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**The Influence of Ventilation Tube Design on the Magnitude of Stress
Imposed at the Implant/Tympanic Membrane Interface**

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Abstract

The design of ventilation tubes or grommets is thought to have a considerable influence on their performance. A computational model (finite element method) was used to investigate the significance of four design parameters of a commonly-used design of ventilation tube. The design parameters were: the length of the shaft, the diameter of the flanges, the thickness of the flanges, and the material type. A statistical analysis technique, known as a factorial analysis of variance, was used to examine the importance of the four design parameters on the dynamical behaviour of the middle-ear with the implant *in situ* and on the magnitude of stress induced at the implant/tympanic membrane interface. We predicted that the ventilation tube alters the frequency response of the middle ear; specifically the shaft length and the thickness of the flanges were found to have a significant effect upon the vibratory pattern at the umbo. A reduced length of tube and an increased size of flange were also found to be significant for minimising membrane stress (both with $P < 0.001$). Thus design parameters of critical influence on optimising performance were identified.

Keywords: *Biomechanics; Medical Engineering Design; Mechanobiology, Reuter-Bobbin*

Introduction

Otitis media with effusion is common in young children and is symptomatic of a general loss in hearing [1]; if left untreated it can inhibit a child's speech and language development [2]. An effective treatment for otitis media with effusion is surgical intervention by insertion of a ventilation tube or grommet into the tympanic membrane. The device was first introduced by Armstrong [3] and functions to restore ventilation to the middle ear, drain fluid, and immediately improve hearing. While the procedure is most often a success, the presence of a ventilation tube or grommet may cause a change in the mechanical stress generated in the tissue of the tympanic membrane; changes include otorrhea, local atrophy, perforation of the membrane, or tympanosclerosis – this latter condition being characterised by sclerosis of the middle ear mucous membrane [4]. The more severe complications such as cholesteatoma or medial displacement may also occur [5,6]. The incidents of otorrhea, tympanosclerosis, and drum perforation, have been found to correlate with ventilation tube retention beyond two years and with repeated tube insertion [6-8].

Ventilation tubes are often categorised by their expected duration of retention, i.e. short (~4-9 months), medium (~12-18 months), and long term (~24 months +). Gibb [9] assessed this variation in ventilation tube design as the propensity of a tube to resist the process of epithelial migration that is theorised to eventually cause extrusion. However, by resisting extrusion, long term tubes have been found to increase the likelihood of complications such as tympanic membrane perforation and cholesteatoma [6]. The importance of design on rate of extrusion was also emphasised by Gibb and Mackenzie [10], over and above other factors such as the site of the incision, the state of the membrane, or the competence of the surgeon.

Lesser *et al.* [11] established that there may be a biomechanical basis for tympanosclerosis by showing that, following intubation, the pattern of elevated membrane

shear stress coincided with areas where tympanosclerosis is most likely to occur. Prendergast *et al.* [12] examined the biomechanical consequences of ventilation tubes on the vibratory motion and stress within the tympanic membrane using the finite element method. Their results revealed that the implant material affects the motion of the membrane, with lighter materials allowing a more physiological membrane movement. An increase in the mass of a ventilation tube was shown to inhibit physiological vibrations at the umbo. Gan *et al.* [13] presented a finite element model showing that perforation of the tympanic membrane reduced sound pressure levels across the membrane, especially at low pressure levels and that there was no significant effect of the location of the perforation.

In our opinion it is plausible to suggest that the stress, and hence the local tissue reaction, induced by a ventilation tube is responsible for the implant-dependent structural change observed in the tympanic membrane. In this study we investigated the effect of varying specific design features of a commonly implanted tube (the Reuter-Bobbin design), on the stress induced within the tympanic membrane. The Reuter Bobbin design consists of a number of simple design features that can be systematically investigated in a finite element study, and it was for this reason that the Reuter Bobbin design was chosen for this study. If those features of this ventilation tube design that most effect stresses could be identified, it should be possible to suggest scientific approach to design ventilation tubes for improved performance.

Material and methods

To identify the influence of design on ventilation tube performance a computational technique (finite element method) was used to compute implant and membrane displacements and stresses. A statistical analysis of variance was used to assess the model results. Since the hypothesis is that over-stressing of the membrane is a contributory factor

in the onset and development of complications, it was necessary to characterise stress as an inhibitory factor in the performance of a ventilation tube.

The finite element model

In our previous study to examine the effect of ventilation tubes on the stresses and vibratory motion of the tympanic membrane (Prendergast *et al.* [12]), a finite element model of the outer and middle ear was developed, but with a simplified (i.e. straight) outer ear canal geometry. For the present paper, a more sophisticated vibroacoustic finite element model of the outer and middle ear developed by Kelly *et al.* [14], was adapted through the refinement of the tympanic membrane and outer ear canal to incorporate a standard Reuter Bobbin styled design of ventilation tube (Fig. 1a; b); therefore the full complexity of the outer ear canal is included in the model. The accuracy of the newly refined mesh, compared favourably against the previously validated model of Kelly *et al.* [14]. (A preliminary mesh density revealed that increasing the mesh density by a factor of 4 results in differences in stress values of the order of 10%. While such differences are significant, we believe that the computational cost of increasing the mesh density in a large comparative, analysis of variance study, as presented here, is not justified).

The CUBIT Mesh Generation Toolsuite (Sandia National Laboratories, New Mexico, USA) was used to generate the hexahedral finite element mesh of the ventilation tube, the tympanic membrane, and the ear canal, from volumetric models generated in the solid modelling package Rhino 3D (Robert McNeel & Associates, Seattle, USA).

The geometry of the tympanic membrane and outer ear canal was previously obtained using nuclear magnetic resonance spectroscopy and is anatomically representative of a healthy human. Linear shell elements have been used to model the tympanic membrane by including the variation in thickness across the structure, as detailed by Kirikae [15]. An

orthotropic material model was used to represent the network of radial and circumferential fibres that compose the fibrous layer of the tympanic membrane. Within the radial direction of the tympanic membrane the Young's modulus increases from 20 MPa at the membrane circumference to 40 MPa at the manubrium of the malleus. In the circumferential direction, the fibres are more plentiful around the periphery of the membrane and so the Young's modulus decreases from 40 MPa at the border to 20 MPa at the manubrium. To ensure full integration of the ventilation tube within the outer ear canal mesh a compromise had to be made regarding the position of the ventilation tube so as to accommodate each tube design. The inferior-posterior quadrant was selected so that the bulk of the tube resides in the middle ear cavity, with no contact occurring between the lateral flange and the drum membrane. The implant is orientated to form an oblique angle with the profile of the tympanic membrane (see Fig. 1b; c). The interface between the implant and the tympanic membrane was modelled as a fully bonded with implant and membrane elements sharing the same nodes. The connection between the tympanic membrane and the manubrium was modelled using a network of link elements aimed at dispersing the load uniformly.

The finite element package ANSYS was used to determine the response of the tympanic membrane and implant, to pressure stimuli (80 dB SPL) initiated at the opening to the ear canal and applied over a frequency range of 0–6 kHz. A fluid-solid interface was defined to effectively transfer the pressure load propagating through the outer ear canal to the lateral portion of the implant and the drum membrane. The effect of gravity was included in the model through the implementation of an inertial loading condition. ANSYS allows the simulation of gravity (by using inertial effects) by accelerating the structure in the direction opposite to gravity. Accelerations are combined with the element mass matrices to form a body force load vector term. The boundary conditions used in the model are quite complex; they involve a spring restraint at the periphery of the tympanic membrane and the

stapedial articular ligament, and restraint of middle ear ligaments – the reader is referred to Kelly *et al.* [14] and Ferris and Prendergast [16] for details.

Analysis of variance design

A factorial experiment was designed to identify the effect of four design parameters (known as factors). These factors are:

- the length of the shaft (A),
- the diameter of the flange (B),
- the flange thickness (C),
- and the material type (D),

see Fig. 2. The effect of each of these design parameters on what is termed the “response variable” was determined. Two response variables were considered,

- (1) the peak maximum principal stress at the implant/tympanic membrane interface calculated by computing the interface principal stress (always tensile) at the interface nodes and returning the highest value, and
- (2) the displacement *norm* of the ventilation tube, computed from the $x y z$ components of displacement for a designated node on the medial flange of the implant.

Each of the four factors (A, B, C, & D) is represented at two levels, a low and a high value, which corresponds to the extremes found in currently marketed ventilation tubes (see Table 1a). Titanium (density = 4500 kg/m³; Young’s modulus = 116 GPa; and Poisson’s ratio = 0.34) and PTFE (density = 2100 kg/m³; Young’s modulus = 0.4 GPa; and Poisson’s ratio = 0.40) respectively were the heavier and lighter implants assessed in this study. With four design factors, the analysis was designed to comprise of 2⁴ test combinations (as outlined in Table 1b) and so required 2⁴=16 separate finite element models. A 2⁴ factorial analysis of variance was performed on the results to highlight the effect of individual factors, termed the

“main effects”, along with any coupled interactions that may have occurred between factors. The statistical software environment *R* was used to perform the factorial analysis of variance¹.

As the results will show, it was found that the flange diameter (factor B) and the flange thickness (factor C) were highly significant. Therefore, a second trial was conducted to better observe the B:C interaction. The length of the ventilation tube (factor A) and material type (factor D) were fixed based on the findings from the previous trial. The factorial design involved two factors at three levels each, and therefore comprised of $3^2=9$ individual models variants; Table 2a shows the values used and Table 2b displays the experimental design.

Results

Ventilation tube design was predicted to have a pronounced affect on the frequency response of the tympanic membrane. This is evident when the amplitude of vibration at the umbo is plotted against frequency, see Fig. 3. For instance, the predicted drop in the amplitude of vibration at the umbo, within the 1-2 kHz range, is more severe when the implant incorporates a minimal flange thickness (i.e. the 1, A, B, AB, D, AD, BD, ABD tube variants), see Fig. 3b. The discernible drop in the amplitude of vibration, which is apparent within the 4-5 kHz range, is identified with resonance of the outer ear canal. These resonance characteristics were also found to be affected by specific design features. For example, tubes with a large flange thickness, i.e. the C, BC, CD, and BCD tube variants (refer to Table 1b), were predicted to initiate resonance at a higher frequency level than those other tube designs (see Fig. 3a). In effect, the findings highlight the importance of

¹ <http://www.r-project.org/>, last accessed 11 December 2006

design variables, namely the flange thickness (factor C) and the interaction between the shaft length and the flange thickness (the A:C interaction) on the vibratory response of the tympanic membrane, which is found to affect the whole membrane and is not only limited to the locality of the ventilation tube.

The stress state of the tympanic membrane, specifically at the site of incision, was found to be greatest at frequencies below 2 kHz. As expected, the magnitude of ventilation tube displacement was also greatest within this frequency range. For ventilation tubes of high mass a sharp peak was observed in the interface stress within the 0-1 kHz range (see Fig. 4a) whereas a more gradual increase was predicted for the lighter tubes, with the peak stress found in the 1-2 kHz range (see Fig. 4b). Beyond 2 kHz a significant reduction in stress is predicted. For the heaviest tube, a peak maximum principal stress of almost 7.5 kPa is predicted at lower frequencies at the site of incision. This compares to a predicted peak stress of 2.08 kPa for a static analysis of the heaviest tube (label ABCD), and 1.11 kPa for the lightest tube (label 1).

In the 0-2 kHz range where stresses were predicted to be highest, the analysis of variance highlighted those factors which were found to have a significant effect on the magnitude of stress at the implant/tympanic membrane interface. The tube shaft length (factor A) was predicted to have a significant effect ($P < 0.001$) on the predicted maximum principal stress at the implant/membrane interface. By minimising the length of the shaft a corresponding decrease in stress at the membrane/implant interface was predicted (refer to Fig. 5a). A significant interaction was also distinguished between the flange diameter (factor B) and the flange thickness (factor C) ($P < 0.001$), in which the effect of one factor was reliant upon the level of the other. As Fig. 5b indicates the use of a large flange thickness appears most advantageous, while the combination of a large flange diameter and a large flange thickness was predicted to be the optimal configuration. An equally significant

finding was the interaction between the flange thickness (factor C) and the material type (factor D) ($P < 0.001$). Similarly, the use of a large flange thickness is crucial in minimising stress, regardless of the chosen material type (refer to Fig. 5c).

Turning to the analysis of implant displacement within the 0-2 kHz range, the factors of significance were: the exclusive effect of tube length (factor A) ($P < 0.001$) (termed the main effect), the flange diameter and the flange thickness interaction (B:C) ($P < 0.1$), and the flange thickness and material interaction (C:D) ($P < 0.05$). Over the 0-6 kHz range no interactions are present, while the main effect of tube length (factor A) ($P < 0.001$) and flange diameter (factor B) ($P < 0.05$) were predicted to be the most significant at minimising tube displacement.

The results from the second trial, which focused on the interaction between the flange diameter and the flange thickness (B:C), indicated that a reduction in the peak maximum principal stress was achievable through an increase in the thickness/diameter of the flanges (i.e. B2:C3 and B3:C3). While increasing flange diameter (factor B) is detrimental in the case of the tube with the lowest flange thickness, see Fig. 6. At low frequencies (0-1 kHz) the *recessive* tube (i.e. B1:C1, in which all the factor levels are low) was shown to displace less and so induce less stress than the opposing designs (see Fig. 7). When examining the 1-2 kHz range the *recessive* design is no longer found to be optimum; rather, the heavier tubes (i.e. B3:C2 and B3:C3) are predicted to stress the membrane less, see Fig. 8. The 1-2 kHz range is found to coincide with an increase in the displacement of the recessive tube. A reverse of this phenomenon is observed in the case of the larger tubes (i.e. B2:C3, B3:C2, B3:C3) which displace less within this 1-2 kHz range.

Discussion

The onset of otorrhoea, atrophy, retraction of the tympanic membrane and tympanosclerosis,

while associated with ventilation tube insertion, are also symptomatic of acute middle ear infection and relate to a structural change in the membrane. It is therefore reasonable to assume that prolonged stress is a primary cause of such complications, whether it is a consequence of intubation or middle ear infection. A similar theory was proposed by Lesser *et al.* [11], who observed that the regions where tympanosclerosis is commonly found to occur coincide with the regions of maximum shear stress imposed by a ventilation tube. He concluded that excessive stress may initiate a repair response that contributes to tympanosclerosis. This agrees with the mechanobiological concept that high cyclic strains promote fibrous tissue formation [17]. One would expect that trauma and degradation is more likely to occur through prolonged and repeated insertions, which have been observed to heighten the risk of complications [6].

To assess the mechanical consequence of ventilation tube design on the stress state of the tympanic membrane a finite element model has been developed that includes an anatomically accurate outer ear canal and ossicles, which were absent from our previous analysis of ventilation tubes. While the complex interaction between the bones of the middle ear and the tympanic membrane have been accounted for, the influence of the middle ear cavity has been ignored in this study however other finite element simulations have shown that including the middle-ear cavities does not significantly affect the vibration mode of the tympanic membrane to a significant degree [18]. For comparative purposes it was not thought necessary to include the cavity which would have added additional complexity to an already computationally expensive model. A number of other assumptions have been made in modelling the contact between the ventilation tube and the membrane at the site of the incision. A bonded interface was used to couple the tube shaft to the drum i.e., there is no slippage allowed. With the bonded interface it was assumed that the residual stress imposed upon the membrane at insertion, which may equate to a tightness of fit, was negligible. The

implant fit primarily relates to the size of incision and may so be termed a surgical factor. By standardising the interface, and therefore the fit, it was possible to isolate only those design related parameters. When reporting the peak stresses at the interface, nodal values of stress are reported rather than the values at the Gauss points. Given that nodal values are interpolated from the Gauss points, accuracy is lost when reporting such values, however nodal values were chosen as an estimate of the peak stresses at the interface, which are important when investigating injury due to implantation. With regard to other surgical factors, namely the incision site and the orientation of the incision, the published evidence tends to suggest that these factors have little influence on the implant success [19,20]. When examining the effect of various parameters on the extrusion rate, Gibb and Mackenzie [10] concluded that “the design of the tube was the only factor found to be a significant determinant of the extrusion rate”, and this would support our having focussed on implant design in our analyses.

The use of a design of experiment technique in combination with the finite element method is, to the authors’ best knowledge, a novel approach when used to evaluate an implants design parameters. Previous studies have concentrated simply on using direct comparisons to quantify and grade the success of one implant design over another [10] and therefore do not highlight the statistical significance of individual design components. In this study, to remove unwanted variability the commonly implanted Reuter Bobbin design was chosen. The standard form and symmetry of the Reuter Bobbin meant that it was possible to characterise the design using very few design variables (i.e. the flange diameter and thickness, the length of the tube and the internal and external shaft diameters). When selecting the size of the factorial design a compromise had to be sought between the number of chosen factors, their levels and the available computational resources. With this in mind, the initial trial was set-up to evaluate the significance of four design factors, with each factor

observed at two levels. A limitation of this approach is that any local deviation in the general trend is unidentifiable when bound to using extremes. It was for this reason that the second, refined analysis was conducted to further examine the interaction between the flange diameter and the flange thickness (factor B and factor C) by broadening the observable levels.

The findings from this study corroborate Gibb and Mackenzie [10] that design is an influential component upon ventilation tube performance. Among the design features examined, decreasing the length of the tube (factor A) and increasing the size of the flanges (determined by factor B and factor C) was found to be most significant when reducing stress generated at the implant/tympanic membrane interface. The predicted benefit of reducing tube length may relate to the high rates of failure associated with long-term ventilation tubes (i.e. T-tubes), which often incorporate a long shaft length to prevent early extrusion. In an attempt to rationalise the clinical variation in extrusion of the Sheehy collar button and the Shepard ventilation tube, Gibb and Mackenzie [10] concluded that the shorter length of the Sheehy design was a significant factor in reducing the extrusion rate, despite the similarity between the designs. Our results support a reduction in the shaft length to minimise extrusion. A long length of shaft will increase the rotational moment of the ventilation tube, which is likely to stretch and elastically deform the membrane at the implant/tympanic membrane interface. This trend is apparent in Figure 9 where a reduction in the stress is predicted with the shortest shaft length in the 0-1 kHz range (i.e in Fig. 9 the design variant with A have highest stress): this further highlights the significance of shaft length, above all other examined factors, on the induced stress at the interface. Furthermore, the effect of increasing the ventilation tube weight, while maintaining a long length of shaft, is predicted to increase the membrane stress and coincides with an increased tendency of an implant to rotate in situ, see Fig. 9.

An alternate trend is apparent within the 1-2 kHz range as a large thickness of flange (factor C) is shown to diminish the stress in the membrane by inhibiting the displacement of the ventilation tube (refer again to Fig. 9). As proposed by Prendergast *et al.* [12] a heavier design is perhaps less likely to loosen and extrude prematurely. The static analysis of the stress in the tympanic membrane for the ABCD tube indicated that, for the size of tubes analysed, the recorded stress was minimal under gravitational loading alone, when compared against the dynamically recorded peak stress. The significance of the B:C (flange diameter and flange thickness) and C:D (flange thickness and material component) interactions relate to the inertia affect imposed by the size of the flanges. The tendency of a ventilation tube to resist rotation motion seems beneficial, since reduced movement equates to less deformation of the membrane and lower stress.

Conclusion

A computational approach has been implemented to assess the significance of specific ventilation tube design features upon the stress induced within the tympanic membrane. The findings indicate a direct correlation between the displacement of a ventilation tube and the magnitude of stress induced in the membrane surrounding the incision. A reduction in the tube shaft length was found to minimise the magnitude of the stress at the tympanic membrane/implant interface. It is theorised that a reduction in the moment arm generated by the length of the implant shaft is likely to limit membrane deformation at the incision site and so reduce tissue trauma. Increased flange size (which was governed by the flange thickness and the flange diameter) was also observed to be significant at limiting the membrane stress. It is surmised that the increase in rotational inertia associated with an increase in the size of the flanges is likely to inhibit excessive tube movement which may deform and overly stress the tympanic membrane.

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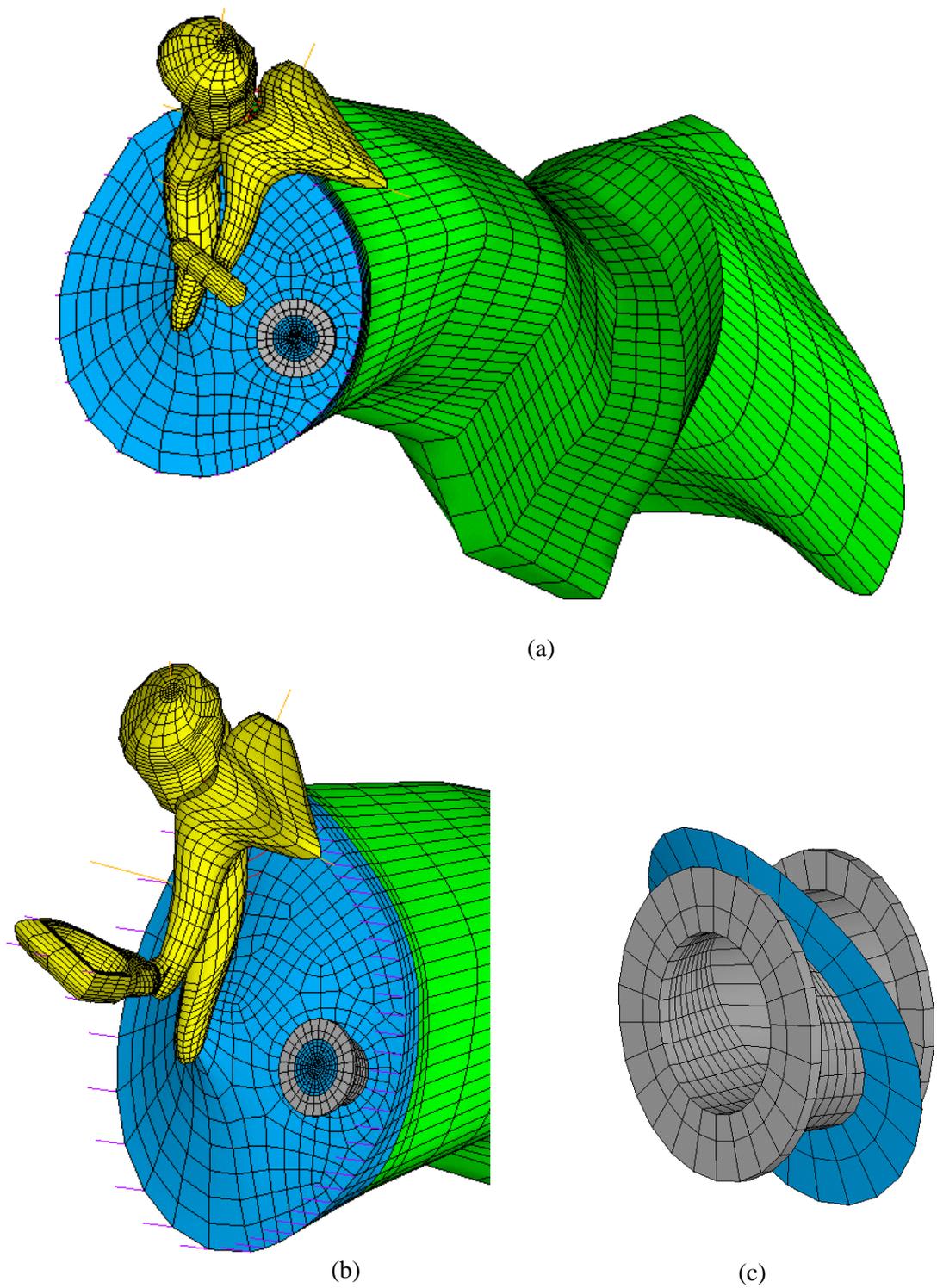


Figure 1: (a) Finite element model of the middle ear and the outer ear canal. (b) A close-up of the finite element mesh with ventilation tube in situ and the ossicles (malleus, incus and stapes) clearly visible. (c) Orientation of ventilation tube (Reuter-Bobbin styled design) at the location of the incision.

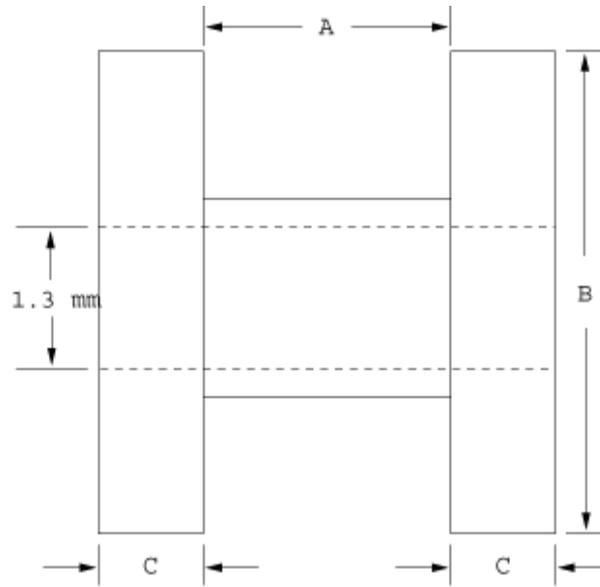


Figure 2: A schematic of the ventilation tube design. The shaft tube length (factor A), the flange diameter (factor B), the flange thickness (factor C) are identified.

Table 1a: Properties for each factor and level combination in the 2^4 factorial design.

<i>Factors</i>		<i>Level Low (-)</i>	<i>Level High (+)</i>
<i>Shaft Length</i>	A	0.90 mm	1.28 mm
<i>Flange Diameter</i>	B	2.24 mm	2.80 mm
<i>Flange Thickness</i>	C	0.09 mm	0.38 mm
<i>Material Type</i>	D	PTFE	Ti

Table 1b: The design of the 2^4 factorial experiment, involving the four factors (A = the length of the shaft, B = the flange diameter, C = the flange thickness, D = the material type), each of which is observed at two levels (represented as +/- in table). The column entitled *Label* refers to the factors which are positive for each model variant (e.g. the variant AD conveys that the factors A and D are at a positive (+) level while the factors B and C factors are at a low (-) level).

<i>Label</i>	<i>A</i>	<i>B</i>	<i>C</i>	<i>D</i>	<i>Model No.</i>
1	-	-	-	-	1
A	+	-	-	-	2
B	-	+	-	-	3
AB	+	+	-	-	4
C	-	-	+	-	5
AC	+	-	+	-	6
BC	-	+	+	-	7
ABC	+	+	+	-	8
D	-	-	-	+	9
AD	+	-	-	+	10
BD	-	+	-	+	11
ABD	+	+	-	+	12
CD	-	-	+	+	13
ACD	+	-	+	+	14
BCD	-	+	+	+	15
ABCD	+	+	+	+	16

Table 2a: The properties are presented for each factor (B and C) and level combination (termed 1, 2, and 3) in the secondary trial.

<i>Factors</i>		<i>Level (mm)</i>		
		1	2	3
<i>Flange Diameter</i>	B	2.80	3.00	3.20
<i>Flange Thickness</i>	C	0.09	0.38	0.45

Table 2b: Design of the secondary trial involving 2 factors (B, C), each of which is examined at three levels (1, 2, and 3). Therefore, the variant B1:C2 conveys that the factor B is at level 1 and factor C is at level 2.

<i>Label</i>	<i>B</i>	<i>C</i>	<i>Model No.</i>
B1:C1	1	1	1
B2:C1	2	1	2
B3:C1	3	1	3
B1:C2	1	2	4
B2:C2	2	2	5
B2:C3	3	2	6
B3:C1	1	3	7

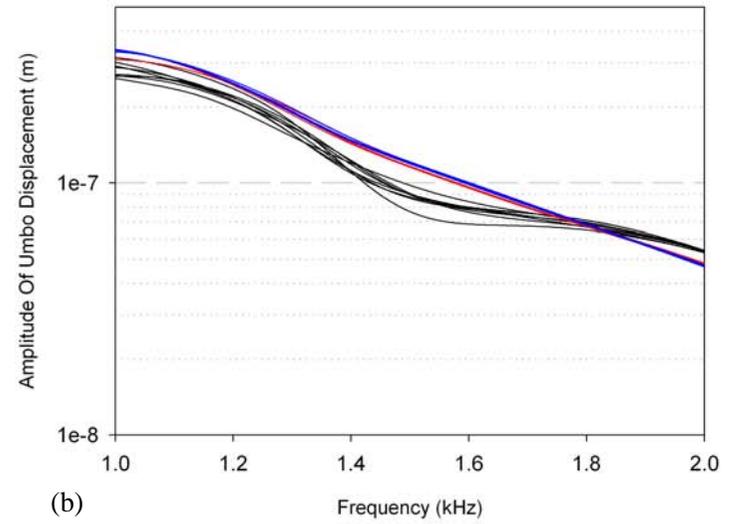
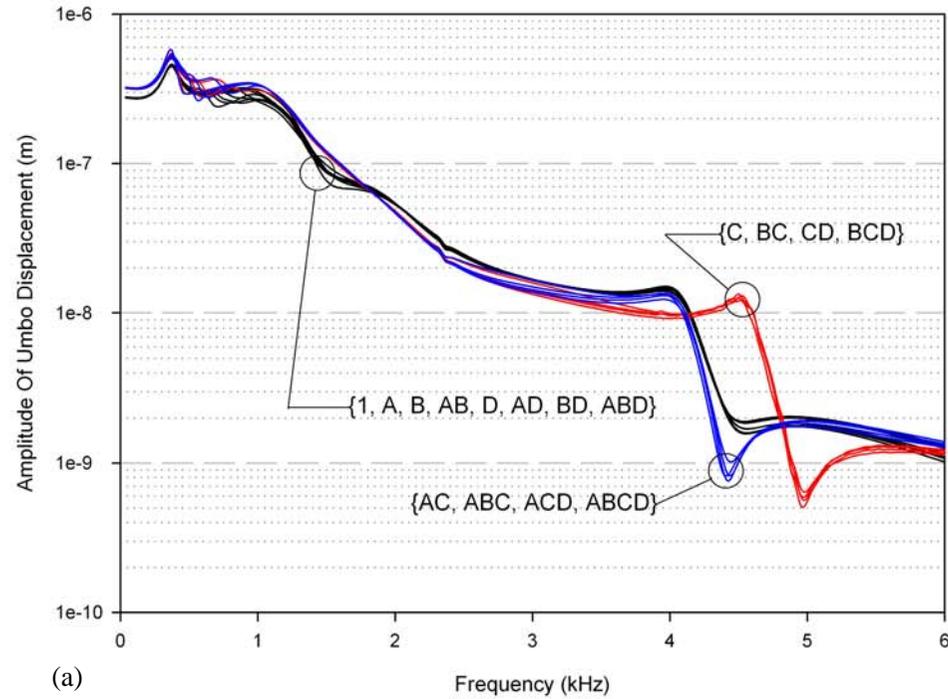


Figure 3: Log scale plot of the amplitude of umbo displacement observed for each of the model variants (a) over the 0-6 kHz range and (b) when plotted over the 1-2 kHz range. The variation in the umbo displacement emphasises the significance of ventilation tube design on the acoustic response of the system, this is most pronounced in the 0-2 kHz range. The coloured lines correspond to specific ventilation tube design sets (as indicated above). Refer to Table 1 for a description of the notation.

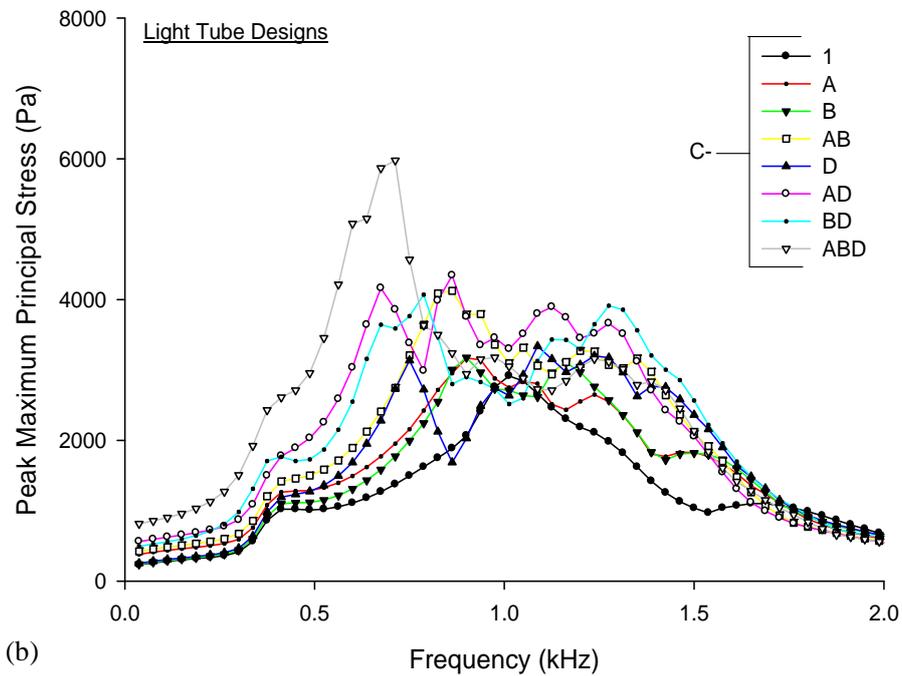
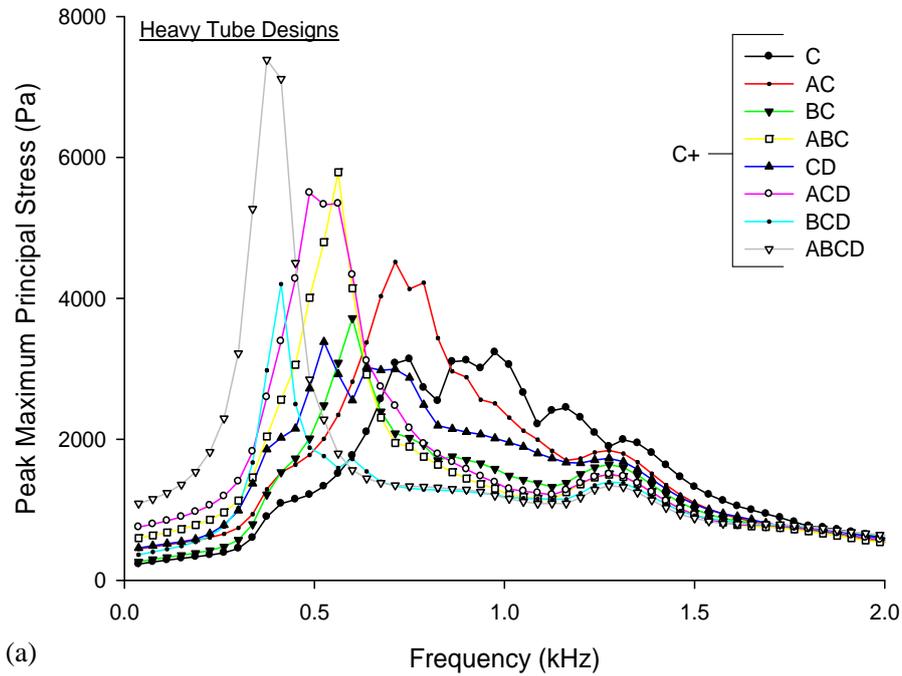


Figure 4: Plot of the peak maximum principal stress in the membrane surrounding the incision for (a) the tubes incorporating a large flange thickness (referred as C+) (denoted the *heavy* tubes) and (b) the tubes of reduced flange thickness (referred as C-) (denoted the *light* tubes), across the 0-2 kHz frequency range.

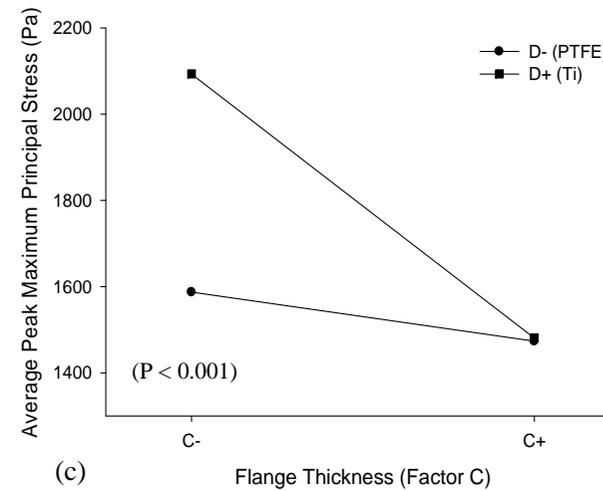
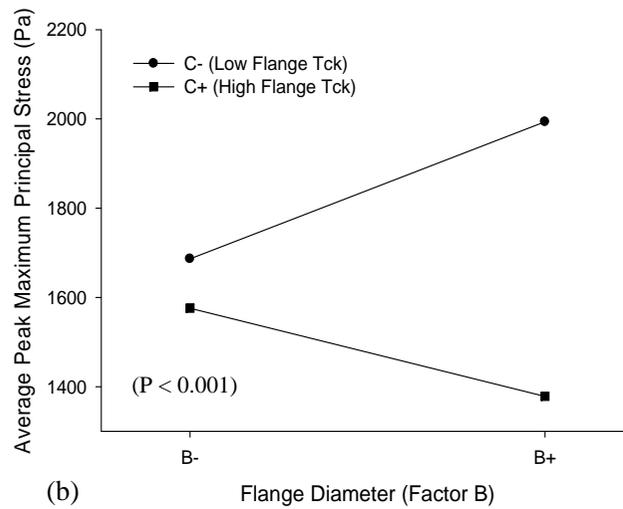
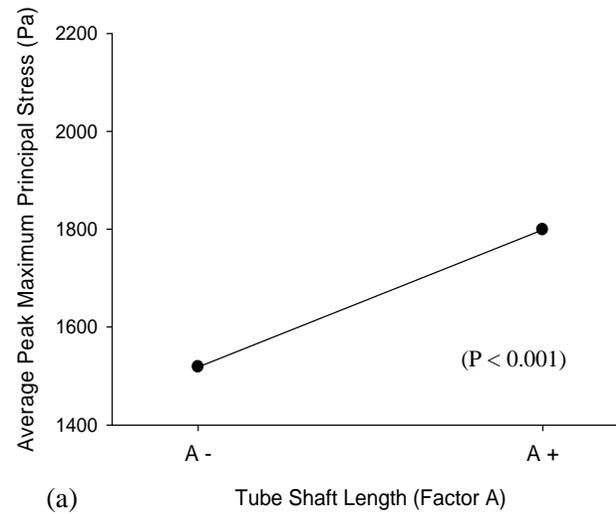


Figure 5: (a) Main effect of factor A, (b) B:C interaction, and (c) C:D interaction plots, from the 2^4 factorial analysis of variance, averaged over the 0-2 kHz frequency range. The main effect of factor C & D cease to have much significance by themselves as the effect of these factors is influenced by the B:C and C:D interactions.

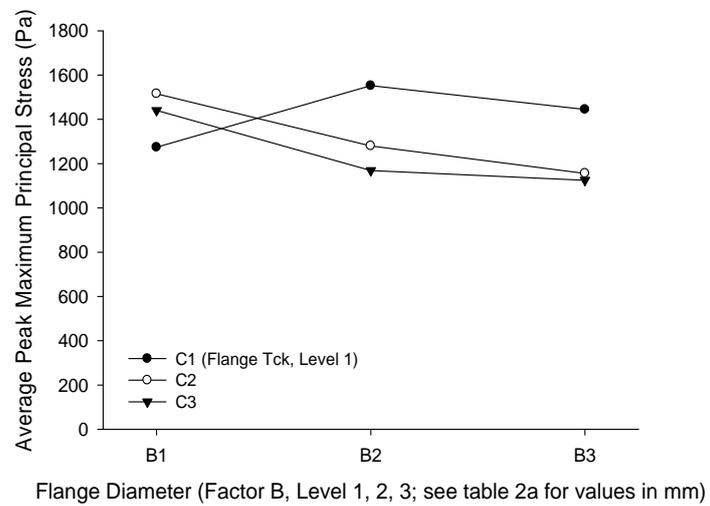
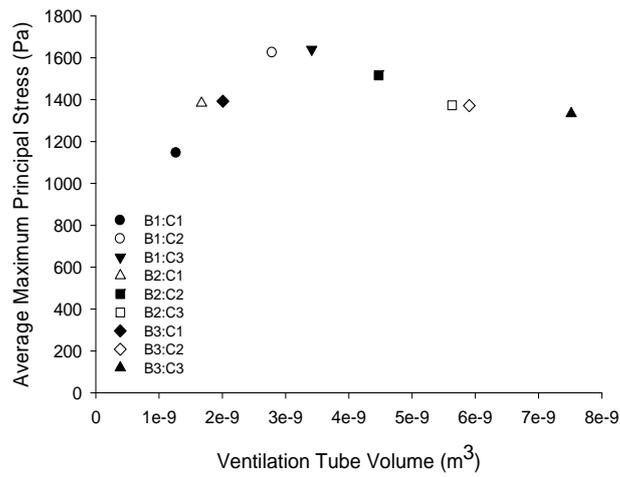
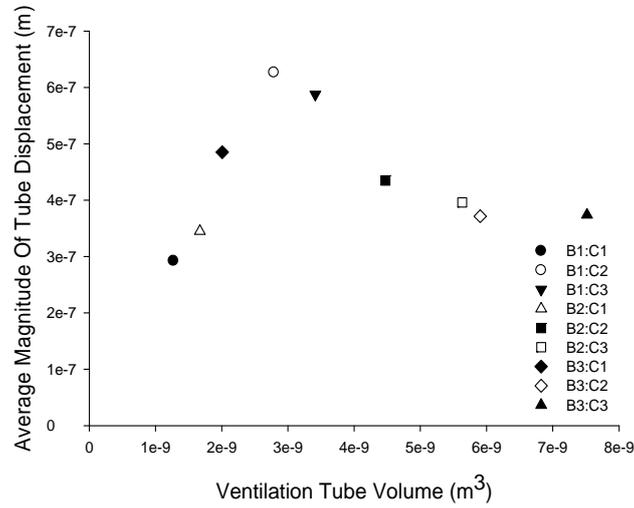


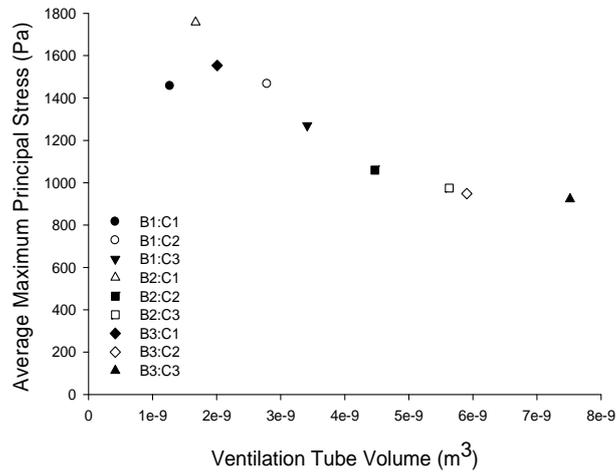
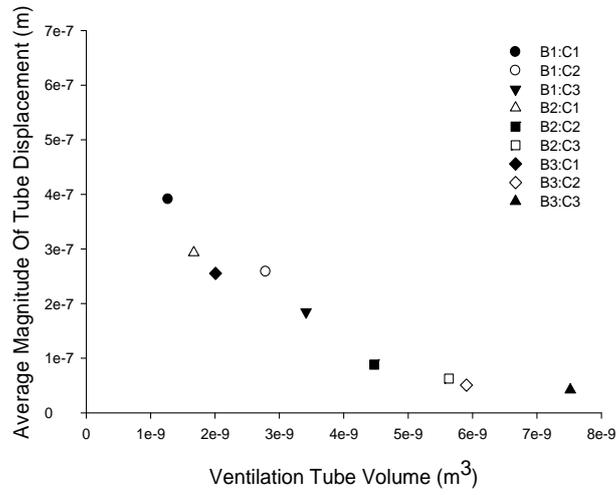
Figure 6: Average peak maximum principal stress plot recorded in the membrane surrounding the incision for each of the secondary trial ventilation tube designs. The peak maximum principal stress is averaged over the 0-2 kHz frequency range. Refer to Table 2 for the notation.



(a)

(b)

Figure 7: Within the 0-1 kHz frequency range **(a)** average magnitude of ventilation tube displacement and **(b)** average peak maximum principal stress within the membrane surrounding the incision, against ventilation tube volume for each of the implant variants (refer to Table 2a & Table 2b).



(a)

(b)

Figure 8: Within the 1-2 kHz frequency range (a) average magnitude of ventilation tube displacement and (b) average peak maximum principal stress within the membrane surrounding the incision, against ventilation tube volume for each of the implant variants (Refer to Table 2a & Table 2b)

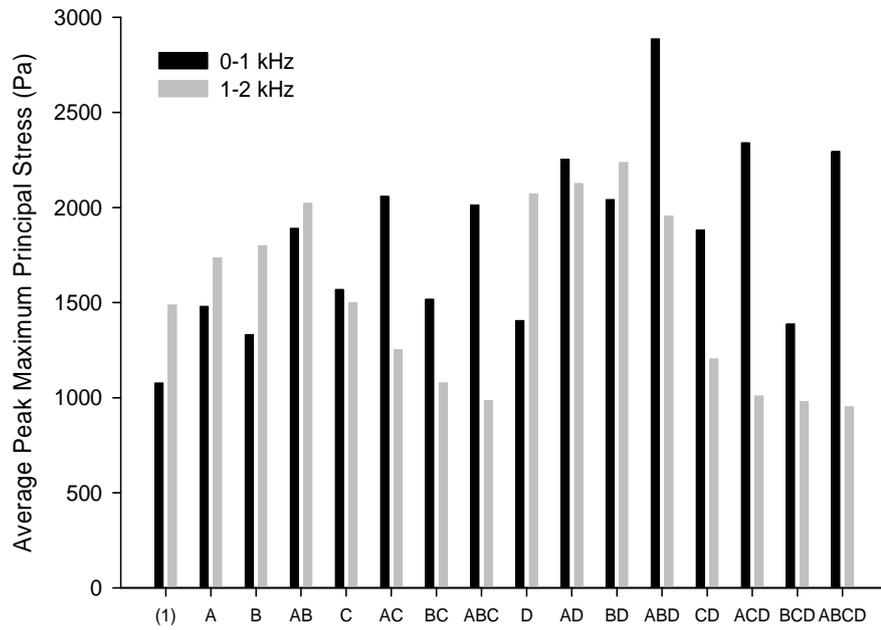


Figure 9: Average peak maximum principal stress for each of the design variants, predicted within the drum membrane at the location of the incision, for the 0-1 kHz and the 1-2 kHz ranges. The effect of the tube shaft length (factor A) is apparent within the 0-1 kHz range, while a large flange thickness (factor C) is found to be most effective at reducing stress within the 1-2 kHz range. Refer to Table 1b for key to design variants.