Non-suture dural repair using polyglycolic acid mesh and fibrin glue: clinical application to spinal surgery

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Abstract

Background: In spinal surgery, repair of the dura is difficult when it is torn, fragile, or is ossified as in cases with OPLL. We report our experience with a non-suture dural repair technique in patients undergoing spinal surgery; it employs a dura substitute composed of polyglycolic acid (PGA) mesh and fibrin glue. Here we report the efficacy and safety of non-suture duroplasty using PGA mesh and fibrin glue (PGA-fibrin sheet).

Methods: The artificial dura mater is composed of a PGA-fibrin sheet. The dural defect is covered with a patch sprayed with fibrin glue without suturing to the dura mater. We first evaluated this technique in an experimental study by performing water leakage tests. Between May 2001 and January 2005 we used it in 160 spinal surgeries that required intraoperative dura repair.

Results: Our preliminary tests showed that the threshold for water pressure without leakage was 161 ± 42 mmHg and 96.5 ± 32 mmHg when the unsprayed margin around the perimeter of the patch was 5 mm and 2 mm, respectively. Of the 160 operated patients, 10 (6.3%) experienced subcutaneous CSF leakage. Of these, 6 required a second operation, in the other 4 the CSF collection diminished spontaneously. There were no other complications such as allergic reaction, adhesion, or infection.

Conclusion: In combination with CSF diversion, the PGA-fibrin sheet is a viable alternative

method for dural repair in spinal surgery.

Keywords: dura substitute, CSF leakage, fibrin glue, polyglycolic acid, duroplasty

Introduction

Cerebrospinal fluid (CSF) leakage is a common complication after intradural spinal surgery. As persistent CSF leakage puts patients at significant risk for meningitis and arachnoiditis, meticulous suturing is important. However, primary dural closure can be difficult especially if the dura is fragile or the dura mater is ossified.

When dural substitution is necessary due to dural defects, autografts derived from muscle and fascia can be used [25], but these tissues are not always available in the desired quantity and shape. Therefore, we developed a dura substitution technique that uses bioabsorbable fabric and fibrin glue.

Our method has several advantages. The fabric can be cut to the desired size and shape and as suturing is unnecessary, operative time may be shortened. We here report our experience with 160 patients who underwent spinal surgery and dura repair using our PGA-fibrin sheet.

Materials and Methods

Experimental Study

We first designed experiments to estimate the water pressure that could be tolerated by our PGA-fibrin sheet without resulting in leakage. Our experimental device consisted of a plastic

bottle filled with colored water, a digital manometer, and a pressure syringe connected by a tube to the water bottle (Fig. 1A). After mounting a rabbit skin securely on the device we produced an oval, 20 x 6 mm diameter defect with a #11 blade knife. Then we cut an oval patch larger than the defect from a sheet of PGA mesh (Neoveil; Gunze, Kyoto, Japan), covered a 2-mm or 5-mm wide area around the perimeter with aluminum foil, and sprayed the exposed area of the patch with fibrin glue (Bolheal; Chemo-Sero Therapeutic Research Institute, Kumamoto, Japan) (Fig. 2a). The glue thus forms a fibrin clot supported by the PGA mesh that is surrounded by a 2- or 5-mm area free of glue. We refer to the PGA mesh-fibrin clot complex as the PGA-fibrin sheet and the fibrin-free perimeter as the pasting margin (Fig. 2b). PGA, polyglycolic acid, is a homopolymer with a molecular weight of 10^4; it is hydrolyzed by pyruvic acid to water and carbon dioxide. The PGA fabric used in our study is produced under the trade name Neoveil (Gunze, Kyoto, Japan). The fibrin glue, Bolheal, is produced by the Chemo-Sero-Therapeutic Research Institute (Kumamoto, Japan). It is composed of a fibrinogen solution that contains, per ml, 80 mg fibrinogen, 75 units of blood coagulation-factor XIII, and 1000 units of bovine aprotinin per mL, plus a thrombin solution that contains 250 units of thrombin and 40 mmol of calcium chloride per ml. Bovine aprotinin was extracted from Uruguayan bovine lung (category III) and filtered through a virus removal membrane (pore size 15 nm). Fibrinogen, thrombin, and blood coagulation factor XIII were derived from the national pool of donated

blood and tested negative for nucleic acids from HBV, HCV, and HIV.

To determine whether the width of the pasting margin affects the water pressure that can be sustained without leakage, we performed 2 sets of experiments using rabbit skin and our pressure-testing device. In group I (n=6), the pasting margin was 5 mm, in group II (n=6) it was 2 mm. The skin used in the experiments was wiped dry and then 0.1 ml of the fibrinogen solution was dripped onto and manually rubbed into the skin. Then the skin defect was covered with the PGA-fibrin patch, fibrin-sprayed side down, fibrin glue was sprayed over the patch and surrounding skin (Fig. 1b), and 5 min later, colored water was manually injected under the patch using a syringe. As shown in Fig. 1c, the patch rose and finally ruptured between the patch and the pasting margin**.** The water pressure at the inception of leakage at the margin or through the patch was measured with the manometer.

Clinical Study

Patients

Our study included 160 patients scheduled for spinal surgery at our institute or affiliated hospitals between March 2001 and January 2005. This study was approved by the Human Subjects Committee of University of Hokkaido Graduate School of Medicine; prior written consent was obtained from all patients**.** The surgical indications are listed in Table 1. In 62 of the 160 patients we used the PGA-fibrin sheet to patch a dural defect; in 98 the patch was used to

reinforce the fragile dura mater (Fig. 3).

Surgical Technique

After intradural surgery, the size of the dural defect is measured. A patch larger than the immediate area of the defect is cut from the PGA-fibrin sheet, an area 2-5 mm in width around the perimeter of the patch is covered with aluminum foil, and fibrin glue is sprayed on the uncovered area of the patch to obtain a fibrin clot membrane supported by the mesh. The glue-free margin around the perimeter of the clot is used for pasting the patch to the dura. Before applying the patch to the dura, the edge of the dura mater is treated with fibrinogen solution. The patch is then placed, fibrin-sprayed side down, on the dural defect, and the area is sprayed with fibrin glue to fix the patch to the dura mater. Suturing between the sheet and the dura is unnecessary. An epidural drain is placed and then the fascia of the paraspinal muscles, the subcutaneous tissue, and the skin are sutured in layers. Spinal drainage is continued for 5 to 7 days.

We performed MRI scans in all patients within a week of the operation to check for CSF leakage.

Results

Experimental Study

The mean water pressure that could be sustained without leakage was 161 ± 42 mmHg in the group with the 5-mm pasting margin and 96.5 ± 32 mmHg in the group with the 2-mm margin (Fig. 4). The difference, analyzed by the Mann-Whitney U-test using Stat View 5.0 statistical software, was statistically significant ($p<0.05$).

In all but one case, leakage occurred at the margin of the patch. In the exceptional case the water pressure was 238 mmHg and leakage was through the surface of the PGA-fibrin sheet.

Our experimental study showed that the PGA-fibrin sheet was sufficiently water-resistant to use as a seal, that the margin-area of the patch was sufficiently pressure-tolerant, and that patches with the wider (5 mm) margin exhibited stronger attachment to the rabbit skin.

Clinical Study

Postoperative subcutaneous CSF accumulation occurred in 10 (6.3%) of the 160 cases; 4 of these patients required reoperation, i.e. dural plasty. Of the 20 patients with syringomyelia with Chiari type I malformation, 3 manifested postoperative CSF leakage. They had undergone foramen magnum decompression with dural opening. Two of these patients had received a previous operation at another institution. Of our 3 patients with ossification of the yellow ligament (OYL), 2 showed CSF collection after surgery; one required a second operation. In patients with OYL, the dura mater was extensively ossified bilaterally and we were unable to

obtain a good seal because the pasting margin was not large enough. In 4 of the 10 patients with leakage the subcutaneous CSF was spontaneously absorbed and disappeared within a few months. We now routinely use lumbar CSF drainage for the first 5 to 7 postoperative days. We encountered no other complications such as allergic reaction, adhesion or infection.

Illustrative Cases

Case 1

This 51-year-old man first complained of dysesthesia in both hands 3 years earlier. He experienced dysesthesia in both feet and gradually worsening gait disturbance one year prior to admission. Neurological examination upon admission to our institution revealed spastic tetraparesis, increased deep tendon reflexes in both lower extremities, bilateral positive Babinski reflex, hypalgesia and hypesthesia below the C5 level, impaired vibratory sensation below the waist, and spastic gait. Sagittal images of 3D reconstruction CT disclosed marked ossification of posterior longitudinal ligament (OPLL) at the C5 and C6 level (Fig 5A). On axial CT images there was marked OPLL at the bone window level (Fig. 5B). T2-weighted MRI showed severe compression of the spinal cord by OPLL (Fig.6A,B).

We used the anterior approach with C5 and C6 vertebrectomy. The dura mater was found to be ossified at the level of C5 and C6. After removing the OPLL, only the arachnoid

membrane remained on the cervical cord. A PGA-fibrin patch was applied to seal in the CSF (Fig. 7A-D), and postoperative MRI showed no evidence of CSF leakage (Fig. 8).

Case 2

This 6-year-old girl was found to have myelo-menigocele and a Chiati type II malformation at birth; she underwent VP shunting 9 days later. She was referred to our institute for surgery. Neurological examination on admission disclosed areflexia in both Achilles tendons, gait disturbance, and bladder and bowel dysfunction. MRI study showed that her spinal cord descended to the level of S1 and the presence of lipoma from the tip of the spinal cord to S3 (Fig 9A,B). We performed spinal cord untethering surgery. Upon exposure of the lamina from L5 to S2 we found marked adhesion under the dura mater. We dissected the tethered cord, the lipoma, and the root from the dura mater. The tip of the spinal cord exhibited ball-shaped gliosis that was tethered caudally. It was dissected and wrapped with a gortex membrane to prevent re-adhesion (Fig. 10A-D). As there was a large dural defect, we used 3 sutures to apply some tension to the dura mater and covered the dural defect with a PGA-fibrin patch and fibrin glue spray. This patient remained neurologically unchanged postoperatively; MRI disclosed that the caudal end of the spinal cord had been dissected and that it was surrounded by sufficient CSF space (Fig. 11).

Discussion

Patients with dural defects and persistent CSF leakage are at significant risk for meningitis, arachnoiditis, and pseudo-menigocele.When the dura is closed or repaired during spinal surgery it must be meticulously sutured to avoid CSF leakage due to increased hydrostatic pressure in the supine or upright position. However, primary dural closure is difficult when the dura mater is fragile in patients undergoing a second operation or when the operating field is too narrow to allow proper stitching of the dura mater. In addition, difficulties may be encountered in closing the dura in cases of meningioma, nerve sheath tumors, OYL, OPLL, and intradural spinal surgeries**.**

To avoid the problems associated with CSF fistula meticulous pimary closure or repair with a dural substitute is essential. While autografts derived from fascia or periosteum are acceptable because they do not induce an immunological reaction [25], these tissues are not always available in the required size and shape, and they may be associated with additional morbidity. Therefore, allografts, such as lyophilized human dura (Lyodura), have been used. However, due to concerns regarding Creutzfeldt-Jacob disease [4], these allografts have been withdrawn as a dural substitute by the World Health Organization. Chronic inflammatory immune reaction has been reported in cadaveric dural grafts and adhesion between the dura and

brain has been observed [1]. Although xenografts from porcine or bovine pericardium, peritoneum, and intestinal submucosa have been used [2, 5, 17], the danger of zoonosis, e.g. BSE must be considered [2, 9, 17]. To surmount these problems, synthetic dural substitutes have been developed [3, 11, 18, 19, 24, 31].

While bioabsorbable materials such as collagen film and Vicryl mesh do not induce chronic inflammatory reactions, their degradation precedes the development of strong connective tissue [12, 13, 19, 31]. Synthetic grafts such as silicon, polyglactin 910, and polyester urethane have been tested as dural substitutes [6, 7, 8, 11, 19, 25]. The use of silicon artificial dura resulted in intracranial hemorrhage and foreign body reaction [6, 11, 15, 16, 22, 26]. Malliti et al. [10] reported an infection rate of 15% when polyester urethane (Neuro-Patch) was used; this rate is 5% for autografts. In addition, CSF leakage occurred more frequently when synthetic grafts rather than autografts were used (13% vs 1.6%) [10].

While the expanded polytetrafluoroethylene sheet (ePTFE sheet; Gore-Tex Dura Substitute) is now used widely as a dural substitute [27], no long-term follow-up studies are available. Nagata et al. [13] compared the results when ePTFE sheets alone, and ePTFE sheets combined with PGA fabric and fibrin glue were used. They found that CSF leakage occurred in 12 of 59 patients (20%) in the former, and 1 of 33 (3%) patients in the latter group. They used the PGA fabric and fibrin glue to seal needle holes in the ePTFE sheet and named this the

“Mesh-and-Glue Technique”.

Our complex consisting of PGA fabric and fibrin glue represents an artificial dural substitute. One of us (Terasaka) developed this substitute by coating the bioabsorbable fibers with fibrin glue; this resulted in high closing ability and adhesion-prevention and reduced the incidence of CSF leakage [20, 21, 23, 24]. Yamada et al. [29, 30] reported a bioabsorbable synthetic dural substitute composed of a non-woven PGA fabric and an L-lactic acid-e-caprolactone copolymer film. Their animal experiments revealed that the synthetic dura was dissolved and replaced by dura-like connective tissue within 6 months of graft placement. However, the patches must be sutured to the edge of the residual dura mater and 15 of their 53 patients (28%) manifested subcutaneous CSF collection.

Our method of dural closure represents an advance over previous techniques because the fabric can be cut to the desired size and shape and, as suturing is unnecessary, operating time is minimized. However, if the dural edge is too narrow for adequate pasting with fibrin glue, CSF leakage may not be avoided. When postoperative MRI or CT suggests the presence of CSF in the epidural space, spinal CSF drainage must be started immediately.

The PGA fabric has been used in the clinical setting as artificial pleura [14]. The fate of the implanted PGA-fibrin sheet is unclear. Zund et al. [32], who seeded human fibroblasts on PGA fabric, observed attachment, spreading, and division of the seeded cells. This led them to

postulate that theirs may be a model for constructing synthetic human tissue. Sawamura et al. [21] studied the histological changes of fibrin glue used in the human body by examining sprayed fibrin clots obtained at reoperative intracranial surgery, and reported that the clots were replaced by collagenous connective tissue at 4 weeks after the first operation. In addition, one of us (S.T.) used PGA sheets in 12 canine cerebral hemispheres. Histologically, there was tissue replacement of the dural substitute by collagenous fibers after 2 months and there was no evidence of adhesion to the canine brain surface [24]. We postulate that the PGA sheet plays a different role at different stages: In the early stage after introduction it serves as a frame to reinforce the fibrin clot membrane and in later stages the PGA fibers represent a cradle for collagen fiber synthesis. As the PGA sheet hosting the fibrin clot membrane is subsequently replaced by newly synthesized dura-like connective tissue, it may represent a novel alternative to currently available artificial dural substitutes

Acknowledgements

We thank Dr. Paul R. Cooper for his constructive comments. And experimental study was supported by Chemo-Sero Therapeutic Research Institute, Kumamoto, Japan to supply their fibrin glue (Bolheal).

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Figure Legends

Figure 1

Pressure leakage test

A: A digital manometer and pressure syringe are connected via a tube to a plastic bottle filled with colored water

B: A dural defect introduced on rabbit skin is covered with the PGA-fibrin sheet as a dura substitute

C: Water pressure is applied and recorded when leakage of the colored water is observed or when the digital manometer shows a pressure decrease

Figure 2

Preparation of PGA-fibrin sheet

A: Fibrin glue is sprayed onto the PGA sheet

B: We refer to the PGA sheet and fibrin clot complex as the PGA-fibrin sheet and to the fibrin-free space as the pasting margin

Figure 3

Schema of two types of PGA patches used to prevent CSF leakage

A: To substitute for dural defect

B: To reinforce fragile dura mater

Figure 4

The water pressure at the time of leakage was 161 ± 42 mmHg and 96.5 ± 32 mmHg when the pasting margin was 5 mm and 2 mm, respectively.

Figure 5 - Case 1

A: 3D reconstruction of a sagittal CT image showing remarkable OPLL at the level of C5 and C6

B: Axial CT image reveals marked OPLL in the bone window level at the C6 level

Figure 6 - Case 1

A: T2-weighted MRI (sagittal view) showing severe spinal cord compression by OPLL. The axial image also revealed marked spinal cord compression

Figure 7 - Case 1, intraoperative findings

A: After OPLL removal, the dura mater was absent

B: Note the long dural defect after OPLL removal

C. Application of the PGA fibrin sheet

D. After spraying with fibrin glue

Figure 8 - Case 1

Postoperative MRI showing no signs of CSF leakage and a well-decompressed spinal cord.

Figure 9 - Case 2

A: T1-weighted MRI showing tethered cord and a bulb-shaped mass

B: On T2-weighted MRI, the bulb-shaped mass contains a high-intensity area

Figure 10 - Case 2

Intraoperative findings

A: After tethering the spinal cord, the bulb-shaped mass was found to be gliosis

B: A thin Gortex membrane was wrapped around the spinal cord to prevent adhesion

C: Tension was applied to the residual dura mater with 3 absorbable sutures

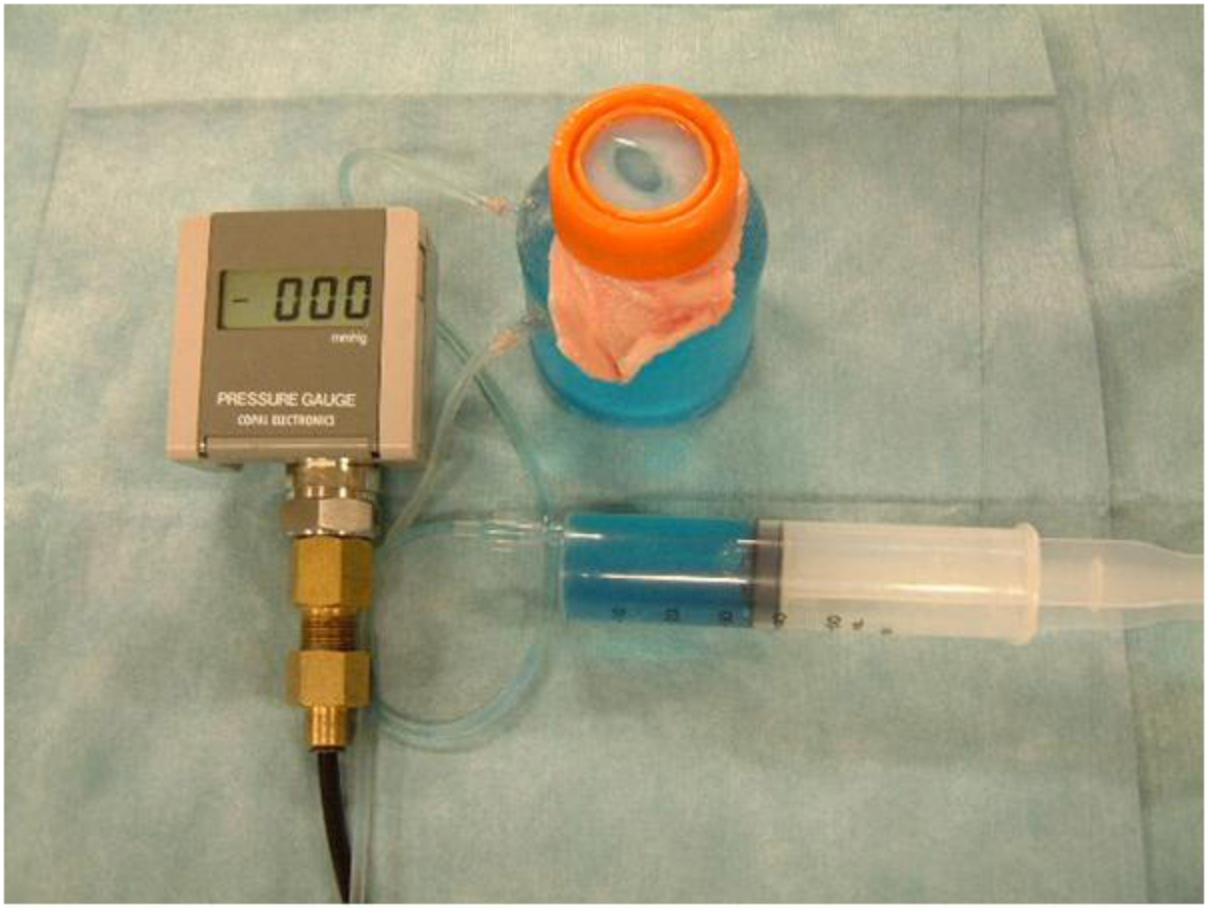
D: The PGA sheet was applied and sprayed with fibrin glue

Figure 11 - Case 2

Postoperative MRI showing no evidence of CSF leakage. There is sufficient space for the CSF around the untethered spinal cord.

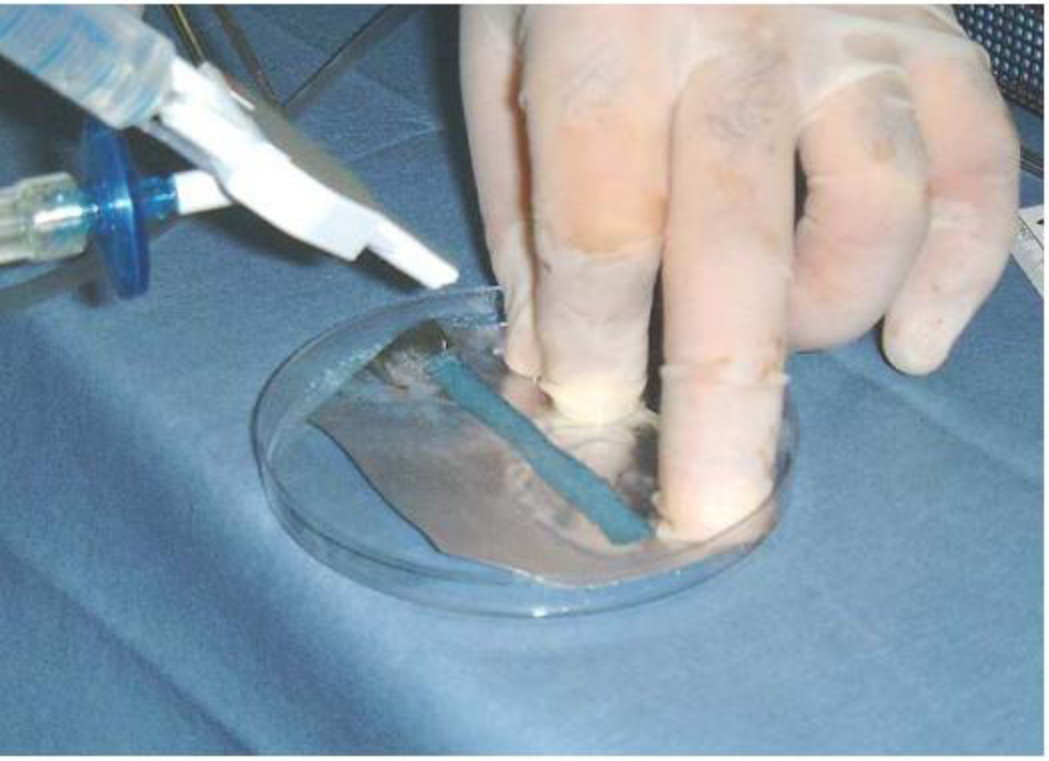
Table 1: Diseases of 160 patients treated by spinal surgeries in which the PGA sheet was used.

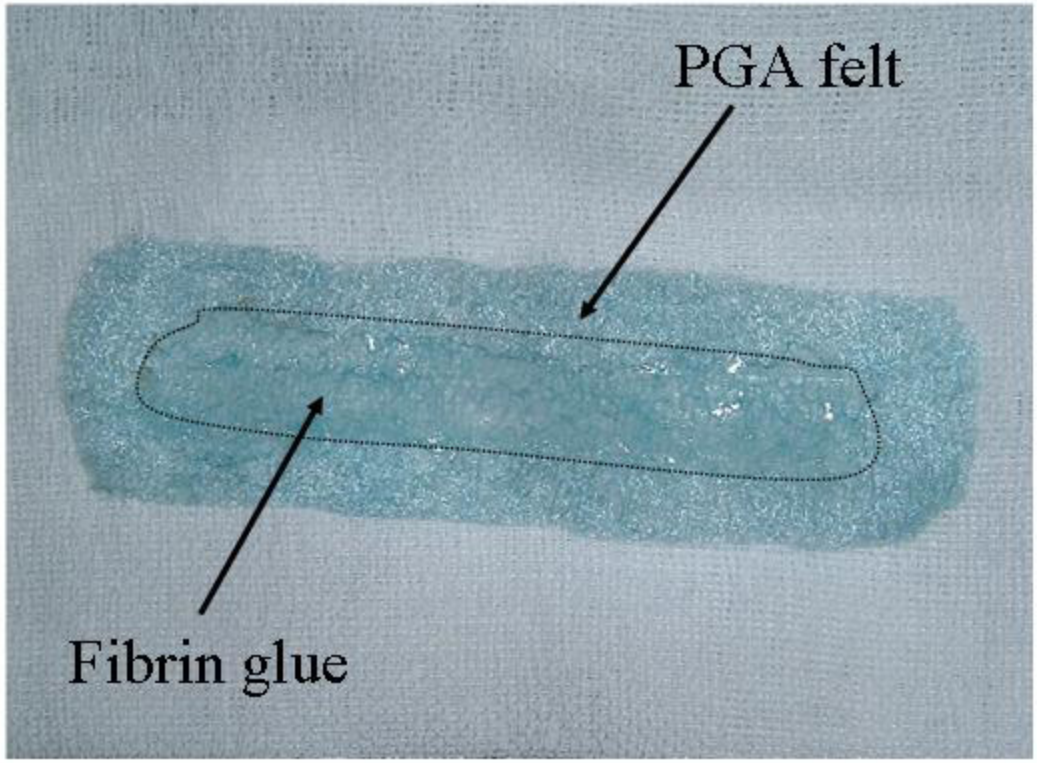
Table 2: Results obtained in 160 patients who underwent spinal surgeries in which the PGA sheet was used.



A

Fig. 1





A **B**

Fig. 2

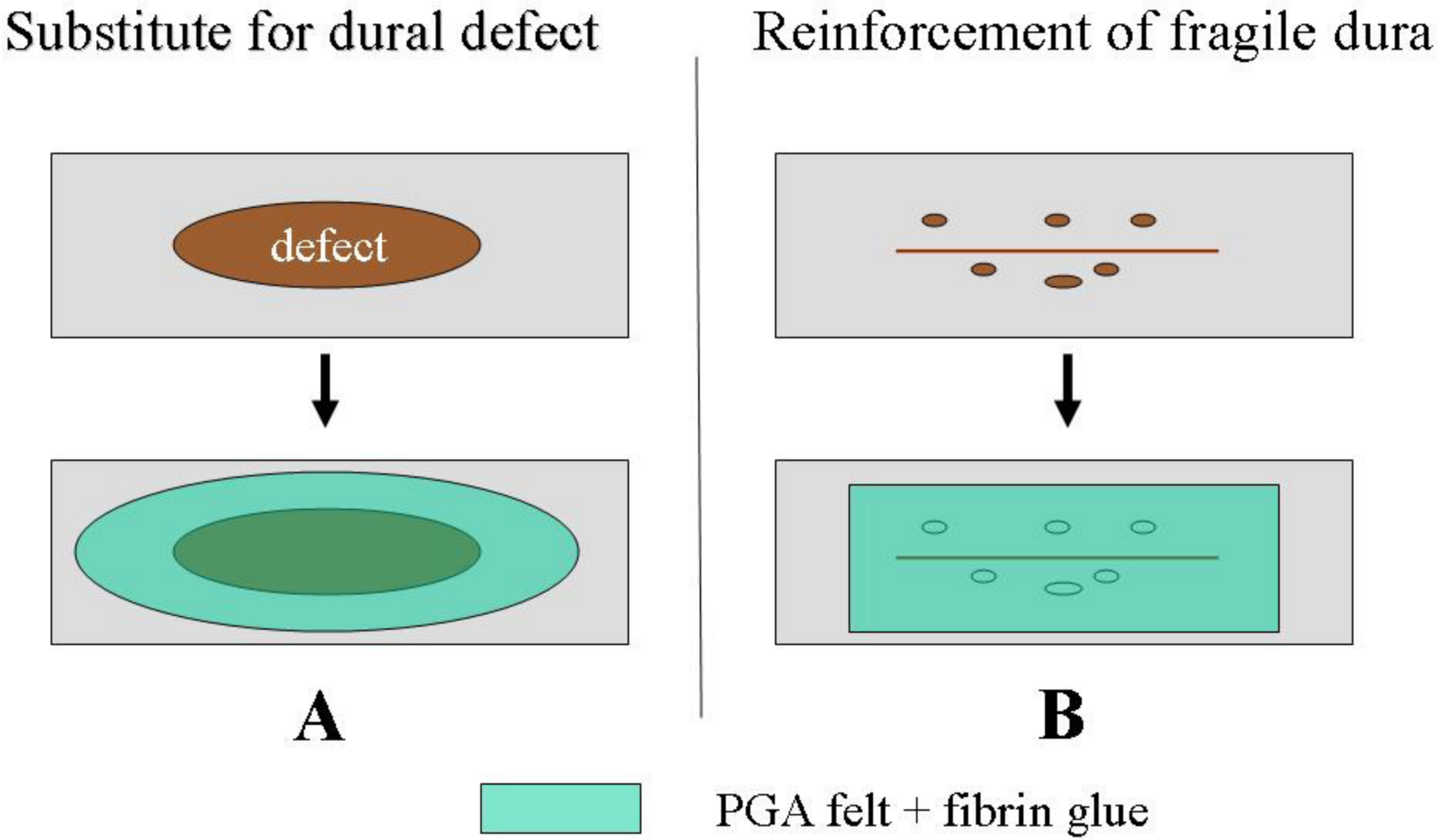

Substitute for dural defect
Reinforcement of fragile dura
defect
A
B
PGA felt + fibrin glue

Fig. 3

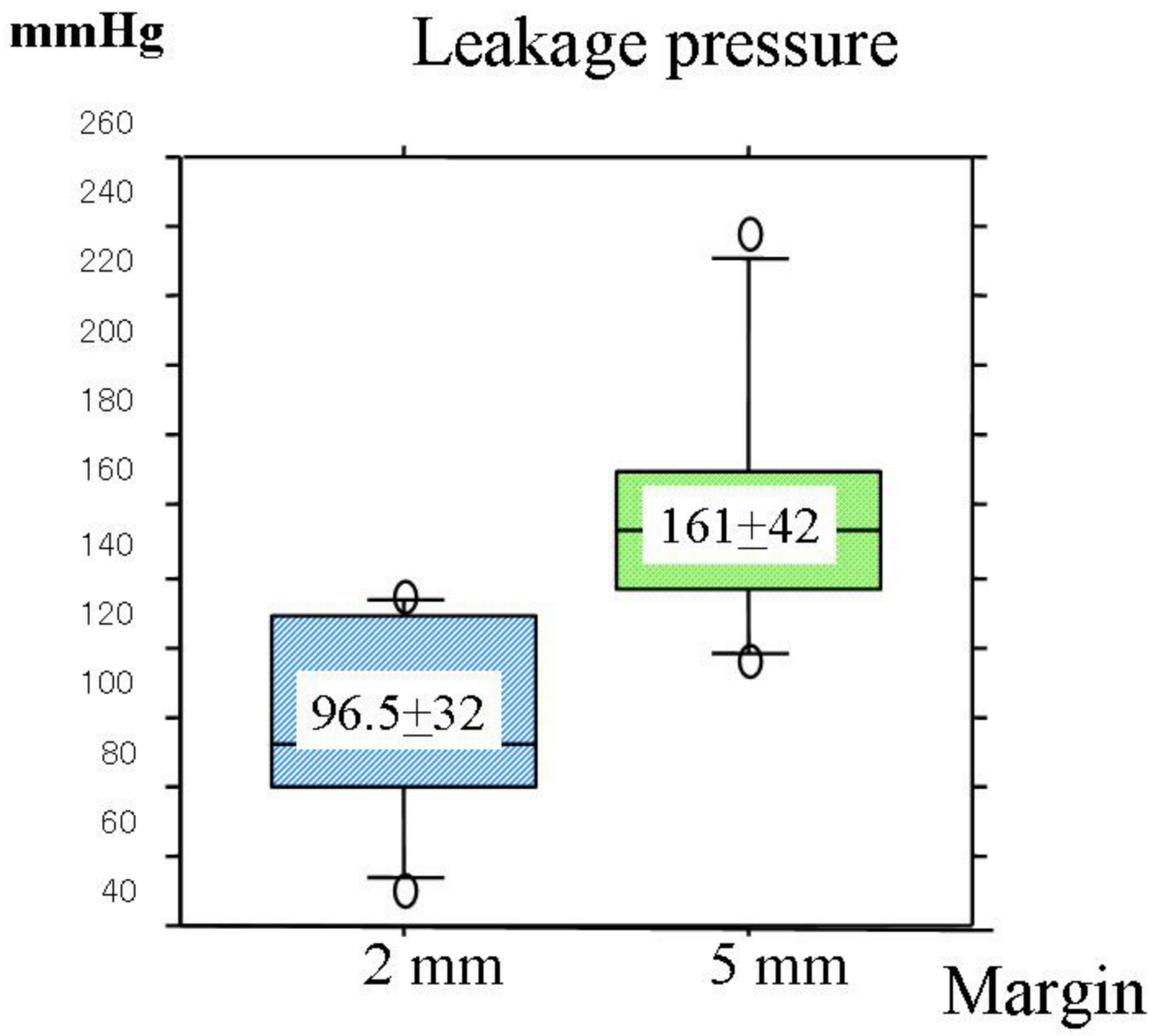
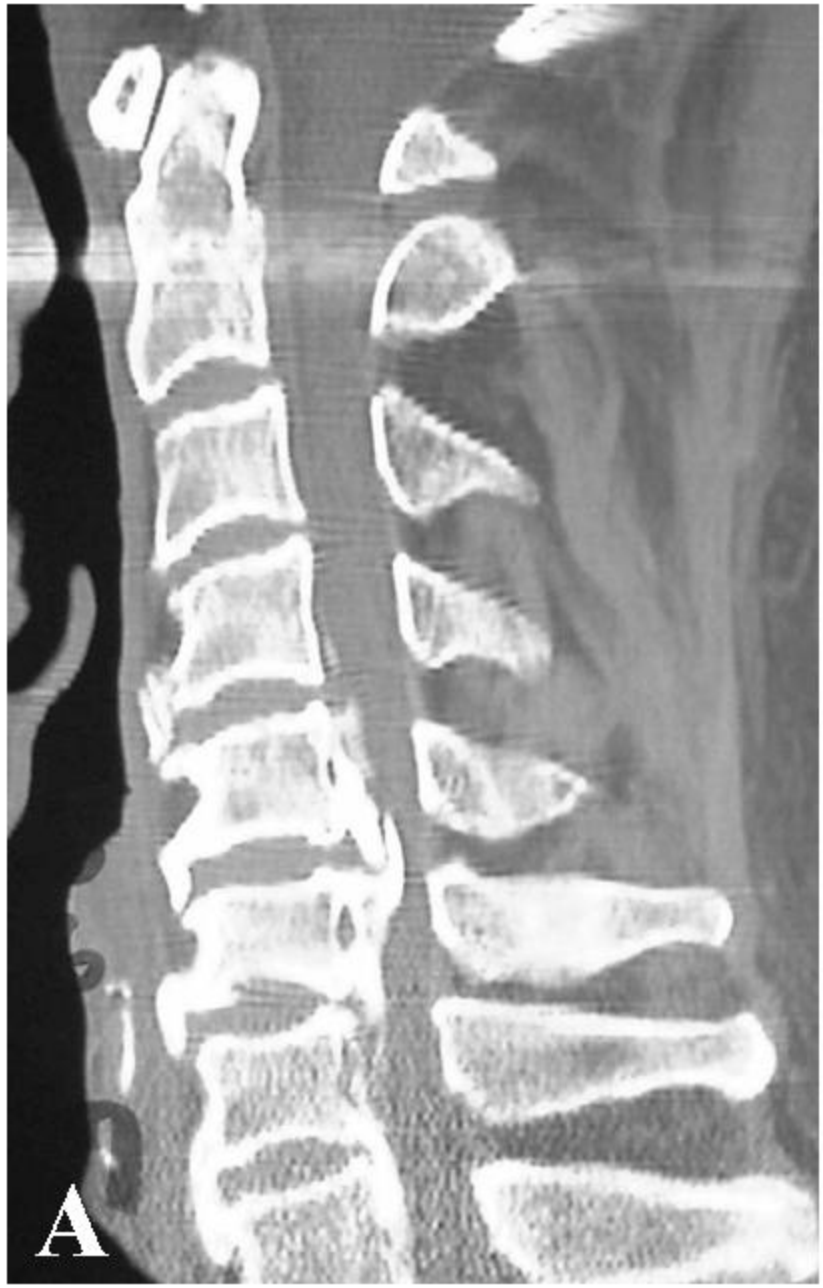
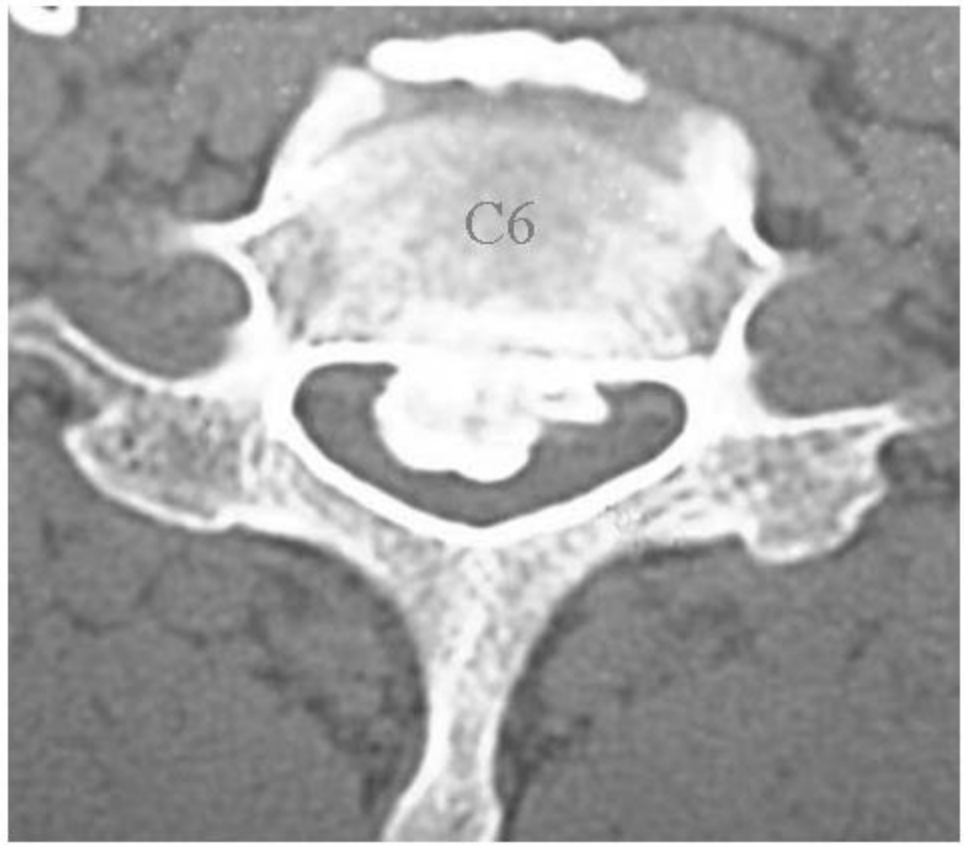

mmHg
Leakage pressure
260
240
220
200
180
160
140
120
100
80
60
40
96.5±32
161±42
2 mm
5 mm
Margin

Fig. 4





B

Fig. 5

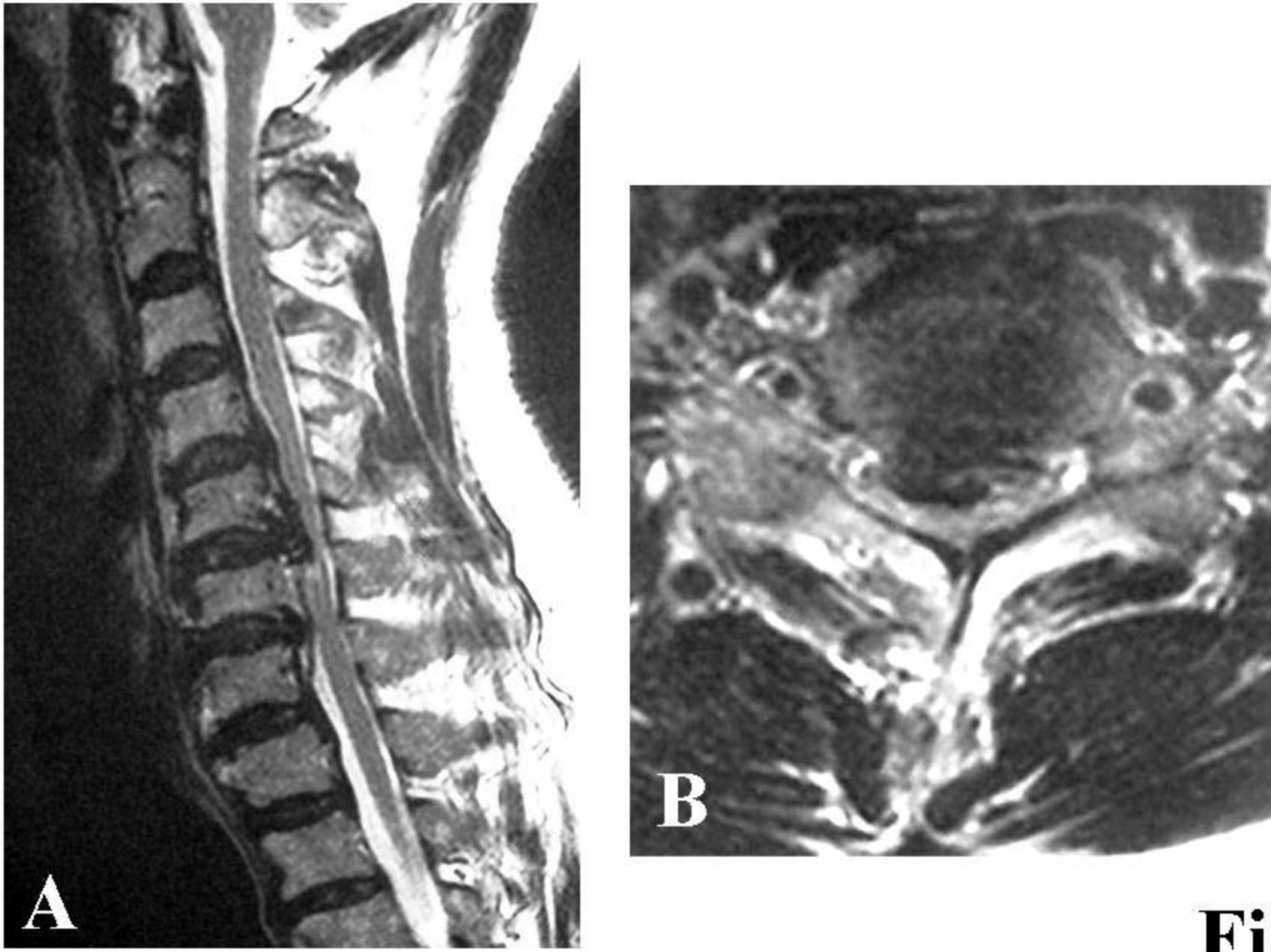


Fig. 6

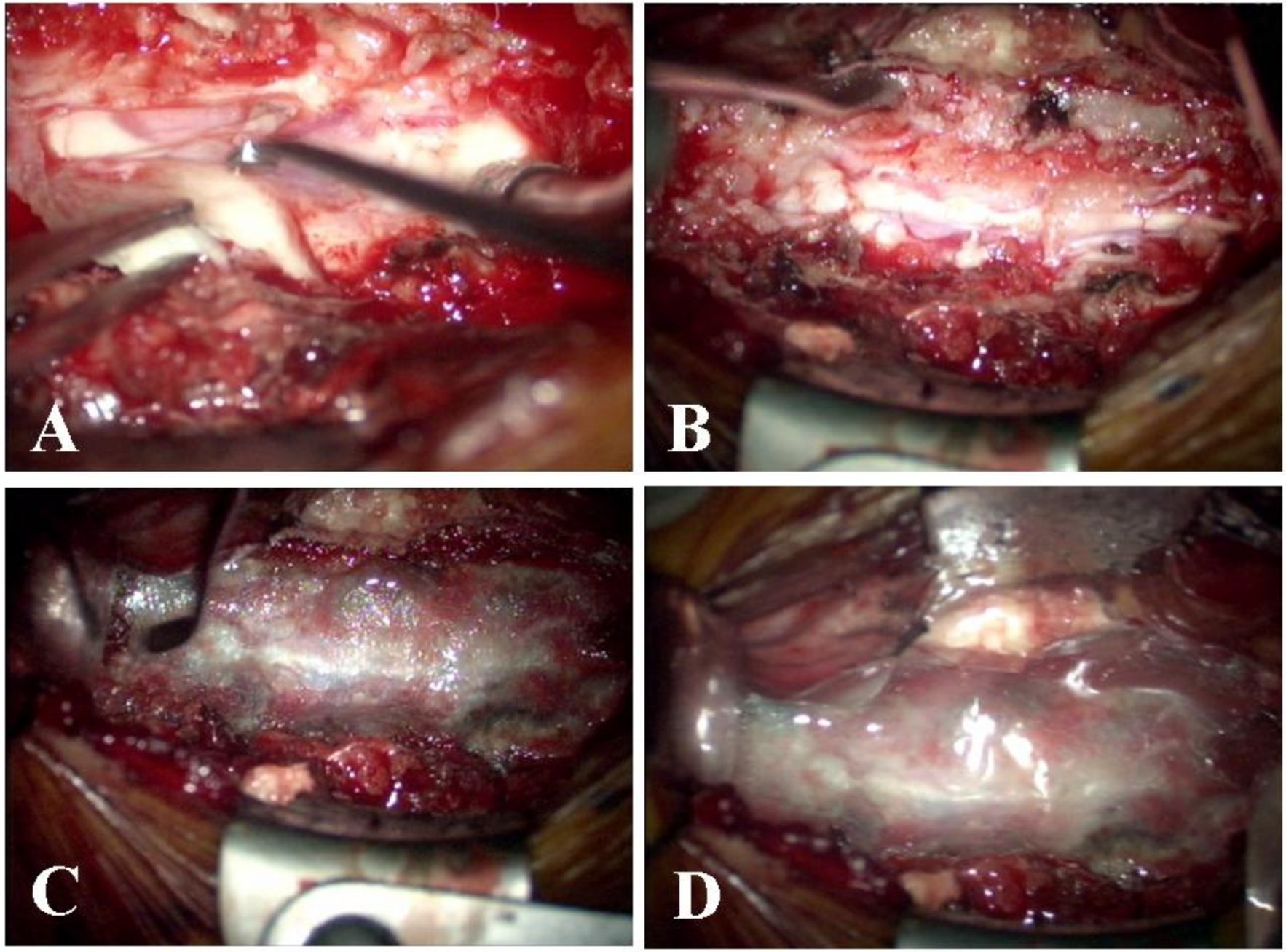


Fig. 7

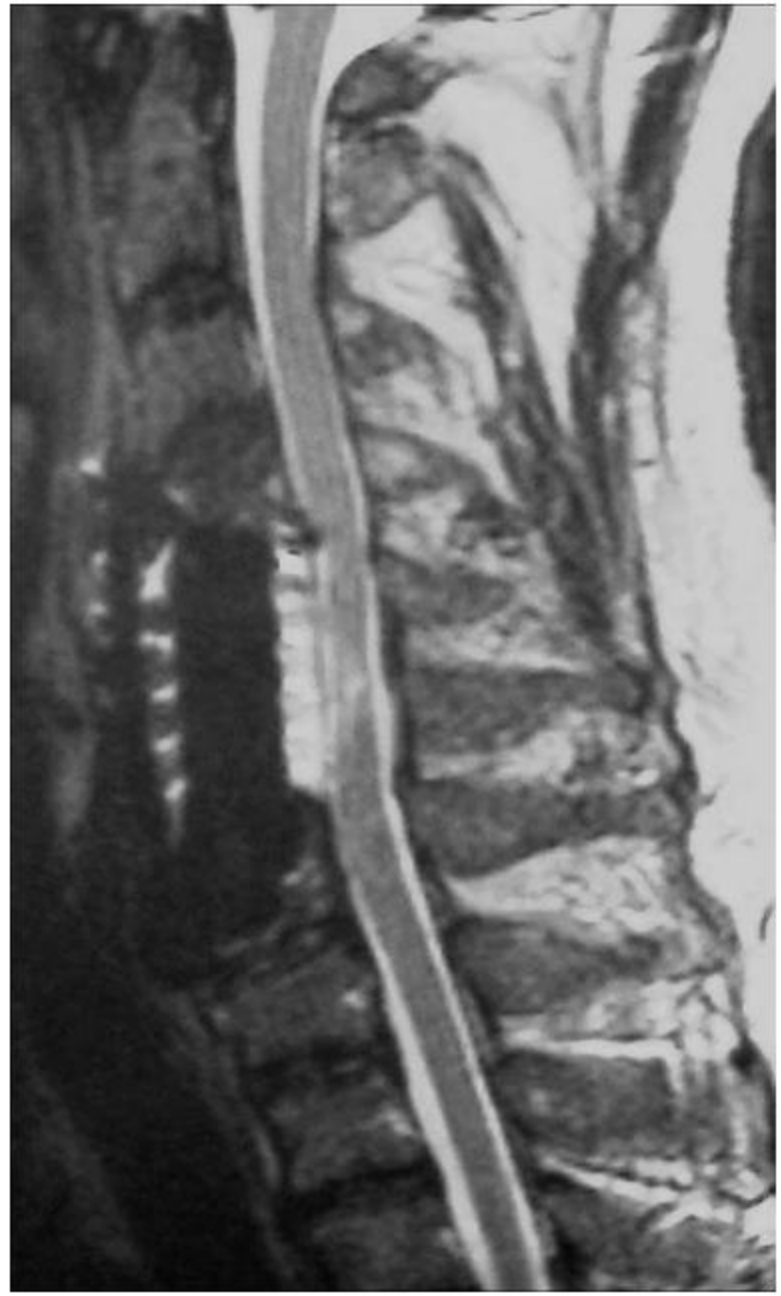
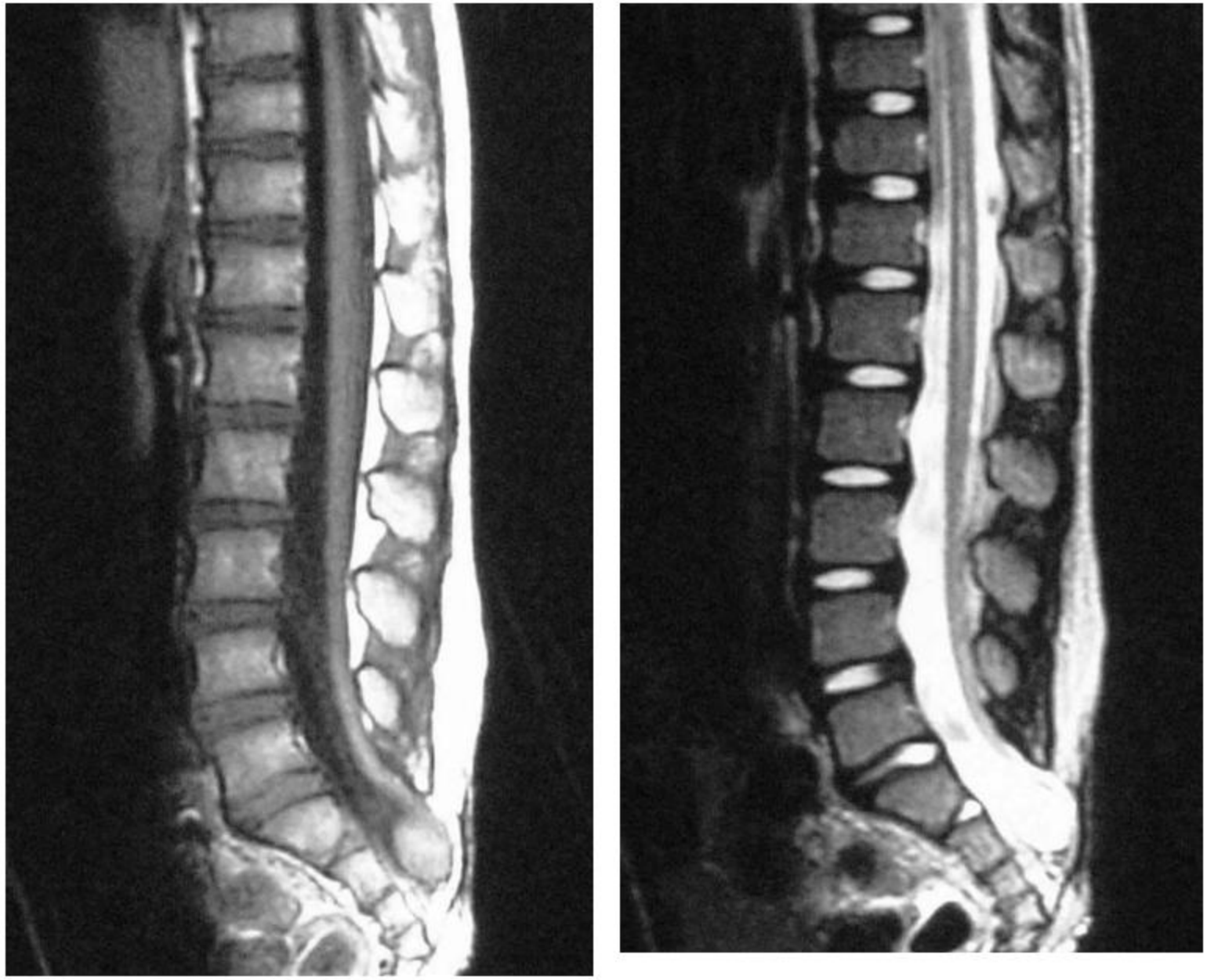


Fig. 8



A

B

Fig. 9

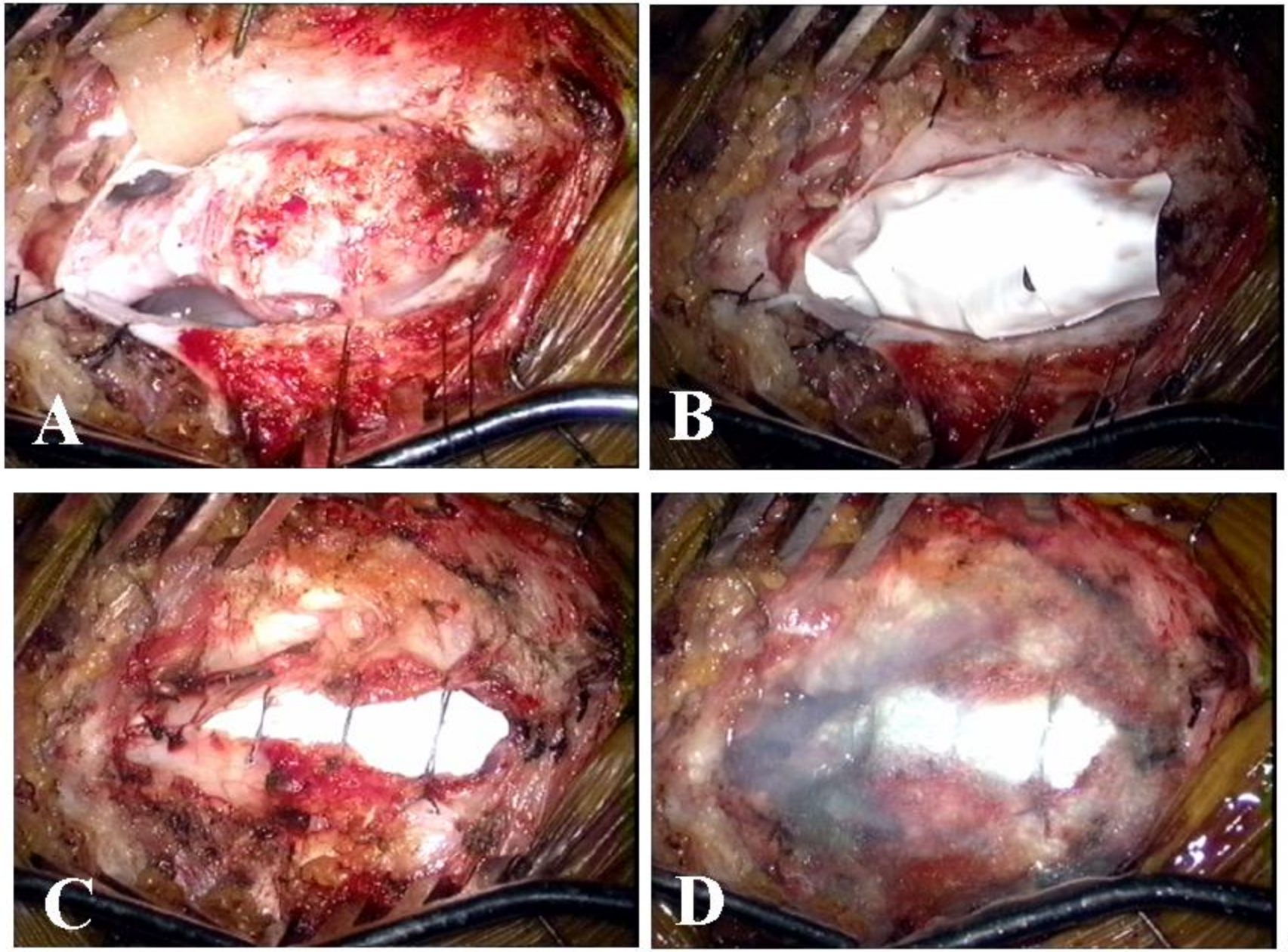


Fig. 10

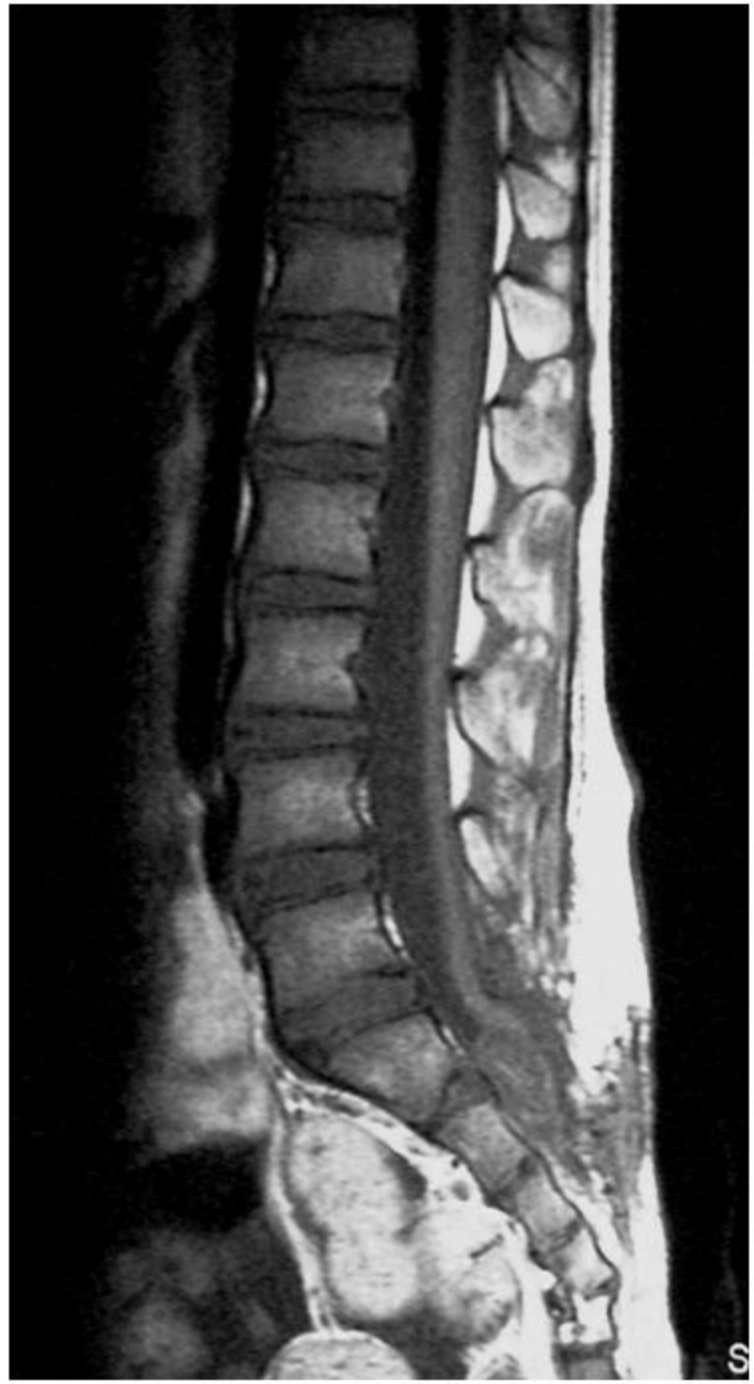


Fig. 11

Intramedullary tumor	35
Spinal schwannoma	22
Syringomyelia with Chiari type I malformation	20
Spinal AVM	18
Spina bifida	17
Adhesive arachnoiditis	12
Spinal meningioma	8
Traumatic syringomyelia	7
OPLL	5
Chiari malformation	3
Ossification of yellow ligament	3
Arachnoid cyst	3
Syringobulbia	2
Miscellaneous	5
Total	160

Table 1

	No.	CSF leakage	Re op
Intramedullary tumor	35	1	
Spinal schwannoma	22	2	1
Syringomyelia with Chiari type I malformation	20	3	2
Spinal AVM	18		
Spina bifida	17		
Adhesive arachnoiditis	12	1	1
Spinal meningioma	8		
Traumatic syringomyelia	7		
OPLL	5		
Chiari malformation	3		
OYL	3	2	1
Arachnoid cyst	3		
Syringobulbia	2		
Miscellaneous	5	1	1
Total	160	10 (6%)	6 (4%)

Table 2