



VIII CONGRESSO
NAZIONALE
PIEDE DIABETICO
INTERASSOCIATIVO SID-AMD

*Focus sul piede nella
gestione del diabete*

ROMA, 18-20 GIUGNO 2026
HOTEL NH VILLA CARPEGNA

LA MEDICAZIONE SPECIFICA PER OGNI LESIONE

Elisabetta Iacopi
SD Piede Diabetico - AOUP

Disclosure

Dichiaro di NON aver ricevuto negli ultimi due anni compensi o finanziamenti da Aziende Farmaceutiche e/o Diagnostiche

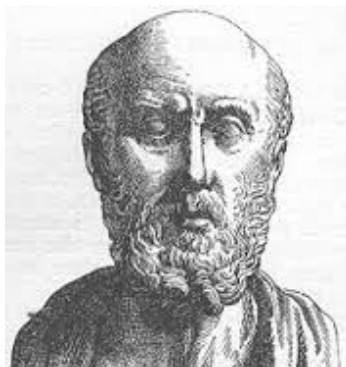
Dichiaro altresì il mio impegno ad astenersi, nell'ambito dell'evento, dal nominare, in qualsivoglia modo o forma, aziende farmaceutiche e/o denominazione commerciale e di non fare pubblicità di qualsiasi tipo relativamente a specifici prodotti di interesse sanitario (farmaci, strumenti, dispositivi medico-chirurgici, ecc.).



Le prime linee guida....



La «Cura» Locale



[Ippocrate – De Ulceribus – 377 aC]



[Santi Cosma e Damiano, Cattedrale di Rimini, XIV secolo]

[Claudio Galeno – 129 – 216 dC]



[Pierre Dionis, chirurgo, XVI secolo]





DF CLINIC



DF SPECIALIST



...ed in epoca moderna?



Guidelines on
interventions to
enhance healing of
foot ulcers in people
with diabetes

IWGDF 2023 update

Part of the 2023 IWGDF Guidelines on
the prevention and management of
diabetes-related foot disease





Part of the 2023 IWGDF Guidelines on the prevention and management of diabetes-related foot disease



9 quesiti clinici 31 raccomandazioni

Forza della raccomandazione:

19 alta

11 condizionata

Qualità dell'evidenza

29 bassa

2 moderata

[<https://iwgdfguidelines.org/wp-content/uploads/2023/07/IWGDF-2023-07-Wound-Healing-Guideline.pdf>]





Part of the 2023 IWGDF Guidelines on the prevention and management of diabetes-related foot disease



Quesiti clinici

Raccomandazioni

1	Debridement	6
2	Medicazioni	6
3	Ossigeno e altri gas	3
4	Azioni fisiche sul letto di lesione	1
5	Sostituti cutanei	3
6	Prodotti autologhi	5
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[<https://iwgdfguidelines.org/wp-content/uploads/2023/07/IWGDF-2023-07-Wound-Healing-Guideline.pdf>]



Part of the 2023 IWGDF Guidelines on the prevention and management of diabetes-related foot disease



Recommendation 9: Consider the use of the sucrose-octasulfate impregnated dressing as an adjunctive treatment, in addition to the best standard of care, in non-infected, neuro-ischaemic diabetes-related foot ulcers which have had insufficient change in ulcer area with best standard of care including appropriate offloading for at least 2 weeks (Conditional; Moderate).



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

Michael Edmonds, José Luis Lázaro-Martínez, Jesus Manuel Alfayate-García, Jacques Martini, Jean-Michel Petit, Gerry Rayman, Ralf Lobmann, Luigi Uccioli, Anne Sauvadet, Serge Bohbot, Jean-Charles Kerihuel, Alberto Piaggese

Summary

Lancet Diabetes Endocrinol
2018; 6: 186-96

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This online publication has been corrected. The corrected version first appeared at thelancet.com/diabetes-endocrinology on March 6, 2018

See [Comment](#) page 159

Diabetic Foot Clinic, King's College Hospital London, UK

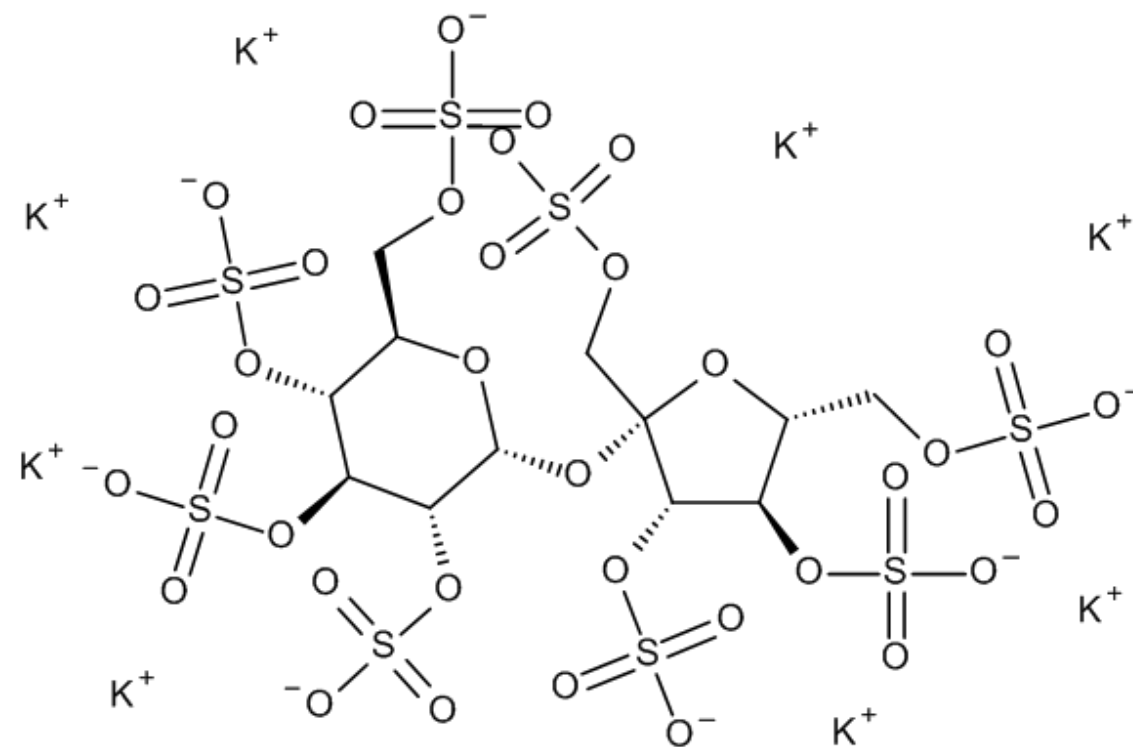
Background Diabetic foot ulcers are serious and challenging wounds associated with high risk of infection and lower-limb amputation. Ulcers are deemed neuroischaemic if peripheral neuropathy and peripheral artery disease are both present. No satisfactory treatment for neuroischaemic ulcers currently 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 cm² 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 cm² and 5–30 cm²), to treatment with either

[Edmonds M et al – Lancet D&E - 2018]

[<https://iwgdfguidelines.org/wp-content/uploads/2023/07/IWGDF-2023-07-Wound-Healing-Guideline.pdf>]

- Gelifica a contatto con essudato
- Attiva fibroblasti, cheratinociti e macrofagi
- Ambiente umido
- Inibisce MMPs





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

Michael Edmonds, José Luis Lázaro-Martínez, Jesus Manuel Alfayate-García, Jacques Martini, Jean-Michel Petit, Gerry Rayman, Ralf Lobmann, Luigi Uccioli, Anne Sauvadet, Serge Bohbot, Jean-Charles Kerihuel, Alberto Piaggini

	Control dressing group	Sucrose octasulfate dressing group	Adjusted odds ratio (95% CI; p value) or p value
Primary efficacy outcome (ITT cohort)			
Wound closure, confirmed by the investigator	34/114 (30%)	60/126 (48%)	2.60 (1.43–4.73; p=0.002)
Secondary efficacy outcomes (ITT cohort)			
Kaplan-Meier-estimated time to closure (days); mean (95% CI)	180 (163–198)	120 (110–129)	p=0.029
Extrapolated instantaneous Gilman parameter at week 20 (mm per week)	..	..	
Mean (SD)	0.3 (1.1)	0.5 (0.8)	NA
Median (IQR)	0.2 (0.0–0.5)	0.4 (0.0–0.8)	p=0.021 for median comparison
Absolute wound area reduction from day 0 to week 20 (cm ²)	..	..	NA
Mean (SD)	2.3 (5.5)	3.2 (5.2)	NA
Median (IQR)	1.2 (0.6–2.4)	1.8 (0.9–3.8)	p=0.022 for median comparison
Relative wound area reduction from day 0 to week 20 (%)	..	..	
Mean (SD)	42 (115)	72 (47)	NA
Median (IQR)	90 (29–100)	98 (58–100)	p=0.024 for median comparison

[Edmonds M et al – Lancet D&E - 2018]



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

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research

Optimal wound closure of diabetic foot ulcers with early initiation of TLC-NOSF treatment: post-hoc analysis of Explorer

Objective: In March 2018, the Explorer study, an international, double-blind, randomised controlled trial (RCT), established that adding a TLC-NOSF (UrgoStart Contact, Laboratoires Urgo, France) dressing to good local standard of care (SoC) significantly and substantially increases wound closure and reduces the healing time of neuroischaemic diabetic foot ulcers (DEU). Besides the TLC-

maximal difference between the two treatments was reported in wounds with a duration of ≤ 2 months (71% versus 41%, 30 percentage points difference, Relative Risk 1.7, 95% Confidence Interval 1.1 to 2.8). Regarding wound location subgroup analyses, the outcomes were always in favour of the TLC-NOSF treatment, with closure rates ranging between 43% and 61% within the TLC-NOSF

[Lazaro-Martinez JL et al – JWC– 2019]



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Recommendation 20: Consider the use of autologous leucocyte, platelet and fibrin patch for diabetes-related foot ulcers as an adjunctive therapy to standard of care, where best standard of care alone has been ineffective, and where the resources and expertise exist for the regular venepuncture required. (Conditional; Moderate)

Articles

LeucoPatch system for the management of hard-to-heal diabetic foot ulcers in the UK, Denmark, and Sweden: an observer-masked, randomised controlled trial



Frances Game, William Jeffcoate, Lise Tarnow, Judith L Jacobsen, Diane J Whitham, Eleanor F Harrison, Sharon J Ellender, Deborah Fitzsimmons, Magnus Löndahl, for the LeucoPatch II trial team

Summary

Background The LeucoPatch device uses bedside centrifugation without additional reagents to generate a disc comprising autologous leucocytes, platelets, and fibrin, which is applied to the surface of the wound. We aimed to test the effectiveness of LeucoPatch on the healing of hard-to-heal foot ulcers in people with diabetes.

Methods This was a multicentre, international, observer-masked, randomised controlled trial of people with diabetes and a hard-to-heal foot ulcer done in 32 specialist diabetic foot clinics in three countries (UK, Denmark, and Sweden). After a 4-week run-in period, those with a reduction in ulcer area of less than 50% were randomly allocated (1:1) by computer-generated, web-based randomisation (block sizes of two, four, and six) to either prespecified good standard care alone or care plus weekly application of LeucoPatch. The primary outcome was the proportion of ulcers that healed within 20 weeks assessed in the intention-to-treat population (all participants with post-randomisation data

Lancet Diabetes Endocrinol 2018

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See Online/Comment
[http://dx.doi.org/10.1016/S2213-8587\(18\)30262-6](http://dx.doi.org/10.1016/S2213-8587(18)30262-6)

Department of Diabetes and
Endocrinology, Derby Teaching
Hospitals NHS Foundation

[\[https://iwgdfguidelines.org/wp-content/uploads/2023/07/IWGDF-2023-07-Wound-Healing-Guideline.pdf\]](https://iwgdfguidelines.org/wp-content/uploads/2023/07/IWGDF-2023-07-Wound-Healing-Guideline.pdf)

LeucoPatch system for the management of hard-to-heal diabetic foot ulcers in the UK, Denmark, and Sweden: an observer-masked, randomised controlled trial

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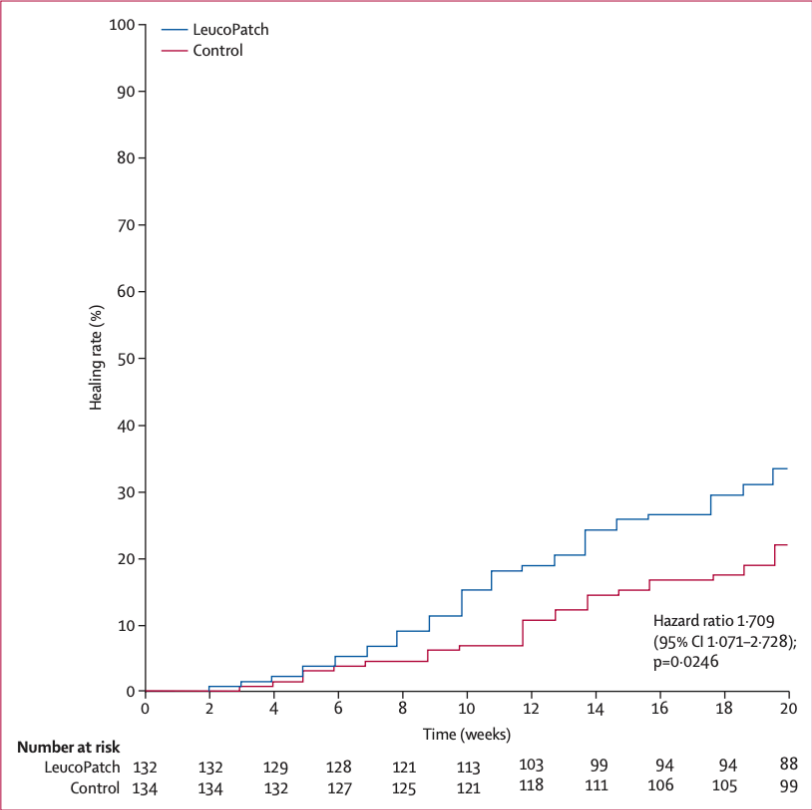


Figure 2: Time to healing
Survival curve showing proportion of ulcers healed, with healing defined as complete epithelialisation without any drainage sustained for at least 4 weeks, in the intention-to-treat population randomly assigned to standard care alone (n=134) or standard care and LeucoPatch (n=132).

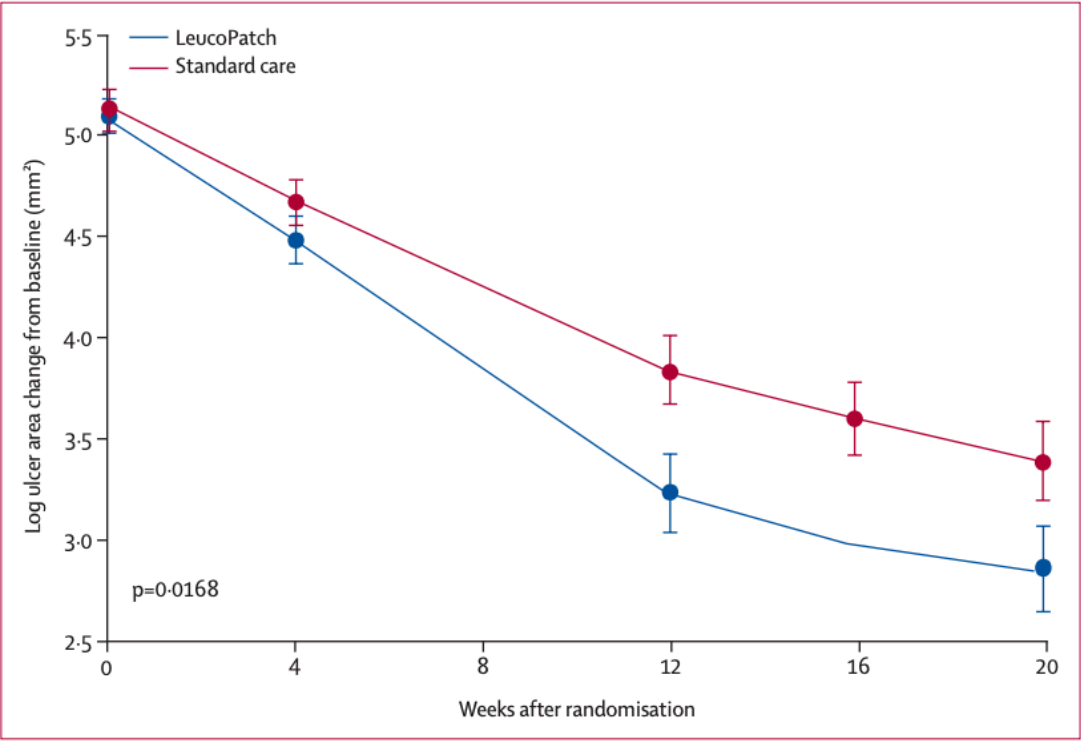
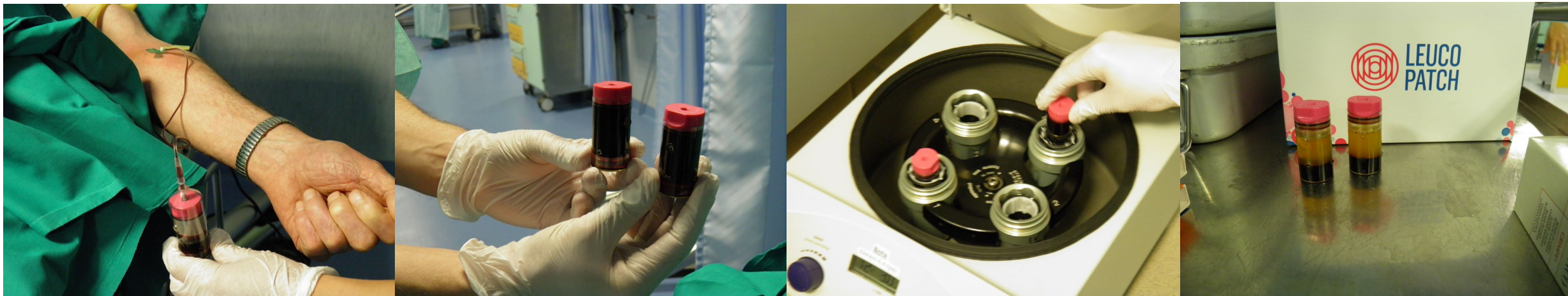


Figure 3: Reduction in ulcer area
Data are mean of log, with 95% CI error bars.

[Game F et al – Lancet D&E - 2018]



3CP™

Centrifugation Coagulation Compaction Process



Centrifugation
(to separate
cells)



Coagulation
(complete fibrin
polymerisation)



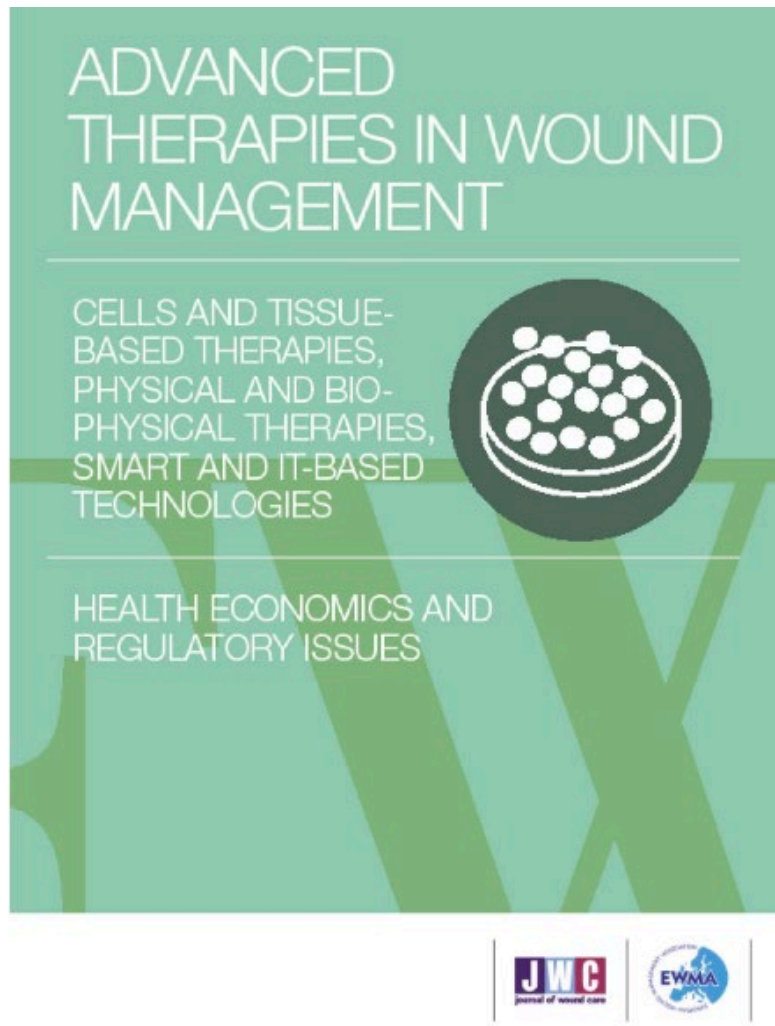
Compaction
(of fibrin to
form the patch)

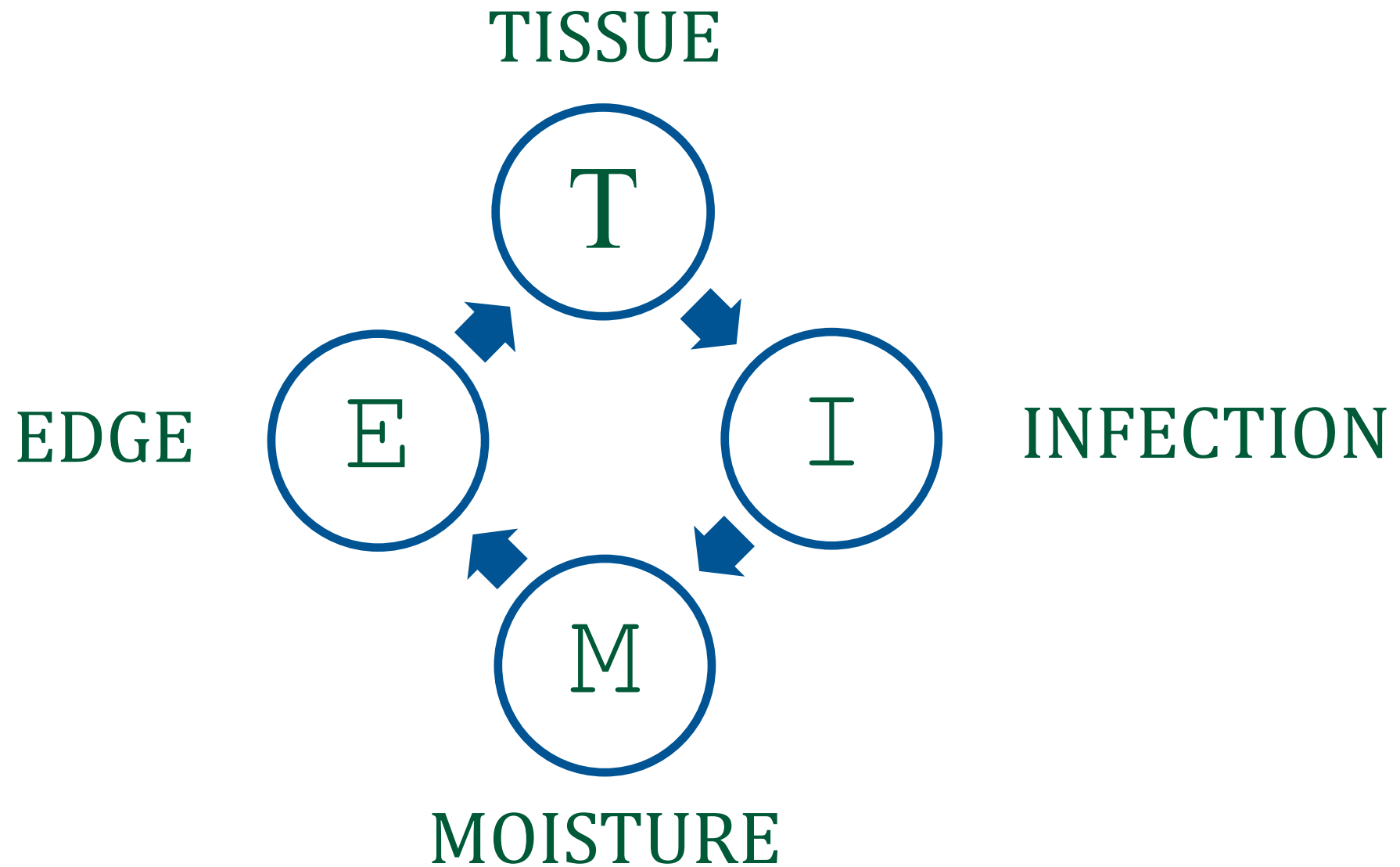
→ Fibrina

→ Piastrine

→ Leucociti

[Game F et al – Lancet D&E - 2018]





FASE FLOGISTICA

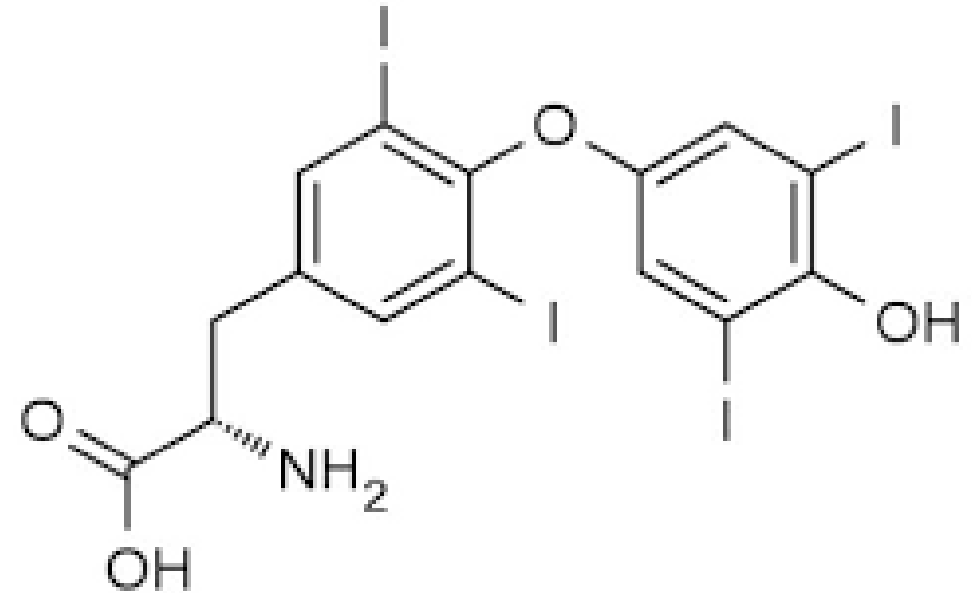
FASE RIPARATIVA

Iodio	Alginati
Alginati con Ag	Idrofibre
Idrofibre con Ag	Schiume di poliuretano
Carbone	Cellulosa ossidata
Ipertoniche	Saccarosio octasulfato
Miele	Collagene
Poliesametilbiguanide	Garze grasse
Captazione batterica	ROS
Idrocolloidi e idrogeli	ETV
Schiume di poliuretano a scopo protettivo	Emoglobina spray/NO
Ossido di rame	Acido ialuronico



Iodio

- ✓ Il primo antisettico utilizzato, può essere utilizzato pure o diluito a varia concentrazione
- ✓ Attenzione nel paziente allergico o con disfunzione tiroidea
- ✓ **Nota lesività verso il tessuto di granulazione**



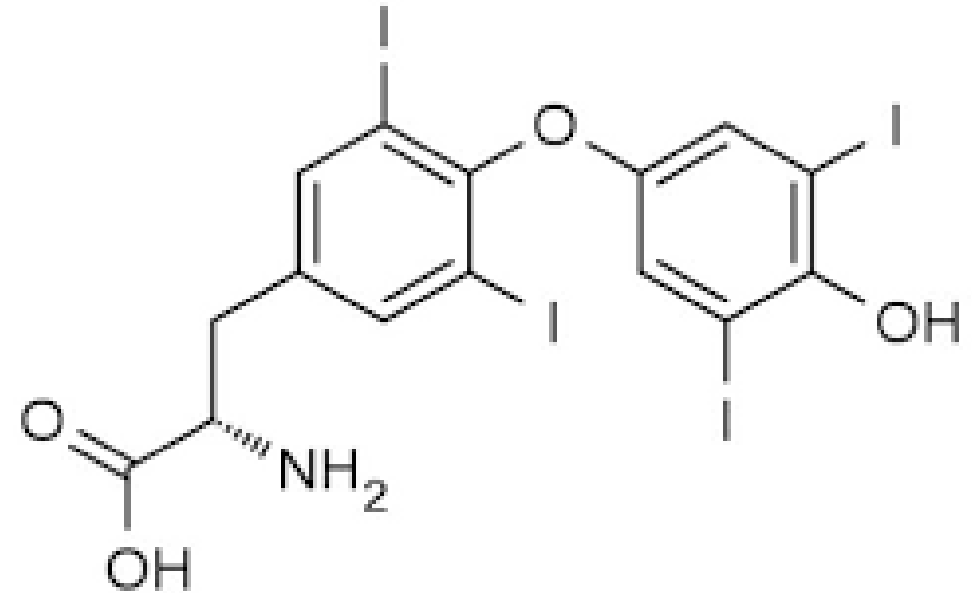
Iodio

3 differenti formulazioni

Povidone

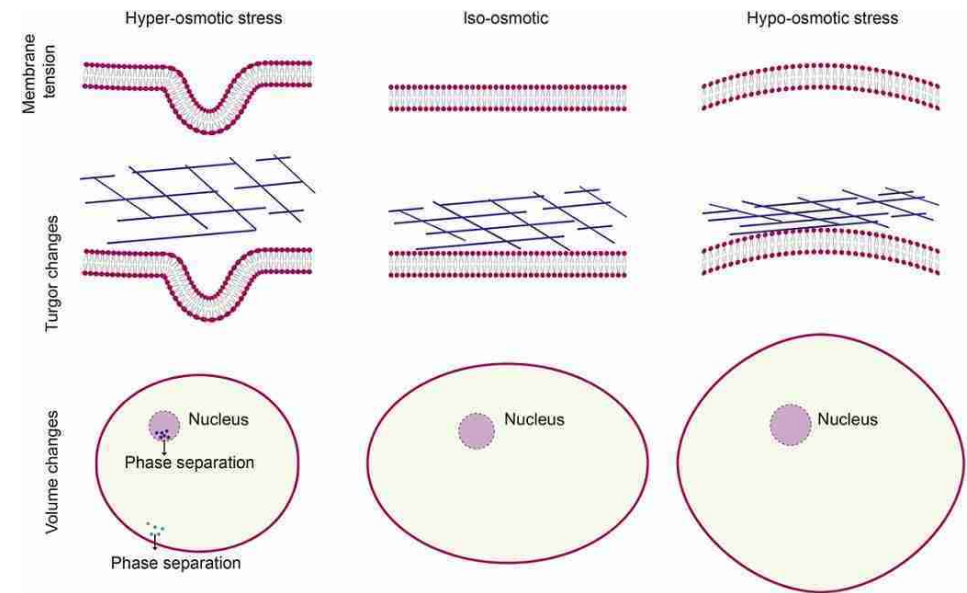
Cadexomero Iodico

Iodoformio



Garze ipertoniche

- ✓ Garze impregnate di cristalli di sale al 20%
- ✓ Azione battericida potente
- ✓ **Molto lesive del tessuto di granulazione sano**



Miele



- ✓ Produzione di perossido di idrogeno
- ✓ Azione antisettica simile allo zucchero
- ✓ Degradazione residui tissutali con detersione delle ferite (no resistenze)
- ✓ Sbrigliamento autolitico

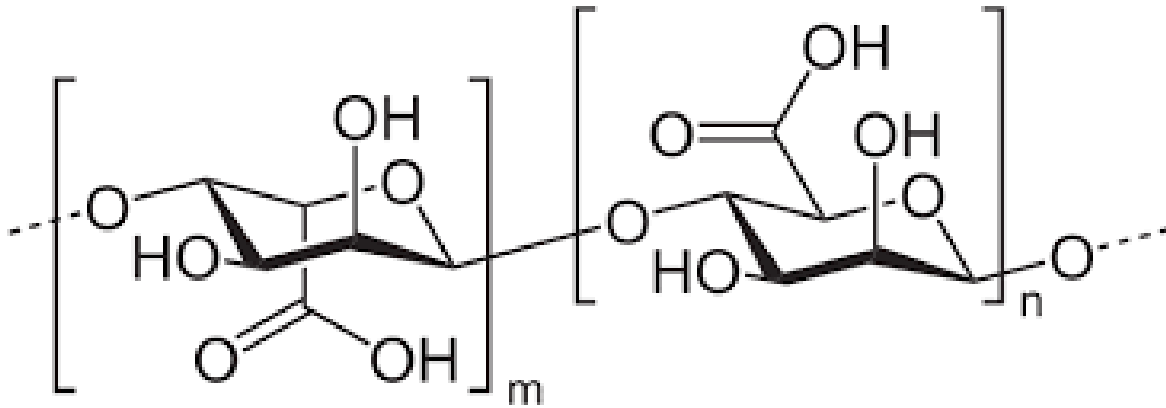


Carbone

- ✓ Sfruttano azione antisettica del carbone
- ✓ **Istiolesiva: NON medicazione primaria**
- ✓ Talvolta impregnate di Ag



Alginati



Sali di acido alginico

- ✓ Non idrolizzabile se non con tecniche specifiche
- ✓ Assorbe liquidi fino a 300 volte la sua massa



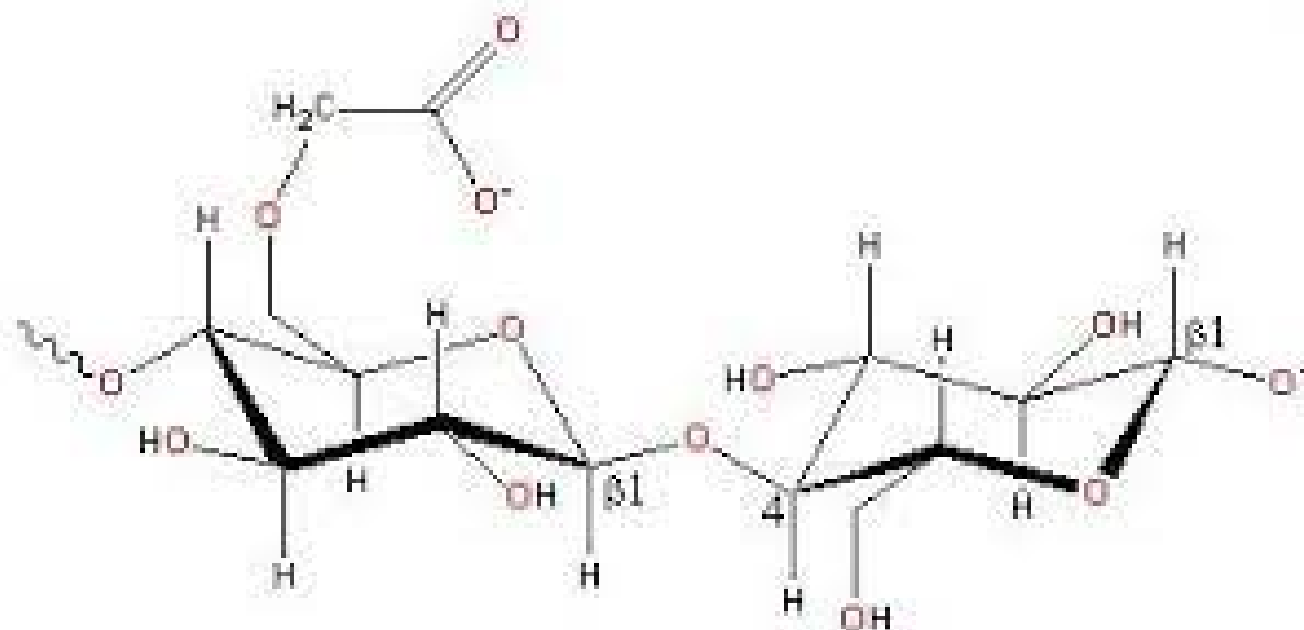
Alginati

- ✓ Medicazione in fibra di tessuto non tessuto
- ✓ Gelificano a contatto con fluidi
- ✓ Alto potere assorbente (lesioni cavitare, tragitti fistolosi)
- ✓ Proprietà emostatiche
- ✓ Possono essere impregnati di Ag



Idrofibre

Medicazione in fibra di
carbossimetilcellulosa sodica



Idrofibre

- ✓ Gelificano a contatto con fluidi
- ✓ Alto potere assorbente (< Alginati)
- ✓ **Assorbimento verticale**
- ✓ Possono essere impregnati di Ag
- ✓ Non sono aderenti
- ✓ Rimozione non traumatica
- ✓ Sono non occlusive (scambio gassoso ma isolamento)



Idrocolloidi

Medicazioni composte da un composto colloidale di acqua e mucopolisaccaridi o carbossimetilcellulosa

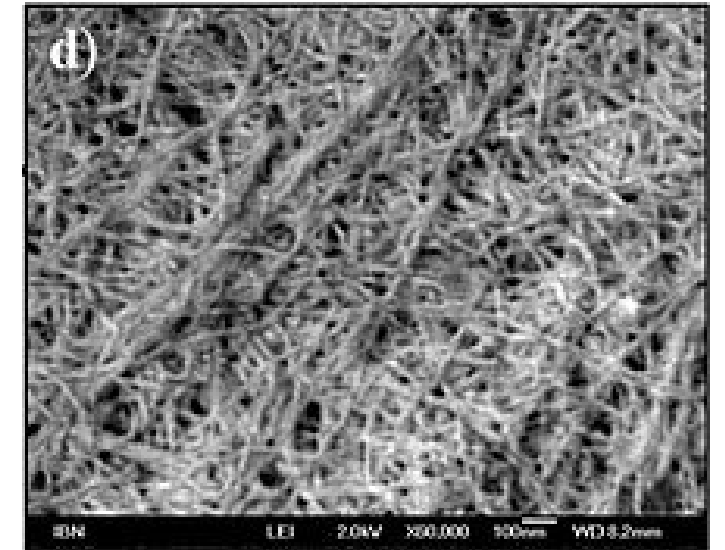
DEBRIDEMENT AUTOLITICO

- ✓ Scarso controllo esercitato dall'operatore
- ✓ Dannose su tessuti perilesionali e tessuto di granulazione
- ✓ Medicazioni occlusive
- ✓ Ambiente umido
- ✓ Assorbono medie quantità di essudato producendo un gel
- ✓ In placca o pasta



Idrogeli

- ✓ Gel colloidali composti da:
 - Acqua (dal 50 al 99%)
 - Catene polimeriche (agar-agar, molecole polisaccaridiche, silicomi, poliacrilammide)

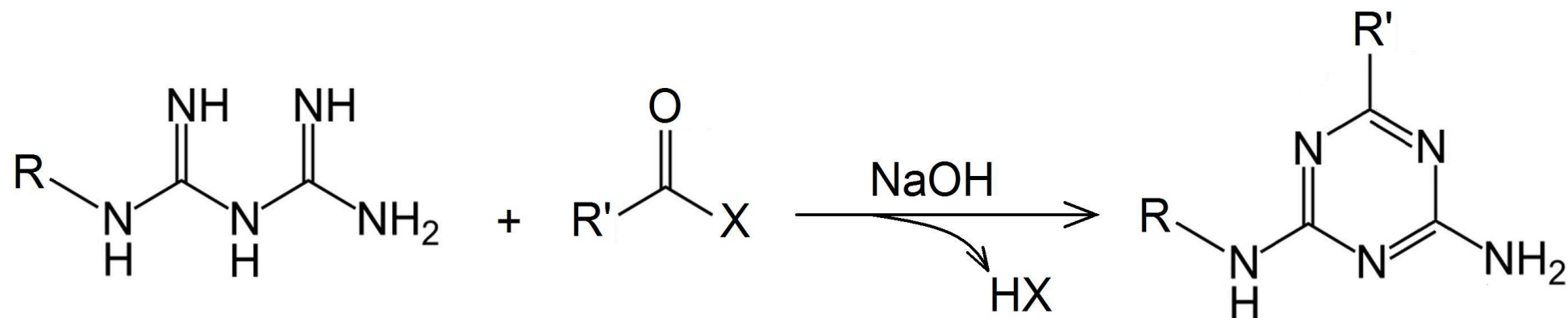


Idrogeli

- ✓ Maggiore contenuto acquoso maggiore capacità di idrolisi
- ✓ Esercitano debridement autolitico di minore aggressività
- ✓ Richiedono medicazione secondaria non assorbente
- ✓ Rischio di macerazione
- ✓ Possono essere inerti o impregnati di varie sostanze
- ✓ Potere assorbente con espansione della massa



Poliesametil biguanide



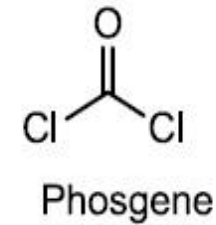
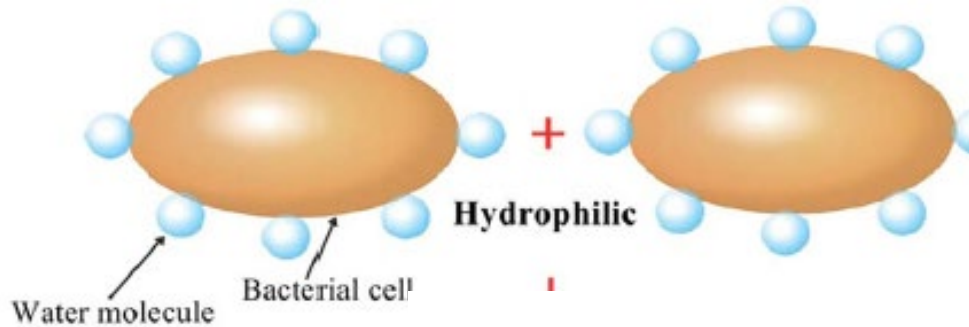
Poliesametil biguanide

- ✓ Scinde la matrice MPS
- ✓ Inibisce la formazione di biofilm
- ✓ Riduce la formazione di essudato
- ✓ Ambiente umido

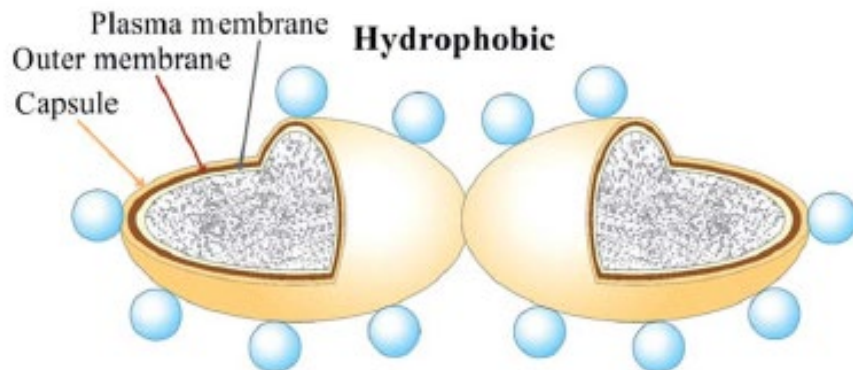
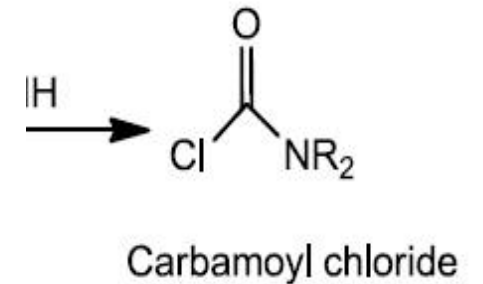
Particolarmente attivo verso
Ps. Aeruginosa, S.Aureus, E.Coli ed Entrobatteri (KPC)



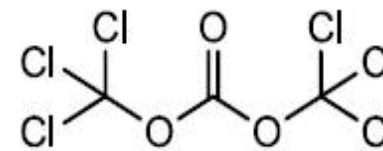
Garze a captazione batterica



Dialchil-carbamoil chloride



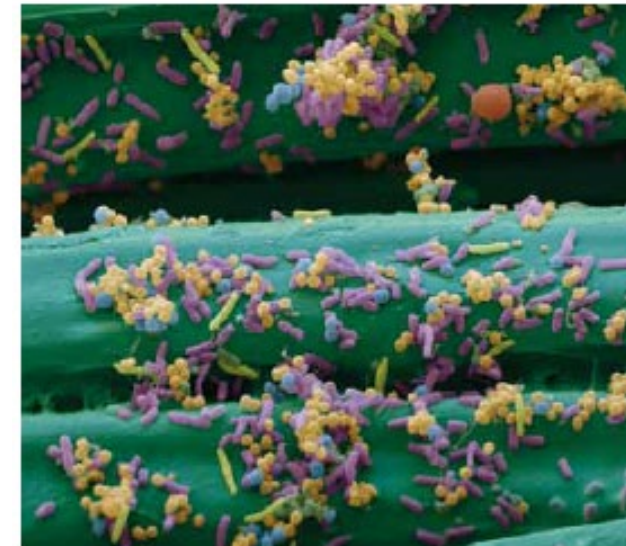
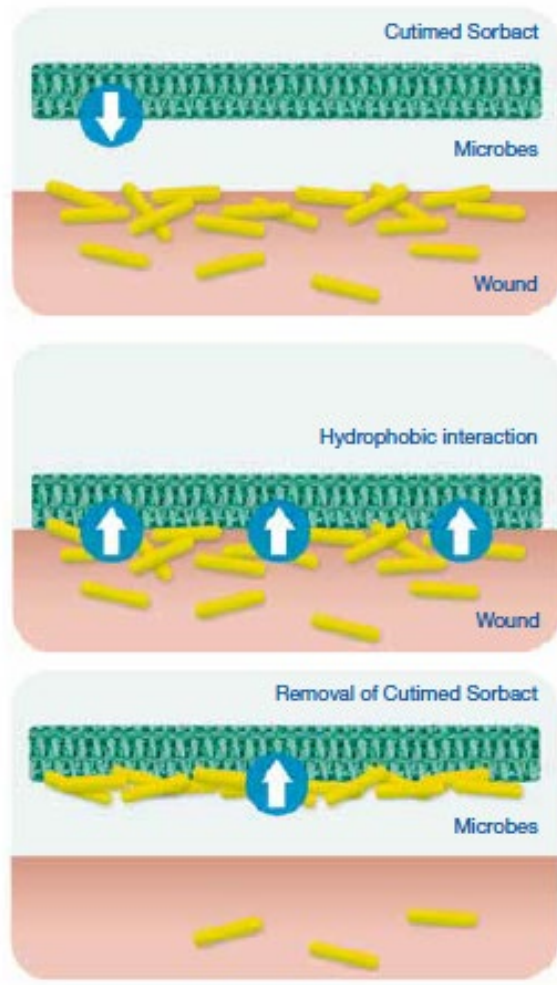
Diphosgene(DPG)



Triphosgene(BTC)

Garze a captazione batterica

Tecnologia DACC



Garze a captazione batterica

- ✓ No stimolo infiammatorio
- ✓ No resistenze bt
- ✓ No reazioni allergiche
- ✓ No citotossicità

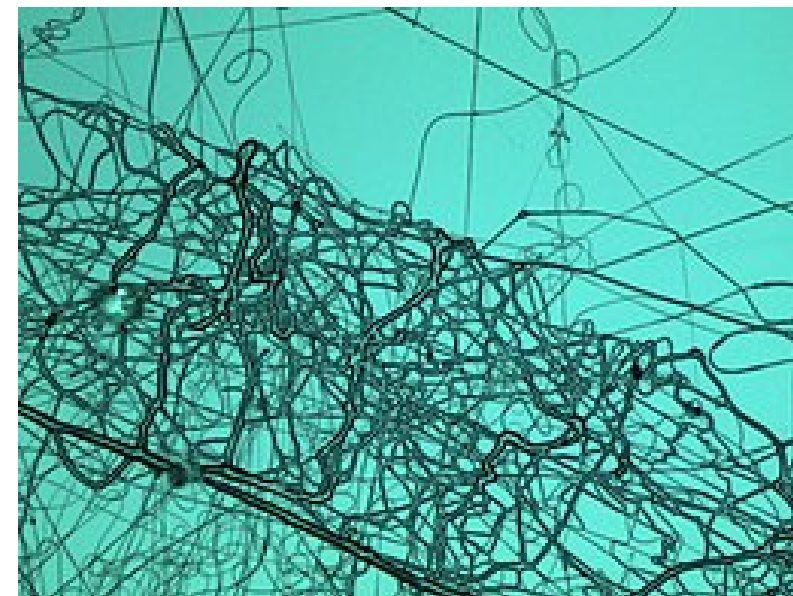
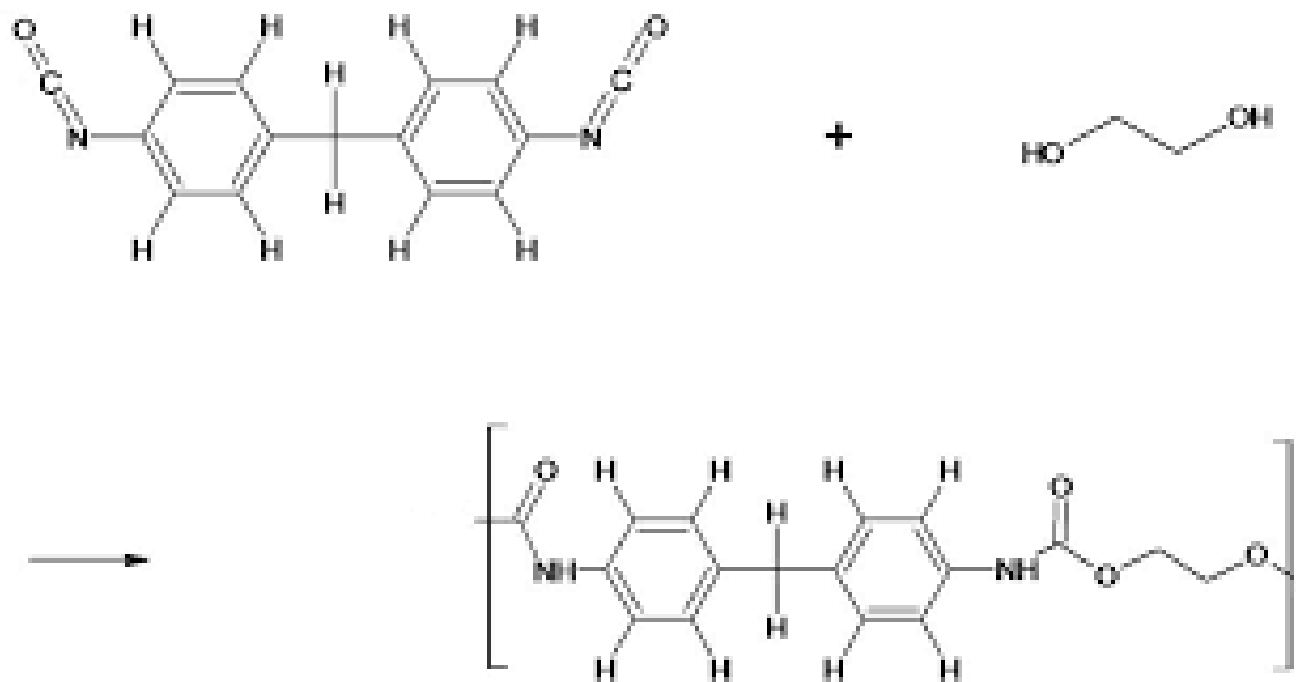


Particolarmente attivo
verso MRSA, Streptococchi e Enterococchi

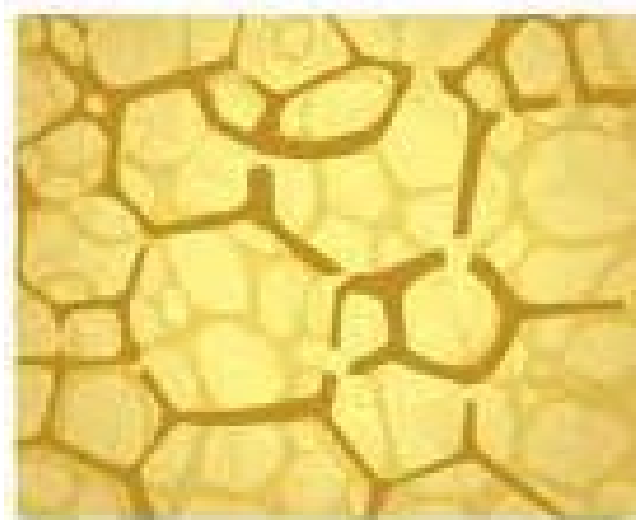


Schiume di poliuretano

Ampia famiglia di polimeri utilizzati in sede industriale a scopo di riempimento, isolamento e imbottitura

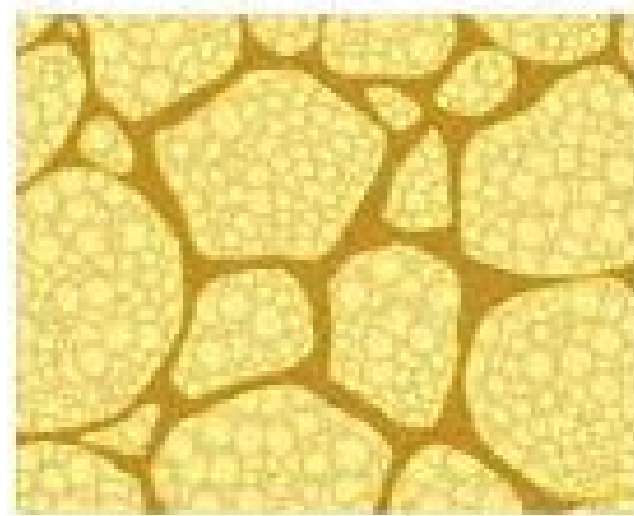


Schiume di poliuretano



Celle aperte

> Assorbenza
< Sostegno



Celle chiuse

< Assorbenza
> Sostegno

- ✓ Funzione di assorbimento (verticale)
- ✓ Funzione di protezione da traumatismi
- ✓ Funzione di scarico



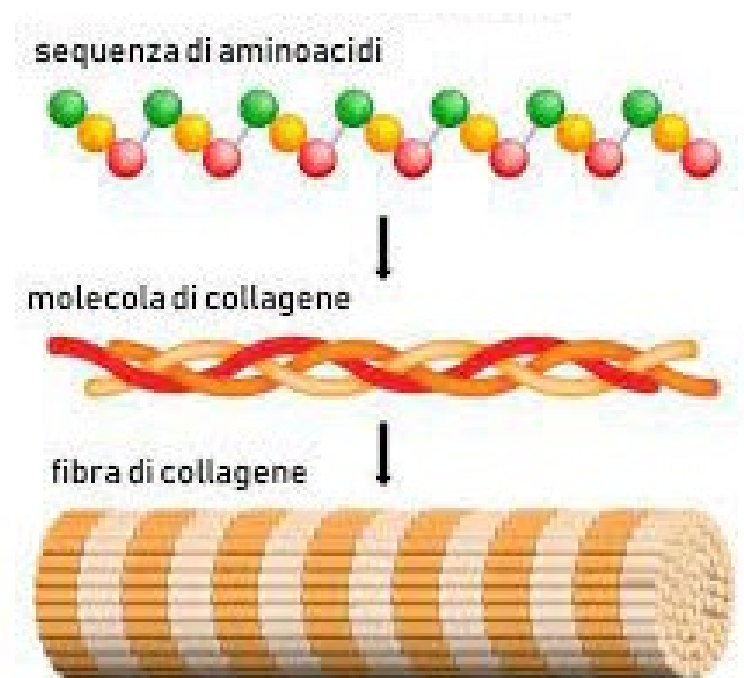
Schiume di poliuretano

- ✓ Inerti
- ✓ Impregnate di Ag
- ✓ Impregnate di PhMB
- ✓ Impregnate di Ibuprofene
- ✓ Con bordo adesivo
- ✓ Sagomate



Collagene

- ✓ Proteina del tessuto connettivo degli animali
- ✓ Responsabile della forza di trazione della pelle
- ✓ Scheletro per lo sviluppo di fibroblasti e cellule endoteliali
- ✓ Spesso associata ad alginati, tipicamente di Calcio



Collagene

Deposizione e organizzazione fibre di collagene e tessuto di granulazione

La medicazione si lega a metalloproteasi di matrice e rappresenta un bersaglio alternativo a maggiore affinità



Ridotta attività delle MMP nei confronti del collagene deposto

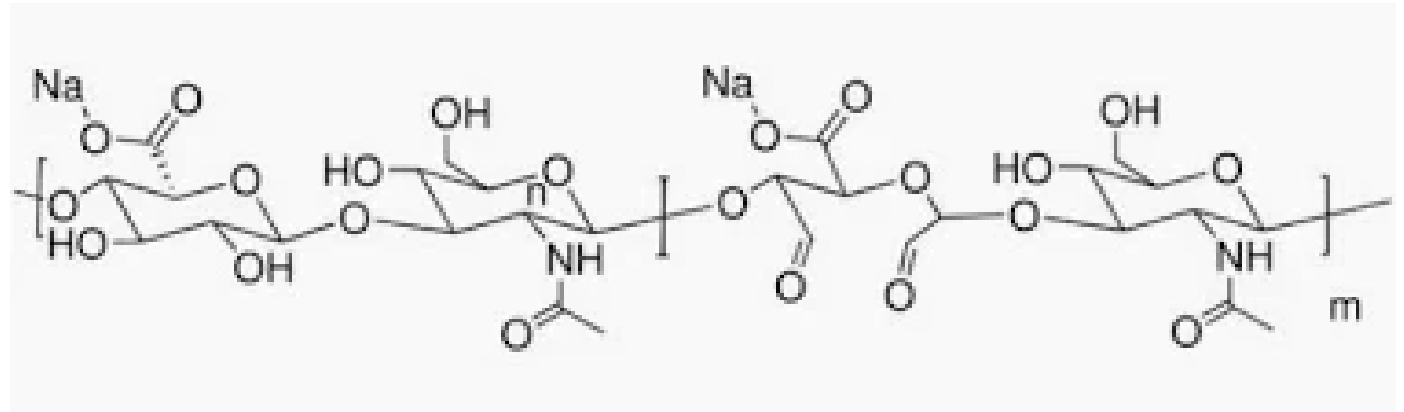


Aumento della guarigione delle ferite



Acido ialuronico

- ✓ Glicosamminoglicano della matrice extracell
- ✓ Crea lo scheletro per la migrazione e l'allineamento dei fibroblasti
- ✓ Microambiente umido ideale



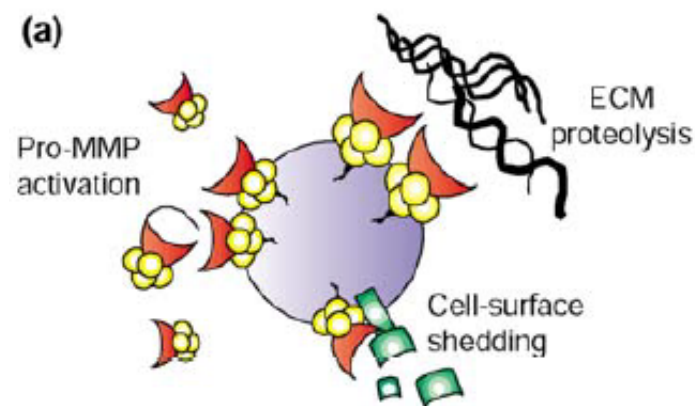
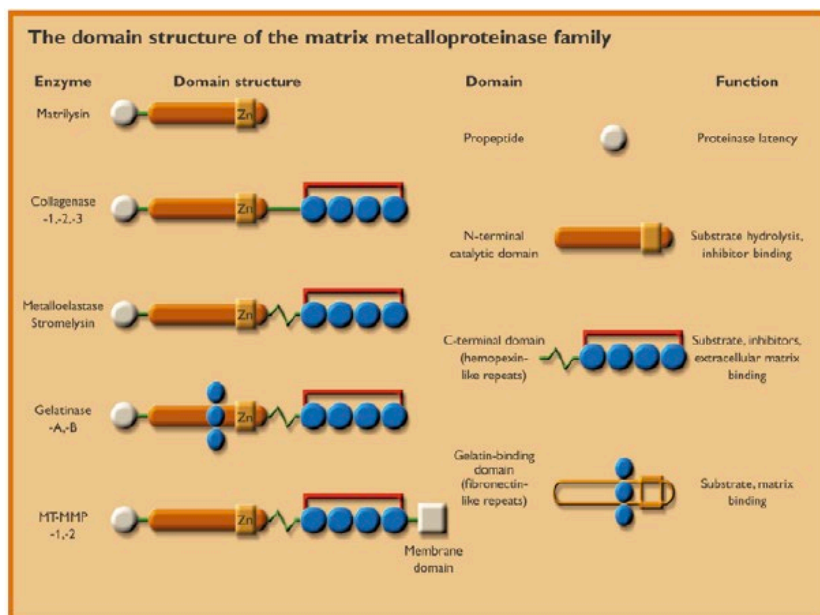
Cellulosa ossidata

- ✓ Matrice completamente riassorbibile
- ✓ Viene degradata dall'essudato e si integra nella lesione
- ✓ Particolarmente efficace in lesioni molto essudanti e hard to heal
- ✓ Rimozione ogni 48-72 ore



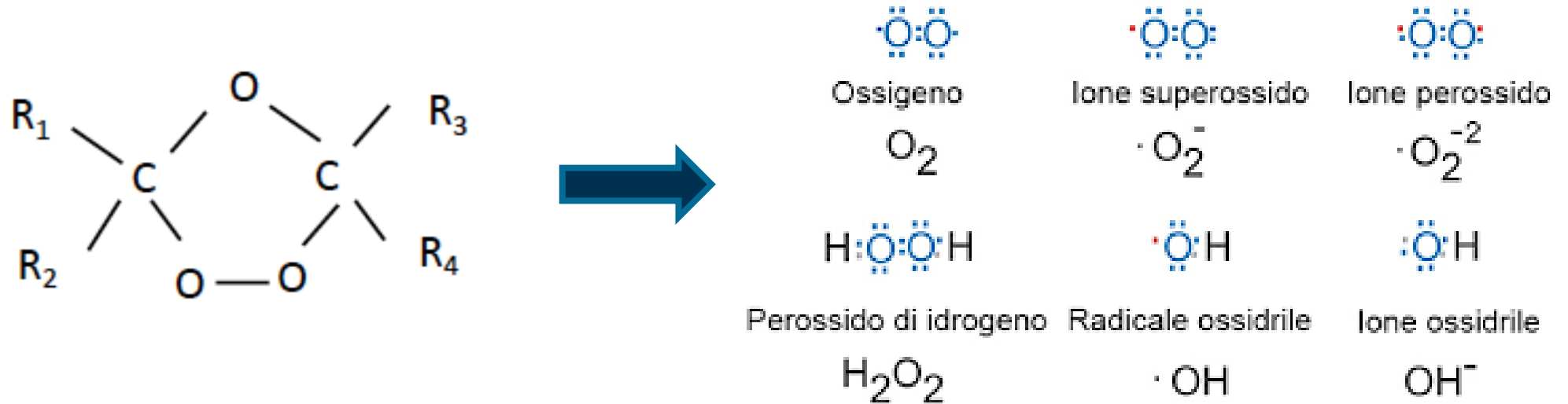
Cellulosa ossidata

- ✓ Inibizione metalloproteasi (MMP4)
- ✓ Riduzione citochine infiammatorie
- ✓ Attivazione piastrinica
- ✓ Stimolo fibroblastico (Collagene)



Specie reattive dell'ossigeno

Matrice oleica carica di ossigeno ed ozono



Rilascio di ROS a dosaggio «controllato»



Specie reattive dell'ossigeno

Rilascio di ROS a dosaggio «controllato»

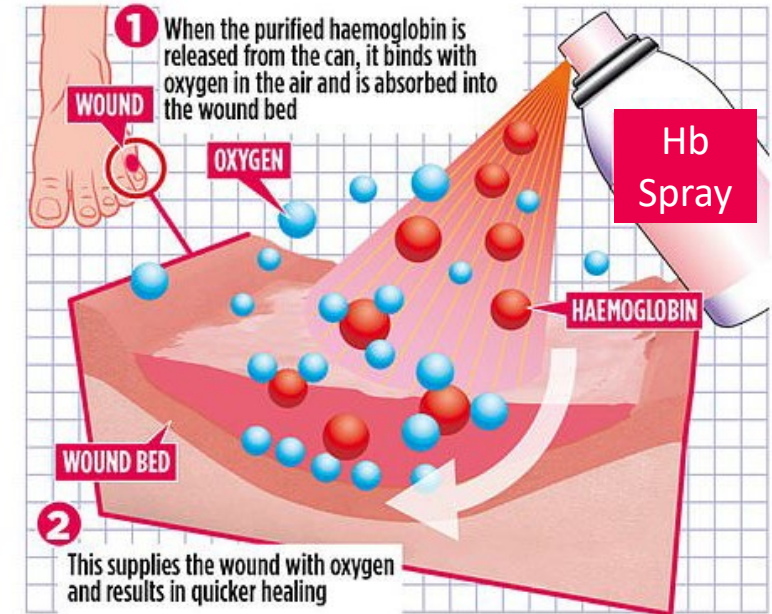
- ✓ Proliferaazione cellulare
- ✓ Incremento del flusso sanguigno
- ✓ Angiogenesi
- ✓ Sintesi di collagene

Inibizione della
proliferazione batterica e fungina



Emoglobina spray

- ✓ Rilascio di emoglobina ultrapura
 - ✓ Si lega con l'essudato della lesione
 - ✓ Stimola la crescita dei fibroblasti
-
- ✓ Aumento del tasso di guarigione in 8-12 settimane
 - ✓ Riduzione del tempo di guarigione di circa la metà
 - ✓ Riduzione del 40% dei costi
 - ✓ Riduzione del dolore a 4 settimane

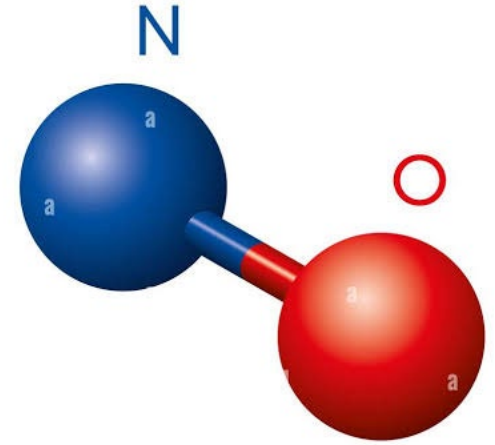


[Hunt S et al – JWC - 2018]

[Dissemont J et al – JWC - 2015]



Ossido nitrico

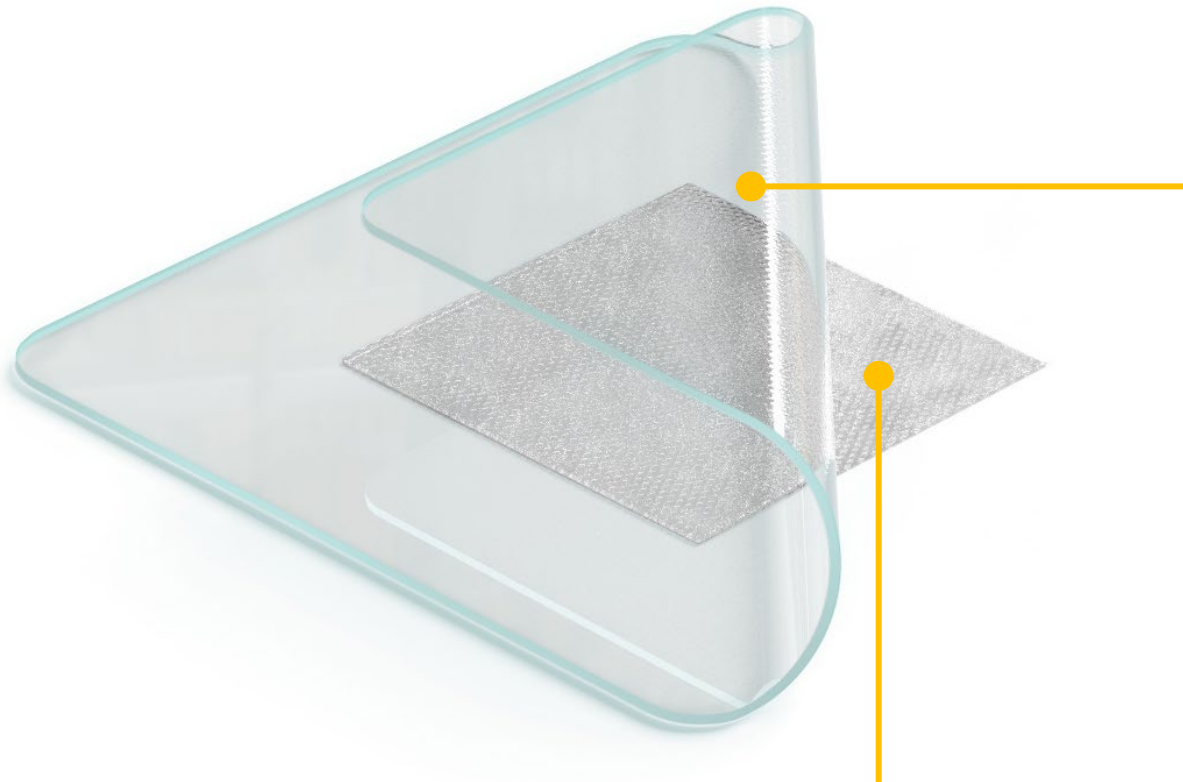


- ✓ Gas biatomico, ROS con un'emivita di circa 2 secondi
- ✓ Prodotto dai neutrofili e dai macrofagi attivati nella nostra risposta immunitaria innata
- ✓ L'NO è un agente antimicrobico ad azione rapida e locale, con molteplici bersagli microbici (parete e membrana cellulare, DNA, ribosomi)
- ✓ L'NO è intrinsecamente **antibiofilm**, con molteplici bersagli

NO non può essere immagazzinato
deve essere generato in situ durante la permanenza della medicazione

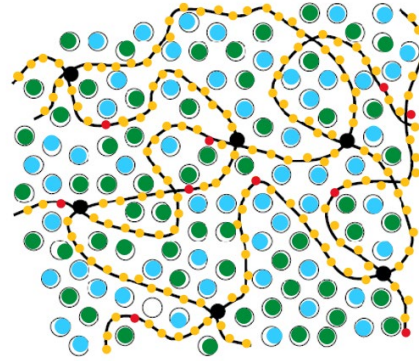


Ossido nitrico



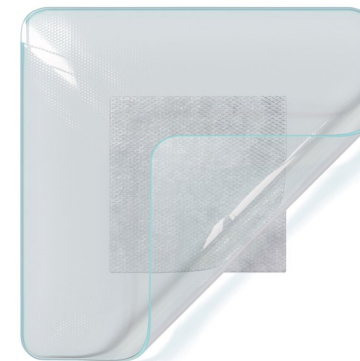
STRATO VETTORE:

6,9% (1 M) di nitrito di sodio (precursore dell'Ossido Nitrico) in una rete di polipropilene



STRATO PROTETTIVO ASSORBENTE :

Polimero adesivo superassorbente, reticolato, acido (pH ~4) (AMPS), con supporto in poliuretano



Nitrito + acido
Ossido Nitrico



Conclusioni

- ✓ Adattare la medicazione al paziente
- ✓ Adattare la medicazione alla lesione
- ✓ Adattare la medicazione al quadro clinico

Cambiare idea ~~si~~ si può!!! **DEVE!!!**



GRAZIE

DELL'ATTENZIONE



SAVE THE DATE

The 21st Meeting of the Diabetic Foot Study Group

24 - 26 September 2026 · Florence · Italy

www.dfsg.org



17th Pisa International Diabetic Foot Course 2026

Management of the Diabetic Foot

Theory & Practice 30 September - 3 October 2026 · Pisa · Italy



VIII CONGRESSO NAZIONALE PIEDE DIABETICO

Focus sul piede nella gestione del diabete

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ROMA, 18-20 GIUGNO 2026

HOTEL NH VILLA CARPEGNA