# STABILIZATION WITHOUT FUSION, WITH DYNESYS

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The process of spinal disc degeneration is natural. It is a silent process, which means that it is painless process. But from time to time, problems will occur in the lumbar spine if the inter-vertebral stability is questionable and no longer asymptomatic. Spine stabilization with dynamic neutralization restores normal segmental rigidity and returns the patient to the natural vertebral disc aging process. Dynesys implantation is one step toward slowing down detrimental progression in the lumbar spine. During the course of the natural evolution of vertebral disk degeneration starting from incipient diskopathy up to stenosis with fixed terminal deformation, the functional tripol (disk and facets) will experience a long period of destabilization with abnormal movements. Dynamic stabilization with the Dynesys Dynamic Stabilization System (Zimmer Spine, Inc., Warsaw, IN) provides distinct benefits in the phase of degeneration where symptoms are caused by diskovertebral dyskinesis ; that is, between early stages of symptomatic degenerative changes of the spinal segment and structural deformities associated with spontaneous ossification. The goal of dynamic stabilization with Dynesys is to realign and stabilize one or more intervertebral lumbar or lumbosacral segments in a position close to the normal anatomical position, with the intent of encouraging return to improved intervertebral physiology while enabling a certain degree of range of motion. At the present time, more than 45 000 surgical procedures have been performed in over 15 different countries. The longest follow-up period is 17 years.

**Technical Aspects:** To achieve this goal, Zimmer has developed a dynamic stabilization system called Dynesys (Dynamic Neutralization System for the Spine). The Dynesys system consists of titanium alloy (Protasul 100) pedicle screws, polyester (Sulene-PET) cords and polycarbonate-urethane (Sulene-PCU) spacers. The cord and the spacer meet the International Standards Organization (ISO) 10993 international standards and the pedicle screws fulfill those of ISO 5822-11. The cord controls the range of motion in flexion, whereas the spacer limits extension movements, enabling the posterior elements to be repositioned in accordance with a near normal anatomical situation. All individual components and interconnections were tested for their static as well as for their dynamic behavior to assess the safety of the system. Fatigue testing of the complete assembly was performed to 10 million cycles, which is believed to represent a time in vivo of approximately 5 years. In an initial phase (1-2 million cycles), the system showed stress relaxation and remained stable at a substantial load level afterward. The same remarques was done with a recent animal study with baboons. Several biomechanical in vitro experiments were conducted to study the efficacy of the system. One recently published study tested six lumbar cadaver spines, loading them with pure moments in the three motion planes. The spines were tested intact, with a defect of the middle segment, stabilized with Dynesys, and fixed with an internal fixator. For the instrumented segment, Dynesys stabilized the spine and was more flexible than the internal fixator, particularly in extension where Dynesys restored the range of motion to the intact condition. A second in vitro study found that increased spacer length increased the mobility in the segment. These biomechanical studies have confirmed that the stiffness of an instrumented segment was close to that of an intact spinal column. It therefore reinstates stiffness of the destabilized spinal segment on an experimental basis to a degree close to that of a normal and intact spine. This internal bracing device enables the posterior elements, annulus, and posterior longitudinal ligament to be retensioned. It repositions the articulating

surfaces to the areas in which they function normally, suppresses dyskinetic movements caused by loss of viscoelasticity of the disk, and restores the posterior pretensioning. It thus brings about anatomical conditions of the intervertebral joint that enable restoration of a better diskovertebral physiology, allowing a certain degree of freedom to be preserved due to the elasticity of the spacer. It limits the impact of the biomechanical stresses on the adjacent levels. This device shows some potential for healling to take place in the disk space as well as in the end plates (see Performance).

**Indications:** The indications for Dynesys are based upon their design and biomechanical effects. Dynesys addresses instabilities of all kinds : excessive or pathological motion and gradually developing deformity, including iatrogenic instability. This may involve low back pain as well as neurogenic pain. The main goal of Dynesys is to address dynamic instability with autoreducible lesions in the early stages of degeneration as defined by Kirkaldy-Willis. As a result of the instability, the patient may experience several types of clinical symptoms. These include dynamic stenosis or stenosis with degenerative olisthesis as evidenced by either or both neurogenic pain and low back pain. Other indications for Dynesys are mono-or multisegmental denegerative disk disease (DDD) causing low back pain as well as iatrogenic instability following decompression. Just kyphotic deformation is a contra indication for DYNESYS ® alone. In multilevel DDD, Dynesys may also be combined with a fusion procedure such as posterior lumbar interbody fusion (PLIF) ; depending on the severity of segmental disk disruption. In case of long fusion with trans pedicular or trans articular osteotomies we prefer today, to use D.T.O. (DYNESYS TRANSITION OPTIMA®) with long rod and cord on line.

**Surgical Technique:** The surgical approach is along the median line, opening the lumbar aponeurosis, rasping the paravertebral muscles if the surgeon wishes to carry out intracanal activities aimed at associated decompression at the same time as the dynamic

stabilization procedure. If not intracanal procedure is needed and if the lesion is of the dynamic stenosis  type due to a soft lesion, then an intermuscular bilateral approach according to Wiltse or an intermuscular paraspinal approach can be performed. This approach does not interfere with the posterior muscles or the lumbar aponeurosis and provides direct access to be articular-transverse junction without interfering with the articulating surface and its capsule. It also enables the screw to be implanted at an angle that is almost always perfect.  Whatever approach is used, it is important not to interfere with the articular processes and their capsule. The point of intrapedicular penetration must be located at the external junction of the articular and transverse surfaces.  The steps for posterior compression or distraction of the heads of the screws enable determination of the exact length (6-45mm) of the spacer that is required. This choice depends on the pathology being treated and on the degree of stabilization to be achieved.  With interpedicular distraction, the length of the spacer must ensure that the end plates of the level where Dynesys is implanted are perfectly parallel to avoid causing kyphosis of the segments. Restoration of lordosis of the segments may be left to the surgeon's discretion ; however, hypercompression of the facet joints must be avoided under all circumstances because this may be detrimental to the appropriate functioning of the device as well as contrary to the underlying concept.  The assembly is completed with insertion of the cord and tensioning of the system. (pretensioning to three hundred newtons is needed).

Performance Treatment of unstable mobile discopathies, in particular with restoration of stability, has previously consisted of medical and physical procedures. In cases of prolonged failure and as long as the displacements can be dynamically reduced, surgical stabilization, such as with the Dynesys, can be suggested.  At best, the images accompanying clinical improvement clarify the contribution of dynamic stabilization toward restoring improved anatomy and physiology of the stabilized segment. The first effect is been in postoperative myelograms, which show that the posterior annulus no longer bulges during

flexion-extension movements. This is probably one of the reasons for the improvement of pain because the posterior longitudinal ligament is highly reflexogenic. In addition, various « regeneration » phenomena have been described anecdotally by Dynesys users. One prospective cohort study specifically addresses this. In a consecutive series of 110 patients, Specchia found that after implantation of the Dynesys, Modic type I changes had disappeared at the time of follow-up. This has also been found in other hospitals. Modic type I changes have been described as being a strong predictor of a painful disk and also of having some correlation with pain and function in general. Also, in 10% of the patients, a partial restoration of the T2-weighted magnetic resonance imaging (MRI) signal of the nucleus occurred. The latter is a strong indicator for disk rehydration. This finding is in accordance with the results of an experimental study in New Zealand white rabbits where it was found that degenerated dehydrated disks may regenerate after undergoing dynamic distraction. As a whole, these observations suggest that the persistence of mechanical problems contributes to the biochemical phenomenon of degeneration. Due to the suppression of the intravertebral dyskinesis, an actual healing process of the annula rand then of the intradiskal lesions may take place. It is possible to imagine the following repair sequence : Suppression of the parasitic movements that cause the problems between the disk and the end plates (that may alos interfere with nutrient exchange) to persist due to mechanical instability. Mechanical neutralization which, due to suppression of the bulging, would enable healing with disappearance of the neovascularization at the level of the annular lesion.

Reestablishing new centers of rotation of the segment that suppresses segmental hyperpressure. This will foster the disappearance of neovascularization at the level of the end plates and will probably enable resumption of exchange between the subchondral bone and the intradiskal environment, which can enable rehydration in a later stage and, perhaps, reorganization of the nuclear structure. Because the intradiskal liquid can be mobilized by

the effect of pressure, and these pressures are redistributed and returned to a situation that resembles normality more closely, the alternating movements may be restored between the subchondral bone and the intradiskal environment. Given that this movement of liquid governs the balance between cell anabolism and catabolism, it will allow restoration of the fundamental substance, consisting of a highly hydrated proteoglycan gel inside the network of collagen (mainly type II). This interpretation was prompted by the clinical improvement of those patients who had benefited from dynamic stabilization and by the findings of the radiological follow-up. But till now it's a purely intellectual construction.

**Clinical Results:** Some high-quality studies are in progress, and several peer-reviewed journal publications on Dynesys are already available. Stoll TM et al presented their first results with Dynesys in 2002. Their prospective, multicenter study evaluated the outcome of a consecutive series of 83 patients treated with Dynesys for lumbar instability conditions, the pathology mainly involving lumbar stenosis (60% of patients) and degenerative diskopathy (24%). Thirty patients had had previous lumbar surgery. The mean age at operation was 58.2 (range 26.8-85.3) years ; the mean follow-up time was 38.1 months (range 11.2-79.1). In 56 patients the Dynesys instrumentation was combined with a direct decompression procedure . Pain, function as measured by the Oswestry Disability Index (ODI), and radiological data were evaluated pre-and postoperatively and improved significantly from baseline to follow-up as follows : back pain scale from 7.4 to 3.1, leg pain scale 6.9 to 2.4, Oswestry Disability Index 55.4 to 22.9%. Most of the complications were unrelated to the implant. Additional lumbar surgery in the follow-up period included implant removal and conversion into spinal fusion with rigid instrumentation for persisting pain in three cases, laminectomy of an index segment in one case, and screw removal due to loosening in one case. In seven patients, adjacent segment degeneration necessitated further surgery. The authors concluded that the study results compare favorably to those obtained by

conventional procedures : however, mobile stabilization is less invasive than fusion. The natural course of polysegmental disease in some cases necessitates further surgery as the disease progresses. Dynamic stabilization with Dynesys proved to be a safe and effective alternative in the treatment of unstable lumbar conditions. Cakir B et al published a retrospective comparative study in 2003 where they analyzed the functional outcome (ODI) and the quality of life (short form (SF) – 36 Health Survey) of patients with degenerative lumbar instability with spinal stenosis who underwent decompression surgery with posterior dynamic stabilization. In a small group of patients (n = 20), they showed a slightly better outcome for the Dynesys group. Furthermore, hospital stay and operation time where much shorter in the nonfusion group. They conclude that dynamic stabilization seems to be a promising alternative to fusion in patients with degenerative instability with spinal stenosis but point out the need for bigger studies. Putzier et al compared the outcome after implantation of Dynesys in three different indication groups in 2004. The compared patients with disk herniation (N=35), spondylarthrosis/early osteochondrosis (N=22), and severe degenerative changes (i.e., Modic II and III or spondylolisthesis up to grade II) (N=13) using functional (ODI) and pain [visual analog scale (VAS)] outcome parameters. After a follow-up time of 33 months, they found that Dynesys yielded very good results in the first two groups but was not advisable for use in marked deformities. But in an other hand we know today the works of DI SILVESTRE that shows interesting result with DYNESYS in the eldest patients with degenerative scoliosis comparing to conventional fusion. The same group of researchers matched the subgroup of disk herniation patients of the previous study to a historical control group (N=49) with the same pathology that had only received a nucleotomy. In addition to the functional and pain outcome, they also analyzed the radiological outcome. At the time of follow-up (34 months), the patients who had received a Dynesys had a better functional (ODI) and pain (VAS) outcome than the other group. Besides this, progression of segmental

degeneration was observed radiologically in 12% of the patients who had undergone sole nucleotomy and not in a single patient in the group where in addition Dynesys had been implanted. The autors conclude that Dynesys is useful to prevent progression of initial degenerative disease after nucleotomy. Currently, our own series on patients with DDD and stenosis treated with Dynesys are being analyzed separately and will be published soon. Further publications on comparative studies are in preparation.

**Discussion:** Dynamic stabilization with Dynesys is therefore indicated for mobile and self-reducible lesions when they occurduring diskovertebral degeneration. The suppression of parasitic movements enables improvement of the pain symptoms and the appearance of healing at both the posterior and nuclear annular-ligamentary level and at the level of the endplates and articular processes. Due to the preservation of a certain degree of freedom in an area that functions normally from the anatomical point of view, this facilitates a return to local conditions that foster healing of the cartilaginous structures. Achieving this moderate postoperative intervetebral mobility is, moreover, the most important problem because it means that primary fixation of the pedicle implants must be absolutely perfect, with no technical error what ever and, in particular, no screw back-out during implantation because of the conical shape of the screw. The postoperative findings, based in particular on radiological examination of the patients, raised several questions and have encouraged us to envision other stages of research to achieve better histological understanding of the end plate lesions as described by Modic, and their possible reversibility. We should also consider studies on the disk, which appear to be even more complex, involving both histological and biochemical concepts. In any case, healing phenomena do seem to exist, at least in the initial phase ; that is, during the mobile phase of diskovertebral degeneration, and this should inspire great restraint in the future when faced with surgical choices. Irreversible procedures should probably be considered only when the lesions themselves are also irreversible.

**Conclusion:** * At the present time, (2011) we believe it is possible to conclude that the concept of dynamic stabilization with Dynesys does have a place in the treatment of degenerative diskovertebral lesions. It deals in particular with the period of dynamic instability with mobile lesions that can still be self-reduced. The best example is probably dynamic stenosis and its clinical variants. The concept of dynamic stabilization is served well by the Dynesys system, which enables stabilization without fusion, preserves a controlled rang of motion that facilitates local healing, and lowers the impact on the adjacent segments.

It is advisable to analyze the true place of the Dynesys, in particular in the framework of subligament herniating diskopathy. This indicates local instability confirmed by abnormal intervertebral movements shown by dynamic imaging. Implanting pedicle screws constitutes the crucial point of the surgical procedure and requires technical perfection to optimize primary stability. All the results of retrospective EU studies (14) are now confirmed by the randomised prospective I.D.E study made in USA (Maxwell, Davis, Wingate, Anaud, Delamater- SAS 2006-2007, 2008-AAOS 2009) as well as the maintenance of disc height and lordosis following Dynesys implantation.

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