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A new semirigid implant for instrumentation of scoliosis: preliminary report

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Abstract A new set of pedicle screws, lamina and pedicle hooks, longitudinal rods and a titanium cable was developed to overcome the increasingly obvious hazards of overly rigid spinal instrumentation. Results of the first 12 consecutive scoliosis patients with this new system are reported, with an average follow-up time of 18 months. No major complications occurred. The average correction of the deformity was well within the range of more rigid systems. The new Dorsal Dy-

namic Spondylodesis (DDS) system proved to be easy to use, fast, powerful, safe, versatile, and biomechanically sound. Reduction of stress-shielding effects and protection of adjacent segments can be expected, and the system warrants future application in selected prospective cases with long-term follow-up.

Keywords Spine · Scoliosis · Semirigid implant · Biomechanics · Follow-up studies

Introduction

Overly rigid spinal instrumentation is known to carry the inherent danger of segment instability adjacent to the fused levels, as well as stress shielding and bone-implant interface failure, with cascading pseudarthrosis. In the search for an instrumentation that avoids these hazards, a new set of pedicle screws, lamina and pedicle hooks, longitudinal rods and a titanium cable was developed – the Dorsal Dynamic Spondylodesis (DDS) system. The 5-mm-diameter lubricant-free cable, manufactured as a 19-wire strand, can be connected to the other elements unilaterally or bilaterally on the convex side of the deformity. In this configuration, the system is primarily under tension, despite its ability to sustain considerable compression and torsional forces without damage. Although the system had been successfully used previously in different types of spinal instabilities [32, 34], this paper focuses on our first 12 patients with a history of idiopathic or congenital scoliosis who received posterior spinal fusion and instrumentation with the cable system. Development of the system was based upon considerations of its physiological effect, the strength of the instrumentation and operative time.

From the work of Rohlmann et al. [38, 39], it is known that even after bony consolidation of an instrumented spinal fusion there are still considerable loads passing through the implant instead of the bone graft. This effect is directly related to the system's stiffness, and is less pronounced with more elastic systems. Between 1988 and 1994, the year when the DDS implant finished undergoing comprehensive biomechanical testing [5, 30, 31, 33], such stress protection with osteopenia and contingent graft resorption was the subject under debate in several original publications [6, 7, 10, 14, 22, 27, 28, 42]. The concept that stress shielding may lead to bone graft resorption, osteopenia, and implant failure in the spine was made particularly popular by Goel et al. [17] and Kabins et al. [23].

Despite this, the most popular implants for scoliosis instrumentation are, according to ASTM standards [1, 16], very rigid, with a bending stiffness of about 6 Nm/mm and a torsional stiffness of more than 7 Nm/°. The semirigid cable system in a bilateral configuration exhibits a torsional stiffness of only 1.2 Nm/° in this test. Unfortunately, semirigid constructs cannot be tested according to the ASTM test protocol, which was modified to better characterize the semirigid spinal implant [5]. Spinal fusion is generally known to promote adjacent segment de-

generation and instability [3, 20, 41]. An increasing number of instrumented and fused segments, which are characteristic for scoliosis cases, add to this effect [5, 47]. We have found that rigid instrumentation (in short-distance lumbar fusions) leads to more postoperative distraction and a reduction of physiologic lordosis than does semirigid instrumentation [35], and thus may adversely influence adjacent segments more. It should be possible to avoid a flat back syndrome [44] with the new semirigid system.

Overly rigid systems tend to exhibit mechanical failure at the bone-implant interface and are susceptible to implant fracture resulting from small rod diameters and surface stress-risers. Fatigue testing of bilateral semirigid constructs utilizing cables exhibited no failures after 5×10^6 bending-compression cycles at 50% of their static failure load, which manifested itself as cable slippage. In-vitro cable slippage at the screw head appeared at the clinically irrelevant load of 2400 N, well below the failure load of the cable (12,812 N), making a potential hazardous cable fracture most unlikely. Thus, superior long-term performance of the implant can be expected.

Reducing intraoperative time may be essential in correction of spinal deformities. Lower operation times correspond well with reduced blood loss and co-morbidity. In a separate study of degenerative cases, the average operation time was 20 min less in the semirigid group, due to facilitated insertion of the flexible cable compared to rods, which occasionally needed some pre-bending when the screw-rod angle exceeded 30° [36].

Materials and methods

The fully biocompatible [46] Ti6Al4 V alloy instrumentation system combines three different types of hooks and self-tapping, low-profile, top-loading, tapered 6.5-mm pedicle screws connected with rods or cables via locking nuts (Fig. 1). Two types of laminar hooks are available; one has a 10-mm neck length and a blunt tip and the other type has neck lengths of between 7.5 and 11 mm with a sharp tip. The third hook type comes as a pedicle hook with a neck length of 3.5 or 7 mm. The rods and cables can be positioned within the slotted screw or hook head to $\pm 30^\circ$ in the sagittal plane using a half-ball-in-socket fixture. There are no outriggers, crosslinks, or plates to damage the soft tissue or to increase operation time. The steps of the instrumentation are the same as for a conventional posterior procedure until the longitudinal elements are inserted (we usually place an „anchor“ screw in the lowest vertebra and two counteracting laminar and pedicle hooks on the top-most lamina on the convex side). Following the recommendations of Dubousset and Cotrel [9], we start on the concave side of the deformity by inserting a pre-bent rod. The locking nuts of the hooks and screws are loosely mounted, and the rod is then axially rotated by means of clamping pliers. The rod position is temporarily secured by tightening the locking nuts in the center of the instrumentation. From here, distraction and compression tools can be mounted and utilized. Following distraction or compression, all locking nuts are secured. A cable is then inserted on the opposite side after capping the ends that protrude beyond the last hook or screw with sleeves. Prior to tailoring the instrumentation to its final length, a flexible template is used to measure the appropriate length. The cable is held taut in the desired position, being careful

Fig. 1 The Dorsal Dynamic Spondylodesis (DDS) system as described in the text

not to add correction, but firmly holding the position. Finally, the cable locking nuts are fastened. Bone grafting and dissection of the facet joints follow as usual.

We have, to date, operated on 12 consecutive patients with an average age at time of intervention of 18 years (SD 4.2 years), 11 of whom were suffering from idiopathic scoliosis and one from congenital scoliosis (Klippel-Feil syndrome, patient 5). They were prospectively followed for on average 18 months (SD 13.3 months). Their anthropometric data are given in Table 1. All patients included in the current study received preoperative standard anteroposterior, lateral, and bending radiographs of the entire spine prior to surgical planning. All operations were conducted by a single experienced spine surgeon (P.G.), who was not involved in the follow-up examination. Controlled hypotension was applied in all patients, and cell-saver and wake-up tests were applied in a minority of four patients. All patients obtained autologous bone grafts; in three cases additional homologous material was added. None of the scoliosis patients needed anterior procedures prior to or after the operation. One patient (patient 1) had to undergo 6 weeks of preoperative halo treatment prior to operation, which we considered necessary for an adequate correction, on the basis of previous extension and bending radiographs.

The levels and extent of instrumentation were chosen according to the recommendations of King et al. [24]. Postoperative treatment was brace free. The clinical assessment and radiological follow-up using standard radiographs was carried out according to the recommendations of the German Orthopaedic and Traumatologic Society (DGOT) [21] and Wojcik et al. [48]. Paired *t*-tests with a significance level of $P \leq 0.05$ were utilized for analysis of the radiological parameters over time.

The following parameters were evaluated preoperatively, postoperatively, and at follow-up:

Table 1 Anthropometric data of the patients

Patient no.	Sex	Age	Inpatient days	Major curve	Minor curve	King type	Levels instrumented
1	m	18	14	T4–L1	T11–L4	II	T3–L2
2	f	16	16	T7–L2	L2–5	II	T6–L2
3	f	13	16	T5–L1	n.a.	IV	T4–L1
4	f	20	17	T4–L2	T12–L5	II	T4–L2
5	f	13	18	T5–L1	L1–5	II	T4–L2
6	f	14	16	T5–L1	n.a.	IV	T3–L1
7	f	24	18	T5–L2	T12–L4	II	T4–L1
8	f	12	16	T5–L2	T12–L3	II	T3–L2
9	m	16	17	T7–L1	L1–5	II	T4–L1
10	f	12	16	T5–L2	T12–L4	II	T4–L1
11	f	22	14	T5–L2	T12–L5	II	T4–L1
12	f	24	14	T7–L2	T12–L4	II	T5–L1

- Clinical parameters
- Blood transfusion amount
- Operation time
- Duration of inpatient treatment
- Major and minor complications intraoperatively, postoperatively and at follow-up
- Satisfaction with the operative result

Radiographic analysis

The following radiographic measurements were carried out in the frontal plane:

- Cobb-angle between the superior endplate of the cranial and inferior endplate of the most caudal vertebra for the primary curve (CAP) and the secondary curve (CAS)
- Tilt angle of the lower vertebra of the primary curve (TA)
- Pelvic obliquity – angle including a line connecting the hip head centers and the horizontal line in standing radiographs (PO)
- Clavicular obliquity – angle including a line connecting the intersections of the first ribs with the clavicular centers and the horizontal line in standing radiographs (CO)
- Distance of plumb line through C7 from the plumb line through S1 (CSF)

Measurements in the sagittal plane comprised:

- Thoracic kyphosis T4–T12 (DD)
- Lumbar lordosis L1–S1 (LL)
- Thoraco-lumbar lordosis T10–L2 (TLL)
- Distance of plumb line through C7 from the plumb line through S1 (CSS)

Results

Clinical parameters

The average blood transfusion amount was 2 units, mostly erythrocyte concentrate. In adult patients this amount included the transfusion of previously donated autologous blood. The average operation time (skin to skin) was 216 min (SD 29.9 min). The average duration of inpatient treatment was 16 days (SD 1.4 days).

There was no intraoperative and one minor postoperative complication (patient 4: 60 ml of sterile hematoma,

which was drained; wound healing followed uneventfully). There was no overt pseudarthrosis, as could be derived from persistent pain, or mechanical implant failure or dislocation at follow-up. The only mechanical implant failures seen were loosening of a caudal cable sleeve (patients 2, 5) and one screw breakage at the pedicle site (patient 8), all of which were of negligible importance for the correction of the deformity. Despite the fact that the sleeves do not serve as blockers or buttresses for screws and hooks, but simply prevent fraying of the cable ends, the design of the tool for crimping the sleeves was improved. After that, no sleeve fell off any of the cables. None of the pedicle screws were suspected of being malpositioned.

One very slim patient (patient 7) felt uncomfortable with a subcutaneously prominent hook 8 months postoperatively. The hook was removed and the tension of the cable tested with a clamp: there was still considerable tension on the cable, which could by no means be dislocated, so the hook had to be cut out with an air drill.

All patients were satisfied with the operative result and nearly pain free at follow-up. Slight donor site pain persisted in only a few cases.

Radiological parameters

There was a learning curve in the application of this new system. The first patient had the most severe ($CAP_{pre} = 70^\circ$) and most rigid scoliosis of all patients, as seen on bending radiographs. Despite administering preoperative halo-traction, the patient developed the least correction and the highest loss of correction for CAP and CAS combined at follow-up. The second patient obtained the shortest fusion of all patients (T6–L2), and developed some thoracic hypokyphosis postoperatively. This was compensated by some loss of correction, especially in the thoracolumbar junction and thoracic segments between T6 and T4, as can be seen in the figures (Fig. 5, Fig. 6, Fig. 7, Fig. 8). A slight postoperative average decrease in DD was some-

Fig. 2 Individual changes (in degrees) over time in the Cobb angle of the primary curve (CAP)

times observed; however, this was fully reversible at follow-up, so that none of the patients developed significant flat back.

Primary Cobb angle

The mean value of the Cobb angle of the primary curve (CAP, Fig. 2) was 57.1° (SD 7.5°) preoperatively, 25.6° (SD 9.8°) postoperatively, and 31.3° (SD 10.6°) at follow-up. This made for a postoperative mean correction of 55.2% ($P \leq 0.001$) and loss of correction of 9.9% ($P \leq 0.001$), as related to the preoperative angles. If the first two patients are excluded from the calculations, due to the problems mentioned above, the mean postoperative correction remains virtually unchanged, but loss of correction decreases to only 8.1%.

Secondary Cobb angle

The mean Cobb angle of the secondary curve (CAS, Fig. 3) was 37.2° (SD 9.2°) preoperatively, 19.2° (SD 11.0°) postoperatively, and 23.3° (SD 14.3°) at follow-up, making a postoperative reduction of 48.4% ($P \leq 0.001$) and loss of correction of 11% ($P \leq 0.030$).

Tilt angle

The mean tilt angle of the lower vertebra of the primary curve (TA, Fig. 4) was -26.8° (SD 6.2°) preoperatively, -12.3° (SD 7.2°) postoperatively, and -14.4° (SD 8.1°) at follow-up, corresponding to a postoperative correction of 54.4% ($P \leq 0.001$) and a loss of correction of 8.1% ($P \leq 0.013$). The negative values are attributed to the fact that all the thoracic curves had their convexity to the right.

Fig. 3 Individual changes (in degrees) over time in the Cobb angle of the secondary curve (CAS)

Fig. 4 Individual changes (in degrees) over time in the tilt angle (TA)

Pelvic obliquity

The mean value for pelvic obliquity (PO) was 0.5° (SD 1.1°) preoperatively, 0.2° (SD 0.9°) postoperatively, and 0° (SD 1.3°) at follow-up, all sloping down to the left.

Clavicular obliquity

Mean values for clavicular obliquity (CO) were 0.1° sloping down to the left (SD 2.0°) preoperatively, 2.4° (SD 2.5°) sloping down to the right postoperatively, and 0.8° (SD 1.7°) at follow-up, again with the right side lower. Changes were partly significant, with $P_{\min} \leq 0.050$.

Overall lateral deviation (frontal plane)

The mean distance of a plumb line drawn through C7 from one drawn through S1 (CSF) was accordingly 0.2 cm

with C7 oriented left of S1 (SD 1.8 cm) preoperatively, and 0.6 cm (SD 1.8 cm) postoperatively, with a further slight increase at follow-up to 1.0 cm, with C7 towards the left side of the patients (SD 1.1 cm).

Thoracic kyphosis

Mean thoracic kyphosis, measured between T4 and T12 (DD, Fig. 5) was 19.6° (SD 12.9°) preoperatively, 15.5° (SD 7.4°) postoperatively, and 20.3° (SD 10.6°) at follow-up, which meant a postoperative reduction of 20.9% followed by a restitution of preoperative lordosis of 24.3%.

Lumbar lordosis

Mean lumbar lordosis values measured between L1 and S1 (LL, Fig. 6) amounted to 50.0° (SD 8.8°) preoperatively, 49.1° (SD 10.2°) postoperatively, and 52.1° (SD

Fig. 5 Individual changes (in degrees) over time in thoracic kyphosis (DD)

Fig. 6 Individual changes (in degrees) over time of lumbar lordosis (LL)

Fig. 7 Individual changes (in degrees) over time of thoracolumbar lordosis (TLL)

Fig. 8 Individual changes (in centimeters) over time in overall sagittal deviation (lateral plane) (CSS)

Fig. 9A–C Patient 9 in anteroposterior and lateral projection preoperatively, postoperatively, and at follow-up

table osteochondrosis at follow-up. Crankshafting did not occur, but will have to be re-evaluated for younger patients. Figure 9 presents a typical case.

9.5°) at follow-up. A postoperative decrease of 1.8% was countered by an increase of 6.0% at follow-up.

Thoraco-lumbar lordosis

Mean values for thoraco-lumbar lordosis, measured between T10 and L2 (TLL, Fig. 7), decreased from 6.1° (SD 9.8°) preoperatively to 4.4° (SD 4.3°) postoperatively, and rose again to 6.3° (SD 5.8°).

Overall sagittal deviation (lateral plane)

The distance of the plumb line through C7 from the plumb line through S1 (CSS, Fig. 8) reflected the fact that no persistent hypokyphosis was encountered. C7 was shifted from a mean of 0.1 cm (SD 3.0 cm) behind the plumb line through S1 preoperatively to a mere 1.0 cm (SD 3.1°) in front of S1 postoperatively, and, finally, to a CSS of 1.2 cm (SD 2.2°) at follow-up.

Other radiological parameters

Angle and distance changes over time were statistically insignificant, if not otherwise mentioned above.

None of the adjacent segments in the vicinity of the fusion mass revealed any signs of overt instability or no-

Discussion

Reduction of spinal instrumentation rigidity can be achieved by reducing the diameter of the longitudinal components or by making the screw head fixture mobile; both of which increase the risk of implant failure. An alternative method is to insert semirigid components, such as cables, into the heads of the pedicle screws. This technique has advantages for restoring and maintaining the sagittal profile, especially of the kyphotic spine, while having the added advantage of easy alignment of the instrumentation. However, it must be borne in mind that the rigidity of a spine-implant construct is dependent upon several other factors not inherent to the implant design itself.

Although the application of thick cables in spine surgery is completely new, the biomechanical approach described (Fig. 10A) has some predecessors, namely, tension-band systems, despite the fact that they were rarely aimed at scoliosis surgery. Augmentation devices, fashioned as springs or artificial ligaments [2, 18, 45] showed a high rate of mechanical implant failure, which can easily be explained by the fact that they are not designed to achieve a stable fusion, and are thus exposed to high cycle fatigue loading.

Dwyer's 1/8-in.- (0.32-cm-) diameter cable system [12] was rarely used posteriorly; however, when it was used posteriorly it was mostly for degenerative conditions [25]. This system had a lot of mechanical complications inher-

Fig. 10A–C Biomechanical concepts of cable instrumentation as mentioned in the text. **A** The DDS system, **B** the Luque-type instrumentations, and **C** Siemsen's proposed posterior cable device. Direction of distractive and transversal forces represented by *black arrows*, compressive forces by *open arrows*

ent to its design [13] and was soon abandoned. Cables for sublaminar wiring, for example in Luque-type instrumentations [43] (Fig. 10B), fall into another category.

In 1983 an experimental posterior cable device was first mentioned by Siemsen (see Griss [19]) (Fig. 10C), but was never applied clinically (personal communication). He recommended attaching a tension cable to a hook at the convex side of the apex, acting as a fulcrum after tensioning the cable between the top and bottom distraction hooks of the Harrington rod at the end vertebrae on the concave side. Compared to a horizontal Cotrel rod traction, which was commonly used at this time, the method of Siemsen achieved better straightening of the spine in the frontal plane. Unfortunately, the fixation on the concave side introduces a torsional moment in the wrong direction. This problem can be avoided by keeping tension solely on the convex side of the deformity.

Many surgeons in the 1970s gave up using the Harrington compression device and used the distraction rod only, questioning whether the compression device caused extra loading on the distraction rod. This was supported by material failure of the notched Harrington rod, with its many surface stress risers. No material failure of the smooth titanium rod was observed in the present study, and the question of whether the cable exerts additional stress on the rod still awaits to be answered by additional biomechanical studies, e.g., finite element analyses. In vitro tests are less suitable, due to the inherent mechanical and anatomical variability of scolioses and the poor availability of scoliotic cadaver spines.

We depicted absolute angles, their absolute variations and percentage changes, because these values are commonly cited in the literature. Proper assessment of the instrumentation can only be performed when all of the parameters are examined as a whole. Percentage changes from the preoperative values were overly impressive with minor scolioses, whose improvement can only be adequately appreciated by looking at the absolute values. Absolute values, alas, may give a wrong impression, as for example the value of LL in one of our patients (patient 3) with a steep lumbosacral angle due to spondylolysis with spondylolisthesis at L5 – no mainly thoracic instrumentation, as applied here, could ever improve this angle. Comparison of absolute values over time as well as the percentage change made it clear that in no case did the instrumentation create a pathologic hyperlordosis between L1 and S1. Neither did the opposite effect of producing a flat back occur, either in the thoracolumbar or in the lumbar spine, with the new method: reduction of TLL was statistically insignificant as were the changes of LL and DD. Mean CSF was restored to normal, meaning that C7 remained less than 2 cm in front of S1 [26], at follow-up.

Generally, correction and loss of correction with the new system are very similar to the values obtained with highly rigid systems such as TSRH and CD instrumentation [4, 37, 40, 48]. No pseudarthroses could be detected at follow-up, but it must be borne in mind that the implants' low susceptibility to mechanical failure under fatigue loading, and the absence of severe loss of correction and pain in all patients does not totally exclude pseudarthrosis. Reli-

able methods for detecting pseudarthrosis, such as CT scans or anteroposterior tomography [8], were not utilized for ethical reasons in this set of young pain-free patients.

Measuring angles in lateral total spine radiographs in severe scoliosis cases is sometimes difficult, due to vertebral tilting and the difficulty in identifying the vertebral endplates [11]. In such cases, the recommendations of Frobin et al. [15] were very helpful. Nevertheless, it should be borne in mind that measurements in the sagittal plane have a high inter-observer error and a relatively low repeatability. This means that qualitative observations as related to the preserved or restored sagittal and coronal balance of the spines in our series are of at least the same importance.

Highly rigid deformities should undergo an anterior release of the major curve prior to posterior instrumenta-

tion, preferably in an open technique [29]. Through this strategy, preoperative halo traction can be abandoned, leading to an even better correction of the deformity.

Conclusion

The new system is easy to use, fast, powerful, safe, versatile, and biomechanically sound. Care should be taken not to use it in cases with overly rigid scoliosis and not to choose too short a fusion range. Under these precautions it will in our department be the standard implant for future scoliosis surgery in cases of King II and King IV curves similar to those presented above.

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