

# Wound Bed Preparation: Improving Outcomes using Hypochlorous Solution as a Wound Therapy

Steven J. Kavros, DPM, FACCCWS, CWS, MAPWCA

Vascular Surgery Associates  
Minneapolis, MN

President  
American Professional Wound Care Association



18<sup>th</sup> Annual Conference

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THE PERIPHERAL EVENT OF THE YEAR



# DISCLOSURE

- NONE

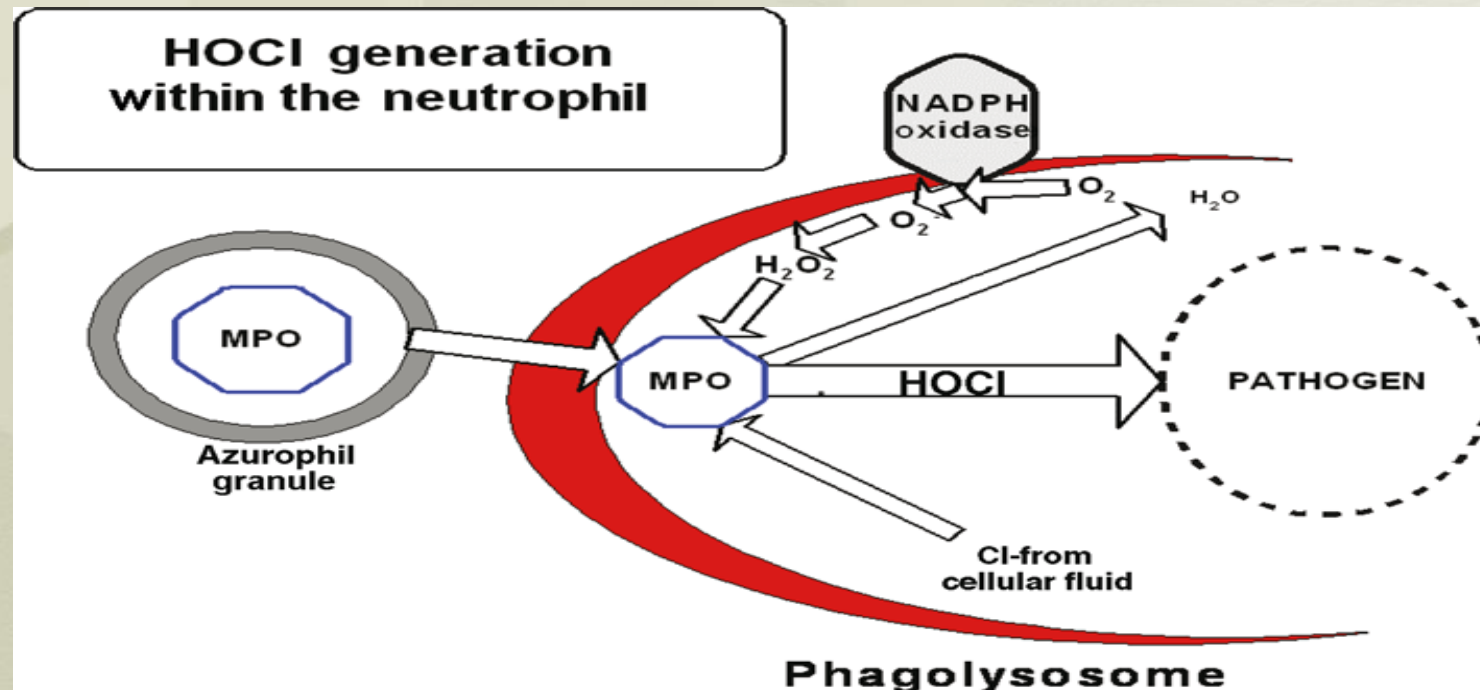
# Retrospective Study

- Retrospective evaluation of 128 patients
- Diabetic foot ulcer and Venous leg ulcer patients
- Hypochlorous solution was used as a primary therapy for wound healing
- Silver Hydrogel for DFU patients as a comparison
- Silver Alginate for VLU patients as a comparison
- Study performed at Mayo Clinic, Rochester, MN (2010 – 2012)

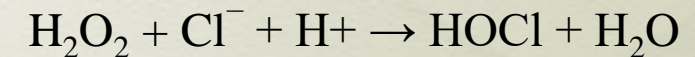
# Wound Bed Preparation

- Wound bed preparation is a systematic approach to wound management.
- Basic concepts and procedures should be clearly understood and followed for optimal outcomes.
- T.I.M.E
  - T: Tissue Management
  - I: Infection/Inflammation
  - M: Moisture Imbalance
  - E: Edge Advancement

# Formation of HOCl in Mammalian Cell



During a respiratory burst, neutrophils produce  $H_2O_2$ , which is converted to HOCl by the activity of the granule enzyme myeloperoxidase in the following reaction.



# Commercial Manufacturing of HOCl

- Involves conversion of a sodium chloride solution to a hypochlorous solution via an electrolysis oxidation/reduction (Redox) process.
- Buffered to simulate the pH environment of human skin (4.5 -6.5)

# Mechanism of Action

- HOCl denatures the protein of the bacterial cell wall.
  - HOCl can enter the injured bacterial cell and inhibit the DNA replication
  - Bacterial cell death ensues
- HOCl acid acts as a preservative that is antimicrobial within the solution.

# FDA Cleared 510(k) - Professional HOCl

- Cleansing
- Irrigating
- Moistening
- Debridement



# Professional Wound Indications

- Acute and chronic wounds
- Partial and full thickness wounds
- 1<sup>st</sup> and 2<sup>nd</sup> degree burns
- Diabetic ulcers
- Stasis ulcers
- Pressure ulcers (Stages I – IV)
- Post-surgical wounds
- Grafted and donor sites

# Safety

- There are no known drug or treatment interactions
- There are no clinical contraindications of HOCl
  - Non-cytotoxic
  - Non-irritating
  - Non-sensitizing

# Single Center, Retrospective Analysis of 128 patients

- Mayo Clinic, Rochester, MN, 2010 – 2012
- Chronic wounds: 4 - 16 weeks duration
  - DFU
  - VLU

# DFU Patients

- 64 patients in DFU arm
  - 32 patients used HOCl wet/moist BID
  - 32 patients used Silver Hydrogel BID
- Offloading: footwear, bracing, CAM walker, CROW boot
- Sharp debridement at each weekly visit
- Wound cultures taken at initial visit
  - repeated at week 4 and 8
- Patients had TcPO<sub>2</sub> of 30mmHg or above
  - repeated at week 4 and 8

# VLU Patients

- 64 patients in VLU arm
  - 32 patients used HOCI wet/moist BID
  - 32 patients used Silver Alginate BID
- All patients used a compression therapy:
  - ACE, Profore, Farrow wraps, venous compression pump
- Sharp debridement at each weekly visit
- Wound cultures taken at initial visit
  - repeated at week 4 and 8

# DFU and VLU Patients

- Qualitative documentation at time of visit:
  - Granulation tissue (<25%, 50%, >75%)
  - Slough (mild, moderate, significant)
  - Drainage (mild, moderate, significant)
  - Odor (mild, moderate, significant)

# DFU Results

- HOCl Arm: culture results
  - Initial: 32/30 (94% positive culture)
  - Week 4: 30/8 (74% reduction)
  
- Silver Hydrogel Arm: culture results:
  - Initial: 32/28 (88% positive culture)
  - Week 4: 28/22 (32% reduction)

# DFU Results - Qualitative

- Granulation tissue in 4 weeks
  - HOCl Arm: 60% improvement
  - Silver Hydrogel Arm: 30% improvement
  
- Granulation tissue in 8 weeks
  - HOCl Arm: 90% improvement
  - Silver Hydrogel Arm: 60% improvement



# VLU Results

- HOCl Arm: culture results
  - Initial: 98% positive culture
  - Week 4: 90% reduction
  
- Silver Alginate Arm: culture results:
  - Initial: 96% had positive culture
  - Week 4: 58% reduction

# VLU Results - Qualitative

- Granulation tissue in 4 weeks
  - HOCl Arm: 74% improvement
  - Silver Alginate Arm: 38% improvement
  
- Granulation tissue in 8 weeks
  - HOCl Arm: 95% improvement
  - Silver Alginate Arm: 65% improvement

# VLU Results - Qualitative

- Odor and Drainage in 4 weeks:
  - HOCl Arm: 95%
  - Silver Alginate Arm: 30%
  
- Odor and Drainage in 8 weeks
  - HOCl Arm: 95%
  - Silver Alginate Arm: 60%

# DFU Results – Quantitative

## TcPO<sub>2</sub> Evaluation

- Increased 6 - 10mmHg from patient baseline in the HOCl arm
  - Measured one hour after treatment
- No increase with Sliver Hydrogel arm
  - Measured one hour after treatment

# Conclusion

- Hypochlorous solution is clear hypotonic solution that is topically applied to the wound bed.
- It is safe and effective in using as a therapy for DFU and VLU chronic wounds.
- Further basic and clinical science research is warranted to explore the attributes of HOCl as a dermal wound therapy.

Thank you



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