

Results of Biphasic Calcium Phosphate Bone Graft with Submicron-Sized Needle-Shaped Surface Topography as Standalone Alternative to Autograft are Favorable in Prospective, Randomized, Observer and Patient Blinded, Multi-Center, Intra-Patient Controlled Trial¹

Casey Butrico, PhD¹; Diyar Delawi, MD, PhD²; Eric Hoebink, MD³; DHR Kempen, MD, PhD⁴; Job L C Van Susante, MD, PhD⁵; Moyo Kruyt MD, PhD⁶
 1. Kuros Biosciences 2. St. Antonius Ziekenhuis 3. Amphia, Breda 4. OLVG Amsterdam 5. Rijnstate, Arnhem 6. UMC Utrecht

Introduction

Recent discoveries have shown that a novel Biphasic Calcium Phosphate (BCP) bone graft with submicron-sized needle-shaped surface topography can enhance bone healing by harnessing the immune system via recruitment of pro-healing M2 macrophages.²⁻³

This trial was initiated to determine non-inferiority of a novel BCP with submicron needle-shaped topography (BCP_{<μm}), as compared to autograft in instrumented posterolateral spinal fusion. This is the analysis for the safety and fusion rate of the 91 patients enrolled with compliant follow-up.

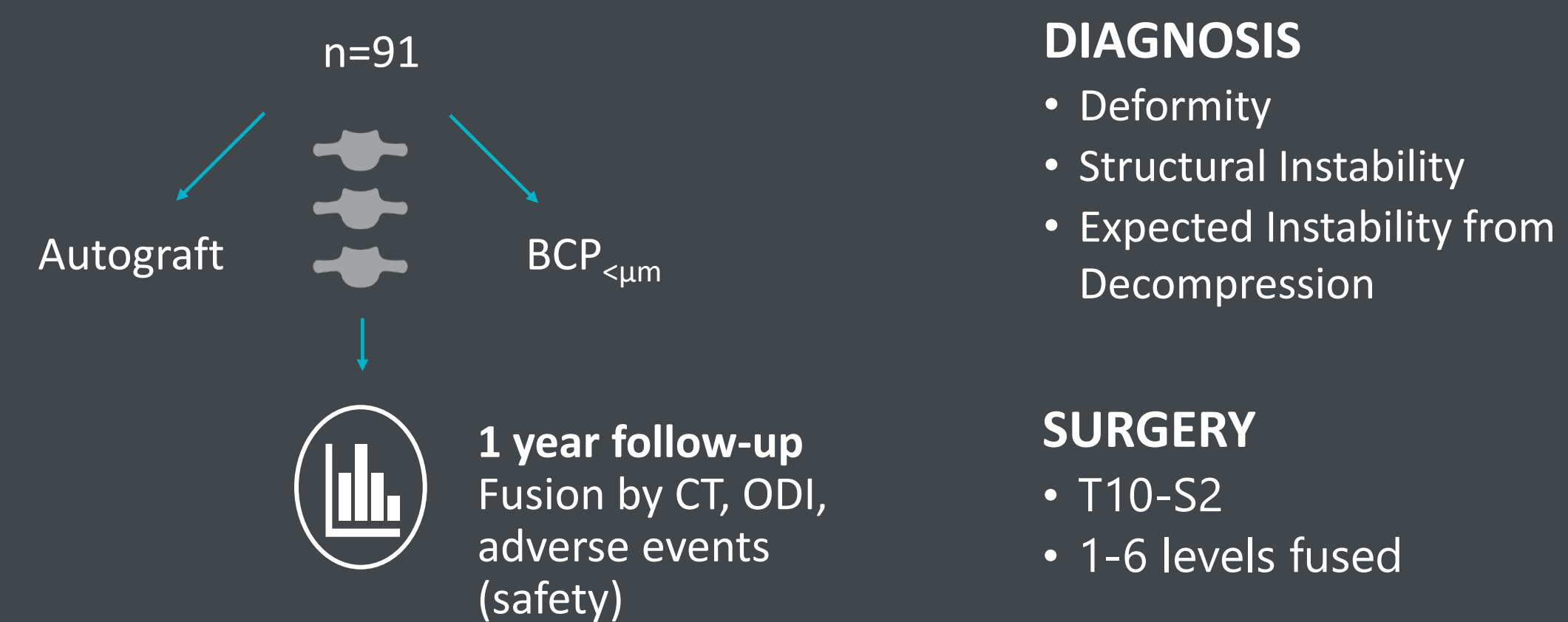
Materials & Methods

Following approval from the medical ethics review committee, adult patients undergoing instrumented posterolateral spinal fusions of one to six levels from T10 to S2 consented to this study.

After standard instrumentation and preparation of the fusion bed, one side (right or left) was randomly grafted with 10cc of standalone BCP_{<μm} per level, whereas the contralateral side received 10cc of autograft.

Prospective follow-up included adverse events, the Oswestry Disability Index (ODI), and radiographic imaging at one year. Fusion was systematically scored as “fusion” or “no fusion” per level per side by two spine surgeons blinded to the procedure and bone graft.

Results



Results

Radiographic Results

Segments fused of 128 total determined via Fine-Cut (<1mm) CT

	BCP _{<μm}	Autograft
Overall	79% (101/128)	47% (60/128)
Smokers 19%	80%	32%
Non-Smokers 81%	77%	49%

Case Study 1

79-year-old female

Diagnosis:

Expected instability from decompression

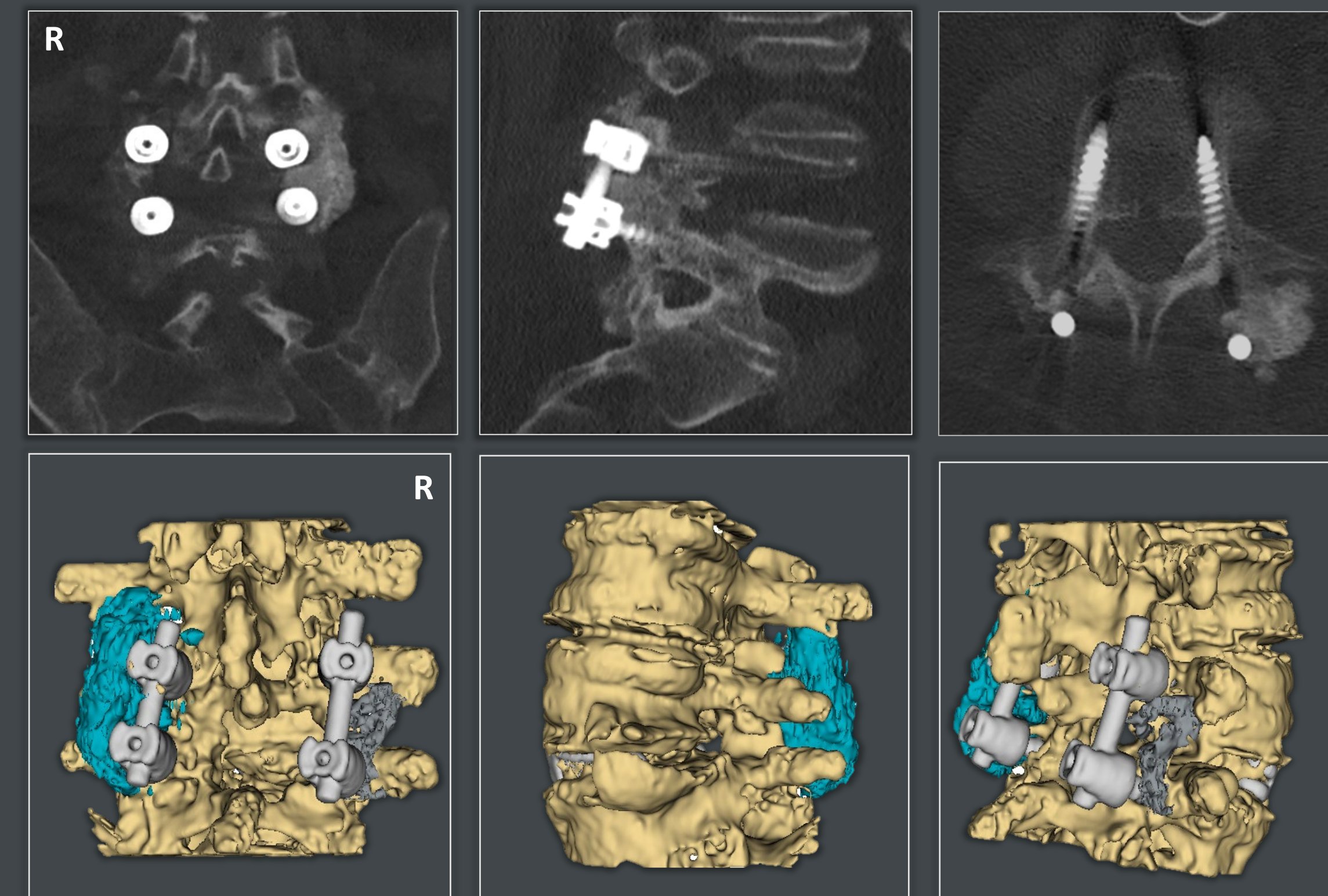
Procedure:

One-level PLF at L4-L5 (with TLIF)

- Right side: Autograft
- Left side: BCP_{<μm}

Radiographic Outcomes:

Both the BCP_{<μm} side and the autograft side were fused. Greater bone volume was observed on the BCP_{<μm} side.



Coronal, Sagittal, and Axial Fine-cut CT scans at one-year follow-up.

3D reconstructions at one-year follow-up. Key: BCP_{<μm}: Blue; Autograft: Gray; Instrumentation: Light Gray

Case Study 2

70-year-old male

Diagnosis:

Spinal deformity

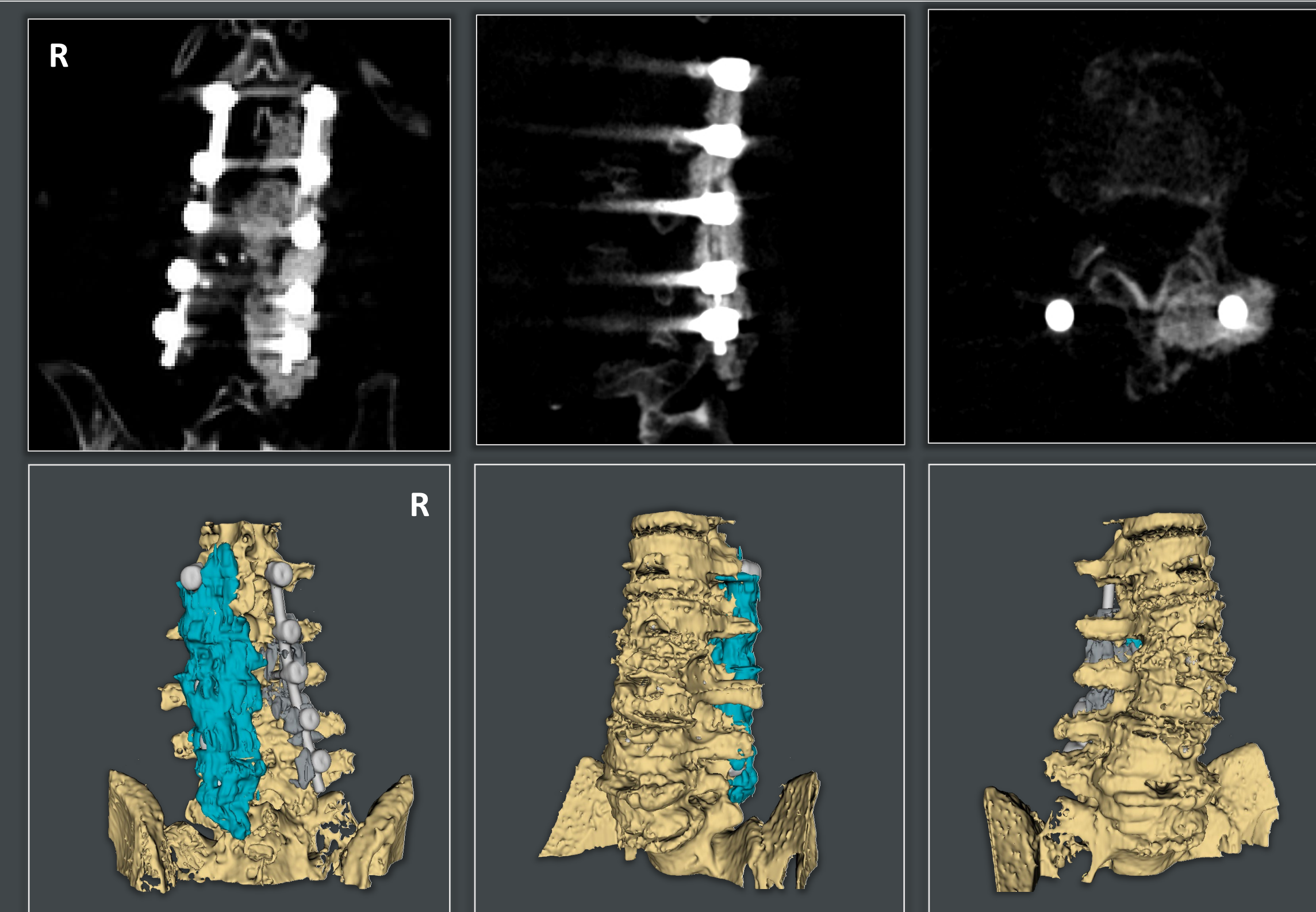
Procedure:

Four-level PLF at L1-L5 (with TLIF)

- Right side: Autograft
- Left side: BCP_{<μm}

Radiographic Outcomes:

BCP_{<μm} side fused at all four levels, whereas the autograft was fused at two levels. The interbody was fused.



Coronal, Sagittal, and Axial Fine-cut CT scans at one-year follow-up.

3D reconstructions at one-year follow-up. Key: BCP_{<μm}: Blue; Autograft: Gray; Instrumentation: Light Gray

Results

Radiographic outcomes via fine-cut CT scans at one-year post-operatively showed that BCP_{<μm} reached higher fusion rates versus autograft both overall and per number of levels.

In smokers, 80% of MagnetOs segments were fused, while 32% of autograft segments were fused at one year.

Interbody fusion data, patient reported outcome measures (PROMs), adverse events (AEs), and fusion rates are not statistically analyzed or peer-reviewed. Publication is forthcoming.

Discussion

Although Iliac Crest Bone Graft (ICBG) is the gold standard in bone grafting, known limitations include lack of supply and donor site morbidity. The next generation of synthetic bone grafts is predicated on advanced surface topography modulating an augmented bone healing response.

With a 79% fusion rate, the fusion outcomes of BCP_{<μm} surpassed the fusion rates reported for other synthetic bone grafts in studies of similar design.⁴

The fusion rates are further evidenced with statistical analysis to remove confounding variables and with clinical outcome measures in the form of ODIs.

Conclusion

This study aimed to determine the non-inferiority of BCP_{<μm} Granules used standalone when compared to autograft. The analyses are ongoing, although preliminary and interim results are promising.

References

1. Data on file.
2. Duan, et al. eCM. 2019;37:60-73.
3. Van Dijk, et al. JOR Spine. 2018;e1039.
4. Lehr, et al. Spine. 2020;45(14):944-951.