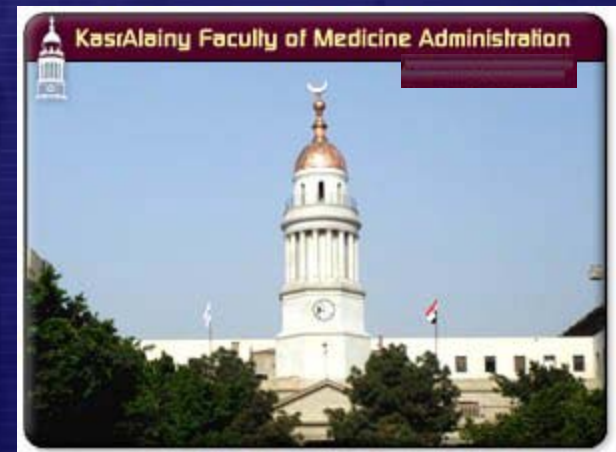


# Coflex Dynamic Interlaminar- interspinous distraction stabilization device for lumbar degenerative disease (Initial Experience)

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[The Vth Annual International Neurosurgery Conference](#)





# Disclaimer



“ The author has no financial relationship with any medical industry “





# Degenerative diseases of the lumbar spine (Vertebral Arthrosis)

- Affects
  - the intervertebral discs,
  - the vertebral endplates,
  - the facet joints and
  - the intervertebral posterior ligaments
- Increasing number of patients needs new management strategies

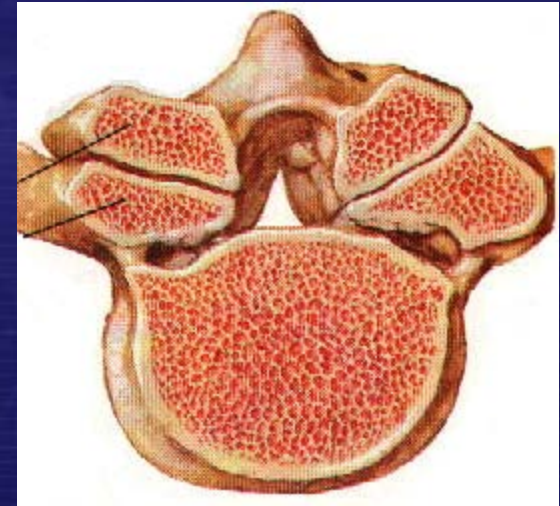




# From a functional standpoint

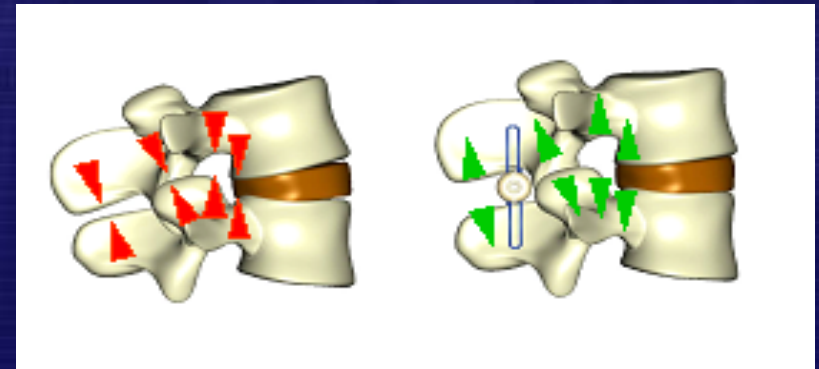
## 1. Hypermobility of the joints

- weak ligaments
- no longer perfect coaptation of the joint surfaces.



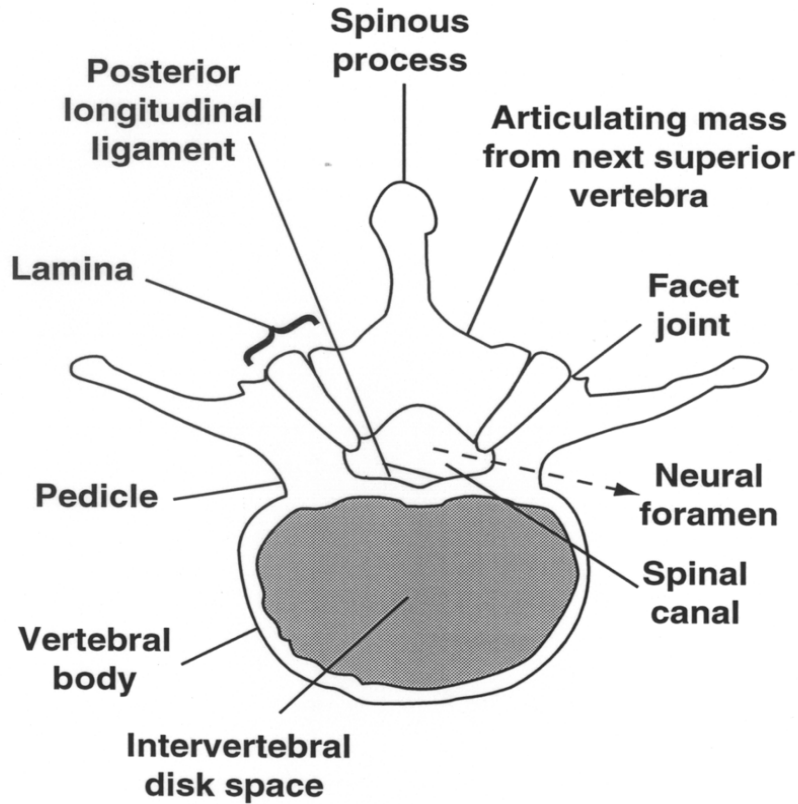
## 2. Then **morphological changes** causing narrowing of the affected segment and its exit foramina,

## 3. Ending in some form of **degenerative instability**

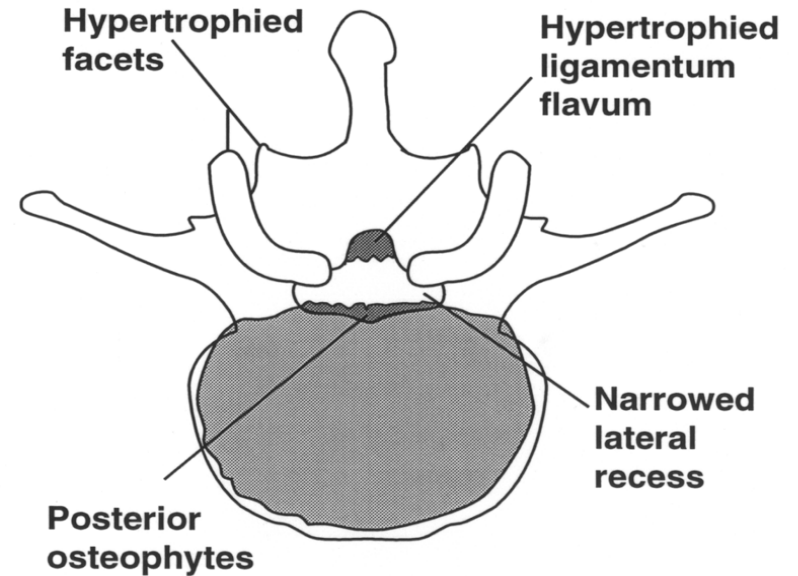




# Factors contributing to Spinal Stenosis (narrowing of the spinal canal)



**A**  
Normal



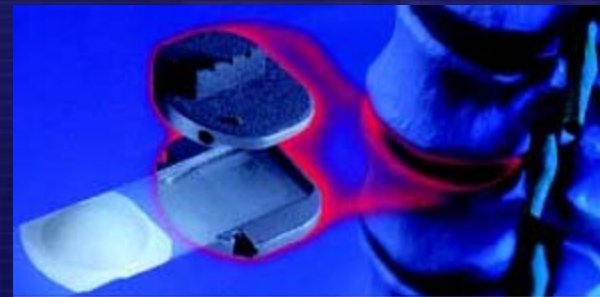
**B**  
Stenotic





# ISP devices & Motion segment preservation Soft tissue preservation

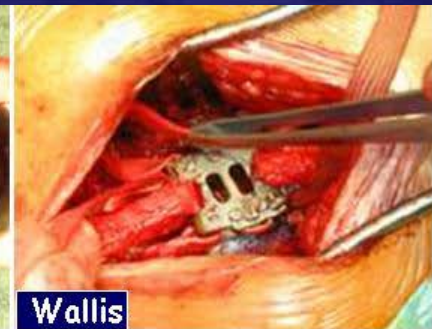
- A recent advanced concept
- Provide biomechanical strengths and dynamic stabilization
- Without motion segment fixation,
- A good alternative for fusion procedures.





# Interspinous process (ISP) devices

- Alternative treatment for LCS,
- Several types have been introduced,
- Each device has its own indications and characteristics,
- Common theoretical purpose of:
  - Restricting extension,
  - Unloading of the facets,
  - Enlarging the neural foramina and
  - Reducing the pressure in the posterior annulus.





# Spinal stenosis is a known disease of the facet joints

(The main indication for implanting Coflex™ device)

Reaches the anatomical centre of rotation (COR)  
Reaches the level of the facet joints



Range of motion of the facet joints controlled,  
Joint slightly distracted,  
Foraminal height restored,  
the height maintained (metallic stiffness).

Plus decompression



LBP is relieved.



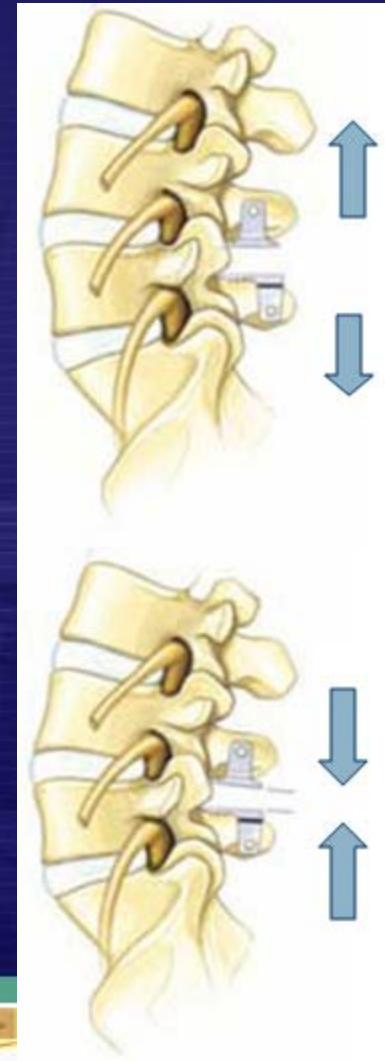




# The Coflex® Dynamic Interlaminar–Interspinous Distraction Stabilization (DIDS) Device

## Offers

- **Functional dynamic stabilization:**
  - compressible in extension,
  - While limiting flexion
- **Interlaminar orientation**
  - with increased rotational stability
  - the center of rotation being close to spinal canal
- **Protection of posterior elements**
  - stress reduction on facet joints
  - maintenance of foraminal height





# Why is this study being conducted?

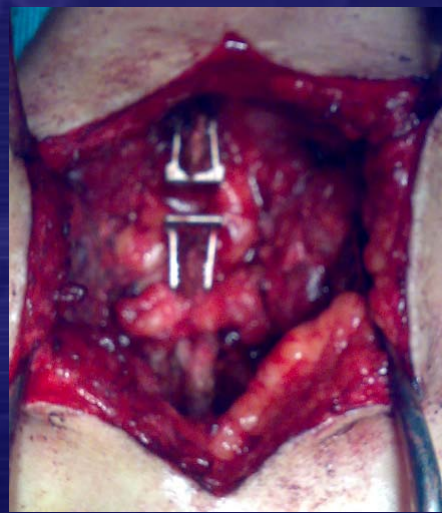
- Over **35,000** people outside the U.S. have been implanted with the coflex® device.
- **Early clinical results** for the coflex,® in **Germany** include:
  - 1.86% reported relief in LBP** that allowed patients to significantly increase their walking distance.
  - 2. reduced post-operative** disability and pain scores as compared with pre-operative scores.





# Study Design

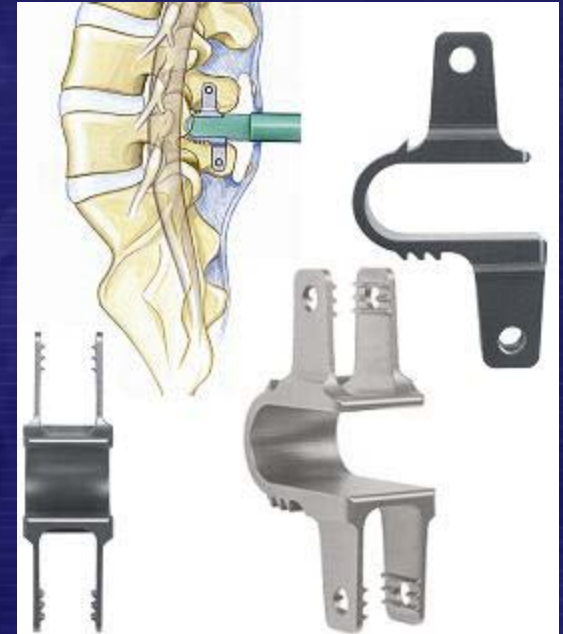
a multi-center, prospective study,  
designed to evaluate the safety and  
effectiveness of Coflex dynamic ISP device  
to treat spinal stenosis





# Study Overview

- Enrollment of 14 patients
- From June 2008 until July 2009
- Median follow-up 7.5 months.
- At the time of follow-up all patients had questionnaires, clinical examination and x-ray taken.
- Patients are followed at 4 weeks, 3 months, 6 months, 1 year.





# Inclusion Criteria

1. 40–80 years old
2. Appropriate candidate for surgery
3. At least moderate lumbar stenosis
4. No more than 2 levels should require surgery
5. No prior lumbar fusion
6. Must have had at least 3–6 months prior care and failed non-operative treatment

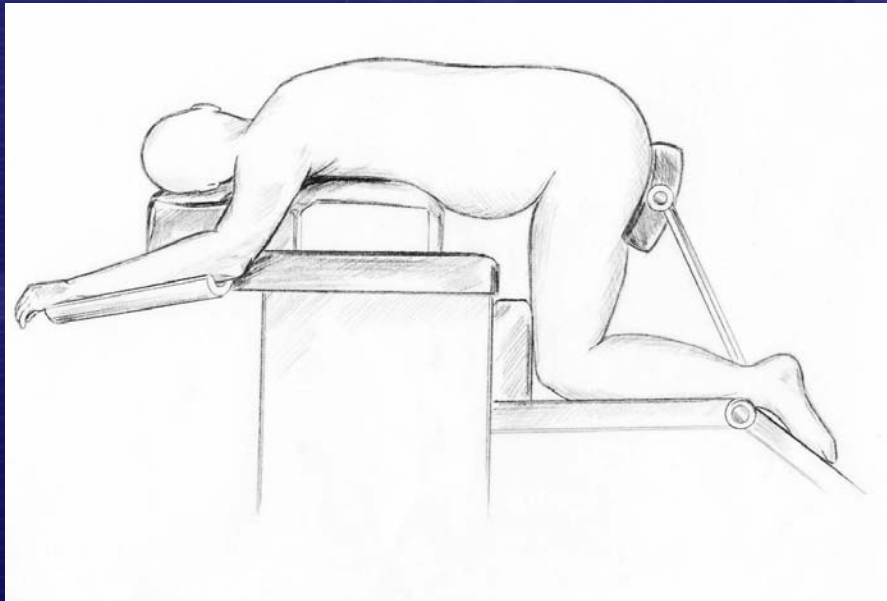




# 1. Surgical technique

Under **light general anesthesia**  
in the **prone position**

A midline incision **3 cm** on the  
spinous processes of the stenotic  
level



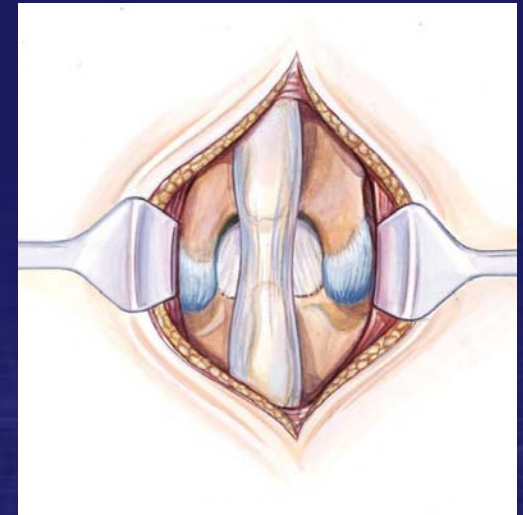


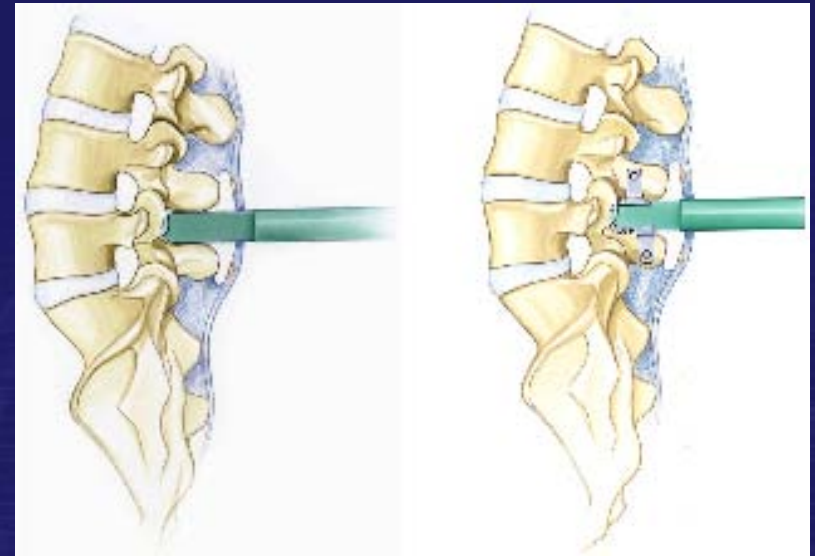
The **paraspinal muscle** elevated to the level of the facets and laminae.

The **supraspinous ligament** partly detached from the adjacent two spinous processes and preserved

The **interspinous ligament** removed

Foraminal **decompression** with partial laminotomy





Proper **implant size** determined (a trial inserter)

Coflex **inserted tightly** into the interspinous space

The wing **clamps** of the implant tightened

**Wound closure**







## 2. Clinical assessment

### Clinical Outcome Scores

Visual analogue scale (VAS) scores  
Activities of daily living (ADL)  
The Oswestry Disability Index (ODI)



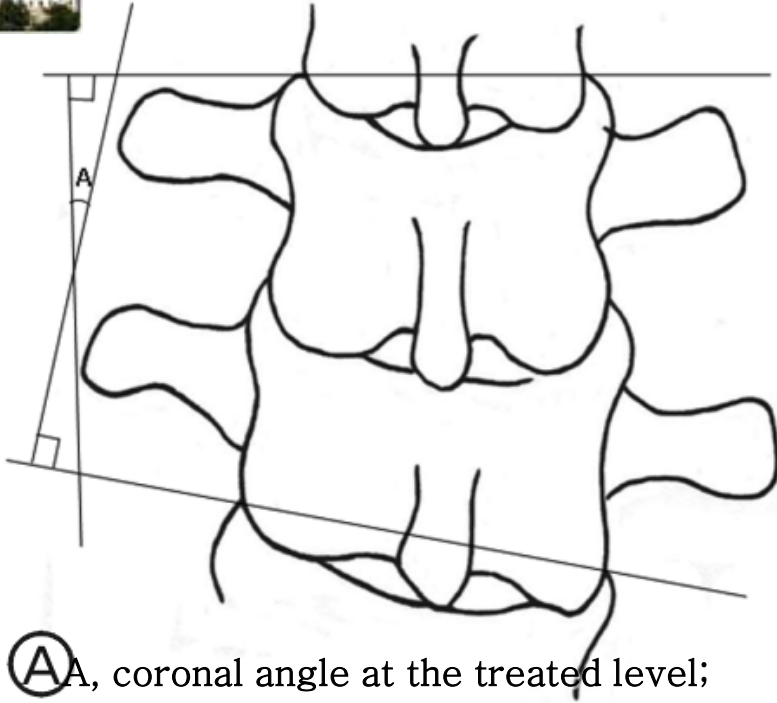


### 3. Radiologic assessment

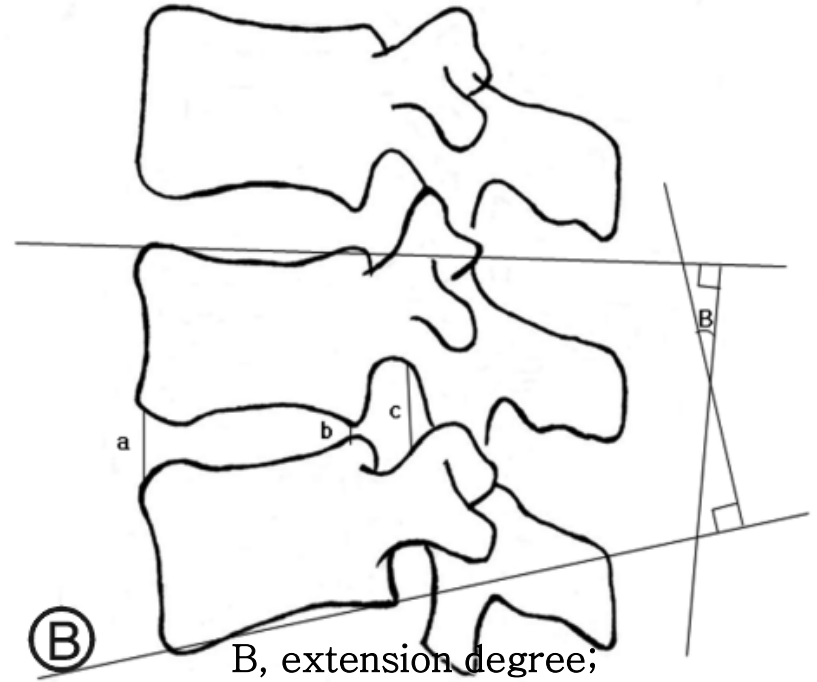
At the treated level  
anterior disc height,  
posterior disc height,  
foraminal height,  
Coronal angle and endplate angles

Theoretical results of ISP devices are  
postoperative height values  
would be bigger than preoperative values





Ⓐ, coronal angle at the treated level;

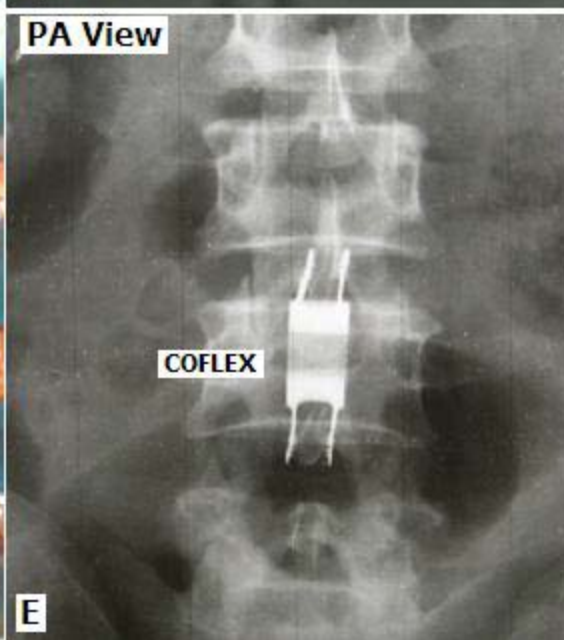
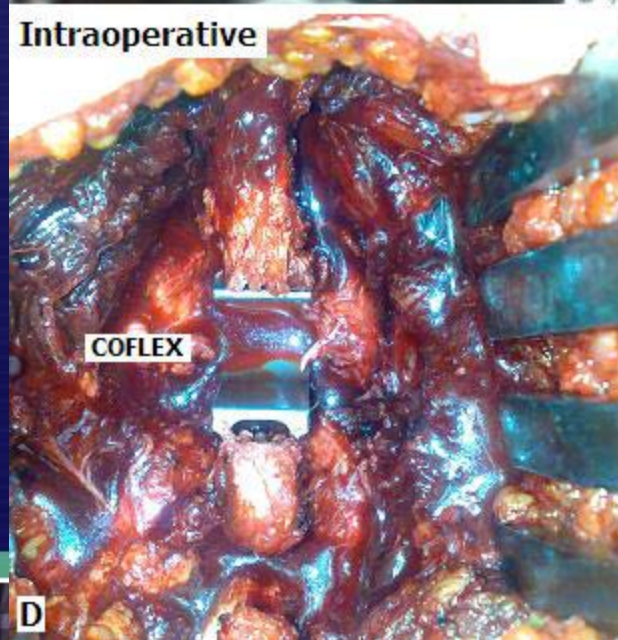
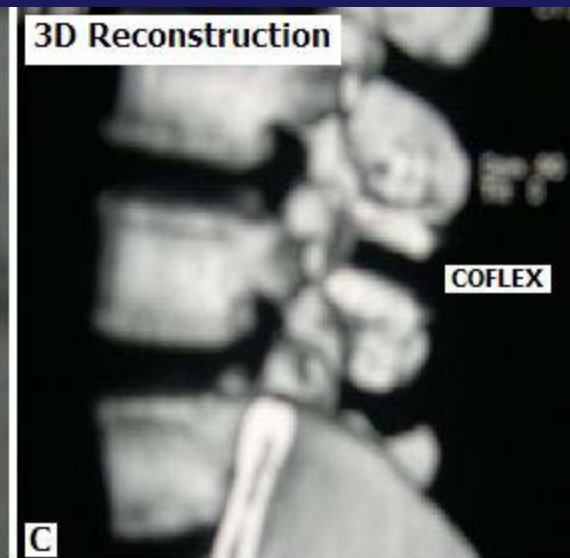
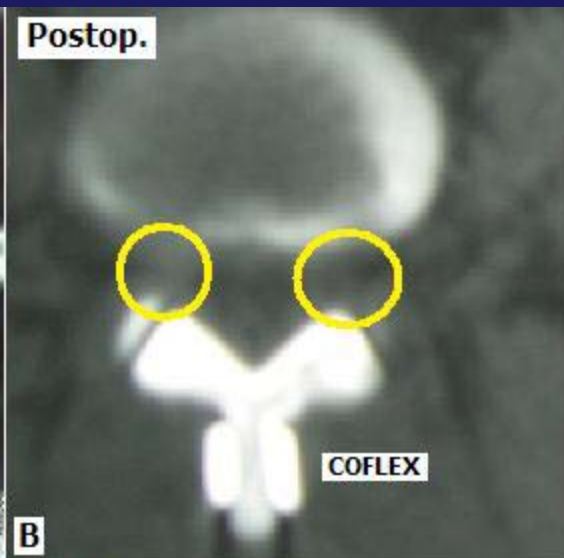
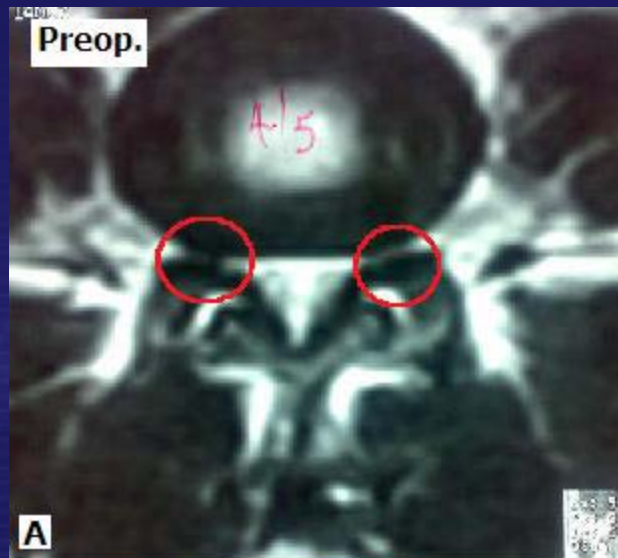


Ⓑ, extension degree;  
a, anterior disc height;  
b, posterior disc height;  
c, foramen height

a, anterior disc height;  
b, posterior disc height;  
c, foramen height

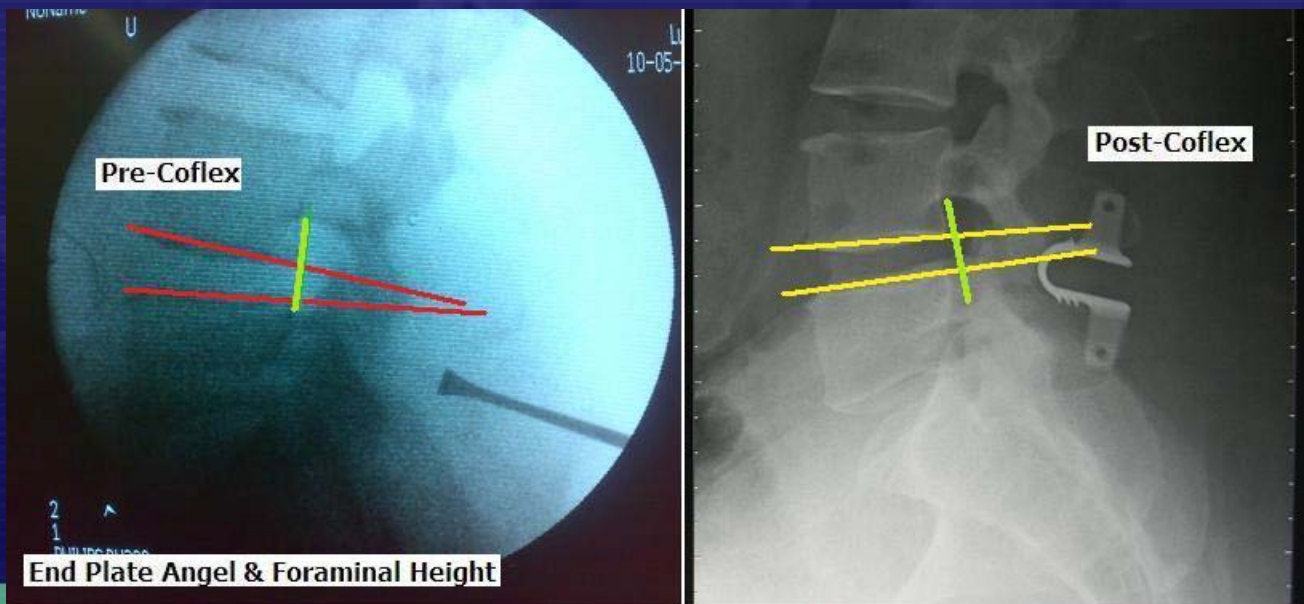
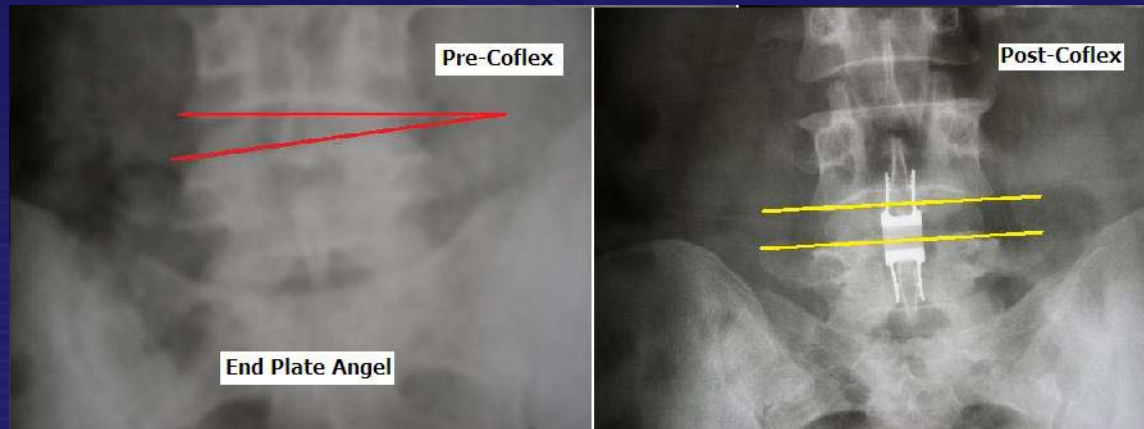


# L4,5 lateral recesses stenosis



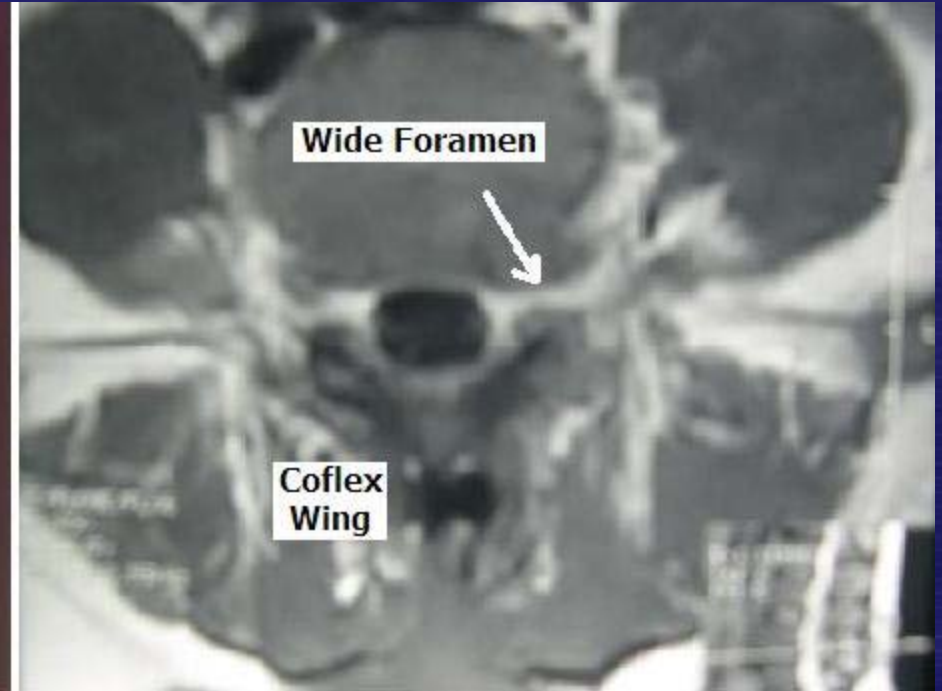


# Endplate Angles & Foraminal height





# Foraminal Opening



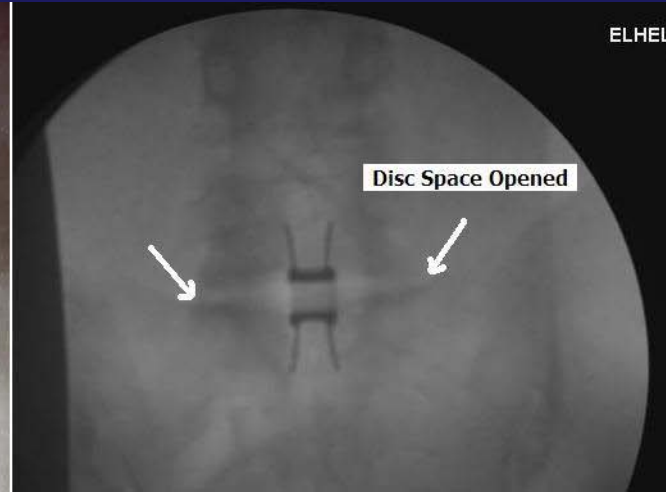
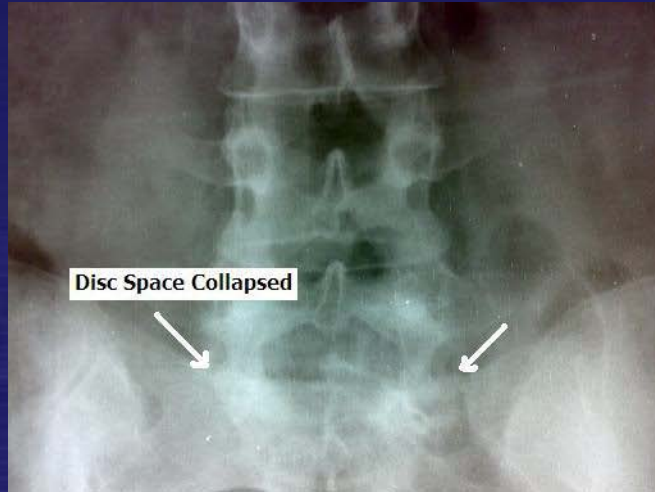


### Decompression of Stenosed Foramena





# Disc Space Height



Anterior & Posterior Disc Heights







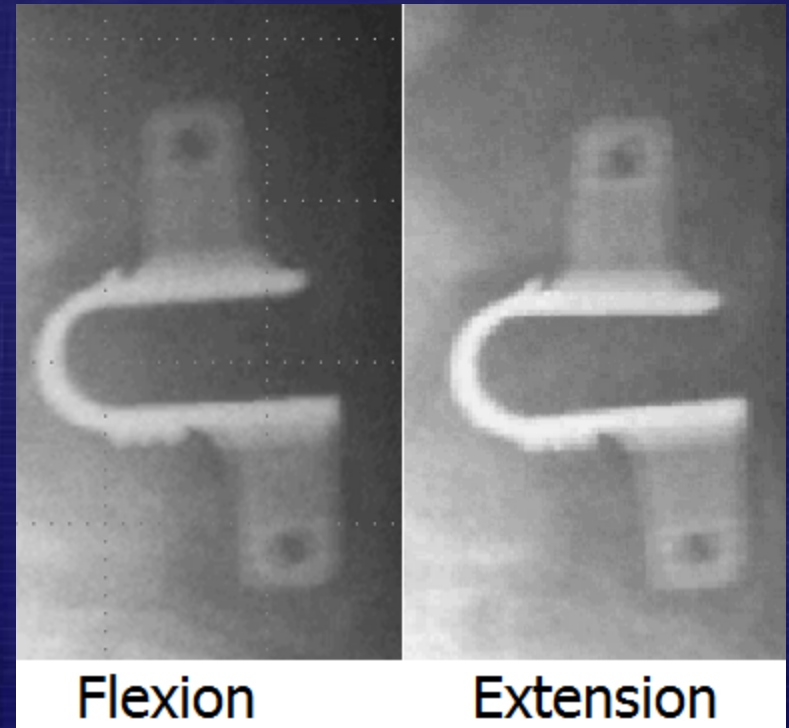
# Interlaminar Orientation





# Radiological Results

1. **Endplate Angles:** always become less acute
2. **Foraminal height:** always increases
3. **Disc Height:** definitely changes in both anterior and posterior disc heights.
4. Maintained **Dynamic Movements:** in flexion and extension views at the operated level.





# Clinical Results

- **LBP** decreased by 66% (from moderate to mild) at 3-month follow-up, and mostly disappear at the 1-year follow-up.
- Mean preoperative **walking distance** was < 1000m in 86% patients.
- Postoperatively 100% patients could walk >1000m.
- **Significant pain relief** (> 50%) in months was calculated.
- The **short-term** pain relief outcome (3 months), indicated a success rate (significant pain relief) 93%.
- **Late follow-up** (12 months), indicated a success rate of 97%.
- Significant pain relief was manifest, best at late follow-up visits.
- Follow-up visits did show an increase of **patient's satisfaction**.





# Complications

- **No infectious or hardware-related complications:**
  - No patients had the coflex removed.
  - No broken or deformed coflex
  - No migrated coflex
- **Immediate postoperative complications:**
  - 3 (21%) patients, (1 seroma, 2 worsening of existing numbness)
  - All were temporary
- No patients needed further fusion (**within 1 year**)
- 1 patient presented with **recurrent disc herniation.**





# Our Results

Matches concurrent results in the recent literature, about the use of the Coflex® DIDS device in DDLS especially LCS, to be safe and effective in relieving patient's symptoms





# This study confirmed

- The known positive effect of **distraction decompression of neural structures** on claudication and leg pain.
- Distraction increased the **dimensions of the spinal canal and neural foramina** at the implanted level in extension, but it did not alter the dimensions of the adjacent, intact levels in the extended, flexed, or neutral positions





# This study confirmed

Procedural aspects of Coflex implantation also add to the safety and effectiveness of the procedure.

It is an **easy, rapid, minimally invasive** approach, with no reported complications. None of the complications reported in the literature for related surgeries, were observed during or after the Coflex procedure.





# Conclusion

- Merging the clinical and radiological results of the current study suggest that these effects produce a clinical benefit for LCS patients treated with the Coflex spacer.
- Though this series has limitations of a smaller sample size, it nevertheless confirms the satisfactory results.
- Because it is still unclear whether those good results deteriorate with time or not, as was the case with some other lumbar surgical procedures; we will continue to follow the patients enrolled in this study, together with new cases and will report on the longer follow-up.





# Thank You

