

Palatal implants surgery effectiveness in treatment of obstructive sleep apnea: a numerical method with 3D patient specific geometries

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Abstract

Obstructive sleep apnea (OSA) affects a large part of the population and is increasingly recognized as a major global health problem. One surgical procedure for OSA is to implant polyethylene (PET) material into the soft palate, but its efficacy remains to be discussed. In this study, we provide input to this topic based on numerical simulations. Three 3D soft palate finite element models including the mouth close and mouth open cases are created based on three patient specific CT images. A simplified material modeling approach with the Neo-Hookean material model is applied and nonlinear geometry is accounted for. Young's modulus for the implant material is obtained from uniaxial tests and the PET implant pillars are inserted in the 3D soft palate model. With the finite element model, we design different surgical schemes and investigate their efficacy with respect to avoiding the soft palate collapse. Several pillar schemes are tested, including different placement directions, different placement positions, different settings for the radius and the array parameters of the implant pillars, and different Young's moduli for the pillars. Based on our simulation results, the longitudinal direction implant surgery improves the stiffness of the soft palate to a small degree, and implanting in transverse direction is evaluated to be a good choice to improve the existing surgical scheme. In addition, the Young's modulus of the polyethylene material implants has an influence on the reinforcement efficacy of the soft palate.

Keywords: Palatal implants, Soft palate, 3D modeling, Numerical simulation, Obstructive sleep apnea

1. Introduction

Recently, Obstructive Sleeping Apnea (OSA) has become an active research topic due to the increasing prevalence of the disease, with up to 34% of men and 17% of women suffering from this respiratory syndrome (Redline, 2017). Several medical conditions are linked to the development of OSA, the most significant being hypertension (Brooks et al., 1997), development of insulin resistance (IP et al., 2002), and the risk for increased daytime sleepiness and motor vehicle accidents (Tregear et al., 2009). In the upper airway, the soft palate's biomechanical behavior plays a key role in the investigation of OSA (Young et al., 2005; Cho et al., 2013), and

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8 describing the changes in soft tissue biomechanics during sleep is mandatory in understanding the pathophysi-
9 ology of the disease. During the upper airway obstruction process, the drop in pressure will result in complete or
10 partial obstructions (Ryan and Bradley, 2005), which in turn are responsible for periods of oxygen desaturations
11 and arousals during sleep.

12 Treatment of OSA is varied and often based on differences in the individual upper airway anatomy and
13 the severity of the disease. It reflects the fact that the underlying mechanisms causing the disease are poorly
14 understood. The conservative line of treatment consists of: physical weight loss and sleep position altering.
15 The interventional line of treatment consists of either some forms of positive airway pressure (CPAP/biPAP),
16 or surgery. Weight loss and altering sleep position are often found to be the first step of OSA treatment. CPA-
17 P/biPAP treatment inhibits the negative pressure drop by applying a pneumatic splint and has been shown to
18 have high success rates, but the long term compliance to the patient may be a problem (Kribbs et al., 1993). The
19 surgical therapy by removing redundant tissue is called uvulopalatopharyngoplasty (UPPP) (Fujita et al., 1981),
20 but the long term success rates have been shown to be moderate (Sher et al., 1996). In addition to tissue remov-
21 ing surgery, the maxillomandibular advancement surgery (MMA) has been found to improve OSA in selected
22 groups of patients (Holty and Guilleminault, 2010).

23 In recent years, another surgical treatment called palatal implants surgery was presented (Nordgård et al.,
24 2004). It has the advantage of being a minimal invasive procedure with little discomfort for the patients and is
25 easily performed under local anesthesia. The main characteristic of the palatal implants surgery is that some
26 pillar shape implants will be inserted into the soft palate through a specific implant system. The typical one
27 is called the Palatal Implant System (PillarTM System, Restore Medical, St Paul, MN) consisting of an implant
28 device and a delivery part. Through the palatal implants surgery, the stiffness of soft palate is thought to be
29 increased (Nordgård et al., 2004; Friedman et al., 2006a,b). The palatal implants surgery efficacy to the snoring
30 treatment has been clarified to be ideal (Friedman et al., 2008). However, to the OSA treatment, the success
31 rate of the palatal implants surgery varies from different patients and the efficacy remains to be discussed. It has
32 been pointed out that the overall effectiveness was not confirmed (Steward et al., 2008). This conclusion is also
33 supported by some other research works, such as (Maurer et al., 2012) and (Choi et al., 2013).

34 Therefore, a study of the efficacy of the palatal implants to the OSA treatment is of interest. A clinical study
35 needs patient participation and the study management and outcome validation are complex. However, in recent
36 years, computational biomechanics has been used to simulate the biomechanical behavior of human soft tissue.
37 Huang et al. presented a computational model of the upper airway to estimate the implant surgery success
38 rate and suggested that the computational modeling can be used to predict the efficacy of the clinical implants
39 surgery (Huang et al., 2007). However, only 2D and partial 3D models were presented in their study. Recently,
40 medical imaging technologies, such as computed tomography (CT) or magnetic resonance (MR), have been
41 used to create the upper airway's 3D geometry (Mihaescu et al., 2008; Mylavarapu et al., 2009; Sera et al.,
42 2015).

43 In order to achieve more representative anatomical simulations, we present 3 patient specific 3D models

44 of the soft palate based on the corresponding CT images including the mouth-close condition and mouth-open
45 condition to estimate the efficacy of the palatal implants surgery. Additionally, different surgical schemes can
46 be designed and tested including different placement directions of the pillar implants, different radiuses of the
47 pillars and different interval spaces between the pillars. Comparing the efficacy of different schemes, we can
48 determine the most efficient surgical scheme. The objective of this study is to employ 3D patient specific
49 geometries of the soft palate and numerical simulations to determine how different pillar insertions affect the
50 soft palate stiffness. Procedures giving increased stiffness may improve the OSA state for the patients. The
51 comparison between different surgical schemes may provide a guide for the medical doctors to improve current
52 treatments.

53 **2. Materials and methods**

54 *2.1. Pillar implants surgery schemes*

55 In general, the common palatal implants surgical scheme presented in the literature is three pillar shape
56 implants (a segment of braided polyethylene terephthalate (PET)) implanted into the soft palate from anterior
57 side to posterior side (longitudinal) (see Fig. 1 (A)) with an implants delivery device. Until now, the presented
58 surgical schemes all choose the longitudinal implant type. In this study, we will also investigate the alternative
59 transverse direction implant surgery (Fig. 1 (A)) with the finite element (FE) model.

60 In addition to the different implant directions, the array parameters (Fig. 1 (B)) of these three implants
61 pillars also remain to be tested to investigate the efficacy of the palatal implants surgery. Some of the surgical
62 schemes from the literature for these 3 parameters are listed as Table 1. In order to surgically place the pillars
63 into the soft tissue with moderate trauma, the diameter cannot be too large. An implant diameter of 1.5-2 mm is
64 optimal for a feasible insertion needle that does not cause unnecessary harm. The length of the pillars is usually
65 set to 18 mm, which is approximately 50% of the mean length of the soft palate (37-45mm) (Kurt et al., 2011;
66 Lim et al., 2017). This ensures that the placement of the pillars with the cylindrical tube does not protrude in
67 the distal end or interferes with the bony periosteal layer of the hard palate. In Table 1, in one case, the implants
68 are inserted along the entire length of the soft palate (Friedman et al., 2006b). It means the implants are inserted
69 as deep as possible until they approach the posterior surface of the soft palate.

70 As Fig. 2 shows, different placement positions are investigated. Also, the influences of the number of pillars
71 and the Young's modulus of the implants are evaluated with our numerical 3D model. In total, the summary of
72 the tested schemes are listed in Table 2.

73 *2.2. Numerical modeling*

74 *2.2.1. 3D patient specific geometry*

75 In this study, based on the specific patients' CT images, we present a way to model the soft palate. The
76 academic use of these images was approved by the Norwegian Regional Committee for Medical Research
77 Ethics (REK) and was registered in Clinicaltrials.gov. (NCT01282125). In order to have a feasible study, three

78 patients' CT images were used (patient 1, patient 2 and patient 3). In addition, since many obstructive sleep
 79 apnea (OSA) patients have been found to breath with mouth-open during sleep, and the mouth-open breathing
 80 during sleep has been clarified to be a risk factor for bringing OSA (Lee et al., 2007; Kim et al., 2011), the
 81 mouth-open (patient 3) sleep conditions was also investigated. The soft palate anatomy characteristics and
 82 demographic information of these three patients are listed in Table 3.

83 In detail, for 3D modeling, first the DICOM file was imported into the commercial software MIMICS.
 84 Through some basic operations like segmentation and mask editing, the soft palate was then isolated with some
 85 parts of the pharynx wall. In order to obtain a smoother geometry and refined mesh, we exported the planar
 86 polylines representing the airway and applied a smoothing edit on these polylines. Then, by importing them
 87 into ABAQUS, the final geometry was generated and meshed (Fig. 3). The modeling method for patient 2 and
 88 3 is the same as that of patient 1 shown in Fig. 3.

89 The 3D model includes the airway in the soft palate region and a part of the pharynx wall to account for the
 90 airway's obstruction (Fig. 4 (A)). The geometrical boundary between the soft palate and tongue was determined
 91 manually according to the CT images and the tongue's influence on the soft palate's biomechanical behavior
 92 is neglected in this study. Additionally, for the mouth-open condition, the soft palate will move in anterior
 93 direction toward the tongue. Then, part of tongue is modeled for patient 3 (Fig. 4 (A)). The modeling of the
 94 pillar implants is achieved through some partition operations in ABAQUS. We assume the implants pillars are
 95 fully bonded to the soft tissue, i.e. the boundary surface of the pillars and soft tissue share the same nodes in
 96 the FE models (Fig. 3).

97 2.2.2. Material property and boundary conditions

98 The soft palate is modeled as a Neo-Hookean material defined by the following strain-energy function:

$$\Psi(\bar{I}_1, J) = \underbrace{c(\bar{I}_1 - 3)}_{\text{isochoric-isotropic}} + \underbrace{\frac{1}{D_1}(J - 1)^2}_{\text{volumetric}}. \quad (1)$$

99 \bar{I}_1 is the first invariant of the modified right Cauchy-Green tensor $\bar{\mathbf{C}}$. c, D_1 are material parameters derived from
 100 the Young's modulus E and Poisson ratio ν with the following relations (Berry et al., 1999):

$$c = \frac{E}{4(1 + \nu)}, D_1 = \frac{6(1 - 2\nu)}{E}. \quad (2)$$

101 We use the Young's modulus determined from in vivo magnetic resonance elastography measurements pro-
 102 vided by (Cheng et al., 2011) for the human soft palate. Assuming a Poisson ratio value of 0.49, the Young's
 103 modulus was calculated to be 7.539 kPa based on the measured shear modulus 2.53 kPa. For patient 3, the
 104 Young's modulus of the tongue was determined using shear modulus 2.67 kPa provided by (Cheng et al., 2011).
 105 For simplicity, the pharynx wall part was assigned the same property as the soft palate. In addition, we per-
 106 formed uniaxial tension tests of the pillar implants, and the Young's modulus was measured to be 244 MPa.
 107 This agrees with the description for PET materials in (Lam et al., 2003). The Poisson ratio was assumed equal

108 to 0.49 and the corresponding material property was assigned to the pillars in the 3D soft palate model (Fig. 4
109 (A)).

110 For 3D soft palate model, the anatomical influence of the lateral side tissue of the soft palate should be
111 considered in the numerical simulation. In addition, the pharynx wall should also be constrained considering
112 it is attached to the cervical vertebra. Therefore, the boundary conditions for the soft palate FE model were
113 as shown in (Fig. 4 (B)). In addition, the bottom surface of the tongue in patient 3's numerical model was
114 constrained. Finally, for the negative pressure loading, we applied a uniform pressure field corresponding to
115 the pressure difference between the anterior and posterior sides of the soft palate (Fig. 2) on the surface where
116 the soft palate contacts with the airway (Fig. 4 (B)). In this study, for the mouth-close condition, the negative
117 pressure is defined as:

$$P_{\text{negative}}^{\text{mouth-close}} = P_{\text{posterior}} - P_{\text{anterior}}. \quad (3)$$

118 Note that the definition of the negative pressure for the mouth-open condition is:

$$P_{\text{negative}}^{\text{mouth-open}} = P_{\text{anterior}} - P_{\text{posterior}}. \quad (4)$$

119 When the negative pressure develops, the soft palate will have a posterior oblique deformation in the mouth-
120 close condition and an anterior oblique deformation in the mouth-open condition. If the negative pressure is
121 large enough, the soft palate will stick to the pharynx wall and the tongue for the above two conditions. Then,
122 OSA occurs. We call this critical negative pressure the closing pressure, which will be regarded as a critical
123 parameter to evaluate the efficacy of the palatal implants surgery because the more negative pressure value
124 means it will be more difficult for the soft palate to collapse. This indicates that if one surgical scheme has a
125 more negative closing pressure than another one, then it will be more efficient. A normal closing pressure for
126 persons not having OSA problems has been found to be -13 cm H₂O (Schwartz et al., 1988). Typical closing
127 pressures for OSA patients are -4-(-8) cm H₂O (Han et al., 2002). In addition, we use the following ratio to
128 compare different procedures:

$$R_{\text{strengthening-rate}} = \frac{(P_{\text{closing-implant}} - P_{\text{closing-reference}})}{P_{\text{closing-reference}}}, \quad (5)$$

129 where $P_{\text{closing-implant}}$ denotes the closing pressure for the implants inserted model and $P_{\text{closing-reference}}$
130 denotes the closing pressure for the model without the implants.

131 2.2.3. Mesh convergence study

132 The 3D patient specific FE models were meshed with four noded hybrid tetrahedral elements (C3D4H
133 ABAQUS type). A mesh convergence study was performed on the patient 1 3D model, and the displacement
134 of a point in the mid-section of soft palate posterior surface was chosen as a critical parameter and compared
135 for different mesh densities. A -5 cm H₂O negative pressure was applied and the Neo-Hookean model with the
136 aforementioned material properties data was assigned to the 3D patient specific model. Four mesh densities were

137 tested with 139 338, 397 716, 651 742 and 852 870 elements, corresponding to Mesh 1, Mesh 2, Mesh 3, and
138 Mesh 4, respectively. The difference for the critical parameter between Mesh 3 and Mesh 4 was 0.7%. There-
139 fore, considering the simulation accuracy and computational time efficiency, we used Mesh 3 in the remainder
140 of this paper, and the models for patient 2 and patient 3 share the same mesh density as Mesh 3.

141 **3. Results**

142 *3.1. Longitudinal direction surgery with 3 pillars*

143 For commonly used longitudinal direction surgery, 5 different schemes (schemes 1-5) based on different
144 array parameters of the implant pillars were designed. The detailed information is listed as Table 2. The
145 placement position is illustrated in Fig. 2 (A). Moreover, the reference closing pressures (without the implants
146 inserted) for these three patients were calculated to be -5.75 cm H₂O, -9.29 cm H₂O and -2.55 cm H₂O based
147 on the patient specific FE models, respectively.

148 According to the calculation results (Fig. 5), the implant surgery stiffens the soft palate since the clos-
149 ing pressure was calculated to be more negative than the reference value for all three patients. However, the
150 strengthening rate (see Table 4) calculated with Eq. (5) is moderate and the most negative closing pressure
151 (among schemes 1-5) is obtained from scheme 5, i.e. for the longest pillars with the largest radius. Therefore,
152 based on the obtained simulation results evaluated with the closing pressure (Fig. 5), we know that the radius
153 of the pillars and the interval space between the pillars have limited influences on stiffening the soft palate, but
154 increasing the length of the pillars contributes to improving the strength of the soft palate (scheme 3 and 5). In
155 addition, as Fig. 2 (A) shows, the influence of the anterior-posterior position of the implants pillars was investi-
156 gated in scheme 12 using the same pillar parameters as scheme 1 (see Table 2). The calculation results show a
157 small closing pressure variation between schemes 1 and 12. This indicates that the influence of the anterior and
158 posterior positions for the pillars on the global response of the soft palate is very small.

159 *3.2. Transverse direction surgery with 3 pillars*

160 Here we investigate a new surgical scheme: the transverse direction implant scheme. Since there is still
161 no transverse surgery being applied in the clinic, the investigation is interesting for further clinical research
162 to improve the surgical efficacy. Similar to the longitudinal case, different schemes were tested. Here, for
163 simplicity, the length of the pillars for the transverse case was assigned with a length of 25 mm since it has been
164 shown earlier that increased pillar length will improve the surgery efficacy (Fig. 5). Moreover, as Fig. 2 (B)
165 shows, the difference between the proximal and distal positions can be tested. In total, four schemes (schemes
166 6-9) listed in Table 2 were addressed to investigate the efficacy of the transverse direction surgery.

167 The simulation results are shown in Fig. 5 for schemes 6-9. According to Table 4, the strengthening
168 percentage of scheme 9 is calculated to be the most efficient. Except for patient 3, patient 1 and patient 2
169 show a more than four times improved efficacy compared to scheme 5 that is the most efficient scheme for
170 the longitudinal surgery schemes. Due to a larger width of the airway (30 mm) for patient 3, the improvement

171 is not so large, but still increased significantly. In addition to scheme 9, the other schemes in the transverse
172 case also show a strengthening effect of the soft palate. This means that the transverse implant surgery has a
173 higher efficacy compared to the longitudinal implant surgery based on our numerical simulation. Moreover, for
174 the transverse implant surgery, according to the simulation results (Fig. 5), a distal placement (scheme 7 and
175 scheme 9) of the implants might be preferable.

176 Additionally, the influence of the pillars in the soft tissue was investigated. Based on the simulation results,
177 we obtained the main stress distribution characteristics. Due to the fully coupled pillar to soft tissue, there is a
178 sharp transition in tissue stresses from the interface between the soft tissue and pillars into the surrounding soft
179 tissue. The stress concentrations due to the pillars are observed, but the stress level in most of the tissue remains
180 at the same level as for the tissue without implants. The detailed stress analysis is provided in the supplementary
181 material.

182 3.3. Simulation for 5 pillars implant surgery and the influence of the pillar Young's modulus

183 Hypothetically, one can postulate that an increased number of implanted pillars might increase the strength-
184 ening efficacy. For simplicity, the array parameters of pillars for the 5 pillars scheme (scheme 13 in Table 2)
185 were set to be same as the scheme 1, also in the longitudinal direction. As the simulation results (Fig. 6) show,
186 increasing the number of the pillars may not be an efficient way to stiffen the soft palate.

187 In addition, as mentioned in the material section, the Young's modulus of the implants material is set to be
188 244 MPa based on our experimental test result for some implants material samples. The Young's modulus of
189 the palatal implants reported in (Gillis et al., 2016; Huang et al., 2007) was set to be 2 MPa. Therefore, we
190 compare the response for the different Young's moduli. We denote 244MPa the strong stiffening case while the
191 2MPa is denoted the slight stiffening cas. Scheme 3 for the longitudinal case and scheme 7 for the transverse
192 case were addressed for the comparison. The corresponding slight stiffening schemes were named scheme 10
193 and scheme 11 (see Table 2), respectively.

194 According to the simulation results (Fig. 5), the surgery with implants having a large Young's modulus
195 shows a more negative closing pressure, especially in the transverse case. In detail, comparing with scheme 10,
196 scheme 3 has an average 2.3% lower closing pressure for these three patients. For the transverse case, comparing
197 with scheme 11, scheme 7 improves the soft palate stiffness dramatically and has an average 23.4% lower
198 closing pressure. Therefore, the effect of increasing the Young's modulus of the implants to improve the soft
199 palate stiffness in longitudinal direction is moderate. However, the larger Young's modulus implants contribute
200 to stiffening the soft palate efficiently for the transverse distal implant surgery. In addition, a comparison study
201 of the stress distribution for these two different material properties cases are addressed. In short, the Young's
202 moduli of 2 MPa (slight stiffening case) and 244 MPa (strong stiffening case) have a large influence on the stress
203 levels in the pillars. Highest Young's modulus leads to about a factor 10 higher stresses in the pillars. However,
204 except for the tissue near the interface to the pillars, the stress levels in the remaining tissue are similar for the
205 two pillar stiffness cases. The detailed results are provided in supplementary material.

206 4. Discussion

207 In this study, we present a method to evaluate the efficacy of the palatal implants surgical schemes using
208 3D numerical simulations. A new scheme of transverse implant surgery was addressed. The simulation re-
209 sults show an improved stiffness of the soft palate when the palatal implants surgery is applied. However, the
210 strengthening rate of the longitudinal direction implant surgery shows a moderate efficacy to the OSA (see Fig.
211 5 and Table 4) that agrees with clinical study results (Steward et al., 2008; Maurer et al., 2012). In light of this,
212 our 3D numerical simulation to some degree reflects the reality of clinical upper airway surgery. Moreover,
213 the transverse direction implant surgical scheme shows a higher efficacy with more negative closing pressure
214 compared to the longitudinal direction implant surgery. A typical high efficacy close to 50% strengthening rate
215 is observed in the transverse distal implant scheme (see Fig. 5). Note that the 5 pillars for the transverse implant
216 surgery are not addressed due to practical challenges with the surgery. In addition, the deviation of the uvula
217 part is also considered for the arrangement of placement positions (proximal and distal) in the transverse case.

218 Surgical treatment has favoured the longitudinal placement of pillars not only due to the easy handling of
219 the delivery instrument in the anterior to posterior axis, but also due to the tradition of applying radiofrequency
220 ablation of the soft palate in the same direction. In a clinical experiment, placement of the pillars in the new,
221 transverse and distal position should not be more time-consuming or more surgically challenging than placement
222 in the longitudinal direction when patients are under general anaesthesia. However, there might be a need for
223 new commercial hardware that is more suited to placing transverse pillars. In this regard, one should also
224 consider the length of the pillars when performing the transverse placement in a future clinical trial. One could
225 try a strict midline placement with uniform and rather long pillars, or one could try placing two shorter pillars
226 laterally to each side of the midline. Our simulations do not show a definite strengthening efficacy when using 5
227 instead of 3 pillars. This reduces both the surgical timescale and the risk of adverse events such as the chance of
228 postoperative infection. Finally one should remember that the stiffness of the pillar material will influence the
229 movement of the palate, and that a too stiff or a too soft pillar could cause problems with successful ingrowth
230 with the surrounding tissues, or even the extrusion of the pillars, which will lead to surgical removal of the
231 implants. Supplementary material provides stress distributions in the pillars and soft tissue. It is observed
232 that in the strong stiffening case (pillar Young's modulus 244 MPa), the stress concentration is large and high
233 stresses and strains occur at the interface between the pillars and the soft tissue. Still, the levels are not as high as
234 measured failure strains measured (Peña, 2011; Martin and Sun, 2013). Further clinical studies using implants
235 of different stiffness may reveal whether there is an optimal ratio between pillar and soft tissue stiffness.

236 We defined different schemes based on the existing surgery scheme in the literature shown as in Table 1.
237 However, a more comprehensive optimization study of pillar designs is of interest and is proposed for further
238 work. A topology optimization can be used for the pillar arrangement when the complex 3D patient specific
239 geometry is addressed. This current work shows a first step that provides a general and comprehensive mechan-
240 ical knowledge for the palatal implants surgery. This also provides input for a next step topology optimization
241 study.

242 In our numerical study, since the corresponding experimental data of the human soft palate is not available,
243 the anisotropy from the muscle tissue and its neuromuscular activation effect are neglected. In order to refine our
244 implants surgery numerical model, a more accurate material model is needed in the future work to obtain a more
245 physiological simulation result for the global response of soft palate. For simplicity, we applied the negative
246 pressure as a uniformly distributed load. However, this is not the case in reality. Therefore, fluid-structure
247 interaction analysis may be employed to predict a more realistic pressure distribution for the large deformation
248 problems. This will be a task in further studies of the soft palate's response.

249 **5. Conclusion**

250 Based on the 3D FE models of the soft palate, we simulated different palatal implant surgical schemes with
251 the numerical method. Our main findings can be summarized as follows:

252 1, The existing longitudinal palatal implant surgery can improve the stiffness of the soft palate, but the
253 efficacy is moderate. This is coherent with clinical trials that show moderate efficacy on OSA in adults ([Steward
254 et al., 2008](#)).

255 2, The influence of the pillars' array parameters is small, but increasing the length of the pillars will increase
256 the strengthening efficacy. In addition, increasing the number of pillars may not be an efficient way.

257 3, Based on the obtained closing pressures, placement of the implants in the transverse direction strengthens
258 the soft palate more than placement in the longitudinal direction.

259 4, Based on our numerical studies we propose a possible clinical trial in which 3 palatal implants pillars are
260 placed in the transverse direction and distal position with the following array parameters: $a=5$ mm, $r=1$ mm.
261 The Young's modulus of the implants material should be large and have a good compliance with the soft tissues
262 of the soft palate.

Conflict of interest statement

The authors declare that they have no conflict of interest.

Acknowledgements

The project has been funded in part from a grant from the Research council of Norway and a grant from NTNU, Norway. The authors are also grateful for professor Ståle Nordgård (from the department of Otolaryngology/Head and Neck Surgery, St. Olavs Hospital and NTNU) providing the implants samples for the uniaxial test.

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Table 1. Summary of palatal implants surgeries for OSA with different array parameters of the pillars previously presented in the literature

Reference	Orientation	a (mm)	b (mm)	r (mm)
(Nordgard et al., 2006)	Longitudinal	5	18	0.75
(Goessler et al., 2007)	Longitudinal	No data	18	1
(O'Connor-Reina et al., 2008)	Longitudinal	3	18	0.75
(Walker et al., 2006)	Longitudinal	2	18	0.9
(Friedman et al., 2006b)	Longitudinal	3	Entire length (25)	No data

Table 2. Summary of designed surgical schemes in this study. Implant positions are described in Fig. 2 (A) for the longitudinal orientation and in Fig. 2 (B) for the transverse orientation.

No.	Position	a (mm)	b (mm)	r (mm)	orientation	Number of pillars	E (MPa)
Scheme 1	Anterior	5	18	0.75	Longitudinal	3	244
Scheme 2	Anterior	2	18	0.75	Longitudinal	3	244
Scheme 3	Anterior	5	25	0.75	Longitudinal	3	244
Scheme 4	Anterior	5	18	1	Longitudinal	3	244
Scheme 5	Anterior	5	25	1	Longitudinal	3	244
Scheme 6	Anterior – proximal	5	25	0.75	Transverse	3	244
Scheme 7	Anterior – distal	5	25	0.75	Transverse	3	244
Scheme 8	Anterior – proximal	5	25	1	Transverse	3	244
Scheme 9	Anterior – distal	5	25	1	Transverse	3	244
Scheme 10	Anterior	5	25	0.75	Longitudinal	3	2
Scheme 11	Anterior – distal	5	25	0.75	Transverse	3	2
Scheme 12	Posterior	5	18	0.75	Longitudinal	3	244
Scheme 13	Anterior	5	18	0.75	Longitudinal	5	244

Table 3. Anatomy information of the soft palate for three patients. The thickness is the average of three sections along the length, and the length is the distance between 'a' and 'b' (Fig. 3). Note that, the width denotes the width of the airway in the section connected to the hard palate. Body mass index (BMI) and apnea hypopnoea index (AHI) are included.

No.	Gender	Age	Condition	Thickness (mm)	Length (mm)	Width (mm)	BMI	AHI
Patient1	Male	67	Mouth – close	9	34	23	28.4	22.8
Patient2	Male	44	Mouth – close	10	36	24	31.4	22.4
Patient3	Male	43	Mouth – open	8	37	30	24.3	18.0

Table 4. Summary for the strengthening percentage of the designed schemes including the longitudinal schemes and transverse schemes based on the obtained closing pressures

No.	Patient1 (%)	Patient2 (%)	Patient3 (%)
Scheme 1	0.2	0.4	5.0
Scheme 2	0.5	0.5	4.4
Scheme 3	6.5	3.8	9.4
Scheme 4	0.8	0.9	6.2
Scheme 5	9.6	5.8	11.8
Scheme 6	7.7	7.2	4.1
Scheme 7	44.4	36.1	12.2
Scheme 8	9.0	9.5	4.7
Scheme 9	52.8	45.3	14.0
Scheme 10	4.2	4.0	4.6
Scheme 11	9.0	7.8	3.8

Figure captions

Fig. 1. Schematic of the palatal implants surgery: (A) the longitudinal and transverse implant surgeries adapted from the reference paper (Friedman et al., 2006b), (B) the array parameters for the pillar shape implants, the parameters a , b and r denote the interval space, the length and the radius, respectively.

Fig. 2. Placement positions of the pillars. (A) Schematic of the longitudinal implant surgery with the midsagittal view of soft palate. The pillars have a 5 mm interval to boundary section between the soft palate and the hard palate (Friedman et al., 2006b). (For patient 2, due to the complex geometry, this interval is set to be 2 mm when the pillars' length is set to be 25 mm.) The distance between the centerline of the pillars and the anterior surface is set to be 1.75 mm for the anterior scheme and 6.75 mm for the posterior scheme. (B) Schematic for the proximal and distal place positions in the transverse direction case with the midsagittal view of soft palate. 10 mm interval and 15 mm interval to the section connected to the hard palate are used for the proximal and distal positions, respectively. Note that the uvula part is distinguished in the 3D models and transverse placement positions of the pillars are deviated from the uvula part.

Fig. 3. 3D geometry reconstruction of the soft palate with respect to patient 1's CT images and Mimics. The markers 'a' and 'b' denote the side between the soft palate and the hard palate and the distal edge of the soft palate, respectively. In addition, a refined mesh was assigned to the pillars in the 3D FE model.

Fig. 4. 3D numerical modeling: (A) schematic of the implants region partition in the 3D model for the longitudinal case (up-left) and transverse case (up-right) and the collapse of the soft palate including the mouth-close condition (down-left) and mouth-open condition (down-right) with the midsagittal view of soft palate, (B) boundary conditions for the numerical model of the soft palate, the external surface of the pharynx wall, the lateral sides and the side connected to the hard palate were constrained in all directions, and the negative pressure is distributed on the inner airway surface.

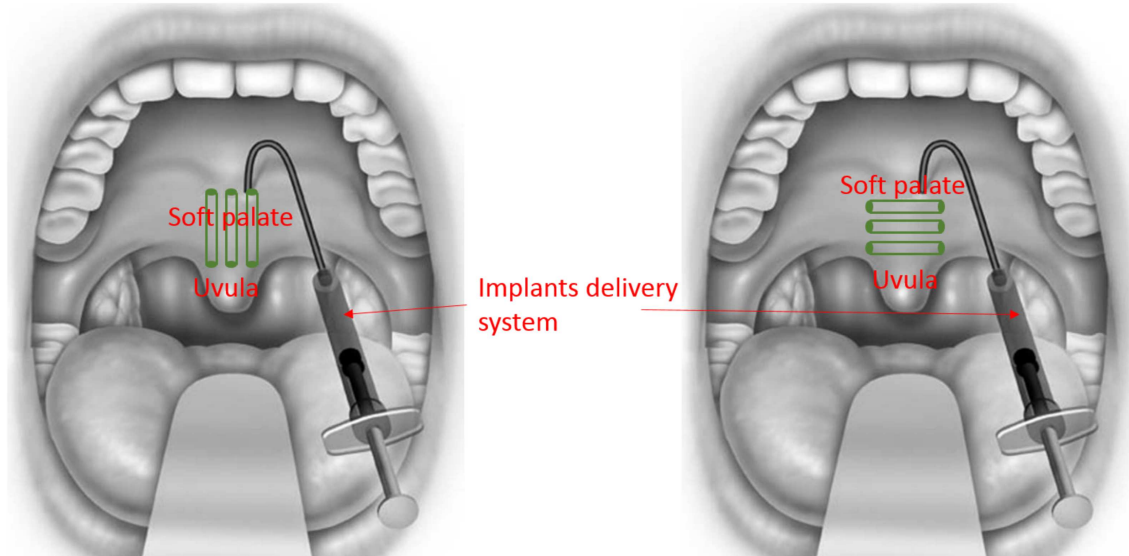
Fig. 5. Closing pressure for different surgical schemes in both the longitudinal and transverse orientation cases for three patients: (A) patient 1, (B) patient 2, (C) patient 3. The same variation trend of different schemes for these three patients is presented, and the scheme 7 and scheme 9 are found to be more efficient than other schemes.

Fig. 6. Comparison between 3 and 5 pillars longitudinal implant surgery. A very limited strengthening efficacy is presented for the 5 implanted pillars surgical scheme compared with the 3 pillars scheme.

A

Longitudinal scheme

Transverse scheme



B

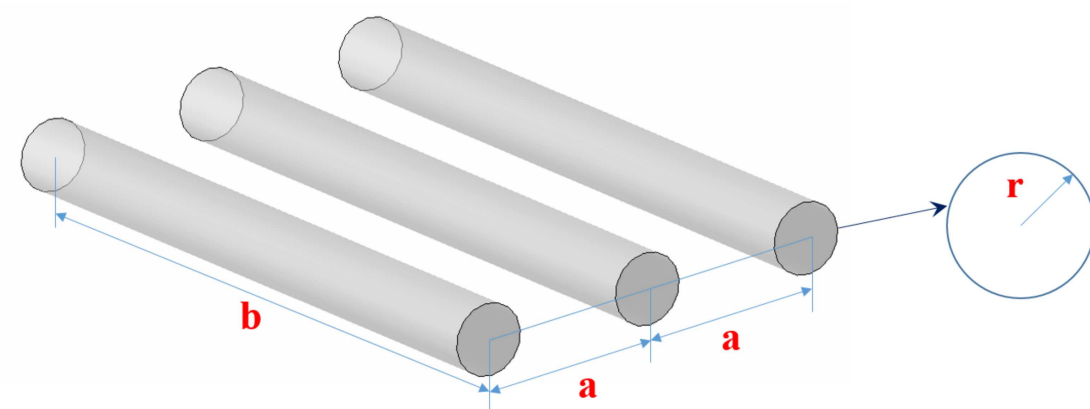
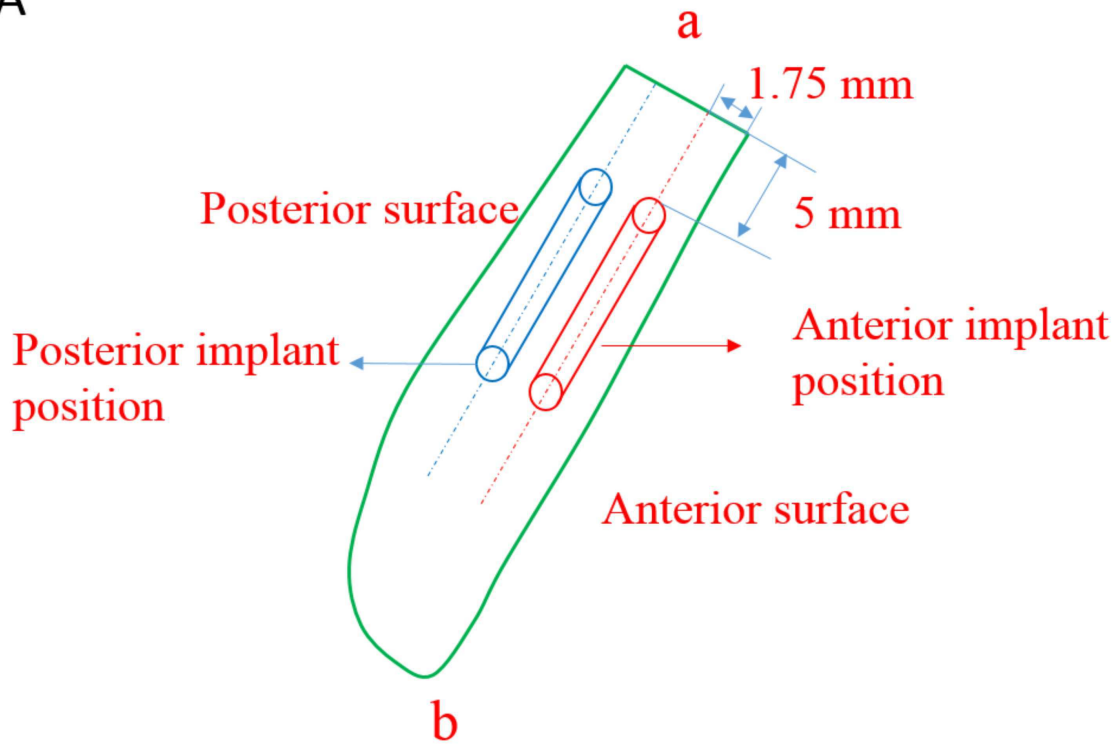


Fig. 1

A



B

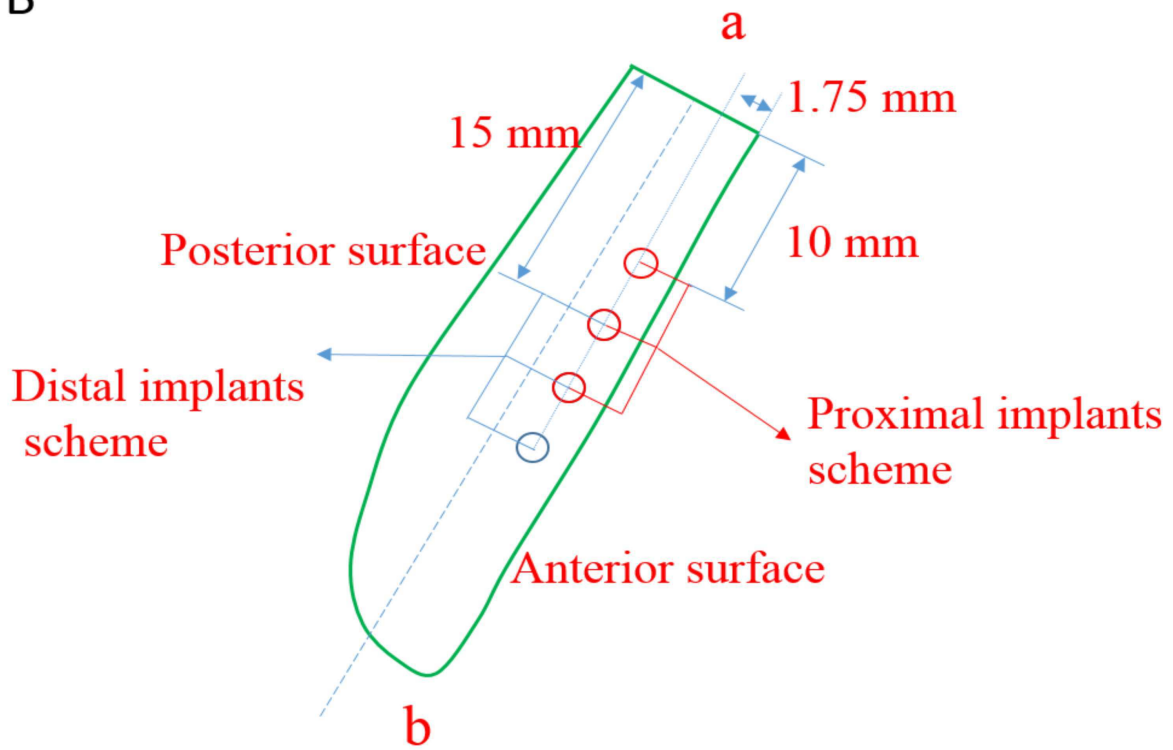


Fig. 2

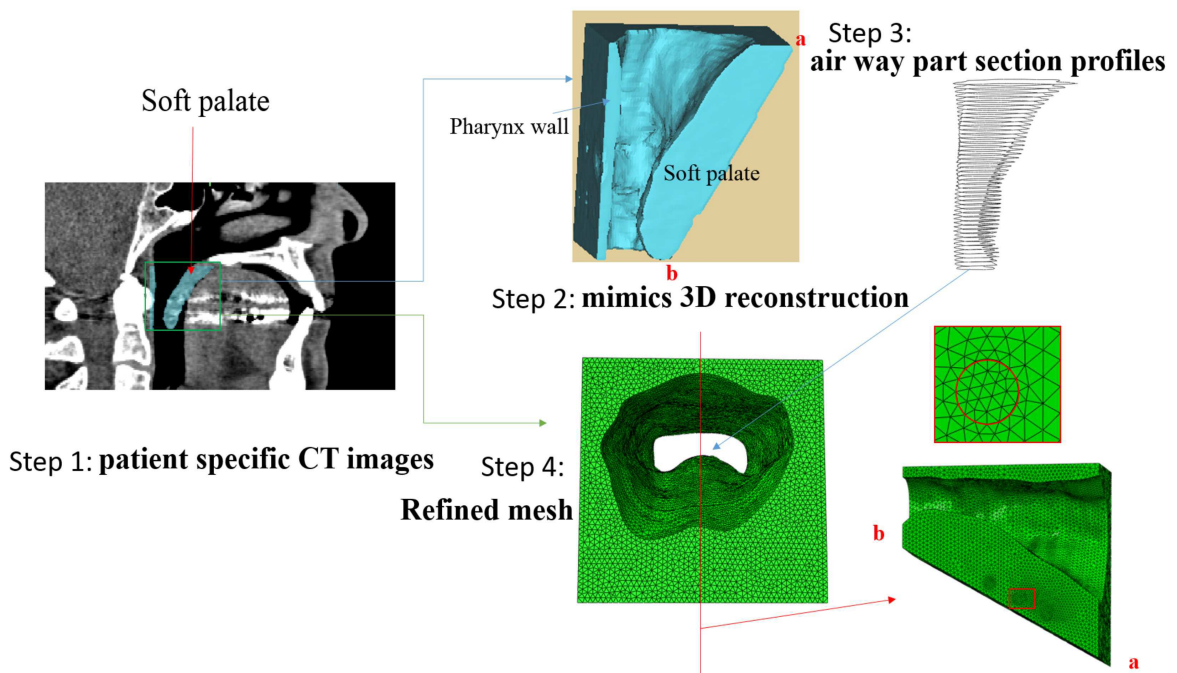


Fig. 3

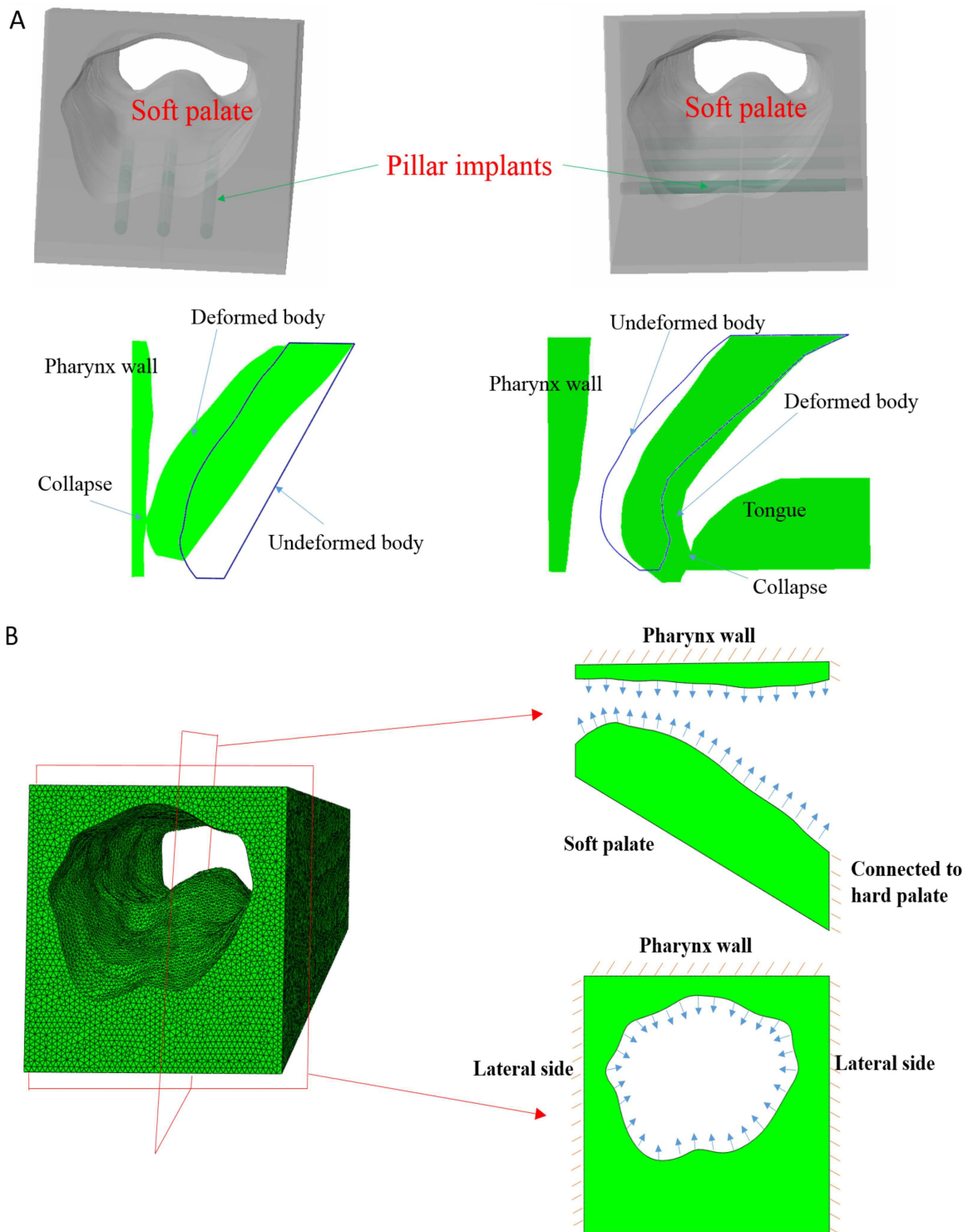


Fig. 4

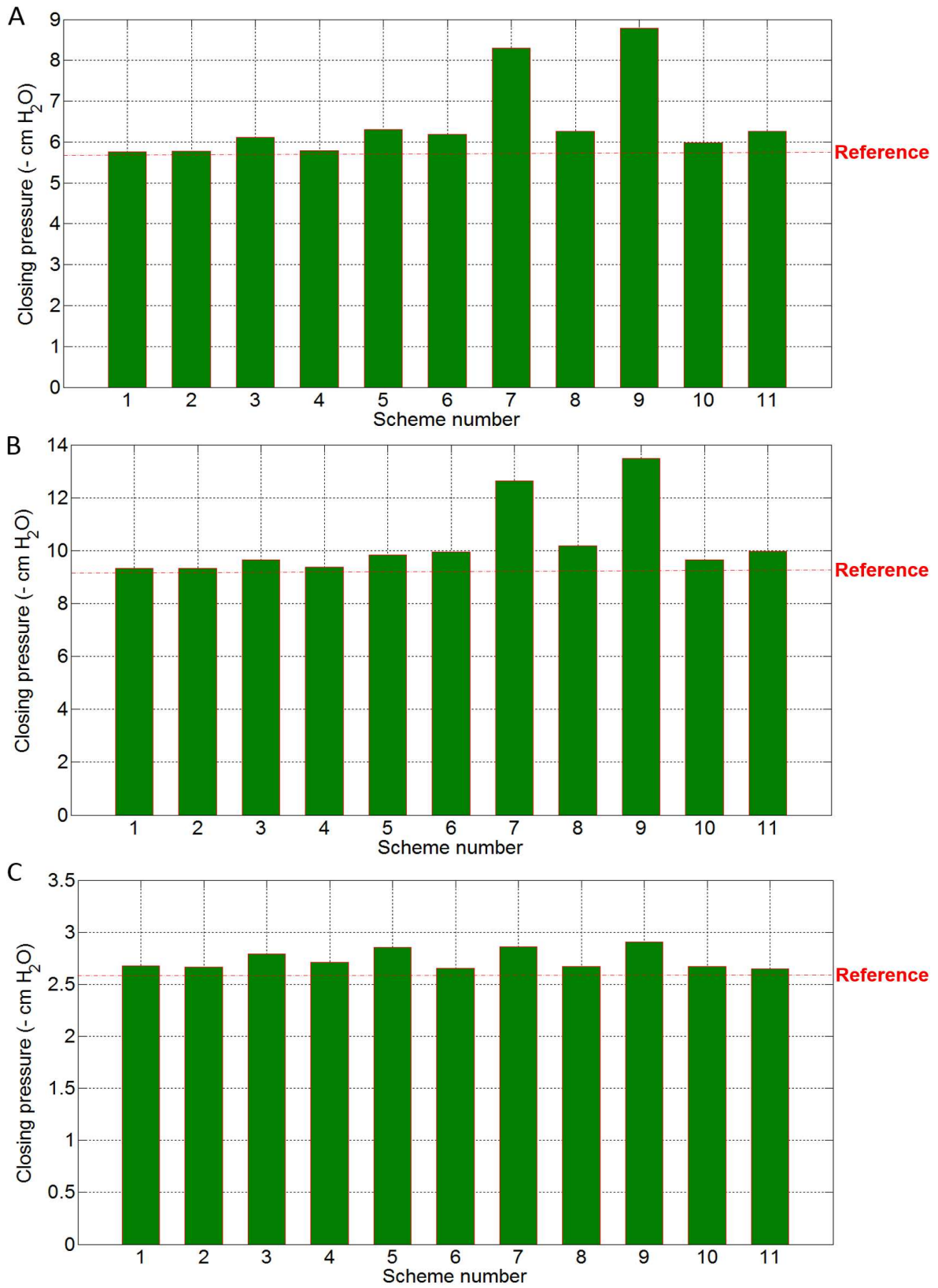


Fig. 5

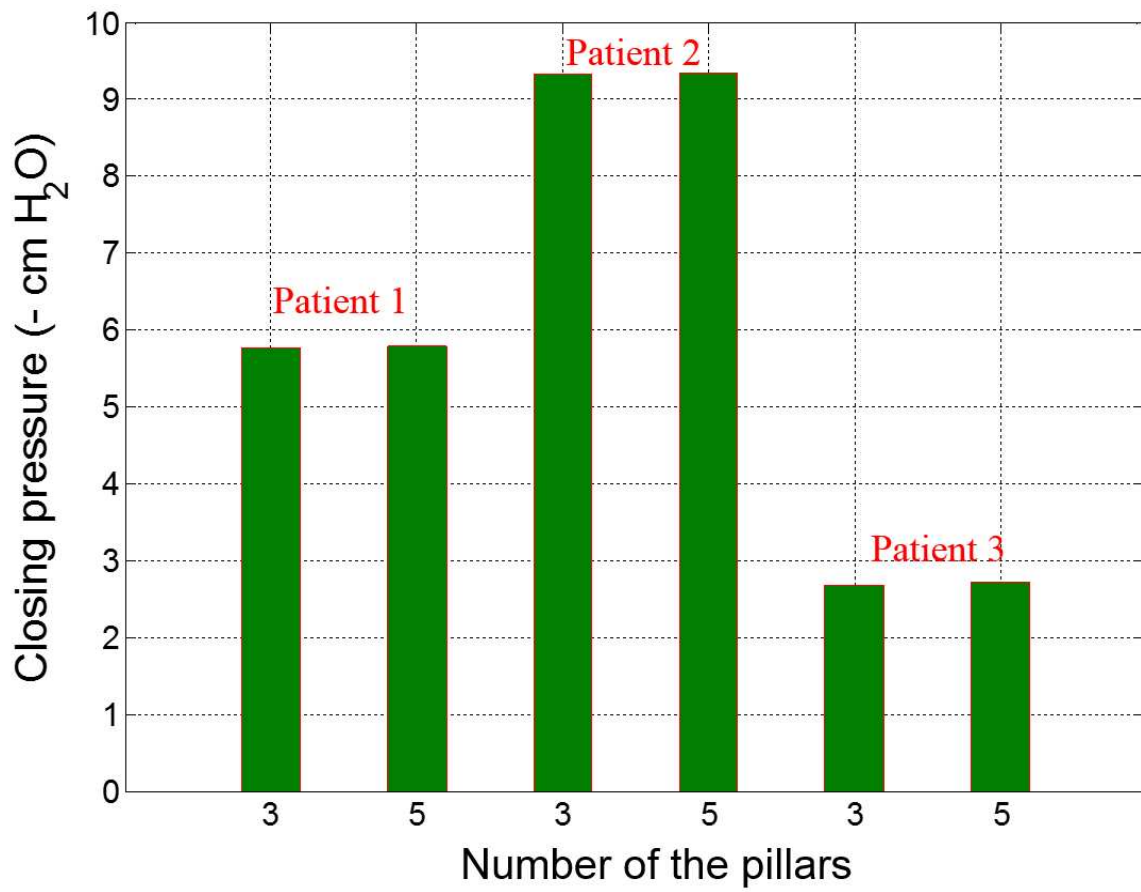


Fig. 6