Case Series

Innovative Bioactive Glass Fiber Technology Accelerates Wound Healing and Minimizes Costs: A Case Series

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ABSTRACT

OBJECTIVE: To evaluate the efficacy and value of a novel borate-based bioactive glass fiber (BBGF) advanced wound matrix in the treatment of chronic wounds.

METHODS: Four patients with chronic wounds that had failed multiple prior treatments were identified and treated with the BBGF technology. Patient demographics, wound characteristics, and prior treatment history were obtained. Costs associated with prior treatments were estimated and recorded using available cost data.

RESULTS: The average wound duration prior to initiation of BBGF treatment was 391 days. All of the patients had a history of multiple failed interventions, including operative procedures, negative-pressure wound therapy, cellular and/or tissue-based products, dermal grafts, and synthetic wound matrices. Prior interventions resulted in an average estimated cost of $87,750 per patient. All of the patients achieved complete wound closure in an average of 55 days using BBGF treatment. Patients were treated with 3.3 applications of the BBGF product on average, with an average cost of $3,564. The use of the BBGF advanced wound matrix on initial presentation could have saved the healthcare system an average of $84,186 per patient and reduced wound duration by an average of 336 days.

CONCLUSIONS: The BBGF advanced wound matrix resulted in the healing of chronic wounds that had failed multiple prior interventions. In this series of challenging cases, BBGF accelerated healing while minimizing costs and improving patient outcomes. By offering an effective therapy at a low cost, BBGF has the potential to add significant value for both the healthcare system and the patient.

KEYWORDS: advanced wound matrix, bioactive glass, chronic wound, cost analysis, ulcer, wound care

ADV SKIN WOUND CARE 2020;33:1–6.

DOI: 10.1097/01.ASW.0000672504.15532.21

INTRODUCTION

Chronic wounds represent a significant challenge in global health, affecting an estimated 6.5 million people in the US alone. In addition to the detrimental effects of chronic wounds on patient quality of life, they are also a significant strain on the healthcare economy. With an estimated annual cost of $25 billion, it is no surprise that wound care has become a huge commercial enterprise.[1]

Year after year, expensive new products enter the market for a chance at capturing a piece of this pie. Although each new product comes with self-proclaimed "improved efficacy" over standard of care, the hidden costs of these new devices go understated. As a result of their increased costs, patient access to such treatments centers largely on insurance reimbursement for application and use. With the increasing emphasis by healthcare organizations on cost-cutting efforts, and the negative optics of expensive new technology, there is a need for an advanced wound care therapy that offers value, that is, quality outcomes with reasonable cost. A recently developed innovative borate-based bioactive glass fiber (BBGF; MIRRAGEN Advanced Wound Matrix, ETS Wound Care, Rolla, Missouri) may be well suited to meet this new wound care paradigm. This article reports the efficacy and hypothetical healthcare cost reduction associated with BBGF use in a series of patients with chronic wounds that had failed months of prior wound interventions.

METHODS

Two wound care professionals, one surgeon and one certified wound nurse, identified four patients at two community hospital outpatient clinics and treated their wounds with the BBGF advanced wound matrix. They also obtained patient demographics, wound characteristics, and prior treatment history (Table 1), as well as informed consent to publish case information and photographs. Costs associated with prior treatments were estimated by the author and recorded using available cost data.[2–5] A general estimate of "cost of treatment" was determined using published costs associated with the relevant Current Procedural Terminology codes for

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Table 1. CASE CHARACTERISTICS

Characteristic	Case 1	Case 2	Case 3	Case 4
Age, y	69	64	78	50
Sex	Male	Female	Female	Male
Comorbidities	Diabetes, PVD, renal failure on hemodialysis, osteomyelitis, pacemaker, malnutrition, seizure disorder, multiple sclerosis	Diabetes, PVD, renal failure on hemodialysis	Diabetes, PVD, osteomyelitis	Diabetes, PVD, osteomyelitis
Wound site	Elbow	Foot	Foot	Foot
Wound type	Pressure ulcer	DFU	DFU	DFU
Previous treatments	Operative debridement ×2, hospital readmission, IV antibiotics, NPWT	Failed operative closure ×2, Integra, MicroMatrix	Promogran Prisma Matrix, Endoform, Silver alginate, Collagen flakes, NPWT, hyperbaric oxygen, IV antibiotics, recommended amputation	Failed operative closure ×2, Integra, GraftJacket
Site of care during previous treatments	Inpatient, outpatient	Inpatient, outpatient	Inpatient, outpatient	Inpatient, outpatient
Wound duration prior to BBGF	212 d	420 d	540 d	Several months
Days to closure after BBGF	56	42	66	56
No. of BBGF treatments	7	1	3	2
Site of care during BBGF treatments	Outpatient	Outpatient	Outpatient	Outpatient

Abbreviations: BBGF, borate-based bioactive glass fiber; DFU, diabetic foot ulcer; NPWT, negative-pressure wound therapy; PVD, peripheral vascular disease.

operative interventions, average cost of an overnight stay at the inpatient level of care, and reported costs associated with product usage (where applicable).[2–5]

Prior to initial BBGF application, wounds were sharply debrided by either the surgeon or the wound care nurse until a healthy vascular wound bed remained. The BBGF advanced wound matrix was then applied to the entire wound surface. It was covered with a secondary dressing as a bolster to minimize disruption of the bioactive glass (BG)-wound bed interface. Secondary dressings included a bordered foam dressing, 4 × 4-inch gauze, or Adaptic and gauze. The choice of secondary dressing was largely dependent on the level of exudate from the wound.

The wounds were reevaluated every 3 to 7 days on an outpatient basis with no manipulation of the BBGF or wound bed, but the secondary dressing was changed during this interval if it was noted to be supersaturated by underlying wound exudate. At approximately 1-week intervals, based on wound appearance, wound healing, and provider preference, the BBGF matrix was reapplied as needed in the office during these visits. No additional debridement was performed at subsequent follow-up visits (no evidence of eschar or necrotic debris within the wound bed or at the wound periphery). A new secondary dressing was applied after each reapplication. Patients continued to follow up weekly with their provider until complete wound closure.

After complete wound closure, the cost of treatments were calculated and recorded by the author using available cost data. In this case, the cost of BBGF treatment included the average CMS reimbursement for an established outpatient office visit, as well as the unit price for all products used at each visit.

RESULTS

Table 2 shows a summary of the case results including average costs, wound durations, and BBGF applications.

Case 1

This was a 69-year-old man with a chronic left elbow wound following two operative incision and drainage and debridement procedures for an infected olecranon bursa with osteomyelitis and exposed bone. The wound had persisted for 212 days prior to initiating BBGF treatment (Figure 1). The patient was wheelchair dependent and malnourished with poorly controlled diabetes, was on chronic hemodialysis, and had a pacemaker, left upper extremity arterio-venous graft, multiple sclerosis, and a seizure disorder.

Previous treatments included two operations, five admissions to the hospital (with four readmissions for wound complications), 33 total inpatient hospital days, several months of IV antibiotic use for osteomyelitis, and 3 months of negative-pressure wound therapy with minimal improvement. The estimated cost of all prior

Table 2. COMPARISON OF WOUND TREATMENTS BEFORE AND AFTER MATRIX USE

Parameter	Prior to BBGF Matrix	After BBGF Matrix	Hypothetical Improvement
Healed wounds	0%	100%	100% healed wounds
Average wound duration	391 d	55 d	336 d
Average treatment cost	$87,750	$3,564	$84,186 per patient
Treatments	Surgery, negative-pressure wound therapy, Integra, MicroMatrix, Promogran Prisma, placenta graft	BBGF	Reduction in necessary inventory

Abbreviation: BBGF, borate-based bioactive glass fiber.

wound interventions, including inpatient hospital stays and readmission, was approximately $139,850.

The BBGF matrix was applied a total of seven times. It was applied in the outpatient clinic during weekly 10-minute visits. The wound healed 56 days after BBGF treatment was initiated (Figure 2). The total cost of closure with BBGF was $2,175. In comparing the estimated costs of the patient's prior treatment with the cost to closure using the BBGF matrix, this patient could have achieved a hypothetical reduction in treatment costs of $137,675, as well as a potential reduction in wound duration of 156 days. Had the BBGF matrix been applied at the outset of treatment and the same results achieved, it could have prevented four re-admissions and reduced lengths of hospital stay, thereby significantly improving key hospital performance indicators.

Case 2

This was a 64-year-old woman with a chronic left diabetic foot ulcer that had persisted for 420 days. The patient presented with poorly controlled diabetes and peripheral vascular disease and required chronic hemodialysis. Previous treatments included two failed operations for surgical closure, as well as prior use of Integra (Integra Life Sciences, Plainsboro, New Jersey) and MicroMatrix (Acell, Columbia, Maryland). The estimated cost of her prior wound interventions was approximately $68,500. One 2 × 2-inch BBGF matrix was applied during a third surgical intervention. In this case, because of evidence of rapid healing, additional BBGF was not applied at subsequent outpatient visits. The wound healed 42 days after initial application. The total cost of closure with the BBGF matrix was $1,280. This equates to a potential cost reduction of $67,220 and a potential wound duration reduction of 378 days.

Figure 1. PATIENT 1 LEFT ELBOW WOUND PRIOR TO MATRIX APPLICATION

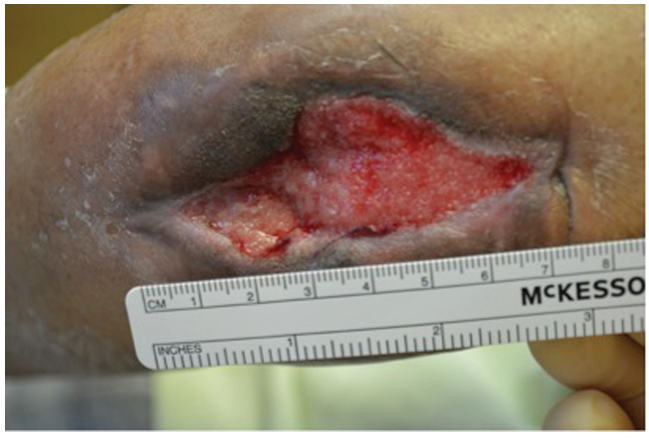
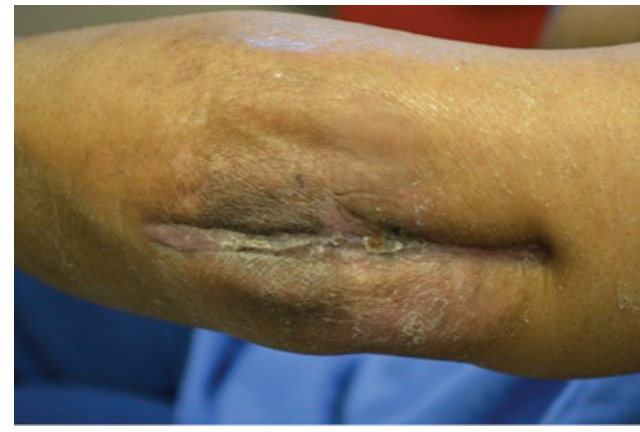


Figure 2. PATIENT 1, LEFT ELBOW WOUND HEALED AFTER 56 DAYS



Case 3

This was a 78-year-old woman with a chronic diabetic ulcer present on her left leg for 540 days prior to initiation of BBGF therapy. The patient had poorly controlled diabetes and a prior below-the-knee amputation of her right leg secondary to peripheral vascular disease. The left leg wound was complicated by bone exposure and osteomyelitis. Previous treatments included prolonged use of PROMOGRAN PRISMA Matrix (KCI, San Antonio, Texas), Endoform (Hollister Inc, Libertyville, Illinois), silver alginate, collagen flakes, negative-pressure wound therapy, hyperbaric oxygen, and multiple courses of antibiotics. There was no improvement after 18 months, resulting in recommendations for amputation. The estimated cost of all prior wound interventions was approximately $75,000.

Prior to performing the recommended amputation, the BBGF advanced wound matrix was trialed. Over the course of the patient's outpatient follow-up visits, BBGF was applied a total of three times. The wound healed

66 days after initiation of treatment. The total cost of closure with the BBGF was $3,600. The BBGF matrix use in this patient resulted in limb salvage with a potential cost reduction of $71,400 and a potential wound duration reduction of 474 days if the BBGF matrix had been used at the outset with similar results.

Case 4

This was a 50-year-old man with a history of chronic left diabetic foot ulcers and osteomyelitis requiring a left-sided transmetatarsal amputation. He subsequently developed a chronic foot wound following the amputation. The wound had persisted for longer than 6 months. The patient had poorly controlled diabetes and peripheral vascular disease. Previous treatments included multiple failed operations for surgical closure, as well as prior use of Integra and GraftJacket (KCI). The estimated cost of his prior wound interventions was approximately $67,650.

The BBGF matrix was applied twice, with the first application during an operative intervention and the second application occurring in the outpatient setting approximately 1 week after the first. The wound healed 56 days after initiation of treatment. The total cost of closure with the BBGF was $7,200. Comparing the estimated costs of prior treatment with cost to closure using BBGF, this results in a hypothetical cost reduction of $60,020 in this patient.

DISCUSSION

Wound healing has become a huge commercial enterprise, with the market for wound care products exceeding $15 billion annually. Treating aberrant wound scarring accounts for another $12 billion.[1] Not surprisingly, year after year, expensive new products enter the advanced wound care space for a chance at capturing a share of the market. Although new products may offer some reported advantages over older technologies, they also often carry with them the burden of significant costs.

For example, over the last decade, a growing number of cellular and/or tissue-based products (CTPs) have been introduced. Many of these are created with synthetic, allogenic, or xenogenic tissue constructs that attempt to deliver "biologic" growth factors locally at the site of the wound. Although these CTPs have shown improved healing compared with older, traditional wound care methods, they can be cost-prohibitive, with some biologic CTPs costing several thousand dollars per application. Despite improved healing, patients may experience adverse events or allergic reactions after CTP use. In some cases, multiple applications of the expensive advanced wound care product results in an exponential increase in economic costs with little clinical benefit.

As a result of their increased costs, patient access to advanced wound treatments centers largely on insurance reimbursement for application and use. Unfortunately, this lack of access likely affects the most disadvantaged and marginalized patient populations disproportionately (ie, uninsured, underinsured, Medicaid, etc). The ideal path forward in advanced wound care is with a sensible treatment plan that offers greater value, that is, optimized clinical effectiveness with minimized costs. The BBGF technology was developed to meet this new wound care paradigm.

The utility of BGs in orthopedic and dental applications has been well studied and spans 40 years.[1,6,7] Since their discovery by Hench et al in 1971, they have been used in dental applications for small bone implants, to coat orthopedic implants, to fill bone defects, and as a therapeutic delivery system for inoperable liver cancer.[6,7] Recent interest in the use of BGs in soft tissues has developed as a result of their intrinsic regenerative and angiogenic effects.[6] Whereas many CTPs and synthetic scaffolds attempt to deliver angiogenic growth factors (ie, vascular endothelial growth factor and basic fibroblast growth factor) and extracellular matrix proteins topically, BGs promote angiogenesis by their own degradation, namely, the release of stimulating bioactive ions as the glass is absorbed in the presence of physiologic fluids. This pathway is appealing because the duration and efficiency of growth factor release are better controlled and tied directly to the known chemical degradation process of the material itself.[6] Although the use of BGs as angiogenic agents in tissue engineering is still in its infancy, this angiogenic potential is appealing for wound healing and soft tissue repair.[6]

In addition to angiogenesis stimulation, BGs have biostimulatory properties that positively impact all four phases of the healing cascade. For instance, BGs have been shown to stimulate rapid hemostasis, likely related to an increase in calcium ion availability at the wound site through dissolution of the glass fiber, as well as the microstructure of the fiber itself, which closely mimics the microstructure of fibrin clots. Further, BGs effectively modulate the inflammatory response such that the initial reaction is reduced and controlled, and are proven to increase healing with a less inflammatory scar.[6,7]

These positive wound healing effects have been demonstrated in a recent preclinical small-scale human study of BBGF use for the treatment of chronic wounds in patients with multiple comorbidities. In this study, BBGF was used to treat chronic wounds in multiple patients with diabetes who had failed numerous prior wound treatments.[7] The results of this study revealed accelerated healing with a significant decrease in scar tissue formation compared with conventional wound treatments. The dramatic results observed in this study further solidified the hypothesis that BBGF treatment offers wound healing without the need for lengthy

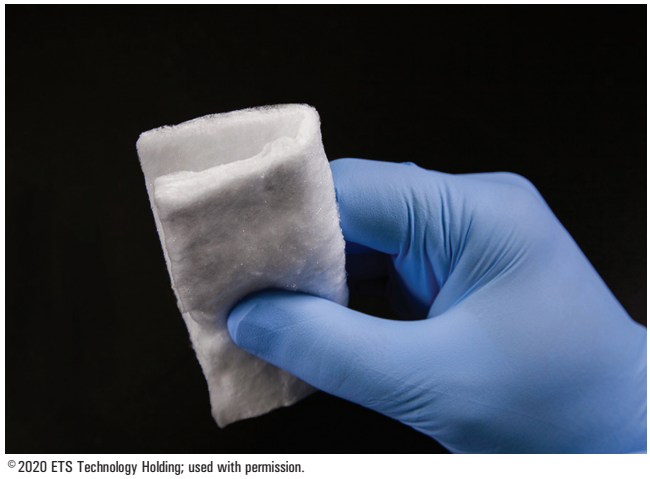
hospital stays or expensive equipment. The success of these initial trials also led to expanded use of BBGF for limb salvage.[6,7]

In addition, BGs are antimicrobial and disrupt biofilm.[8,9] As with their angiogenic properties, many new CTPs synthetically introduce antimicrobial properties within or onto their scaffolds and matrices; although this can eliminate bacteria and biofilm, this process increases the cost of the product and may lead to allergic reactions or bacterial resistance. In contrast, the BBGF advanced wound matrix allows for the controlled release of boron, a known antimicrobial ion, directly at the wound interface.[8,9] This property is intrinsic to the material and its natural biodegradation, offering the benefits of bacterial elimination without the increased cost of "attaching" these properties ad hoc.

The BBGF provides all of the benefits of BGs in an easy-to-apply fiber dressing. It comes in a sterile package and conforms easily to any wound geometry, including wounds with tunneling or undermining (Figure 3). Because the physiologic wound healing benefits come as a result of the properties of the glass and fiber structure itself, the cost is extremely low compared with the deliverable effects.

The results of this case series nicely illustrate the significant value of BBGF use in wound care. In these four challenging cases, all patients had significant comorbidities that can alter the wound healing milieu. Likewise, they all failed multiple prior treatments. As a result, the average patient in this series had been living with a wound for more than 1 year (391 days). In addition to the incredible costs associated with managing these wounds during that time, the physical and emotional toll of these wounds and their respective treatments on the patient's quality of life cannot be overstated.

Figure 3. ADVANCED WOUND MATRIX



After initiation of BBGF, all wounds healed in an average of 56 days. In this series, had BBGF been employed at initial wound presentation with the same healing results, the hypothetical reduction in average cost of care is $84,186 per patient, with an average reduction in wound duration by 336 days. It is safe to say that the effects of these outcomes on patient quality of life would have been notable as well. In addition to the purely economic benefits and the ability to treat patients in an outpatient setting, the BBGF can improve key healthcare performance indicators such as readmission and hospital length of stay through mitigation and prevention of treatment complications and/or accessibility issues with expensive or cumbersome wound devices.

Based on the known and observed benefits of BBGF, it could benefit many types of wounds. Further, the intervention is safe to use without concern for complications, or allergic reactions. To date, there have been no reported complications or allergic reactions directly associated with BG use. For other products on the market to provide similar benefits in one product, they require the addition or synthesis of expensive growth factors, antimicrobials, and hemostatic factors, or the hassles of tubing, vacuum seals, and external battery packs. In these cases, the add-on benefits result in incremental cost increases.

Limitations

The limitations of this study are similar to those of any other small case series. In addition, it would be naive to expect a 100% success rate for any intervention in the advanced wound care space, including BBGF, given the complexity of these patients. That said, the results of this series, along with preclinical data, suggest that BBGF has a success rate that exceeds the commonly reported industry standard of 50% to 70% of wounds healed; further, it could facilitate an earlier transfer of wound care patients into outpatient care, reduce healthcare costs, and improve quality of life.

Last, the term "cost" can have many definitions and interpretations. This study estimated the costs of prior treatments using Current Procedural Terminology codes and published costs associated with inpatient/outpatient sites of care, as well as published data regarding product costs. Therefore, the estimated costs of treatment included here are just that—estimates.

Although the results of this study are promising, it is important that additional research be performed in routine chronic wound patients to better elucidate the performance of BBGF and its associated cost-effectiveness in a prospective or randomized controlled trial. This would lessen confounding variables, and cost data can be recorded more accurately through a prospective approach. Likewise, with at least two treatment cohorts,

direct product comparisons would be more reliable. The author is hopeful that the results of this initial study will motivate other interested researchers to evaluate BBGF in their own practices.

CONCLUSIONS

Based on the physiologic properties of BGs at the wound interface, this innovative BBGF advanced wound matrix accelerates healing while minimizing the costs of care and improving outcomes. Although this study included only a small series of patients, the potential cost reductions and reduced wound durations cannot be ignored. Further studies on BBGF matrix use for wound management are warranted and will further elucidate the role of this new technology in a growing wound care market. ●

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