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A dynamic neutralisation system for the spine. DYNESYS SYSTEM
Experience in 94 cases

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Summary

Objective. **To assess the results obtained by using the Dynesys system (Dynamic Neutralisation System for the spine) in a series of 94 patients, as a new concept for the treatment of degenerative lumbar pathology based on lumbar stabilization with preservation of articular function versus traditional arthrodesis movement restriction.**

Material and methods **We present a series of 94 patients in whom this system was used; 62 patients were men and 32 were women and mean age was 46.4 years. Patient pathology was disc hernia in 27 cases, degenerative disc disease in 54 cases and canal stenosis in 13 cases. Follow-up period was 14 to 24 months and the patient clinical picture was evaluated using Oswestry scale and return to work.**

Clinical results **Oswestry scale results were 21.4% post-operatively, compared with 56.8% previous to treatment and return to work rate was 82%. Sciatic nerve condition and lumbalgia remitted in practically all cases and there was 60% improvement in cases of claudication. We highlight two cases of complications due to the technique, one due to malpositioning of screws and another to pedicle breakage. Two cases of subcutaneous seroma and two tardive subclinical infections were also observed.**

Conclusions **Dynamic neutralisation obtained with this system should not be considered as arthrodesis. Treatment with Dynesys widens the candidate patient population who can undergo surgery to those who were not initially candidates for standard fixation, but posed problems for the surgeon regarding the application of techniques without instrumental support, while incorporating the concept of functionality versus movement restriction. The system can be defined as a disc prosthesis placed externally to the disc. We obtained good results in most of our patients. However, we consider that the follow-up period should be extended.**

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KEY WORDS: Spinal instability. Degenerative lumbosacral pathology. Dynamic stabilisation. Neutralisation system. Dynesys.

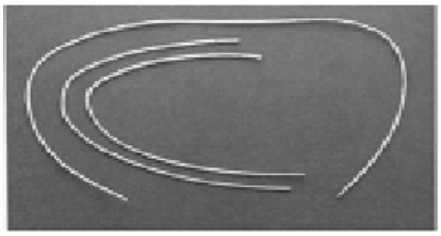
Summary

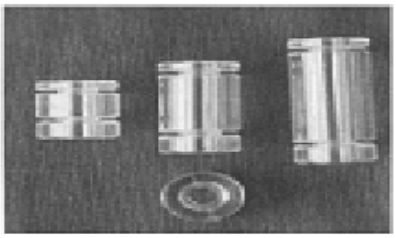
Objective. **To assess the results obtained using the Dynesys system (Dynamic Neutralisation System for the spine), in a group of 94 patients This new system for treating lumbar degenerative pathology is based on lumbar stabilisation and preservation of articular function, as opposed to traditional arthrodesis restrictions.**

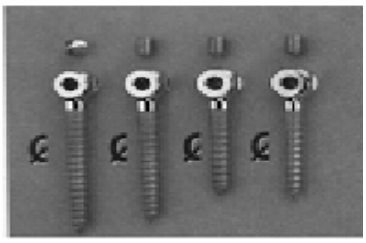
Material and methods. **We analyzed a series of 94 patients in whom this system was used. 62 were males and 32 females with an average age of 46.4 years. The pathologies treated were disc herniation in 27 cases, degenerative discopathy in 54 cases and lumbar channel stenosis in 13 cases. Follow-up was carried out between 14 and 24 months, assessing the clinical picture according to the Oswestry scale and the return to work.**

Results. **The final results on the Oswestry scale were 21.4% with respect to 56.8% prior to the treatment and the return to work was 82%. There was a remission of the sciatica symptoms in almost all the cases, as well as of the lumbar pain, and there was a 60% improvement in the claudication cases. With regard to complications, we would like to point out two cases due to the technique, one because of the wrong positioning of the screws and the other due to the rupture of the pedicle. There were two cases of subcutaneous seroma and two late subclinical infections.**

Conclusions. **The dynamic neutralisation obtained using this system, should not be considered as an arthrodesis. Treatment using Dynesys enlarges the population of patient candidates for surgery to who initially do not apparently need a standard fixation, but who raise doubt regarding the application of techniques without instrumental support, incorporating the functionality concept as opposed to restricting movement. This system can be defined as a disc prosthesis fitted**







Figures 1, 2 and 3

externally to the disc. We have obtained good results in the majority of our patients, although we believe that the follow-up should be increased.

KEY WORDS: Lumbar instability. Degenerative lumbosacraI pathology. Dynamic stabilisation. Dynesys neutralisation system.

Introduction

The history of the treatment of degenerative lumbar disease covers numerous techniques which vary in their degree of invasiveness, but with two primary objectives: the decompression of the neurological structures, on the one hand involving laminectomy, discectomy, and percutaneous techniques and achieving stability of the affected spinal segments, and on the other, involving lumbar fixation with or without instrumental support. The aim of all of these techniques is the mechanical control of the spine while reducing pain symptoms[7-9,13,14].

We had the opportunity of using a system based on a new concept, which attempts to achieve these principles of stability and reduction of clinical pain while preserving the functionality of the dynamic elements integrated in the lumbosacral spine[21].

The system is known as Dynesys and consists of a cylindrical spacer (Sulene pcu) that ensures primary stability of the system by absorbing load forces, a stabilising cord (Sulene pet) that absorbs tension forces; the braided design impedes extension but allows flexion, and pedicle anchor screws of various sizes made from Protasul-100 that allow cord fixation and favour compression of the modular spacers. (Figures 1, 2 and 3).

The concept of functionality versus movement restriction led us to consider that this could be a new approach in the treatment of degenerative lumbar disease and we present the results of the application of this system in 94 interventions where we observed significant and definite improvements in the clinical condition of these patients[22].

Anatomopathological approach

Lumbalgia is the first symptom of the presence of discopathy in the natural evolution of degenerative disc disease. This discopathy develops progressively and can lead to several stages of disc prolapse which, after the onset of mechanical destabilisation of the three-joint unit (disc and facets), can cause the upper vertebrae to collapse into the lower vertebrae[1]. Once the upper vertebrae have collapsed, discopathy can lead to either asymptomatic spontaneous fusion or stenosis (lateral or central) which, in combination with arthritic spondylolisthesis, is very painful for the patient.

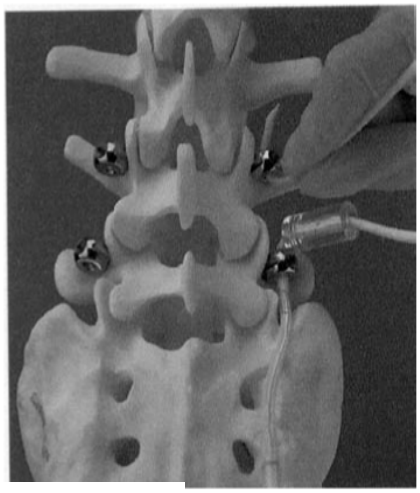
There is a stage during the evolution of destabilisation in which possible lesions and deformities can be reduced and even reverted. Initial mechanical lesion of the disc and later evolution can be viewed with the help of NMR imaging with Modic variations. NMR imaging permits viewing of the inflammatory oedema which was first produced, the creation of fatty tissue and final sclerotisation[15,16,18].

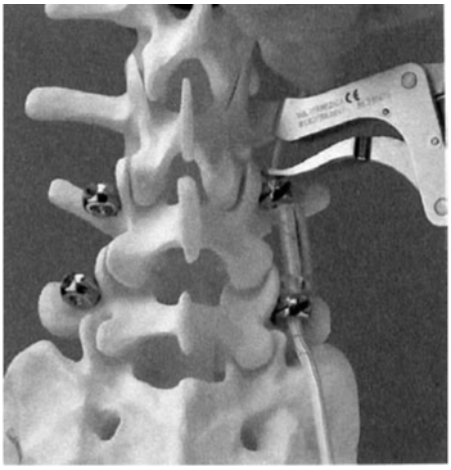
Disc degeneration has an impact on the facets, ranging from loss of articular space with facet deformation to hypertrophic osteophytosis which will later produce lateral and central stenosis.

Apart from the disc, the posterior and capsule ligaments and the articular faces are known to be the main nociceptive sources of pain. Therefore, the objective of the Dynesys system is to realign and restabilise the segments proximal to the functional anatomical elements[5,17].

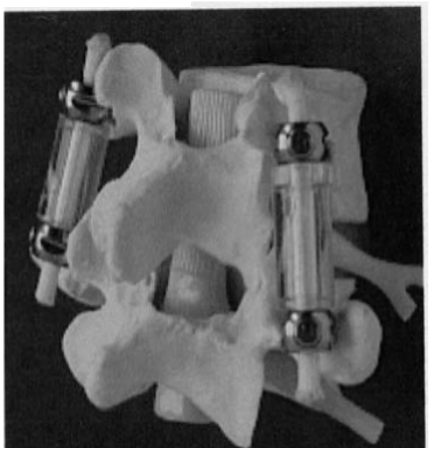
We believe that during the evolution of this dynamic stage, restabilisation can place the intervertebral segment in a more anatomical position, allowing for possible cure and a subsequent pain-free condition. The Dynesys system makes it possible to achieve real stabilisation with a controlled range of movement by means of:

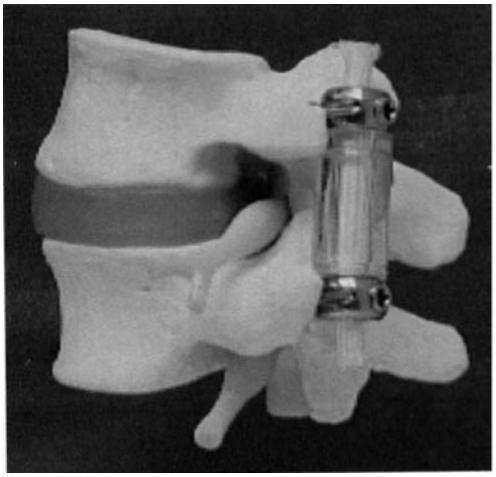
1. Dynamic neutralisation that absorbs non-physiological loads in compression and flexion-extension





Figures 4 and 5





Figures 6 and 7

and which suppresses parasitical movements.

2. The spinal segments can be relocated to a more physiological anatomical position that eliminates pain[19].

Material and methods

The sample included 94 patients who underwent intervention between March 2002 and December 2003, of whom 62 were men and 32 were women. Patient ages ranged from 26 to 68 years with mean of 46.4 years.

Preoperative and postoperative Oswestry tests were performed with results of 56.8% and 21.4%, respectively. Radiological studies performed were preoperative and postoperative NMR imaging and simple X-rays which compared disc profiles and their repercussion on corresponding roots, direct and indirect signs of preoperative and postoperative lumbar stability, placement of pedicle screws and measurement of distances between the screws, in consecutive controls. Possible variations of Modic signs and of rehydration of the intervertebral disc were also evaluated.

The surgical technique used was standard approach through the mid-line of the spine until the articular capsule was identified. In cases of discectomy, routine procedures were used to free the neuronal elements. Screws were then placed in the transverse facet plane, the stabiliser cord was tunnelled, always beginning at the lowest level, and the spacer cylinder, whose length had been previously measured, was then placed (Figures 4 and 5).

In general, and unless a specific distraction was required, average distraction was 2-3 mm on both sides, beginning with the problem side. The side contralateral to the problem was measured after the system was placed in the side of the lesion because the distance could have varied. The stabiliser cord was attached by press screws which are placed on the head of the

transpedicle screw and the system is set to a pre-established tension of 300 N with a specific tension clamp. (Figures 6 and 7).

In cases where approaching the spinal canal was not required, a transmuscular paravertebral approach was performed to locate the transverse process and implant the system from there. This was accomplished with the aid of specific, novel instruments that render the technique more comfortable and less invasive. The consequential advantages of the technique are time-saving, reduction of surgical wounds and, above all, less postoperative pain and preservation of muscular function.

Clinical data

The pathology that was treated was determined by using the G. Dubois classification of degenerative diseases (Chart 1), which he based on the so-called degenerative cascade of Kirkaldy-Willis, from 1978. G. Dubois, inspired by Husson, began to implement this system in phases 3 to 6 of that classification, which correspond to disc degeneration, canal stenosis and instability[10]. The most frequently treated pathology was degenerative disc disease. (Table 1)

Chart I
STAGES OF DESTABILISATION

- I. Spondyloarthrosis + primary discopathy
- II. Disc prolapse + I
- III. Hypomobile discopathy + I
- IV. Functional instability + III
- V. Monosegmental stenosis + IV
- VI. Multisegmental stenosis + IV
- VII. Structural deformities

Table I
Pathologies that underwent intervention

Primary disc hernia	27 cases
Degenerative discopathy	54 cases
Canal stenosis	13 cases

The clinical picture always corresponded to problem lesions. Sciatic nerve condition, lumbalgia, functional alterations, loss of walking capacity and pseudoclaudication were the traditional clinical conditions presented by patients, as well as neurological deficits, especially at the sensory level and, in certain cases, at the motor level due to spinal lesion. This symptomatology was primarily chronic (only 9 cases of acute evolution were treated, Table II).

Table II
Clinical condition

Lumbalgia	21 cases
Lumbo-sciatic	63 cases
Claudication	10 cases

Table III
Levels treated

L4-L5	38 cases
L5-S1	28 cases
L3-L4-L5	7 cases
L4-L5-S1	19 cases
L3-L5 D ;L4-L5 1	1 case
L2-L3 ; L5-S1	1 case

Intervention always took place at one or two levels, the most frequent of which was L4-L5, alone or in relation to adjacent lumbar spaces (Table III).

Case L3-L5 right; L4-L5 left refers to a fracture of the L4 right pedicle, which required the screw to be anchored at a higher level. Case L2-L3; L5-S1 refers to non-treatment of the intermediate space, as though these were two distinct interventions due to different problems during the same operation, with a disc hernia at L5-S1 and disc collapse with grade 1 listhesis and compression of the spinal sac at L2-L3. This technique was considered as an alternative to placing the Dynesys system in the lower space and a rigid transpendicular fixation in the upper space, given that articular function recovery was observed during the operation.

Results

In general terms, we observed a remarkable improvement of patient symptoms in the 94 cases treated with this method. Sciatic nerve symptoms disappeared in 96.8% of cases, absence of lumbar pain was 70% and the reduction of symptoms was sufficient to allow most patients to resume normal daily activity; preoperative Oswestry test results of 56.4% were 21.4% in postoperative testing (Table IV).

Table IV
Results

Lumbalgia	21 cases:	15 asymptomatic, 5 improvements, 1 unchanged
Sciatica	63 cases:	52 asymptomatic, 9 improvements, 1 unchanged, 1 worse
Claudication	10 cases:	6 improvements, 3 unchanged, 1 worse

Recovery permitting return to work occurred in 76 cases or 82% of patients. We can see that return to work became more difficult, depending on the demands of the activity involved (Table V). We understood Category I activities to be activities such as construction, driving heavy loads, loading and unloading, elite-class athletics, etc. Medium range activities included domestic activities, care work, etc., requiring movement but not the need to carry loads and in the sedentary group are included desk jobs, civil servant jobs, and so on.

As regards operating time, we observed a significant reduction in this technique when compared with traditionally implemented arthrodesis, although not being able to compare it with microsurgical techniques. Blood loss was also reduced as well as in-bed time, hospital stay and postoperative recovery times (Table VI).

Radiological results showed articular realignment and vertebral realignment in cases of lateral claudication by means of small distractions and small reductions in disc hernias allowing the preservation of disc structure in cases of non-extruded protrusions (Figures 8 and 9).

In the postoperative NMR imaging controls, from 8-9 months of follow-up, we observed changes in signs of oedema

Table V

Category I sedentary	20 cases: returned 19
Category II average activity	30 cases: returned 27
Caterory III heavy	44 cases: returned 30

Figures 8 and 9

vertebral plates (Modic I) in 6 cases and in 9 of the 20 cases with the longest follow-up periods, we observed signs of disc rehydration, following the parameters of the study by Specchia (Figures 10, 11, 12 and 13).

In cases where the spine was compromised by disc extrusion, we performed discectomy first and then implanted the Dynesys system, although in certain cases where access to the space was difficult due to vertebral collapse or the surgical position, it was decided to implant first in order to enlarge the space and make the disc approach easier (Figures 14 and 15).

Complications

Although complications were infrequent, we can

Table VI
Mean times

	Arthrodesis	*Dynesys*	*Microdiscectomy*
Operating room	4 hours	2.5 hours	1 hour
Hospital stay	5 days	2-3 days	1 day
Return to work	6-8 months	1.5-2.5 months	1.5 months

Neurocirurgia
2005; 16: 499-506

Figures 10,11,12 and 13.

distinguish between those that were due to the technique and those that were not. Complications due to the technique were one case of malpositioning of screws and another of pedicle fracture, already mentioned. Complications not due to the technique were two cases of subcutaneous seroma and two subclinical infections that required removal of instrumentation material.

A high percentage of patients referred to postoperative unilateral or bilateral pain in the femoral skin region, which disappeared spontaneously in two to three days and which we attribute to the position of the patient on the operating table. This problem is reduced by placing pillows under the anterior spinal illiac region.

The appearance of pains in the sacroilliac region were relatively frequent and possibly caused by muscular detachment in this region, which sometimes required local infiltration.

Figures 14 and 15

This condition was reversible in almost all of the cases, except one where no aetiological cause was identified. Once the minimally invasive system of paravertebral approach was adopted, this condition did not reappear, which leads us to believe that muscular detachment technique was the cause.

Discussion

In 1995, dynamic neutralisation was implemented for the first time to treat a case of degenerative disc disease. Dubois et al[2] referred to this system as Dynesys (dynamic stabilisation system). In 1998 they published the first results in 50 cases and in 2000 an update of 150 cases. In these publications, the authors not only presented the technique but also showed the indications based on their own classification of degenerative lumbar pathology according to the Kirkaldy-Willis chart of degenerative diseases, excluding primary disc pathology, hypomobile discopathy and structural deformities[11,12].

In May, 2000, Stoll et el published their results, which expanded their indications to single degenerative diseases of the intervertebral disc with segmental instability, having presented 50 and 76 cases, respectively, gathered from multicentre studies[21].

In July 2003, Schnake et al presented their experience in degenerative diseases with spinal stenosis and spondylolisthesis with a 2-year follow-up[20].

The results of our series of patients are statistically comparable to the results of other authors who indicate the use of Dynesys system in patients with degenerative disc disease. However, our indications include monosegmental disc protrusion, in which we implanted the system without approaching the disc, in an attempt to realign the facets. A comparative criterion can not be established in single-disc pathology, since arthrodesis had never been performed previously in these cases. However, the results with Dynesys were good. On the other hand, we consider that the decision to use the dynamic neutralisation system in monosegmental structural deformities is highly useful in younger patients, as they preserve adequate functionality of articular structures.

The primary comparative advantage of instrumental fixation lies precisely in the fundamental concept of preservation of the mobile elements versus the concepts underlying the use of arthrodesis.

In summary, our results overlap those of other statistics regarding the use of this technique and we consider them to be an improvement on arthrodesis treatments for the same pathology. In addition, they represent an increase in the indications for degenerative disc pathology. We consider these results to be excellent based on clinical follow-up criteria (Oswestry test), which provided a change in overall results from 56.8% to 21.4%[3,4,6]. Radiological results after long-term follow-up showed disc rehydration and attenuation in Modic findings.

Conclusions

1. The Dynesys system is a new concept for the treatment of degenerative lumbar disc disease, based on maintaining articular function versus movement restriction in traditional arthrodesis.

2. Placement is very feasible in technical terms, with significant reduction of time in the operating room and mean hospital bed and hospital stay times are improved.

3. NMR imaging is the exploration technique of choice for diagnosis and follow-up of patients treated with Dynesys system, supported by dynamic radiological studies.

4. An increase in the number of indications for which the system can be used has been determined. In monosegmental structural deformities on the one hand, and in simple non-extruded disc pathology on the other, where the disc is not approached.

5. The technique allows a second operative period in the event of failure (arthrodesis), although in our series none was needed.

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