ZAVATION

LABYRINTH™ IN-VITRO & IN-VIVO STUDY

Zavation's patented porous PEEK technology proven to outperform solid PEEK in vivo and solid PEEK, Titanium, and porous Titanium in cell culture. [1, 2]

3670 Flowood Drive — Flowood, MS 39232 — 601.919.1119 — sales@zavation.com
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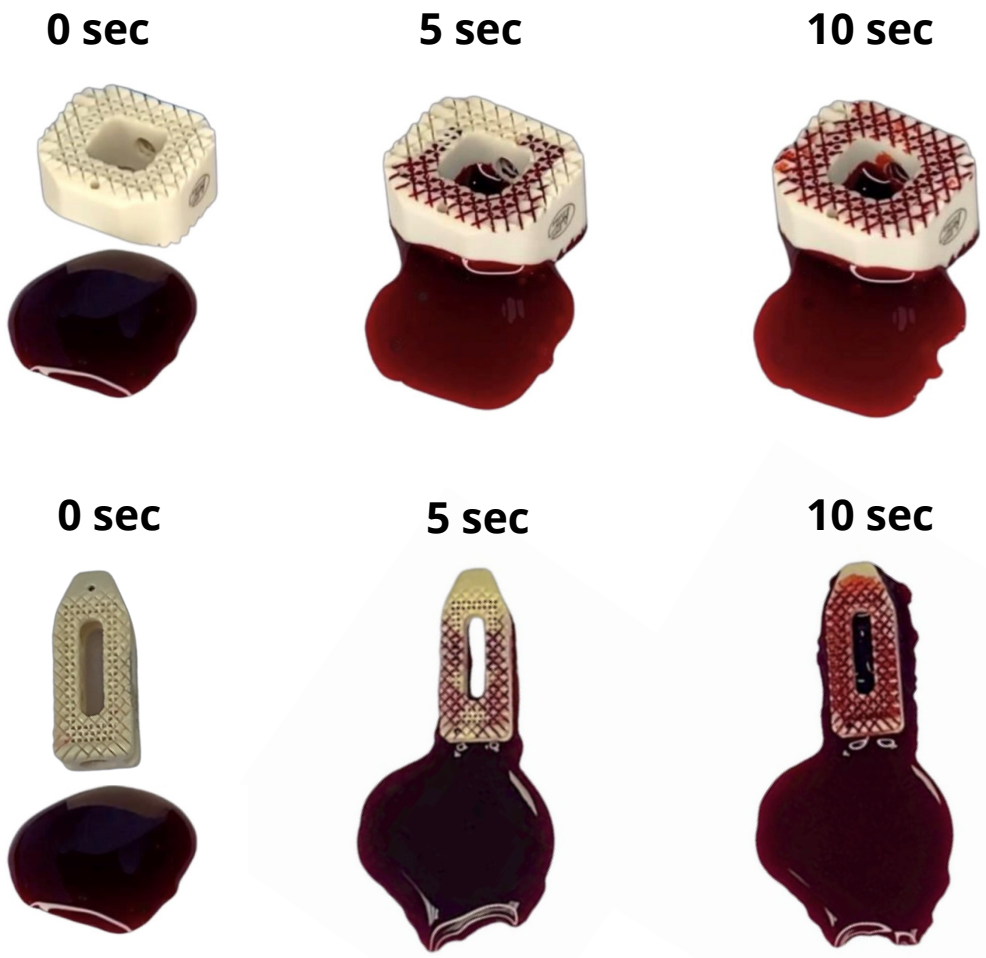

Key findings from in-vitro and in-vivo studies

- LABYRINTH™ technology produced higher osseointegration capability when compared to solid PEEK, solid Titanium, and porous Titanium in cell culture. [1]
- LABYRINTH™ technology possessed higher fusion and quality of fusion grades at 12- and 26-weeks post-op when compared to solid PEEK. [2]
- LABYRINTH™ technology proved to obtain new bone formation throughout porous structure. [2]

A 21 day in-vitro study was conducted on LABYRINTH™ and compared to solid PEEK, porous Titanium, and solid Titanium. Figure 1 on the next page details bone mineralization after 21 days. LABYRINTH™ outperformed all other samples for osteoblast differentiation, maturation, and mineralization.

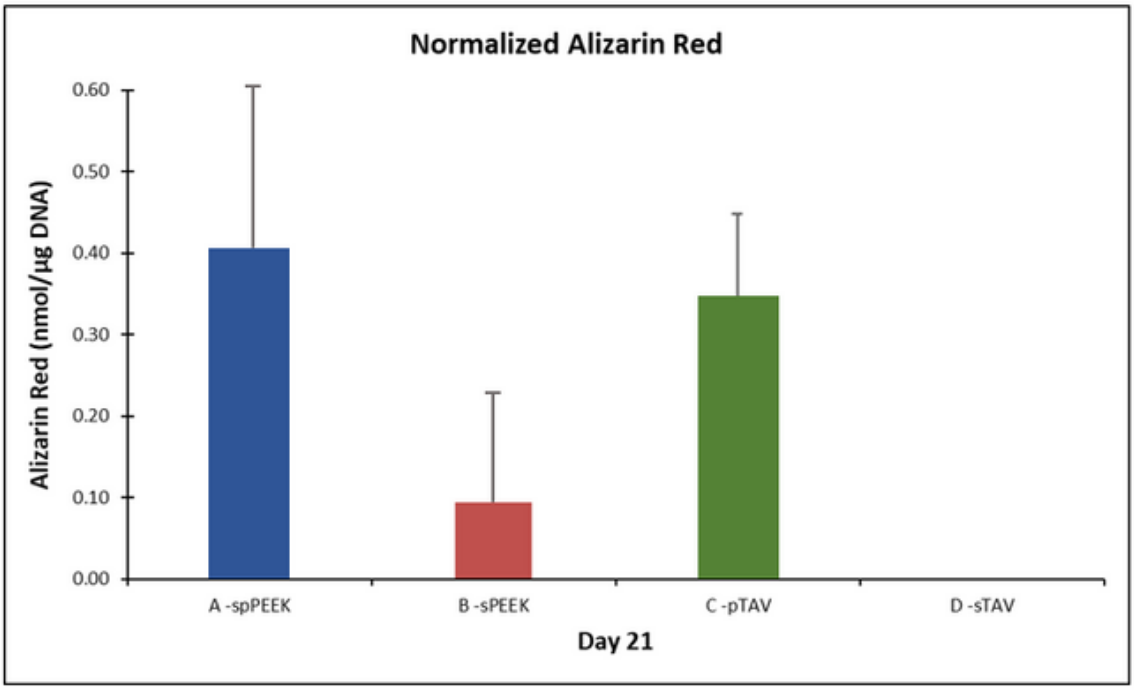

Figure 1: *Alizarin Red data comparing the mineralization at day 21 for LABYRINTH™, solid PEEK, porous Titanium, and solid Titanium [1]*

µCT analysis and histopathology was performed on LABYRINTH™ during an in-vivo study and compared to a solid PEEK interbody. Figure 2 is an axial µCT image of LABYRINTH interbody at 26 weeks post-op with bone growing completely through the porous structure.

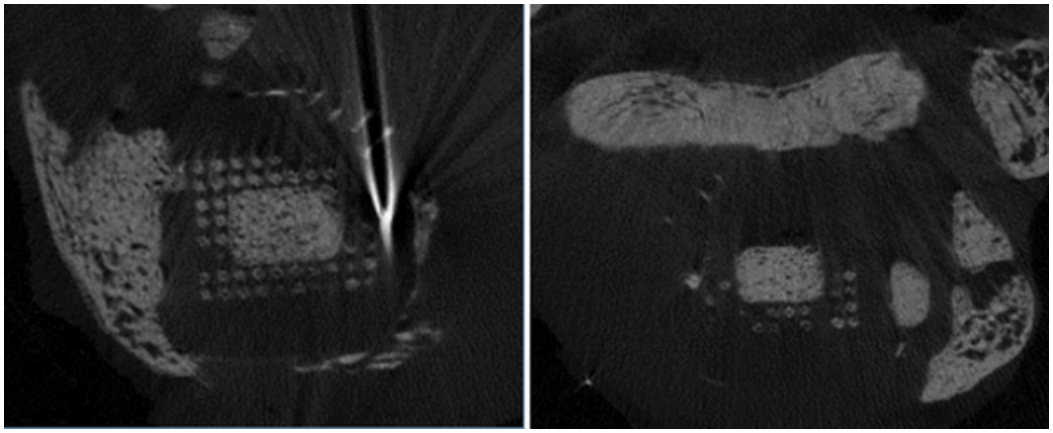

Figure 2: *Axial CT image of LABYRINTH™ interbody detailing bone growth through porous structure [2]*

Histopathology images of LABYRINTH™ interbody through porous structure sections reveal bone in-growth entirely through the pores. New bone formation is shown in Figure 3 on the following page.

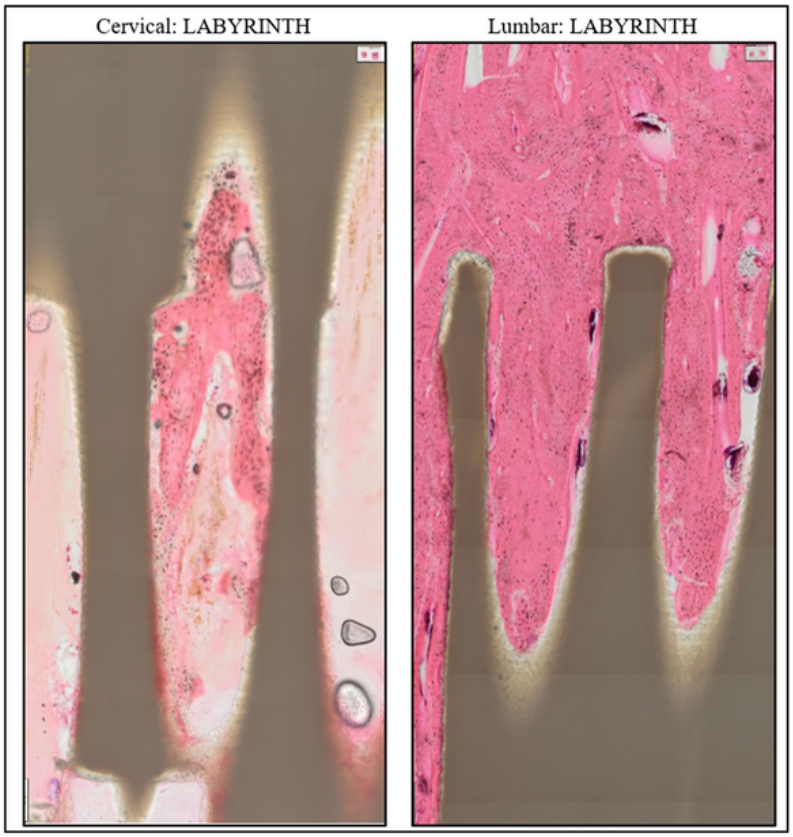

***Figure 3**: New bone formation within porous structure of LABYRINTH™ interbody [2]*

Histopathology sections were compared between LABYRINTH™ interbody and a solid PEEK interbody at 12 weeks and 26 weeks post-op. Zavation's LABYRINTH™ interbody proved to outperform solid PEEK interbody for bone on-growth, bone in-growth, and tissue adherence, as shown in Figure 4.

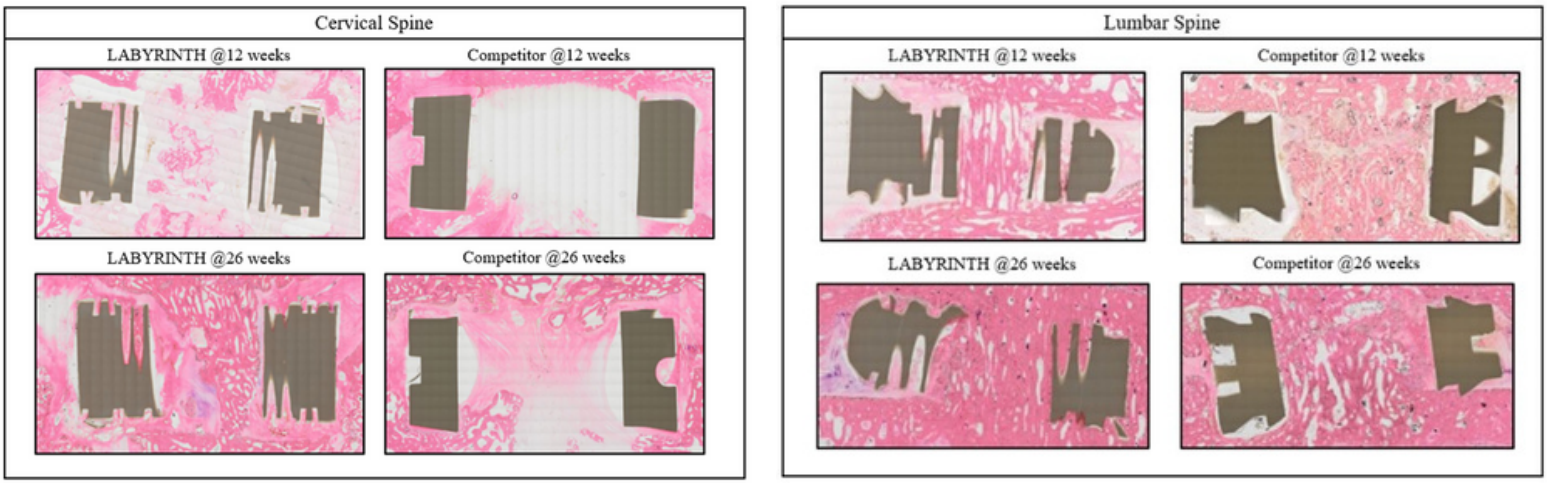

***Figure 4**: Histopathology sections comparing LABYRINTH™ interbody and solid PEEK interbody at 12 and 26 weeks [2]*

For product information, including indications, contraindications, warnings, precautions, potential adverse effect, and patient counseling information, see the package insert at http://zavation.com/distributor-page/

ACKNOWLEDGEMENTS

Zavation would like to acknowledge the University of Mississippi Medical Center and the University of Iowa for providing the effort and equipment for in-vitro and in-vivo studies.

REFERENCES

1. S. Williamson, K. Nobles, P. Pall, A. Janorkar, Pre-Osteoblastic Cell Response on Combination Hydroxyapatite Coated and Patterned PEEK Versus Titanium Alloy Surfaces. (2021).
2. D. Fredericks, Evaluation of Porous PEEK Interbody Spacer (LABYRINTH) in a Sheep Cervical and Lumbar Interbody Fusion Model. (2022).