The coflex-F™ - A new minimally invasive device for the PLIF procedure

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1. Problem
In many patient cases, the PLIF technique with pedicle screws is a state of the art surgery for the treatment of lumbar instability in combination with an additional narrowing of the spinal canal and widely performed after a decompression procedure. For the implantation of the pedicle screw based posterior part of this fusion technique a rather big or an additional approach is needed. Most of these procedures could be treated in a less invasive way.

With the coflex-F™ the approach is limited to the small incision that is needed for the decompression, disectomy and implantation of the intervertebral cages.

2. Fusion with coflex™-F
The implant allows the minimal invasive stabilization of the spine in combination with Fusion Cages as an alternative to a posterior fixation with a pedicle screw system. Biomechanical studies have shown that the rigid assembly of the implant wings on top of the spinous process with the screw proves to give a high stability to the Construct which is almost close to a pedicle screw system.

3. Implant

4. Indication
The treated pathologies were:
- instability up to Meyerding 1° in combination with lumbar spinal stenosis caused by hypertrophic changes of the ligaments and/or the facet joints.
- used in patients with degenerative disc disease
- indicated for use with an interbody cage as an adjunct to fusion at a single level in the lumbar spine (L1 - S1)
- intended for attachment to the spinal processes
- providing stabilization and promoting fusion

5. Patient Population

Period of examination:
24 months (2008 – 2010)

Patients: n=31 patients; male=22; female=9
Age: ø 69 years (50-86 years)
Weight: ø 82 kg (59-124 kg)

Operation: disectomy, decompression, intervertebral cages (PEEK or Titanium) and the coflex-F™

Follow up: Registration of ODI, VAS and patient satisfaction after 3, 6, 12 and 24 months. A neurological examination and X-Ray control were performed.

5.2 Clinical Results

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<tr>
<th>VAS PreOP vs. 3, 6, 12, 24 month</th>
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<tbody>
<tr>
<td>Back Pain</td>
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<tr>
<td>Right Leg</td>
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<td>Left Leg</td>
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<table>
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<th>ODI PreOP vs. 3, 6, 12, 24 month</th>
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Satisfaction - How satisfied?
12 month (n=24)
- very satisfied
- somewhat satisfied
- somewhat dissatisfied
- very dissatisfied

Satisfaction - Surgery again?
12 month (n=23)
- definitely yes
- probably yes
- probably not
- definitely not

6. Conclusion
The combination of intervertebral Cages and the coflex-F™ is an easy and less invasive modification of the well established PLIF-procedure in the treatment of degenerative changes of the lumbar spine. Beside the very limited blood loss due to the small approach it is a safe and fast technique. Even if there are very promising results according clinical outcome and fusion rate further investigations in a bigger amount of patients are necessary.

7. Patient Case
male, born 11.03.1933

Symptoms:
Since years lumbago and since 1 year stabbing, burning pain in right leg, tickling paresthesia and hypesthesia L5 dermatome right.

MRI: small intraforaminal herniated disc L4/5 right
X-Ray: Listhesis L4/5 Meyerding 1°

Surgery: Fusion L4/5 with Cages and coflex-F™ 05/14/2008
Postop. Position Check: right implant positioning
Hospital Discharge: mild lumbago, slight hypesthesia L5 right

Follow-up for 2 years, X-Ray verification for osseous fusion, clinically intermittent mild lumbago