Policlinico Abano Terme
Presidio Ospedaliero Regione Veneto

FONDAZIONE LEONARDO
PER LE SCIENZE MEDICHE

Centro di Riferimento Regione Veneto per la cura del Piede Diabetico

Update medico-chirurgico per il trattamento del piede diabetico

Enrico Brocco
Foot&Ankle Clinic
Policlinico Abano Terme

Prevalence of amputations within each wound category

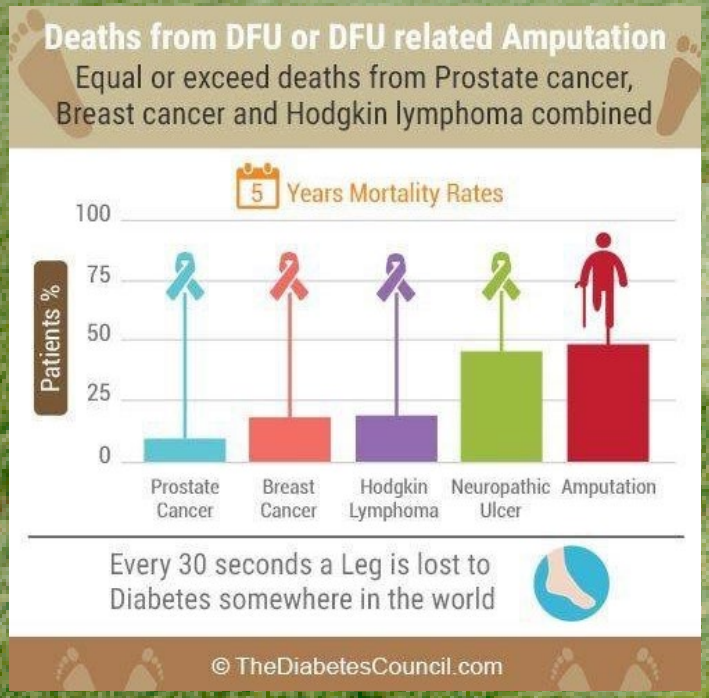
GRADE

STAGE

	0	I	II	III
A	Pre or post ulcerative lesion epithelialized 0%	Superficial wound 0%	Wound penetreting to tendon or capsule 0%	Wound penetrating to bone or joint 0%
B	Infection 12.5%	Infection 8.5%	Infection 28.6%	Infection 92%
C	Ischemia 25%	Ischemia 20%	Ischemia 25%	Ischemia 100%
D	Infection and ischemia 50%	Infection and ischemia 50%	Infection and ischemia 100%	Infection and ischemia 100%

Armstrong D. et al: Validation of a diabetic wound classification system.*Diabetes Care Vol.21 n.5 855 (1998)*

Mortalità nei pazienti ulcerati o amputati



Original Article

Diabetes & Vascular Disease Research
1–7

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SAGE

Survival of diabetes patients with major amputation is comparable to malignant disease

Martin Hoffmann[1], Peter Kujath[1], Annette Flemming[2], Moritz Proß[1], Nehara Begum[1], Markus Zimmermann[1], Tobias Keck[1], Markus Kleemann[3] and Erik Schloericke[4]

Abstract

Introduction: Almost all studies on diabetic foot syndrome focused on prevention of amputation and did not investigate long-term prognosis and survival of patients as a primary outcome parameter.

Methods: We did a retrospective cohort study including 314 patients who had diabetic foot syndrome and underwent amputation between December 1995 and January 2001.

Results: A total of 48% of patients received minor amputation (group I), 15% only major amputation (group II) and 36% initially underwent a minor amputation that was followed by a major amputation (group III). Statistically significant differences were observed in comparison of the median survival of group I to group II (51 vs 40 months; $p = 0.016$) and of group II to group III (40 vs 55 months; $p = 0.003$).

Discussion: The prognosis of patients with major amputation due to diabetic foot syndrome is comparable to patients with malignant diseases. Vascular interventions did not improve the individual prognosis of patients.

UNA SITUAZIONE “SPINOSA”

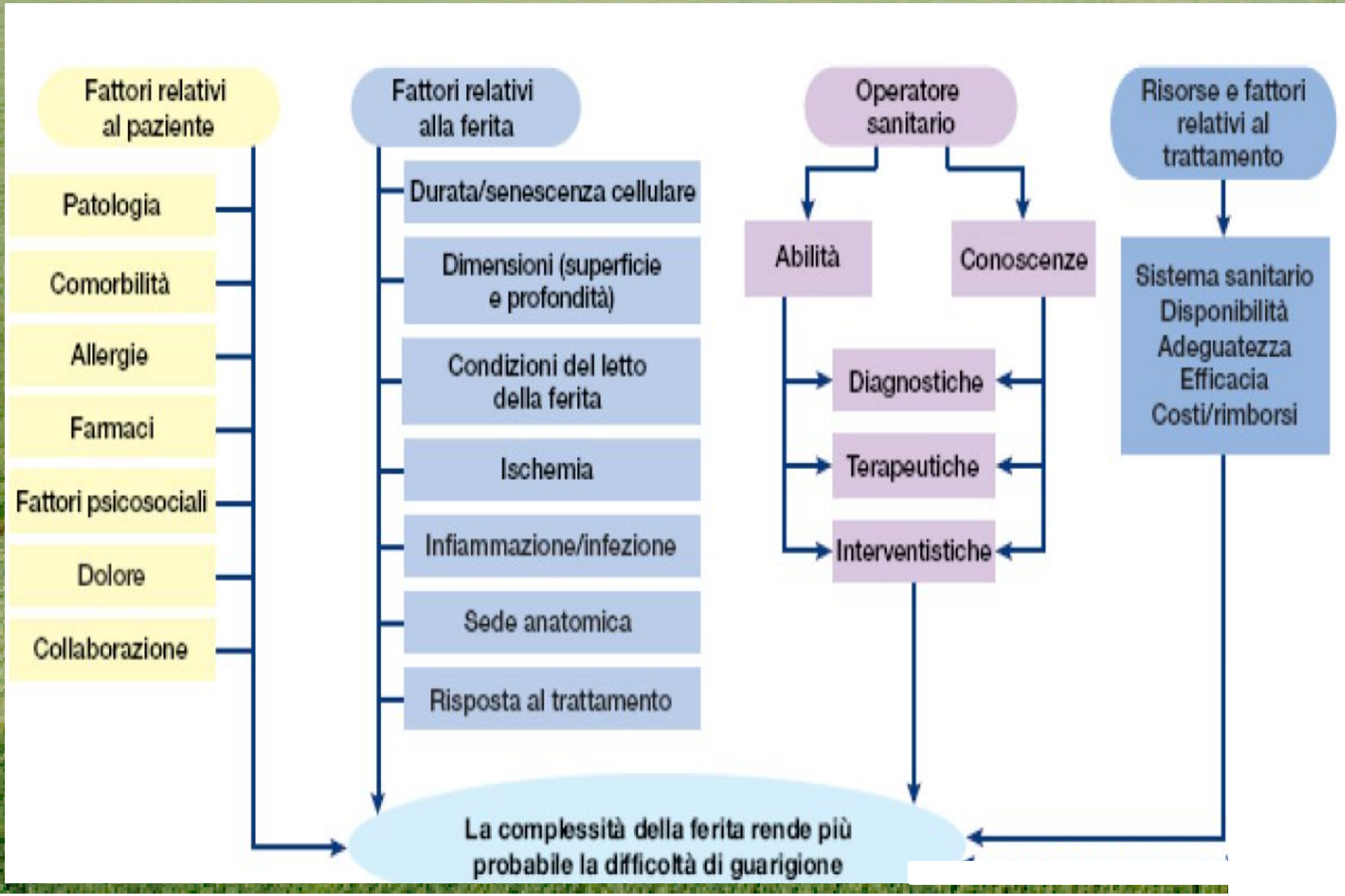
IL PIEDE NEUROPATICO

IL PIEDE NEUROISCHEMICO

IL PIEDE INFETTO

IL PIEDE DI CHARCOT

TRATTAMENTO MEDICO



Fattori che possono influenzare il trattamento delle ferite

Documento di Consenso Internazionale sul Piede Diabetico

Traduzione Italiana

di "International Consensus on the Diabetic Foot & Practical Guidelines on the management and prevention of the diabetic foot" (2007)

by the International Working Group on the Diabetic Foot

Gruppo di Studio Intersocietario Piede Diabetico SID-AMD

Terza Edizione Italiana - 2010

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Terza Edizione Italiana - 2010

Le cause che determinano ulcere al piede nei diabetici sono complesse ed i fattori che ritardano la loro guarigione sono poco chiari, e questo fa si che la terapia corrente è generalmente coadiuvante e richiede l'impegno di diverse figure sanitarie, con vari interventi e spesso per un periodo di tempo prolungato. In tali circostanze, l'obiettivo (guarigione dell'ulcera) probabilmente solo in parte dipende da un singolo intervento terapeutico e può quindi essere difficile dimostrare l'efficacia di un intervento con studi che utilizzano il numero di guarigione di ulcere come obiettivo primario. Inoltre, la complessità della patogenesi delle ulcere croniche dei piedi fa si che i diversi fattori causali possono essere responsabili in maniera diversa nei vari individui. Ne consegue che, se l'efficacia di un intervento è limitato a un particolare tipo di ulcera, di arto o di persona, può essere mascherata in uno studio che impegna un numero relativamente alto di persone necessarie per uno studio controllato randomizzato. Infine, la valutazione dell'efficacia degli interventi chirurgici pone particolari difficoltà poiché si ricorre generalmente alla chirurgia solo quando le altre terapie hanno fallito, e quindi necessariamente in un gruppo di popolazione selezionato e piuttosto piccolo.

ORIGINAL ARTICLE

Effectiveness and Safety of a Nonremovable Fiberglass Off-Bearing Cast Versus a Therapeutic Shoe in the Treatment of Neuropathic Foot Ulcers

A randomized study

CARLO CARAVAGGI, MD
EZIO FAGLIA, MD
ROBERTO DE GIGLIO, MD
MANUELA MANTERO, MD
ANTONELLA QUARANTIELLO, MD
EMANUELA SOMMARIVA, MD
MICHELA GINO, MD
CHIARA PRITELLI, MD
ALBERTO MORABITO, PHD

OBJECTIVE — To evaluate and compare the rate of reduction of the surface area of neuropathic plantar ulcers in diabetic patients treated with nonremovable rigidity-differentiated fiberglass off-bearing casts or a cloth shoe with a rigid sole with unloading alkaform insoles. The secondary aim was to evaluate the side effects and degree of patient acceptance of treatment.

RESEARCH DESIGN AND METHODS — Fifty diabetic patients with neuropathic plantar ulcers were consecutively enrolled and randomized to one of two treatment groups. Of the 50 patients, 24 were treated with a specialized cloth shoe with a rigid sole and an unloading alkaform insole (shoe group), and 26 patients were treated with a nonremovable off-bearing fiberglass cast (cast group). All patients in both study groups returned to the clinic for weekly control visits. Their ulcers were treated with a standard dressing. Tracings of the ulcer area using a transparent dressing were performed on the day of entry to the study and after 30 days of treatment. The presence of new ulcerations caused by the use of the pressure-relief apparatus was recorded. Patient acceptance of the treatment was measured using a visual analog scale.

RESULTS — At the end of the treatment period, an 8.3% increase of the ulcer area was observed in two patients in the shoe group, whereas in the cast group, no patient presented an increase. The reduction of the ulcer area was statistically more rapid in the cast group (Mann-Whitney test, $P = 0.0004$). Furthermore, the number of ulcers completely healed at the 30-day time point was 13 (50%) in the cast group and 5 (20.8%) in the shoe group ($P = 0.03$). In both groups, no side effects were recorded. The average score ± SD of patient acceptance was 91.15 ± 9.9 in the shoe group and 88.33 ± 17.3 (NS) in the cast group.

CONCLUSIONS — Our study has shown a significant difference in the speed of the reduction of neuropathic plantar ulcers treated with a fiberglass cast compared with a specialized cloth shoe. The use of fiberglass material with variable rigidity has also shown two important results: the elimination of side effects including ulcers caused by the cast, and high patient acceptance. These data show that the use of off-bearing casts made with fiberglass bandages of variable rigidity is the elective treatment of neuropathic plantar ulcers.

Diabetes Care 23:1746–1751, 2000

From the Center for the Study and Treatment of Diabetic Foot Pathology, Ospedale di Abbiategrasso (C.C., R.D.G., E.S., C.P); Internal Medicine Unit (E.F., M.M., A.Q., M.G.), Policlinico Multimedica, Sesto S. Giovanni (Milan); and the Institute of Medical Statistics and Biometry (A.M.), University of Milan, Milan, Italy.

Address correspondence and reprint requests to Carlo Caravaggi, MD, Centro per la Cura e lo Studio del Piede Diabetico, Pz Mussi 1, Abbiategrasso (Milano) 20080, Italy. E-mail: cara@mail3.telnetwork.it.

Received for publication 7 April 2000 and accepted in revised form 21 July 2000.

Abbreviations: ABI, ankle-brachial index; TCC, total contact cast.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

Neuropathic ulcers result when several causative factors occur together. The presence of a peak in plantar pressure normally causes the onset of a neuropathic plantar ulcer (1,2).

The relief of pressure from the ulcerated area, surgical debridement, and the use of an adequate dressing are the essential treatments for complete healing of this type of ulcer (3,4). However, this approach is ineffective in treating a plantar ulcer that has not been adequately unloaded.

The treatments used most commonly to reduce the pressure peak in the ulcerated region of the foot are either a therapeutic shoe with an unloaded insole or a total contact off-bearing cast (5). Both of these devices give the patient partial walking autonomy.

Therapeutic shoes have been produced using a variety of techniques and materials, including felted foam or shoes that only provide a rear foot platform (6). In our clinical experience, we have used a shoe with a rigid rocker-bottom sole with a rolling point positioned beside the metatarsal arch. This technical solution allows unloading of the metatarsal and midfoot area, which reduces the local pressure peak (7). This shoe has always been used together with a personalized alkaform insole shaped to reduce pressure in the ulcerated area (8).

Among the off-bearing devices, the total contact cast (TCC) has been effective in healing more ulcers in a shorter time than the accommodative shoe (9). The TCC is considered by many authors to be the "gold standard" for the treatment of neuropathic plantar ulcers (10). However, the use of the TCC made of plaster of Paris bandages and fiberglass bandages has been associated with numerous side effects (11). The most frequent side effects are abrasions or cutaneous ulcers caused by friction of the cast on bony protrusions. Joint rigidity and muscular atrophy caused by prolonged immobilization in rigid casts have also been documented.

SCARICARE LA LESIONE

TOTAL CONTACT CAST

STABIL D PODARTIS

TUTORE VACOPED

Fase acuta

OBIETTIVO:
Scaricare l'area ulcerata

PROBLEMA		SOLUZIONI
ULCERE DIGITALI 	DORSALI	**TERAPES** Taglie: 35-47 
	PLANTARI	**TD** Taglie: 35-47  **WPS** Taglie: 35-47  **PLANTARE MODUS** Taglie: 35-46 o **PLANTARE IN TALISMO SU MISURA** 
	SENZA INFEZIONE E/O ISCHEMIA	**TCC**
ULCERE AVAMPIEDE 	SENZA INFEZIONE E/O ISCHEMIA	**TCC "GOLD STANDARD"**
	CON INFEZIONE E/O ISCHEMIA	**TD** Taglie: 35-47  **STABIL D** Taglie: 35-47  **WALKER**  **PLANTARE MODUS** Taglie: 35-46 o **PLANTARE IN TALISMO SU MISURA** Taglie: 35-48 o **PLANTARE SU MISURA** 
ULCERE MESOPIEDE 	SENZA INFEZIONE E/O ISCHEMIA	**TCC "GOLD STANDARD"**
	CON INFEZIONE E/O ISCHEMIA	**WALKER**  **STABIL D** Taglie: 35-47  **TD** Taglie: 35-47  **PLANTARE MODUS** Taglie: 35-46 o **PLANTARE SU MISURA** 
ULCERE RETROPIEDE 	SENZA INFEZIONE E/O ISCHEMIA	**TCC**
	CON INFEZIONE E/O ISCHEMIA	**WALKER**  **TERAHEEL** Taglie: S-M-L-XL  **HEELBOOT** Decubito/sedia a rotelle Taglie: S-M-L-XL 

Presented at the American Podiatric Medical Conference, Nashville, Tennessee 2017

Evaluation of a Pixelated Innersole Designed to Offload Areas of Elevated Pressure on the Soles of At-Risk Feet

James McGuire DPM, PT, LPed, FAPWHc, James Furmato DPM, PhD., Jesse Borys BS

Temple University School of Podiatric Medicine, Philadelphia, PA.

Background

The Total Contact Cast (TCC) has been recognized as the "gold standard" to treat diabetic foot ulcers due to its superior healing rate and ability to reduce pressures at the site of ulceration (1). Total contact casts have been shown to heal a higher proportion of DFUs and to heal them faster than some types of removable cast boots and shoe-based systems (SBS). Only a very small minority of clinicians who identify themselves as wound experts (1.7%-6%) use total contact casts. Many other clinicians do not have the training or the resources to use total contact casting. In addition many patients have conditions that make the TCC contraindicated or ill-advised. In those cases alternative devices such as the removable cast walker (RCW) or a shoe-based system has to be used. (2),(3)

According to the International Working Group on the Diabetic Foot, when a TCC or other knee-high device is contraindicated or cannot be tolerated, you should consider offloading with a forefoot offloading shoe, cast shoe, or custom-made temporary shoe to heal a neuropathic plantar forefoot ulcer in a patient with diabetes when the patient can be expected to be adherent to wearing them. Because an appropriate foot-device interface is recommended for use in the TCC and knee high devices it is implied that these should also be included in the shoe-based systems (4)

Numerous over the counter and professionally modified off-loading devices have been produced to provide a foot-device interface that would reduce pressure on ulcerated areas of the foot. Few of these have studies with data to show that they demonstrated any degree of pressure reduction or improvements in healing outcomes.(5-8) Only a limited number of studies have been done to look at the offloading capabilities of individual innersoles and less have looked at the comparative effectiveness of foot-device interfaces. (9-13)

Abstract

This study evaluated the effectiveness of the **FORS-15 Offloading Innersole® (Saluber**, San Zeno, Italy) in reducing pressure under focal areas on the sole of the foot. A simulated pressure site was created under the right first metatarsal head. Normal subjects walked wearing a surgical shoe while pressure was measured under the foot in three conditions: no insole, unmodified insole and insole modified for offloading. The study was able to demonstrate an average 43% reduction in maximum pressure under the first metatarsal head when using the modified insole.

Data

	Peak submetatarsal 1 pressure (kPa)					
	Cond 1	Cond 2	Cond 3	change 1>2	Change 2>3	Change 1>3
S1	165.913	162.7826	130.087	1.9%	20.1%	21.6%
S2	162.7826	128.4638	102.029	21.1%	20.6%	37.3%
S3	121.7391	96.69565	48.34783	20.6%	50.0%	60.3%
S4	74.08696	65.73913	43.13043	11.3%	34.4%	41.8%
S5	55.30435	43.47826	29.56522	21.4%	32.0%	46.5%
S6	59.36232	29.56522	21.91304	50.2%	25.9%	63.1%
S7	65.3913	66.43478	45.21739	-1.6%	31.9%	30.9%
S10	82.43478	18.08696	12.86957	78.1%	28.8%	84.4%
S11	104	99.13043	93.56522	4.7%	5.6%	10.0%
S12	169.3913	142.9565	99.47826	15.6%	30.4%	41.3%
S13	77.91304	34.08696	44.52174	56.3%	-30.6%	42.9%
S14	61.21739	47.65217	38.26087	22.2%	19.7%	37.5%
S15	124.1739	107.1304	66.31884	13.7%	38.1%	46.6%
			mean change	24.3%	23.6%	43.4%
			mean deviation	23%	19%	19%

Results

The average pressure reduction by the insole alone was 24.3% and with the pixels removed 43.4%, reflecting an average additional pressure reduction of 19.1% when the pixels are removed.

Procedures and Data Analysis

After giving consent each subject was examined and the first metatarsal head of the right foot identified and a 1/4 inch thick 1.5 inch circle of skived adhesive felt prepared to apply to the plantar skin over the area.
The subjects were then observed in three conditions: barefoot in a standard surgical shoe, barefoot in the surgical shoe with an unmodified insole, and barefoot in the surgical shoe with an insole modified to remove pixels from under the designated areas of high pressure. The subjects were allowed time to acclimate to the off-loading device and then data was collected while subjects walked in the surgical shoes. Dynamic plantar pressures were collected at 100 Hz while subjects walked at self-selected speeds in a straight line. The FScan® in-shoe dynamic pressure measuring system and software (Tekscan, Boston, MA) was used to record pressures ranging from 30 – 1,500 kPa. Pressure insoles were calibrated for each subject to ensure accurate data acquisition.
Three gait trials were performed five mid-gait steps identified from each trial for evaluation. Pressure distributions were calculated for a total of 15 steps for each subject. There were consent issues regarding subjects 8,9 so they were eliminated from the data pool.
Custom written Matlab (Mathworks Inc, Natick, MA) codes will be used to visualize maximum pressures in ten regions of each foot. Descriptive statistics for each condition were calculated and conditions compared using the Student t-test. No funding was received from any outside source for this study.

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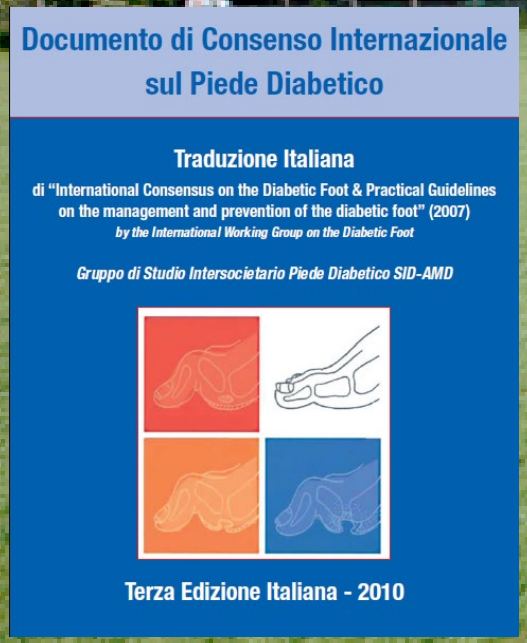


9. L'efficacia degli interventi per migliorare la guarigione delle ulcere croniche del piede nei diabetici

- una Linea Guida basata sull'evidenza -

Preparata dal gruppo di lavoro IWGDF sulla guarigione delle ferite

EVIDENZE?

REVIEW | Annals of Internal Medicine

Advanced Wound Care Therapies for Nonhealing Diabetic, Venous, and Arterial Ulcers

A Systematic Review

Nancy Greer, PhD; Neal A. Foman, MD, MS; Roderick MacDonald, MS; James Dorrian, MD; Patrick Fitzgerald, MPH; Indulis Rutks, BS; and Timothy J. Wilt, MD, MPH

Background: Nonhealing ulcers affect patient quality of life and impose a substantial financial burden on the health care system.

Purpose: To systematically evaluate benefits and harms of advanced wound care therapies for nonhealing diabetic, venous, and arterial ulcers.

Data Sources: MEDLINE (1995 to June 2013), the Cochrane Library, and reference lists.

Study Selection: English-language randomized trials reporting ulcer healing or time to complete healing in adults with nonhealing ulcers treated with advanced therapies.

Data Extraction: Study characteristics, outcomes, adverse events, study quality, and strength of evidence were extracted by trained researchers and confirmed by the principal investigator.

Data Synthesis: For diabetic ulcers, 35 trials (9 therapies) met eligibility criteria. There was moderate-strength evidence for improved healing with a biological skin equivalent (relative risk [RR], 1.58 [95% CI, 1.20 to 2.08]) and negative pressure wound therapy (RR, 1.49 [CI, 1.11 to 2.01]) compared with standard care and low-strength evidence for platelet-derived growth factors and silver cream compared with standard care. For venous ulcers, 20 trials (9 therapies) met eligibility criteria. There was moderate-strength evidence for improved healing with keratinocyte therapy (RR, 1.57 [CI, 1.16 to 2.11]) compared with standard care and low-strength evidence for biological dressing and a biological skin equivalent compared with standard care. One small trial of arterial ulcers reported improved healing with a biological skin equivalent compared with standard care. Overall, strength of evidence was low for ulcer healing and low or insufficient for time to complete healing.

Limitations: Only studies of products approved by the U.S. Food and Drug Administration were reviewed. Studies were predominantly of fair or poor quality. Few trials compared 2 advanced therapies.

Conclusion: Compared with standard care, some advanced wound care therapies may improve the proportion of ulcers healed and reduce time to healing, although evidence is limited.

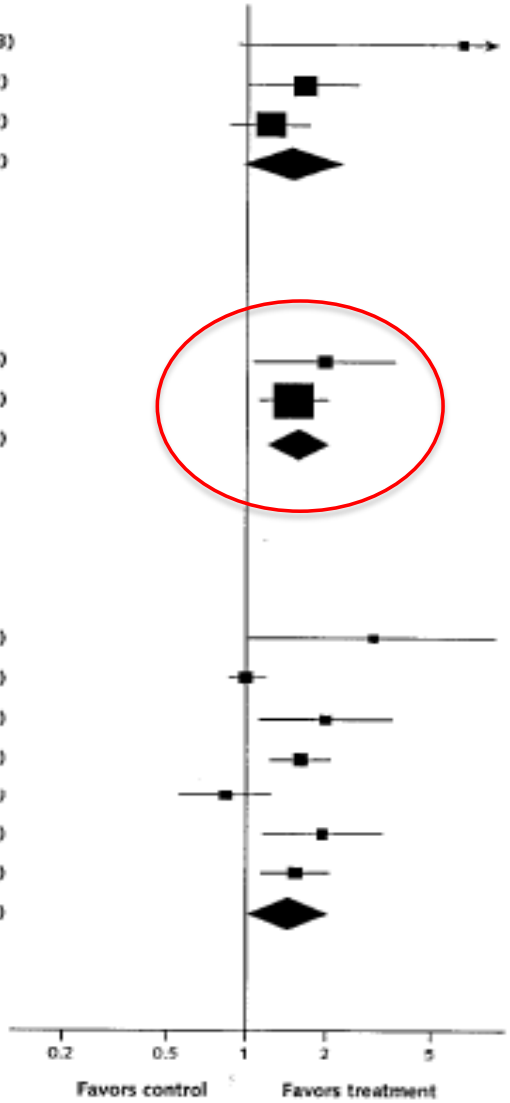
Primary Funding Source: Department of Veterans Affairs, Veterans Health Administration, Office of Research and Development, Quality Enhancement Research Initiative.

Ann Intern Med. 2013;159:532-542. www.annals.org

For author affiliations, see end of text.

Appendix Figure 2. Meta-analyses of the proportion of diabetic ulcers healed.

Study, Year (Reference)	Events/Total, n/N: Treatment	Events/Total, n/N: Control	Weight, %	Relative Risk M–H, Random (95% CI)
BSE (Dermagraft*) vs. standard care				
Gentzkow et al, 1996 (16)	6/12	1/13	4.7	6.50 (0.91–46.43)
Marston et al, 2003 (18)	39/130	21/115	42.1	1.64 (1.03–2.62)
Naughton et al, 1997 (17)	42/109	40/126	53.2	1.21 (0.86–1.72)
Subtotal	87/251	62/254	100.0	1.49 (0.96–2.32)
Heterogeneity: tau-square = 0.06; chi-square = 3.53; $P = 0.172$; $I^2 = 43\%$				
Test for overall effect: $Z = 1.78$ ($P = 0.075$)				
BSE (Apligraf†) vs. standard care				
Edmonds et al, 2009 (20)	17/33	10/38	19.2	1.96 (1.05–3.66)
Veves et al, 2001 (19)	63/112	36/96	80.8	1.50 (1.11–2.04)
Subtotal	80/145	46/134	100.0	1.58 (1.20–2.08)
Heterogeneity: tau-square = 0.00; chi-square = 0.56; $P = 0.45$; $I^2 = 0\%$				
Test for overall effect: $Z = 3.26$ ($P = 0.001$)				
PDGF vs. standard care				
Agrawal et al, 2009 (23)	9/14	3/14	6.7	3.00 (1.02–8.80)
Bhansali et al, 2009 (25)	13/13	11/11	18.5	1.00 (0.86–1.17)
d'Hemecourt et al, 1998 (30)	15/34	15/68	12.4	2.00 (1.11–3.59)
Hardikar et al, 2005 (24)	47/55	31/58	17.3	1.60 (1.23–2.08)
Jaiswal et al, 2010 (27)	15/25	18/25	19.2	0.83 (0.56–1.25)
Steed, 2006 (29)	29/61	14/57	13.3	1.94 (1.14–3.27)
Wieman et al, 1998 (26)	61/123	41/127	16.6	1.54 (1.13–2.09)
Subtotal	189/325	133/360	100.0	1.45 (1.03–2.05)
Heterogeneity: tau-square = 0.16; chi-square = 39.50; $P < 0.001$; $I^2 = 85\%$				
Test for overall effect: $Z = 2.11$ ($P = 0.035$)				
Test for subgroup differences: chi-square = 0.15; $P = 0.93$; $I^2 = 0\%$				



BSE = biological skin equivalent; M–H = Mantel–Haenszel; PDGF = platelet-derived growth factor.
* Shire Regenerative Medicine, San Diego, California.
† Organogenesis, Canton, Massachusetts.

Hydrocolloid dressings for healing diabetic foot ulcers (Review)

Dumville JC, Deshpande S, O'Meara S, Speak K

THE COCHRANE COLLABORATION®

This is a reprint of a Cochrane review, prepared and maintained by The Cochrane Collaboration and pub
2013, Issue 8

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Alginate dressings for healing diabetic foot ulcers (Review)

Dumville JC, O'Meara S, Deshpande S, Speak K

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Foam dressings for healing diabetic foot ulcers (Review)

Dumville JC, Deshpande S, O'Meara S, Speak K

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J Diabetes. 2018 Oct 15. doi: 10.1111/1753-0407.12871. [Epub ahead of print]

Comparative Efficacy of 9 Different Dressings in Healing Diabetic Foot Ulcer :A Bayesian Network Analysis.

Zhang X[1], Sun D[2], Jiang G[1].

Author information

Abstract

BACKGROUND:

There is a wide variety of dressings currently available for the treatment of diabetic foot ulcers (DFUs), and due to the lack of evidence from head-to-head randomized controlled trials (RCTs), the relative effects of any of these dressings in DFU patients remains unclear. The purpose of this study was to compare the efficacy of nine dressings in healing DFU.

METHODS:

MEDLINE (PubMed), EMBASE and the Cochrane Central Register of Controlled Trials (CENTRAL) were searched. Reports published from 1993-2017 that focused on dressings for healing DFU were identified.

RESULTS:

The final results included 21 RCTs with a total of 2159 patients. Bayesian network analysis showed that amniotic membrane dressings were superior to alginate, basic wound contact, foam, honey-impregnated, hydrocolloid, and iodine-impregnated dressings. Hydrogel dressings were better than basic wound contact dressings.

Other dressings showed no significant differences. According to the probability of ranking results, amniotic membrane and hydrogel dressings are the preferred solutions for healing DFUs.

CONCLUSIONS:

The 9 dressings of this study had respective advantages in promoting the healing of DFU, but most of the differences among the dressings were not significant. According to the analysis of rank probability, amniotic membrane and hydrogel dressings are the most advantageous in terms of promoting DFU healing. It is recommended that the most suitable dressing should be selected according to the conditions of exudate control, comfort and cost.

✓Alginati, schiume e idrocolloidi non hanno evidenziato nessun vantaggio in termini di efficacia

✓Idrogel probabilmente più efficaci della garza salina sterile nelle ulcere del piede diabetico

✓Debridement chirurgico più efficace del trattamento standard

✓Trials condotti su pochi pazienti

✓Molti potenziali errori (bias)

✓Follow up brevi

✓Nessuna evidenza, si scelga in base al rapporto costo/beneficio

✓**Better quality research is needed**

THE COCHRANE COLLABORATION®

Wound Bed Preparation

T — Rimozione dei tessuti non vitali (Debridement) →

- -Chirurgico
- -Enzimatico/autolitico
- -Meccanico
- -Biologico

-Idrogel
-Collagenasi
-Larve di mosca
-Poliuretano

I — Controllo della carica batterica →

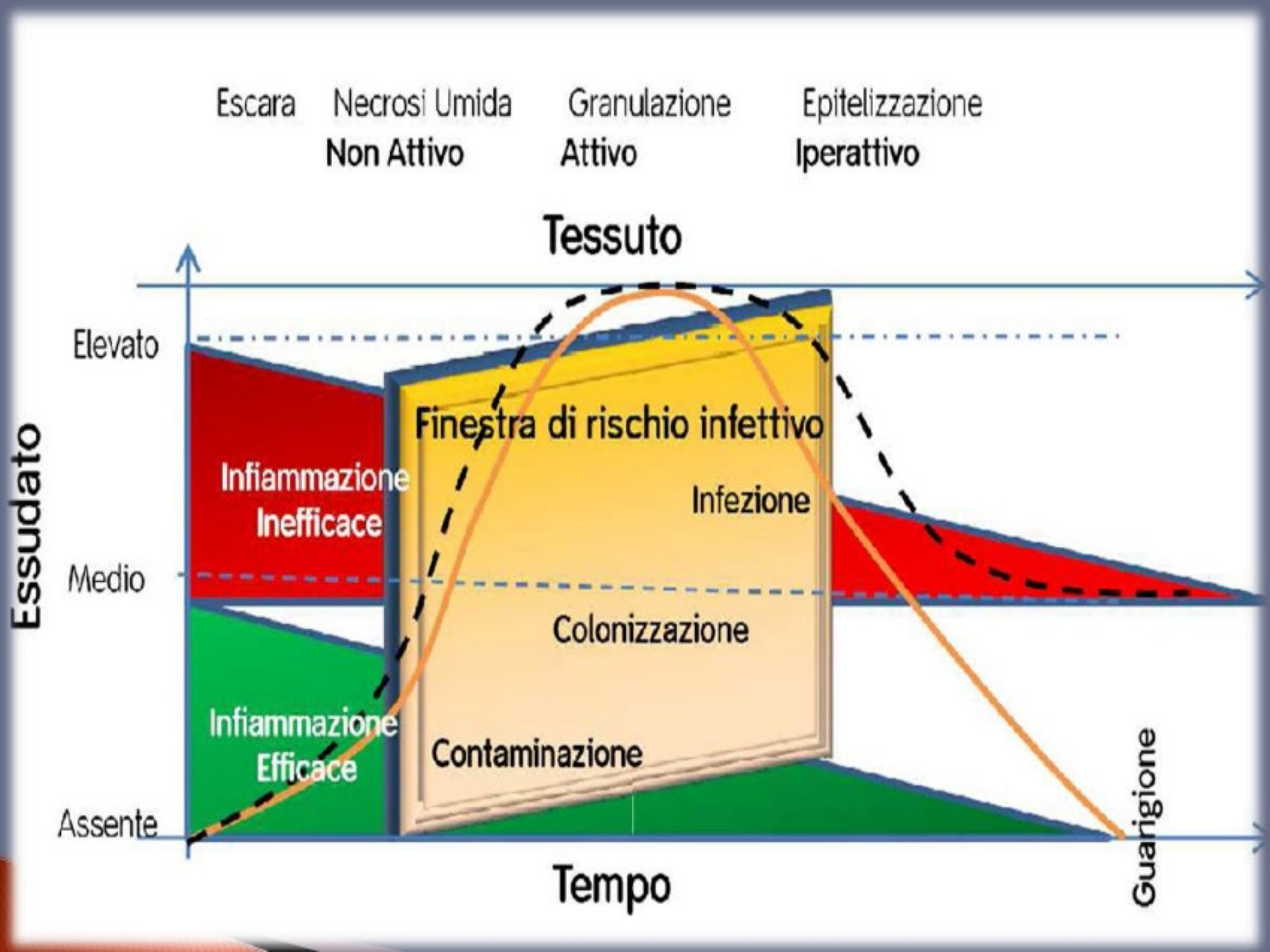
-Garze iodate
-Garze all' argento
-Detergenti
-Antibiotici topici
-Acqua superossidata

M — Gestione dell' essudato →

-Schiume
-Alginati di Ca e Na
-Idrocolloidi

E — Promozione della riepitelizzazione →

-Innesti cute
-Acido ialuronico
-Sostituti dermali
-Garze grasse


Escara
Necrosi Umida
Non Attivo
Granulazione
Attivo
Epitelizzazione
Iperattivo
Tessuto
Essudato
Elevato
Medio
Assente
Finestra di rischio infettivo
Infiammazione
Inefficace
Infezione
Colonizzazione
Infiammazione
Efficace
Contaminazione
Guarigione
Tempo

Lancet Diabetes Endocrinol. 2018 Mar;6(3):186-196. doi: 10.1016/S2213-8587(17)30438-2. Epub 2017 Dec 20.

Sucrose octasulfate dressing versus control dressing in patients with neuroischaemic diabetic foot ulcers (Explorer): an international, multicentre, double-blind, randomised, controlled trial.

Edmonds M[1], Lázaro-Martínez JL[2], Alfayate-García JM[3], Martini J[4], Petit JM[5], Rayman G[6], Lobmann R[7], Uccioli L[8], Sauvadet A[9], Bohbot S[9], Kerihuel JC[10], Piaggesi A[11].

Author information

Erratum in

Correction to Lancet Diabetes Endocrinol 2018; 6: 186-96. [Lancet Diabetes Endocrinol. 2018]

Abstract

BACKGROUND:

Diabetic foot ulcers are serious and challenging wounds associated with high risk of infection and lower-limb amputation. Ulcers are deemed neuroischaemic if peripheral neuropathy and peripheral artery disease are both present. No satisfactory treatment for neuroischaemic ulcers currently exists, and no evidence supports one particular dressing. We aimed to assess the effect of a sucrose octasulfate dressing versus a control dressing on wound closure in patients with neuroischaemic diabetic foot ulcers.

METHODS:

We did a randomised, double-blind clinical trial (Explorer) in 43 hospitals with specialised diabetic foot clinics in France, Spain, Italy, Germany, and the UK. Eligible participants were inpatients or outpatients aged 18 years or older with diabetes and a non-infected neuroischaemic diabetic foot ulcer greater than 1 cm^2 and of grade IC or IIC (as defined by the University of Texas Diabetic Wound Classification system). We excluded patients with a severe illness that might lead to them discontinuing the trial and those who had surgical revascularisation in the month before study entry. We randomly assigned participants (1:1) via a computer-generated randomisation procedure (concealed block size two); stratified by study centre and wound area (1-5 cm^2 and 5-30 cm^2), to treatment with either a sucrose octasulfate wound dressing or a control dressing (the same dressing without sucrose octasulfate) for 20 weeks. Both groups otherwise received the same standard of care for a 2-week screening period before randomisation and throughout the 20-week trial. Dressings were applied by nursing staff (or by instructed relatives for some outpatients). Frequencies of dressing changes were decided by the investigator on the basis of the clinical condition of the wound. Patients were assessed 2 weeks after randomisation, then monthly until week 20 or occurrence of wound closure. The primary outcome, assessed by intention-to-treat, was proportion of patients with wound closure at week 20. This trial is registered with ClinicalTrials.gov, number NCT01717183.

FINDINGS:

Between March 21, 2013, and March 31, 2016, we randomly assigned 240 individuals to treatment: 126 to the sucrose octasulfate dressing and 114 to the control dressing. After 20 weeks, wound closure occurred in 60 patients (48%) in the sucrose octasulfate dressing group and 34 patients (30%) in the control dressing group (18 percentage points difference, 95% CI 5-30; adjusted odds ratio 2·60, 95% CI 1·43-4·73; p=0·002). In both groups, the most frequent adverse events were infections of the target wound: 33 wound infections in 25 (20%) patients of 126 in the sucrose octasulfate dressing group and 36 in 32 (28%) patients of 114 in the control dressing group. Minor amputations not affecting the wound site were also reported in one (1%) patient in the sucrose octasulfate dressing group and two (2%) patients in the control dressing group. Three (2%) patients assigned to the sucrose octasulfate dressing and four (4%) assigned to the control dressing died, but none of the deaths were related to treatment, procedure, wound progression, or subsequent to amputation.

INTERPRETATION:

A sucrose octasulfate dressing significantly improved wound closure of neuroischaemic diabetic foot ulcers without affecting safety after 20 weeks of treatment along with standard care. These findings support the use of sucrose octasulfate dressing as a local treatment for neuroischaemic diabetic foot ulcers.

FUNDING:

Laboratoires Urgo Medical.

- The more elevated the MMP-9 levels at baseline, the poorer the wound healing observed after weeks of standard treatment[44-46]
- Elevated levels of MMP-9 observed in chronic wounds at admission decreased while wound healing occurred.[26,41,44,47]

Table 4. Wound healing predictive value of MMP Levels in cohorts of patients with DFUs: specificity and sensibility of the [illegible] threshold

Studied Populati[illegible]	Biological sample, MMP detection method and outcome predicted	Best cutoff [illegible] ound healing predictive va[illegible] of MMP levels at presentation	Reference
DFUs (n=62) mostly neuropathic (77%) Grade A to D (TWC)—Antibiotics for 83% of patients Mean ulcer area: 3.2 cm² Mean ulcer duration: 118 days Following period: 12 weeks Debridement, offloading and standard [illegible]res	Wound fluid Gelatin zymography and ELISA Wound healing at week 12	ProMMP-9 +TIMP-1 >480 pg/ml +TGF-β1 >115 pg/ml Sensitivity: 87% Specificity: 91% Area under the curve 0.94*	46
Neu[illegible]athic DFUs (n=93) Grade 1 to 3 B ([illegible]—Antibiotics for 97% of patients Posterior tibial and pedal pulses or ABPI≥0.9 Ulcer area from 0.5 to 3.2 cm² Ulcer duration from 18 to 51 days Following period: 12 weeks Debridement, offloading and standard cares	Serum ELISA [illegible]	MMP-9/TIMP-1 ratio <0.395 Sensitivity: 63.6[illegible] Specificity: 58.6% Area under the curve 0.66‡	49
Neuropathic DFUs (n=16)‡ Grade 1 to 3 A (TWC) Not infected, no severe arteriopathy Posterior tibial and pedal pulses or ABPI≥0.9 Ulcer area from 0.95 to 5.1cm² Ulcer duration from 1 to 6 months Following period: 12 weeks Standard care/no dressing or drug known to interfere with MMP levels	Wound fluid Gelatin zymography and ELISA RWAR of 82% at week 4	MMP-1/TIMP-1 ratio >0.39 Sensitivity: 71% Specificity: 87.5% Area under the curve: 0.82	47

MMP–matrix metalloproteinase; DFU–diabetic foot ulcer; TWC–Texas Wound Classification; ABPI–ankle brachial pressure index; ELISA–enzyme-linked immunosorbent assay; RWAR–relative wound area reduction; TIMP–tissue inhibitor of metalloproteinase; TGF–transforming growth factor. ‡The 16 patients included are reported to present DFU with grade 1–3A according to the TWC, during the study, two patients have received oral antibiotics for proven osteomyelitis, and an IPS<0.9 was later detected in four patients. Due to the small number of patients included in this trial, these bacterial and ischemic contributions may have partially influence some of the results.
*$p<0.00001$ ‡$p<0.001$

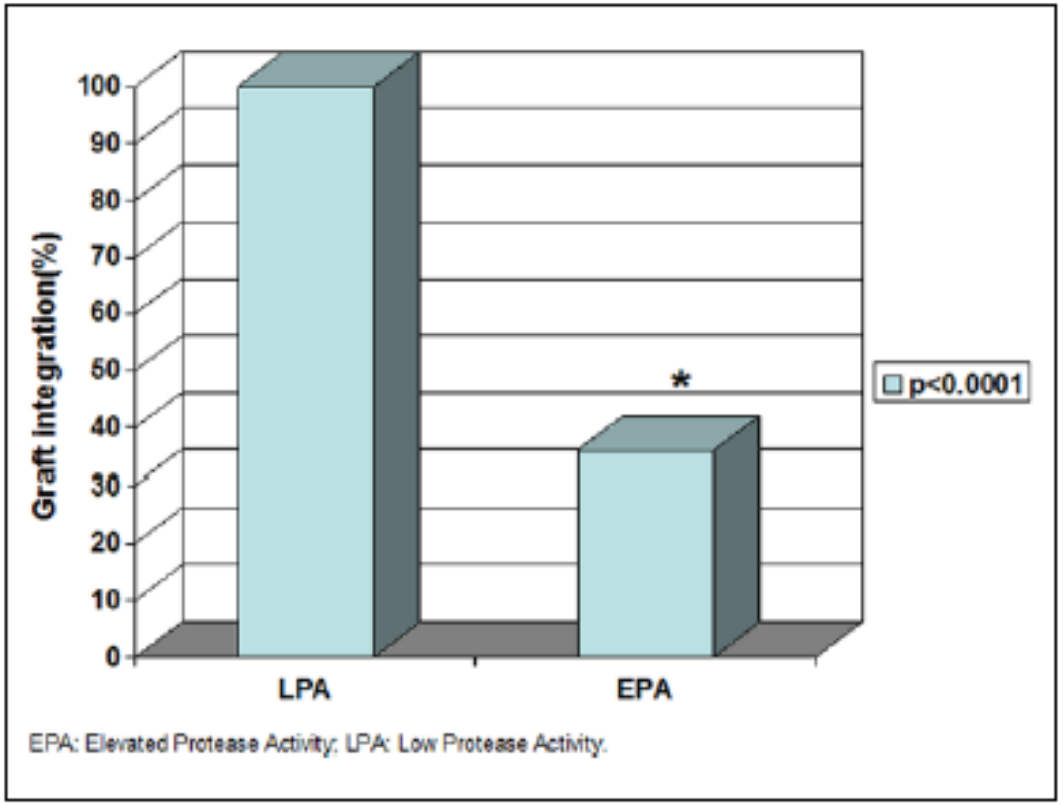


Figure 2. Dermal graft integration according to MMP levels.

Clinical and Translational Research

High Matrix Metalloproteinase Levels Are Associated With Dermal Graft Failure in Diabetic Foot Ulcers

The International Journal of Lower Extremity Wounds
2014, Vol. 13(3) 191–196

DOI: 10.1177/1534734614544959
ijl.sagepub.com
SAGE

Valentina Izzo, MD[1], Marco Meloni, MD[1], Erika Vainieri, MD[1], Laura Giurato, MD[1], Valeria Ruotolo, MD[1], and Luigi Uccioli, MD[1]

WOUND CLEANSING:
Which solution?

Practical demonstration through clinical cases with Nexodyn® AcidOxidizing Solution (AOS)

Thursday, 4 May 2017
Meeting Room E108

First program: 11.15 - 12.15
Repeated program: 14.30 - 15.30

NEXODYN®
AcidOxidizing Solution (AOS)

Cleansing as a valuable add-on in the therapeutic approach of a DFU patient: a clinical case

Enrico Brocco, MD

Veneto Regional Referral Center for the Treatment of Diabetic Foot.

Policlinico Abano Terme, Italy.

Centro di Riferimento Regione Veneto per la cura del Piede Diabetico

FONDAZIONE LEONARDO PER LE SCIENZE MEDICHE

REGIONE DEL VENETO

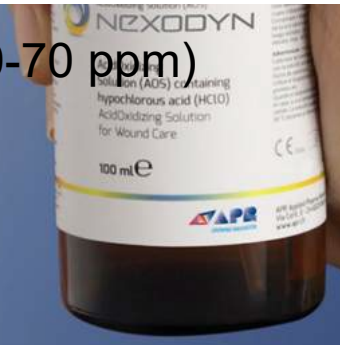
Policlinico Abano Terme
Presidio Ospedaliero Regione Veneto

NEXODYN AcidOxidizing Solution (AOS)

Nexodyn* is a spray liquid medical device developed for topical treatment in the field of acute and chronic wound management

Main product features are

- Acidic pH (2.5 – 3.0)
- High Oxidation Reduction Potential (ORP) (higher than 1,000 mV)
- High purity (>95% HClO of free chlorine species; 40-70 ppm)
- Long stability (24 months unopened; 30 days from first opening)



* Nexodyn has been developed based on APR's proprietary technology TEHCLO®, enabling the production of acidic and super-oxidizing solutions containing free chlorine species, of which stabilized hypochlorous acid (HClO) in very high concentration (> 95%), as formula preservative.

NEXODYN IS ACTIVE AGAINST SUPERBUGS

BIOBURDEN

Bactericidal activity tests	Results
Time Kill Assay EXTENDED-SPECTRUM BETA-LACTAMASE (ESBL) PRODUCING ENTEROBACTERIACIAE	**>99.9999%** (> 6.23 Log_{10}) reduction of *ESBL-producing Enterobacteriaciae* after 15 second exposure time
Time Kill Assay MULTI-DRUG RESISTANT (MDR) STAPHYLOCOCCUS AUREUS	**>99.999%** (> 5.44 Log_{10}) reduction of *MDR-Staphylococcus aureus* after 15 second exposure time
Time Kill Assay VANCOMYCIN INTERMEDIATE RESISTANT STAPHYLOCOCCUS AUREUS (VISA)	**>99.999%** (>5.84 Log_{10}) reduction of *VI-Staphylococcus aureus* after 15 second exposure time
Time Kill Assay VANCOMYCIN RESISTANT (VR) ENTEROCOCCUS FAECALIS	**>99.999%** (> 5.87 Log_{10}) reduction of *VR-Enterococcus faecalis* after 15 second exposure time
Time Kill Assay MULTI-DRUG RESISTANT (MDR) AND OXA-48 PRODUCING KLEBSIELLA PNEUMONIAE	**>99.999%** (> 5.32 Log_{10}) reduction of *MDR- and oxa-48 producing Klebsiella pneumoniae* after 15 second exposure time
Time Kill Assay EXTENDED-SPECTRUM BETA-LACTAMASE (ESBL) PRODUCING PROTEUS MIRABILIS	**>99.999%** (>5.99 Log_{10}) reduction of *ESBL-producing Proteus mirabilis* after 15 second exposure time
Time Kill Assay MULTI-DRUG RESISTANT (MDR) ESCHERICHIA COLI	**>99.999%** (>5.92 Log_{10}) reduction of *MDR-Escherichia coli* after 15 second exposure time


ANIKA
Anika Therapeutics S.r.l.
10x10 cm

Uso di sale di DNA frazionato quale adiuvante della guarigione di lesioni nel piede.

REGIONE DEL VENETO

Centro di Riferimento Regione Veneto per la cura del Piede Diabetico

Enrico Brocco[1], Sasa Ninkovic[1], Mariagrazia Marin[1], Christine Whisstock[1], Marino Bruseghin[1], Giovanni Boschetti[1], Raffaella Viti[1], Mariano Palena[1], Roberto Anichini[2], Antonio Volpe[1].

1Foot & Ankle Clinic, Policlinico Abano Terme

2 U.O. Diabetologia, Pistoia

FONDAZIONE LEONARDO PER LE SCIENZE MEDICHE

Policlinico Abano Terme Presidio Ospedaliero Regione Veneto

	Gruppo S	Gruppo C	Stats
Non guariti	3/30 (10%)	7/30 (27,3%)	
Tempo di guarigione (wks)	5,74 ± 1,16	8,22 ± 2,92	p=0,001 Mann-Whitney
T0 Area (cm^2)	23,59 ± 5,03	22,50 ±4,94	ns
T1(1 week) VS T0 Area (cm^2)	15,82 ± 4,06	15,39 ± 5,40	ns t-paired test
T4 Area (cm^2)	4,06 ± 2,62	5,67 ± 3,50	p<0,005 t-paired test






Questo studio ha evidenziato:

- tempo di guarigione significativamente inferiore nei pazienti trattati con ss-DNA rispetto ai controlli;
- una superficie di lesione residua dopo un trattamento di 4 settimane significativamente inferiore nei soggetti trattati rispetto ai controlli.

TRATTAMENTO CHIRURGICO

TASC 2007: "Investigation" 5D.2

Rest pain or ulcer or gangrene +

AP < 70 mmHg
(or TP < 50 mmHg)

or TcPO2 < 30 mmHg

Recommendation 19: Diagnosis of critical limb ischemia (CLI)

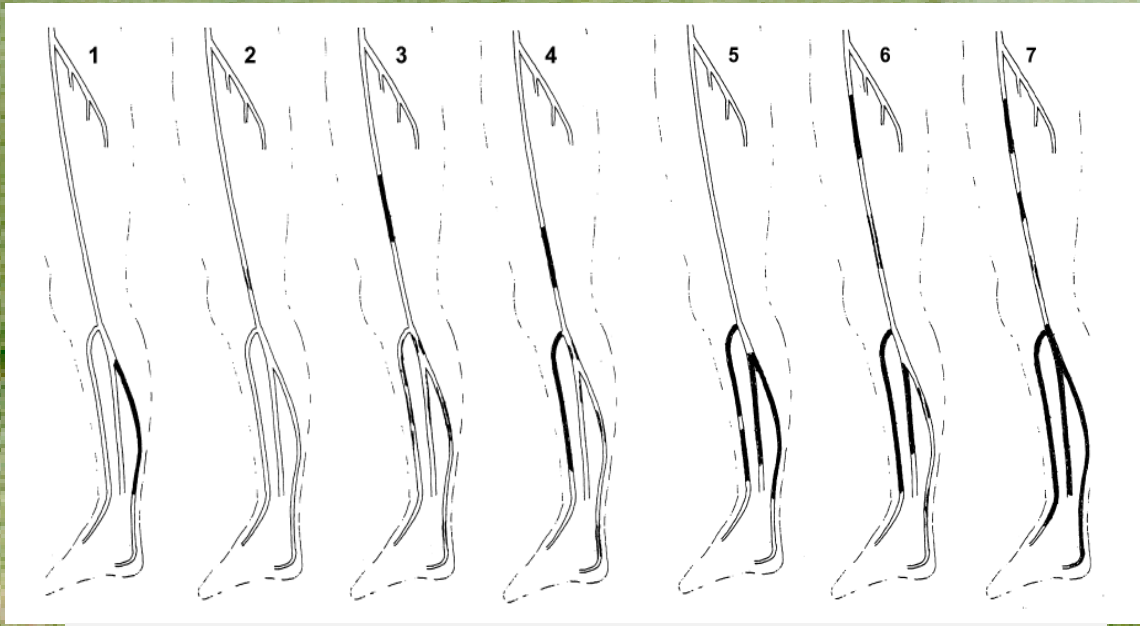
- CLI is a clinical diagnosis but should be supported by objective tests [C]

Recommendation 20. Indications for evaluation for critical limb ischemia

- All patients with ischemic rest pain symptoms or pedal ulcers should be evaluated for CLI [B]

Lesions Distribution

Graziani et al. Eur J Vasc Endovasc Surg 2007



1	2	3	4	5	6	7
1%	8%	14%	36%	11%	27%	1%

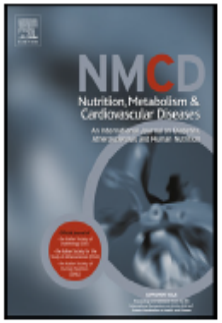
- ~ 50% long occlusions (>10cm)
- ~ 30% three-vessel occlusive lesions
- ~ 50% at least one patent distal foot vessel

Nutrition, Metabolism & Cardiovascular Diseases (2014) **24**, 355–369

Available online at www.sciencedirect.com

Nutrition, Metabolism & Cardiovascular Diseases

journal homepage: www.elsevier.com/locate/nmcd

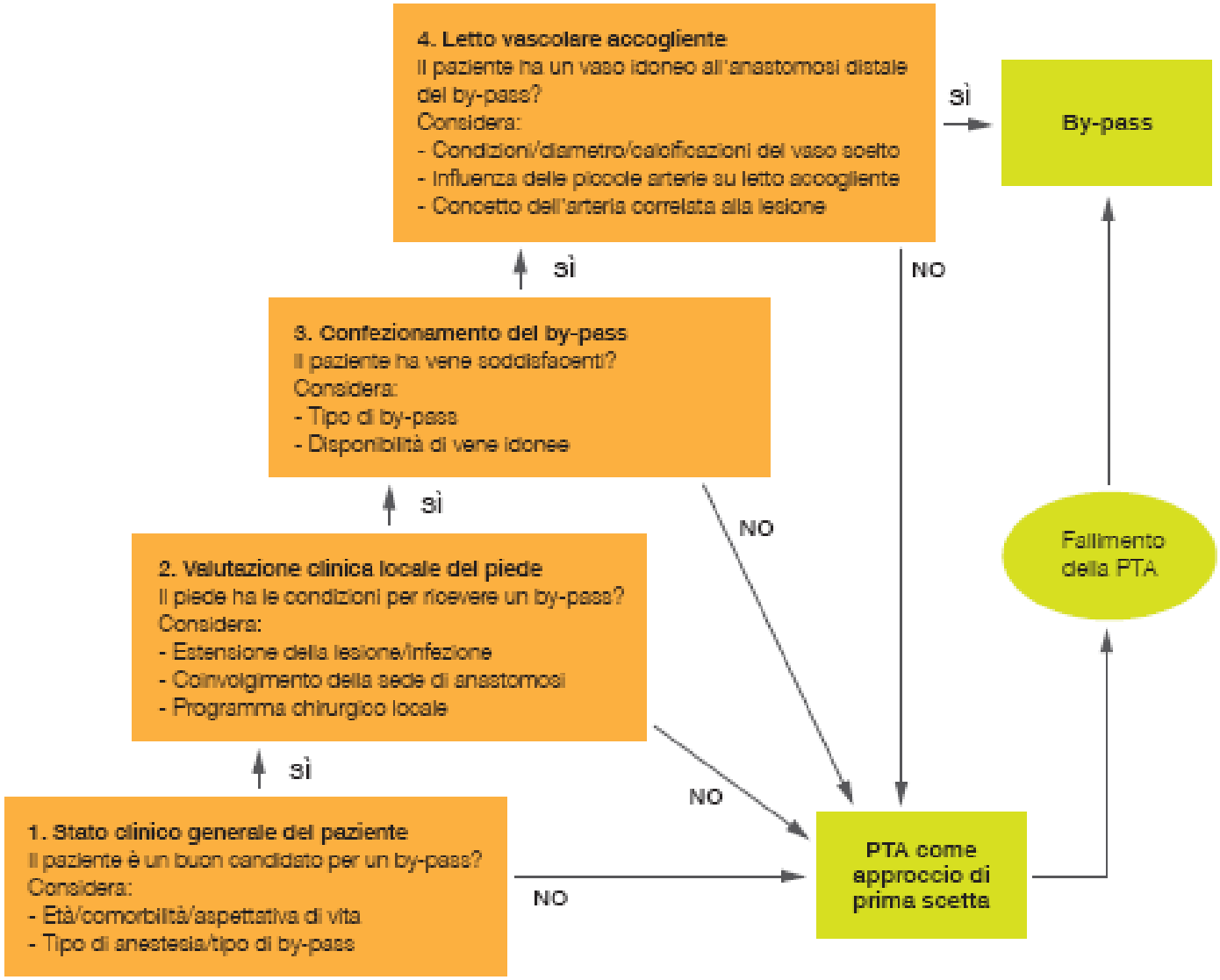


SPECIAL ARTICLE

Treatment of peripheral arterial disease in diabetes: A consensus of the Italian Societies of Diabetes (SID, AMD), Radiology (SIRM) and Vascular Endovascular Surgery (SICVE)

A. Aiello [a], R. Anichini [b], E. Brocco [c], C. Caravaggi [d], A. Chiavetta [e], R. Cioni [f], R. Da Ros [g], M.E. De Feo [h], R. Ferraresi [i], F. Florio [j], M. Gargiulo [k], G. Galzerano [l], R. Gandini [m], L. Giurato [n], L. Graziani [o], L. Mancini [p], M. Manzi [q], P. Modugno [r], C. Setacci [l], L. Uccioli [n,*]

Figura 1 **Rivascolarizzazione percutanea**



La rivascolarizzazione nei diabetici con ischemia critica dovuta a stenosi / occlusioni croniche ed estese dell'asse femoro-popliteo e/o dei vasi infrapopliteI

Predictive Values of Transcutaneous Oxygen Tension for Above-the-ankle Amputation in Diabetic Patients Meeting the TransAtlantic Inter-Society Consensus Diagnostic Criteria for Critical Limb Ischemia

E. Faglia,[1*] G. Clerici,[1]

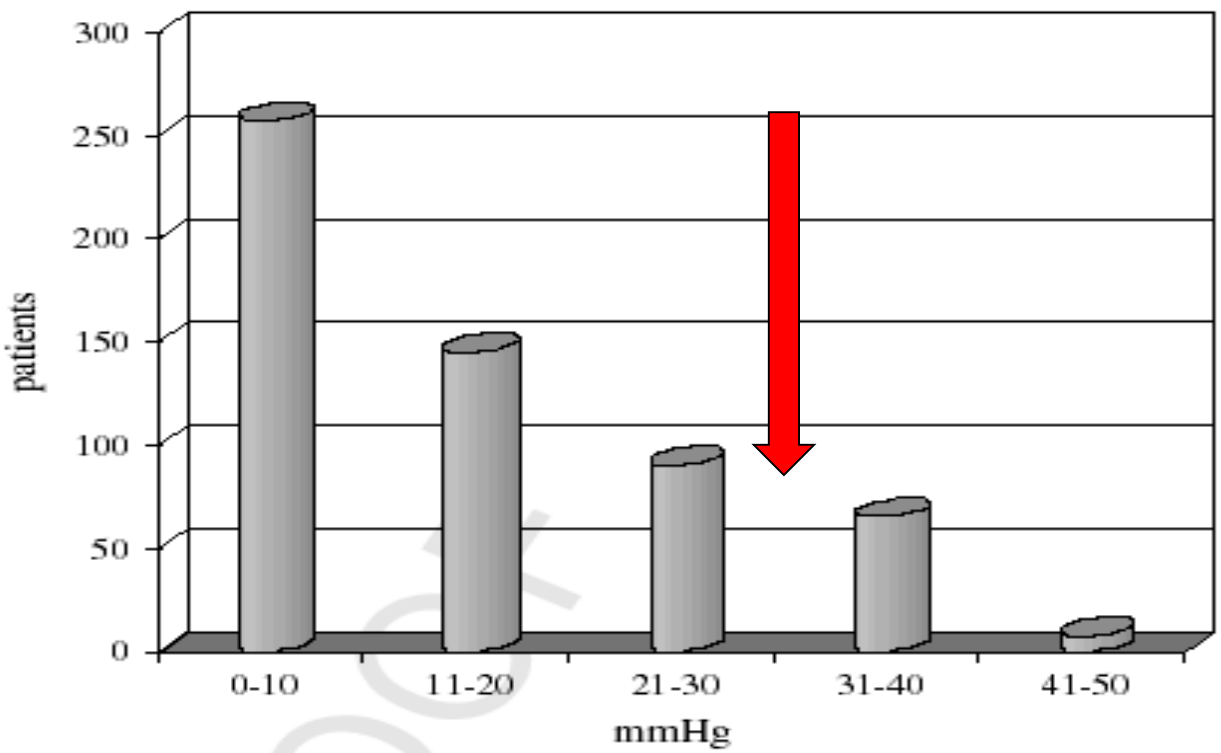
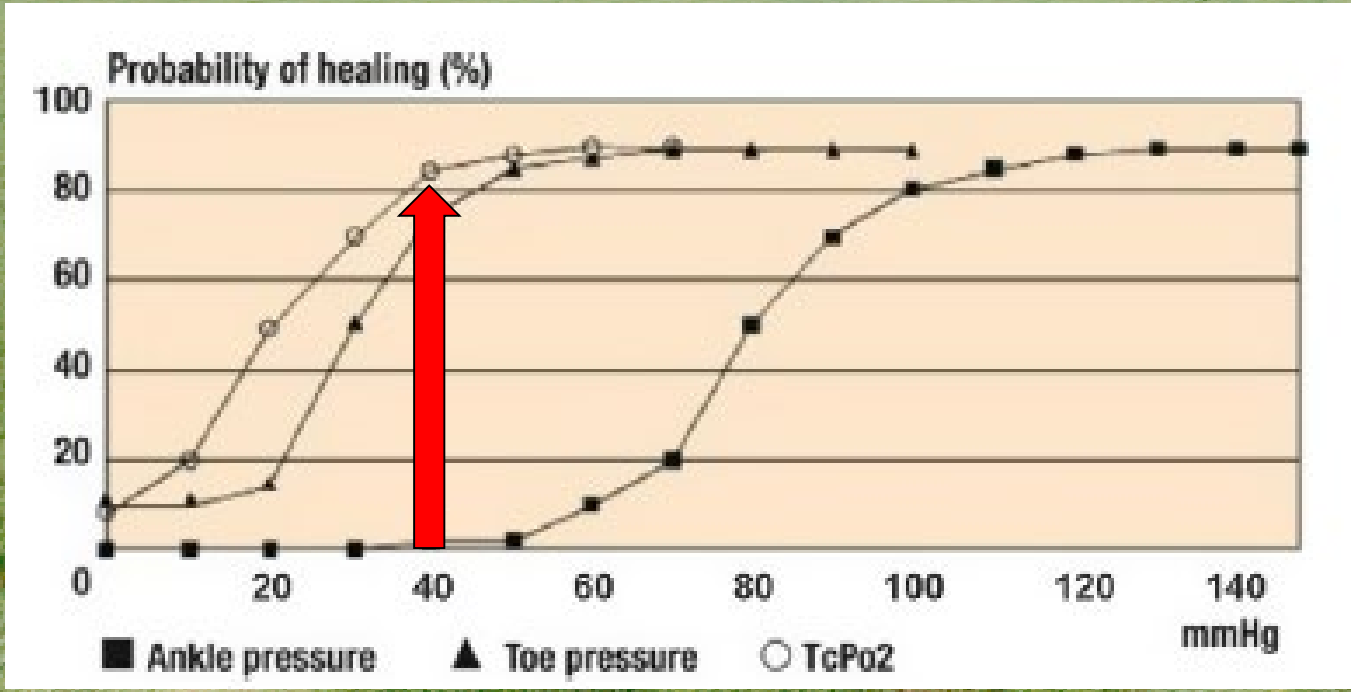


Fig. 1. $TcPO_2$ values distribution by 10 mmHg classes in study population at the study entry ($N = 564$).

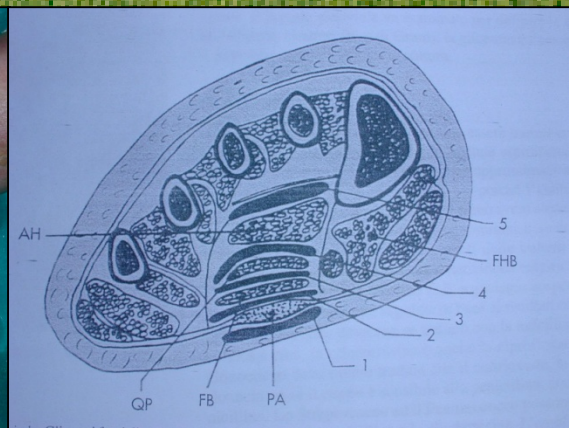
Eur J Vasc Endovasc Surg 2007



European Journal of Vascular and Endovascular Surgery (2011) **42**(S2), S60-S74

Three Main Plantar Compartments

- **Medial**
- **Central**
  - **superficial and deep**
- **Lateral**



“Infections follow fascial planes...
surgeons should as well”

WF Todd

THE IMPORTANCE OF THE "TIMING"

(Severe Infected Diabetic Foot)

The Role of Early Surgical Debridement and Revascularization in Patients with Diabetes and Deep Foot Space Abscess: Retrospective Review of 106 Patients with Diabetes

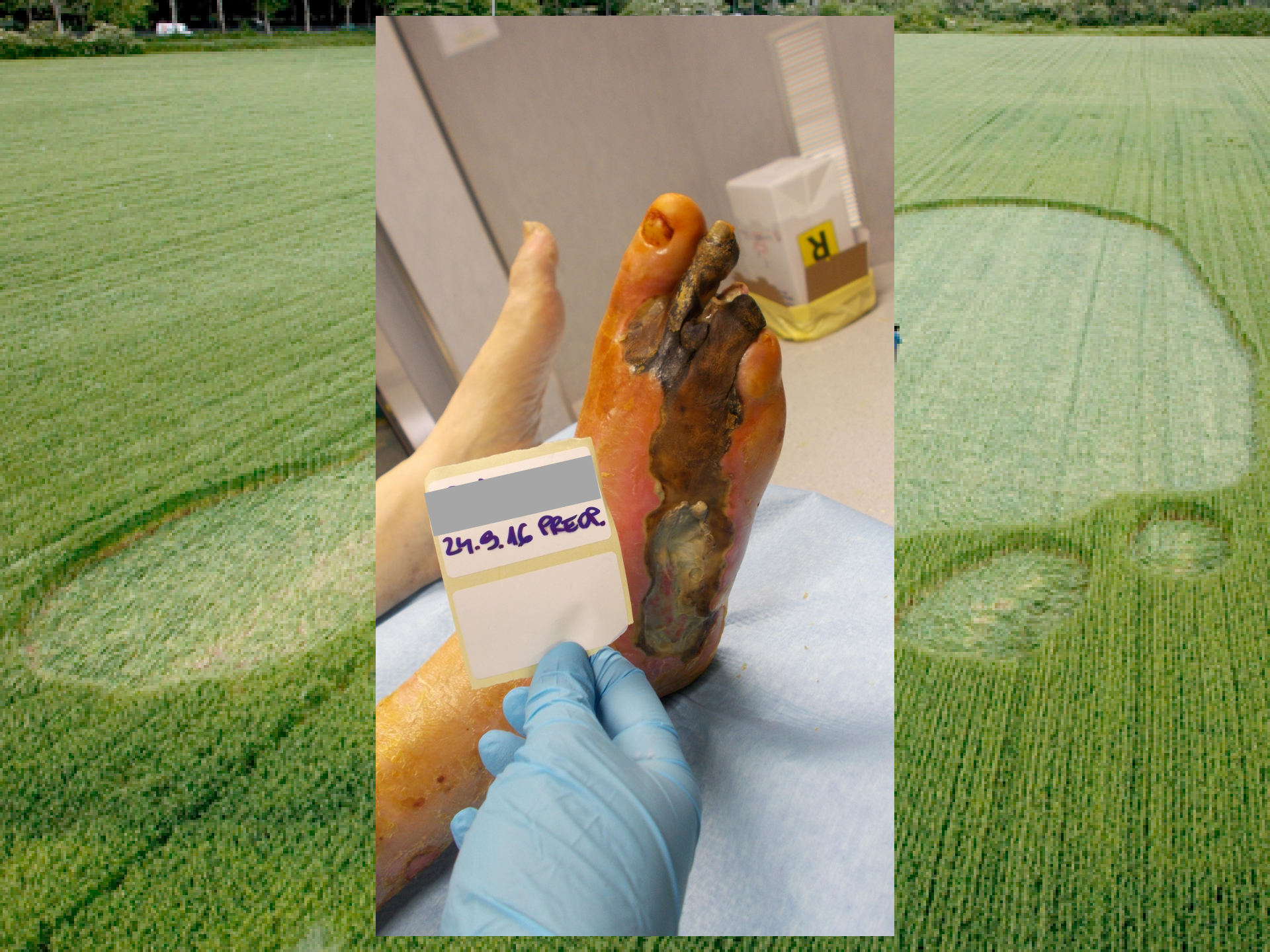
Ezio Faglia, MD,[1] Giacomo Clerici, MD,[2] Maurizio Caminiti, MD,[3]
Antonella Quarantiello, MD,[4] Michela Gino, MD,[5] and Alberto Morabito, PhD[6]

TABLE 4 Final outcome of surgical treatment of patients directly hospitalized (group A) and referred from other hospitals (group B)

Surgical intervention	Group A	Group B	
Drainage without amputation	9	4	
One or more ray amputation	21	21	$\chi^2 = 24.4$
Transmetatarsal amputation	12	10	$P < .001$
Chopart amputation	1	23	
Above-the-ankle amputation	—	5	

J Foot Ankle Surg. 2006 Jul-Aug;45(4):220-6.


Debridement
Chirurgico
urgente
AngioPTA
26 11 2004
8 2 2005
4 1 2005


24.9.16 PREOP.
R

PTA


POST OPER.
[redacted]
4·10·16


[redacted]
23·11·'16


PRE OPER.
[redacted]
09.01.'17


[redacted]
13.01.17
DIMESSO

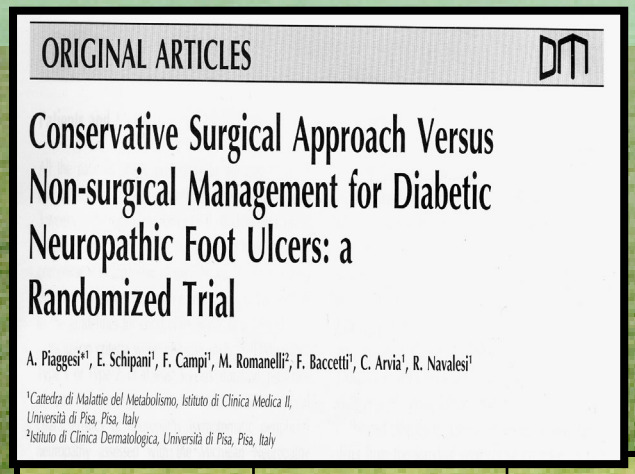

29.9.17

Indicazioni per approccio chirurgico

Deformità

Amputazione transmetatarsale

Surgical versus Non-surgical Management of Foot Ulcers



ORIGINAL ARTICLES

Conservative Surgical Approach Versus Non-surgical Management for Diabetic Neuropathic Foot Ulcers: a Randomized Trial

A. Piaggesi*[1], E. Schipani[1], F. Campi[1], M. Romanelli[2], F. Baccetti[1], C. Arvia[1], R. Navalesi[1]

[1]Cattedra di Malattie del Metabolismo, Istituto di Clinica Medica II, Università di Pisa, Pisa, Italy
[2]Istituto di Clinica Dermatologica, Università di Pisa, Pisa, Italy

Group	Age years	Duration DM yrs	Healing Rate	Healing Time days	Ulcer Recurrence
A Non-Surgery	63.24 ±13.46	18.2 ±8.41	79.2% 19/24	128.9 ±86.60	8
B Surgery	65.53 ±9.87	16.84 ±10.61	95.4% 21/22	46.73 ±38.94	3

TRATTAMENTO CHIRURGICO
Osteomielite

- Rischio operatorio "calcolato"
- Tempi operatori brevi
- Anestesia tronculare
- Guarigioni più rapide


12.3.12


R
ap


DX


13.4.12


14.3.12


SN


SN


Casa di Cura Privata Abano Terme ie 1580
Zancanaro Luciano ID 17772 tsrm Alek
01/03/2004 14:09 SUPINO


Casa di Cura Privata Abano Terme ie 1400
Zancanaro Luciano ID 17772 tsrm Alek
01/03/2004 14:09 SUPINO


P.M. 27.11.01


05.08.11

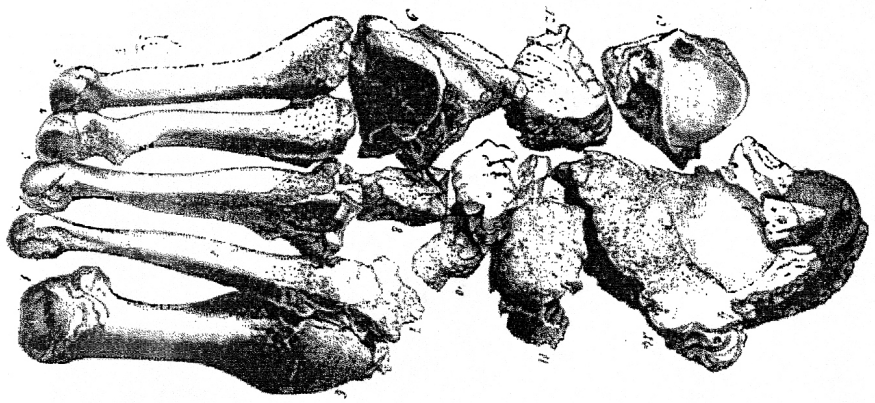

09/9/11
OPERANDO


[redacted]
POST OP
10/9/2011


[redacted]
PRE-OP


14-10-11
POST-INJ


12.04.2012



Squelette d'un pied ataxique : 1, 2, 3, 4, 5, métatarsiens ; 6, 7, premier et deuxième cunéiformes soudés aux métatarsiens correspondants ; 8, fragment osseux paraissant être le troisième cunéiforme ; 9, cuboïde ; 10, 11, deux fragments du scaphoïde ; 12, 13, b. b. et corps de l'astragale ; 14, calcanéum.


YES
BAIANO A.
19.10.2009
YES
BAIANO A.
19.10.2009
BAIANO A.
23.10.2009
BAIANO A.
23.10.2009
BAIANO A.
23.10.2009

Foot & Ankle® INTERNATIONAL

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August 2006 / Volume 27 / Number 8

Use of a retrograde nail for ankle arthrodesis in Charcot neuroarthropathy: a limb salvage procedure

L.Dalla Paola, A.Volpe , E. Brocco et al.

Foot Ankl Int.
Sept.2007

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Syndesmosis Fixation: A Comparison of Three and Four Cortices of Screw Fixation Without Hardware Removal
Joel A. Moore Jr., M.D.; M.P.H.; John R. Shank, M.D.; Steven J. Morgan, M.D.; Wade R. Smith, M.D.

Modified Coughlin Procedure for Surgical Treatment of Symptomatic Tailor's Bunion: A Prospective Followup Study of 33 Consecutive Operations
Patrick Vienne, M.D.; Meike Oesselmann, M.D.; Normann Espinosa, M.D.; Rolf Ischebeck, M.D.; Patrick Zingg, M.D.

Correction of Moderate to Severe Hallux Valgus Deformity by a Modified Chevron Shaft Osteotomy
José Antonio Vega Sanhueza, M.D.

Long-Term Results after Metatarsal Head Resection in the Treatment of Rheumatoid Arthritis
Patrick Reize, M.D.; Carmen Isa Lächele, M.D.; Ulf Günther Lächele, M.D.; Jörg Schatzlaucher, M.D.

Staged Reconstruction for Chronic Rupture of Both Peroneal Tendons Using Hunter Rod and Flexor Hallucis Longus Tendon Transfer: A Long-Term Followup Study
Kristi L. Wagner, M.D.; John S. Taras, M.D.; Sheldon S. Lin, M.D.; Wen Chan, M.D.

Necrotizing Soft-Tissue Infection of a Limb: Clinical Presentation and Factors Related to Mortality
Metin Onalay, M.D.; Gurhan Orhun, M.D.; Sercan Akgünat, M.D.; Murat Ali Hersekli, M.D.; Relos N. Tetedogian, M.D.

Foot Orthoses for the Treatment of Plantar Fasciitis
Eva Rome, Ph.D., P.T.; Mikael Engström, B.Sc., C.P.O.; Bengt Söderberg, B.Sc., C.P.O.

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George A. Arangio, M.D.; Thomas Wenger, Ph.D.; Albert Ragnarsson, B.S.

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American Orthopaedic Foot and Ankle Society
Swiss Foot and Ankle Society
The Japanese Society for Surgery of the Foot
The Korean Society of Foot Surgery
Australian Orthopaedic Foot and Ankle Society
Argentine Society for Foot and Leg Medicine and Surgery
Italian Society of Medicine and Surgery of the Foot and Ankle
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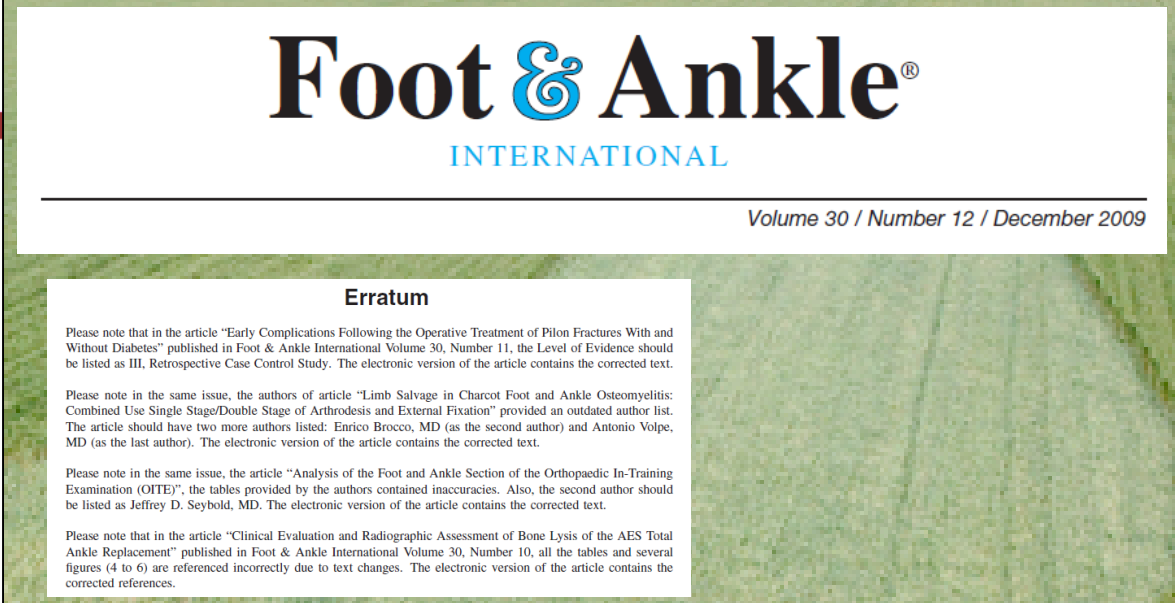
August 2006 / Volume 27 / Number 8



Foot & Ankle® INTERNATIONAL

Volume 30 / Number 12 / December 2009

Erratum

Please note that in the article "Early Complications Following the Operative Treatment of Pilon Fractures With and Without Diabetes" published in Foot & Ankle International Volume 30, Number 11, the Level of Evidence should be listed as III, Retrospective Case Control Study. The electronic version of the article contains the corrected text.

Please note in the same issue, the authors of article "Limb Salvage in Charcot Foot and Ankle Osteomyelitis: Combined Use Single Stage/Double Stage of Arthrodesis and External Fixation" provided an outdated author list. The article should have two more authors listed: Enrico Brocco, MD (as the second author) and Antonio Volpe, MD (as the last author). The electronic version of the article contains the corrected text.

Please note in the same issue, the article "Analysis of the Foot and Ankle Section of the Orthopaedic In-Training Examination (OITE)", the tables provided by the authors contained inaccuracies. Also, the second author should be listed as Jeffrey D. Seybold, MD. The electronic version of the article contains the corrected text.

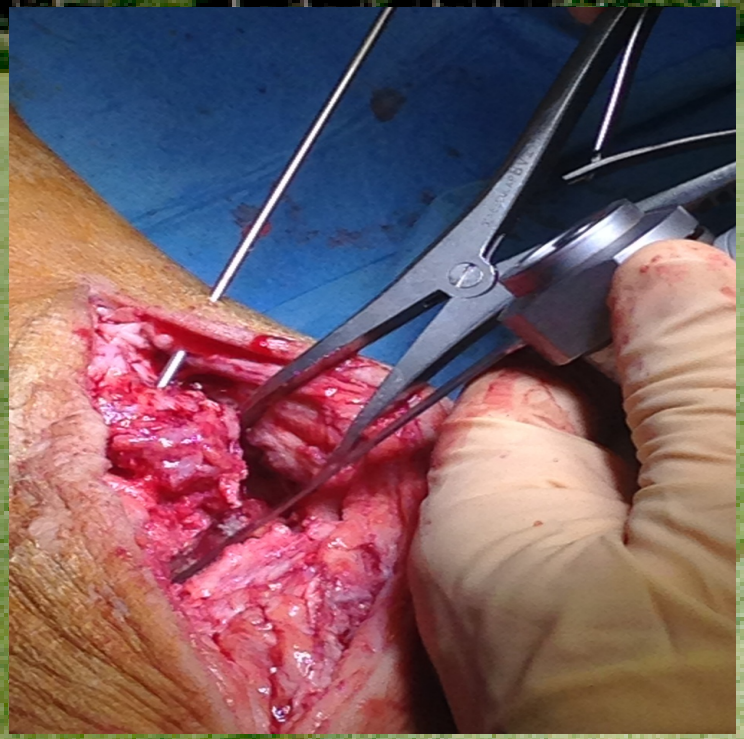
Please note that in the article "Clinical Evaluation and Radiographic Assessment of Bone Lysis of the AES Total Ankle Replacement" published in Foot & Ankle International Volume 30, Number 10, all the tables and several figures (4 to 6) are referenced incorrectly due to text changes. The electronic version of the article contains the corrected references.

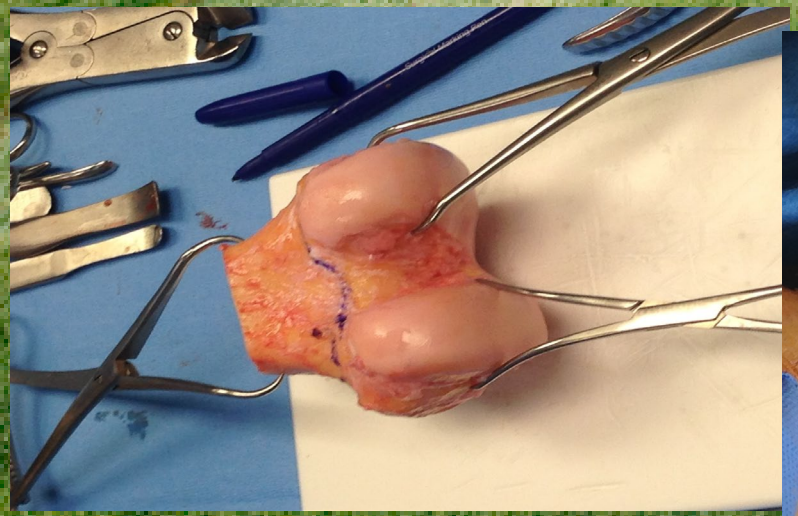
Limb Salvage in Charcot Foot and Ankle Osteomyelitis: Combined Use Single Stage/Double Stage of Arthrodesis and External Fixation

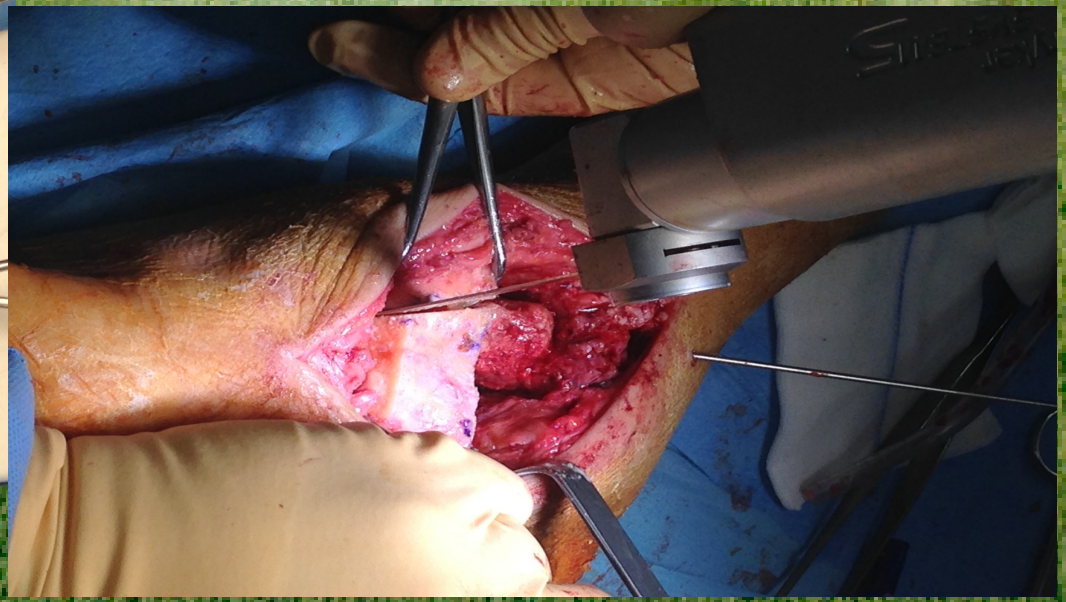
Luca Dalla Paola, MD; Enrico Brocco, MD; Tanja Ceccacci, MD; Sasa Ninkovic, MD; Sara Sorgentone, MD; Maria Grazia Marinescu, MD; Antonio Volpe, MD

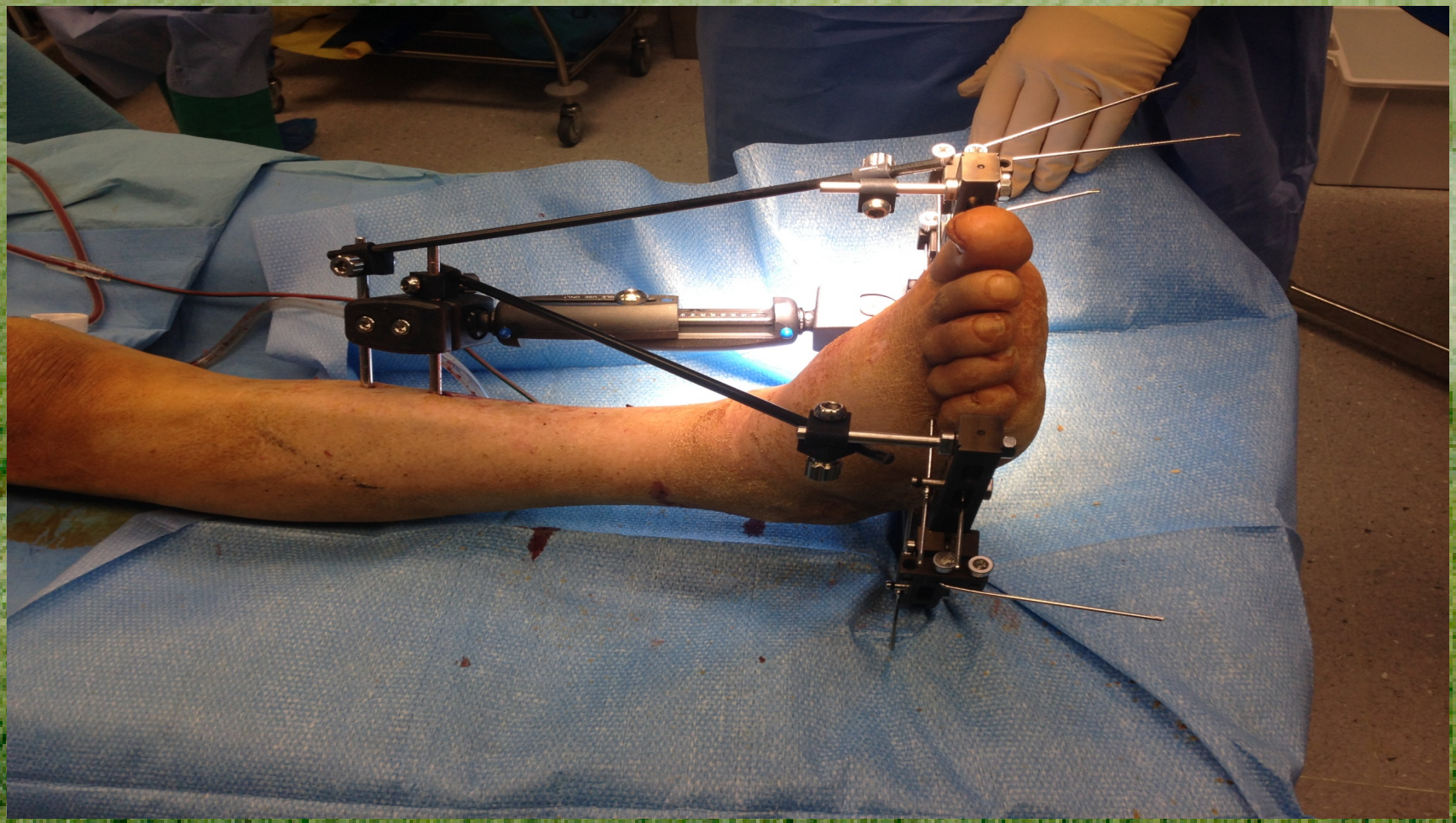
Venezia-Padova, Italy

G.Giovanni 61 yrs
CNA with large bone loss
Severe instability
Marked deformity
Misunderstood/mistreated for 2 years



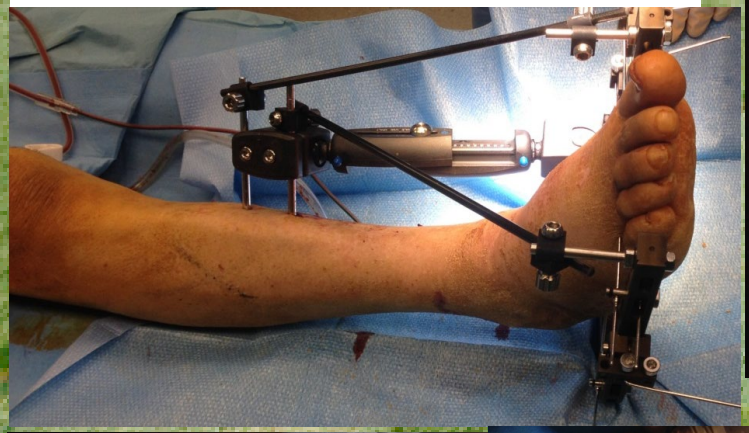






G.Giovanni a 61

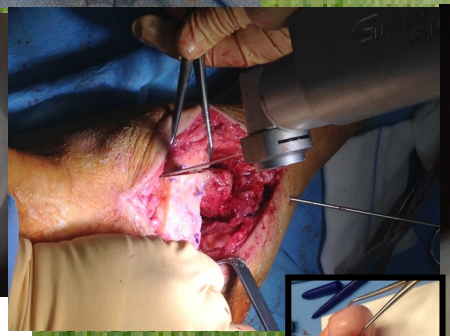
EXTREME ATTEMPT OF LIMB SALVAGE WITH MASSIVE BONE GRAFTING AND EXTERNAL FIXATOR



CNA MIDFOOT
G.Giovanni PRIMA

CNA MIDFOOT
G.Giovanni DOPO

CNA MIDFOOT
G.Giovanni PRIMA



CNA MIDFOOT
G.Giovanni DOPO

CNA MIDFOOT
G.Giovanni anni 61 DOPO

6 - 8 September 2018 · Helsinki, Finland

37th Annual Meeting of the
European Bone and Joint Infection Society

RADIOLOGICAL AND CLINICAL OUTCOMES IN THE MEDIUM-TERM OF THE USE OF AN ANTIBIOTIC BONE SUBSTITUTE IN THE DIABETIC FOOT

C. Whisstock, M. Marin, M. Bruseghin, S. Ninkovic, G. Boschetti, R.Viti and E. Brocco.

Foot&Ankle Clinic Policlinico Abano Terme

Policlinico Abano Terme
Presidio Ospedaliero Regione Veneto

Centro di Riferimento Regione Veneto per la cura del Piede Diabetico

FONDAZIONE LEONARDO
PER LE SCIENZE MEDICHE

METHODS

In nine patients from July 2014 to December 2016 we used a calcium Sulphate Hemihydrate + Hydroxyapatite + Gentamicin Sulfate (CSH + HA + GS) compound to fill resected bone voids following surgical intervention in OM diabetic foot cases.
Of these nine patients, three were female and six were male and their ages were between 49 and 72 years


BOLZONELLA, CARLO
Nato il 02/09/1945
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26.09.2014


BOLZONELLA, CARLO
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VAC tp


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10.2.15

RESULTS

All patients are now wearing suitable shoes as post-operative wounds have healed.


25.5.18

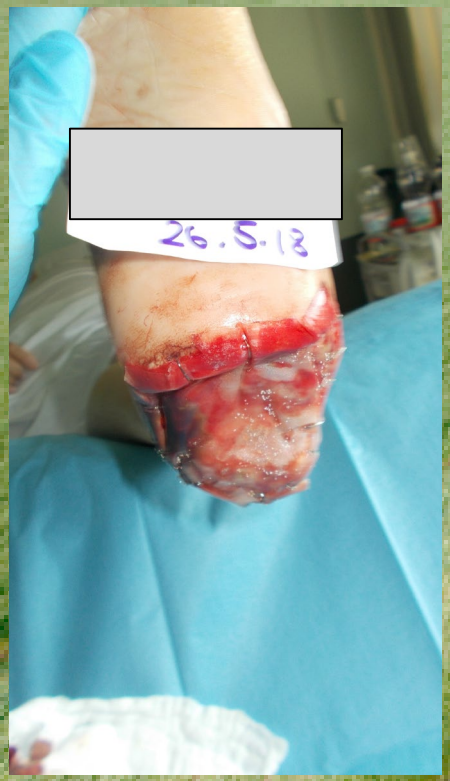

L
lat

Raccolta lipo-aspirato

Micro-filtrazione

Centrifugazione

SVF purificata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25.07.18
25/07/2018 08:15


Esame del 11/07/2018
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OSTI, ARMIDO
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Sesso: M
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Esame del 28/09/2018
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Acc#: 91006455
lat
WWWL 26342/17154
RX CAVIGLIA SX
Dose: 0.794

OPEN ACCESS Freely available online

PLOS | ONE

Lower Extremity Amputations in Persons with and without Diabetes in Italy: 2001–2010

Flavia L. Lombardo[1], Marina Maggini[1], Alessandra De Bellis[2], Giuseppe Seghieri[2], Roberto Anichini[2]*

1 National Centre for Epidemiology, Surveillance and Health Promotion, National Institute of Health, Roma, Italy, **2** Diabetes Unit and Diabetic Foot Unit, Department of Internal Medicine General Hospital Pistoia, Pistoia, Italy

Abstract

Objective: To analyze hospitalization for lower extremity amputations (LEAs) and amputee rates in persons with and without diabetes in Italy.

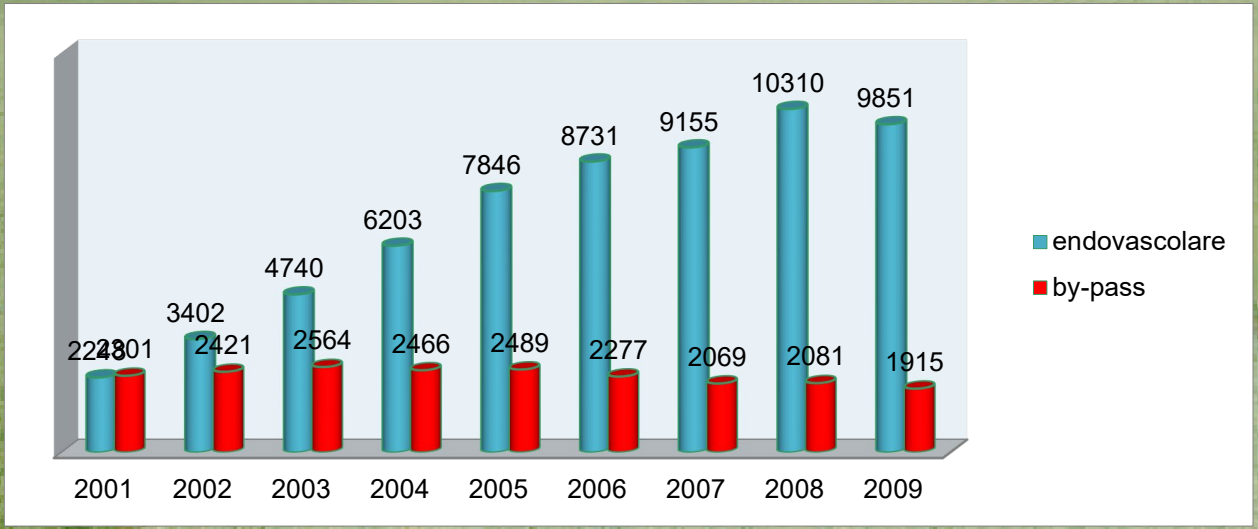
Research Design and Methods: All patients with LEAs in the period 2001–2010 were identified analyzing the National Hospital Discharge Record database. For each year, amputee and hospitalization rates for LEAs were calculated either for persons with diabetes or without. Time trend for major and minor amputations were analysed.

Results: From 2001 to 2010 a mean annual number of 11,639 individuals underwent a lower extremity amputation: 58.6% had diabetes accounting for 60.7% of total hospitalizations. In 2010, the crude amputee rate for LEAs was 20.4 per 100,000 inhabitants: 247.2 for 100.000 persons with diabetes, and 8.6 for those without diabetes. Having diabetes was associated to an increased risk of amputation (Poisson estimated RR 10.9, 95%CI 9.4–12.8). Over the whole period, a progressive reduction of amputee rates was observed for major amputations either among persons with diabetes (−30.7%) or without diabetes (−12.5%), while the rates of minor amputations increased progressively (+22.4%) among people without diabetes and were nearly stable in people with diabetes (−4.6%). A greater number of minor amputations were performed among persons with than without diabetes: in 2010, the minor-to-major ratio among persons with diabetes (2.5) was more than twice than in those without diabetes (1.0).

Conclusions: The nationwide analyses confirm a progressive reduction of hospitalization and amputee rates for major LEAs, suggesting an earlier and more diffuse approach aimed at limb salvage.

Citation: Lombardo FL, Maggini M, De Bellis A, Seghieri G, Anichini R (2014) Lower Extremity Amputations in Persons with and without Diabetes in Italy: 2001–2010. PLoS ONE 9(1): e86405. doi:10.1371/journal.pone.0086405

Editor: Christian Herder, German Diabetes Center, Leibniz Center for Diabetes Research at Heinrich Heine University Duesseldorf, Germany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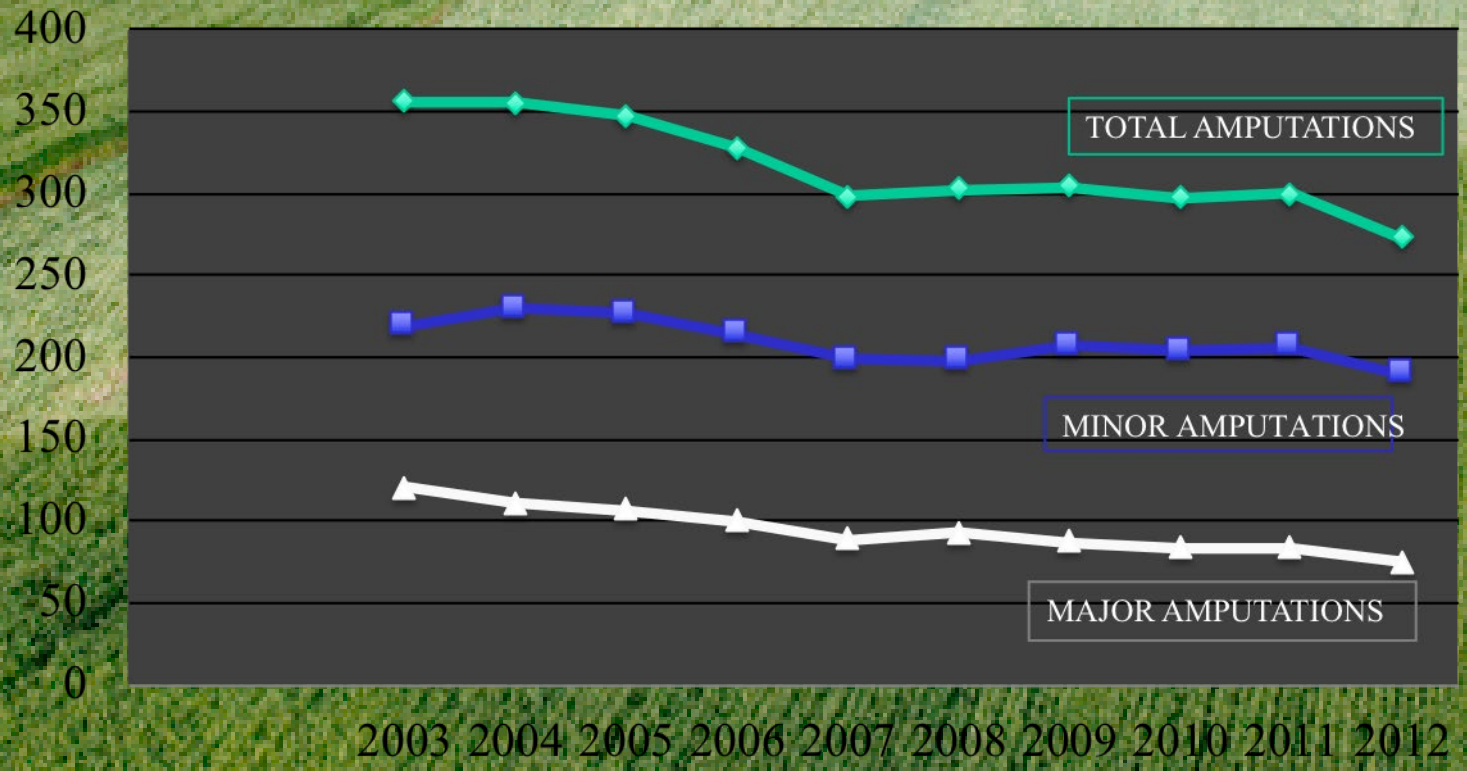
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TOTAL AMPUTATIONS
MINOR AMPUTATIONS
MAJOR AMPUTATIONS
2003 2004 2005 2006 2007 2008 2009 2010 2011 2012

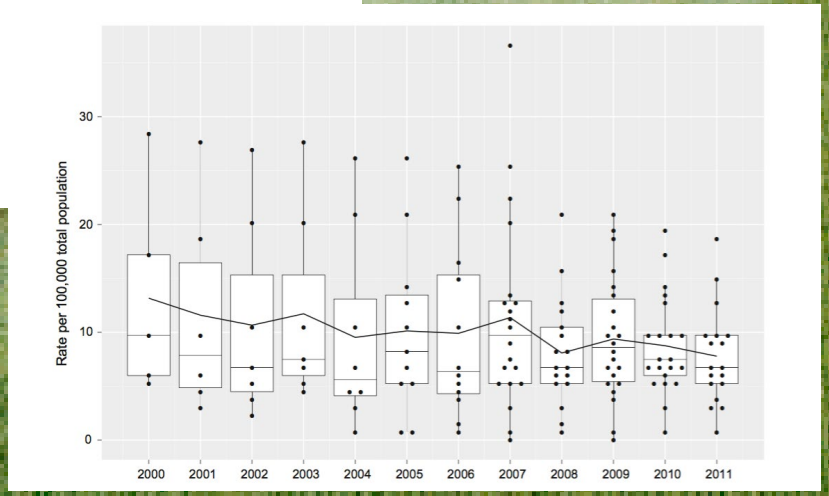
Acta Diabetol
DOI 10.1007/s00592-016-0879-4

ORIGINAL ARTICLE

Received: 15 January 2016 / Accepted: 20 June 2016

Lower extremity amputation rates in people with diabetes as an indicator of health systems performance. A critical appraisal of the data collection 2000–2011 by the Organization for Economic Cooperation and Development (OECD)

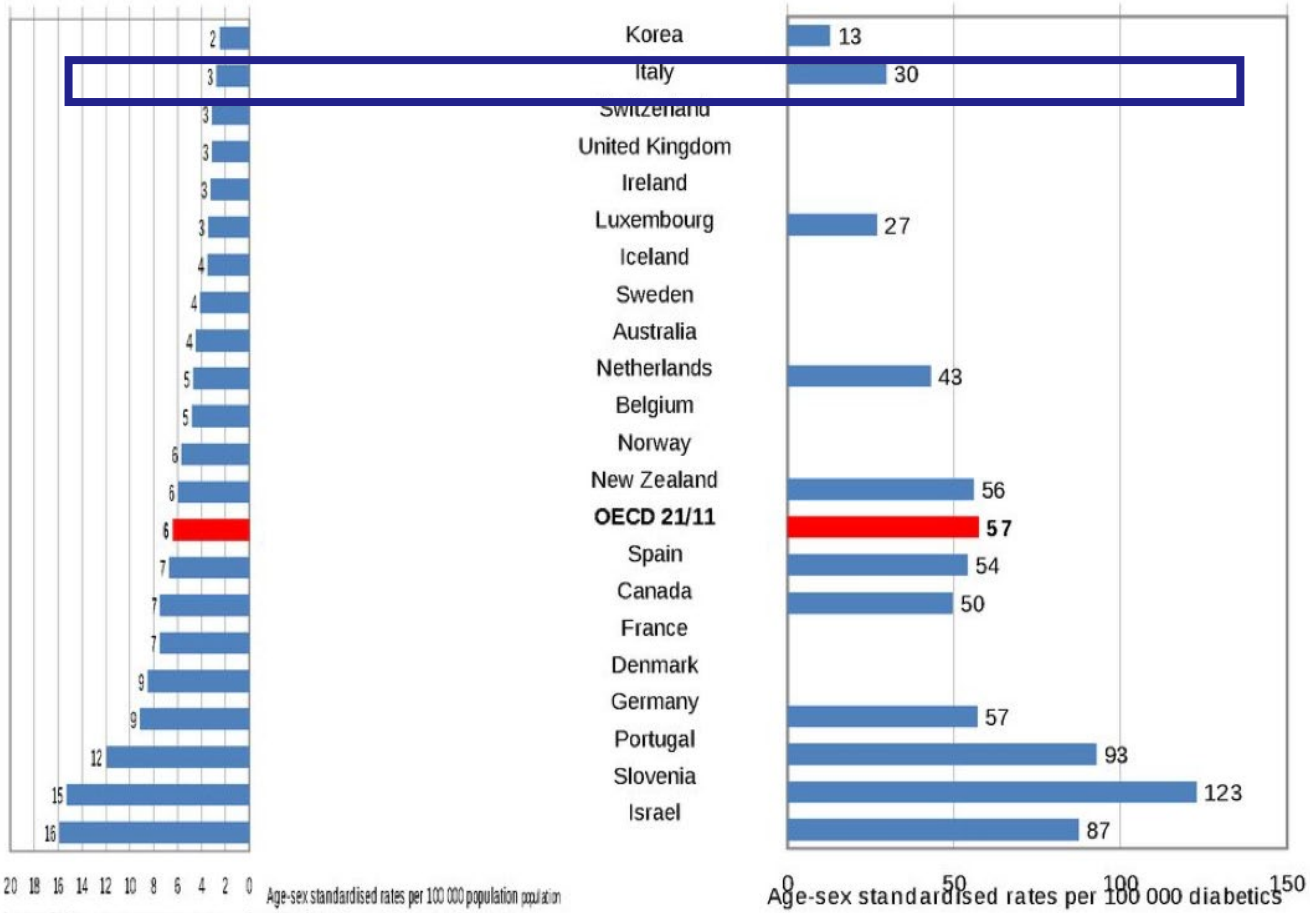
F. Carinci[1] · M. Massi Benedetti[2] · N. S. Klazinga[3,4] · L. Uccioli[5]



Gender	Country	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011
Total	Australia									6.9	6.4	5.5	5.0
	Belgium	17.5	18.5	20.0	19.9	20.6	20.6	22.1	20.1	15.9	15.9		
	Canada								11.9		10.0	9.6	10.0
	Denmark								22.3		19.2		
	Finland								6.8	6.4	6.5	6.5	5.8
	France								13.4			7.4	7.1
	Germany								36.4		20.6		18.4
	Hungary					0.6	0.7	0.8	1.1	1.5	0.7	1.0	1.1
	Iceland	5.7	3.1	2.5	4.6	2.8	1.1	1.6	0.0	0.4	0.0		
	Ireland	5.1	4.8	3.6	5.2	4.3	5.3	4.4	5.6	5.0	4.9	5.2	3.8
	Israel	28.1	27.3	26.8	27.4	26.2	26.3	25.7	25.1	20.7	18.6	19.5	
	Italy		5.9	6.7	6.6	6.4	6.4	5.8	5.6	5.9	5.7	5.9	5.7
	Korea								8.8	9.4	9.6	9.5	9.8
	Luxembourg			4.9	7.7	4.8	5.5	3.6	7.7	6.0	4.6	7.0	2.8
	Mexico										8.3	9.5	9.2
	Netherlands						12.5		12.8	11.6	11.6	13.5	
	New Zealand						8.5	6.7	7.0	7.9	7.6	7.1	6.7
	Norway								11.0		9.3	7.8	8.7
	Poland						14.0	15.3	12.6	12.8	13.3	13.9	
	Portugal												12.8
	Slovenia										14.0	12.5	15.1
	Spain	9.4	9.9	10.1	10.6	10.5	10.5	10.8	10.5	10.4	10.6	9.7	9.6
	Sweden								3.2	3.2	3.6	3.2	3.3
	Switzerland							16.8		7.9		7.1	
	United Kingdom							5.2	5.3	5.4	5.3	5.3	5.1
	United States							37.5		34.5		17.1	

Dataset: Health Care Quality Indicators
Value: Age(-sex) standardised rate per 100 000 population
Age Group: 15 years old and over

8.4. **Major lower extremity amputation in adults with diabetes, 2013 (or nearest year)**



Note: Three-year average for Iceland and Luxembourg.

Source: OECD Health Statistics 2015, http://dx.doi.org/10.1787/health-data-en.

Amputazioni Italia vs USA in diabetici dati 2010

Italia 2005 / 2010

Numero 7014 / 7373

Rate di amputazione x 10000 = 28.9 / 24,7

USA 2005 / 2010

Numero 69074 / 73067

Rate di amputazione x 10000 = 35,5 / 28,4

Se venisse applicato lo stesso rate di amputazione registrato negli USA alla popolazione diabetica italiana si avrebbe un **aumento** del numero di amputazioni di **1100 unità** l'anno !!!

Prevenire ed Educare Ma dove porre l'Attenzione

N Engl J Med 2017;376:2367-75.
DOI: 10.1056/NEJMra1615439

REVIEW ARTICLE

Julie R. Ingelfinger, M.D., *Editor*

Diabetic Foot Ulcers and Their Recurrence

David G. Armstrong, D.P.M., M.D., Ph.D., Andrew J.M. Boulton, M.D., and Sicco A. Bus, Ph.D.

COMPLICATIONS OF DIABETES THAT AFFECT THE LOWER EXTREMITIES ARE common, complex, and costly. Foot ulceration is the most frequently recognized complication. In a community-based study in the northwestern United Kingdom, the prevalence of active foot ulcers identified at screening among persons with diabetes was 1.7%, and the annual incidence was 2.2%.[1] Higher annual incidence rates have been reported in specific populations: 6.0% among Medicare beneficiaries with diabetes, 5.0% among U.S. veterans with diabetes, and 6.3% in the global population of persons with diabetes.[2-4] On the basis of 2015 prevalence data from the International Diabetes Federation,[5] it is estimated that, annually, foot ulcers develop in 9.1 million to 26.1 million people with diabetes worldwide. The proportion of persons with diabetes and a history of foot ulceration is understandably higher than the proportion with an active ulcer; 3.1 to 11.8% of persons with diabetes, or 12.9 million to 49.0 million persons worldwide and 1.0 million to 3.5 million in the United States alone, have a history of foot ulceration.[1,5-7] The lifetime incidence of foot ulcers has previously been estimated to be 15 to 25% among persons with diabetes,[8] but when additional data are considered, between 19% and 34% of persons with diabetes are likely to be affected (for the calculation, see the Supplementary Appendix, available with the full text of this article at NEJM.org).

From the Southern Arizona Limb Salvage Alliance (SALSA), Department of Surgery, University of Arizona College of Medicine, Tucson (D.G.A.); Faculty of Biology, Medicine, and Health, University of Manchester, Manchester, United Kingdom (D.G.A., A.J.M.B.); and the Department of Rehabilitation Medicine, Academic Medical Center, University of Amsterdam, and Amsterdam Movement Sciences — both in Amsterdam (S.A.B.). Address reprint requests to Dr. Armstrong at SALSA, Department of Surgery, University of Arizona College of Medicine, 1501 N. Campbell Ave., Tucson, AZ 85724, or at armstrong@usa.net.

N Engl J Med 2017;376:2367-75.
DOI: 10.1056/NEJMra1615439

Ulcers Recurrence: central point

The NEW ENGLAND JOURNAL of MEDICINE

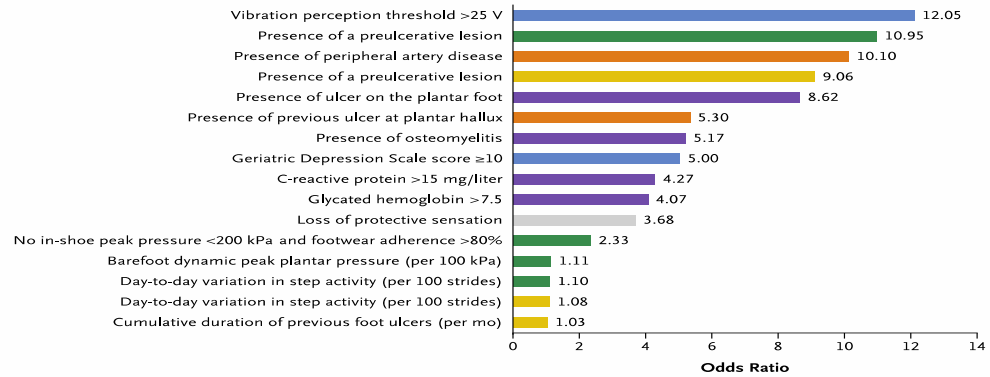


Figure 3. Risk Factors Independently Associated with Ulcer Recurrence.
Data are from five studies that reported an odds or risk ratio.[28,33,42,52,56] According to Monami et al.[42] (blue), risk factors for ulcer recurrence are a vibration perception threshold greater than 25 V and a Geriatric Depression Scale score of 10 or higher (scores range from 0 to 15, with higher scores indicating more severe depression). According to Peters et al.[56] (orange), risk factors for ulcer recurrence are the presence of peripheral artery disease and location of the previous ulcer at the plantar hallux. According to Dubský et al.[28] (purple), a plantar location of the ulcer, the presence of osteomyelitis, and elevated blood levels of C-reactive protein and glycated hemoglobin (all of which were determined at the time of study enrollment for patients with an active foot ulcer) are independent predictors of recurrence of foot ulcers. According to Reiber et al.[33] (gray), loss of protective sensation is a risk factor for recurrence of an ulcer on the plantar surface of the foot. According to Waaijman et al.,[52] risk factors for recurrence of an ulcer on the plantar surface of the foot (yellow) include the presence of a preulcerative lesion, low day-to-day variation in step activity, and a long cumulative duration of previous foot ulcers; risk factors for recurrence of a pressure-related plantar ulcer (green) include the presence of a preulcerative lesion, lack of both in-shoe peak pressure below 200 kPa and therapeutic-footwear adherence higher than 80%, high barefoot dynamic peak plantar pressure, and low day-to-day variation in step activity.

The patients in Remission

SPECIAL COMMUNICATION

Toward a Change in Syntax in Diabetic Foot Care

Prevention Equals Remission

David G. Armstrong, DPM, MD, PhD*
Joseph L. Mills, MD

Because neuroischemic complications are associated with a high rate of recurrence, we propose a slight shift in the mechanism by which we counsel and communicate risk daily

More useful to think of patients
Who have archived wound Closure Ad being *In remission rather than Being healed*

Conclusioni

La *recurrence delle ulcere* è il problema cardine nel trattamento del Piede Diabetico.

Necessità di rifocalizzare gli aspetti legati prevenzione */educazione* e riallocazione delle risorse dalla guarigione delle ulcere alla massimizzazione dell' ulcer free days.

La Chiave del successo sta nel *Low foot Pressure and High adherence.*

E' necessaria una sistematica *scientific-based data driven approach sulla footwear design* e la valutazione effettive degli outcome valutati scientificamente.

Passare dall' approccio artigianale e personale allo «*integrated state-of-art approach»*

Le calzature terapeutiche….come una medicina……

Implementazione delle linee guida dell'IWGDF su calzature e scarico per prevenire e consentire la guarigione delle ulcere distali in pazienti diabetici

Redatta dal Gruppo interassociativo AMD-SID "Podopatia diabetica"

Calzature terapeutiche

Vi è stato un sostanziale accordo con il documento guida

- Per prevenire una recidiva di ulcera plantare del piede in un paziente diabetico a rischio, è necessario prescrivere ortesi plantari su misura e calzature terapeutiche con dimostrata riduzione della pressione plantare durante la deambulazione (vale a dire il 30% di riduzione rispetto alle scarpe non terapeutiche) ed incoraggiare il paziente ad indossarle.
- Anche quando è presente una deformità del piede o una lesione pre-ulcerativa, è raccomandata la prescrizione di scarpe terapeutiche, ortesi plantari su misura od ortesi digitali.
- Per calzature terapeutiche si devono intendere scarpe progettate per permettere una forma di trattamento del piede. Sono scarpe con maggiore profondità (extra-fonde) per accogliere le deformità e ridurre la pressione sulle zone a rischio sulle superfici plantari e dorsali del piede. Possono essere prefabbricate o costruite su misura.
- L'ortesi plantare su misura è un plantare su calco, confezionato sulla forma del piede del paziente, accomodante, e in una struttura multistrato.
- Dalla discussione è emerso che la prescrizione dei presidi ortesici ed il relativo collaudo deve essere effettuato da un team in grado di rilevare l'efficacia del dispositivo attraverso una dimostrata riduzione della pressione plantare.

Gruppo interassociativo AMD-SID
podopatia diabetica

World Health Organization

EQUIPPING, ENABLING AND EMPOWERING

Priority Assistive Products List

Improving access to assistive technology for everyone, everywhere

37 Spectacles; low vision, short distance, long distance, filters and protection

38 Standing frames, adjustable

39 Therapeutic footwear; diabetic, neuropathic, orthopaedic

40 Time management products

44 Walking frames/ walkers

45 Watches, talking/ touching

46 Wheelchairs, manual for active use

47 Wheelchairs, manual assistant-controlled

WHO 2016

Nuova Normativa Prescrizione Ausili
19-3-2017 **LEA**

Solo scarpe su misura con plantari personalizzati.

Classi di rischio avanzate o con ”grande deformità”

SERIE GENERALE

GAZZETTA UFFICIALE
DELLA REPUBBLICA ITALIANA

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podopatia diabetica

6° Congresso Nazionale del Gruppo di Studio della Podopatia Diabetica

Il Piede Diabetico in Italia nel terzo millennio: discipline diverse, professionalità integrate in un percorso unitario con il paziente diabetico al centro

Presidente del Congresso: Dr. Roberto Anichini
Responsabile Scientifico: Dr. Roberto Da Ros

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Trieste, 31 gennaio / 2 febbraio 2019

SEGRETERIA ORGANIZZATIVA
A.I.C. Asti Incentives & Congressi Srl
P.zza San Uomobono, 30 - 56126 Pisa
Tel. 050 541402/598808
Fax 050 598688
amd-sid-trieste@aicgroup.it

PROVIDER ECM ID n. 373
SID Società Italiana di Diabetologia e Malattie del Metabolismo
Via Pisa, 21 - 00162 ROMA
Tel. 06 44240967
Fax 06 44292060
siditalia@pec.siditalia.it

GRAZIE PER L’ATTENZIONE