

Screw Loosening after Posterior Dynamic Stabilization – Review of the Literature

Uvolnění šroubů po zadní dynamické stabilizaci – přehled literatury

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ABSTRACT

PURPOSE OF THE STUDY

The malposition of pedicle screws in the lumbar spine is associated with a potential risk of iatrogenic injury of neurological structures but also with a decrease of biomechanical stability. The correct position of the pedicle screws of a dynamic stabilization device, as a long-term implant, seems to be of great importance. A high incidence of screw loosening could influence both the rate of revision surgeries and the clinical results. We compared screw loosening in our own patients with published data after navigated and non-navigated implantation of Dynesys.

MATERIAL AND METHODS

Posterior instrumentation with the Dynesys system was performed in 19 patients after improvement of facet joint infiltrations. Seven (37 %) patients underwent conventional surgery (group I), five (26 %) were operated on using a CT-based navigation (group II) and seven (37 %) using a fluoroscopic-based navigation (group III). Pre-operatively, the "Oswestry Low Back Pain Disability Questionnaire (OQ)" and the "Short Form 36 Health Survey Questionnaire (SF-36)" were used to obtain pain and functional scores. Furthermore, radiographs, MRI and CT examinations were performed before surgery. Screw position was analyzed on post-operative CT scans. At a minimum follow-up of twelve months, clinical examination, plain and dynamic X-rays were performed, and pain and functional scores (OQ, SF-36) were obtained.

RESULTS

Pedicle perforation of minimum 2 mm was detected in two group I patients, in one group II and in two group III patients. Regarding OQ and SF-36, an improvement was observed in all patients, except for one column of SF-36. One patient (group I) underwent revision surgery due to symptomatic screw loosening and another patient (group III) due to persistent pain without signs of screw loosening.

DISCUSSION

In former publications the majority of patients improved after Dynesys implantation with or without the use of navigation methods. Malposition of screws was not always followed by screw loosening. Revision surgery due to screw loosening, but without clinical symptoms, was not necessary in the majority of cases.

CONCLUSIONS

It still remains unclear if screw loosening after Dynesys implantation influences the clinical results or the rate of revision surgery and if malposition of screws will be followed by a higher rate of screw loosening.

Key words: dynamic stabilization, Dynesys screw loosening navigation lumbar spine.

INTRODUCTION

In recent years, several non-fusion devices for the lumbar spine has been introduced. For anterior dynamic stabilization implants were developed, which replace the complete intervertebral disc with a prosthesis (12) or the nucleus pulposus with an elastic spacer under protection of the anulus fibrosus (8, 17). Posterior dynamic stabilization devices comprise, amongst others, interspinous implants (21) and posterior pedicle screw based systems. The Dynamic Neutralization System for the lumbar spine (Dynesys™, Zimmer®, Warsaw, USA) (2, 20) consists of pedicle screws, cords and spacers (Figure 1). The cords should limit the flexion bend and the spacers the

extension bend. The facet joints and the intervertebral discs should be unloaded, segmental motions should be controlled and the segmental alignment should be restored.

However, the placement of pedicle screws in the lumbar spine is a challenging and risky procedure. Neurological complications due to perforations of the spinal canal or the neuroforamen are not rare (3). To reduce the rate of misplaced pedicle screws, computer navigation was developed in recent years. Laine et al. (9) could demonstrate in their study, that pedicle screws could be implanted more accurately and safely with CT based navigation in comparison to the conventional method. In the following years, fluoroscopic based navigation

systems were developed, which promised lower rates of misplaced pedicle screws compared with conventional insertion techniques (6). A misplacement of pedicle screws can affect the biomechanical stability of the system besides the iatrogenic injury of neural structures, which depends on the screw positioning in the pedicle and the vertebral body (1).

The correct pedicle screw position within the dynamic stabilization is important, because this system is theoretically a long term implant. Misplacement of pedicle screws could influence the rate of revision surgeries and the clinical long term results. Therefore, we compared own results with reported values in the literature. The aim of the current study was to evaluate the reported incidence of screw loosening and whether the implantation of Dynesys with conventional and navigated procedures causes different results regarding rates of loosening, revision surgeries and the clinical results.

MATERIAL AND METHODS

Indications for Dynesys implantation were degenerative disc disease, degenerative spondylolisthesis with spinal canal stenosis, degenerative scoliosis and symptomatic spondylarthropathy. The patients complained of lumbalgia with or without ischialgia and varying degree of reduction of walking distance. Improvement (>50 %) after infiltrations of the facet joints with local anaesthetics on the operating segments was also a prerequisite for surgery. Preoperatively the „Oswestry Low Back Pain Disability Questionnaire (OQ)“ and the „Short Form 36 Health Survey Questionnaire (SF-36)“ were obtained as pain and functional scores. Concerning this matter, the importance of evaluation of the quality of life in patients with degenerative disorders of the lumbar spine was exactly explained (13).

Furthermore, X-rays in two planes and dynamic X-rays in sagittal plane in flexion and extension of the lumbar spine were performed before surgery. Every patient achieved additionally MRI and CT examination with pedicle parallel reconstructions.

The surgical duration, the perioperative blood loss, the number and level of instrumented and decompressed segments, and the number of pedicle screws were documented. The follow-up was minimum twelve months.

At follow-up, a clinical examination, plain X-rays (ap; lateral view) and dynamic X-rays (flexion/extension) of the lumbar spine were performed as well as pain and functional scores (OQ, SF-36) were obtained.

RESULTS

The posterior instrumentation with Dynesys was performed in 19 patients with a median approach to the lumbar spine. The pedicle screws were implanted with the conventional method according to Magerl. Seven (37 %) patients underwent conventional surgery (group I), five (26 %) patients were operated with CT based navigation (group II) and seven (37 %) patients with fluoroscopic

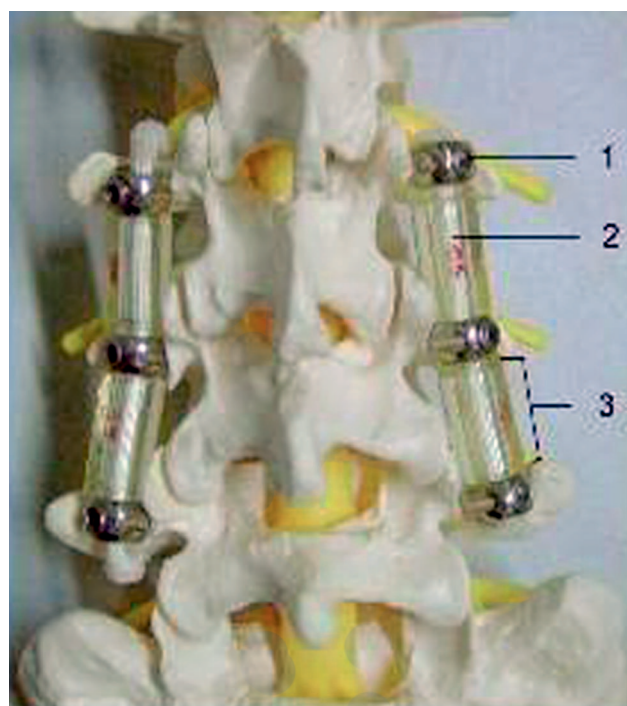


Figure 1. Dorsal aspect of the Dynesys at a „sawbone model“, consisting of pedicle screws (1), cords (2) and spacers (3)

based navigation (group III). If a spinal canal stenosis was present, a selective decompression with excision of hypertrophic ligamenta flava and undercutting of the facet joints were performed.

Evaluation of screw position was accomplished on postoperative CT scans. The screw position in the pedicle was defined according to Ebmeier et al. (4) (Table 1). Postoperatively, neither neurological complications nor infection signs were observed in all three groups. Screw breakages or other implant referred complications were not documented.

Table 1. Classification of the postoperative screw position in the pedicle relating to Ebmeier et al. (4)

Screw position in the pedicle
• no perforation
• perforation of 1 and 2 mm
• perforation of 3 and 4 mm
• perforation over 4 mm

Table 2. Accurate evaluation of the screw position in the three groups

Patient	group I (conventional)	group II (CT based)	group (fluoroscopic based)
1	1 mm (3x)	1 mm (1x)	1 mm (2x), 2 mm (1x)
2	1 mm (4x)	no perforation	1 mm (2x), 2 mm (1x)
3	no perforation	1 mm (3x)	no perforation
4	1 mm (2x), 2 mm (1x)	2 mm (1x)	1 mm (1x)
5	1 mm (2x)	1 mm (2x)	no perforation
6	1 mm (3x), 4 mm (1x)	---	1 mm (1x)
7	1 mm (2x)	---	1 mm (5x)

Figure 2. Preoperative and postoperative results of the Oswestry Low Back Pain Disability Questionnaire (OQ) in the different groups

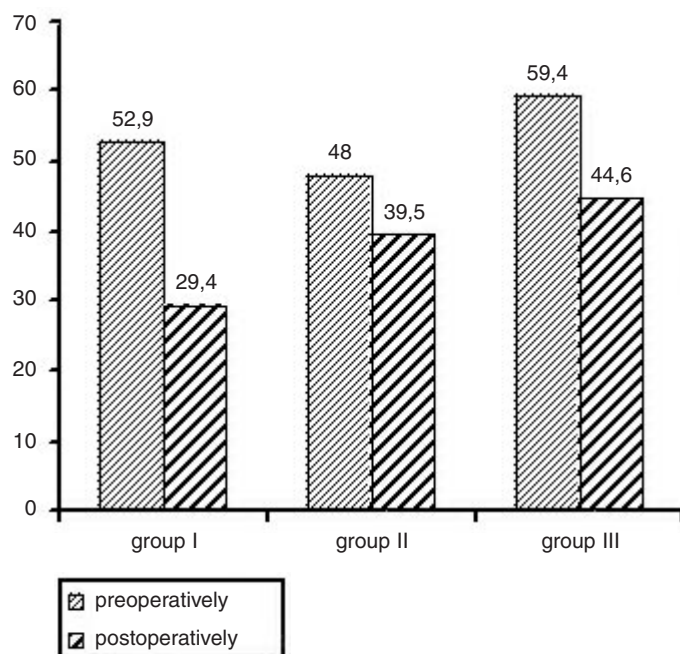
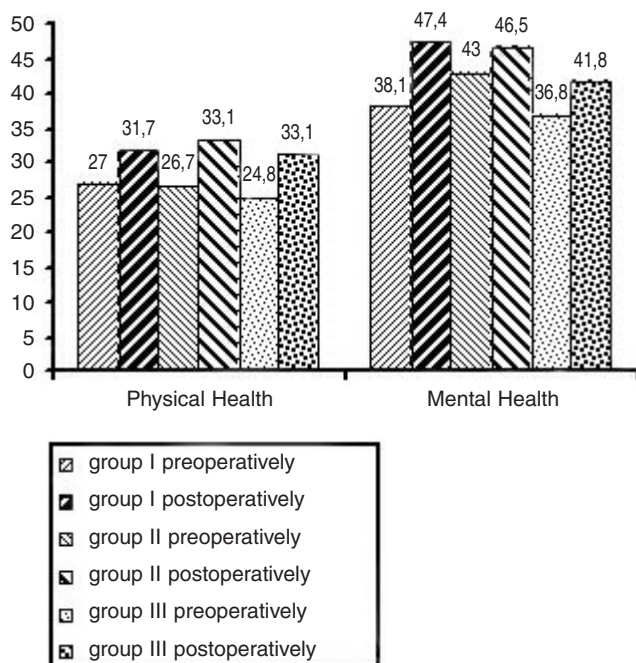
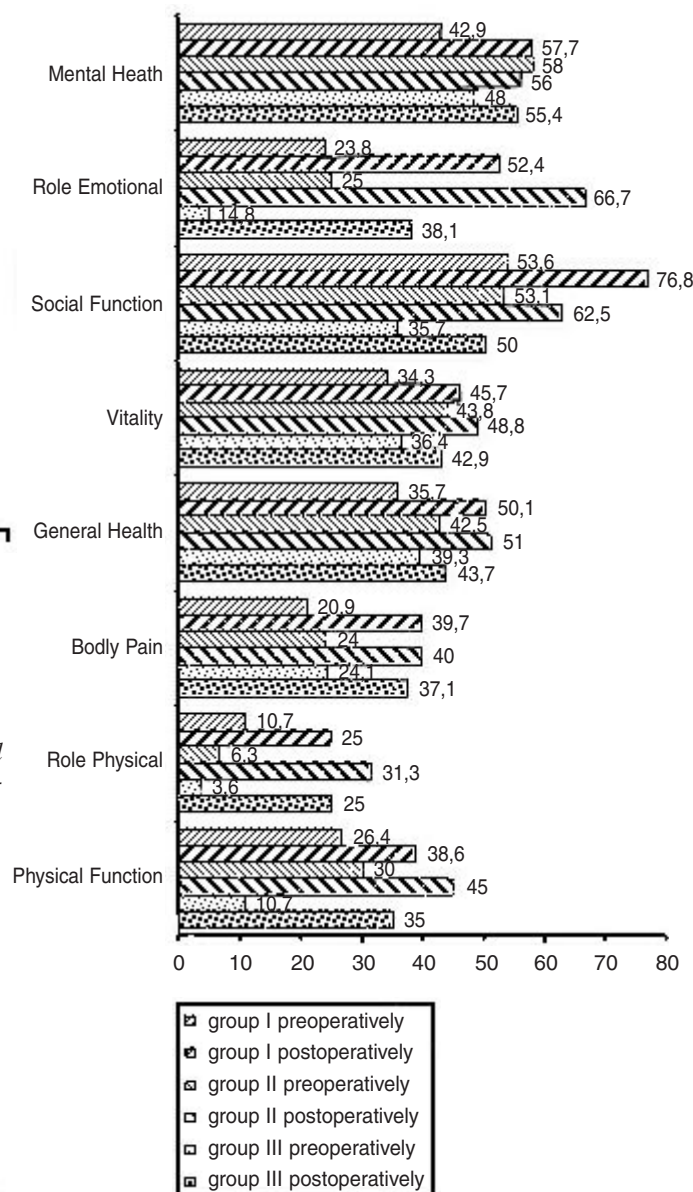


Figure 3. Preoperative and postoperative results of Physical and Mental Health in Short Form 36 Health Survey Questionnaire (SF-36) in the different groups



Regarding the postoperative screw position, a pedicle perforation of minimum 2 mm, confirmed by CT examination, was detected in group I in two of seven patients, in group II in one of five patients and in group III in two of seven patients (Table 2). Postoperatively, an improvement was observed with regard to OQ and SF-36 in all patients, except for one column of SF-36 (Figures 2, 3 and 4).

Figure 4. Preoperative and postoperative results of the different subgroups of SF-36 in the three groups



In one case with conventional surgical technique, Dynesys was removed one year postoperatively due to symptomatic screw loosening (Patient 5, Table 2) and a 270° fusion was performed (Figure 5). Same procedure was also necessary in one patient in the fluoroscopic based group after nine months due to persistent pain without signs of screw loosening (Patient 1, Table 2). There were no revision surgeries in the CT based group.

DISCUSSION

Although the posterior dynamic system Dynesys is used more than five years, no data exist until now concerning revision surgeries, which were caused due to screw loosening. Furthermore, there is insufficient knowledge of the influence of screw loosening on the clinical result.

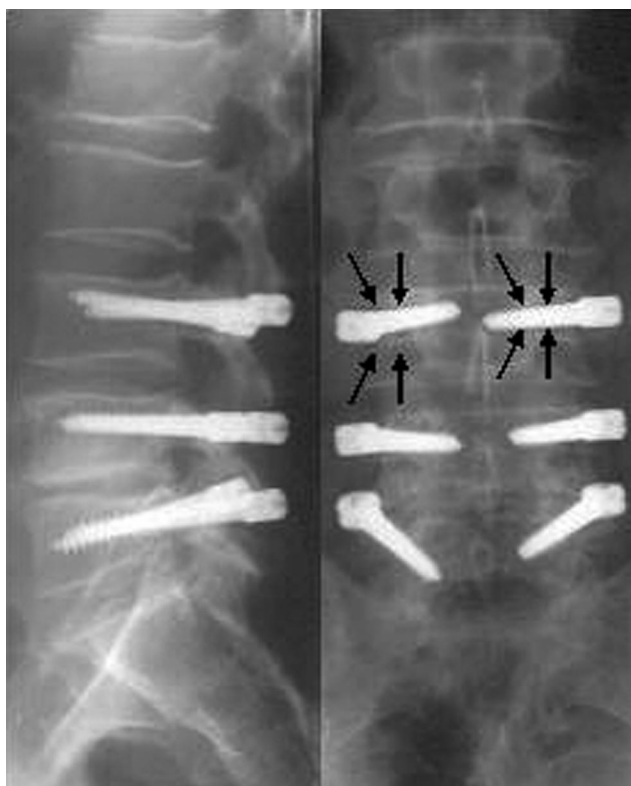


Figure 5. Plain X-rays of the lumbar spine (ap lateral view) with loosening of the pedicle screws in L3 after dynamic stabilization L3 to L5 (→ loosening signs)

Stoll et al. (20) have performed dynamic stabilization with Dynesys in 83 patients without navigation systems. In 56 patients the dynamic stabilization was combined with decompressive surgery. At least follow-up (averaged 38.1 months) the following implant based complications were observed: two patients (2.4 %) were diagnosed with screw malpositioning. One of these patients was revised due to nerve root alteration. Eight patients (9.6 %) had radiological signs of screw loosening in terms of a screw migration and / or lysis (definition of the authors). Seven of these eight patients had no complaint despite screw loosening. In one patient with clinical symptoms removal of two loosened screws without instrumentation was performed. The majority of screw loosening was observed less than six months postoperatively. After one year further screw loosening was not detected. The pain and functional scores (VAS, OQ, SF-36) showed a significant improvement at least follow-up.

In summary, the authors recommend the dynamic neutralization as an effective solution for the treatment of lumbar instability.

Putzier et al. (15) have implanted Dynesys in 70 patients also in conventional technique. The patients were divided preoperatively into three groups. Group I included 35 patients with initial disc degeneration and disc herniation. 50 % of these patients got additional nucleotomy. Group II included 22 patients with osteochondrosis and spondylarthrosis and group III 13 patients with

high-grade segmental degeneration or degenerative spondylolisthesis.

Plain X-rays (ap; lateral view) and MRI examinations were used three months postoperatively for determination of screw position. Within the follow-up period (averaged 33 months) screw loosening (2.9 %) was observed in two patients (one patient in group II and in group III). In both patients complete implant removal without instrumentation was performed. But the authors did not mention in both cases, whether screw loosening was accompanied by clinical symptoms. One screw breakage in group III was accompanied by increasing pain, which resulted in an implant removal and a dorso-ventral stabilization after 21 months. The Oswestry score and the VAS showed postoperatively a significant improvement in groups I and II, but not in group III. In conclusion, the implantation of Dynesys was not recommended with radiologically progressive deformities or planned decompressive surgery.

In another study of Putzier et al. (16) nucleotomy was performed in 84 patients with symptomatic lumbar disc herniation and initial disc degeneration. In 35 patients (42 %) Dynesys was used in addition without navigation systems.

At least follow-up period (averaged 34 months) screw malpositioning, screw breakage or screw loosening were not observed. For radiological evaluation plain X-rays (ap; lateral view) and MRI examinations were performed. The results have to be interpreted critically, because accurate identification of screw malpositioning and / or screw loosening could only be detected with CT scans. The OQ and VAS showed within the follow-up period a significant increase only in the non-stabilized group. In summary, the authors recommended the implantation of Dynesys for prevention of progressive disc degeneration after nucleotomy.

Schnake et al. (18) have performed a dynamic stabilization with Dynesys and additional decompression without the use of navigation systems in 26 patients with degenerative spondylolisthesis and accompanying lumbar spinal canal stenosis. Screw malpositioning was not observed with plain X-rays and dynamic X-rays. But it is remarkable, that screw positioning was judged only with X-rays and without additional postoperative CT scans. At least follow-up period (averaged two years) signs of screw loosening were documented in four of 24 patients (17%), and screw breakage in one case (4 %). Revision surgeries were not necessary due to missing clinical symptoms. A significant decrease of the leg pain and a significant improvement of the walking distance of the patients were documented. Implant referring complications had no influence on the satisfaction and the low back pain of the patient. Compared to Putzier et al. (15), the implantation of Dynesys with decompressive surgery due to degenerative spondylolisthesis with spinal canal stenosis was recommended as an alternative instead of fusion.

Grob et al. (7) were the only study group until now, which published their results after navigated implantation of Dynesys. Dynamic stabilization was performed

Table 3. Summary of published data concerning number of patients, navigation method, follow-up, screw malpositioning and screw loosening in comparison with own results

	Stoll et al. (20)	Putzier et al. (15)	Putzier et al. (16)
Year of publication	2002	2004	2005
Number of patients	83	70	35
Navigation method	no	no	no
Follow-up on average	38.1 months	33 months	34 months
Screw malpositioning (%) – revised	2 patients (2.4 %) – 1 patient (1.2 %)	no patient (0 %)	no patient (0 %)
Screw loosening (%) – revised	8 patients (9.6 %) – 1 patient (1.2 %)	2 patients (2.9 %) – all (2.9 %)	no patient (0 %)
Features	no	Screw breakage (1 patient) with revision	no
	Schnake et al. (18)	Grob et al. (7)	Our results
Year of publication	2006	2005	19
Number of patients	26	50	19
Navigation method	no	yes (24 % of the patients)	yes (63.2 % of the patients)
Follow-up on average	minimum 24 months	24 months	minimum 12 months
Screw malpositioning (%) – revised	no patient (0 %)	3 patients (6 %) – no patient (0 %)	no malpositioning – no patient (0 %)
Screw loosening (%) – revised	4 patients (17 %) – no patient (0 %)	4 of 31 patients (12.9 %) – all (12.9 %)	1 patient (5.3 %) – 1 patient (5.3 %)
Features	Screw breakage (1 patient) without revision	only half the patients profited	no

in 50 patients, additional decompression in 21 patients (42 %).

Computer navigation was used in twelve patients (24 %). Indications for the intervention were spondylosis, degenerative disc disease, spinal canal stenosis, degenerative spondylolisthesis and revision surgeries. Screw malpositioning was observed in three patients (two patients after navigated implantation) and screw loosening in one case (conventional technique) on plain X-rays. The averaged follow-up was two years in 31 patients (62 %). Implant removal and conversion to fusion was necessary due to screw loosening in four of 31 cases (12.9 %). However, the authors did not mention, whether screw loosening had influence on the clinical result and whether the revised patients got surgery with CT based navigation or with conventional technique. In summary, only half of the patients could profit by the dynamic system at least follow-up (averaged two years).

Nevertheless, most of the mentioned patients treated with Dynesys were satisfied, which could be confirmed by pain and functional scores. Similar results could be achieved for 360-degree spondylodesis with using the Visual Analogue Scale (VAS) and the Oswestry Disability Index (ODI) (11).

Due to our limited number of patients, statistical relevant differences regarding screw loosening, screw malpositioning and revision surgeries could not be shown compared with published results. Therefore, statistical calculations with more patient data would be necessary for the validity of our results. The rate of screw loosening for dynamic procedures seems to be not higher than for rigid instrumentations (14). Assimilable rates were documented for screw breakage (19).

Midterm results with dynamic systems are comparable to fusion. An overview of the literature concerning patient data, used navigation methods, follow-up examinations, screw malpositioning, screw loosening and special features compared to our results is presented in Table 3.

For insertion of pedicle screws, in most cases the conventional technique is used. Concerning this challenge, orientation in sagittal and transversal plane is complicated. Malpositioning of pedicle screws could cause neurological complications like nerve root or myelon lesions (10). Many studies about CT guided and fluoroscopic based navigation excluded a cumulation of these complications, although their appearance depends also on the experience of the surgeon (4, 5). High radiation exposure due to preoperative CT and high price of available systems are known as disadvantages of CT based navigation.

However, this navigation method is associated with an improved 3-dimensional orientation and can be used for difficult anatomical situations. Fluoroscopic based navigation is based on intraoperative images and screw placement can be performed without repetitive radiation exposure.

Until now, there are few studies about the implantation of Dynesys using navigation systems. In our opinion, a possible contact of the pedicle screw to the facet joint can influence the dynamic stabilization due to a possible impingement compared to fusion. Furthermore, accurate position of the pedicle screws, as a long term implant, seems to be of great importance for Dynesys.

Regarding our results, no significant influence on the clinical result was observed with the use of navigation methods. Concerning current studies, extreme malpositioning of pedicle screws could be avoided within greater patient populations due to computer navigation. However, not every screw malpositioning influences the surgical outcome (e. g. due to neurological problems). For this reason, possible advantage of computer navigation for the implantation of pedicle screws is not observed in greater patient populations yet. From biomechanical view, asymmetric screw positioning in the vertebral body seems to support the stability with regard to screw loosening.

In addition, the question arises whether screw loosening is always associated with worse clinical results. In this context, the patients with satisfying clinical results and screw loosening could be problematic, because no standardized procedure exists until now concerning this matter.

It is still unclear, whether revision surgery should be performed due to screw loosening without clinical symptoms. In case of revision another question arises, whether change of the loosened screw or conversion to fusion should be accomplished.

CONCLUSION

It remains to be seen, how far the clinical results and the rate of revision surgeries will be influenced due to screw loosening in long-term follow-up after implantation of Dynesys. In this regard, another question arises, whether better results can be achieved with navigation methods.

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