Regenity

A Material Difference

Clinical Experience and Prospective Study: OssiMend® Bioactive Moldable in posterolateral instrumented lumbar fusion

Posterolateral lumbar fusion is a surgical procedure used to correct problems with the series of vertebrae that make up 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 the gold standard for bone graft substitute in 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]

To take advantage of the surface bioactivity of bioactive glass and minimize the use of autologous graft, Regenity Biosciences developed a bioactive glass collagen anorganic bone composite, OssiMend® Bioactive Moldable Bone Graft Matrix (OssiMend BA). The product 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 OssiMend BA 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-resorbing. 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 other carrier. Unlike other biologic solutions, OssiMend BA incorporates carbonate apatite bone mineral, which has a natural mineral structure similar to human bone mineral. Anorganic carbonate apatite bone mineral has a balanced resorption profile when compared to synthetics like β-TCP and hydroxyapatite.[4,5]

Making the switch

Carmina F. Angeles, M.D., PhD., a board-certified neurosurgeon, specializes in adult degenerative disc diseases and performs approximately 140 lumbar spinal fusions each year. Dr. Angeles has used some form of biologics since the beginning of her practice 14 years ago. As bone graft materials became more advanced, Dr. Angeles began researching options. She switched to OssiMend BA, a bone graft substitute with better handling properties that could also promote growth.

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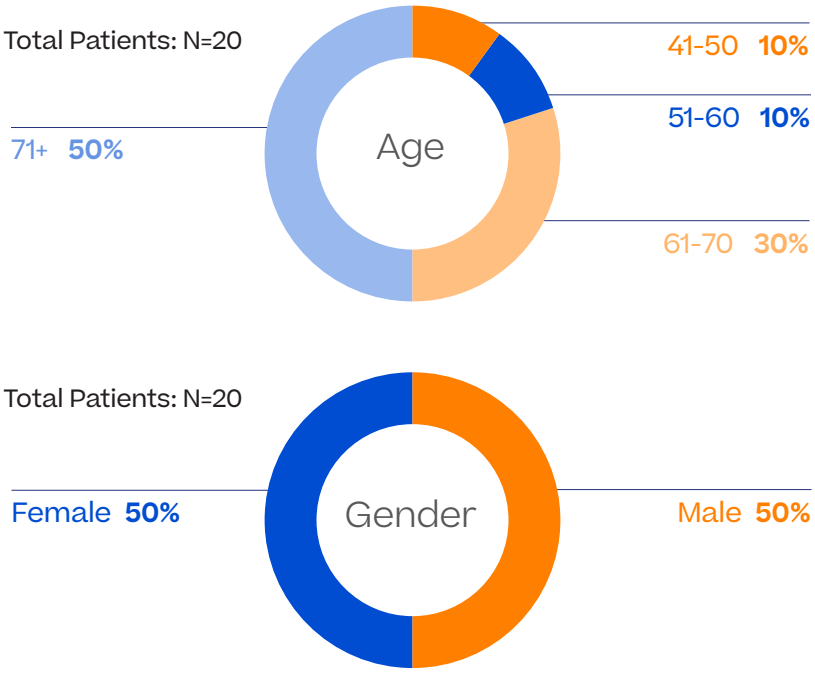
Dr. Angeles has been using OssiMend BA since 2020. She says it is a softer material that is easier to mold in the posterolateral gutters. “It is fairly soft and compressible, so it has better handling, which is especially important if I’m placing it near a nerve root,” she explained.

“I’ve always believed that to get a good fusion, you need a combination of different elements. What I like about OssiMend BA is that it brings together osteoinductive, osteoconductive and osteogenic components to achieve bony fusion—the mineral, which is bioglass, carbonate apatite and Type I collagen. Furthermore, the bone graft matrix is resorbed over a normal physiologic time frame and replaced by new bone tissue during the natural healing process,” reported Dr. Angeles.

Figure 1: *Prospective Study Patient Sample*

OssiMend BA Prospective Bone Graft Matrix Clinical Case Series



Real-world experience

To present assessment of bony fusion, pain remission and quality of life with use of OssiMend BA in posterolateral instrumented lumbar fusion, Dr. Angeles conducted a prospective study. The study comprised 20 patients 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 six months. The patients underwent posterolateral instrumented lumbar fusion incorporating OssiMend BA in the posterolateral gutter.

Surgical technique

Single-level transforaminal lumbar interbody fusion with posterolateral fusion:

- 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 OssiMend BA 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 VAS* pain score was 9.5, compared to 65.9 pre-operatively. Smokers had lower fusion rates, which is to be expected. “The VAS scores, ODI* scores and SF36* scores are in line with improvement in quality of life, which is the goal of the surgery,” says Dr. Angeles.

“The lumbar fusion surgery addresses a combination of low back and leg symptoms or pain. The biggest motivating factors are pain, loss of function and impact on social environment,” says Dr. Angeles. After surgery, “patients say they got their life back.”

*See page 5 for definition.

User-friendly features

The strip form of OssiMend BA has a unique two-in-one feature. It can be used as a strip or molded into another shape. Dr. Angeles uses it as a strip for a one-level posterolateral lumbar fusion.

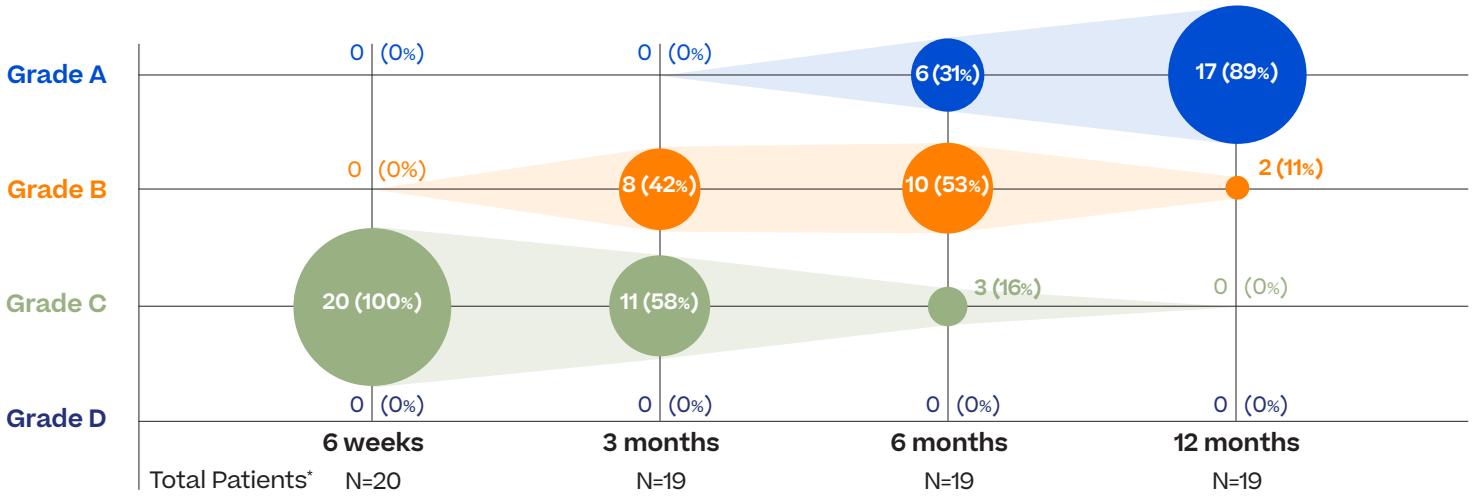
"I use the 10-cc strip and divide it lengthwise. Five cc of the strip is combined with 5 cc of autologous bone and placed in the gutter," she explains. In addition to mixing autologous bone, she also hydrates the strip with bone marrow aspirate. When total facet joint excision is not necessary, Dr. Angeles molds the bone graft and fits it right into the facet joint. In addition to the strip form, OssiMend BA is available in a puck form, similarly ideal for molding.

"It has good handling capability, especially the moldable putty," says Dr. Angeles. "The product is consistent, and the quality continues to be exceptional. It's spongy enough that it can absorb and hold onto the bone marrow aspirate. It's easy to use, it molds and it can hold the shape."

Figure 2: ***Evaluation of Spine Fusion – All Patients***

OssiMend BA Prospective Bone Graft Matrix Clinical Case Series

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



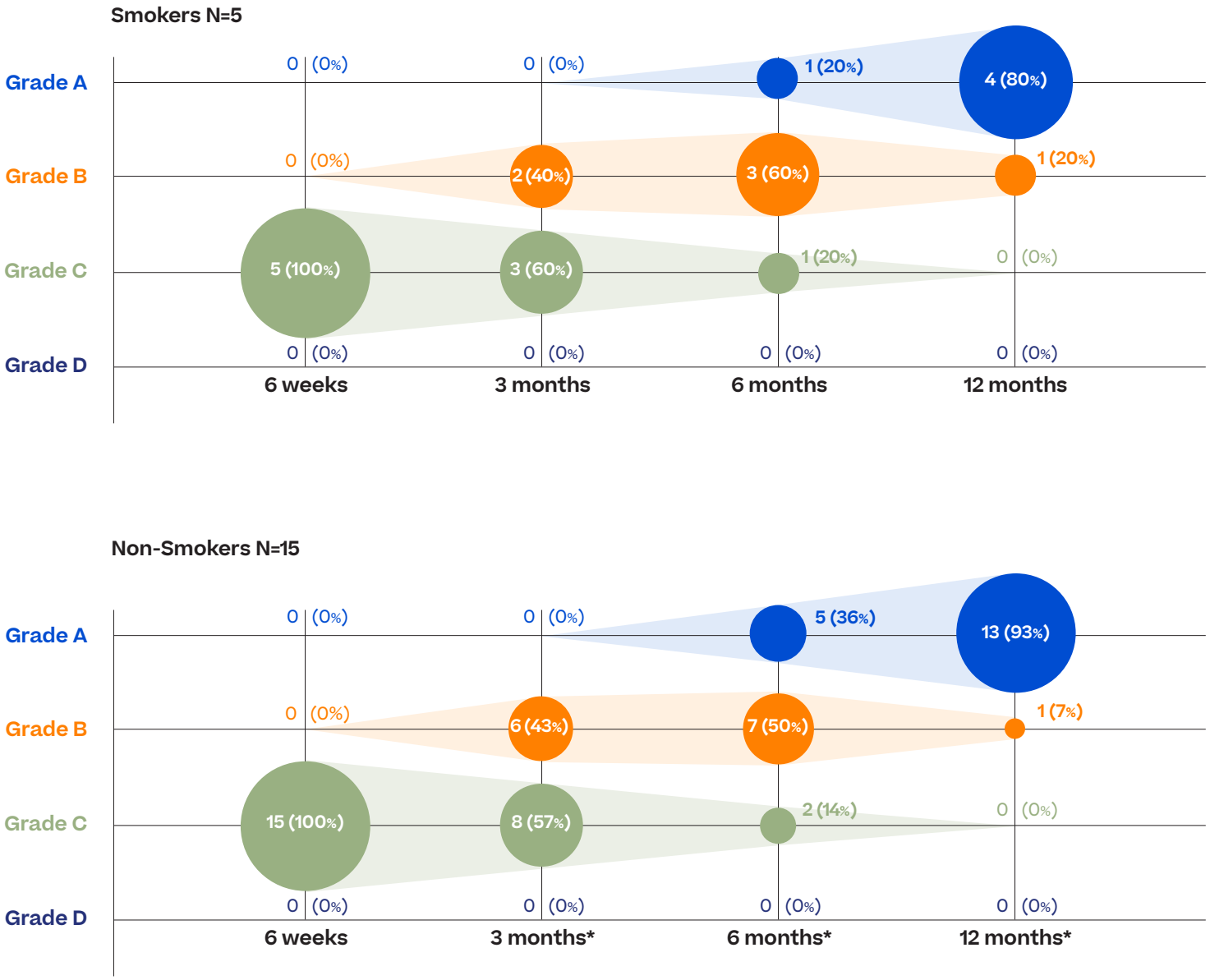
Radiographs are scored using Lenke's classification of posterolateral fusion success

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

*One patient missed the 3 months appointment, but attended the 6 and 12 months appointments. Another patient was lost to follow-up at 6 months and 12 months.

Figure 3: *Evaluation of Spine Fusion by Smoking Status*

OssiMend BA Prospective Bone Graft Matrix Clinical Case Series



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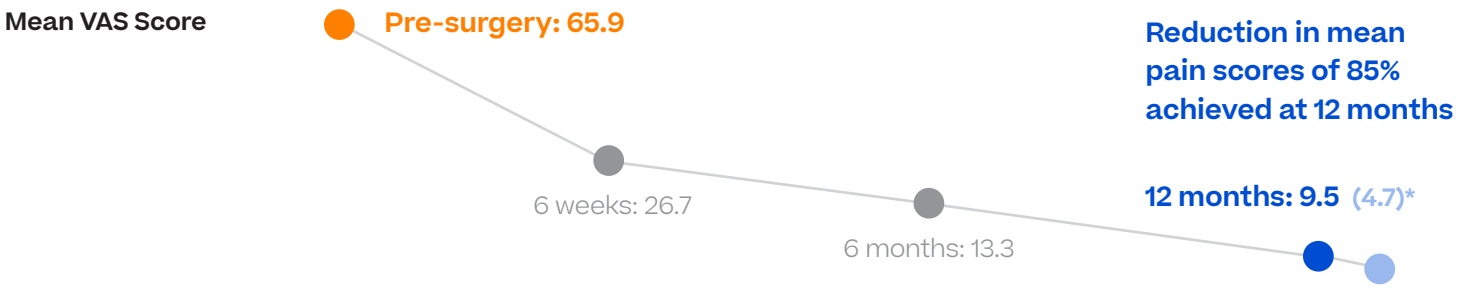
Visual Analog Scale (VAS) is a measure of pain intensity, used to record patients' pain progression, or compare pain severity between patients with similar conditions. This decreases as quality of life improves.

The Short Form (36) Health survey (SF36) is a 36-item patient reported survey of patient health. This score increases as quality of life improves.

The Oswestry Disability Index (ODI) is a 10-item score from 0 to 100 that encompasses limitations in activity, sleeping, social life, work, and personal care resulting from low back pain. Higher scores indicate more severe disability. This decreases as quality of life improves.

Figure 4: *Evaluation of Pain*

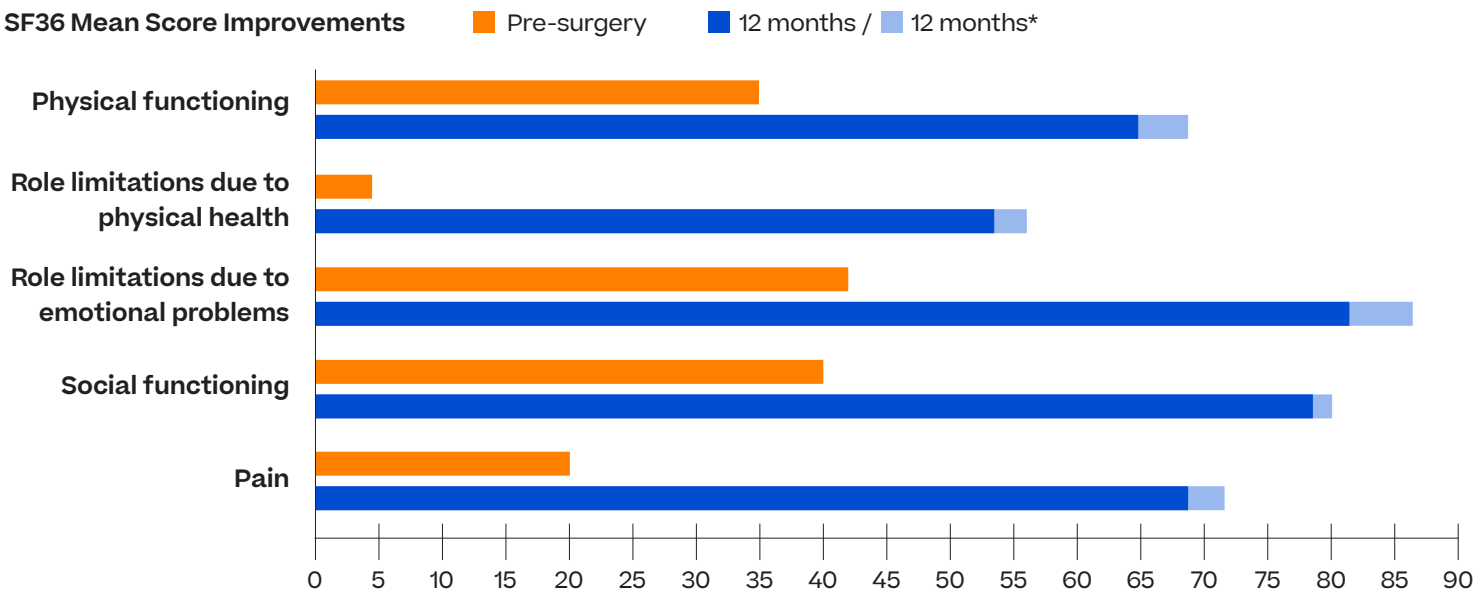
OssiMend BA Prospective Bone Graft Matrix Clinical Case Series



*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: *Evaluation of Quality of Life*

OssiMend BA Prospective Bone Graft Matrix Clinical Case Series



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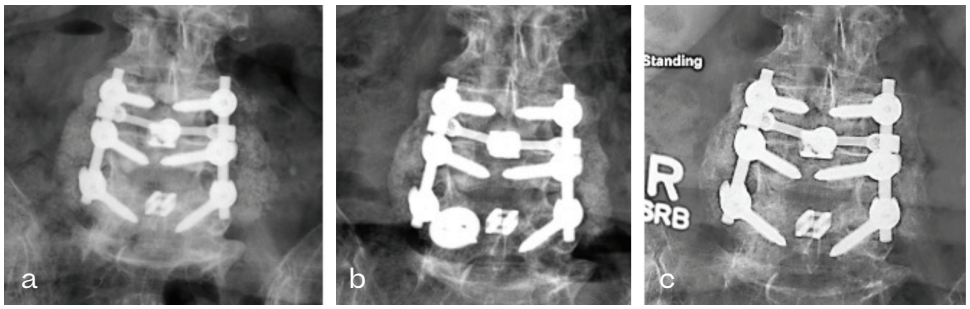

Figure 6-a,b,c: Comparative AP X-ray radiographs of patient #7 at 3 months (a), 6 months (b), and 12 months (c) following L4-5, L5-S1 posterolateral fusion. There is notable progression of posterolateral bony fusion over the 12-month period with robust solid posterolateral bony fusion at 12 months.

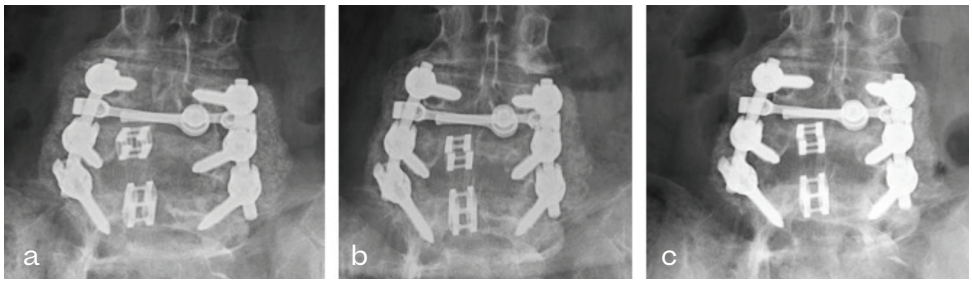

Figure 7-a,b,c: Comparative AP X-ray radiographs of patient #15 at 3 months (a), 6 months (b), and 12 months (c) following L4-5, L5-S1 posterolateral fusion. There is notable progression of posterolateral bony fusion over the 12-month period with robust solid posterolateral bony fusion at 12 months.

Comparing OssiMend BA with other materials

"I can assess the posterolateral fusion more easily on X-rays than with other products," says Dr. Angeles.

"Progression of bony fusion is much better visualized with OssiMend than other bone graft substitutes. The amount of posterolateral fusion material that is seen on X-rays is progressively robust at each time point, and particularly robust-appearing at 12 months, compared to other products. I think the patients tend to heal faster because a lot of them achieve bony fusion sooner."

"Some biologics are quite difficult to assess on X-rays and require a CAT scan to confirm bony fusion. But OssiMend BA is different. A CAT scan is not necessary because solid bony posterolateral fusion is well visualized on X-rays. And, if fusion in any patient was unclear on X-ray, the CAT scans confirmed posterolateral solid fusions."

Conclusion

Patients undergoing posterolateral instrumented lumbar fusion using the OssiMend BA strip 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 pre-operatively.

"My results have been exceptionally good in terms of fusion rates since I started using OssiMend BA. I'm able to replicate good results using the same techniques and the same product," says Dr. Angeles. "Since I started using OssiMend BA, my general impression is that patients do better and are able to get back to normal activities sooner."

Based on the results of this study, Dr. Angeles plans to continue using OssiMend BA. Dr. Angeles expects the see the similar results from other research sites of this multi-center study.

References

1. American Academy of Orthopaedic Surgeons. "Posterolateral Lumbar Fusion." *OrthoInfo,* https://orthoinfo.aaos.org/en/treatment/posterolateral-lumbar-fusion/. Accessed 5 May 2022.
2. Hench, L.L., *J Mater Sci:* Mater Med (2006) 17: 967-978.
3. Xynos, I.D., A. J. Edgar, et al. (2000). *Biochem Biophys Res Commun* 276(2): 461-465
4. Ellies, LG., Carter, J.M., Natiella, J.R., Featherstone, J.D.B., Nelson, D.G.A. (1988). Quantitative analysis of early in vivo tissue response to synthetic apatite implants. *J. of Biomed. Mater. Res.,* 22, 137-148.
5. Matsuura, A., Kubo, T., Doi K., Hayashi, K., Morita, K., Yokota, R., Hayashi, H., Hirata, I., Okazaki, M., Akagawa, Y. (2009). Bone formation ability of carbonate apatite-collagen scaffolds with different carbonate contents. *Dental Materials Journal,* 28(2), 234-242.

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