Cervical Fusion Using PliaFX® Prime Moldable Demineralized Fibers

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CASE STUDY

Degeneration of the discs and instability in the cervical spine can result in neck pain and radiculopathy causing pain, numbness, or weakness in the chest or arms.[1] If conservative treatment options fail to relieve pain and disability, cervical fusion is a surgical option to address these issues. Autograft harvested from a second surgery site on the patient may be used to support fusion, but it is associated with drawbacks such as donor-site pain, increased infection risk, and increased operating room time.[2] Demineralized allograft bone is an alternative which addresses the risks associated with autograft while still providing an osteoconductive scaffold with osteoinductive potential to support new bone growth and fusion.

LifeNet Health developed PliaFX Prime to provide optimized handling capabilities, undiluted osteoinductive potential, and a hospitable scaffold and void filler for cellular attachment[3-10] — all using 100% allograft bone fibers without synthetic or xenograft carriers. These long, interconnected cortical bone fibers are optimally demineralized using LifeNet Health's patented PAD® technology and provide a surface that is rough enough to promote cellular attachment, yet contiguous enough to promote cell spreading and intercellular connection. The superior handling of PliaFX Prime comes from the length and width of the fibers, which are designed to promote malleability, while microhooks allow the fibers to interlock, thereby maintaining the graft's shape and ensuring retention at the implant site.

The following case describes the use of PliaFX Prime in cervical fusion.

Patient

- 51-year-old female patient with a BMI of 29 kg/m^2
- Cervical spondylolisthesis, foraminal stenosis, and adult spinal deformity (Figures 1, 2)
- Patient experienced degenerative symptoms for 7 years
- Patient was taking anti-seizure/mood-altering, blood pressure, diuretic, and pain medications concomitantly
- Previous surgical history of ACDF at C5-6

Procedure

- Two levels (C2 and C3) were treated using the Synthes Symphony™ Spine System
- 10 cc PliaFX Prime was mixed with approximately 1.1 cc local autograft (9:1)

Results

- Fusion was assessed radiologically at 6, 12 (Figure 3), and 24 (Figure 4) weeks postoperative

Conclusion

- All levels were successfully fused at 6 months postoperative (Figure 4)
- There were no notable postoperative complications

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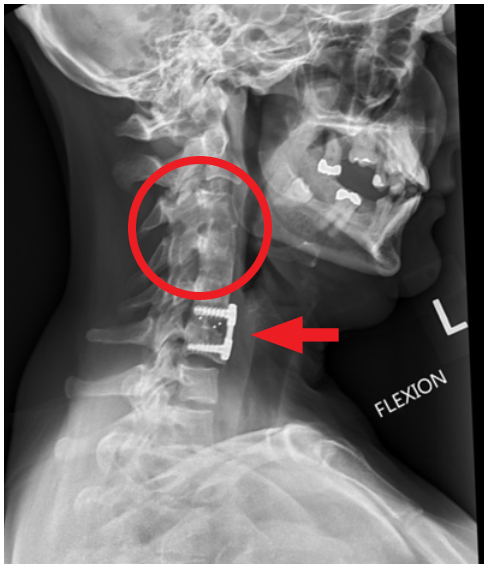

Figure 1.
Preoperative lateral X-ray showing area of interest (red circle) and existing hardware from previous surgery (red arrow).

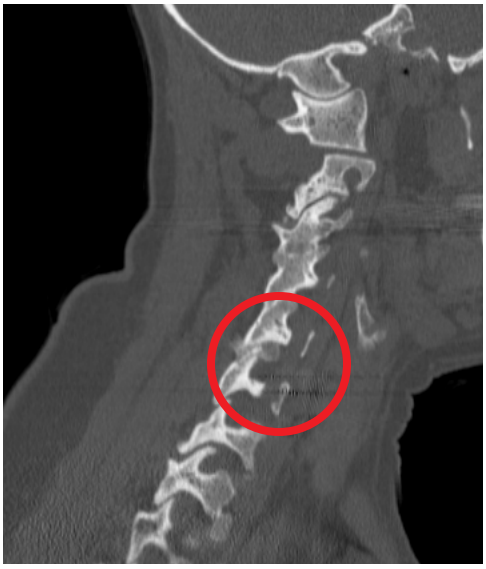

Figure 2.
Preoperative lateral computed tomography (CT) scan showing area of interest (red circle).

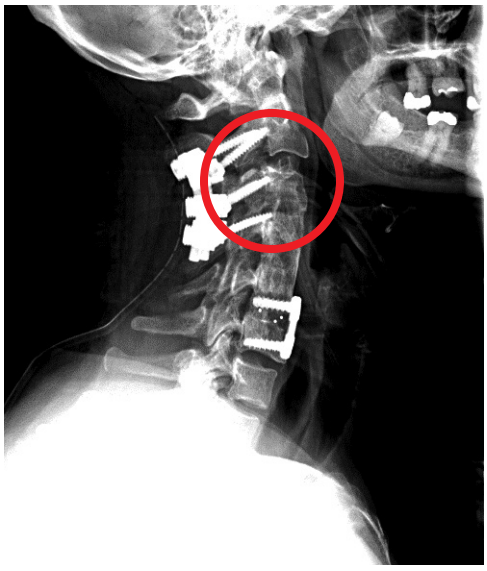

Figure 3.
Lateral X-ray at 3 months postoperative showing formation of bridging bony callus at the graft implant site (red circle).

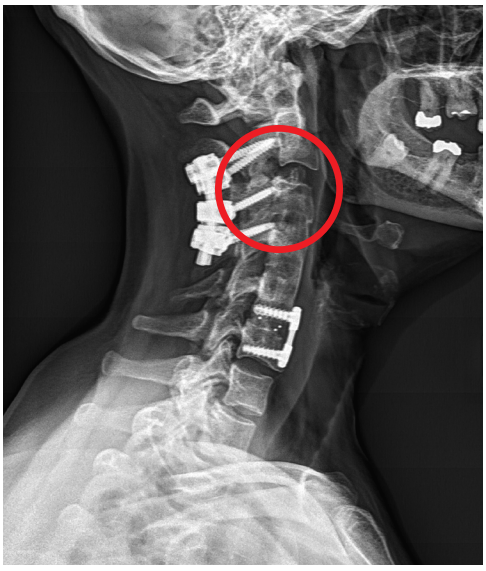

Figure 4.
Lateral X-ray at 6 months postoperative showing bony fusion at the graft implant site (red circle).

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References

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Results from case studies are not predicative of results in other cases. Results in other cases may vary.

Please refer to the instructions for use for a complete list of indications, contraindications, warnings, and precautions.

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