><strong>Stage A</strong> no infection</td>
<td></td>
</tr>
<tr>
<td>Health Science</td>
<td></td>
<td><strong>Stage B</strong> infection</td>
</tr>
<tr>
<td>Center at San Antonio</td>
<td></td>
<td><strong>Stage C</strong> ischemia</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Stage D</strong> infection and ischemia</td>
</tr>
<tr>
<td></td>
<td><strong>Grade 0</strong> epithelialized wound</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Grade 1</strong> superficial wound</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Grade 2</strong> wound penetrating tendon or capsule</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Grade 3</strong> wound penetrating bone or joint</td>
<td></td>
</tr>
<tr>
<td><strong>IDSA (Infectious</strong></td>
<td><strong>Grade 1</strong> infection with at least two of following criteria: localized swelling, erythema, pain, warmth, purulent discharge; PEDIS 1; IDSA infection severity: uninfected</td>
<td></td>
</tr>
<tr>
<td>Disease Society</td>
<td></td>
<td><strong>Grade 2</strong> local infection involving only skin and subcutaneous tissue with erythema &gt;0.5 cm and &lt; 2 cm around ulcer; PEDIS 2; IDSA infection severity: mild</td>
</tr>
<tr>
<td>of America**</td>
<td></td>
<td><strong>Grade 3</strong> local infection with erythema &gt; 2 cm or involving structures deeper to skin and subcutaneous tissue with no signs of systemic inflammation; PEDIS 3; IDSA infection severity: moderate</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Grade 4</strong> local infection with systemic inflammation response signs (SIRS) with two or more of the following criteria: temp &gt; 38 degrees or &lt; 36 degrees, heart rate &gt; 90 beats/min, respiratory rate &gt; 20 breaths/min or PaCO2 &lt; 32 mm Hg, white blood count (WBC) &gt; 12,000 or &lt; 4000 cells/microliter or &gt; 10% immature band forms; PEDIS 4; IDSA infection severity: severe</td>
</tr>
<tr>
<td>Grading Classification</td>
<td>Grade Tier</td>
<td>Grading System</td>
</tr>
<tr>
<td>------------------------</td>
<td>------------</td>
<td>----------------</td>
</tr>
<tr>
<td>Strauss Wound Score</td>
<td>Five assessments, each graded 0 – 2 points (half points used for mixed or intermediate findings)</td>
<td>Appearance (wound base)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2 points for red</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 point for white (biofilm-fibrous membrane) yellow (exudate)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0 points for black (necrotic, wet gangrene or fluctuant eschar)</td>
</tr>
<tr>
<td>Healthy wound</td>
<td>7.5 – 10 points</td>
<td>Size</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2 points for less than the surface area of patient’s thumbprint</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 point for thumbprint to fist-size</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0 points for larger than fist size</td>
</tr>
<tr>
<td>Problem wound</td>
<td>3.5 – 7 points</td>
<td>Depth (including maximum depth of probe)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2 points for skin coverage and 1.5 points for subcutaneous tissue</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 point for muscle and/or tendon</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0 points for bone and/or joint</td>
</tr>
<tr>
<td>Pustule wound</td>
<td>0 – 3 points</td>
<td>Biofilm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2 points for colonized</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 point for cellulitis, maceration, and/or deep infection (bone, joint, bursa, or cicatrix)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0 points for septic (unstable blood sugars, leukocytosis, positive blood cultures, fever, chills)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Perfusion (use secondary findings of color, temperature &amp; capillary refill if exam obscured by edema, scar, hidebound skin and/or previous surgery)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2 points for palpable pulses</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 point for biphasic or triphasic dopplerable pulses (cool, pale or dusky, capillary refill 2-6 sec)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0 points for monophasic or imperceptible pulses (cold, black/cyanotic/purplish, capillary refill &gt; 5 sec)</td>
</tr>
<tr>
<td>Society for Vascular Surgery</td>
<td>4 grades for Each of Three Criteria of Wound, Ischemia and Foot Infection (WIFI) System</td>
<td>Wound</td>
</tr>
<tr>
<td></td>
<td>Grade 0: no ulcer or gangrene</td>
<td>Grade 1: shallow ulcer, no gangrene</td>
</tr>
<tr>
<td></td>
<td>Grade 2: deeper ulcer with exposed joint or tendon; gangrene limited to digits</td>
<td>Grade 2: deeper ulcer with exposed joint or tendon; gangrene limited to digits</td>
</tr>
<tr>
<td></td>
<td>Grade 3: deep ulcer involving forefoot, midfoot, heel; extensive gangrene involving forefoot, midfoot, or heel</td>
<td>Grade 3: deep ulcer involving forefoot, midfoot, heel; extensive gangrene involving forefoot, midfoot, or heel</td>
</tr>
<tr>
<td>Ischemia</td>
<td>Grade 0: ABI = 0.90; arterial systemic pressure &gt; 100 mm Hg; and/or TeiPO2 &gt; 60 mm Hg</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Grade 1: ABI 0.6-0.79; arterial systemic pressure 70–100 mm Hg; and/or TeiPO2 40–59 mm Hg</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Grade 2: ABI 0.4-0.59; arterial systemic pressure 50–70 mm Hg; and/or TeiPO2 30–39 mm Hg</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Grade 3: ABI &lt; 0.39; arterial systemic pressure 50–70 mm Hg; and/or TeiPO2 &lt; 30 mm Hg</td>
<td></td>
</tr>
<tr>
<td>Infection</td>
<td>Grade 0: uninfected; no signs or symptoms</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Grade 1: local infection: erythema &gt; 0.5 cm and ≤ 2 cm with pain, warmth, purulent discharge (mild)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Grade 2: local infection with &gt; 2 cm erythema; involves deeper structures (moderate)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Grade 3: local infection with signs of SIRS (refer to IDSA definition) (severe)</td>
<td></td>
</tr>
<tr>
<td>Study</td>
<td>Treatment groups HBO₂ protocol</td>
<td>Results</td>
</tr>
<tr>
<td>------------</td>
<td>--------------------------------</td>
<td>---------</td>
</tr>
<tr>
<td>Doctor 1992</td>
<td>15 HBO₂ vs. 15 SC, 3 atm abs x 45 min, 4 treatments over 2 weeks</td>
<td>Sub-groups: All, Wagner 2, Wagner 3, Wagner 4</td>
</tr>
<tr>
<td>Faglia 1995</td>
<td>36 HBO₂ vs. 34 SC, 2.2-2.5 atm abs x 90 min, 5-7 days/week</td>
<td>Sub-groups: All, Wagner 2, Wagner 3, Wagner 4</td>
</tr>
<tr>
<td>Abidía 2003</td>
<td>9 HBO₂ vs. 9 HBAir (sham), 2.4 atm abs daily x 90 min, 3 days/week vs. 9 sham</td>
<td>Sub-groups: All, Wagner 2, Wagner 3, Wagner 4</td>
</tr>
<tr>
<td>Özgür 2009</td>
<td>50 HBO₂ vs. 50 SC, 2.2-2.5 atm abs x 90 min, 5-7 days/week</td>
<td>Sub-groups: All, Wagner 2, Wagner 3, Wagner 4</td>
</tr>
<tr>
<td>Löndahl 2010</td>
<td>49 HBO₂ vs. 46 HBAir (sham), 2.2-2.5 atm abs x 90 min, 5-7 days/week</td>
<td>Sub-groups: All, Wagner 2, Wagner 3, Wagner 4</td>
</tr>
</tbody>
</table>

* Whenever possible, intention-to-treat analysis was used if denominator of each group could be extrapolated from the manuscript.
Diabetic Foot Infections: Treatment

Algorithm for the use of HBO\textsubscript{2} \textsuperscript{1}

Wagner Grading System: \textsuperscript{2}

A. Grade 1: Superficial Diabetic Ulcer

B. Grade 2: Ulcer with deep structures involved:
   - ligament, tendon, joint capsule or fascia
   - \textit{no active infection} (abscess or osteomyelitis)

C. Grade 3: Ulcer with deep structures involved:
   - ligament, tendon, joint capsule or fascia
   - \textit{+ evidence of infection} (abscess or osteomyelitis)

D. Grade 4: Gangrene to portion of forefoot

E. Grade 5: Extensive gangrene of foot

---

Osteomyelitis

Infected bone is hypoxic*

- **Normal Oxygen Tension** *(21% O₂ at sea level)*
  - Healthy Bone = 45 mmHg
  - Infected Bone = 21 mmHg

- **Hyperbaric Oxygen Tension** *(100% O₂ at 2 ATA)*
  - Healthy Bone = 321 mmHg
  - Infected Bone = 104 mmHg

* Rabbit animal model
HBO₂ & Antibiotics with Osteomyelitis in Rats

Mendel et al. Undersea Hyperb Med 26:169, 1999
Benefits of HBO

- Tissue oxygen tension restored to > 30 mmHg
  - required by Neutrophils to destroy bacteria by oxidative killing mechanisms\(^{(1,2)}\)
- Direct suppressive effect on anaerobic pathogens \(^{(3,4)}\)
- Augments transport of certain antibiotics across bacterial cell walls
  - active transport of antibiotics (e.g. gentamicin, tobramycin, amikacin) across bacterial cell walls does not occur if tissue oxygen tensions are below 20 to 30 mmHg\(^{(5)}\)
- Enhances osteogenesis \(^{(6)}\)
- Reduces tissue edema \(^{(7)}\)
- Promotes capillary angiogenesis \(^{(8)}\)
- Prevents polymorphonuclear leukocytes from adhering to damaged blood vessel linings
  - decreases the degree of inflammation which may accompany the surgical treatment of refractory osteomyelitis
- Can reduce treatment costs of complicated refractory osteomyelitis by approximately 5x \(^{(9)}\)
Benefits of HBO₂: References

The management of diabetic foot: A clinical practice guideline by the Society for Vascular Surgery in collaboration with the American Podiatric Medical Association and the Society for Vascular Medicine

Anil Hingorani, MD, a Glenn M. LaMuraglia, MD, b Peter Henke, MD, c Mark H. Meissner, MD, c Lorraine Loretz, DPM, MSN, NP, c Kathya M. Zinszer, DPM, MPH, FAPWCA, c Vickie R. Driver, DPM, MS, FACFAS, c Robert Frykberg, DPM, MPH, MAPWCA, c Teresa L. Carman, MD, FSVM, c William Marston, MD, c Joseph L. Mills Sr, MD, c and
Mohammad Hassan Murad, MD, MPH, 1 Brooklyn, NY; Boston and Worcester, Mass; Ann Arbor, Mich; Seattle, Wash; Danville, Ill; Providence, RI; Phoenix Ariz; Cleveland, Ohio; Chapel Hill, NC; Houston, Tex; and Rochester, Minn
Recommendation 5: For DFUs that fail to demonstrate improvement (>50% wound area reduction) after a minimum of 4 weeks of standard wound therapy, we recommend adjunctive wound therapy options. These include negative pressure therapy, biologics (platelet-derived growth factor [PDGF], living cellular therapy, extracellular matrix products, amnionic membrane products), and hyperbaric oxygen therapy. Choice of adjuvant therapy is based on clinical findings, availability of therapy, and cost-effectiveness; there is no recommendation on ordering of therapy choice. Re-evaluation of vascular status, infection control, and off-loading is recommended to ensure optimization before initiation of adjunctive wound therapy (Grade 1B).

Recommendation 10: In patients with DFU who have adequate perfusion that fails to respond to 4 to 6 weeks of conservative management, we suggest hyperbaric oxygen therapy (Grade 2B).
65 y/o Male DFU With Osteomyelitis

- 7-20-2016 MRI showed evidence of osteomyelitis.
- 7-22-2016 ABI with no evidence of significant arterial insufficiency.
- 7-24-2016 S/P partial 5th ray amputation left foot.
- 8-24-2016 referred to HBO2/Wound Care by treating DPM.
- During course plastic surgery recommended split thickness skin graft for closure, (patient refused).
- Treatment included:
  - Sharp debridement
  - Mechanical NPWT
  - Total Contact Cast
  - Placental derived skin substitute
  - IV Antibiotics via PICC
  - HBO2 Therapy (3x/week)
65 y/o Male DFU With Osteomyelitis

9-2-2016
65 y/o Male DFU With Osteomyelitis
65 y/o Male DFU With Osteomyelitis

11-21-2016
Osteoradionecrosis: CMS Proposed Changes

- HBO$_2$ therapy is not considered medically necessary for:
  - Osteoradionecrosis of the jaw unless there is evidence of overt fracture or bony resorption.
    - “Data to justify HBO$_2$ prophylaxis for osteoradionecrosis in a previously irradiated mandible undergoing tooth extraction is lacking at this time; consequently this is a non-covered service.”
  - HBO$_2$ therapy is not covered to prepare the patient for dental extraction, when radiation therapy has not been done at least 6 months prior, in order to prevent the development of osteoradionecrosis.
Mild Traumatic Brain Injury (mTBI): Update

- Effects of HBO\textsubscript{2} on symptoms and quality of life among service members with persistent post-concussion symptoms (PPCS)\textsuperscript{1}
  - Prospective, double-blind, sham-controlled conducted as part of the DoD HBO\textsubscript{2} research program
  - 72 military service members with ongoing symptoms at least 4 months after mild traumatic brain injury
    - Participants were randomized 1:1:1 to 40 HBO\textsubscript{2} sessions
    - Intervention pressure (1.5 ATA breathing 100% oxygen)
    - Sham pressure (1.2 ATA breathing room air)
      - Better characterized as dose varying
    - No supplemental chamber procedures

---

Effects of HBO$_2$ on symptoms and quality of life among service members with persistent post-concussion symptoms (PPCS)$^1$

- Studies suggest no conclusive differences in outcomes between sham and active intervention groups.
- However, compared with the no intervention group both groups undergoing supplemental chamber procedures showed improvement in symptoms.

Mild to Moderate Traumatic Brain Injury: Update

- B-level evidence in mild to moderate traumatic brain injury/persistent post-concussion syndrome (mTBI/PPCS)¹

  - Review of published, peer-reviewed articles of HBO2 therapy prospective and controlled trials of mTBI/PPCS symptoms.

  - Doses of O₂ applied:
    - 100% O₂ at pressures ≥ 1.5 ATA
    - ≥ 21% O₂ at pressures > 1.2 ATA
    - Control: non-chamber standard of care or 10.5% O₂ at 2.0 ATA


- Hyperbaric oxygen (HBO) and hyperbaric air (HBA) at 1.2–2.4 ATA produce improvements that are superior to the combined standard of care (SoC) or the 21% oxygen equivalent concentration control (10.5% oxygen at 2.0 ATA) values.
- Error bars are SD.
- ImPACT 5 Immediate Post-Concussion Assessment and Cognitive Testing.
- PCL-M 5 PTSD Check- list–Military.
- RPQ 5 Rivermead Post-Concussion Questionnaire.
B-level evidence in mild to moderate traumatic brain injury/persistent post-concussion syndrome (mTBI/PPCS)¹

- Hyperbaric oxygen and hyperbaric air have demonstrated therapeutic effects on mTBI/PPCS symptoms and can alleviate posttraumatic stress disorder symptoms secondary to a brain injury in 5 out of 5 peer-reviewed clinical trials.

- The current use of pressurized air (1.2–1.3 ATA) as a placebo or sham in clinical trials biases the results due to biological activity that favors healing.

Role Of Hyperbaric Oxygen Therapy – Covered By CMS

1. Acute carbon monoxide intoxication
2. Decompression illness
3. Gas embolism
4. Gas gangrene
5. Acute traumatic peripheral ischemia - adjunctive treatment to be used in combination with accepted standard therapeutic measures when loss of function, limb, or life is threatened
6. Crush injuries and suturing of severed limbs - adjunctive treatment when loss of function, limb, or life is threatened.
7. Progressive necrotizing infections (necrotizing fasciitis)
8. Acute peripheral arterial insufficiency
9. Preparation and preservation of compromised skin grafts (not for primary management of wounds)
10. Chronic refractory osteomyelitis, unresponsive to conventional medical and surgical management
11. Osteoradionecrosis as an adjunct to conventional treatment
12. Soft tissue radionecrosis as an adjunct to conventional treatment
13. Cyanide poisoning
14. Actinomycosis, only as an adjunct to conventional therapy when the disease process is refractory to antibiotics and surgical treatment
15. Diabetic wounds of the lower extremities in patients who meet the following three criteria
   a. Patient has type I or type II diabetes and has a lower extremity wound that is due to diabetes
   b. Patient has a wound classified as Wagner grade III or higher
   c. Patient has failed an adequate course of standard wound therapy
Role Of Hyperbaric Oxygen Therapy – Not covered By CMS

1. Cutaneous, decubitus, and stasis ulcers.
2. Chronic peripheral vascular insufficiency.
3. Anaerobic septicemia and infection other than clostridial.
4. Skin burns (thermal).
5. Senility.
7. Cardiogenic shock.
8. Sickle cell anemia.
9. Acute thermal and chemical pulmonary damage, i.e., smoke inhalation with pulmonary insufficiency.
10. Acute or chronic cerebral vascular insufficiency.
11. Hepatic necrosis.
12. Aerobic septicemia.
14. Tetanus.
15. Systemic aerobic infection.
16. Organ transplantation.
17. Organ storage.
18. Pulmonary emphysema.
19. Exceptional blood loss anemia.
20. Multiple Sclerosis.
22. Acute cerebral edema.
23. Idiopathic sudden sensorineural hearing loss (SSNHL)