

17 **Abstract**

18 In percutaneous coronary intervention (PCI), stent malapposition is a common complication
19 often leading to stent thrombosis (ST). More recently, it has also been associated with
20 longitudinal stent deformation (LSD) normally occurring through contact of a post balloon
21 catheter tip and the protruding malapposed stent struts.

22 The aim of this study was to assess the longitudinal integrity of first and second generation drug
23 eluting stents in a patient specific coronary artery segment and to compare the range of variation
24 of applied loads with those reported elsewhere. We successfully validated computational models
25 of three drug-eluting stent designs when assessed for longitudinal deformation. We then
26 reconstructed a patient specific stenosed right coronary artery segment by fusing angiographic
27 and intravascular ultrasound (IVUS) images from a real case. Within this model the mechanical
28 behaviour of the same stents along with a modified device was compared. Specifically, after the
29 deployment of each device, a compressive point load of 0.3N was applied on the most
30 malapposed strut proximally to the models. Results indicate that predicted stent longitudinal
31 strength (i) is significantly different between the stent platforms in a manner consistent with
32 physical testing in a laboratory environment, (ii) shows a smaller range of variation for
33 simulations of *in vivo* performance relative to models of *in vitro* experiments, and (iii) the
34 modified stent design demonstrated considerably higher longitudinal integrity. Interestingly,
35 stent longitudinal stability may differ drastically after a localised *in vivo* force compared to a
36 distributed *in vitro* force.

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39 **1. Introduction**

40 Percutaneous coronary intervention (PCI) is now the dominant method of revascularization, with
41 proven symptomatic and prognostic efficacy. Since the introduction of drug-eluting stents (DES)
42 there has been a marked reduction in events associated with stent failure, in particular in-stent
43 restenosis (ISR). However, DES have been associated with allergic reactions, stent
44 malapposition and inflammation leading to early and late stent thrombosis (ST) [1]. Furthermore,
45 there are on-going concerns about the attritional nature of the potential sources of failure of PCI,
46 including ISR, ST and, more recently, longitudinal stent deformation (LSD).

47 Stent malapposition has been proven clinically to be connected with late stent thrombosis [2, 3]
48 and can be categorised into acute malapposition and late malapposition. Clinical studies [2, 4, 5]
49 have shown that each type of malapposition is connected with several factors, such as reference
50 diameter, balloon pressure, longer lesions, longer stents, more than one stent or stent overlap. In
51 those studies stent malapposition was investigated by intravascular means such as intravascular
52 ultrasound (IVUS) or optical coherence tomography (OCT). When malapposition is observed
53 clinically, post stent deployment with non-compliant balloon dilation is used to further reshape
54 the stent. Such post-deployment techniques, including also re-wiring or IVUS, can potentially
55 contribute to stent distortion. Studies [6-8] indicate that those deformations are more likely to
56 occur when the proximal struts are incompletely apposed.

57 There has been a well-established association between stent design and adverse events. Factors
58 including particularly strut thickness [9], but also geometry, have been correlated with ISR, ST
59 and LSD. It is apparent that the iterative process of design in DES has led to reduced ISR (along
60 with anti-inflammatory stent coatings) with reduction in strut thickness, but that an increased

61 reporting of LSD may be a consequence of this evolution [6-8, 10]. It is therefore important that
62 new stent designs are tested as thoroughly as possible to detect potential flaws.

63 To date, there have been two experimental (engineering) studies shedding light on LSD [11, 12],
64 and one computational study [13] investigating the longitudinal integrity of small stent segments
65 (two rings) after free expansion, but no patient specific computational studies have been
66 reported. It is likely that sophisticated computer modelling will have an increasing role in this
67 process of validation and testing.

68 In this study, a patient specific artery segment was constructed from angiographic images; a
69 computer model was developed for the deployment in this segment of different coronary stent
70 architectures based upon one first generation and two second generation DES; post-deployment
71 malapposition was assessed; and the effect of stent malapposition and stent architecture on the
72 response of the devices to a compressive longitudinal force was modelled. The proposed
73 approach allows quantification and visualisation of LSD along the entire length of the model, in
74 contrast to the currently used LSD measurement techniques based on IVUS cross sectional
75 images. We sought to validate this model as a potential tool for assessment of stent design
76 behaviour and to test it using previously reported physical bench testing data.

77 **2. Materials and Methods**

78 A patient-specific right coronary artery (RCA) reconstruction was carried out by fusing multiple
79 IVUS frames and two bi-plane angiographic images from an actual case. The geometry segment
80 was reconstructed in IVUS-Angio Tool, a freely available software [14], and Rhinoceros 5.0
81 (Robert McNeel & Associates, USA), a commercially available NURBS package. Stent designs

82 were created in Rhinoceros 5.0. For the simulations, the commercially available FEA solver,
83 ABAQUS/ Explicit v.6-12 (Simulia Corporation, USA) was used.

84 *2.1. Geometry, meshes and constitutive models*

85 The vessel reconstruction procedure has been presented in detail in our previous work [15], (and
86 is summarized in Appendix A.1).

87 Many constitutive models have been used to characterize arteries with the most representative
88 being that reported by Holzapfel et al. [16]. In the current study, the wall of the vessel is modeled
89 by using a hyperelastic, neo-Hookean strain energy function. The assumption was based on the
90 fact that the average material of the vessel wall is plaque and the difficulty to extract the plaque
91 composition from the IVUS images; therefore, constitutive parameters for a soft plaque were
92 selected. The latter is proposed by Wong et al. [17] and its parameters were used within our
93 group previously [18]. Thus, the strain energy per unit of reference volume is

$$94 \quad U = C_{10}(\bar{I}_1 - 3) + \frac{1}{D_1}(J - 1)^2 \quad (1)$$

95 where C_{10} and D_1 are temperature-dependent material parameters related to the shear and bulk
96 moduli ($\mu_0 = 2C_{10}$, $K_0 = 2/D_1$), \bar{I}_1 is the first deviatoric strain invariant defined as

$$97 \quad \bar{I}_1 = \bar{\lambda}_1^2 + \bar{\lambda}_2^2 + \bar{\lambda}_3^2 \quad (2)$$

98 where the deviatoric stretches $\bar{\lambda}_i = J^{-1/3}\lambda_i$, J is the total volume ratio, J is the elastic volume
99 ratio, and λ_i are the principal stretches.

100 The vessel was meshed using eight node linear brick reduced integration elements with hourglass
101 control (ABAQUS element type C3D8R). The wall thickness was discretised by two elements.

102 The total number of elements which were used to mesh the reconstructed vessel was 21214, and

103 32019 nodes, based on a mesh sensitivity study (i.e. accepting differences of maximum and
104 minimum displacements between coarse and finer meshes less than 2%). The elements were
105 checked for invalid geometry so as to avoid numerical inaccuracies.

106 For the stents, firstly we generated two balloon expandable stent models whose architecture is
107 closely based upon contemporary stent designs used in the clinical arena. Stent A, which
108 resembles the Promus Element (Boston Scientific, USA), is an ‘offset peak to peak stent’ and
109 stent B, which resembles Xience (Abbott Lab., USA), is an ‘in-phase, peak to valley stent
110 design’ as categorised in Prabhu et al. [12]. Secondly, we modified Stent A by constructing two
111 additional connectors between the first two proximal hoops (see Appendix A.2) and we model an
112 old out-of-phase, peak-to-peak device, which resembles the Cypher (Johnson & Johnson co.,
113 USA), used by this group previously [19]. Figure 1A&B depict the computer-aided design
114 (CAD) generation of stent B. Both current generation stents were constructed based on the unit
115 strut creation by NURBS curves. The unit strut is offset to the stent width and then extruded to
116 the strut thickness. The solid unit strut is copied along the circumference so as to form a full
117 circumferential ring which is then copied along the longitudinal axis to generate the flat 3D solid
118 stent architecture. The final step contains the transformation of the flat stent onto a cylinder so as
119 to represent a cylindrical stent configuration, as shown in Figure 1B. Thereafter, our design
120 approach (see Appendix A.3) is to geometrically transform the stent on to the reconstructed
121 catheter line so as to avoid the additional numerical analysis step of stent implantation and
122 positioning (c.f. Figure 1C). Table 1 provides information about the stent designs, alloys and
123 number of links which were assumed for the investigated devices.

124 The stent platforms are defined as isotropic elastic-plastic materials. Their material properties
125 have been adopted by O’Brien et al. [20](c.f. Table 2). The stents were meshed using eight node

126 linear brick, reduced integration elements with hourglass control (ABAQUS element type
127 C3D8R). Stents A, B, and C were discretised by assigning two elements along the strut thickness
128 and three elements along the strut width resulting in 34786, 46216, 35286 elements, respectively.
129 Stent D was discretised by assigning four elements along the strut thickness and three elements
130 along the strut width resulting in 76352 elements. The discretization of the stents was based on
131 mesh sensitivity studies (i.e. accepting differences of maximum and minimum displacements
132 between coarse and finer meshes less than 2%).

133 *2.2. FEA simulations*

134 All the events of the FEA analysis were simulated as quasi-static where the inertia forces arise
135 only from the deformation of structure and are not dominating in the analysis. Throughout the
136 whole period of each step, the kinetic and internal energies of the deforming materials were
137 monitored so as to keep their ratio less than 5%, as indicated for a quasi-static event [21]. Since it
138 is computationally impractical to model the process in its natural time period, the analysis was
139 based on the extraction of the fundamental frequency (first natural frequency) of the stent models
140 by running frequency analysis in ABAQUS/Standard 6.12. It is recommended that the load to be
141 applied over a period calculated from the fundamental frequency has to be ten to fifty times
142 longer than the lowest frequency. The chosen loading rate was chosen based on a period
143 sensitivity test (the kinetic energy and the maximum displacement of the model had differences
144 less than 1% between different simulated time periods).

145 *2.2.1. Simulated bench test validation*

146 In order to validate the ability of our model to detect and/or reproduce longitudinal compression,
147 we simulated previously published [11] physical bench testing in which a compressive force was

148 applied as a distributed longitudinal load. In order to mimic the experimental method, the devices
149 were constrained distally during the compression test and only 10mm of their length was
150 exposed to the compressive load. The load was imposed proximally to the devices and
151 distributed on the edges of the circumferential crowns. The LSD was calculated from the
152 displacements of the nodes on which the distributed load was imposed.

153 *2.2.2. Virtual stent expansion in the reconstructed vessel*

154 In order to reduce computational cost, two different design simulation approaches were followed
155 and compared in previous work [15], (summarised in Appendix A.3). The first approach consists
156 of three steps (crimping, positioning, and expansion) and the second of two steps (crimping and
157 expansion). Thereafter, a comparison between two expansion techniques was carried out in
158 order to simplify the deployment step (c.f. Appendix A.4). In the first method, for stent
159 deployment, a realistic five folded balloon was used whilst, in the second method, a deformable
160 surface was used. The comparisons have indicated that similar results can be taken from the
161 investigated methodologies and, as a result, the less computationally expensive methodologies
162 are followed in this study. The contact between the stent and the vessel was modelled by
163 defining hard normal behaviour and a 0.05 friction coefficient for the tangential contact property
164 [22, 23]. All other contacts (including self-contacts) were modelled with 0.2 friction coefficient
165 for the tangential contact behaviour [24, 25].

166 Stents were implanted in the reconstructed vessel at the same location, aligned at the proximal
167 ends. Then, the devices were crimped and expanded by deformable surfaces with controlled
168 predefined displacement, and shown in Figure 2. This method has been proven an optimal choice
169 when simulating stent expansions, as it is less computationally expensive, and it provides similar

170 results (with a balloon expansion) regarding the final stent shape (and thus, the stresses and
171 strains the stent is subjected to) when reaching its nominal diameter [25]. At the end of the
172 expansion step, the relative stent malapposition was evaluated by measuring the minimum
173 distance between the upper nodes of the stent and the inner nodes of the vessel.

174 *2.2.3. Virtual longitudinal deformation of the stents*

175 To undertake the virtual assessment of longitudinal integrity of the stents, following deployment,
176 a compressive load was imposed on the stent strut that was most malapposed, labelled as CL in
177 Figure 2. This strut was chosen because it represents the area most likely to come into contact
178 with the leading edge of a post stent device moving forwards on the coronary line. The direction
179 of the compressive load is represented by the white arrow in Figure 2. The LSD was calculated
180 from the displacement of the node to which the localised load was imposed.

181 **3. Results**

182 *3.1. Validation of the stent longitudinal behaviour*

183 Figure 3 depicts images of the investigated stents expanded to a diameter of 3.00mm and
184 deformed by a compressive load applied proximally to each device. The stent compression
185 (millimetres) against the compressive force (Newton) for the investigated devices is depicted in
186 Figure 4. Stent A was compressed with 0.4N and Stent B was compressed with 1.2N resulting in
187 displacements of 4.75mm and 5.14mm, respectively. This numerical bench test shows that the
188 modelled stents, A & B, demonstrated similar longitudinal deformation to that presented by
189 Ormiston et al. [11], and their experimental results for corresponding devices are superimposed
190 on the same figure (c.f. Figure 4). Therefore, one can observe that the numerical bench test is
191 well matched with the experimental results within the acceptable range of 2.8% to 5% of the

192 final displacement. Stents C and D were compressed with 1N and 3N resulting in displacements
193 of 4.80mm and 1.16mm, respectively.

194 *3.2. Stent Malapposition*

195 The contour plots of the 3D stent malapposition along with cross sectional images proximal,
196 middle and distal to the devices (broken lines) are depicted in Figure 5. All the devices show
197 similar results in this regard: specifically, stent malapposition occurs predominantly at the
198 proximal edge. The maximum distance between a stent node and a vessel wall node is
199 0.3775mm, 0.3483mm, 0.3329mm, and 0.3325 for Stents A, B, C, and D, respectively.

200 *3.3. LSD within the reconstructed coronary segment*

201 The LSD was evaluated virtually after stent deployment in the reconstructed segment by
202 applying a localised compressive load of 0.3N proximally to the stent on the malapposed struts
203 of all models as shown in Figure 2. Relative performance between the stents can be assessed by
204 considering the force needed to displace by 0.5mm the node at which the load is applied. This
205 displacement also coincides with the onset of noticeable protrusion of struts in the lumen as
206 depicted in the insets of Figure 6 (cross-sectional images are depicted proximally to the model-
207 broken lines-where significant strut protrusion for Stents A and B occurs due to the LSD). In
208 Figure 7 the longitudinal deformation is depicted with respect to the compressive load. Forces of
209 0.19N and 0.29N, respectively, are needed for stents A and B. In contrast, Stent C does not
210 deform significantly in terms of strut protrusion (Figure 6) in the lumen although the node at
211 which the load is applied almost reaches a displacement of 0.5mm at the peak load of 0.3N
212 (Figure 7). Stent D shows negligible compression both in terms of strut protrusion or
213 displacement (c.f. Figures 6 and 7).

214 4. Discussion

215 In a recent study [26], a new methodology was developed to study stent malapposition
216 numerically with finite element analysis. In our study a similar technique was used to calculate
217 stent malapposition numerically. Our technique was based on the shortest distance between the
218 nodes which lie on the outer surface of the stent and the nodes which lie on the inner surface of
219 the reconstructed vessel (relative malapposition). The results showed that for this patient specific
220 case, stent malapposition is similar for all the investigated devices. This suggests that the
221 proximal malapposition is primarily dependent on the variation in vessel diameter and the
222 associated diameter mismatch that occurs when sizing the stent on the distal diameter.

223 Longitudinal deformation results in protrusion of stent struts in the lumen (Figure 6) hence
224 potentially obstructing further manipulation [10]. Most cases reported of LSD involve very thin
225 device platforms with open cell designs (offset peak to peak). Whilst reducing strut thickness and
226 increasing the area between the struts improve the stent flexibility, stent deliverability and stent
227 conformability, the subsequent compromise of stent longitudinal integrity may produce reduced
228 resistance to potential compression loads. Two recent experimental studies [11, 12] which have
229 investigated current generation stents have reported similar results and have emphasized the
230 importance of the number and the angulation of the connectors between the hoops to resist
231 compression. Specifically, the offset peak to peak device with the open cell design had the
232 poorest behaviour in longitudinal integrity. In contrast, devices with more than two connectors
233 were relatively resistant to compressive loads.

234 In this computational modelling study, from the compression simulations, we observed that stent
235 A with two connectors (with 45° connector angulation) showed significantly less longitudinal

236 strength than stent B with three connectors (aligned with the longitudinal axis of the device).
237 This is consistent with the concept that stents with two connectors are more susceptible to LSD
238 than devices with three connectors. At the other end of the spectrum, we observed considerable
239 resistance to LSD in a stent with six connectors (Stent D) in which a force of 3N compresses the
240 stent only 1mm. From the LSD-graph (Figure 4) Stent A seems to have a more linear behaviour
241 than stent B which demonstrates an initial “hardening” to the first 2mm. This behaviour is
242 consistent with the experimental laboratory-derived results taken from Ormiston et al. [11] and
243 the virtual LSD simulations extracted from the present study, shown in Figure 7.

244 For the bench test, stent C demonstrated a significant stiffer response than stent A to compressive
245 loads but inferior to stent B. Modifying stent A by constructing additional connectors
246 proximally, the longitudinal integrity increases significantly (more than the double amount of
247 force was required for a 5mm compression, Figure 4). Also, it is observed that the proximal end
248 of the modified stent is not distorted by the compression, Figure 3, a fact that can explain the
249 “hardening” of the stent’s response between 4mm and 4.5mm in Figure 4.

250 Interestingly, the computer simulations of deformation in the RCA segment, Figure 7, indicate
251 that devices A, B and C do not oppose the load proportionally to the bench tests (c.f. Figure 4).
252 Only Stent D shows similar stiff behaviour in both cases. The virtual compressive simulations
253 indicate that Stent C opposes the compressive force successfully and no significant distortion of
254 the device was observed (c.f. Figures 6 and 7). Also, in contrast to the bench test, Stent C
255 demonstrates higher resistance than Stent B (c.f. Figures 4 and 7). This indicates that in contrast
256 to bench tests, *in vivo* failure of different stent devices may not occur at such drastically different
257 localised loads.

258 From our model using compression simulations, it is clear that LSD is dependent on the number
259 of the stent connectors and their angulation with the stent longitudinal axis. Apart from the
260 number of the connectors, considerations should be made on the phase angle between stents'
261 sequential hoops. Out-of-phase devices seem to resist more under compressive loads. Further
262 research is needed to investigate variations in the proximal phase angle of the circumferential
263 rings in the offset peak-to-peak device.

264 This study, to the best of the authors' knowledge, is the first to investigate longitudinal
265 deformation and stent malapposition virtually in a patient specific reconstructed vessel. Such
266 numerical studies for research purposes can provide useful information in 3D along the entire
267 length of the models. Figures 5 and 6 illustrate very clearly the investigated clinical problems
268 and it is strongly believed that such quantitative information can predict and further improve the
269 associated complications by optimising the implanted device in any given challenging geometry.

270 *4.1. Limitations and future directions*

271 This study has some limitations. Firstly, for the purposes of this work, only one patient specific
272 case was used and therefore the results cannot necessarily be generalised to other lesions.
273 Second, in our model, the vessel wall is assumed to be hyperelastic and isotropic comprising a
274 single layer. This is due to the fact that our reconstruction method is based on IVUS images from
275 which the plaque composition is difficult to extract. Current imaging techniques such as
276 computed tomography (CT), magnetic resonance imaging (MRI) and IVUS in combination with
277 contrast agents can provide a better differentiation between the arterial layers and the plaque.
278 Therefore, a multi-layer model will of course have some influence on the results.

279 As shown by Gee et al. [27], taking the in-vivo geometry (reconstructed by the imaging data) of
280 abdominal aortic aneurysms as stress-free is not suitable for computational simulations as this
281 results in non-physical deformations under realistic loading. In a recent study [28], the vessel
282 wall pre-stretch was incorporated in a computational framework to investigate the positional
283 stability of aortic endografts. It was shown that one of the factors affecting the positional stability
284 is the variation of friction coefficient. However, due to the comparative rationale of this study,
285 tissue pre-stretch and arterial blood pressure (averaged 100 mmHg) was neglected. Also, the
286 friction coefficient was chosen to be uniform between the contact surfaces. Future studies will
287 incorporate more analytical vessel models taking into account the different arterial layers and the
288 pre-stress/pre-strain state of the vessel wall. Moreover, the pulsatile compressive loads imposed
289 by the myocardium on the coronary arteries have to be further investigated.

290 Deformable surfaces were used to expand the stents instead of a balloon model. However, for
291 this patient specific model, we compared the stent malapposition after the surface expansion with
292 a realistic five folded balloon expansion and we obtained similar results in terms of stent
293 malapposition (see the Appendix A.4). This method has also shown to provide similar
294 computational results (final stent shape) with a balloon expansion strategy as shown in previous
295 studies [13, 25]. At the end, the investigated stent devices were generated in commercial CAD
296 software. As a result, they are not identical to the real devices they resemble.

297 **5. Conclusions**

298 In conclusion, we have constructed a computational engineering model of a coronary lesion that
299 has allowed for simulation of stent malapposition and LSD in three stent designs and a modified
300 device that are based upon one first generation and two second generation DES. Our results are

301 consistent with previous laboratory based experiments of LSD. Also, the simulations suggest that
302 the threshold where the stent loses its longitudinal resistance may differ *in vivo* compared to *in*
303 *vitro*, particularly with respect to the range of variation in loads needed to deform second
304 generation drug eluting coronary stents We believe that such a model may provide a useful tool
305 for testing the integrity and validation of new stent designs.

306 **Conflict of interest statement**

307 Prof. Curzen has received unrestricted research funding from Medtronic and Haemonetics. He
308 has received speaking and/or consultancy fees from Boston Scientific, St. Jude Medical,
309 Medtronic, Abbott Vascular, Lilly/DS and Haemonetics. Prof. Bressloff and Mr. Ragkousis have
310 no conflict of interest to declare.

311 Appendix A

312 A.1. RCA 3D reconstruction

313 Several IVUS frames and two orthogonal bi-planar angiographic images have to be collected and
314 imported into the IVUS Angio-Tool where the catheter path definition and the lumen with the
315 vessel wall segmentation are carried out. The catheter path is defined by both LAO (left anterior
316 oblique) and RAO (right anterior oblique) angiographic images which differ by approximately
317 90°; the LAO is shown in Figure 8A. The segmentation of lumen and media-adventitia border
318 contours is carried out by active contours models [29] (c.f. Figure 8B). This editing can then be
319 written as a point-cloud in a text file which is imported in Rhinoceros 5.0 for further processing.
320 In Rhinoceros 5.0, the realistic 3D IVUS pullback path is reconstructed as the intersection of the
321 two bi-plane orthogonal curve extrusions. The resultant curve is scaled down to its real
322 dimensions according to:

323
$$L_{ivus} = \frac{N_{frames}}{f} * S_{pullback} \quad (3)$$

324 where normally $f=30frames/sec$ and $S_{pullback}= 0.5mm/sec$. The resultant 3D catheter curve
325 comprises the backbone on which the lumen and the wall contours are positioned after being
326 converted into real dimensions calculated from IVUS-Angio Tool. At each location point on the
327 curve, the Frenet trihedron is calculated (Figure 8C). The precise position of the IVUS contours
328 on the catheter line is formulated by orientating the contours at each location point with
329 geometrical transformations which map three units vectors {X,Y,Z} (defined on each cross
330 section contour) to the Frenet trihedron {T,N,B} (at each location point). The final orientation is
331 then calculated by rotating all the contours by a specific angle around the T vector such as when
332 re-projecting the reconstructed vessel onto the RAO and LAO views, a satisfactory matching is
333 accomplished. Figure 8D shows the 3D realistic representations of the reconstructed lumen from
334 LAO and RAO.

335 *A.2. Modified Stent*

336 In order to improve the longitudinal integrity of Stent A, we constructed two additional
337 connectors in each of the first two proximal hoops. The planar sketch of the modified design is
338 depicted in Figure 9. The circles illustrate the four additional connectors proximally on the
339 device.

340 *A.3. Comparison of two Simulation Design Methodologies*

341 In order to reduce the computational time, we compared two different simulation design
342 methodologies. The first consists of three steps (crimping, positioning, and expansion), whilst the
343 second consists of two steps (crimping, expansion). Figure 10 illustrates the different approach

344 followed. Specifically, in the first approach (from the top left and anticlockwise), the positioning
345 of the stent into the diseased site is undertaken within the FEA package, a fact that increases the
346 total computational time. On the other hand, the second approach (from the top left and
347 clockwise) positions the stent system into the vessel within the CAD software with geometrical
348 transformation which maps the central axis of the stent system on the reconstructed IVUS
349 catheter line. In Figure 11, boxplots of the average nodal Von Mises stresses of the stent, for the
350 two simulation methodologies, are illustrated indicating almost identical results at the end of the
351 stent expansion in terms of stent malapposition. The discrepancy of maximum, minimum and
352 average Von Mises stress yield values within the acceptable range of 0.7-3.7% (see Table 3).

353 *A.4. Simplification of the expansion method*

354 We performed stent deployment with a deformable surface and a realistic five folded balloon
355 (see Figure 12). Thereafter, we plotted cumulative distribution function (CDF) graphs of the
356 resulting malapposition at the end of the expansion steps (see Figure 13). The CDF graphs
357 indicate that for both expansion methods in this patient specific case, the stent malapposition is
358 identical following device deployment.

359

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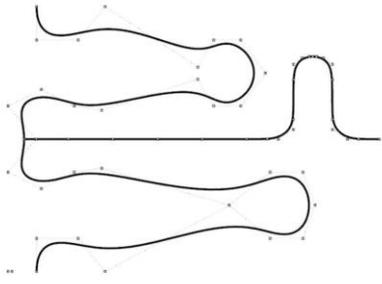
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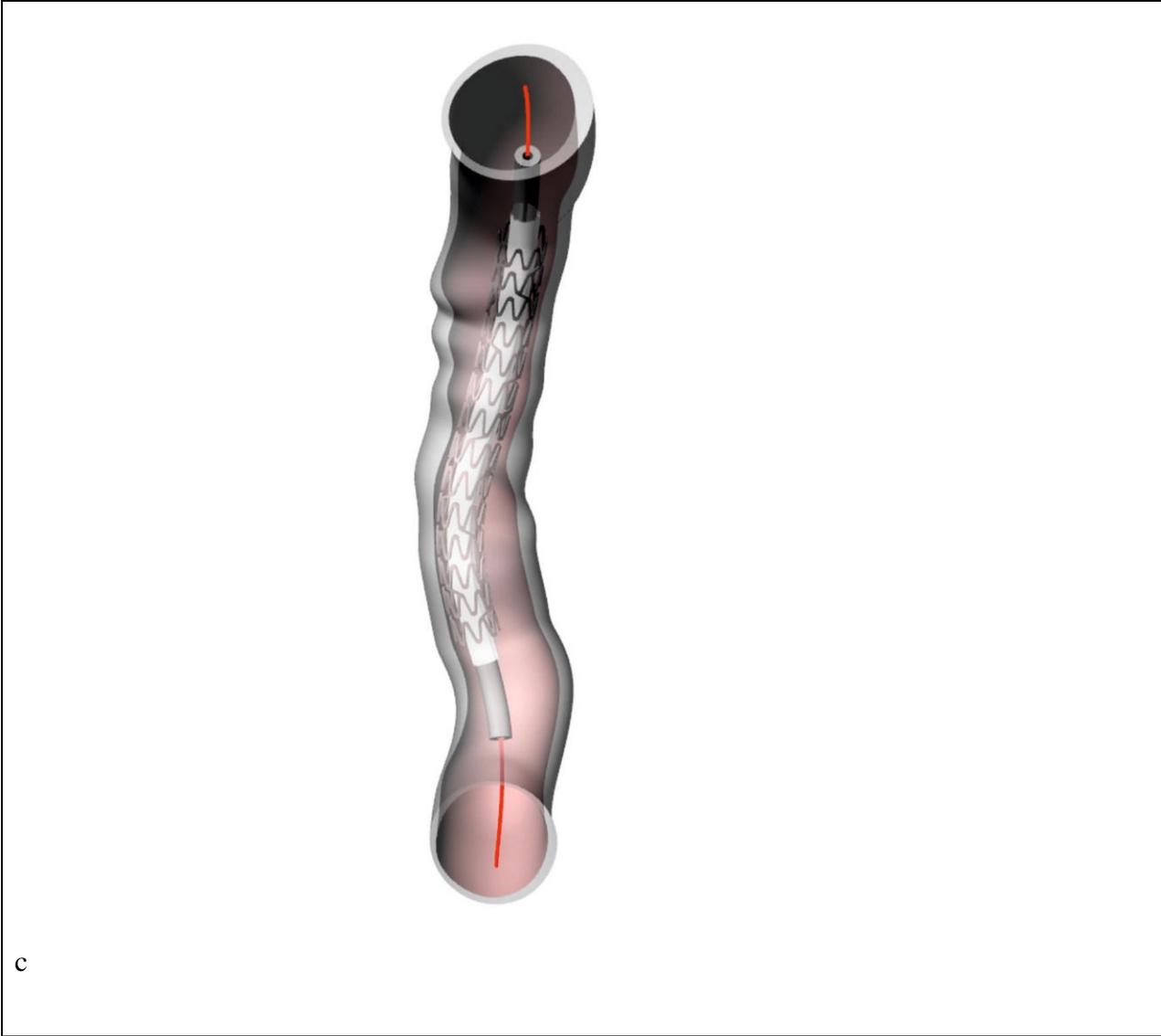
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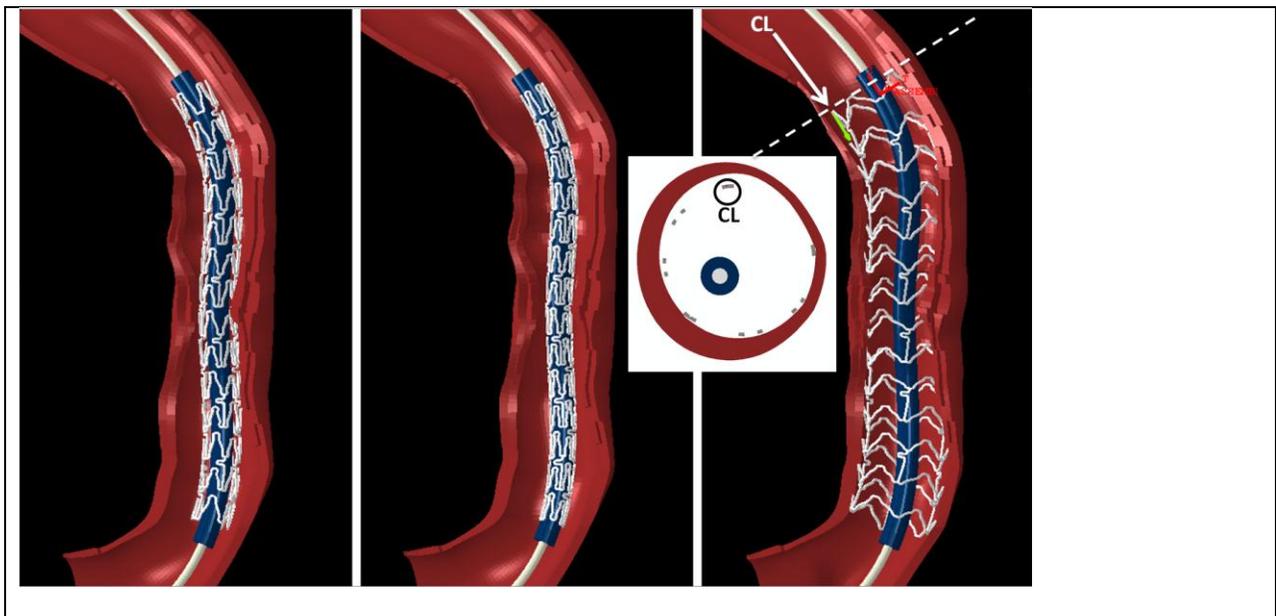
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Figure 1: CAD model generation

A) Five degree NURBS curves are depicted for the unit strut generation. B) The solid stent B is generated based on the five degree curve. C) Stent A translated onto the 3D reconstructed IVUS pullback catheter path (red line).

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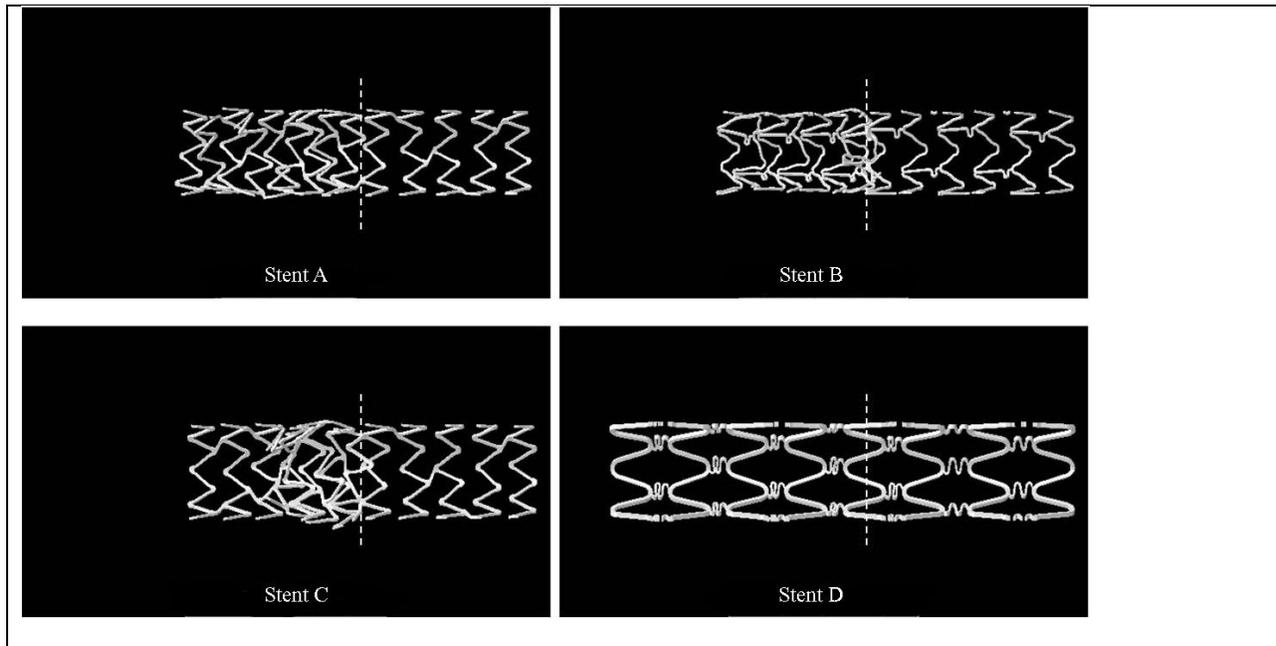


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Figure 2: Simulation Steps

Stent pre-flown on the catheter shaft (left), stent crimped on the catheter shaft (centre) and stent expanded from the 3D reconstructed catheter line (right). The imposed compressive load, CL (white arrow), proximally to the model with respect to a reference coordinate system and the cross-sectional image at the proximal edge of the stent are depicted (right).

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Figure 3: Simulated bench test

Virtual bench test validating the longitudinal integrity of the investigated stents. The devices were expanded to a nominal diameter of 3mm and were constrained along their length so that 10mm of the stents were exposed to the distributed load (broken lines).

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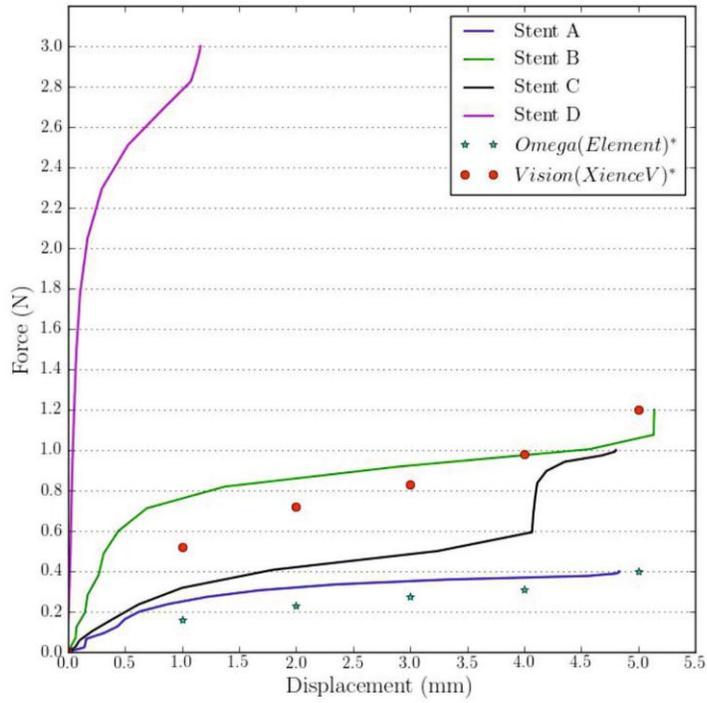


Figure 4: Distributed compressive load and stent deformation

Compressive force and stent longitudinal deformation after numerical bench test. Superimposed experimental results (*) published by Ormiston et al [11] showing LSD in good agreement with our numerical results.

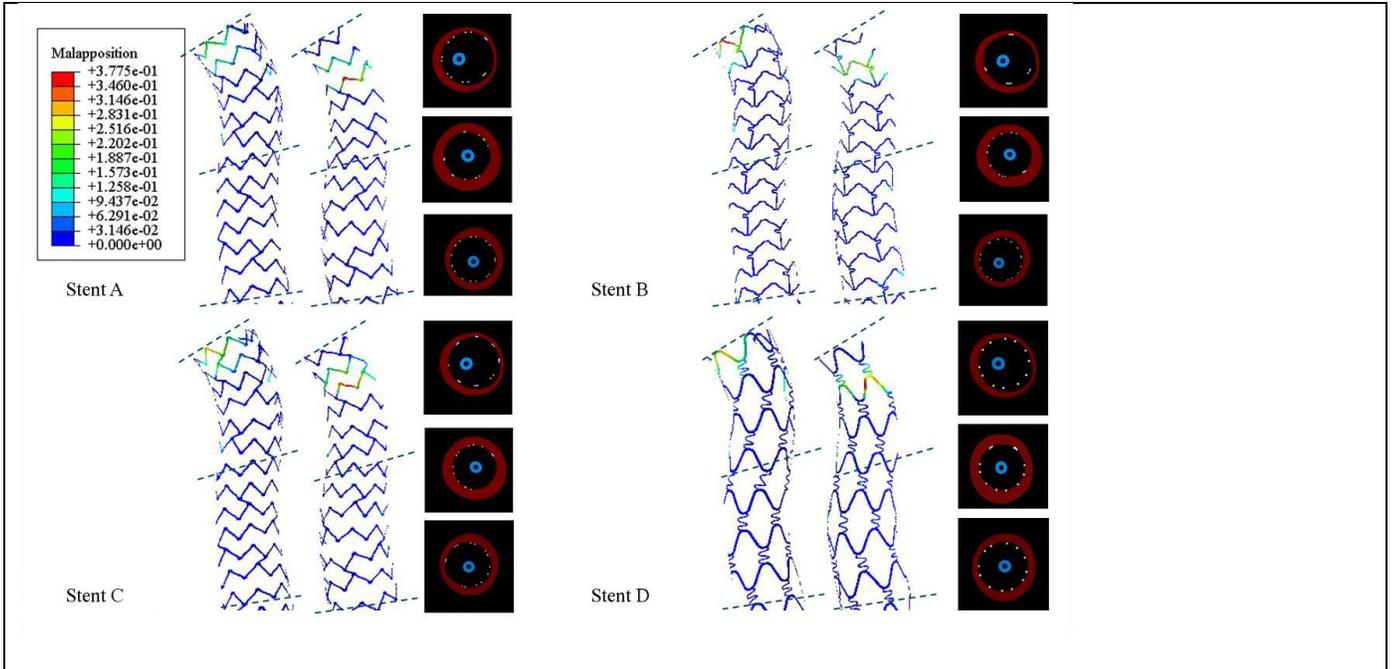


Figure 5: Virtual Stent Malapposition

Stent malapposition (mm) after the expansion of the investigated devices. For each device, cross sectional images were taken at the proximal, middle and distal area (broken lines) of the model.

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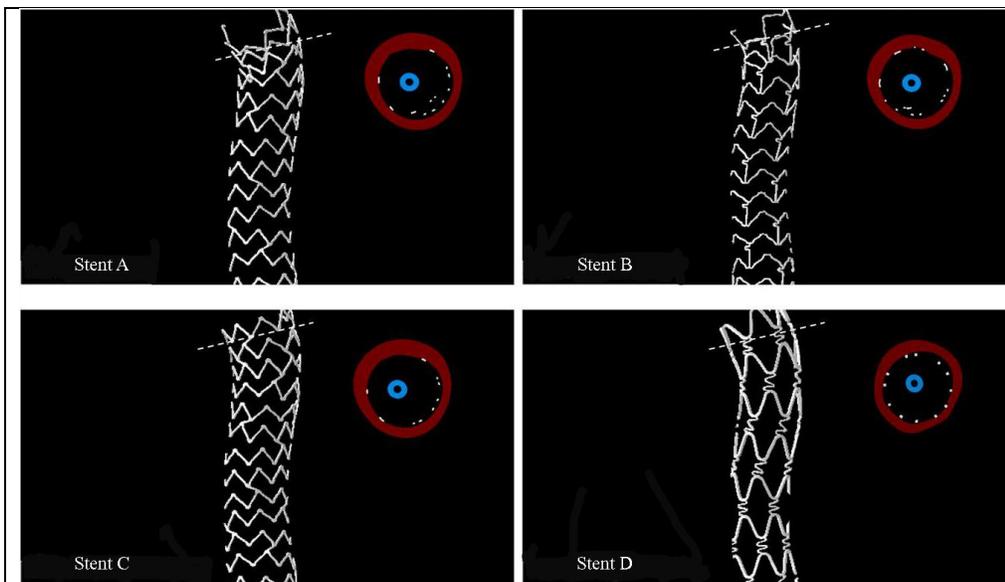


Figure 6: Virtual stent longitudinal deformation

Stent computer models cut longitudinally after they had been compressed by a 0.3N localised load at the most malapposed strut proximally to the device. For each model, a cross sectional image was taken proximally (broken lines) so as to identify potential strut protrusion due to stent deformation.

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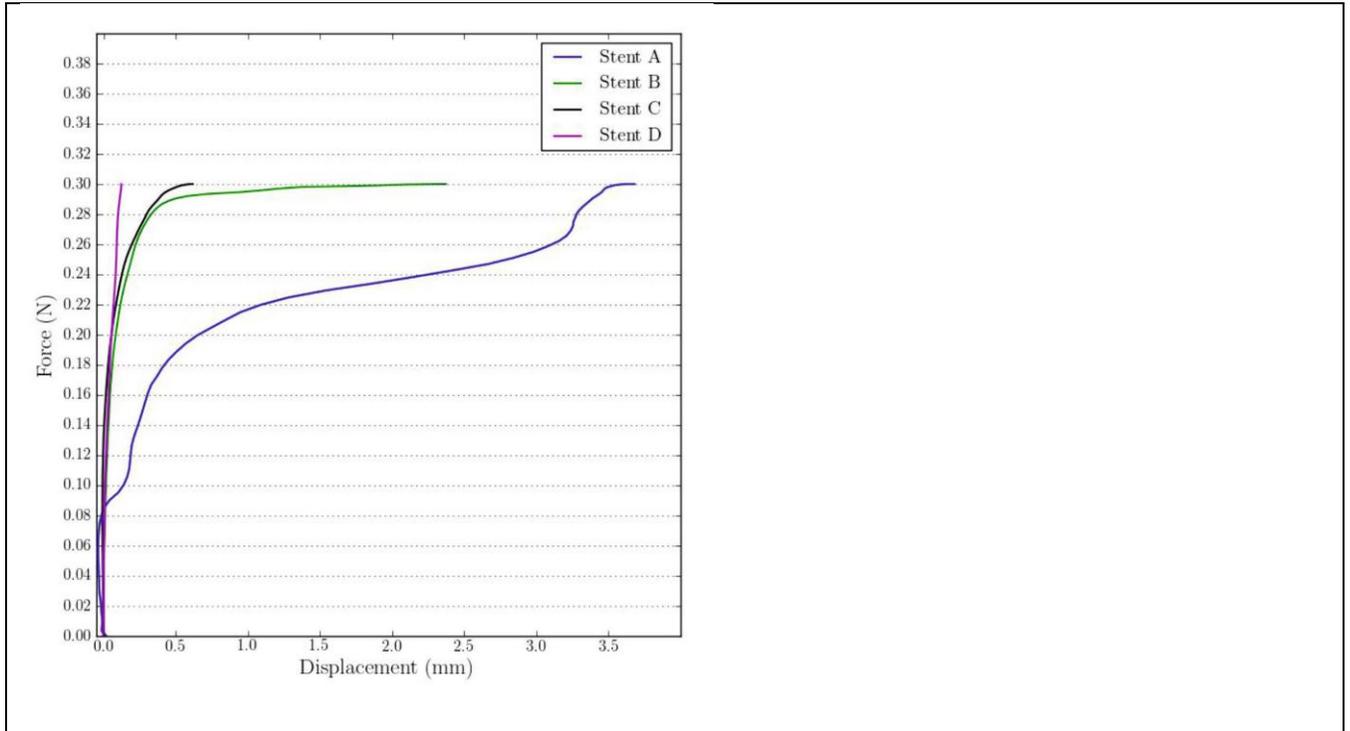
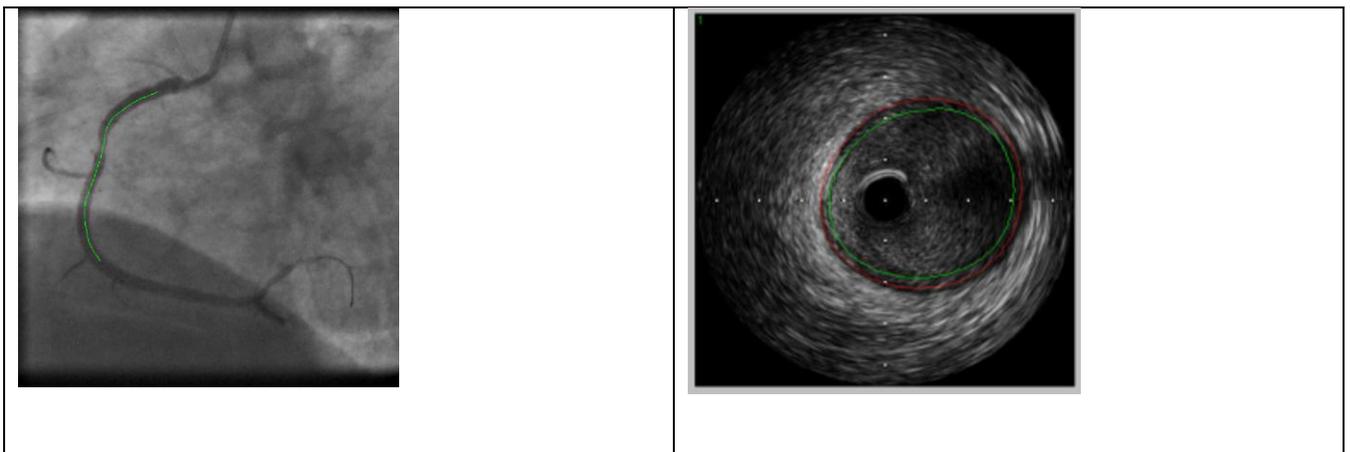


Figure 7: Localised compressive load and stent deformation

Stent compression (mm) against a compressive point load. For all devices, a 0.3N load was applied smoothly so as to evaluate longitudinal resistance.



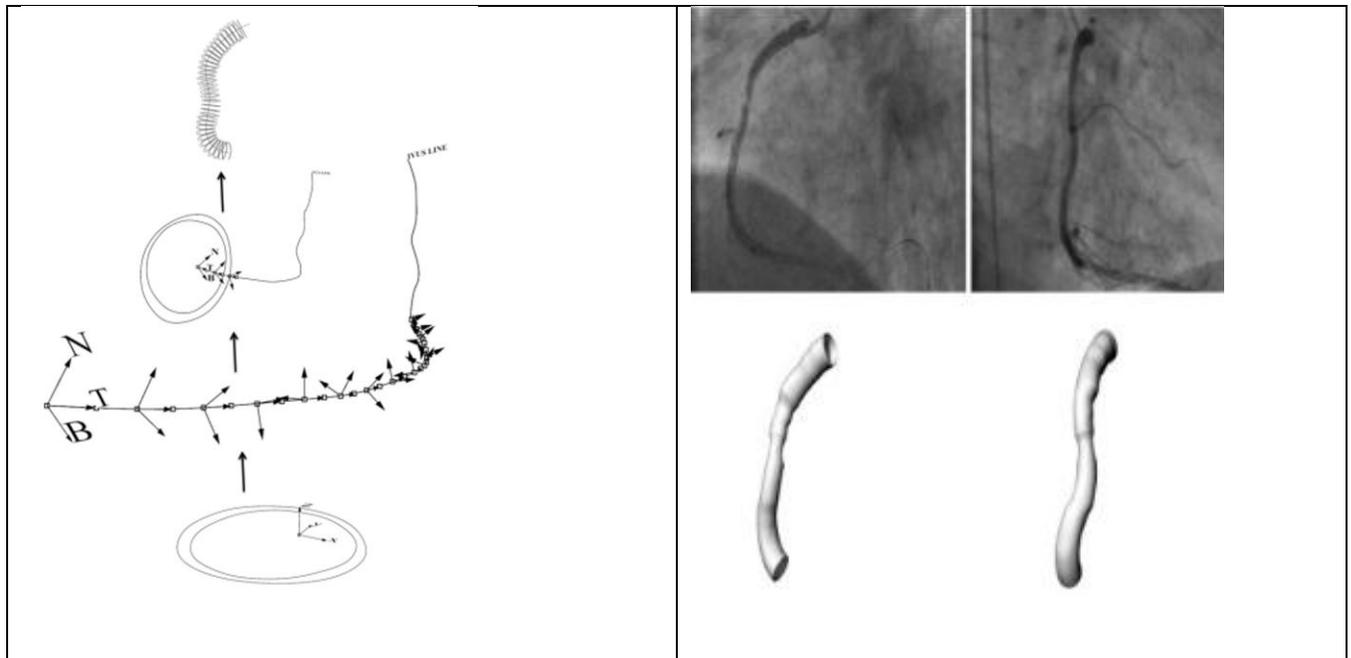


Figure 8. Right coronary artery (RCA) reconstruction. (A) Left anterior oblique (LAO) angiographic image. (B) Intravascular ultrasound (IVUS) image segmentation in IVUS Angio-Tool. (C) Segmented cross section orientation on the reconstructed catheter line according to the calculated Frenet trihedron at each position point. (D) Final reconstructed lumen surface from LAO and RAO.

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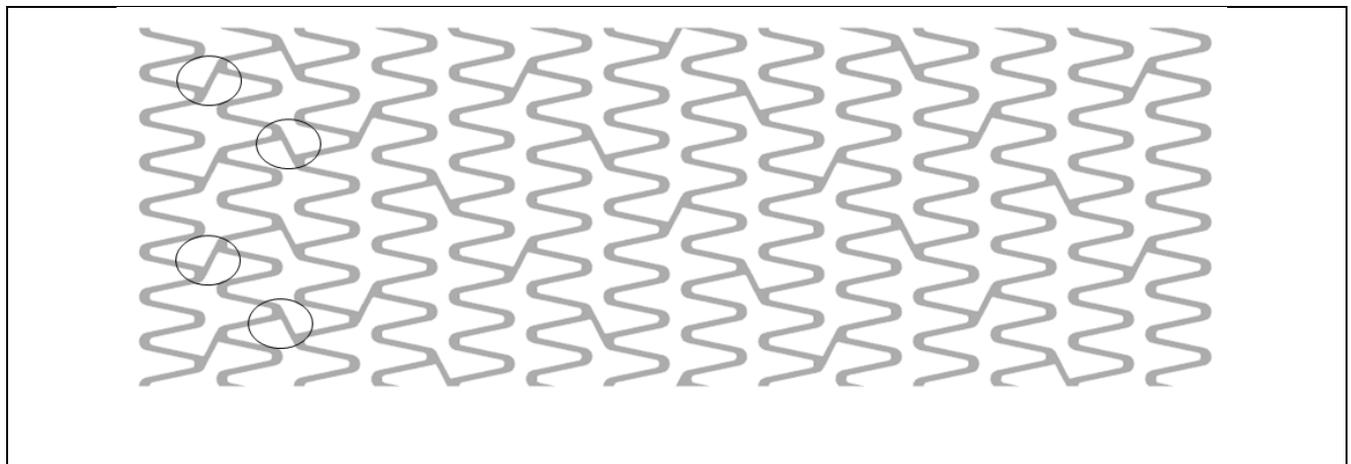


Figure 9. Planar sketch of the modified stent C. In total, four additional connectors were constructed at the proximal end of the device.

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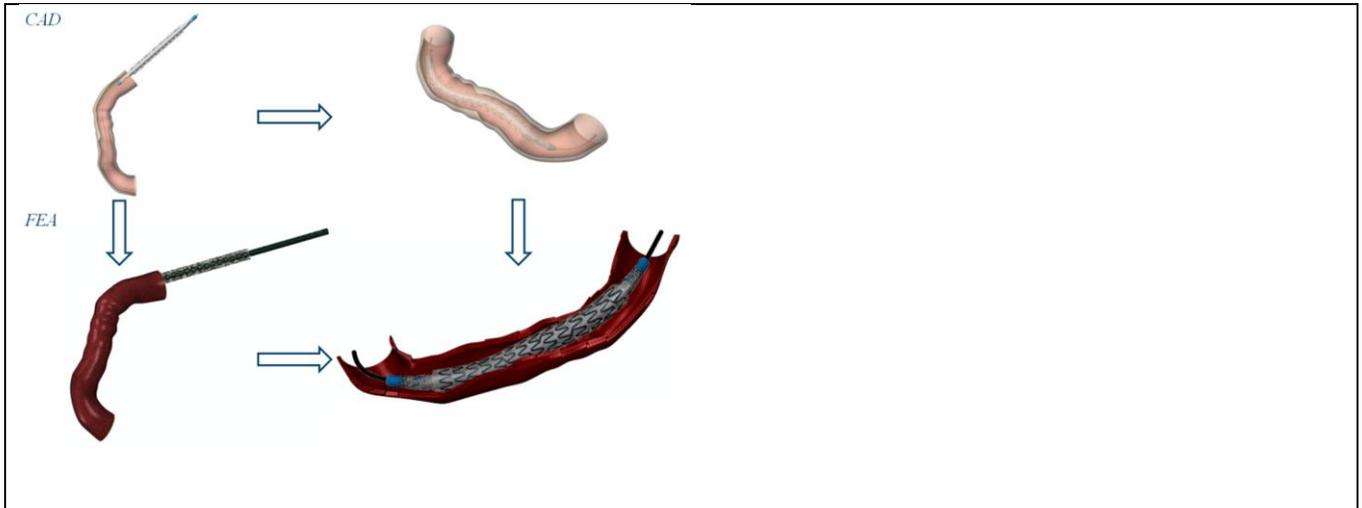


Figure 10. Illustration of the two simulation design strategies. Approach 1, from the top left and anticlockwise to the bottom right. Approach 2, from the top left and clockwise to the bottom right.

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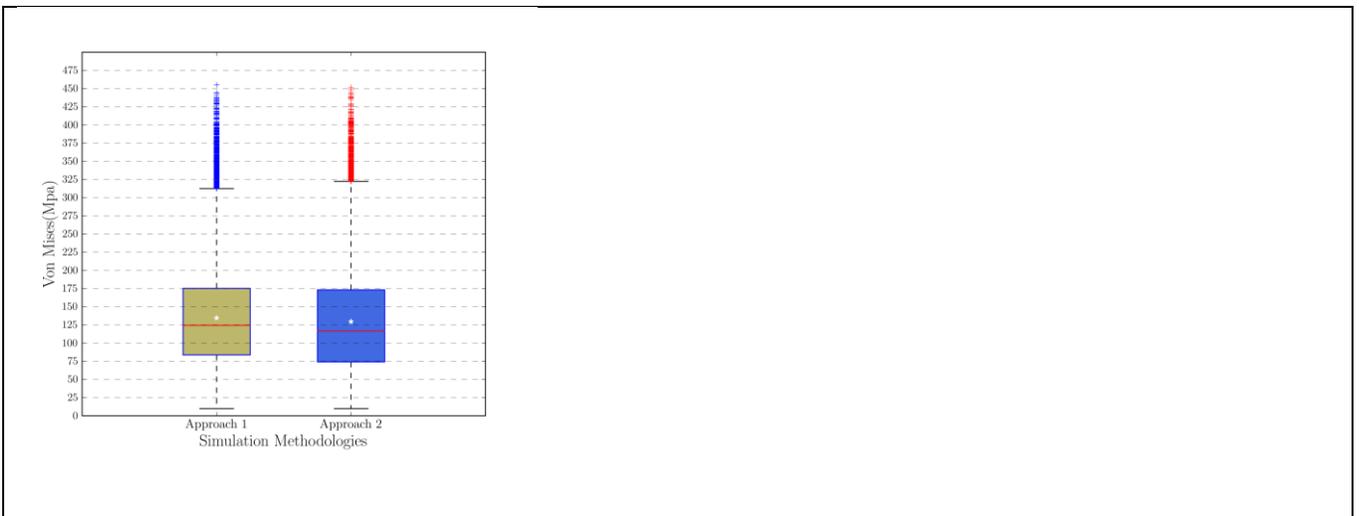


Figure 11. Boxplots of the average Von Mises distribution of the expanded stent between the two simulation approaches.

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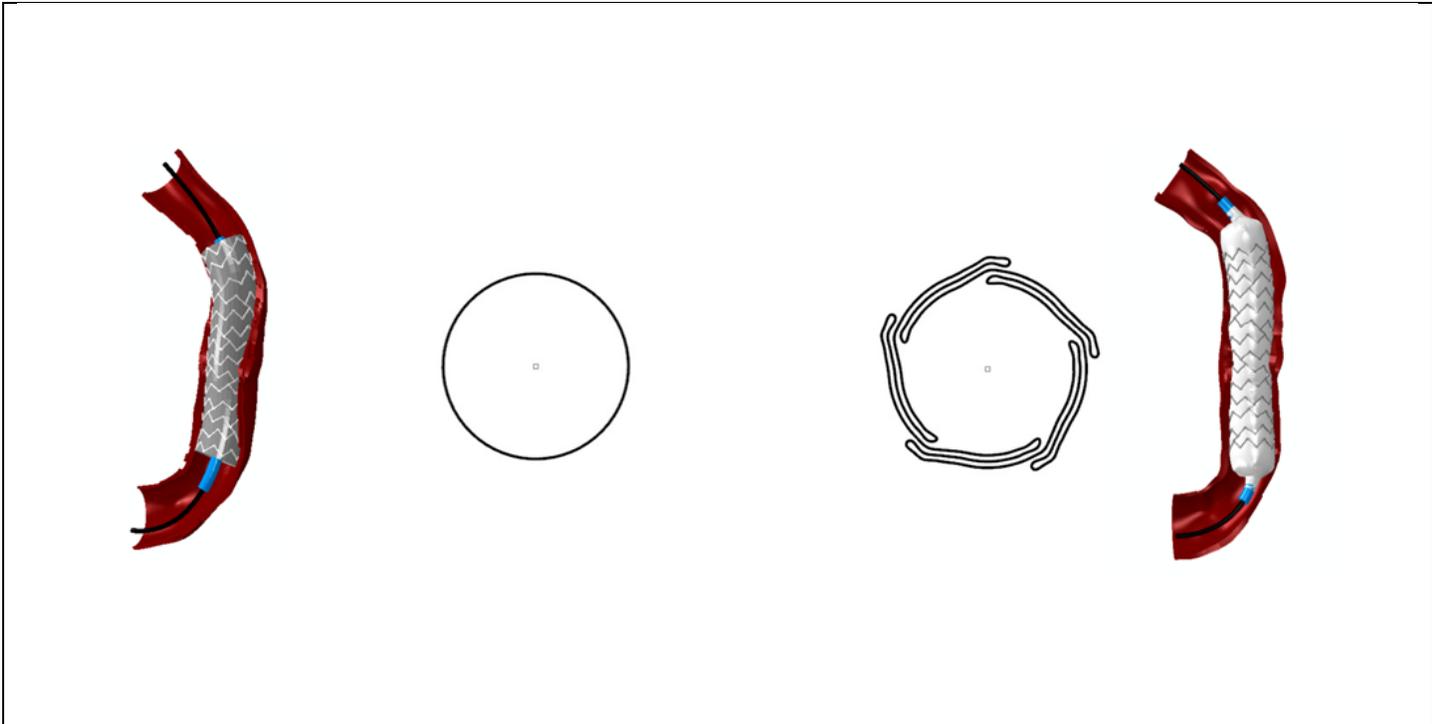


Figure 12. Illustration of stent expansion with a deformable surface (left) and a realistic five folded balloon (right). Cross sections of the expansion means are depicted next to each model.

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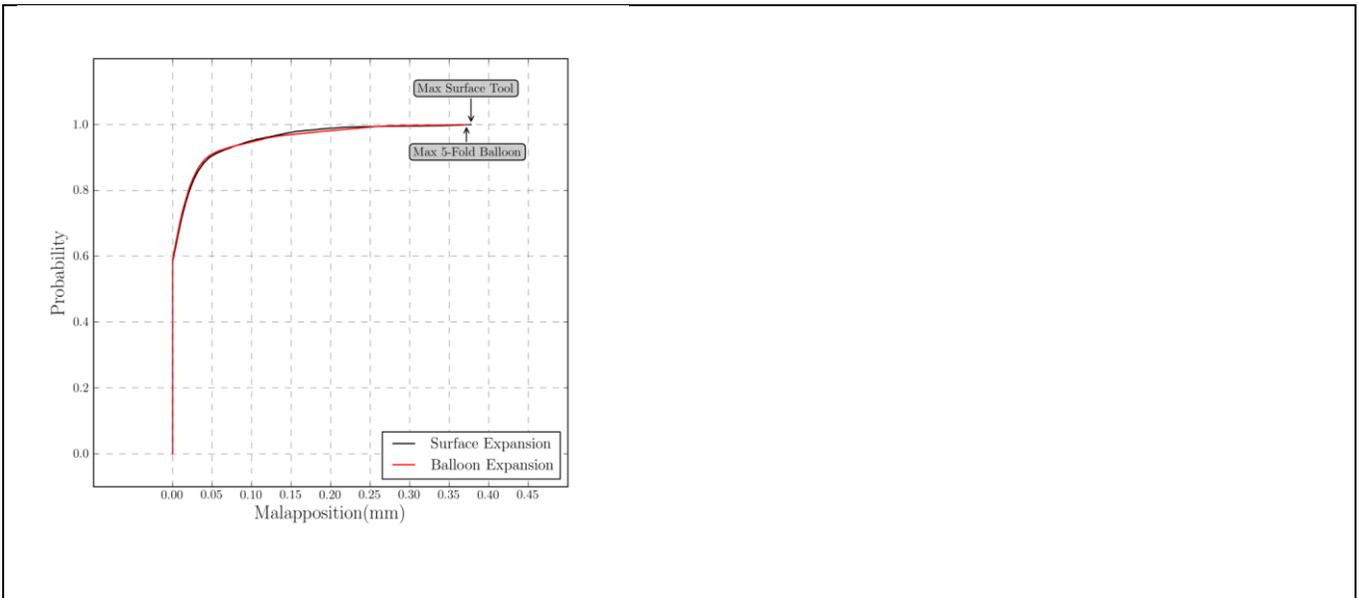


Figure 13. Cumulative distribution functions (CDF) were plotted after each expansion step measuring

the stent malapposition. The CDF graphs are almost identical demonstrating that for this patient specific case, a deformable surface could be used for simplicity.

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