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## Lumbar Model Generator

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1 **Lumbar Model Generator: a tool for the automated generation of a parametric scalable**  
2 **model of the lumbar spine**

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25 **ABSTRACT**

26 Low back pain is a major cause of disability and requires the development of new devices to  
27 treat pathologies and improve prognosis following surgery. Understanding the effects of  
28 new devices on the biomechanics of the spine is crucial in the development of new effective  
29 and functional devices. The aim of this study was to develop a preliminary parametric,  
30 scalable and anatomically accurate finite element model of the lumbar spine allowing for  
31 the evaluation of the performance of spinal devices.

32 The principal anatomical surfaces of the lumbar spine were first identified, and then  
33 accurately fitted from a previous model supplied by S14 Implants (Bordeaux, France).  
34 Finally, the reconstructed model was defined according to 17 parameters which are used to  
35 scale the model according to patient dimensions. The developed model, available as a  
36 toolbox named the Lumbar Model Generator (LMG), enables generating a population of  
37 models using subject-specific dimensions obtained from data scans or averaged dimensions  
38 evaluated from the correlation analysis. This toolbox allows patient-specific assessment,  
39 taking into account individual morphological variation. The models have applications in the  
40 design process of new devices, evaluating the biomechanics of the spine, and helping  
41 clinicians when deciding on treatment strategies.

42 **Keywords: Biomechanics; Finite Element Analysis; Lumbar spine; Morphing; Parametric**  
43 **model; Spine.**

44

## 45 **1 Introduction**

46 Low back pain (LBP) is one of the main musculoskeletal disorders with major disability  
47 effects on the population worldwide (1). In England, LBP is one of the first causes of activity  
48 limitation, sick leave, and hospitalisation. The related economic effects burden  
49 governments, individuals and the society more widely (2) and in the USA, from 1998 to  
50 2008, the healthcare costs have increased from \$4.3 to \$33.9 billion(3). Typical non-surgical  
51 treatments are muscle relaxation and anti-inflammatory medications, steroid injections,  
52 physical therapy and spinal manipulations (4). Surgical intervention is the last resort, with  
53 the most common intervention being spinal fusion (5). Spinal fusion is associated with  
54 prolonged recuperation time, loss of mobility at the fused level and has been shown to  
55 increase stress at the adjacent unfused levels (6,7) potentially resulting in degeneration and  
56 pseudarthrosis (8). With these limitations in mind, there is scope to develop new devices to  
57 improve the efficacy of the treatment and surgery, and improved methods to assess such  
58 new assistive devices.

59 To meet design and regulatory requirements, a medical device is subjected to a review  
60 between each phase of the product design (9). Each of these reviews introduces additional  
61 costs to the device development delaying its final release. New technologies, such as 3D  
62 printing, have assisted with this iterative design process, allowing for the rapid production  
63 of cost-effective prototypes. However, the design process of a medical device has to be  
64 evaluated in relation with the bodies and tissues with which it interfaces. These interactions  
65 can be simulated using finite element (FE) models and can be combined with iterative  
66 optimization of the design topology and mechanical properties.

67 Lumbar spine models available in literature are mostly subject-specific models based on  
68 magnetic resonance (MR) or computed tomography (CT) imaging (10,11), or models based  
69 on averaged approximated dimensions which use relatively simplified geometries (12–16).  
70 While models based on medical images precisely represent the subject-specific geometry,  
71 the process to generate these models is both time consuming and expensive. Moreover, to  
72 provide wider understanding, beyond a single individual, subject-specific models require a  
73 number of models to be solved, for statistical power (17). However, idealised models based  
74 on average dimensions often lack the anatomical detail that is necessary to be of clinical  
75 value, with their geometries typically too simplistic. Further, several studies have  
76 highlighted the importance of anatomically representative geometry in simulations of the  
77 spine (18,19) due to its effects on the intradiscal pressure, the range of motion and facet  
78 joint contact forces. Clearly, this is of relevance to any spinal devices developed which use  
79 such geometry for the spine.

80 Recently, the Food and Drug Administration (FDA) and the Medical Device Innovation  
81 Consortium (MDIC) focused on the necessity of improving the regulatory system delivering  
82 new devices more quickly through the use of computer modelling and simulations (20).  
83 Accordingly, parametric and anatomically accurate models are needed to implement the

84 range of combinations of geometrical features necessary to evaluate the huge variety of  
85 clinical cases that can be addressed using the designed device. This methodology would  
86 speed up the acceptance of new devices, reducing the risk of failure of the device. Although  
87 parametric models have great potential in evaluating a wide range of cases, in order to  
88 incorporate them as part of the regulatory workflow, considerable work is needed to verify  
89 and validate the results obtained against experimental studies.

90 The aim of this study was to develop an automated technique to obtain a population of  
91 anatomically representative models, which can be used to evaluate the effects of spinal  
92 implants on distinct anatomical features of the spine. In this study, a software toolbox  
93 named the Lumbar Model Generator (LMG) was developed and implemented using  
94 MATLAB. Using a parameterized baseline model, the LMG can be used to create a  
95 population of geometric models of the lumbar spine (from the L1 to L5 including the  
96 intervertebral discs), whose surfaces and solid regions are meshed allowing for direct use in  
97 FE models. The parametric model generated by LMG, has an anatomically accurate  
98 geometry, as evaluated through a comparison with the male dataset of the Visible Human  
99 Project (VHP) (21), described in Section 4.

100 The models can be reconstructed through the definition of 17 parameters. The parameter  
101 set is either determined directly from subject-specific measurements, or can be estimated  
102 from correlation analyses based on subject age and height (described in Section 3). Thus,  
103 geometric models are fully parametrized and scalable, so a range of anatomical geometries  
104 can be easily generated and replicated. In this paper the capabilities of the LMG toolbox are  
105 described, which includes: (i) the methodology for developing the geometry, (ii) the  
106 correlation analyses implemented to evaluate the anatomical dimensions, (iii) the process to  
107 obtain the meshed solid model ready to use in FE software.

108 The innovation of the LMG includes the generation of an accurate geometry of the lumbar  
109 spine, based on a set of parameters, and the automatic pre-processing of the solid meshed  
110 model. This model is compatible with FE simulations (here briefly introduced but to be  
111 included in further publications). Previous studies developed automatic models for the  
112 lumbar (18,22) and cervical spine (23,24), based on highly simplified geometries or  
113 reconstruction from scans. Comparing these studies with the current study, this toolbox  
114 generates models with an accurate geometry based on the definition of only a few  
115 parameters. The material properties are easily controlled and implemented in the model to  
116 reproduce a model for an individual subject. The FE pre-processing is then performed with  
117 the automatic definition of boundary conditions and contact properties and then simulation  
118 can be directly run from MATLAB, using FEBio (FEBio Software Suite). As far as the authors  
119 know, the LMG is the first toolbox which allows the accomplishment of the entire workflow  
120 (described in Figure 1) from the generation of a geometrical model, the pre-processing of  
121 the FE model and then obtaining the solution of the analysis.

## 122 **2 The Lumbar Model Generator (LMG) toolbox**

## 123 2.1 General features of the toolbox

124 A LMG software toolbox that can generate the geometry for biomechanical models of the  
125 lumbar spine was developed and implemented in MATLAB (MATLAB®, R2017a,  
126 9.2.0.538062, The MathWorks Inc., Natick, MA, USA). The workflow of the toolbox is shown  
127 in Figure 1. The toolbox generates a complete lumbar spine model, including the five  
128 vertebral bodies (L1 to L5) and the four intervertebral discs (IVD) interposed between them.  
129 The main geometric features of the vertebrae and IVD follow recommendations from  
130 previous studies (13,25) reported as linear and angular parameters used in the generated  
131 model (Figure 2). Models are parameterized such that they can be generated using two  
132 alternative techniques: (i) based on subject-specific dimensions (which can be directly  
133 inputted by the user) directly measured from subject-specific data (e.g. image data and  
134 scans), or (ii) using average dimensions derived from correlation analysis based on subject  
135 height and age ( Section 3).

136 Once the geometrical data has been generated, the triangulated surface geometries can be  
137 exported to a stereolithography (STL) file, which is compatible with computer aided design  
138 and finite element analysis software packages. Further, the surface model can be meshed  
139 with solid elements and exported to FE software. Using FEBio to run the FE analysis, the  
140 meshed model can be pre-processed. Defining materials, boundary conditions and contact  
141 properties through MATLAB, the simulations can be requested as an output of the LMG.

## 142 2.2 Geometrical model

### 143 2.2.1 *Vertebrae model*

144 An STL file of a lumbar spine (50<sup>th</sup> percentile) was supplied by an industrial partner (S14  
145 Implants, Pessac, France), used in a previous study (26). This model was used as a template  
146 to reproduce the geometry of the lumbar vertebrae and the intervertebral discs. The two  
147 key assumptions were: (i) the geometry of the healthy spine is reproduced and (ii) the  
148 lateral symmetry, across the mid-sagittal plane, applies to both the vertebrae and IVD (15).

149 Each vertebra was divided into four regions: the vertebral body, the pedicles, the transverse  
150 processes and the spinous process (Figure 1B). The surfaces characterizing each region were  
151 identified and the best fitting polynomial curves were selected to be used to build an  
152 accurate and scalable model of the vertebrae. The solid model was parametrised,  
153 identifying the dimensions reported in literature for each region, to obtain a scalable model.  
154 The parameters identified (listed in Figure 2) can be independently scaled according to the  
155 dimensions obtained from the subject-specific scans or from the correlation analysis  
156 (described further in section 3). The following vertebral dimensions have been  
157 implemented:

- 158 • width of the upper and inferior endplates (EPWu, EPWi);
- 159 • depth of the upper and inferior endplates (EPDu, EPDi);

- 160 • pedicle height and width (PDH, PDW);
- 161 • spinal canal depth and width (SCD, SCW);
- 162 • width of the upper and inferior transverse process (TPWu, TPWi);
- 163 • spinous process length (SPL);
- 164 • vertebral posterior body height (VBHp);
- 165 • pedicle sagittal inclination (PDIs);
- 166 • pedicle transverse inclination (PDIt);
- 167 • intervertebral disc width and depth (IVDw, IVDd);
- 168 • intervertebral disc height (IVDh);
- 169 • lumbar curvature ( $\alpha$ )

### 170 2.2.2 Intervertebral disc model

171 The key variable to describe the disc geometry is the IVD height (18,19), thus only the  
172 superior and inferior surfaces have been reconstructed with the best fitting polynomial  
173 curves. The height is not constant throughout all the geometry, but it is characterized by  
174 different heights in the posterior and anterior aspects (27,28). However, the average height  
175 for the IVD has been used for the LMG, consistent with literature (29), and the anterior and  
176 posterior aspect were linearly scaled. Moreover, the perimeter of each endplate was  
177 simplified to be kidney-bean shaped (25,26,27).

178 The IVD was exported as composed of two different parts, the annulus fibrosus (AF) and the  
179 nucleus pulposus (NP). The volumetric percentage of the two bodies has been reported in  
180 the literature (30–32) and a proportion of 44% NP and 56% AF, corresponding to a healthy  
181 spine, was used to guide the model (30). However, these values can be altered to simulate  
182 different pathologies. Disc degeneration affects the mechanical behaviour of the IVD, with  
183 changes in the composition of the AF and NP, and through structural changes of the disc.  
184 Thus, by implementing the volumetric fraction and the height and width of the disc as  
185 variables, it is feasible to use the model developed to simulate the mechanical behaviour of  
186 degenerated discs (33).

### 187 2.3 Three-dimensional orientation

188 The IVDs and vertebral bodies generated from the lumbar generator (Section 2.1) were  
189 arranged in 3D space (Figure 3). Four types of lordosis can be identified in the population  
190 (34) and in this paper, the 3-D orientation typical of the fourth type, in which the five  
191 lumbar vertebrae are in lordotic configuration, is implemented. The lumbar sector can be  
192 approximated as an arc of circumference, where the angle  $\alpha$  (Figure 2) is the angle between  
193 the lines connecting posteriorly the upper surface of the L1 and the lower surface of the L5.  
194 In this study, the value of  $43.39^\circ$  was used, based on available literature (35). The centroid  
195 of each vertebral body and IVD bodies were evaluated and used to distribute the bodies in  
196 3D space. The vertebrae have been rotated to follow the lumbar angle ( $\alpha$ ), aligned over the  
197 lumbar curvature and spaced using the IVD height at each level. The lumbar curvature is a

198 further input parameter ( $\alpha$ ) which can be varied by the user if required for instance, to  
 199 simulate pathological conditions.

### 200 3 Correlation analysis and evaluation of dimensions

201 The LMG includes a function which enables the automated generation of full vertebrae and  
 202 discs based on the stature and age of a subject. This follows previous studies which have  
 203 correlated these two parameters to vertebral dimensions (13,14,25,29,36–38). According to  
 204 Jason & Taylor (38), the combined length of the cervical, thoracic and lumbar spine (C-T-L)  
 205 can be correlated with the stature of a subject according to Equation 1:

$$206 \quad h = a l_{CTL} + b \quad (1)$$

207 where  $a$  and  $b$  are the correlation coefficients, listed in Table 2, between the stature ( $h$ ) of a  
 208 person and the length of the cervical-thoracic-lumbar segments ( $l_{CTL}$ ) of the spine (where  
 209 CTL refers to cervical-thoracic-lumbar). Then, the posterior height for each vertebral body of  
 210 the lumbar spine can be evaluated as a percentage of the total length,  $l_{CTL}$  (Table 3) (37).

211 **Table 2** Correlation analysis between the stature of a person and the spine segments, reported in Jason & Taylor 1995 (38).  
 212 The parameters  $a$  and  $b$  are the coefficients of the regression Equation 1, where  $a$  has no units and  $b$  is in [mm].

	Segment	$a$	$b$ [mm]
White males	C-T-L	2.069	47.258
	Lumbar	4.058	95.562
White females	C-T-L	2.334	29.735
	Lumbar	4.375	82.367
Black males	C-T-L	2.420	29.395
	Lumbar	4.696	85.723
Black females	C-T-L	1.661	70.336
	Lumbar	3.926	91.507

213

214 **Table 3** Percentage of the posterior height of the lumbar vertebrae, relative to the full length of the vertebral column  
 215 (Tibbetts 1981) (37).

	Vertebra	Male	Female
216	<b>L1</b>	5.55	5.59
217	<b>L2</b>	5.60	5.77
218	<b>L3</b>	5.66	5.89
	<b>L4</b>	5.63	5.87
219	<b>L5</b>	5.71	5.91

220 Likewise, the IVD height is correlated with the age of the subject according to the Equation  
 221 2:

$$222 \quad h_{IVD} = c n_{age} + d \quad (2)$$

223 where  $h_{IVD}$  is the height of the IVD,  $n_{age}$  the age of a person and  $c$  and  $d$  the correlation  
 224 coefficients listed in Table 4 (39).



225 Table 4 Correlation coefficients ( $c$  and  $d$ ) describing the relationship between height and age (see Equation 2). These  
 226 equations are valid for male and female subjects between 20 and 69 years (39).

IVD level	Males		Females	
	$c$ [mm]	$d$ [mm]	$c$ [mm]	$d$ [mm]
<b>T12-L1</b>	0.04903	5.19	0.04840	4.33
<b>L1-L2</b>	0.06201	6.80	0.04771	6.27
<b>L2-L3</b>	0.06687	8.32	0.04982	8.17
<b>L3-L4</b>	0.05455	11.05	0.05052	9.85
<b>L4-L5</b>	0.06952	10.76	0.05979	10.51
<b>L5-S1</b>	0.08630	9.73	0.08170	9.26

227

228 The dimensions of the vertebra, described in Figure 2 have been correlated in previous  
 229 studies to the vertebral posterior height (VBHp) (13,14) based on datasets originally  
 230 published by Panjabi (25). Due to the axial symmetry hypotheses and to the more complete  
 231 description of the anatomical features, the correlation analysis used by Breglia (14) has been  
 232 implemented in the LMG according to the Equation 3:

$$233 \quad V_{par} = f V_{BPHp} + g \quad (3)$$

234 where  $V_{BPHp}$  is the vertebral body posterior height,  $V_{par}$  identify the parameters identified  
 235 in Figure 2,  $f$  and  $g$  are correlation coefficients shown in Table 5.

236 The entire sets of equations based on correlation analyses from literature, described above,  
 237 were used to generate a full lumbar spine model. Once the age and the height of a patient  
 238 were defined, these values were automatically evaluated in the script and sent as input  
 239 parameters ready for use in the LMG (Section 2), which generates the geometrical model in  
 240 the order of seconds.

241 **Table 5** Correlation coefficients of the lumbar vertebra with the posterior height of the vertebra.

Linear Parameters			
	Parameters	$f$ [-]	$g$ [mm]
<b>EPWu</b>	Upper endplate width	1.684	-1.598
<b>EPWi</b>	Inferior endplate width	1.762	-0.765
<b>EPDu</b>	Upper endplate depth	1.233	2.838
<b>EPDi</b>	Inferior endplate depth	1.135	5.391
<b>SPL</b>	Spinous process length	2.002	13.823
<b>PDH</b>	Pedicle height	0.553	2.049
<b>PDW</b>	Pedicle width	0.368	1.218
<b>TPW</b>	Transvers process width	1.407	36.851
<b>SCW</b>	Spinal canal width	0.090	16.553
<b>SCD</b>	Spinal canal depth	0.121	17.777
<b>SPL</b>	Spinous process length	2.0017	13.823
Angular Parameters			
	Parameters	$f$ [°/mm]	$g$ [°]
<b>PDIs</b>	Pedicle sagittal inclination	-1.246	46.075
<b>PDIt</b>	Pedicle transverse inclination	0.042	4.683

242 **4 Accuracy**

243 The accuracy of the model generated through the LMG was assessed through comparison  
 244 with the male dataset of the Visible Human Project (VHP) (21). The male dataset was  
 245 segmented from the axial cryosection photographs of a 38 year old man, of height 180.34  
 246 cm. The geometry of the lumbar vertebrae and intervertebral discs were segmented from  
 247 the visible human male dataset into two-dimensional (2D) axial images, by professional  
 248 clinicians (21). These segmented 2D axial images were then processed in Matlab and were  
 249 imported into Mimics v17.0-v19.0 (Materialise, Leuven, Belgium) for reconstruction of  
 250 three-dimensional (3D) geometry of the lumbar vertebrae and intervertebral discs. Two  
 251 models were generated, importing the dimensions with the two procedures described  
 252 above (section 1):

- 253 1. The vertebral dimensions were generated following correlation analyses, importing  
 254 only the age (38 years old) and height (180.34 cm) of the VHP dataset.
- 255 2. The vertebral dimensions were directly measured from a 3D reconstruction of the  
 256 VHP (Table 6 and Table 7), and implemented directly into the LMG (i.e. following  
 257 case-2 in Section 2.1).

258 **Table 6** Vertebral dimensions measured from the VHP.

<b>Vertebrae Dimensions [mm]</b>	<b>L1</b>	<b>L2</b>	<b>L3</b>	<b>L4</b>	<b>L5</b>
<b>EPWu</b>	46.60	49.74	48.97	52.69	54.50
<b>EPDu</b>	36.16	43.51	42.53	40.23	37.94
<b>EPWi</b>	48.85	50.47	52.19	53.44	54.19
<b>EPDi</b>	37.72	44.75	39.04	38.73	36.13
<b>VBHp</b>	29.40	31.63	30.72	30.13	28.98
<b>PDH</b>	15.72	16.28	17.42	18.05	17.26
<b>PDW</b>	8.19	9.29	13.60	14.96	15.00
<b>SPL</b>	36.06	38.58	42.63	36.72	36.00
<b>PDIs</b>	15.02	14.74	14.40	14.57	14.12
<b>PDIt</b>	5.73	5.74	5.75	5.74	5.76
<b>SCD</b>	18.00	16.90	16.04	17.00	17.00
<b>SCW</b>	22.27	22.24	22.56	24.00	25.00
<b>TPWu</b>	74.21	88.84	96.89	96.79	97.45
<b>TPWi</b>	24.97	22.43	26.80	31.25	42.14

260 **Table 7.** Dimensions of the IVD measured from the VHP.

<b>IVD dimensions [mm]</b>	<b>L1-L2</b>	<b>L2-L3</b>	<b>L3-L4</b>	<b>L4-L5</b>
<b>IVDh</b>	9.07	11.11	12.91	11.07
<b>IVDd</b>	36.16	43.51	42.50	40.23
<b>IVDw</b>	46.60	49.74	48.97	52.50

262 The accuracy of the generated vertebrae and IVD models were evaluated against the VHP  
 263 model using CloudCompare (version 2.9, GPL software, retrieved from  
 264

265 <http://www.cloudcompare.org/>). The Iterative Closest Point algorithm was used to register  
 266 the STL models and assess the RMS (Root Mean Square) error values. Moreover, the  
 267 accuracy of the 3D orientation of the generated model, using the VHP dimensions, and the  
 268 VH model has been examined, evaluating the RMS errors.

269 **Table 8** RMS error values of the accuracy test between the VHP model and the models obtained with the LMG toolbox  
 270 using the two procedures: evaluating the dimensions on the VHP model and using the measurements obtained from the  
 271 correlation analyses.

Vertebrae	VHP dimensions	Age and height correlation	IVD	VHP dimensions	Age and height correlation
	RMS [mm]	RMS [mm]		RMS [mm]	RMS [mm]
L1	1.51	1.68	L1-L2	1.11	3.19
L2	1.54	1.59	L2-L3	1.18	3.90
L3	2.13	2.39	L3-L4	1.31	3.38
L4	1.82	2.54	L4-L5	1.57	3.72
L5	2.94	4.30			

272

## 273 5 FE model pre-processing

### 274 5.1 Solid tetrahedral meshing

275 The geometrical model produced by the LMG is in the form of a point cloud and this section  
 276 outlines the steps required to import the model into FEA software. In this section, the  
 277 meshing procedures are described. Once a model has been created and meshed, the LMG  
 278 allows the user to choose to work either with commercial or open source software in the  
 279 model implementation. Alternatively the model can be prepared using the LMG toolbox and  
 280 solved directly with FEBio.

281 The pre-processing of the geometry developed (defined in section 2 and 3) for FEA was  
 282 performed in two separate steps for the vertebrae and the IVD.

#### 283 5.1.1 Vertebral bodies

284 The point cloud of each vertebra was meshed in MATLAB, using the GIBBON toolbox (40),  
 285 and Tetgen (41). In order to simulate the cortical shell in the vertebral bodies, during the  
 286 meshing procedure, the internal cancellous core was selected and different element indexes  
 287 have been assigned. The thickness of the cortical shell can be defined by the user and any  
 288 value required can be assigned, along with different material properties (Figure 4).

#### 289 5.1.2 Intervertebral discs

290 The high complexity of the IVD microstructure, where collagen fibres are embedded in the  
 291 ground substance, required the definition of a structured mesh. A custom algorithm was  
 292 developed in MATLAB, using the Gibbon toolbox, to mesh the AF and the NP. The

293 parameters to define the mesh size are the perimeter points of the AF ( $pp$ ), the volumetric  
294 percentage ( $VP$ ) of the IVD, the number of layers ( $nl$ ) which will be implemented in the AF  
295 and the number of elements in the axial direction ( $nz$ ) (Figure 5). Initially, a 2D mesh  
296 structure was defined, which combined the concentric alignment of the elements and an  
297 internal rectangular grid, subsequently smoothed with an elliptical perimeter to improve the  
298 mesh quality. The positions of the perimeter points are concentrically scaled and replicated  
299  $nl$  times to reproduce the concentric alignment of the collagen fibres. The mesh element  
300 size depends on the  $VP$ , on the number of layers and on the number of points taken on the  
301 perimeter (Figure 5). The elements in the AF were oriented following the perimeter and  
302 arranged in concentric layers, in order to mimic the layers of fibres of collagen and assign  
303 their material properties so as to represent fibre-orientation.

### 304 5.1.3 Solid mesh quality

305 In order to check the mesh quality in the generation of several models, the mesh quality was  
306 evaluated through a sensitivity analysis. In the case of the vertebral bodies, two cases were  
307 evaluated:

- 308 1. Different mesh dimensions were considered (1.2 to 2.2 mm);
- 309 2. Three models were generated based on different person heights (1.75 m, 1.80 m,  
310 and 1.82 m).

311 The mesh quality criteria evaluated from TetGen included the aspect ratio, the face angles  
312 and the dihedral angles (the definitions are reported in (41)). The evaluation of the mesh  
313 quality does not have a unique definition, but it depends on the application (41,42).  
314 Consistent with previous studies, the mesh quality was judged satisfactory when at least  
315 95% of the elements had an aspect ratio less than 4, and face angle less than  $100^\circ$  and  
316 dihedral angles were less than  $130^\circ$  (42–45). A mesh convergence test was performed in  
317 FEBio for the L1 vertebra at different mesh sizes (1.4 mm, 1.6 mm, 1.8 mm, 2.0 mm, 2.2  
318 mm), applying 1 MPa pressure over the superior surface. The difference in the stress  
319 between the model with the finest mesh and the others was evaluated and the results led  
320 to the selection of 1.6 mm with an error of less than 5% (as compared to subsequent mesh  
321 refinement). The frequency distribution of the quality criteria of the L1 vertebrae was then  
322 compared either with the distribution of the other vertebrae (L2 to L5) or the distribution of  
323 the models based on different body dimensions, through a quantile-quantile plot (QQ-plot).

324 The IVD mesh was evaluated through a sensitivity study on varying the parameters which  
325 influence the mesh size  $pp$  (64, 72, 80, 88, 96),  $nl$  (8, 9, 10, 11, 12) and  $nz$  (6, 8, 10, 12, 14),  
326 described above. The influence of the volumetric percentage,  $VP$ , has not been reported in  
327 this study since it is not a parameter relevant to the structural properties of the IVD. A  
328 pressure of 0.5 MPa has been applied to the upper surface with the lower surface fully  
329 constrained, further, neo-hookean material properties were assigned to both the AF and NP  
330 ( $E_{AF} = 5$  MPa,  $\nu_{AF} = 0.3$ ;  $E_{NP} = 3$  MPa,  $\nu_{NP} = 0.3$  , where  $E_{AF}$  and  $E_{NP}$  are the Young's modulus

331 and  $\nu_{AF}$  and  $\nu_{NP}$  the Poisson's ratio for the AF and NP (11) automatically converted in Lamé  
332 coefficients by FEBio).

## 333 **6 Model evaluation**

### 334 6.1 Comparison between the LMG generated model and the VHP model

335 A comparison between the VHP spine and the generated models are shown in Figure 7, and  
336 the RMS values are reported in Table 8. The quantitative analysis highlighted the areas of  
337 the model which differ most from the VHP model. In particular, the largest differences have  
338 been identified in the posterior vertebral structures, where the superior and the inferior  
339 articular facets, lamina and pedicles of the generated geometry are less detailed. For all the  
340 vertebrae, the maximum RMS error for the models generated with the correlation analysis  
341 were higher than for the models generated using the VHP dimensions. In both cases, the L5  
342 vertebrae geometry showed the highest RMS values. Lower RMS values are shown when  
343 the dimensions are directly measured on the subject specific model and then imported into  
344 the algorithm. In fact, using the correlation analysis method based on previous studies  
345 (13,14), the model is affected by the grade of correlation between the variables. High and  
346 moderate errors have been shown in the dimensions, which had low ( $R^2$  less than 0.5: PDW,  
347 SCW, SCD, TPW, PDIt, PDIs) and moderate correlation coefficients ( $R^2$  between 0.5 and 0.8:  
348 SPL, PDH), provided by Breglia (14). Figure 8 shows the accuracy of the 3D orientation  
349 between the generated model and the VH model. Due to the supine position of the  
350 cadaveric specimen during the image acquisition, the curvature of the lumbar curve is  
351 reduced as compared to an upright position. Nevertheless, using CloudCompare a best fit  
352 registration has been performed, obtaining a mean RMS value of 2.73 mm.

### 353 6.2 Mesh quality evaluation

354 Assessment of mesh convergence demonstrated a suitable compromise between a mesh  
355 size (which preserves geometric precision) and variation in predicted results. In the case of  
356 vertebral bodies, the differences in stress from the finer model are less than 5%, where the  
357 fine model has a mesh size of 1.2 mm. The mesh convergence study on the IVD found that  
358 the differences in the stress values were less than 6% varying the nl, nz and pp parameters  
359 (Figure 6).

360 A sensitivity analysis was performed to evaluate potential differences in the mesh quality  
361 throughout the vertebrae (L1-L5) or on varying the dimensions selecting different body  
362 heights of a patient. The mesh quality obtained in both approaches was checked through a  
363 QQ-plot where the vertebra L1 with element size of 1.6 mm, generated as average model  
364 based on a person of 1.75 m height, was taken as reference. The QQ-plots in Figure 9  
365 demonstrate that there were no differences between the distributions on varying either the  
366 vertebrae considered (Figure 9a) and the dimensions of the specimens (Figure 9b). The

367 sensitivity analysis on varying the geometrical dimensions, in both the IVD and vertebrae  
368 bodies, showed that there were no effects on the mesh quality.

369 The mesh quality reported that more than 95% of elements had an aspect ratio of less than  
370 4, more than 98% of elements had a face angle less than 100° and more than 95% of  
371 elements had a dihedral angle less than 130°, consistent with other studies (39).  
372 Quantitative results of the distribution of the dihedral angle are shown in Figure 10, where  
373 the two histograms show the distribution of the maximum and minimum dihedral on the  
374 total number of elements.

## 375 **7 Discussion**

376 The Lumbar Model Generator (LMG) is a toolbox which allows the generation and  
377 simulation of finite element models for the lumbar segment. It is possible to obtain  
378 averaged models, imported using as input only the height, age and gender of a patient,  
379 where the dimensions are evaluated from a subroutine based on the correlation analysis  
380 described above. Another option is to input the data evaluated from subject specific scans,  
381 or alternatively opting for a hybrid use of the tool, changing the dimensions desired from  
382 the averaged model. In the case of the former, it is not necessary to have clinical data  
383 available, and a population of models can be generated based on the gender, age and  
384 height of patients. The output can then be pre-processed in commercial software able to  
385 read STL file or input file for commercial software can be requested (e.g. Abaqus,  
386 Hyperworks). The main novelty is the possibility to obtain from the LMG, using as input a set  
387 of dimensions: 1. a geometrical model, based on dimensions obtained from subject-specific  
388 scans or on correlation analysis; 2. obtain a solid meshed model; 3. pre-process the model  
389 directly in MATLAB; 4. run the simulations using FEBio.

390 The LMG could be seen as having two end-user applications: (i) clinical/industrial  
391 applications where a device is assessed using FEA on a range of models; (ii) engineering  
392 science applications where multiple variables are assessed to determine the sensitivity of  
393 whole spine mechanics to these variables. Pathological conditions can be evaluated  
394 implementing models with different lumbar curvatures to compare to the averaged lumbar  
395 curvature, or changing the volumetric ratio between the NP and AF or varying their material  
396 properties (46).

397 Considering that the LMG was meant to be an averaged model, which cannot take into  
398 account the subject-specific anatomical variations, the models generated through the LMG  
399 toolbox are anatomically realistic. Moreover, subject-specific models are affected by errors  
400 due to the segmentation procedure. In fact, the accuracy of the geometry obtained from  
401 scans depends on the type of scan used (CT or MR), their respective resolutions (inter-slice  
402 resolution ranging between 0.6 mm to 2.5 mm), the technique used for the segmentation  
403 and the operator expertise (47,48). Hence, the RMS errors obtained in this study are  
404 comparable to the range of accuracy of subject-specific models and is thus considered

405 acceptable. The highest differences between the VPH model and the generated one have  
406 been highlighted in the accuracy test and they are principally localised in the posterior area  
407 of the vertebrae. The effect of the geometry of the spinous processes on the biomechanics  
408 of the spine has been evaluated (18,19), however, no direct influence has been identified.  
409 The caveat being the evaluation of interspinous devices, for which this model may have  
410 great limitations. The limitations due to the simplified geometry of spinous processes will be  
411 investigated further in future work through FE analysis. The RMS error values, showed good  
412 agreement with the subject-specific model, even though greater difference has been  
413 highlighted at the L5 level. This is justified by assessing previous studies (13,49,50), which  
414 did not consider the L5 vertebrae in morphometric studies due to the high variability of its  
415 geometry. Moreover, the higher RMS values are related to the lumbar vertebrae obtained  
416 from the correlation analysis, which are affected by uncertainties. In fact, the correlation  
417 analyses performed by Breglia (14) and Kunkel (13) are both based on the Panjabi dataset  
418 (25), which evaluated 12 specimens and larger studies are required to obtain improved  
419 statistics. A brief preliminary correlation analysis was evaluated with the data collected by  
420 Wolf et al (51) and Alam et al (52) and compared with the previous correlation analyses.  
421 Evaluating these correlations on other morphological studies, conducted by Alam et al (n =  
422 55) and Wolf et al (n = 49), it is possible to obtain higher values for the  $R^2$  values for  
423 regression analysis in certain cases. Unfortunately, the measurements between the  
424 different studies could not be merged since those studies did not consider the same  
425 anatomical parameters, gender or ethnic group, which would affect the whole correlation  
426 analysis (52,53). Further studies are required to obtain more complete datasets of  
427 morphological measurements and to evaluate new correlation analyses. This preliminary  
428 model is to be developed more, the fitting of the posterior part of the vertebrae, the  
429 connection between transverse process, lamina and facet joints shapes, shall be improved  
430 and further parameters (i.e.: thickness and height of the spinous processes) will be added to  
431 better describe their geometry.

432 Furthermore, the results on the mesh quality and its reproducibility on different geometries  
433 showed that the automated generation leads to valid meshed models. Using a fixed mesh  
434 size, according to the mesh convergence test, it showed that the mesh quality of the  
435 vertebrae was not sensitive to the variation of the vertebral dimensions. Hence, the FE  
436 model can be directly set up to run the simulations without other time-consuming actions.

437 Several models have been developed based on subject specific datasets (54–57). Subject  
438 specific models have the advantage to reproduce the anatomy of the patient accurately,  
439 with the possibility to include soft and hard tissue with high resolution. However, they  
440 reproduce the anatomy of an individual subject and reconstructing these individual models  
441 is time expensive. Further, they require extensive pre-processing. This final point is actually  
442 a barrier to clinical implementation because of the need to have someone dedicated to  
443 develop and solve the models. In reply to these issues, the LMG offers anatomically  
444 representative models, scalable to average human dimensions, which do not require

445 extensive segmentation processes. Moreover, the pre-processing is accelerated further  
446 since the models can be directly meshed and the material properties, boundary and loading  
447 conditions can be imported in order to obtain a ready-to-solve FE model.

448 In the last decades several models have been created using average dimensions  
449 (15,16,18,58) obtaining models to get quantitative analysis over the biomechanics of the  
450 lumbar spine. However, all of them have used approximations in the anatomy of the  
451 vertebrae. Campbell et al. (59) developed an automatic tool to reconstruct models from  
452 data scans without user intervention and with low computational cost. This enables highly  
453 detailed models from subject specific data. However, the limitation of this is that it requires  
454 having data from clinical studies. As far as the authors know, our current study is the first  
455 parametric model which generates a full finite element model and includes the potential for  
456 anatomical variability and the flexibility to input the dimensions of an individual subject. The  
457 advantages of this tool in the short term are that the models could be used to perform  
458 sensitivity analysis, varying the dimensions most subjected to change in the population.  
459 These models could be used in the design process of new devices, or to develop custom  
460 made implants and assess their performance, as recently recommended by the FDA and  
461 MDIC (20). The biomechanics of the spine has been identified as being sensitive to  
462 parameters such as the lumbar curvature, the vertebral body height, IVD height and the  
463 width of transverse processes (60,61). Therefore, the evaluation of the functionalities of  
464 new devices and how they influence the biomechanics of the spine, in several anatomical  
465 configurations, will lead to the design optimization and customization of new implants. The  
466 intention is to implement the lumbar model to assess the validity of devices such as BDyn, a  
467 posterior stabilization device produced by S14 Implants and described elsewhere (62), to  
468 assess the performance of the device and its effect on the spine. Further optimisation of  
469 posterior stabilization devices is of value because, unlike fusion, such devices retain motion  
470 at the spinal segment of interest.

471 The current study has focused on the concept of developing an anatomically accurate but  
472 automated model. Future releases of the toolbox are planned to include the definition of  
473 the 1-D non-linear spring elements to simulate the action of ligaments (54,63), which will be  
474 placed in the corresponding anatomical location. The facet cartilage will be included,  
475 defined as a 1D element in between the facet joints and the definition of the facet contact  
476 properties will be automatically implemented. The toolbox has been released on Zenodo  
477 (64) and the development version is freely available on [GitHub](#). The future release will be  
478 provided with a complete GUI (Graphic User Interface) with more complete pre-processing  
479 features which allows implementing further loading conditions and exporting the file ready  
480 to solve if using other solvers. In future studies, FEA will be evaluated to assess the  
481 influence of the anatomical features (i.e. the *VP* ratio and the vertebral dimensions) on the  
482 biomechanics of the lumbar spine and how it is affected using devices such as BDyn and disc  
483 replacement devices.



## 484 **8 Conclusion**

485 The LMG toolbox has been developed with the intent of helping in the design optimization  
486 of spinal devices such as posterior stabilization devices as well as the development of  
487 custom devices. The developed toolbox enables an automated workflow which is user  
488 independent and fully compatible with open-source software (Octave, FEBio, Calculix). It  
489 constitutes a tool that can be used in clinical studies to improve the decision making process  
490 to select the best intervention. The clinicians, supported by experts, using the GUI would be  
491 able to simulate and understand the effect on the biomechanics of the specific patient  
492 taking in to account the anatomical variation. In fact, it will enable the use of average  
493 dimensions or importing the dimensions measured from data-scans or evaluating a hybrid  
494 model where the dimensions of a desired structure can be altered, then evaluating the  
495 specific case to treat. In the short term, this toolbox will be released using an on-line  
496 platform with a user-friendly GUI, which will allow the quick evaluation of the biomechanics  
497 of specific cases. It can then be used to aid clinician's practice when assessing the  
498 biomechanics of the spine of their patients, and it could lead to improve the decision  
499 making process to select the best intervention.

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503

## 504 **Data accessibility**

505 The LMG toolbox is freely available on GitHub (64).

506

## 507 **Author contributions**

508 CEL conceived the presented idea and developed the toolbox, including the geometrical  
509 development of the model and validation, participating in the study design and drafting the  
510 manuscript. KMM participated in developing the custom meshing algorithm used; PVSL,  
511 KMT and DR participated in the study design related to the VHP model, DME and DETS  
512 participated in the study design and supervised the project. All the authors contributed in  
513 revising the manuscript.

## 514 **Conflict of Interest**

515 There are no conflicts of interest to declare.

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688 **Figure 1.** Workflow of the lumbar model generator, from the generation of the geometrical model to the solution of the FE simulation. The FE model is shown for the purpose of description and will be described in details in a future publication. A. The inputs of the LMG are the baseline model previously generated and the dimensions, measured on subject-specific scans or average dimensions based on the height, age and gender of a patient. B. Parameterization of the geometrical model. The anatomical dimensions have been identified in each region of the vertebrae and IVD and then independently scaled. Accordingly with the input, the output of this step can be a population of geometrical models or a subject-specific model. C. Generation of a triangulated surface model and output of STL files. D. Solid meshing of the vertebrae (tetrahedral elements) and the IVD (hexahedral elements). The output of this step can be exported to commercial software. E. Pre-processing of the meshed model, defining the material properties, boundary conditions, contact properties and then run the simulations in FEBio.

**Figure 2.** The picture shows the input requested in the toolbox, in the first and simplest case only body height, age and gender are requested. In the second case, the dimensions identified have to be added as input.

**Figure 3.** Lumbar spine model (a.lateral, b.anteriorposterior views) generated from subject-specific measurements obtained from the VHP and listed in Table 6 and Table 7.

**Figure 4.** The vertebral body was divided into cancellous and cortical bone. The thickness of the cortical bone can be defined by the user in the toolbox.

**Figure 5.** IVD mesh. (a) Representation of the surface, meshed by quadrangular elements, where in the AF they follow the external perimeter, arranged in  $n_l$  layers. (b) Division between NP and AF, and the volumetric ratio (VP) is an input of the toolbox. (c) The number of elements  $n_z$  can be defined to obtain a finer mesh.

**Figure 6.** Mesh convergence test on varying the geometrical parameters ( $n_l$ ,  $pp$ ,  $n_z$ ) for the IVD mesh.

**Figure 7.** Accuracy evaluation. Qualitative evaluation of the accuracy between the VHP model in black and the generated model in orange a. IVD, b. vertebrae; c. quantitative evaluation of the accuracy through the RMS error values for the vertebrae.

**Figure 8.** Accuracy on the whole model. The VH model (black) has been overlapped on the model generated (orange), using the best fit registration in Cloudcompare. Due to the supine position of the cadaveric specimen, the lumbar curvature is lost in the VH model.

**Figure 9.** QQ plots between a. the L1 vertebrae and the other vertebrae at mesh size of 1.6 mm; (b) and between the geometrical model based on a person 1.75m height and those ones at 1.80m and 1.82m. The three different criteria are showed: (a1 and b1 ) aspect ratio,( a.2 and b.2) face angle, (a.3 and b-3) dihedral angle.

**Figure 10.** Qualitative analyses of the dihedral angles for the tetrahedral elements of the vertebral bodies. The minimum (a) and maximum (b) dihedral angles are shown and the colormaps refer to the histograms below. The figure shows the unloaded geometry of the spine, in a non-physiological status, where the bodies were only placed in their locations and no loads are applied.