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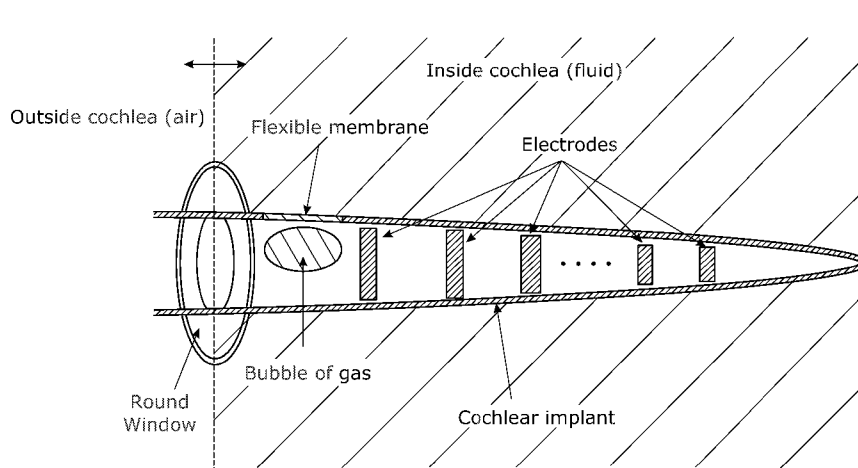


Figure 13

(57) Abstract: A cochlear implant comprising a compliant element arranged to couple to fluid in the scala tympani, and in use arranged to act as a tuned region of compliance in order to permit, through said coupling to the fluid in the scala tympani, the excitation of the slow wave along the cochlea that gives rise to acoustic hearing.

COCHLEAR IMPLANT

Technical Field

This invention relates to a method of improving the residual acoustic hearing in
5 patients fitted with a cochlear implant.

Background

Current cochlear implants can cause a negative impact on auditory hearing. Although
the main aim of a cochlear implant is to electrically excite the nerves and provide
10 'electrical hearing' at high audio frequencies; many patients still retain some residual
'acoustic hearing' at low frequencies. The combination of these two forms of hearing,
at both high frequencies and low frequencies, is known to significantly improve the
patient's ability to interact with the auditory world, by improving their understanding
of speech for example.

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Unfortunately, insertion of the cochlear implant is known to have a negative impact on
the residual 'acoustic hearing', measured in patients, which is believed to be as a result
of, amongst other factors, a loss in compliance in the vicinity of the round window.
The round window normally provides pressure relief for the process of acoustic
20 hearing, and this stiffening (lowering of compliance) on insertion of the implant is
believed to contribute to a loss in the residual hearing of about 20 dB at low
frequencies.

For these reasons, the significant benefits of using cochlear implants come at the
25 'price' of a loss of low frequency 'acoustic hearing'. The invention herein described of
an additional compliant element in the cochlear implant at the site of the round
window optimizes the trade-off between the gain in 'electrical hearing' from use of the
device against the reduction in low frequency 'acoustic hearing' from the use of any
such implant.

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Now for the first time, the mechanisms behind the low frequency auditory hearing loss
are described in comprehensive detail and the inventors have determined a prediction
model for potential hearing loss relating to device induced increased 'stiffness' in the
round window zone. This increased stiffness inhibits the excitation of the 'slow wave'
35 along the cochlear, which gives rise to acoustic hearing, when the cochlear is driven

acoustically via the middle ear. The new model, a lumped parameter model (described in greater detail below), shows strong concordance between the level of actual hearing reduction and the (change in stiffness) predicted lumped parameter model outcomes. It is thus possible to vary the key parameters in the model, stiffness and compliance –
5 to target (to 'tune') an improved device which seeks to minimize the low frequency auditory hearing loss effects.

Summary

According to the invention there is provided a cochlear implant component according
10 to claim 1.

The compliant member may comprise a flexible membrane.

The compliant member may comprise an air bubble.
15

The compliant member may comprise a foam. The foam may comprise a material comprising a number of air or gas cells. The foam is preferably compressible.

The compliant member may be arranged, in situ, to be in intimate or contiguous
20 contact with the cochlear fluid.

The compliant member may comprise a surface area which is arranged to be contiguous with the cochlear fluid which surface area is inferior to the total surface area of the cochlear implant.
25

The compliant member may form a portion of the external surface of the cochlear implant. The compliant member may be termed a compliant portion.

A number of discrete compliant members may be provided. The compliant members
30 may be distributed or spaced apart over a region of the cochlear implant.

The compliant member may be viewed as providing pressure release near, or in the vicinity of, the round window.

35 The compliant member may comprise a compressible or deformable portion.

All or part of the compliant element could also be incorporated with a compliant element inside the cochlear implant, such as an air bubble.

5 The cochlear implant may comprise a multi-electrode array, for example comprising a carrier which retains or houses a plurality of electrodes arranged to be located in the cochlear in proximity to an auditory nerve. The carrier is preferably made of a flexible material to allow required positioning of the electrodes in the cochlear such that the electrodes may be inserted in cochlear of a recipient. The carrier may be of tubular form, and the electrodes provided within an internal space of the carrier.

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The electrodes may be spatially distributed along at least part of the length of the carrier to provide a corresponding spatial distribution along the cochlear nerve in the cochlear when the carrier is inserted in cochlea.

15 The compliant member may be of reduced stiffness compared to the stiffness of the carrier (in which the compliant member is located or incorporated with), or put another way, the compliant member may be more compliant than the material of the carrier.

20 The invention may be viewed as an improved cochlear implant device that is a practical solution and method for improving residual acoustic hearing in patients, which includes the addition of a compliant element within the cochlear implant in the close vicinity of the 'round window'.

25 The compliant element may incorporate a number of parts or components. An internal cavity of the cochlear implant may be provided in the vicinity of the round window and may be filled with a fluid or fluids and a flexible membrane which may cover over the aperture allowing access of the incorporated fluid or fluids into the internal cavity. In some embodiments, the compliant member may comprise a flexible membrane
30 covering a void. The flexible membrane may seal the cavity from the cochlear fluid.

One embodiment of the invention may comprise a cochlear implant component comprising a compliant element which includes a fluid contained within an internal cavity of the cochlear implant; and a flexible membrane; and arranged to be situated
35 within a part of the cochlear implant that sits near the round window; such that in use

it serves to act as a tuned region of greater compliance in order to permit, through coupling to the fluid in the scala tympani, the excitation of the base wave along the cochlear.

- 5 An aspect of the invention may be viewed as providing a region of a cochlear implant which interfaces with or presents to cochlear fluid with a required compliance.

The invention may comprise one or more features as described in the description and/or as shown in the drawings, either individually or in combination.

10

Brief Description of the Drawings

Various embodiments of the invention are now described, by way of example only, with reference to the following drawings in which:

- 15 **Figure 1** is a diagrammatic representation of the middle ear,

Figure 2 is a diagrammatic representation of an impedance model used to study the effect of round window stiffness,

- 20 **Figure 3** is a diagrammatic representation equivalent circuit diagram of the lumped parameter model,

Figure 4 is a plot of the variation in the impedances of the various components of the impedances in Figure 2 over the frequency range of interest,

25

Figure 5 shows two finite element models of the round immersed in air and its response when it is driven by a uniform pressure towards the apical direction, in which (left) intact round window, and (right) round window with cochlear implant,

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Figure 6 is a plot of volume velocity, velocity multiplied by the area, at the round window,

Figure 7 is a plot of the calculated magnitude and phase of Z_C ,

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Figure 8 is a plot of the variation of the magnitude and phase of p_{BM}/p_{ME} with frequency as the round window stiffness is increased,

Figure 9 is a plot of the predicted hearing loss due to the stiffening of the round window,

Figure 10 is a plot of pre-operative and post-operative pure-tone audiometric individual thresholds (thin lines) and mean value (thick lines) for cochlear implant recipients,

Figure 11 is a plot of hearing loss due to cochlear implantation, which is equal to the difference between pre-operative and post-operative pure-tone audiometric thresholds for cochlear implant recipients,

Figure 12 is a plot of predicted hearing loss using the lumped parameter model, and

Figure 13 is a schematic representation of an embodiment of the invention

Detailed Description

In the description below the causes and mechanisms of the auditory hearing loss are first quantified. There then follows description of some exemplary embodiments.

The effect of round window stiffness on the response of the cochlea

Many effects may lead to a degradation of residual hearing after the insertion of a cochlear implant, one of which is the increased stiffness of the round window. This may be due to the physical presence of the cochlear implant in the round window, but also because of a subsequent hardening of the round window over time. A lumped parameter model is developed to study the effects of increasing the stiffness of the round window on the acoustic response of the cochlea. As the round window stiffness increases, it is found that the effects of the cochlear and vestibular aqueducts become more important and give rise to some surprisingly complicated behaviour predictably forecast by the new model. Surprisingly, while increasing the stiffness by a factor of 10 has little effect on auditory response, further increases, such as when increased by a factor of 100, then reduces the acoustic sensitivity of the cochlear by about 20 dB

below 1 kHz. A finite element model developed is used to estimate the changes in the round window stiffness due to a cochlear implant passing through it, which is found to be a factor of about 100.

5 The increasing interest in the preservation of residual low-frequency hearing after cochlear implantation is partially motivated by the observation that residual low-frequency hearing can be used in a complimentary way to electrical excitation from the cochlear implant to give significantly improved speech perception (Helbig et al., 2011; Causon et al., 2015). This improvement is thought to be due to better pitch
10 perception (Talbot and Hartley, 2008), better recognition of the fundamental frequency and first formant (Zhang et al., 2010; Verschuur et al., 2013) and improved timing cues (Gifford et al., 2013). In the longer term there is also a strong desire amongst cochlear implant surgeons not to damage the normal acoustic mechanism of hearing, in case future regenerative treatments become available (Rubel et al., 2013).

15

The average loss of residual hearing after cochlear implantation is about 20 dB below 1 kHz (Adunka et al., 2013; Friedmann et al., 2015), as measured about 12 months after the surgery, when the direct physical trauma caused by the insertion of the electrode into the scala tympani and the associated acute inflammatory response
20 are expected have died away (Causon et al., 2015). Longer term hearing loss may be linked to chronic inflammation and the development of fibrotic tissue within the cochlear (Causon et al., 2015). Another possible mechanism for the loss of residual hearing is the stiffening of the round window either because of the presence of the cochlear implants, if it is implanted through the round window, or the subsequent
25 growth of fibrotic tissue around it. The inventors have conducted the ground-breaking research and described the effect on acoustic hearing of increasing the round window stiffness can be predicted (by the new model), in order to help understand the role that this mechanism helps to play in the loss of residual hearing after cochlear implantation.

30

A lumped parameter model is used for this prediction and the following section describes the development of this lumped parameter model and the estimation of its parameters. A finite element model of the round window is also developed in order to estimate the increase in its stiffness due to the presence of a cochlear implant passing
35 through it. The cochlear input impedance is then calculated using the model and is

shown to be similar to that previously measured, if the normal value for the stiffness of the round window is assumed, but the input impedance is seen to get significantly larger at some frequencies if the round window stiffness is increased. The lumped parameter model is then used to predict the reduction in pressure difference across the basilar membrane, and hence the hearing loss, due to an increase in round window stiffness.

The Lumped parameter model

We predict the change in residual hearing due to increases in the stiffness of the round window. It is assumed that the mechanism of slow wave propagation along the cochlear is unaffected by this change in stiffness, but that it is the excitation of this wave, by the pressure difference across the basilar membrane at the base of the cochlea, that is altered. It is well known that the ratio of this pressure difference to the alternating volume velocity in each of the fluid chambers is almost real and independent of frequency (Zwislocki, 1962), and this may be termed the acoustic wave impedance, Z_{WA} . Physically, the wave impedance is determined by the properties of the forward travelling wave at the base of the cochlear (which may otherwise be known as the slow wave) since, under normal hearing conditions, any reflected wave has a much lower amplitude.

20

The response along the basilar membrane at any given frequency will be entirely determined by the pressure difference driving the basilar membrane at the base, and so the hearing response will be directly proportional to this pressure difference. This will be true whether the cochlear is entirely passive or whether it retains any element of the cochlear amplifier. The change in the pressure difference at the base of the cochlear can thus be investigated by considering the change in the acoustic pressure at the base of each of the fluid chambers. A simplified sketch of the middle ear and the uncoiled cochlear is shown in Figure 1. As well as the oval window, OW, and round window, RW, this also includes the vestibular aqueduct, VA, in the scala vestibuli, SV, and the cochlear aqueduct, CA, in the scala tympani, ST. The middle ear, driven by the eardrum, is shown as ME. The acoustic pressure at the base of the scala vestibular, p_{SV} , is driven by the pressure at the eardrum by the dynamics of the middle ear. The pressure at the base of the scala tympani, p_{ST} , is determined by the volume velocity along this chamber and the terminating impedance at the round window. Since there is little wave propagation involved in the dynamic behaviour in both of

35

these places it is reasonably well approximated by lumped parameter models, as described in this section. The historical development of lumped parameter models of the cochlear has recently been thoroughly discussed by Marquardt and Hensel (Marquardt and Hensel, 2013) who described the earlier models of Dallos (Dallos, 1970), Lynch et al. (Lynch et al., 1982) and Franke and Dancer (Franke et al., 1985). Stenfelt (Stenfelt, 2015) has also recently used a lumped parameter model to estimate the different contributions to bone conduction.

Figure 1 shows a diagrammatic representation of the middle ear and the uncoiled cochlear to show the arrangement at its base. The middle ear, ME, drives the scala vestibuli, SV, via the Stapes and oval window, OW, to give the pressure, p_{SV} , which excites the pressure difference across the basilar membrane, BM, given by $p_{SV} - p_{ST}$, where p_{ST} is the pressure in the scala tympani, ST, opposite the round window, RW. The vestibular aqueduct, VA, and cochlear aqueduct, CA, are also found to be important when the round window becomes stiffer.

Figure 2 shows the lumped parameter model of this system used in the present study. The middle ear is represented by its Thévenin equivalent blocked pressure response, p_{ME} , and its internal impedance, Z_{ME} , which is the impedance seen by the pressure in the SV looking out into the middle ear, and which includes the dynamics of the oval window. The pressure in the SV is the sum of the pressure difference across the BM, p_{BM} , and the pressure in the ST, p_{ST} .

The impedance model used to study the effect of round window stiffness, included in Z_{RW} , on the pressure across the basilar membrane, p_{BM} , which is the difference between the pressure in the scala vestibuli, p_{SV} and that in the scala tympani p_{ST} , when p_{ME} and Z_{ME} are the Thévenin equivalent source and impedance of the middle ear, Z_{BM} is the impedance across the basilar membrane and Z_{VA} and Z_{CA} are the impedances of the vestibular and cochlear aqueducts.

The impedance Z_{BM} relates p_{BM} to the volume velocity entering the fluid chambers and is largely resistive. Under normal circumstances p_{ST} would be much smaller than p_{BM} , since the impedance of the round window, Z_{RW} , is much smaller than Z_{BM} . As the stiffness of the round window increases, however, this is no longer true and Z_{RW} can become so large that the impedances of the cochlear and vestibular aqueduct's, Z_{CA}

and Z_{VA} , which are normally too large to play a significant part in the generation of p_{BM} , also become important. The form of these individual impedances take is described below.

5 Estimation of the individual impedances

Middle ear impedance

A Thévenin equivalent source is used for the middle ear, so Z_{ME} is the impedance looking out of the cochlear into the middle ear. The impedance Z_{ME} is thus the same as the parameter m_3 in the analysis of Puria (Puria, 2003). Puria (Puria, 2003) fits a lumped parameter, mass spring damper, model to this impedance so that it is modelled as

$$Z_{ME} = i\omega L_{ME} + R_{ME} + \frac{1}{i\omega C_{ME}}, \quad (1)$$

where Z_{ME} is the ratio of pressure to volume velocity, so that C_{ME} , R_{ME} and L_{ME} are the acoustic compliance, resistance and inertance of the middle ear. The values of these parameters estimated for the human ear by Puria (Puria, 2003) are listed in Table 1, together with the values of all of the other parameters used in this model.

Impedance across the basilar membrane

The ratio of the pressure across the basilar membrane to the volume velocity that travels down the scala at the base of the cochlear is denoted Z_{BM} . Z_{BM} is significant lower than the impedances of the two aqueducts, Z_{CA} and Z_{VA} , as will be shown below. Also, under normal circumstances, Z_{RW} is much less than Z_{BM} , so that the acoustic input impedance to the cochlear is approximately equal to Z_{BM} under these conditions. Z_{BM} is made up of two components, the first is a result of the propagation of the slow wave down the cochlea, and is largely resistive and will be noted as R_{WA} , the other component is due to the inertance of the fluid in the two chambers, L_{FL} . These two impedances appear in parallel, since they are driven by the same pressure difference, and so

$$Z_{BM} = \left(\frac{1}{R_{WA}} + \frac{1}{i\omega L_{FL}} \right)^{-1}. \quad (2)$$

The acoustic inertance, L , of the fluid in a tube of length l and area A is given by

$$L = \frac{\rho l}{A}. \quad (3)$$

This expression can be used to estimate L_{FL} for the two fluid chambers in the cochlear assuming that l is equal to twice the length of the human cochlea, i.e. 70 mm, and that
 5 its area is 1 mm², to give the value of L_{FL} shown in table 1, which also shows an estimate of the value of R_{WA} , taken from Aibara et al. (Aibara et al., 2001).

Taking the values of R_{WA} and L_{FL} from Table 1, it can be seen that the magnitude of the impedance due to the fluid inertia is greater than that of the wave impedance
 10 above about 20 Hz and so the presence of this inertance could be ignored in the frequency range of interest here, which is above 100 Hz, although it has been included here for completeness. In fact the impedance of the fluid in the chambers is also increased by the impedance of the helicotrema, but this is ignored since it would only act to the lower the frequency above which R_{WA} is dominant in the parallel
 15 combination of R_{WA} and L_{FL} .

Round Window

The acoustic impedance of the round window has been measured by Nakajima et al. (Nakajima et al., 2009). We now account for some additional factors as are now
 20 described. The inertance estimated from these experiments, corresponds to a physical mass of about 9 mg, assuming an area of 3 mm² for the round window. This is partially due to the physical mass of the RW, which is about 70 μm thick (Sahni et al., 1987; Goycoolea and Lundman, 1997), and assuming a density of 1200 kg/m³ (Zhang and Gan, 2013), would be about 0.2 mg, but it is also due to the local motion of the
 25 fluid in the ST driven by the RW. This can be estimated from the inertance of a piston driving a half space of fluid, which is given by that of a disc of fluid of area equal to that of the round window, πa^2 where a is the radius, and of thickness due to the 'end correction' for radiation under these conditions, which is approximately $0.85a$ (Pierce, 1981). The additional fluid mass is thus equal to $0.85\pi a^3$, which estimated
 30 to be around 2.7 mg.

This minor correction, escribed above, is applied to these measurements in order to account for the rocking of the stapes, since the volume velocity in the experiments was estimated from the linear velocity at the edge of the stapes. With this correction,

the acoustic impedance of the round window under normal conditions is found to be reasonably well approximated, up to about 5 kHz, by a mass, spring damper model such that

$$Z_{RW} = i\omega L_{RW} + R_{RW} + \frac{1}{i\omega C_{RW}}, \quad (4)$$

5

where the values of the acoustic compliance, resistance and inertance deduced from Appendix A are listed in Table 1. The value of the RW compliance under these normal conditions is denoted in Table 1, since this will be divided by various factors to provide the increase in round window stiffness used in the later simulations.

10

Impedance of the aqueducts

The elements Z_{VA} and Z_{CA} in Figure 2 represent the acoustic impedances of the vestibular aqueduct and the cochlear aqueduct. Stenfelt (Stenfelt, 2015) has modelled these impedances as comprising the inertance and resistance of the aqueducts together with the compliance of a cranial space. The compliance of this space, however, has an impedance that is much lower than that due to the inertance and resistance of the aqueducts in the frequency range of interest here and so has been ignored, so that we assume

15

$$Z_{CA} = i\omega L_{CA} + R_{CA}, \quad (5)$$

20 and

$$Z_{VA} = i\omega L_{VA} + R_{VA}, \quad (6)$$

The values of the acoustic inertances have been calculated using equation (3) above, with the lengths and areas of the two aqueducts as suggested by Stenfelt (Stenfelt, 2015), who assumed that the length of the cochlear aqueduct was 10 mm and that its diameter was 0.15 mm, and that the vestibular aqueduct was made up of a tube of length 1.5 mm with a diameter of 0.3 mm, in series with a tube of length 8.5 mm and a diameter of 0.6 mm. These inertance values and those of the corresponding resistances are given in Table 1.

30

The overall circuit diagram for these components is shown in Figure 3 and the magnitudes of these individual impedances are shown on a log-log scale in Figure 4 to illustrate their relative values at different frequencies, following Marquardt and Hensel (Marquardt and Hensel, 2013). (The complete equivalent circuit diagram of

the lumped parameter model used to analyse the effect of changing the round window stiffness, $1/C_{RW}$, on the pressure across the BM, p_{BM} .)

Figure 4 shows the variation in the impedances of the various components of the impedances in Figure 2 over the frequency range of interest. Since a log-log scale is used the impedances of the inertances rise at 1 decade/decade and those of the compliances fall at 1 decade/decade. This graph will be used to help understand the results presented below.

10 Finite element model of the round window

A finite element model of the round window has been developed here to predict the effect of stiffening due to a cochlear implant on the volume velocity close to the base. The round window is a thin and nearly circular membrane and is assumed here to have a diameter of about 2 mm and a thickness of about 70 μm (Zhang and Gan, 2013). Density of the round window is assumed as 1200 kg m^{-3} and Young's modulus is assumed to be 1×10^6 Pa in order to produce a similar frequency response to the experiment across the frequency range of 200 $\sim$ 8000 Hz. The model is built using Ansys (v15.0) and the membrane is meshed with solid 185 element, as shown in Figure 5. The edge of the round window is assumed to be clamped (Toth et al., 2006; Li et al., 2007). The stiffening effect due to insertion of a cochlear implant is simulated by assuming a cylinder shape with the same thickness of the round window and a diameter of about 1 mm. When calculating frequency response, a uniform pressure is applied on the round window surface and the volume velocity, as shown in Figure 6, is calculated by accumulating the predicted nodal velocity and then multiplying the round window area.

Prediction of the cochlear input impedance

Although an objective is to predict the effect of increases in the round window stiffness on hearing levels, the lumped parameter model, presented above, also readily allows the prediction of the changes in cochlear input impedance as the round window stiffness increases. These results are included here since they may provide an easier method of experimentally validating the lumped parameter model than using the rather more inaccessible changes in the pressure across the BM.

The cochlear input impedance, Z_C , which is the ratio of the pressure in the SV to the stapes volume velocity can be derived from Figure 2 as

$$Z_C = \frac{Z_{VA}(Z_{BM}Z_{RW} + Z_{BM}Z_{CA} + Z_{CA}Z_{RW})}{(Z_{VA} + Z_{BM})(Z_{RW} + Z_{CA}) + Z_{CA}Z_{RW}} \quad (7)$$

5

shows the calculated magnitude and phase of Z_C when the compliance of the round window takes its normal value and when it is decreased by a factor of 10, 100, or 1000. Under normal conditions Z_{RW} is significantly less than R_{WA} up to about 3 kHz, and so Z_C is mainly resistive at low frequencies, as measured by Aibara et al. (Aibara et al., 2001) and Puria (Puria, 2003) for example. Above about 5 kHz, the inertance associated with the round window is predicted to dominate Z_C , causing an increase in its magnitude and a drop in its phase. Unfortunately, the lumped parameter model of the round window is not very accurate in this frequency region, as seen in Appendix A, since both the stapes motion (Sim et al., 2010) and the round window motion (Zwacz et al 2011) becomes more complicated than the in-phase behaviour seen at low frequencies.

When the round window stiffness is increased by a factor of 10, Z_C is dominated by the inertance of the VA at low frequencies, but this then combined with the compliance of the RW to give a parallel resonance at about 200 Hz and hence a peak in the cochlear impedance, as can be verified by noting the crossover point for these two impedances in Figure 4. As the round window stiffness is further increased, the frequency range over which Z_C is dominated by L_{VA} increases and the resonance is pushed up to about 800 Hz and 2.5 kHz when CRW is 1/100 or 1/1000 of its normal value, C_{RW}^0 . The dominant acoustic resistance in the circuit for Z_C is R_{WA} , and so the Q of this resonance, Q_C , is approximately given by

$$Q_C = \frac{1}{R_{WA}} \sqrt{\frac{L_{VA}}{C_{RW}}} \quad (8)$$

30 So that Q_C increases as C_{RW} decreases.

Prediction of the hearing loss

The lumped parameter circuit in Figure 3 can be used to calculate the ratio of the pressure across the BM, p_{BM} , which generates the slow wave that eventually excites the inner hair cells in the cochlea, as a function of the blocked middle pressure, p_{ME} ,
 5 as

$$\frac{p_{BM}}{p_{ME}} = \frac{Z_{BM}Z_{VA}(Z_{RW}+Z_{CA})}{Z_{BM}(Z_{VA}+Z_{ME})(Z_{RW}+Z_{CA})+Z_{CA}Z_{RW}(Z_{VA}+Z_{ME})+Z_{VA}Z_{ME}(Z_{RW}+Z_{CA})} \quad (9)$$

p_{ME} depends on the pressure in the ear canal and if it is assumed that this is not
 10 significantly affected by changes in the RW stiffness, then the changes in the ratio of p_{BM} to p_{ME} can be taken as a measure of the change of the acoustic excitation of the cochlea.

Figure 8 shows the variation of the magnitude and phase of p_{BM}/p_{ME} with frequency as
 15 the round window stiffness is increased. Under normal circumstances Z_{RW} is small compared to Z_{BM} , which is itself large compared to Z_{VA} and Z_{CA} , so that the ratio of the pressures is given approximately by

$$\left. \frac{p_{BM}}{p_{ME}} \right|_{C_{RW}^0} \approx \frac{Z_{BM}}{Z_{BM}+Z_{ME}} \quad (10)$$

20

where Z_{BM} is almost equal to R_{WA} . This equation predicts the results in Figure 8 reasonably well under normal conditions, with the ratio of pressures showing a broad peak at the series resonance frequency of L_{ME} and C_{ME} , which is found to occur at about 1.5 kHz using Figure 4.

25

If the round window stiffness is increased by a factor of 10, the compliances that dominates the response at low frequencies becomes C_{RW} and C_{ME} , and a well damped peak is generated when this resonates with L_{VA} at about 150 Hz, but the high frequency response is largely unchanged.

30

When the round window stiffness is increased by a factor of 100, the compliance then dominates at low frequencies is C_{ME} , so that the response is reduced, and this then

resonates with L_{VA} to give a peak in the response at 200 Hz. Above 200 Hz the dynamics are dominated by C_{RW} and R_{WA} , so that the response increases with frequency, until C_{RW} has a well-damped resonance with L_{RW} at about 5 kHz, as can be deduced from Figure 4.

5

When the stiffness is increased by a factor of 1000, then a parallel resonance occurs between C_{RW} and L_{CA} at about 700 Hz, generating a high impedance below Z_{BM} in Figure 2. and reducing the volume velocity supplied by p_{ME} to generate a notch in the response. Above this frequency the dynamics are again dominated by C_{RW} and R_{WA} ,
10 although C_{RW} is now reduced compared with the cases considered above and so too is the response.

The predicted hearing loss due to the stiffening of the round window is shown in Figure 9 as calculated by the level of p_{BM} under normal conditions divided by p_{BM}
15 under the stiffened condition. This quantity is equal to 0 dB, by definition, under normal conditions, but is also not greatly affected if the RW stiffness is increased by a factor of 10. As the stiffness increases by a factor of 100, however, the hearing loss is predicted to be about 20 dB below about 500 Hz, gradually recovering to 0 dB at about 3 kHz. When the stiffness is increased by a factor of 1000, the hearing loss gets
20 considerably worse above 200 Hz, due to the parallel resonance between C_{RW} and L_{CA} at 800 Hz, and remains more than 20 dB down until about 4 kHz only recovering to 0 dB at 8 kHz.

So, the model predicts approximately the same amount of residual hearing loss
25 below 1 kHz as was measured by Adunka et al. (Adunka et al., 2013) and Friedman et al. (Friedmann et al., 2015) if the RW stiffness is increased by about a factor of 100.

Figure 10 shows Pre-operative and post-operative pure-tone audiometric individual thresholds (thin lines) and mean value (thick lines) for cochlear implant recipients at
30 the University of Southampton Auditory Implant Service (Carl Verschuur). (Plot mean value and envelop/shaded area) and Figure 11 shows the hearing loss due to cochlear implantation, which is equal to the difference between pre-operative and post-operative pure-tone audiometric thresholds for cochlear implant recipients at the University of Southampton Auditory Implant Service (Carl Verschuur) (thin lines)
35 individual hearing loss and (thick line) mean value.

Figure 12 shows the predicted hearing loss using the lumped parameter model when the length and diameter of VA and CA are varying, and the round window compliance is assumed to be 100 times less than its normal condition. Green lines for $C_{RW} = C_{RW}^0/100$, blue line for $C_{RW} = 120\% \times C_{RW}^0/100$, and orange lines for $C_{RW} = 80\% \times C_{RW}^0/100$.

What has been described therefore is the surprisingly complicated behaviour of stiffening in the cochlear and vestibular aqueducts (when $\sim 100 \times$ stiffness) reduces the acoustic sensitivity of the cochlear and we now describe how insights from the new lumped parameter model allows a modified implant design.

As described above, an objective here is to redress the greater round window stiffness caused by the insertion of a cochlear device. In embodiments of the invention, an element that reduces stiffness in at least one specific region of the cochlear device is included. Since compliance (displacement per unit force OR pressure) is the reciprocal of stiffness (force OR pressure per unit displacement), the element is herein termed the compliant element (resulting in greater compliance).

Reference is made to Figure 13 which shows an embodiment of the invention. The cochlear implant comprises an (outer) casing or carrier, of generally tubular form, which retains in its internal space a multitude of electrodes, longitudinally spaced.

The lumped parameter model developed indicates that the optimum positioning of any compliant element is in the part of the cochlear implant that is positioned in the fluid inside the scala tympani. In the embodiment shown in Figure 13, the use is made of a bubble of gas, which is incorporated into a part of the cochlear implant that sits near the round window, coupled to the fluid in the scala tympani via a flexible membrane. The use of a gas as the compliant fluid medium is especially advantageous since a very small volume can have a significant benefit in increasing the 'round window' zone device compliance. The flexible membrane is incorporated as defining part of the outer or external surface of the implant. The bubble of gas is located in a cavity or void defining with the casing. In this embodiment the compliant element can be said to collectively comprise the flexible membrane and the bubble. The flexible membrane seals the gas inside the cavity.

In another embodiment of the invention, which includes a gas bubble described above, the gas bubble may be incorporated such that it has a pressure below atmospheric pressure, so as to further increase its compliance.

- 5 In other embodiments, a cochlear implant is provided with a plurality of compliant members are provided, in discretised fashion.

- In yet further embodiments, a portion of foam may be provided (in a cavity of the cochlear implant), which may couple directly to the cochlear fluid, or a flexible
10 membrane may be provided at an external surface of the implant so as to contain the foam portion.

- In another embodiment, a bubble of gas or air may be provided, but without a flexible membrane, and the bubble being retained within the implant by way of its surface
15 tension.

APPENDIX A

Table 1 Parameter values in the lumped parameter model and their source.

Parameter	SI units	Value	Source
L_{ME}	$N s^2 m^{-5}$	4.4×10^5	(Puria, 2003)
C_{ME}	$N^{-1} m^5$	1.2×10^{-14}	
R_{ME}	$N s m^{-5}$	1.0×10^{10}	
R_{WA}	$N s m^{-5}$	2.0×10^{10}	(Aibara <i>et al.</i> , 2001)
L_{FL}	$N s^2 m^{-5}$	7.0×10^7	Fitted based on (Nakajima <i>et al.</i> , 2009)
L_{RW}	$N s^2 m^{-5}$	1.0×10^6	
R_{RW}	$N s m^{-5}$	2.5×10^9	
C_{RW}	$N^{-1} m^5$	1.0×10^{-13}	
L_{VA}	$N s^2 m^{-5}$	5.1×10^7	(Stenfelt, 2015)
R_{VA}	$N s m^{-5}$	1.0×10^{16}	
L_{CA}	$N s^2 m^{-5}$	5.6×10^8	(Stenfelt, 2015)
R_{CA}	$N s m^{-5}$	6.4×10^{11}	
L_{OW}	$N s^2 m^{-5}$	3.0×10^5	

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CLAIMS

1. A cochlear implant comprising a compliant element arranged to couple to fluid in the scala tympani, and in use arranged to act as a tuned region of compliance in order to permit, through said coupling to the fluid in the scala tympani, the excitation of the slow wave along the cochlear that gives rise to acoustic hearing.
3. A cochlear implant as claimed in claim 1 in which the compliant member comprises a flexible membrane.
4. A cochlear implant as claimed in claim 1 or claim 2 in which the compliant member comprises an air bubble.
5. A cochlear implant as claimed in any preceding claim in which the compliant member comprises a foam.
6. A cochlear implant as claimed in any preceding claim in which the compliant member is arranged, in situ, to be in intimate or contiguous contact with the cochlear fluid.
7. A cochlear implant as claimed in any preceding claim in which the compliant member comprises a surface area which is arranged to be contiguous with the cochlear fluid which surface area is inferior to the (total) surface area of the cochlear implant.
8. A cochlear implant as claimed in any preceding claim in which the compliant member is incorporated or provided at or adjacent to an external portion of the cochlear implant.
9. A cochlear implant as claimed in any preceding claim in which at least a portion of the compliant member defines an external surface of the cochlear implant.
10. A cochlear implant as claimed in any preceding claim wherein the compliant element comprises of a bubble of gas sealed within a suitable flexible membrane

11. A cochlear implant as claimed in claim 10 wherein the fluid of the compliant element is a bubble of gas sealed within a suitable flexible membrane, where this bubble is arranged to have a pressure below atmospheric pressure

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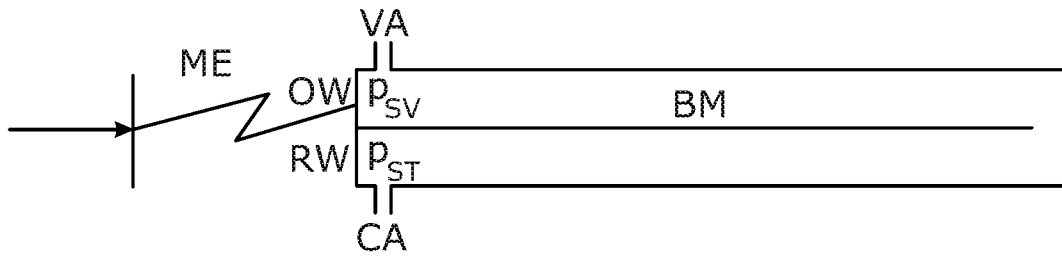


Figure 1

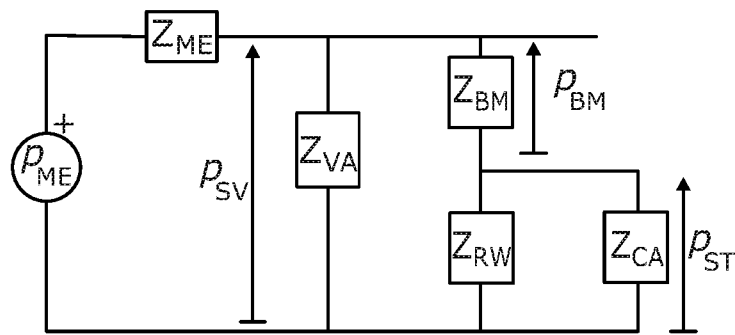


Figure 2

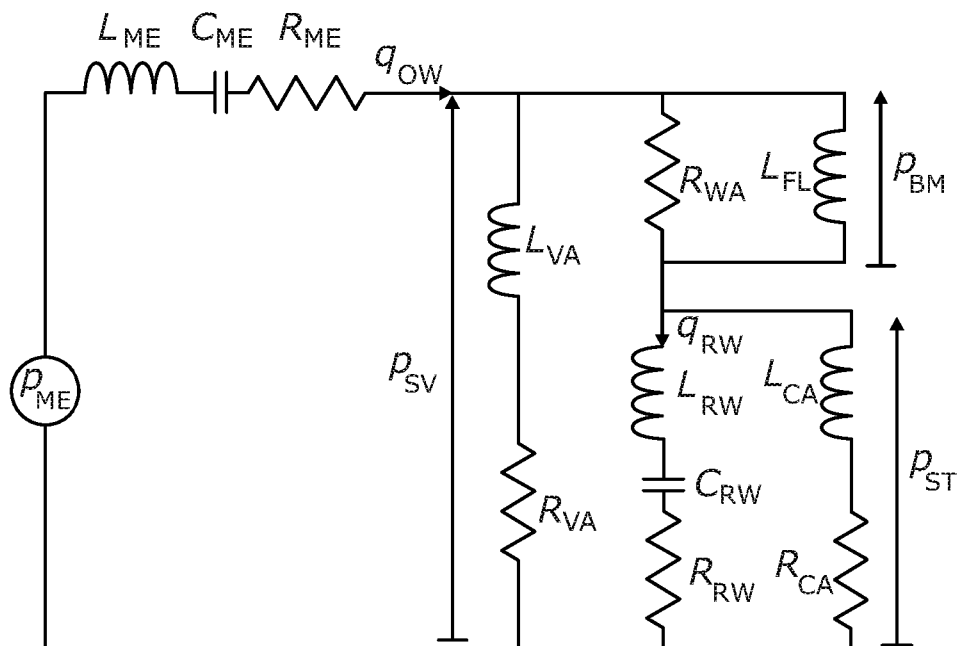


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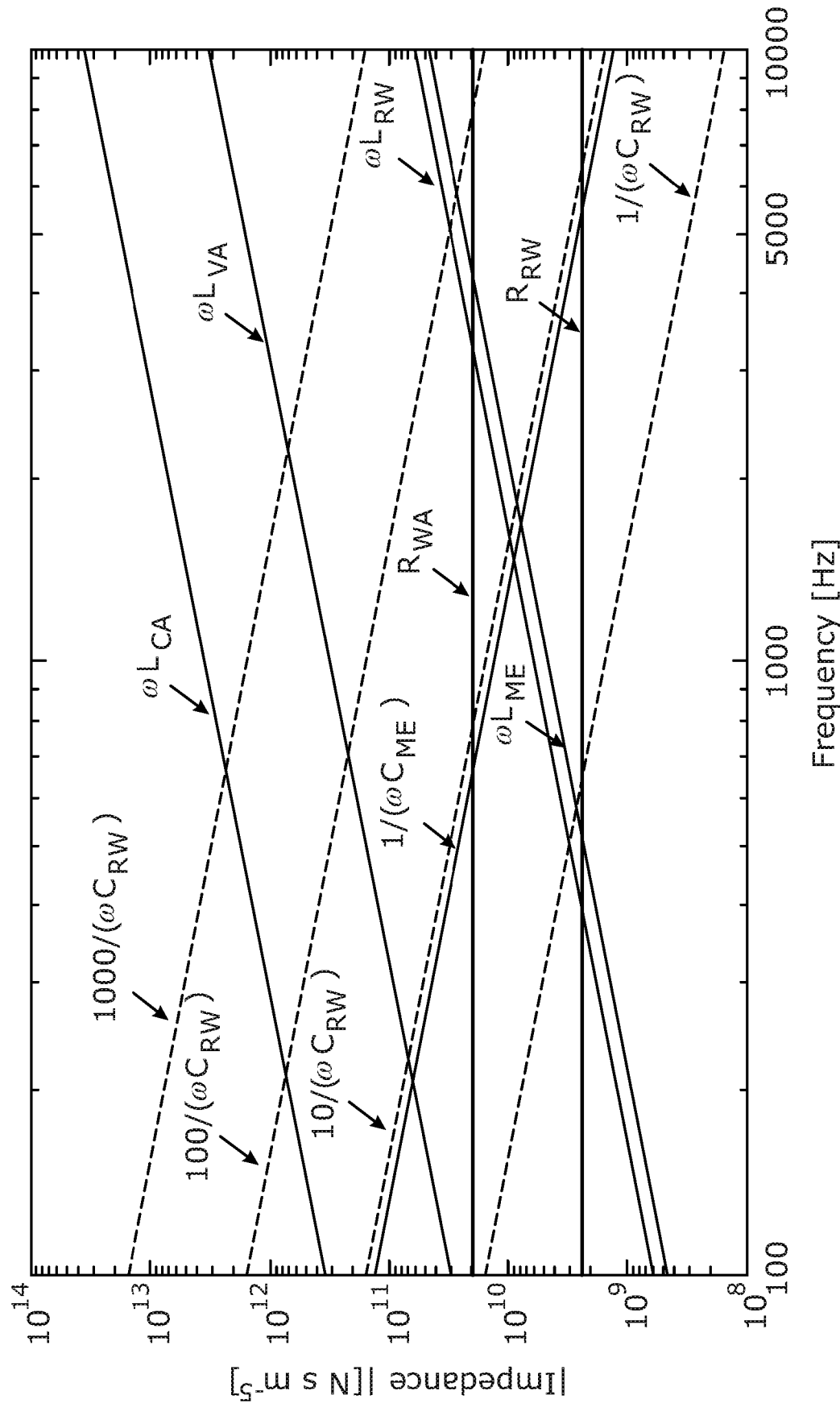


Figure 4

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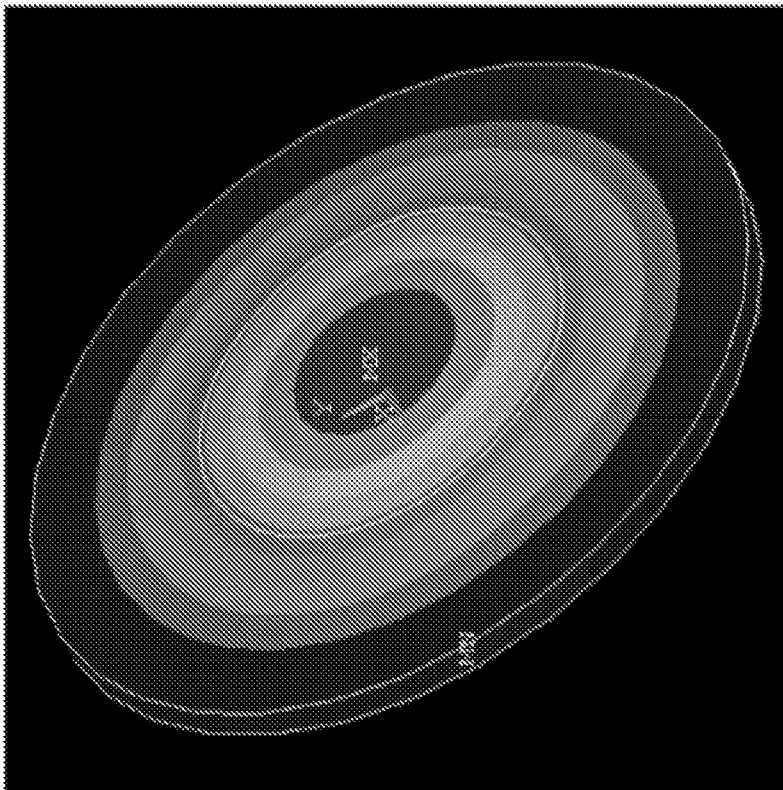
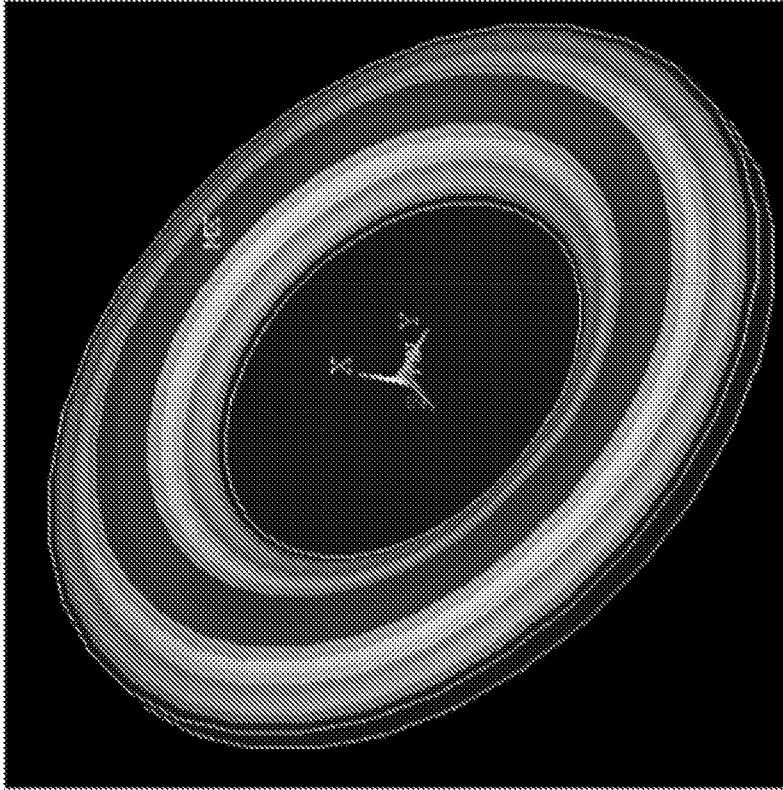


Figure 5

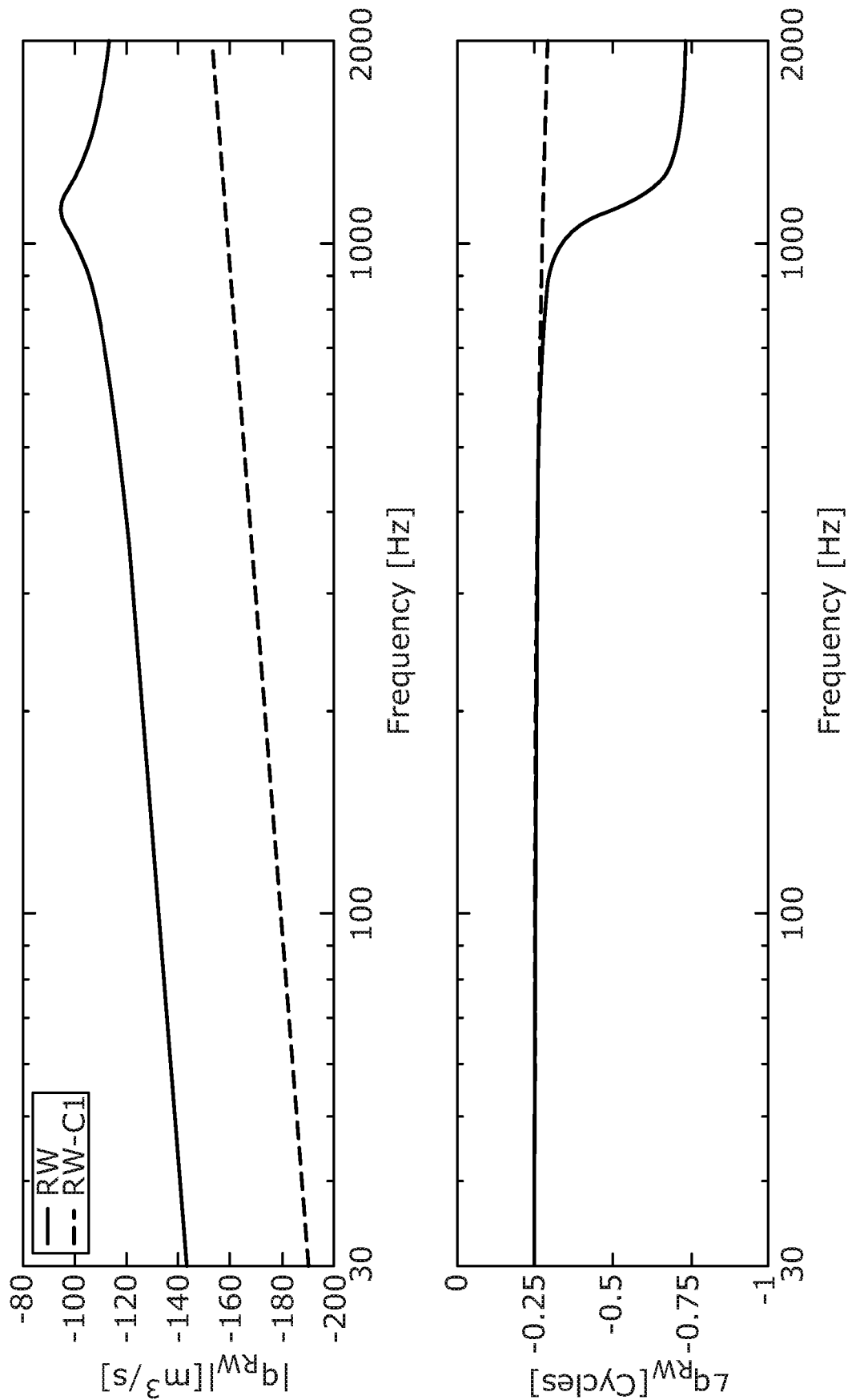


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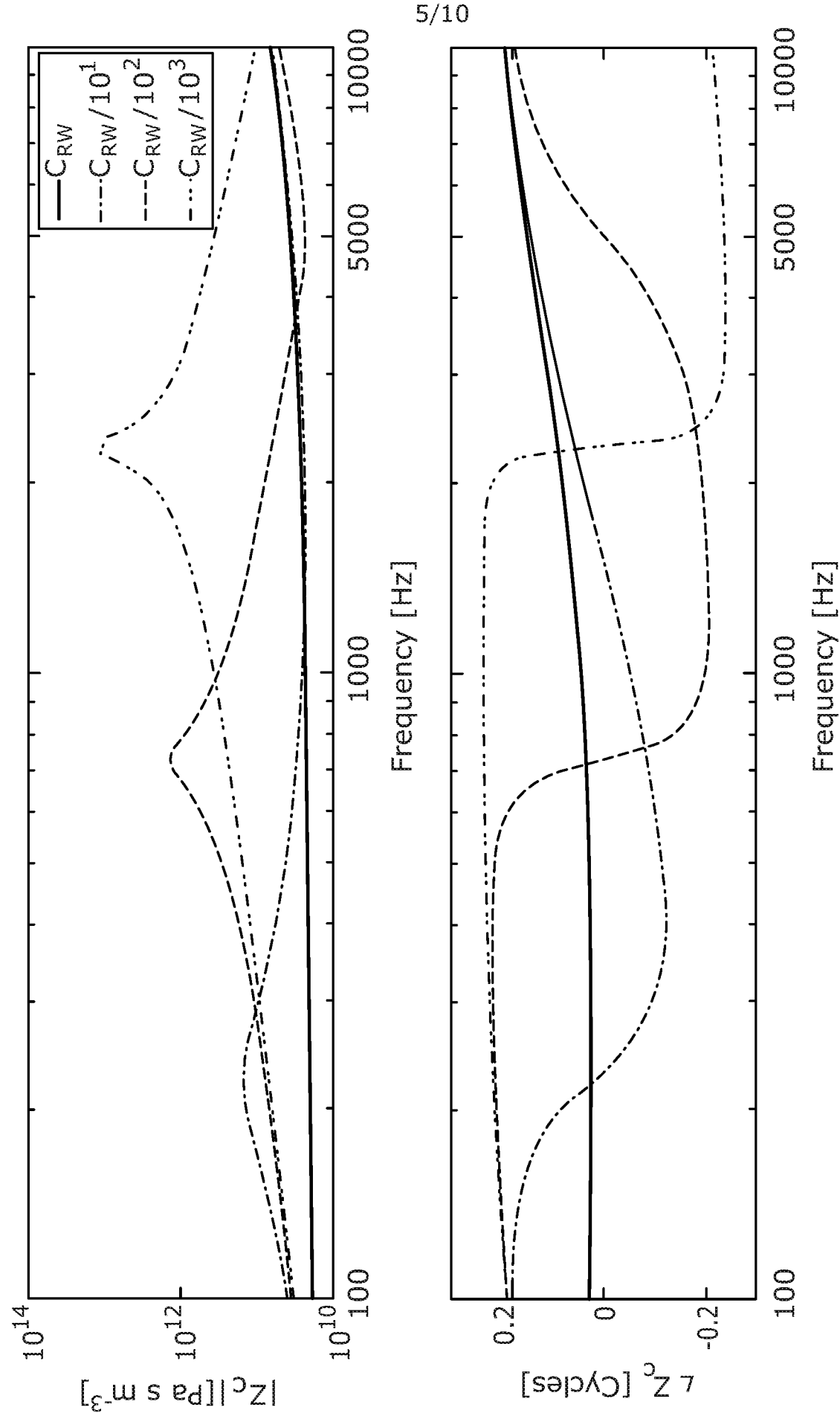


Figure 7

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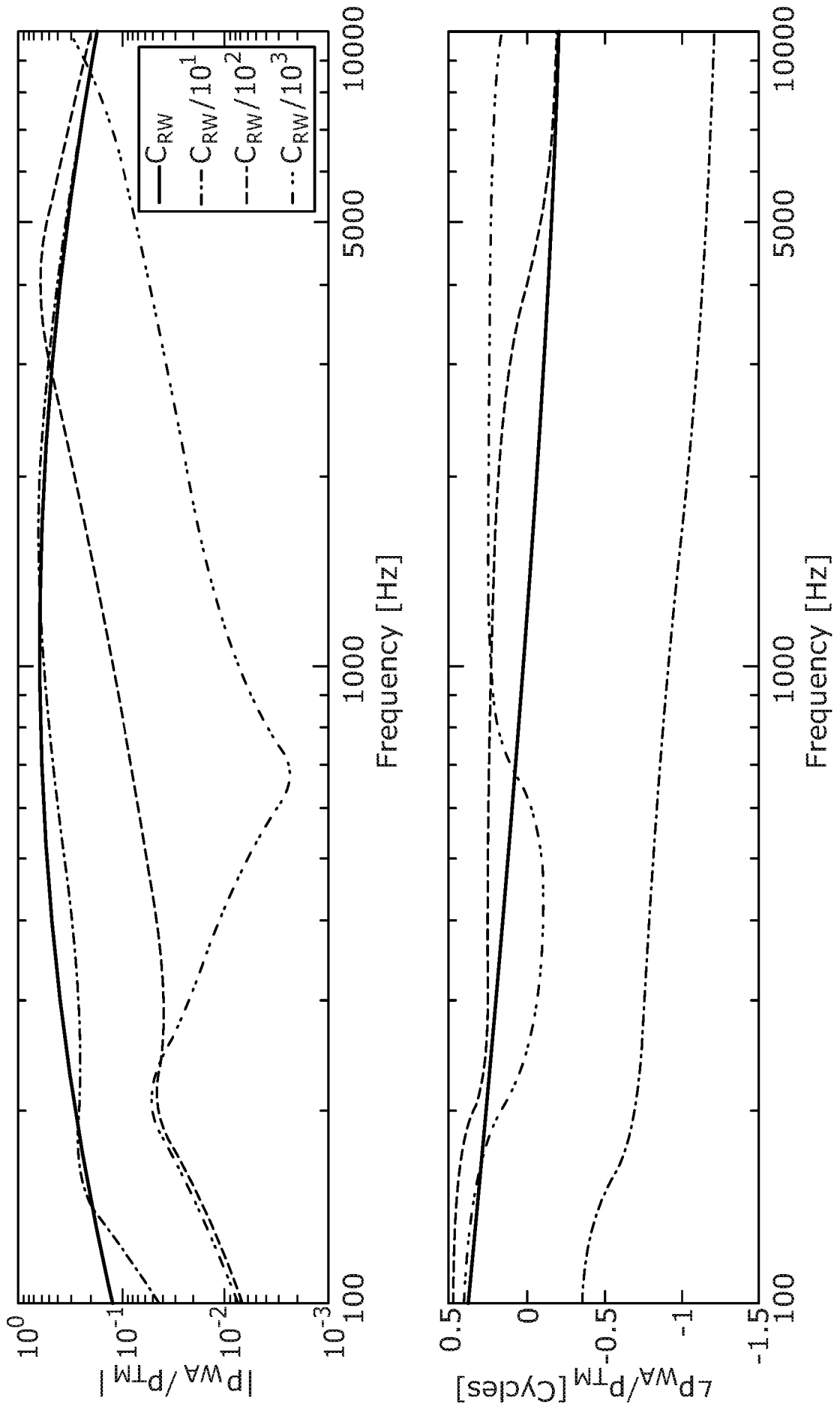


Figure 8

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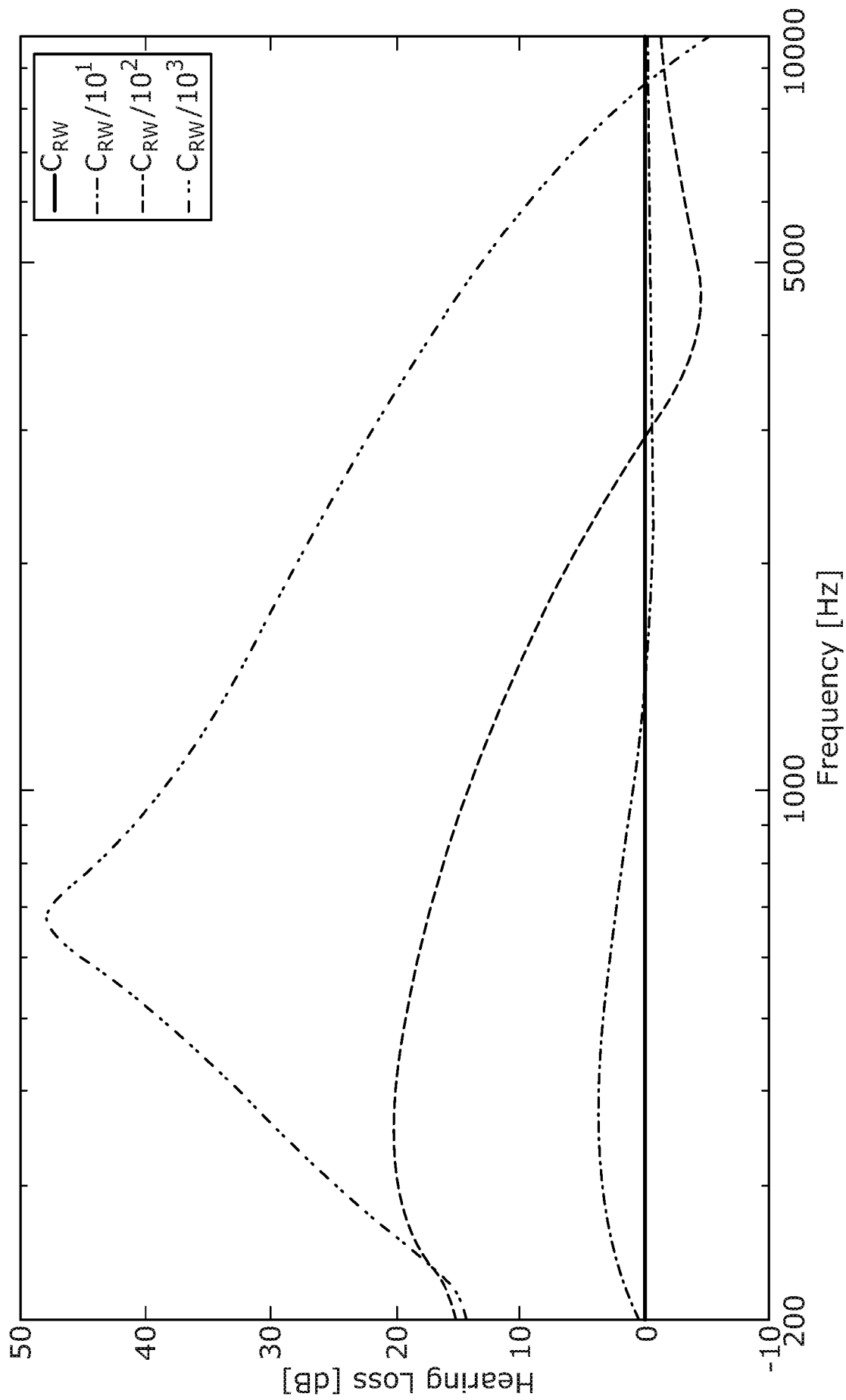


Figure 9

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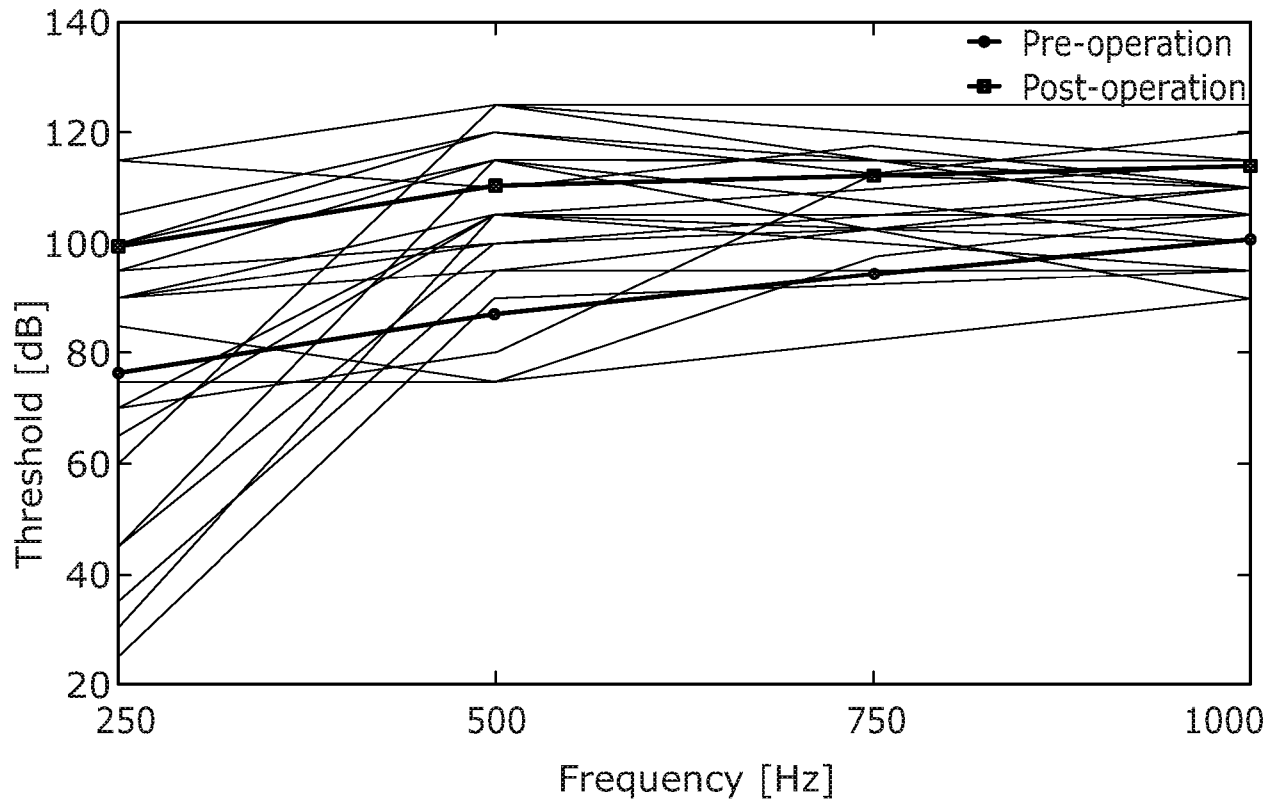


Figure 10

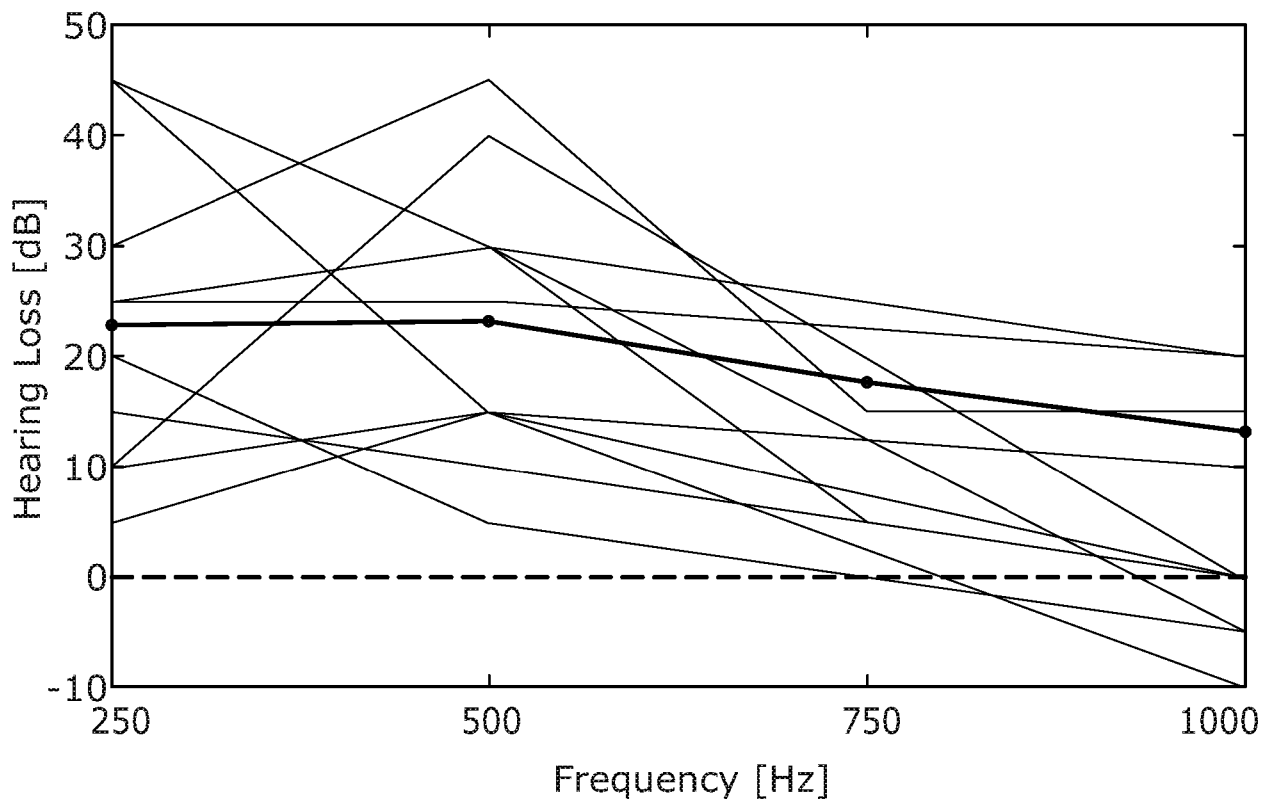


Figure 11

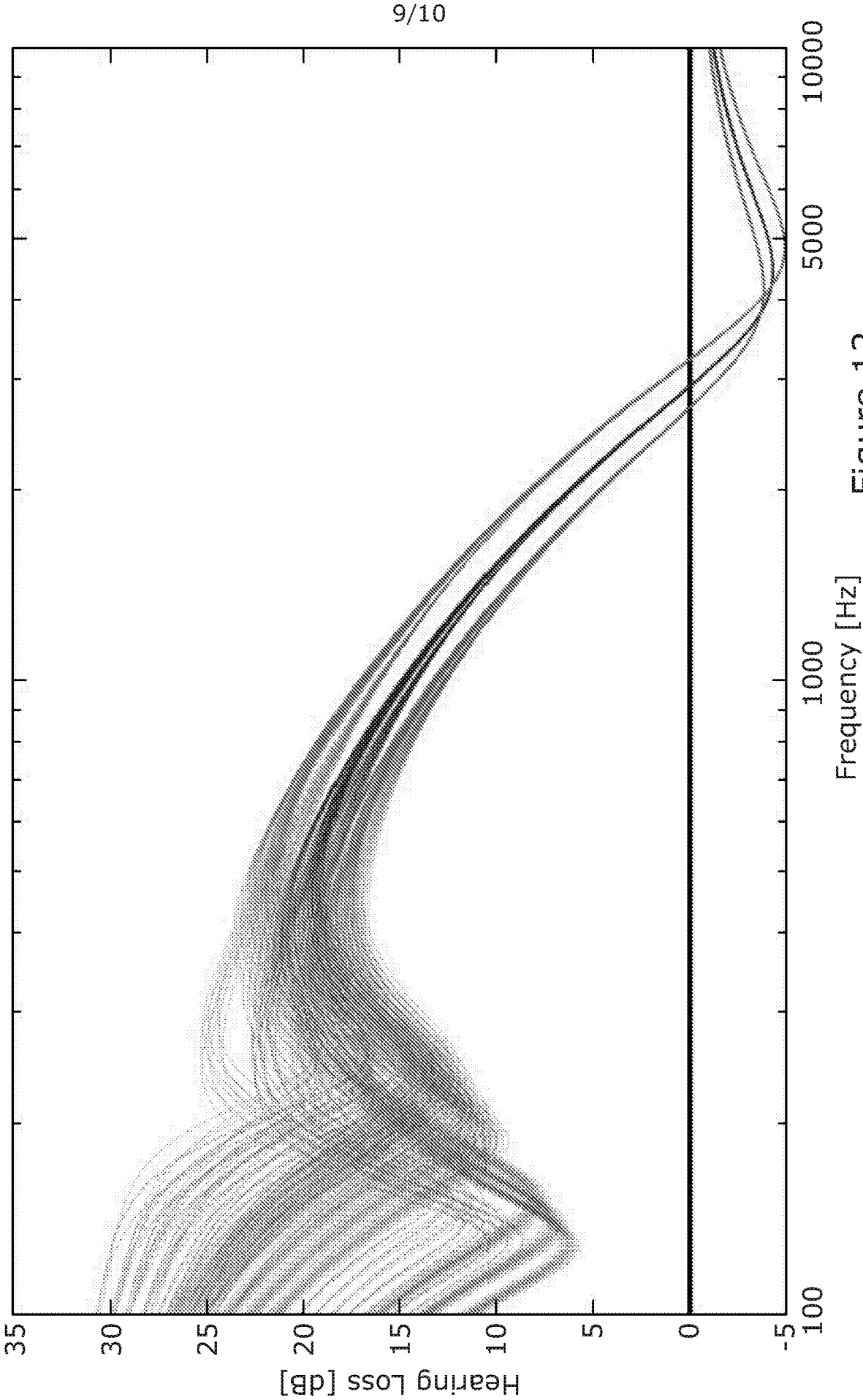


Figure 12

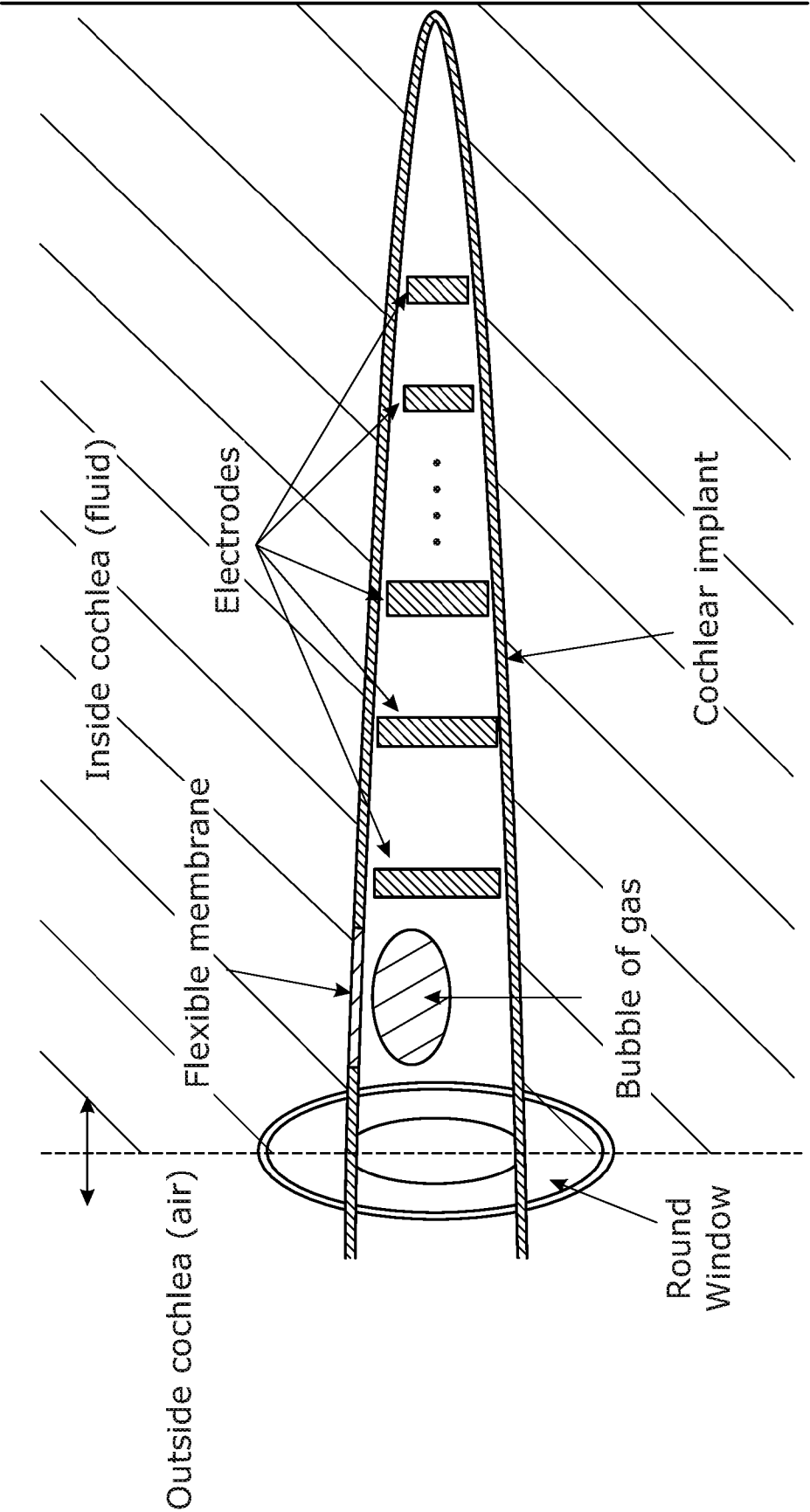


Figure 13

INTERNATIONAL SEARCH REPORT

International application No

PCT/GB2017/050587

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61N1/36
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2011/112355 A1 (VAN DEN HEUVEL KOEN [BE]) 12 May 2011 (2011-05-12)	1-9
A	paragraphs [0019] - [0057]; figures 1, 2A-2B, 3A-3B	10
X	US 2011/245714 A1 (VOLCKAERTS BART [BE]) 6 October 2011 (2011-10-06)	1
A	paragraphs [0030] - [0061]; figures 1-5	10
X	US 2010/324355 A1 (SPITAEELS HARTMUT H R [BE] ET AL) 23 December 2010 (2010-12-23)	1
A	paragraphs [0179] - [0285]; figure 21	10
A	US 2013/079749 A1 (OVERSTREET EDWARD H [US] ET AL) 28 March 2013 (2013-03-28) the whole document	1-10
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Smit, Jos

INTERNATIONAL SEARCH REPORT

International application No

PCT/GB2017/050587

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,P	ELLIOTT STEPHEN J ET AL: "Modelling the effect of round window stiffness on residual hearing after cochlear implantation", HEARING RESEARCH, ELSEVIER SCIENCE PUBLISHERS, AMSTERDAM, NL, vol. 341, 30 August 2016 (2016-08-30), pages 155-167, XP029785929, ISSN: 0378-5955, DOI: 10.1016/J.HEARES.2016.08.006 the whole document -----	1-10

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/GB2017/050587

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2011112355 A1	12-05-2011	CN 102105192 A EP 2296750 A1 US 2011112355 A1 WO 2009152528 A1	22-06-2011 23-03-2011 12-05-2011 17-12-2009
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