

# Biomechanical behaviour of the TIPEEK Titanium Coated PEEK cages

**MedactaLIF** TIPEEK

TI-COATED INTERBODY FUSION DEVICE



## Abstract

*Purpose:* The objective of the following study was to perform a series of in vitro analyses to evaluate and confirm the performance of the addition of Titanium Coating to Medacta PEEK Interbody Cages (TiPEEK). The main goal was to evaluate resistance to delamination.

*Methods:* Biomechanical tests were conducted in order to compare TiPEEK mechanical strength with the related ASTM and ISO International Standard of Characterization as well as guidance provided by the U.S. FDA.

*Results:* The behaviour of Medacta TiPEEK implants was significantly superior to all acceptance criteria stated in the FDA guidance and the prescribed ASTM and ISO International Standard. Based on these findings the Medacta TiPEEK cages can be considered better than existing devices in term of Resistance to delamination of the Ti-coating.

## Introduction

Polyetheretherketone (PEEK) is a material widely used in spine surgery for the interbody fusion devices manufacturing; Its main advantages are the radiolucency, which facilitate the imaging assessment and its physiological-like stiffness which may helps to drive a proper mechanical support [1].

The TiPEEK cages, where a thin layer of Titanium is plasma sprayed on a PEEK substrate, result in a composite devices with enhanced biocompatibility [1] and optimized friction to increase the shear strength between implant and bone [2, 3] and potentially reducing the risk of loosening.

The purpose of this mechanical testing was to investigate the behaviour of the TiPEEK cages and understand if the impact insertion technique into the disc space as well as the long lasting permanence in situ can result in wear debris or delamination of the coating.

The mechanical properties most relevant for in vivo behaviour were tested in order to evaluate the resistance to delamination as per the following conditions:

1. Tensile Stress and Adhesion Strength
2. Static Shear strength
3. Shear Fatigue
4. Resistance to Abrasion
5. Wear Analysis

## Methods - Reference Standard

Development of the TiPEEK -Titanium Coated Cages was validated through dedicated biomechanical tests in order to confirm satisfactory performance. These Biomechanical Tests were conducted in accordance with the American Society of Testing and Materials (ASTM) guidelines for coatings, the Food and Drug Administration (FDA) Guidance on coated implants and the ISO characterization for wear of implant materials [4]. Standardized testing provides a meaningful evaluation of performance for spinal implants.

## Biomechanical Tests

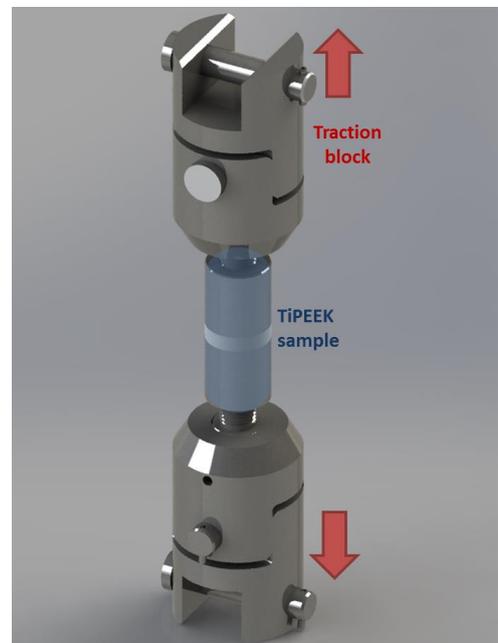
### 1. Adhesion Strength

This test aimed to investigate the resistance of the coating to potential delamination due to tensile stress. The clinical relevance of testing tensile forces relates to the coated surface adhesion to the bony tissue. Reference volumes are meant to verify that the coating does not separate from the bulk material when bone binds to the coating.

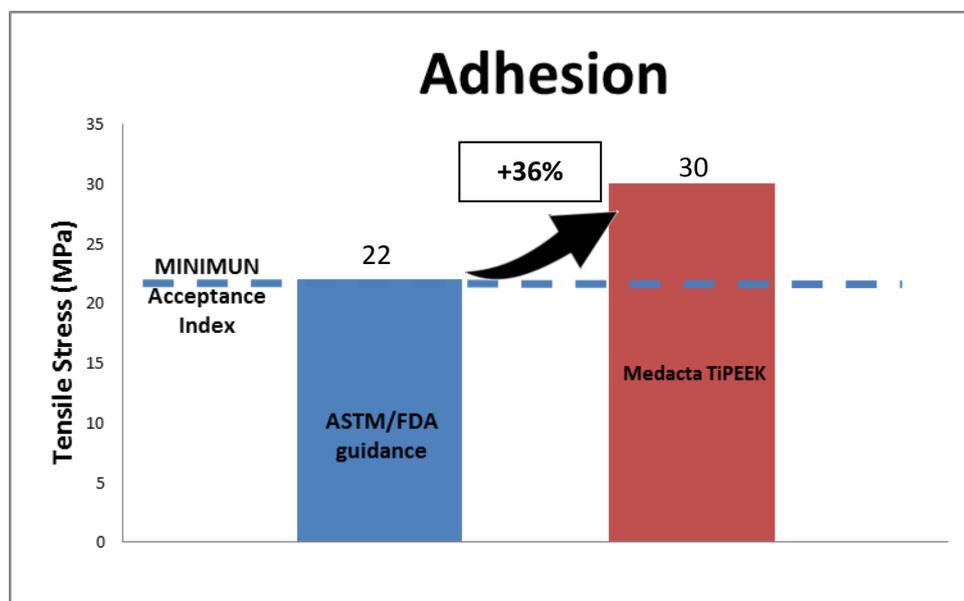
#### Test Description

The detachment force of the Titanium coating from TiPEEK samples under Tensile stress is measured.

A Tensile testing machine is used to apply a progressive pulling force until detachment of the coating. The force at detachment is measured as tensile adhesion strength of the Titanium coating.



#### Results



The adhesion force of the coating on the TiPEEK cages exhibited a value higher than the Tensile Force prescribed by the Standardized Guidance. The TiPEEK cages exhibited a Tensile Strength about 40% higher than the Acceptance Criteria given by the Guidance Index.

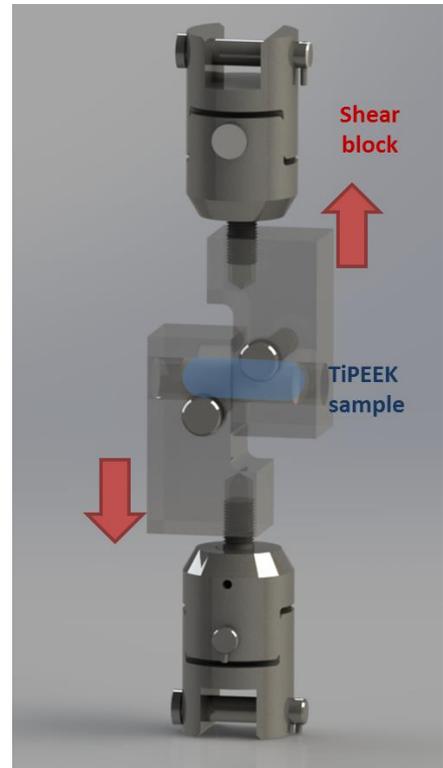
## 2. Static Shear Strength

This test aimed to investigate the resistance of the coating to potential delamination due to shear stress. The clinical relevance of shear forces relates to the friction experienced mainly during cage impaction/insertion.

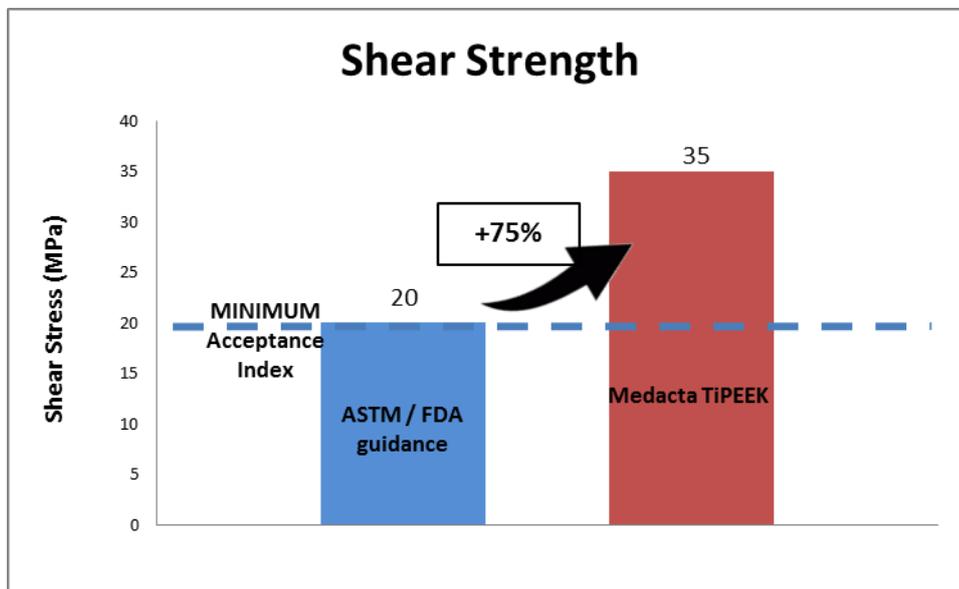
### Test Description

The force of detachment of the Titanium coating from TiPEEK samples under Tensile Transverse Load is measured.

The TiPEEK cages are mounted in a transverse loading direction testing machine, so that the maximum shear load on the coating-substrate interface is measured.



### Results



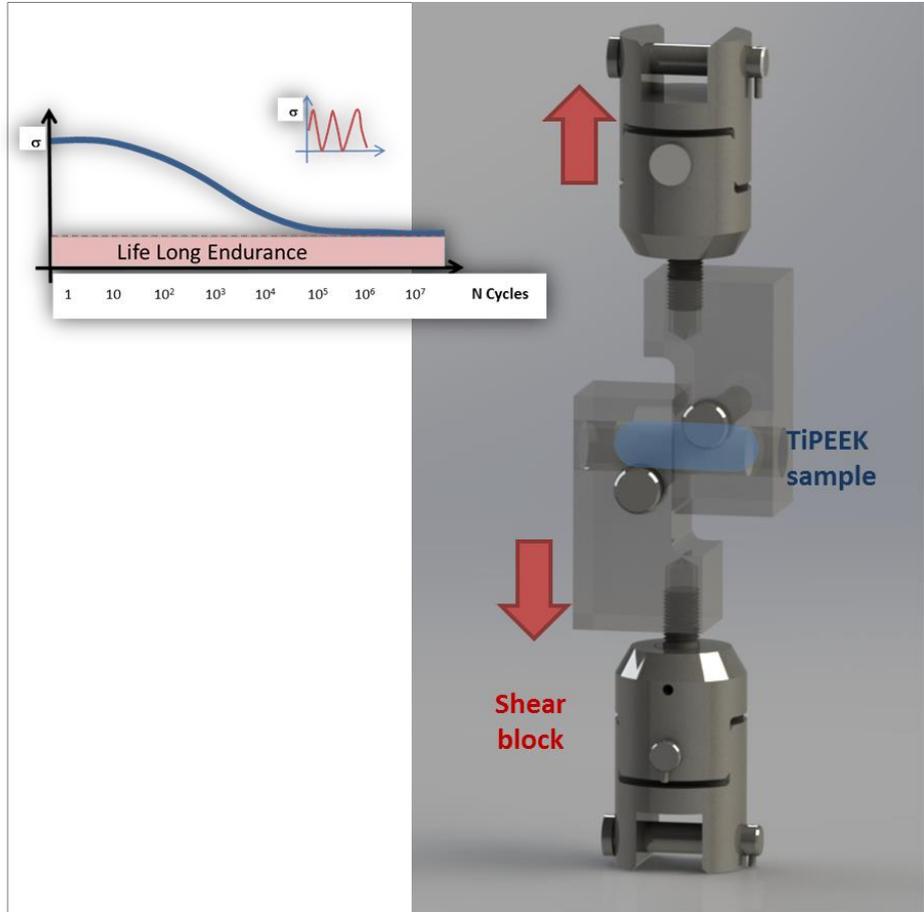
The adhesion force of the coating on the TiPEEK cages was higher than the Tensile Force prescribed by the Standardized Guidance. The TiPEEK cages exhibit a Tensile Strength which is 75% higher than the Acceptance Criteria given by the Guidance Index.

### 3. Shear Fatigue Strength

This test aimed to investigate the resistance of the coating to potential delamination due to cyclically repeated shear loads. The clinical scenario that is relevant to this test is the relative movement of consecutive vertebral bodies subjecting the bone/implant interface to cyclic shear stresses.

#### Test Description

The TiPEEK cages are mounted in a transverse loading direction testing machine and loaded with a cyclic shear stress for 10 Million ( $10^7$ ) cycles. The test is passed if no detachment of the coating occurs after 10 Million cycles. *In vitro* fatigue tests conducted over 10 Million ( $10^7$ ) cycles is considered to mimic the *in-vivo-like* response of “life long” resistance of the TiPEEK cages, once implanted in the human body.



#### Results

FDA Guidance Acceptance Criteria	Medacta Results
10 Million cycles without delamination	<b>10 Million cycles without delamination</b>

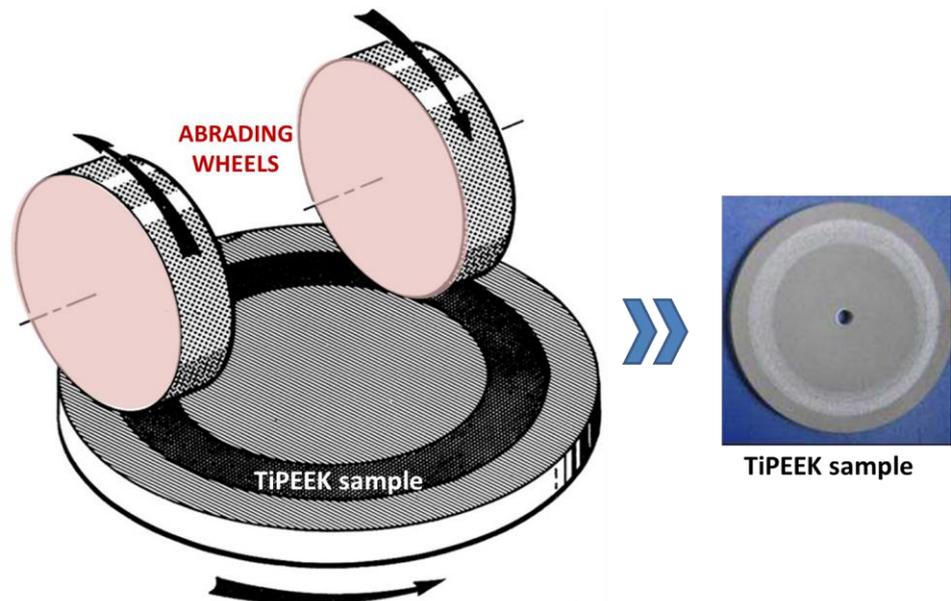
The TiPEEK coated cages exhibited an ability to pass the 10 Million cycle test with no delamination of any of the tested specimens.

#### 4. Abrasion Resistance

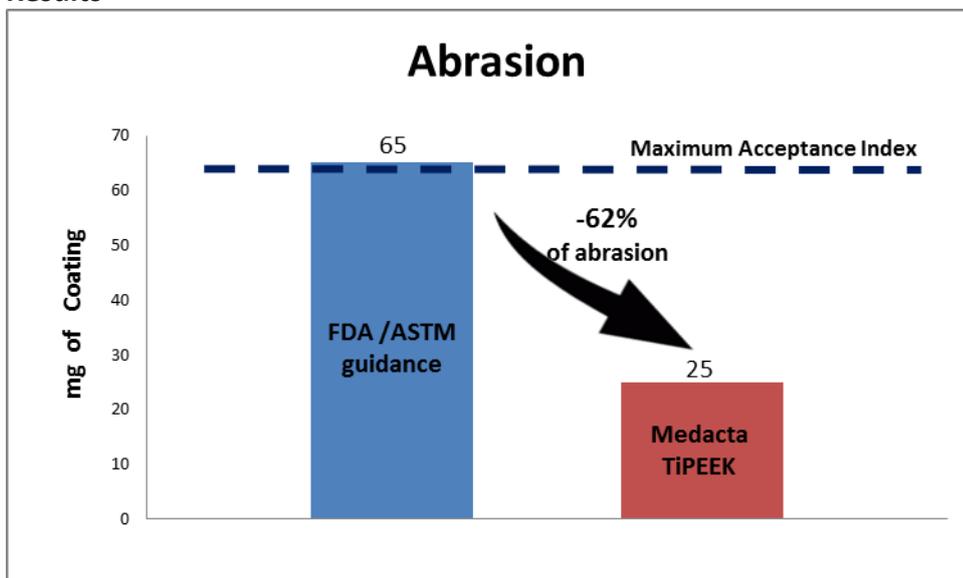
This test aimed to investigate the delamination resistance of the coating to abrasion; the clinical situation mimicked by this test is the cyclic micro movement at the cage/endplate interface before fusion has taken place.

##### Test Description

The TiPeek samples are mounted on a setup where a turning grinding mass (abrading wheels) provides continuous surfaces scraping, so that the coated surface experience a cyclical rubbing motion. The abrasion of the coating is evaluated in term of weight loss due to titanium debris detachment after 100 cycles of scraping.



##### Results



The abrasion resistance of the Titanium coating on TiPeek cages was higher than that mandated in the Standardized Guidance. The loss of Titanium due to abrasion was less than half (62% LESS THAN) the maximum allowed.

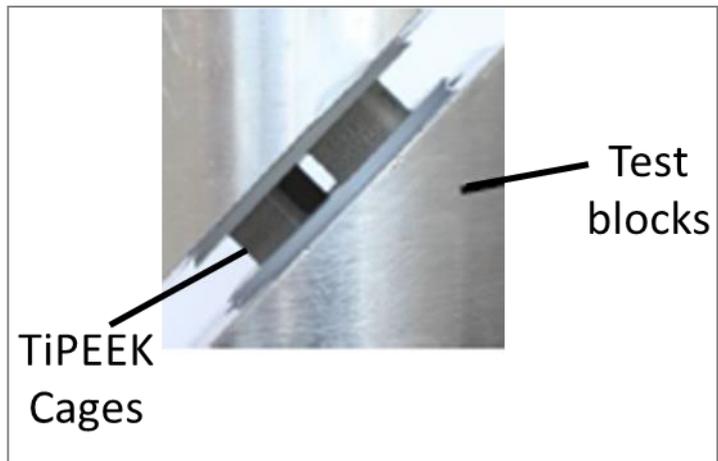
## 5. Wear Analysis

This test aimed to investigate the resistance of the coating to potential wear after simulation of life-long usage; this test mimics the potential wear related to repeated micro movements at the cage/endplate interface or the adhesion of the Titanium coating to bony tissue that may occur in the *in vivo milieu*.

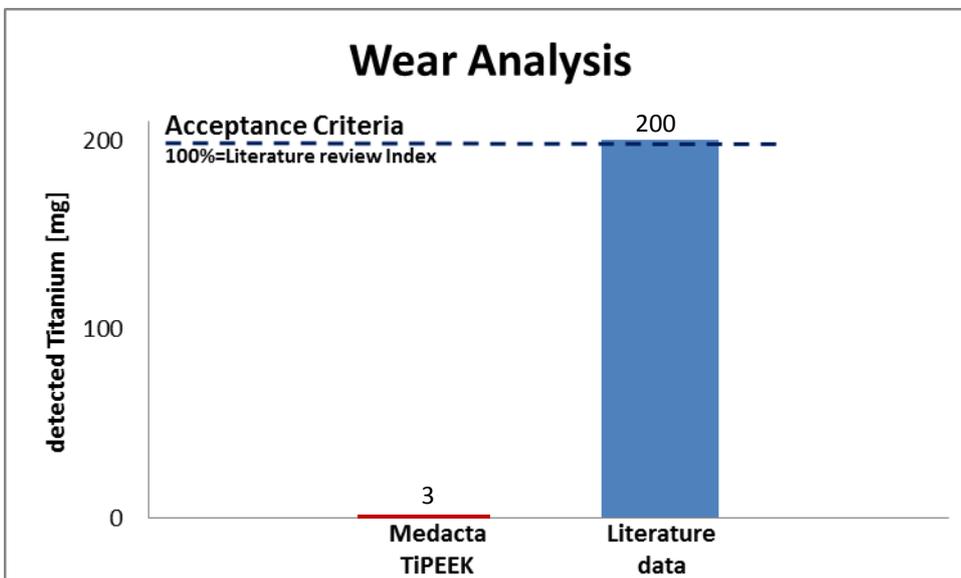
### Test Description

The test is performed in an “environmental chamber” that mimics physiological ambience and the implant is loaded in axial and shear compression under repeated cycles. *In vitro* cyclical dynamic tests conducted over 5 Million ( $5 \cdot 10^6$ ) cycles mimic the *in vivo-like* response for “life-long” wear resistance of the TiPEEK cages, once implanted in the human body.

The TiPEEK implant Weight loss and Wear particles detached from the coating are analysed to evaluate the Titanium coating response to the applied stress.



### Results



Multiple tests were performed. The worst case wear was found to be 3 mg, measured by weight loss, a small amount compared to the reference value of 200 mg which emerged from literature analysis. Several tests did not reveal any detectable amount of Titanium wear particles, suggesting that the coating is not significantly prone to wear out of the TiPEEK cage.

## Discussion & Conclusion

Based on these findings, the behaviour of Medacta TiPEEK implants was very significantly superior to all acceptance criteria in all recommended tests and can be considered overall better than existing devices in term of Resistance to delamination of the Ti-coating. All test results comply with the acceptance criteria stated in the FDA guidance and the prescribed ASTM and ISO International Standard of Characterization.

The static shear load resistance of the TiPEEK samples was 75% higher than the value indicated by the Guidance and is 100% higher than the shear force exhibited during pullout tests of the TiPEEK cages after 12 weeks of implantation in an animal model (test on Medacta internal files). This evidence suggests that TiPEEK Titanium coating would not be expected to delaminate during cage insertion and that TiPEEK cages exceed mandated safety standard for human use.

The fact that the Titanium coating is fully preserved after 10 Million cycles under shear cyclical loads, suggests that TiPEEK implants would withstand expected loads *in vivo* prior to the onset of functional fusion.

Existing scientific literature provides *in vivo* experimental data describing various quantities and sizes of particles injected or implanted into spinal surgical sites of rabbits. Studies using such methodology describe mild, local physiological reaction to foreign material, without evidence of serious injuries or pathological neural or systemic reactions, nor evident risk for the outcome of the surgery itself.

Based on comparisons with existing literature, the extremely low amount or even absence of detectable Titanium particles from TiPEEK cages provide significant inputs on safety for patients who have received implantation of these devices.

The results reported above suggest that Ti-coating provides sufficiently strong adhesion on PEEK Cages and that TiPEEK devices fulfil the requirements of the FDA guidance for industry on the testing of metallic plasma sprayed coatings on orthopaedic implants.

Based on this evidence, we conclude that Titanium coated PEEK implants are reliable and safe to be implanted with the recommended level of impaction force into the intervertebral body space.

## References

- [1] *Sagomyants KB et al. The in vitro response of human osteoblasts to polyetheretherketone (PEEK) substrates compared to commercially pure titanium Biomaterials [29]; 2008.1563-1572*
- [2] *Walsh WR et al, Plasmasprayed titanium coating to polyetheretherketone improves the bone implant interface Spine J 2014;15:1041–9.*
- [3] *Walsh WR. Titanium coated interbody device, 8th M.O.R.E. International Symposium 2016*
- [4] *FDA guidance, ISO and ASTM standard tests remain on Medacta Internal files.*