The Georgetown Team Approach to Diabetic Limb Salvage: 2013

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Disclosures:

None
Need a TEAM…?

- Rapid assessment
- Simultaneous approach
- Give patient and family Reassurance and Confidence
- Effectively engage advanced therapeutics
- Practice Evidence Based Medicine
Limb Salvage Team

Goals of Concept

• Raise awareness of limb salvage
• Increase Options
  – Diabetes
  – Renal Disease
  – Venous disease
• Become a referral source for the community
• Improve financial viability
  – Streamline care
  – > 50% of patients are Medicare
  – Decrease the “steps” required for access
  – Limb salvage less expensive than amputation?
“Reducing amputation rates in patients with diabetes at a military medical center: the limb preservation service model.”


• RESULTS:
  – Diabetes increased 48% from 1999 to 2003
  – LEAs decreased 82% from 1999 to 2003
  – Amputations of the foot, ankle, and toe comprise 71% of amputations among patients with diabetes
Change in the amputation profile in diabetic foot in a tertiary reference center: efficacy of team working.


Overall amputation rate was 39.4% before team vs. 36.7% after team established

- Data suggest that amputation is still a frequently encountered outcome
- Amputation profile changed to distal
- The implementation of a diabetic foot care team has decreased the rate of major amputations
Cost of Diabetic Foot Ulcers

- Average $27,721 US
- Average cost 4 x higher with PAD
- 9 to 20% Require Hospitalization
- Major Cost is Inpatient Care
  - 74 to 84% of total costs
- Patients hospitalized with diabetes are 28 x more likely to have an amputation than patients without diabetes
- 2/3 of all amputations are paid for by Medicare

Wound Care Market?

- $10 billion Worldwide Market for Products and Services
- 5 to 7 million Projected Annual Wounds
- Market Growth ~5% Annually
Coming events cast their shadows before... 

Thomas Campbell
Epidemiology of Amputation

- >60% of all amputations involve diabetes in US
- 9-20% of ulcerations end in amputation
- ~84% of lower extremity amputations are preceded by ulceration


Pathways to Ulcers and Amputations in the Diabetic Foot

- Callus/Trauma
- High Foot Pressures/LJM Neuropathy
- Vascular Disease
- Ulceration
- Failure to Heal
- Amputation
- Infection
Reported Risk Factors For Ulceration

- Peripheral neuropathy
- Vascular disease
- Limited joint mobility
- Foot deformity
- Abnormal foot pressure
- History of ulceration or amputation
- Impaired visual acuity
Peripheral Sensory Neuropathy

- Importance of neurologic evaluation
- Strong risk factor easily identified
- Offloading and Mechanical Correction
C.R.O.W. Walker
The Problem Wound Microenvironment

• Chronic wound fluid is known to contain:
  – High levels of harmful proteases
  – Low levels of growth factors
  – Significant bioburden

Identify Problem Wounds Early and Transition to Advanced Therapy

• “Good” Wound Care
  – History
  – Assessment
  – Debridement
  – Warm, Moist Environment
  – Offloading
  – Topical Care

• Advanced Wound Care
  – Hyperbaric Medicine
  – Growth Factors
  – Bioengineered Alternative Tissues
  – Negative Pressure Therapy
  – Biologic Dressings
  – Active Topicals
  – Plastic Surgery
  – Curative Surgery

Diabetes Care. 2003 Jun;26(6):1879-82. Percent change in wound area of diabetic foot ulcers over a 4-week period is a robust predictor of complete healing in a 12-week prospective trial. Sheehan P, Jones P, Caselli A, Giurini JM, Vees A.
Cellular and Tissue Based Products for Wounds

Non-Living Tissue Adjuncts (*DermoConductive)*:

- porcine intestinal submucosa
- porcine urinary bladder
- bovine collagen and chondroitin-6-sulfate
- gamma irradiated human allograft skin
- human dermal allograft
- equine pericardium

Living Tissues (*DermoInductive)*:

- living human dermal fibroblasts and epidermal keratinocytes in bovine collagen matrix
- living human dermal fibroblasts cryo-preserved in polyglactin mesh
- amnionoic membrane?
- skin gun?
Advanced Tissue Graft Pivotal Trial: More Effective Than Conventional Therapy

Improved healing outcomes\(^1\)

\[ P = 0.0042 \]

Incidence of complete wound closure after 12 weeks, %

- 38%
- 56%

\({}^1\)The average number of Apligraf applications received per patient during the study period was 3.9 (minimum of 1, maximum of 5). This study was not designed to determine the necessary number of applications to achieve complete wound closure. DFU patients received up to 5 applications over 4 weeks. Apligraf was reapplied if coverage was less than 100%.\(^2\)

Conventional therapy consisted of surgical debridement, saline gauze and total off-loading\(^2\)


Advanced Tissue Graft Pivotal Trial: More Effective Than Compression Therapy in Ulcers >1-year duration

Significant reduction in median time to wound closure (99 days vs. 184 days, respectively) \([P=0.0074]\)^{2,a}

(a) Adjusted time to complete wound closure using the Cox Proportional Hazards Regression Analysis.\(^2\)
Conventional therapy consisted of compression dressing and zinc-impregnated gauze.\(^1\)

Negative Pressure Wound Therapy

- Closed Wound Environment
- Stimulates Angiogenesis
- Efficient Exudate Removal
- Moist Wound Base
- Minimal Disruption of Wound
- ‘Exercise’ Cell Membrane
- Continuous vs. Intermittent
- Re-approximates Skin Edges
- Amputations vs. Ulcers
- Adjunct to grafting and other wound closure techniques
Negative Pressure Wound Therapy after Partial Diabetic Foot Amputation: a multicentre, randomised controlled trial.

- **Study Summary:**
  - 162 patients
    - 16 week study
    - 18 centers in USA
  - **Inclusion Criteria**
    - Partial foot amputation up to TMA
    - Adequate perfusion
  - **Study Arms:**
    - NPWT (n=77) with dressing changes q48h
    - Control (n=85) standard moist dressings
    - Treated to healing or 112 days
Negative Pressure Wound Therapy after Partial Diabetic Foot Amputation: a multicentre, randomised controlled trial.

- **Findings:**
  - More patients healed in the NPWT than control
    - 43 (56%) vs. 33 (39%) with p=0.040
  - Rate of wound healing was faster in NPWT than control
    - Based on time to complete closure with p=0.005
  - Rate of granulation tissue formation was faster in NPWT than control
    - Based on time to 76-100% formation in the wound bed p=0.002
  - Frequency and severity of AE was similar in both treatment groups
  - NPWT patients were less than a fourth as likely as control to need a second amputation
Case Study: CT

- **Patient Information:**
  - 39 y/o male left forefoot ulceration x 11 months

- **Medical History:**
  - Diabetes Type 2 x 7 years
  - Hypercholesterolemia, HTN
  - 1989 Foot injury following lawnmower incident

- **Surgical History:**
  - 1989 Achilles tendon repair

- **Medications:**
  - Cozar, Lipitor Humalog, Lantus

- **Family History:**
  - Diabetes, Stroke

- **Social History:**
  - Denies ETOH and Smoking
Debridement, Tendon Lengthening, and Bioengineered Tissue Application
Georgetown University
Limb Salvage Team

- RN / NP / Resident Team
- Vascular Specialist
- Plastic Surgery
- Podiatric Surgery
- Orthopaedic Surgery
- Infectious Disease
- Endocrinology
- Nephrology
- Rheumatology
- Hospitalist
- Prosthetist / Pedorthotist
- Physical Therapy
- PATIENT

Comprehensive foot care programs reduce amputation rates 45-85%  

2011 National Diabetes Fact Sheet
Centers for Disease Control and Prevention
Prevention of Recurrence?

- Patient Education
- Accommodation of Deformity
- Recognize Etiology
Conclusions