

A Current Review Of Outcome Studies On The Dynesys® System For Dynamic Stabilization Of The Lumbar Spine

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Abstract

The current article reviews the literature on the effectiveness of the Dynesys® system of dynamic lumbar spine stabilization from 2008-2010, updating the review conducted by the UK National Institute for Clinical Excellence in 2009. A systematic search was conducted using PubMed, MEDLINE, and The Cochrane Library for studies including pain and/or disability as outcome measures, yielding 13 studies. While the results of earlier studies question the advantage of the Dynesys® system, the most studies, with follow-ups as long as 52 months, reported significant, positive changes in pain and disability. These results are limited by the predominant use of case studies.

The Dynesys® system is designed for the dynamic stabilization of the lumbar spine to improve stability of the spine while lessening pain and disability without the rigid fixation found in more traditional systems. While the Dynesys® system uses a traditional pedicle-based system of screws, what makes it different is that it maintains anatomical features of the lumbar spine and uses flexible materials between the pedicles. Designed and developed in France, the Dynesys® system was first implanted in 1994.¹ Some facilities, like the Orthopaedic Clinic of the S. Chiara Hospital in Pisa, Italy, have been using this system since 1999.² The Dynesys® system has been used worldwide in more than 40,000 surgeries.³ A recent overview of this system is provided by Schwarzenbach and Berlemann.⁴

A comprehensive review of the literature on the Dynesys® system was conducted by the National Institute for Clinical Excellence (NICE) of the National Health Service (NHS) in the United Kingdom.⁵ They were unable to find any previously published reviews of the literature. This 2009 report by the NICE Interventional Procedures Program reviewed the literature on the effectiveness and safety of the Dynesys® interventional procedure of non-rigid stabilization techniques for the treatment of low back pain. This document reviewed outcome studies that included a total of 743 patients from 4 non-randomized comparative studies and 3 case series. The publication dates for these studies were, with one exception, from 2001 – 2007. The exception was one study published in 2009. Outcome measures for the

reviewed studies included range of motion (ROM) and further disc deterioration, with follow-up data as long as 75 months. They also looked at patient reported outcomes such as pain, quality of life, disability, and satisfaction. Safety of the Dynesys® system was also reviewed.

The review conducted by the NICE Interventional Procedures Program formed the basis for the NHS 2010 Interventional Procedure Consultation Document⁶ recommendations which concluded that Dynesys®, as a dynamic stabilization technique for some patients with intractable lumbar pain is both safe and efficacious. This cleared the way for spinal surgeons in the UK to offer Dynesys® as one of a range of treatment options.

The purpose of the current article is to provide an update on the results of studies that have been published since those reviewed in the NICE report.^v The one exception is the article published in 2009 cited in the NICE report.⁷ In the current update, a systematic search was conducted using PubMed, MEDLINE, and The Cochrane Library from 2008 through 2010. While more than 40 articles meeting these criteria were found, and from researchers world wide, only those studies using living human patients (as opposed to animals or cadavers), and only those related to the lumbar spine, were reviewed. Articles were also limited to those that included measures of pain and/or disability. This procedure yielded 13 studies, all of which are summarized herein.

STUDIES FROM 2008

Six relevant articles that considered pain and disability using Dynesys® were published in 2008. A summary of the findings of these five studies are as follows: Two of these early studies questioned the advantages of the Dynesys® System. viii, ix A third study, which looked only at radiological findings found that degeneration continued, which may have been due to the progressive nature of the disease. x The other three studies published in 2008 found more positive outcomes, with reports of Dynesys® as a possible alternative to traditional fusion, to “very good results,” to “excellent clinical and radiologic results.” Xi, Xii, Xiii A more detailed review of these studies follows.

A prospective study of 37 patients ⁸ who underwent decompression and the use of the Dynesys® System were evaluated 3 and 12 months post-operatively. While leg, back, and overall pain improved, lumbar pain did not, leading the authors to question the advantages of the Dynesys® System.

Another early study published in 2008 ⁹, questioned the superiority of the Dynesys® System when compared to traditional fusion when they looked at outcomes for 40 consecutive Dynesys® patients. Measures of pain and activities of daily living improved for 73% of the patients with an average follow-up of 16 months.

A 2008 prospective case study ¹⁰ of 32 patients who underwent spinal surgery (20 with Dynesys®; 12 with additional fusion at > 1 level) were examined to determine the radiologic changes in the intervertebral discs after the Dynesys® procedure. Pre-operative and 2-year post-operative MRIs were compared. Although these researchers found that disc degeneration at the bridged and adjacent segment continued, they could not rule out the possibility that natural disease progression caused the continuing degeneration.

For 20 patients who underwent decompression and the Dynesys® System where Visual Analogue Scale Leg Pain (VAS) and disability ratings using the Oswestry Disability Index (ODI) were measured, a 2008 study ¹¹ with more positive results after a 26 month follow-up found no implant failures, a preservation of motion in the stabilized segments, and clinical improvement. Unlike the previous two studies, these authors concluded that “dynamic stabilization systems with adequate decompression may be an alternative surgical option to conventional fusion.”

Positive findings were also reported in a prospective study ¹² published in 2008 that looked at 25 patients with degenerative lumbar spondylolysis and central canal stenosis who received the Dynesys® system. These researchers defined the results as “very good” if there was a relative gain results of more than 70%. Actually 72% of the patients in this study had results in the very good category and 28% in the “good” category (reflecting a relative gain of 40-70%). There were no patients whose outcomes were less than “good.” These results were obtained with a follow-up objective testing ranging from 2-6 years, with a mean follow-up of nearly 3 years.

Even more positive findings were reported in a prospective clinical study ¹³ published in 2008 that tested whether Dynesys® could maintain enough stability to prevent progression of spondylolisthesis in long-term follow-up. They used 26 consecutive patients whose symptoms included lumbar spinal stenosis and degenerative spondylolisthesis and who underwent decompression and stabilization with Dynesys®. Patients were evaluated clinically and radiologically with an average follow-up of 52 months. Pain and walking distance, which improved by year 2, were maintained at follow-up. Radiological findings were that spondylolisthesis did not progress and the spinal stability remained over time. In this study, 95% of the patients reported that they would have the same procedure again. The conclusion of these researchers was that the Dynesys® system produced significantly positive clinical and radiologic results.

STUDIES FROM 2009

2009 found two studies that looked at improvement associated with the Dynesys® System, but only one of which was published. The 2009 published study ¹⁴ consisted of a retrospective radiographic analysis of lumbar spine range of motion (ROM) after fusion as compared to Dynesys® system for 26 patients. The results revealed a significant reduction of the global ROM of the lumbar spine and the ROM of the fused segment in the fusion group, whereas adjacent level ROM did not change significantly. In contrast, no significant changes of global lumbar spine ROM and segmental ROM were seen in the Dynesys® group. While no data was provided for VAS or ODI, the relative superiority of ROM for Dynesys® is an important finding.

The other study, while not published in a journal, was issued as a report by the Food and Drug Administration of the U.S. Department of Health and Human Services in 2009. ¹⁵ An

FDA Panel issued an Executive Summary on the Dynesys® system, reporting on the results of a randomized controlled study comparing the Dynesys® system with traditional fusion. The goal of the study was to demonstrate the equivalence (non-inferiority) of the Dynesys® system with more traditional fusion. The primary measures that went into the determination of Overall Clinical Success were the VAS, ODI, neurological status, complications, and any additional surgery after a 24 month post-operative period. As predicted, the results of the two procedures were similar on most measures (e.g., very few complications or second surgeries). However, the study showed statistically better results on VAS Leg Pain success for Dynesys® (87%) than traditional fusion (73%) patients. Furthermore, the Overall Clinical Success rate for Dynesys® patients (52%) was significantly greater than for traditional fusion patients (40%). The outcome of the Advisory Panel vote was a failure to support approval of Dynesys® as a stand-alone procedure; however, Dynesys® can still be used as an adjunct to fusion. The panel was able to see the potential of the Dynesys® system as being able to:

preserve motion at the treated segment, which may reduce the incidence of symptomatic adjacent-segment disease. In addition, implantation of Dynesys is intended to be a less invasive procedure than fusion procedures which require autograft harvest. Therefore, it may reduce the intra-operative and postoperative morbidity and may allow earlier return to activity.

STUDIES FROM 2010

2010 was a productive year for research on Dynesys® in that five studies, all providing positive findings, were published this year. One study¹⁶ followed 102 patients who had received the Dynesys® system for 36 months. The results of this study indicated Dynesys® improved subjective feelings, morphological findings, pain, and functional status in the patients with Degenerative Disc Disease (DDD) in the three-year post-operative period. The conclusions stated that the Dynesys® System had salutary effects of the patients' quality of life.

A retrospective study¹⁷ reported on the incidence rate and effect of pedicle screw loosening with the Dynesys® system. Using radiographic films over an average follow-up of 16 months, Ko et al., found an average per screw loosening rate of 4.6%. Screw loosening, however, had no effect on clinical improvement measured by VAS and ODI.

Another recently published study¹⁸, using consecutive case studies of 31 patients, found a lower rate of screw loosening (0.45%) over an average follow-up period of 39 months. The uniqueness of this study was that it combined the use of Dynesys® at some segments and interbody fusion at other segments. Using VAS and ODI, the authors concluded that Dynesys® is a safe and effective surgical treatment for multilevel DDD.

Even for patients with degenerative lumbar scoliosis, a study with 29 patients in their 60s demonstrated that the Dynesys® system with decompression reduced disability and pain by approximately 50%. It was also shown to prevent the progression of scoliosis and spinal instability.¹⁹

Another recent study²⁰ using a radiological prospective clinical design with the Dynesys® system followed 6 patients using postoperative radiographs to measure flexion, extension, bending and 3-dimensional reconstruction. Repeated measures were taken up to 2 years postoperatively. The researchers found support for Dynesys® to stabilize degenerative spondylolisthesis, but also noted the limited ROM compared with normal spinal motion.

DISCUSSION

This review focused on research for the years 2008-2010 primarily concerned with safety, pain and disability of patients treated with a surgical system, Dynesys®, for the dynamic stabilization of the lumbar spine. Two early studies in 2008 questioned the superiority of Dynesys® when compared with traditional fusion and a third study found that degeneration continued, in all likelihood as a result of the disease process. The majority of studies, even in 2008, with follow-ups as long as 52 months, reported major, positive changes in VAS Pain and ODI disability, concluding that Dynesys® is a viable alternative to traditional fusion, with one study concluding "excellent results," with 95% of patients reporting they would have the surgery again.

The majority of articles since then have produced positive results. Hundreds of patients have been involved in case studies. The weakness of the current studies on dynamic stabilization with Dynesys® is, with the exception of the FDA-referenced study, the research lacks the rigor of randomized clinical trials, instead utilizing case study methodologies. While most of the studies were prospective or retrospective rather than using more robust designs, the sheer number of studies, consistency of positive results using a variety of different measures, and with long term follow-

up, certainly provide support for the use of this procedure. Future strength in support of the Dynesys® system will come from improved experimental designs. Another limitation of current studies is the use of the Dynesys® for one or two levels of lumbar stabilization. Also of interest would be findings for more than two levels of stabilization which was the limit for most if not all of the patients included in the studies reviewed.

The results of the publications reviewed indicate that Dynesys® is safe, with reductions in pain and disability as much as 50%, and with positive results even when there is screw loosening. There are even indications that the Dynesys® System can stabilize degenerative spondylolisthesis and spinal instability. Moreover, Dynesys® was shown to be superior on some measures (e.g., ROM) and is noted, because it is less invasive, as having fewer risks associated with it. In fact, one recent article²¹, Long Term Results of the Dynesys System, concluded that “[t]he results in patients with spinal stenosis with or without degenerative spondylolisthesis can be considered good.”

Future research should also consider factors that predict which patients are most likely to benefit from dynamic stabilization systems. Given that current evidence is not able to point out specifically which patients are most likely to benefit from this system, we support the NICE recommendation vi that relies on physician experience and the unique circumstances of each patient: “Patient selection should be carried out by specialist spinal surgeons who are able to offer patients a range of surgical treatment of surgical treatment options.”

References

1. Davis, R. J. Dynesys Dynamic Stabilization System. In JL Yue, R Bertagnoli, PC McAfee, & HS An (Eds). *Motion Preservation Surgery of the Spine: Advanced Techniques and Controversies*. Philadelphia: Saunders, 2008, 465.
2. Calvosa, G., Dubois, G., Tenucci, M., et al. *Rehabilitation in the dynamic stabilization of the lumbosacral spine*. Heidelberg: Springer Medizin Verlag, 2008.
3. Posted on the ORTHOSuperSite November 4, 2009. Downloaded October 15, 2010 from <http://www.orthosupersite.com/view.aspx?rid=50313>
4. Schwarzenbach O, Berlemann U. Dynamic posterior stabilization with the pedicle screw system DYNESYS®. *Oper Orthop Traumatol*. 2010; 22: 545-57.
5. NICE Interventional Procedures Program (October 2009). *Interventional procedure overview of non-rigid stabilisation techniques for the treatment of low back pain*. Downloaded September 26, 2010 from <http://www.nice.org.uk/nicemedia/live/11204/49541/49541.pdf>
6. NICE Consultation Document. *Non-rigid stabilisation techniques for the treatment of low back pain - Consultation Document*. Downloaded September 26, 2010 from <http://www.nice.org.uk/guidance/index.jsp?action=article&o=49540>.
7. Cakir B, Carazzo C, Schmidt R, et al. Adjacent segment mobility after rigid and semirigid instrumentation of the lumbar spine. *Spine* 2009; 34: 1287-91
8. Würigler-Hauri CC, Kalbarczyk A, Wiesli M, et al. Dynamic neutralization of the lumbar spine after microsurgical decompression in acquired lumbar spinal stenosis and segmental instability. *Spine* 2008; 33: 66-72.
9. Bothmann M, Kast E, Boldt GJ, et al. Dynesys fixation for lumbar spine degeneration. *Neurosurg Rev*. 2008; 31: 189-96.
10. Kumar A, Beastall J, Hughes J, et al. Disc changes in the bridged and adjacent segments after Dynesys dynamic stabilization system after two years. *Spine* 2008; 33: 2909-14.
11. Lee, SE., Park, SB, Jahng, TA, et al. Clinical Experience of the Dynamic Stabilization System for the Degenerative Spine Disease. *J Korean Neurosurg Soc*. 2008; 43: 221–226.
12. Ricart O, Serwier JM. Dynamic stabilisation and compression without fusion using Dynesys for the treatment of degenerative lumbar spondylolisthesis: A prospective series of 25 cases. *Rev Chir Orthop Reparatrice Appar Mot*. 2008; 94: 619-27.
13. Schaeren S, Broger I, Jeanneret B. Minimum four-year follow-up of spinal stenosis with degenerative spondylolisthesis treated with decompression and dynamic stabilization. *Spine* 2008; 33: 636-42.
14. Cakir B, Carazzo C, Schmidt R, et al. Adjacent segment mobility after rigid and semirigid instrumentation of the lumbar spine. *Spine* 2009; 34:1287-91.
15. FDA Orthopedic and Rehabilitation Devices Panel. (November 2009). *FDA Executive Summary for Zimmer Spine's Dynesys Spinal System*. Downloaded October 7, 2010 from <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/OrthopaedicandRehabilitationDevicesPanel/UCM188734.pdf>
16. Cienicala J, Chaloupka R, Repko M, et al. Dynamic neutralization using the Dynesys system for treatment of degenerative disc disease of the lumbar spine. *Acta Chir Orthop Traumatol Cech.*, 2010; 77: 203-8.
17. Ko CC, Tsai HW, Huang WC, et al. Screw loosening in the Dynesys stabilization system: radiographic evidence and effect on outcomes. *Neurosurg Focus*. 2010; 28:E10.
18. Schwarzenbach O, Rohrbach N, Berlemann U. Segment-by-segment stabilization for degenerative disc disease: A hybrid technique. *Eur Spine J*. 2010;19:1010-20.
19. Di Silvestre M, Lolli F, Bakaloudis G, et al. Dynamic stabilization for degenerative lumbar scoliosis in elderly patients. *Spine*. 2010; 35: 227-34.
20. Fayyazi AH, Ordway NR, Park SA, et al. Radiostereometric analysis of postoperative motion after application of dynesys dynamic posterior stabilization system for treatment of degenerative spondylolisthesis. *J Spinal Disord Tech.*, 2010; 23:236-41.
21. Klöckner C. Long-term results of the Dynesys implant. *Orthopade*. 2010; 39:559-64.

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