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Functional Outcomes after Stabilization with Dynesys in Patients with Spinal Degenerative Diseases

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Abstract

Objective: To know the impact of the Dynesys system on the functional outcomes in patients with spinal degenerative diseases.

Summary of background data: Dynesys system has been proposed as an alternative to vertebral fusion for several spinal degenerative diseases. The fact that it has been used in people with different diagnosis criteria using different tools to measure clinical outcomes makes very difficult unifying the results available nowadays.

Methods: The data base of Medlars Online International Literature (MEDLINE) via PubMed©, EMBASE©, and the Cochrane Library Plus were reviewed in search of all the studies published until November 2012 in which an operation with Dynesys in patients with spinal degenerative diseases and an evaluation of the results by an analysis of functional outcomes had taken place. No limits were used to article type, date of publication or language.

Results: A total of 134 articles were found, 26 of which fulfilled the inclusion criteria after being assessed by two reviewers. All of them were case series, except for a multicenter randomized clinical trial (RCT) and a prospective case-control study. The selected articles made a total of 1507 cases. The most frequent diagnosis were lumbar spinal canal stenosis (LSCS), degenerative disc disease (DDD), degenerative spondylolisthesis (DS) and lumbar degenerative scoliosis (LDS). In cases of lumbar spinal canal stenosis Dynesys was associated to surgical decompression. Several tools to measure the functional disability and general health status were found. Oswestry Disability Index (ODI), the ODI Korean version (K-Odi), Prolo, Sf-36, Sf-12, Roland-Morris disability questionnaire (RMDQ), and the pain Visual Analogue Scale (VAS) were the most used. They showed positive results in all cases series reviewed. In most studies the ODI decreased about 25% (e.g. from a score of 85% to 60%). Better results when dynamic fusion was combined with nerve root decompression were found. Functional outcomes and leg pain scores with Dynesys were statistically non-inferior to posterolateral spinal fusion using autogenous bone. When Dynesys and decompression was compared with posterior interbody lumbar fixation (PLIF) and decompression, differences in ODI and VAS were not statistically significant.

Conclusions: In patients with spinal degenerative diseases due to degenerative disc disorders, spinal canal stenosis and degenerative spondylolisthesis, surgery with Dynesys and decompression improves functional outcomes, decreases disability, and reduces back and leg pain. More studies are needed to conclude that dynamic stabilization is better than posterolateral and posterior interbody lumbar fusion. Studies comparing Dynesys with decompression against decompression alone should be done in order to isolate the effect of the dynamic stabilization.

Keywords: Functional outcomes; Back and leg pain; Disability; Spinal degenerative diseases; Dynesys

Introduction

Spinal fusion is a widely accepted treatment to degenerative spinal diseases [1]. Nevertheless this technique has some complications such as screw loosening, pain in the donor area if iliac bone graft is used and adjacent segment disease. In many cases these complications are a reason of revision surgery [2]. To avoid some of these unwanted effects, dynamic stabilization systems have been developed [3]. The pedicular dynamic stabilization system Dynesys (Figure 1) (Zimmer Inc., Indiana, USA) was presented by the Dr Gilles Dubois [4,5]. It was introduced in the clinical practice in Europe in the year 2000 and it was approved in the USA in 2009 to provide spinal alignment and stabilization in patients with radiculopathy and degenerative spondylolisthesis or retrolisthesis (up to Grade I), spinal stenosis or other stenosing lesion [6]. The system replaces rigid rods with pedicle screws made of Ti-Al-Nb joined by polyethylene terephthalate cord (Sulene-PET) that runs in the center cylindrical spacer made of a polycarbonate urethane (Sulene-PCU) unloading the facet joints and allowing some movement in the bridged segment [7,8]. One of the main ways to evaluate this technique is to measure the functional, disability, and pain outcomes.

Putzier et al. [9] investigated the variation of the Oswestry Disability Index (ODI) in patients with degenerative disc disease (DDD). Di Silvestre et al. [10] analyzed the Roland Morris Disability Questionnaire (RMDQ) in patients with degenerative lumbar scoliosis (DLS), and Schaeren et al. [3] studied the change in the Prolo Functional and Economic Status (PFS) (PES) in cases of spinal canal stenosis (SCS) and degenerative spondylolisthesis (DS).

Due to the great variety of tools to measure the functional

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outcomes and to the different diagnosis coexisting in spinal degenerative disorders, it is difficult to unify the conclusions of the articles available nowadays. Therefore the objectives of this study were: to know the impact of the Dynesys system on functional results in patients with spinal degenerative diseases, and to know the diagnosis and sociodemographic data of the population who underwent this technique.

Methods

Study design

Systematic review.

Literature search and selection of studies

All the data used was on the following Internet scientific data bases:

- Medlars Online International Literature (MEDLINE), via PubMed©
- EMBASE©
- The Cochrane Library Plus

Due to the fact that there is not Medical Subject Heading (MeSH) for Dynesys, therefore the following terms were used: "dynamic neutralization system", "dynesis" and "dynesys" combined by boolean operator "OR" forming the searching equation "dynamic neutralization system" [Title/Abstract] OR "dynesis" [Title/Abstract] OR "dynesys" [Title/Abstract]. The terms were combined with the highly sensitive search strategy to identify randomized controlled trials (RCTs) developed by the Cochrane Collaboration [11]. The searching equation was used in the MEDLINE data base through Pubmed and afterwards it was adapted to the other data bases.

No limits were used for article type, year of publication or language. The date of the last search was November 2012. The selection of the articles was made in relation to the following inclusion criteria:

1. Articles about surgery with Dynesys in alive humans beings older than 18 years.
2. Studies that assess the result of surgery with Dynesys by some functional or feeling of pain tools.
3. Any type of scientific study design, excluding narrative reviews, opinion articles and conference abstracts.

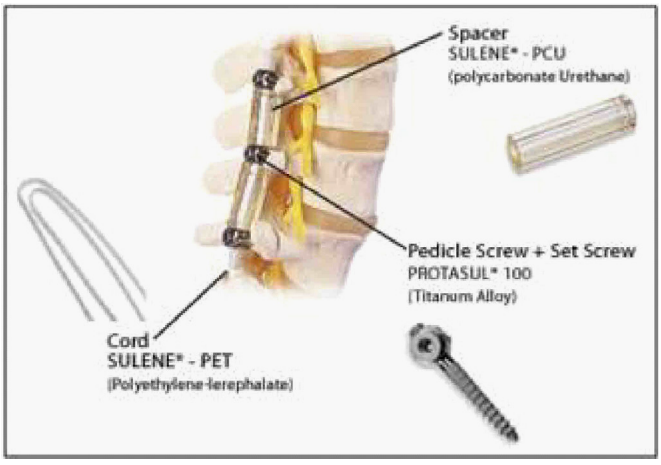

Figure 1: Dynesys Dynamic Stabilization System®.

4. Spinal degenerative diseases, excluding tumors, infections and traumatic injuries.

All those patients who had received a Dynesys together with another implant that may confuse the results were excluded.

Hand searching

In addition, as a secondary search, and to reduce the possible publication bias, the bibliographic list of the selected articles was examined to identify the studies which were not detected in the electronic review.

Study selection

The documents were assessed by two reviewers (M. S-T and D. F-S). To justify the choice of them, a grade of agreement was established by an index kappa ≥ 0.60 [1]. The possible disagreement was solved by a third author (C. W-B.).

Quality assessment of the studies

Although it was planned in the design phase, it was impossible to apply tools to evaluate their quality (like the Jadad or the Newcastle-Ottawa score) [12-15] because the majority of studies included in the review were case series with no control group.

Data extraction

The following data were extracted from the studies: (1) study design; (2) number of participants, gender, age, (3) diagnosis characteristics; (4) intervention; (5) number of bridged levels; (6) characteristics of the outcomes: outcome measures, instruments, and scores; (7) follow up.

Results

Literature search and study characteristics

A total of 134 articles were identified: 123 from electronic data bases 71 in Medline, 60 in Embase and 2 in the Cochrane Library), and one study from the bibliographic references. From the 124 articles, 57 were excluded because they were redundant, 54 did not fulfill the inclusion criteria, two articles [16,17] published partial results of a multicenter clinical trial, 26 studies were therefore selected.

The agreement by the reviewers through the Kappa index was of 1. The Price index [18] which gives the percentage of articles with age <5 year, was of 73% (n=19).

The 69% (n=18) of the articles were of European origin (Table I).

In all the studies, the design was case series, except for one multicenter randomized clinical trial (RCT) and one case- control [19,20]. They compared Dynesys and decompression against posterolateral and posterior lumbar interbody fusion respectively.

Sociodemographic data

The selected articles (Table 1) studied a heterogeneous number of subjects including sample sizes from n=10 to n=367 for a total of 1507 cases [19,21]. The distribution by sex was stated in all documents, except in one [22]. The sex percentage was of 52% of women. This distribution was not uniform in all the articles, 7 of them showed a sex distribution of 2:1 for the female sex [1,3,10,23-26].

The age of the subjects was given by their mean age, being older than 50 years in 73% (n=19) of the studies included. Some studies also mentioned the age range of the participants. In those cases, that range comprised ages between 23 and 87 years [3,27]. Only one document did not give any data about this variable [22].

Author	Study Design	Population	Diagnosis criteria	Treatment	Instrumented levels	Follow up	Results
Hoppe [29]	Case series	N:39 Gender M/W:9/30 Age:49	- Degenerative lumbar spondylolisthesis - Lumbar spinal stenosis	- Dynesys + decompression	1 level 39	86 months	Back pain improved in 89 % and leg pain improved in 86% of patients compared to preoperative status. At last follow up: -ODI mean 17.518.8 % -SF-36 functional status 45±10.3 -EQ-5D score 0.8± 0.25
Sapkas et al. [36]	Case series	N:114 Gender M/W:66/48 Age:49	- Degenerative disk disease - Lumbar spinal instability - Lumbar spinal stenosis	-Dynesys + decompression	1 level 49 2 level 40 3 level 18	81 months	-ODI improved from 57 % to 22% -Roland Morris Dissability Questionnaire improved from 52% to 35%
Fay et al. [33]	Case series	N:38 Gender M/W:18/20 Age:63.7 ± 8.5	-Lumbar spinal stenosis with or without spondylolisthesis	-Dynesys + decompression	1 level 16 2 level 22	41 montths	-VAS improved from 6.0 to 1.9 (p<0.001) -ODI improved fron 50.6 to 27.3(p<0.001)
Yu et al. [20]	Case-Control	N: 53 Gender M/W: G1: 10/17 G2: 11/18 Age: G1: 52.2 ± 8.3 G2: 55.5 ± 6.9	-Lumbar spinal stenosis with or without spondylolisthesis - Lumbar spinal stenosis with or without grade I degenerative spondylolisthesis L4L5, - severe instability (dynamic view > 15°, translation > 4 mm)	G1:27/53 Dynesys +decompression G2: 26/53 PLIF+ decompression	1level	36 months	-ODI: G1 improved 32.74 % P=0.254 G2 improved 29.31 % -VAS back pain: G1 improved 4.3 points P<0.801 G2 improved 4.15 points
Yu et al. [32]	Case series	N: 60 Gender M/W: G1: 15/20 G2: 13/12 Age: G1: 60.8±4.8 G2:63.1±4.4	-Lumbar spinal stenosis with or without sponsylolistesis grade 1. -Degenerative disc disease	G1: Dynesys + decompression G2: PLIF + decompression	3 levels G1: 35 G2:25	36 months	The degree ofimprovements in ODI and VAS back pain were significantly greater in the Dynesys group than in the PLIF group. -ODI: G1 improved 50.70 % P<0.006 G2 improved 41.11 % -VAS back pain: G1 improved 56.39 % P<0.04 G2 improved 36.92 %
Hu [31]	Case series	N:32 Gender M/W:19/13 Age: 58 (43-78)	-DDD -Lumbar spinal stenosis - Degenerative lumbar isthmic spondylolisthesis	- Dynesys + Decompression (laminectomy)	1 level 23 2 levels 9	16.4 months	-ODI ODI improved from preoperative 69% ± 12.6% to postoperative 28% ± 15.7% (P < 0.001). - VAS leg pain, root and low back pain was significantly improved
Kim [23]	Case series	N:21 Gender M/W:6/15 Age: 61.3±6.5	-Degenerative spinal stenosis with neurologic intermittent claudication -Spondylolisthesis grade I and/or dynamic instability	G1: 7/21 Dynesys + Single level decompression (laminectomy or laminotomy) G2: 14/21 Dynesys + Multiple level decompression (laminectomy or laminotomy)	- Lumbar levels 1 level 7 2 levels 10 3 levels 4	24 months	-K-ODI improved in both groups (p<0.05) -VAS improved in both groups (p<0.05)
Nemec [40]	Case series	N: 117 Gender M/W:52/65 Age: 62	- Degenerative lumbar spinal stenosis	G1: Posteolateal fusion + autograft + Decompression G2: Posterior fusion + autograft + Decompression G3: Dynesys + Decompression	- Lumbar levels	36 months	- ODI: improved from 53 to 37 in 3 groups. - SF-36 significant improvement in 3 groups - VAS back and leg pain no significant improvement.
Cienciala [45]	Case series	N: 102 Gender M/W:65/37 Age: 54 (M 28-72 W 41-71)	- Degenerative disc disease - Spinal canal stenosis	- Dynesys + Decompression	- Lumbar levels 1 level 61 2 levels 38 3 levels 3	36 months	- VAS improved from 7.3 to 4.7 (p<0.05) - ODI improved from 54.5 to 39.9 (p<0.05)

Ko et al. [37]	Case series	N: 82 71 completed the trail. Gender M/W: 32/39 Age: 59.2 ± 11.65 (23–80).	- Lumbar spinal stenosis and/or - Grade 1 degenerative spondylolisthesis	- Dynesys + Decompression (laminectomy) G1: loose screws G2: solid screws	- Lumbar levels 1 level 29/71 2 levels 42/71	16.6 months	- VAS, no significant differences between the loose screw group and the solid screw group - ODI, no significant differences between the loose screw group and the solid screw group.
Kocak [22]	Case series	N:19 Gender M/W: No reported Age: No reported	- Degenerative disc disease - Degenerative spondylolisthesis with spinal canal stenosis - Degenretaive scoliosis - Symptomatic spondylarthropathy	-Dynesys + Decompression G1: 7/19 Conventional surgery G2: 5/19 CT navigated surgery G3: 7/19 Xrays navigated surgery.	- Lumbar levels	12 months	- ODI, improvement was observed in all patients (no statiscal analisis) - SF-36, improvement was observed in all patients (no statiscal analisis)
Di Silvestre [10]	Case series	N: 29 Gender M/W: 11/20 Age: 68.5 (61–78)	- Degenerative lumbar scoliosis with: -Associated Spinal canal stenosis - Associated Spondylolisthesis	- Dynesys - Dynesys + Decompression (laminectomy)	- Lumbar-Thoracic level T12-L1 3 level 18 4 levels 5 5 levels 2 6 levels 4	54 months	- ODI: Improvement 51.6%(p<0.01) - Roland Morris: improvement 58.2% (p<0.01) - VAS leg pain improvement form 6.7 to 4.1 = 51.7% (p<0.02), - VAS back pain improvement from 6.6 to 3.3= 57.8% (p<0.01).
FDA [19]	Multi-center, prospective, randomized, non-blinded trial.	N: 367 Gender M/W: G1: male 48% G2: male 41 % Age: G1: 56.9 ± 11.7 G2: 58.0 ± 11.5	-Degenerative spondylolisthesis or retrolisthesis (up to Grade I) - Spinal stenosis or other stenosing lesion.	G1:253 Dynesys +Decompression G2: 114 Posterior lateral spinal fusion (PLF) with Silhouette + Autogenous bone + Decompression	G1: 1level 137 2 levels 116 G2: 1level 69 2 levels 45	24 months	VAS Leg Pain Success G1: 87% G2: 73% p=0.01 ODI Success G1: 76% G2: 70% p=0.34
Vaga et al. [21]	Case series	N:10 Gender M/W: 4/6 Age:43.5 ± 9	- Lumbar discopathy - Segmental instability with or without narrow spinal canal.	- Dynesys + Decompression (flavectomy, laminotomy ,foraminotomy)	- Lumbar levels 1 level 3 2 levels 6 3 levels 1	6 months	- VAS improved from 7.6 to 3.1 (p =0.0014) - Oswestry from 54% to 25% (p =0.00023) - Prolo FS+ ES evaluation results showed an improvement in 9/10 patients (p= 0.06).
Lee [24]	Case series	N: 20 19 completed the trail. Gender M/W: 7/13 Age: 61±6.98 (46-70)	- Spinal stenosis with degenerative spondylolisthesis - Degenerative spinal stenosis - Adjacent segmental disease after fusion - Spinal stenosis with degenerative scoliosis	Dynesys + Decompression (central and foraminal)	- Lumbar levels 1 level 9 2 levels 9 3 levels 1	27.25 months	- VAS decreased from 8.55 to 2.20 (p<0.001), - K- ODI improved from 79.58% to 22.17% (p<0.001).
Ricart and Serwier [25]	Case series	N: 25 Gender M/W: 6/19 Age: 71(53—83).	- Degenerative lumbar spondylolysis associated with degenerative spinal canal stenosis	-Dynesys + Decompression (laminectomy)	- Lumbar levels 1 level 12/25 2 levels 13/25	34 months	- Beaujon functional score -Very good results in 72% of patients. -Good results in 28% of patients.
Schaeren [3]	Case series	N: 26 19 completed the trial. Gender M/W: 8/18 Age:71(47–87)	- Lumbar spinal stenosis associated with degenerative spondylolisthesis grade I and II.	-Dynesys + Stabilization in situ + Decompression (laminotomy)	-Lumbar levels 1 level 26/26	48 months	- VAS Scale decreased from 8 to 2.5 (p<0.001). - Prolo Economic Scale. 8/19 patients (42%) were more active than before the onset of their symptoms.
Würgler-Hauri [6]	Case series	N: 38 37 completed the trial. Gender M/W: 15/22 Age: 58	- Acquired lumbar stenosis, - Segmental instability - Degenerative disc disease	- Dynesys + Decompression (laminotomy or laminectomy + microsurgical radicular decompression)	- Lumbar levels 1 level 11 2 levels 17 3 levels 9 4 levels 1	12 months	- VAS Leg improved from 8.4 to 3.1 - VAS back improved from 6.7 to 4 - Prolo ES 21.6 % had a result of 5 - Prolo FS 10.8% had a result of 5. - Stauffer Coventry Scale results: 70% excellent or good outcome 29.7 % fair or poor outcome

Bothmann [28]	Case series	N:54 40 completed the trial Gender M/W: 28/26 Age:56 (28-84)	- Stenosis of the spinal canal - Degenerative disc disease - Spondylolisthesis Type I Meyerding - SegmentaInstability - Recurrent herniation of the lumbar disc	- Dynesys + Decompression - Dynesys + Plif	- Lumbar levels 1 level 32 2 level 20 3 level 2	12 months	- Hannover Activities of Daily Living improved form 33.8 to57.5 - VAS back improved from 8.3 to 4.9 points(p<0.001). - VAS Leg pain improved from 7.2 to 2.9 points.(p<0.001) - Clinical outcomes improvement was best when dynamic fusion was combined with nerve root decompression (p<0.05)
Sapkas et al. [34]	Case series	N: 68 Gender M/W: 42/26 Age: 42.8	- Degenerative diskopathy or disk herniation - Lumbar spine stenosis	- Dynesys + Decompression (Bilateral laminectomy or foraminotomy)	- Lumbar levels 1 level 30 2 levels 32 3 levels 6	36.2 months	- ODI :improved from 55.4% to 22.9% - Roland-Morris Disability Questionnaire :improved from 52% to 35%
Schnake [26]	Case series	N: 26 24 completed the trial. Gender M/W: 8/18 Age: 71 (47–87)	- Lumbar spinal stenosis and degenerative spondylolisthesis	-Dynesys + Stabilization in situ + Decompression (laminotomy)	- Lumbar levels 1 Level 26/26	24 months	-VAS decreased significantly from 8 to 2.3 (p=0.0001). - Prolo ES 62.5% had a result of 5.
Bordes-Monmeneu [35]	Case series	N: 94 patients Gender M/W: 62/32 Age: 46.4 (26-68)	- Disc herniation - Degenerative disc disease - Lumbar channel stenosis	Dynesys + Decompression Dynesys + Decompression + Discectomy	- Lumbar levels 1level 66/94 2 levels 27/94 3 levels 1/94	24 months	- ODI improved from 56,8%/ to 21,4% . - Improvement of radiculopathic symptoms 96'8% (61/63). - Return to work was 82%.
Putzier [9]	Case series	N: 84 patient Gender M/W: G1:22/13 G2: 29/20 Age: G1: 39 (23–58)) G2: 36 (21–59)	- Disc prolapase - Degenerative disc disease (MODIC I) on MRI	G1: 35/84 Dynesys + nucleotomy G2: 49/84 Nucleotomy alone	- Lumbar levels 1 level 84/84	34 months	- ODI significant increase in nucleotomy alone group - VAS significant increase in nucleotomy alone group.
Grob [1]	Case series	N: 50 31 completed the trial. Gender M/W: 11/20 Age: 50±13	- Degenerative disc disease with associated instability.	G1:18/31 Dynesys G2:13/31 Dynesys + Decompression	- Lumbar levels 1level 33% 11 2 levels 52% 15 3 levels 13% 4 4 levels 3% 1	24 months	Answer the question Quality of life after operation? (p= 0.10) G1: Better 35 % G2: Better 69 % VAS back improved form 7 to 4.7 67% (G1+G2) VAS leg improved from 6.6 to 3.8 64% (G1+G2)
Putzier [27]	Case series	N: 70 Gender: M/W: 41/29 Age: 47(23-72)	- Degenerative disc disease - Disc herniation - Osteochondrosis and facet joint osteoarthritis. - Segment degeneration - Degenerative spondylolisthesis	G1(Disc herniation) :35/70 Dynesys + Nucleotomy G2(osteochondrosis and facet joint osteoarthritis.) : 22/70 Dynesys G3(degenerative spondylolisthesis):13/70 Dynesys	- Lumbar levels 1level 70/70	33 months	Group 1: - ODI and VAS improved significantly Group 2: - ODI and VAS improved significantly Group 3: - ODI and VAS no significant changes.
Stoll [4]	Prospective, multi-center	N: 83 73 completed the trail. Gender M/W: 34/49 Age: 58.2 (26.8–85.3)	- Spinal stenosis - Unstable segmental conditions - Degenerative disc disease - Disc herniation	- Dynesys + Decompression - Dynesys + Nucleotomy	- Lumbar levels 1level 55/83 2 levels 17/83 3 levels 8/83 4 levels 3/83	38.1 months	- VAS back improved form 7.4 pre to 3.1 (p<0.01) - VAS leg improved from 6.9 to 2.4.(p<0.01) - ODI improved from 55.4% to 22.9%. (p<0.01). - Prolo functional and economic status improved significantly - Total incapacity 47.9 % preoperative 2.7% follow up

Table 1: Articles included.

Diagnosis criteria

A great variability of spinal degenerative diseases was found as it is shown on table 1. The most frequent were: degenerative lumbar spinal canal stenosis (LSCS) (also referred to as "degenerative lumbar spinal stenosis", "narrow spinal canal", and "acquired lumbar stenosis") in 92% of the studies (n=24); degenerative disc disease (DDD) (also referred to as "disc degeneration", "disc prolapse" or "disc heniation") in 54% (n=14) of the works (Figure 2), and degenerative lumbar spondylolisthesis (DS) grade I or II in 54% (n=14) of the documents There were 3 studies (14%) which included patients with degenerative lumbar scoliosis [10,22,24].

Surgical technique

The Dynesys was applied without any other additional maneuver in those cases that there was not any data of LSCS, in those cases that this condition was present; a decompression was added during surgery through laminotomy, laminectomy, foraminotomy or microsurgical radicular decompression [28]. The implant was placed through either a midline or paraspinal Witlse approach depending on the need. If

a nucleotomy was necessary it was done after dura and nerve root manipulation [9]. The pedicle screws were positioned under image intensifier control without injuring the facet joints [1]. One study analyzed the differences between using computerized tomography (CT) navigated surgery, X rays navigated surgery and the conventional method according to Magerl to place the pedicular screws of the Dynesys system [22]. When Dynesys and decompression was compared to posterolateral fusion, the control group received Silhouette Spinal Fixation System without intersomatic vertebral cages [19]. When it was compared to PLIF, a Synthes Click'X spinal implant was added [20].

Bridged segments

The segment operated was the lumbo-sacral from L1 to S1 in all the studies, except for one which used Dynesys at thoracic level [10].

Bridged segments went from 1 to 3 lumbar levels; except in 4 articles [4,6,10,27] which included ≥ 4 levels, and only one study bridged 6 levels, from T12 to S1 [10].

The follow up ranged from 6 to 86 months [21,29].

Patient related outcomes by tools

The ODI [27] was the most used tool in 76% (n=20) of the articles reviewed. It decreased in all of them, being statistically significant in 10 studies [4,9,10,20,21,23,24,27,30-33]. It comprises 0-20% Minimal disability, 20-40% Moderate disability, 40-60% Severe disability, 60-80% Crippled, 80-100% bed-bound or exaggerating their symptoms. The greatest decrease registered was in patients with SCS and DS [24] going from a score of 79.58% to 22.17% (p<0.001). In most studies that

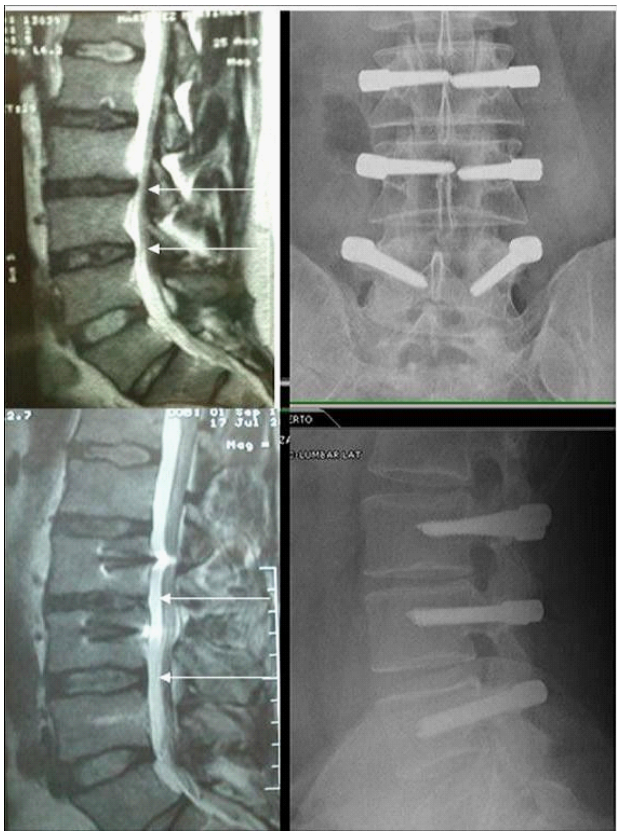

Figure 2: 37 year old man with degenerative disc disease L2-L3-L4 (white arrows), treated with Dynesys without decompression. See the MRI before (above) and after (below) reabsorbing small disc bulgings.

difference was smaller, decreasing about 25% (e.g. from a score of 85% to 60%) [4,20,21,33-36].

There were no significant differences in the ODI between patients with radiological signs of Dynesys screw loosening (ODI score 28%) and those who did not (ODI score 24.6%) [37].

When the Dynesys system was compared to posterolateral fusion, the authors considered that the intervention had been a success if there was a reduction of 15 points in the scale from 0 to 100 between the pre and postsurgery evaluation [19]. That happened in 76% of the cases in the Dynesys group, compared to 70% of the cases in the solid fusion group, being this non significant difference (p=0.34) at 24-month follow-up.

When Dynesys and decompression was compared with posterior interbody lumbar fixation (PLIF) and decompression, differences in ODI were not statistically significant, with a decrease of 32.74 % and 29.31% respectively from a total score 0-100% [20].

The assessment with Prolo [38] scale was used in 28% (n=6) of the documents. The Prolo scale scores from 1 to 5 the functional status (PFS) and the economic status of the patient (PES), being 5 the best possible result. Stoll et al. found that after Dynesys there was a decrease, from 47.9% to 2.7%, of the patients with a score 1 (total incapacity) in the PFS [4].

The best Prolo postoperative score (PES 5 working with no restrictions) after dynamic stabilization varied between the different studies. Schnake et al. [26] communicated this result in 65% of the patients; Würgler-Hauri et al. [6] noticed this result in 21.6% of the sample studied, while Shcaeren et al. [3] had this punctuation in 42% of the cases. In the comparative study [19] between the Dynesys vs. posterolateral fusion the addition PFS+PES was used, having a scale from 0 to 10, the difference was not significant between the two groups (p=0.24).

The questionnaire SF-36 [39] was used in 11% (n=3) of the studies [22,29,40]. The SF-36 consists of eight scaled scores, and two meta-scores, the Physical Component Summary (PCS) and the Mental Component Summary (MCS). In patients with SCS the SF-36 questionnaire showed a significant improvement in both categories after surgery with dynesys and decompression [40].

No differences in the SF-36 were observed between using CT navigated surgery; X rays navigated surgery, and conventional surgery according to Magerl to place the pedicular screws [37].

The questionnaire SF-12 was used in one study [19]. This tool is a multipurpose short-form of the SF-36, in which the Physical Component Summary (PCS) and Mental Component Summary (MCS) were designed to have a mean score of 50 and a standard deviation of 10 in a representative sample of the US population [41]. Scores greater than 50 represent that the patient is above average health status. In this study Dynesys was compared to posterolateral fusion. First, when the PCS was analyzed, an average result of 41.1 points in the Dynesys group and 37.4 points in the fusion group was observed (p=0.03). On the other side, when analyzing the MCS, the result was of 51 and 50 points respectively (p=0.53). This meant that in the Dynesys group there was a better health status in the PCS.

The Roland Morris Disability Questionnaire (RMDQ) showed an improvement in the 3 studies in which it was used. RMDQ does not provide descriptions of the varying degrees of disability. Clinical improvements over time can be graded based on the analysis of serial questionnaire scores [42]. Di Silvestre et al. [10] informed that in

patients with degenerative lumbar scoliosis, the mean preoperative RMDQ score was 12.5, and the mean postoperative score was 6.1 for a 58.2% mean improvement (p=0.01). Sapkas et al. [34] in patients with degenerative discopathy or disc herniation and SCS found a 32% mean improvement, without giving any data about the statistical signification.

The visual analogue scale (VAS) considers the feeling of pain from 0 to 10 [43]. The 20 studies which used it registered positive results (table 1). Some of the studies specified the VAS score for back and legs [1,4,6,10,28] while the rest only assessed the general pain. The 8 studies which analyzed the VAS for back and legs obtained different results. In one study [4] the decrease was similar, in another study [10] that decrease was greater in the back, and in the last 6 articles [1,6,20,28,32,33] there was a greater decrease in legs than in the back. The greatest decrease registered [24] went from 8.5 cm to 2.20 cm (6.3 cm) in patients with DS grade I and II with data of the SCS (p<0.001). Putzier et al. [9] proved that there was a higher decrease in the VAS when the nucleotomy was in addition to Dynesys in comparison to nucleotomy alone.

Dynesys vs. fusion:

In the RCT included in this review [19], a decrease of 2 cm of the VAS leg pain in relation to its pre surgery score was considered as a success. This result was found in 87% of the patients treated with Dynesys in relation to 73% of those treated with posterolateral fusion, being that difference statistically significant (p=0.01).

In the other study [20] that compared Dynesys and decompression against PLIF and decompression, no differences in leg pain improvement were founded.

Dynesys vs. Dynesys and decompression:

Bothmann et al. [28] found VAS for back and leg pain was best when dynamic fusion was combined with nerve root decompression (p<0.05). Grob et al. [1] reported an overall trend for poorer results in the Dynesys goup compared with the Dynesys and decompression group (p>0.05).

Discussion

In the European Union, Dynesys is not considered a drug but a sanitary product. Therefore a clinical trial is not an essential requirement to approve it [44]. This fact may justify that any of the 16 documents published in the European Union since the year 2002 uses this type of design. The only clinical trial with Dynesys made was developed in the USA in order to be approved by the Food and Drug Administration (FDA) in 2009. However, this is an unpublished study, which was evaluated by the FDA as part of an application to obtain the approval for the stand-alone use of Dynesys, eventually rejected. The panel meeting highlighted several methodological weaknesses of the study, mainly in missing data, potential conflicts of interest, and extent of the prerandomization blinding [19].

Spinal degenerative diseases include a wide range of diseases. In most of the studies [1,3,4,6,9,10,19-28,34-37,45] the LSCS diagnosis was associated to DS and/ or DDD. This is a common condition of the aging spine and makes these heterogeneous patient populations difficult to compare [46,47]. The presence of SCS required a decompression maneuver associated to Dynesys. That is why it was impossible to isolate the effect of the Dynesys intervention alone. Notably, in the present study, when the patients who underwent decompression in addition to Dynesys were compared with those who only received Dynesys, the results were generally more favourable for the former group. In the face of such potential confounding factors, caution must be exercised in attributing the results to the Dynesys per se.

In the case of patients with degenerative spondylolisthesis, some authors specified the grade according to the Meyerding classification [3,6,26,28,30,41] while others only mentioned the general DS diagnosis [1,4,10,25,27,34]. Grades III and IV, that is to say, spinal displacements bigger than 50%, were not specifically found; therefore we have to be prudent in those grades of displacement.

In patients with degenerative lumbar scoliosis [10,22,24] similar results about functional outcomes and pain scores were obtained in relation to the results of decompression and instrumented fusion published in the literature [48,49]. Nevertheless, the results are limited to 31 cases, being Di Silvestre et al. who had the larger sample with 29 cases [10]. An excluding criteria of patients with degenerative scoliosis >10° at the affected motion was considered in the only clinical trial reviewed [19].

In young patients (<50 years) long term outcome data are limited, in fact follow up time in this subgroup has not ever exceeded 3 years [9,19,27,34,37]. This is not the case of other rigid fusion techniques, of which consequences and complications have been thoroughly described [50-52]. Therefore, it is mandatory to keep after-market monitoring [53] and we should avoid prematurely concluding that dynamic stabilization of lumbar spine in young patients is able to stop or partially reverse degenerative disc disease [21].

Some authors [10] claim that the percentage of screw loosening (Figure 3) with the dynamic system may be lower than rigid systems, because the flexible rods allow some degree of mobility, discharging the pedicle screw [3,21]. However in the studies of Yu [20,54] comparing these two systems, obtained a similar percentage of screw loosening with the dynamic system compared with the rigid system, being 14.3% versus 20% of patients, respectively (p=0.728).

The dynamic stabilization system can be effective at several lumbar levels [9,10,23]. In relation to the available evidence in the thoracic segment, it is limited to one study which gave the experience of 4 patients [10], in opposition to what happens with the spinal fusion which has been widely studied [55,56].

The great variability of the measurement tools found to evaluate the functional outcomes makes impossible to compare the studies. Even those documents which used the same measurement tool, the way to express the result was different. There were authors who expressed improvement by the change of the mean score, while other authors showed the results in percentage of patients who improved. Some documents, assessed functional results only after surgery, without

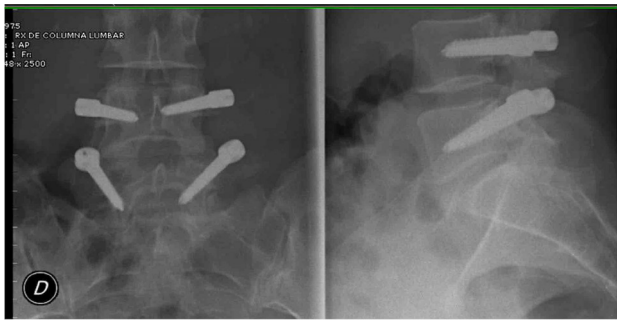

Figure 3: Right L4 screw loosening "Double halo sign" (radiolucent zone surrounded by an outer radioopaque rim of dense bone).

describing the previous condition of the patients, and therefore it was impossible to evaluate the changes.

The lumbar disc degeneration together with load transmission through the degenerated facet joints are the most important causes of low back pain [55,56]. Leg irradiated pain symptom triggers when there is a space compromise of a nervous root [57]. In that sense it was expected to find that the use of the Dynesys system, which unloads the facet joints and intradiscal pressure [58,59], implied a greater decrease of the VAS in back than in legs. Nevertheless, in the studies which compared this data, a greater decrease of the VAS leg pain was found [1,6,20,28,32,33]. This leads us to two possibilities, assuming that the different samples of the different studies were comparable. The first one is that the VAS leg decrease was due to an associated decompression that behaves as a confusing factor which interferes with the real value of the dynamic system about the improvement of the leg irradiated pain. In that sense Grob et al. [1] and Bothmann et al. [28] found better results when dynamic fusion was combined with nerve root decompression. The second possibility is that the decrease in leg pain when the decompression was not done may be due to the fact that the Dynesys system allows reabsorbing small disc bulgings that may be causing a space conflict in the exit of the nervous root, as Bordes-Monmeneu and Vaga state in their radiological studies [21,35].

The results that compare Dynesys with spinal fusion are only based on the comparison with the posterolateral and PLIF fusion technique. No document evaluated the Dynesys system in relation to other spinal fusion procedures, such as anterior lumbar interbody fusion, extreme lateral lumbar interbody fusion or transforaminal lumbar interbody fusion.

In this review we decided to include all the tools that evaluate in any way the functional capability of the patients, although some of the tools selected are considered as quality of life or general health status questionnaires or disability questionnaires by many authors [30,39].

Restrictions

Even though it would be better to limit the systematic reviews to randomized clinical trials which allow us to give advice with a high degree of evidence [60], there are areas of knowledge where it is very difficult to apply this type of designs. That is the case of this review, in which all the studies found have been included on condition that an operation with the Dynesys system and an analysis of the functional results had been done. This has led us to a review based on 95% in case series studies in which it was impossible to apply tools to evaluate their quality on the basis of allocation concealment, randomization procedure and masking [14,15].

It is evident that the population of the studies reviewed presented very diverse data in different aspects, such as number of subjects included, age, gender, or diagnosis. In spite of these restrictions, we think that this review includes all the knowledge of functional results of Dynesys available at this moment.

Conclusion

The case series reviewed suggest that surgery with Dynesys associated to surgical decompression improves function in patients with lumbar and radicular pain caused by degenerative disc disease, degenerative spondylolisthesis or lumbar degenerative scoliosis with concomitant spinal canal stenosis. More studies are needed to conclude that dynamic stabilization is better than posterolateral and posterior interbody lumbar fusion. Studies comparing Dynesys with decompression against decompression alone should be done in order to isolate the effect of the dynamic stabilization.

Conflict of Interest Statement

The authors declare that they have no conflict of interest related to the publication of this manuscript.

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