Trabecular Metal™ Material is made of elemental tantalum (atomic number 73), one of the most chemically stable and biologically inert metals used in orthopaedic implants, making it highly biocompatible and corrosion-resistant. Tantalum is the ideal material for this ingrowth structure, becuase it has high fatigue strength and a compressive modulus that allows it to bend before breaking.3

Trabecular Metal Material is produced at a dedicated facility in Parsippany, New Jersey. Utilizing a proprietary thermal deposition process, elemental tantalum is deposited onto a substrate, creating a nanotextured surface topography and building Trabecular Metal Material one atom at a time.

A prospective randomized controlled trial compared radiological and clinical outcome of Trabecular Metal™ (TM) spacers in PLIF, used as standalone (SA) devices, to TM spacers in PLIF with pedicle screw fixation (PF), in patients with single-level degenerative disc disease (DDD).

Patients (n = 80) with chronic low back pain and single-level degenerative disc were randomly assigned to the SA PLIF (n = 40) or PLIF with PF (n = 40). The primary radiological outcome was the evaluation of a long-term (±6 years; range 6.0-7.7 years) stable construct measured by dynamic X-rays. CT scan does not allow judging the bony bridging between vertebrae, because of Tantalum artefacts. The clinical evaluation (6 weeks, 6, 12 and 24 months) consisted of the Oswestry Disability Index (ODI) score, intensity of low back pain (Visual Analogue Scale) and quality of life (Short Form-36).

At 6-year follow-up, X-rays showed a stable construct in 94 % of patients treated by SA TM-500 spacers and in 97 % of those with additional PF. Neither subsidence nor migration was observed in either the SA or the PF group. The average improvement in ODI scores at 24-month clinical follow-up was 14.4 and 13.8 for the SA and PF group, respectively. The VAS score showed an average improvement of 6.4 (SA) and 6.7 (PF), 2 years after implantation. No significant difference between groups was observed at all the evaluation points.

In this study, TM spacers were found to provide a solid construct at more than 6-year follow-up after PLIF for DDD both with and without additional pedicle fixation. The clinical, but also radiological results were not significantly different between both cohorts. Future studies focusing on the differences of SA and PF at L4/5 level should be powered to study differences in post-surgery stability at the long term [1)].

1)
Van de Kelft E, Van Goethem J. Trabecular metal spacers as standalone or with pedicle screw augmentation, in posterior lumbar interbody fusion: a prospective, randomized controlled trial. Eur Spine J. 2015 Sep 11. [Epub ahead of print] PubMed PMID: 26362051.