SPINALCOLUMN

Newsletter

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PARADIGM SPINE
the movement in spine care

The data is coming. Get ready for the coflex® experience.

coflex™ IDE Study

By Toni Mateus da Silva

Dear colleagues,
After a lot of currency invested and even more time spent over the last seven years, the first results of the coflex™ IDE study have been analyzed during the past months and also been presented at various national and international congresses in 2011.
The results of the study are astonishing, not only for the surgeons who participated in the study but also for all surgeons who have contributed to the various presentations and podium talks. As we can see coflex™ proves to be superior compared to the control group in various categories. Almost more important, the outcome of coflex™ was not inferior in any category!
For the first time, we have a prospective, randomized, multicenter Level 1 clinical study in our hands which delivers conclusive results regarding the well-known and widely discussed adjacent segment disease, showing clearly that the motion preserving treatment with coflex™ does not negatively affect the adjacent segment, whereas fusion leads to instability of the same.

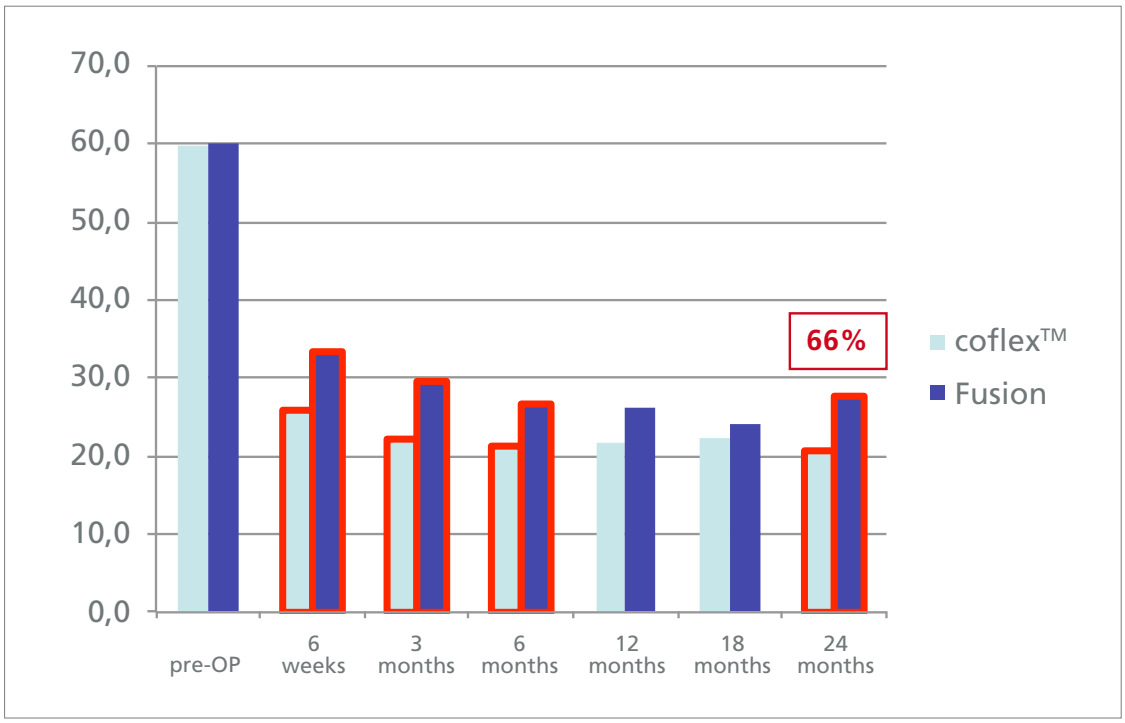
The data presented in this article will give you a first snapshot about the results of this landmark study, publications will follow soon…stay tuned!

Study design:

- Multicenter study: Decompression + posterior fusion vs. decompression and coflex™ on 1-2 levels
- Patient-cohort 1: spinal stenosis with low back pain
- Patient-cohort 2: degenerative Spondylolisthesis ≤Grade 1
- Prospective, Randomized, Concurrently-Controlled Multi-Center FDA IDE Trial from 20 US Sites – Level 1 study
- 335 Randomized Patients Surgically Treated – Presenting Results on 219 Interim Analysis Patients at 2 Years
- Patient follow-up at 24 month 97%
- Used scores: ODI, VAS, ZCQ, SF

Results:
Clinical outcome based on scores (red framed graphs show statistical significance!):

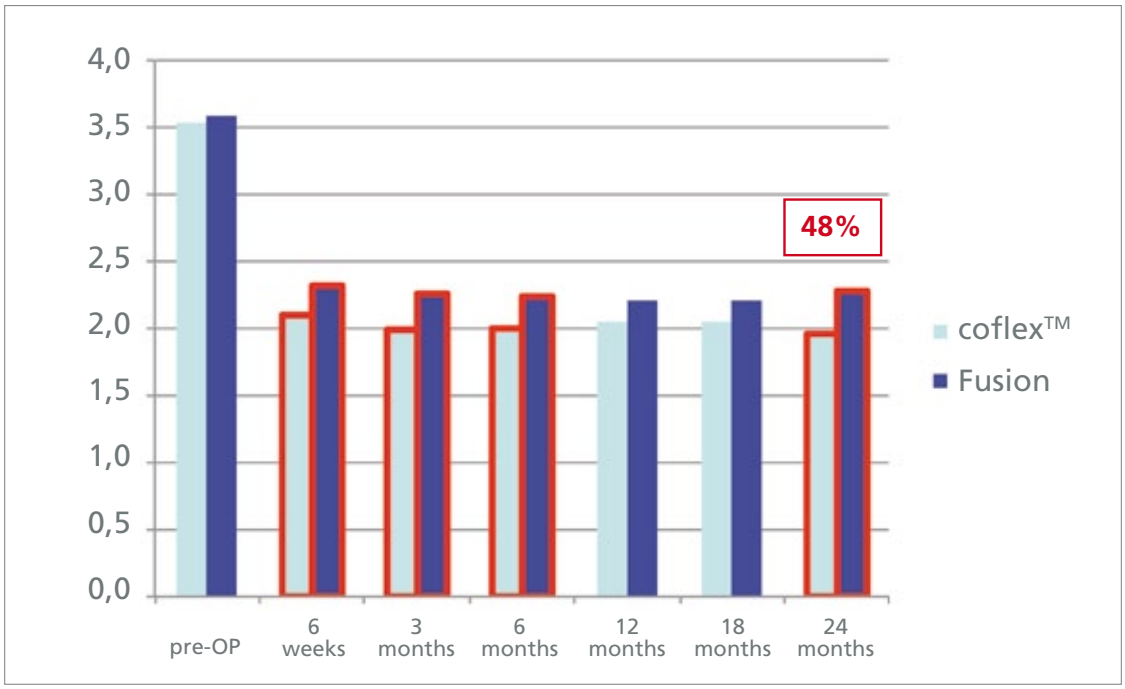
Oswestry Disability Index (ODI)



- coflex™ patients with constantly better outcome in the ODI
- outcome significant better after 6 weeks, 3, 6 and 24 months

Improvement of the ODI in the coflex™ group of 66% 2 years post-OP!

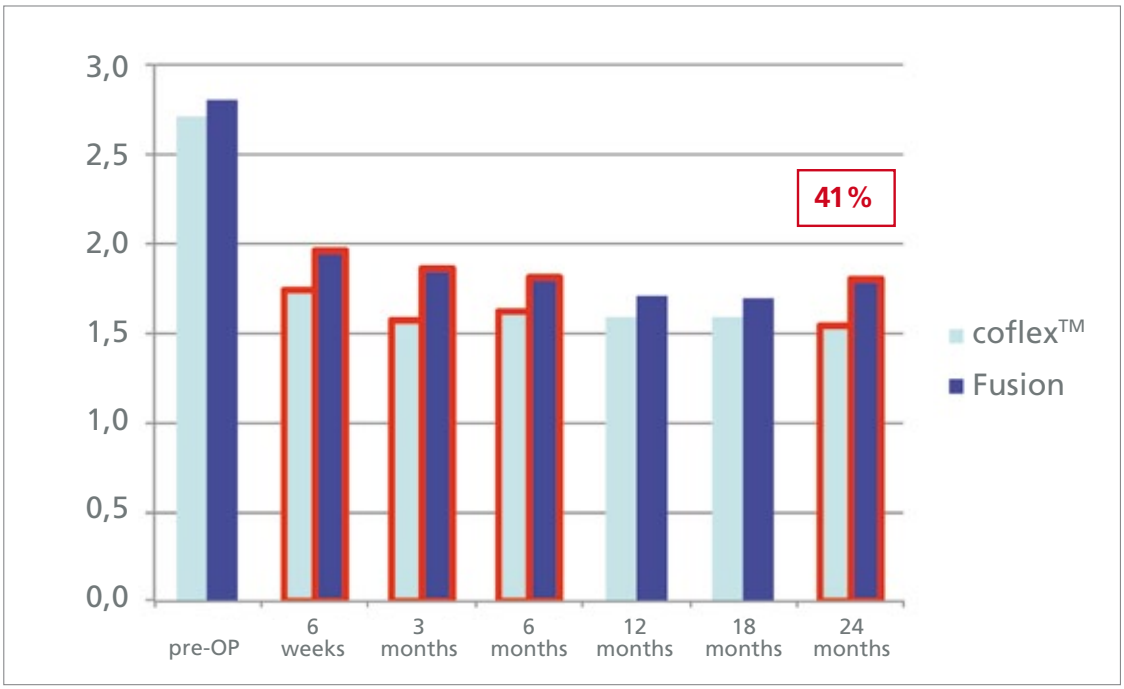
ZCQ – Symptom severity



- coflex™ patients with constantly better outcome in the ZCQ
- outcome significant better after 6 weeks, 3, 6 and 24 months

Improvement of the ZCQ in the coflex™ group of 48% 2 years post-OP!

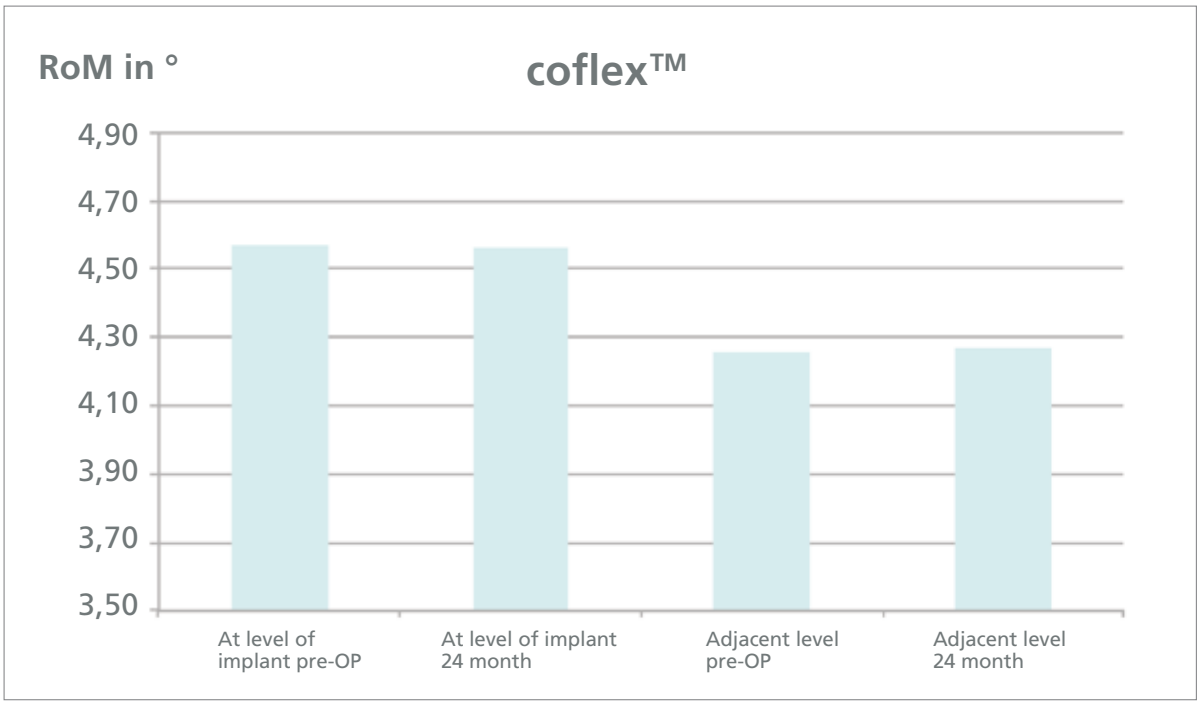
ZCQ – Physical function



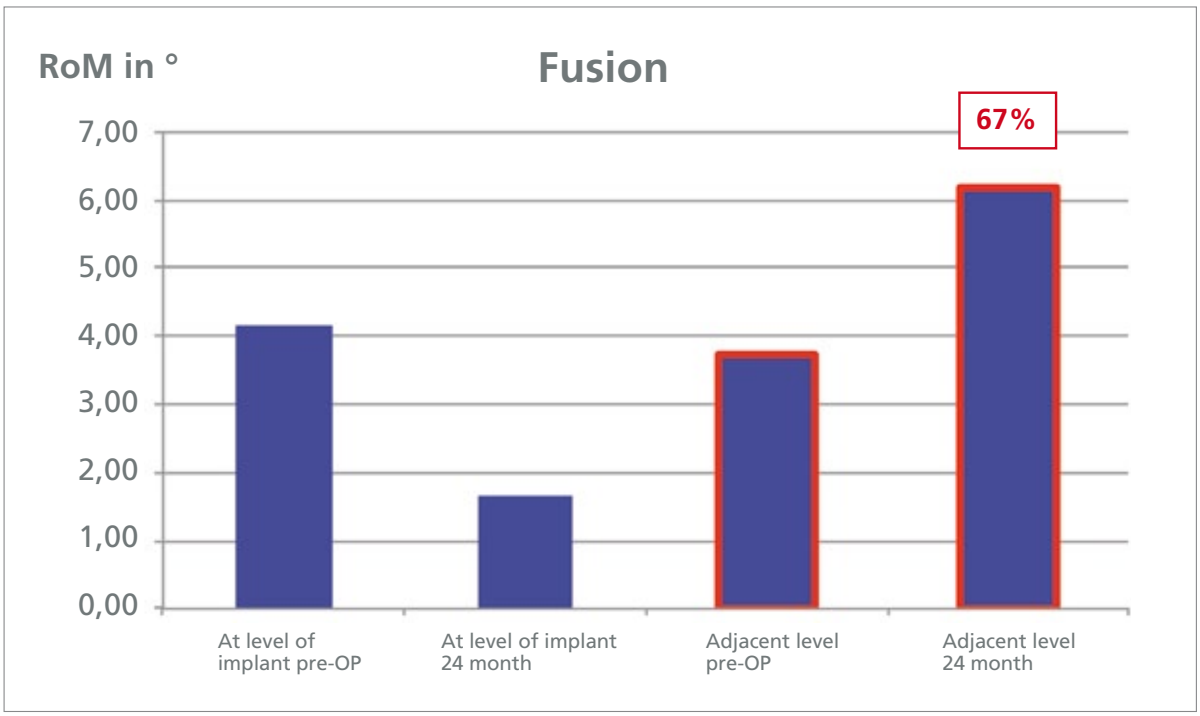
- coflex™ patients with constantly better outcome in the ZCQ
- outcome significant better after 6 weeks, 3, 6 and 24 months

Improvement of the ZCQ in the coflex™ group of 41% 2 years post-OP!

Protection of adjacent segments:
A major principle of motion preserving stabilization - as performed with coflex™ - is the protection of the adjacent segments. It is assumed that rigid fixation increases the Range of Motion in the adjacent segment leading to a faster degeneration of that segment. The results of the coflex™ IDE study strongly support this! We analyzed the RoM in the adjacent segments after fusion as well as after implantation of coflex™. We can see here that the RoM in the adjacent segment increased significantly in the fusion group whereas it remained unchanged after implantation of coflex™.

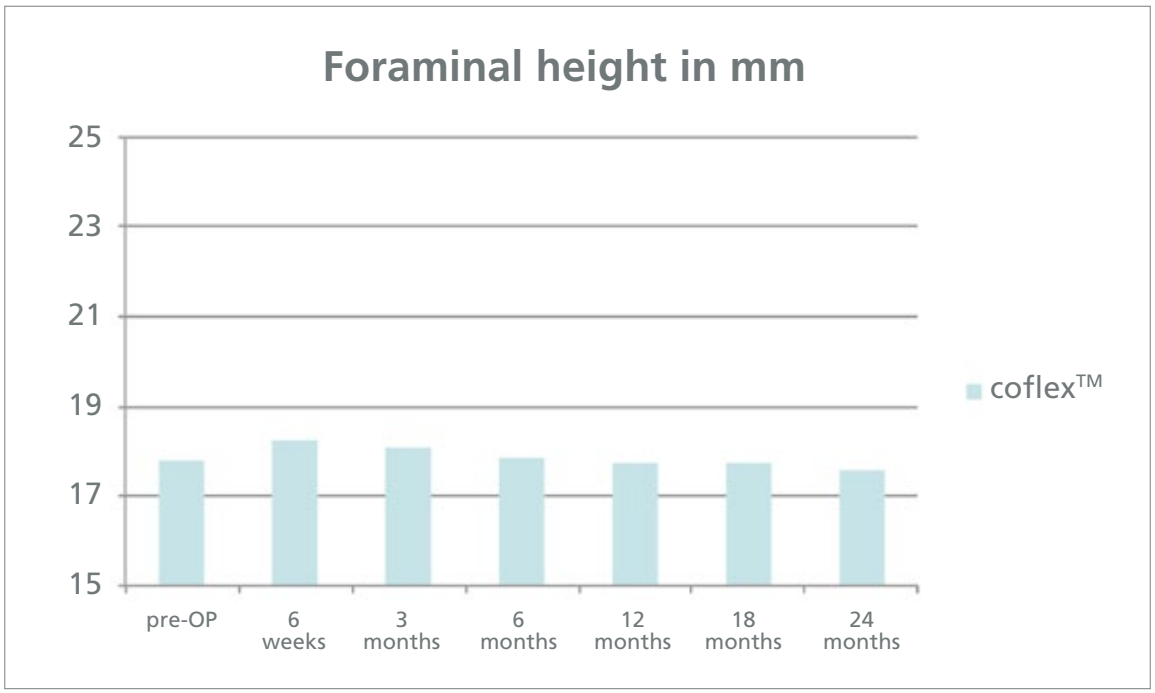


RoM remains unaffected in the adjacent segment after coflex™ implantation!
RoM identical 24 months post OP at implant level



RoM in the adjacent segment increased after fusion about 67% 2 years post-OP!

Maintenance of foraminal height:
Maintenance of foraminal height helps to ensure that the good result after decompression is preserved and minimizes the risk of a recurrent stenosis. The coflex™ IDE study delivers the scientific proof for that statement by showing that the foraminal height remains unchanged 24 months after surgery.



coflex™ - safety data and economic aspects:
Both patient groups have been analyzed regarding complications during surgery, implant caused problems and any adverse or severe adverse events. There has been no difference compared to the control group. This shows that coflex™ is a safe and secure implant.
Due to the less invasive surgical technique minimizing significantly blood loss, operative time and days of hospitalization compared to fusion, economic benefits for the surgeon using coflex™ can be expected.

Summary
To summarize the study, it showed that direct decompression and interlaminar stabilization proved equivalent or superior to laminectomy and posterior spinal fusion at 2 years in the treatment of spinal stenosis with back pain or degenerative spondylolisthesis.
The patients that received a coflex™ experienced significant improvements over fusion with respect to operative times, blood loss, hospital length of stay, ODI and ZCQ at minimum 2 years. Operative and adjacent level motion was maintained with coflex™, while fusions experienced significantly increased adjacent level angulation and translation. These results demonstrate safety, efficacy, and non-inferiority with interlaminar stabilization using coflex™ compared with fusion. The usage of coflex™ led to significantly improved perioperative outcomes, significant improvements in multiple clinical outcomes measures compared with fusion at 2 years, and maintenance of motion at operative and adjacent levels. The study shows clearly that the interlaminar stabilization with coflex™ is a safe and efficacious alternative, and provides several distinct advantages over lumbar spinal fusion with pedicle screw instrumentation.

Bibliography:
The coflex™ IDE trial has been presented (podium and/ or posters – abstracts available at PARADIGM SPINE) during:
NASS 2011
IMAST 2011
DWG 2011 (German Spine Society)

The results of the study enable us, dear colleagues, to scientifically support the features and benefits of coflex™. It also underlines the scientific integrity of PARADIGM SPINE being the leading company in spinal stenosis treatment. Please use this study in your communication towards potential and existing customers and let us continue the coflex™ success story!