Effects of a Novel Non-Biologic Desiccant to Remove Bacteria Using Deep Dermal Wounds in a Porcine Model

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Wound Bed Preparation

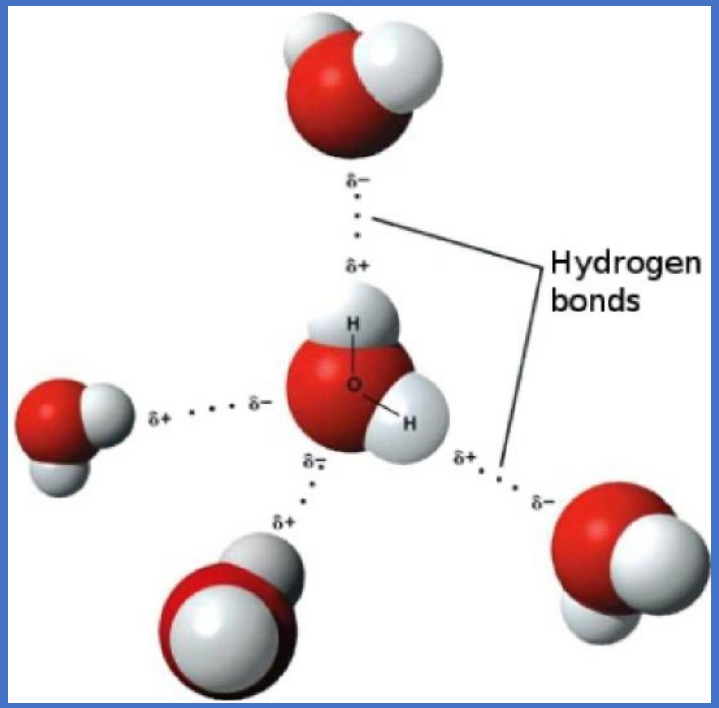
- The focus of converting a chronic wound to an acute wound is attention to wound bed preparation.
  - Sharp debridement
  - Ultrasonic debridement
  - Hydro surgical debridement
  - Autolytic debridement
  - Biologic debridement
  - *“Desiccation debridement”*

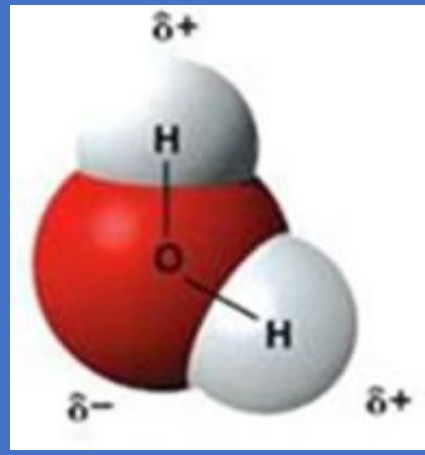
Non-Biologic Desiccant Technology

- Michael Basara, MD: inventor and developer of the technology.
- Composition:
  - Two sulfonic acids
  - Sulfuric acid
- Delivery System
  - Semi-viscous liquid or gel
  - Application time: 10 – 60 seconds

Mechanism of Action

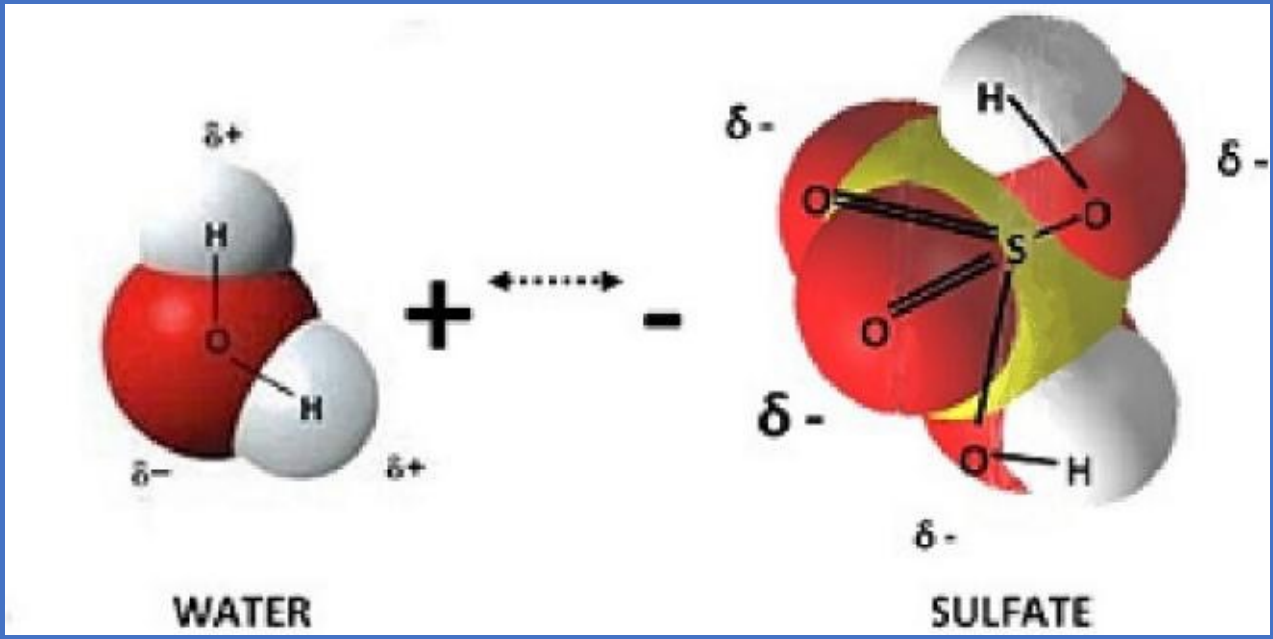
- “Desiccation Shock” is the term that describes the MOA.
- Contact delivers a very brief , focal, intense water extraction from the superficial layers or the tissue.
- A coagulum on the surface of the wound bed is formed as a result of the desiccation process.
- The electrostatic charges of the sulfate groups of the product and the electrostatic charges of the surface of water molecules makes their surfaces highly polar and complementary.





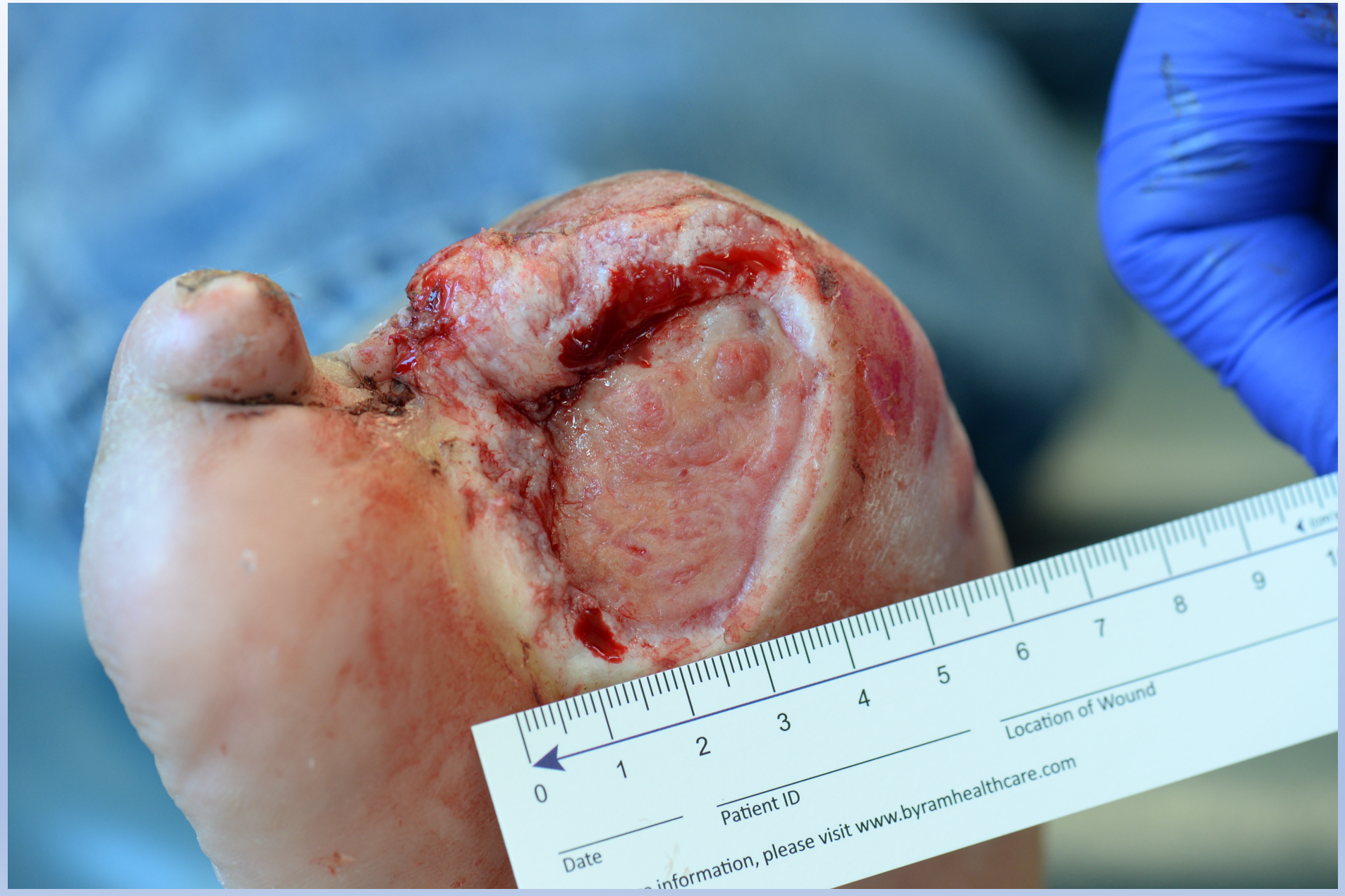
Water Molecule Dipole Structure

Water Shell



Post sharp debridement

Post application – 45 seconds



7 days, post application

“Effects of a Novel Non-Biologic Desiccant to Remove Bacteria Using Deep Dermal Wounds in a Porcine Model”

University of Miami - Miller School of Medicine

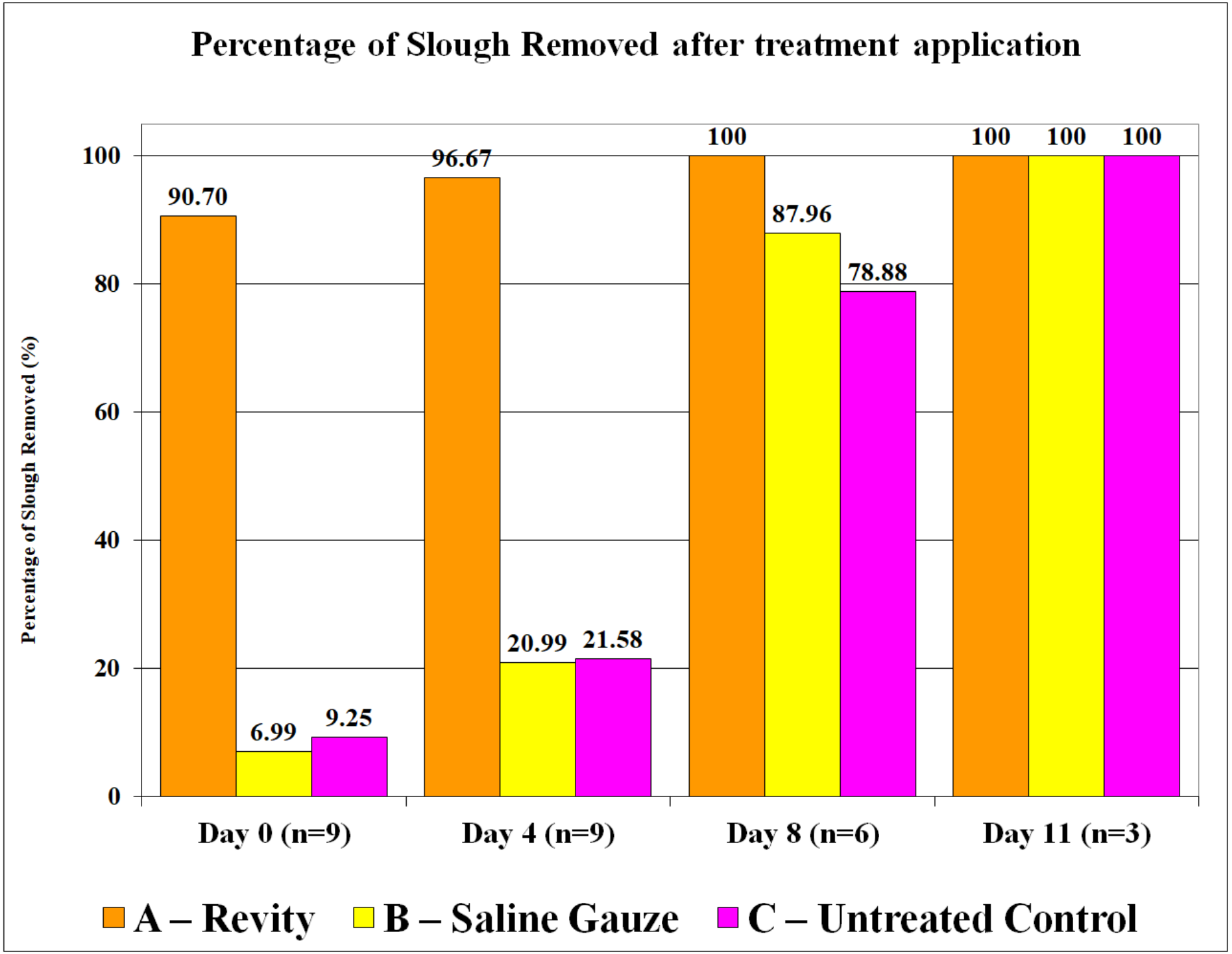
- Debridement plays a critical role in wound bed preparation and management.
- Removing necrotic tissue, debridement can eliminate bacteria that are frequently harbored within the tissue.
- Infected wounds, particularly with drug-resistant bacteria have a high-risk of impending the healing progress.
- The purpose of this pilot study was to examine the ability of a novel debridement method which uses a cellular and molecular cleaning technology, to remove both necrotic tissue and bacteria from infected wounds using a porcine model.

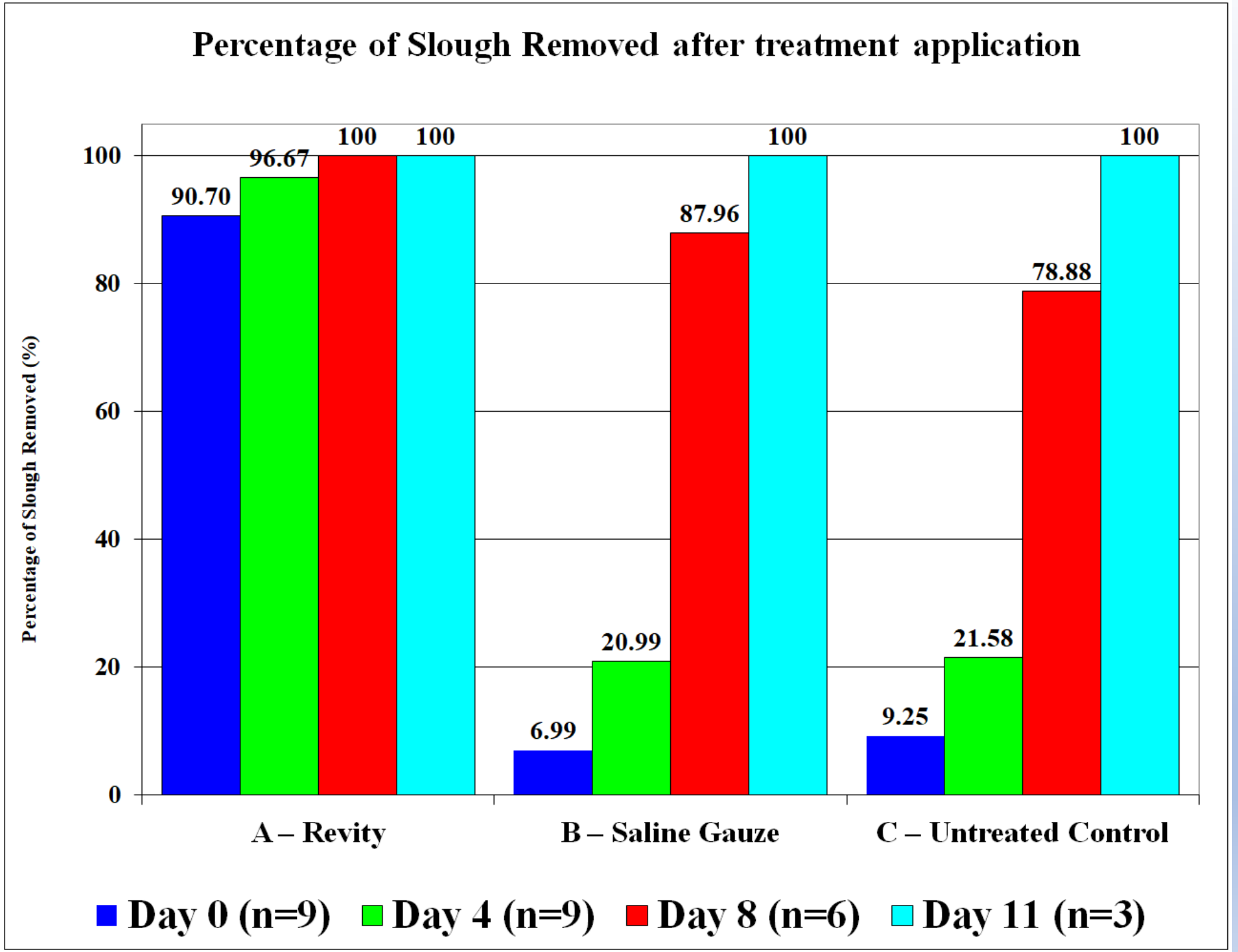
Protocol

- 33 deep dermal wounds (22mm x 22mm 3mm) were created and inoculated with MRSA.
- Wounds were covered for 72 hours with a polyurethane dressing to allow biofilm formation.
- 3 wounds were biopsied for baseline counts prior to treatment application and the remaining wounds were randomly assigned to one of the 3 following groups:
  - Novel Debridement Formulation
  - Gauze with sterile saline
  - Untreated control

Protocol

- All wounds were treated for 30 seconds and then rinsed with 10ml sterile saline.
- After the treatment application, a sterile gauze was used to remove the slough and the wounds were covered with polyurethane film.
- Wounds were assessed after treatment for slough removal using digital planimetry.
- Biopsies were taken at days 4, 8 and 11 post treatment for quantitative bacteriology and histological assessment.


Percentage of Slough Removed after treatment application
Percentage of Slough Removed (%)
100
80
60
40
20
0
90.70
6.99
9.25
96.67
20.99
21.58
100
87.96
78.88
100
100
100
Day 0 (n=9)
Day 4 (n=9)
Day 8 (n=6)
Day 11 (n=3)
A – Revity
B – Saline Gauze
C – Untreated Control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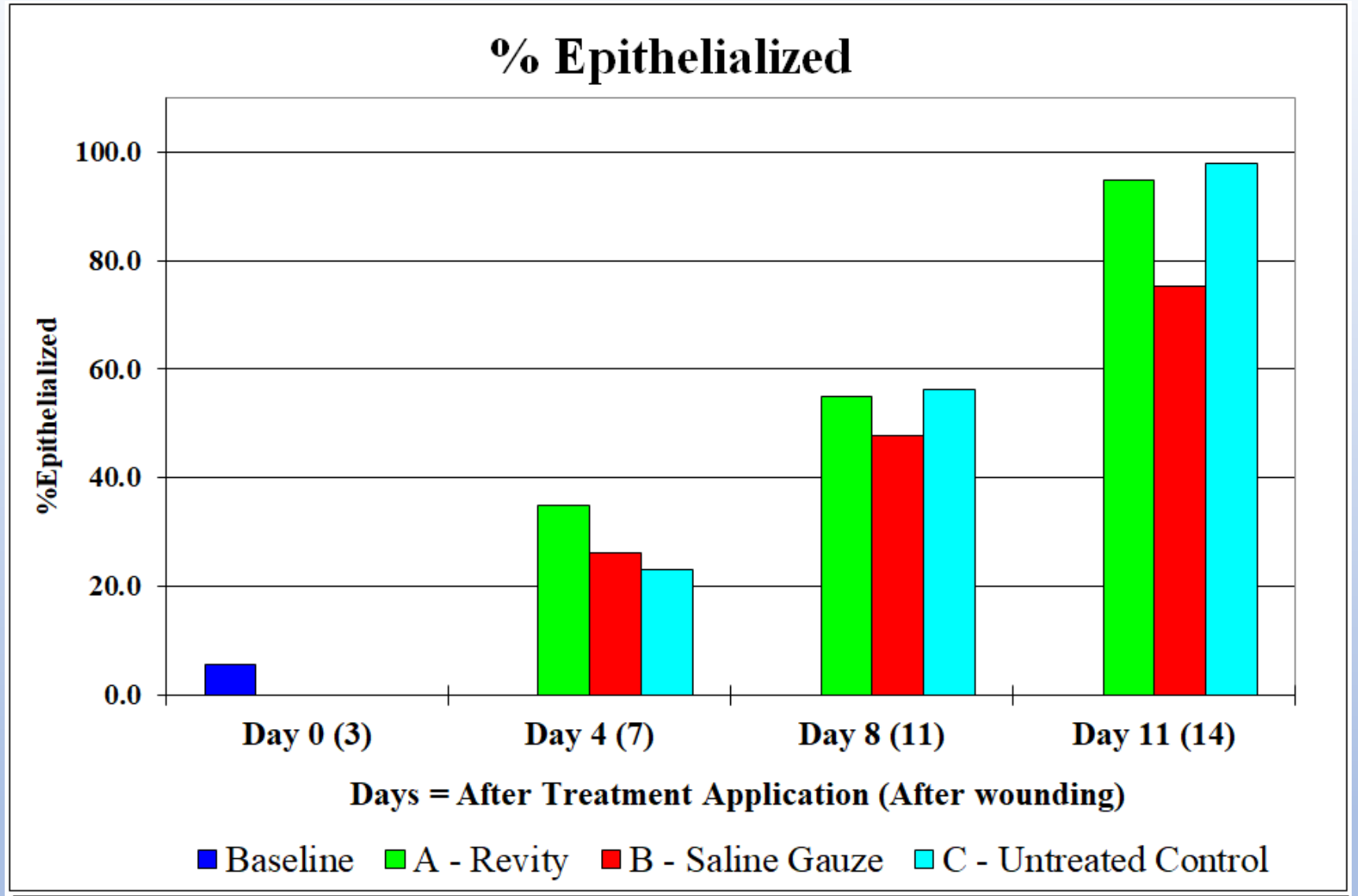
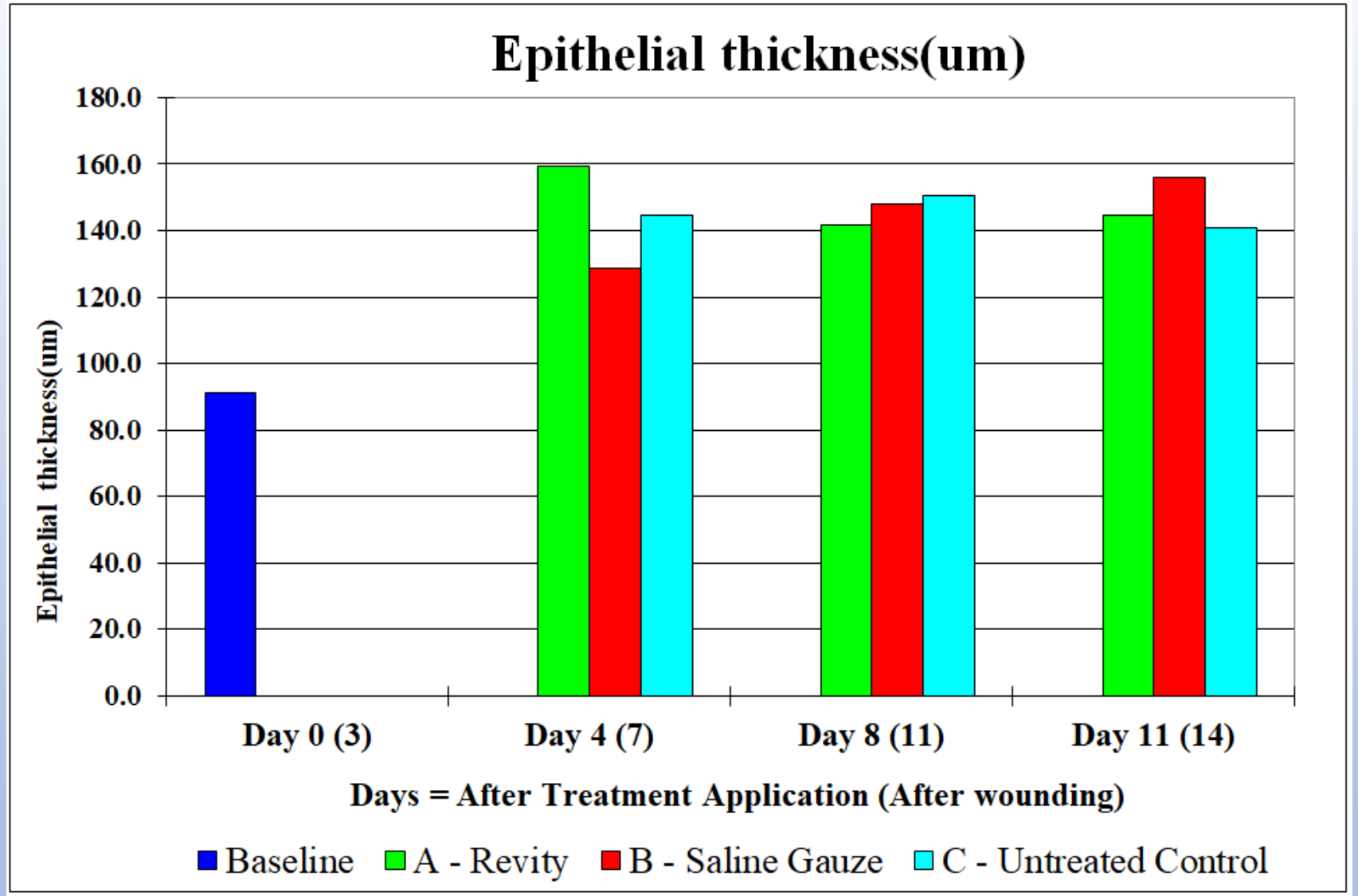
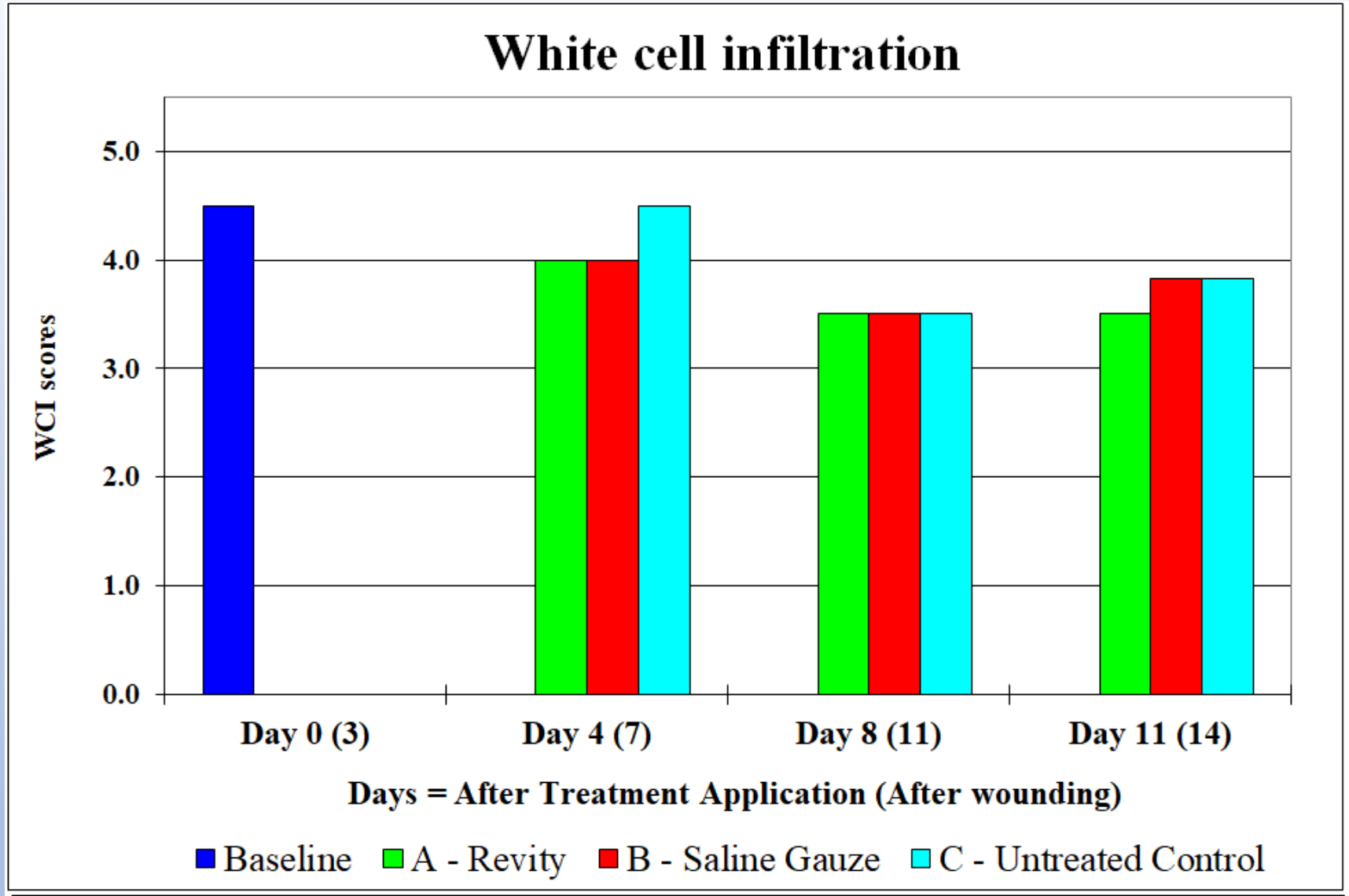


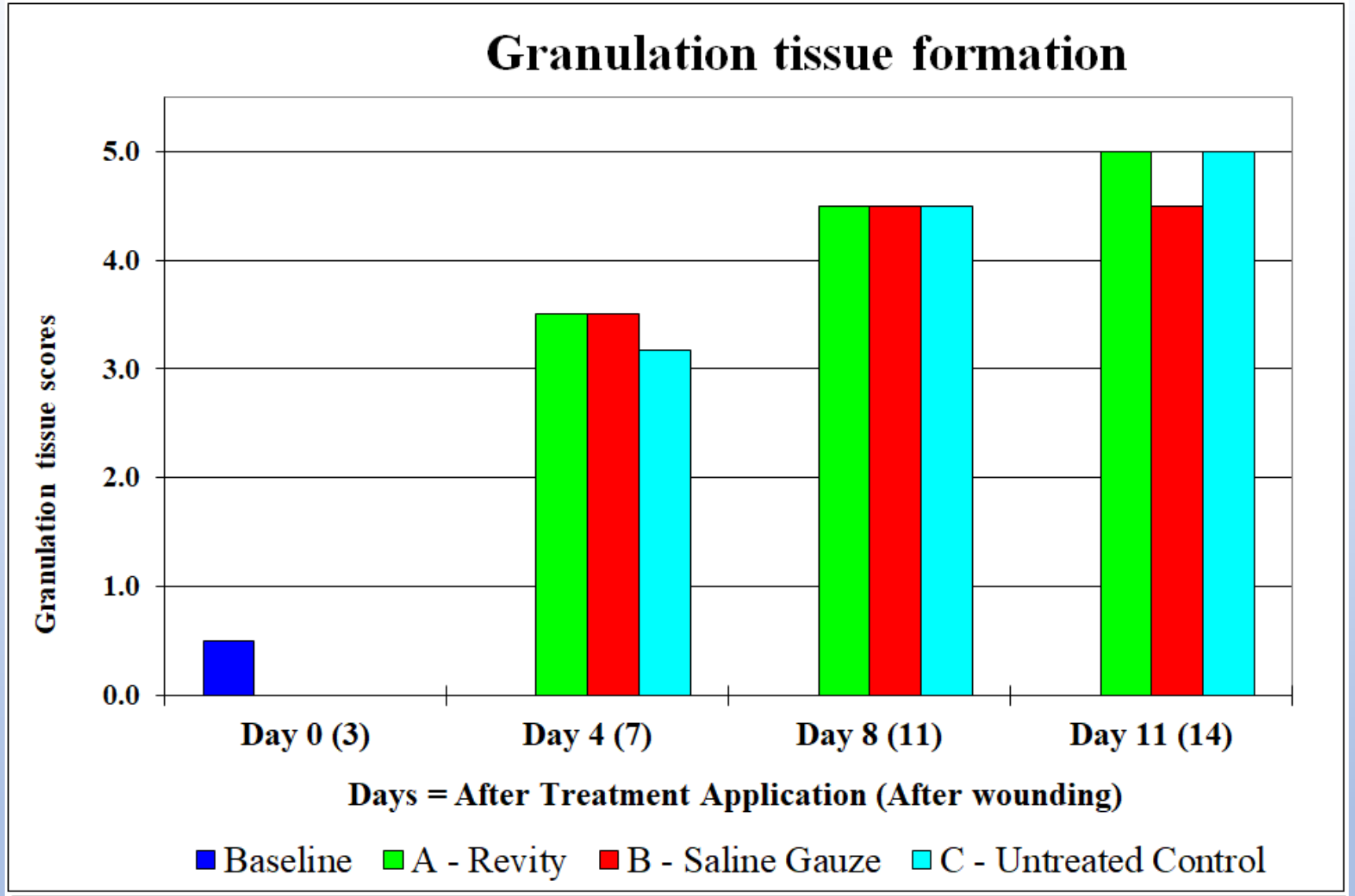
%Epithelialized	Baseline	A - Revity	B - Saline Gauze	C - Untreated Control
Day 0 (3)	5.7	0.0	0.0	0.0
Day 4 (7)	0.0	34.8	26.2	23.2
Day 8 (11)	0.0	54.8	47.9	56.4
Day 11 (14)	0.0	94.8	75.3	97.9



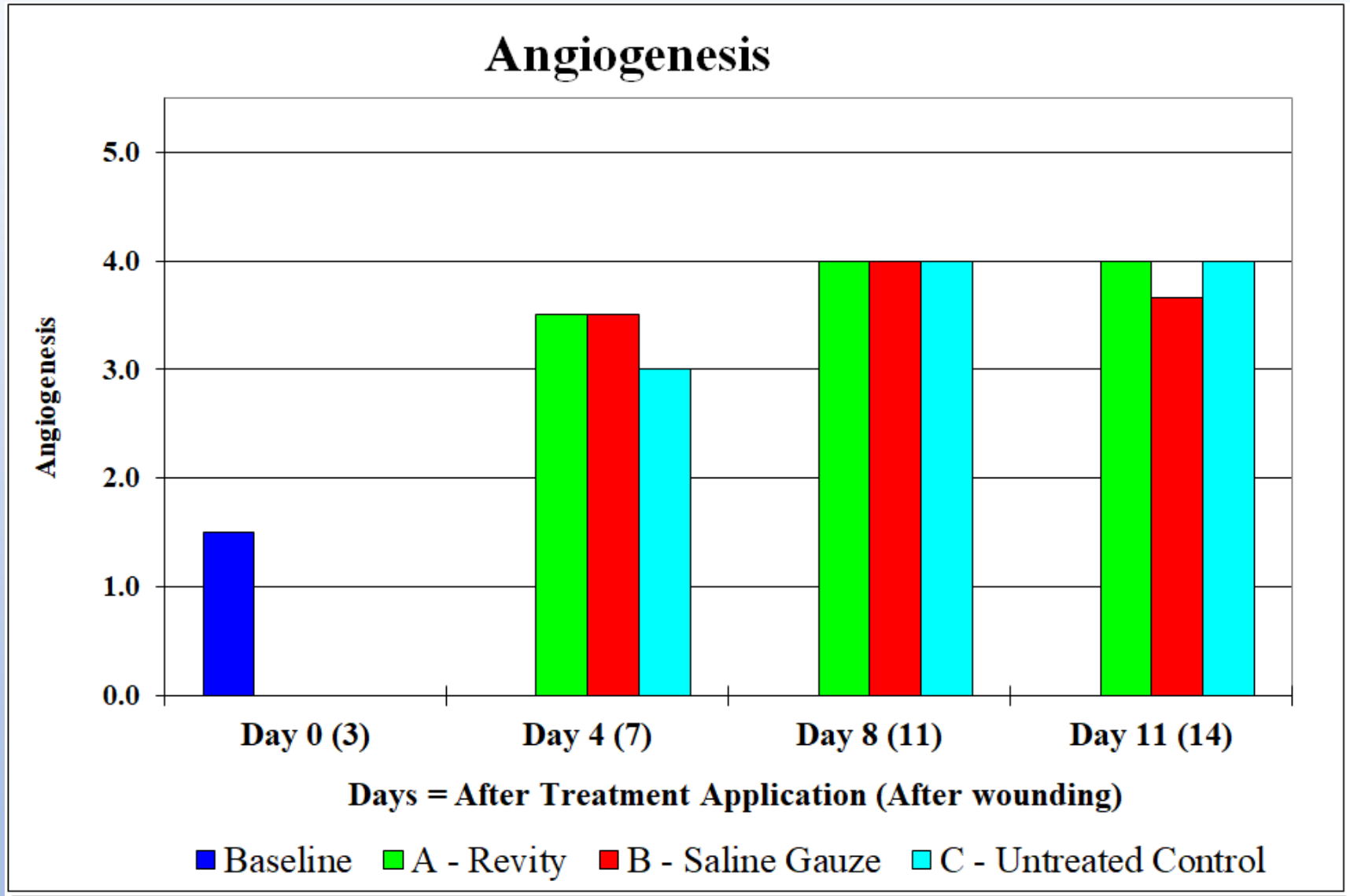
Epithelial thickness(um)	Baseline	A - Revity	B - Saline Gauze	C - Untreated Control
Day 0 (3)	91.2	0.0	0.0	0.0
Day 4 (7)	0.0	159.2	128.8	144.8
Day 8 (11)	0.0	141.6	148.0	150.4
Day 11 (14)	0.0	144.8	156.0	140.8



White cell infiltration	Baseline	A - Revity	B - Saline Gauze	C - Untreated Control
Day 0 (3)	4.5	0.0	0.0	0.0
Day 4 (7)	0.0	4.0	4.0	4.5
Day 8 (11)	0.0	3.5	3.5	3.5
Day 11 (14)	0.0	3.5	3.8	3.8



Granulation tissue formation	Baseline	A - Revity	B - Saline Gauze	C - Untreated Control
Day 0 (3)	0.5	0.0	0.0	0.0
Day 4 (7)	0.0	3.5	3.5	3.2
Day 8 (11)	0.0	4.5	4.5	4.5
Day 11 (14)	0.0	5.0	4.5	5.0



Angiogenesis	Baseline	A - Revity	B - Saline Gauze	C - Untreated Control
Day 0 (3)	1.5	0.0	0.0	0.0
Day 4 (7)	0.0	3.5	3.5	3.0
Day 8 (11)	0.0	4.0	4.0	4.0
Day 11 (14)	0.0	4.0	3.7	4.0

Regulatory Pathway

- Desiccation Debridement Technology (REVITY®) – Submitted to FDA as a 510(k) medical device.
- MDR for CE Marking – completing the process for submission
- Dental and Oral cavity (HybenX®) :
  - FDA cleared [510(k) medical device].
  - Over 10 Million oral application treatments.
  - Distributed in over 28 countries worldwide

Summary

- Novel desiccation debridement technology.
- Intended as an adjunctive therapy to sharp debridement in wound bed preparation and maintenance.
- Cellular and molecular desiccation properties.
- Strong safety profile.
- Intended for acute, chronic and surgical wounds and burns.
- Evidence based medicine and healthcare economics.