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Systematic review

Management

A systematic review to assess whether dynamic stabilisation provides any improvement in validated clinical outcome measures in adult patients with degenerative lumbar spondylolisthesis

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Abstract

Introduction

Dynamic stabilization in degenerative spondylolisthesis is a relatively new concept and has been designed to overcome the negative effects of spinal fusion, i.e. increase in spine stiffness, chronic back pain and acceleration of degenerative process at the adjacent levels.

To our knowledge and to date, this is the first systematic review presenting the results of an evaluation of the clinical effectiveness of dynamic stabilization devices in patients with degenerative lumbar spondylolisthesis as the sole diagnosis.

Materials and methods

A detailed search was conducted through several databases (up to February 2013): MEDLINE, CINAHL, AMED, British Nursing Index, SPORTDiscus, EMBASE and Journals@Ovid; an extensive handsearch, including grey literature and reference lists of the articles was conducted. The methodological assessment was performed by two reviewers using the McMaster University framework.

Results

The search identified a total of 493 titles. Ten studies were included in the final review of which only one was a randomized controlled trial. The reported validated clinical outcome measures were: Oswestry Disability Index, Short Form - 36, Visual Analogue Score for back and leg pain and Patient Satisfaction Index. Each study reported a statistically significant improvement of the outcome measures.

Conclusion

Although the results of dynamic stabilization in degenerative spondylolisthesis are encouraging, the authors cannot safely recommend the use of these devices to the general population as yet due to the moderate methodological quality of the included primary papers. The authors recommend that future research should include properly designed randomized controlled studies, preferably multi-centred, demonstrating solid methodology.

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Introduction

Description of the Condition

Degenerative lumbar spondylolisthesis is a condition which occurs when a lumbar vertebra displaces forward in relation to the vertebra situated one level below, due to degeneration of the spinal structures[1] (Figure 1). There are three main symptoms associated with degenerative spondylolisthesis: neurogenic claudication, radicular pain and low back pain.

The prevalence of degenerative lumbar spondylolisthesis increases from the fifth to the eighth decade[2]. This condition is three times more common in females than males[2] and it mainly affects the level between the fourth and the fifth lumbar vertebrae[3]. First line treatment for the degenerative lumbar spondylolisthesis is non-operative (analgesia, sacral epidural injections and physical therapy in the form of bracing, electrical stimulation, exercises or ultrasound) but surgery is indicated if conservative measures fail to offer any improvement of symptoms and quality of life is severely impaired. It is important to understand the biomechanics of degenerative lumbar spondylolisthesis because the principles of dynamic stabilization devices are to limit this abnormal motion and restore the loading pattern of the affected segment but at the same time to preserve the mobility of the adjacent level[4].

Description of the Intervention

Treatment options for degenerative lumbar spondylolisthesis are non-operative (analgesia, sacral epidural injections, bracing, electrical stimulation, exercises or ultrasound) and operative (decompression, fusion or dynamic stabilization). The main disadvantages of fusion surgery are related to an increase in spine stiffness, chronic back pain and acceleration of degenerative processes at the adjacent levels[5,6]. Dynamic stabilization systems have been designed to address the complications associated with spinal fusion and can be described as systems which improve the mobility of a spinal segment by providing stability, but also preventing fusion at the operated level[1]. The main advantages of dynamic stabilization systems are considered to be: protection of the adjacent levels, preservation of normal posture whilst the patient is sitting and protection of rotatory stress to the sacroiliac joints[8].

How the Intervention Might Work

Two classes of dynamic stabilizers have been designed:

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Table 1: Inclusion/Exclusion criteria of the searched studies.

	Inclusion Criteria	Exclusion Criteria
Population	Adult (male or female) suffering with degenerative spondylolisthesis	Any other form of spinal instability or degeneration (isthmic spondylolisthesis, degenerative disc disease, spinal stenosis alone)
Intervention	Dynamic stabilization using interspinous or pedicle screw based systems	Non-operative treatment
Outcomes	Studies reporting at least one validated clinical outcome measure: Oswestry Disability Index, Short Form Questionnaire – 36, Visual Analogue Score for Back and Leg Pain, Zurich Claudication Questionnaire or Patients Satisfaction Index	Other outcome measures (Non-validated)
Study design	Quantitative studies: Randomised Controlled Studies Non-randomised studies with/without comparative group (cohort, before and after, case series, case reports)	Qualitative studies

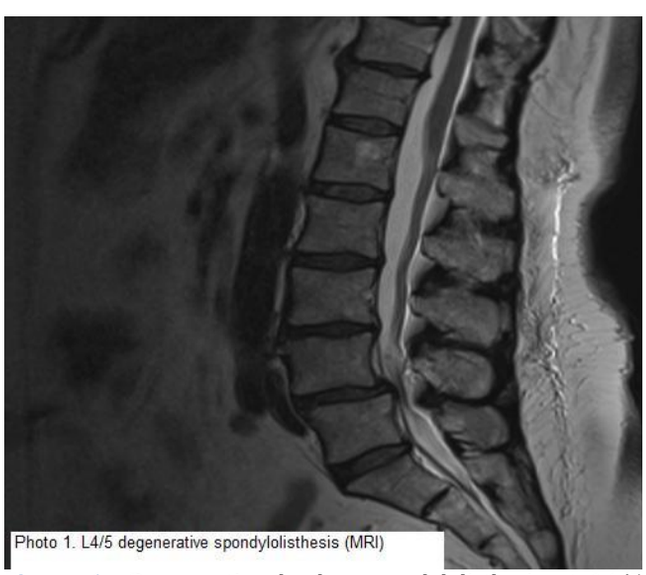

Figure 1: Degenerative lumbar spondylolisthesis at L4/5 level.

interspinous (stabilise the lumbar spine by placing the device between the spinous processes of the vertebrae) and pedicle screw based (stabilize the spine by inserting screws into the pedicles and these screws are then connected by rods/spacers/artificial ligaments on each side, (Figure 2)).

Why is it Important to Undertake this Review?

Dynamic stabilization is a relatively new concept and its use has increased over the recent years. The National Institute for Clinical Excellence in the UK conducted a review in 2005 (and updated in 2010) on 'non-rigid stabilization techniques for the treatment of back pain'[7]. A group of specialist advisors evaluated the efficacy and safety of dynamic stabilization implants. They suggested lack of long term data and the necessity of a careful patient selection. The efficacy of these implants was difficult to assess because the use of dynamic stabilization devices is usually combined with decompression of the neural structures; thus it is difficult to know to what extent the clinical improvement is attributable to the implant itself. Current literature on dynamic stabilization has reported controversial results. For example, some authors[9] reported a high failure rate of the X-Stop implant (58%) whereas others[10] reported a 63.4% clinical improvement using the same implant. Controversies were also reported on the use of Dynesys system: while clinical improvement and preservation of spine mobility was demonstrated by some authors[3,4,11], others have expressed their concerns on the efficacy of the implant[12].

To our knowledge, this is the first systematic review conducted on the clinical effectiveness of dynamic stabilization devices in patients with degenerative lumbar spondylolisthesis as a sole diagnosis.

The primary purpose of conducting this review was to assess whether dynamic stabilization provides any improvement of validated clinical outcome measures in adult patients with degenerative lumbar spondylolisthesis.

Materials and methods

Criteria for Considering Studies for This Review

The Inclusion and Exclusion criteria are summarized in Table 1.

Search Methods for Identification of Studies

Electronic Searches. A detailed search was conducted through several databases by accessing two resource centres: EBSCOhost online gateway and Ovid SP. MEDLINE,

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Table 2: Results of methodological quality assessment of the included studies. Y-Yes, N-No, UC-Unclear, *Max 3 points could be scored for this question.

		Konno and Kikuchi	Schaeren et al (2008)	Schnake et al (2006)	Kanayama et al (2005)	Hong et al (2010)	Lee SH et al (2010)	Anderson et al (2006)	Kaner et al (2010)	Lee DY et al (2010)	Lee SH et al (2012)
	Questions										
Study Purpose	Was the purpose stated clearly?	Y (1)	Y (1)	Y (1)	Y (1)	Y (1)	Y (1)	Y (1)	Y (1)	Y (1)	Y (1)
Literature	Was the relevant background literature reviewed?	Y (1)	Y (1)	Y (1)	Y (1)	Y (1)	Y (1)	Y (1)	Y (1)	Y (1)	Y (1)
Study Design	Quantitative study?*	Y (2)	Y (1)	Y (1)	Y (1)	Y (1)	Y (1)	Y (2)	Y (2)	Y (1)	Y (1)
	Was the study design appropriate for the question?	Y (1)	Y (1)	Y (1)	Y (1)	Y (1)	Y (1)	Y (1)	Y (1)	Y (1)	Y (1)
Sample	Was the sample described in detail?	Y (1)	Y (1)	Y (1)	Y (1)	Y (1)	Y (1)	Y (1)	Y (1)	Y (1)	Y (1)
	Was sample size justified?	N (0)	N (0)	N (0)	N (0)	N (0)	N (0)	N (0)	N (0)	N (0)	N (0)
	Was there ethical approval?	UC(0)	UC(0)	UC(0)	UC(0)	UC(0)	UC(0)	Y (1)	UC(0)	UC(0)	UC(0)
	Was informed consent obtained?	Y (1)	Y (1)								

CINAHL, AMED, British Nursing Index, SPORTDiscus were accessed via EBSCOhost, while EMBASE and Journals@Ovid were searched via Ovid SP. The comprehensive search was performed using the Boolean operators 'AND' and 'OR'. An "alert" system was activated within the EBSCOhost online gateway; so that any new published paper would be identified by the author and included in the review process. The Cochrane Library was also searched through Ovid SP for any existing systematic reviews or meta-analysis on the same topic.

Searching Other Resources

Reference checking was part of the search strategy in order to identify any studies which could have escaped the detailed search. Searching for Grey Literature

Grey literature was searched on SIGLE (System for Information on Grey Literature), Journal of Bone and Joint Surgery Proceedings (2002-2011) and Spine Conference websites. The annual meetings for the following spine societies were searched for relevant abstracts: Spine Arthroplasty Society (SAS), British Association of Spine Surgeons (BASS), Spine Society of Australia, North American Spine Society (NASS). Other electronically searched meetings which could include abstracts on the relevant topic were: European Federation of National Associations of Orthopaedics and Traumatology (EFORT), British Orthopaedic Association (BOA), Canadian Orthopaedic Association (COA), American Orthopaedics Association (AOA).

An English language limit was applied to the search. All existing studies until March 2013 were included in the review process.

Data Collection and Analysis

Selection of Studies

Studies were evaluated and selected by two review authors based on reading the titles and abstracts. Potentially relevant studies were then independently analysed by the same authors by reading the full text. No disagreements were encountered between the two reviewers.

Data extraction and management

Data extraction was performed independently using a standardized data extraction form which was designed by the two authors and based on the research question. This form followed the Population, Intervention and Outcome (PIO) framework. The research question followed the PIO and not a PICO structure because valid information could have been missed from relevant studies which did not contain a comparison group.

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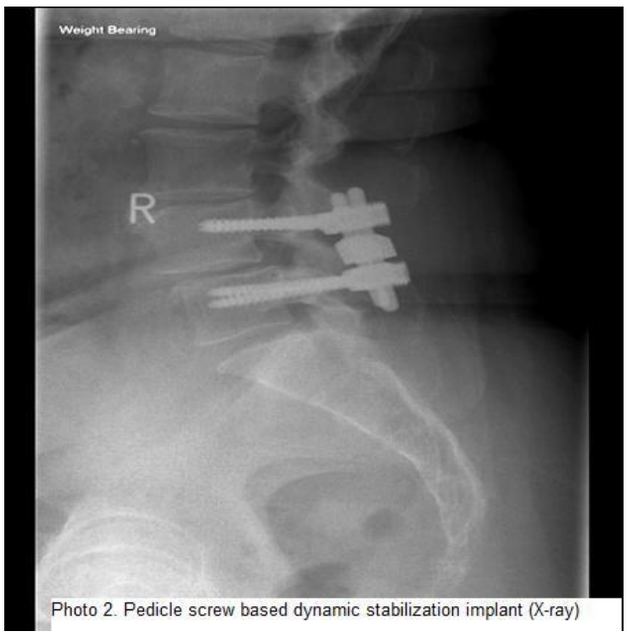

Figure 2: Pedicle screw based dynamic stabilization (lateral view lumbo-sacral spine X-ray).

Assessment of Risk of Bias in Included Studies

Risk of bias or methodological quality assessment of all included studies was performed using the McMaster University framework[13] using 15 relevant questions. A question scored 1 if the response was 'yes' and 0 if the response was 'no' or 'unclear'. Question 3 ('Quantitative study?') could score up to 3 points depending on the type of quantitative study: good quality randomized controlled trial 3 points, prospective cohort study or poor quality randomized controlled trial 2 points, other type of quantitative study 1 point. This method of differential scoring of studies is based on the Levels of Evidence published in the Journal of Bone and Joint Surgery[14]. A total score of 21 could be achieved when any study answered 'Yes' for all questions. Although a classification of the scoring system using the McMaster framework has not been designed, the authors of this review considered a study to be of good quality if it scored 85% or greater (at least 18 points), moderate quality between 65-84% (14-17 points) and poor less than 65% (13 points and less). The results of methodological quality assessment of the included studies are presented in Table 2.

Results

Results of the search

The electronic search identified 482 titles. 11 articles were identified by hand search. A total of 25 full text articles were reviewed.

Included studies

Ten studies were included for the final review. The details of all the included articles are presented in Table 3.

Excluded studies

Fifteen research papers were excluded after reading the full text. The reasons for this were the absence of validated outcome measures[9] or the impossibility of identifying the relevant outcomes for degenerative lumbar spondylolisthesis patients only. In all these investigations degenerative lumbar spondylolisthesis was presented along with other degenerative spine conditions.

Types of Treatments

The two types of dynamic stabilization systems were identified as intervention: interspinous[10,17,18,20,21] and pedicle screw-based[3,11,15,16,19]. Prior to the insertion of the dynamic stabilization device, adequate decompression was performed in order to relieve the pressure on the nerves and alleviate the source of leg pain. In one study[10] the decompression was indirect and accomplished by increasing the dimension of the intervertebral foramina and thus releasing the pressure on the neural structures.

Participants

A total of 338 patients received dynamic stabilization for degenerative lumbar spondylolisthesis (Grade I or II). The largest sample size (65) was reported by Lee SH et al.[21] whereas the smallest sample size (23) was presented by Lee SH et al. [17,] Hong et al.[18] and Lee DY et al.[20]. Mean age at operation was 64.75 years; 229 female and 109 male patients received dynamic stabilization. The overall ratio of males: females were 1:2.1 and the mean duration of symptoms was 37.6 months. The latter parameter was not consistently reported by all studies.

A comparison group was present in five articles[10,15,16,17,18]. There were no statistically significant differences between the surgically and non-surgically treated groups in terms of patients' demographics, apart from the study of Hong et al.[18] which failed to report the similarity between these two groups. Alternative treatments (control group) for symptomatic degenerative spondylolisthesis were: conservative therapy in the form of sacral epidural injections[10], spinal decompression alone without instrumentation[16,18] and instrumented spinal fusion[15,17]. Anderson et al.[10] presented a control group which included subjects receiving a various number of sacral epidural injections. Use of non-steroidal anti-inflammatory drugs and physiotherapy were complementary therapies, but this varied from patient to patient. Therefore, there was quite significant variation within the conservative treatment received by patients in the control group. Variations in the treatment received by the subjects in the control group could have a significant impact on the internal validity of the study.

Effectiveness of intervention

All papers reported a significant clinical improvement following dynamic stabilization for symptomatic degenerative lumbar spondylolisthesis, irrespective of the dynamic device. Four studies compared the results of dynamic stabilization with other types of surgery (spinal

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decompression only[16,18] or spinal fusion[15,17]) and in one case[10] the comparison was made with conservative therapy in the form of sacral epidural injections. Results were not statistically significant between the dynamic stabilization and the fusion group. In the paper of Anderson et al.[10] dynamic stabilization showed superior results to conservative treatment.

Revision surgery rate was an average of 4.7% (16/338). The highest incidence of revision (9.5%) was reported by Anderson et al.[10], but there was no clear explanation for the reasons for revision. Dynamic stabilization seems to have a lower revision rate than spinal fusion which has a reported incidence of 12% at 2 years and 15% at 4 years[22].

Outcomes

The results of recorded outcome measures are presented in Table 4 and Table 5.

Risk of Bias in Included Studies

Patients' Selection

Within all the included studies the patients selected for inclusion differed with respect to the severity of the condition. Whilst six papers[10,17,18,19,20,21] only considered patients with Grade I spondylolisthesis, three studies[3,11,15] included patients with both Grade I and II severity and one study[16] did not mention the grade of spondylolisthesis in the inclusion criteria.

Previous surgery constituted an exclusion criterion for five articles[3, 11,15,16,17]. Other exclusion criteria were: worker's compensation, other types of spinal instability (degenerative disc disease, isthmic sponylolisthesis, vertebral fracture), scoliosis, walking distance less than 50 feet, inability to sit for longer than 50 minutes, more than one level of spondylolisthesis.

Table 3: Studies characteristics.

	Study design	Population	Intervention	Outcomes
Schaeren et al (2008)	Retrospective (Before-After)	**Sample size:** 26, **Age:**71, **Gender:** 18-F, 8-M. **Inclusion criteria:** DSL Gr I/II at single level which failed conservative treatment; spinal claudication with back pain. **Exclusion criteria:** Lytic spondylolisthesis, more than one level of spondylolisthesis and previous lumbar spine fusion. **Diseased level:** L4/5 – 22 cases, L3/4 – 4 cases. **Duration of symptoms:** 35 months	Decompression and dynamic stabilization with Dynesys system. **Type of implant:** pedicle-screw based. **Period of study:** Nov 1999 – Nov 2000. **Drop-outs:** 7 patients lost to follow-up: 1-died, 1 moved out of country, 1- severe COPD bedridden, 1- severe dementia, 3-subsequent lumbar surgery	VAS leg pain, Walking distance: 250 m (pre-op), >1000m (post-op). **Frequency of recording**: pre-operatively, then final follow-up (average: 52 months, range: 48-57 months). **Statistical significance:** p<0.001 (VAS), p<0.003 (walking distance). **Complications:** 4-implant failure (3-screw loosening, 1- screw breakage), 3-dural tear, 9-adjacent segment instability
Schnake et al (2006)	Retrospective (Before-After)	**Sample size:** 26, **Age:**71, **Gender:** 18-F, 8-M. **Inclusion criteria:** DSL Gr I/II at single level which failed to conservative treatment; spinal claudication with back pain. **Exclusion criteria:** not discussed. **Diseased level:** L4/5 – 22 cases, L3/4 – 4 cases. **Duration of symptoms:** 35 months	Decompression and dynamic stabilization with Dynesys system. **Period of study:** Nov 1999 - Nov 2000. **Type of implant:** pedicle screw-based. **Period of study:** Nov 1999 – Nov 2000. **Drop-outs:** 2 (1 died of unrelated pathology, 1 vertebral fracture)	VAS leg pain; Walking distance: 250 m (pre-op), >1000m (post-op). **Frequency of recording**: pre-operatively, then final follow-up (average: 26 months, range: 24-33 months). **Statistical significance:** p<0.001 (VAS), p<0.001 (walking distance). **Complications:** 2 - transient leg paraesthesia, 1 - revision for insufficient decompression, 7-adjacent level degeneration
Anderson et al (2006)	Randomized Controlled Trial	**Sample size:** 42 – X-Stop, 33 – Conservative treatment, **Age:** 71.4 (Experimental group), 68.5 (Control group), **Gender:** 23-F,19-M (Experimental group), 22-F, 11-M (Control group). **Inclusion criteria:** symptomatic spinal stenosis and Gr I DSL, 6 months failed conservative treatment. **Exclusion criteria:** unable to walk for at least 50 feet, unable to sit for>50 min or >25% anterior slippage. **Diseased level:** 1-2 levels. Exact level not stated. **Duration of symptoms:** <2 years and >2 years	Studied group - X-STOP device. Control group - sacral epidural injections, non-steroidal anti-inflammatories and physiotherapy as needed. **Type of implant:** interspinous. **Period of study:** not stated. **Drop-outs:** 98.9% of the treatment group and 92.1% of the control group were followed-up for 2 years. No explanations about reasons for drop-out.	ZCQ, PSI, SF-36, Patient satisfaction. **Frequency of recording**: Pre-intervention and 24 months post-op. **Statistical tests:** Correlation analysis and the Spearman rank coefficient analysis. **Statistical significance:** Intra-group significance: ZCQ (p<0.001) and SF-36 (statistical significance, but no p-value) in the Experimental group, not significant in Control group (no p-value). Between groups: statistical significance in PSI (no p-value). **Complications:** 5 patients required revision surgery (laminectomy+/-fusion); 1 infection - resolved with 1 week antibiotic therapy; 1 malpositioned implant, but asymptomatic.

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Table 3 (continued)

	Study design	Population	Intervention	Outcomes
Kaner et al (2010)	Prospective comparative	**Sample size:** 26 – Dynamic stabilization, 20 – Fusion, **Age:** 63.65 (Experimental group), 58.10 (Control group), **Gender:** 20-F, 6-M (Experimental group), 13-F, 7-M (Control group). **Inclusion criteria:** symptomatic Grade I/II DSL. **Exclusion criteria:** failed medical treatment. **Diseased level:** not stated. **Duration of symptoms:** not stated	One group - Decompression and Dynamic stabilization (Cosmic dynamic pedicular screw-rod system); the other group - Decompression and fusion. **Type of implant:** pedicle screw-based. **Period of study:** 2004 – 2007. **Drop-outs:** not reported	VAS, ODI **Frequency of recording**: Pre-intervention, then 3,12, 24 months post-op. **Statistical significance:** Intra-group significance: p<0.001 in both groups between pre-op and post-op scores. No statistical significance between the 2 groups. C**omplications:** 1-screw malposition; 1-ongoing pain and required fusion – Experimental group. 1-adjacent level degeneration – Fusion groupVAS, ODI **Frequency of recording**: Pre-intervention, then 3,12, 24 months post-op. **Statistical significance:** Intra-group significance: p<0.001 in both groups between pre-op and post-op scores. No statistical significance between the 2 groups. C**omplications:** 1-screw malposition; 1-ongoing pain and required fusion – Experimental group. 1-adjacent level degeneration – Fusion group
Konno and Kikuchi (2000)	Cohort	**Sample size:** 46 – Graf stabilization; 42 – Decompression alone, **Age:** 65 – Graf group, 63 – Decompression group, **Gender:** 32 – F, 14 – M. **Inclusion criteria:** leg pain, limited walking distance or standing endurance, age>50 and radiographic evidence of nerve root/cauda equina compression. **Exclusion criteria:** Previous lumbar surgery. **Diseased level:**L4/5. **Duration of symptoms:**57 months	Both groups - laminectomy. Studied group also received stabilization with Graf system. **Type of implant:** pedicle screw-based. **Period of study:** 1993 – 1996. **Drop-outs:** Not reported	VAS back pain, VAS leg pain **Frequency of recording**: pre-operatively, then 1 year and 3 years post-surgery. **Statistical significance:** p<0.05 (intra-group), Not significant (inter-group, no p-value). **Complications:** 2-postoperative radicular pain due to malpositioning of screws; 20% screw malpositioning.
Kanayama et al (2005)	Retrospective (Before-After)	**Sample size:** 64, **Age:** 66 (range: 50-79), **Gender:** 45-F, 19-M. **Inclusion criteria:** symptomatic spinal stenosis and Gr I DSL, <25% of vertebral slip, coronal facet articulation and minimal disc space narrowing. **Exclusion criteria:** worker's compensation. **Diseased level:** 51 - L4/5, 2 - L3/4, 10 - L3-4-5, L4-5-S1. **Duration of symptoms:** not reported.	Posterior decompression by partial medial facetectomy and dynamic stabilization. 53 patients - single-level stabilization; 10 patients: 2-level stabilization. **Type of implant:** pedicle-screw based. **Period of study:** not stated. **Drop-outs:** Not reported.	VAS back pain, VAS leg pain **Frequency of recording**: pre-operatively, then final follow-up (average: 67 months, range: 36-112 months). **Statistical significance:** p<0.05 for VAS back and leg pain. **Complications:** Further surgery - 4 cases (6.3%) for adjacent segment morbidity: Spinal stenosis (2), Disc herniation (1), Foraminal stenosis (1); 1 patient: PLIF for residual spinal instability

Allocation

Random allocation was performed by a centrally administered system in the only RCT included in the review[10]. Kaner et al.[15] allocated the subjects to each of the two groups according to patients' preference.

Incomplete Outcome Data

Kaner et al.[15], Konno and Kikuchi[16], Kanayama et al.[19] and Lee DY et al.[20] did not report any drop-outs. Schnake et al.[3], Schaeren et al.[11], Hong et al.[18] and Lee SH et al. [21] clearly presented the reasons for drop-out; these included inadequate follow-up, incomplete radiological data or death, migration, significant co-morbidities affecting patient's capability to continue within the trial and subsequent lumbar surgery. Although Anderson et al.[10] reported 1 drop-out in the dynamic stabilization group, the author failed to explain the reasons and this could affect the internal validity of the study.

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Table 3 (continued)

	Study design	Population	Intervention	Outcomes
Hong et al (2010)	Retrospective comparative	**Sample size:** 23 – Interspinous ligamentoplasty, 18 – Decompression alone, **Age:** 57.3 (Experimental group), 61.2 (Control group), **Gender:** 15-F, 8-M (Experimental group), 22-F, 11-M (Control group). **Inclusion criteria:** symptomatic spinal stenosis and Gr I DSL, 6 months failed Conservative treatment, **Exclusion criteria:** scoliosis, lat translation, advanced disc prolapse, foraminal stenosis. **Diseased level:** L4/5. **Duration of symptoms:** not reported.	Studied group - decompression and stabilization with Interspinous Ligamentoplasty. Control group - laminotomy only. **Type of implant:** interspinous. **Period of study:** 2001 – 2002. **Drop-outs:** 9 patients. Reasons: inadequate follow-up and radiological data.	VAS back pain, VAS leg pain, ODI **Frequency of recording**: Pre-intervention and final follow-up, which varied between 60-77 months post-op (mean: 64.6 months). **Statistical significance:** p<0.05 for VAS back and leg pain and ODI (between pre and post-op scores). Between groups: p=0.185 (VAS back pain), p=0.804 (VAS leg pain), p=0.049 (ODI). **Complications:** 1-infection (required fusion), 1-symptomatic instability (required fusion), 1-adjacent segment disease
Lee SH et al (2010)	Retrospective comparative	**Sample size:** 23 – Interspinous soft stabilization, 22 – Posterior interbody lumbar fusion. **Age:** 58.9 (Experimental group), 56.7 (Control group), **Gender:** 17-F, 6-M (Experimental group), 14-F, 8-M (Control group). **Inclusion criteria:** symptomatic Grade I DSL, levels between L3-5. **Exclusion criteria:** advanced segmental instability, previous surgery, vertebral fracture, retrolisthesis, degenerative scoliosis. **Diseased level:** 17 - L4/5, 6 – L3/4 (Studied group), 18 – L4/5, 4 – L3/4 (Control group). **Duration of symptoms:** 20.9 months	One group - decompression and ISS; the other group - PLIF. **Type of implant:** interspinous. **Period of study:** April 2001 – November 2003. **Drop-outs:** Not reported.	VAS back pain, VAS leg pain, ODI, PSI **Frequency of recording**: Pre-intervention, then at final follow-up (mean: 75.8, range: 68-83 months) **Statistical significance:** Intra-group significance: p<0.05 for VAS back and leg pain, ODI and PSI (between pre and post-op scores). Between groups: results not significant, but no reported p-value. **Complications:** not reported.
Lee DY et al (2010)	Retrospective (before-after)	**Sample size:** 23, **Age:** 62.1 years (range: 45-81). **Gender:** 17-F, 6-M. **Inclusion criteria:** symptomatic lumbar canal stenosis with grade I DSL, which failed to conservative treatment for at least 6 weeks. **Exclusion criteria:** grade II DSL or higher and DSL associated with foraminal disc herniation/stenosis. **Diseased level:** 4 – L3/4, 19 – L4/5. **Duration of symptoms:** 27.6 months (range: 2-120)	Bilateral minimal laminotomy and medial facetectomy and foraminotomy followed by insertion of the Locker system. **Type of implant:** interspinous. **Period of study:** 2006. **Drop-outs:** Not reported	VAS back pain, VAS leg pain, ODI **Frequency of recording**: Pre-intervention, then at final follow-up (Mean: 28.3 months, range: 24-32). **Statistical significance:** All three outcome measures improved significantly post-op (p<0.001). **Complications:** 1 patient underwent secondary fusion due to persistent back and leg pain
Lee SH et al (2012)	Retrospective (before-after)	**Sample size:** 65, **Age:** 60.3 years, **Gender:** 45-F, 23-M. **Inclusion criteria:** grade I, single level DSL for at least 6 weeks, more than 3 months leg pain relief following surgery. **Exclusion criteria:** not presented. **Diseased level:** 12 – L3/4, 53 – L4/5. **Duration of symptoms:** minimum 6 weeks (mean: 31.4 months)	Bilateral laminotomy with partial facetectomy and insertion of an artificial ligament. **Type of implant:** interspinous. **Period of study:** 2002-2004. **Drop-outs:** 16 patients (20%) - death or incomplete follow-up.	VAS back and leg pain, ODI, PSI **Frequency of recording**: Pre-intervention, then at final follow-up (Mean: 72.5 months). **Statistical significance:** Intra-group significance: p<0.01 in both groups between pre-op and post-op scores. Between groups: significantly better results in optimal group as compared to suboptimal group, correlated with restoration of lumbar lordosis. **Complications:** 1 patient - hypersensitivity to the artificial ligament. 3 patients required fusion surgery due to continuing back pain and stooped posture

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Table 4: Summary of clinical outcomes. ODI – Oswestry Disability Index, PSI – Patient Satisfaction Index, VAS-BP – Visual Analogue Score – Back Pain, VAS-LP – Visual Analogue Score – Leg Pain, ZCQ – Zurich Claudication Questionnaire.

	Outcome measures																
	ODI			ZCQ			SF-36			VAS-BP			VAS-LP			PSI	
Study	Pre-op	Post-op	p-value	Pre-op	Post-op	p-value	Pre-op	Post-op	p-value	Pre-op	Post-op	p-value	Pre-op	Post-op	p-value	%	p-value
Schnake et al (2006)													80	23	0.00001		
Anderson et al (2006)				50.4	23.05		31.53	41.19								63.4	
Schaeren et al (2008)													80	25	<0.001		
Kaner et al (2010)	73.46	9.23	0.001							7.42	0.84	0.001					
Konno and Kikuchi (2000)										7.7	3.1	<0.05	8.1	3.5	<0.05		
Lee SH et al (2010)	54.2	26.5	<0.05							6.4	3.4	<0.05	5.8	2.3	<0.05	65.7	<0.05
Hong et al (2010)	42.4	13.1	<0.01							5.4	1.9	<0.01	7.7	2.0	<0.01		
Kanayama et al (2005)										71.7	14.2	<0.05	76.3	14.5	<0.05		

Discussion

The aim of this review was to assess the existing evidence on dynamic stabilization systems and their influence on validated clinical outcome measures in patients with degenerative lumbar spondylolisthesis. Life expectancy has continuously increased in developed countries and therefore the worldwide health services will face an increasing number of pathologies specific to an ageing population. With the concurrent advancements in the development of new technology the aim for the newly designed implants is to reproduce the natural biomechanics encountered in normal spine motion. Therefore, dynamic stabilization implants have been designed in an attempt to replace standard fusion devices which present with higher rates of co-morbidities, i.e. adjacent level degeneration and bone graft donor site pain[5,23].

Measuring the outcomes of a quantitative piece of research probably has the most significant effect on the internal validity of the undertaken study. These outcomes have to be valid (the degree to which an instrument measures what it is intending to measure) and reliable (the degree to which an instrument measures in a similar way the same outcome for the same group of patients). Validity of the reported outcome measures was one of the essential conditions for a study to be included within the systematic review. All included outcome measures had demonstrable reliability and validity as reported by previously published papers and have been accepted by the North American Spine Society as being appropriate in evaluating the post-operative results: Oswestry Disability Index (ODI)[24], Short-Form Questionnaire 36 (SF-36)[25], Zurich Claudication Questionnaire (ZCQ)[26] and Visual Analogue Score (VAS) for back and leg pain[27]. Patient Satisfaction Index was found to be a valid instrument, but it failed to identify the treatment effect and distinguish between clinically significant changes in a previous study[28]. Anderson et al.[10] explained that the decision for choosing the ZCQ as an outcome measure was because it was shown to be more sensitive than the ODI in patients presenting with spinal claudication symptoms.

A few methodological issues have been identified regarding patients' selection, intervention and data recording and these issues are discussed below.

Lee DY et al.[20] excluded from final follow up patients who had less than 3 months leg pain relief following dynamic stabilization, suggesting that this could be a result of incomplete neural decompression. Therefore, false positive outcomes could have been achieved at final follow up.

The authors also identified controversies regarding the grade of degenerative lumbar spondylolisthesis amenable to dynamic stabilization. These differences will have increased the heterogeneity within the systematic review in that studies which only included Grade I[10,17,18,19,20,21] may have shown greater treatment effects than studies which included grades 1 and 2 [3,11,15]. Lawhorne et al.[8] suggest that all cases presenting with more than Grade I spondylolisthesis should be treated with spinal fusion, the reason being that a slippage higher than 25% reflects a higher degree of instability. Therefore, the normal intervention would be to provide adequate rigid stabilization. Another reason for limiting dynamic stabilization to Grade I spondylolisthesis is implant related, when the chosen implant is the Graf ligament. Leeks et al.[29] clearly recommends that the Graf ligament should not be implanted in patients with more than 25% slippage, due to friction that can occur between the ligament and the osseous structures.

Six of the studies[16,17,18,19,20,21] were performed on Asian populations who commonly present with flat-back

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Systematic review

Table: 5: Clinical outcomes in studies with a comparison group. CG – Control Group, DS – Dynamic Stabilization, IS – Interspinous device, NS – not statistically significant, ODI – Oswestry Disability Index, PS – Pedicle Screw based device, PSI – Patient Satisfaction Index, SS – statistically significant, VAS-BP – Visual Analogue Score – Back Pain, VAS-LP – Visual Analogue Score – Leg Pain, ZCQ –.

Outcomes		Anderson et al (2006)			Kaner et al (2010)			Lee SH et al (2010)			Hong et al (2010)			Konno and Kikuchi (2000)		
		DS (IS)	CG (conserv)	p-value	DS (PS)	CG (fusion)	p-value	DS (IS)	CG (fusion)	p-value	DS (IS)	CG (decomp)	p-value	DS (PS)	CG (decomp)	p-value
ODI	**Pre**				73.46	75.70	0.671	54.2	59.7	NS	42.4	43.7	0.049			
Post			9.23	10.20	26.5	21.7	13.1	26.1								
ZCQ	**Pre**	50.40	51.26	<0.0001												
Post	23.05	47.40														
SF-36	**Pre**	31.53	28.19	not reported												
Post	41.19	28.14														
VAS-BP	**Pre**				7.42	7.85	0.942	6.4	6.7	NS	5.4	6.8	0.185	7.7	7.4	NS
Post			0.84	1.00	3.4	2.4	1.9	4.4	3.1	3.5						
VAS-LP	**Pre**							5.8	7.3	NS	7.7	8.6	0.804	8.1	8.5	NS
Post					2.3	1.9	2.0	4.0								

postures when compared to Western subjects[21]. There was also great variability in the mean follow-up (between 28-72 months) with the longer follow-ups also being recorded within the Asian articles. Therefore due to anatomical population differences, the results of these studies may not be applicable to a worldwide population.

Concomitant use of analgesia is probably one of the most common co-interventions encountered in the post-operative period and this can threaten the internal validity of a study. Use of analgesia during the preoperative or postoperative period was reported by Schnake et al.[3] and Schaeren et al.[11]. In the study of Anderson et al.[10] the control group received additional forms of pain management: non-steroidal anti-inflammatory medication and physical therapy. Long term use of analgesia during the post-operative period could be considered a confounding factor because it is difficult to determine how much improvement is due to dynamic stabilization itself. In real life though, painkillers are regularly prescribed following any type of surgery. A systematic review conducted by Chou et al.[30] compared surgical versus non-surgical treatment in patients with degenerative spine disease. In patients with spinal stenosis with or without degenerative lumbar spondylolisthesis, the authors reported moderately better results following surgery on short term (1-2 years), whereas results of both treatments are comparable on long term, the beneficial effect of surgery being therefore questionable.

One of the potential advantage of dynamic stabilization is reduction of adjacent level degeneration which was found to be a negative effect of spinal fusion[6,12]. In the three included studies comparing fusion with dynamic stabilization[16,17,18], only 2 patients (3.3%) in the fusion group and 1 patient (1.4%) in the dynamic stabilization group developed adjacent level degeneration. Moreover, the results presented by Schaeren et al.[11] and Kanayama et al.[19] showed a significant incidence of adjacent level disease with dynamic stabilization implants: 36% and 6.3%, respectively. It is therefore difficult to conclude the positive effect of dynamic stabilization in reducing adjacent level degeneration.

The action mechanism of X-STOP devices contradicts the principles of stabilization in degenerative lumbar spondylolisthesis. The X-STOP implant limits the extension but not the flexion of the spine, which is responsible for increasing the instability in spondylolisthesis. Based on the biomechanical function of extension limiting interspinous devices, Park et al.[31] expressed an important criticism to their use. Use of X-STOP devices in degenerative lumbar spondylolisthesis is considered by Verhoof et al.[9] a contraindication following a high failure rate (58%) reported in their study.

It is also desirable that outcomes are recorded by independent observers to decrease bias and also to ensure that the validity of results is not threatened. Only two of the included studies mentioned the independency of outcome observers[18,20] and therefore it has been assumed that the post-operative evaluation was performed by one of the researchers involved in the study, not blinded to the surgical procedure.

In conclusion, the results of this systematic review suggest that dynamic stabilization seems to be an efficient intervention in improving patients' symptoms, but its superiority to other types of surgical procedures (fusion, decompression only)[15,16,17,18] cannot as yet be demonstrated. However, dynamic stabilization showed superior results to conservative treatment[10].

Reasons why a meta-analysis has not been performed

Many authors suggest that a meta-analysis should only include properly designed randomized controlled trials[29] which this review has not identified. The selected studies could not be combined due to heterogeneity of populations. These are the reasons why a meta-analysis was not conducted.

Limitations of the study

The review only included studies published in English. However, studies published in English are more likely to be frequently cited and identified by search engines, but this does not exclude the presence of non-English articles which could have contributed to the final conclusions.

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Conclusion

In conclusion this systematic review has demonstrated that although the effectiveness of dynamic stabilization on degenerative lumbar spondylolisthesis is encouraging, the authors cannot safely generalise or recommend the use of these devices to the general population presenting with this degenerative spinal condition. All studies have been found to be of moderate quality with important methodological weaknesses.

The authors recommend that future research should include properly designed randomized controlled studies, preferably multi-centred, demonstrating solid methodology.

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