Clinical Experience and Prospective Study: Bone Graft Substitute BoneSync™ BioActive Bone Void Filler in Posterolateral Instrumented Lumbar Fusion

Study Summary

This paper summarizes findings from Regenity report CER.021.024.072 and CIR.072.

Introduction

Posterolateral lumbar fusion is a surgical procedure used to correct problems with the lumbar series of vertebrae in the spine. The problematic vertebrae are identified and fused together to create a single, stable vertebral segment. When movement or deterioration of certain vertebral segments is contributing to nerve compression and discomfort, fusion of these segments can stabilize the bone, alleviating the source of pain.[1] To promote fusion, surgeons employ bone graft materials as an integral part of these spinal procedures. Recent research has helped optimize these materials for improved patient outcomes.

Advances in Bone Graft Materials

Autologous bone has long been a relied-upon bone graft substitute for spinal fusion procedures. However, the limited supply and donor-site morbidity associated with using autologous graft material led to the development of alternative biologics, including silicate-based bioactive glasses, which can create a strong bond with living bone tissue. Bioactive glasses have a long history of biomedical use and have been shown to facilitate mineral deposition in vitro.[2,3] BoneSync BioActive bone void filler is a uniformly distributed combination of three components: 30% 45S5 bioactive glass, 20% bovine type I collagen, and 50% bovine anorganic bone mineral. When combined, they provide an optimal scaffold to support the body's natural ability to regenerate new bone.

The resorption and remodeling profiles of BoneSync BioActive bone graft matrix are more similar to normal human bone than those of synthetic materials typically used in collagen bone graft matrices, such as beta-tricalcium phosphate (β-TCP) or hydroxyapatite.[4] β -TCP typically resorbs away rapidly, while hydroxyapatite is very slow to resorb. Current collagen–mineral-based composites on the market may attempt to mimic a balanced resorption profile by incorporating a combination of the two synthetic mineral components along with either a collagen or different carrier. Unlike other biologic solutions, BoneSync BioActive bone graft matrix incorporates carbonate apatite bone mineral, which has a natural mineral structure similar to human bone mineral. An organic carbonate apatite bone mineral has a balanced resorption profile when compared to synthetics like β-TCP and hydroxyapatite.[4,5]

Real-World Experience

A 20-patient prospective study was conducted to assess bony fusion, pain remission, and quality of life with use of BoneSync BioActive bone graft matrix in posterolateral instrumented lumbar fusion. The patients were 18 years of age or older, 50% female and 50% male, with a diagnosis of degenerative disc disease, who had failed to respond to nonoperative treatment for at least 6 months. The patients underwent posterolateral instrumented lumbar fusion procedures that incorporated BoneSync BioActive bone graft matrix in the posterolateral gutter.

Table 1. Prospective study patient sample (N = 20)

Age Range	Patients	Percentage
41-50	2	10%
51-60	2	10%
61-70	6	30%
71+	10	50%

Sex	Patients	Percentage
Female	10	50%
Male	10	50%

Surgical Technique

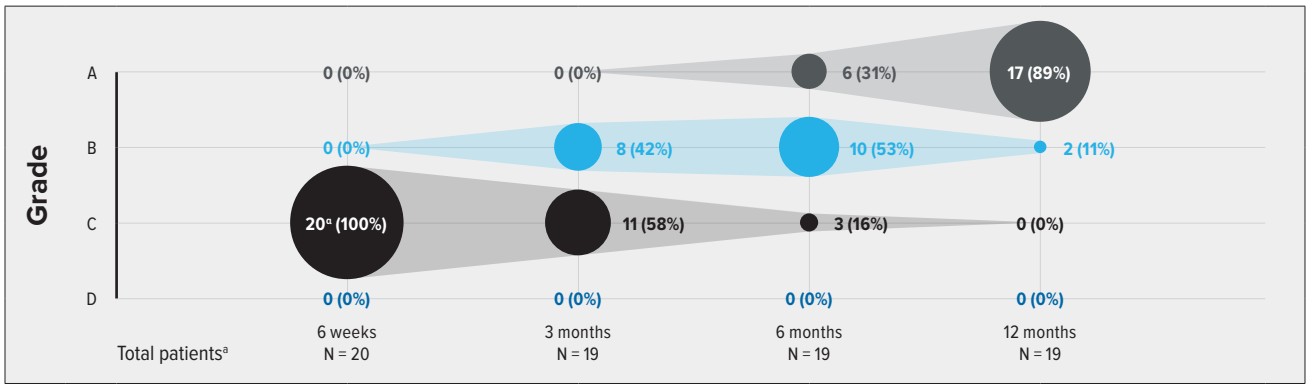
Single-level transforaminal lumbar interbody fusion with posterolateral fusion included:

- 7 cm incision
- Lamina and facet joints exposed bilaterally
- Inferior lamina taken down from pars to pars
- Neural elements decompressed
- Discectomy and interbody fusion using an expandable cage
- Locally harvested autologous laminectomy bone combined with BoneSync™ BioActive strips placed in the posterolateral gutters bilaterally
- Pedicle screw system placed through the midline incision

Patient Outcomes

At 12 months, grade A spine fusion was visible in 89% of patients and mean visual analog scale (VAS) pain score was 9.5, compared to 65.9 preoperatively. Smokers had lower fusion rates, which is to be expected. Researchers concluded that VAS scores, Oswestry Disability Index (ODI) scores, and Short Form Health Survey 36 (SF-36) scores were in line with improvements in quality of life, which is the goal of the surgery.

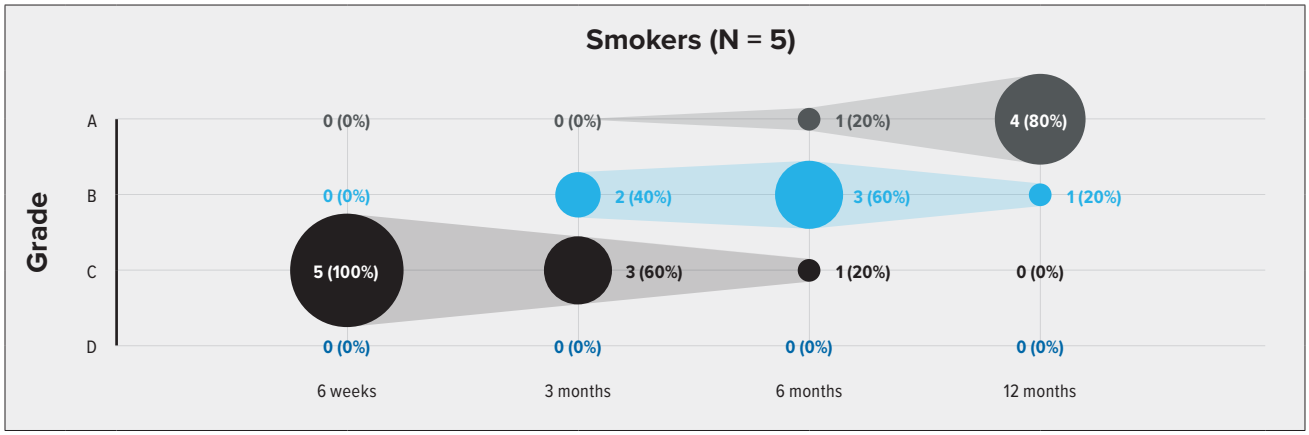
Figure 1. Evaluation of spine fusion



Grade A spine fusion was achieved in 89% of patients at 12 months.

[a] One patient missed their 3-month follow-up appointment, but attended at 6 and 12 months. Another patient was lost to follow-up at 6 months and 12 months.

Figure 2: Evaluation of spine fusion by smoking status



Grade A: Definitely solid with bilateral trabeculated 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

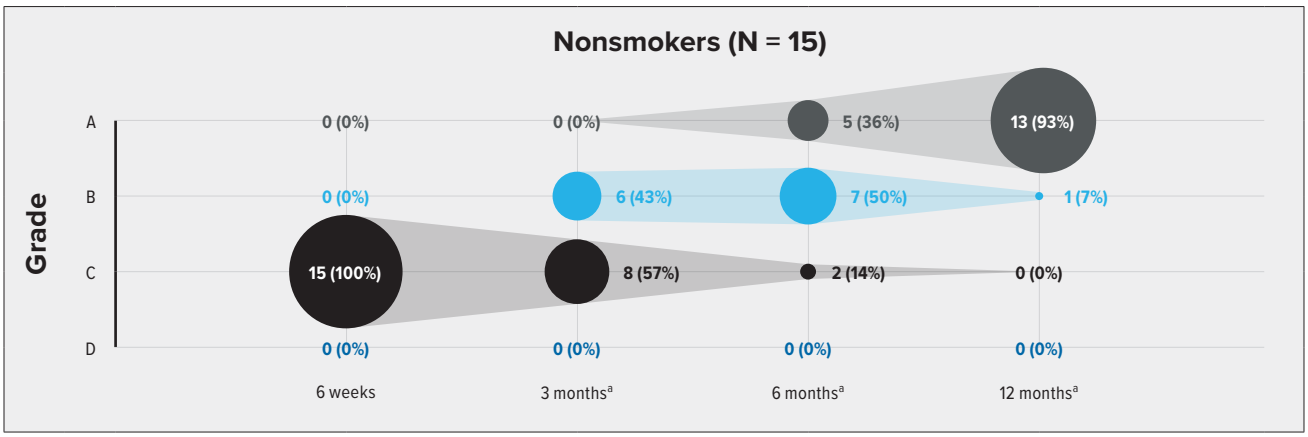


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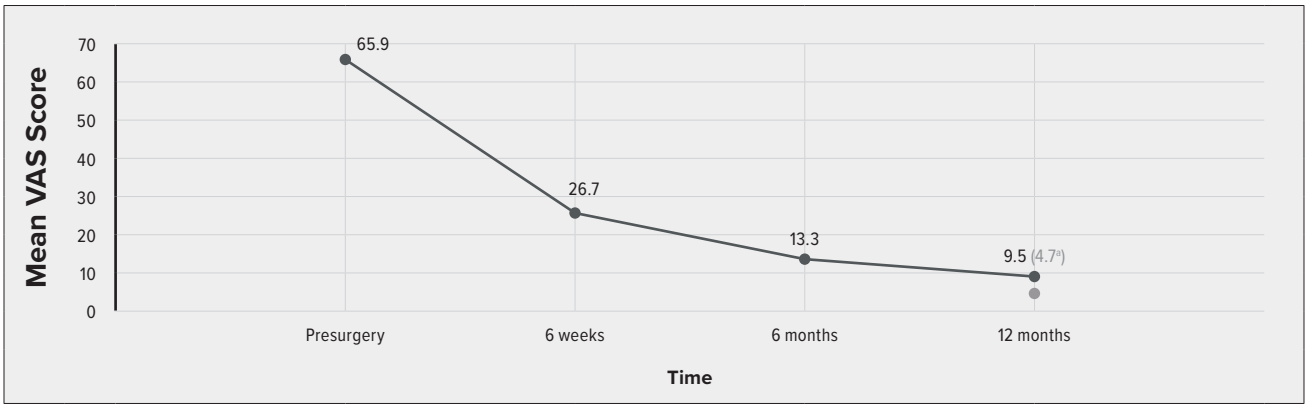
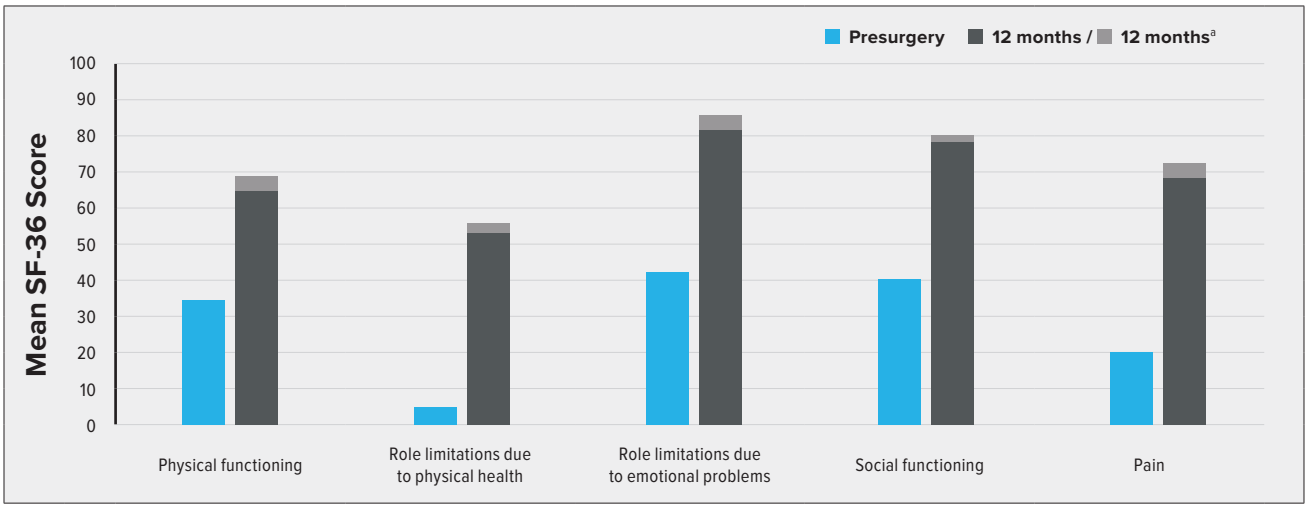
Figure 3. Evaluation of pain



Reduction in mean pain scores of 85% achieved at 12 months.

Figure 4. Evaluation of quality of life



[a] Outlier in secondary clinical outcome measures affects the total score at 12 months; one patient had multiple comorbidities and a second intervention not at the initially surgically treated level.

Figure 5. Comparative AP x-ray radiographs of patient #7 at 3 months **(a)**, 6 months **(b)**, and 12 months **(c)** following L4-L5, L5-S1 posterolateral fusion. There is notable progression of posterolateral bony fusion over the 12-month period with robust solid posterolateral bony fusion at 12 months.

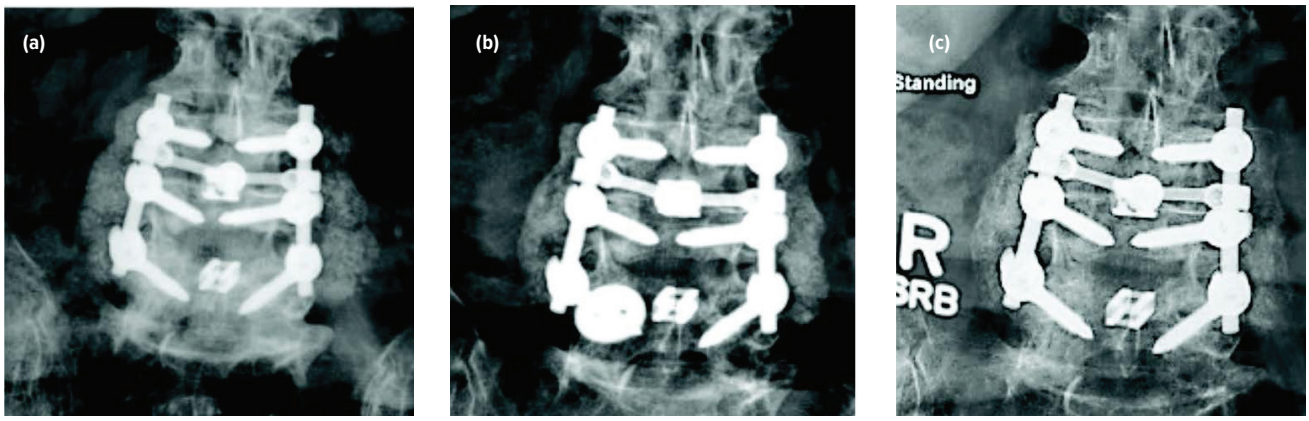
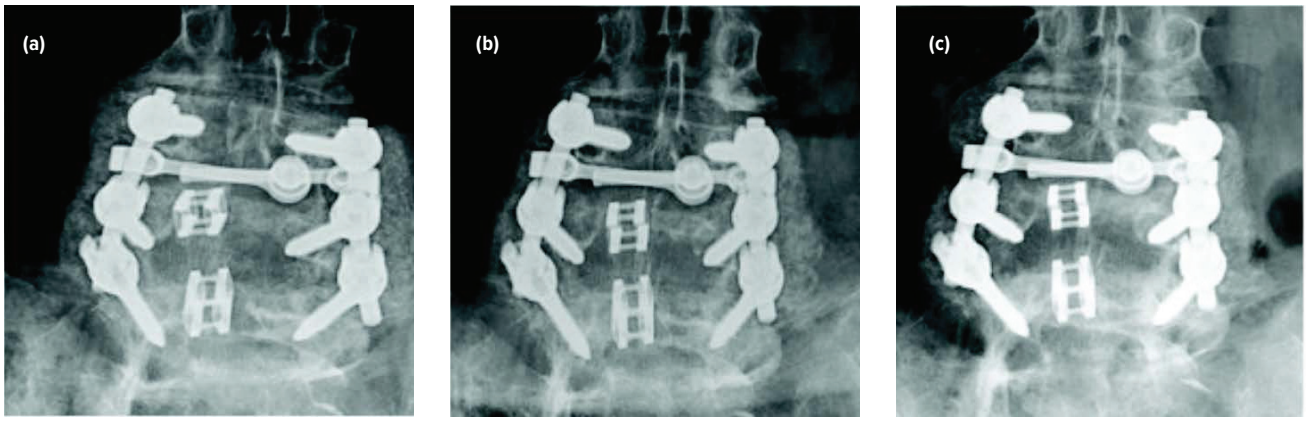


Figure 6. Comparative AP X-ray radiographs of patient #15 at 3 months **(a)**, 6 months **(b)**, and 12 months **(c)** following L4-L5, L5-S1 posterolateral fusion. There is notable progression of posterolateral bony fusion over the 12-month period with robust solid posterolateral bony fusion at 12 months.



Conclusion

Patients who underwent posterolateral instrumented lumbar fusion using BoneSync™ BioActive strips achieved significant spine fusion and pain reduction and improved quality of life. Grade A spine fusion was visible in 89% of patients and mean VAS pain score was 9.5, compared to 65.9 preoperatively.

References

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