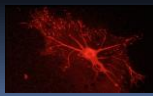


Advanced Care Practices "Off Loading DFU's"

Vickie R. Driver MS, DPM, FACFAS
Professor, Orthopedic Surgery, Brown University,
President, Assoc. for the Advancement of Wound Care, AAWC
Chief, Podiatric Surgery VA Healthcare New England, RI
Director, Research, Wound Healing- RI Hospital
Director, Research Fellowship Program



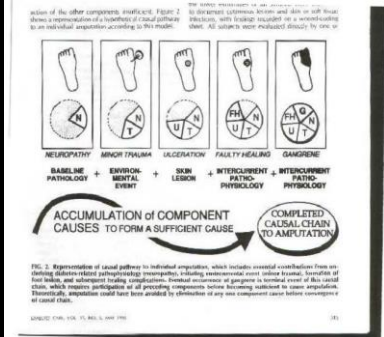
Limb Preservation: Research and Education

Objectives:

- Understand advanced tenants for DFU's, debridement, off loading and advanced therapies.
- New Off-Loading Consensus Guidelines
- TCC, Overwhelming Evidence
- Patient Selection & Tips

Limb Preservation and Education Research

PECORARO: Diabetes Care 1990




ACCUMULATION of COMPONENT CAUSES TO FORM A SUFFICIENT CAUSE

COMPLETED CAUSAL CHAIN TO AMPUTATION

FIG. 2. Representation of causal pathway to individual amputation, which begins several years before onset of diabetes-related pathologic changes, including microvascular vessel disease, formation of foot lesions, and subsequent loading conditions. Several measures or programs to interrupt event of this causal chain, which requires participation of all preceding components before becoming subject to some amputation. Theoretically, amputation could have been avoided by identification of any one component before completion of causal chain.

Advanced Therapy for DFUs : Team Approach



Advanced Therapy for DFUs : Team Approach



- Elliot Joslin, diabetologist
- Founded first hospital based foot care clinic at New England Deaconess Hospital in 1928
- Team approach including foot care, medical nutrition, exercise, prompt treatment of foot infections, specialized surgical care

Advanced Therapy for DFUs : Team Approach

- NE Deaconess Hospital legacy
 - 1940s - Leland McKittrick – TMA
 - 1950s - Frank Wheelock – vascular surgery
 - 1980s – Gary Gibbons, David Campbell, Frank Pomposelli
 - 1990s – Frank Logerfo (1984 NEJM)
 - Extreme distal revascularization (Gibbons 1993)
 - 1990s – Frykberg, Habershaw, Chrzan, Giurini, Rosenblum – podiatry / foot preservation

Advanced Therapy for DFUs : Team Approach

CLINICAL BENEFIT

Reducing Amputation Rates in Patients with Diabetes at a Military Medical Center

- Limb Preservation Service (LPS) – multidisciplinary foot care clinic for diabetics at Madigan Army Medical Center
- Evaluation of program structure and success in reducing lower extremity amputations

Driver et al, DiabetesCare, 2005

Advanced Therapy for DFUs : Team Approach

LPS : Focused care for high risk diabetic feet

- Prevention and education : complete LE exam
- Infection management, Vascular intervention
- Foot surgery- emergent, routine or reconstructive
- Wound care team
- Surgical / hospital management
- Orthotics, prosthetics, specialized shoeing
- Community and regional education

Driver et al, DiabetesCare, 2005

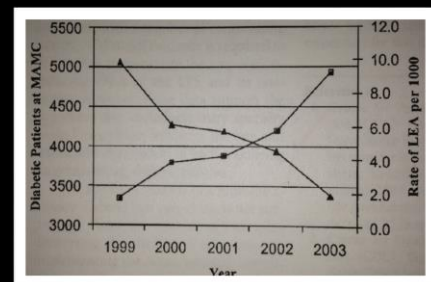
Advanced Therapy for DFUs : Team Approach

LPS : Treatment Principles

- Aggressive treatment of **infection** – surgical
- Diagnose **ischemia** and prompt revascularization
- Relief of **pressure** to wound – offload
- Improve **wound environment** with debridement and advanced care treatments

Driver et al, DiabetesCare, 2005

Advanced Therapy for DFUs : Team Approach



Driver et al, DiabetesCare, 2005

Advanced Therapy for DFUs : Team Approach

LPS Clinical Outcomes – Summary

- 82%** decrease in LE amputations (33→9) despite 48% increase in diabetic patients
- More distal amputations – **71%** foot, ankle or toe
 - Quality of life impact

Driver et al, DiabetesCare, 2005

Advanced Therapy for DFUs : Team Approach

The role of interdisciplinary team approach in the management of the diabetic foot
(Joint Statement from SVS and APMA, JVS 2010)

- Link efficiently and coordinate team of specialists to manage complex comorbidities, in addition to foot pathology
- Leadership role in education, dissemination of information
- Infrastructure to design and implement clinical research trials, develop algorithms for optimal management

Advanced Therapy for DFUs : Team Approach

ECONOMIC BENEFIT

The Costs of Diabetic Foot

- **Magnitude** – 80% LE amputations preceded by ulcer
- **Costs**

Diabetics with LE ulcer 2.4X higher cost of care – more inpt stays and ED visits

- Avg cost/ulcer episode >\$13,000, increased with Wagner grade (2K -> 28K)

Driver et al, JVJS, 2010

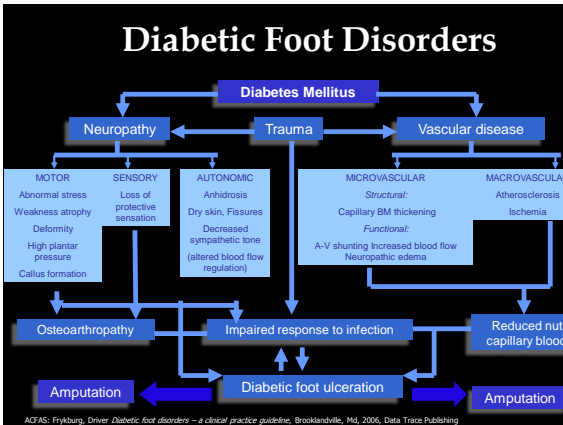
Advanced Therapy for DFUs : Team Approach

ECONOMIC BENEFIT

Limb Salvage Team reduces costs

- Gibbons / NEDH 1993 – reduced major amputations, LOS, cost of care with team care in retro review 1984 – 1990
- Larsson / Sweeden 1995 – 78% decrease in major amputations after team implemented
- Ragnarson 2001 – Markov model → implementation of guidelines (IWGDF) prevention strategy → 25% decline DFU & amps

Driver et al, JVJS, 2010



Final Amputation Triggers

- Ischemia: 5%
- Faulty wound healing: 14%
- Gangrene: 40%
- Infection: 41%

Pecoraro RE, Reiber GE, Burgess EM. Pathways to diabetic limb amputation. Basis for prevention. Diabetes Care 13

Many Factors Affect Wound Care Outcomes

- Setting of care
 - Experience / knowledge of provider(s)
- Type of wound and its chronicity
- Health status of patient / co-morbidities
- Concomitant medications may interfere
- Timely selection of interventions that address defects in wound microenvironment

NATURAL HISTORY OF DIABETIC FOOT ULCERS

Metanalysis of placebo arms of 9 RCTs (total 10 control arms)

Total n of pts: 622

Ulcers: non infected, non ischemic neuropathic DFUs

Follow up 20 wks: 6 RCTs (450 pts)

Follow up 12 wks: 2 RCTs (139 pts)

Follow up 18 wks: 1 RCT

Follow up 10 wks: 1 RCT

Margolis et. Al Diabetes Care 1999

NATURAL HISTORY OF DIABETIC FOOT ULCERS

NON INFECTED, NON ISCHEMIC, SUPERFICIAL NEUROPATHIC DFU
GRADE 1A ULCERS

HEALING AT 12 WKS: 24.2% -> 1/4 DFUs

HEALING AT 20 wks: 30.9% -> 1/3 DFUs

Margolis et. Al Diabetes Care 1999

Good Ulcer Care

- **Pressure Control (offload or compression)**
- **Debridement**
- Metabolic Control and Nutrition
- Bacterial Burden
- Chronic Inflammation
- Moisture Balance



NATURAL HISTORY OF DIABETIC FOOT ULCERS
IS IT POSSIBLE TO IMPROVE THE OUTCOME?

AGGRESSIVE OFFLOADING OF NEUROPATHIC PLANTAR ULCERS IN DIABETIC PATIENTS **IS NOT AN ADJUNCT** TO TREATMENT

IT IS THE MOST EXTENSIVELY STUDIED TREATMENT

NATURAL HISTORY OF DIABETIC FOOT ULCERS
IS IT POSSIBLE TO IMPROVE THE OUTCOME?

NON INFECTED, NON ISCHEMIC, SUPERFICIAL NEUROPATHIC DFU

OFFLOADING (12 wks= 84 days)

	RCTs	% healing	Average healing time	Ulcer grade
TCC	5	73-90%	31-69 days	UT1A
TCC	1	90%	85 days	UT1,2A
Shoes	4	32-72%	35-85 days	UT1A
Rem. Boot	2	35-52%	48-58 days	UT1A
Felted Foam	1	Not reported	75 days	Wagner 1,2

Mueller 1989; Caravaggi 2000; Armstrong 2001; Peters 2001; Zimny 2002; Ha Van 2003; Katz 2005; Armstrong 2005; Faglia 2010

Cross-Section of a Total-Contact Cast Formed to a Patient's Foot.

The rubber heel, which is placed under the midfoot, permits ambulation. Soft black foam covers the anterior portion of the foot to prevent injury. The cast is changed 24 to 48 hours after application and then weekly.

Caputo, Gregory M, Cavanagh, Peter R., Ulbrecht, Jin S., Gibbons, Gary W., Karchmer, Adolf W. Assessment and Management of Foot Disease in Patients with Diabetes N Engl J Med 1994 331: 852-860

Removable cast walkers (RCWs)



Removable cast walkers are hypothesized to decrease forefoot plantar pressure by keeping the ankle at 90 degrees and subsequently limiting propulsion.

Martin N, Claxton MJ, Oldani T. Continuing Education: A Guide To Offloading The Diabetic Foot. Podiatry Today. 18 (9): 67-74, 2005.

Half-Shoe



The half-shoe helps confine weight-bearing to the heel or the forefoot.

Bloomgarden, ZT. "American diabetes association 60th scientific sessions, 2000: the diabetic foot." Diabetes Care 24: 946-951 2001

Orthosis and Shoes

PTB orthosis

- Used in conjunction with therapeutic shoes

Prefabricated walking braces and custom fabricated AFO

Commercially available walking braces

CROW (Charcot restraint orthotic walker)

- Edema control
- Effective ankle and foot immobilization
- Near normal ambulation

Cahney DR, Thompson RC: Fractures associated with neuropathic arthropathy in adults who have juvenile-onset diabetes. J Bone Joint Surg 70A:1192, 1988.
Guse ST, Alvine FG: Technique tip: Treatment of diabetic foot ulcers and Charcot neuroarthropathy using the patellar tendon-bearing brace. Foot Ankle Int 18:675-677, 1997.
Leslie JP, Maurer RC: Tarsometatarsal dislocations and midfoot arthropathy in neuropathic diabetic feet. Natural course and principles of treatment. Clin Orthop 240:225, 1989.

Useful off-loading mechanisms include reduction of walking speed, alteration of foot rollover during gait, and transfer of load from affected areas to other areas of the foot or the lower leg.

Van Deursen, R. Mechanical loading and off-loading of the plantar surface of the diabetic foot. Clin Int Dis 33: S87-91, 2004.

NATURAL HISTORY OF DIABETIC FOOT ULCERS IS IT POSSIBLE TO IMPROVE THE OUTCOME?

NON INFECTED, NON ISCHEMIC, SUPERFICIAL NEUROPATHIC DFU

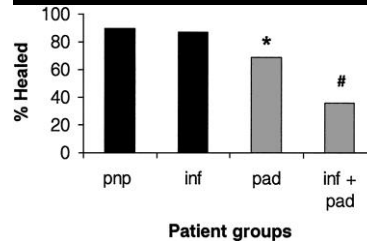
OFFLOADING (12 wks= 84 days)

RCT	N of pts	% healing At 12 weeks	Ulcer grade
TCC vs. rem cast walker vs. half shoe	63	89 vs. 61 vs. 28	UT1A
Non rem cast walker vs. rem cast walker	50	83 vs. 52	UT1
TCC vs. non rem cast walker	41	74 vs. 80	UT1A
Fiberglass TCC vs. non rem cast walker	40	95 vs. 85	UT1A

Armstrong et al. Diabetes Care 2001;24:1019-22
Armstrong et al. Diabetes Care 2005; 28: 551-4
Katz et al. Diabetes Care 2005; 28: 555-9
Piaggessi et al. Diabetes Care 2007; 30: 586-90

NATURAL HISTORY OF DIABETIC FOOT ULCERS IS IT POSSIBLE TO IMPROVE THE OUTCOME?

Real World TCC



Prospective cohort of 90 patients

Average healing rate: 76%

Average healing time: 33 days

COMPLICATIONS


9% new ulcers (average healing time under modified TCC: 13 days)

Prelucrative lesions: 28% (resolved with adaptatin of the TCC)

Nabuurs-Franssen et al. Diabetes Care 2005; 28:243-7

THE MANAGEMENT OF DIABETIC FOOT ULCERS THROUGH OPTIMAL OFF-LOADING.

Building Consensus Guidelines and Practical Recommendations to Improve Outcomes



Journal of the American Podiatric Medical Association. Vol 104, No. 6. Nov/Dec 2014

Consensus statements

Statement	Grade	Recommendation
3 The panel endorses the Charcot foot in diabetes consensus report ¹ <i>The Charcot Foot in Diabetes</i> ADA & APMA Guidelines Diabetes Care, 2011		
4 Total contact casting (TCC) is the preferred method for off-loading diabetic plantar foot ulcers, as it has most consistently demonstrated the best healing outcomes and is a cost-effective treatment		

1. Rogers LG, Freiberg RG, Armstrong DG, et al. The Charcot foot in diabetes. J Am Podiatr Med Assoc. 2011;101(5):437-46. Review.
2. Snyder RJ, et al. The Management of Diabetic Foot Ulcers through Optimal Off-loading. Building Consensus Guidelines and Practical Recommendations to Improve Outcomes. Journal of the American Podiatric Medical Association. Vol 104, No. 6. Nov/Dec 2014

Consensus statements

Statement	Grade	Recommendation
5 There currently exists a "gap" between the evidence supporting the efficacy of DFU off-loading and what is performed in clinical practice		
6 The likelihood of DFU healing is increased with off-loading adherence		

Snyder RJ, et al. The Management of Diabetic Foot Ulcers through Optimal Off-loading. Building Consensus Guidelines and Practical Recommendations to Improve Outcomes. Journal of the American Podiatric Medical Association. Vol 104, No. 6. Nov/Dec 2014

Consensus statements

Statement	Grade	Recommendation
7 Advanced therapeutics are unlikely to succeed in improving wound-healing outcomes unless effective off-loading is achieved		
8 The panel supports the development of a per-visit off-loading quality measure to address the gap between evidence of off-loading and its current use in clinical practice		

Snyder RJ, et al. The Management of Diabetic Foot Ulcers through Optimal Off-loading. Building Consensus Guidelines and Practical Recommendations to Improve Outcomes. Journal of the American Podiatric Medical Association. Vol 104, No. 6. Nov/Dec 2014

Off-loading options by condition




Products:
A: Total contact cast; B: CROW boot; C: Prefabricated walker; D: DH walker; E: IPOS shoe; F: Ortho wedge; G: PostOp shoe; H: Healing sandal; I: Reverse IPOS; J: L'hard splint; K: PTB brace; L: MABAL shoe.

Location of DFU:
1: dorsal digit; 2: plantar digit; 3: plantar metatarsal; 4: medial metatarsal; 5: lateral metatarsal; 6: heel. Reproduced with permission by Ostomy Wound Management.¹⁶

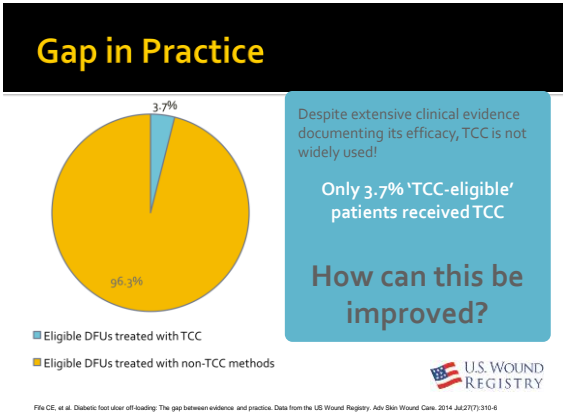
Figure adapted from Snyder et al. Consensus Recommendations On Advancing The Standard Of Care For Treating Neuropathic Foot Ulcers in Patients With Diabetes. Ostomy Wound Management. 2010;56.

Off-loading options BY Amount of evidence

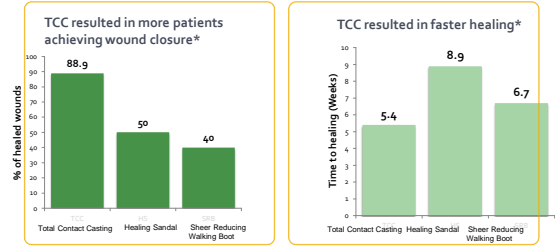


Products:
A: Total contact cast; B: CROW boot; C: Prefabricated walker; D: DH walker; E: IPOS shoe; F: Ortho wedge; G: PostOp shoe; H: Healing sandal; I: Reverse IPOS; J: L'hard splint; K: PTB brace; L: MABAL shoe.

Figure adapted from Snyder et al. Consensus Recommendations On Advancing The Standard Of Care For Treating Neuropathic Foot Ulcers in Patients With Diabetes. Ostomy Wound Management. 2010;56.

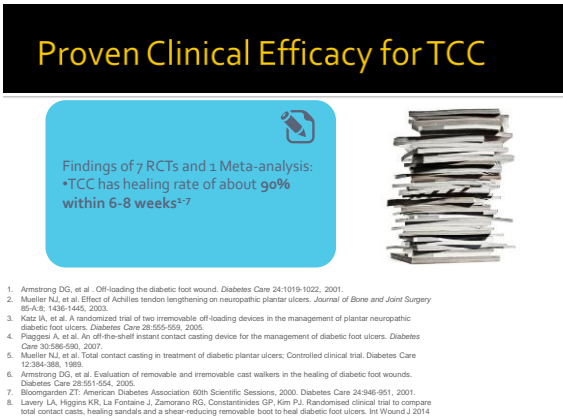


Proven Clinical Efficacy for TCC, 2014



Patient satisfaction was equal for all modalities.

*Per-protocol analysis: * only subjects who completed the study were included in the analysis.
Lavery LA, Higgins KR, La Fontaine J, Zamorano RG, Constantinides GP, Kim PJ. Randomised clinical trial to compare total contact casts, healing sandals and a shear-reducing removable boot to heal diabetic foot ulcers. Int Wound J 2014; doi: 10.1111/ijw.12013



USWR DFU "Off-loading in Practice" Project

Fife CE, et al. Diabetic Foot Ulcer Off-loading: The Gap Between Evidence and Practice. Data from the US Wound Registry

Advances in skin & wound care 2014, vol. 27 No. 7

96 clinics in 23 states and Puerto Rico
5 year, 2008-2013

Total patients: 11,784
Total DFUs: 25,114
Total clinic visits: 221,192
Data was obtained from 23 different states
Mean Age: 63.9
Payer Mix: Medicare 50%, Private Insurance 34%, Medicaid 5%, other 11%

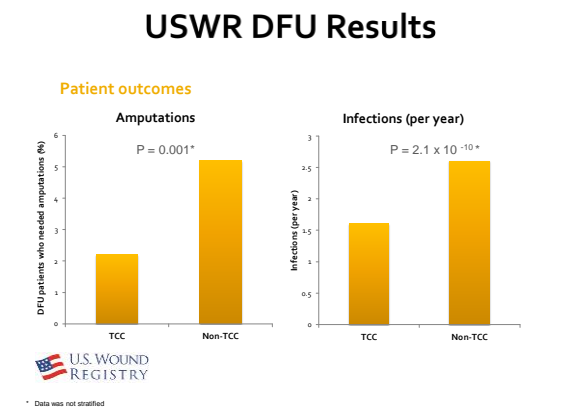
USWR DFU "Off-loading in Practice"

Only 2.2% of visits reported any off-loading

OPTION	VISIT COUNT	%
Post-op shoe*	1803	36.8
TCC	781	16.0
Shoe modification	652	13.3
DH walker	469	9.6
Half shoe	266	5.4
Custom insert	259	5.3
CROW walker	174	3.6
Other	492	10

* The post-operative shoe was used 2 times more than any other off-loading device despite the lack of evidence to support its efficacy

Based on EHR billing data. Only TCC billable so other off-loading probably underreported.



How Does It Work?

- TCC decreases pressure in 1st met by 69% and decreases heel pressure by 45%¹
- Full contact with weekly custom fit cast provides control of shear
- Reduced foot pressure and shear allows skin to heal
- Ensures 100% compliance



Wertsch, et al, Plantar Pressures with Total Contact Casting. J Int Rehab Resch & Dev, 32:3:205-209, 1995.

How Total Contact Casting Works



Wertsch, et al, Plantar Pressures with Total Contact Casting. J Int Rehab Resch & Dev, 32:3:205-209, 1995.e

Patient Selection

Wound Types:

Diabetic Foot Ulcers

Located on the plantar, mid-foot or heel



Post-Operative Care

Including but not limited to Charcot reconstruction, delayed primary closure, post TAL



Charcot Neuroarthropathy

Acute or sub-acute (Recommended in ADA Guidelines)³



Patient Check List:

- ☑ Patient agrees to healing regimen
- ☑ Confirmed adequate vascular supply
- ☑ No sign of active infection
- ☑ No bone infection (osteomyelitis)
- ☑ Debride all non-viable tissue (clean wound)
- ☑ Patient able to follow protocol of care
- ☑ Patient has transportation & loose pants (if needed)

TCC Indications & Contraindications

Indications:

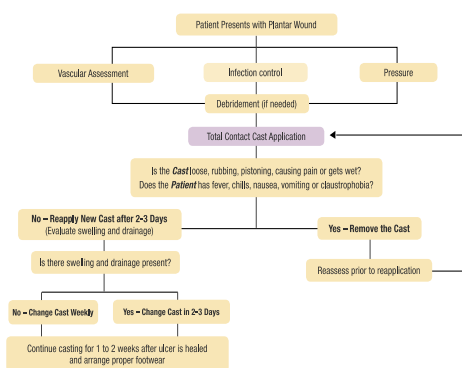
- Non-Infected neuropathic foot ulcers without deeper structures
- Post-operative care (Charcot reconstructing, delayed primary closure)
- Charcot Neuroarthropathy
- Pre-ulcerative conditions
- Adequate blood supply to heal (Vascular consult recommended)

Contraindications

- Ulcer has signs of infection
- Vascular status not adequate for healing
- Ulcers deeper than they are wide
- Non-compliance with visits
- Allergy to casting material
- Excessive leg or foot swelling and fragile skin
- Claustrophobia
- Wounds that probe to tendon, capsule and bone and are abscessed

¹ Nabuurs-Franssen M, et al. Total Contact Casting of the diabetic foot in daily practice. Diabetes Care 29:243-247, 2006.
² Armstrong DJ, et al. Off-loading the diabetic foot wound. Diabetes Care 24:1018-1025, 2001.
³ Wu SC, Cross FT, Armstrong DG. The pivotal role of off-loading in the management of neuropathic foot ulceration. Current Diabetes Rep. 2003;3(6):452-459 review.

TCC Treatment Pathway






How to use TCC- with Charcot

- TCC- Charcot Boots (Large & XL)
- Foam insert has 3 levels, each progressively firmer to prevent bottoming out
- Easily customizable (cut out extra foam, cushion possible problem areas)



Lessons from Practice

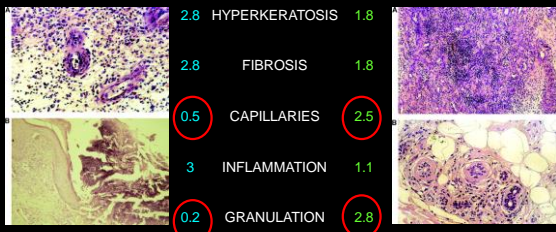
-  TCC is vastly underutilized in DFU treatment
 - There is a BIG "Gap in Practice"
-  Easier-to-apply kits may increase the % of DFUs treated with TCC
-  In a real world setting, TCC **decreases** amputation rate by **50%** and **lowers** infection incidence
 - We can assume this translates to overall cost savings
 - We NEED Cost savings . . .

IS IT POSSIBLE TO IMPROVE THE OUTCOME?

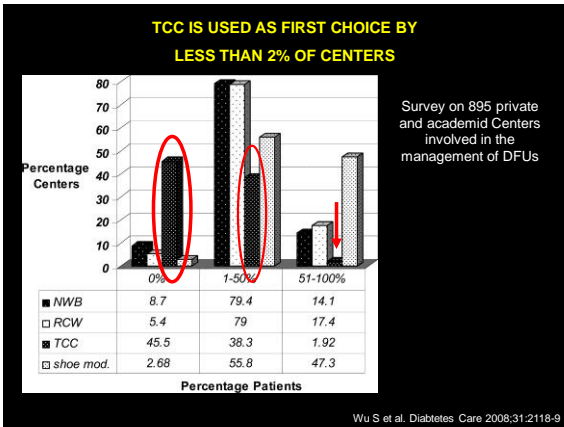
Semiquantitative analysis of histological features of neuropathic DFU: effect of pressure relief

SCORE: 0, absent; 1, present in <33%; 2, present in 34-66%; and 3, present in >67% of the lesion

Feature	No TCC (n=10)	TCC (n=10)
HYPERKERATOSIS	2.8	1.8
FIBROSIS	2.8	1.8
CAPILLARIES	0.5	2.5
INFLAMMATION	3	1.1
GRANULATION	0.2	2.8



Plaggiati et al. Diabetes Care 2003; 26:3123-8



- ## Good Ulcer Care
- Pressure Control (offload or compression)
 - **Debridement**
 - Metabolic Control and Nutrition
 - Bacterial Burden
 - Chronic Inflammation
 - Moisture Balance
- G.S.Schutz, et al., Wound Rep Reg Suppl, 2003;11:1-28

Maintenance Debridement

Definition:
Repeated removal of necrotic tissue throughout the lifespan of the chronic wound

- Required for chronic wounds
 - Fibrotic and necrotic tissue continue to accumulate in the wound
- Continually prepares the wound bed for healing

Falanga V. Wound bed preparation and the role of enzymes: A case of multiple actions of therapeutic agents. WOUNDS 2002;14(2):47-57.
Falanga V. Introducing the concept of wound bed preparation. International Forum on Wound Care 2001;16(1):1-4.

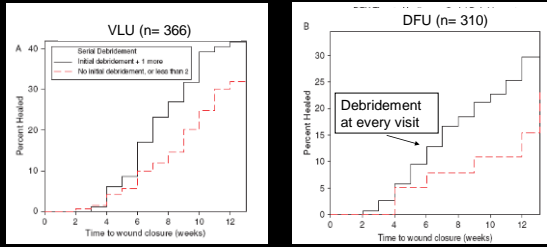
Debridement

- Enables the true dimensions of the ulcer to be perceived
- Allows drainage of exudate and removal of dead tissue rendering infection less likely
- Enables a deep swab to be taken for culture
- Encourages healing

Edmonds et al. 2000

SHARP DEBRIDEMENT IN THE CLINIC: AVAILABLE EVIDENCE

SERIAL DEBRIDEMENT IMPROVES TIME TO HEALING IN VLU AND DFU



Cardinal, Driver et al. Wound Repair and Regeneration 2009;17: 306-11

AGGRESSIVE-CONSERVATIVE MANAGEMENT OF THE DIABETIC FOOT: CONCLUSIONS

DEBRIDEMENT

Sharp debridement with a scalpel seems to influence the healing time of DFU

Real Life



Clinical Evidences of PRP in Wound Care

Benefits of Clinical Relevance	Study Group	Control Group	p value	OR	Notes	Author
Faster healing of wound	42.9	47.4	*	0.69	Healing rate (days)	Driver VR et al.
	3.5	5	0.0001	41.67	Healing rate (weeks)	Mazzucco L et al.
	8.6	15	0.0002	42.67	Weeks for epithelialization at 500%	Knighton DK et al.
Higher rate of healing	81.30%	42.10%	0.036	93.11	% of healing	Driver VR et al.
	100%	80%	*	17.05	% of healing	Knighton DK et al.
Shorter hospital stay	15	15.5	<.0001	71.43	Hospital stay, dehiscent sternal wounds (days)	Mazzucco L et al.
	11.5	12.5	0.0001	45	Hospital stay, necrotic skin ulcers (days)	Mazzucco L et al.



PRP

Highly Significant P Values

*p value not available

Application of TCC



Case 2

Ulcers for 17 years
Scleroderma PAD, DM
Obesity & Depression
Infection



Surgical Debridement

- Debrided via curettage, scalpel and Versajet



Combined Therapy

- Ultra Sound+ PDGF bb + NPWT +Skin Graft



Case 3

Not all Cases Require Products





TCC-EZ® Reimbursement: Medicare 2015

Payment for the application of TCC-EZ® based on site of care:

CPT® Procedure Code	Description	HOSPITAL OUTPATIENT FACILITY PAYMENT*		Physician Payment**	
		APC	Payment	Hospital	Office
29445	Application of rigid total contact cast	0058 Level II Casting	\$223.20	\$107.76	\$138.81

*Outpatient facility payment rates based on 2015 National Medicare Average Payments. *Federal Register notice [CMS-1613-FC], November 11, 2014.* **Physician CPT rates reflect a conversion factor of \$35.8013. *Federal Register notice [CMS-1612-FC], November 13, 2014.*

Supplies such as TCC-EZ® are included in the APC payment and may be billed separately in the office setting based on payer contract.

Disclaimer: This has been intended for informational purposes only. It does not represent a guarantee, promise or statement by Derma Sciences Inc. concerning availability of reimbursement, levels of reimbursement, payment or charges. It is not intended to increase or maximize reimbursement. The decisions as to procedure code selection, completion of a claim form, and the amount to bill, are exclusively the responsibility of the provider.



Summary:

- Advanced tenets for DFU's, debridement, off loading and advanced therapies have their place.
- A comprehensive interdisciplinary approach is needed to manage complex patients with DFU's and non-healing ulcers.

Limb Preservation and Education Research

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Thank You