S. Caserta
G. A. La Maida
B. Misaggi
D. Peroni
R. Pietrabissa
M. T. Raimondi
A. Redaelli

Elastic stabilization alone or combined with rigid fusion in spinal surgery: a biomechanical study and clinical experience based on 82 cases

Received: 12 March 2002
Accepted: 21 March 2002
Published online: 13 September 2002
© Springer-Verlag 2002

S. Caserta (✉) · G.A. La Maida
B. Misaggi · D. Peroni
Spine Division,
Gaetano Pini Orthopaedic Institute,
Piazza Cardinale Andrea Ferrari no. 1,
20122 Milan, Italy
e-mail: caserta@g-pini.unimi.it

R. Pietrabissa · M.T. Raimondi
A. Redaelli
Politecnico di Milano,
Bioengineering Department, Laboratory
of Biological Structure Mechanics,
Piazza L. da Vinci, 32, 20133 Milan, Italy

Abstract The authors report their experience with the treatment of lumbar instability by a kind of spine stabilization. The elastic stabilization, which follows a new philosophy, is obtained by an interspinous device, and should be used alone in degenerative disc disease, recurrent disc herniation and in very low grade instability, or in association with rigid fusion for the prevention of pathology of the border area. In collaboration with bioengineers, we carried out an experimental study on a lumbar spine model in order to calculate stresses and deformations of lumbar disc during simulation of motion, in physiological conditions and when elastic stabilization is combined with rigid fusion. Results suggest

that elastic stabilization reduces stresses on the adjacent disc up to 28° of flexion. Based on this preliminary result, we began to use elastic stabilization alone or combined with fusion in 1994. To date, we have performed 82 surgical procedures, 57 using stabilization alone and 25 combined with fusion, in patients affected by degenerative disc disease, disc herniation, recurrence of disc herniation or other pathologies. Clinical results are satisfactory, especially in the group of patients affected by recurrent disc herniation, in whom the elastic device was used alone.

Keywords Elastic stabilization · Discopathy · Disc herniation recurrence · Border area

Introduction

One of the biggest problems in spinal surgery is the treatment of vertebral instability.

The diagnostic instruments used to identify instability are standard and dynamic X-rays, and magnetic resonance (MR) images, on which early disc degeneration can be identified by so-called Modic signs [9]. Discography is the only investigational device that can identify the pain source (memory pain) through a provocative test. Computed tomography (CT) is important for the detection of bone diseases and analysis of the status of facet joints.

Many different surgical procedures are employed to treat vertebral instability: postero-lateral fusion (PLF), intersomatic fusion (ALIF or PLIF) and posterior instrumented fusion alone (screw fixation) or combined with in-

tersomatic fusion (circumferential fusion). All these procedures may achieve the goal of fusion, with good radiological results; however, at the same time they can create a pathology of the level adjacent to the fused area.

Butler et al. [1] performed a study to determine the relationship between facet joint osteoarthritis and disc degeneration in subjects in whom both MR images and CT scans had been obtained. The MR images were used to determine disc degeneration, the CT scans to determine the presence of facet joint osteoarthritis. The authors hypothesized that disc degeneration would sometimes occur without the presence of facet joint osteoarthritis, but that facet joint osteoarthritis would only occur in the presence of disc degeneration. They concluded, on the basis of their results, that disc degeneration occurs before facet joint osteoarthritis, which may be secondary to mechanical changes in loading of the facet joints. If this concept is true for a

non-instrumented spine, imagine applying this to a functional spinal unit near a fused area, in which stresses are more concentrated.

Elastic stabilization could be a good alternative to fusion in cases in which arthrodesis is an excessive procedure. It should also be used in addition to lumbar stabilization in cases in which the disc adjacent to the fused area is initially degenerated. We call this a combined stabilization.

Indications for elastic stabilization alone are very low grade instability, initial disc degeneration in young people, recurrent disc herniation with or without scar tissue formation and lumbar stenosis.

Using the interspinous device, we increase the stability of the segment, we discharge the posterior facets, and we obtain an increase in the neuroforamina size. Senegas, with his work, confirmed these concepts [10].

Before starting with the *in vivo* application of the device, we performed a biomechanical study, in collaboration with bioengineers of the Politecnico di Milano. The aim of the study was to understand better the efficacy of the Bronsard's ligament when applied on a model simulating the lumbar spine.

Materials and methods: biomechanical model

We conceived a schematic representation of lumbar spine (Fig. 1) composed of contiguous segments representing the spine in a sagittal plane.

To simplify the scheme, we decided to consider the spine as formed by elastic discs, with a circular hollow section interposed to rigid bodies with a circular full section. We did not consider the nucleus pulposus properties. All data regarding mechanical and geometrical characteristics were deduced from other mechanical models reported in literature [3, 8].

Fig. 1 Schematic representation of the lumbar spine: α_i is the angle between two adjacent discs; γ_i is the angle of inclination of each vertebral body; S_i is the height of the vertebral body

Fig. 2 Scheme of a vertebral body unit during anterior flexion. C and M represent the weight and muscular forces. LLP represents the posterior longitudinal ligament, LIT the ligamentum flavum and the intertransverse ligament, LIS the interspinous and supraspinous ligaments

We studied the lumbar spine in a standing position; our purpose was to evaluate stress and deformation of intervertebral disc during flexion.

We decided to consider only flexion, at first, to simplify the evaluation, which could be very complex for other movements owing to the different components included. During forward flexion some torsion components are present, but they are so slight that we can consider the flexion movement as a pure one, completely contained in the median plane of the subject.

The lumbar spine is subject to a system of loads in which body weight, muscle and ligament actions are all involved, maintaining the trunk's balance in all degrees of flexion.

In Fig. 2 we present a schematic representation of a vertebral motion segment during flexion, showing the various forces involved.

By means of a classic technique normally used in engineering for hyperstatic structures, we analysed the internal actions and the main stresses and deformations of intervertebral discs that develop at different degrees of flexion up to 40°.

The simulations carried out concerned physiological movement, movement at one or two levels with rigid stabilization and finally the movement at one level with rigid stabilization combined with the elastic stabilization outlined above, using Bronsard's ligament.

Results: biomechanical model

Figure 3 presents the results of the simulation, showing the maximal stress values in the L3-L4 disc (y-axis) for angles of lumbar flexion up to 40° (x-axis).

The graph shows maximal solicitation in the disc adjacent to a fused area increases by more than the values calculated in physiological conditions, and much more if there is a two-level fixation. If we put an elastic stabilization on the disc above, this value reduces, but only if lumbar flexion is less than 28°. For a higher grade of flexion, the value increases.

Elastic stabilization seems to reduce the concentration of stresses applied on the bordering disc during flexion by up to about 30°.

Fig. 3 The y-axis shows that the maximum strain is at the L3-L4 intervertebral disc; the x-axis shows the angle of lumbar flexion

The increase in stresses for higher grades of flexion is probably due to the mechanical properties of the Bronsard's ligament. This could mean that the artificial ligament we used may be too stiff.

We now use the DIAM interspinous device, which is less stiff than the Bronsard one, and we intend to test it on the same biomechanical model.

Materials and methods: patient series

From January 1994 to December 2001 we performed 82 surgical procedures; 57 were elastic stabilization alone and 25 were associated with instrumentation and fusion (combined stabilization). The mean age was 43 years and the admission diagnosis was degenerative disc disease in 50% of the cases, disc herniation in 25.6%, recurrent disc herniation in 11% and some other diagnosis in 13.4% of the cases (Table 1).

Two patients were affected by L5 spondylolisthesis. We performed a reduction and a combined stabilization in both cases. Fusion was performed from L4 to S1, associated with an elastic stabilization in L3-L4 because of initial degeneration of the disc.

Four patients suffered from a lumbar stenosis. We performed a one- or two-level laminectomy associated with elastic stabilization.

Fifty-seven patients (57/82) underwent elastic stabilization alone (Table 2). In 61.4% of these cases we performed a one-level L4-L5 elastic stabilization. Six patients underwent a two-level procedure, four of them had an L3-L4 and L4-L5 stabilization. In one case we performed an L5-S1 stabilization using the Dynasys system with an L4-L5 interspinous device (DIAM).

Table 1 Admission diagnosis

Admission diagnosis	N
Degenerative disc disease	41
Disc herniation	21
Recurrent disc herniation	9
Lumbar instability	5
Spondylolisthesis	2
Lumbar stenosis	4
Total	82

Table 2 Elastic stabilization alone

Level	N
L2-L3	6
L3-L4	10
L4-L5	35
L1-L2 and L2-L3	1
L3-L4 and L4-L5	4
L4-L5 and L5-S1	1
Total	57

Fig. 4 Dynamic radiographs of a 35-year-old woman affected by L4-L5 degenerative disc disease. Low-grade L4-L5 instability is evident

Fig. 5 Magnetic resonance (MR) image shows an L4-L5 bulging disc

In Fig. 4 we present the case of a 35-year-old woman affected by L4-L5 degenerative disc disease with initial signs of instability on dynamic radiographs. MR images (Fig. 5) demonstrate the presence of a bulging disc. She suffered from persistent back pain, and

Fig. 6 One-year follow-up dynamic radiographs after implantation of the L4-L5 interspinous device

Table 3 Elastic stabilization combined with fusion (combined stabilization)

Fused area	Elastic stabilization	N
L5-S1	L4-L5	6
L4-S1	L3-L4	11
L4-L5	L3-L4	4
L4-L5	L2-L3 and L3-L4	1
L3-L4	L2-L3	1
L3-L4	L2-L3 and L4-L5	1
L5-S1	L3-L4 and L4-L5	1
Total		25

we decided to perform an L4-L5 elastic stabilization. The dynamic radiographs taken at 1-year follow-up (Fig. 6) demonstrate the good position of the device and increased stability of the segment. The patient is pain free.

In twenty-five patients (25/82) we performed a combined stabilization (Table 3).

L4-S1 rigid stabilization with fusion associated with an L3-L4 elastic stabilization was performed in 44% of these cases. Three patients underwent spinal fusion associated with two-level elastic stabilization; in one of them we performed a one-level fusion with interspinous devices on the level above and below.

Figure 7 shows the intraoperative view of an L5-S1 fusion combined with an L4-L5 elastic stabilization. The suture of the supraspinous ligament follows the interspinous device placement.

Figure 8 and Fig. 9 show a 60-year-old man affected by multilevel disc disease and lumbar instability. At 4 years of follow-up (Fig. 10) good bone fusion from L4 to S1 and a restored height of the L3-L4 space are evident.

Results: patient series

We reviewed 61 patients (61/82) with a mean follow up of 20 months (minimum 12 months; maximum 6 years). Clinical results are highly satisfactory, especially in the group of patients affected by recurrent disc herniation, in whom the elastic device was used alone.

Fig. 7 Intraoperative view of an L5-S1 fusion combined with an L4-L5 elastic stabilization

Fig. 8 Lateral radiograph and MR image of a 60-year-old man, showing multilevel disc disease

Fig. 9 Anteroposterior radiograph shows the presence of L4-S1 degenerative processes

No complications related to the material were detected.

Although elastic stabilization with an interspinous device seems able to prevent the recurrence of disc herniation [11], in our series one patient developed a recurrence 2 years after the intervention of elastic stabilization. Our mean follow-up period is too short to reach any conclusion on this.

The best results were for a single-level elastic stabilization positioned at L4-L5. No differences in results were observed if two devices were placed one above the other. The L5-S1 level should be avoided because of the poor quality of the S1 spinous process.

Discussion

Freudiger et al. [6] published an in vitro study on dynamic neutralization of the lumbar spine. They concluded that the dynamic neutralization system they used reduces bending angles and horizontal translations, but increases vertical translations. They also concluded that the bulging of the posterior anulus was reduced.

Some authors [5, 7] have used elastic stabilization for the treatment of initial lumbar instability, with satisfactory results, while Dubois et al. [4] classified dynamic destabilization into phases in order to facilitate recognition of the early signs and symptoms of lumbar instability. Based on

Fig. 10 At the 4-year follow-up after L4-S1 fusion associated with L3-L4 elastic stabilization, good bone fusion from L4 to S1 and a restored height of the L3-L4 space are evident

their classification they operated on 57 consecutive patients with the Dynasys system. They concluded that their dynamic stabilization system is applicable to a wide range of nonstructural lumbar instability.

From our experience, we believe that elastic stabilization with an interspinous device (DIAM) is a safe procedure with good clinical results, especially in patients affected by recurrent disc herniation.

It can also be used with good results in patients affected by degenerative disc disease, lumbar stenosis and very low grade instability.

When used in association with lumbar stabilization arthrodesis, we think that elastic stabilization reduces the mechanical stresses applied on the disc above. In this way the bordering area can be protected from accelerated degenerative process [2].

This is an hypothesis, which requires a scientific demonstration. We are therefore carrying out a radiological study (X-rays and MRI) on patients operated, in order to obtain evidence on whether a minor rate of precocious degenerative processes is detected in this group compared to a control group.

References

1. Butler D, Trafimow JH, Andersson GB, McNeill TW, Huckman MS (1990) Discs degenerate before facets. *Spine* 15:111–113
2. Caserta S, Misaggi B, Peroni D, La Maida GA (2001) Elastic stabilization combined with rigid fusion: a prevention of pathology of the border area. Proceedings of the 24th National Congress of the Italian Spine Society. *Eur Spine J* 10:352–362
3. Chazal J, Tanguy A, Bourges M, Gaurel G, Escande G, et al (1985) Biomechanical properties of spinal ligaments and a histological study of the supraspinal ligament in traction. *J Biomech* 18:167–176
4. Dubois G, de Germay B, Schaerer NS, Fennema P (1999) Dynamic neutralization: a new concept for restabilization of the spine. In: Szpalski M, Gunzburg R, Pope MH (eds) *Lumbar segmental instability*. Lippincott Williams & Wilkins, Philadelphia, pp 233–240
5. Fassio B, Cohen R, Beguin C, Jucopilla N (1991) Traitement des instabilités lombaires dégénératives L4-L5 par ligamentoplastie inter-épineuse. *Rachis* 3: 464–474
6. Freudiger S, Dubois G, Lorrain M (1999) Dynamic neutralization of the lumbar spine confirmed on a new lumbar spine simulator in vitro. *Arch Orthop Trauma Surg* 119:127–132
7. Graf H (1992) Instabilité vertébrale. Traitement à l'aide d'un système souple. *Rachis* 4:123–137
8. Kapandj IA (1994) *Fisiologia articolare*, vol 3, 5th edn. Monduzzi, pp 78–121
9. Modic M, Pavlicek W, Weinstein M, et al (1984) Magnetic resonance imaging of intervertebral disc disease. *Radiology* 152:103–111
10. Senegas J (1991) Surgery of the intervertebral ligaments: alternative to arthrodesis in the treatment of degenerative instabilities. *Acta Orthop Belg* 57 [Suppl 1]:221–226
11. Voydeville GP, Feldmann L (1992) Ligamentoplastie intervertébrale avec cale souple dans les instabilités lombaires. Etude préliminaire. *Orthop Traumatol* 2:259–264