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Diabetic Foot Italy
Gruppo Interassociativo AMD - SID
podopatia diabetica



6° Congresso Nazionale del Gruppo di Studio della Podopatia Diabetica

La Sindrome del Piede Diabetico in Italia nel terzo millennio:
un approccio globale, discipline diverse, professionalità integrate
in un percorso unitario con "il paziente diabetico al centro"

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



Starhotels Savoia Excelsior Palace
Trieste, 31 gennaio / 2 febbraio 2019

APPROCCIO CHIRURGICO DALL'INTERVENTO ACUTO ALLA CORREZIONE DELLE DEFORMITA' - Nuovi Approcci -



P E D E R Z O L I

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SOMMARIO

SOMMARIO

- ✓ Ruolo dei carrier antibiotati nel trattamento delle osteomieliti
- ✓ «Novità» nella terapia ricostruttiva

RATIONALE FOR THE USE OF TOPICAL ANTIBIOTIC THERAPY

- Achievement of high antibiotic concentrations in affected area (10-100 times higher than serum levels)
- Limited systemic absorption (toxicity, liver and renal function)
- Reduction of development of resistant micro-organisms

NON-RESORBABLE

➤ **PMMA beads**

- Impregnable with glycopeptides / aminoglycosides
- High release up to 72 hours, then quick fall
- Require surgical removal

RESORBABLE

- Gradually resorb, can act as matrix for new bone growth
- Impregnable with water-soluble antibiotics
- After degradation, additional release of drug (prolonged action)
- No surgical removal

- **Calcium sulfate**
- **Hydroxyapatite**
- **Natural protein-based polymers**
- **Synthetic polymers**
- **Composite carriers**

Local Antibiotic Delivery Systems: Current and Future Applications for Diabetic Foot Infections

Konstantinos Markakis, MD, PhD ¹, Alan Robert Faris, MBChB ², Hamed Sharaf, MD ¹, Barzo Faris, MD ³, Sharon Rees, MSc, PhD ⁴, and Frank L. Bowling, DPM, PhD, DSc ^{1,5}

The International Journal of Lower Extremity Wounds
1-8
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DOI: 10.1177/1534734618757532
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Table 1. Published Clinical Data on Local Antibiotic Delivery in Diabetic Foot Infections.

Roeder et al ⁵⁰	2000	Case series	Tobramycin-impregnated PMMA beads in 2 cases of forefoot OM in conjunction with local resection of bone Vancomycin-impregnated PMMA beads placed in the dead space after subtal calcaneotomy in a case of MRSA OM of the heel	In conjunction with systemic antibiotic treatment Healed
Salgami et al ⁵¹	2007	Case report	Tobramycin-impregnated calcium sulfate pellets inserted as part of forefoot OM management	In conjunction with systemic antibiotic treatment
Lipsky et al ⁵⁸	2008	Randomized controlled double-blind multicenter	835 patients with mild infections of diabetic foot ulcers were randomized One group was treated with topical pexiganan, one group with oral ofloxacin Each group received the respective inactive placebo Application of tobramycin-impregnated calcium sulfate beads post TMA in 49 patients in addition to standard care Compared with 16 TMA cases with no beads applied	Equivalent result between topical and systemic treatment was reported for microbiological eradication and healing Development of resistance was reported in some ofloxacin cases None was found for pexiganan The beads group outcomes were better for lower rate wound breakdown and further surgery No difference in length of hospital stay or rate of conversion to below knee amputation
Krause et al ⁵⁵	2009	Retrospective cohort study	Resection of distal fibula and insertion of tobramycin-impregnated PMMA beads in Charcot ankle OM	In conjunction with systemic antibiotic treatment No recurrence of OM
Ramanujan and Zgonis ⁵³	2010	Case report	Insertion of vancomycin cerement beads with bone resection for forefoot osteomyelitis	Healed without requiring further surgery/removal of beads
Karr ⁵²	2011	Case report	Randomly allocated treatment of 38 infected diabetic foot ulcers with gentamicin collagen sponge in addition to standard care	Treatment group had a significantly higher clinical cure rate
Lipsky et al ⁵⁷	2012	Randomized controlled multicenter study	Compared with 18 cases who received standard care alone	
Varga et al ⁵⁶	2014	Randomized trial (no placebo group)	50 patients requiring minor amputations were randomized: half received a bioabsorbable collage sponge impregnated with gentamicin and half had no treatment	The topical antibiotic group require significantly less time to healing Hospital stay and further surgery were not different between groups All healed
Jogia et al ⁵⁴	2015	Case series	20 patients with forefoot ulcers with OM previously failed to respond to systemic antibiotics, regular wound debridement, and off-loading Excision of sequestrate and bone was packed with calcium sulfate pellets impregnated with vancomycin and gentamicin	No recurrence at 12 months Need of postoperative systemic antibiotics was decided individually (not clear how many received systemic antibiotics)
Panagopoulos et al ⁶	2015	Case series	8 patients with chronic metatarsal or calcaneal OM Use of PMMA beads or bone graft substitutes loaded with gentamicin	In conjunction with systemic antibiotics and minor surgery OM successfully treated in all cases
Morley et al ⁷	2016	Case report	A limb-threatening forefoot infection complicated with OM was debrided and drained then packed with calcium sulfate beads impregnated with vancomycin and gentamicin	In conjunction with systemic antibiotic treatment Healed

Abbreviations: PMMA, polymethylmethacrylate; OM, osteomyelitis; MRSA, methicillin-resistant *Staphylococcus aureus*; TMA, transmetatarsal amputation.

ANTIBIOTIC-LOADED CALCIUM SULPHATE HYDROXYAPATITE BIOCOMPOSITE IN **DIABETIC FOOT** SURGERY

N Vasukutty, M Metcalfe... - Orthopaedic ... 2018 - online.boneandjoint.org.uk

... Conclusions. A multidisciplinary approach and a strict protocol including augmented debridement and **Cerament** G injection are effective for treatment of chronic osteomyelitis in **diabetic foot** disease. The early results with this ...

☆ 77 88

Adjuvant antibiotic loaded bio composite in the management of **diabetic foot** osteomyelitis- A multicentre study

NS Niazi, E Drampalos, N Morrissey, N Jahangir... - The **Foot**, 2019 - Elsevier

... forefoot osteomyelitis using **Cerament** Bone Void Filler impregnated with vancomycin: off label use ... amputation in patients with **diabetes** ... Tables: Table 1 University of Texas **Diabetic** Wound Classification Stages A No infection or ischemia B Infection present C Ischemia present ...

☆ 77 88

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

C Whisstock, M Marin, S Ninkovic... - Orthopaedic ... 2018 - online.boneandjoint.org.uk

... Google+ Share; Reddit; Email. Abstract. Aim. The aim of this work was to evaluate, via **foot** and ankle TC scans, the outcomes of the use of a bone substitute (**CERAMENT**TMG) and the growth of native bone in the treatment of osteomyelitis (OM) of the **diabetic foot**. Method ...

☆ 77 88

Single stage treatment of **diabetic** calcaneal osteomyelitis with an absorbable gentamicin-loaded calcium sulphate/hydroxyapatite biocomposite: The Silo technique

E Drampalos, HR Mohammad, C Kosmidis, M Balal... - The **Foot**, 2018 - Elsevier

... for treating and local deliver of antibiotic for calcaneal osteomyelitis in patients with **diabetes**. Principles of calcaneal osteomyelitis treatment in **diabetic** patients, include a thorough debridement sparing as ... for this proper positioning and filling of the constructs with **Cerament** G ...

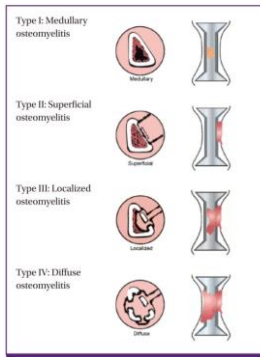
☆ 77 Citato da 4 Articoli correlati Tutte e 3 le versioni

16 pz con OM del piede Type III e IV (CM)
Gentamicina loaded, team multidisciplinare
Infection clearance 88% (14/16), FU 38 weeks

70 pz con OM del piede TUC 3B/3D
Gentamicina loaded, team multidisciplinare
Infection clearance 90% (63/70), FU 12 weeks

Evidenza TC di osso neoformato a 2-4 anni

12 pz con OM calcaneare
Gentamicina loaded, team multidisciplinare
Infection clearance 100% (12/12), FU 16 weeks





Osteomyelitis sequestrectomy and application of an antibiotic-eluting bone substitute to avoid minor amputation and preserve mechanical stability in the Diabetic Foot



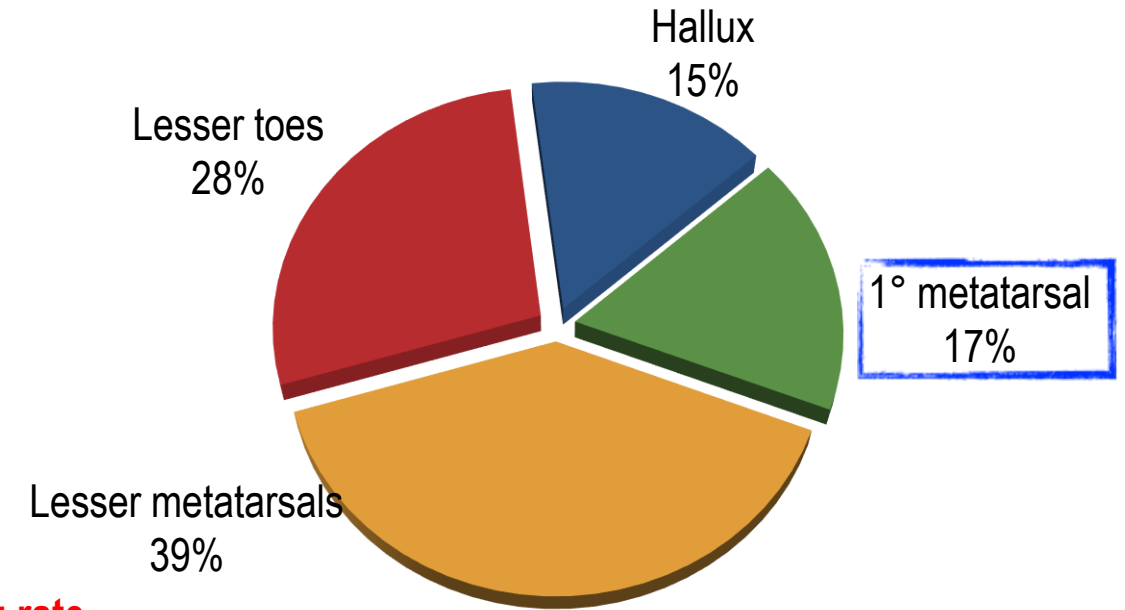
Cristian Nicoletti, MD
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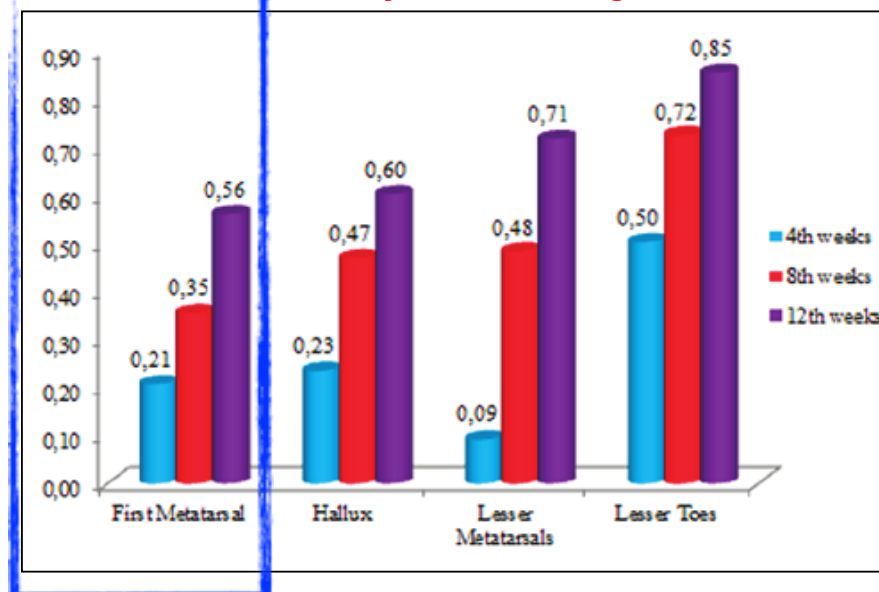
Background



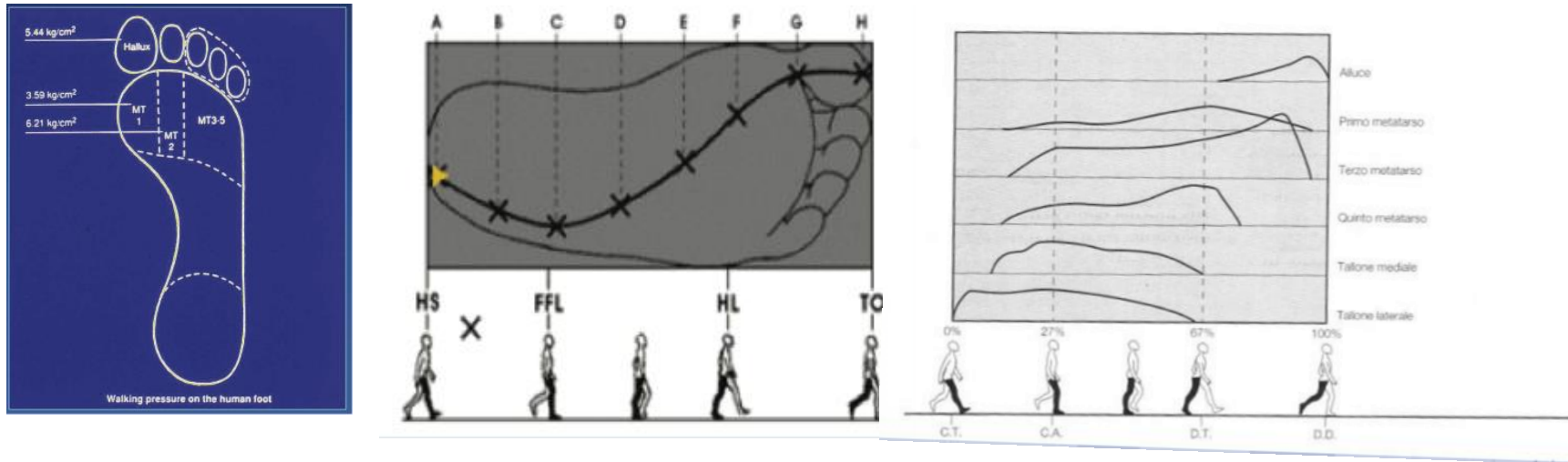
Osteomyelitis Site	Level of Initial Amputation	Transfemoral Amputation Outcome	P
Forefoot (n = 300)			
Toe	136	—	$\chi^2 = 128.4$, $P < .001$
Ray	164	1	
Midfoot (n = 27)			
Transmetatarsal	19	2	
Lisfranc	3	—	
Chopart	4	3	
Heel (n = 23)			
Partial calcaneotomy	17	6	
Primary transfemoral amputation	6	6	



Forefoot osteomyelitis healing rate

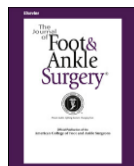


Biomechanics' inputs



The hallux and the first metatarsus are essential elements in the intermediate and final (propulsive) phases of the gait cycle

In stance, first MTPJ complex provides contact with the ground and maintains the medial longitudinal arch of the foot



Does First Ray Amputation in Diabetic Patients Influence Gait and Quality of Life?

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⁷Research Head, Don Carlo Gnocchi Onlus Foundation, Milan, Italy

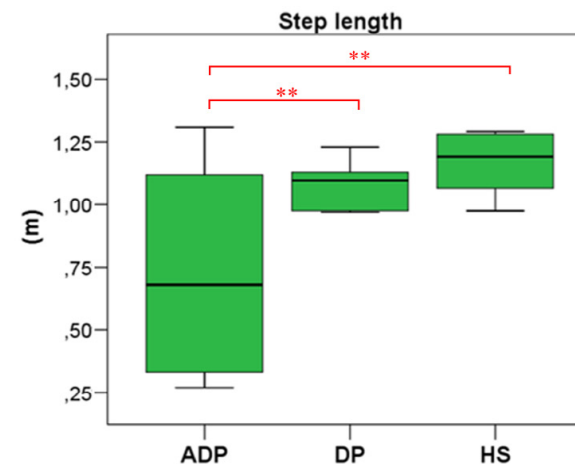
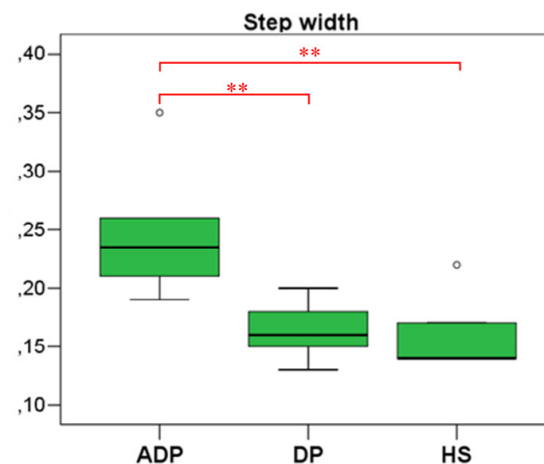
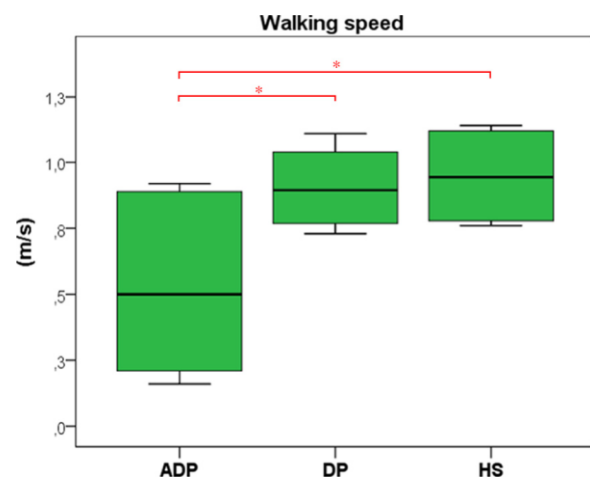
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⁹Research Head, Biomedical Technology Department, IRCCS Don Carlo Gnocchi Foundation, Milan, Italy

Table 2

Pain and quality of life assessment questionnaire scores

Variable	ADPs (n = 6)	DPs (n = 6)	p Value
Pain			
ID-PAIN*	1.4 ± 1.14	1.0 ± 0.63	NS
NRS	3.4 ± 3.51	1.3 ± 0.88	NS
NPSI			
Burning (superficial) spontaneous pain	2.3 ± 2.63	0.0 ± 0.0	NS
Pressing (deep) spontaneous pain	2.9 ± 1.44	0.1 ± 0.20	<.01
Paroxysmal pain	1.3 ± 1.66	0.6 ± 0.55	NS
Evoked pain	3.8 ± 1.02	0.0 ± 0.0	<.05
Paresthesia/dysesthesia	5.1 ± 2.02	1.0 ± 1.13	<.05
Total score	15.3 ± 3.76	1.7 ± 1.65	<.01
QoL			
SF-36			
Physical function	39.5 ± 28.56	84.3 ± 3.56	<.01
Role physical	37.5 ± 41.08	100 ± 0.00	<.05
Bodily pain	35.2 ± 24.45	79.7 ± 12.86	<.01
General health	44.8 ± 14.23	54.2 ± 16.19	NS
Vitality	45.8 ± 24.58	55.8 ± 10.68	NS
Social function	52.5 ± 23.05	94.0 ± 6.57	<.01
Role emotional	33.3 ± 51.64	94.5 ± 13.47	NS
Mental health	52.7 ± 27.30	72.8 ± 4.22	NS
Physical composite score	33.7 ± 7.50	49.7 ± 3.61	<.01
Mental composite score	40.2 ± 12.70	51.0 ± 2.28	NS
NASS			
Lumbar spine neurogenic symptoms	67.8 ± 19.69	91.7 ± 16.02	NS
Lumbar spine pain/disability	61.8 ± 20.21	97.3 ± 3.93	<.01



What happens after First Ray amputation...?

Terminal stance
and preswing



pairs signed-rank test to compare the peak plantar pressures between amputated and intact feet. We used SPSS statistical software to perform the analysis (SPSS, Chicago, IL).

RESULTS — Mean peak plantar foot

suggests that amputation of the great toe and first metatarsal significantly alters the function, structure, and pressure distribution of the foot and potentially puts these patients at greater risk of developing another ulceration or requiring a subsequent amputation. Our results help



Plantar Pressure Distribution in Patients with Diabetic Peripheral Neuropathy and a First-Ray Amputation

Iona Borg, BSc*†
Stephen Mizzi, PhD†
Cynthia Formosa, PhD†

Background: Elevated dynamic plantar pressures are a consistent finding in diabetic patients with peripheral neuropathy, with implications for plantar foot ulceration. This study aimed to investigate whether a first-ray amputation affects plantar pressures and plantar pressure distribution patterns in individuals living with diabetes and peripheral neuropathy.

Methods: A nonexperimental matched-subject design was conducted. Twenty patients living with diabetes and peripheral neuropathy were recruited. Group 1 (n = 10) had a first-ray amputation and group 2 (n = 10) had an intact foot with no history of ulceration. Plantar foot pressures and pressure-time integrals were measured under the second to fourth metatarsophalangeal joints, fifth metatarsophalangeal joint, and heel using a pressure platform.

Results: Peak plantar pressures under the second to fourth metatarsophalangeal joints were significantly higher in participants with a first-ray amputation ($P = .008$). However, differences under the fifth metatarsophalangeal joint ($P = .734$) and heel ($P = .273$) were nonsignificant. Pressure-time integrals were significantly higher under the second to fourth metatarsophalangeal joints in participants with a first-ray amputation ($P = .016$) and in the heel in the control group ($P = .046$).

Conclusions: Plantar pressures and pressure-time integrals seem to be significantly higher in patients with diabetic peripheral neuropathy and a first-ray amputation compared with those with diabetic neuropathy and an intact foot. Routine plantar pressure screening, orthotic prescription, and education should be recommended in patients with a first-ray amputation. (J Am Podiatr Med Assoc 108(3): 225-230, 2018)

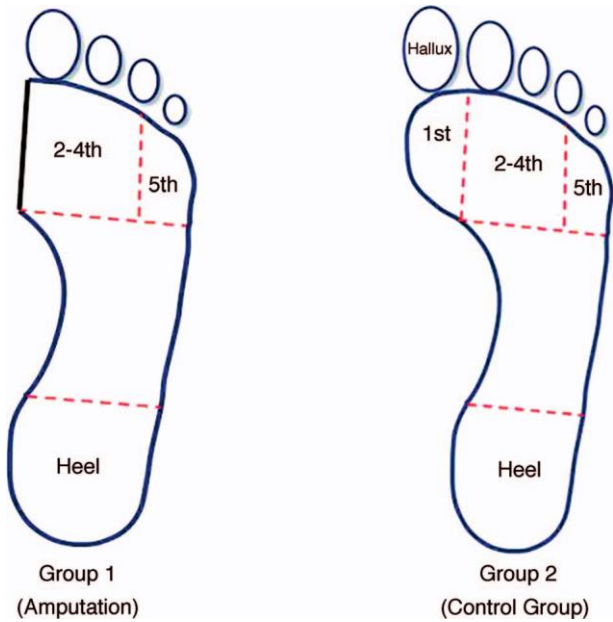
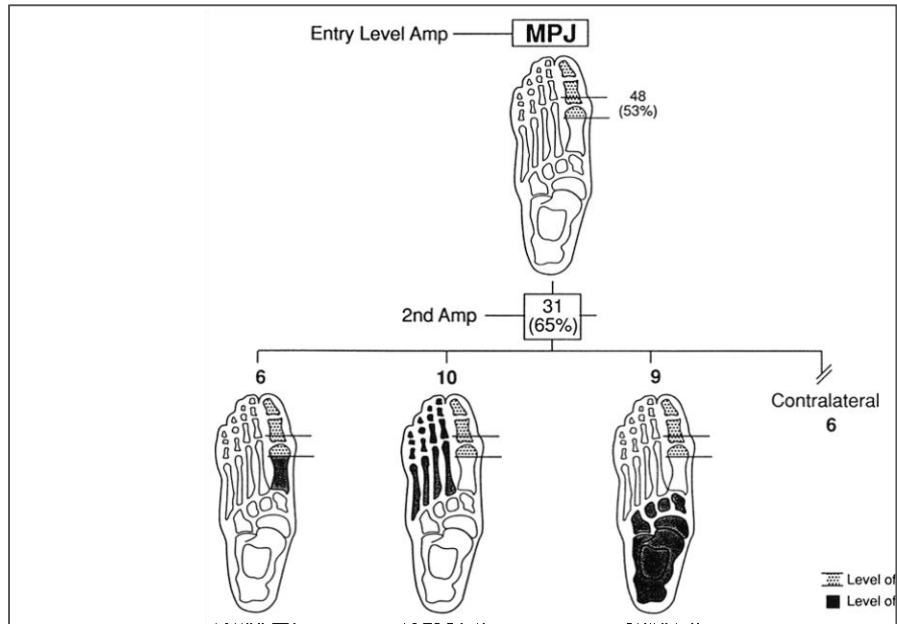


Table 1. Peak Plantar Pressures by Group (Mann-Whitney Test)

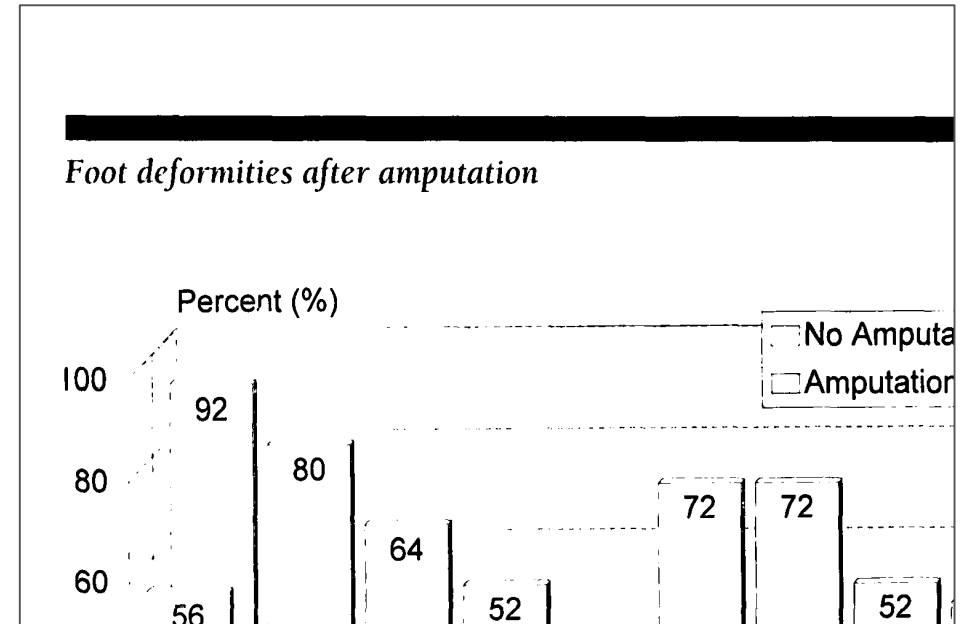
			Peak Plantar Pressure (kg/cm ²)			U Value	P Value
Group		Sample Size (No.)	Median	Mean	SD		
Second to fourth MPJs	Controls	10	3.7	4.39	1.96	15.0 ^a	.008 ^a
	Amputation	10	9.8	8.81	3.58		
Fifth MPJ	Controls	10	2.07	2.81	2.04	45.5	.734
	Amputation	10	3.12	3.43	2.36		
Heel	Controls	10	3.44	3.80	1.25	35.5	.273
	Amputation	10	2.90	3.76	3.12		

What happens after First Ray amputation

Re-amputations



Ulcer recurrence



What happens after First Ray amputation...?

	Re-Amp (%)	Toes-Ray (%)	TMA-Lisfranc- Chopart (%)	Major Leg Amputation (%)	1 year re- ulceration (%)
Murdoch 1997	60	29	11	20	-
Dalla Paola 2003	9	7	2	-	-
Ahmed 2010	18	-	4	14	-
Sizer 1972	7	-	7	-	-
Borkosky 2013	42	13	12	17	69
Quebedeaux 1996	-	-	-	-	68
Sanz-Corbalan 2015	-	-	-	-	63
Molines-Barroso 2014	-	-	-	-	41
OVERALL	22	8	7	7	

Aim of the study

Observational study to test the effectiveness of an antibiotic-eluting bone substitute (gentamicin or vancomycin loaded) to reduce minor amputations and ulcer recurrence and to preserve mechanical stability in diabetic patients with 1° ray osteomyelitis

Study design



DX

27 consecutive diabetic patients with first ray OM since January 2017

All patients underwent bone biopsy before bone substitute application

All patients had revascularization if needed, local treatment, systemic antibiotic therapy and offloading according to the currently available international guidelines on diabetic foot

A biocompatible ceramic bone void filler, consisting of calcium sulfate and hydroxyapatite, loaded with vancomycin or gentamycin was applied





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A biocompatible ceramic bone void filler, consisting of calcium sulfate and hydroxyapatite, loaded with vancomycin or gentamycin was applied

After the application of bone substitute, patients were recorded for **HEALING RATE**, **AMPUTATION** and **ULCER RECURRENCE** after 1, 2, 3, 6, 12, 18 and 24 months

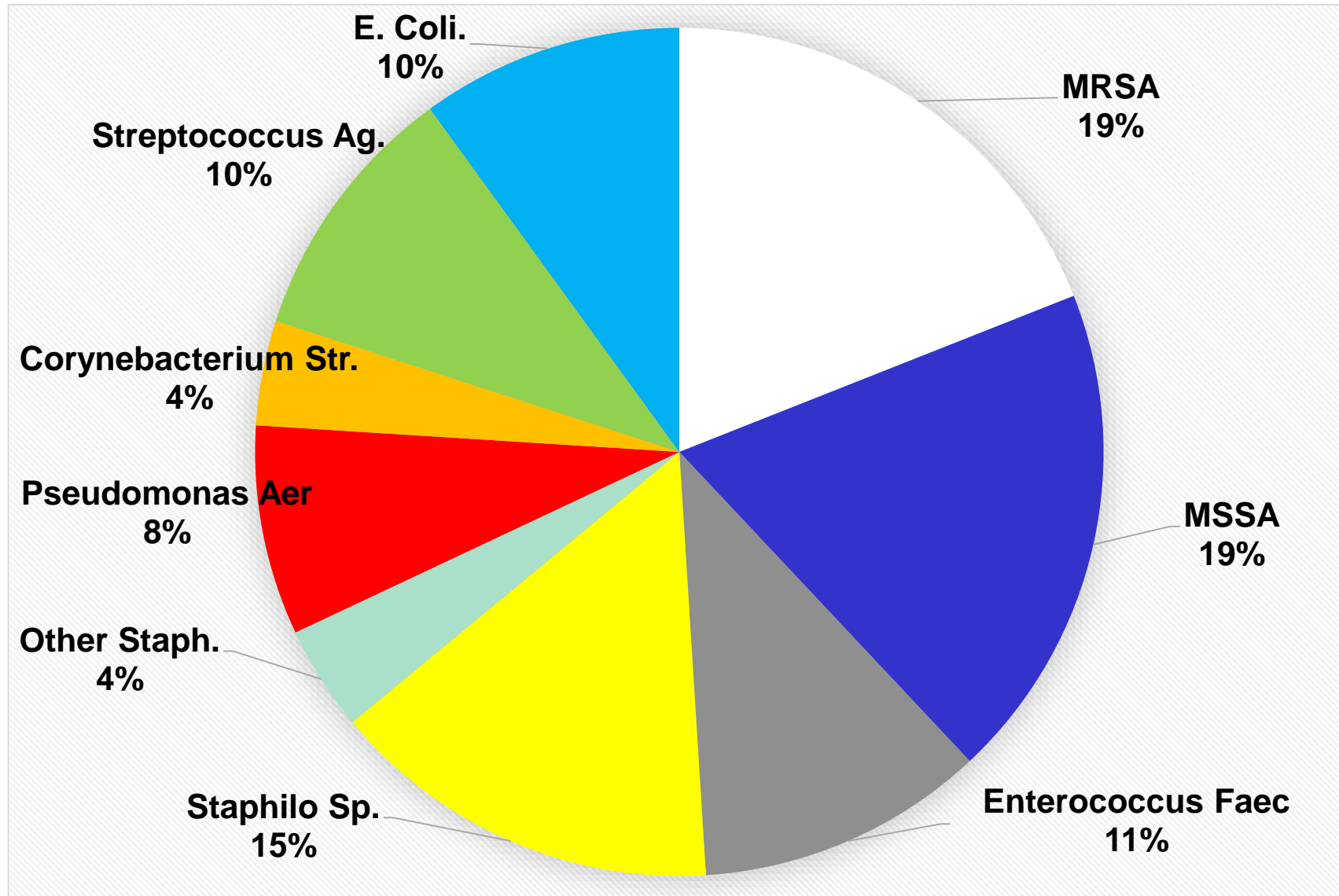
Study flow chart

Patient	FU 1m	FU 2m	FU 3m	FU 6m	FU 12m	FU 18m	FU 24m
1	*	*	*	*	*	*	*
2	*	*	*				
3	*	*	*	*	*	*	*
4	*	*	*	*	*	*	*
5	*	*	*	*	*	*	*
6	*	*	*	*	*	*	
7	*	*	*	*	*	*	
8	*	*	*	*	*	*	
9	*	*	*	*			
10	*	*	*	*	*	*	
11	*	*	*	*	*	*	
12	*	*	*	*	*	*	
13	*	*	*	*	*		
14	*	*	*	*	*		
15	*	*	*	*	*		
16	*	*	*	*	*		
17	*	*	*	*	*		
18	*	*	*	*	*		
19	*	*	*	*	*		
20	*	*	*	*	*		
21	*	*	*	*			
22	*	*	*	*			
23	*	*	*	*			
24	*	*	*	*			
25	*	*	*	*			
26	*	*	*				
27	*						

Characteristics of population at baseline

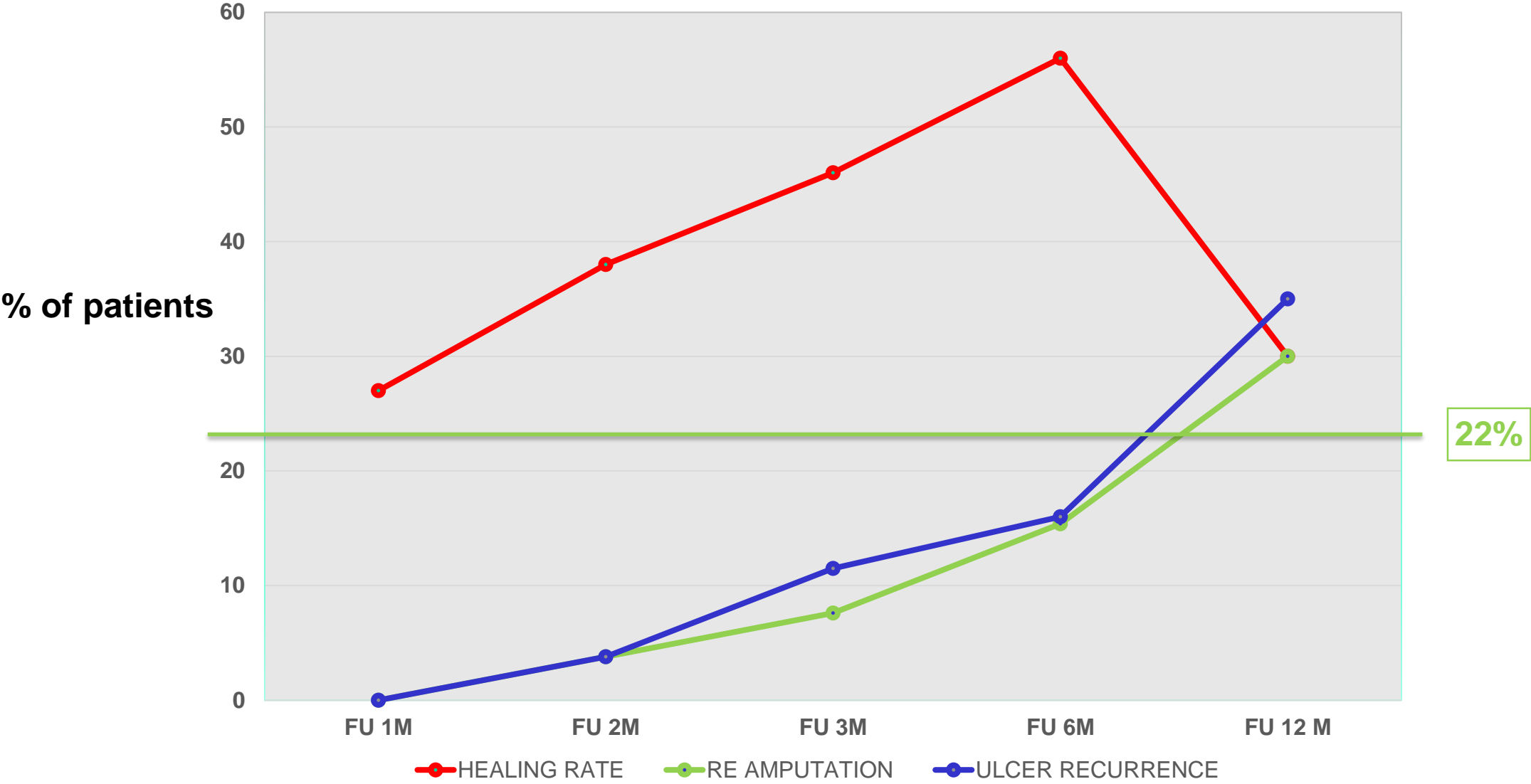
N	26	
Male	20	(77%)
Age (y)	71 ± 9	
Diabetes	26	(100%)
HbA1c (mmol/mol)	55,2 ± 18,1	(nv 20-42)
Gentamycin / Vancomycin Load	19 / 7	(73 / 27 %)
TcpO2 (mmHg)	49 ± 8	
Previous Revascularization	14	(54%)
ESRD	5	(19%)
PCR (mg/L)	16,9 ± 23,7	(nv < 5)
WBC-N count (10E9/L)	4,8 ± 1,7	(nv 1,8-7,7)
ESR (mm)	43,5 ± 33,3	(nv < 37)

Bacteria isolated by bone biopsy



Partial results

	FU 1m	FU 2m	FU 3m	FU 6m	FU 12 M
HEALING RATE	27% (7/26)	38% (10/26)	46% (12/26)	56% (14/25)	30% (6/20)
RE AMPUTATION	0% (0/26)	3.8% (1/26)	7,6% (2/26)	15.4% (4/25)	30% (6/20)
ULCER RECURRENCE	0% (0/26)	3.8% (1/26)	11.5% (3/26)	16% (4/25)	35% (7/20)



Patients undergoing Re-amputations...

	Level	Reason why	Time
P04	BTK	Septic shock	FU 2m
P20	TMA	CLI relapse with forefoot gangrene	FU 3m
P18 (ESRD)	TMA	CLI relapse with forefoot gangrene	FU 6m
P14	2° toe	Osteomyelitis	FU 6m
P15	TMA	CLI relapse with forefoot gangrene after IMA and Coronary Unit	FU 12m
P08	1° ray	CLI relapse – low compliance to offloading	FU 12m

P09 and P18 (both ESRD) died at FU 12 m for heart attack

Conclusions

The use of antibiotic-eluting bone substitute after sequestrectomy in diabetic patients with first ray osteomyelitis seems to be effective in reducing re-amputation rate and ulcer recurrence in a short time follow up period (up to 6 months)

In a longer follow up period, until now we have recorded an increase in re-amputations, due to typical risk factors of diabetic patients such as CLI, low compliance and Heart Attack

To have a final opinion, completion of this observational study and a new controlled prospective trials are needed



Letter to the Editor

BIOACTIVE GLASS S53P4: a new opportunity for the treatment in the diabetic foot osteomyelitis

ARTICLE INFO

Keywords:

Diabetes
Diabetic foot
Internal medicine

Diabetes mellitus is one of the major public health problems worldwide. With the aging of the population, improvements in living standards, and changes in lifestyle, the prevalence of the disease is growing rapidly. There have been many studies regarding high prevalence of diabetes and diabetes complication among patients admitted to Internal Medicine Wards and costs for diabetic patients, both in North America and Europe. Most have shown that the medical costs of diabetes are responsible for a very high proportion of total healthcare expenditure, with the proportion of costs increasing year by year [1,2].

Although diabetic foot complications occurred in only a small portion of hospitalized diabetic patients the associated hospitalization costs were the highest, and twice that of patients without foot damage. The high cost of diabetic foot damage was associated primarily with a longer LOS because of a relapse of foot ulcers and expensive surgical and rehabilitation costs [3].

Approximately 33% of diabetes-related costs have been linked to the treatment of foot ulcers, the majority of which are related to inpatient hospital admissions, frequently in Internal Medical Wards for the treatment of related diabetic foot infection and osteomyelitis, that require a multidisciplinary approach [4].

Osteomyelitis is a bone infectious process and represents one of the most challenging conditions in diabetic foot; it is usually due to non-healing ulcers and it is associated with high risk of major amputation [5]. Osteomyelitis diagnosis (optimally defined by bone culture and histology) and treatment can be difficult [6]. The surgical debridement of the osteomyelitis process often requires a resection or loss of bone substance that forms an unfilled cavity with repercussions on the firmness, function and strength of the bone. With debridement you cannot be sure that you have removed all the bone involved in the infectious process. The rate of recurrence of osteomyelitis is high, in some cases relapse after some months. It is mandatory an adequate blood flow in the area of the infection, otherwise a distal revascularization is required [7]. Gram positive bacteria as *Staphylococcus aureus* are the most involved in diabetic foot infections. The ulcers complicated by osteomyelitis often require a long antibiotic therapy too, which can induce the development of methicillin-resistant *Staphylococcus aureus* (MRSA) [8]. Often prolonged antibiotic therapy is easily characterized

by side effects that may require interruption. Non-healing, prolonged treatment times and relapses result in high health costs.

Bioactive glass (BAG-S53P4 - BonAlive® granules, Bon Alive Biomaterials Ltd. Finland) is an antibacterial synthetic bone substitute. The BAG-S53P4 received EU approval for the indication of treatment of osteomyelitis in 2011. The antibacterial properties of the glass is ascribed to an elevation of pH and also of osmotic pressure that are caused by the chemical reactions at the glass surface, which take place as soon as the glass is implanted into the body. The antibacterial, osteostimulative and osteoconductive bone substitute BAG-S53P4, is suitable as bone void filler in the treatment of chronic osteomyelitis. The treatment of osteomyelitis can be performed in a one-stage procedure with excellent results. This makes the treatment protocol cost-effective with a trend towards a reduction in the length of the hospital stay as well [9,10].

In our experiences we have treated 25 patients from March 2017 to March 2018 affected by osteomyelitis in diabetic foot and after debridement and antibiotic therapy we have used bioactive glass. The application of the product, after the due debridement of the bone plane affected by the infectious process, was easy and fast. At a mean follow-up of 12 months (6 to 12), all patients showed no sign of recurrence of infection. At latest follow-up, the radiographs showed partial incorporation of all bone substitutes; the biomaterial were still seen on the plain radiographs, although there were no signs of osteolysis or periosteal reactions. These preliminary results seem to be promising for the surgical treatment of chronic osteomyelitis in patients with diabetic foot.

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Bioactive Glass

IWGDF linee guida sull'uso di procedure per migliorare la guarigione delle ulcere croniche del piede nel paziente diabetico

Redatte dall' IWGDF Working Group on Wound Healing

Raccomandazioni

1. Detergere regolarmente con acqua pulita o soluzione salina le ulcere, debridement quando possibile, al fine di rimuovere i detriti dalla superficie della lesione e coprirle con medicazione sterile inerte al fine di controllare l'essudato eccessivo e mantenere un ambiente caldo e umido per favorire la guarigione. (Grado di Raccomandazione: Forte; qualità delle prove: Basso)
2. In generale rimuovere slough, tessuto necrotico e ipercheratosi circostante con tagliente, valutando le relative controindicazioni, come una grave ischemia (Forte; Basso)
3. Selezionare medicazioni principalmente sulla base del controllo dell'essudato, comfort e costo. (Forte; Basso)
4. Non usare medicazioni antimicrobiche con l'obiettivo di migliorare la guarigione delle ferite o prevenire l'infezione secondaria. (Forte; Moderato)
5. Considerare l'uso di ossigeno terapia iperbarica sistemica, anche se ulteriori studi in cieco e randomizzati sono necessari per confermare la sua economicità, nonché di identificare la popolazione con più probabilità di trarre beneficio dal suo uso. (Debole; Moderato)
6. La terapia a pressione negativa topica può essere considerata nelle ferite post-chirurgiche, anche se l'efficacia e il rapporto costo-efficacia dell'approccio rimane da stabilire. (Debole; Moderato)
7. Non scegliere agenti per migliorare la guarigione delle ulcere che alterano la biologia della ferita, compresi i fattori di crescita, prodotti per la pelle di bioingegneria al posto dei trattamenti standard accettati per un'assistenza di buona qualità. (Forte; Basso)
8. Non scegliere agenti per avere un impatto sulla guarigione delle ulcere attraverso l'alterazione dell'ambiente fisico, ad es, attraverso l'uso di elettricità, magnetismo, ultrasuoni e onde d'urto, al posto di standard accettati per un'assistenza di buona qualità. (Forte; Basso)
9. Non scegliere trattamenti sistemici per migliorare la guarigione delle ulcere, compresi i farmaci e terapie a base di erbe, al posto di standard accettati per un'assistenza di buona qualità. (Forte; Basso)

Ci sono diversi problemi relativi a questi prodotti, come il processo di applicazione complessa, i costi e la qualità non ottimale della pelle dopo la guarigione. Per questo motivo riteniamo che è necessario un più alto livello di evidenza per giustificare il loro uso di routine.

Implementazione delle linee guida dell'IWGDF sull'uso di procedure per migliorare la guarigione delle ulcere croniche del piede nel paziente diabetico

Redatta dal Gruppo interassociativo AMD-SID "Podopatia diabetica"

Anche sul punto 6 la debolezza del grado di raccomandazione stride con la qualità delle prove che risulta essere moderata Il giudizio negativo degli esperti non è stato compreso, peraltro nella discussione è emerso chiaramente da parte di tutti il vantaggio clinico dell'utilizzo della terapia a pressione negativa in molti pazienti con piede diabetico.

Indubbiamente nel nostro territorio la terapia a pressione negativa viene utilizzata con molta soddisfazione nella cura del piede diabetico e questo dal punto di vista clinico è un vantaggio che è stato testimoniato da tutti partecipanti alla discussione.

Riteniamo quindi che il grado di raccomandazione è nel nostro caso forte.

Sul punto 7 Il giudizio negativo degli esperti non è stato completamente compreso peraltro nella discussione è emerso chiaramente il vantaggio clinico di alcune metodiche come ad esempio il fondamentale utilizzo di sostituti dermali in alcuni situazioni cliniche particolari.

Sul punto 8 sostanziale accordo con gli autori delle linee guida Indubbiamente la maggioranza delle tecniche riportate sono più o meno innovative e quindi necessitano di maggior tempo per poter dimostrare la loro utilità

Failure rates of artificial dermis products in treatment of diabetic foot ulcer: A systematic review and network meta-analysis.

190 records, 785 participants

Table 3. Outcomes in the included studies

Study	Failure rate	Complete Re-epithelialization rate	Lower limb amputation	Healing time (days)	Follow up	Recurrent DFU	Rehealed of failure
	(n)	(n)	(n)				
Gentiletti, 1999	4 (10%)	33 (99%)	0	12 weeks	12 weeks	No	73
Pham et al, 1999	4 (25%)	12 (75%)	0	1-12 weeks	12 weeks	No	43
Meier et al, 2002	49 (44%)	63 (56%)	7	13 weeks	12 weeks	7	3
Hoff et al, 2002	4 (29%)	10 (71%)	0	12 weeks	12 weeks	No	4
Bergqvist et al, 2005	2 (4%)	12 (86%)	0	16 weeks	16 weeks	No	5
Regerman et al, 2009	14 (30%)	33 (70%)	0	5-7 weeks	12 weeks	No	170*
Edmonson et al, 2009	16 (49%)	17 (52%)	0	12 weeks	12 weeks	2	65
Qureshi et al, 2010	13 (31%)	86 (71%)	0	86	Yes	No	
Leon et al, 2013	6 (20%)	24 (80%)	0	8-61 weeks	12	No	200*
Leon et al, 2013	40% (4)	60% (6)	0	67	16 weeks	No	100
Morimoto et al, 2014	6 (7%) (2)	93 (93%) (20)	0	60	12 weeks	No	33
Yoo et al, 2014	5 (6%)	26 (89%)	0	12 weeks	12 weeks	No	25
Lawer et al, 2014	19 (39%)	31 (62%)	0	12 weeks	12 weeks	No	48

ORIGINAL ARTICLE

The use of a dermal substitute to preserve maximal foot length in diabetic foot wounds with tendon and bone exposure following urgent surgical debridement for acute infection

Giacomo Clerici, Maurizio Caminiti¹, Vincenzo Cudi, Antonella Quarantiello, Ezio Paglia

Abstract A bilayered artificial dermis (AD) composed of an upper silicone sheet and a lower collagen sponge has been used in the treatment of chronic ulcers. In this study, we compared the neovascularization of conventional AD seeded with autologous fibroblasts (cultured dermis: CD) and collagen/gelatin sponge (CGS), which is a novel artificial dermis capable of sustained release of basic fibroblast growth factor (bFGF) after application using laser Doppler imaging (LDI). CD ($n = 5$) and CGS impregnated with bFGF ($n = 6$) were applied to diabetic foot ulcers after debridement. Perfusion units (PUs) were measured just after, and 1, 2 and 3 weeks after application, and complete healing rates within 16 weeks were compared. No significant differences in PUs were seen 1, 2 and 3 weeks after application and in healing rates within 16 weeks between the two groups. This study suggested that CD and CGS treatments were effective, but there were no significant differences between them in the treatment of diabetic ulcers.

Keywords: Dermal substitute • Diabetic foot infection • Foot length • Minor amputation

J Artif Organs (2014) 17:352–357
DOI 10.1007/s10047-014-0782-0

ORIGINAL ARTICLE

Artificial Skin, Muscle, Bone / Joint, Neuron

Comparison of neovascularization in dermal substitutes seeded with autologous fibroblasts or impregnated with bFGF applied to diabetic foot ulcers using laser Doppler imaging

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Received: 7 April 2014 / Accepted: 23 June 2014 / Published online: 16 July 2014
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Abstract A bilayered artificial dermis (AD) composed of an upper silicone sheet and a lower collagen sponge has been used in the treatment of chronic ulcers. In this study, we compared the neovascularization of conventional AD seeded with autologous fibroblasts (cultured dermis: CD) and collagen/gelatin sponge (CGS), which is a novel artificial dermis capable of sustained release of basic fibroblast growth factor (bFGF) after application using laser Doppler imaging (LDI). CD ($n = 5$) and CGS impregnated with bFGF ($n = 6$) were applied to diabetic foot ulcers after debridement. Perfusion units (PUs) were measured just after, and 1, 2 and 3 weeks after application, and complete healing rates within 16 weeks were compared. No significant differences in PUs were seen 1, 2 and 3 weeks after application and in healing rates within 16 weeks between the two groups. This study suggested that CD and CGS treatments were effective, but there were no significant differences between them in the treatment of diabetic ulcers.

Keywords Skin / Diabetes complications / Skin transplantation

Received: 19 Mar 2013 • Revised: 15 May 2013 • Accepted: 20 Jun 2013
pISSN: 2234-0163 • eISSN: 2234-0171 • http://dx.doi.org/10.1007/s10047-013-0414-03 • Arch Plast Surg 2013;140:403–408

APS
Archives of Plastic Surgery

Treatment of Diabetic Foot Ulcer Using Matriderm In Comparison with a Skin Graft

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Background For patients with neuropathy, vasculopathy, and impairment of wound healing, treatment of a diabetic foot ulcer poses many challenges. A large number of dermal analogues have been invented in an effort to overcome these challenges. Matriderm, a dermal analogue, is made from bovine collagen and elastin. This study was conducted in order to evaluate the effectiveness of Matriderm for treatment of diabetic foot ulcers, in comparison with skin grafting.

Methods Sixty patients with diabetic foot ulcer were included in this prospective study. The average age of the patients, who had type II diabetes mellitus, was 58 years old. The patients were allocated to an experimental or control group with their consents. The patients were selected with their consent for inclusion in an experimental group and a control group. Patients in the experimental group received a Matriderm appliance and a split-thickness skin graft, while those in the control group received only a split-thickness skin graft.

Results A shorter hospitalization period (7.52 weeks) was observed in the experimental group than in the control group (9.22 weeks), and a shorter period of time (8.61 weeks) was required for complete healing, compared with the control group (12.94 weeks), with statistical significance ($P < 0.05$). A higher desloughing ratio of the affected side to the non-affected side was observed in the experimental group, compared with the control group ($P < 0.01$).

Conclusions Matriderm enables effective healing and improves elasticity in treatment of patients with diabetic foot ulcer.

Keywords Skin / Diabetes complications / Skin transplantation

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This article was presented at the 70th Congress of the Korean Society of Plastic and Reconstructive Surgeons on November 5–11, 2012 in Seoul, Korea.

No potential conflict of interest relevant to this article was reported.

Collagene acellulare di bovino + condroitin-6-solfato e silicone

Collagene porcino + silicone

Sostituto dermico acellulare da bovino

Average healing time (days)	86	60	67
Complete re-epithelialization rate	86,7 %	60 %	93,3 %
Failure rate	13,3 %	40 %	6,7 %
Lower limb amputation	0	0	0
Ulcer recurrence during FU	No	No	No

Thank You..

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