3 DIMENSIONS OF FUSION

Just the Facts about Interbody Materials

PERCEPTION

- Only material matters for biological fixation.
- PEEK causes fibrous layers to form between the implant and vertebral body.
- Titanium coated implants delaminate.
- PEEK implants cause osteolysis.
- Biological cellular response is not influenced by topography.

REALITY

- The **surface texture** is a better predictor of biological fixation. [1,2]

  In vivo animal studies show bone formation at interface is dependent on surface modification.

- **Surface texture**, or the lack thereof, is the reason for fibrous layer formation.[3, 4]

  In the dental field, it is well known that presence of a fibrous layer can be avoided by controlling the surface properties of the implant.[13] In animal studies, more fibrous tissue contact was observed on implants with smooth surfaces compared to roughened surfaces.

- Available data is inconsistent and varies depending on manufacturing process or other variables.[5, 6]

  In a mechanical study, Kienle et al., observed detached wear particles of titanium-coated implants but no full delamination.

  In Medtronic-sponsored mechanical testing of proprietary implants, no delamination occurred.

- Data points to other factors causing osteolysis, not material. In a case report, Takenada et al found that an osteolytic vertebral defect was induced by cellulose particles from cotton gauze fibers.[7, 8]

- Topography has been shown to influence cellular response.[1, 9-12]

  In several *in vitro* studies, surface texture was found to affect cell proliferation, differentiation, and growth factor production.

Animal models are not necessarily indicative of human clinical outcomes.

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Medtronic

3 DIMENSIONS OF FUSION

For intervertebral bony fusion, interbody spacers (i.e., intervertebral devices or cages) are used to increase disc height, restore segmental lordosis, and stabilize the vertebral segment until arthrodesis and permanent stabilization take place. Interbody spacers have different geometries and functionality, to meet the requirements of a given procedure, and are made of different materials . The most commonly used spinal interbody devices for lumbar interbody fusion are composed of metallic (e.g., titanium [Ti] and its alloys) or polymer (e.g., polyetheretherketone [PEEK]) materials. Titanium-aluminum vanadium alloy (Ti-6Al-4V, TiAlV) is the most common Ti alloy. The materials of synthetic spacers have been shown to have desirable biocompatibility, and mechanical properties.

While *in vivo* animal studies have shown that surface texture plays a role in achieving biological fixation (i.e., bony formation at the bone to implant interface and mechanical integration), there are currently no controlled, clinical studies correlating long-term fusion outcomes with surface topography.

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