



# Tritanium<sup>®</sup> pre-clinical study summary

## Introduction

Numerous types of materials (metals, polymers, ceramics, etc.) have been used in designing interbody implants for clinical use<sup>1</sup>. With the evolution of traditional manufacturing techniques, the application of 3D printing technology to spinal implants offers the potential to enhance today's implant options. Stryker's Spine division has developed a new 3D printed interbody fusion cage utilizing Stryker's proprietary Tritanium Technology, a novel, highly porous titanium alloy material designed for bone in-growth and biological fixation<sup>2</sup>. Although PEEK is a popular option, it is inherently hydrophobic, and bone does not bond with or grow onto it<sup>3,4</sup>. Some companies have applied a thin layer of titanium to the surface of the PEEK implant. However, bone growth is still limited, and the titanium plasma sprayed coating may delaminate during impaction<sup>5</sup>.

## Objective

The purpose of this pre-clinical study is to compare the performance of three different materials (PEEK, titanium plasma sprayed PEEK, and Tritanium) based on histology and biomechanics in an ovine two level lumbar interbody fusion model. Multiple imaging techniques were used peri- and post-operatively to identify imaging indicators of both bone in-growth and fusion.

## Materials and methods

Interbody fusions were performed at (L2-L3 and L4-L5) in 27 mature sheep using three different interbody cages (i.e. polyetheretherketone [PEEK], titanium plasma sprayed PEEK and the 3D printed porous Tritanium PL Cage) packed with iliac crest bone graft. There were ten implants per group for the 8-week time-point and eight implants per group for the 16-week time-point. Outcome measures included biomechanical and radiographic analysis.<sup>3</sup>

Non-destructive kinematic testing was performed in the three primary directions of motion (axial rotation, flexion / extension and lateral bending). The specimens were then analyzed using micro-computed tomography ( $\mu$ CT), and quantitative measures of the bony fusion were performed. Histological sections were then taken in the sagittal plane through the interbody device and put through a multi-step staining process to allow for the differentiation of collagen and bone. Histomorphometric measurements were calculated to quantify the area of new bone within the following: implant, graft window and total fusion area (endplate-to-endplate including implant and graft). All endpoints were calculated between cage designs and sacrifice time-points.

# Results

## Histology

The histology images visually demonstrate bone in-growth into the porous architecture of the Tritanium PL Cage at both 8- and 16-week follow-up time points. Additionally, histomorphometric analyses confirmed that within the implant, graft window and total fusion area the Tritanium PL Cage demonstrated a statistically significant increase ( $p < 0.02$ ) in the amount of bone at the 16-week time point compared to the 8-week time point. This statistically significant increase in bone was not evident in any other of the treatment groups. Additionally, the Tritanium PL Cage demonstrated a statistically significant increase in the amount of bone within the total fusion area at the 16-week time point compared to all PEEK implants at the 16-week time point.



Figure 1: Histology images at 8 weeks post-op (sagittal view)

Within the implant, the Tritanium PL Cage demonstrated a statistically significant increase in the amount of bone at both the 8- and 16-week time points compared to all other treatment variants at the respective time points ( $p < 0.01$ ). The Tritanium PL Cage also demonstrated a statistically significant increase in the amount of biologic elements (bone marrow cells, blood cells, etc.) within the implant at both 8- and 16-week time points compared to all other treatment groups at both the 8- and 16-week time points. A qualitative bridging bone assessment was conducted using a blinded 3rd party to determine the degree of the bridging bone observed in the histology samples. The Tritanium PL Cage demonstrated a statistically greater bony bridging score at the 16-week time point compared to all other treatment groups ( $p < 0.05$ ).



Figure 2: Histology images at 16 weeks post-op (sagittal view)

## Micro-CT analysis

The 3D reconstructions from the Micro-CT scans visually demonstrated bone in-growth into the Tritanium PL Cage at both 8 and 16 weeks. Additionally, the Tritanium PL Cage demonstrated statistically greater bone volume / total volume at both the 8- and 16-week time points as compared to all other treatment variants ( $p < 0.01$ ).

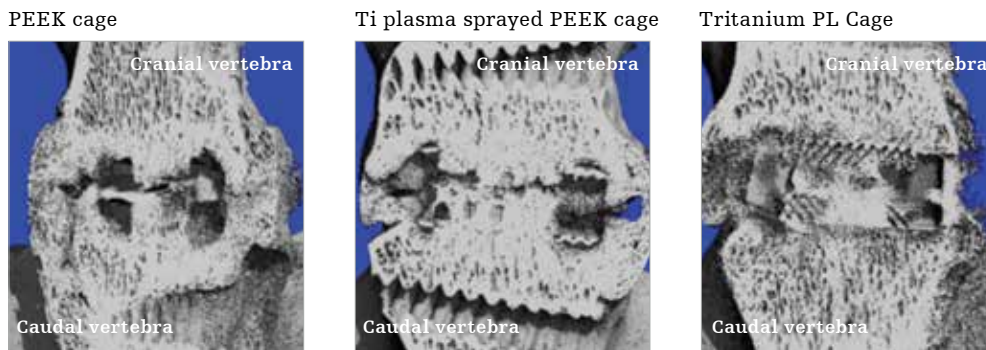


Figure 3: Micro-CT images at 16 weeks post-op (coronal view)

## Biomechanics

Across all three primary loading directions (axial rotation, flexion / extension and lateral bending), the Tritanium PL Cage demonstrated a statistically significant decrease in ROM and increase in construct stiffness following 16 weeks of healing compared to the 8 week samples ( $p < 0.02$ ). This difference was not evident in any other of the treatment groups. Furthermore, the Tritanium PL Cage demonstrated a statistically significant decrease in ROM for flexion / extension compared to all other treatment variants ( $p < 0.04$ ). The Tritanium PL Cage consistently had the lowest ROM mean magnitude and the highest stiffness in all loading directions at 16 weeks.

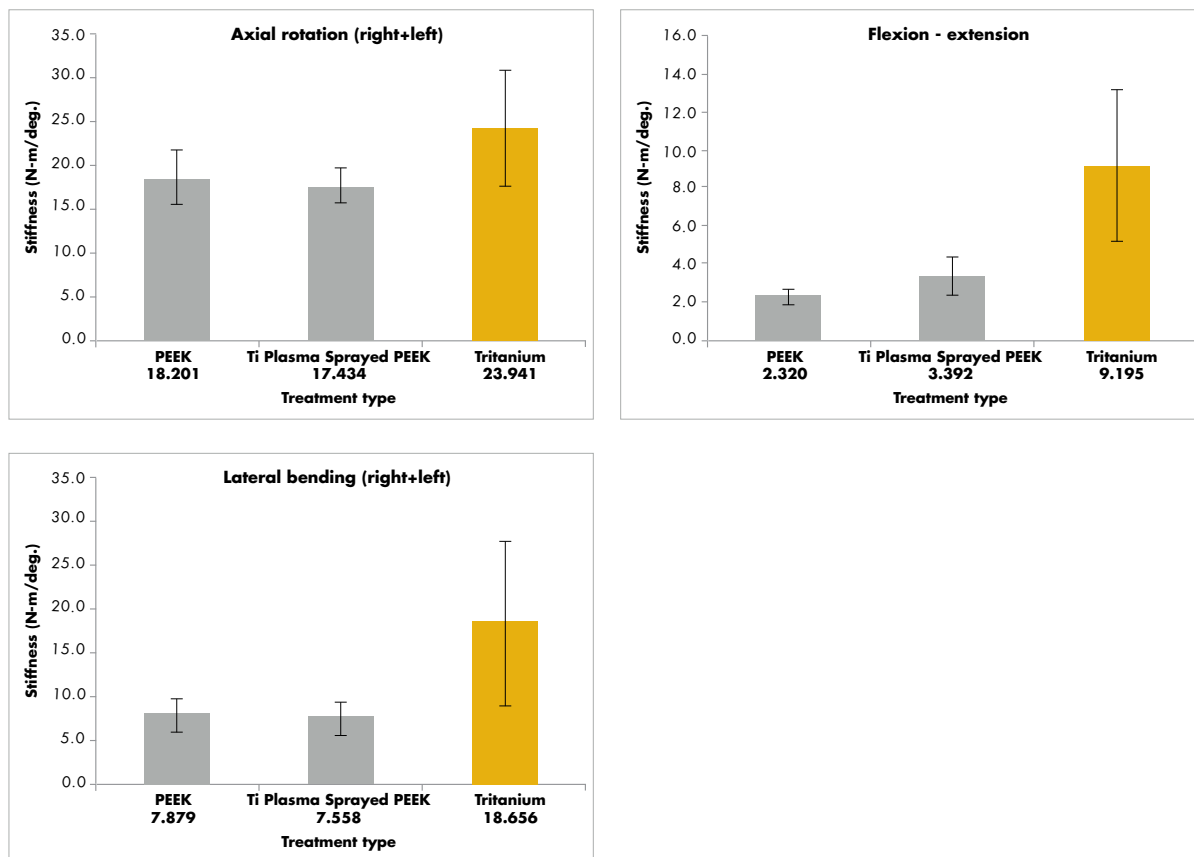


Figure 4: Mean biomechanical stiffness in axial rotation, flexion – extension and lateral bending

# Conclusions

The results from this two level lumbar interbody fusion study in an ovine model provide direct comparison between interbody implants utilizing different materials, and demonstrate significant and measurable differences in biomechanical and histologic performance. In this pre-clinical interbody fusion study, the use of a 3D printed porous Tritanium PL interbody cage resulted in a statistically superior ROM, bone in-growth profile and greater average construct stiffness compared to PEEK and titanium plasma sprayed PEEK cages. Both quantitative and qualitative assessments of the images produced from this pre-clinical study confirmed that the Tritanium PL Cage results in bone in-growth at both the 8- and 16-week follow-up time points, however correlation to human clinical outcomes has not been demonstrated or established.

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## References

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- <sup>2</sup> PROJ 43909 | Tritanium technology claim support memo
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- <sup>6</sup> SRL 15-02 / Stryker -02-15 | Pre-clinical study final report

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