The Effect of Regenerative Debridement Technology (RDT) on Wound Bed Preparation with Respect to pH Modulation and Normalization

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Disclosure

- CMO – EPIEN Medical, Inc

Chronic Wounds – so many issues to consider

- Neuropathy
- Ischemia
- Infection
- Pressure
- Edema
- Malnutrition
- Autoimmune disease
- Proinflammatory Factors
  - Cytokine (Interleukins)
  - Protease (MMPs)
  - TNFα

- Chemical and environmental aspect of the wound bed:

pH

Influence of pH on Wound Healing

- For over 3 decades, it has been recognized that a low pH value is a favorable factor for wound healing
- Normal skin and dermal pH:
  - Skin surface: 4.4 – 5.6
  - Dermis: 5.4 – 5.9
- Chronic wounds are typically alkaline, pH value: >7.2
- Lowering the pH can potentially reduce protease activity, increase fibroblast activity and increase oxygen release
- Pathogenic bacteria need pH values above 6 to grow exponentially. Their growth is inhibited by a low pH value
  - The same applies to dermatophytes and Candida species
- Proinflammatory factors, proteases (MMPs), cytokines (IL), TNFα all contribute to increase wound bed pH

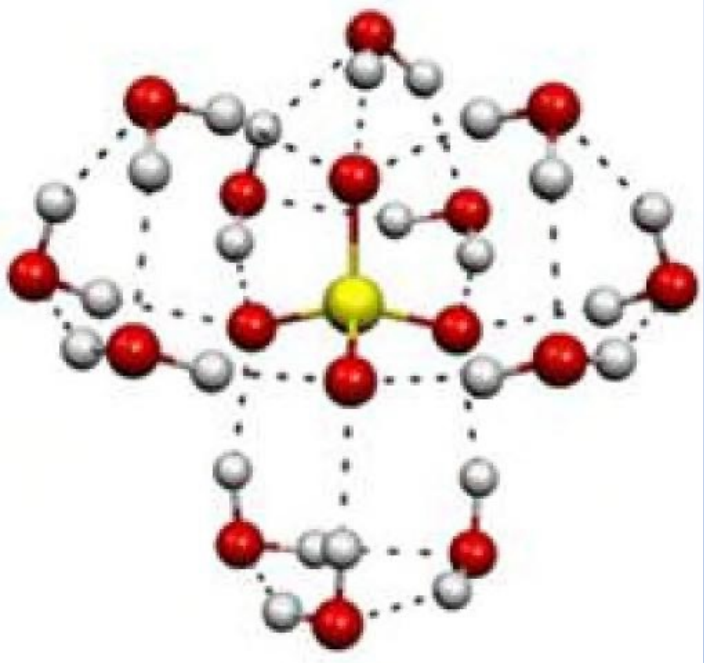
Schneider LA, Korber A, Grabbe S. Arch Dermatol Res (2007) 298413-420
Power G, Moore Z, O'Connor T. Jour Wound Care (2017) Vol 26, No 7 381-397

Regenerative Debridement Technology (RDT)
Non-Biologic Desiccant Technology

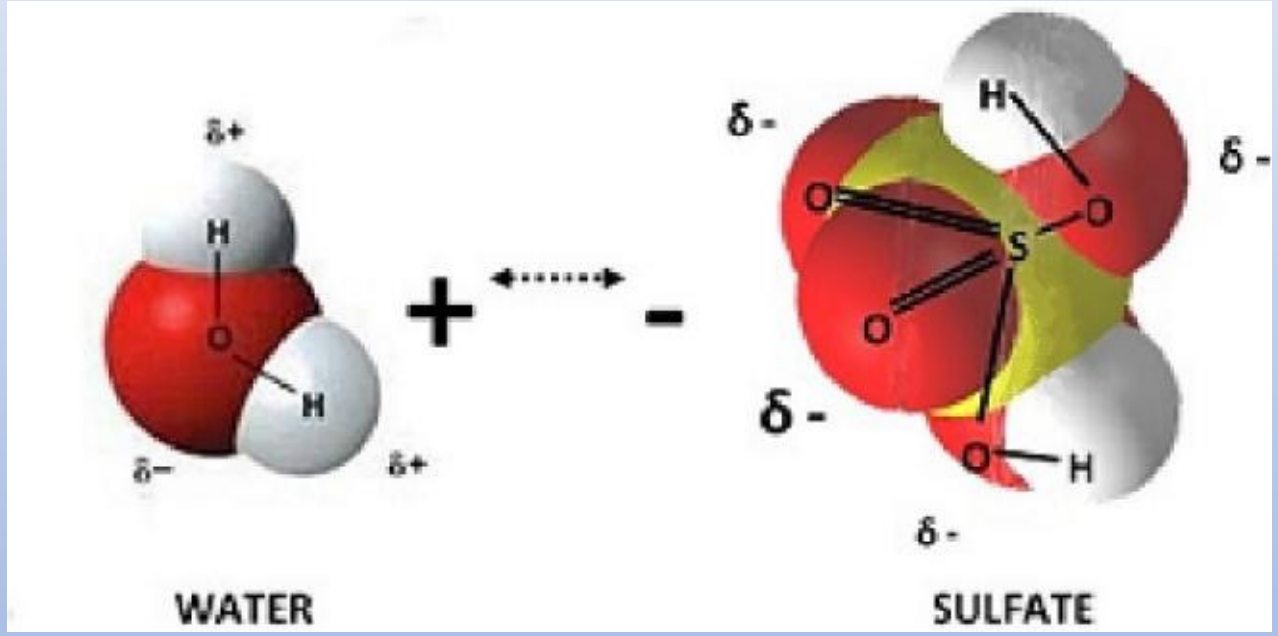
- Chemical formulary of RDT:
  - sulphonated phenolic acids (phenol and guaiacol)
  - sulfuric acid
  - 10% water
- Two separate chemical reactions take place:
  - Sulfonation of hydroxybenzene (phenol)
  - Sulfonation of hydroxymethoxybenzene (guaiacol)
- The reaction produces the aromatic sulfonic acid, residual free sulfuric acid and water

Regenerative Debridement Technology (RDT)

- Non-Biologic Desiccant Technology
- Two mechanisms of action [MOA]:
- Mechanical:
  - Due to the viscosity of the liquid or gel, the sheer force loosens and removes necrotic tissue, bacteria and fungi from the wound bed. Rinsing with water or saline augments the removal.
- Chemical:
  - The sulfate groups attract water from the wound bed - electrostatic bonding
  - A coagulum is formed, and this harbors necrotic tissue, biofilm, bacteria, fungi, yeast, and proinflammatory factors (MMP, IL, TNF α)



Water Shell



Attributes of RDT as Evidenced by Multiple Studies Performed at University Miami, Miller School of Medicine

- Removal of slough and necrotic tissue in wound bed
  - Reduced 85% more than controls
- Removes bacteria and biofilm from the wound bed
  - Eliminated 99.7% more than controls
- Removes dermatophytes and Candida from the wound bed
  - 3.5 – 4.0 log reduction compared to Lamisil control
- Removes cytokines, proteases and TNFα
  - Reduced up to 62% as compared to controls

Post sharp debridement

Post application – 45 seconds

The Effect of Regenerative Debridement Technology (RDT) on Wound Bed Preparation with Respect to pH Modulation and Normalization

- Prospective evaluation of the effect of RDT on pH in the chronic wound bed
- Evaluated a small cohort of patients with chronic DFUs and VLUs
- Patients had multiple comorbidities including:
  - Diabetes mellites (types 1 and 2)
  - Hypertension
  - Autoimmune disease (RA, PA)
  - History of CVA
  - Chronic renal insufficiency
  - Peripheral neuropathy
  - Venous hypertension
  - Cardiac arrythmia (AF)

Application Procedure for Wound Bed Preparation

- Sharp debridement
- Dry wound bed
- Apply RDT and with a gloved finger to the wound bed
- 45 sec of RDT contact in the wound bed, rinse with saline or water
- Apply dressing:
  - DFU – hydrogel
  - VLU - alginate

pH Meter and Measurement Technique

- Hanna H198100 pH meter
- Calibrate with buffered saline 7.0
- Surface exudate sample obtained, place in vial with buffered saline
- Digital read out obtained
- Recalibrated with buffered saline after each assessment

Patient and Wound Parameters

Study patients

- DFU: 13 patients (5 male, 8 female)
  - Duration of ulceration: 2 – 16 months
  - 11 – type 2 DM
  - 2 – type 1 DM
  - median volume – 734 mm^3
  - range: 384mm^3 – 1900 mm^3
- VLU: 15 patients (6 male, 9 female)
  - Duration of ulceration: 4 – 38 months
  - median volume – 1675mm^3
  - range: 192mm^3 – 5952mm^3

Control patients

- DFU: 5 patients (2 male, 3 female)
  - Duration of ulceration: 3 - 15 months
  - 4 – type 2 DM
  - 1 – type 1 DM
  - median volume – 614 mm^3
  - range: 448mm^3 – 1056mm^3
- VLU: 5 patients (2 male, 3 female)
  - Duration of ulceration: 3 – 26 months
  - median volume – 1270mm^3
  - range: 792mm^3 – 1792mm^3

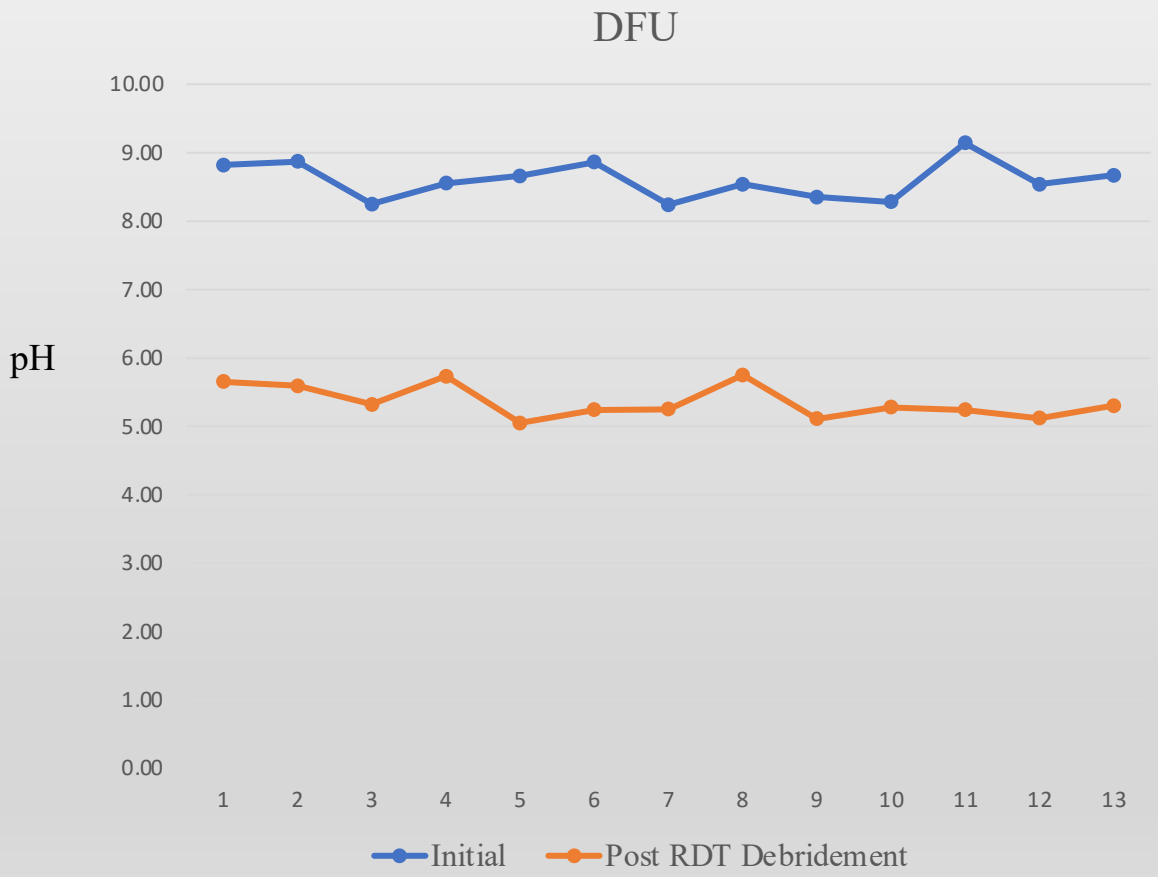
Data Collection for pH Assessment

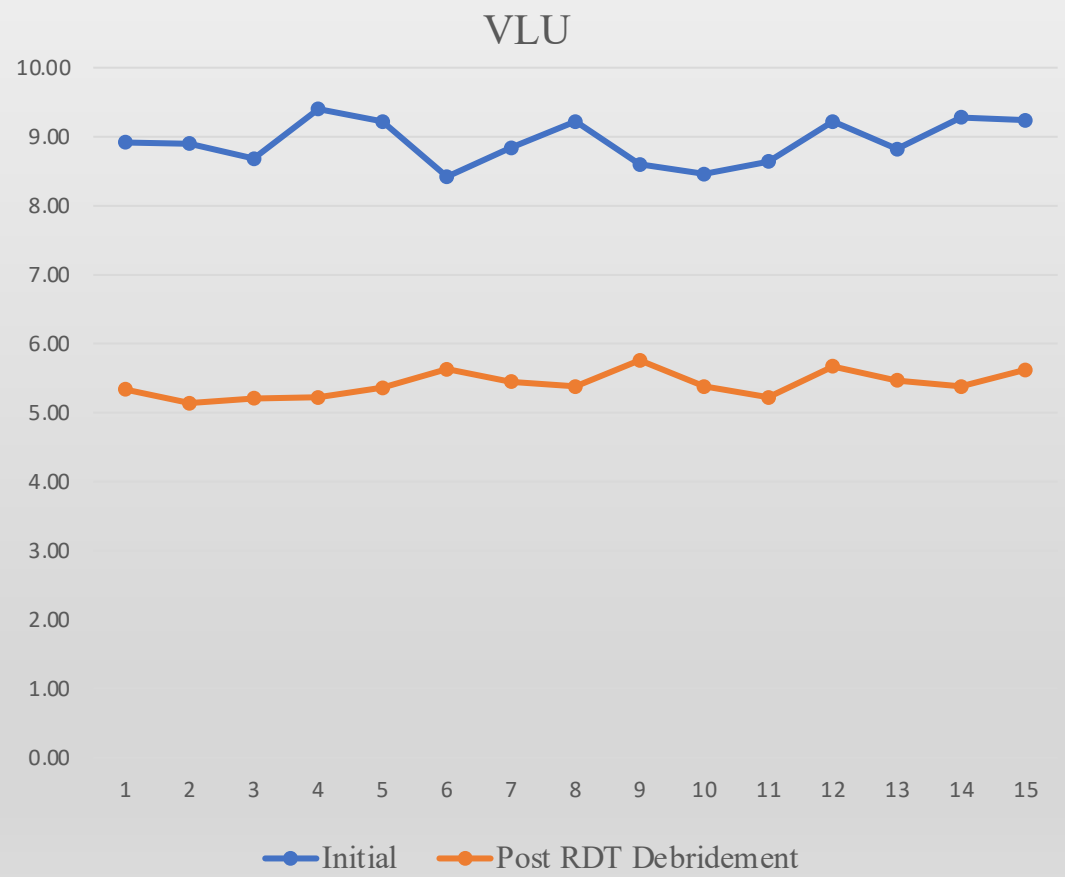
- Wound bed samples were collected and pH assessed
- Only one (1) application of RDT for 45 seconds on day 1

- Day 1
  - Initial assessment – prior to any debridement or treatment.
  - Post sharp debridement
  - Post RDT debridement
- 24 hours post RDT debridement
- 7 days post RDT debridement
- 14 days post RDT debridement
  - Post sharp debridement

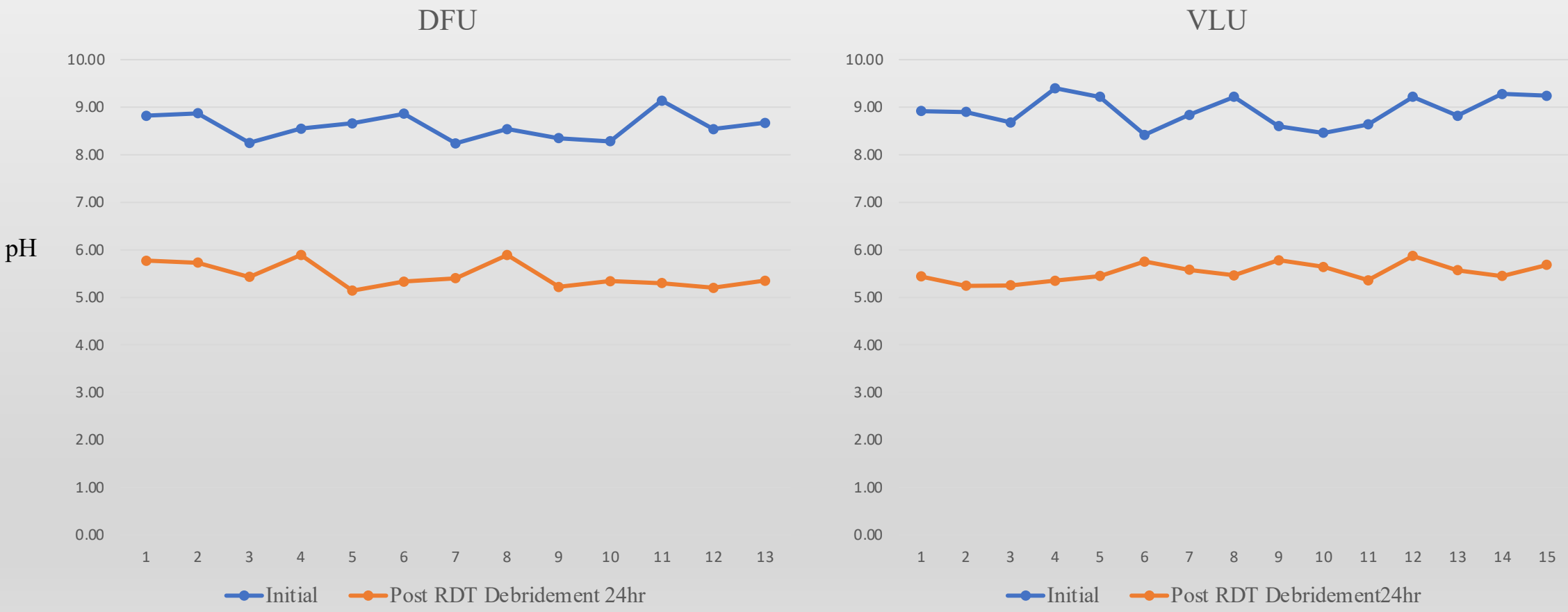
Initial and Post Sharp Debridement pH

Initial and Post RDT Debridement



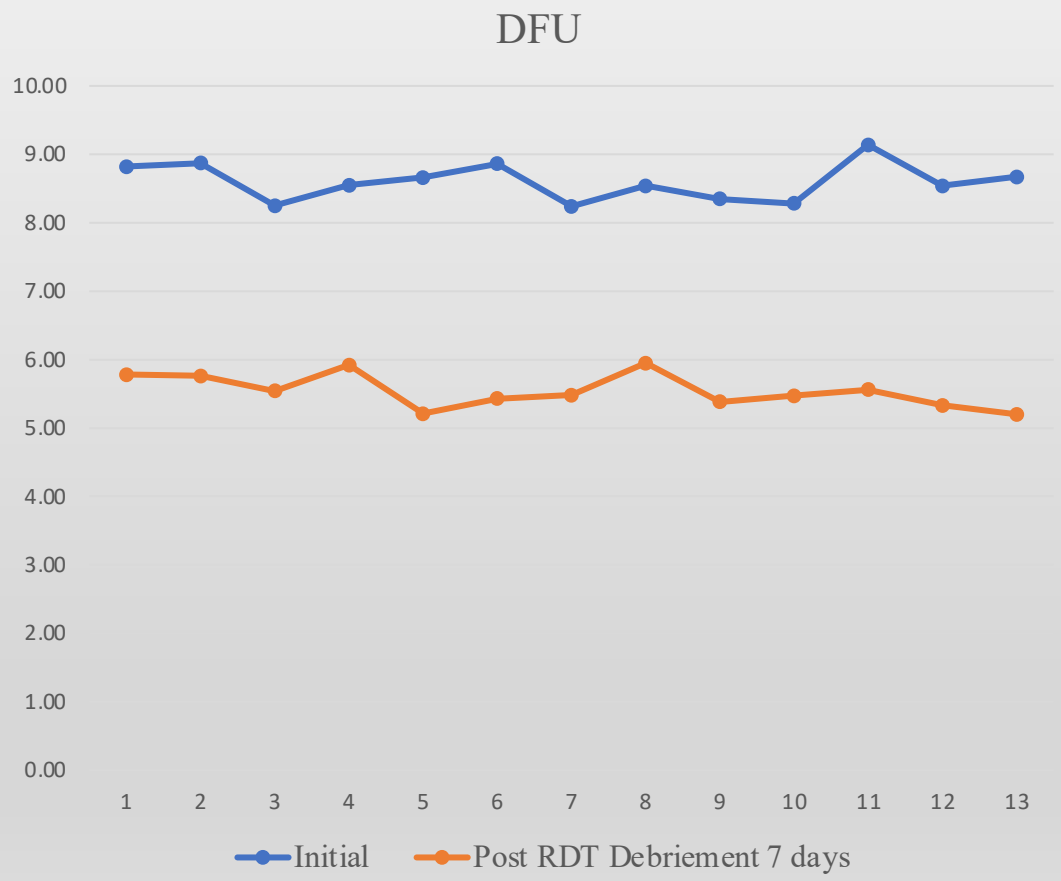


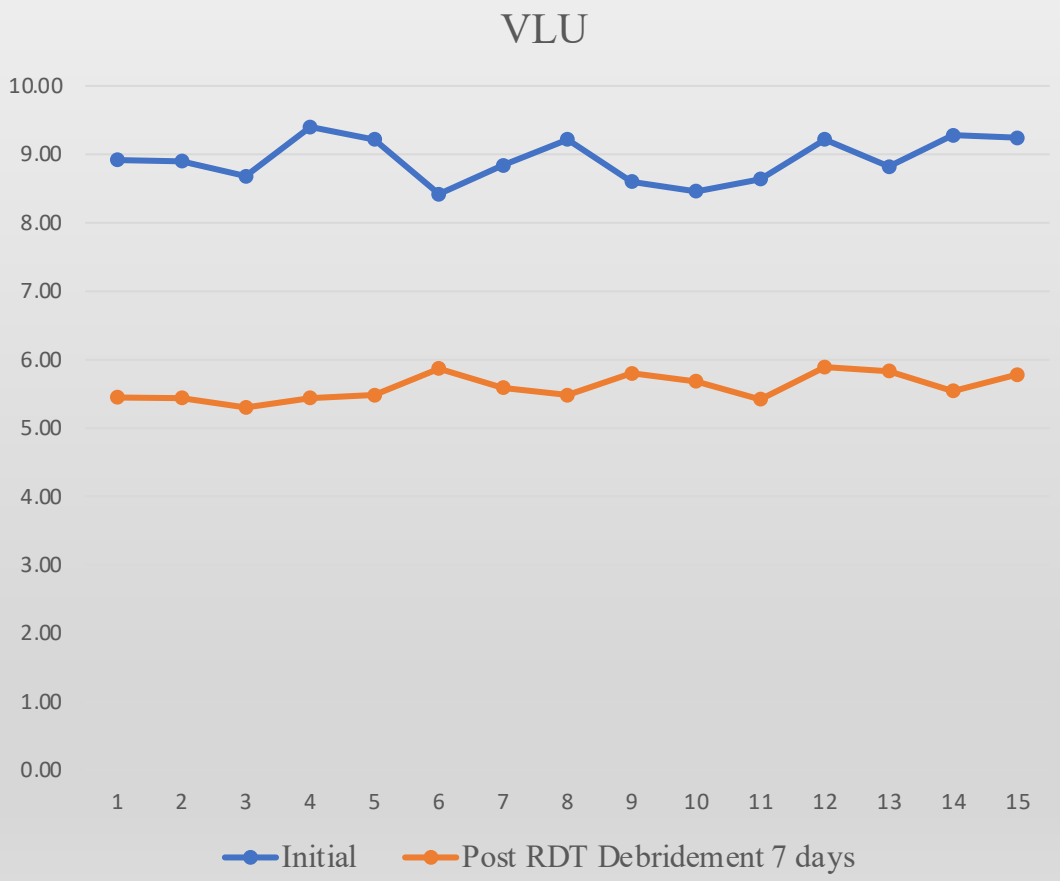
Initial and Post RDT Debridement – 24 hours



Initial and Post RDT Debridement – 7 days

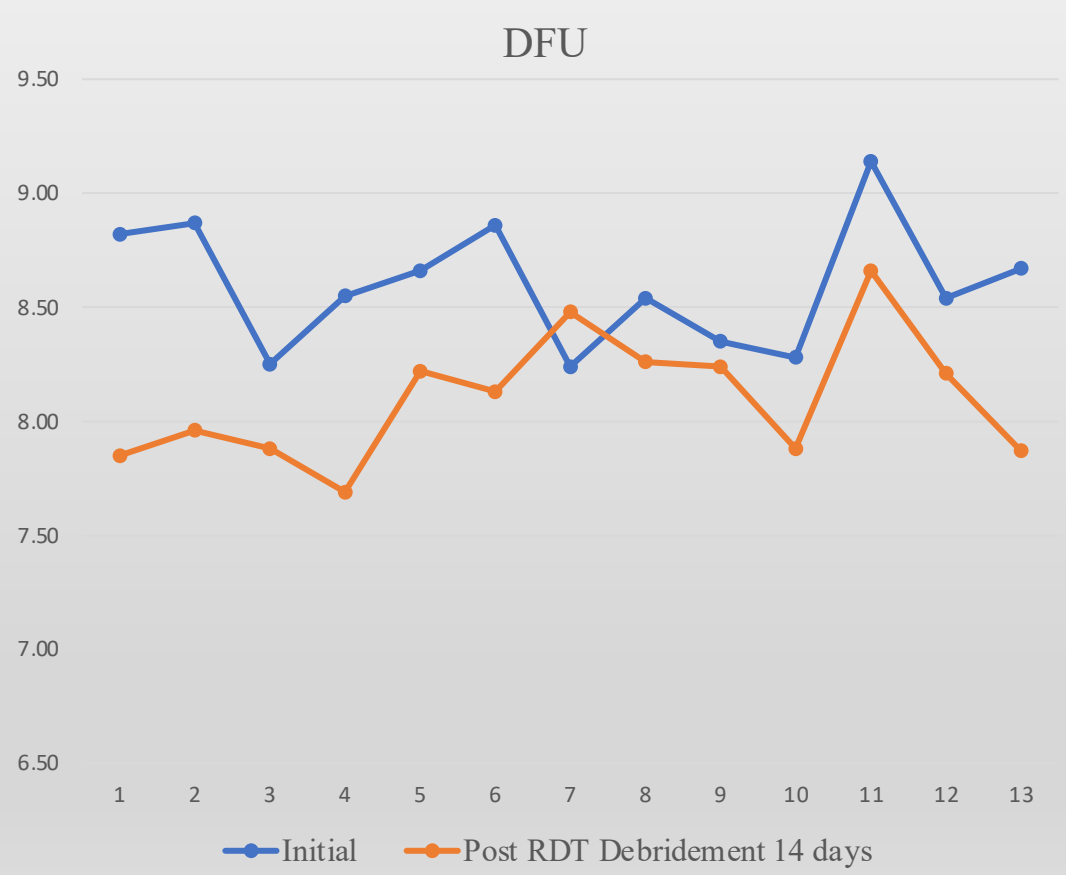
pH

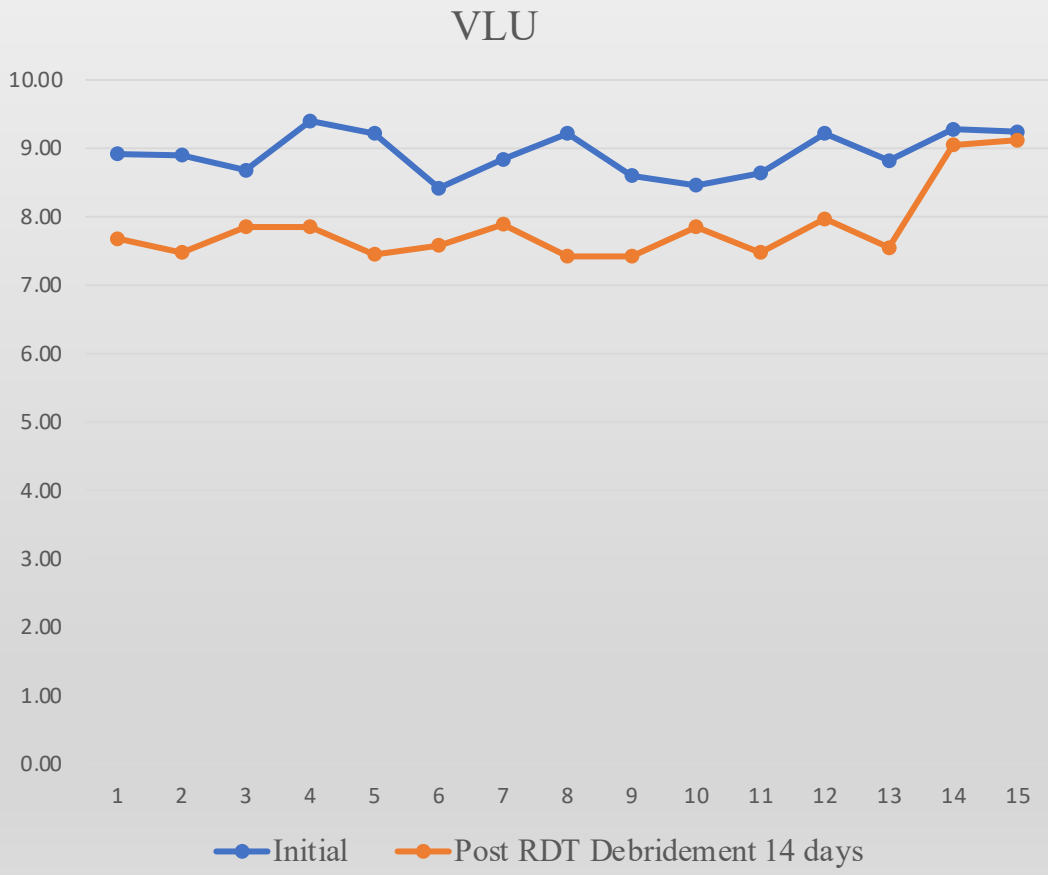




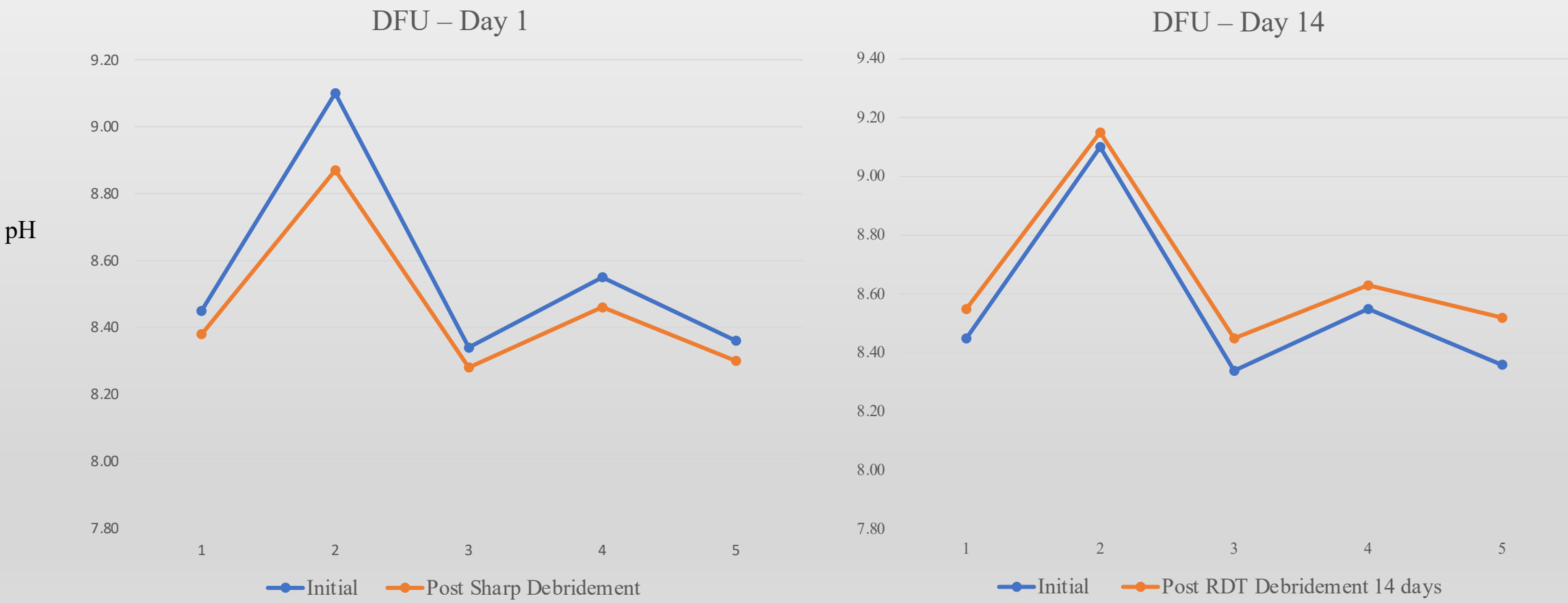
Initial and Post RDT Debridement – 14 days

pH



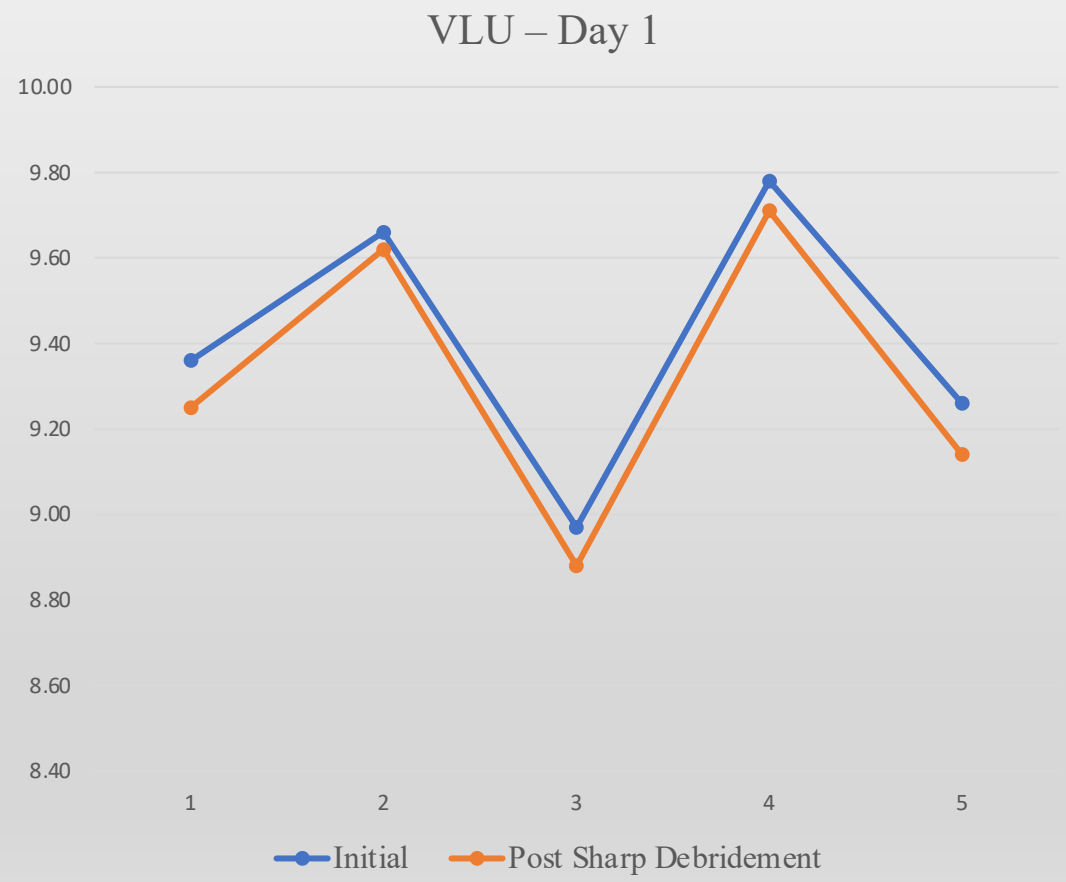


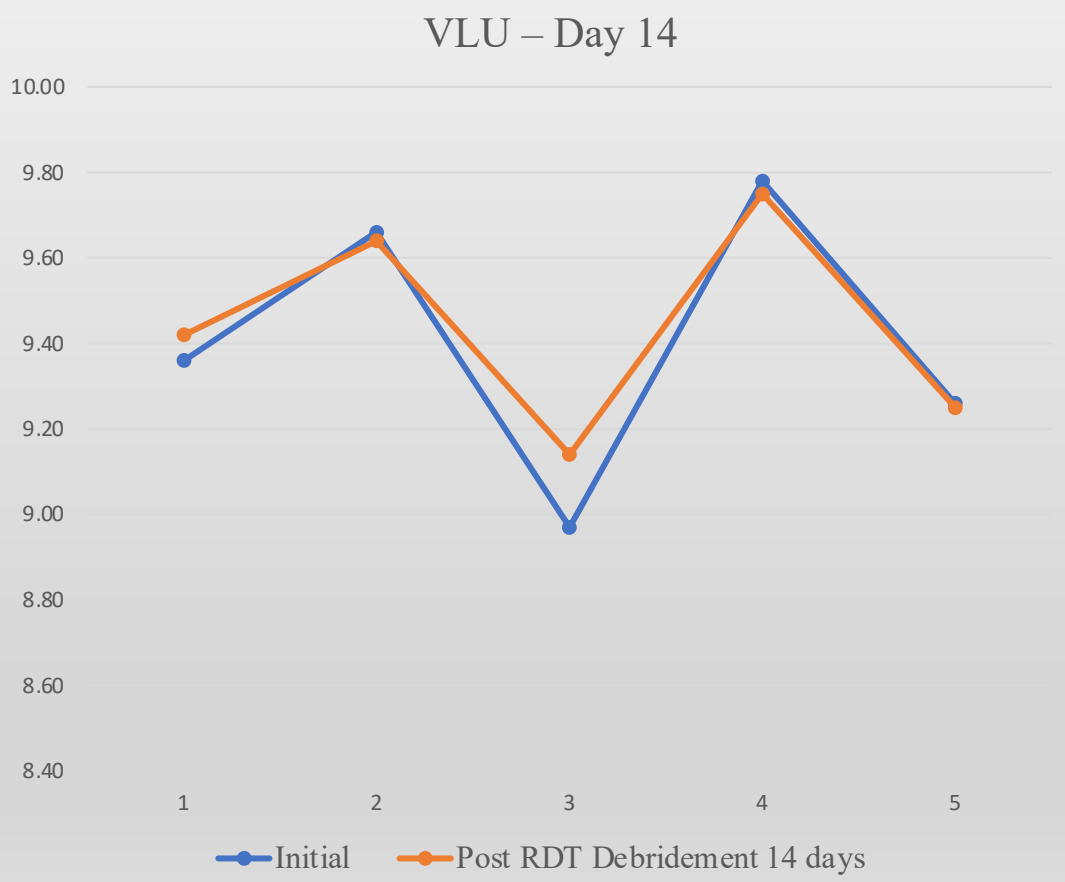
DFU Control patients



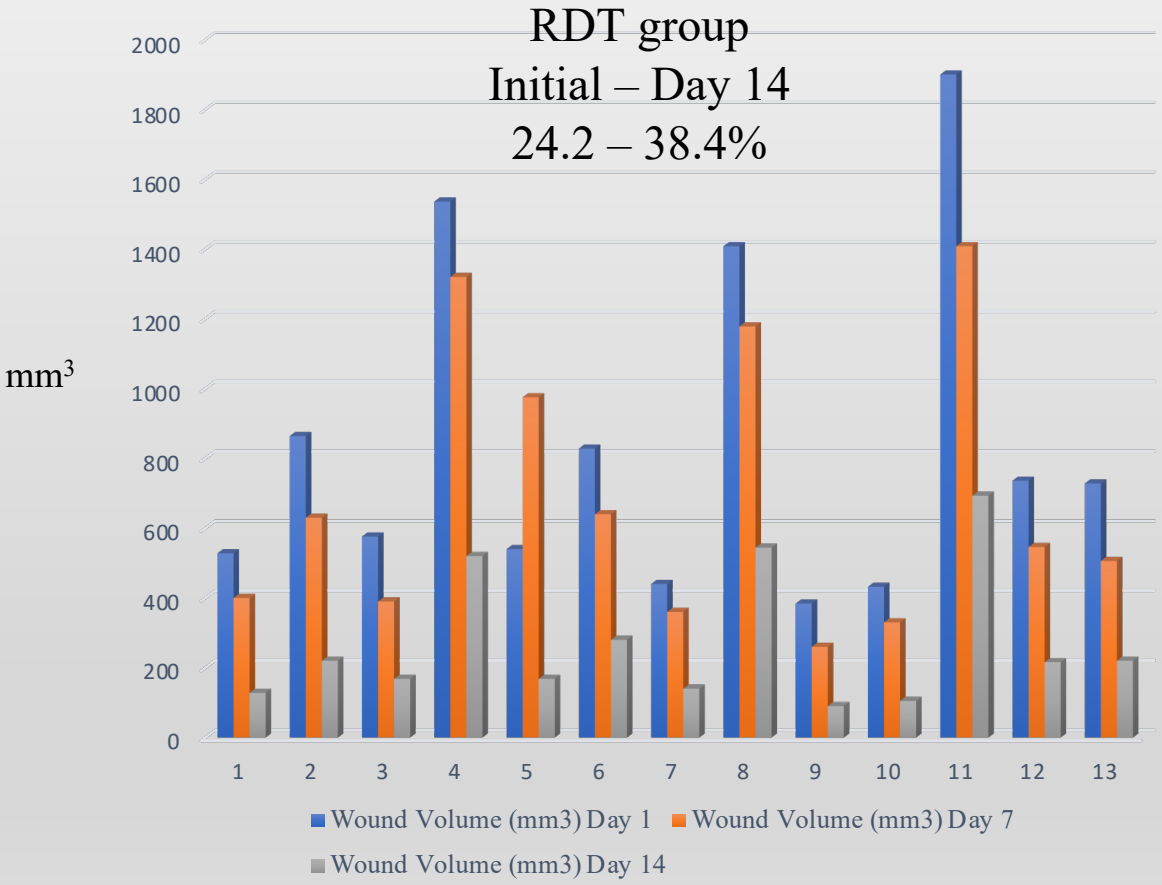
VLU Control patients

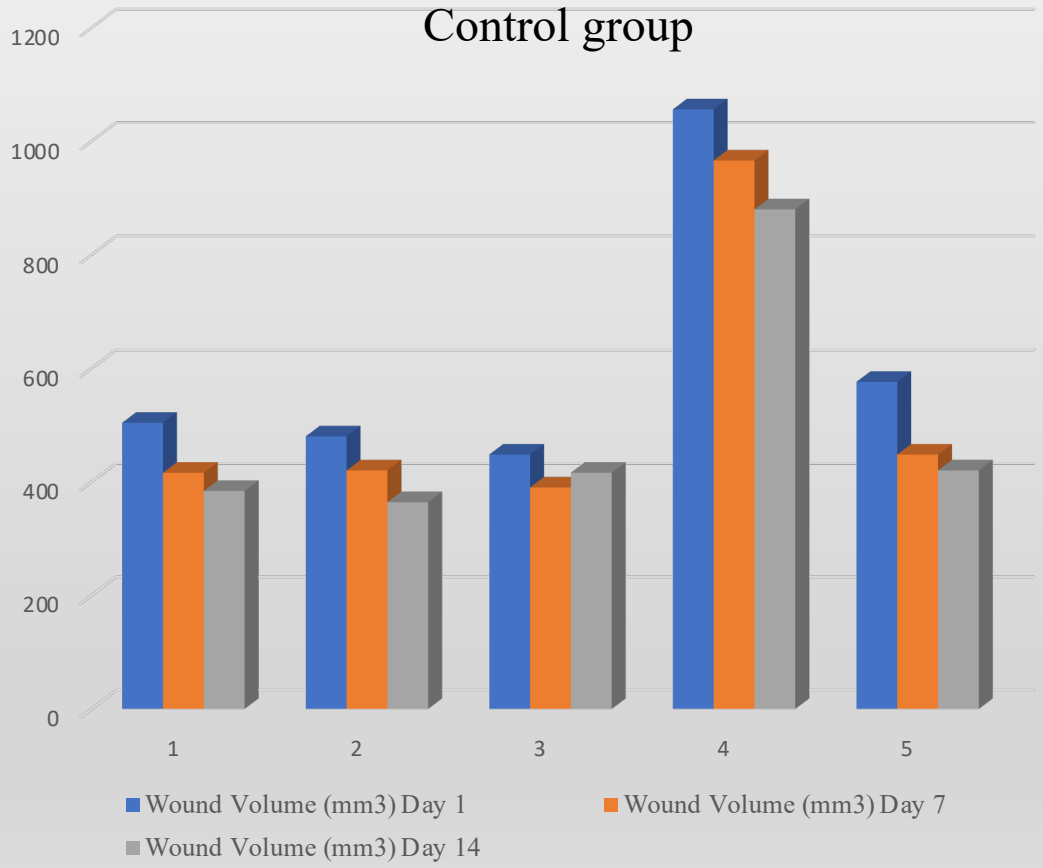
pH





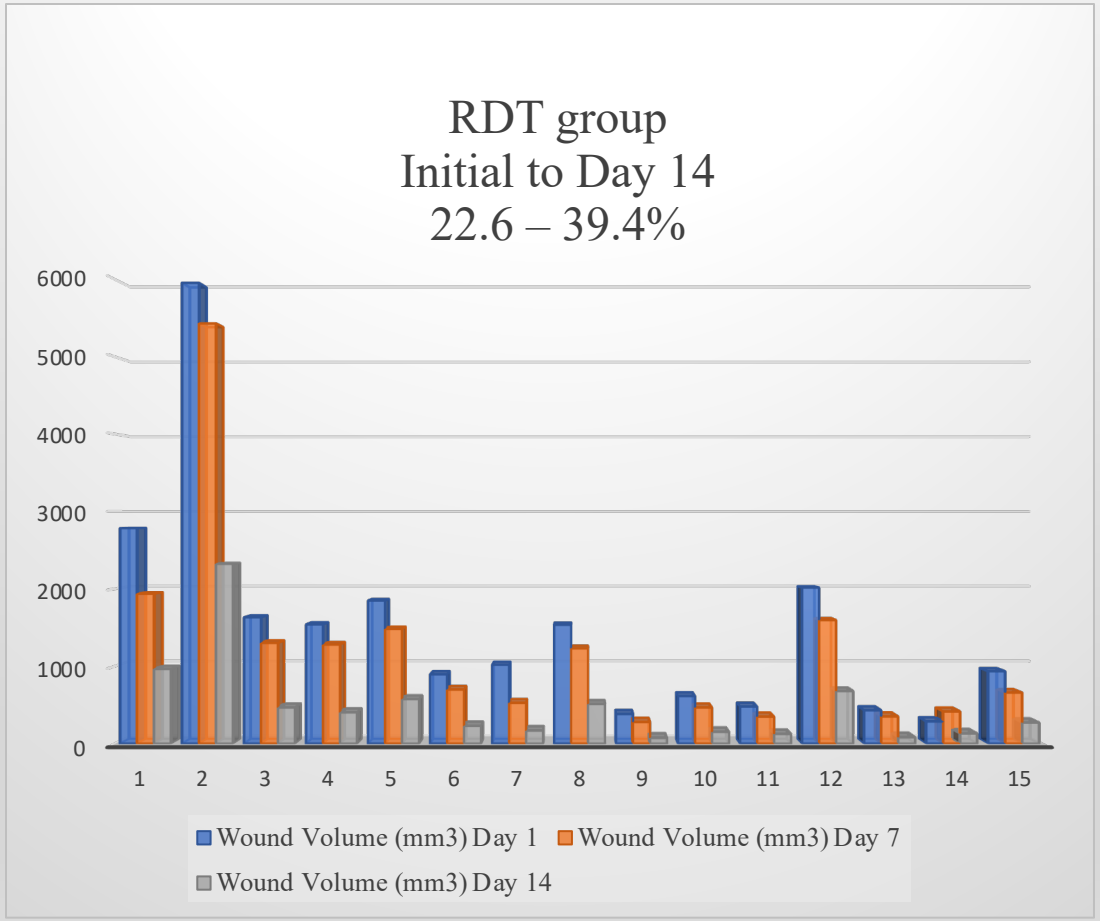
DFU Wound Volumes

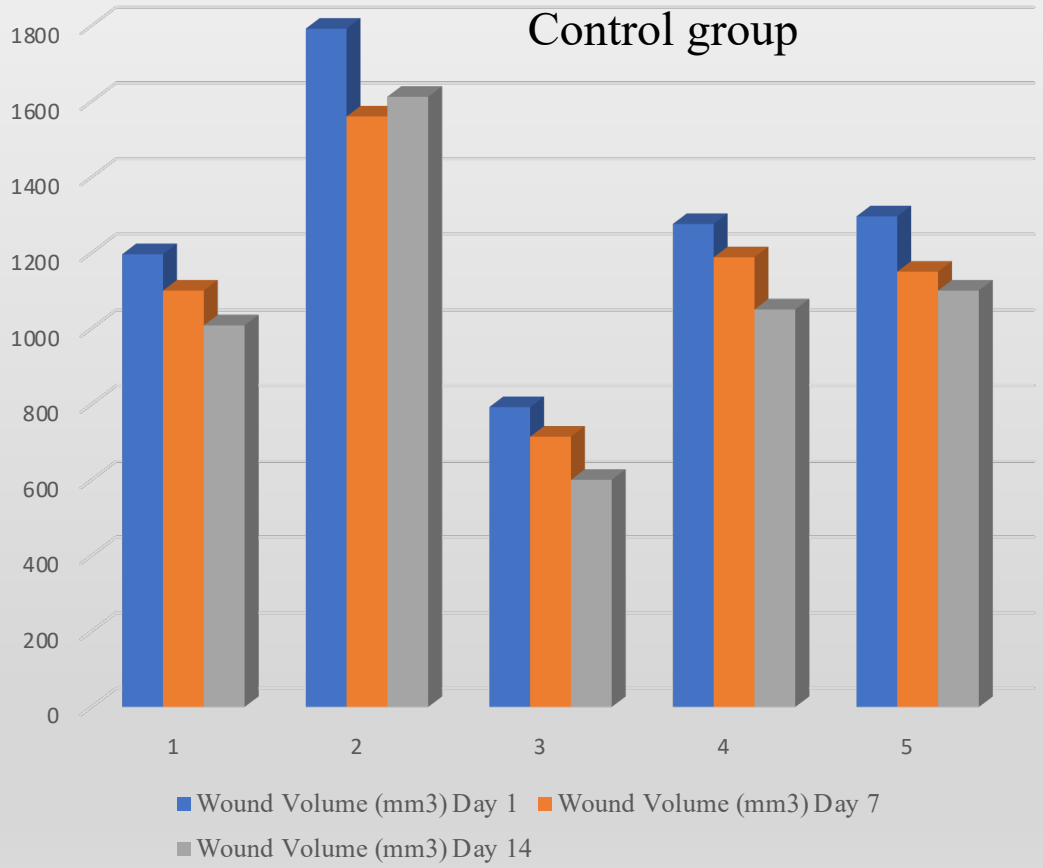




VLU Wound Volumes

mm^3





Conclusion

- RDT has a significant impact upon normalizing dermal pH in the chronic wound bed of DFUs and VLUs
- This is not a transient effect, the normalized pH of the wound bed is maintained through 7 days post single application
- Normalizing the wound bed pH can allow the wound bed environment to proceed to a better healing trajectory

Thank you