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DENTISTRY
ORTHOPAEDICS
NEUROSURGERY
AESTHETIC MEDICINE

PMCF Report, 25th September 2023

SpherHA (Synthetic bone substitutes)
Based on bio-mimetic nano-structured hydroxyapatite; injectable paste produced by Tiss'You.

Degenerative lumbar disease and instability
Stenosis, disc disease, spondylolisthesis

49 patients
20-75 years

Up to 3 months
of follow-up

Background

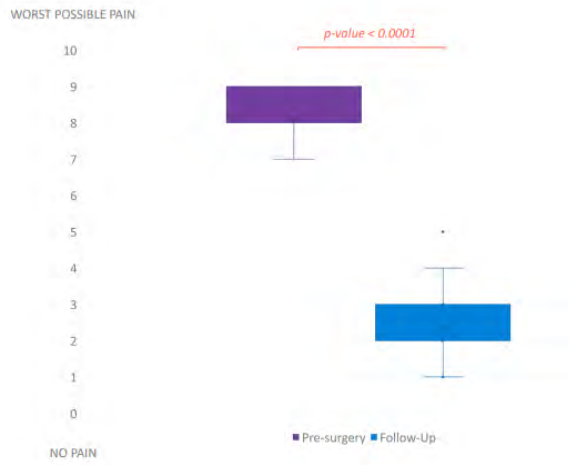
The utilization of lumbar interbody cages in clinical practice finds its indication in addressing degenerative disc disease, e.g., pseudarthrosis, spondylolisthesis, or vertebral deformities, necessitating anterior arthrodesis. The primary goal is to facilitate the formation of a bone bridge, ensuring a stable and enduring arthrodesis, consequently leading to notable improvements in both pain management and functional disability (Zdeblick & Philips, 2003).

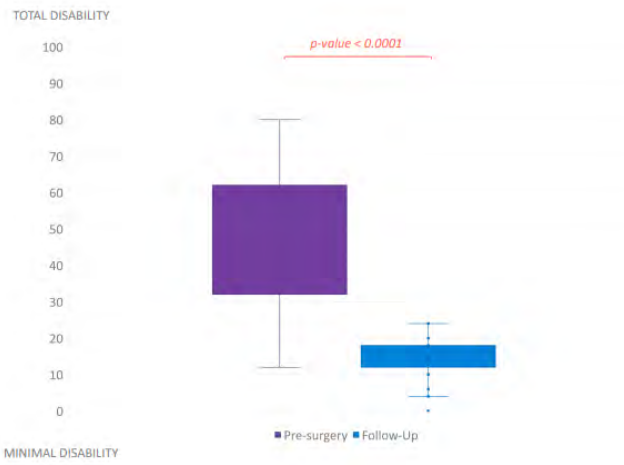
Incorporating bone tissue within the interbody cage significantly contributes to interbody fusion and arthrodesis. This approach enhances stability, promoting a more robust foundation for successful fusion. The present study focuses on post-market clinical follow-up, assessing the clinical outcomes and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

Methods

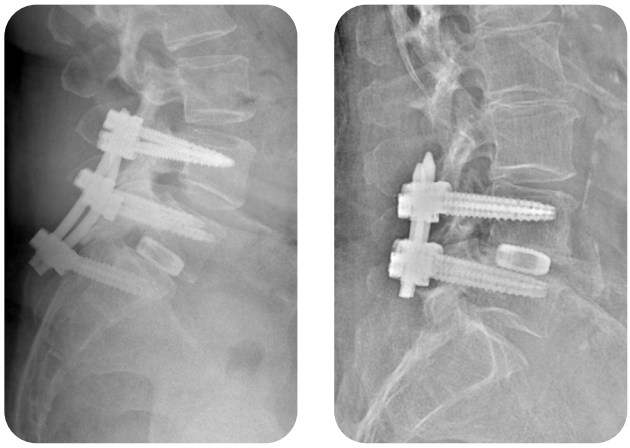
The national study (Italy) was multicentric and it involved 49 patients aged between 20 and 75, all diagnosed with degenerative disc disease. Treatment comprised lumbar interbody cage insertion, specifically utilizing Monza cages from Clover Orthopedics. Surgical approaches included transforaminal lumbar interbody fusion (TLIF) for 90% of the patients and monolateral posterior lumbar interbody fusion (PLIF) for the remaining 10%. SpherHA synthetic injectable bone paste (Tiss'You, San Marino) was 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.

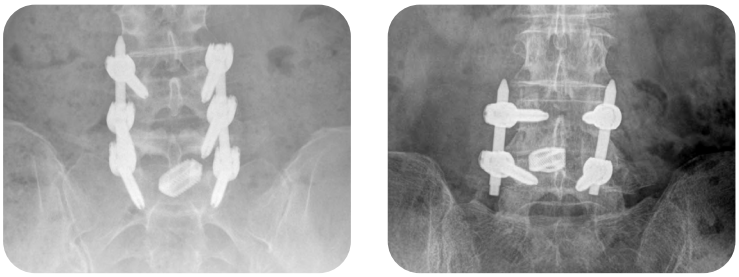
Results





Ninety-five percent of the patients achieved an initial state of interbody fusion at the 3-month follow-up, indicating successful integration of the lumbar interbody cages. Furthermore, the study revealed that all patients, constituting 100% of the cohort, experienced no device-related complications, revisions, or infections, underscoring the safety and efficacy of the surgical intervention. Moreover, within this patient population, a significant improvement in both pain and functional disability was observed. Ninety-five percent of patients reached successful interbody fusion, accompanied by a substantial improvement in the Visual Analog Scale (VAS) for pain by 71% and the Oswestry Disability Index (ODI) by 70%. Radiological assessment showed device integrity and arthrodesis stability; the injectable paste 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 lumbar interbody cages in the surgical treatment of degenerative disc disease.





Representative x-ray images of two patients at 3-month follow-up, showing device integrity and arthrodesis stability.

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