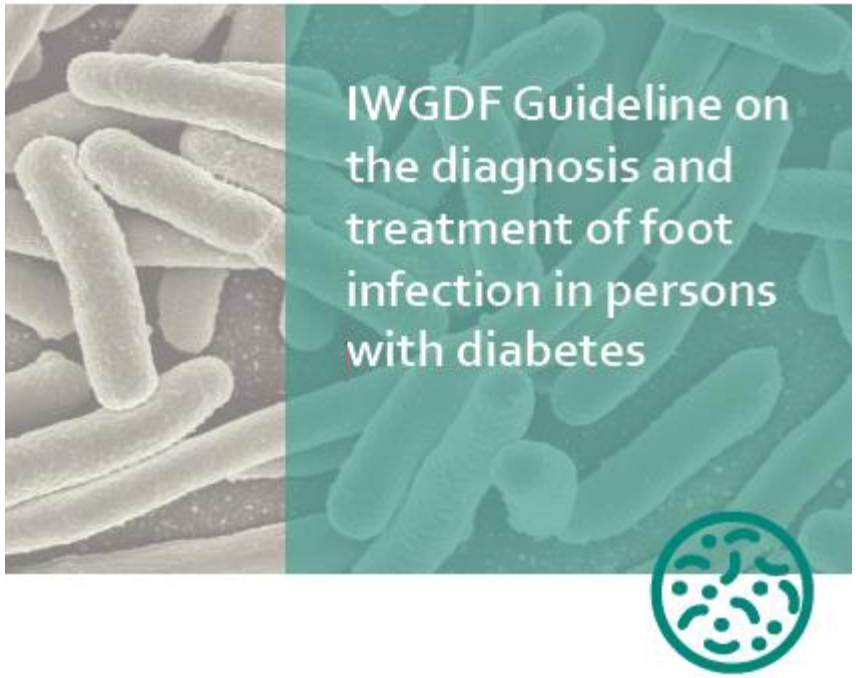
Biovetro S53p4,
nelle Osteomieliti del Piede Diabetico,
efficacia clinica e microbiologica

SESSIONE 13 | Sala del Castello

IL RUOLO DEL LABORATORIO DI MICROBIOLOGIA NELLA GESTIONE DELLE FERITE ACUTE E CRONICHE

Roberto De Giglio

Bianca Osnaghi



Part of the 2019 IWGDF Guidelines on the Prevention and Management of Diabetic Foot Disease

IWGDF Guidelines

Of particular importance, Diabetic Foot Infections remain the most frequent diabetic complication requiring hospitalization and the most common precipitating event leading to lower extremity amputation

Di particolare importanza, le infezioni del piede diabetico rimangono la complicanza diabetica più frequente che richiede il ricovero in ospedale e l'evento precipitante più comune che porta all'amputazione degli arti inferiori

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Tan TW, Shih CD, Concha-Moore KC, et al.
Disparities in outcomes of patients admitted with diabetic foot infections.
PLoS One 2019;14:e0211481.

DIABETICMedicine

DOI: 10.1111/dme.13537

Research: Complications

Prognosis of the infected diabetic foot ulcer: a 12-month prospective observational study

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[1]Department of Nursing and Midwifery, University of the West of England, Bristol, [2]Academic Rheumatology Unit, University Hospitals Bristol NHS Foundation Trust, Bristol, [3]Clinical Trials Research Unit, University of Leeds, Leeds, [4]Leeds Institute of Rheumatic and Musculoskeletal Medicine, University of Leeds, Leeds, [5]Division of Medical Sciences, University of Oxford, Oxford, [6]School of Biomedical Sciences, University of Leeds, Leeds, [7]Bradford Royal Infirmary, Bradford, [8]Tameside and Glossop Integrated Care NHS Foundation Trust, Ashton-Under-Lyne, [9]University of Manchester, Manchester and [10]Schoool of Healthcare, University of Leeds, Leeds, UK

Accepted 25 October 2017

Abstract

Aims To determine clinical outcomes and explore prognostic factors related to ulcer healing in people with a clinically infected diabetic foot ulcer.

Methods This multicentre, prospective, observational study reviewed participants' data at 12 months after culture of a diabetic foot ulcer requiring antibiotic therapy. From participants' notes, we obtained information on the incidence of wound healing, ulcer recurrence, lower extremity amputation, lower extremity revascularization and death. We estimated the cumulative incidence of healing at 6 and 12 months, adjusted for lower extremity amputation and death using a competing risk analysis, and explored the relationship between baseline factors and healing incidence.

Months after enrolment	Incidence of healing (95% CI)	Participants healed	Amputation (competing event)	Death (competing event)	Number censored	Number left
6	27.5% (22.4% to 32.5%)	82	32	17	0	168
12	44.5% (38.9% to 50.1%)	133	40	30	93	3

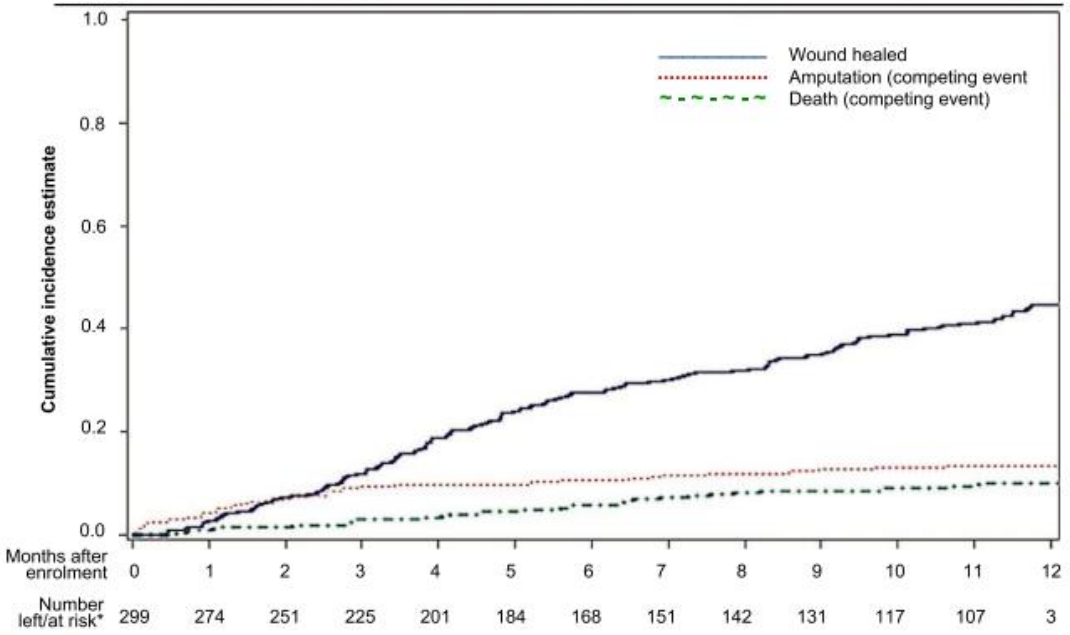
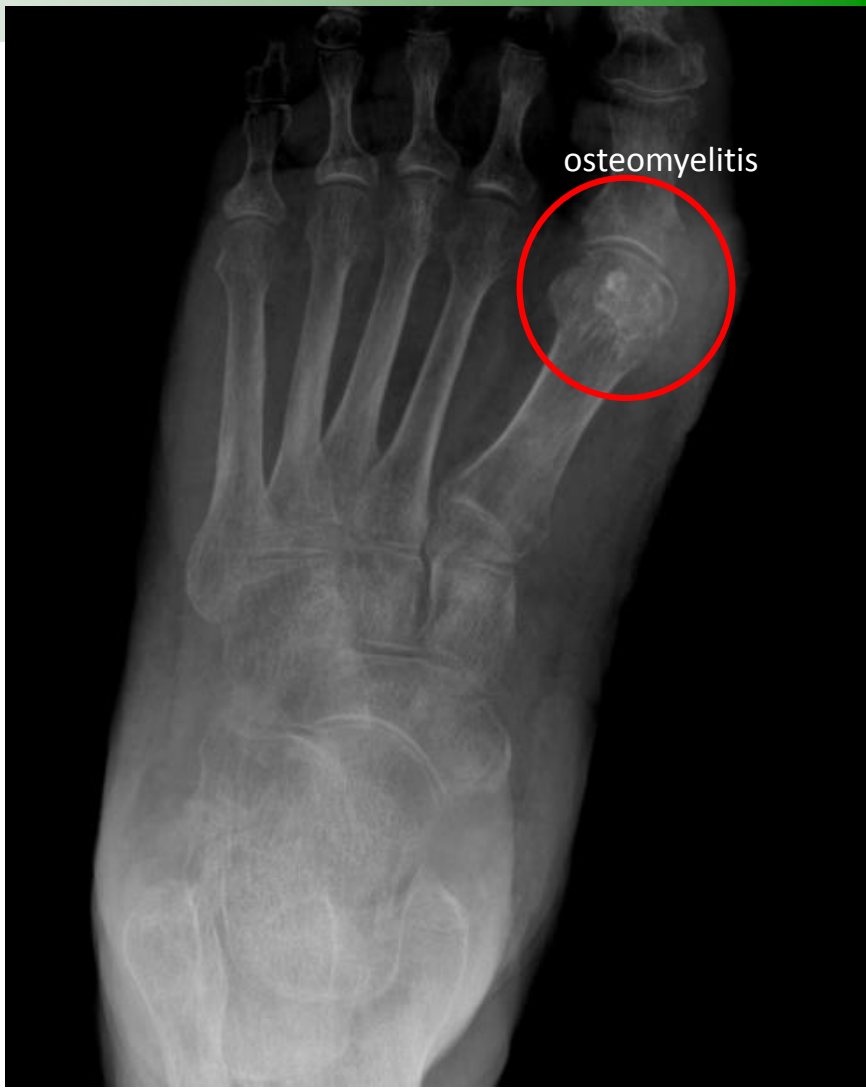


FIGURE 2 Healing estimates and cumulative incidence functions of the time to healing in the presence of competing risks of death or amputation. *This refers to the number of participants left in the 'risk' set consisting of those uncensored without an event (healing, death, or amputation).

Outcomes in patients presenting with an infected diabetic foot ulcer are poor: in one large prospective study at the end of one year the ulcer had healed in only 46% (and it later recurred in 10% of these), while 15% had died and 17% required a lower extremity amputation.

ENDPOINT

The primary endpoint was to obtain complete **resolution of osteomyelitis** with no additional surgical procedures and no additional cycle of antibiotic therapy in the 12 months following surgical debridement



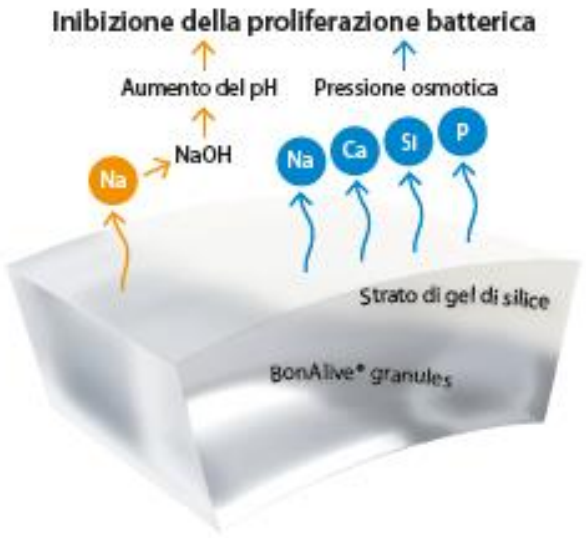
BIOVETRI

Il professor Larry Hench li scoprì nel 1969 presso l'Università della Florida a Gainesville.
Il biovetro è una ceramica vetrosa composta da :

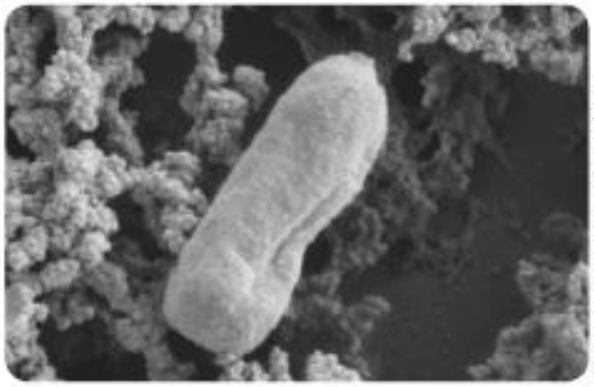
- Biossido di silicio (45%)
- Ossido di sodio (24.5%)
- Ossido di calcio (24.5%)
- Pentossido di fosforo (6%)

Inibizione della proliferazione batterica

BonAlive® granules inibisce la proliferazione batterica, ma non contiene antibiotici.[2,3] Il meccanismo opera mediante il rilascio di ioni che danno origine a un ambiente alcalino (pH elevato) e a un aumento della pressione osmotica all'interno del difetto osseo.[1]



Effetto del vetro bioattivo S53P4 su *Klebsiella pneumoniae*, resistente alla meticillina. L'inibizione della proliferazione batterica è rilevabile tramite variazioni morfologiche dei batteri.



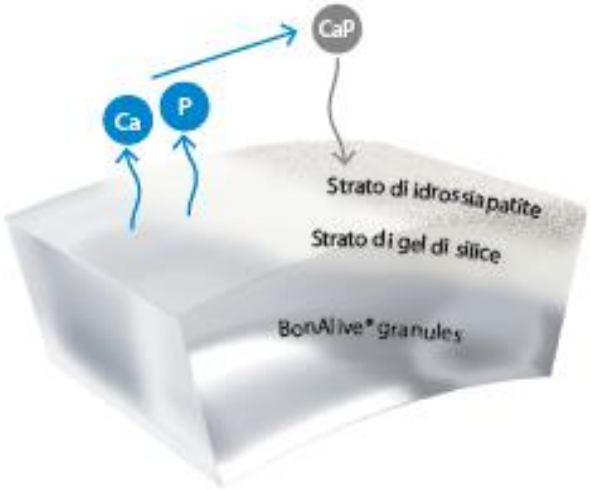
Per gentile concessione del Prof. Lorenzo Drago
Università di Milano, Italia

Formazione ossea efficace

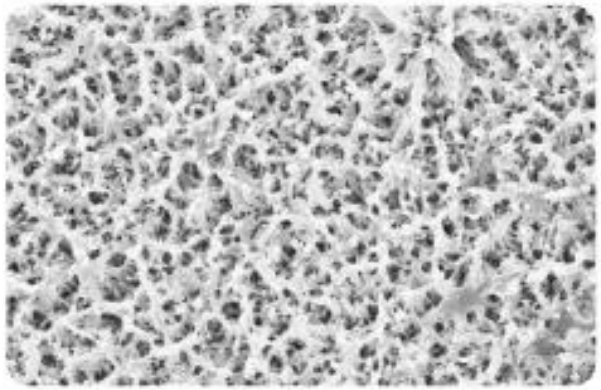
BonAlive® granules si lega chimicamente con l'osso, stimolando la crescita di nuovo tessuto osseo,[4] secondo un meccanismo noto come osteostimolazione*, nell'ambito del quale vengono attivati i geni responsabili della formazione dell'osso nelle cellule osteogeniche.[5]

*non osteoinduttivo

Formazione di idrossiapatite naturale



L'immagine al microscopio elettronico a scansione (SEM, ingrandimento 10.000x) mostra lo strato di idrossiapatite naturale che si forma sulla superficie del vetro bioattivo.



Efficacia ad ampio spettro

I granuli BonAlive® granules risultano efficaci nell'inibire la proliferazione di oltre 50 specie batteriche comuni (fra cui *MRSA e MRSE*).

Batteri Gram-positivi

- *Bacillus cereus*
- *Bifidobacterium adolescentis*
- *Clostridium difficile*
- *Clostridium perfringens*
- *Clostridium sepsicum*
- *Corynebacterium ulcerans*
- *Enterobacter cloacae*
- *Enterococcus faecalis*
- *Enterococcus faecium*
- *Eubacterium lentum*
- *Listeria monocytogenes*
- *Micrococcus sp.*
- *Mycobacterium tuberculosis*
- *Peptostreptococcus anaerobius*
- *Peptostreptococcus magnus*
- *Propionibacterium acnes*
- *Propionibacterium propionicus*
- *Staphylococcus aureus*
- *Staphylococcus epidermidis*
- *Staphylococcus hominis*
- *Staphylococcus lugdunensis*
- *Streptococcus agalactiae*
- *Streptococcus mutans*
- *Streptococcus pneumoniae*
- *Streptococcus pyogenes*
- *Streptococcus sanguis*

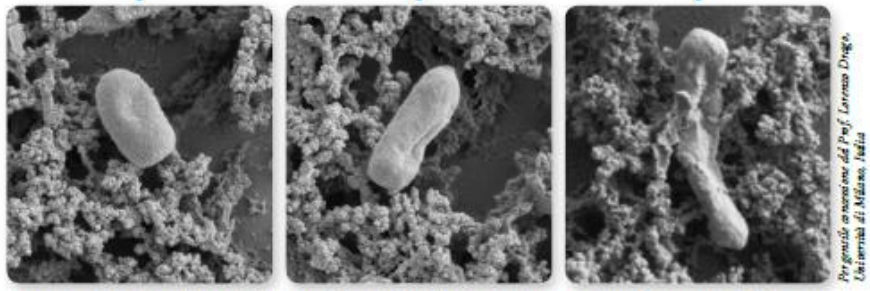
Batteri Gram-negativi

- *Acinetobacter baumannii*
- *Bacteroides fragilis*
- *Bacteroides thetaiotaomicron*
- *Chryseobacterium (in precedenza Flavobacterium) meningosepticum*
- *Enterobacter aerogenes*
- *Enterobacter amnigenus*
- *Escherichia coli*
- *Fusobacterium necrophorum*
- *Fusobacterium nucleatum*
- *Haemophilus influenzae*
- *Klebsiella pneumoniae*
- *Moraxella catarrhalis*
- *Neisseria meningitidis*
- *Pasteurella multocida*
- *Porphyromonas gingivalis*
- *Prevotella intermedia*
- *Prevotella melaninogenica*
- *Proteus mirabilis*
- *Pseudomonas aeruginosa*
- *Salmonella typhimurium*
- *Shigella sonnei*
- *Veillonella parvula*
- *Yersinia enterocolitica*

Batteri resistenti alla meticillina

- *Pseudomonas aeruginosa*
- *Staphylococcus aureus (MRSA)*
- *Staphylococcus epidermidis (MRSE)*

I test batteriologici eseguiti utilizzando ceppi di *Porphyromonas gingivalis* pigmentati mostrano che i batteri non riescono ad aderire e proliferare sulla superficie dei granuli BonAlive® granules.



Le immagini illustrano l'effetto del cristallo bioattivo S53P4 sui batteri *Staphylococcus aureus, Klebsiella pneumoniae e Acinetobacter baumannii*, resistenti alla meticillina. L'inibizione della proliferazione batterica è rilevabile tramite variazioni morfologiche dei batteri quali deformazione delle cellule e comparsa di fori nelle membrane cellulari.

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Romanò CL, Logoluso N, Meani E, Romanò D, De Vecchi E, Vassena C, **Drago** L.

Dr. L. DRAGO

Dr. CL. ROMANÒ

Uso di BIOACTIVE GLASS S53P4 nel trattamento della Osteomielite del Piede Diabetico: STUDIO RETROSPETTIVO - COMPARATIVO

- Studio comparativo retrospettivo 44 pazienti diabetici affetti da osteomielite localizzata a livello del piede

- Debridement del focolaio osteomielitico e applicazione locale di bioactive glass S53P4 (gruppo A) di 22 pz

- Abbiamo osservato lo stesso numero di pazienti con le stesse caratteristiche (gruppo B) sottoposti a trattamento tradizionale (debridement e/o ad amputazione)

Uso di BIOACTIVE GLASS S53P4 nel trattamento della Osteomielite del Piede Diabetico: STUDIO RETROSPETTIVO - COMPARATIVO

Entrambi i gruppi erano stati trattati con :

- terapia antibiotica sistemica sulla base del risultato di esami colturali microbiologici
- in tutti i pazienti era stato valutato il grado di vascolarizzazione periferica e se non sufficiente erano stati sottoposti a rivascolarizzazione mediante angioplastica endoluminale

Uso di BIOACTIVE GLASS S53P4 nel trattamento della Osteomielite del Piede Diabetico: STUDIO RETROSPETTIVO - COMPARATIVO

RISULTATI (1) :

dopo lo stesso periodo di follow up (15 ± 6 mesi) :

la risoluzione della osteomielite era significativamente aumentata nel gruppo A trattato con Bioactive glass confrontato con il gruppo B (90% vs. 61,9%, rispettivamente p = 0.03)

	Overall	Bioglass	Controls	P
Percutaneous transluminal angioplasty (%)	70.5	72.7	68.2	0.74
Hospitalization (days)	13.1±10.1	12.9±10.2	13.2±10.3	0.94
Antibiotic therapy (%)	28.6	13.6	45.0	0.07
Wound healing (days)	145.6±77.7	162.6±82.1	120.8±65.8	0.14
Osteomyelitic focus recurrence (%)	12.5	5.5	21.4	0.18
Osteomyelitis resolution (%)	75.6	90.0	61.9	0.03

Uso di BIOACTIVE GLASS S53P4 nel trattamento della Osteomielite del Piede Diabetico: STUDIO RETROSPETTIVO - COMPARATIVO

RISULTATI (2) :

La probabilità del gruppo trattato con Bioactive glass di raggiungere la risoluzione dell'osteomielite era 5.54 volte più grande rispetto al gruppo trattato con trattamento tradizionale (OR 5.54, 95% CI 1.10-30.5)

	Overall	Bioglass	Controls	P
Percutaneous transluminal angioplasty (%)	70.5	72.7	68.2	0.74
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Uso di BIOACTIVE GLASS S53P4 nel trattamento della Osteomielite del Piede Diabetico: STUDIO RETROSPETTIVO - COMPARATIVO

RISULTATI (3) :

L'uso del Bioactive glass era associato all'81% di minore probabilità di terapia antibiotica rispetto al gruppo B trattatato con solo debridement chirurgico (OR 0.19, 95% CI 0.04-0.87)

	Overall	Bioglass	Controls	P
Percutaneous transluminal angioplasty (%)	70.5	72.7	68.2	0.74
Hospitalization (days)	13.1±10.1	12.9±10.2	13.2±10.3	0.94
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Uso di BIOACTIVE GLASS S53P4 nel trattamento della Osteomielite del Piede Diabetico: STUDIO RETROSPETTIVO - COMPARATIVO

I nostri risultati dimostrano che il debridement dell'osteomielite seguito dall'applicazione di Bioactive glass può essere considerata una valida opzione nel trattamento dell'osteomielite del piede diabetico

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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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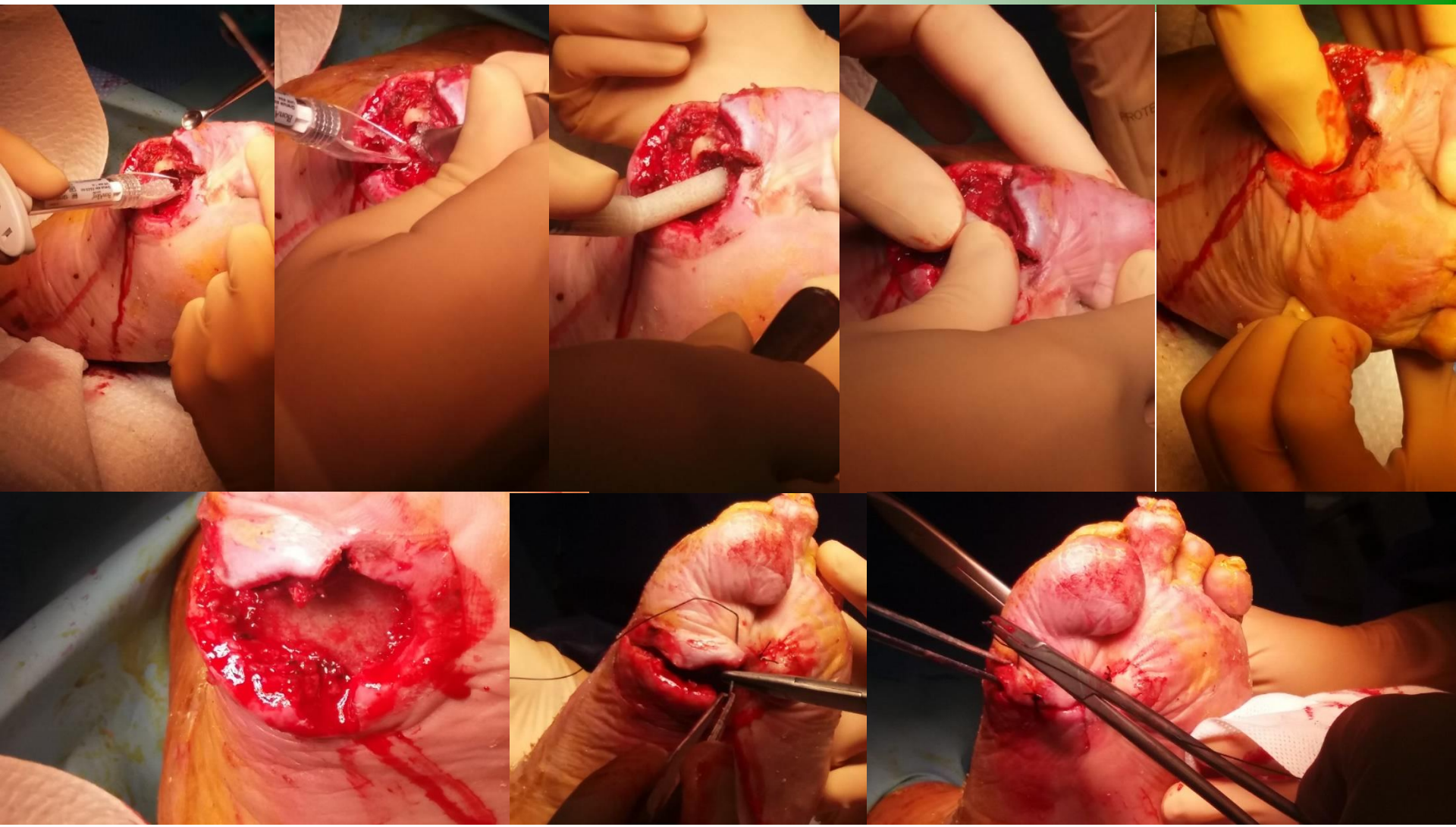
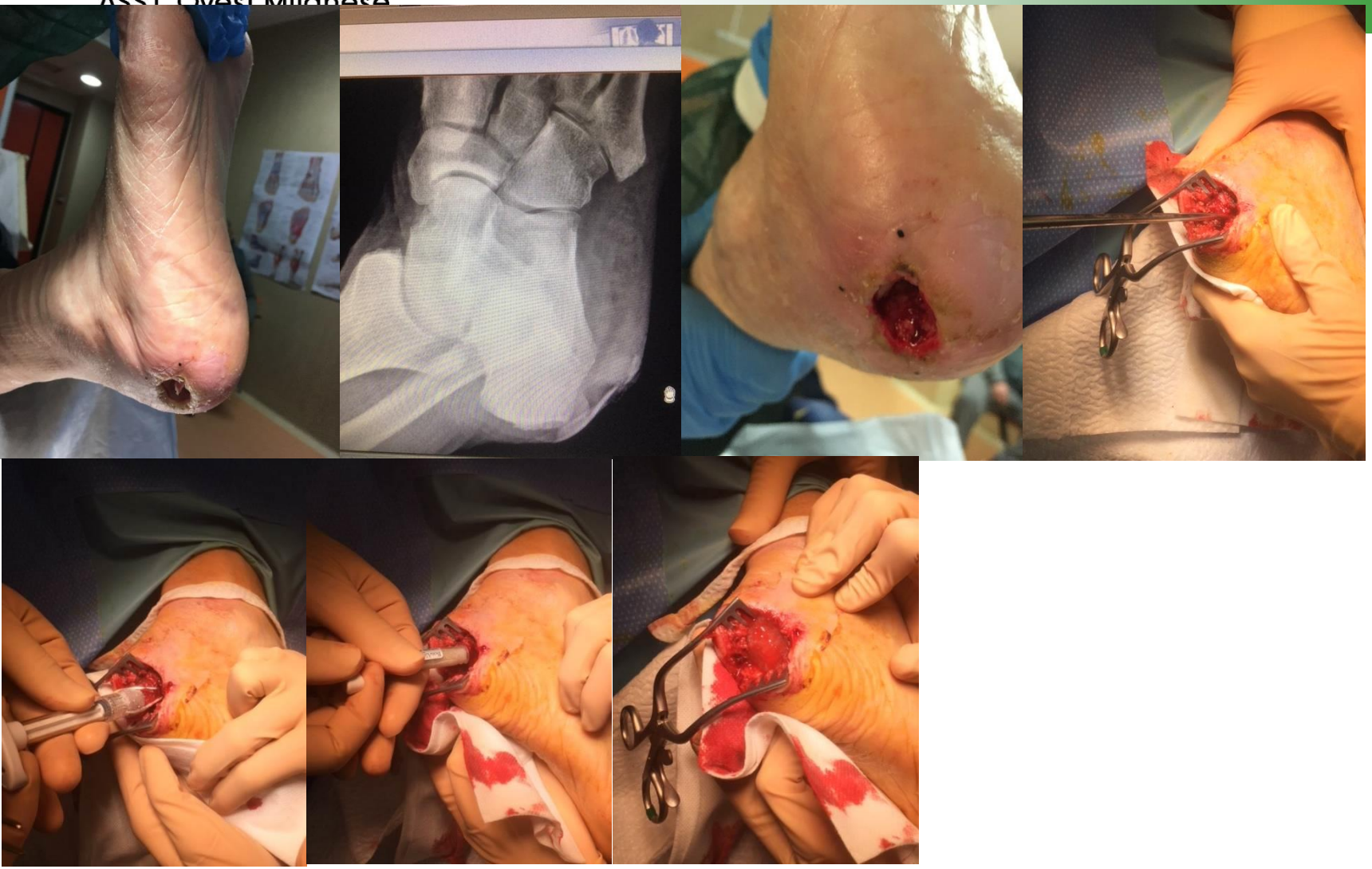
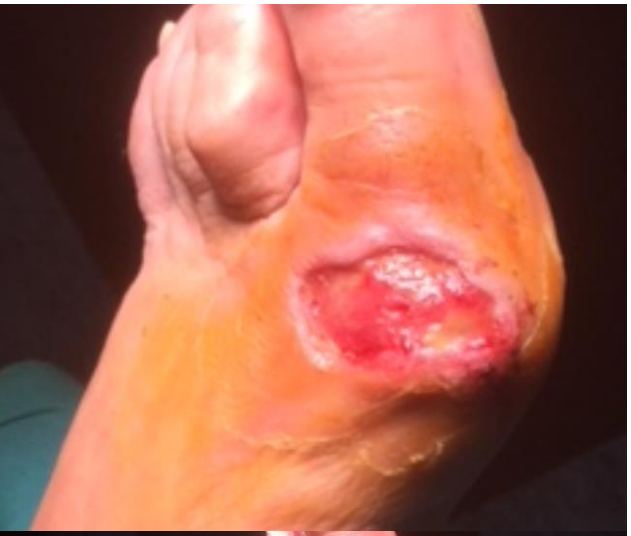
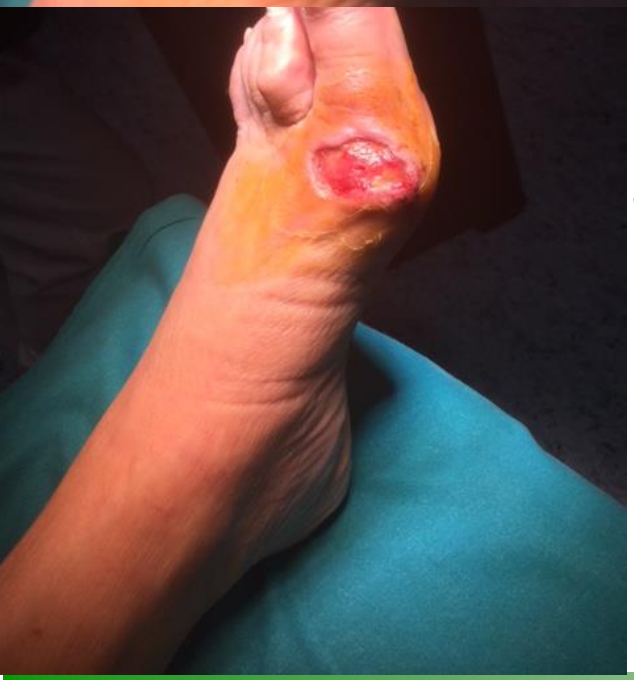






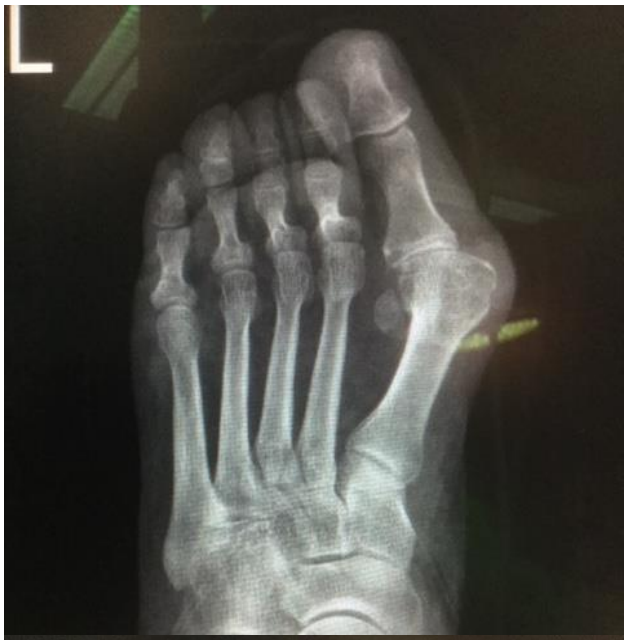


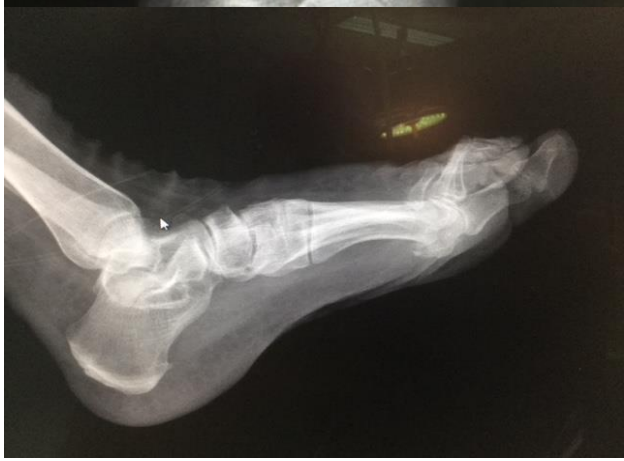
CLINICAL CASE

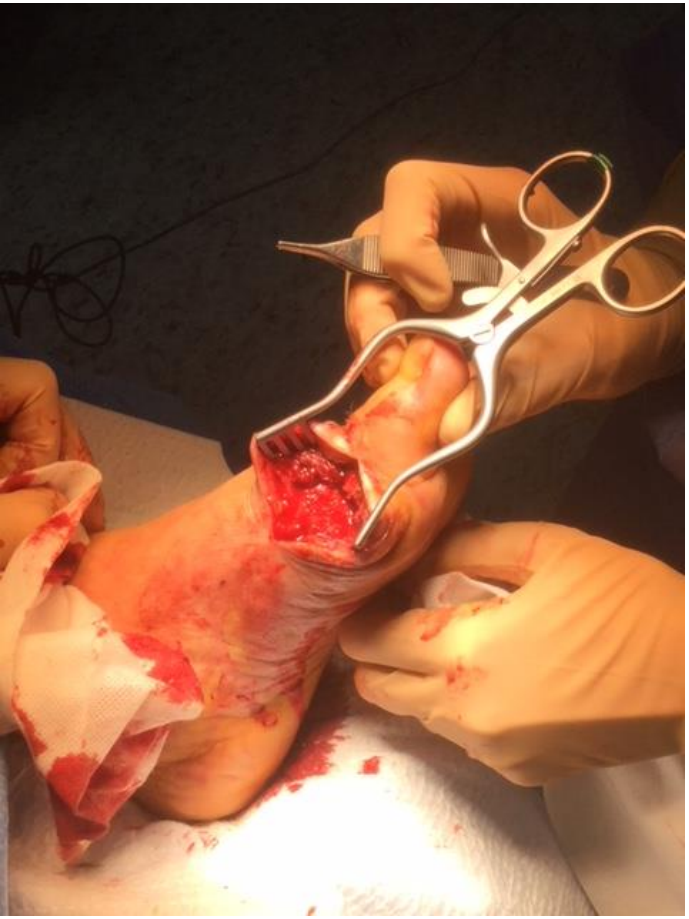
- Female, aged 68
- Type 2 diabetic since 2000
- Thyroidectomy for nodules, in substitutive therapy with LT4
- Smoker: 10 /dye

- Three months before start of lesion to the first metatarsal of the right foot

- Comes to our attention for the first time with ulcer I metatarsal ray and positive test probe to bone, previously treated with different therapies without healing.



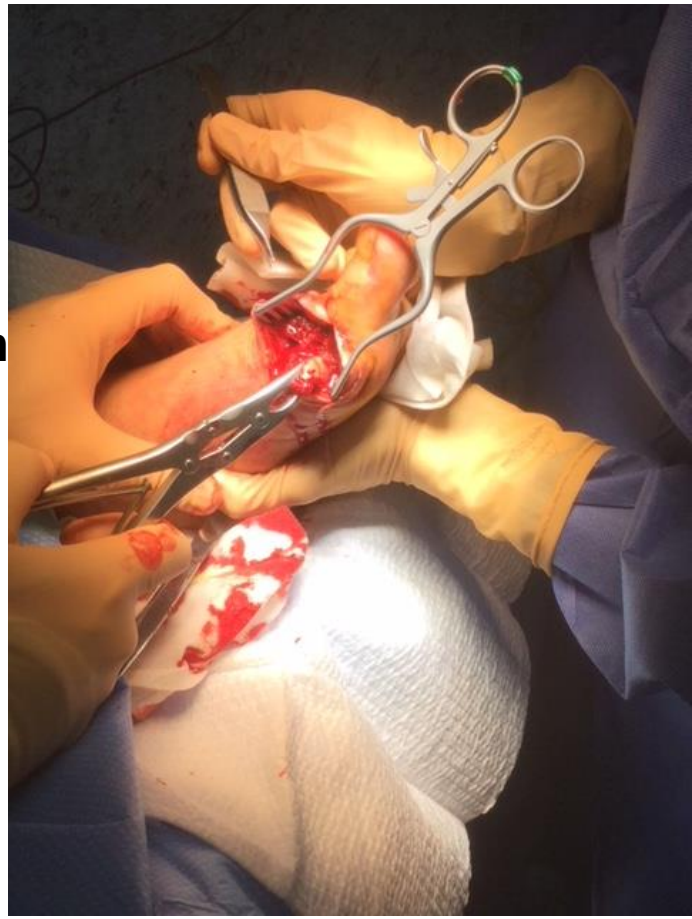




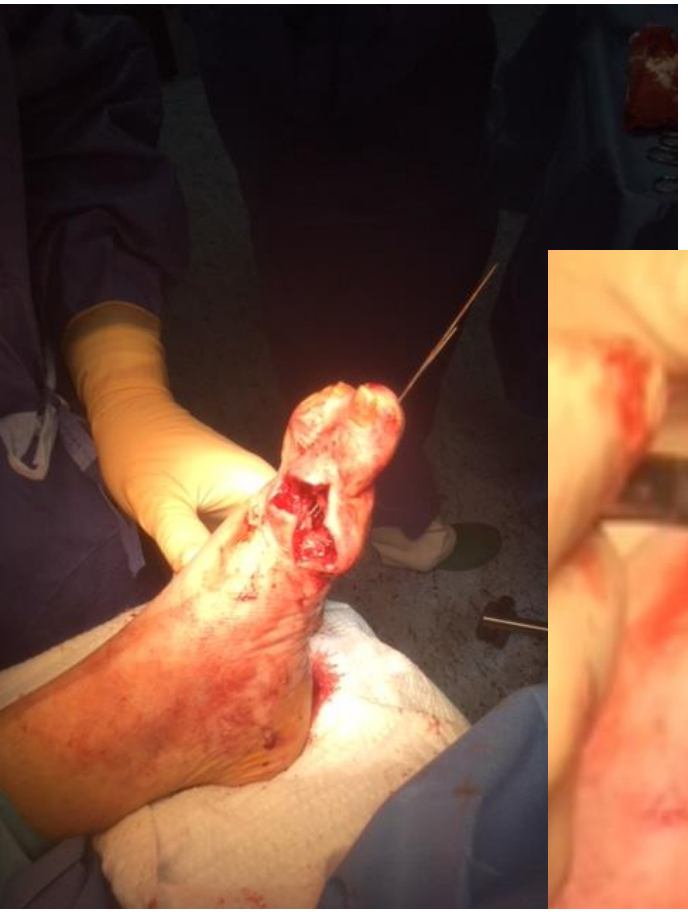
Surgical bone debridement : on December 21°, 2017

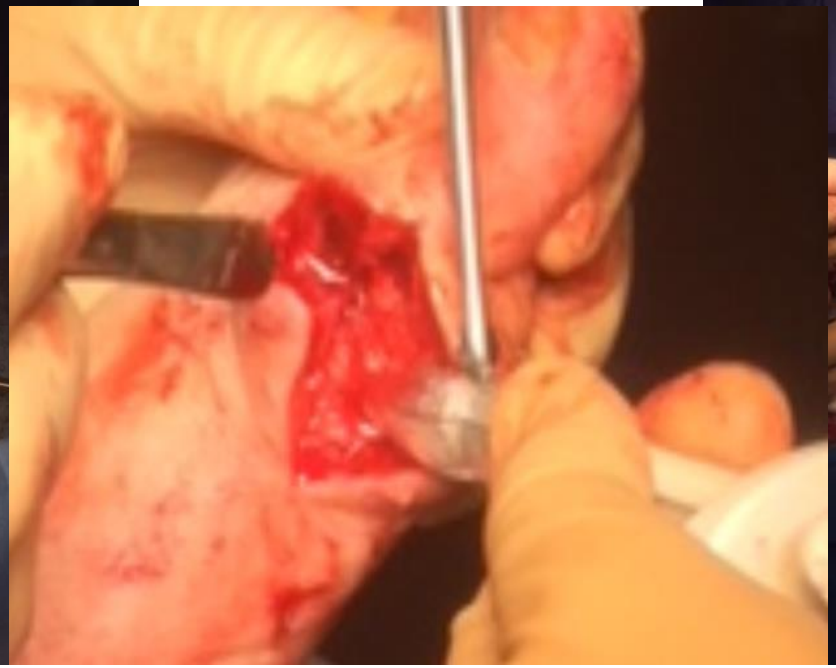
Antibiotic therapy with Piperacillin/tazobactam 4,5 gr x 3/die

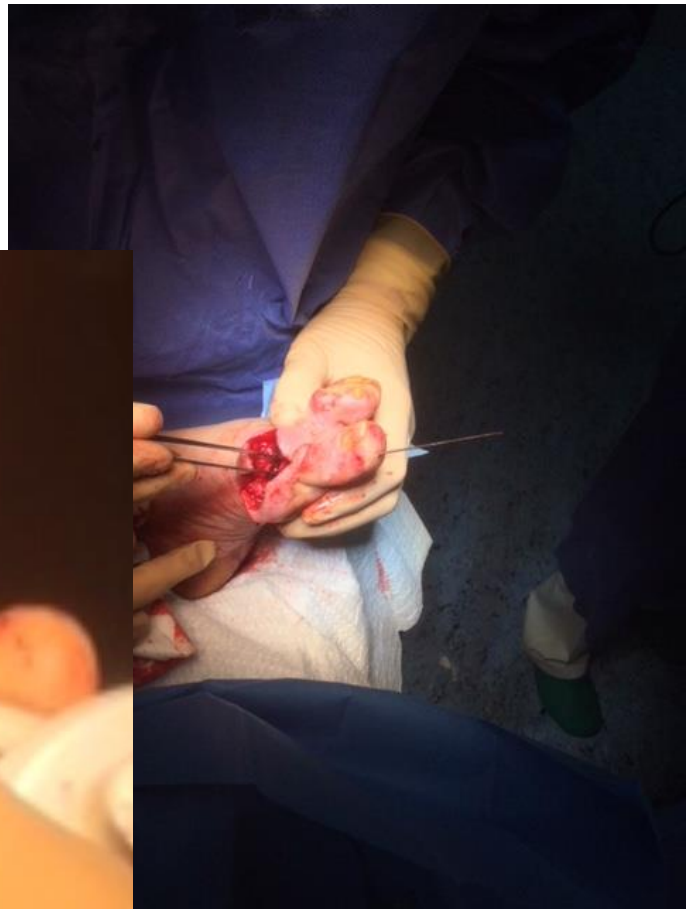
No vascular problem



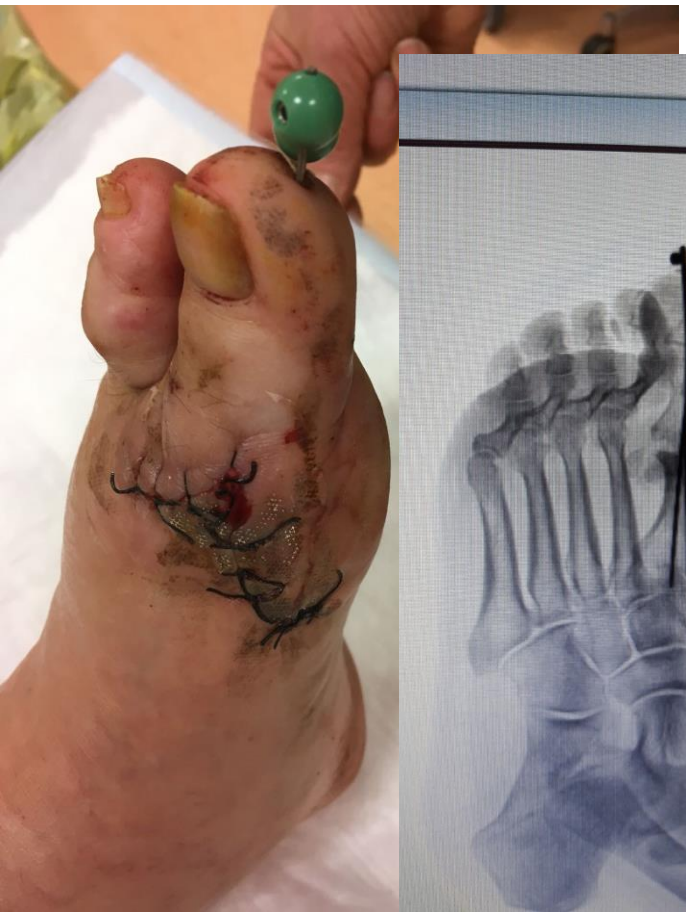
Surgical debridement of the osteomyelitis and stabilization of the metatarsal ray with K-wires arthrodesis

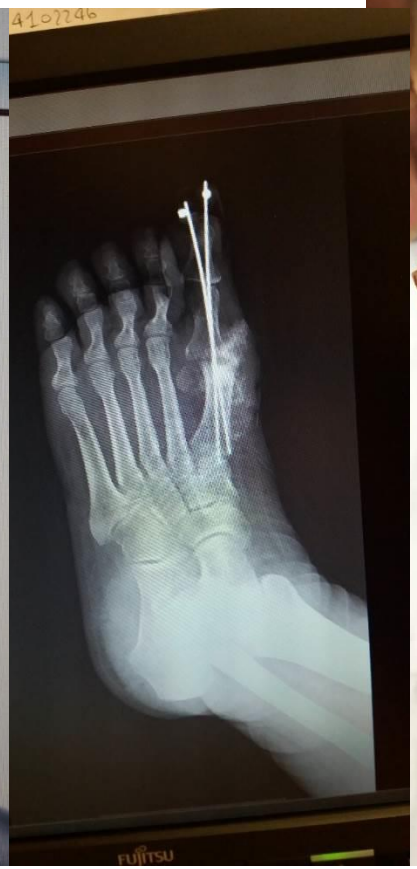


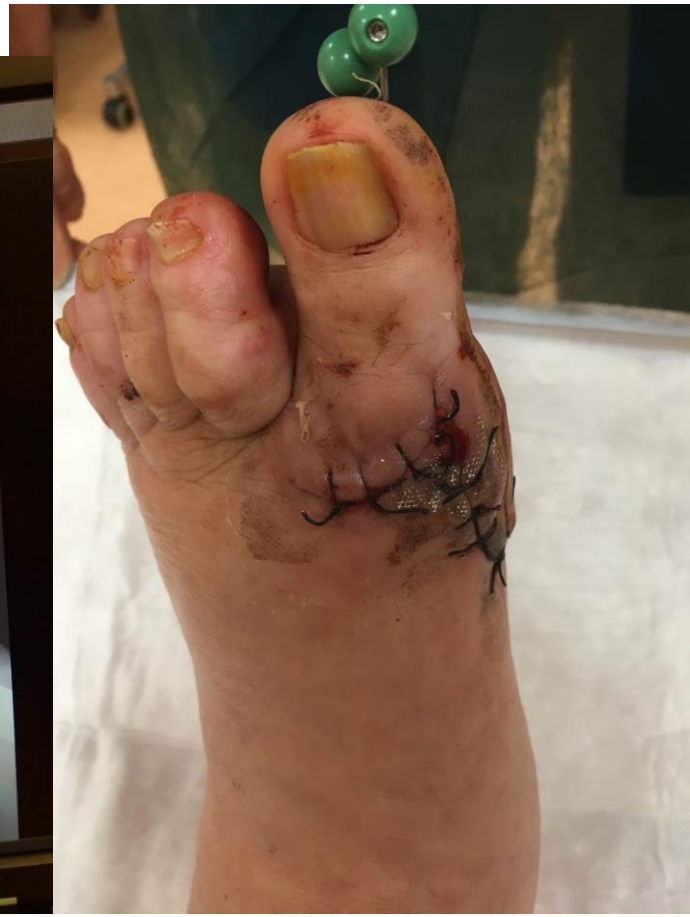




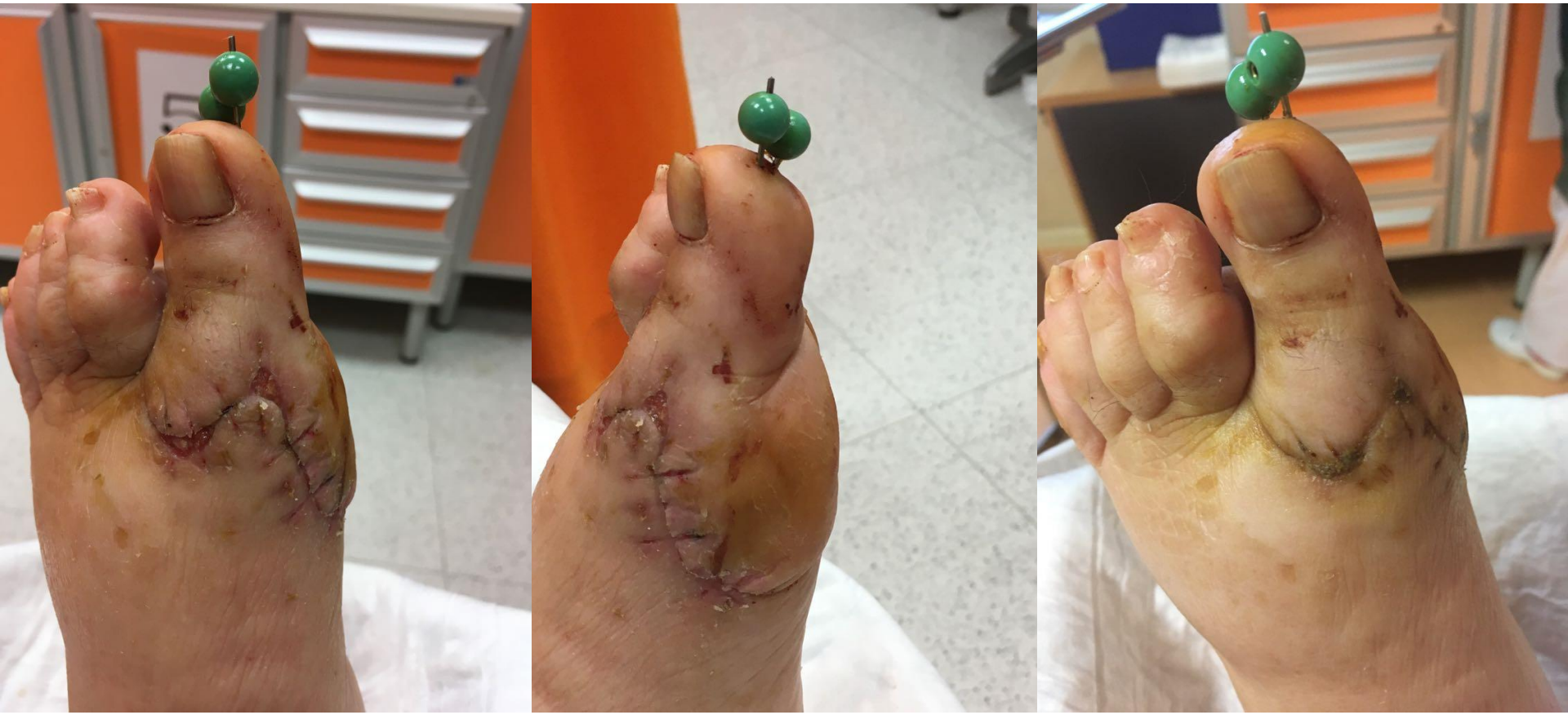
one week after



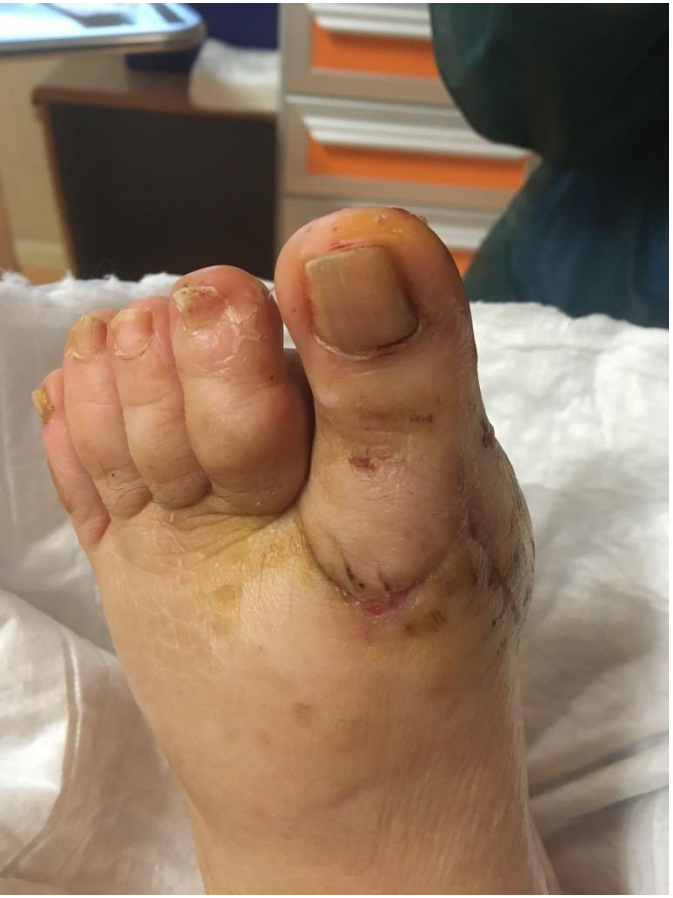


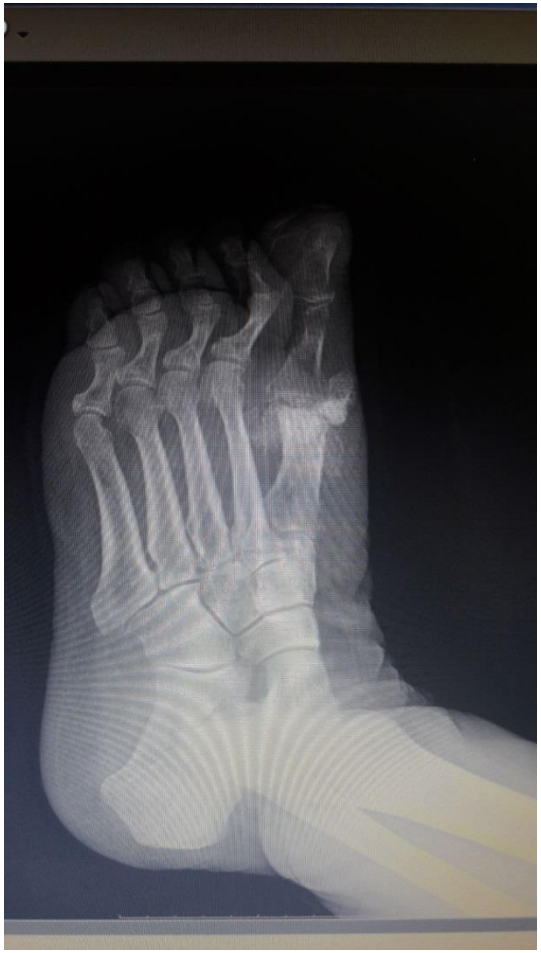


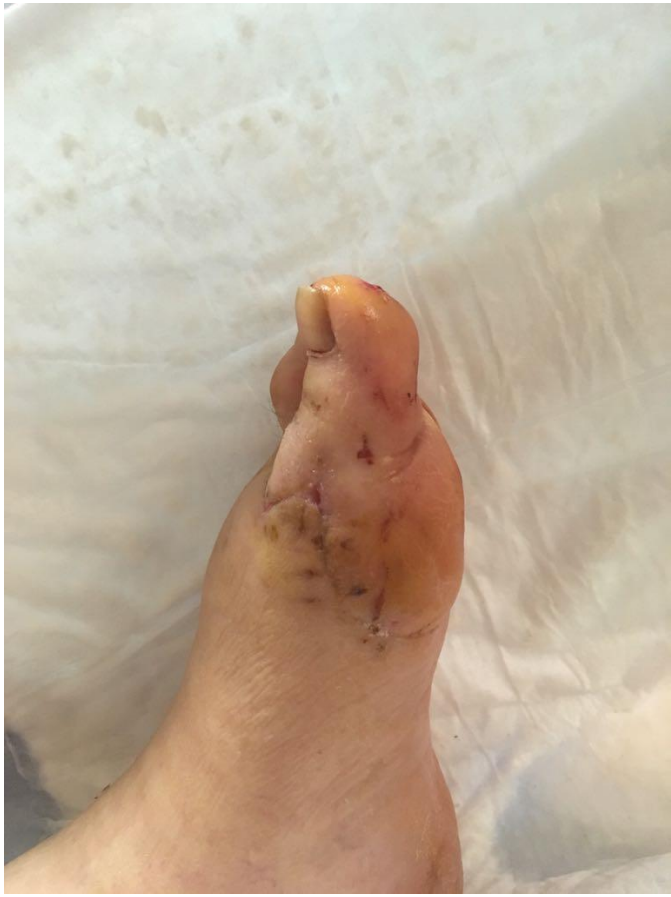
7 weeks after



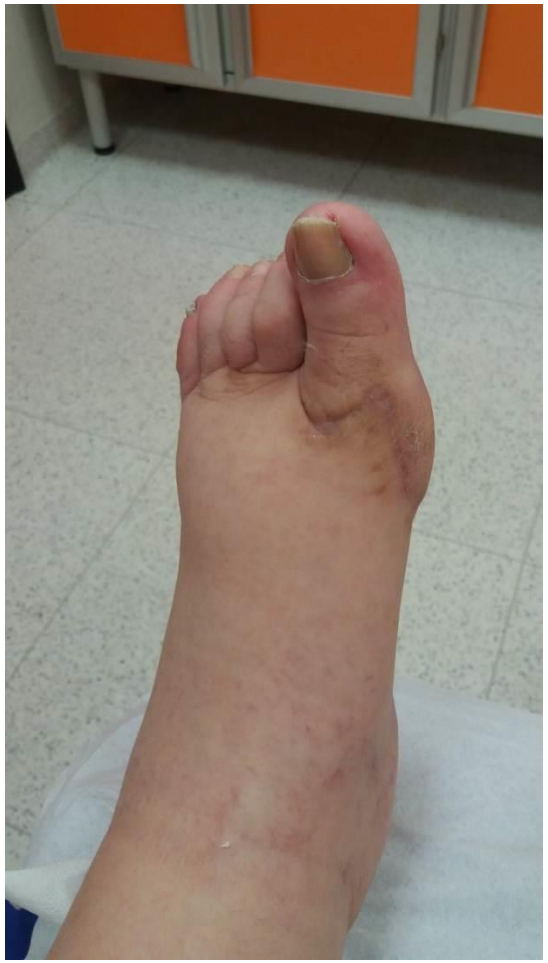
9 weeks after

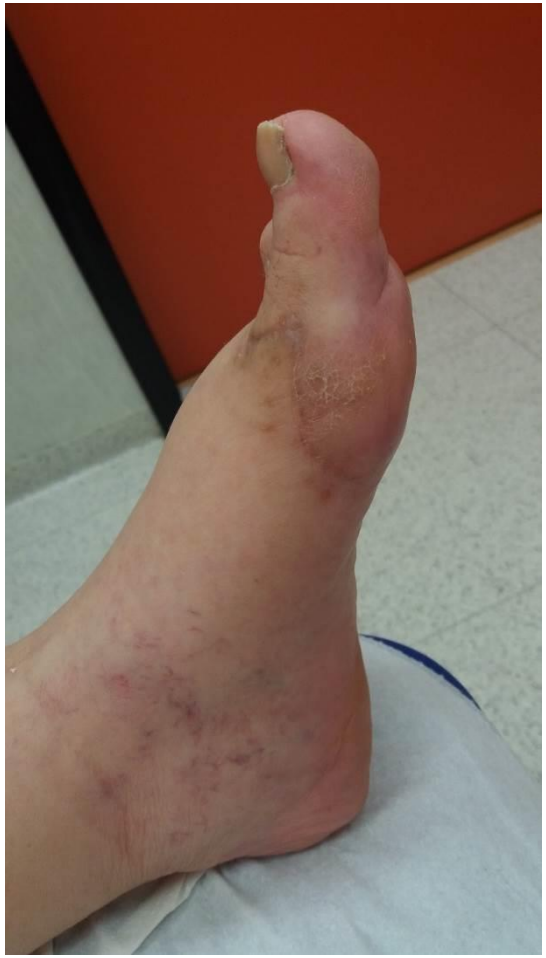


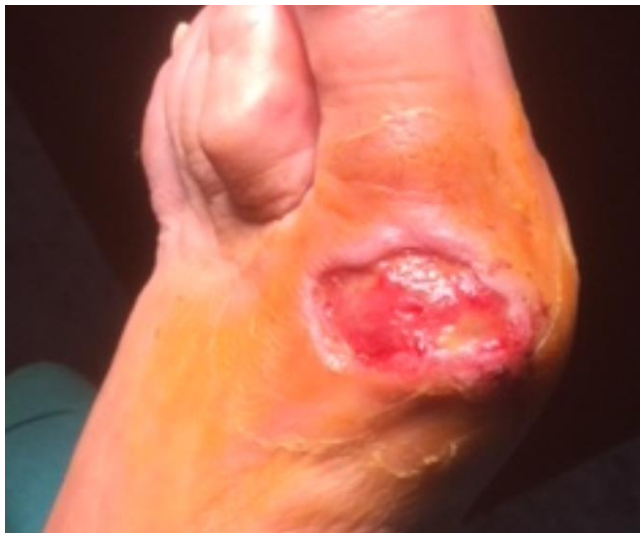




20 weeks after







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Follow up microbiologico

<u>TEMPO</u> 12 mesi , dalla data dell'intervento.

20 Pazienti (10 per gruppo)

<u>N° di Recidive</u> valutate per materiale, batteri, antibiogramma, profili di resistenza.

Materiali		FO	Frammento osseo	
		TESS	Tessuto molle	
		PF	Pus ferita	

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Gruppo di Controllo
10 pazienti sottoposti a debridment chirurgico

CONTROLLO						
Pazienti	**DN**	**Data Int.**	**MAT**	**Batteri**	**RECIDIVE**	
CR	19/06/1949	12/04/2016	FO	MRSE	2	
AG	01/01/1943	05/07/2016	FO	E.coli EN	3	
PF	23/01/1943	21/07/2016	FO	MRSA,MRSE	2	
FM	24/09/1934	01/09/2016	FO	MRSA	4	
RE	**15/10/1949**	**13/09/2016**	**FO**	**EN,MRSA**	**8***	
RC	17/06/1949	15/09/2016	FO	MRSE,Citrobacter	2	
GR	24/04/1939	11/10/2016	FO	MSSA,MSSE	2	
MM	29/08/1950	15/12/2016	FO	MRSA	4	
FG	**15/03/1945**	**01/03/2016**	**FO,TESS**	**MSSA,S.marcescens**	**5**	
PS	**31/10/1964**	**01/03/2016**	**PF**	**MSSA,S.marcescens**	**4**	

Risultati

Gruppo di Controllo 10 pazienti tutti con recidive

	Recidive
40%	2
10%	3
30%	4
10%	5
10%	8

4 paz. verso stesso materiale (FO)

6 paz. verso materiali diversi

7 paz. Stessi batteri

3 paz. Diversi batteri

Pazienti	DN	Data Int.	MAT	Batteri	RECIDIVE		
RE	15/10/1949	13/09/201	FO	EN MRSA	8*		

Anno 2016 ricovero dal 15-3 al 31-12

Anno 2017 ricovero dal 5-1 al 24-12 con brevi periodi ad accesso ambulatoriale

8* Paziente Dializzato

Diabetico

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Gruppo Biovetro

10 pazienti sottoposti a debridment chirurgico e applicazione locale Biovetro S53p4

BIOVETRO									
Pazienti	**DN**	**Data Int.**	**MAT**	**Batteri**	**RECIDIVE**				
BV	12/06/1955	04/04/2017	FO	MRSA	0				
MA	19/04/1963	04/04/2017	PUS	EN MRSA	5*				
TA	18/07/1959	23/05/2017	FO	EN C.striatum	2				
FG	15/03/1945	08/09/2017	FO	NEG	0				
PS	31/10/1964	14/09/2017	FO	MSSA,C.striatum	0				
FA	24/09/1934	26/09/2017	FO	NEG	0				
GE	20/04/1945	05/10/2017	FO	PSA,Kl.aerogenes	0				
SR	13/02/1946	12/10/2017	FO	MSSA	0		**14/12/18**	**PF**	**MRSA**
CG	08/09/1946	19/10/2017	FO	PSA	0		**7/6/19**	**PF**	**MRSA**
CE	19/09/1959	19/10/2017	FO	MRSA,St:agal,EN	1				

Paziente

Pazienti	DN	Data Int.	MAT	Batteri	RECIDIVE
MA	19/04/1963	04/04/2017	PUS	EN MRSA	5*
5*	Paziente	Dializzato			
		Oncologico			
		Cardiopatico			
		Diabetico			
		Prima amputazione		2010	
Materiali	2017	PUS			
		FO	06/06/2017		

Pazienti	DN	Data Int.	MAT	Batteri	RECIDIVE
CONTROLLO					
FG	15/03/1945	01/03/2016	FO,TESS	MSSA,S.marcesce	5
PS	31/10/1964	01/03/2016	PF	MSSA,S.marcesce	4
BIOVETRO					
FG	15/03/1945	08/09/2017	FO	NEG	0
PS	31/10/1964	14/09/2017	FO	MSSA,C.striatum	0

Risultati Microbiologici

Materiali
Colture
Ceppi MDR

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Risultati Microbiologici

	Gennaio-	Giugno				
Materiale	2016					
	Degenti	Colture Pos	%	Amb	Colture Pos	%
Frammento osseo	80	70	87.5	10	10	100
Tessuti molli	78	70	89.8			
PUS(PD)	38	34	89.5	3	2	66.7
	2017					
	Degenti	Colture Pos	%	Amb	Colture Pos	%
Frammento osseo	121	104	86	16	16	100
Tessuti molli	40	37	93	4	4	100
PUS(PD)	40	33	83	0	0	0

Gennaio- Giugno

	2018					
	Degenti	Colture Pos	%	Amb	Colture Pos	%
Frammento osseo	153	135	88	23	23	100
Tessuti molli	54	50	93	5	5	100
PUS(PD)	36	26	72	1	1	100
	2019					
	Degenti	Colture Pos	%	Amb	Colture Pos	%
Frammento osseo	182	58	32	44	16	36
Tessuti molli	41	17	41	12	6	50
PUS(PD)	43	35	81.4	1	1	100

....in sintesi

	FO		TESS	
	n°	%	n°	%
2016	80	87.5	78	89.8
2017	121	86	40	93
2018	153	88.2	54	92.6
2019	182	32	41	41

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Batteri - Resistenze

PAZIENTI 65	2016				
	MRSA	A.bau. MDR	KI KPC	Ps. MDR	En.VRE
FRAMMENTO OSSEO	30	4			
TESSUTI MOLLI	21	2	1		
PUS (pd)	25				
PAZIENTI 47	2017				
	MRSA	A.bau. MDR	KI KPC	Ps. MDR	En.VRE
FRAMMENTO OSSEO	40	1		2	
TESSUTI MOLLI	15			2	
PUS (pd)	27			4	

PAZIENTI 47	2018				
	MRSA	A.bau. MDR	KI KPC	Ps. MDR	En.VRE
FRAMMENTO OSSEO	43	3		1	
TESSUTI MOLLI	16	2	4		1
PUS (pd)	11			3	
PAZIENTI 24	2019				
	MRSA	A.bau. MDR	KI KPC	Ps. MDR	En.VRE
FRAMMENTO OSSEO	19			1	
TESSUTI MOLLI	7	2	1		
PUS (pd)	3	1		1	

S53P4 un nuovo sostituto osseo dalle grandi potenzialità

Considerazioni

Importante e necessario

è

..lavorare sempre in team multidisciplinare

..valutare l'efficacia clinica e microbiologica, di tutti i trattamenti

..misurare i costi/benefici, relativi alla variazione della spesa terapeutica

materials

MDPI

Article

Cost-Effectiveness Study of One-Stage Treatment of Chronic Osteomyelitis with Bioactive Glass S53P4

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Grazie