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info@tissyou.com

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Xenys cancellous chips (4-6 mm)
Natural bone substitutes of equine origin developed and produced by Tiss'You through its own patented process EstRem (WO2020058813A1).

Evangelos Christodoulou, MD

St. Vincent Hospital - *Düsseldorf, Germany*

5 patients
57-72 years

Spine disease and instability
Spondylodiscitis, degenerative lumbar scoliosis with pseudarthrosis, and traumatic fracture

Up to 3 months
of follow-up

Background

The utilization of lumbar interbody cages in clinical practice finds its indication in addressing degenerative disc disease, e.g., pseudarthrosis, spondylolisthesis, or vertebral deformities, necessitating anterior arthrodesis. The primary goal is to facilitate the formation of a bone bridge, ensuring a stable and enduring arthrodesis, consequently leading to notable improvements in both pain management and functional disability.

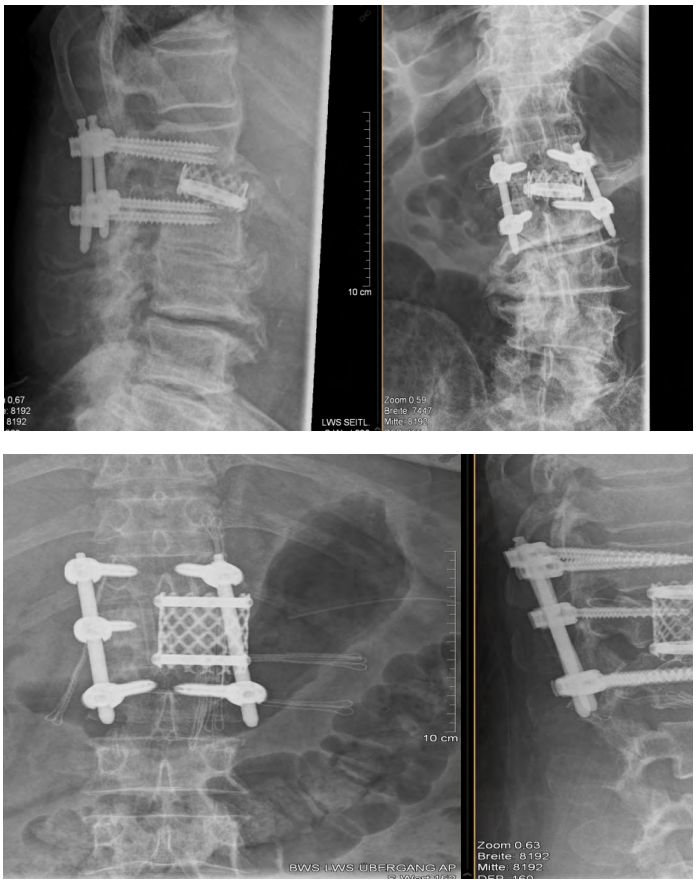
Incorporating bone tissue within the interbody cage significantly contributes to interbody fusion and arthrodesis. This approach enhances stability, promoting a more robust foundation for successful fusion. The present study focuses on post-market clinical follow-up, assessing the clinical outcomes and efficacy of cages with bone chips filling in patients undergoing spinal surgery.

Methods

This study involved 5 patients aged between 57 and 72, with different spine conditions, e.g., spondylodiscitis, degenerative lumbar scoliosis with pseudarthrosis, and traumatic fracture. Treatment comprised arthrodesis with interbody cage insertion. The Xenys bone chips (diameter of 4-6 mm; Tiss'You, San Marino) were consistently applied within the interbody cage during surgery. Two primary clinical outcome measures were employed to evaluate treatment efficacy and safety. The Visual Analog Scale (VAS) for Pain, measuring pain intensity on a scale of 0 to 10, and the Oswestry Disability Index (ODI), a questionnaire assessing functional disability related to lower back pain. Assessments using VAS and ODI were conducted at a 3-month follow-up post-surgery to gauge treatment outcomes. Concurrently, adverse events were meticulously monitored and documented to ensure patient safety throughout the study.

Results

All patients achieved an initial state of interbody fusion at the 3-month follow-up, indicating successful integration of the interbody cages. Furthermore, the study revealed that all patients experienced no device-related complications, revisions, or infections, underscoring the safety and efficacy of the surgical intervention. Moreover, within these five patients, a significant improvement in both pain and functional disability was observed. The Visual Analog Scale (VAS) for pain was reduced by 83% and the Oswestry Disability Index (ODI) by 50%. Radiological assessment showed device integrity and arthrodhesis stability; the Xenys cancellous bone chips promoted osteointegration without leakage/dispersion events at implant site. These results collectively demonstrate the favorable clinical outcomes and safety profile associated with the utilization of interbody cages in the surgical treatment of traumatic and degenerative disc diseases.



Representative post-operative x-ray images. Panel A shows patient with spondylodiscitis, panel B show patient with L4/L5 degenerative lumbar scoliosis with pseudarthrosis, panel C shows patient with L1 traumatic fracture.

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