

Clinical assessment of single level arthrodesis using interspinous fusion device (Coflex-F) with bone substitute

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Introduction

The purpose of this clinical assessment is the evaluation of the capability of the interspinous system (Coflex-F) to create a single level fusion in combination of bone substitute. The clinical experience would support the in vitro results reported above showing that the system is an effective means of synthesis.

Methods

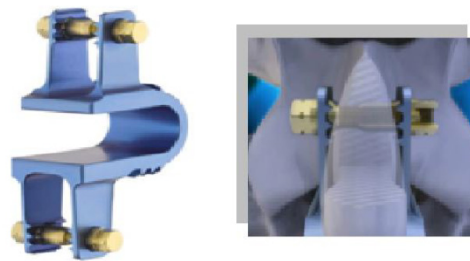
This clinical assessment enrolled 25 patients with lumbar stenosis (L1-L5) with or without low-grade spondylolisthesis. The patients have already undergone conservative treatment for six months without achieving significant success or improvements in their clinical picture.

Patients were enrolled in three months from 1 June 2011 to 01 December 2011 and subject to the following analyzes and questionnaires:

- The personal data and identification of the clinical picture of the patient
- Descriptive data of the surgical procedure
- VAS - pre-operative, post-operatively, six months and twelve months
- ODI - preoperative, postoperative, six months and twelve months
- CT scan - preoperative, postoperative, six months and twelve months

The subjective evaluation of pain by the VAS and ODI questionnaires and evaluating radiological arthrodesis obtained determine the reliability and effectiveness of the device.

interspinous fixation (Coflex-F)



Fixation device with rivets to fix to the spinous processes

Results

This clinical assessment involves subjective evaluation of pain by the VAS and SF-36 questionnaires with analysis of the indices:

- Pre-operative
- Six months post-operative
- Twelve months post-operative

The study is complemented by radiological assessment of patients to determine the degree of arthrodesis reached in the treated level.

The early results are promising and initial radiological signs of fusion are demonstrated on x-ray and CT studies.

Learning Objectives

Evaluation of interspinous procedure for single level arthrodesis.

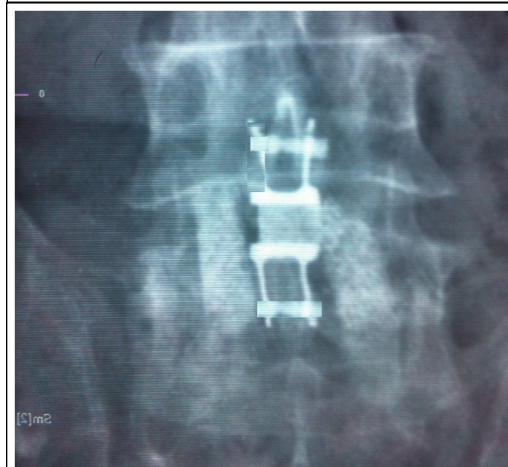
Conclusions

The result obtained shows how the interspinous system is capable of inducing spinal stability with arthrodesis, comparable to that obtainable with of pedicle screw and rod systems, but with clearly many clinical advantages such as:

- Reduced skin incision.
- Reduced muscle trauma due to minimally invasive procedure.
- Reduced operating risk of pedicle screw and their related problems.
- Reduction in time of surgery.



Early post-op Xray AP/LL



AP view 6 month Xray controls

References

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- Jutte P, Castelein R. Complications of pedicle screws in lumbar and lumbosacral fusions in 105 consecutive primary operations *European Spine Journal* Volume 11, Number 6, 594-598.



LL view 6 month Xray controls