In silico evaluation of a new composite disc substitute with a L3–L5 lumbar spine finite element model

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Received: 15 October 2009 / Revised: 26 January 2011 / Accepted: 6 February 2011 / Published online: 5 March 2011
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Abstract When the intervertebral disc is removed to relieve chronic pain, subsequent segment stabilization should restore the functional mechanics of the native disc. Because of partially constrained motions and the lack of intrinsic rotational stiffness ball-on-socket implants present many disadvantages. Composite disc substitutes mimicking healthy disc structures should be able to assume the role expected for a disc substitute with fewer restrictions than ball-on-socket implants. A biomimetic composite disc prototype including artificial nucleus fibre-reinforced annulus and endplates was modelled as an L4–L5 disc substitute within a L3–L5 lumbar spine finite element model. Different device updates, i.e. changes of material properties fibre distributions and volume fractions and nucleus placements were proposed. Load- and displacement-controlled rotations were simulated with and without body weight applied. The original prototype reduced

greatly the flexibility of the treated segment with significant adjacent level effects under displacement-controlled or hybrid rotations. Device updates allowed restoring large part of the global axial and sagittal rotational flexibility predicted with the intact model. Material properties played a major role, but some other updates were identified to potentially tune the device behaviour against specific motions. All device versions altered the coupled intersegmental shear deformations affecting facet joint contact through contact area displacements. Loads in the bony endplates adjacent to the implants increased as the implant stiffness decreased but did not appear to be a strong limitation for the implant biomechanical and mechanobiological functionality. In conclusion, numerical results given by biomimetic composite disc substitutes were encouraging with greater potential than that offered by ball-on-socket implants.

Keywords Composite disc substitute · Lumbar spine finite element modelling · Adjacent level effects · Biomechanics · Body weight

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Introduction

25–30% of the EU-27 active population is estimated to suffer from low back pain at least once in their lives [26, 32]. The medulla facet joints (FJ) and bony endplates (BEP) are the main sources of pain habitually produced by intradiscal pressure (IDP) loss, intervertebral disc (IVD) height reduction, and annulus fibrosus lesion. Accordingly, severe sciatic pain can be eliminated by disc removal [20].

Sustainable treatments following IVD excision should primarily restore intervertebral space and segment mobility which is the objective of total disc replacement. A statistical

advantage of disc replacement over fusion has been suggested [14] and to date the most used and successful disc substitutes are the SB CHARITÉ® and the PRODISC®. Both consist in a polyethylene core articulating with two metallic endplates. Such ball-on-socket (BoS) designs were reported to be clinically successful [13, 49]. Nevertheless, BoS implants have a high axial stiffness and the articulated endplates slide freely over the polyethylene ball which can generate adjacent bony endplate damage and local over-flexibility, respectively. Indeed, overall complication rates of about 80% have been reported [40].

Known post-surgery complications, e.g. vertebral body fracture [6], prosthesis migration into the adjacent bone [4], spontaneous ankylosis [4, 33], and accelerated FJ degeneration [39] can be related to the BoS design as numerically suggested [2, 8, 35]. Also because prosthesis shapes are standardized geometrical patient-specificity is limited and strong correlations exist between prosthesis placement and clinical complications [4]. In the end, despite a significant number of follow-up studies advocating for a relative short-term clinical success of the CHARITÉ® PRODISC® and similar devices [50], long-term results are still not convincing [6, 50]. Such outcome seems independent on the treated low spine level, i.e. L4–L5 or L5–S1 [50].

Oswestry disability indexes suggested that FJ pain is the most recurrent negative outcome in BoS implant patients [39]. Accordingly, numerical finite element (FE) analyses pointed out that the constrained or semi-constrained transversal deformability of the segments treated with BoS devices could strongly affect FJ biomechanics [21, 37]. An IVD substitute made of fully deformable materials instead of rigid bodies with predefined relative motions would give instantaneous centres of rotation that better respect the interactions among spinal components including FJ contacts. The intrinsic stiffness of the deforming constituents would also allow controlling kinematical instability and endplate loading.

Following such view, Langrana et al. [17] virtually developed a deformable synthetic IVD where each component corresponded to a healthy IVD component. They investigated material properties and configurations that allowed reproducing some aspects of the healthy disc behaviour but never assessed the interaction of the resulting design with any lumbar spine structure.

Thus the present study aims to evaluate a prototype composite artificial disc [7] by modelling it as a L4–L5 IVD substitute within a L3–L5 lumbar spine FE model. Mechanical interactions of the prosthesis with the bi-segment model were investigated under different boundary conditions and several methods of improvement were explored.

Materials and methods

Intact model (IM)

The L3–L5 lumbar spine FE model used in this study had statistically averaged dimensions and included all the bony and IVD structures reported in [23] (Fig. 1a). The seven main ligaments were modelled. The capsular ligament formed a ring around the FJ that were C-shaped with central and ventral gaps of about 2 and 4 mm, respectively [23]. Inter-facet volume was filled by the upper and lower cartilage layers modelled as deformable contact bodies. The annulus was modelled as a composite reinforced material with 20 radial mono-oriented fibre layers embedded in a continuum matrix [22].

Tissue material properties are summarized in Table 1. NP and annulus ground substances were phenomenologically modelled as incompressible hyperelastic materials. For the FJ cartilage a general Mooney–Rivlin model was able to reproduce experimental compressive data [10]. Ligaments and annulus fibres were defined as hypoelastic unidirectional materials with tension-only tangent stiffness that depended on the spine level (ligaments) [28, 31] and on collagen Type I and II contents (annulus fibres) [22] (Fig. 1b, c).

Disc substitute

The disc substitute body consisted of a nucleus-like part made of 2-hydroxyethyl-methacrylate/polymethyl-methacrylate (*p*-HEMA/PMMA) and laterally enclosed by an annulus-like part of wound polyethylene-terephthalate (PET) bundles embedded in *p*-HEMA/PMMA (Fig. 2) [7]. The PET bundles had a volume fraction of 0.4 and diameter of 1.2 mm. They formed mono-oriented concentric layers organized in a criss-cross pattern and their orientation with respect to the transverse plane ranged from 45° to 35° from the inner to the outer layer. To limit placement problems during surgery the prosthesis design foresaw a nucleus-like part shape adapted to the morphology of the segment to treat. Accordingly, the modelled device matched exactly the contours of the surrounding vertebrae when inserted in the bi-segment model. PET fibres were represented by seven rebar mono-oriented layers with geometrical arrangements and volume fraction as defined for prototyping.

The device endplates were made of HAPEX™ a composite of hydroxyapatite and polyethylene [42]. The central section was 1-mm thick and the borders provided a 2-mm high rim to retain the prosthesis body (Fig. 3a). Uniformly distributed pegs 1 mm in height separated from each other by about 2 mm covered the outer surfaces. To limit the

Fig. 1 L3–L5 lumbar spine bi-segment model definitions including **a** a sagittal cut anterolateral view of a with detail of the modelled tissues and the longitudinal stress–strain behaviour of the modelled **b** ligaments and **c** annulus fibre bundles

Table 1 Summary of the material properties used for the model

Material	Constitutive law	E (MPa)	ν	G (MPa)			
Trabecular bone [23]	Isotropic transverse, linear elastic	140 ^a	0.45 ^a	48 ^a			
		140	0.18	77			
		250	0.32	77			
Cortical bone [23]	Isotropic transverse, linear elastic	8,000 ^a	0.4 ^a	2,857 ^a			
		8,000	0.23	2,400			
		12,000	0.35	2,400			
Bony endplate [45]	Isotropic, linear elastic	1,000	0.3	–			
Bony posterior elements [38]	Isotropic, linear elastic	3,500	0.3	–			
Cartilage endplate [25]	Isotropic, linear elastic	24	0.4	–			
Facet cartilage [22]	Generalized Mooney–Rivlin incompressible	$W = C_{10}(\overline{I}_1 - 3) + C_{01}(\overline{I}_2 - 3) + C_{11}(\overline{I}_1 - 3)(\overline{I}_2 - 3) + C_{20}(\overline{I}_1 - 3)^2 d\underline{\underline{\underline{S}}} = 2\frac{\partial W}{\partial \underline{\underline{\underline{C}}}}^{\frac{\partial W}{\partial \underline{\underline{\underline{C}}}}}$					
		$C_{10} = 0.227$ MPa, $C_{01} = 0.007$ MPa, $C_{11} = 1.824$ MPa, $C_{20} = 0.111$ MPa					
Ligaments [24]	Hypoelastic (Fig. 1b)	$dS = k(E) dE^{\#}$ $k(E) = 0 \quad \text{if} \quad E \leq 0$ $k(E) = A B E^{A-1} \quad \text{if} \quad 0 < E \leq E_t$ $k(E) = C \quad \text{if} \quad E \geq E_t$					
		A	B (MPa)	E_t	C (MPa)		
		Supraspinous	L3–L4	15.76	8.70×10^9	20.21×10^{-2}	7.70
			L4–L5	15.76	8.08×10^9		7.15
		Interspinous	L3–L4	4.07	4.66×10^9	15.77×10^{-2}	6.53
			L4–L5	4.07	6.32×10^2		8.85
		Ligamentum flavum	L3–L4	5.64	3.10×10^5	10.35×10^{-2}	47.30
			L4–L5	5.64	2.82×10^5		43.10
		Capsular	L3–L4	13.60	8.90×10^{15}	6.31×10^{-2}	92.57
			L4–L5	13.60	9.00×10^{15}		93.83
		Intertransverse	–	3.76	9.17×10^4	8.86×10^{-2}	424.91
		Posterior longitudinal	L3–L4	1.68	68.50	11.61×10^{-2}	26.60
			L4–L5	1.37	35.20		21.70
		Anterior longitudinal	L3–L4	3.18	7.28×10^2	12.72×10^{-2}	25.70
			L4–L5	2.96	4.58×10^2		23.88
		Annulus fibrosus fibres [22]	Hypoelastic (Fig. 1c)	$dS = f_b k(E)_{\text{collagen}} dE^{\#}$			
				$k(E)_{\text{collagen}} = 0$ MPa if $E \leq 0$	Outer AF (layers 1–5)		$f_b = 0.60$
$k(E)_{\text{collagen}} = 2.20 \times 10^6 E^{3.15}$ MPa	Mid-outer AF (layers 6–10)			$f_b = 0.45$			
if $0 < E \leq 1.51 \times 10^{-2}$	Mid-inner AF (layers 11–15)			$f_b = 0.31$			
$k(E)_{\text{collagen}} = 847.40$ MPa	Inner AF (layers 16–20)			$f_b = 0.26$			
if $E \geq 1.51 \times 10^{-2}$							
Annulus fibrosus matrix [5]	Neo-Hookean incompressible	$W = C_{10}(\overline{I}_1 - 3)$		$d\underline{\underline{\underline{S}}} = 2\frac{\partial W}{\partial \underline{\underline{\underline{C}}}}^{\frac{\partial W}{\partial \underline{\underline{\underline{C}}}}}$			
		$C_{10} = 0.25$ MPa					
Nucleus pulposus [41]	Mooney-Rivlin incompressible	$W = C_{10}(\overline{I}_1 - 3) + C_{01}(\overline{I}_2 - 3)$		$d\underline{\underline{\underline{S}}} = 2\frac{\partial W}{\partial \underline{\underline{\underline{C}}}}^{\frac{\partial W}{\partial \underline{\underline{\underline{C}}}}}$			
		$C_{10} = 0.12$ MPa, $C_{01} = 0.03$ MPa					

^a The Young's moduli are presented, respectively, in the 11, 22 and 33 directions. The Poisson's ratios and the Coulomb's moduli are given, respectively, in the 12 23 and 31 directions; 1: coronal plane horizontal direction 2: sagittal plane horizontal direction 3: axial direction [†] $\bar{I}_1$ and $\bar{I}_2$ are, respectively, the 1st and the 2nd invariant of the right Cauchy–Green tensor $\bar{\underline{\underline{C}}}$ deviatoric part and $\bar{\underline{\underline{S}}}$ is the 2nd Piola–Kirchhoff stress tensor. [#] $k(E)$ is the Green–Lagrange strain, E dependent unidirectional longitudinal stiffness in the fibre direction

number of elements the mesh of the body was kept coarser than that of the endplates, and both parts were glued together using a contact model (Fig. 3a). Device constitutive laws and material parameters were based on mechanical testing of both the constituent materials and manufactured prototype [7] (Table 2).

Starting from the prototyped design different cumulative changes were introduced to make the device more similar to the healthy IVD. In addition to the bi-segment model with the original prosthesis, i.e. the OP model device changes led to different treated models, i.e. the AFL, FNL, DS, FVL, and NPL models whose characteristics are

Fig. 2 Manufacture and design of the composite intervertebral disc substitute studied. **a** Mould used for the nucleus-like part. **b** Mandrel for annulus-like winding. **c** Schematic description of the winding process leading to the peripheral criss-crossed mono-oriented fibre layers embedded in the polymeric matrix. **d** Postero-coronal view of the final device prototype (reproduced from [23])

described in Table 3. Updates including alternative materials resulted from a search among commercial biomedical products. To virtually replace the stiff *p*-HEMA/PMMA matrix non-biodegradable foams and hydrogels with large strain elasticity were reviewed. Mechanically suitable candidates were the PurSil® AL (DSM Biomedical Materials B.V.) products aliphatic thermoplastic silicone polyether urethane copolymers. As an alternative to the stiff PET fibres PTFE was chosen since it is used for artificial ligaments [12] and allows stiffness that range from MPa to GPa. Fibre distribution and volume fractions were also adjusted and some of the implant modifications

were combined with a posterior shift of the NP-like part by one third of the initial annulus-like part thickness [34].

Treated model

The L4–L5 IVD of the IM was replaced by the device model (Fig. 3b). L4–L5 longitudinal ligaments were removed and the endplates adjacent to the prosthesis were thinned at the periphery simulating surgical placement by sawing [19, 27]. Peripheral pegs penetrated into the vertebrae through the BEP. Two contact models prevented separations between BEP and anchored pegs and allowed

Fig. 3 **a** Sagittal cut of the modelled disc substitute. **b** Device inserted in the treated model as a L4–L5 disc substitute

Table 2 Summary of the material properties used for the original prosthesis model

Material	Constitutive laws	E (MPa)	ν
HAPEX TM	Isotropic linear elastic	5,000	0.40
Annulus-like fibres	Unidimensional linear elastic	Traction 13,000 Compression 0	–
<i>p</i> -HEMA/PMMA matrix	Neo-Hookean compressible	Annulus-like 36 Nucleus-like 42	0.48 0.48
$\underline{\underline{\sigma}} = \frac{E}{2} \left[\frac{\frac{1}{2} - 2(J^{-1/3} - \frac{1}{2})^2}{(1-2\nu)J} \underline{\underline{I}} + \frac{\underline{\underline{B}}}{(1+\nu)J} \right]$			

J is the Jacobian determinant and $\underline{\underline{B}}$ the left Cauchy-Green tensor

non-anchored pegs pressing against the adjacent bone. The mesh of the vertebrae was locally refined to be congruent with the peg elements. Refined bone mesh was glued to the rest of the vertebrae sufficiently away from the regions of interest so that node linking did not affect the analysis.

Simulations

Bending moments of 7.5 Nm in sagittal flexion–extension and axial rotation were applied to the top of L3 while the lower endplate of L5 was fixed. Predicted ranges of motion (ROM) were compared with experimental data used in [23] and FJ contact forces and kinematics and BEP octahedral shear strains were calculated.

Possible effects of in vivo voluntary motions displacement-controlled rotations were simulated by imposing a sagittal flexion angle similar to that achieved in the IM under load control. Results were compared with the hybrid method proposed by Panjabi et al. [30]. Applied rotations were

additionally combined with follower compressive forces (BW) simulated as surface pressures to approximate the influence of body weight and muscle stabilization. The main compressive load acting on the mid-transverse area of L3 was 1100 N for the sagittal rotations and 500 N for the axial rotations [36]. Normal to the L4 mid-transverse area corrective loads of 200 N (sagittal rotations) and 150 N (axial rotations) were applied so that IDP increments from L3–L4 to L4–L5 corresponded to collected in vivo values [36]. All ROM calculated with BW loads had the relaxed standing posture as reference, i.e. 500 N follower force only.

Results

Intersegmental rotations

Comparing the ROM measured and predicted with similar boundary conditions the IM appeared to behave similarly to

Table 3 Summary of the successive device updates performed from the original prototype with names and abbreviations used for the corresponding treated models

Device model	Changes	Ojective	Characteristics	Combined change
Original prototype (OP)	None	Reference treated model	Constituent materials about 10 times stiffer than IVD tissues	None
AF and fibre material-like (AFL)	<i>p</i> -HEMA/PMMA matrix replaced by commercial PU-silicone composite PET fibres replaced by PTFE fibres	Use FDA approved implantable materials with mechanical properties close to those of IVD tissues	Matrix undeformed stiffness ~6 MPa Fibre stiffness = 850 MPa	None
Fibrous network stiffness-like (FNL)	Reduce PTFE fibre network apparent stiffness to 136 MPa	Mimic the overall fibre network stiffness of the healthy AF	Implant fibre volume content = 40% PTFE fibre stiffness = 340 MPa	None
Distributed fibres (DS)	Reduce fibre diameter to 0.6 mm ²	Increase the number of concentric layers and improve load distributions in the implant AF-like part	Number of concentric PTFE fibre layers = 14	Posterior shift of the implant NP-like part
Fibre VF-like (FVL)	Reduce the implant fibre volume fraction to 0.16	Bring the volume fraction of the PTFE fibres to a similar value to that described in the healthy AF.	PTFE fibre stiffness = 340 MPa PTFE fibrous network apparent stiffness ~54 MPa	Posterior shift of the implant NP-like part
NP stiffness-like (NPL)	Update PU-silicone composite grade for the implant NP-like part	Bring the stiffness of the implant NP-like part close to that of the healthy NP	NP-like part undeformed stiffness ~2 MPa	Posterior shift of the implant NP-like part

in vitro tested specimens (Fig. 4a). Moreover, when computed with BW forces extension motions of about 3° at the L3–L4 level led to L3–L4 IDP of about 0.5 MPa and L4–L5 motions of about 4° gave IDP of about 0.65 MPa. Under flexion with BW forces ROM of about 5° and 7° at the L3–L4 and L4–L5 level, respectively, gave IDP around 1.1 MPa at both levels. All these predictions were in line with the combined ROM and IDP in vivo values reported [36].

The OP model gave L4–L5 ROM values about 75 and 90% lower than those of the IM far below the experimental range (Fig. 4a). Simulated device modifications helped recovering flexibility at the treated level and greatest improvements were generally obtained with the AFL model. Under flexion–extension the global ROM of cadaveric specimens could not be achieved, but the L4–L5 segment of the NPL model with shifted NP was only about 9% stiffer than the stiffest specimens. Under axial rotation experimental L4–L5 ROM were reproduced after the stiffness of the prosthesis fibres had been adjusted. All further device updates allowed the flexibility of the treated segment progressing up to about 80% of the mean experimental value. Axial rotation results were similar for both right and left motions and only left rotation was reported.

Among the simulated pure rotations L4–L5 extension was particularly difficult to restore after virtual implantation (Fig. 4c). Under both extension and rotation NP posterior shift usually helped to progress towards the mobility of the

IM (Fig. 4c, d). Under axial rotation all modifications performed on the device fibrous network except fibre redistribution significantly improved the implant behaviour. Under flexion changes brought by the DF model had more effect than under other rotations and the NP posterior shift did not always help to recover the IM motion (Fig. 4b). Nevertheless, combined with the NPL model NP posterior shift always gave the best ROM outcomes (Fig. 4b–d).

BW forces often contributed to decrease the L4–L5 ROM. Under flexion this was particularly pronounced in all treated models which strongly hindered ROM restoration (Fig. 4b). Under extension L4–L5 motions in the IM were so reduced that prosthesis effects were not significant anymore (Fig. 4c). In the case of axial rotation the updated versions of the device seemed promising independently of the BW forces (Fig. 4d).

Under hybrid and displacement-control flexions, the loss of flexibility at the treated level induced adjacent level effects (ALE) represented by a L3–L4 ROM increase of about 30% in the OP model. BW loads did not affect this relative increase. However, with BW forces improvements predicted with the device updates were at least 10% higher with the hybrid than with the displacement-control method. In general the NPL model gave the lowest ALE and best ROM recovery at the treated level. With BW loading and for the hybrid method such improvement resulted in L3–L4 motions about 10% higher and L4–L5 motions about 50% lower than the IM motions.

Fig. 4 Ranges of motion predicted by the different models under **a** pure total flexion–extension and axial rotation compared with experimental data **b** flexion with and without follower compressive forces (BW) **c** extension with and without BW and **d** unilateral (*left*) axial rotation with and without BW

Facet joint biomechanics

Facet contact forces calculated with the IM under extension ranged between 25 and 30 N at the L3–L4 level and between 38 N and 45 N at the L4–L5 level depending on the presence of BW loads (Fig. 5a). Under axial rotation IM contact forces ranged between 48 and 83 N (Fig. 5b) also depending on the BW. Most of these computed values laid within the ranges of 10–50 N and 55–110 N measured under 7.5 Nm extension and axial rotation, respectively [46].

For most applied loads the presence of the device affected the FJ biomechanics at both the treated and adjacent levels. As such under extension L3–L4 facet contact forces generally decreased by about 45% without BW and 15% with BW loads. Under axial rotation L3–L4 facet loads increased up to 20% in presence of BW forces. At the treated level the OP model gave reduced FJ contact forces under both extension and axial rotation. Without BW loads the different device updates helped to recover the IM values except under extension. With BW loads modified prosthesis versions overloaded the L4–L5 FJ by up to 47 and 31% under extension and axial rotation, respectively. Under flexion BW loads had only minimal influence. With both the displacement-control and hybrid methods L4–L5 facet contact forces were zero in the IM but rose up to 75°N in the OP model. Such overloading was generally lowered by about 50% in the FVL and NPL models.

Figure 5c, d shows the absolute difference between the mean displacements among the inferior and superior facets of the L3–L4 and L4–L5 FJ, referred to as relative joint sliding distance. Under pure extension relative joint sliding distances tended to decrease with the device except the L3–L4 craniocaudal ones that were up to 20% higher in the OP model than in the IM. At the treated level values were partially restored with the device updates up to 15 and 75% of the IM dorsoventral and craniocaudal relative sliding. With BW loads L4–L5 dorsoventral FJ relative displacements were low within the IM and full restoration was predicted in the NPL model. However, the NPL model craniocaudal displacements were restored only to a maximum of 40% of the IM ones.

Bony endplate loading

Figure 6 shows octahedral shear strain peak values computed in the BEP adjacent to the device. Different threshold values on the graph defined the type of tissue that is likely to appear during bone healing [16]. Octahedral shear strains were always higher in the peg insertion areas and in the L5 upper BEP. While for pure rotations predicted shear strains remained in the numerical domain of bone formation in presence of BW most models gave L5 BEP shear strain values corresponding to cartilage formation.

Fig. 5 Predicted facet joint (FJ) biomechanics and kinematics with and without follower compressive forces (BW) including calculation of normal contact forces under **a** extension and **b** unilateral (*left*) axial

rotation and **c** dorsoventral and **d** craniocaudal FJ relative sliding under extension

Extension heavily loaded the L5 upper BEP up to about 8.5% strain (Fig. 6a). Under both extension and axial rotation the modified devices generally led to L5 BEP octahedral shear strains significantly higher than those calculated with the original device (Fig. 6a, b). Under pure flexion limited differences appeared between the displacement-control and hybrid loadings (Fig. 6c, d), and device updates lowered the L4 BEP maximum octahedral shear strain by more than 50%. With BW loads device modifications led to significant L4 BEP shear strain reduction with the hybrid method only (Fig. 6d). At the L5 upper BEP device updates also showed better outcomes under hybrid loading.

Discussion

The intact L3–L5 bi-segment model had generic linear and angular dimensions taken from a large pool of level-specific morphological measurements [23]. Despite approximations due to phenomenological constitutive equations and limited mesh refinements that aimed to optimize the computational cost, simulated ROM were in good

agreement with reported in vitro data. Also, computed facet contact forces were in line with experimental data showing that segment kinematics and load sharing between the anterior and posterior spine was predicted with reasonable accuracy. In terms of boundary conditions the BW loads simulating the static effects of muscle and body weight loads produced IDP close to those registered in vivo. Thus, although this paper is a purely comparative study of different models, segment kinematics and device effects calculated are expected to be clinically relevant. Nevertheless, different limitations will be treated along the rest of this discussion and should be remembered as safety barriers.

Segment kinematics

For all load cases studied the original prosthesis was too stiff to preserve the ROM calculated with an intact IVD. Supporting previously reported numerical results [48] constant rotational moments did not allow predicting any ALE due to homogeneous distributions of local moments along the bi-segment model. Simulating spine segment kinematics with either the displacement-control or hybrid

Fig. 6 Maximum octahedral shear strain values calculated with and without follower compressive forces (BW) in the treated model bony endplates (BEP) adjacent to the modelled devices under **a** extension **b** unilateral (left) axial rotation and flexion with **c** displacement-control and **d** hybrid control loading. Areas labelled “Bone” “Cartilage” and “Fibrous tissue” are the octahedral shear strain areas where the named tissue phenotypes could theoretically appear at zero interstitial fluid velocity [16]

method seems more realistic and led to significant ALE. Nonetheless, both loading methods deserve to be compared.

Under displacement-controlled flexion, the lack of flexibility of the implanted segment resulted in most of the imposed rotation occurring at the adjacent level and internal loads are not evenly distributed. Such loading method can be easily patient-specific, but the ALE calculated can be smoothed out over different intact segments and depend on the length of the model. The hybrid method might be more consistent since it ensures even load distributions along all modelled segments representing extra muscle efforts required to achieve prescribed bending angles. Nevertheless, as implemented in this and other numerical studies [8, 11] the interpretation of the hybrid method in terms of muscle activity is limited by the fact that BW loads remained constant. In this study the displacement-control and hybrid methods gave almost similar kinematical predictions, suggesting that both approximations are equally valid. However, the model was probably too short so that spine curvature-related intersegmental shear loads could significantly depend on the simulation method [9, 43].

Under pure rotation every device update showed its potential to contribute to ROM restoration and ALE minimization according to the fact that the implant was progressively more similar to an intact IVD. Under extension, earlier FE predictions showed that BoS implants could affect surgical level ROM by 50% [37] to 120–140% [47] at 7.5 Nm and by 80–90% under 10 Nm [1, 2]. In the present study the best device version led to a maximum ROM relative change of about 50%. Under axial rotation the composite devices had the potential to fully restore the motion at 7.5 Nm while up to 40–100% of over flexibility was predicted with BoS implants at 6 Nm [3]. Under hybrid flexion the SB CHARITÉ® was reported to affect adjacent level motions by up to about 10% [8] which is similar to the ALE calculated with the NPL model.

Under flexion–extension, best ROM restoration was nearly complete when assessed against in vitro measurements, but separately flexion and extension motions were not similarly affected by the prosthesis updates. Actually principal tensile strains in the intact L4–L5 annulus rose up to 20% under extension and up to 10% under flexion. Results showed that prosthesis matrix stiffness was determinant and the tangent stiffness of the PU-silicone matrix at 10 and 20% strain appeared to be, respectively, 5 and 8 times higher than that of the IVD ground substance. Strong matrix stiffness non-linearity also explains why the updated device versions were not always able to virtually restore the ROM in presence of BW loads.

Such limitation suggests that low-density hydrogel matrices may be preferred over covalently linked rubber-

like materials. However, considering mechanical stability over time the choice of adequate hydrogels to substitute natural IVD ground substances becomes highly challenging unless gels can be biologically maintained or replaced. Alternatively, the present study showed that motion-specific device tunings can be done with different material distributions. As such, the posterior shift of the NP-like part in the NPL model has shown to improve the global behaviour of the treated segment with special influence on the extensive motion. Prosthesis fibre adjustments particularly affected the axial rotation flexibility of the treated segment because facet contact reduced the matrix stiffness influence. Also locally adjusting fibre orientations could help controlling both axial and sagittal motions [22].

Facet joint biomechanics

Under axial rotation the updated versions of the composite disc substitute were able to restore FJ contact forces except when BW loads were applied. Actually, coupled intersegmental tractions occur [22] and might be strongly affected by the extra stiffening of the device matrix with BW loads. Under sagittal rotations FJ contact forces were affected at both the treated and adjacent levels independently on the amount of ROM restoration probably because of altered intersegmental anteroposterior shear deformations. Also under extension while ROM were partially restored FJ contact was displaced either to the central or to the upper part of the upper L5 facet. Due to both concavity and orientation contact area displacement over this facet led to contact losses. Unfortunately, facet geometrical characteristics are rather patient-specific [29, 44] and the present generic model can be hardly clinically rated in terms of FJ loading. Such result supports previous interpretations reported about semi-constrained BoS implants [37]. Nonetheless, FJ contact forces computed with the updated devices were within the range of in vitro measured values and did not show relative alterations of up to 150–660% as predicted with BoS implant models [1, 2, 37].

BEP loading

Device migration within the adjacent endplates is one of the problems encountered with BoS implants. Comparing the maximum contact loads between central pegs and BEP with BEP indentation loads measured at failure revealed that predicted forces were about 75% lower than measured loads, i.e. 23 N versus 80–120 N [15]. Although quantitative comparisons should involve force values per unit of area such result is encouraging in terms of possible preservation of BEP integrity in the initial time period after implantation. Nevertheless, the central pegs not

contributing to initial anchoring aim to favour late osteo-integration within the cavity between BEP and device and can be replaced if their indentation effect leads to problems.

For the pegs inserted into the vertebrae, simulated interactions with the BEP allowed calculation of the likely effect of the inserted device on bone maintenance and healing. Because of mesh differences between the IM and the treated models only comparisons were performed among the treated models. Under classically load-controlled rotations increased L4–L5 ROM generally increased the octahedral shear strains within the BEP adjacent to the device. There, strain levels favouring the apparition of cartilage could cast doubt about the ability of the updated devices to respect BEP healing/integrity at the anchoring points. Under hybrid or displacement-control flexion largest BEP strain values tended to decrease along the device updates probably because reduced ALE limited anteroposterior intersegmental deformations. Here it should be highlighted that unlike segment kinematics quantitative BEP biomechanics significantly depended on the loading method.

Unfortunately, the potential bone mechanobiology computed in this study has strong limitations. First, because the glue contact between the vertebral bone and the anchored pegs does not allow possible bone-implant relative motions as in the real initial postoperative state though muscles should help keeping the prosthesis in place. Second, fluid flow influences both spine biomechanics [18] and bone marrow stromal cell differentiation [16] but was not simulated because of computational time. In any case, problematic BEP strains could be minimized with softer prosthesis endplates.

Conclusions

The L3–L5 FE model presented in this study allowed exploring the design and possible optimizations of a novel composite artificial disc as a L4–L5 disc substitute. Prosthesis effects were linked with different intersegmental load components so that results can be extrapolated to other lumbar spine levels such a L5–S1 by considering known differences in biomechanical environment with L4–L5. Thanks to their intrinsic deformability and easy geometrical customization composite devices might represent a better alternative to fusion and BoS devices. The most critical and unresolved issue for complete ROM restoration was the device matrix stiffness. Nonetheless, device structural updates could allow motion-specific tunings especially relevant to patient-specific designs. In this sense presented results showed that the definitive prosthesis structure should take into account particular facet geometries. Clinical images would efficiently feed a patient-specific

FE model so that particular designs can be tuned based on simulations.

Acknowledgments The authors are thankful to Dr. Roberto De Santis and Dr. Filippo Causa for the discussions about the original disc prosthesis prototype. Dr. David Eglin is also kindly acknowledged for his recommendations about alternative disc substitute materials. This research was funded by the European Commission under the DISC project (G5RD-2000-CT-00267) and by the Spanish Ministry for Science and Innovation under the grant AP2002-2395.

Conflict of interest None.

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