Dynamic Neutralization: A New Concept for Restabilization of the Spine

G. Dubois, B. de Germay, Nicolas S. Schaerer, and P. Fennema

ANATOMOPATHOLOGIC APPROACH

In the natural evolution of discovetebral degeneration, lumbago is the first sign of the presence of a discopathy. The discopathy will develop progressively and can lead to different states of disc protrusion (3) (from protrusion underneath the ligamental structures to the migrated transligamental hernia), which, after a phase of mechanical destabilization of the functional tripod (disc and facets), can cause subsiding of the upper vertebra into the lower one. After this subsiding of the upper vertebra, the discopathy can either lead to a nonsymptomatic spontaneous fusion or a stenosis (lateral or central), which, in combination with arthritis spondylosis, is very painful for the patient.

In this evolution of destabilization, there is a phase during which the occasional lesions and deformities are reducible and, from our clinical experience, even reversible.

The initial mechanical lesion of the disc and its evolution can be visualized with the aid of magnetic resonance imaging (MRI) as described by Modic (6, 7). With MRI, the first provoked inflammatory edema, the creation of fat tissue, and the final scleroticization can be recognized.

The discovetebral degeneration has an impact on the facets, which pass from loss of the articular space, subchondral geode, deformation of the facets (leading to an exhausting arthritis), and, finally, hypertrophic osteophyresis, which is the origin of the lateral or central stenosis.

Especially the disc, posterior, and capsular ligaments as well as the vertebral end plates have been found to be major sources of nociception leading to pain (4). Destabilization and the resulting physiologic movements (e.g., pseudospondylolisthesis) may lead to annular distortion, which could facilitate cyst formation.

In the evolution of this dynamic phase, we believe a restabilization can bring the intervertebral segment to a more anatomic condition in which healing can take place and therefore reach an anatomic condition. Inspired by the works of Husson (2) and Kirkaldy-Willis (3), we defined a classification of the dynamic destabilization phase in which a restabilization could be performed.

The spinal implant presented here is an innovative concept for the dynamic neutralization of one or more intervertebral segments: the DYNEYSYS system (DYnamic Neutralization SYstem for the spine). The DYNEYSYS system seems to allow a real stabilization with a controlled range of motion through a dynamic neutralization absorbing the nonphysiologic loads.
in compression and flexion-extension, and suppressing parasitary movements. With the DYNESYS system, the spinal segments can be repositioned in an anatomic subnormal situation in which the pain is relieved. DYNESYS tends to bring the destabilized structures in the vertebral tripod to a more anatomic condition in which healing of lesions can take place. Reposition and restabilization of the spinal segments close to the normal functional anatomy is the goal of the DYNESYS system.

CLINICAL APPROACH

Study Design

The study was designed as a noncomparative prospective clinical study. It analyzes the first 57 cases to use the DYNESYS system at the Clinique de l’Union, St. Jean, France, between April 1994 and January 1996.

Objectives

This study determined the first clinical results with the DYNESYS system. The paper presents results related to pain, sciatica, and clinical assessment as described by McNab (5), as well as complications.

Subjects and Methods

Beginning in April 1994, 57 consecutive patients with lumbar instabilities were treated with the DYNESYS system. Mean age at operation was 47 years, with a range of 23 to 77 years. The average follow-up was 13 months, with a range of 2 to 31 months.

The operations were performed by the two neurosurgeons at the Clinique de l’Union, St. Jean, France; postoperatively each subject was assessed at this clinic by one person (G. D.). Before surgery, the subjects were assessed clinically and radiologically, to determine baseline information. At every postoperative assessment X-rays were obtained to determine complications. Subjects additionally underwent MRI, myelography, and/or computed tomography (CT); however, we did not define these radiographs in the protocol, resulting in a great quantity of missing data.

Clinical findings were recorded on a questionnaire. All questions were ordinally scaled. Subjects were assessed on pain and sciatica. Pain was registered on a four-point scale. Activity level was evaluated according the classification as detailed by McNab (5).

All patients complained of low back pain due to pathologies of degenerative origin. Most of the subjects (72%) required a DYNESYS implantation involving L-4 to L-5. Seventy-two percent required a monosegmental implantation only.

Inspired by the work of Husson (2) and Kirkaldy-Willis (3), we classified the dynamic destabilization phases (Table 1). Classification of the population by one person (G. D.), retrospectively, was done by evaluating the preoperative MRI or CT and (functional) X-rays, in combination with an evaluation of the clinical symptoms according to the patient history file.

Results

None of the patients was lost to follow-up. At the most recent follow-up (Table 2), 63% of the subjects were free of pain, and 30% had mild lumbago only. Seven percent complained of
serious backache. Remarkably, that pain seemed to decrease relatively early postoperatively, and appeared to stay stable afterward. From 1½ years postoperatively, a small number of subjects returned to the clinic with pain in adjacent level(s). Younger patients especially seemed to experience these kind of postoperative complaints.

Similarly, a remarkable decrease in neurologic symptoms was noted. Sciatica was present in less than 10% of the subjects postoperatively, whereas motor disturbances in the lower extremities were not found at all.

Intake of analgesics decreased dramatically postoperatively: More than 85% of the population did not take any analgesics at all or only occasionally.

Subjects who received the DYNESYS implantation could be classified in groups 3 to 6 in our classification system. Seventy percent were rated as having discopathy without signs of stenosis; 30% percent experienced neurologic signs due to lumbar stenosis.

No significant difference was found regarding pain (p = .23), intake of analgesics (p = .31), or on the McNab score (p = .24) (Kruskal-Wallis test, α = 0.05). This contrasts with our expectation that postoperative results would be relatively more heterogeneous compared to groups 4 to 6. Further investigation is needed.
Complications

The device had to be removed in four of the first 57 patients. In two patients, the clinical investigator decided to perform arthrodesis on three levels. In the other two patients, one of the pedicle screws had been placed extrapedicularly, which resulted in neurologic symptoms. The clinical and radiologic postoperative outcome was in each case highly satisfactory in relation to both pain and stability.

Besides these, a protrusion of the intervertebral disc in the adjacent level was found in two subjects.

No complications related to the material (pedicular screws, cords, or spacers) have been found.

Conclusion

The DYNESYS system is believed to be a secure technique for patients requiring stabilizing spine surgery, despite some explanations the authors had to perform. The efficacy with respect to clinical results is very encouraging. The study has not been able to answer the question of whether the implant is capable of providing a gradual junction with its adjacent levels, thus reducing the risk of early degeneration. We believe the system is applicable to the wide range of nonstructural lumbar instabilities.

BIOMECHANICAL APPROACH

The DYNESYS system is composed of titanium alloy (Prosast 100) pedicular screws, polyester (Sulene-PET) cords, and polycarbonateurethane (Sulene-PCU) spacers. The cord and the spacers fulfill the international standards of ISO 10993, and the pedicle screw fulfills those of the ISO 5832-11.

Following the internal guidelines of Sulzer Orthopedics Ltd., the single parts, their connections, and the whole system were tested and optimized using static and dynamic biomechanical models. To study the effect on the kinematics of the human spine, in vitro experiments additionally were conducted.

In this documentation, the static biomechanical testing of connection of the cord and the pedicle screw will be presented.

Objectives

The aim of the static biomechanical testing of the connection cord/pedicle screw was to define the optimal torque of the set screw and examine the rigidity of the connection. Furthermore, the influence of the overlength of the cords on the rigidity of the connection should be examined.

<table>
<thead>
<tr>
<th>Table 3. Material used in the investigation</th>
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<tbody>
<tr>
<td>Name</td>
</tr>
<tr>
<td>Pedicle screw 6.0 x 45 mm</td>
</tr>
<tr>
<td>Set screw</td>
</tr>
<tr>
<td>Cord</td>
</tr>
<tr>
<td>Spacer</td>
</tr>
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</table>
FIG. 1. Pull-out model for the determination of the connection rigidity of the cord and the pedicle screw. The lengths $l$ and $a$ equaled 40 mm and 10 mm, respectively. $F$ represents the applied pull-out force.

Material and Methods

The material used in this study is described in Table 3. To define the optimal torque of the set screw, pull-out tests were conducted. The cord was fixed in the head of the pedicle screw, varying the applied torque on the set screw from 2 to 7 Nm. Furthermore, two groups were examined, one with an overlength of the cord of 10 mm, and one in which the cord was cut underneath the pedicle screw head (no overlength). For each torque of both groups, three cords were examined.

The model used in this study is shown in Fig. 1. The lengths “$l$” and “$a$” equaled 40 mm and 10 mm, respectively. All experiments were conducted in Ringer’s solution to have friction properties closer to those in the human body. The pull-out speed was 60 mm per minute.

A clinical validated model for pedicular screws of internal fixators was used for the anchorage of the pedicle screw. In a large pilot study (1), the in vivo failure mode of a spinal fixator with a dowel/screw fixation in the pedicle was reproduced. It was found that the anatomic features of the pedicle must be incorporated into a testing model. In vivo, the posterior part of the pedicle screw is supported by cortical bone and the frontal part of the screw is surrounded by cancellous bone.

Several investigations have documented tests performed with the pedicle screws inserted into polyethylene blocks. As our dynamic testing could not reproduce the in vivo fractures of the above-mentioned system, and the pedicle screws inserted in the polyethylene blocks loosened rapidly, a new test model was developed at Sulzer (1).
Using this test model, the in vivo fractures of an internal fixator were reproduced, and the fatigue strength of the pedicle screws for an internal fixator in the lumbosacral area of the spine could thus be evaluated. (Although the pedicle screws of the DYNEYSYS system are less loaded than those of an internal fixator, the evaluated fatigue strength was used as reference when testing the pedicle screws of the DYNEYSYS system.)

Results

The measured maximal pull-out forces are presented in Tables 4 and 5 and in Fig. 3.

**TABLE 4.** Measured maximal pull-out forces in dependence of the applied torque on the set screw with an overlength of 10 mm

<table>
<thead>
<tr>
<th>Torque (Nm)</th>
<th>Average pull-out force (N)</th>
<th>Standard deviation</th>
<th>Standard deviation (%)</th>
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<tr>
<td>2</td>
<td>649.67</td>
<td>22.30</td>
<td>3.43</td>
</tr>
<tr>
<td>3</td>
<td>824.09</td>
<td>42.57</td>
<td>5.17</td>
</tr>
<tr>
<td>4</td>
<td>1059.33</td>
<td>101.40</td>
<td>9.57</td>
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<tr>
<td>5</td>
<td>1196.67</td>
<td>92.59</td>
<td>7.73</td>
</tr>
<tr>
<td>6</td>
<td>1219.33</td>
<td>78.24</td>
<td>6.42</td>
</tr>
<tr>
<td>7</td>
<td>1312.33</td>
<td>74.57</td>
<td>5.68</td>
</tr>
</tbody>
</table>

**TABLE 5.** Measured maximal pull-out forces in dependence of the applied torque on the set screw with no overlength

<table>
<thead>
<tr>
<th>Torque (Nm)</th>
<th>Average pull-out force (N)</th>
<th>Standard deviation</th>
<th>Standard deviation (%)</th>
</tr>
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<tr>
<td>2</td>
<td>585.00</td>
<td>69.38</td>
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<tr>
<td>4</td>
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<td>5</td>
<td>1222.0</td>
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<tr>
<td>6</td>
<td>1274.00</td>
<td>40.63</td>
<td>3.19</td>
</tr>
<tr>
<td>7</td>
<td>1424.00</td>
<td>92.96</td>
<td>6.53</td>
</tr>
</tbody>
</table>
**Discussion**

Using the Student's t-test (confidence interval of 5%), no significant difference was found between the two groups for the same torque. The p value always was higher than .18 (highest was .75), an insignificant difference between fixed cords with an overlength of 10 mm and cords with no overlength.

The comparison of the resulting pull-out force depending on the applied torques within the same group, however, showed a bigger sensibility in the group with no overlength. In this group there was no significant difference between the pull-out forces with the application of a torque of 4, 5, or 6 Nm (p > .10), whereas in the group with no overlength, the differences were significant, with p values less than .015.

The pull-out characteristic of a cord with overlength fixed with 4 Nm was continuous, and there was less damage of the cord in comparison with higher torques. The biggest lesion of the cord was seen when a torque of 7 Nm was applied (Fig. 4). From a torque of 2 Nm to
4 Nm, there is an increment of approximately 63% of the average maximal pull-out force. With a torque of 5 Nm, there is an increment of approximately 20%. With 6 Nm, only an additional increment of 4% is achieved.

The pull-out characteristic of the cords with no overlength was independent of the applied torque abrupt.

Conclusions

Because of the higher sensitivity to variations of the applied torque and the abrupt pull-out characteristic, the cord should not be cut underneath the head of the pedicle screw.

A torque of the set screw of 4 Nm is considered the minimal damage of the cord and the pull-out characteristic as the optimal torque, for reasons of the achieved rigidity of the connection.

The failure load of the ligamentum flavum, the capsular ligament, and the interspinous and supraspinous ligament is in the range of maximal 500 N (9). As the required tensile force to pull out the cord (with a torque of the set screw of 4 Nm) of the pedicle screw equals about 1,000 N, the connection of cord/pedicle screw is considered safe. In fact, in the running clinical study (follow-up 30 months) with more than 50 implantations and approximately 270 screws placed, no loosening of the cord from the pedicle head has been seen.

To determine the loosening and stretching effect of the cord with a torque of the set screw of 4 Nm, fatigue testing of the cord was performed.

ACKNOWLEDGMENTS

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REFERENCES