30 YEARS OF PROGRESS/CRYSTAL BALL: WHAT DOES THE FUTURE LOOK LIKE?

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Cambridge, MA

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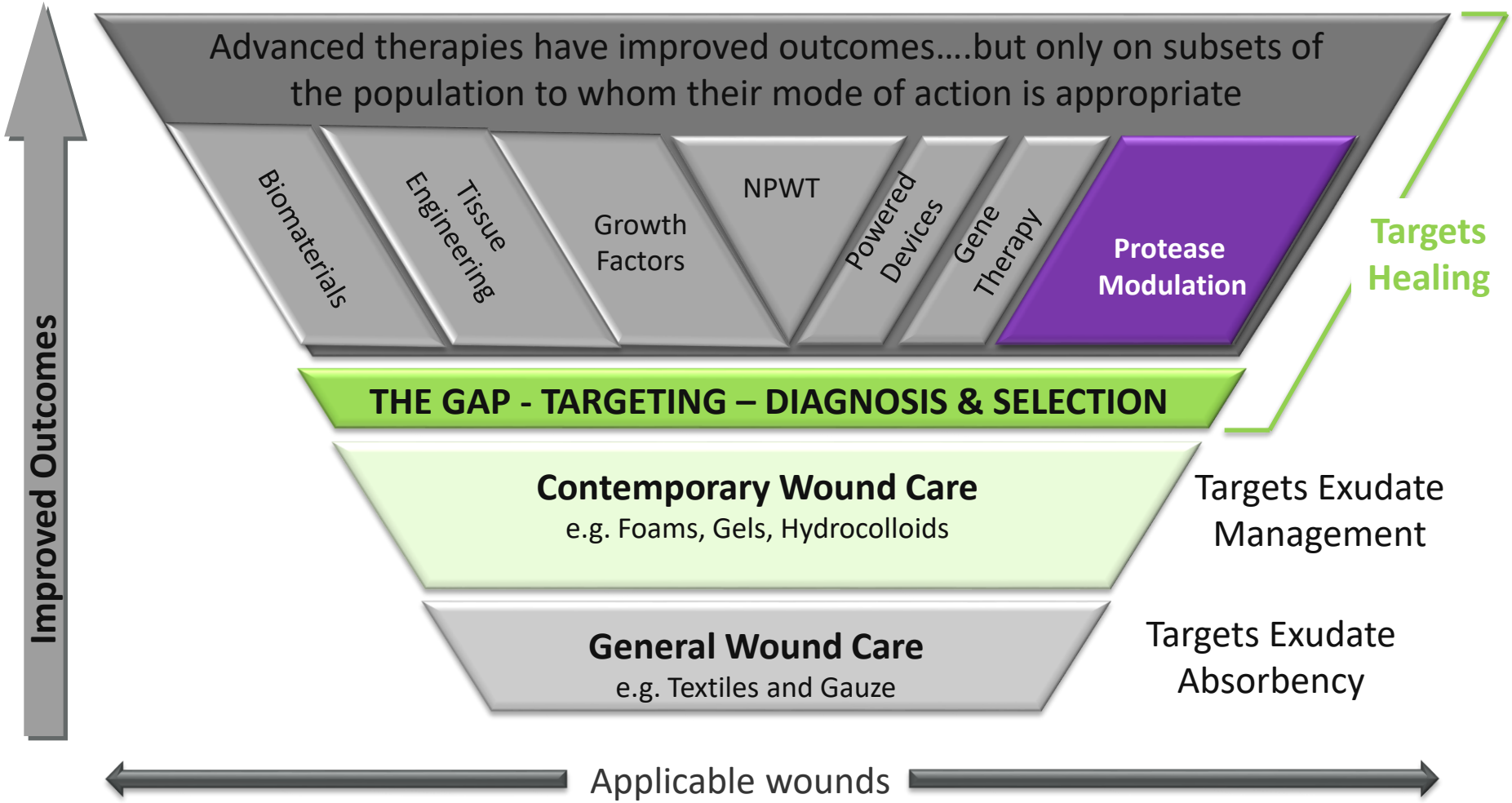
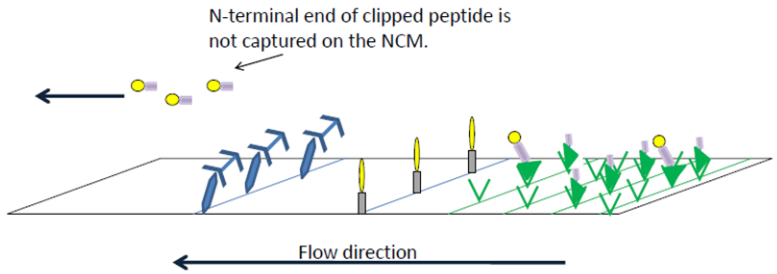
SerenaGroup R&D innovation

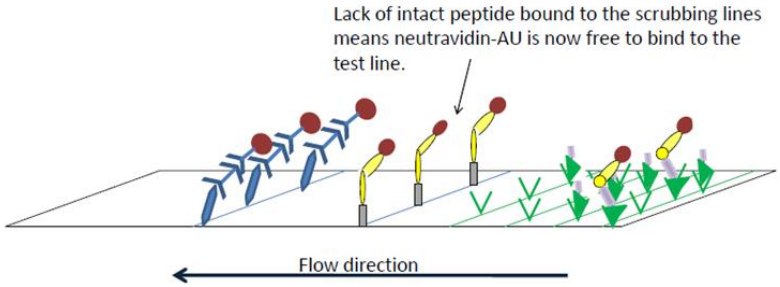
SerenaGroup
building the nation's leading wound care team.

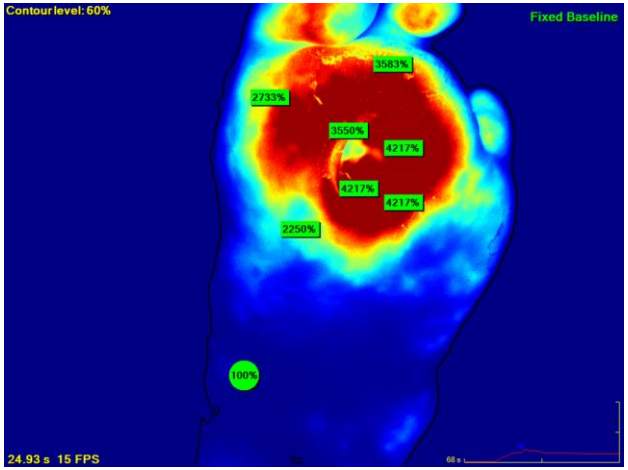
Diagnostics/Theranostics –Filling the Gap



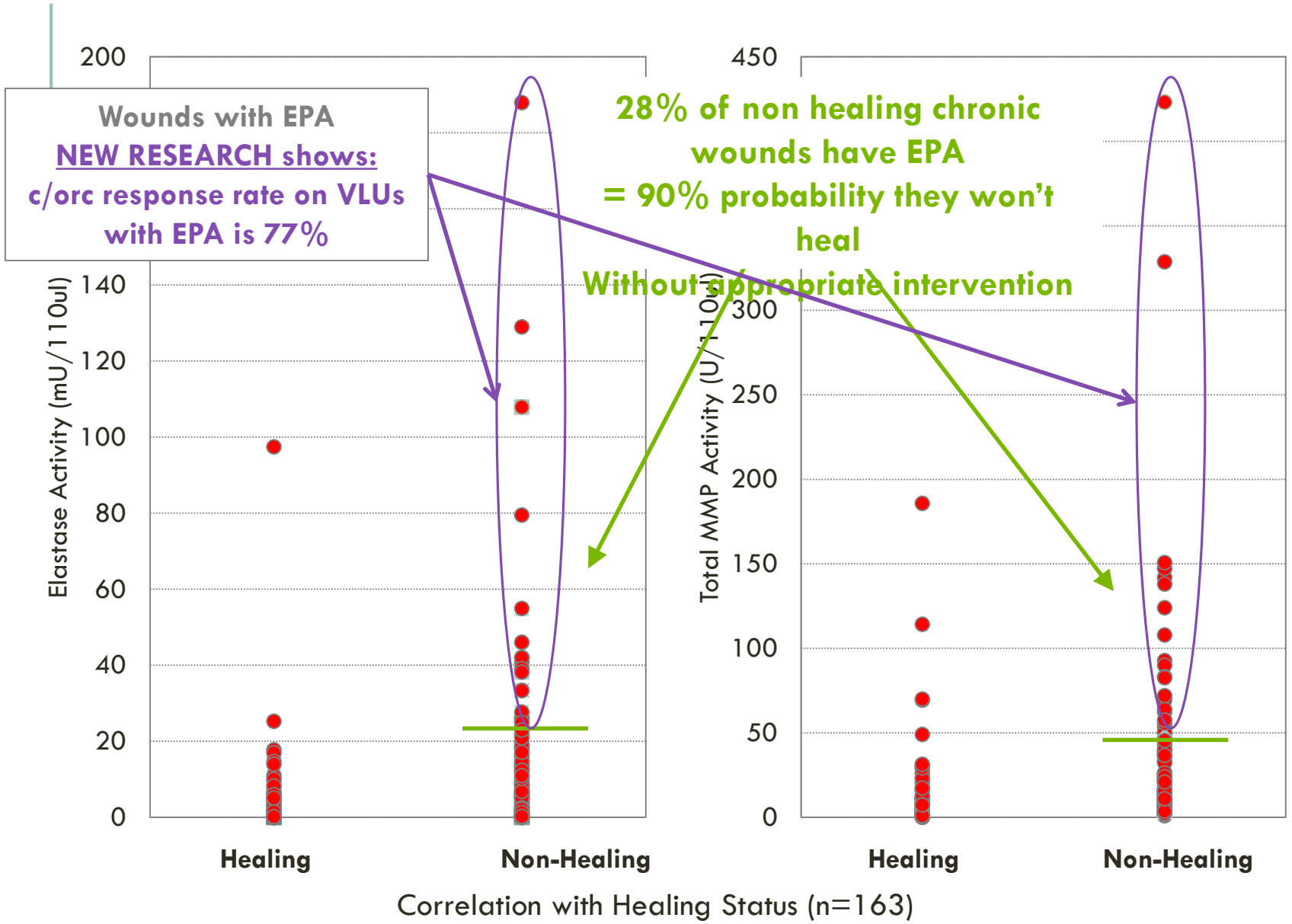
DIAGNOSTICS:







28%/90% RULE FOR ELEVATED PROTEASE ACTIVITY (EPA)

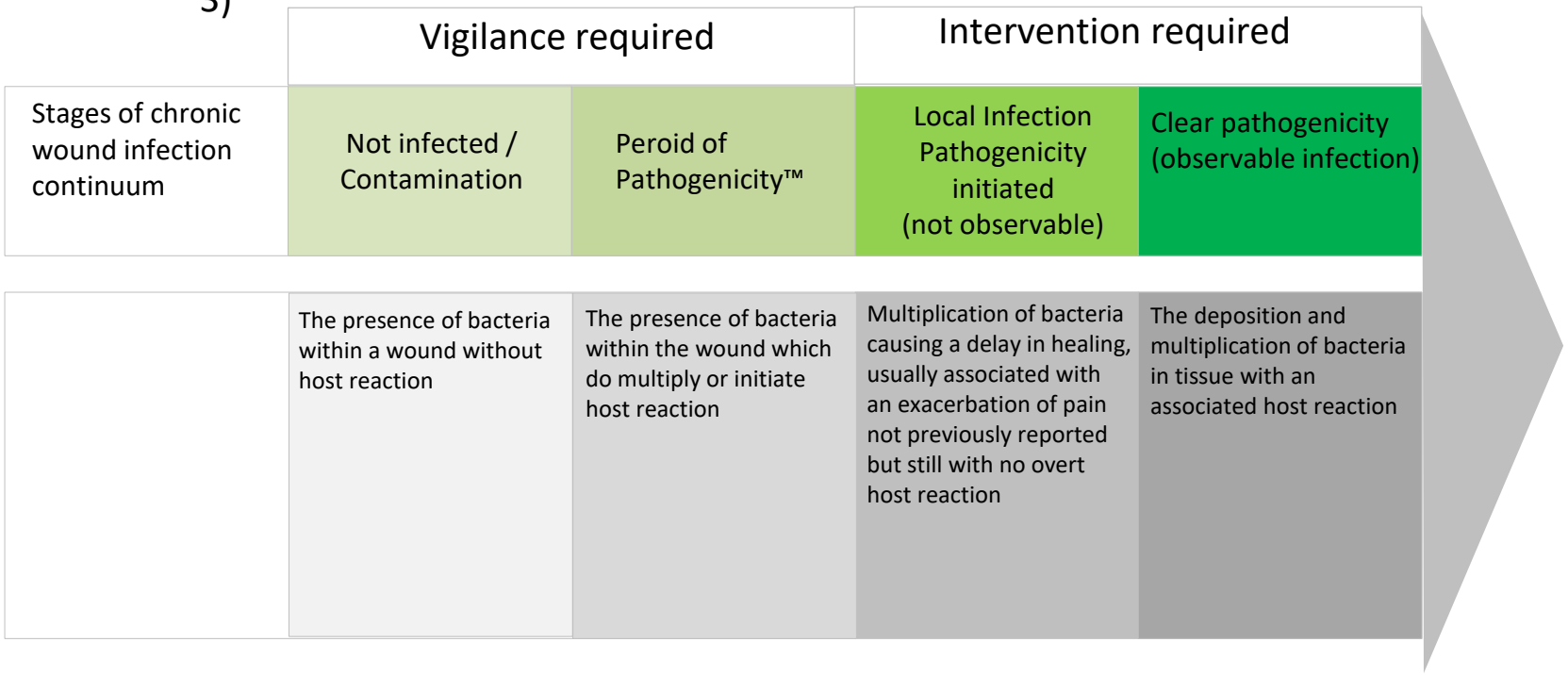


Serena T. et al. Protease activity levels associated with healing status of chronic wounds. Poster, Wounds UK 2011.

POC Test #2: Bacterial Protease Activity (BPA)

Effectively identifying wounds that are in a '**period of pathogenicity™**' and are infected or are becoming infected and would benefit from appropriate intervention is clinically challenging.

The Chronic Wound Infection Continuum (adapted from ref. 2 & 3)



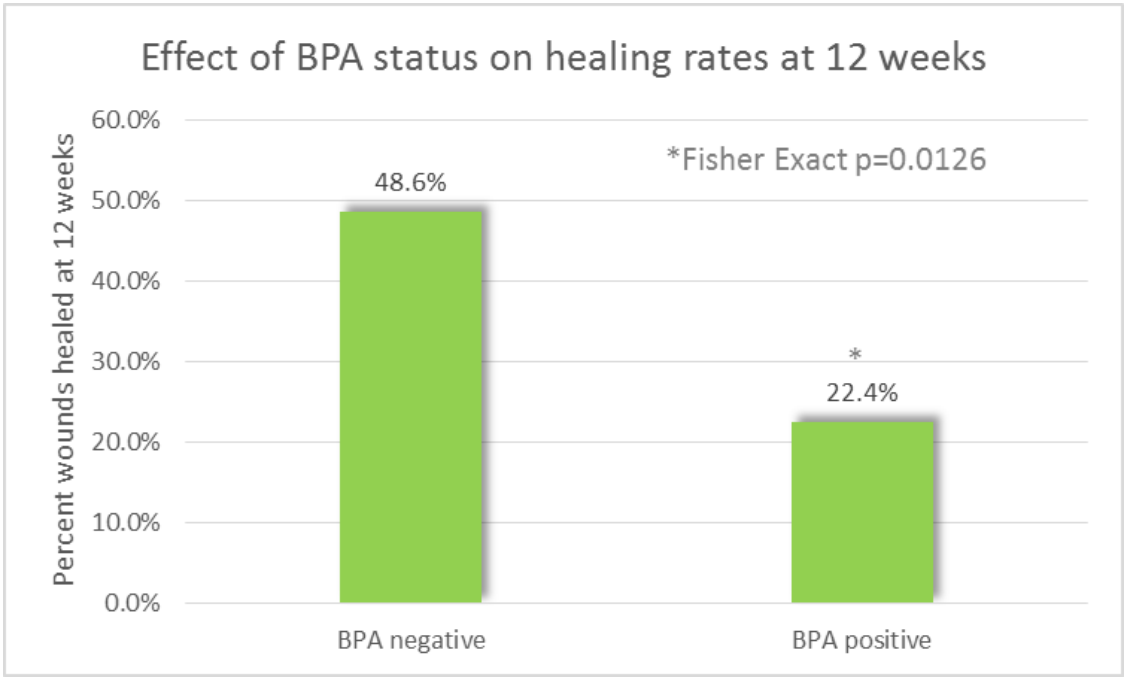
2. Wound Infection in Clinical Practice: An international consensus. *International Wound Journal* 2008; 5 (3): 1-11.

3. Collier M. Recognition and management of wound infections. *World Wide Wounds* 2004.

INTERIM ANALYSIS OF A CLINICAL STUDY TO EVALUATE THE EFFECT OF BPA STATUS ON 12 WEEK HEALING RATE

n=[xxx] wounds at 7 US Wound Clinic trial sites. Includes pre-FDA clinical trial data plus [xx%] of completed 510(k) clinical trial data:

[48.6%] [(17/35)] of the wounds that reported WOUNDCHEK™ Bacterial Status* negative tests had healed as opposed to only [22.4% (15/67)] of the wounds reporting positive WOUNDCHEK™ Bacterial Status* tests.



***Product in Clinical Trial**

WOUNDCHEK LABORATORIES

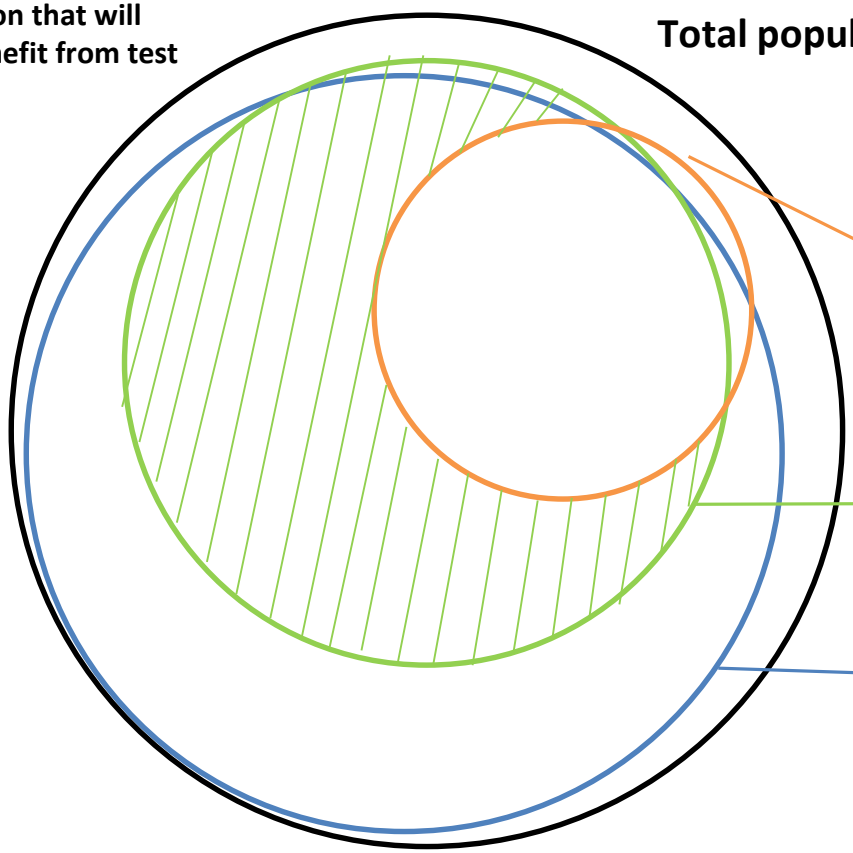
Bacterial Status in chronic wounds

Development of Test:

Clinical research data to support test concept : BPA = bacterial protease activity

Population that will most benefit from test

Chronic wounds showing <3 NERDS, i.e. not clinically assessed as infected, that are BPA positive, would most benefit from the test and pro-active treatment to address bacterial pathogenesis



Benson R. et al, Bacterial protease activity, an indicator of bacterial pathogenicity in chronic wounds even in the absence of overt clinical signs, Wounds UK, Harrogate, 2013

CASE STUDY #1 – DIABETIC FOOT ULCER, RIGHT PLANTAR

Week 0 :

- No clinical signs of infection
- **Positive for BPA**
- Treatment : Mepilex & Mepitel

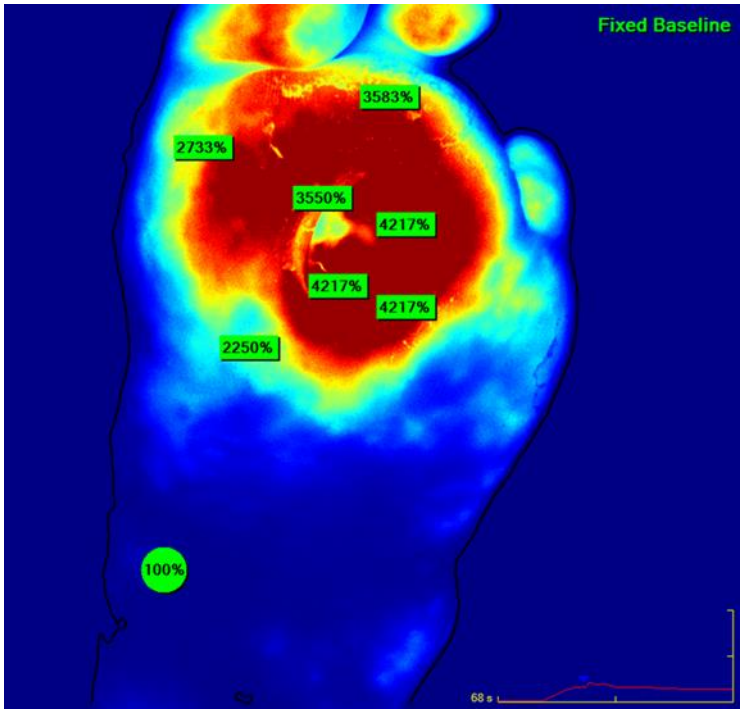
Week 4 :

- No clinical signs of infection
- **Positive for BPA**
- Treatment : Aquacel

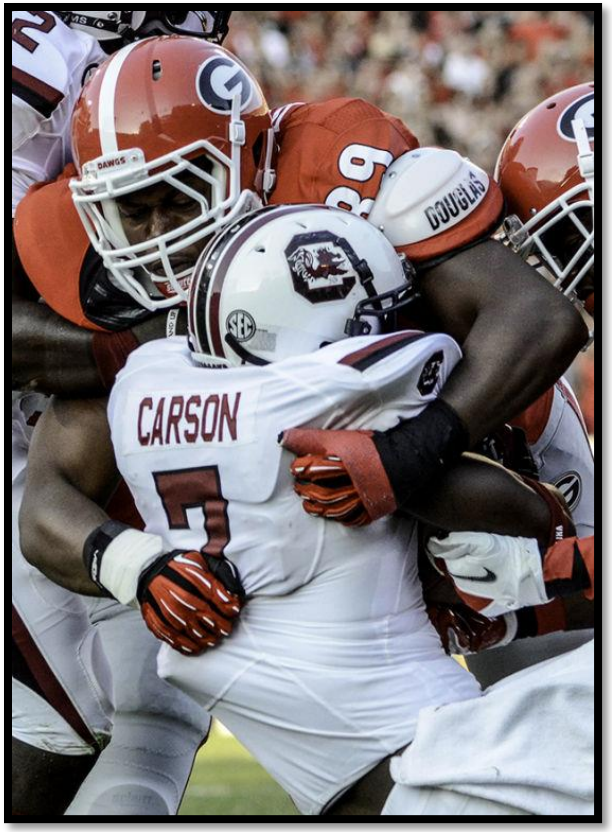
Week 5 :

- Patient bed ridden with chills and pains
- Foot swollen and increased odour
- Third digit is purple and 9x8cm area of redness on dorsal foot
- Patient referred to surgery for amputation

DIAGNOSTICS IN HYPERBARIC MEDICINE



STUDENT ATHLETES : TRAUMATIC BRAIN INJURY



COOPERATIVE GROUP BOOK OF RCTS IN HBOT.

Indocyanine Fluorescent Angiography (LUNA) vs Standard care for selecting patients with diabetic foot ulcers for hyperbaric oxygen therapy.

HBOT vs standard wound care in patients with ischemic tissue loss after indirect revascularization.

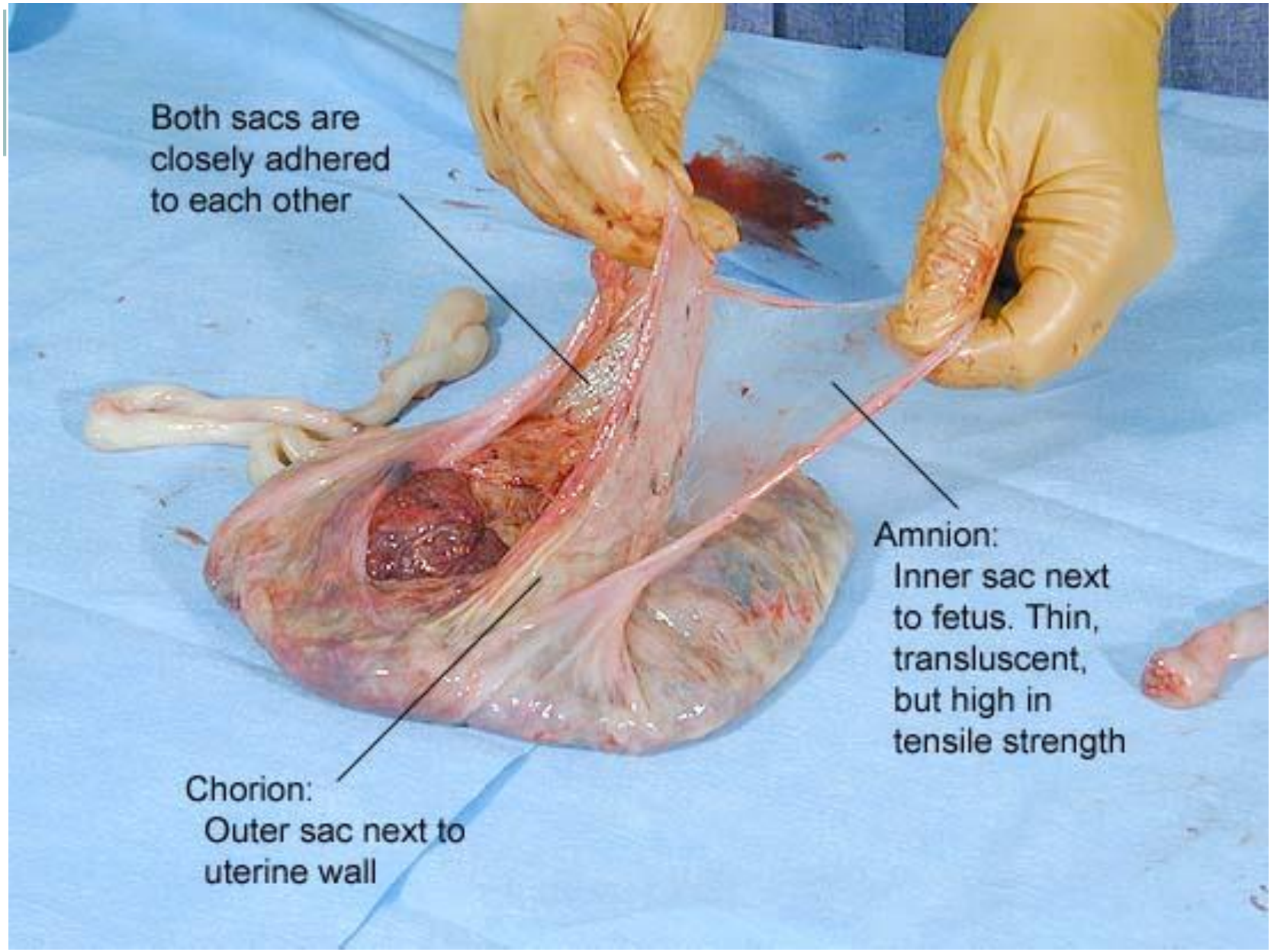
HBOT pre and post surgery vs standard surgical intervention without HBOT in nipple sparing mastectomy procedures.

HBOT and SOC vs SOC in patients with interstitial cystitis.

HBOT in the treatment of patients with the erectile dysfunction secondary to late effects of radiation therapy.

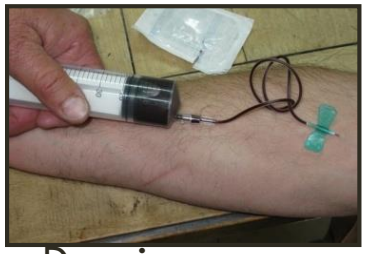
HBOT in the treatment of Traumatic Brain Injury in Student Athletes

HBOT vs Standard of care in the Treatment of Patients with Autism Spectrum Disorder


Both sacs are closely adhered to each other
Amnion:
Inner sac next to fetus. Thin, transluscent, but high in tensile strength
Chorion:
Outer sac next to uterine wall

A NEW SOURCE OF AMNIOTIC MEMBRANE

RESEARCH AROUND THE WORLD



Drawing

Mixing

Clotting

Placing

Dressing

AUTOLOGOUS TISSUE

NUTRITIONAL RESEARCH: ORAL AND PARENTERAL

Provide sufficient calories

- 30 – 35 kcal/kg body weight for individuals under stress (e.g. pressure ulcers)
- More may be required if they are underweight.

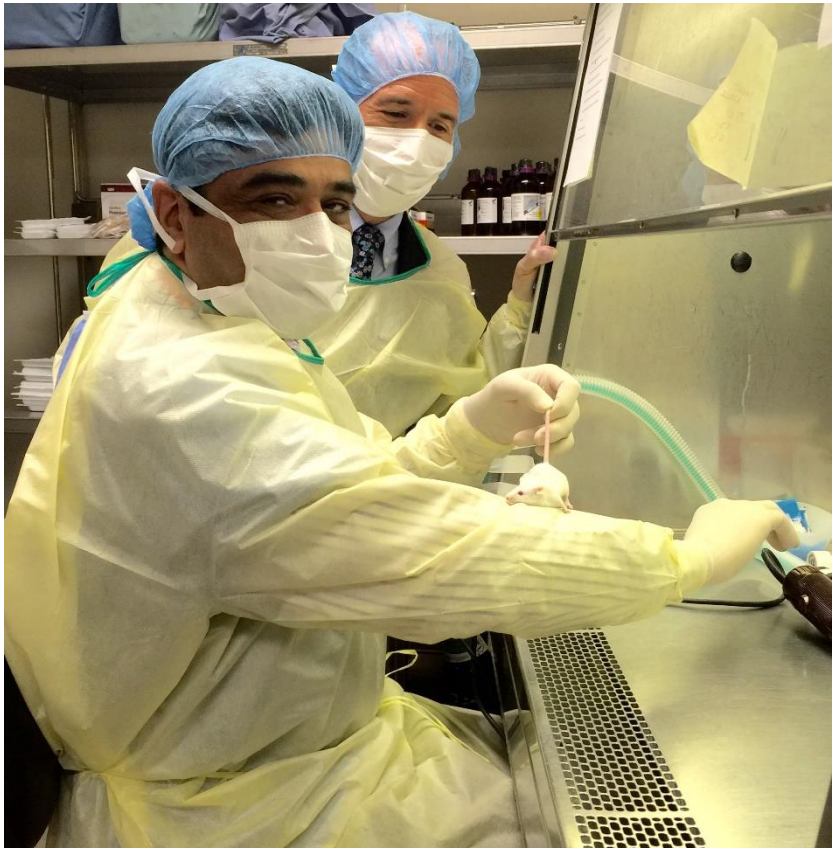
Provide adequate protein for positive nitrogen balance

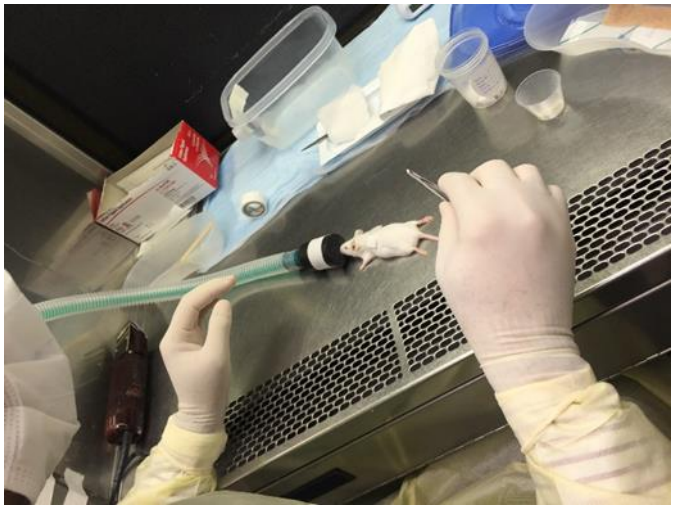
- 1.25 – 1.5 grams protein/kg body weight
- Caution with renal insufficiency

INTERACTIVE LEARNING SYSTEM: Wound Care Quality Measures

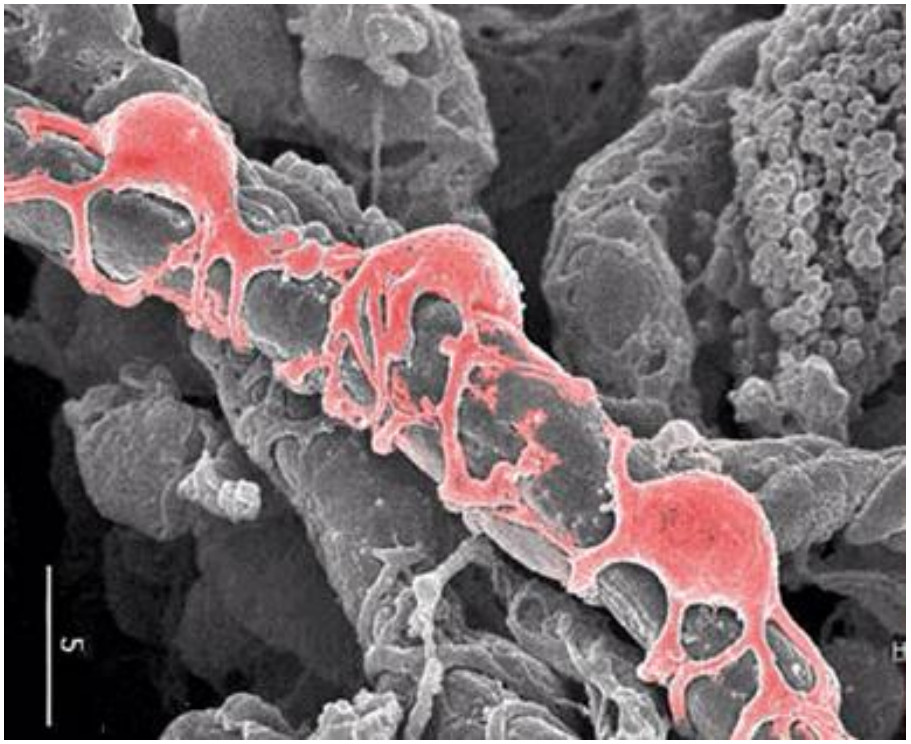
Measure Type	Domain	Measure Description
Process	Effective Clinical Care	Adequate Off-loading of DFU at Each Visit
Outcome	Effective Clinical Care	DFU Healing or Closure
Process	Effective Clinical Care	Comprehensive Diabetic Foot Examination
Process	Effective Clinical Care	Adequate Compression at Each Visit for Patients with VLU
Outcome	Effective Clinical Care	VLU Healing or Closure
Process	Care Coordination	Plan of Care for VLU not Achieving 30% Closure at 4 Weeks
Process	Effective Clinical Care	Appropriate Use of HBOT for Patients with DFU
Process	Effective Clinical Care	Appropriate Use of Cellular or Tissue Based Products for Patients Aged 18 Years or Older with a DFU or VLU
Process	Effective Clinical Care	Vascular Assessment of Patients with Chronic Leg Ulcers
Process	Effective Clinical Care	Wound Bed Preparation Through Debridement of Necrotic or Non-Viable Tissue
Outcome	Patient Engagement	Wound Related Quality of Life
Outcome	Effective Clinical Care	Hemoglobin A1c Poor Control
Process	Effective Clinical Care	Diabetic Foot and Ankle Care, Peripheral Neuropathy Evaluation
Process	Patient Safety	Documentation of Current Medications
Process	Community Population Health	Tobacco Use: Screening and Cessation Intervention

TRANSLATIONAL RESEARCH: ONLY THE BEGINNING

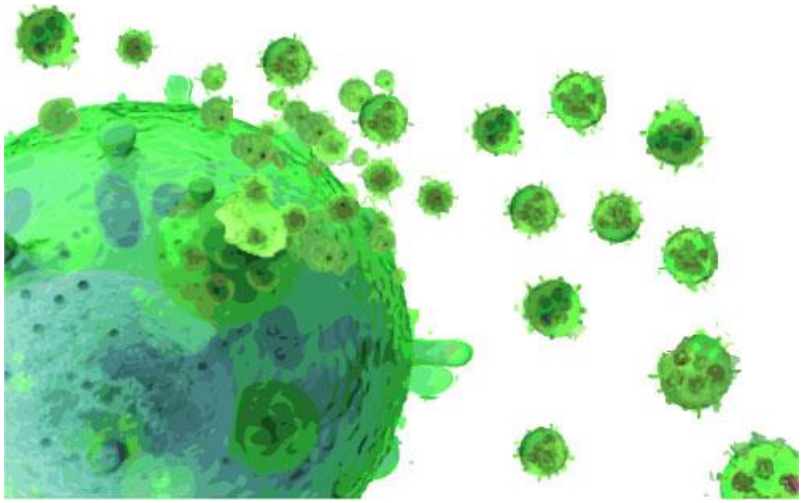




MECHANISM OF ACTION TRIALS: STEM CELLS



PERICYTES



EXOSOMES