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ORIGINAL ARTICLE

Optimal stiffness of a pedicle-screw-based motion preservation implant for the lumbar spine

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Abstract
Purpose Pedicle-screw-based dynamic implants are intended to preserve intervertebral mobility while releasing certain spinal structures. The aim of the study was to determine the as yet unknown optimal stiffness value of the longitudinal rods that fulfils best these opposing tasks.
Methods A finite element model of the lumbar spine was used which includes the posterior implant at level L4/5. More than 250 variations of this model were generated by varying the diameter of the longitudinal rods between 6 and 12 mm and their elastic modulus between 10 MPa and 200 MPa. The loading cases flexion, extension, lateral bending and axial rotation were simulated. Evaluated optimization criteria were the ranges of motion, forces in the facet joints, posterior bulgings of the intervertebral disc and the intradiscal pressures. Various objective functions were evaluated.
Results The results show that the objective values depend more on the axial stiffness of the rods than on bending and torsional stiffness, rod diameter and elastic modulus. The optimal stiffness value for most of the investigated objective functions is approximately 50 N/mm and is achieved, e.g. using a rod diameter of 6 mm and an elastic modulus of 50 MPa. The design with the least axial stiffness was the best one with regard to the mobility. The forces in the facet joints and the intradiscal pressures were reduced mostly by an implant with the highest axial stiffness. When minimal posterior disc bulging was the criterion, the optimal axial stiffness was also approximately 50 N/mm.
Conclusions The optimal axial stiffness of a pedicle-screw-based motion preservation implant for the lumbar spine is approximately 50 N/mm.

Keywords Biomechanics · Dynamic implant · Stiffness · Finite element method · Optimization

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Introduction

Pedicle-screw-based motion preservation implants are used in patients with symptomatic, slightly degenerated discs as well as in patients after decompression surgery to stabilize the segment. These implants are thought to reduce the loads on the intervertebral discs and the facet joints while maintaining physiological intersegmental motion. After decompression, the flexibility of the segment should be reduced to normal. The mechanical effect of a dynamic implant on load reduction and segmental flexibility depends mainly on its stiffness. The shape of the longitudinal part of a pedicle-screw-based dynamic implant may vary. Solid rods, helical springs, combination of a spacer and a cord etc. are used. Stiffness of an implant is determined by its shape and elasticity and therefore varies considerably for existing dynamic implants [1–4]. Its optimal value depends on local conditions and is still unknown.

Schmidt et al. [5] optimized the axial and bending stiffness of the DSS^{TM} dynamic implant (Paradigm Spine; Wurmlingen, Germany) using the finite element method. Their results were confirmed in an in vitro study [4, 5]. The authors assumed that an optimal dynamic implant has a stiffness which reduces the spinal motion by 30% from the intact value. They found that a low stiffness value for the longitudinal rods is already sufficient to increase the stability of the spine-implant combination to a normal value.

In a previous probabilistic study it was shown that a pedicle-screw-based motion preservation implant (Elaspine™, Spinelab AG, Winterthur, Switzerland) reduces the forces in the facet joints, except for some cases during axial rotation of the upper body [2]. Furthermore, the intradiscal pressure (IDP) is reduced in all cases, except for a few design combinations during flexion. The intervertebral rotation (IVR) usually decreases with increasing stiffness of a dynamic implant.

A dynamic implant should fulfil two oppositional tasks. On the one hand it should allow physiological intervertebral rotations and on the other hand it should reduce the loads on spinal structures. Taking into account motion and varying loading conditions, the optimal stiffness of a pedicle-screw-based nonfusion implant has not yet been determined.

In an optimization process, the best solution within a defined domain of the input parameters (e.g. different rod diameters and elastic moduli) is determined. This is done by determining the best value of an objective function within the defined domain. The objective function is defined by a combination of output values (e.g. IVR, IDP) which depend on the input parameters. The best value of an objective function is generally found by applying an optimization strategy (e.g. a gradient-based or an evolutional one). In a complex field such as spine biomechanics, different objective functions and different types of domains can be chosen which in principle can deliver different optimal input variables.

Important design parameters of the longitudinal rod of a dynamic implant are its diameter and elastic modulus (assuming a linear elasticity). Axial, bending and torsional stiffnesses of the rod all depend on both design parameters. It is not clear which of these stiffnesses correlates best with the objective values of the result parameters IVR in the loading plane, facet joint force (FJF), posterior disc bulging (PDB) and IDP. It is assumed that these mechanical parameters are most important for clinical success.

The aim of this study was to determine the optimal stiffness of the solid rods of a simple pedicle-screw-based dynamic implant with respect to different objective functions. The kind of stiffness should be used that correlates best with these objective functions.

Methods

Finite element model

A finite element model of the lumbar spine, ranging from L3 vertebra to the sacrum, was used (Fig. 1). Hexahedron elements were used for the vertebrae and sacrum. The curved facet joints had a thin cartilaginous layer and a gap of 0.5 mm in the unloaded position. These could only transmit compressive forces. The annuli fibrosi were modelled as a fibre-reinforced hyperelastic composite. The fibres were arranged in concentric rings around the nucleus pulposus in two times seven layers in criss-cross pattern under angles of about 30° and 150° relative to the cross-section of the disc. The nuclei pulposi were simulated as incompressible fluid-filled cavities. All eight major ligaments were included in the model. The material properties of various structures were taken from the literature (Table 1). The model was described in detail elsewhere [6, 7]. It has been extensively validated in regard to intersegmental rotation and IDP [8–10].

A pedicle-screw-based dynamic implant was simulated at level L4–L5 (Fig. 1). It consisted of four screws and two rods. The screws had a diameter of 5 mm and an elastic modulus of 110,000 MPa. A rigid bond was assumed to be present between the screws and the vertebrae as well as between the screws and the rods. The diameter of the rods was varied between 6 and 12 mm in steps of 0.5 mm and their elastic modulus between 10 and 200 MPa in steps of 10 MPa, leading to 260 possible combinations. The pedicle screws (titanium) and the longitudinal rods (polycarbonate-urethane, PCU) were modelled using beam elements. The ranges chosen are based on a previous probabilistic and sensitivity study [2].

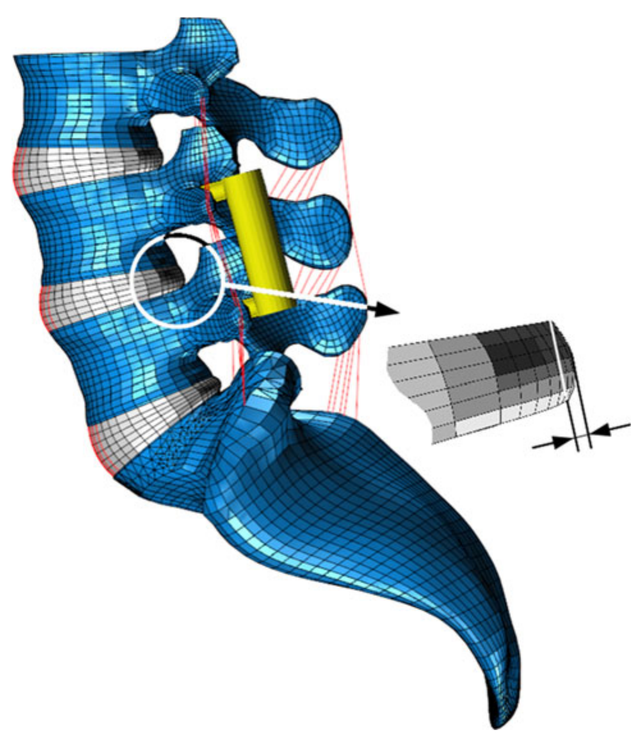

Fig. 1 Finite element model of the treated spine and definition of disc bulging

Table 1 Material properties and element types used for the different components

Component	Elastic modulus in MPa	Poisson ratio	Element type	References
Cortical bone	10,000	0.30	8-Node Hex	[16]
Cancellous bone (transverse isotropic)	200/140	0.45/0.315	8-Node Hex	[17]
Posterior bony elements	3,500	0.25	8-Node Hex	[18]
Ground substance of annulus fibrosus	Hyperelastic, neohookean $C_{10} = 0.3448$, $D_1 = 0.3$		8-Node Hex	[19]
Fibres of annulus fibrosus	Nonlinear and dependent on the distance from the disc centre		Rebar	[18]
Nucleus pulposus	Incompressible fluid-filled cavity		Fluid	[7]
Ligaments	Nonlinear		Spring	[16, 20]
Cartilage of facet joint	Soft contact			[21]
Pedicle screws	110,000	0.30	Beam	
Longitudinal rods	10–200	0.30	Beam	

Table 2 Applied loads for the different loading cases

Loading case	Follower load (N)	Moment (Nm)	Moment direction	References
Standing	500			[11]
Extension	500	7.5	Extension	[14]
Flexion	1,175	7.5	Flexion	[14]
Axial rotation	720	5.5	Left axial rotation	[13]
Lateral bending	700	7.8	Right lateral bending	[12]

The loading cases for flexion, extension, lateral bending and axial rotation were all studied (Table 2). In order to simulate these activities, a follower load was applied in a first step, representing the compression force during standing [11]. In a second step, a moment representing the associated activity was applied and simultaneously the follower load was increased to the corresponding value as given in Table 2 [12–14].

Reference result values for each loading case were calculated using the intact model without implant. Then, a total of 260 calculations were performed for each of the four loading cases, considering all possible combinations of diameter and elastic modulus of the rods. The calculations were evaluated according to the different objective functions explained below.

Stiffness of the longitudinal rod

The axial, bending and torsional stiffnesses of the longitudinal rods for all diameter and elastic modulus combinations were calculated (Table 3). The impact of the different kinds of stiffnesses is determined by calculating the coefficient of determination R^2 for the different kinds of stiffnesses, rod diameter, and elastic modulus and the different objective functions described below. The coefficients of determination were calculated for exponential regression functions (dependent variables) approximating the objective values for the different investigated independent variables (diameter, elastic modulus, axial, bending, and torsion stiffness).

Objective functions

The intended goal of a dynamic implant and thus the objective function may vary. Different objective functions will generally lead to different optimal values for the implant design parameters. In this study, several objective functions were investigated to demonstrate their effect on the optimal value of the input parameters.

The combined objective functions in this study are composed of four base objective functions taking each of the output parameters IVR, FJF, PDB and IDP into account.

For the objective function related to the IVR, the main Cardan angles were used for evaluation. As objective it was assumed that the resulting IVR for each of the four loading cases should be as close as possible to the IVR of the intact spine:

$$f_{\mathrm{IVR}} = \frac{1}{4}\sum_{\mathrm{LC}(4)} \frac{\mathrm{IVR}(\mathrm{LC}, E, d) - \mathrm{IVR}_{\mathrm{worst}}(\mathrm{LC})}{\mathrm{IVR}_{\mathrm{best}}(\mathrm{LC}) - \mathrm{IVR}_{\mathrm{worst}}(\mathrm{LC})},$$

where LC = load case (flexion, extension, lateral bending or axial rotation); E = elastic modulus of rods; d = diameter of rods; best = best value (for definition see Table 4); worst = worst value (for definition see Table 4).

Table 3 Coefficient of determination R^2 for different input and output parameter combinations

Parameter	Proportional to	Output parameters				
		IVR	FJF	PDB	IDP	Combination of IVR, FJF, PDB and IDP
Rod diameter	d	0.23	0.38	0.16	0.14	0.08
Elastic modulus	E	0.73	0.59	0.50	0.81	0.54
Axial stiffness	E, d^2, $1/l$	1.00	0.96	0.93	0.99	0.99
Bending stiffness	E, d^4, $1/l$	0.89	0.96	0.78	0.87	0.71
Torsion stiffness	G, d^4, $1/l$	0.89	0.96	0.78	0.87	0.71

IVR intervertebral rotation, *FJF* facet joint force, *PDB* posterior disc bulging, *IDP* intradiscal pressure, *d* diameter, *E* elastic modulus, *l* rod length, *G* shear modulus

Table 4 Definition of best and worst values of optimization criteria

Optimization criterion	Best value	Worst value
Intervertebral rotation (IVR)	Identical to intact without implant for the corresponding loading case	0°
Facet joint force (FJF)	0 N	Identical to intact without implant for the corresponding loading case
Maximum posterior disc bulging (PDB)	Identical to standing without implant	Identical to intact without implant for the corresponding loading case
Intradiscal pressure (IDP)	Identical to standing without implant	Identical to intact without implant for the corresponding loading case

The fractions are 100% for the best and 0% for the worst objective value with respect to each load case.

The objective for the FJF was to be as small as possible for all loading cases, leading to the following objective function:

$$f_{\mathrm{FJF}} = \frac{1}{4}\sum_{\mathrm{LC}(4)} \frac{\mathrm{FJF}(\mathrm{LC},E,d) - \mathrm{FJF}_{\mathrm{worst}}(\mathrm{LC})}{\mathrm{FJF}_{\mathrm{best}}(\mathrm{LC}) - \mathrm{FJF}_{\mathrm{worst}}(\mathrm{LC})}$$

The PDB was defined as the change in distance of the outer posterior midpoint of the intervertebral disc from the straight line connecting the upper and lower posterior corners of the disc (Fig. 1). Since a short-term increased PDB may already cause pain, the objective was that the maximum PDB of all loading cases should be close to the value for standing without implant. This leads to the following objective function for the PDB:

$$f_{\mathrm{PDB}} = \max_{\mathrm{LC}} \left(\frac{\mathrm{PDB}(\mathrm{LC},E,d) - \mathrm{PDB}_{\mathrm{worst}}(\mathrm{LC})}{\mathrm{PDB}_{\mathrm{best}}(\mathrm{LC}) - \mathrm{PDB}_{\mathrm{worst}}(\mathrm{LC})} \right)$$

The objective for IDP was chosen in such a way that—in all loading cases—it should be as close as possible to that of standing without implant:

$$f_{\mathrm{IDP}} = \frac{1}{4}\sum_{\mathrm{LC}(4)} \frac{\mathrm{IDP}(\mathrm{LC},E,d) - \mathrm{IDP}_{\mathrm{worst}}(\mathrm{LC})}{\mathrm{IDP}_{\mathrm{best}}(\mathrm{LC}) - \mathrm{IDP}_{\mathrm{worst}}(\mathrm{LC})}$$

A combination of the four different base objective functions mentioned above leads to the following final objective function:

$$f_c = \frac{af_{\mathrm{IVR}} + bf_{\mathrm{FJF}} + cf_{\mathrm{PDB}} + df_{\mathrm{IDP}}}{a+b+c+d}$$

A total of 13 different combinations of the weighting factors a, b, c, and d were studied (Table 5). Objective function nos. 1–4 represent a single optimization criterion IVR, FJF, PDB or IDP. The average of the criteria is considered in no. 5. In each of the objective function nos. 6–9, one criterion is excluded. In nos. 10–13 one criterion obtained twice the weight of the others.

The objective function nos. 5–13 are combinations of the four base objective function nos. 1–4 where the investigated loading cases were equally weighted (see formulas for f_{IVR}, f_{FJF}, and f_{IDP}). Another meaningful possibility could be the choice of base objective functions which take into consideration that some loading cases are performed more frequently than others. Therefore, in an additional objective function (no. 14), it was assumed that flexion is 5 times, extension twice and axial rotation 20 times as often performed as lateral bending. The high value for axial rotation was chosen since the spine rotates with each step during walking. Subsequently, the alternative base objective

Table 5 Considered weighted combinations of optimization criteria for the objective function $f_c = \frac{af_{\mathrm{IVR}} + bf_{\mathrm{FJF}} + cf_{\mathrm{PDB}} + df_{\mathrm{IDP}}}{a+b+c+d}$ and calculated optimal values

Number of objective function	Weighting factor				Optimal axial stiffness	Optimal diameter	Optimal elastic modulus	Max. value of objective function (%)
	a	b	c	d				
1 (IVR)	1	0	0	0	11	6	10	82
2 (FJF)	0	1	0	0	754	12	200	96
3 (PDB)	0	0	1	0	47	6	50	76
4 (IDP)	0	0	0	1	754	12	200	67
5	1	1	1	1	47	6	50	73
6	0	1	1	1	47	6	50	70
7	1	0	1	1	47	6	50	73
8	1	1	0	1	58	11	20	73
9	1	1	1	0	47	6	50	76
10	2	1	1	1	47	6	50	74
11	1	2	1	1	47	9.5	20	73
12	1	1	2	1	47	6	50	74
13	1	1	1	2	47	6	50	71
14*	1	1	1	1	48	10	20	68

* $f_{\mathrm{IVR}}, f_{\mathrm{FJF}}$ and f_{IDP} were averaged after considering relative activity numbers of 5, 2, 1 and 20 for flexion, extension, lateral bending and axial rotation, respectively

functions $f_{\mathrm{IVR}}, f_{\mathrm{FJF}}$ and f_{IDP} were then averaged in a manner similar to that in objective function no. 5.

For the finite element calculations, the program ABAQUS, version 6.8 (SIMULIA Inc. Providence, RI, USA) was used.

Results

Best kind of stiffness parameter

The axial stiffness shows the highest values for the coefficient of determination of all parameters studied when an exponential regression was performed (Table 3). Therefore, in the following the objective functions are shown as a function of the axial stiffness.

Objective functions for single output parameters

The objective function nos. 1–4 for the 4 different output parameters (IVR, FJF, PDB, IDP) are represented as a function of the axial stiffness in Fig. 2. Their highest values and the corresponding parameters axial stiffness, rod diameter and elastic modulus are given in Table 5.

The objective function of the IVR decreases with growing axial stiffness. According to this criterion, the optimal design is the one with the least axial stiffness (11 N/mm, Table 5, objective function no. 1), which corresponds e.g. to a rod diameter of 6 mm and an elastic modulus of 10 MPa for the rods. The objective function has a value of about 80% for an axial stiffness between 11 and 60 N/mm.

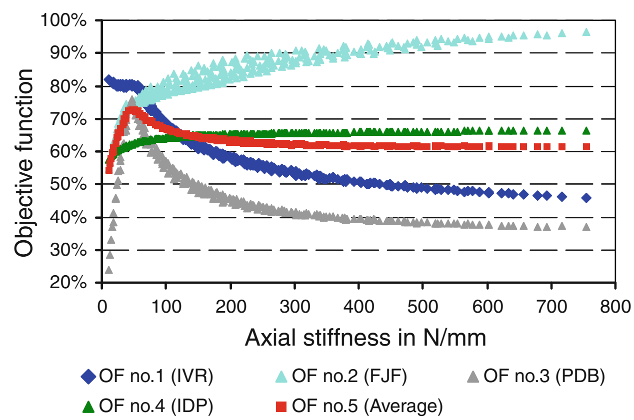

Fig. 2 Objective functions (OF) for the four single optimization criteria intervertebral rotation (IVR), facet joint force (FJF), posterior disc bulging (PDB), and intradiscal pressure (IDP) and for the average of these four criteria (objective function nos. 1–5 in Table 5)

With increasing axial stiffness of the implant, the objective function of FJF increases, which means that the FJFs themselves decrease. The forces are most reduced for a rod diameter of 12 mm and an elastic modulus of 200 MPa (Table 5). However, even for an axial stiffness of 60 N/mm, the objective function has already a high value (75%) and thus a strong reduction of the forces is achieved

(Fig. 2). The large scatter of this curve is due to the nonlinear effect of the rod diameter. For the same axial stiffness, larger diameters better reduce the FJFs than do smaller ones, especially for axial stiffnesses between 60 and 500 N/mm. The coefficient of determination R^2 is 0.96 between FJF and axial, bending as well as torsional stiffness (Table 3).

The axial stiffness has a nonmonotone effect on the objective function of the PDB. The objective function has its maximum value (76%) for an axial stiffness of 47 N/mm. Below that value, the PDB is greatest for the loading case extension. For this loading case, the value of the objective function increases with increasing implant stiffness. For stiffness values higher than 47 N/mm, the PDB becomes largest for the loading case flexion. Here, the objective function decreases with increasing axial stiffness. Thus, the optimal design regarding the PDB has an axial stiffness of 47 N/mm, corresponding e.g. to a rod diameter of 6 mm and an elastic modulus of 50 MPa.

The objective function of the IDP does not vary much for different axial stiffnesses. The objective function values lie between 58 and 67%. Again, the best design has a maximum stiffness which corresponds to a rod diameter of 12 mm and an elastic modulus of 200 MPa, which are the maximum values in the investigated design space.

Effect of weighting factor

Averaging the four base objective functions (nos. 1–4) leads to a typical curve of the objective function with a maximum value for an axial stiffness of 47 N/mm (Fig. 2). The value of the objective function varies between 54 and 73% in the chosen domain.

The different combinations of weighting factors (objective function nos. 6–13 in Table 5) have only a minor effect on the shape of the objective function curves (Figs. 3, 4). The optimal axial stiffness is mostly 47 N/mm

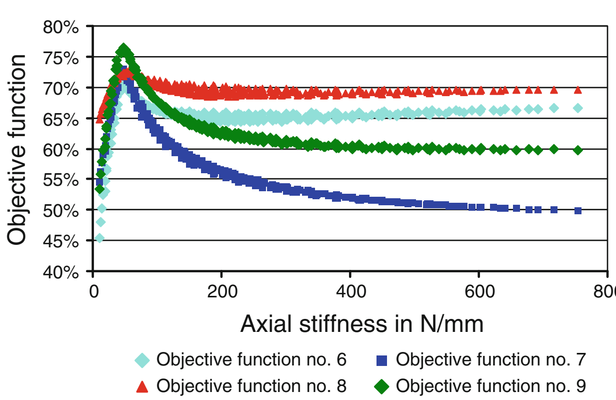

Fig. 3 Objective function nos. 6–9 (Table 5) where one of the four optimization criteria (IVR, FJF, PDB, IDP) was omitted

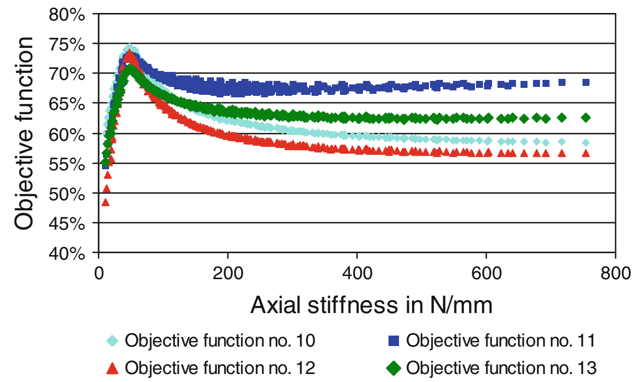

Fig. 4 Objective function nos. 10–13 (Table 5) where one of the four optimization criteria (IVR, FJF, PDB, IDP) was double weighted

corresponding to a rod diameter of e.g. 6 mm and an elastic modulus for the rods of 50 MPa. The same axial stiffness (47 N/mm) is accomplished with a rod diameter of 9.5 mm and an elastic modulus of 20 MPa (objective function no. 11). According to objective function no. 8, the optimal axial stiffness was 58 N/mm (e.g. rod diameter of 11 mm and elastic modulus of 20 MPa). For the different weighting factor combinations, the best objective function value seen is between 70 and 76% (Table 5).

When taking different activity numbers for each of the four loading cases into consideration (objective function no. 14), the axial stiffness was again 47 N/mm, fulfilling the objective function to 68%.

Discussion

Pedicle-screw-based motion preservation implants are intended to fulfil two oppositional tasks, namely to reduce the loads in different spinal structures and to maintain the natural intervertebral range of motion. This is best achieved with an axial stiffness of the longitudinal rods of approximately 50 N/mm. The different objective functions investigated usually have only a minor effect on this value.

It could be shown that the axial stiffness has a stronger correlation with the objective functions than the bending and torsional stiffness as well as the diameter d and elastic modulus E of the rods. As long as these design parameters (d, E) lead to the optimal axial stiffness, their combination is not very relevant with respect to the examined objective functions. The combination should be chosen according to other objectives such as fatigue strength, avoidance of buckling, the available anatomical space, or the availability and costs of approved biocompatible materials with certain elastic moduli. The coefficients of determination (Table 3) were calculated for an exponential regression. The values for bending and torsion stiffness are the same since both are proportional to E, d^4 and $1/l$ (shear modulus G is

proportional to elastic modulus E if the Poisson ratio is constant). Contrary, the axial stiffness is proportional to d^2. The absolute values for R^2 depend on the chosen kind of regression which was always the same in the present study.

In order to acquire an IVR, which is about 80% of the intact, the axial stiffness has to be less than 60 N/mm (Fig. 2). On the contrary, the values for FJF and IDP are most reduced when the rods have the highest axial stiffness. However, a low axial stiffness can already enormously reduce the facet joint forces. Taking the PDB into consideration, an axial stiffness of about 47 N/mm appears most reasonable. When combining all criteria with different weighting factors, the most adequate compromise for the axial stiffness is also approximately 50 N/mm. A dynamic implant with such a stiffness leads to an average IVR reduction of 20% which is even less than the 30% suggested by Wilke, Schmidt et al. [4, 5].

Although the used model was extensively validated, this study has some limitations. Geometry and material properties of the spine were held constant, while in reality they vary inter-individually. The disc of the corresponding segment was considered to be nondegenerated, which is rarely the case for treated segments. In in vitro-studies increased as well as decreased ROMs for flexion/extension and lateral bending were found for slightly degenerated discs compared to healthy ones [15]. Only the segment L4–L5 was investigated. The magnitudes of the loads for the different loading cases were not varied, although the body weight and the muscle forces may vary strongly inter-individually. A rigid bond was assumed between screws and vertebrae. A more realistic bond would affect the stresses at the interface but hardly the results of the present study. All of these parameters affect the optimal axial stiffness value, but the suggested value of about 50 N/mm is merely meant to provide the order of magnitude. Furthermore, the determination of the optimal implant stiffness for a specific patient is presently not possible, among other things due to lacking information about the material properties of the different tissues of that patient. Thus, implants have to be designed for an average patient.

When the implant is used after a defect has been created during surgery, the IVR is usually increased compared to the intact situation. This might require a stiffer implant to reduce the IVR to the normal value. Additional studies are necessary to optimize implant stiffness for that situation.

The optimal design parameters were determined for several objective functions. These functions may vary depending on the chosen priority of the output parameters. If the achievable IVR is considered to be more important than the spinal load reduction, the objective function would be different than that in the case where load reduction had the highest priority. Different objective functions usually lead to different optimized input parameters. However, several sensible objective functions have been investigated in this study, all leading to similar good fulfilment of the objectives. This avoids deciding which objective is most important.

In conclusion, for most of the objective functions chosen, the optimal axial stiffness of a pedicle-screw-based motion preservation implant is approximately 50 N/mm, which corresponds e.g. to a rod diameter of 6 mm and an elastic modulus of 50 MPa.

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