Goals & Objectives

Goals:
1. To provide a description of state-of-art testing and a proven pathway to ensure the most efficacious wound treatment regimen.
2. To explain the impact on the cost of wound healing related to the speed and accuracy of identifying wound etiologies.
3. To provide a description of the various advanced therapies that reduce costs by promoting faster wound healing rates compared to traditional methods.

Objectives:
1. The participant will list the current wound healing strategies that reduce costs in a comprehensive wound healing center.
2. The participant will list outcomes that are linked to cost-effective wound care.
3. The participant will understand the importance of accurate identification of wound etiologies related to healing.
4. The participant will list and describe the key diagnostic screening studies used to identify wound etiologies.
5. The participant will list and describe the major advanced wound therapies used in wound healing including negative pressure therapy, growth factors, biological skin replacements, skin grafts and flaps, advanced dressings, and hyperbaric oxygen therapy.
Wound care is costly!
Treating chronic wounds costs the US healthcare system over $25 billion annually!
- Pressure ulcer treatment: $11 billion per year
- Venous leg ulcers: $2.5-3.6 billion per year
- Diabetes-related limb amputations: >$3 billion/year

Impact of Wound Complications
- Uncomplicated wound: up $8,000 to heal
- Infected diabetic ulcer: up to $17,000
  - Uninfected ulcer treatment $775/month
  - >$2000 per month for cellulitis
  - >$4000 per month for osteomyelitis

Amputation: as high as $45,000!
- At 5 years post-lower extremity amputations:
  - 27% chance that the patient will die
  - 28-50% chance of contralateral amputation
- Skin disorders account for $39 billion of lost wages and medical care involving 65 million Americans

Considering Cost Effective Outcomes
Considerations beyond the per visit/per treatment
- Total cost per episode of care
- Total cost per outcome

Faster healing = less cost and lower incidence of complications regardless of the method of evaluation
Decreased complications = lower cost per episode

Cost effectiveness refers to the cost of achieving a desired outcome of treatment!
Measures of Cost

- **Direct costs:**
  - Hospitalizations, doctors, medication, nursing care, dressings and supplies

- **Indirect costs:**
  - Lost work and lost productivity

- **Intangible costs:**
  - Pain, lost companionship, secondary depression and suffering

Effectiveness Measures in Chronic Wound Healing

- **Expedited healing**
  - Sixteen weeks or less

- **Decreased job time lost**
  - 2 million working days lost per year due to venous ulcers

- **Decreased hospitalizations**
  - Faster healing reduces the opportunity for complications and hospitalizations

- **Decreased recurrence rate**
  - 66% recurrence rate in diabetic foot ulcers

- **Decreased amputation rate**
  - Comprehensive foot care programs can reduce amputation rates by 45% to 85%

Cost Effectiveness: THE BIG PICTURE

Cost effectiveness refers to the cost of achieving a desired outcome of treatment

Krasner, D, Rodeheaver, G, Sibbald, G (2007)
Chronic wound care: A clinical source book for healthcare professionals
Diabetes Facts

Diabetes Prevalence:
- There are 20.8 million diabetics in the United States
  - 7% of the population
- Only 14.6 million have been diagnosed
  - 6.2 million are not aware they have the disease

Diabetes and Amputations:
- 12% - 24% of individuals with a foot ulcer will require amputation
- More than 60% of nontraumatic lower-limb amputations occur among people with diabetes
- The rate of amputation for people with diabetes is 10 times higher than for people without diabetes

Diabetes and Peripheral Arterial Disease (PAD)
- Diabetes Mellitus increases the risk of lower extremity PAD up to 4-fold
- One in three patients with diabetes over the age of 50 has PAD
- Those with PAD should be screened for Coronary Artery Disease (CAD)
- The American Diabetes Association recommends screening for PAD in all diabetic patients older than 50 years

Varying Degrees of Diabetic Foot Ulcers

Cost-Effectiveness:
Many impacting factors to consider

- Speed of debridement
- Prevention of infection
- Speed of re-epithelialization
- Speed of return to full function
- Absence of scarring
- Quality of life
- Pain reduction and/or relief
- Periods of necessary hospitalization
- Prevention of recurrence
Wound Costs: Outpatient Wound Healing Center

- Visits include comprehensive evaluation & diagnostics, treatments, care management and/or coordination
- Costs may include diagnostic testing:
  - Non-invasive preliminary studies
  - Indicated invasive tests
- State-of-the-art advanced therapies
- Other aggressive modalities as indicated

Case Management Approach

Cost effective strategies include the use of a multidisciplinary team, as data supports the influence of the team approach in achieving cost effective outcomes.

Krasner, D, Rodeheaver, G, Sibbald, G (2007)
Chronic wound care: A clinical source book for healthcare professionals

Case management approach to care

- Multidisciplinary approach includes many members of the health care team:
  - Primary care/internal medicine
  - Endocrinologist
  - Surgeon
  - Podiatrist
  - Infectious disease
  - Diabetes educators
  - Dieticians
  - Physical/occupational therapists
  - Social workers
- The Wound Center case manager coordinates a centralized approach toward positive patient outcomes:
  - Diagnostic tests to uncover etiology and underlying conditions
  - Drugs, supplies and durable medical equipment
  - Surgical interventions only when indicated
Service offerings in order of clinical advances

- Simple dressings
- Debridement
- Non-invasive diagnostics
- Invasive diagnostic procedures
- Antibiotic therapy
- Advanced Treatment Modalities
  - HBOT
  - NPWT
  - Bio-engineered Tissue
  - Growth Factors
- Surgical intervention

Timing of Advanced Therapies

- Any wound that remains unhealed after 4 weeks is cause for concern, as it is associated with worse outcomes, including amputations
  (1999 - ADA Consensus Development Conference on DFU care)
- Patients in whom ulcer size fails to reduce by half over the first 4 weeks of treatment are unlikely to achieve wound healing over a reasonable period
  (2003 - Peter Stenvik, MD and Colleagues)
- The failure to reduce the size of an ulcer after 4 weeks of treatment that includes appropriate debridement and pressure reduction should prompt consideration of adjuvant therapy
  (2004 - Andrew J.M. Boulton and Colleagues)
- Arguably, the use of an active therapy such as a bio-engineered skin substitute to stimulate healing in non-responding wounds after 4 weeks' treatment is the optimal care in 2007
  (2007 - David G. Armstrong, DPM, PhD and Colleagues)

Clinical pathway and process in a wound clinic

- Correct diagnosis
- Accurate and specific diagnostic tests
- Treatment specific to the patient indicators
- Appropriate use of advanced therapies
- Judicious use of costly therapies
Evidenced - Based Medicine

- Evidence-based medicine is the integration of best practices and research balanced with the clinical expertise and patient values
- Use of an evidence-based clinical pathway will expedite cost effective wound healing
- Combining evidence-based medicine along with cost effective strategies provides for the best medical treatment in wound care today

First: Correct Diagnosis

Goal: To quickly and accurately diagnose the underlying impediments to wound healing

- An arterial wound misdiagnosed as a venous wound can greatly increase costs and limb loss
- Many wounds have mixed etiologies
- Wound cells can convert to malignant cells

Accurate & Specific Diagnostics

- Diagnostic studies to confirm etiology and diagnosis
- Screening studies to identify co-morbid factors delaying healing
- Determining specific wound etiology drives treatment decisions
- Multi-disciplinary approach promotes holistic management
Screening Studies

- Essential parts of a thorough lower extremity assessment
  - Handheld Doppler
  - Semmes-Weinstein Monofilament
  - Tuning Fork
- Including these tools may lead to identification of factors contributing to wound healing failure

Handheld Doppler

Every patient with a lower extremity wound should receive a hand-held doppler assessment
...even if pulses can be palpated!
- Assesses macrocirculation
- Used to auscultate flow velocity

Semmes-Weinstein Monofilament

- Uses touch pressure sensation by utilizing a 10 gram monofilament
- Defines level of loss-of-protective sensation
- Failed monofilament test defined as inability to sense 4 of 10 locations per plantar aspect of the foot
**Tuning Fork**

- **Function**
  - Assesses vibratory sensation to assess large nerve fibers function
  - Uses 128 Hz fork
  - Important to test bony prominences of the foot
  - Simple to do
  - Impaired vibratory sensation affects 10 – 42% of patients with diabetes

**Assessment: Beyond the baseline**

- Based on the initial assessment and screening studies, additional non-invasive studies may be needed to further evaluate and/or diagnose contributing factors to wound healing failure
- Critical to rule out arterial disease for any patient with a lower extremity ulcer
- American Diabetes Association suggest all patients 50 years old or greater with DM be evaluated for peripheral arterial disease

**Noninvasive Diagnostic Studies**

- **Ankle-Brachial Index (ABI)/Segmental Pressures/Toe Pressures** - Assess pressure at multiple levels on the limb or digit
- **Pulse Volume Recordings** - Demonstrate the volume of change in the limb with each pulse beat
- **Waveforms** - Demonstrate blood flow patterns
- **Arterial Ultrasound** - Duplex ultrasonography of the arteries. Often used to assess patency post revascularization
- **Transcutaneous Oximetry (TCOM orTcPO2)** - Determines the degree of microvascular/tissue perfusion of an area
**Noninvasive Diagnostic Studies**

- **Skin Perfusion Pressure (SPP)** - measures the pressure at which blood flow first returns to the capillaries following a controlled release of occlusion from a blood pressure cuff
- **Venous Duplex Doppler** – color flow Doppler imaging of the veins. Used to determine level of compression, safe use of compression, and need for surgical intervention
- **Radiographic/Imaging Studies** – used to assess for foreign bodies, bony deformities and osteomyelitis
  - **MRI** - recommended by ADA as best non-invasive diagnostic imaging for osteomyelitis

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**Skin Perfusion Pressure: Cost Savings Using Studies**

- **SPP** – can be used to identify safe application of compression therapy
  - Safely applied = decrease edema without significant arterial flow compromise
  - Inappropriate application = compromised arterial flow → complications in healing and/or amputation → increased costs

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**Transcutaneous Oxygen Measurement: Cost Savings Using Studies**

- **TcPO2** – can be used to identify response to oxygen evaluating potential response to hyperbaric oxygen therapy
  - Patients with a response = therapeutic use of Hyperbaric Oxygen Therapy → cost effective use of advanced therapy
  - Patients without a response = no therapeutic effects of Hyperbaric Oxygen Therapy → increased cost of care without therapeutic benefit
Venous Duplex Imaging: Cost Savings Using Studies

Venous duplex imaging - Often used to assess for Deep Vein Thrombosis (DVT)
- Can also be used to identify reflux in deep, superficial and perforating veins
- Reflux may be corrected surgically in some cases
- Surgical correction of reflux → decreased recurrence of ulceration and complications related to re-ulceration → improved quality of life → decreased cost of care

Invasive Arterial Studies

- May be needed to further evaluate arterial disease and determine best intervention
- Angiography
  - Examination of the arteries using x-rays or MRI with/without contrast
  - Assesses structure and physiologic function of the arteries

Up to 60% of people with diabetes have arterial insufficiency!
At $38,077 per amputation procedure, diabetes-related amputations total approximately three billion dollars per year!

Laboratory Data

- Labs:
  - Nutrition panel
    - assess for potential delayed healing related malnutrition
  - Serum studies
    - assess for underlying disease processes
  - Blood sugar studies – HgA1C
    - assess control and undiagnosed disease
  - Cultures & biopsies
    - assess infection and pathology
Diagnostic Challenges

- Availability of equipment and technicians
- Authorization from insurance
- Patient’s availability and transportation
- Delays in diagnostic work-up lead to increased costs

Second: Disease Management

- Correction or optimization of underlying factors
- Multidisciplinary team – holistic approach
- Until underlying issues corrected or optimized, passive/inexpensive dressing are often used
- Goal:
  - Manage exudate
  - Minimize complications

Choosing The Right Therapy

- The most expensive therapy is the therapy that does not work
- Advanced therapies are often a better clinical and economical choice when wounds are unresponsive to conventional therapy
- Healing more wounds and healing them faster avoids expensive complications
Choosing the Right Therapy

- Numerous advanced therapies available
- Clinical evidence supporting effectiveness may or may not be present
- More and more established therapies are gathering data on cost effectiveness

Advanced Therapies: Sharp Debridement

- Serial wound bed preparation removes senescent cells, necrotic tissue and biofilm.
- Debridement converts a chronic wound to an acute wound, re-initiates healing cascade.
- Biofilm protects bacteria from antibiotic therapy; cutaneous wounds lend themselves to infection by methicillin-resistant Staphylococcus aureus (MRSA)
- Centers that utilize sharp debridement exhibit the highest degree of healing.

Advanced Therapies: Sharp Debridement

- Percentage of Office Visits Where Debridement Was Performed

1. REGAINEX Gel 0.30% Placebo Gel
2. Percentage of Wound Closure
3. Percentage of Office Visits Where Debridement Was Performed

- REGAINEX Gel 0.30%
- Placebo Gel

* p < 0.05 compared to placebo

* The results indicate that the difference in wound closure was statistically significant:

- 100% vs. 0% for placebo gel

* Data courtesy of Johnson and Johnson
Advanced Therapies: Sharp Debridement

Progression of Granulation

Day 1

Day 3

Advanced Therapies: Surgical Debridement

Benefits: expedites healing, treats infection

- Preferred method of debridement when topical or local anesthesia can not control the discomfort of debridement.

- More aggressive debridement in a surgical suite may include wide excisions and bone removal

Advanced Therapies: Active Dressings

- Advanced dressings can reduce costs up to 50% particularly when you consider the cost of an infection

- Silver products
  - Provides antimicrobial action by poisoning respiratory enzymes, components of electron transport, and impairs some DNA functions of microbes
  - Reduces costs by:
    - Lengthening dressing life by reducing change frequency and reducing bio-burden
**Advanced Therapies: Active Dressings**

- **Collagen type dressings**
  - Collagen is the major component of skin and connective tissue. Studies have shown that collagen-based dressings enhance the deposition of organized collagen fibers characteristic of the remodeling phase of wound healing.
  - Bio-compatible dressings provide collagen to the wound bed to promote healing:
    - Prisma/Promogran (MMP Controllers)
    - Primatrix
    - Fibracol Plus
    - CellerateRX
    - Stimulen

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**ORC/Collagen Dressings: Proven to Reduce Wound Surface Area**

- 12-week randomized, controlled, multi-centered trial in 73 patients with venous leg ulcers
- **Treatment Protocol**
  - Promogran Matrix plus Adaptic Dressing vs Adaptic Dressing alone with compression
- **Outcomes**
  - Complete Healing: 41% vs 31%
  - Surface Area Reduction: 54.4% vs 36.5%


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**Advanced Therapies: NPWT**

- **Negative Pressure Wound Therapy**
  - Applies sub-atmospheric pressure topically which causes mechanical stress to the cells which can enhance cellular proliferation and neo-angiogenesis
  - Decreases edema
  - Increases local blood flow
  - Removes infectious/noxious material/fluid
  - Enhances granulation tissue formation
  - Cost: studies support healing and costs decrease by half compared to basic wound care
Advanced Therapies: Becaplermin

- **Growth Factors**
  - Topical application of exogenous growth factor promotes chemotaxis and cell proliferation, and enhances granulation tissue formation
  - Cost: evidence demonstrates expedited healing and decreased costs in conjunction with proper off-loading, serial debridement, infection and glucose control, and a moist wound bed

Advanced Therapies: Grafts and Flaps

- **Grafts & Flaps**
  - Applying skin to healthy prepped wound beds to expedite healing
    - **Xenografts**
      - Animals
    - **Allograft**
      - Engineered, cultured human skin, cadaver
    - **Autografts & flaps**
      - Patient’s own skin – split-thickness, full-thickness, composite, pinch, pedicle, free
**Advanced Therapies: SIS Technology**

- Engineered from the inner layer of porcine intestine (Small Intestine Submucosa = SIS)
- Re-hydrated and used to cover the wound bed
- Provides a matrix over which granulation can migrate
- Oasis studies support wounds heal approx. 25 – 50% faster than local wound care alone

*Demling, 2004*

**Advanced Therapies: Apligraf**

- Bilayered bioengineered tissue substitute
- Indication = diabetic and venous wounds
- Easily applied in the clinic setting
- Apligraf plus local wound care = a 12% reduction in costs over the first year of treatment compared with local wound care alone

*Redekop, 2003*

**Advanced Therapies: Autograft/Flap**

- **Autograft**
  - Can be meshed to cover large defects
  - May be a consideration for those with cultural/religious beliefs in conflict with bioengineered tissue use
- **Flap** – reserved for extensively damaged areas
  - Instantly applies full-thickness skin and structures to fill a defect
  - Effectively heals faster and provides coverage which also reduces the incidence of infection and pain
Hyperbaric Oxygen Therapy (HBOT)

HBOT Indications

• Osteomyelitis
• Osteoradionecrosis
• Soft tissue radionecrosis
• Crush injuries
• Failed flaps or grafts
• Gas gangrene
• Necrotizing soft tissue infections
• Carbon monoxide poisoning
• Air or gas embolism
• Decompression sickness
• Clinical studies indicate reduced lower extremity amputation rates in diabetic foot ulcers1
• Total costs are reduced with HBOT for Osteoradionecrosis2

HBOT is Cost Effective for ORN

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Number of patients</th>
<th>Average one year costs</th>
<th>Average total costs</th>
<th>Resolution rate</th>
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<td>NON HBOT</td>
<td>116</td>
<td>$47,000</td>
<td>$162,000</td>
<td>10%</td>
</tr>
<tr>
<td>HBOT w/o Surgery</td>
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<td>$40,000</td>
<td>$83,000</td>
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<td>MARX-UM Protocol</td>
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<td>100%</td>
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<td>MARX-UM Protocol used in Private practice</td>
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<td>$45,000</td>
<td>$45,000</td>
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</tbody>
</table>

UM = University of Miami
Cost Analysis of 300 cases of Osteoradionecrosis in US dollars (Jan. 1, 1992)
Summary

By following an evidence based clinical pathway, that focuses on the correct diagnosis, and utilizes state-of-the-art dressings and treatment modalities favorable wound outcomes will be acquired in a cost effective manner.

References


