

Dynamic Stabilization of the Spine

Effective: July 1, 2018

Next Review: May 2019

Last Review: May 2018

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Dynamic stabilization has been proposed as an adjunct or alternative to spinal fusion for the treatment of severe refractory pain due to degenerative spondylolisthesis, or continued severe refractory back pain following prior fusion. These devices are used in conjunction with spinal fusion to partially preserve spinal motion.

MEDICAL POLICY CRITERIA

Use of any spinal dynamic stabilization device is considered **investigational** for the treatment of disorders of the spine at any level.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

1. [Interspinous and Interlaminar Stabilization/Distraction Devices \(Spacers\)](#); Surgery Policy No. 155
2. [Total Facet Arthroplasty](#), Surgery, Policy No. 171
3. [Interspinous Fixation \(Fusion\) Devices](#), Surgery, Policy No. 172
4. [Image-Guided Minimally Invasive Spinal Decompression \(IG-MSD\) for Spinal Stenosis](#), Surgery, Policy No. 176
5. [Lumbar Spinal Fusion](#), Surgery, Policy No. 187

BACKGROUND

Dynamic stabilization, also known as soft stabilization or flexible stabilization, has been proposed as an adjunct or alternative to spinal fusion for the treatment of severe refractory pain due to degenerative spondylolisthesis, or continued severe refractory back pain following prior fusion, sometimes referred to as failed back surgery syndrome. Dynamic stabilization uses flexible materials rather than rigid devices to stabilize the affected spinal segment(s). These flexible materials may be anchored to the vertebrae by synthetic cords or by pedicle screws. Unlike the rigid fixation of spinal fusion, dynamic stabilization is intended to preserve the mobility of the spinal segment.

REGULATORY STATUS

No dynamic stabilization devices have received approval from the U.S. Food and Drug Administration (FDA) for use other than as an adjunct to spinal fusion. The FDA has specified that separate approval is required for “off-label” marketing of these devices, including but not limited to use as a stand-alone device for spinal stabilization in the absence of fusion.

The following dynamic stabilization devices have received clearance from the FDA *for use in spinal fusion* of the thoracic, lumbar and/or sacral spine for degenerative spondylolisthesis with neurologic impairment, and for failed previous fusion (pseudoarthrosis)

Device Name	Manufacturer
AccuFlex™ System (K0520690)	Globus Medical
BioFlex System with Nitinol spring rod and memory loops (Bio-Spine) (K072321)	Bio-Spine
CD Horizon Agile™ Dynamic Stabilization device (K060615)	Medtronic Sofamor Danek, Inc
Cosmic™ Posterior Dynamic System (K080841)	Ulrich GmbH & Co.
DSS (Dynamic Soft Stabilization) system (K090099)	Paradigm Spine
Dynabolt™ Dynamic Stabilization System (formerly Modified VertiFlex® Spinal Screw System) (K073143)	VertiFlex, Inc
Dynesys® and DTO (Dynesys-to-Optima) (K031511)	Zimmer Spine, Inc
Isobar® (K991326)	Scient'x
NFix™ II Dynamic Stabilization System (K053623)	N Spine, Inc.
REVERE™ Stabilization System (K061202)	Globus Medical
Satellite™ Spinal System (K051320)	Medtronic Sofamor Danek, Inc.
TRANSITION® Stabilization System (K073439)	Globus Medical
Viper™ (K061520) and Expedium™ (K041801)	Depuy Spine

When used as a pedicle screw fixation system, these devices are indicated for use in patients who are receiving fusion with autogenous graft only, and who are having the device removed after development of a solid fusion mass.

The following dynamic stabilization devices have **not** received FDA clearance:

- Bronsard's Ligament
- FASS (Fulcrum Assisted Soft Stabilization) (AO International)
- Graf ligament (SEM Co)

- Leeds-Keio Ligamentoplasty (Neoligament LTD)
- LemiFlex Spinal Stabilization System (Simpirica Spine)
- NFlex™ Controlled Motion System (indicated for non-fusion only) (N Spine, Inc.)
- Stabilimax NZ® Dynamic Spine Stabilization System (Applied Spine Technologies Inc.)

Note: This policy considers only dynamic stabilization devices across pedicle screws. See Cross References section below for separate policies on other surgical spinal stabilization and fusion techniques.

EVIDENCE SUMMARY

The primary beneficial outcomes of interest for treatment of spinal pain are relief of pain and improved function. Both outcomes are subjective and can be influenced by nonspecific effects, placebo response, and the variable natural history of the disease. Therefore, evaluating the safety and effectiveness of dynamic stabilization alone or as an adjunct to spinal fusion requires data from randomized controlled trials (RCTs) comparing dynamic stabilization with spinal fusion using conventional devices (e.g., rigid rods, cages). These comparisons are necessary to determine whether the benefits of dynamic stabilization outweigh potential risks and whether or not they offer advantages over conventional spinal fusion techniques.

RCTs for dynamic stabilization should also include blinding of study participants, caregivers, and investigators to the treatment assignments to help control for bias for or against the treatment; large study populations in order to rule out the role of chance as an explanation of study findings; and sufficient long-term follow-up to determine the durability of any treatment effects of dynamic stabilization compared with conventional fusion.

The following literature review only includes studies with an appropriate spinal fusion control group.

SYSTEMATIC REVIEWS

Lee (2016) published a meta-analysis comparing the efficacy of the Dynesys® pedicle-based dynamic stabilization (PDS) system versus posterior lumbar interbody fusion (PLIF) in patients with degenerative lumbar spinal disease.^[1] Following Preferred Reporting Items for Systematic Reviews (SRs) and Meta-Analyses (PRISMA) guidelines, the authors included seven studies in their review, of which three were prospective (one^[2] is included with in the nonrandomized studies section). Overall, 250 patients underwent PDS, and 256 received PLIF. Clinical outcomes were assessed as pooled mean difference (95% confidence interval [CI]) between PDS and PLIF as evaluated by the Oswestry Disability Index (ODI), visual analog scale (VAS) scores for back and leg pain, and range of motion (ROM) at the treated and adjacent segments after more than two years follow-up. There were no differences between treatment group ODI and VAS scores. Although less instability in the treated segment was found in the PLIF group (mean difference -3.43, CI [-5.25, -1.60]) and less hypermobility at the adjacent segment was found in the PDS group (mean difference 1.13, CI [-0.33, 2.59]), the authors concluded that underpowered analyses and publication bias limit interpretation of these findings.

Chou (2011) conducted a comparative effectiveness review evaluating dynamic stabilization with fusion as a treatment for degenerative disease of the cervical or lumbar spine.^[3] Four comparative studies were analyzed, two^[4,5] of which are included, below. VAS scores for low back and leg pain, and ODI scores were similar between groups for mean percentage

improvement; no statistically significant differences were reported between groups at any follow-up time (up to four years). Adjacent segment disease ranged from 0-9% in the fusion groups, and was not found in the dynamic stabilization groups. Reoperation occurred up to 8% and 9% of the time for dynamic and fusion groups, respectively. Studies included in the review were severely limited by, but not limited to: short term follow-up duration (mean of three years), heterogeneity in devices used, and patient selection bias; therefore, the authors concluded there were no data available to support the use of dynamic stabilization over standard fusion.

Sengupta (2004) identified the pertinent questions in dynamic stabilization as: (a) how much control of motion is desirable, and (b) how much load should be shared by the system to unload the damaged disc.^[6] The author concluded that, while dynamic stabilization procedures may prove to have a promising role in preventing the adjacent segment disease inherent with fusion, RCTs are essential to prove safety, efficacy and appropriateness of these procedures. Schwarzenbach and colleagues reached the same conclusion in their review article.^[7]

RANDOMIZED CONTROLLED TRIALS

Korovessis (2004) reported on a study of 45 adults randomized into three groups.^[5] All patients had decompression and fusion with instrumentation as follows: Group A had rigid instrumentation, Group B had semi-rigid instrumentation, and Group C had dynamic instrumentation. Follow-up was between 33 and 61 months. All fusions in all three groups healed without pseudoarthrosis or malunion within six months after surgery. Hardware failures were seen only in the dynamic instrumentation group and included one asymptomatic and one symptomatic pedicle screw breakage and one symptomatic rod breakage. Donor site pain for six to twelve months postoperatively was reported only in the rigid and semirigid instrumentation groups. There was no degeneration at the adjacent vertebral segments above or below the instrumentation level in any group. Due to the small number of patients and the need for longer follow-up, the authors made no recommendation in favor of any of the devices used in this study.

NONRANDOMIZED STUDIES

Several case series compared the efficacy and adverse effects of conventional spinal fusion with either dynamic stabilization as an adjunct to fusion or dynamic stabilization alone.^[2,4,8,9] Other case series have also studied adjacent level disc degeneration.^[10-13] However, methodological limitations limit the conclusions that can be drawn including non-randomization and selection bias, potential conflict of interest, under-reporting of adverse events, lack of a control group, lack of long-term outcomes, and notable differences in outcomes between study centers.

ADVERSE EVENTS

The most commonly reported symptomatic adverse events of dynamic stabilization were device breakage and screw loosening.^[2,14-18] Other reported adverse effects include but are not limited to the following:^[2,19-24]

- Cerebrospinal fluid pseudocele
- Bleeding
- Impaired wound healing
- Instability with stenosis in adjacent segment
- Persistent pain, stenosis and/or disk protrusion in index segment

- Osteoporotic fracture of adjacent vertebra
- Pedicle perforation
- Screw malposition requiring surgical correction
- Compensatory increase in lordosis in superior adjacent segment
- Symptomatic malalignment (e.g., insufficient lumbar lordosis)

PRACTICE GUIDELINE SUMMARY

NORTH AMERICAN SPINE SOCIETY

The North American Spine Society (NASS) (2014) address “flexible fusion,” defined as dynamic stabilization without arthrodesis, for the treatment of degenerative lumbar spondylolisthesis.^[25] Due to the paucity of literature addressing the outcomes of these procedures, the workgroup was unable to make a recommendation. For future research, the workgroup recommended development of a large multicenter registry database, as well as prospective studies, with long-term follow-up comparing flexible fusion to medical or interventional treatment of this condition.

SUMMARY

There is not enough research to show that spinal dynamic stabilization devices improve health outcomes for people with disorders of the spine at any level. No clinical guidelines based on research recommend spinal dynamic stabilization devices. Therefore, use of these devices by any technique at any spinal level is considered investigational.

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CODES

Codes	Number	Description
CPT	22899	Unlisted procedure, spine
	64999	Unlisted procedure, nervous system
HCPCS	None	

Date of Origin: October 2005