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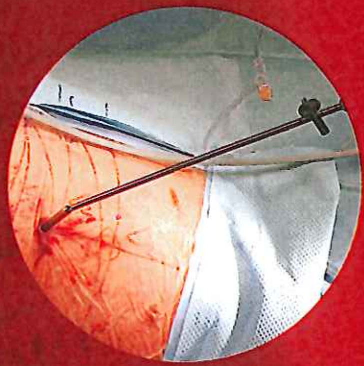
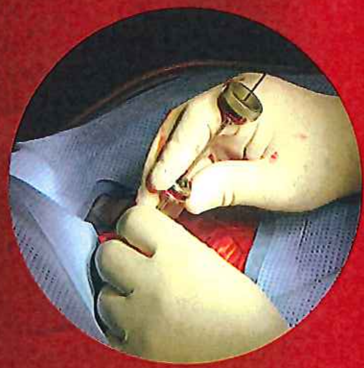
Modern Techniques in SPINE SURGERY





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Forewords

Kuniyoshi Abumi

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CHAPTER

38

Novel Interlaminar Dynamic Stabilization Concept and Device (IntraSPINE) for the Treatment of Early and Late Degenerative Problems in the Lumbar Spine

Darwono A Bambang

Degenerative Cascade of the Lumbar Spine

Degenerative cascade as described by Kirkaldy-Willis, et al. is starting from anterior column—the disk and middle column—the facet (Fig. 38.1).[1]

Baastrup CI[2-4] describes a degenerative changes at the spinous process. The spinous process enlarges by age in width and height, breaking down the interspinous ligament, developing a neoarthrosis between the adjacent spinous process, causing kissing of spinous process and/ or lamina and resulting the loss of lumbar lordosis toward a flat back (Fig. 38.2).

The Auckland study (Aylott, et al.)[2] shows that spinous processes increase 50% in width, increase 30% in height from the age 20–80, and the result is loss of the lumbar lordosis (Fig. 38.3).

The loss of lordosis is not merely due to the decrease of the disk height (Kirkaldy-Willis) but also by the enlargement of the spinous process (Baastrup) (Fig. 38.4).[1-4]

The Anatomical Trilogy of the degenerative cascade may start from any part of the three columns of the spine: Anterior the disk, middle—the facet, and posterior—the spinous processes, even though the end stage will be the same involving all three columns. It can suffer the three columns alone or together, from inflammatory to compressive reaction.[2-4]

Treatment of Lumbar Degenerative Cascade

Since the degeneration may involve the three columns of the spine, the treatment has a very wide range of justification, from conservative to various types of surgeries related to the encountered pathologies. The degenerative cascade changes the biomechanic property of the spinal motion segment (SMS) and the conservative treatment has a disadvantage of being unable to recover the changes.[1,4,5-17]

Various types of surgeries were designed to solve the variable stages of degenerative cascade from minimal invasive until open surgery, but cannot stop the degeneration itself. The stabilization and fusion is designed to solve the early and late degenerative cascade. At the end stage of degeneration involving three columns (*de novo* scoliosis, listhesis, spinal canal and lateral recess stenosis) decompression and fusion stabilization is the gold standard. Even though this technique may solve the static and dynamic component of the SMS, but it may induce the degenerative cascade of the adjacent levels.[12,18-28] The long fusion in some way may solve the deformity, but in another way may disturb the dynamic mobility of some population, i.e. squatting, sitting on the floor.

The dynamic stabilization[10,16,29-38] is designed to solve the static component of SMS and preserving the dynamic component, but the degenerative cascade will come to

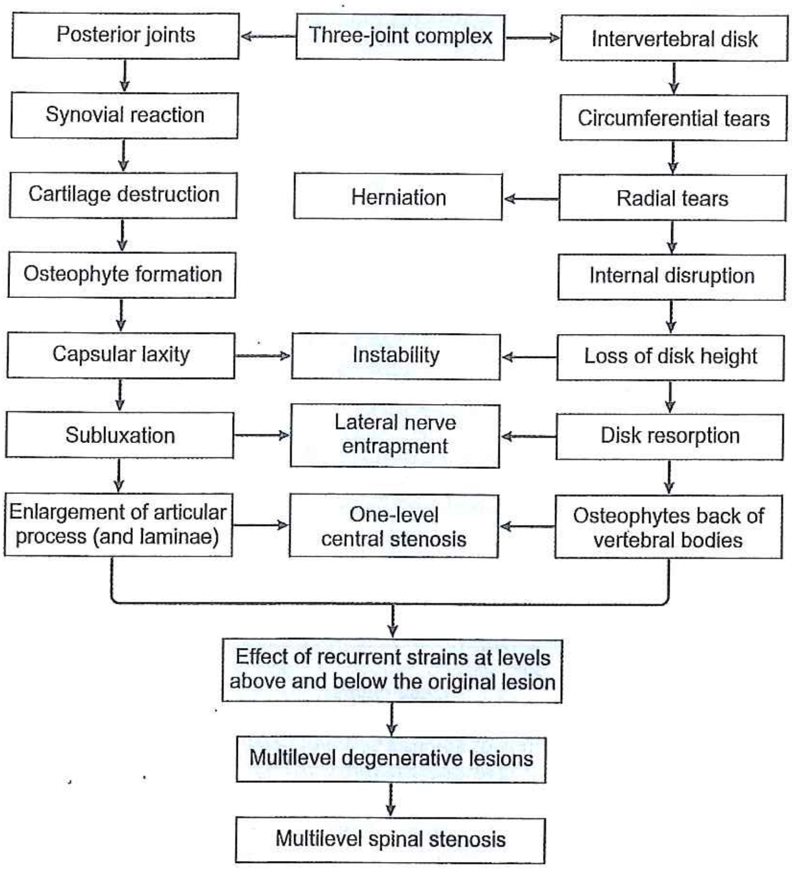


Fig. 38.1 Pathophysiology of multilevel degenerative lumbar spine
Source: Kirkaldy-Willis, et al. Spine. 1978;3(4):319.

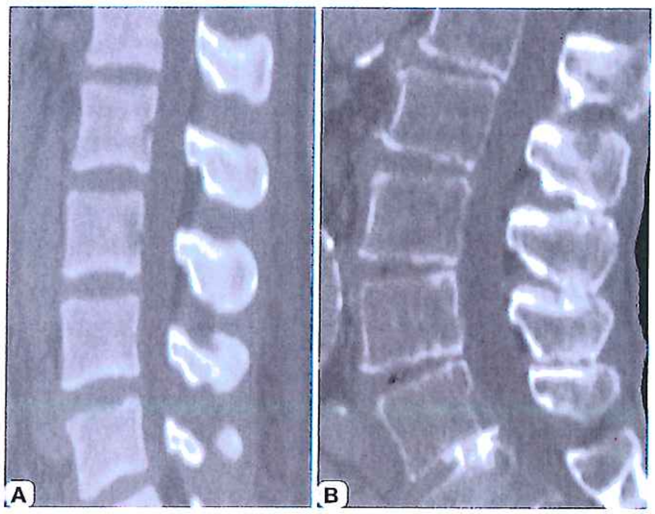
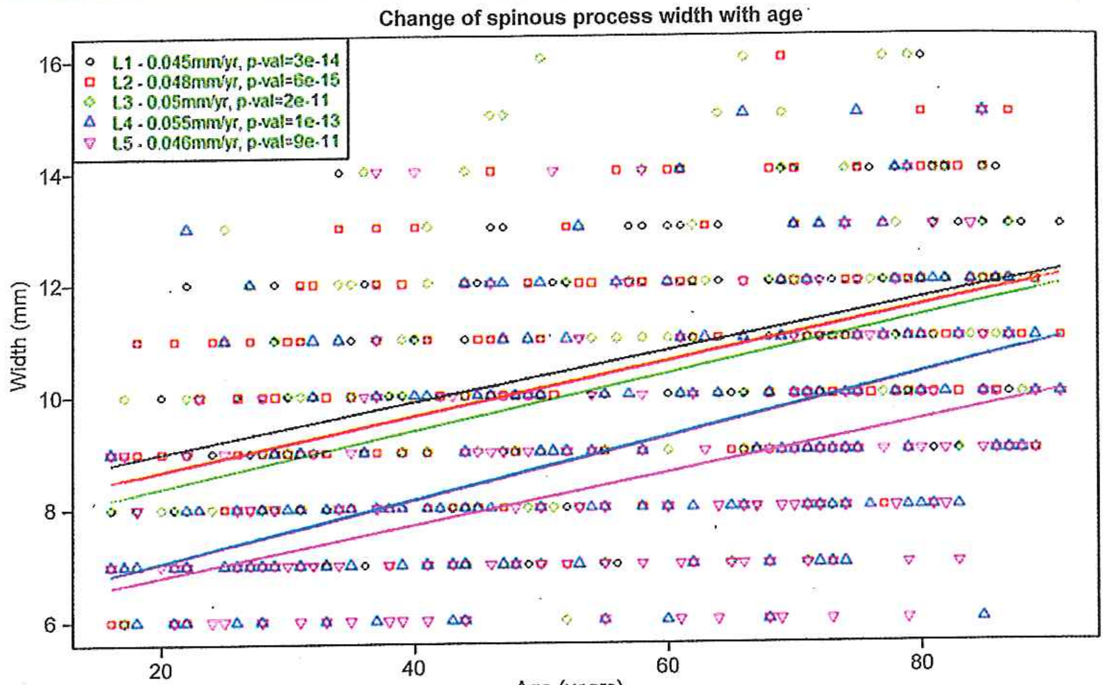
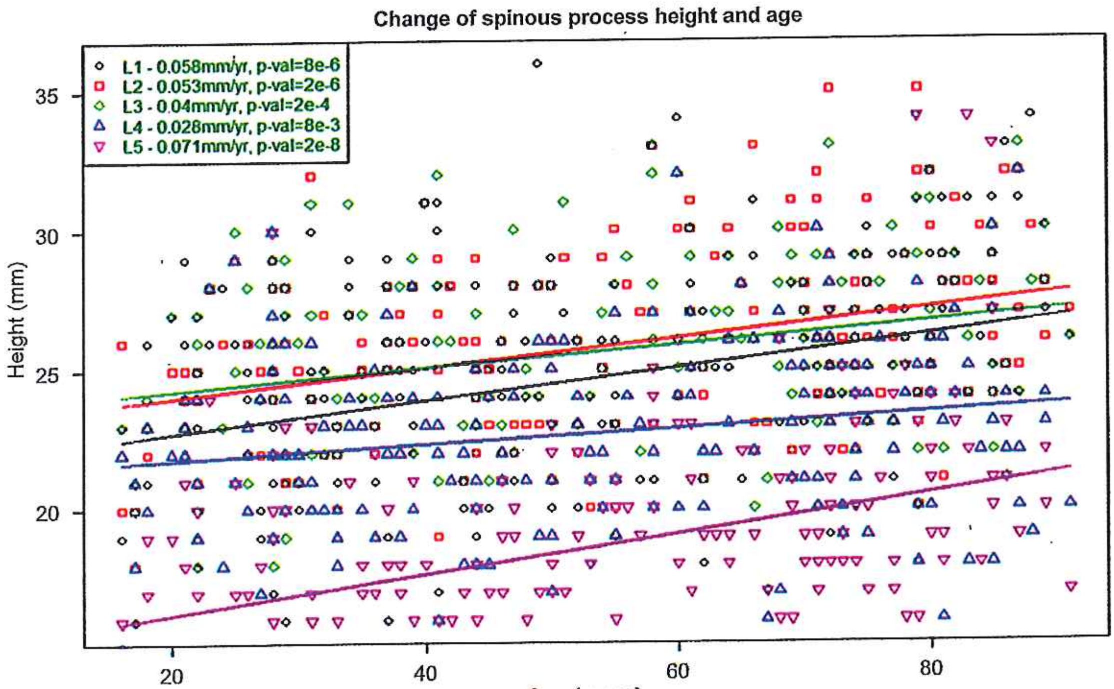


Fig. 38.2 Spinous processes. (A) Young age; (B) Old age


Change of spinous process width with age
L1 - 0.045mm/yr, p-val=3e-14
L2 - 0.048mm/yr, p-val=6e-15
L3 - 0.05mm/yr, p-val=2e-11
L4 - 0.055mm/yr, p-val=1e-13
L5 - 0.046mm/yr, p-val=9e-11
Width (mm)
16
14
12
10
8
6
20
40
60
80
Age (years)

A


Change of spinous process height and age
L1 - 0.058mm/yr, p-val=8e-6
L2 - 0.053mm/yr, p-val=2e-6
L3 - 0.04mm/yr, p-val=2e-4
L4 - 0.028mm/yr, p-val=8e-3
L5 - 0.071mm/yr, p-val=2e-8
Height (mm)
35
30
25
20
20
40
60
80
Age (years)

B

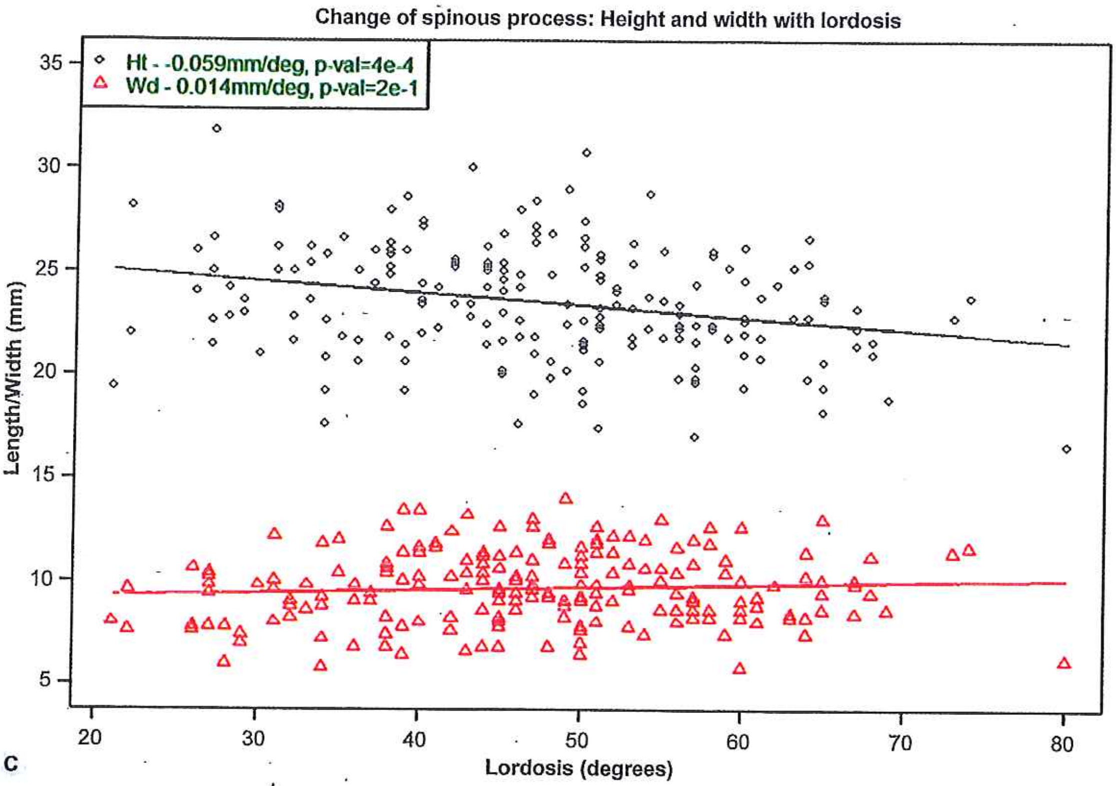


Fig. 38.3 (A) Width increases 50%, p = 0.0004 (Aylott, et al.); (B) Height increases 30%, p = 0.2 (Aylott, et al.); (C) Loss of Lordosis (Aylott, et al.)

Fig. 38.4 The loss of lordosis: Disk degeneration and enlargement of spinous processes

ıe same level. The total disk replacement and various ıterspinous devices are designed to solve a single column egeneration and have a limitation in the amount level. An ternative treatment for the end stage of degeneration is decompression and stabilization using dynamic rod like Dynesis with unlimited amount level. The stabilization is located at the middle column-pedicle and use rod as connector of the pedicle devices.

Middle Column of the Spine

The anterior column-disk[39] is the largest component of the spine with its function as shock absorber since 80% of the burden falls in the front. The posterior column[39] consists of spinous processes, interspinous ligament, muscles and a complex fascia supraspinatus. Its function is the primary limiters in flexion and muscles contraction in extension. Rauschning[40] describes that supraspinatus is not a ligament but a multiple tendon insertion called the complex fascia supraspinatus (CFS) (Fig. 38.5). The CFS in the posterior column is acting as a natural connector like ALL and PLL. Theoretically, preserving the integrity of all natural connectors is very important to gain the stability of the spine.

The middle column[39] consist of pedicles, lamina, transverse processes, and the ganglion which control the back muscles contraction, is located in the middle column as well. The middle column control the load distribution between the anterior column and posterior column,

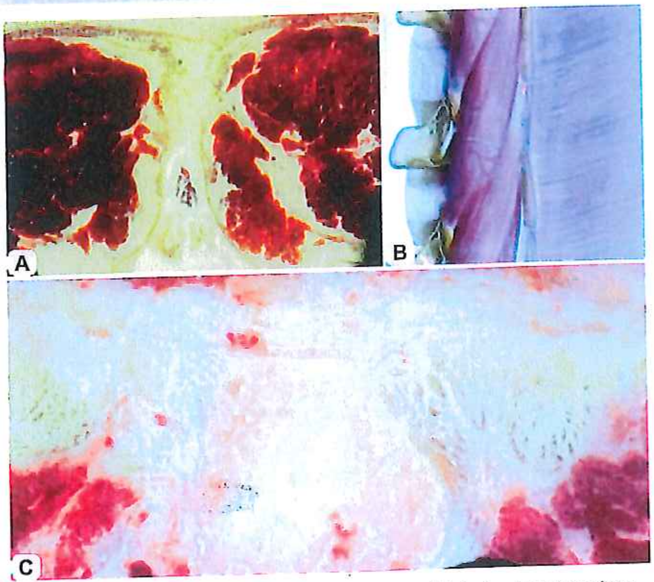


Fig. 38.5 Complex fascia supraspinatus: A multiple tendon insertions. *Courtesy* by Professor Rauschning

similar to crane—mechanically the middle control the load of anterior and posterior part (Fig. 38.6) The middle column with the help of the muscles drives the movement of the mobile segment and are used to control the loads, that changes dynamically in the different position of the spine.[41-49]

The bony neural arch is the only rigid area in the middle column where the device can be placed to control the loads distribution, and the lamina is located close to the axis of instantaneous rotation at the back of the disk (Fig. 38.7).[42-46]

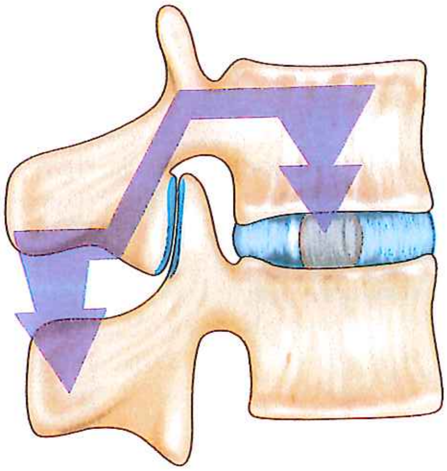


Fig. 38.6 The middle column similar to crane control the loads distribution

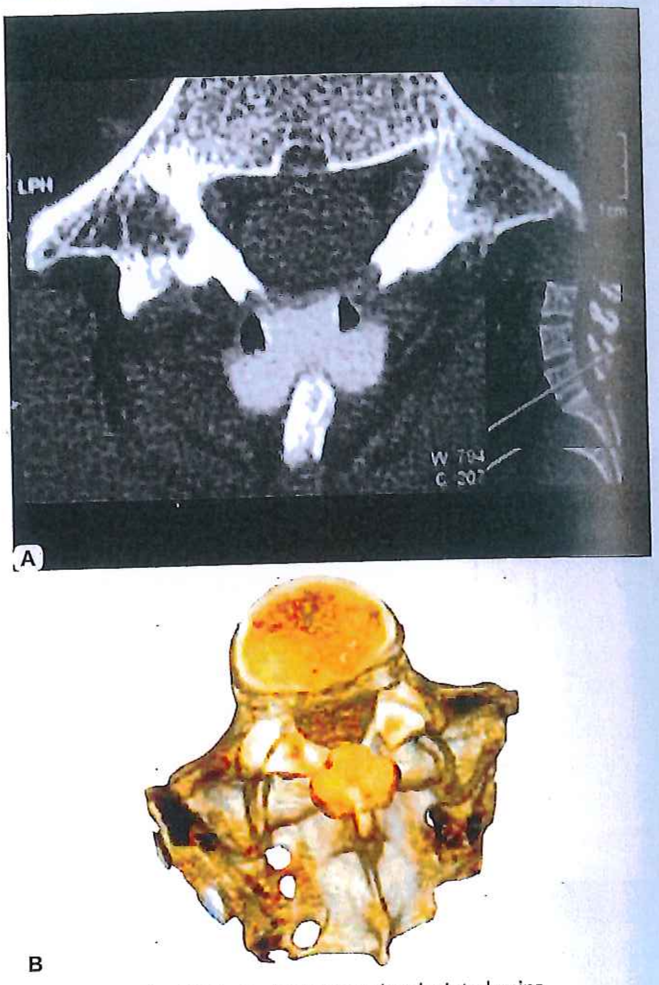


Fig. 38.7 Device is located at the interlamina

Dynamic Interlaminar Device

The device IntraSPINE (Cousin Biotech) is made of Silicone 65 coated by Polyethylene Terephthalate (PET) sleeve. A semi-rigid ligament is also available and can be used to reinforce the CFS in case of insufficiency or laxity (Fig. 38.8).[41-49]

The design of IntraSPINE device (Fig. 38.9):

1. The anterior part = the nose is located at the interlamina (middle column) and the size is related to the interlaminar distance. This part is unloading the disk and facet joints, while controlling the loads distribution between anterior and posterior column.
2. The posterior part = the wing is located at the posterior column to stabilize the device, since the cranial horn is located on the cranial lamina and the caudal horn is located on the caudal lamina.
3. The device do not limit the range of motion of SMS, because the posterior part has a cushion effect created by the holes.

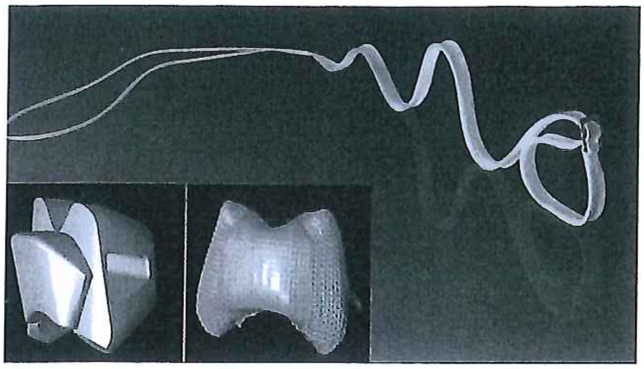


Fig. 38.8 IntraSPINE: Device and semi-rigid ligament (Cousin Biotech)

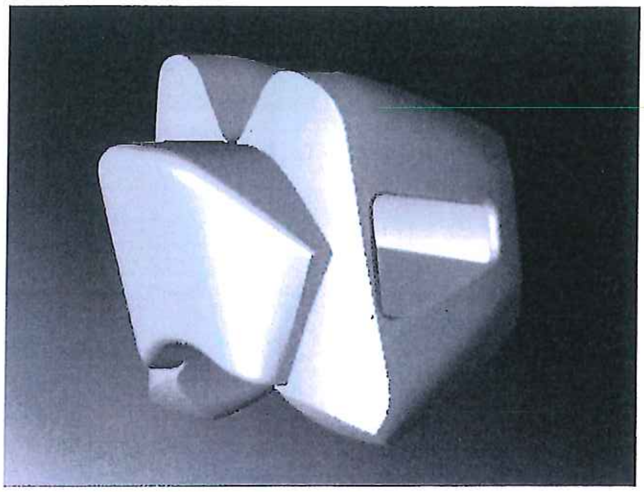


Fig. 38.9 The nose, wing and the hole of the Device (Cousin Biotech)

The interlaminar device can be used as dynamic stabilization for the treatment of the late degenerative cascade after decompression as well as the early degeneration without decompression (Fig. 38.10).[42-46]

The complex fascia supraspinatus is the natural connector in the posterior column and is critically important to preserve it rather to sacrifice as a trick in surgery. In case of an insufficiency or laxity of the CFS due to late degenerative cascade, the semi-rigid ligament can be used to reinforce either at the upper arc and/or the lower arc of the lumbar lordosis as well (Fig. 38.11).[40,42-46]

The Goals of Interlaminar Dynamic Stabilization are:[42-46]

1. Stabilize the segmental instability.
2. Maintain the sagittal balance of the spine.
3. Allow physiologic movement and loads distribution of mobile segment.

Indications[41-49]

1. Early degenerative cascade
   - Large expelled herniated disk in young patients with instability (naturally after removing the hernia)
   - Soft stenosis and/or foraminal stenosis with instability (naturally without decompression)
   - Black disk desease with facet disorder with instability (after a facet joint block test with positive result).
2. Late degenerative cascade:
   - Multilevels degeneration with instability:
     - Canal stenosis, lateral recess stenosis
     - Listhesis (lateral, anterior, retro) grade 1 or less
     - Facet hypertrophy

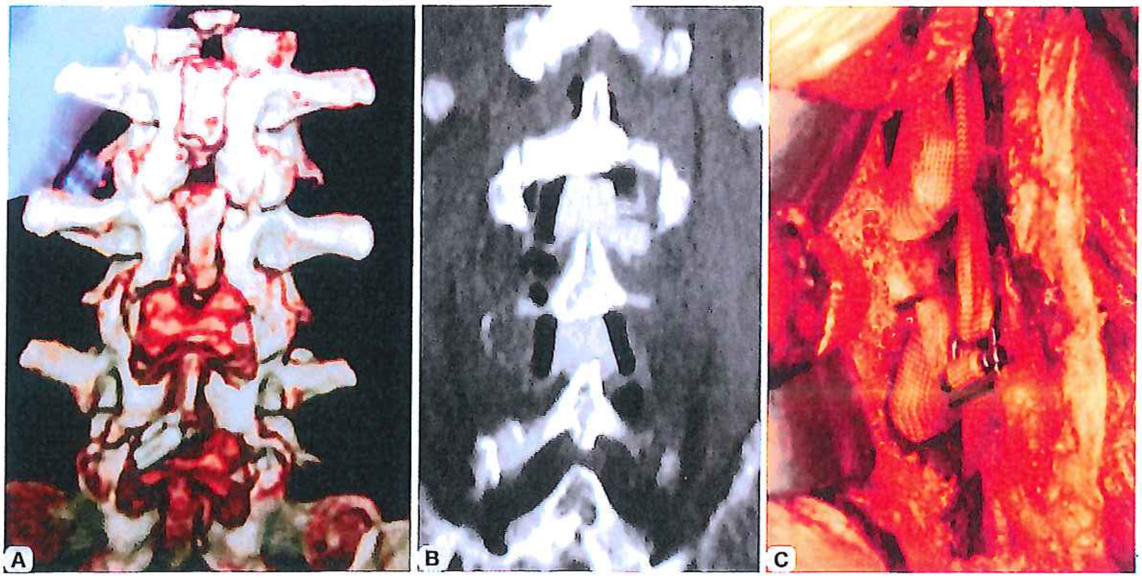


Fig. 38.10 Final position of the interlaminar device

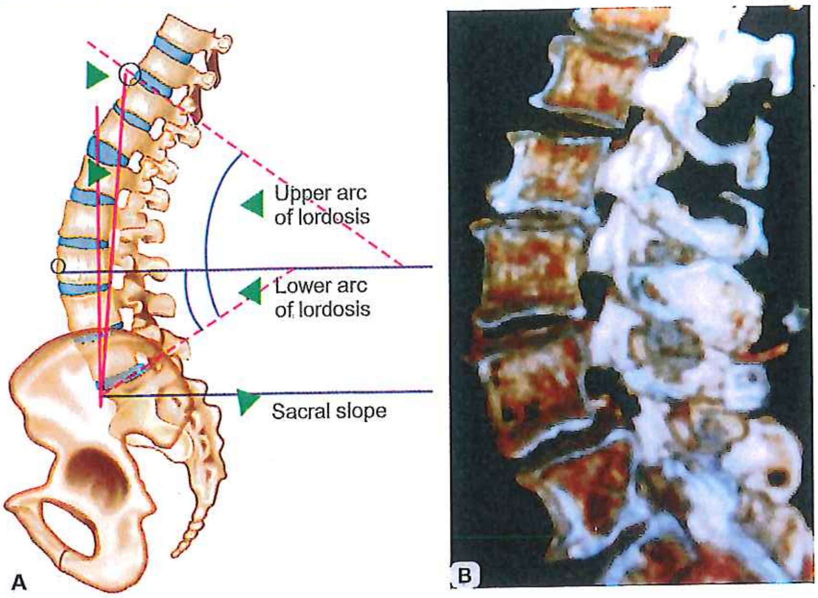


Fig. 38.11 Upper (L1–3) and lower (L3–5) arc of lumbar lordosis

- Disk bulging, resorption
- Flavum ligament buckling, in-folding
- *De novo* scoliosis.

Contraindications[41-49]

- Grade II or III spondylolisthesis
- Fractures at the level now affected
- Spinal tumors
- Congenital bone anomaly at the level now affected
- Significant osteomalacia
- Infection
- Allergic to one of the components
- Dependency of drug and/or alcohol, or psychological problems
- Kissing spine and/or kissing lamina.

Surgical Technique

The basic instrument set for IntraSPINE (Fig. 38.12):[41-46]

- Spinous processes distractor
- Probe sizing device
- IntraSpine grasper and inserter
- Foot pusher
- Semi-rigid ligament inserter
- Semi-rigid ligament tightener
  - Patient position is prone and flexion at the affected level
  - General anesthesia
  - C- Arm/Image intensifier
  - Use needle at the tip of the spinous processes of the affected levels and draw the skin landmark (Fig. 38.13)

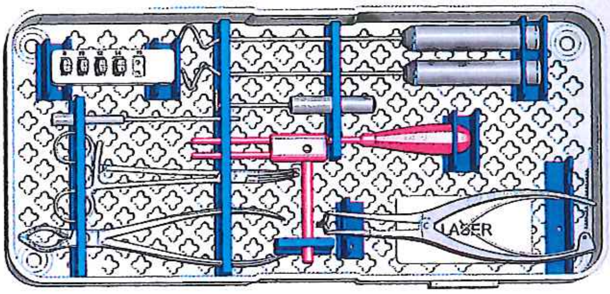


Fig. 38.12 Basic instrument set (Cousin Biotech)

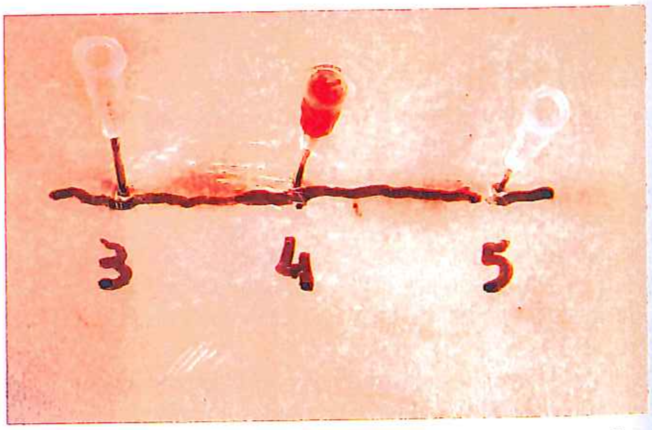


Fig. 38.13 Needle for marking at the tip of spinous process VL3–5

  - Dissecting subcutaneously to the lateral exposing thoracolumbar fascia (Fig. 38.14)
  - Incision of the fascia 1 cm away from midline to preserve the CFS (Fig. 38.15)

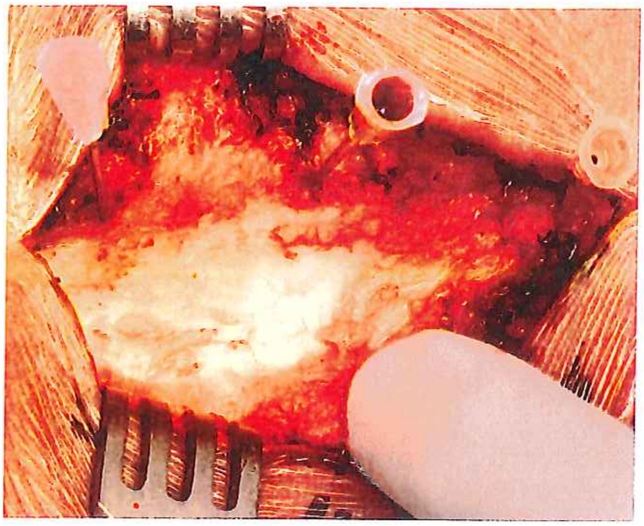


Fig. 38.14 Midline skin incision, and reflecting skin and subcutaneous tissue to lateral

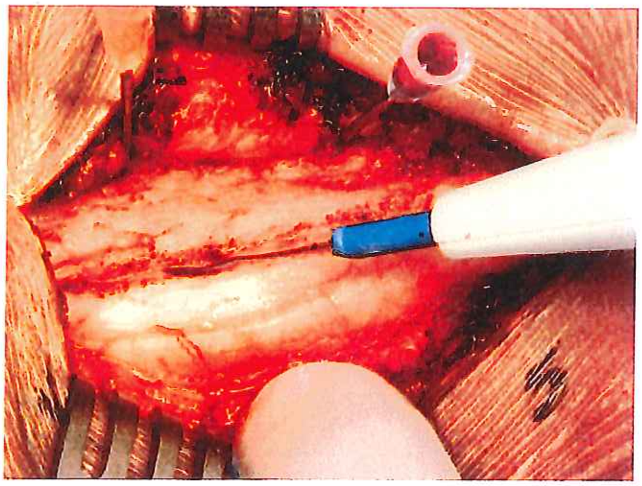


Fig. 38.15 Thoracolumbar fascia incision 1 cm away from midline to preserve CFS

- Reflecting the CFS (Fig. 38.16)
- Separating CFS from muscles (Fig. 38.17)
- Expose the anatomical landmark: spinous process, lamina, facet, interspinous ligament, flavum, CFS (Fig. 38.18)
- Use the interspinous distractor to widen the space for decompression and also to create the maximum tension of the CFS and the ligaments: ALL, PLL, outermost annulus fibrosus of the disk (Fig. 38.19)
- Decompression: Partial facetectomy of the hypertrophied inferior facet using osteotome (Fig. 38.20)
- Flavumectomy of the infolding flavum using no 11 knife and special curve rongeur (Fig. 38.21)
- Partial facet-ectomy of hypertrophied superior facet using osteotome (Fig. 38.22)

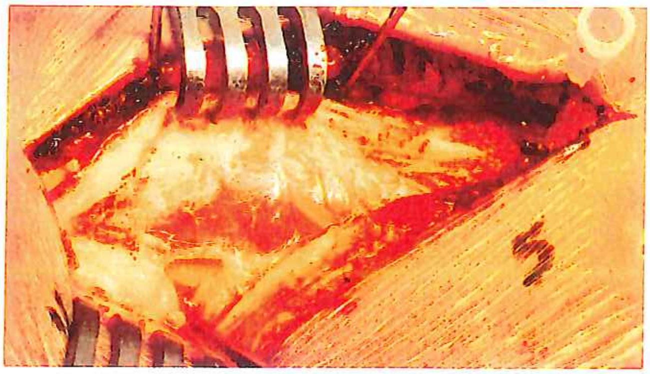


Fig. 38.16 Reflecting the CFS using retractor

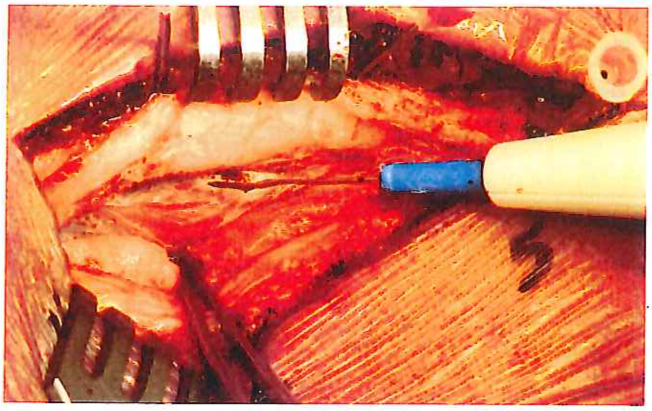


Fig. 38.17 Separate multifidus muscle from CFS

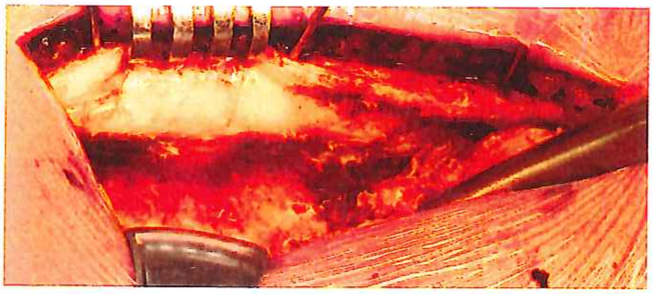


Fig. 38.18 View of spinous process, lamina, facet, ligament flavum after relecting muscles to the lateral

- Sizing the inter lamina space using probe (Fig. 38.23)
- Inserting the IntraSPINE using inserter and foot pusher (Fig. 38.24)
- In any insufficiency or laxity of CFS use the semi-rigid ligament and tightened. Important step before tightening—operation table should be changed from flexion to flat or slight extension (Figs 38.25 and 38.26)
- Closing the CFS and the skin: 3 cm for 1 level, 5 cm for 2 levels, 7 cm for 4 levels, and 10 cm for 4–5 levels (Fig. 38.27).

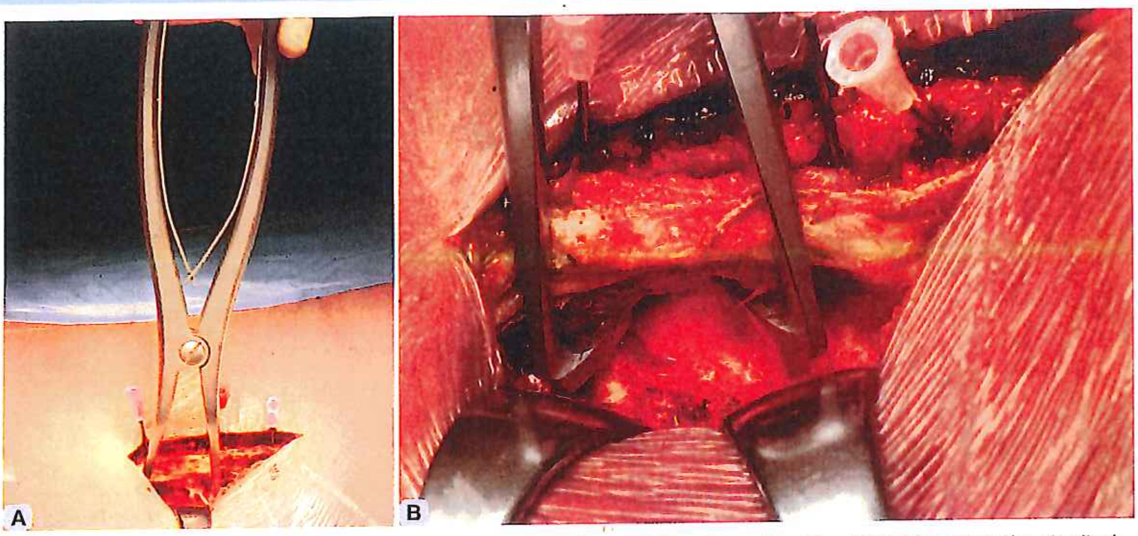


Fig. 38.19 (A) Distraction to widen the interspinous space, and to provide optimum tension of CFS; (B) posterior longitudinal ligament, outermost annulus fibrosus

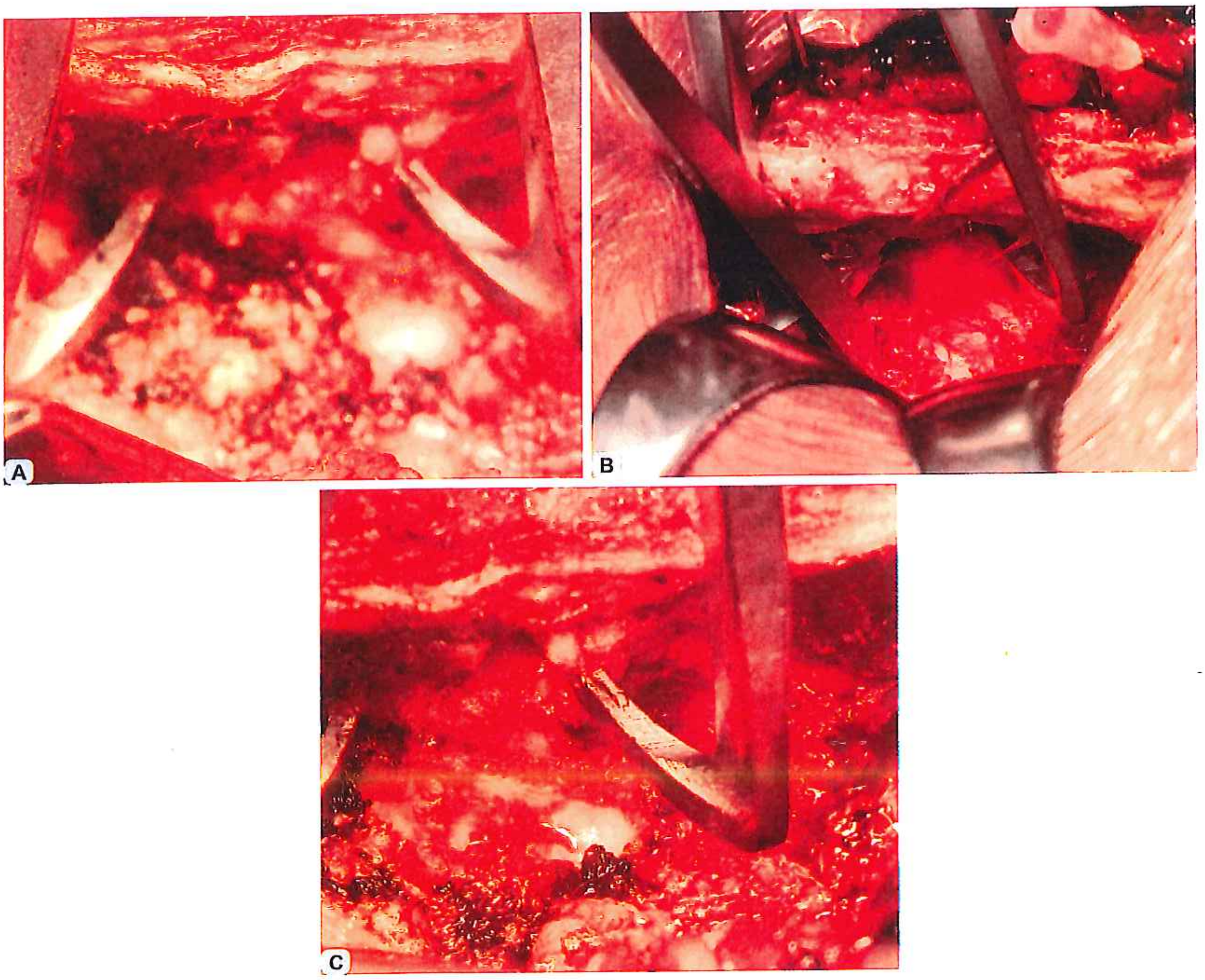


Fig. 38.20 Partial facetectomy of inferior facet using osteotome

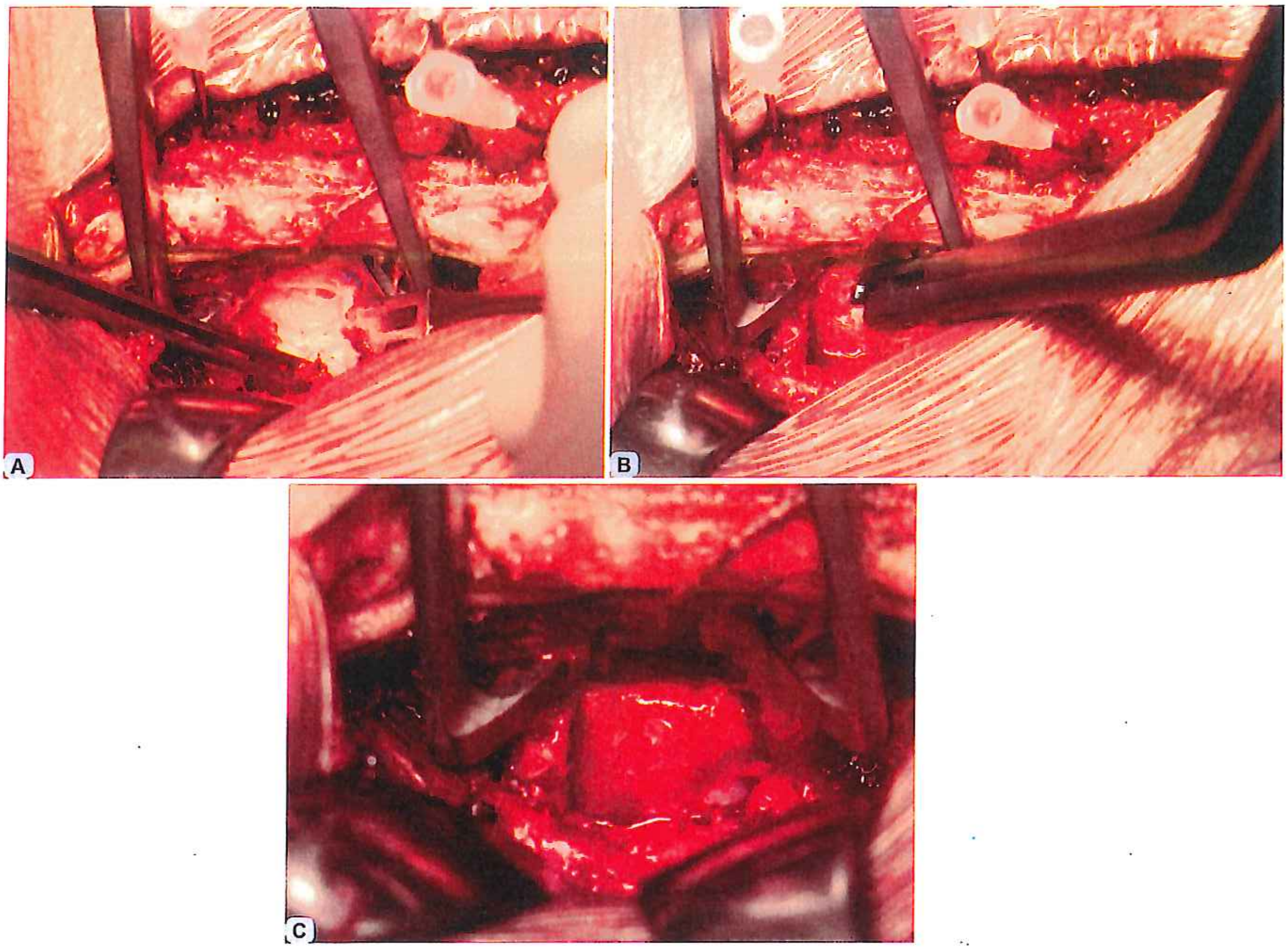


Fig. 38.21 Flavectomy using no. 11 knife and Kerison rongeur

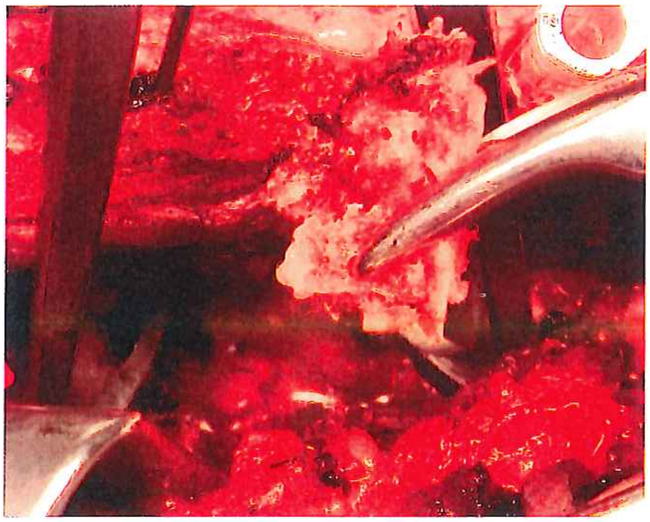


Fig. 38.22 Partial facetectomy of superior facet using osteotome

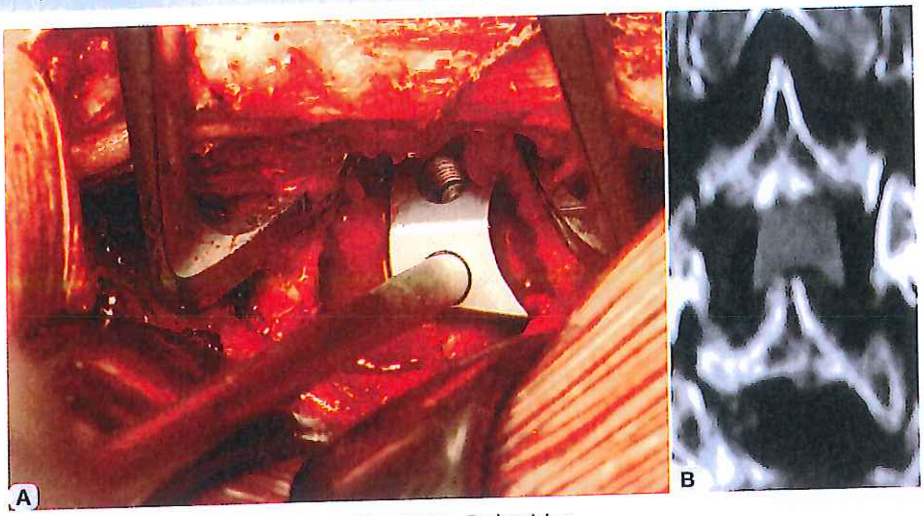


Fig. 38.23 Probe sizing

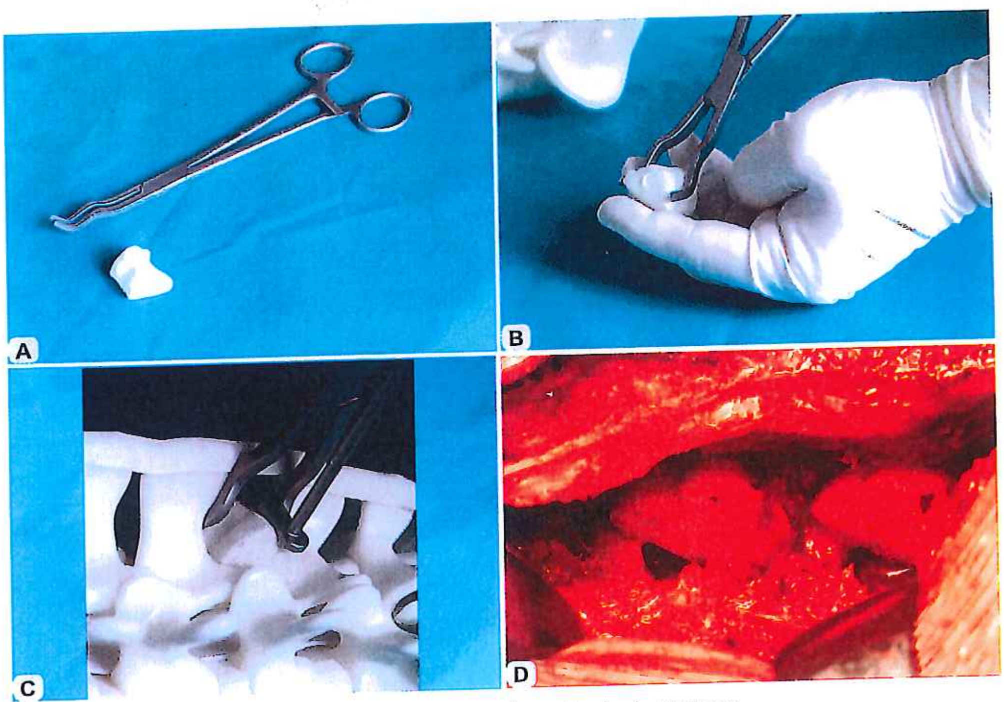


Fig. 38.24 Insert the implant using implant inserter

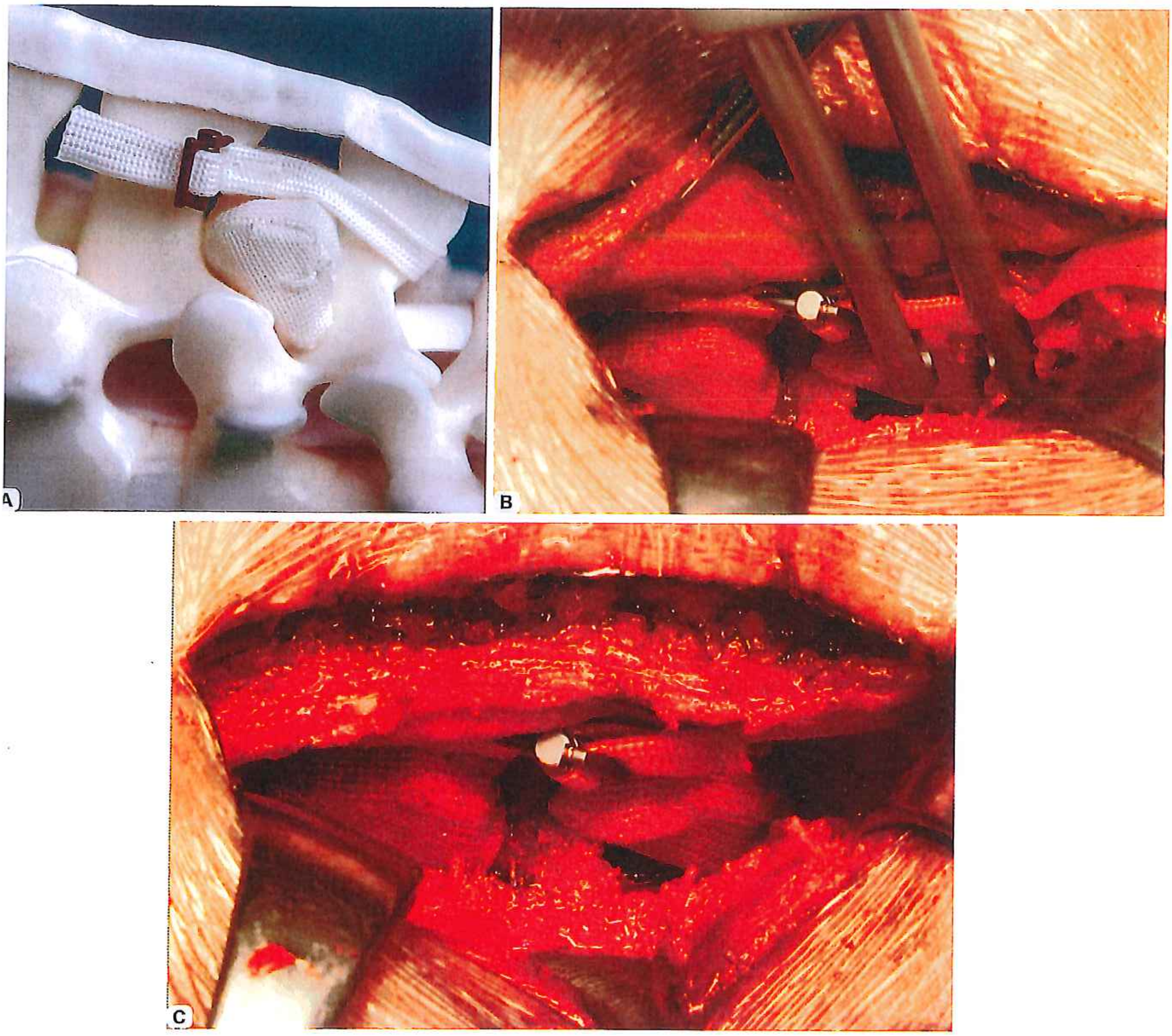


Fig. 38.25 (A and B) Insertion and tightening the semirigid ligament to reinforce the CFS; (C) Final position of the implant with ligament

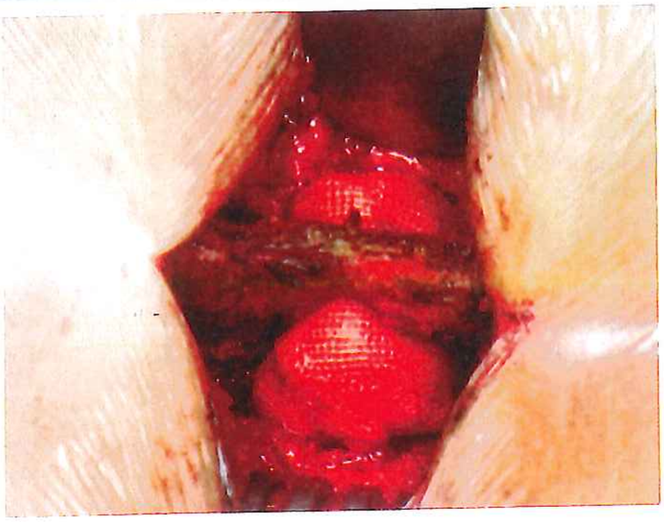


Fig. 38.26 Final position of the implant without ligament

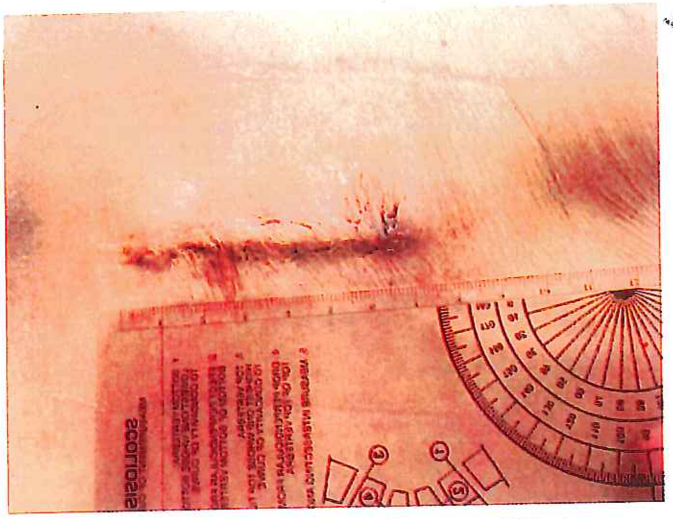


Fig. 38.27 7 cm of skin incision for surgery of 3 levels

Case Studies

Three years non-randomized prospective follow-up study of 60 cases have been treated using IntraSPINE dynamic stabilization for early and late degenerative problems of the lumbar spine. Follow-up made 2 weeks, 1, 2, 3, and 6 months after surgery. The dynamic stabilization using IntraSPINE was performed by a single surgeon. Assessment by dynamic X-ray, MRI, CT-scan, and VAS before and after surgery.

A total of 22 males and 38 females with average age 56.9 (27 – 85 years) were treated with IntraSPINE. The variation level of dynamic stabilization is related to the degenerative level from 1 to 5 levels and from L1–2 until L5–S1. The skin incision is from 3–10 cm, the surgical time for 1 level with decompression is 45′ to 4 hours for 4–5 levels. After 6 months the result is excellent: VAS from average 8.3 to 1.2, dynamic X-ray stable, patient can do normal activity of daily living.[7-11]

Case 1

A female aged 50 years with complaint of low back pain at certain movement. MRI shows an early degeneration on L3–4, L4–5, and L5–S1: bulging disk (Fig. 38.28). 2 years previously she already treated with IDET in another hospital but the complaint still exists. PELD was done for the L5–S1 and IntraSPINE for L3–4, L 4–5 without decompression. Three months after surgery she gain normal ROM of the spine, no complaint of LBP, and a good MRI result (Fig. 38.29).

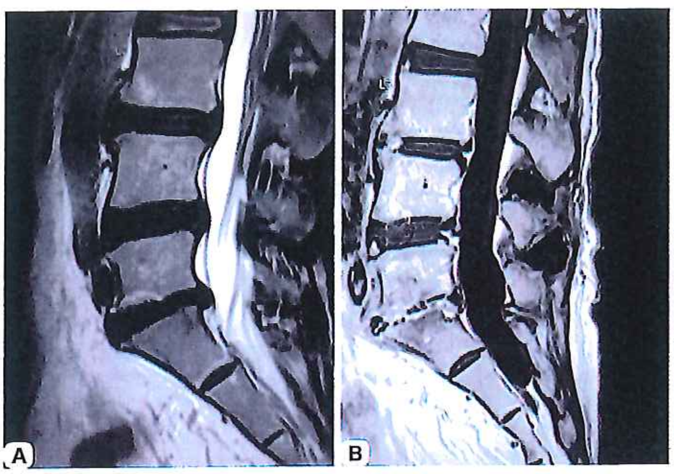


Fig. 38.28 Pretreatment MRI

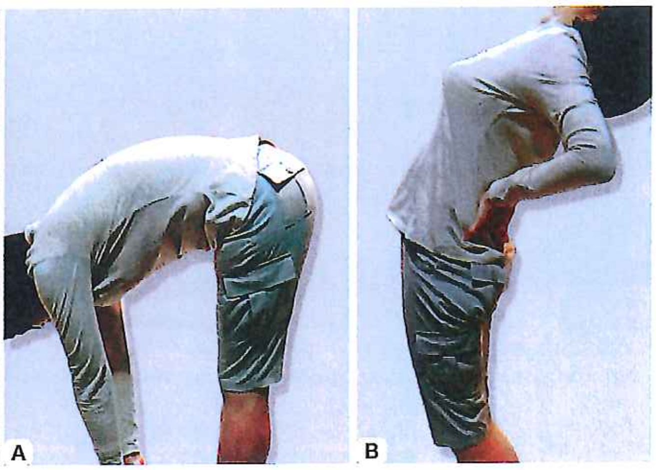


Fig. 38.29 After treatment: normal ROM of spine

Case 2

A female aged 70 years with complaint of severe low back pain and claudication. Dynamic X-ray shows a grade I listhesis and lateral listhesis at L4–5. MRI shows a huge bulging and stenosis at L4–5. IntraSPINE with decompression and diskectomy was performed at L4–5. Three months later she gains a good quality of life and no complaint in any movement (Fig. 38.30).

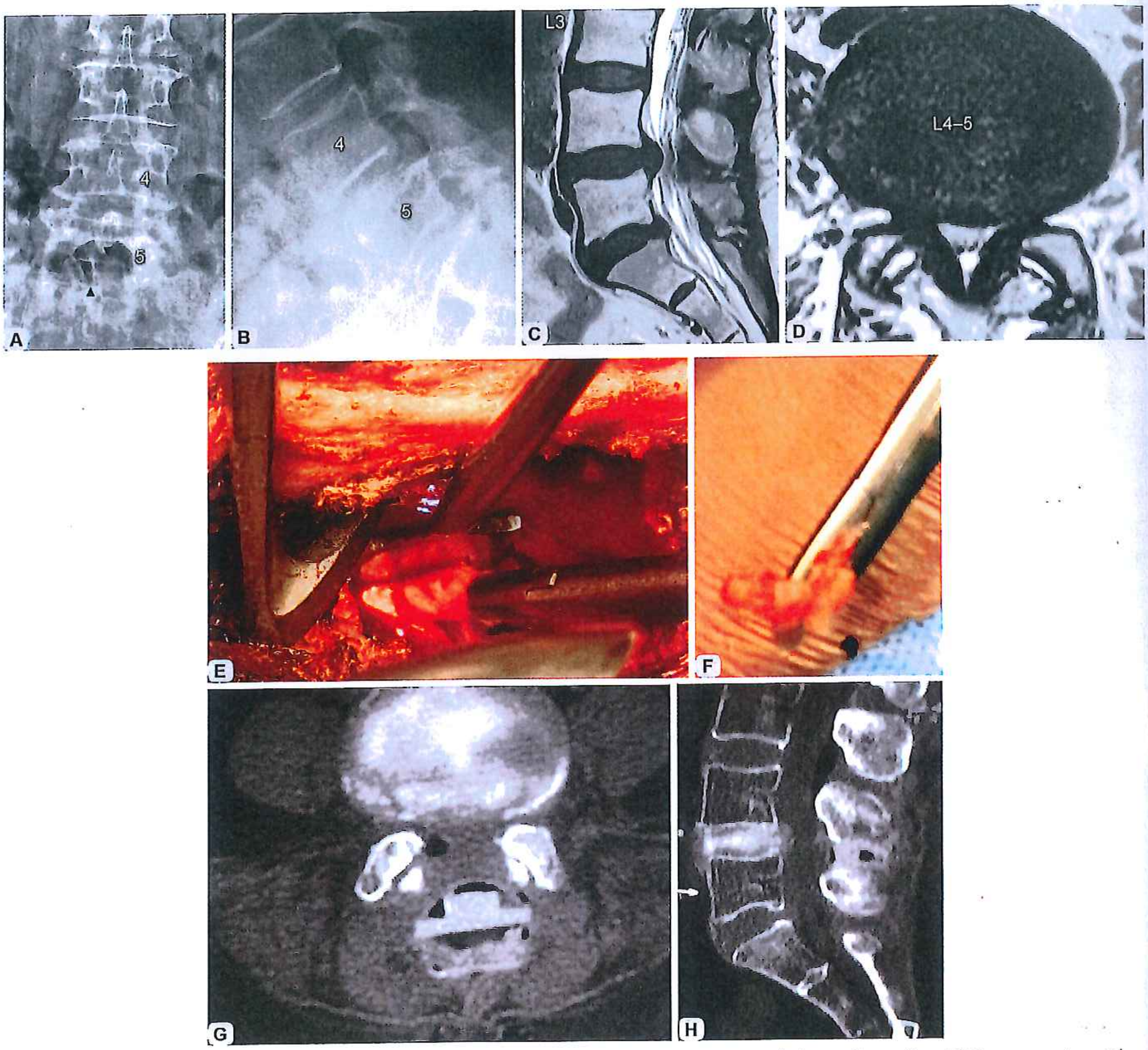
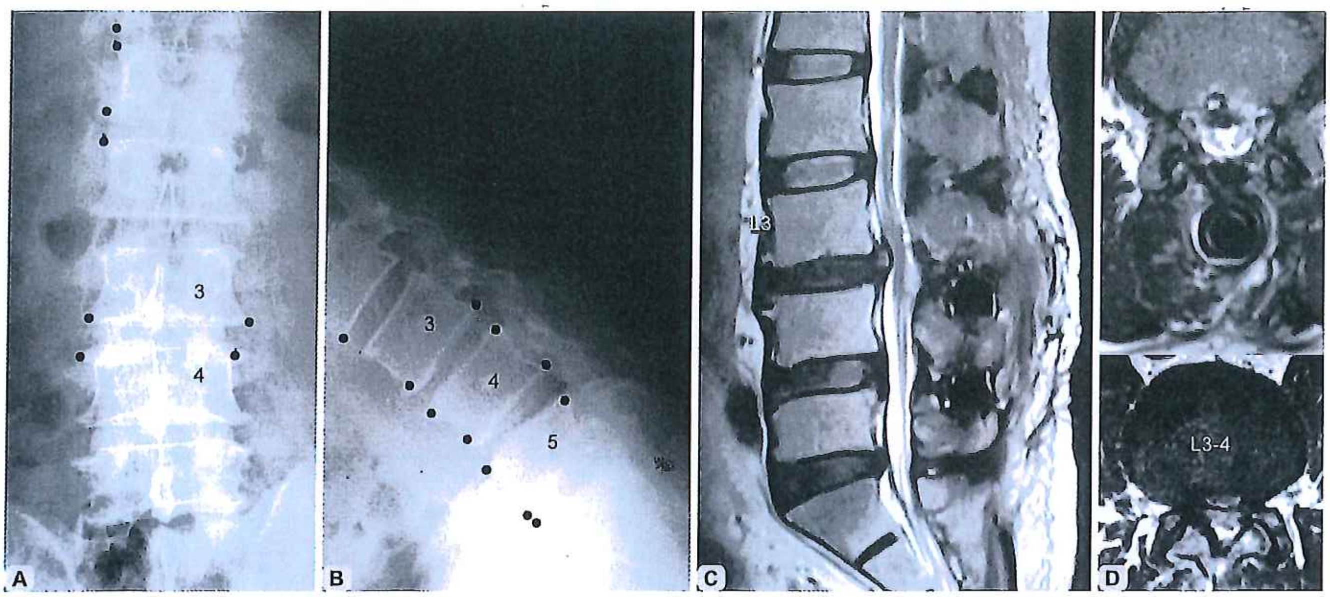


Fig. 38.30 (A and B) Radiographs showing grade I listhesis at L4–5; (C and D) MRI showing a huge bulging of L4–5; (E and F) Decompression and diskectomy performed; (G and H) Postoperative MRI showing no complaint

Case 3

A man aged 53 years with complain of low back pain and sciatica bilateral. Claudication and the pain increase with sitting and flexion. Dynamic X-ray shows instability at L3–4 and L4–5. Two years previously he experienced two levels of operation using interspinous device, but the complaint still exist. The interspinous device were removed and replaced with two levels IntraSPINE and 1 ligament. After 3 months he gains a good ROM and no complain of LBP and sciatica (Fig. 38.31).



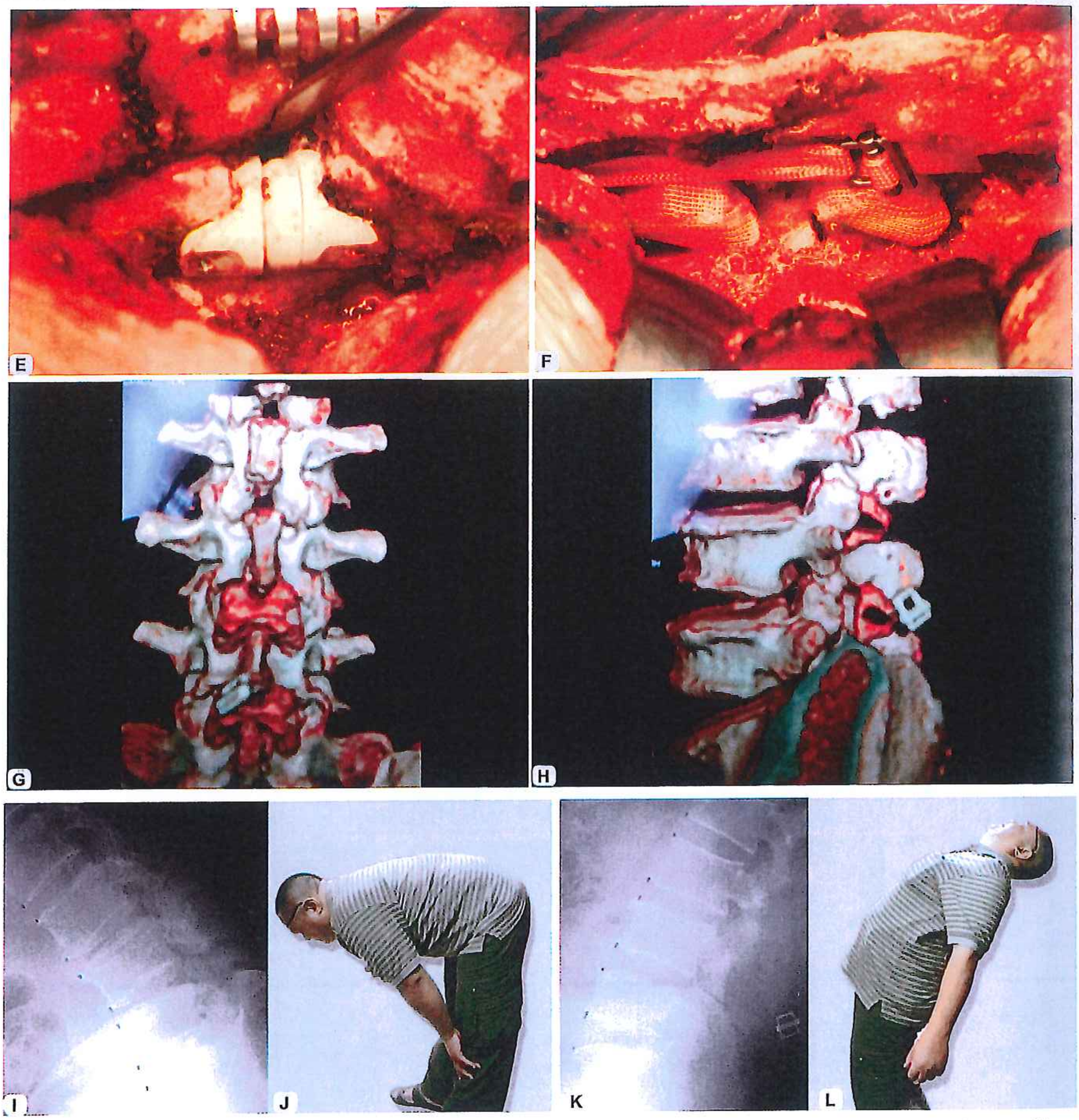


Fig. 38.31 (A to D) Preoperative X-ray and MRI; (E and F) Insertion of intraspine ligaments; (G and H) Postoperative photographs; (I and J) No problem in forward bending; (K and L) No problem in backward bending

Case 4

A woman aged 85 years with complain of low back pain, sciatica bilateral and claudication. She is wheelchair case with sagittal imbalance, pain increase at night and in body movement. Dynamic X-ray shows a scoliosis and *de novo* scoliosis, instability at L2–3, L3–4, L4–5, L5–S1. MRI shows multilevels stenosis, bulging disk and flavum buckling. Four levels IntraSPINE was performed with decompression and 3 months later she can do a good activity of daily living with no complain (Fig. 38.32).

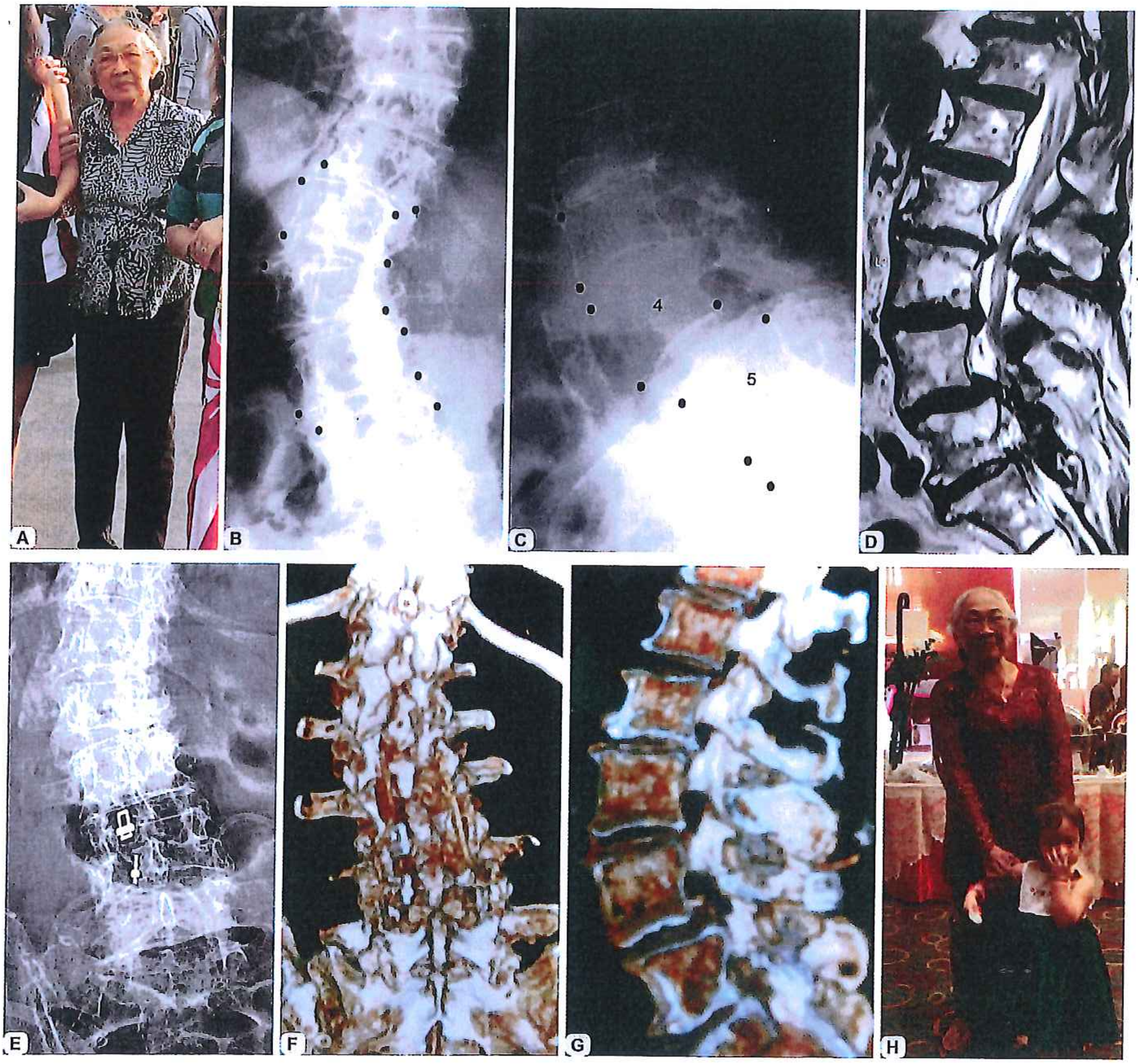


Fig. 38.32 (A) The patient; (B to G) Clinical radiographs of pre- and post-treatment; (H) Patient with no complaints

[redacted]

Conclusion

The fundamental feature in the design of the new device IntraSPINE is related to the anatomical reconstruction of the SMS and regarding the overturned anvil, the anterior part (nose) should be placed in between the lamina (Middle column) to control the load distribution and to achieve the sagittal balance. The interlaminar area is closer to the axis of instantaneous rotation of SMS. The complex fascia supraspinatus (CFS) is being used as Natural connector for this system, which is completely different with metal connector being used in pedicle screw system. In any laxity or insufficiency of the CFS, a semi-rigid ligament can be used to reinforce it either in upper and/or lower arc of lumbar lordosis. The IntraSPINE is made of medical grade silicone 65 shore coated by a pure PET sleeve and do not limit the ROM due to the cushion effect of the hole in the wing.

This system match the goals of dynamic stabilization: 1. Stabilize the segmental instability, 2. Maintain the sagittal balance, 3. Restore the physiologic movement of SMS.[6-11,19-21]

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