"The Oklahoma Effective Care Plan"

Part of the *National Brain Injury Rescue & Rehabilitation* Project:
A Care Pathway for Acute & Chronic Brain Insults from All Sources

Restoring Lives, Reducing Entitlement Costs, Restoring Readiness by Healing Brains in Real Time

Preventing Suicide, Rescuing Injured People and Restoring Hope to Shattered Lives, and Rebuilding America's Safety Net, Repairing the Criminal Justice System, Rehabilitation & Future Productivity

June 1, 2018

Translating Science into Medical Practice to Create Healthcare Solutions for the 21st Century

William A. Duncan, Ph.D., Founder, Patriot Clinics, Inc.
Michael Leddy, President, Patriot Medical Foundation

Untreated Brain Insults Drive Entitlement Costs (cont'd)

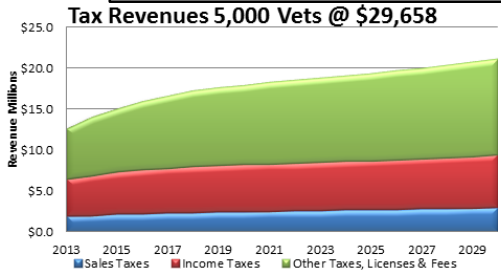
- **Veterans:** (33%+ of all deployed) (All with PTSD)
  - Cost? Current ineffective treatments $8,000-$32,000/yr
  - Savings w/ effective treatment? $Billions in reduced disability costs and increased economic productivity and societal stability
- **Education (IDEA Children & Remedial Education):** 50%+ have untreated brain insults.
  - **If just 20% were brought to normal, savings would be $18 billion per year.**
  - **An $18 billion savings would improve and restore 720,000 children per year.**
- **Welfare:** Almost all women on Welfare (Avg IQ = 85)
- **Homelessness:** 100% Vets, 72-80% all others (14 month return on HBOT treatment investment!)
- **Disability (Worker's Comp & Social Security):** 61,000 TBI plus most mentally retarded
- **Nursing Home Residents:** Dementia, Strokes, Falls
- **Mental Illness:** Most traceable to a brain insult
- **Trafficked & Battered Women & Children:** Traumatic Brain Injury
- **Substance Abuse**: Tracked to self-medication to deal with brain insult. It is even clear why some choose stimulants and others choose depressants as their drug of choice!

Cost to biologically repair and regenerate brain insults:

Acute: $321 - $3,100 (59% reduction in mortality for severe, Prevention of 50% future lifetime income loss/family disintegration!) or
Chronic one time cost: $25,000 (80% return to duty, work or school)
(CMS Reimbursement Rate)

OK State Fiscal Impact of Rescuing 22,000 of 27,500
Unemployed OKNG Injured Veterans: *$79 million/year* to the State Government*
Recovered Revenue to Federal Government: $368.6 million /year

Tax Revenues 5,000 Vets @ $29,658



Fiscally the average revenue increase to the state per 5,000 veterans added to the employment rolls will be **$16.7M** annually from 2013 to 2023

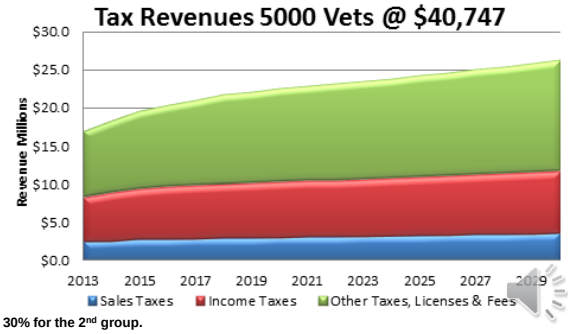
IQ differential between 1st income group & second income group? About 10 IQ points, the IQ improvement in 40 and 80 HBOTs

Fiscally the average revenue increase to the state per 5,000 veterans added to the employment rolls will be **$21.1M** annually from 2013 to 2023

Government average per worker per year is $16,800 federal plus $4,000 state revenue. Thus $20,800 for Federal and State. One-time cost of civilian treatment is $25,000.

Untreated Brain Injury Yields 50% future lifetime income loss!!! (Gamboa)

Tax Revenues 5000 Vets @ $40,747



Source: OK State Department of Commerce, 2013
***OK Dept of Commerce uses 70% for the first group and 30% for the 2nd group.**

The Human Brain is Fragile

- Basic Causes of Brain Insult:
  - Trauma: Falls, Automobile Accidents, Bends & Aviation Decompression Sickness (aviation and tornado events)
  - Hypoxia (Birth Insult, near drowning, near hanging, noxious fumes)
  - Infections (damage from swelling, high fever, etc.)
  - Chemical Poisoning (carbon monoxide, alcohol, legal and illegal drugs, Agent Orange, chemical agents)
  - Heavy Metal Poisoning (Manganese, Mercury, Arsenic, Lead, Plutonium, Uranium)
  - Nutritional Deficienies
  - Genetic Disorders (Fragile X, Mongoloidism)

HBOT is Already Used for Some Acute Brain Insults

- **In 1995, the metastudy was done that showed that the experience of all of the Navies and Air Forces of the world was to get a DCS patient into the chamber within an hour or two of injury, and that resulted in a 90% single Treatment Cure Rate.**
- **Thanks to Dr. Povlishock, editor of the Journal of Neurotrauma, we learned the long white matter tracks are dead by day 14, but they are intact enough by day 10 to rescue.**
- **We have tested this is our patients at Patriot Clinic and found we can basically erase the acute injury in 10 treatments. Thus the basis of the NBIRR-03 protocol**

Hyperbaric Oxygen Therapy has 80 Years of World Wide Research Behind It

- **No Wound Will Heal Without Oxygen**
- **Hyperbaric Oxygen Therapy is the Only non-hormonal Treatment FDA-approved for the Repair and Regeneration of Human Tissue**
- **The therapy uses the Gas Laws of Physics (Henry's, Boyle's and Dalton's Laws) to saturate tissue with 7 to 12x more oxygen than normal.**
  - **The body's fluids (plasma, lymphatic fluids)**
  - **The body's tissues (bone, tendon, connective tissue, organs**
  - **Become supersaturated, depending upon pressure and time at pressure**
- **Result: Reduced swelling, restored mitochondria (energy manufacture), DNA Activation, Stem Cell Activation**
- **Used right after injury, weeks can be cut off of recovery time, with reduced scar tissue and stronger connective tissue repair**
  - **30% faster fracture repair with 30% stronger fusion**

The Great Myth: There is No Treatment for Brain Injury

As John Maynard Keynes observed, "The difficulty lies not in the new ideas, but in escaping the old ones."

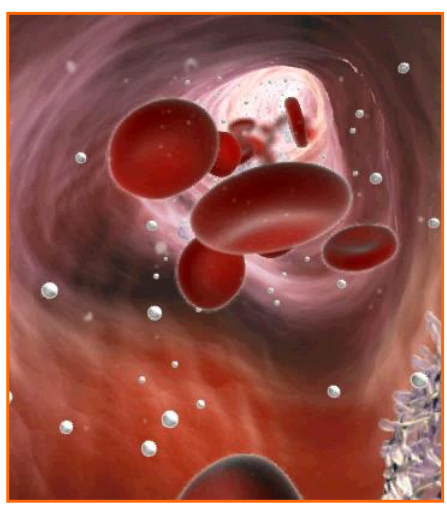
- **Fact 1: Hyperbaric oxygen treatment is already FDA-approved for brain injuries and non-healing wounds including those in the brain!**
- **Fact 2: HBOT is the ONLY non-hormonal treatment FDA-approved for repair and regeneration of human tissue.**
- **Fact 3: We have been treating brain injury, an injury caused by a lack of oxygen, with oxygen at drug level doses, for more than 80 years.**
  - It is the experience of all of the Navies and Air Forces of the world that if they get a neurological decompression sickness patient, DCS-II, into a hyperbaric chamber within 1 hour they have a 90% single treatment cure rate. This started in 1937!
  - Delayed treatment for decompression sickness events still creates improvement…but requires more treatments.
  - For current war veterans, Miller reported in 2014 that "symptoms in both groups [treated with HBOT 1.5 {700% more} and HBAT 1.2 {30% more}] improved compared with [VA & DoD's best] mTBI care without supplemental chamber interventions." (Miller, JAMA Internal Medicine, p. E7)
  - **Those receiving the 40 treatment protocol experienced a 15 pt IQ increase, 39% reduction in Post-Concussion Syndrome, 30% reduction in PTSD, 51% Reduction in Depression, 96% improvement in Emotional Control and greatly reduced pain levels reducing the need for pain medication including narcotics! The 80 treatment NBIRR protocol improves those results by another 1/3rd. Protocol has been used since 1977 for chronic brain injury! (LSU 2012)**
  - **The Acute brain insult protocol is to start treatment within 10 days of the event. Minutes matter and the sooner treatment begins, the better. Only 10 HBOT treatments are required. 2.0 1 hour the first 1.5 ata 1 hour the subsequent treatments.)**

Reduced Suicide Ideation

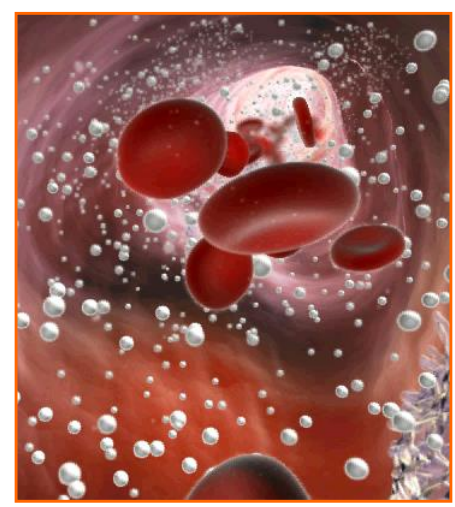
- LSU research demonstrated further
  - **Significant Reduction in Suicide Ideation**
  - **Reduction in psychoactive medication use**
  - **Significant improvement was seen in neurological exam, symptoms, IQ, memory, measures of attention, dominant hand motor speed and dexterity, quality of life, general anxiety, PTSD, depression, and reduced psychoactive medication usage.**
  - **Improvements were maintained 6 months later**
  - **Improvements in TBI Post-concussion syndrome with PTSD in: Clinical medicine, neuropsychology, and SPECT imaging**
  - **Reduced Pain, resulting in no longer needing pain medication, including opiates. If opiates were needed dosage was reduced.**

HBOT: It's About Oxygen Saturation

The body's liquids are saturated with more oxygen, helping areas with compromised circulation.



Before HBOT



After HBOT

Images courtesy of Dr. K. Paul Stoller

Solution: It's Just Oxygen!

HBOT: For 78 years, Oxygen has been used to repair an injury caused by a lack of oxygen!

- **Simple: Lack of oxygen is bad**
- **O2 used in 5,769+ cellular processes**
- **HBOT activates 8,101 Genes!**
  - Down regulates inflammation processes
  - Up regulates growth &repair processes
  - Normobaric O2 does not!
- **We know how HBOT works!**
  - Acutely stops swelling/reperfusion injury
  - Restarts stunned cellular metabolism
  - Restarts stunned mitochondria
    - Mitochondria then requests oxygen (blood supply)
    - Body re-grows blood vessels
  - Activates stem cells 8x normal
    - to repair neural pathways
- **No wound can heal without oxygen**
  - HBOT heals wounds that have not healed
  - HBOT heals wounds 50% faster with less scar tissue
  - HBOT heals broken bones 30% faster & 30% stronger
- **Placebos have to have the potential of being inert**. Saturating injured tissue with any dose of oxygen has never been shown to have a placebo effect!

Pressure causes oxygen to saturate tissues higher than normal breathing:

HBAT 1.3: 50%* more O2
HBOT 1.5: 700% or 7x
HBOT 2.4: 1200% or 12x

HBAT is Compressed Air & HBAT 1.3 is the FDA approved treatment for mountain sickness

HBOT is FDA-approved & available & on-label for neurological conditions & non-healing wounds!

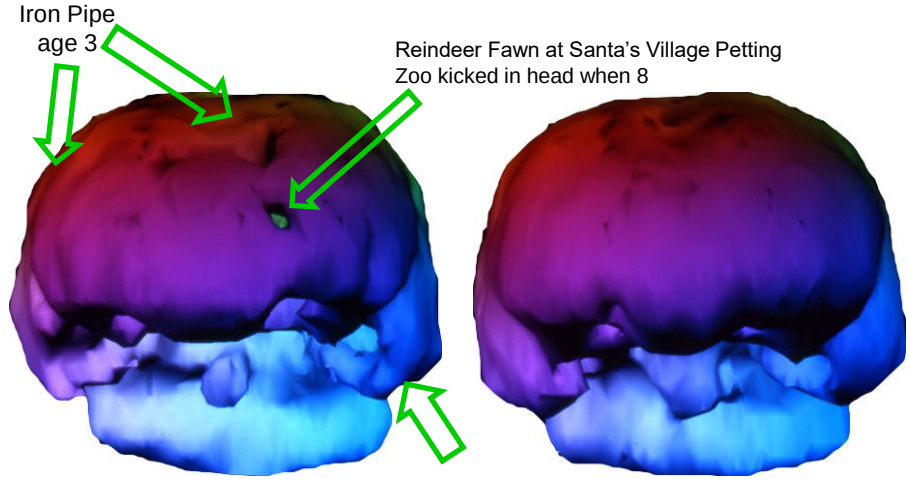
***25% more O2 in tissues is so clinically significant that DoD medicine has spent millions in research trying to achieve it. It is already available on the battlefield with mountain sickness chambers using air!**

Myth: 90% Recover from Brain Injury

Traumatic Brain Injury from Child Abuse - 48 y. male

Blow from Iron Pipe age 3

Reindeer Fawn at Santa's Village Petting Zoo kicked in head when 8



Pre-HBOT 1.5

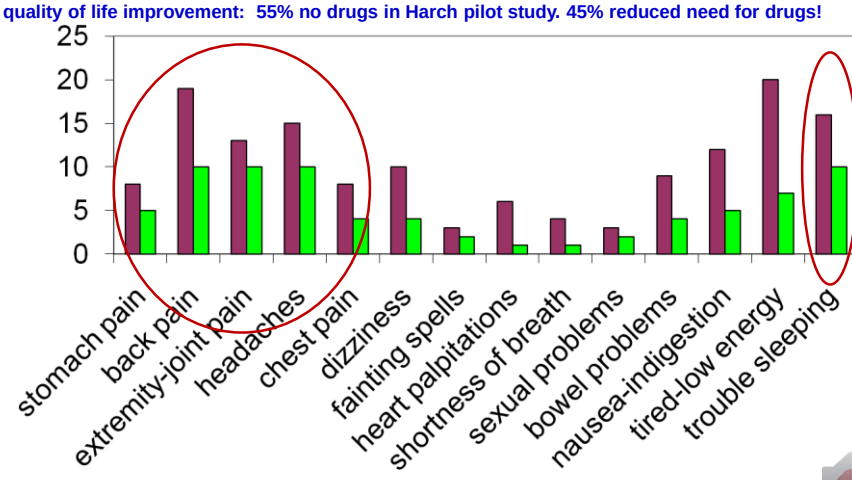
Post-HBOT 1.5

Other damage from repeated violence from alcoholic stepfather

Physical Symptoms Questionnaire

Personal Health Q-15 Results (N = 16)

Eliminated or reduced need for pain or sleep medication: Government cost savings as well as quality of life improvement: 55% no drugs in Harch pilot study. 45% reduced need for drugs!

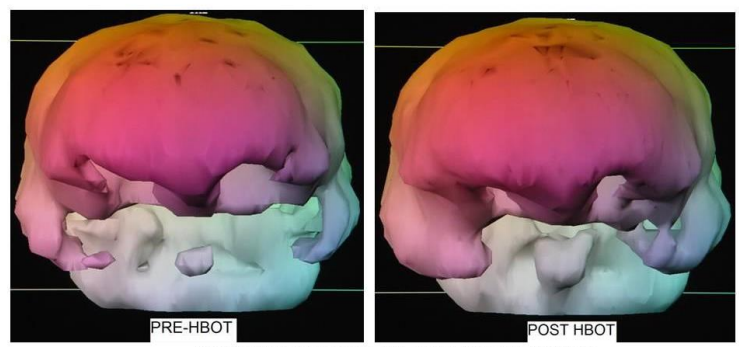


Confidentiality Statement applies.

Solution to Brain Injury: Biologically Repair the Brain

Non-Healing Wound in the Brain

Case Report: Navy SG Meeting - Aug. 2008
25 year old Humvee Machine Gunner
40 HBOT 1.5 treatments (1/2 of the Protocol)



©Retained 2008: Paul G. Harch, M.D., processed by Philip J. Tranchina.

Treated in 2008. PTSD disappeared. From living in a dark room since returning from Iraq, he became gainfully employed, turned down ½ of his VA disability, worked and made $39,000 per year, and has returned to college after 2nd 40 treatments.

Finished Master in Public Administration.

Now working for a major Metropolitan Fire Department

Case Published in: Cases Report June 2009 http://casesjournal.com/casesjournal/rt/suppFiles/6538/31370

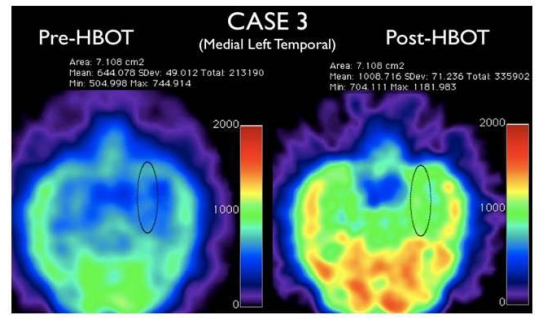
Brain insults often result in a 50% decrease in brain metabolism

HBOT 1.5 Restores Brain Blood Flow & Metabolism

Scale actually goes from 0 to 2000 so it ENDS at 2000. Those pixels that are hitting near 2000 are red and are the most active, the less metabolically active are "cooler" colors of yellow, green and blue. So if you draw a line across the middle of the scale you can see what pixels are registering at 1000 by the corresponding color.

Both pre and post HBOT sets of images are exactly on the same scale. Below is a a quantitative assessment that shows the actually percent increase in up take to an area of the brain quite vulnerable to TBI. Note the mean uptake in the area went from 644 to 1008. Similar changes are evident everywhere else.

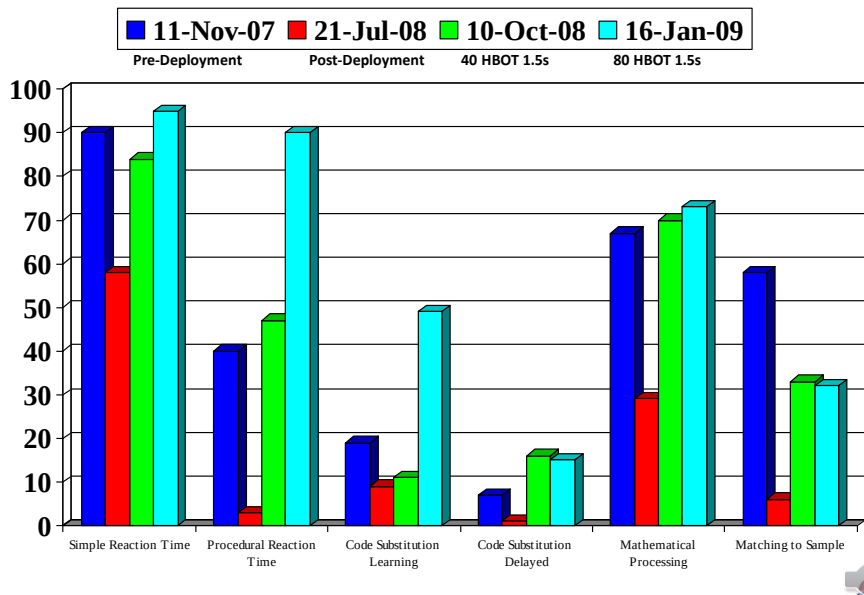
In ballpark numbers a change from green to red is a doubling of metabolism.



Analysis of blast injured veteran in LSU IRB Study # 7051: Edward Fogarty, MD, Neuro-radiologist, Chair, University of North Dakota School of Medicine, (701) 751-9579 **40 Treatments: ½ of NBIRR Protocol**

Case Published in: Cases Report June 2009 http://casesjournal.com/casesjournal/rt/suppFiles/6538/31370

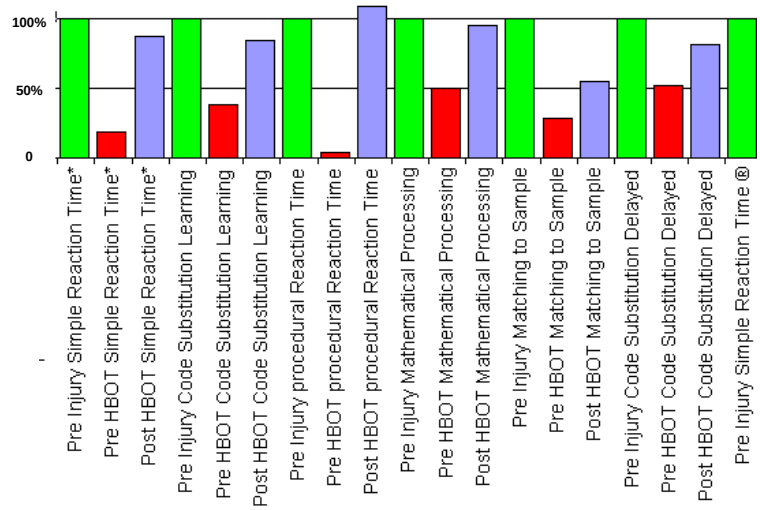
Airman B ANAM Percentile Scores



Confidentiality Statement applies.

ANAM Scores - Pre-injury, Post-injury & after HBOT

Budget savings from restoring 4 military personnel to duty: **$11.2 million** (1st year)
Long term additional savings: $8 million (+$11.2 = **$19.2 million**) **Treatment Cost? $96,000**



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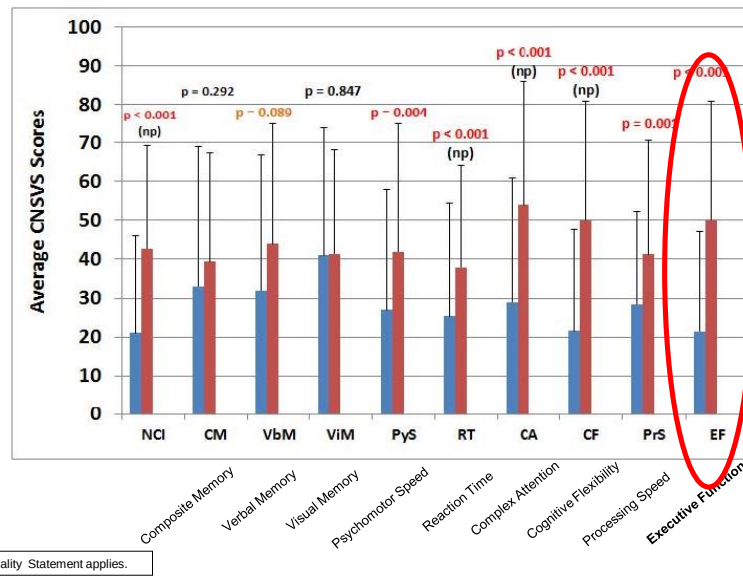
CNSVS Neurocognitive Scores

Executive Function **is a measure of a person's ability to function and manage their daily affairs**



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PATRIOT CLINICS

Effective Treatment Today

ANDI INTERNATIONAL

Member Clinics

- **"The Improbable can be done immediately. The Impossible takes a little planning."**
  Robert T. Frederick (MG,USA,Ret) (Commander, First Special Service Force & 45th Infantry)
- **Over 15,000 treatments in Oklahoma City, 2 person multiplace plus 3 monoplace chambers (April 16, 2018)**
  - **More hyperbaric treatment for those in need in one location in 4 years than any other location in the history of the United States! All patients treated for to ensure they receive the full number of treatments needed.**
  - **$500,000 worth of hyperbaric equipment assembled to enable treatment!**
  - **Nearly 900 patients, most are veterans, plus veteran family members, police officers, firefighters, victims of crime and 14 tornado victims**
  - **Delivered over $4.75 million HBOT, $25,000 Physician, $102,000 Chiropractic, $40,000 acupuncture ($4.82 m) for charity donations & revenue of $420,000 over 4 years!**
  - **Capacity of 40 treatments per day, approaching 80 treatments per day.**
  - **Current: 73 Veterans since January 1, 39 Veterans Currently In Treatment, 7 on waiting list, $627,568 in treatment ($218-$327) since January 1. 2,937 treatments since 1/1 to 4/31 (avg 31/day) 40-80 treatments per patient. 80 treatments is a "brain reset"**
- **OSU, participating in NBIRR-01 with the IHMF, did about 2,600 treatments for 50–60 people from 2010 to 2014 in the State's 14 person multiplace.**
  - Tulsa veterans community saw the results in the veterans treated and the result was support for SB1604.
- **The goal is to treat 5,000 Oklahoma veterans with hyperbaric oxygen therapy within the next year.**
  - **If EVERY hyperbaric chamber in the state is used on a 16 hour day, there are only enough to treat 1,000 per year! Full deployment of effective treatment is necessary to rescue Oklahoma veterans**
- Non-profit Patriot Clinics can be set up quickly and any government, for profit or not-for profit organization in the nation. **This includes every hospital-based hyperbaric center, exactly as provided in SB1604!**
- Our focus is on effective treatment, treatment that addresses the cause of a patient's challenges, not the symptoms. All synergistic treatments are designed to help restore people to work and functional life!
- **The goal is to have hyperbaric treatment within 30 miles of every Oklahoman.**
- **Patriot Clinic OKC—Reopened to the public January 1, 2017 Phone: (405) 999-0965**
- **Patriot Clinic Lawton— Lawton OK – Planned to serve nearly 40,000 injured veterans in the Lawton area**
- **Donations can be made online to www.patriotclinics.com**
- **Optional: Send a donation to Patriot Medical Foundation at 7815 NW 23rd St, Bethany, OK 73008. Patriot Medical Foundation is a 501(c3) public charity. (EIN: 47-1435677) (405) 999-0965 www.patriotmedicalfdn.org**

A $10 donation per month from 1,000 people adds HBOT and Treats 40/day

Patriot Medical Foundation

National Emergency: A War Casualty Crisis

- Service members in **the All-Volunteer Force** are some of the best and brightest in the nation; risk-takers, leaders!
- Today 70% of America's Youth DO NOT QUALIFY to join the infantry! 8 years ago, it was 50% of America's Youth, with the Air Force drawing from the top 25%!
  - This is a major crisis for America's Employers Today!
  - This Directly impacts America's productivity and future economic output!
- If left untreated, a veteran's brain injury destroys their life. They are a **Casualty of War** as much as if they had been left on the battlefield
  - Divorce, unemployment, disability, substance abuse, incarceration, homelessness, suicide
  - Cascade steep for the first 2 years and continues downhill thereafter - 45% will be unemployable

- **Virtually ALL homeless veterans have a brain injury**
  - 72%-80% of all homeless persons have untreated brain insults
- **It costs society more per war casualty not to treat them**
- Current deployments have brought us within 62% of the number the Army deployed in combat operations in WWII.
  - End of **World War II**: by 1949 1/3 of all persons in prison were combat veterans
- **Vietnam**: 66% of prisoners today in jail for violent crimes "harmed" someone they knew."

We Do Not Need to Repeat the Tragedies of Previous Wars!

Veteran Casualty Crisis: Source of Performance Challenges in Veteran Programs

- Military medicine is confused: PTSD shares symptoms with Mild-TBI!
  - Sleep cycle disruption, irritability and difficulty concentrating
  - Cannot get a PTSD diagnosis from VA without 2 of 3 mTBI symptoms
- 40% of all 2.6 million IEF/IOF war veterans are blast/concussion casualties:
  - 98% will experience Post-Concussion Syndrome
  - **Of those 1 million casualties, about 858,000 are likely to experience TBI symptoms, PTSD or depression; all known symptoms of brain injury**
  - Minimum 43,910 are in Oklahoma (15.2% of All Gulf War Era Veterans + 75% of National Guard who have served (27,500) + 16,410 Vietnam War Era population.
    - This yields over 25% of all OK unemployed population (27,200) with another 10,800 discouraged workers and 29,500 marginally attached to the work force.

VETS SHOULD BE TOLD THEY HAVE A BIOLOGICAL INJURY!
PTSD is not because they were not "STRONG" enough to take the rigors of war!
PTSD is not a moral weakness!

Veteran Casualty Crisis: Source of Performance Challenges in Veteran Programs (cont'd)

- Each untreated casualty costs the economy $60,000 per year
  - In safety net, substance abuse & incarceration costs & lost tax revenue
- Each casualty that returns to work
  - Is a $20,800 minimum annual revenue source
    - $ to Federal $16,800 State and Local governments $4,000
  - Has a reduced need for services (TANF, Medicaid, VA medical, incarceration, substance abuse, family services, food stamps, remedial education, psychological counseling, motor vehicle accidents, workers compensation, etc.)
  - Each biologically repaired person who goes to work pays for treatment through taxes and economic productivity - $1 million in lifetime tax revenue
  - Each active duty rescued - minimum $2.6 million per veteran over lifetime

HBOT 1.5 Provided the Largest Published Reduction in PTSD

- **LSU HBOT Pilot Study: 30% ↓ Reduction in 6 weeks!**
- Prolonged Exposure Therapy [PE]: 28% ↓ - Wolf, 2012
- Virtual Reality Exposure Therapy [VRET]: 23% ↓ - Rizzo, 2011
- Transcendental Meditation [TM]: 21% ↓ - Rosenthal, 2011
- Cognitive Processing Therapy [TAU]: 14% ↓ & 4.8% ↓
  Chard, 2011 & Alvarez, 2011
- Trauma Focused Group Treatment [TAU]: 2.2% ↓

Note: All results are time adjusted for the length of treatment in the LSU study

Addition of Acupuncture

- Provides an "off-switch" for the hyperactive Amygdala
- NIH Research Demonstrates that effect for Acupuncture
  - "FMRI connectivity analysis of acupuncture effects on an amygdala associated brain network" Molecular Pain 2008 4.55
- The protocol used has clinically demonstrated the effect of reducing the emotional charge in patients suffering from PTSD.

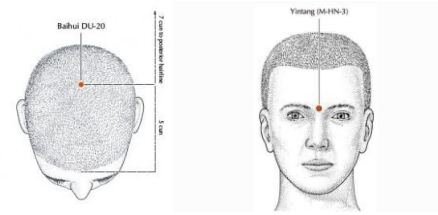
Patriot Clinic 11 Needle Acupuncture Protocol

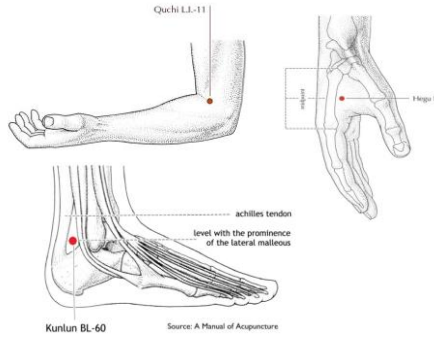
Scott Rigsbee Acu (originally from Vimal DeAlwis, MD Sri Lankan Olympic Team Physician)

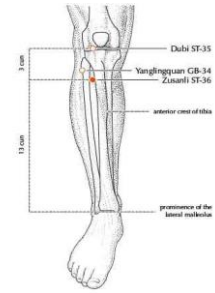
穴位 Xué Wèi (Acupuncture point) list.

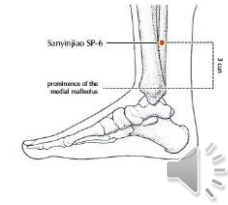
Du-20 百會 Bǎi Huì (Hundred Convergences)
* 印堂 Yin Táng (Hall of Impression)

The points listed below are done bi-lateral
LI-11 曲池 Qū Chí (Pool at the Bend)
LI-4 合谷 Hé Gǔ (Union Valley)
ST-36 足三里 Zú Sān Lǐ (Leg Three Li)
SP-6 三陰交 Sān Yīn Jiāo (Three Yin Intersection)
BL-60 昆仑 Kūn Lún (Kunlun Mountains)
*(Scott's Acupuncture point addition to the DeAlwis PTSD protocol)





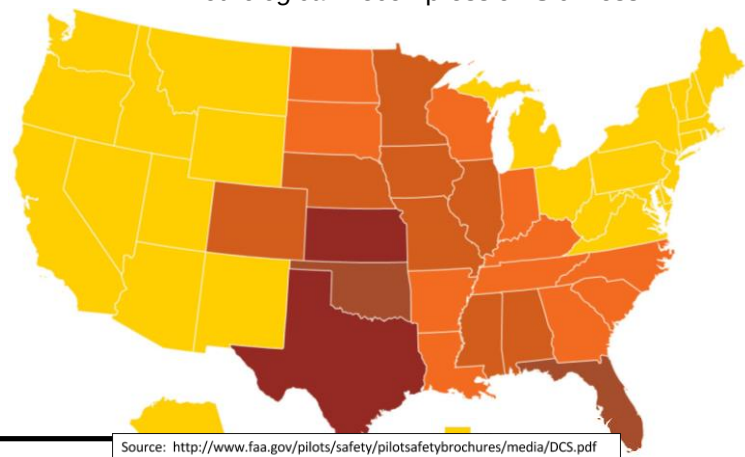




Tornados & Hurricanes Can Cause DCS-II

(Decompression Sickness)

= *Neurological* Decompression Sickness



Source: http://www.faa.gov/pilots/safety/pilotsafetybrochures/media/DCS.pdf

Public Health Advisory from the IHMA:
TO AVOID LUNG TRAUMA DURING A TORNADO
DO NOT HOLD YOUR BREATH
If you develop neurological symptoms following a tornado
Seek medical treatment immediately

Tornados & Hurricanes Impact Millions of Americans

- In Moore, Oklahoma, the school psychologists report a group of mentally handicapped children from the 2013 Moore tornado, just like the group created 9 years before by the 2004 Tornado
- Patriot Clinics treated 11 Tornado victims for other brain insults.
- Most had 14 or more symptoms of DCSII
- One had “all but one”
- FAA Aeromedical wants to work with the IHMA on making HBOT treatment routine at the ER for these victims
- Public Service Message: Don’t Hold Your Breath
- Through NBIRR-03: Acute Brain Insult and NBIRR-04: Chronic Brain Insult, we will be able to get PAID treatments for these weather casualties!

Tornados & Hurricanes Can Cause DCS-II

(Decompression Sickness)

= *Neurological* Decompression Sickness

Table 1. Signs and symptoms of Altitude Decompression Sickness.

DCS Type	Bubble Location	Signs & Symptoms (Clinical Manifestations)
BENDS	Mostly large joints of the body (elbows, shoulders, hip, wrists, knees, ankles)	• Localized deep pain, ranging from mild (a “niggle”) to excruciating. Sometimes a dull ache, but rarely a sharp pain. • Active and passive motion of the joint aggravates the pain. • Pain can occur at altitude, during the descent, or many hours later.
NEUROLOGIC Manifestations	Brain	• Confusion or memory loss • Headache • Spots in visual field (scotoma), tunnel vision, double vision (diplopia), or blurry vision • Unexplained extreme fatigue or behavior changes • Seizures, dizziness, vertigo, nausea, vomiting and unconsciousness may occur
	Spinal Cord	• Abnormal sensations such as burning, stinging, and tingling around the lower chest and back • Symptoms may spread from the feet up and may be accompanied by ascending weakness or paralysis • Girdling abdominal or chest pain
	Peripheral Nerves	• Urinary and rectal incontinence • Abnormal sensations, such as numbness, burning, stinging and tingling (paresthesia) • Muscle weakness or twitching
CHOKES	Lungs	• Burning deep chest pain (under the sternum) • Pain is aggravated by breathing • Shortness of breath (dyspnea) • Dry constant cough
SKIN BENDS	Skin	• Itching usually around the ears, face, neck arms, and upper torso • Sensation of tiny insects crawling over the skin • Mottled or marbled skin usually around the shoulders, upper chest and abdomen, accompanied by itching • Swelling of the skin, accompanied by tiny scar-like skin depressions (pitting edema)

Source: http://www.faa.gov/pilots/safety/pilotsafetybrochures/media/DCS.pdf

FDA Accepted HBOT Indications

HBOT as used by the team is currently in use for 13 FDA-accepted indications (which means the manufacturer or practitioner can advertize those indications) by hundreds of physicians at nearly 1,000 locations across the nation, delivering approximately 10,000 treatments per day.

The 13 accepted indications for HBOT treatment include:

1. Air or gas embolism.
2. **CO poisoning, CO poisoning complicated by cyanide poisoning *(Neurological)***
3. Clostridial myositis and myonecrosis (gas gangrene)
4. Crush injury, compartment syndrome and other acute traumatic ischemias
5. **Decompression sickness *(Neurological)***
6. **Arterial Insufficiency: *(non-healing wound)***
   - **Enhancement of healing in selected problem wounds** (includes uses like diabetic foot wounds, hypoxic wounds and other non-healing wounds, etc.)
7. Exceptional blood loss anemia
8. **Intracranial abscess *(Neurological)***
9. **Necrotizing soft tissue infections**
10. Osteomyelitis (refractory)
11. **Radiation tissue damage (soft tissue and bony necrosis) *(non-healing wound)***
12. **Skin grafts and flaps (compromised) *(non-healing wound)***
13. Thermal burns[1]
14. *(Acute hearing loss has just been added by the UHMS Scientific Committee but it is not yet FDA accepted.)*

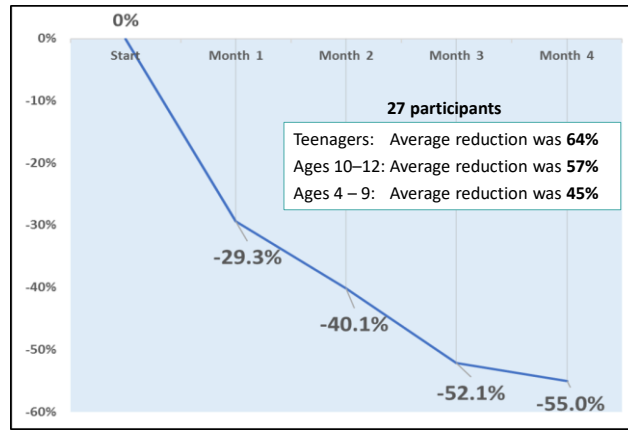
[1] Hyperbaric Oxygen Therapy: 1999 Committee Report. Editor, N.B. Hampson. Undersea and Hyperbaric Medical Society, Kensington, MD. See also: Harch PG. Application of HBOT to acute neurological conditions. Hyperbaric Medicine 1999, The 7th Annual Advanced Symposium, The Adams Mark Hotel, Columbia, South Carolina, April 9-10, 1999; and Mitton C, Hailey D. Health technology assessment and policy decisions on hyperbaric oxygen treatment. Int J of Tech Assess in Health Care, 1999;15(4):661-70.

Examples:
HBOT is Synergistic with Other Treatments

- **Drug Protocols**
  - Patients in the LSU study were on no medication or less medication
  - Medication was now more effective at controlling remaining symptoms
- **Nutritional Programs**
  - NBIRR Nutritional Program reduced aberrant violent behavior in felons in 30 RCT studies by 39-41%
  - Harch did not use NBIRR supplement in his study
- **Cognitive Rehabilitation**
  - Treatment cannot begin until a patient can sleep through the night
  - HBOT repairs sleep cycles and most patients can begin sleeping at 10 HBOT treatments
  - When brain tissue is recovered, it is somewhat disorganized! Cog Rehab reorganizes
  - Prison recidivism reduced from 80% to 3.6% in 7 year study
- **Acupuncture**
- **Bio-Feedback**
- **Counseling & Coping Skills**

2015 Study

Evaluating the Effectiveness of the IonCleanse by AMD relative to ATEC Score for those with ASD



Average ATEC reduction was 55%!

ATEC => Autism Treatment Evaluation Checklist

Patriot Clinics & Public Health Policy Makers: Shared Goals

- **Saving Brains, Lives and Increasing Productivity**
- **Saving the Health Care System**
  - **Better patient outcomes for lower costs**
  - **Increased profits for hospitals**
  - **Increased clinic profits**
- **Fixing Workers Compensation**
- **Reducing Mandatory Gov't Spending**
- **Reducing the Impact and Scourge of Diabetes**
- **Reduced Long Term Disability Payments**
- **Creating Greater Insurance Company Profits**

The Science of Rebuilding Brains Historical Timeline (cont'd)

- 2010, March - NBIRR-01 Begins Enrolling Patients. Preliminary results from multi-site study supports Harch's findings.
- 2011, October 25 - LSU Pilot published in the Journal of Neurotrauma, J Neurotrauma. A Phase I Study of Low Pressure Hyperbaric Oxygen Therapy for Blast-Induced Post Concussion Syndrome and Post Traumatic Stress Disorder PMID: 22026588 Imaging for every patient!
  - Subjects as a group showed significant improvements on most measures of intelligence, function and quality of life
  - All subjects received 1/2 the clinically recommended protocol being used in NBIRR-01 (NCT01105962)
  - Nearly 15 point IQ increase (average) (difference between a high school dropout & a college graduate)(14.8 P<.001)
  - Post-Concussion Syndrome (PCS): 39% Reduction in PCS symptoms (p=0.0002); 87% substantial headache reduction
  - 30% Improvement in PTSD (20 points of a 85 point scale; 10% is considered clinically significant)
  - 51% Reduction in depression indices with large reduction in suicide ideation(p=0.0002)
  - 64% had a reduced need for psychoactive or narcotic prescription medications
  - 100% showed sustained improvement on neuropsychological tests 6 months post treatment
  - Functional improvements: Cognitive 39% (p=0.002); Physical 45% (p<0.001); Emotional 96% (p<0.001)
    - Significant reduction in anger issues!
  - Placebo effect ruled out! Results too great to be placebo effect and neurological imaging is inconsistent with a placebo effect
- 2014, November - Israeli Study: Randomized-Controlled trial plus imaging for every patient.
  - Uses actual HBOT 1.5 protocol: Hyperbaric Oxygen Therapy Can Improve Post Concussion Syndrome Years after Mild Traumatic Brain Injury - Randomized Prospective Trial
  - http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0079995

Currently DoD-VA Only Pays for Symptom Control

They are using off-label drug treatments and none are approved for TBI; and only 2 are on-label for PTSD! Clear Cause of Suicide Epidemic!

Suicides now exceed losses from combat casualties!

Treatments are largely ineffective!

There is no drug currently approved by the FDA to treat TBI and only HBOT (oxygen) is approved to threat 3 kinds of neurological injuries.

The only drugs approved for PTSD are Zoloft and Paxil. All other treatment with drugs for these conditions is off-label and intended to treat symptoms.

In fact, a significant percentage of psychiatric medications are prescribed off-label. Further, the use of antipsychotics in these patients is often as a chemical restraint.

The following list of drugs are FDA approved for psychiatric and neurologic disorders. The great majority of these drugs have been and are currently prescribed by DoD Medicine off-label for TBI/PTSD in the service members Dr. Harch has treated with HBOT 1.5 in New Orleans.

Neurology:

Alzheimer's

- Ebixa
- Klonopin
- Neurontin
- Lyrica
- Topamax
- Dalmane
- Symmetrel

Psychiatry:

Anti-anxiety

- Lectopam
- Tranxene
- Valium

Psychiatry (Con't)

Anti-depressents (All Black Label warning for Suicide)

- Celexa
- Lexapro
- Prozac
- Luvox
- *Paxil
- *Zoloft
- Cymbalta
- Effexor
- Wellbutrin
- Remeron
- Desyrel

Antimanic

- Tegretol
- Lamictal
- Eskalith
- Topamax
- Depakote

Antipsychotics

- Clozaril
- Zyprexa
- Seroquel
- Risperdal
- Geodon
- Abilify

*FDA Approved for PTSD

All in red carry a black label warning for suicidality in those under age 25!

The veteran suicide rate is 120 per week! (CDC Numbers)

All in red fail to beat placebo yet million$ spent!

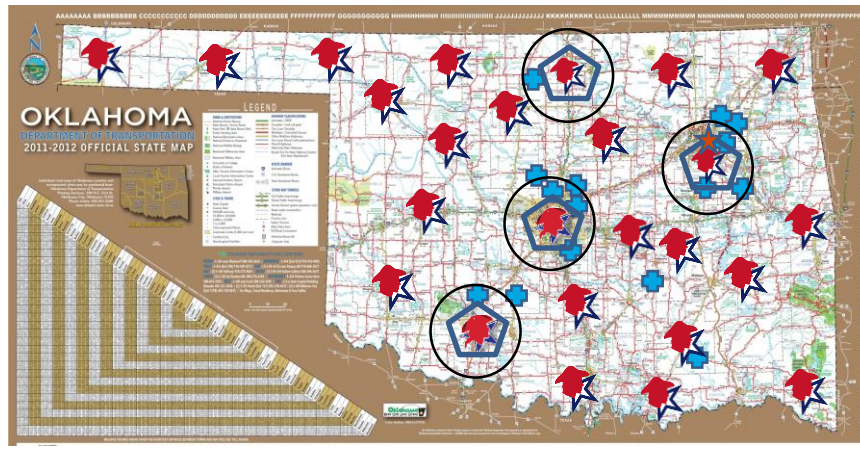
(Journal of Clinical Psychiatry, Nov 29, 2011)

August 2, 2011: $717 million spent by VA on Drug that does not work! DoD could have ,themselves, repaired 176,000 veterans, w/ O2!

"Antipsychotic Doesn't Ease Veterans' Post-Traumatic Stress, JAMA Published Study Finds" - NYTimes.com

Oklahoma HBOT Deployment Map

No current hospitals will sign onto the project until payment pathway and state mandate is clear
Patriot Clinics are NOT Constrained. Goal: No more than 30 miles between chamber availability



Current Hospital/Clinic Facility: 1,000/yr; Goal: 5,000/yr

OSUCHS CAHM

Patriot Clinic Mobile Units

Number Veterans Injured: 43,000 injured
Cameron College (Lawton): 1,500 Vets with PTSD

Patriot Clinic Core Clinic
(30 Treatments per Day, 1200 persons/year)

Types of Hyperbaric Chambers

Monoplace and Multi-place Hyperbaric Chambers

Sechrist

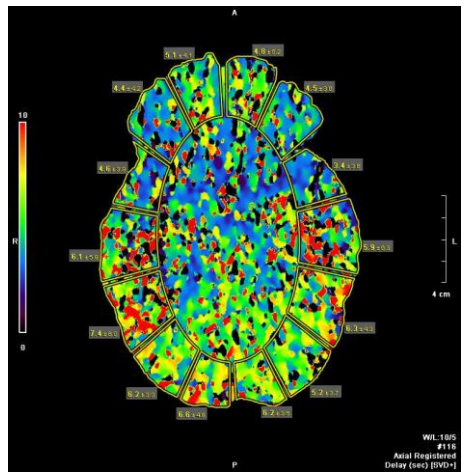
SOS Hyperlite

Perry

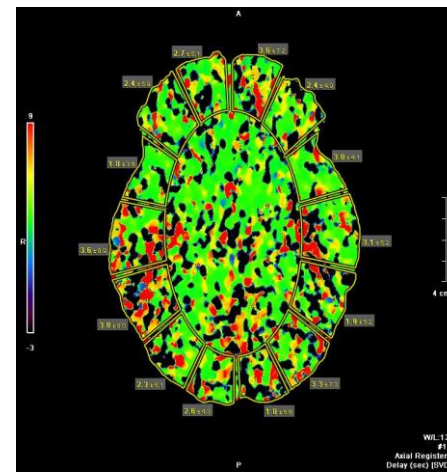
ETC Bara-med XD

Reimers Q-Ball

Severe TBI Patient:
Whole Brain CT Perfusion Pre & Post HBOT



Pre HBOT – 10/16/09



Post HBOT – 10/28/09

Images Courtesy of Dr. Germin, Las Vegas

Non-Healing Wound of the Foot

Diabetic Foot Ulcer: This Wagner Grade III was present for one year and unresponsive to conventional therapy.

1 Day Prior to Scheduled Amputation

26 HBOT Treatments

50 HBOT Treatments

Hyperbaric Oxygenation prevents 75% of amputations in diabetic patients. Therapy approved by CMS for Medicare upon application by IHMA to CMS for coverage, August 2002.

These photographs are the property of Kenneth P. Stoller, MD, FAAP
Permission given by Dr. Stoller to the IHMA to publish on this CD (2004)

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DFU Amputation Prevention with HBO Based on Wagner Score

Wagner Score	Sample Size 'n"	Helped by HBO%	Expected # of Treatments	Expected Cost/ person (Southern CA) Medicare
I	3	100	10	$4,474
II	130	83.1	20	$8,947
III	465	77.2	40	$17,894
IV	138	64.5	40+	$17,894
V	37	29.7	40+	$17,894

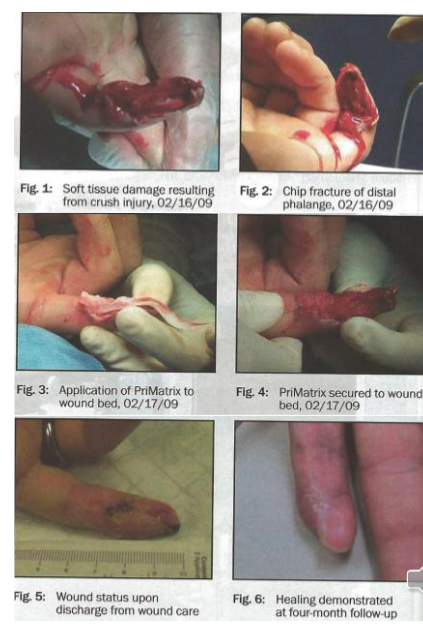
Note: The Regranex (becalpermin) clinical trials in DFU healing involved Wagner II ulcers (922 patients in 4 trials (478 patients received Regranex).

Baseline healing rates of 25%, control healing rates 29%, Regranex healing rates 43%

CDC: Average Cost of an Amputation: $38,077

Acute Amputation Prevention Blunt-Trauma, Crush, Post-Surgical Repair

- Crush injury
- Amputation recommended by orthopedics
- PriMatrix provided
- HBOT 2x daily crush protocol
- Continued as outpatient until healed
- Follow up at 4 months



Source: WC&HM 2010: Higgs

Treating Burn Patients with HBOT Saves Money, Yet Most Burn Patients NEVER Receive HBOT Treatment!

Burning aviation fuel & hot tar from a plane crashing into the roof of the mall where she was shopping.

Illustration 1
A. 23-year-old white female with facial burns from flaming gasoline and tar 12 hours after injury.
B. 24 hours later (36 hours after injury) after two HBO treatments. Note resolution of edema.
C. 72 hours later (84 hours after injury) after six HBO treatments.
D. Shortly before discharge.

Picture courtesy of Paul Cianci, M.D.

Fractures

- **Dr. Wright's Air Force research demonstrated that fractures heal 30% faster and 30% stronger when hyperbaric oxygen is used.**
  - Shorter back to work time
  - Stronger fusion
- Cost effective through reduced down time

The effect of hyperbaric oxygen on fracture healing in rabbits, completed 2003. J Wright

Returning Athletes to Competition

These kinds of injuries are identical to those suffered by workers covered under state workers compensation.

- **U.S. Olympic Team**
  - Treated at San Diego IHMF-NBIRR site
  - Sports injuries
  - Concussions
  - Summer & Winter sports
- **U.S. Navy SEALs & SOCOM Members**
  - Treated for fractures
  - Treated for knee replacement
  - Treated for TBI and PTSD

People who say "it cannot be done" should not interrupt those who are "doing it."

-Aaron Bennett-

PATRIOT CLINICS