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In vitro testing of a new transpedicular stabilization technique

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Abstract The rigidity of a pedicle screw implant is a critical biomechanical variable in lumbar spinal fusions. Sufficient rigidity is required for integration of bone grafts and to promote healing. Osteopenia, stress shielding, and compensatory hypermobility have been described as consequences of excessive rigidity. Little is known about the biomechanical characteristics of "semirigid" compared to "rigid" implants. A new implant, whose rigidity can be varied by selection of different implant components, was tested in vitro under well-defined loading conditions. The three-dimensional load-displacement behavior of all lumbar vertebrae involved in or adjacent to the two-level fusion was evaluated for two fusion modifications: bilateral rigid and bilateral semirigid. Cyclic fatigue loading was subsequently carried out under realistic conditions and motion testing repeated. The rigid device reduced the motion of the L3-4 transfixed segment in the primary movement planes by 87.3% with respect to the intact spine value in flexion/extension (FE), 86.3% in lateral bending (LB), and 76.8% in axial rotation (AR). The semirigid device achieved a reduction in motion of 79.6% (FE), 82.7% (LB), and 51.7% (AR). The semirigid implant was particularly easy to insert, because no bending of rods or plates was necessary. The implants showed no loosening or breakage after the fatigue testing. The results are compared to other available systems and the underlying biomechanics discussed.

Key words Spine · Spinal fusion · Biomechanics · Pedicle screw · Stress shielding

Introduction

It has been shown that internal fixation can increase the chances of successful fusion as well as the speed and end quality of the fusion compared to techniques where no instrumentation is applied. Johnston et al. demonstrated, experimentally in an in vivo goat spine study, that stiffer instrumentation can offer improved fusion quality and fusion rates [16]. A clinical study by Lorenz et al. compared results of fusions done with and without rigid internal fixation at the same hospital for a narrow set of indications. It was shown that fusion rates increased from 56% to 100% with the application of internal fixation. Pain relief and rates of return to work were also drastically improved by the addition of instrumentation [19].

Lack of load sharing between instrumentation and bone can cause pseudarthrosis and bone resorption in the spine. Heggeness and Esses cited preservation of facets and addition of rigid instrumentation as factors related to non-weight-bearing or atrophic pseudarthroses in the spine [15]. Three successive publications, using an in vivo canine spine model, concluded that rigid spine instrumentation was associated with increased vertebral bone poros-

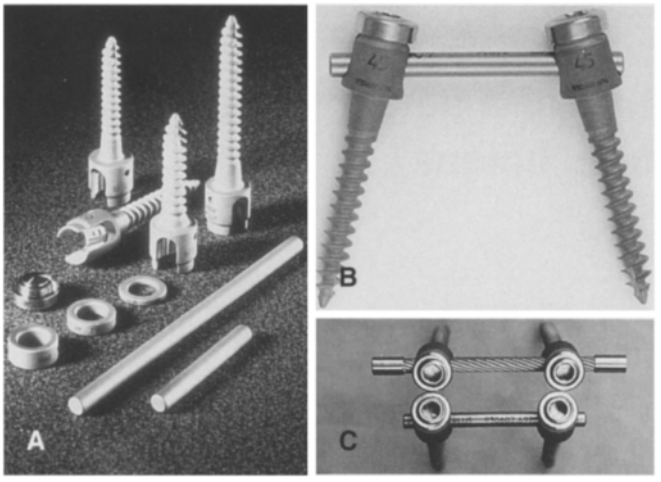


Fig. 1 A–C Dorsal Dynamic Spondylodesis (DDS) implants for rigid and semirigid instrumentation. **A** Assortment of screws, nut, washers and rods. The slotted head of the screw is equipped with a half-ball in socket fixture. **B** The screw allows adjustment of the longitudinal element within a 30° range with a low-profile single locking nut, thus facilitating full three-dimensional adaptation of the instrumentation to the physiological shape of the spine. **C** The two types of longitudinal element are depicted: cable (semirigid) and rod (rigid)

ity and decreased bone formation rate in the vertebral body after posterolateral fusion [5, 22, 23].

Smith et al. used an in vivo canine model to demonstrate that vertebrae bridged by rigid instrumentation showed statistically significant bone mineral loss over a 6-month period [31]. Dalenberg et al. [4] further showed that bone mineral density recovered to preoperative levels within 12 weeks if device rigidity decreased (due to loosening between the bone and implant or within the implant in this case).

Goel et al. compared, using an in vivo canine model, the standard, bilaterally placed Steffee variable screw plate (VSP) with a modified form of the system (MVSP), which included polyethylene washers between the plates and screws. The reduced rigidity of the MVSP decreased the bone loss in the vertebral bodies, which is caused by stress shielding, and that around pedicle screws, which is caused by overstressing [10].

Nagel et al. showed, experimentally with sheep, that excessive motion inhibits intervertebral fusion [24]. Heggeness and Esses, in a retrospective study of pseudarthroses of the human lumbar spine, concluded that over 50% of the pseudarthroses in the study were caused by excess motion [15].

The optimum rigidity of a spine fixation device has not yet been determined, and is probably indication specific. That is, the amount of support that needs to be imparted by an internal fixation device depends on the degree to which the spine is injured or degenerated.

The purpose of this paper is to investigate the biomechanical performance of a semirigid internal fixation device as it compares to rigid fixation. A single system is available that allows a choice of rigid or semirigid instrumentation by change of the longitudinal element components of the implant (Fig. 1). The three-dimensional (3D) motion present in an injured spine to which one of the two forms of this device has been applied will be assessed. Comparisons of the results for the two forms of the device will be made to each other and to other devices from the literature in order to predict the likely surgical outcome when this device is used in the manner and for the injury presented.

Materials and methods

Fresh human lumbar spine specimens (L1-sacrum) were obtained from the bequeathal program at the University of Iowa Department of Anatomy. The spines were X-rayed anteroposteriorly and laterally and their radiological appearance examined by an orthopedic surgeon. Ten spines without signs of malignant tumors, spondylitis, fractures, or spontaneous fusion were selected to be used in this study. The degree of degeneration observable by radiograph was graded.

Biological data of the specimen donors are given in Table 1.

All specimens were freed of excess soft tissue, leaving intact L1-S1 with all discs and ligaments (except the iliolumbar ligament). The specimens were immediately sealed in double plastic bags and frozen at –20° C.

Four 3/8″ (0.95-cm) bolts were inserted through the S2 and S3 foramina and secured with wing nuts and washers. L1 was temporarily attached to a fixture that allowed free 3D alignment of the specimen. The L3-4 level was then oriented horizontally.

The sacrum was then "potted" in a Plastic Padding (polymer resin) base. Care was taken to leave about 15-mm clearance below the L5-S1 disc so that motion at this level was not impeded.

L1 was connected to a square aluminum loading frame via three 1/4″ (0.64-cm) diameter threaded steel rods. The transverse rod passed through the loading frame, into the lateral aspect of the vertebral body, through its geometrical center, and out through the loading frame again. The two other rods passed through the loading frame and were tapped into the anterior and posterior aspects of the vertebral body so that the frame was aligned parallel to the base plate. The rods extended outside of the loading frame for attachment of additional rods for load application. The loading frame was filled with polymer resin. Care was taken that no poly-

Table 1 Biological data of the specimen donors

Age (years)	Gender	Cause of death	Height (cm)	Weight (kg)	Av disc grade[a]
47	Male	Gunshot	183	77.1	2
60	Female	Alcoholism	178	56.7	2
70	Male	Pneumonia	183	63.5	2
58	Female	Tumor (unknown)	173	70.3	2
72	Male	Pneumonia	168	68.0	3
68	Male	Lung cancer	175	70.3	3
64	Female	Colon cancer	152	31.8	2.5
73	Female	M. Alzheimer	168	68.0	2
82	Male	Pneumonia	178	59.0	3
50	Male	Renal failure	180	68.0	2.5

[a] Graded from 1 (no degeneration) to 4 (severe degeneration), according to Galante [7]

mer resin intruded into the spinal canal below the posterior rod where it could impede motion at the L1-2 joint. During the entire potting procedure the specimen was kept frozen [8–10].

Three light-emitting diodes (LEDs) were attached to each vertebra in L2-L5, one to each transverse process and one to the spinous process. Three additional LEDs were attached to the base plate as well as three to the loading frame. On the day of testing, a completely thawed specimen was mounted in the testing frame so that the LEDs faced the two stereophotogrammetric video cameras of a previously calibrated Selspot II system.

Pure bending moments were incrementally applied via adjustable pulleys at the load levels 0, 0.75, 1.5, 2.25, and 3 Nm, and again 0 Nm, by hanging weights from the loading arms of the specimen loading frame. The corresponding 3D displacement data of the LEDs were recorded for each load level. This was repeated for flexion and extension (FE), left and right lateral bending (LB), and left and right axial rotation (AR). This setup had been previously determined as accurate to within 0 milliradians. It has further been described elsewhere [8, 9]. Henceforth, rotation in the same plane as the applied load is called primary motion, and rotations in the other two planes are called coupled motions. This procedure was initially done for the spine without injury (intact state).

Motion testing was repeated after destabilization due to clinically relevant two-level decompression surgery (injured state). Destabilization consisted of bilateral removal of the inferior facets of L3 and L4 and left-posterior nucleotomy at L3, L4, and L5. Specimens were then stabilized with one of the two forms of the DDS (Dorsal Dynamic Spondylodesis) system: five specimens were stabilized with the semirigid system, which consisted of six pedicle screws and two titanium-alloy cables per specimen; and five specimens were equipped with the rigid system, bilateral rods instead of cables.

The longitudinal elements of the semirigid DDS consist of 19 separate 1-mm diameter wires. The wires are twisted into a rope, but otherwise unconnected. The rigid DDS device uses a solid rod of 5-mm diameter circular cross-section. The axial compressile and tensile stiffness of a beam is proportional to the material properties and the cross-sectional area of the beam. The bending (or torsional) stiffness are proportional to the material properties and the area moment of inertia (or polar moment of inertia). Therefore, the semirigid device (not the instrumented spine) theoretically retains about 76% of the rigid device's axial compression and tension stiffness of 929.2 N/mm, while being reduced to only 3% of the bending (or torsional) stiffness of 3.07 Nm/mm (2.58 Nm/°), tested in a missing element model without biological material involved for anterior column support of the rigid implant version [28]. Hence the term "semirigid."

The screws were inserted according to the method of Magerl [21]. The original positions of the vertebrae were not intentionally altered, i.e., no major distraction or compression was induced. The tightening torques of the locking nuts were recorded with an electronic torque wrench. Motion testing was repeated after stabilization was complete (stabilized state).

The specimens were then subjected to 5000 cycles of FE loading at 0.5 Hz. An initial peak load of ± 3 Nm was applied as eccentric bending (off-center axial loading) at a distance of 22 cm from the center of the superior-most vertebra, with an MTS hydraulic materials testing machine. The displacement required to induce that load was recorded. Cycling was conducted with sinusoidal stroke control, with maxima and minima at the displacement that initially produced the ± 3 Nm load. Motion testing was repeated after fatigue loading (post state).

During all steps, the specimen was kept moist by repeated spraying with saline. Cyclic loading was performed with the specimen inside a chamber at 100% relative humidity.

After motion testing was complete, the loosening torques of the locking nuts were recorded and the longitudinal elements (rods or cables) were removed. The longitudinal elements and nuts were checked for signs of damage. Screws were manually checked for loosening in the bone in the axial, cranio-caudal, and mediolateral directions. The vertebral bodies were then separated, dissecting the intervertebral disc. Disc grading according to Galante [7] was carried out (seven discs could not be graded for various reasons). Screw placement was examined to determine whether encroachment of the spinal canal had occurred. The screws were then removed and checked for damage.

All rotational values were normalized with respect to the intact state to eliminate the effects of specimen variability. An explorative computer-based (NCSS) statistical analysis was carried out. For the purpose of comparing the average performance of the different levels at intact, stabilized, and fatigued state, ANOVA for repeated measures was applied. For comparing the intact motion data of the two operative groups (to exclude a bias due to different specimen conditions), *t*-tests were used. For comparing the degeneration scores of each vertebra of the two operative groups, and to evaluate the correlation between body weight and degeneration, non-parametric procedures were used. A value of $P_{max} < 0.05$ was generally considered the significance limit.

Results

Ten spines were tested to determine the stability imparted by the DDS device in its rigid and semirigid forms. The donors of the spines used in the semirigid group had a higher weight at time of death; but body weight did not show a significant influence on the radiological and morphological degeneration scores (compare Table 1). Evaluation of the degree of degeneration of the specimens based on the radiological and morphologic score showed an even distribution among the two instrumentation groups. In the intact state, there was no significant differ-

Table 2 Significant changes in primary motions across fixed levels (L3-4 and L4-5) and at adjacent levels after fixation with rigid and semirigid instrumentation. (Note that these values cannot be derived from the Fig. 2, where only the total range of motion at L3 is depicted)

Primary Motion	Fixation type	Primary motion change		
		L3-4	L4-5	Adjacent levels
Flexion/extension	Semirigid	–80% SD = 36	–82% SD = 31	None
	Rigid	–87% SD = 34	–87% SD = 32	None
Lateral bending	Semirigid	–83% SD = 30	–85% SD = 31	None
	Rigid	–86% SD = 31	–86% SD = 31	L1–2: 7%, SD = 15 L2–3: 5%, SD = 9
Axial rotation	Semirigid	–52% SD = 32	–43% SD = 50	L2–3: 21%, SD = 30
	Rigid	–77% SD = 38	–67% SD = 29	None

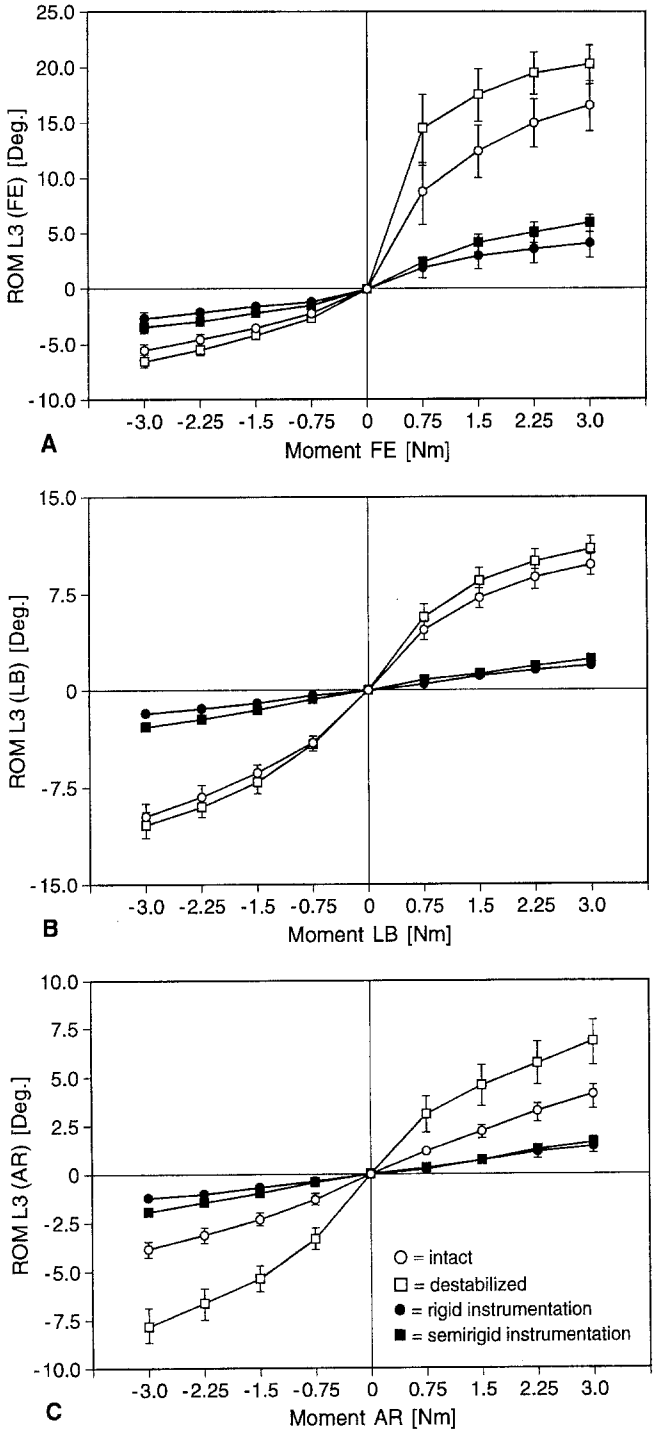


Fig. 2 A–C Comparison of the range of motion (ROM) at L3 for rigid and semirigid instrumentations in the primary motion planes with respect to the load applied. Data shown represent the total ROM at L3 for three of the four states tested: intact, after destabilization (from specimens prior to rigid instrumentation), and after instrumentation, with all corresponding standard deviations. The latter are very small, thus indicating a great interindividual homogeneity of the specimens and of the instrumentation effects. The post-fatigue values were throughout nearly identical with the instrumentation values and were not depicted for the reason of legibility. Results are presented for flexion/extension (**A**), lateral bending (**B**), and axial rotation (**C**)

ence between the motion data of specimens from the two operative groups (semirigid and rigid instrumentation).

The intact specimens showed total ranges of motion (ROM) in the primary motion planes of about 35° FE, 30° LB, and 10° AR for ± 3 Nm load. Destabilization led to a marked increase in the movement at the injured levels in the primary planes. Compared to intact specimens, average movement increased by 162.9% (FE), 25.7% (LB), and 186.7% (AR).

A summary of the significant changes in motion from intact to stabilized specimens is provided in Table 2, including the standard deviations. Semirigid instrumentation significantly reduced the average movement of the transfixed vertebrae in all primary movement planes by between 42.5% and 84.8%, compared to the intact values ($P < 0.001$). Rigid instrumentation significantly reduced the average movement of the transfixed vertebrae in all primary movement planes by between 67.1% and 86.9% ($P < 0.001$).

The ROMs at L3 of all specimens of a particular loading mode, implant type, and experimental status are plotted in Fig. 2. The rigid data, semirigid data, and results of spines tested in the intact state prior to instrumentation for each of the three primary motion planes can also be derived from that figure.

The average movement of L1-2 and L2-3 (adjacent segments) in lateral bending for devices stabilized with the rigid system increased in the stabilized state as compared to the intact state. The semirigid method significantly increased the average motion of the L2-3 motion segment compared to intact specimens in axial rotation. There were no other significant changes in adjacent segment primary motions due to instrumentation (Table 2).

Cyclic loading of specimens did not significantly affect device performance. No detectable loosening occurred at the implant-implant (longitudinal element loosening within the screw head) or at the screw-bone interfaces. No significant increases in motion at any level compared to the stabilized state were present.

Coupled motions are about one order of magnitude smaller than primary motions. This makes analysis of out-of-plane motion more difficult. Possible trends are often obscured because scatter is relatively high. Nevertheless, some observations proved to be statistically significant regarding coupled motions. These are summarized in Table 3, including their standard deviations. Coupled motions at adjacent levels were not significantly affected by any spinal fusion method.

The loosening torques of fixation nuts, after completion of all motion testing and fatigue loading, decreased compared to the tightening torque (< 15 Nm) by 31.5% (SD = 11.2%) for specimens with rods and by 50.8% (SD = 9.5%) for those with cables. However, disassembling the implant did not reveal any loosening at the screw head or failure of the machine threads and locking nuts in any specimen. One specimen from the rigid instrumentation group (afterwards excluded from the study because post

Table 3 Significant changes in coupled motions at fixed levels

Loaded plane	Motion plane	Fixation type	Motion change	
			L3–4	L4–5
Flexion/extension	Lateral bending	Semirigid	ns	ns
		Rigid	ns	ns
	Axial rotation	Semirigid	ns	ns
		Rigid	ns	–112% SD = 97
Lateral bending	Flexion/extension	Semirigid	ns	–52% SD = 109
		Rigid	–90% SD = 40	–103% SD = 49
	Axial rotation	Semirigid	–84% SD = 39	–93% SD = 227
		Rigid	–81% SD = 44	–88% SD = 239
Axial rotation	Flexion/extension	Semirigid	–60% SD = 158	–265% SD = 606
		Rigid	ns	–75% SD = 135
	Lateral bending	Semirigid	–106% SD = 295	–81% SD = 57
		Rigid	–235% SD = 707	–72% SD = 38

fatigue testing could not be performed) was accidentally subjected to a flexion/extension load of ± 12 Nm while fatigue loading was being set up. The sacrum of this specimen broke off in the polymer resin base after about 100 cycles. The implant and instrumented vertebrae remained unaffected.

Discussion

A two-level, clinically relevant instability was chosen for the study: bilateral facetectomy and nucleotomy from a posterior approach. Gwon et al. induced a similar injury to one level in ten fresh ligamentous L1-S1 specimens at L4-5 and subjected them to pure bending moments in FE, LB, and AR. The destabilization procedure was shown to effectively increase motion in the segment [14]. Recently, the destabilizing effect of facetectomy was also confirmed for loads other than pure bending moments [29]. A two-level instability was chosen, because the injury for which the stabilization effect of an implant is tested should be specific for its intended application [26].

The application of pure moments is used extensively in the literature for stability testing, because the precise load is known at every level and does not vary along the length of the spine [27]. To further enhance the accuracy of data acquisition, a 6-Nm pure moment range has been used for lumbar spine motion testing [8, 9], though loads as high as 15 Nm have been reported [26]. Such high loads are not necessary to test the motion characteristics of the instrumented spine. The relative stabilities of each implant did not vary much with respect to the others tested, regardless of load magnitude [1, 27]. The stability of the Steffee VSP did not vary whether tested to a maximum load of 3 Nm or 6 Nm [10, 14, 25]. Additional strictly axial loads were not introduced because, owing to the small number of authors having done so in a 3D study, this would have resulted in less comparable results.

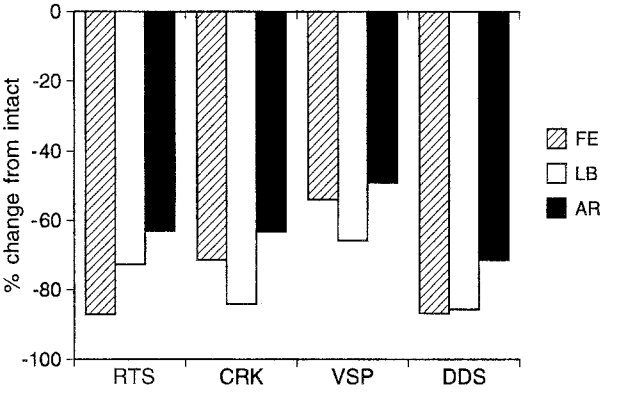
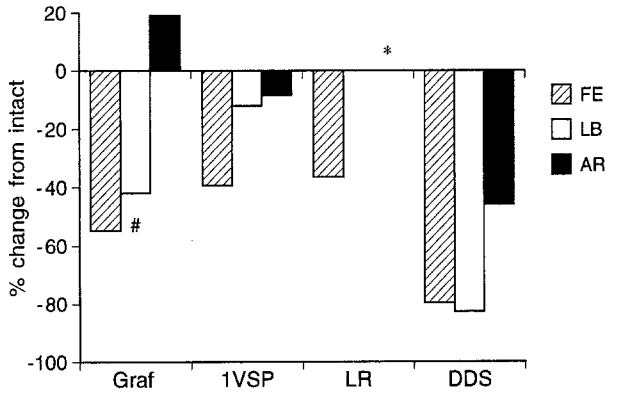


Fig. 3 Comparison of the change in motion imparted by the rigid DDS device with the results for devices tested by Gwon et. al. [14] (*RTS* Rod transpedicular screw system, *CRK* Crock device, *VSP* Steffee variable screw plate, *FE* flexion/extension, *LB* lateral bending, *AR* axial rotation)

The rigid DDS device imparted stabilities similar to currently accepted pedicle screw devices (see Fig. 3) [14].

Flexion and extension after posterior injury with an intact anterior column places posterior instrumentation in mostly tension and compression because of load sharing with the intact anterior column and the forward movement of the instantaneous center of rotation [33]. This is why the semirigid DDS reduces the amount of motion across a segment nearly as well as the rigid DDS in this loading mode.

A summary of biomechanical performances of the semirigid devices is presented in Fig. 4. Other posteriorly placed, reduced-rigidity devices have been shown to perform well in flexion-extension when in construct with an intact anterior column. A Steffee VSP placed unilaterally reduced motion of a posteriorly injured segment by 40% of its intact value, while the device placed bilaterally reduced motion by about 60% [10]. Graf dorsal tension bands [11, 12] reduced primary sagittal rotation by about



* No axial rotation data presented for the Luque rod in the study by Goel et al. [9]
\# Implant tested in injury model with intact facets

Fig. 4 Comparison of the change in motion compared to the intact state imparted by the semirigid DDS device with the results for various devices tested in the literature as tested with similar injury models (*LR* Luque rods, *VSP* unilateral Steffee plate)

50% with respect to its intact value in an injury model that did not include facet removal [32].

Implants attached to the spine with segmental wiring or sublaminar hooks can be considered semirigid, since the implant-bone interface is not as stable as with pedicle screw devices [6, 18, 30]. The segmentally wired Luque closed loop has provided a 36% reduction in motion compared to the intact value in flexion-extension loading [9]. Harrington distraction rods and Luque rectangle rods both reduced flexibility of an injured motion segment in flexion by more than 50% compared to the intact state, though the Harrington device did not perform as well in extension [1, 27].

It is important to have bilaterally placed devices that can resist compression and tension in order to stabilize the spine during lateral bending loads. A pure lateral bending moment is countered by tension in one side of a bilaterally placed device and compression in the opposite. This is why the semirigid DDS was able to reduce motion in this plane as effectively as the rigid implant. A unilaterally placed Steffee VSP did not have the advantage of being placed in tension and compression and, therefore, performed poorly in lateral bending in the testing of Goel et al.: with respect to the intact state, the unilateral VSP reduced motion by 13% compared to 65% for the bilateral VSP [10]. The Graf dorsal tension bands resist tension themselves, but depend on compression of intact facet joints to resist compression [2].

Axial rotation is resisted primarily by bending and twisting of the longitudinal elements. Due to its lower bending and torsional rigidity, axial rotation was less effectively resisted by the semirigid DDS device, which reduced motion by 43% compared to the intact value, while the rigid device reduced motion by 67%. The unilaterally placed VSP performs worse than the semirigid DDS in this loading mode, resulting in 9% reduced motion compared to the intact state while the bilateral VSP reduced motion by 50% in the study by Goel et al. [10]. No such biomechanical data are yet available for other semirigid implants, e.g., ISF [20] or Isolock [13]. The Steffee VSP applied unilaterally has been shown to promote spine fusion successfully [17]. The semirigid DDS provides adequate stability to promote successful fusion, which has in the meantime been confirmed by a clinical study.

It has been proven that stress-shielding effects (vertebral body osteopenia and bone resorption around pedicle screws) can be reduced by reduced implant rigidity [10]. This makes the use of the semirigid DDS particularly attractive. Screw failure in a pedicle screw implant can be very difficult or impossible to correct [3]. Failure risk of the DDS screws, presumably, further decreases with the switch from rigid to semirigid longitudinal elements.

Load sharing with an intact anterior column is surely increased due to semirigidity. Finite-element investigations or experimentation with strain gauges are necessary to determine the increase in load sharing that occurs as a result of semirigidity. In vivo investigations are necessary to confirm that the semirigid device is adequate for fusion and to determine the effects of reduced rigidity on stress shielded bone. These studies are currently underway.

Conclusions

The implant system, in both forms, proved to be practical from a surgical point of view.

The semirigid DDS does not primarily work as a tension band system and can thus also be applied in cases of facetectomy.

The rigid DDS device imparted stability similar to other pedicle screw and rod devices.

The semirigid DDS device provided stability similar to the rigid DDS implant in all loading modes except axial rotation.

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