AccuFuse™
Bioactive Putty

Bone fusion ability with a novel bone graft substitute, bioactive glass collagen-based carbon apatite

In posterolateral lumbar fusion, damaged or unstable vertebrae are fused together so that they heal into a single, stable vertebral segment. This procedure can help reduce pain, since the repaired vertebrae are no longer compressing nearby nerves[1].

Clinical data has been collected for 15 patients who have undergone a spinal fusion using a bioactive glass – collagen-based bone graft. The scope of the assessment evaluated patients' bony fusion and pain scale after 1 year.

Bone graft technology background

Autologous bone has long been used as the standard for bone graft substitutes in spinal fusion procedures. A limited supply and risks of morbidity prompted the development of alternative bone grafts made with biologics such as silicate-based bioactive glasses, which bond with living bone tissue. These bioactive glasses have a history of biomedical use and an ability to facilitate mineral deposition in vitro[2,3].

Tissue engineering developed 3D scaffold biomaterials to promote bone regeneration. These materials are studied for their biocompatibility and research into these materials focuses on the growth of cells into a scaffold and the establishment of a 3D cell structure[4].

A novel bioactive glass collagen anorganic bone composite (hereafter referred to as BGS) has been developed to utilize the surface conductivity of bioactive glass and minimize the use of autologous graft.

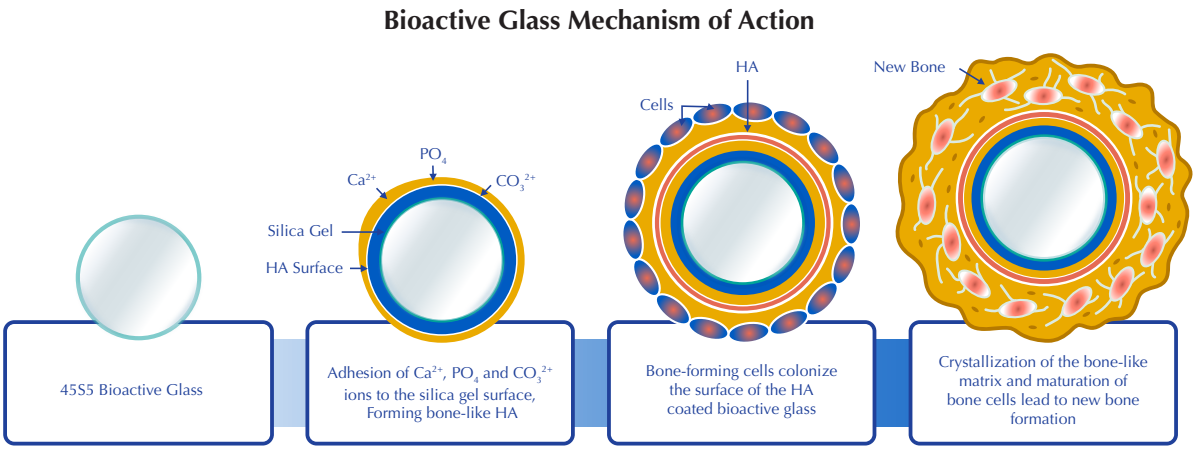
A novel bone graft substitute

BGS includes a careful ratio of three key components: 30% 45S5 bioactive glass, 20% bovine Type I collagen and 50% carbonate apatite bovine anorganic bone mineral.

The bioactive glass promotes cells attraction to the site and starts forming a bond with bone through this sequence[5]:

1. Alkali ions exchange with hydrogen ions from body fluids
2. The surface attracts ions to start forming various bonds
   - Silanol bonds (SiOH) bonds
   - Silica-gel: SiOH + SiOH → Si–O–Si
   - Calcium, phosphocarbonate bonds; Ca + PO_4 + CO_3
3. The surface crystallizes into an HCA (HA; hydroxycarbonapatite) layer
4. The calcium-deficient carbonated apatite (HCA) layer now attracts and allows for biochemical adsorption of growth factors
5. Macrophages activity
6. Stem Cells attach and differentiate
7. The matrix starts to generate and is then crystallized
8. Finally, there is bone growth and proliferation

Figure 1: *Summary of Bioactive glass mechanism of action*



Study purpose

This BGS incorporates carbonate apatite which has a natural mineral structure and crystallinity similar to human bone[4]. The material resorption profile of this BGS is evaluated in this study to derive clinical evidence to support pre-clinical data. This clinical study is an assessment of the bony fusion and pain remission in posterolateral instrumented lumbar fusion in the posterolateral gutters.

Study methodology

A retrospective study examining the performance of this BGS in instrumented lumbar fusion for 15 patients over one year, collecting data for pain remission and bony fusion.

Patient population:

- 15 adults, 60% female and 40% male, with degenerative disc disease. All 15 patients had already tried non-surgical treatments for at least six months, without success. These patients underwent posterolateral instrumented lumbar fusion using BGS in the posterolateral gutter.

Procedure:

- Transforaminal lumbar interbody fusion with posterolateral fusion.
- This included a discectomy and interbody fusion, using an expandable cage.

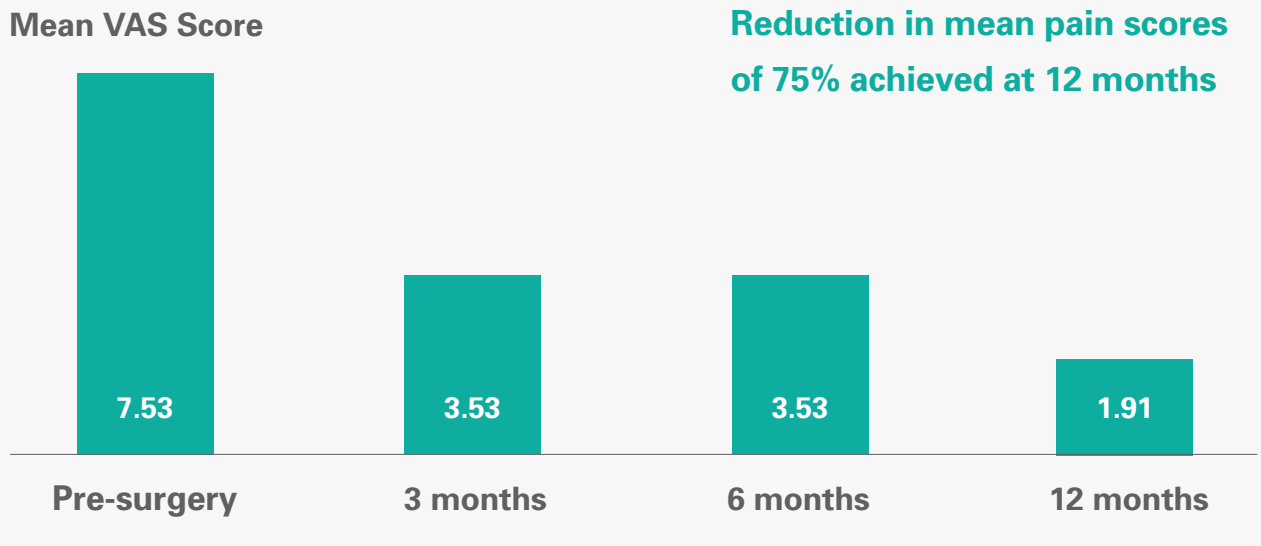
Materials:

- The procedure combined locally harvested autologous laminectomy bone with the BGS.
- 10 cc strip was divided length wise, 5cc of the strip combined with 5cc of.
- The strips were also hydrated with bone marrow aspirate.
- The strips were then placed in both sides of the posterolateral gutters.
- Finally, a pedicle screw system secured the incision.

Results

Twelve months after surgery, 92% of patients had Grade A spine fusion, visible by X-ray. This is defined as results that are "definitely solid with bilateral stout fusion masses present," using the Lenke classification. The patients' average visual analogue scale (VAS) pain score was 1.91 one year after surgery, compared to an average score of 7.53 before the surgery – see figure 2.

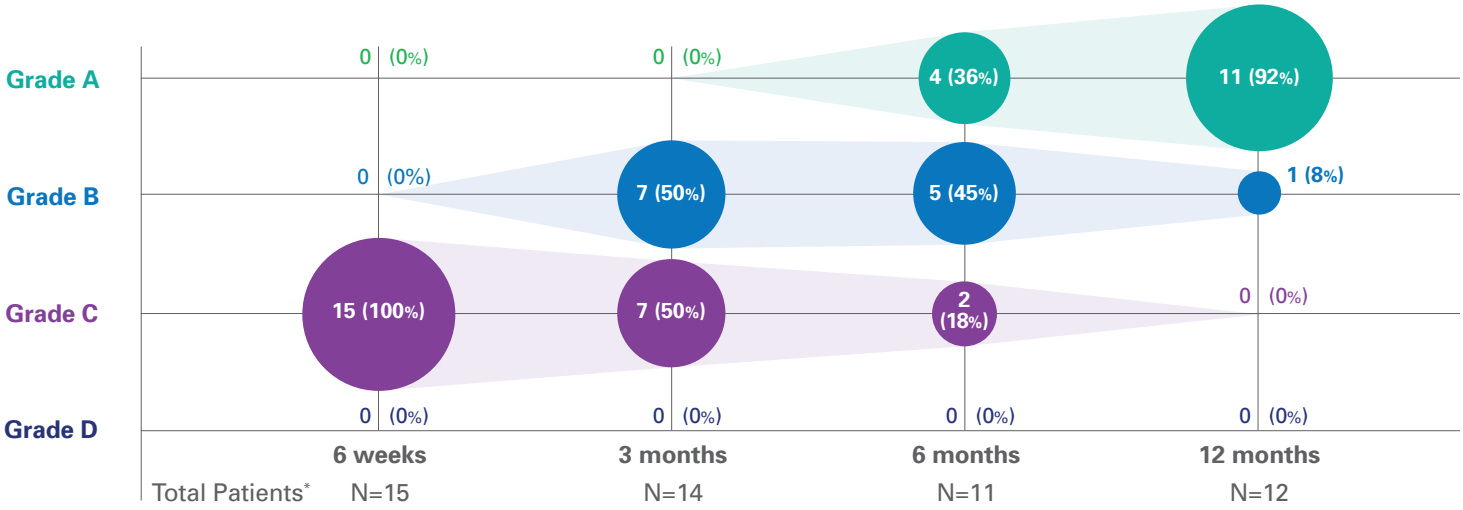
Figure 2: *Evaluation of pain with BGS in retrospective clinical case series*



Overall, the patients reported significant improvement in both leg and back pain after the decompression. These results correlated with X-ray images of the patients during follow-up, which showed signs of a strong bony posterolateral fusion. In 12 months after the procedure, many patients did not return for later follow-up visits because they were doing well enough to think it was not necessary – see figure 3.

Evidenced by the BGS radiopacity, the results from this retrospective clinical case series suggests that BGS promotes strong, obvious bone growth that helps providers track their patients' healing process more easily through x-rays.

Figure 3: *Evaluation of spine fusion with BGS in retrospective clinical case series*



X-ray Radiographs are scored using Lenke's classification of posterolateral fusion success

Grade A: Definitely solid with bilateral stout fusion masses present
Grade B: Possibly solid with a unilateral large fusion mass and a contralateral small fusion mass
Grade C: Probably not solid with a small fusion mass bilaterally
Grade D: Definitely not solid with bone graft resorption or obvious pseudarthrosis bilaterally

*Patients who declined excluded from the percentage (four subjects at 6 months follow-up and three subjects at 12 months follow-up

Conclusion

With the prevalence of spinal injuries and degeneration, there is a significant need for effective materials that encourage positive surgical outcomes. As this BGS is shelf-stable, rather than frozen, it is ready to use out of the packaging after hydrating in the package in a 1:1 ratio. The unique combination of materials helps create a bone graft matrix that provides a reliable scaffold that becomes replaced by new bone tissue over a normal physiologic time period.

The experiences of physicians and patients demonstrate that the bioactive glass collagen-based carbon apatite bone graft substitute (BGS) evaluated in this study, is effective for lumbar fusion procedures. The BGS's unique composition gives physicians a flexible material that encourages x-ray visibility and precision, while offering patients pain relief.

References

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