The Use of Borate-Based Bioactive Glass Fibers and Particulate in the Healing of Multiple Wounds

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(Prospective study reviewed from single practitioner office setting so no IRB was required.)

Introduction

In 1969, Dr. Larry Hench pioneered the use of bioactive glass (BG) to enhance and repair mechanical tissue (e.g. bone and teeth)[1]. Dr. Hench defined "BGs as a category of bio-materials that elicit a specific biological response at the interface with host tissues, which result in the formation of a chemical bond[2]." Hench originally used silicon ion-based glass but other BG have been formulated with (other) ions including Ca2+, P5+, B3+, Cu2+, Zn2+, Ag+, and Ga3+. BG has been shown to be useful as bone replacement material and for soft tissue engineering. Bioactive properties of BG include hemostasis, antimicrobial effect[3], epithelial cell migration, angiogenesis, and fibroblast cell proliferation[4], which are useful attributes during each phase of wound healing. There are increasing reports of BG being used with general wound healing[5]. Recently (late 2016), the FDA approved a borate-based biologically active glass product for use in wound dressings. We reviewed our initial experience using a borate-based bioactive glass (BBG) product in 30 patients with 43 wounds.

Methods (Table 1)

1. Dressing changes were performed 2-7 days depending on exudate.
2. Wounds were cleansed at each visit with 0.9% NS or soap and water.
3. Debridement of necrotic/devitalized tissue was done as indicated.
4. 2-3mm thickness of BBG was applied to cover the wound.
5. Tracts or undermining areas were filled with BBG.
6. Wounds were covered with absorbent material in case of exudate(s).
7. VLU/Lymphedema patients were treated with MLCT or Unna boots.
8. DFU patients were offloaded.
9. Bolsters were used to cover pressure sites.
10. Critical limb ischemia and patients with ABI < 0.7 were revascularized.
11. NPWT was occasionally used (< 5 patients).
12. Cultures were performed when clinically indicated.

Limitations

The goal of this study was to see how BBG works in the office setting with all types of wounds as a general contact dressing. Rudimentary guidelines were initially used but minor modifications evolved to a routine system as we gained experience with the product. While 43 wounds is a fair sample of wound use, further evaluation with a larger population/ variety may be needed to validate our findings. The loss of patients to death, therapy change, or provider (change) further diluted our experience but all wounds seemed to respond favorably to therapy. In addition, as would be expected with any random cohort of wound patients, patient compliance was a serious issue that affected (likely prolonging) successful outcomes. Another variable that limited this study and outcome(s) was that BBG was not available on a few occasions requiring other contact dressing application to be utilized. This study certainly would have been better if randomized or compared to another (control) treatment group.

References

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[2] Naseri, S., Lepry, W., and N Nazhat, S. (2017). Bioactive Glasses in Wound Healing: Hope or Hype?. J. Mater. Chem. B., 5, 31. Doi: 10.1039/c7tb01221g

[3]Ottomeyer, M., Mohammadkan, A., Day, D. and Westenberg, D. (2016) Broad-Spectrum Antibacterial Characteristics of Four Novel Borate-Based Bioactive Glasses. Advances in Microbiology, 6, 776-787. doi: 10.4236/aim.2016.610076

[4] Miguez-Pacheco, Valentina., Hench, L.L. and Boccaccini, A.R. (2015). Bioactive Glasses Beyond Bone and Teeth: Emerging Application in Contact with Soft Tissues. Acta Biomaterialia, 13: 1-15. Doi: 10.1016/j.actbio.2014.11.004

[5]Mirragen®, ETS Wound Care LLC, Rolla, MO

Figure 1

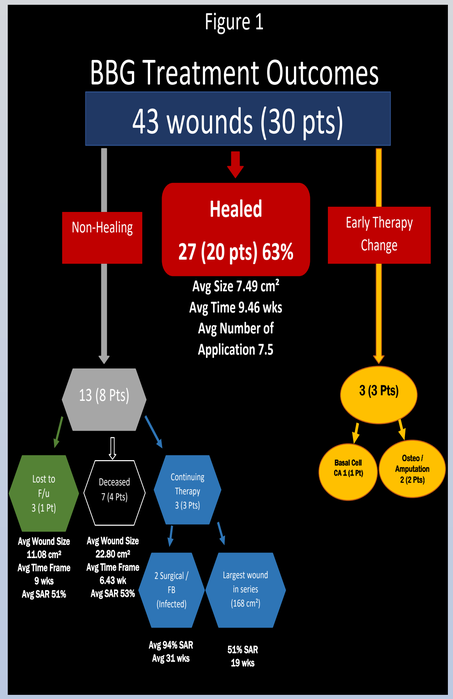
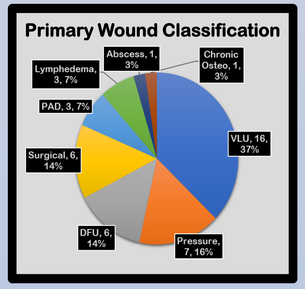


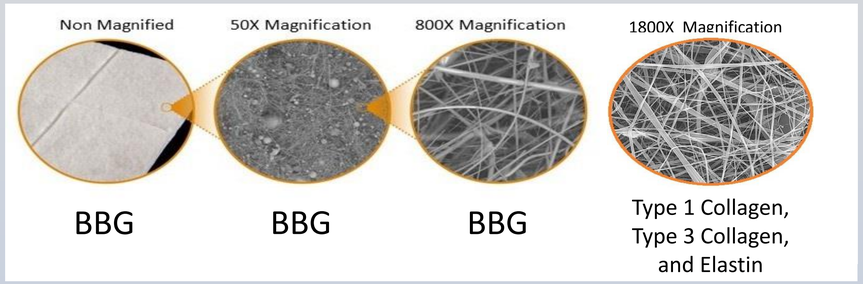
Table 2

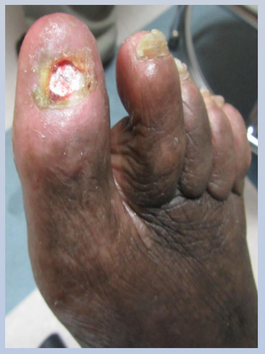
Comorbidities	# Pts
Diabetes	17
Venous Insufficiency	16
PAD	8
ESRD / CKD III	7
Osteomyelitis	6
Surgical	6
Paraplegia	4
Lymphedema	4
Foreign Body	2
Other	7

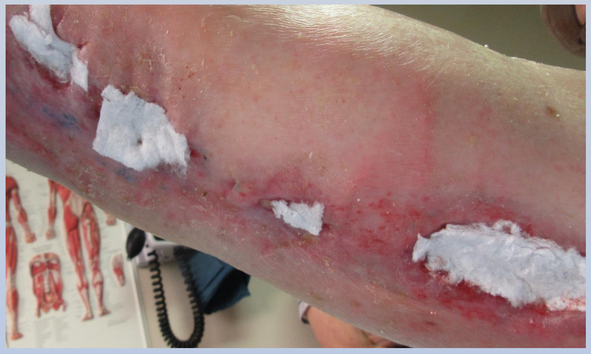
Figure 2



BBG Matrix vs Collagen Matrix







Results

BBG was used as primary therapy in 30 patients (ages 28-98, mean age 66.3) with 43 wounds. 18 patients were male and 12 were female. Our treatment methods are shown in Table 1. 15 patients presented with acute wounds and 15 patients had chronic wounds. Significant co-morbidities were present (Table 1). Wound classification is shown in (Fig 2).

Outcomes are depicted in (Fig. 1). 27 wounds (63%) in 20 patients healed completely. The average wound size of these wounds was 7.43 cm2 (range 1-34.65) but one patient with superficial ulcerations of both legs measuring > 200 cm2 was excluded. The average number of BBG applications in healed wounds was 10 (range 1-25). The average length of healing time was 9.4 (range 2-20) weeks.

Early therapy change was required in 3 (7%) wounds in 3 patients. 2 patients with severe osteomyelitis with bone destruction were referred to podiatry and underwent acute great toe amputation. One basal cell carcinoma patient was referred to dermatology.

4 patients with 7 (16%) wounds died during treatment--these deaths were unrelated to the BBG therapy. Three wounds occurred in a 53 year old diabetic man. He achieved 37% SAR (>50% volume reduction) with 14 applications over 5 weeks but developed urosepsis, SIRS, and died from PE. The other 4 wounds occurred in elderly (ages 80, 90, & 98) bedridden patients with declining health ultimately placed into hospice. The oldest patient died < 2 weeks after presentation. The 80 year old diabetic patient had a very chronic left ischial decubitus and received 17 applications (21 weeks) with 87% SAR. The final patient was treated for her sacral decubitus at home by her son and home health with 17 applications over 7 weeks. Her wound decreased 84% (SAR).

One patient with 3 (7%) complex (ESRD, VLU, PAD) chronic wounds traveled 25 miles and elected to change provider to be closer to her home. She was treated with 10 applications over 9 weeks with 51% SAR.

Ongoing treatment continues with 3 (7%) wounds in 3 challenging patients. Each had chronic (6-24 months) wound at initiation of BBG therapy. 2 of these patients were diagnosed with foreign body infections. One patient with spine hardware achieved 79% volume reduction of his wound after 17 applications of BBG over 20 weeks. Another chronic abdominal wound required 2 trips to the OR to remove retained foreign body. 95% SAR after 40 applications over 40 weeks occurred with this therapy. The final 59 year old diabetic required L Tran-metatarsal amputation but sloughed skin from her left foot after cellulitis episode post-operatively. Her large 168 cm2 wound was treated with 16 applications of BBG over 19 weeks with 51% SAR.

Conclusion

BBG is a versatile wound product that can be used as a ~stand alone contact dressing for a wide variety of wounds. Highly exudative wounds, including VLU, seemed to heal well--especially with acute presentation. BBG was very useful as a wound matrix for packing wound tracts and applying to undermined wounds. Use of BBG worked well with exposed bone as might be expected with most BG products but cautious use with large areas of exposed tendon or fascia is recommended as desiccation of the tendon/fascia was observed on occasion. BBG seems to disrupt biofilm and demonstrated antimicrobial activity as was predicted. Skin growth does occur but seemed possibly slower than some other skin growth therapies. Further study is needed to optimize the use of this product. This series is small but BBG shows great promise as a simple to apply contact dressing for most any wound.