3D titanium interbody fusion cages sharx®
(SLM selective laser melted)

Goal of the study: Does the sharx® intervertebral cage due to innovative material, new design, and lordotic shape solve some problems of currently available cages?

White Paper
prepared by
ti2b® international GmbH,
October 2015

Dr. Ulrich Hubbe
Head of Spine Surgery Division,
Department of Neurosurgery,
University Medical Center Freiburg
sharx® – a lordotic shaped interbody fusion cage made of titanium trabecular sintered structure (SLM). Fusion rate, imaging artefacts and 12 months clinical follow up outcome.

U. Hubbe, Head of Spine Surgery Division, Department of Neurosurgery, University Hospital Freiburg

The aim of this study
The new sharx® intervertebral cage promises to solve problems of some previously available cages by its innovative material, the new design, and the strong lordotic shape.

In the study the laser-sintered titanium material is named “trabecular material”, because the porosity trabecular titanium surface promises - similar to titanium dental implants - a fast and direct ingrowth into the bone and thus a low non-union.

The trabecular structure also reduces the amount of metal per unit volume, so that artefacts in the MRI/CT image forming should be lower.

The new design does not present a large graft cavity, which is intended in the previous designs for filling with bone graft. Characterized is the bearing surface of the cages, as it is increased and a subsidence of the cage into the adjacent endplates will be reduced.

The strong lordotic cage shape of 12° degrees helps to support the restoration of the reduced sagittal balance, which occurs within the scope of the degeneracy of the spine lordosis.

In a clinical study, the clinical and imaging results of operated patients should be evaluated with respect to these facts.

Material and Method

The data of 22 patients treated at the lumbar spine, 3 patients at the thoracic spine in the context of 360 degrees spondylodesis having 1 to 4 cages (38 cages total) were collected for a retrospective evaluation of the prospectively collected data. Clinical data (VAS pain), patient satisfaction, neurological status, and imaging findings (pre and post-op CT, X-ray images and functional spinal radiographs) have been collected during routinely evaluation. The image being affected by metal artifacts were evaluated on the postoperative radiographs and CT images. In addition in 3 cases, an MRI was performed postoperatively, so the image quality could be judged.

Results
In all 38 supplied levels with cage fusion in postoperative CT and functional images, mobility (to 1.3 degrees, 0.1 degrees average) could be detected after one year. The lordosis was increased in all patients by an average of 7 degrees (2 - 14 degrees). A shift of the C7 lots took place on average by -17mm (+ 12mm – -53mm). Distraction by cage (pre- to post- surgical) was on average 5mm (0mm - 16mm), subsidence of cage into the adjacent endplate (pre- to post OP 1 year) was in average 1mm (0mm – 13mm).

In all cases a reduction to preoperative pain was evaluated. 21 patients had a positive result (excellent or good by MacNab criteria) on 4 patients moderate results (1 chronic pain patient preoperatively).

The degradation of image quality due to metal artifacts of cages proved in the radiographs and CT images was surprisingly low. Even the formation of new bone within the cages has been documented and measured in HU units. In the
3 cases, where a postoperative MRI was available, the picture quality showed only in the immediate vicinity of the cages (2-3mm) extinction by metal artifacts. All cases had a good assess ability of the spinal cord, the nerve roots as well as the internal structure of the adjacent vertebrae.

Discussion and Conclusions
The proven fusion rate of 100% is excellent given the reported fusion rates in the literature (65-100%). The determination of fusion was carried out with the current gold standard of multi-planar CT imaging, but also by flexion – extension recording X-ray that are in use for FDA purpose in the USA.

The increase of lumbar and segmental lordosis through proven distraction was evaluated. After 1 year no subsidence and migration into the vertebral endplate was reported as well as no loss of lordosis created by the interbody fusion device. This is also reflected by the improvement of the sagital balance parameters and should in the longer term effect the patient clinical outcome.

The image quality was affected - neither in the radiographs, nor in the CT scans. The assessment of new bone formation inside the cage and threw out the trabecular structure has have been analyzed.

In particular, no significant artifacts have been shown in the MRI, so that the relevant neural structures and the internal structure of the vertebral bodies were always well assessable. This is a significant improvement in imaging properties, especially when compared with cages made of solid titanium or even tantalum. The study results demonstrate, that the new laser-sintered trabecular titanium cage, has met all expectations.

The new material leads to a high fusion rate, although no graft is introduced into the cage, and titanium implants creates extremely low artefacts in X-ray, CT, and MRI imaging.

A controlled distraction and sagital alignment can be obtained and remains stable, until the bony fusion occurs, without significant migration into the end plates. The lordotic implant shape improves the lumbar alignment and corrects with permanently good result the sagital balance.

THREE POST-OPERATIVE CASE REPORTS

CASE REPORT 1

Symptoms:
64 year old male with increasing load dependent immobilising lumbar back pain, Pain increased several years after previous fusion surgery 13 years before. Facet blocks lead to partial pain relief for short time periods only.

Imaging
CT demonstrated severe degeneration in the L3/L4 level adjacent to the fused levels (L4 to S1). Cystic degeneration of the endplates and vacuum phenomenon in the disc space was visible as well as increased bone density around the endplates (images a + c). In addition spondylolysis was detectable on parasagital images.

Functional x-rays showed increased mobility of the segment.
Full spine x-ray showed only mild sagital imbalance.

Diagnosis
Degenerative spondylolisthesis (Meyeiding grad I).

Therapy
With patient in prone position the spondylodesis was prolonged to L3 decompression of the spinal canal, distraction of the intervertebral disc space and interposition of a 12° lordotic shaped sintered titanium OLIF® cage with bone graft via a left sided minimal invasive TLIF approach, and posterior fixation with pedicle screw / rod instrumentation in lordotic position was performed. 

(*OLIF Oblique Lumbar Interbody Fusion)

**Result**

During the postoperative course the patient reported significant reduction of the lumbar back pain (VAS 7/10 to 2/10). He was mobilized on the first postoperative day and was discharged pain free on the 6th postoperative day. The postoperative x-rays showed an improved lordotic shape of the lumbar spine (57° versus 48° preoperatively) and the implants in the correct position. At final follow up after 1 year the lumbar back pain was completely eliminated and the patient was back at work, working 8 to 10 hours a day.

No significant change in the shape of the lumbar spine and no subsidence of the cage could be observed. CT scans (thin slice spiral scan) at final follow up demonstrated solid bony fusion with bony bridging anterior and lateral to the cage. In addition bone formation could also be verified inside the cage via regional Hounsfield Unit (HU) measurement (average 1011 HU inside and 536 HU outside the cage).

**Comment**

For interbody support the sintered titanium OLIF® cage sharx® / ti2b international GmbH was chosen, because of the capability of a close implant-bone interface, the favourable biomechanical properties of the titanium material, the 12° lordotic angulation of its endplates and the optimized shape for the minimal invasive diagonal positioning of the cage. In addition the implant causes minimal artefacts in x-ray, CT and MRI, which has advantageous for postoperative imaging. 

(*OLIF Oblique Lumbar Interbody Fusion)
Case 2
f, 55y, increasing lumbar back pain and new radiating right sided leg pain combined with moderate L5 paresis
OR: 27.11.2013, follow up CT: 9.10.2014

a - c preoperative images
a: sagittal CT showing severe degeneration in L5/S1
b: sagittal MRI (T2) showing MODIC III signs and narrowed disc space L5/S1
c: lat Xray showing severe degeneration in L5/S1

d - g postoperative images
d: sagittal CT showing solid bony fusion mass anterior and posterior of the cage
e + f: axial CT scans demonstrating solid bone mass around and inside the cage
g: lateral X-ray with good distraction and lordotic shape of L5/S1
CASE REPORT 3

A 75 year old female with history of load dependent lumbar back pain and radiating left sided leg pain combined with moderate L5 paresis. OR: 4.12.2013, follow up CT: 26.4.2014

MRI images show lateral recess stenosis caused by a synovial cyst in L3 / 4 on the left side and a spondylolisthesis (Meyerding Grade I). Functional X-rays showed mobility of the spondylolisthesis. Full spine X-ray showed no signs of severe sagittal imbalance.

Diagnosis
Degenerative spondylolisthesis (Meyerding grade I) with consecutive stenosis of the lateral recess L3 / 4 left sides combined with a synovial cyst.

Therapy
Surgery was performed: With patient in prone position a percutaneous spondylodesis L3 / 4 was performed with distraction of the intervertebral disc space, interposition of a 12° lordotic shaped sintered titanium OLIF® cage via a left sided minimal invasive TLIF approach, transplantation of local bone in and around the cage and fixation with a pedicle screw / rod instrumentation in lordotic position. In addition the synovial cyst on the left side was resected. Due to osteoporosis of the spine the screws were cement augmented. (*OLIF Oblique Lumbar Interbody Fusion)

Result
During the postoperative course the patient reported complete relief of the radiating pain into the left leg and of the lumbar back pain. She was mobilized on the first postoperative day and was discharged pain free on the 6th postoperative day. The postoperative X-rays showed an improved lordotic shape of the lumbar spine (45° versus 33° preoperatively) and the implants in the correct position. During the follow up (seven weeks) no significant change in the shape of the lumbar spine and no subsidence of the cage could be observed.

CASE REPORT 4 MRI compatibility

Patient history and background

Symptoms
A 75 year old female with history of load dependent lumbar back pain and radiating pain in the left leg according to the L4 dermatome since three months. Pain is increasing in the last weeks leading to a reduced walking distance of 500m. Half a year before decompression of a lumbar stenosis had been performed in L 2 / 3 and L 3 / 4 on both sides via a unilateral approach from the right side.

Imaging
MRI images show lateral recess stenosis caused by a synovial cyst in L3 / 4 on the
The postoperative MRI, which was performed 16 days after the operation showed, a good local decompression and no signs of postoperative bleeding.

**Comment**

For interbody support the sintered titanium OLIF* cage sharx® / ti2b international GmbH was chosen, because of the capability of a close implant-bone interface, the favourable biomechanical properties of the titanium material, the 12° lordotic angulation of its endplates and the optimized shape for the minimal invasive diagonal positioning of the cage. In addition the implant causes minimal artefacts in X-ray, CT, and MRI, which is advantageous for postoperative imaging. This can easily be observed on the postoperative MRI images, where the artefact of the cage is limited to few millimetres in the immediate neighbourhood of the cage. The spinal canal and even the surrounding disc tissue can be evaluated distortion free.

(*OLIF Oblique Lumbar Interbody Fusion)

**Images 1a/b: preoperative and postoperative X-ray:** showing improved lumbar lordosis by 12° according to the 12° lordosis of the implanted sharx® cage.

Note the minimal artefacts around the cage and distortion free delineation of the spinal canal and even of the disc.

**Image 2b: preoperative MRI.**