

# An assessment of the clinical acceptability of direct acoustic cochlear implantation for adults with advanced otosclerosis in the United Kingdom

**Running head:** Acceptability of DACI for Otosclerosis in the UK

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## **Sources of Funding:**

This work was funded by a research grant from Cochlear Ltd. and infrastructure funding from the National Institute for Health Research (NIHR). The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health.

## 1 **Introduction**

2 Permanent conductive hearing loss can result from otosclerosis, a disease in which abnormal  
3 bone growth may impede the movement of the stapes bone and impair cochlear function.  
4 Examinations of temporal bones suggest that the disease presents bilaterally in approximately  
5 70-80% of cases (Hueb et al., 1991; Menger & Tange, 2003). Temporal bone studies have  
6 estimated a prevalence for otosclerosis of between 2.5% (Declau et al, 2001) and 8.3%  
7 (Altman et al, 1967). These estimates represent the combined sum of both symptomatic  
8 (clinical otosclerosis) and asymptomatic (histologic otosclerosis) cases. The proportion of  
9 these cases that correspond to clinical otosclerosis, where the disease actually interferes with  
10 hearing function, has been estimated to be between 12% (Altman et al, 1967) and 15%  
11 (Guild, 1944). These data therefore suggest that the prevalence of clinical otosclerosis in the  
12 population lies between 0.3% and 1.2%. It is estimated that sensorineural hearing loss also  
13 arises in about 10% of clinical otosclerosis cases (Browning & Gatehouse, 1992; Ramsay &  
14 Linthicum, 1994) and accounts for approximately 5-6% of cases at large cochlear implant  
15 centres (Tange R., personal communication, 2016), which if accurate would correspond to a  
16 prevalence for mixed losses arising from otosclerosis of 0.1% or lower.

17

18 Several treatment options are available for adults with a bilateral mixed hearing loss of a  
19 mild, moderate, or severe degree. If the hearing loss is mild, a conventional acoustic hearing  
20 aid can be sufficient to overcome the conductive and sensorineural components. A hearing  
21 aid may also be beneficial for a moderate-to-severe loss provided the aid can overcome the  
22 conductive component while still providing sufficient residual amplification to aid the  
23 sensorineural component. The conductive component of the loss may also be addressed by  
24 performing stapes surgery where a prosthesis is placed to restore the function of the fixed  
25 stapes bone. The sensorineural component may then be more readily aided using an acoustic

26 hearing aid. In cases where an acoustic hearing aid cannot provide sufficient amplification or  
27 is not tolerated (e.g. ear infections) or surgical correction is not appropriate, a bone-anchored  
28 hearing device (BAHD) may be used to deliver acoustical energy to the cochlea via bone  
29 conduction (Tjellström & Håkansson, 1995). In cases of moderate-to-severe loss where both  
30 acoustic and bone-anchored hearing aids are unsuccessful or contraindicated, a middle-ear  
31 implant may also be considered.

32

33 In the United Kingdom (UK), the treatment options for individuals with a severe-to-profound  
34 mixed hearing loss are limited. The severity of the loss means that an acoustic hearing aid  
35 alone is unlikely to provide benefit without surgical intervention to address the conductive  
36 component. The rate of successful stapes surgery in this patient group has been estimated to  
37 be approximately 60% (defined as the closure of the air-bone gap to <10 dB) and lower than  
38 that observed in patients with mild or moderate losses (Kisilevsky et al, 2010). The capacity  
39 of a BAHD device to provide benefit in these patients is also limited by its ability to provide  
40 sufficient energy transfer to the cochlea to overcome the sensorineural component of the loss.  
41 The introduction of more powerful BAHDs has expanded the candidacy range but aiding  
42 those with more severe sensorineural losses is still restricted by feedback (Bosman et al,  
43 2006). Although individuals with bone-conduction thresholds between 60-90 dB HL are  
44 therefore unlikely to be aided satisfactorily by either acoustic or bone-anchored hearing aids,  
45 they also do not meet current UK candidacy criteria for cochlear implantation (NICE, 2009).

46

47 The Direct Acoustic Cochlear Implant (DACI) was developed to address this gap in treatment  
48 options for individuals with a severe-to-profound mixed hearing loss (Häusler et al., 2008).

49 The DACI is an active implantable device which is composed of two parts. The wholly-  
50 implanted part comprises a receiver-stimulator and a fixation system that couples an artificial

51 incus to a conventional stapes prosthesis (Fig. 1). The external part comprises a speech  
52 processor that converts incoming sound into a digital signal that is transmitted to the  
53 implanted part via a radio-frequency coil. The receiver-stimulator decodes that digital signal  
54 and drives the actuator accordingly via a mechanical piston. By stimulating the intracochlear  
55 fluids directly, the DACI bypasses any existing conduction problems in the middle ear and  
56 can deliver acoustical energy directly to the cochlear perilymph of sufficient power to aid  
57 severe-to-profound sensorineural losses.

58

59 Lenarz et al. (2013) conducted a case series study of the safety and efficacy of the DACI in  
60 15 patients with a severe-to-profound mixed hearing loss defined as bone-conduction  
61 thresholds poorer than 30 dB HL from 0.5 to 4 kHz and an air-bone gap of at least 30 dB at 3  
62 or more test frequencies. On average, implantation of the device did not impair air- or bone-  
63 conduction thresholds, with bone-conduction thresholds improving at 0.75, 1, and 1.5 kHz  
64 post-operatively. The DACI also improved sound-field thresholds measured from 250 Hz to 8  
65 kHz. Among those patients who used a hearing aid pre-operatively, the DACI improved  
66 sound-field thresholds, sentence recognition, and word recognition in quiet. The results of  
67 this preliminary study suggest that the DACI may be efficacious in patients with a severe-to-  
68 profound mixed hearing loss and with moderate bone-conduction thresholds (Busch et al.,  
69 2013).

70

71 Direct acoustic cochlear implantation is not currently provided in the UK. Evidence from a  
72 well-designed prospective evaluation of effectiveness that compared DACI to usual care  
73 would be required to support its provision. However, there is uncertainty over which  
74 comparator intervention(s) should be used to represent usual care. There is also uncertainty  
75 over the audiometric definition of the patient group whose needs are unmet by usual care and

76 who would therefore be included in the future trial. Finally, there is uncertainty over whether  
77 clinicians in the UK would support such a trial. A study was therefore conducted to address  
78 these areas of uncertainty and to inform the design of the future trial.

79

## 80 **Materials and Methods**

81 An online survey was constructed using the Survey Monkey™ software. The patient group of  
82 interest was defined in accordance with the indications for the Codacs™ DACI manufactured  
83 by Cochlear Ltd., Sydney, Australia (Cochlear 2013) as follows: (a) Otosclerosis; (b) Bone  
84 conduction (BC) thresholds of 55 dB or worse; (c) Air conduction thresholds in the severe-to-  
85 profound range; (d) Receive insufficient benefit from conventional hearing aids. It was also  
86 clarified that these patients should be assumed to be otherwise healthy and that they fall  
87 outside the candidacy guidelines for cochlear implantation in the UK following guidance  
88 from the National Institute for Health and Care Excellence (NICE 2009).

89

90 An initial question asked about the professional group to which respondents belonged (ENT,  
91 Audiologist, Hearing therapist, Other) as this survey sought to explore the routine practice  
92 and views of the various professional groups responsible for the care of these patients.

93 Respondents were then asked to consider a vignette that described the patient group of  
94 interest and indicate the preferred treatment option for these patients (Fig. 2). The treatment  
95 options were given as: ‘No intervention’, ‘Audiological / speech-language therapy’,  
96 ‘Amplification with hearing aids’, ‘Combination of amplification and audiological / speech-  
97 language therapy’, ‘Other (please specify)’, and ‘I don't know’. Respondents to the survey  
98 were also asked to indicate the important outcomes to assess when measuring clinical benefit  
99 in the patient group of interest. The available outcome domains were specified based on a

100 review of those assessed in previous clinical studies of DACI (Busch et al 2013; Lenarz et al  
101 2013) and are listed in Table 1.

102

103 Finally, respondents were reminded of the characteristics of the patient group of interest  
104 before being asked three questions about the clinical appropriateness of the DACI device,  
105 whether respondents would be willing to refer these patients into a trial of the DACI device,  
106 and at what stage in their treatment would they be willing to refer. For the latter, the options  
107 given were: ‘Even before initial stapes surgery’, ‘Only after stapes surgery’, ‘Only after  
108 revision stapes surgery’, ‘Other (please specify)’, and ‘I don't know’. The DACI device was  
109 not described by name but rather as a device which: (a) Couples directly to the perilymph of  
110 the cochlea via a conventional stapes prosthesis; (b) Is capable of delivering sufficient gain to  
111 aid bone conduction thresholds of 55 dB or worse; (c) Involves the surgical placement of a  
112 receiver/stimulator similar to that of a cochlear implant; and (d) Involves the use of a behind-  
113 the-ear sound processor similar to that used with a cochlear implant.

114

115 A consensus process was conducted to identify inclusion criteria for a future trial of direct  
116 acoustic cochlear implantation. An initial face-to-face meeting of experts in otosclerosis was  
117 held at which attendees were presented with information on the surgical considerations and  
118 audiological management by clinical professionals who have experience with providing  
119 DACI. A facilitated discussion was then held around three topics: ‘Which patients do not  
120 benefit from current treatment options in the UK?’, ‘Who are potential candidates for  
121 DACI?’, and ‘What factors should guide the design of a future trial and would it be feasible?’  
122 A transcript of the resulting discussions was analysed and used to generate statements around  
123 which a potential consensus could be reached. Two rounds of an online survey were  
124 conducted. In the first round, respondents were asked to state their level of agreement with

125 each of the resulting statements on a five-point Likert scale from ‘Strongly disagree’ to  
126 ‘Strongly agree’. In the second round, respondents were shown the level of agreement that  
127 had been expressed in round 1 and asked to reconsider their response in light of that  
128 information. Consensus was considered to have been reached on a particular statement if at  
129 least 80% of respondents agreed with it.

130

131 The survey and consensus exercise were advertised through national professional bodies:  
132 ENT UK for otolaryngologists, and both the British Academy of Audiology and British  
133 Society of Audiology for audiologists. Invitations to participate were also sent directly to  
134 clinicians working at major referral centres for otosclerosis in the UK.

135

## 136 **Results**

137 Thirty-two clinical professionals completed the online survey comprising nine ENT  
138 specialists, 22 audiologists, and one hearing therapist. All had experience of managing  
139 patients with advanced otosclerosis within the UK National Health Service (NHS). Of those,  
140 30 provided responses to the question about the preferred management options for patients  
141 with advanced otosclerosis (Fig. 2). All but two (93%; 95% CI 78.7 to 98.2) indicated that  
142 their preferred management would include amplification via conventional acoustic hearing  
143 aids with 11 (37%; 95% 21.9 to 54.5) also indicating that they would recommend hearing  
144 therapy in addition to amplification. Only two respondents suggested alternative treatment  
145 options, which were the provision of a bone anchored hearing device and cochlear  
146 implantation.

147

148 Respondents’ choices for the most important outcome to assess when measuring treatment  
149 benefit are shown in Table 1. No outcome domain was chosen by a statistical majority of

150 respondents either as the most or second most important outcome. The most frequently  
151 chosen outcome across either response option was self-reported quality of life, with 55% of  
152 respondents (95% CI 37.5 to 71.6) selecting it as either the most or second most important  
153 outcome to assess treatment benefit.

154

155 When asked about whether DACI would be an appropriate treatment option for the patient  
156 group of interest, 25 of the 29 respondents (86%; 95% 69.4 to 94.5) indicated that it was,  
157 with the remainder selecting 'I do not know'. None indicated that it was inappropriate. All  
158 those who considered it appropriate also indicated a willingness to refer their patients into a  
159 future trial. However, there was variability in when respondents would be willing to refer  
160 patients with 9 (38%; 95% 21.2 to 57.3) willing to do so even before stapes surgery had been  
161 attempted and 8 (33%; 95% 18.0 to 53.3) willing only after stapes surgery had been carried  
162 out. One respondent indicated that they might be willing to refer before stapes surgery but  
163 only if further evidence for the effectiveness of the DACI was available. Three respondents  
164 listed other criteria for referral, which were: (1) only after revision stapes surgery; (2) only  
165 after discussion with the patient; and (3) only after full investigation of non-surgical aiding  
166 options.

167

168 Nineteen clinical professionals participated in the consensus exercise. An analysis of the  
169 transcript of the face-to-face facilitated discussion identified sixteen statements around which  
170 consensus was considered possible. Table 2 lists these statements along with the levels of  
171 agreement after one and two rounds of voting. The consensus was that stapes surgery, either  
172 with or without a hearing aid, is the best available treatment for advanced otosclerosis and a  
173 hearing aid trial is recommended prior to surgery, if that patient is willing. Bone-anchored  
174 hearing devices are an option for some patients and a headband trial would always



175 recommended, but the limit of candidacy for these devices is considered to be BC thresholds  
176 at 50 dB HL. Bone-anchored hearing devices are considered to be not powerful enough for  
177 patients whose BC thresholds are greater than 55 dB HL.

178

179 The consensus was that there is a lack of clear alternative treatment options for those who  
180 have already received the best available treatment, who are outside criteria for both bone  
181 conduction hearing devices and cochlear implantation, and who still receive insufficient  
182 benefit from their hearing aids. These patients would therefore be referred for an implantable  
183 intervention such as a DACI as long as the odds of the patient receiving additional benefit  
184 over their hearing aids were favourable and similar to those expected for benefit from a  
185 cochlear implant. The consensus was also that further trials are needed and that would be  
186 supported by clinical professionals involved in the management of these patients.

187

## 188 **Discussion**

189 It is perhaps as informative to examine the statements that did not reach the required level of  
190 agreement as it is to identify where consensus was reached. The survey responses suggest  
191 that stapes surgery would still be offered to some patients with an air-bone gap as small as 20  
192 dB. The willingness of respondents to carry out stapes surgery even when benefit could be  
193 limited due to poor cochlear function could reflect the fact that pre-operative bone conduction  
194 levels may under-estimate the actual benefit achievable from stapes surgery (Shea et al.,  
195 1999). However, the observed consensus on the need for favourable odds of improvement to  
196 warrant referral for a DACI suggests that there will be a lower limit of cochlear function  
197 beyond which clinicians will not be willing to refer patients. It is therefore important for  
198 future studies to characterise the relationship between pre-operative speech perception and  
199 the odds of a favourable outcome following the provision of a DACI device. Such an

200 approach can be used to define candidacy criteria based on the likelihood that the patient will  
201 improve following the intervention (UKCISG, 2004). However, studies should also consider  
202 the size of change that would be considered meaningful from clinical and patient  
203 perspectives.

204

205 It would also seem logical to assume that there will be an upper limit for the speech  
206 perception abilities of these patients beyond which DACI would either been seen as  
207 unnecessary or inappropriate. However, consensus was not reached on a statement that  
208 restricted referral to those with speech discrimination up to 50% correct, a threshold that has  
209 previously been used to define insufficient benefit from acoustic hearing aids in patients with  
210 more profound losses (NICE 2009). The failure to reach consensus on this point could reflect  
211 a belief that the threshold for referral should be more or less restrictive, but it could also be  
212 that respondents believed ‘insufficient benefit from hearing aids’ cannot be defined  
213 adequately or reliably in terms of a fixed threshold on a test of speech perception conducted  
214 in the artificial environment of an audiology testing booth. In the absence of an agreed  
215 threshold, such a judgement could be based on patient self-report of benefit in real life  
216 situations following the confirmed completion of a hearing aid trial.

217

218 The failure to reach a consensus on whether clinicians were willing to refer for a DACI where  
219 a conductive component remained suggests that referral would be conditional on the outcome  
220 of stapes surgery in those patients where surgery would be recommended. However, the  
221 group failed to reach consensus on a general statement indicating that stapes surgery would  
222 be required before referral for a DACI could be recommended. This result is compatible with  
223 the fact that the needs of patients for whom stapes surgery is not recommended were  
224 considered to be unmet by the available treatment options. Their apparent willingness to refer

225 some patients for a DACI even without having conducted stapes surgery could also have  
226 reflected their views on the needs of patients with losses that are predominantly sensorineural  
227 in origin. The current study did not ask about such patients as it fell outside the current  
228 labelling of the device at the time the study was conducted (Cochlear, 2013).

229

230 The current study aimed to inform the design of a future trial of DACI in the UK, including  
231 identifying the target patient population for whom the intervention is appropriate and needed.  
232 Table 3 lists proposed inclusion and exclusion criteria for a trial based on an analysis of the  
233 statements upon which the respondents reached consensus. The results of the current practice  
234 survey and the consensus exercise both suggest that the trial design needs to account for two  
235 groups: (1) those for whom stapes surgery is recommended where referral for a DACI would  
236 only be supported after that surgery has been conducted; (2) those for whom stapes surgery  
237 would not be clinically appropriate and for whom referral would be supported without prior  
238 surgical intervention. In both cases, the comparator to the DACI should be a trial of an  
239 acoustic hearing aid in combination with hearing therapy. Respondents' views on important  
240 outcome domains suggest that the primary end-point for the trial should be an assessment of  
241 quality of life. Previous early-phase evaluations of the DACI have used a well-established  
242 measure of the impact of listening difficulties on everyday life (the Abbreviated Profile of  
243 Hearing Aid Benefit (APHAB); Cox & Alexander, 1995) and have suggest that outcomes  
244 could be assessed as early as three months after the intervention is provided (Lenarz et al.,  
245 2013). The resulting trial design is shown in Figure 3.

246

247 Prior to conducting such a trial, a feasibility study would be required to assess such practical  
248 issues as the learning curves of surgeons, the structure of the clinical pathway following  
249 provision of a DACI, and the nature and content of post-operative rehabilitation that would

250 be required. The willingness of patients to accept both randomization and the intervention  
251 itself would also need to be confirmed. Should a randomized controlled trial be unacceptable  
252 to patients or not be feasible to conduct, alternative approaches such as the creation of a  
253 matched control group from existing patients populations using propensity score matching  
254 could be considered (McCulloch et al., 2009). In that approach, patients are drawn from a  
255 control group based on their similarity to a smaller group of patients who receive the  
256 treatment on factors that could influence outcome.

257

258 The current study identified quality of life as the outcome domain most frequently chosen by  
259 respondents. This result is one of two key pieces of information that are necessary to  
260 determine the required sample size for the future trial (Williamson et al 2012). The other is  
261 the smallest difference on that outcome that could be considered to be clinically important  
262 and is referred to as the minimal clinically-important difference (MCID) (Gatchel et al 2010).  
263 While the most important outcome domain can be identified through the use of surveys and  
264 consensus techniques (Sinha et al 2011), as demonstrated in the current study, the MCID is  
265 determined by relating the change in outcome to whether the patient perceived a change or  
266 not. The size of the change in outcome among those reporting no change in their hearing  
267 provides an estimate of the minimally-important difference (Jaeschke et al 1989). Further  
268 work would be required to identify an instrument that measures those aspects of quality of  
269 life that are relevant to the specific patients of interest (Buchbinder et al., 2011). Early-phase  
270 studies have already suggested that the APHAB is sensitive to the reductions in everyday  
271 listening difficulty that occur following the provision of a DACI (Lenarz et al., 2013).

272

273 The current study suggests that there is a patient population for whom there is a lack of  
274 treatment options and for whom direct stimulation of the cochlea via the implantation of an

275 auditory prosthesis is considered an appropriate intervention. There appears to be strong  
276 support amongst the clinical professionals who manage the care of these patients to conduct a  
277 clinical trial to evaluate the effectiveness of this novel intervention. A feasibility study is now  
278 necessary to determine how many patients would be required for that future trial, whether  
279 those patients could be recruited within a reasonable timeframe, and whether the proposed  
280 trial design would be acceptable to patients.

281

282

283 **Acknowledgements**

284 The authors wish to thank Cochlear Europe Ltd. for the financial resources to conduct this  
285 feasibility study and the support of Lisa DeBold and Lisa Aubert. The authors also wish to  
286 acknowledge the valuable contributions made to the study by Martin O’Driscoll and Kevin  
287 Green (Central Manchester University Hospitals), Joanne Muff (Cambridge University  
288 Hospitals), Chris Aldren (BMI The Princess Margaret Hospital), John Oates (Spire Little  
289 Aston Hospital), Steve Broomfield (University Hospitals Bristol), Terry Nunn (Guy’s and St.  
290 Thomas’ Foundation Trust), and Shakeel Saeed (University College London Hospitals).

291

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345 **Figure captions**

346 **Figure 1:** A photograph of the implanted component of a direct acoustic cochlear  
347 implant system (left) and a computer rendering of the fixation system (right) used to  
348 attach the mechanical actuator (5) to a conventional stapes prosthesis. 1: Removable  
349 magnet; 2: Receiver coil; 3: implant electronics; 4: lead assembly; 5: actuator; 6: rod; 7:  
350 artificial incus. Reproduced from the surgical instructions for use (Cochlear, 2013).

351 **Figure 2:** The clinical vignette used to assess the preferred management option for the  
352 target patient group with advanced otosclerosis.

353

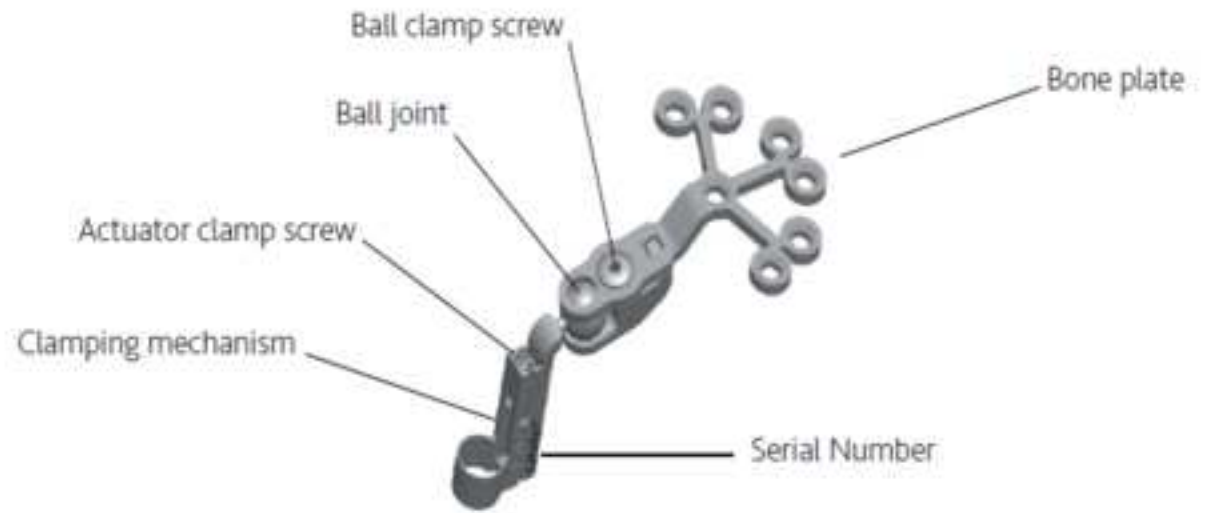


Figure 2

An otherwise healthy patient with otosclerosis currently wears two hearing aids. They have had stapes surgery which closed the air-bone gap to less than 10 dB. Their post-operative audiogram is shown on the right. However, they still report receiving insufficient benefit from their hearing aids.

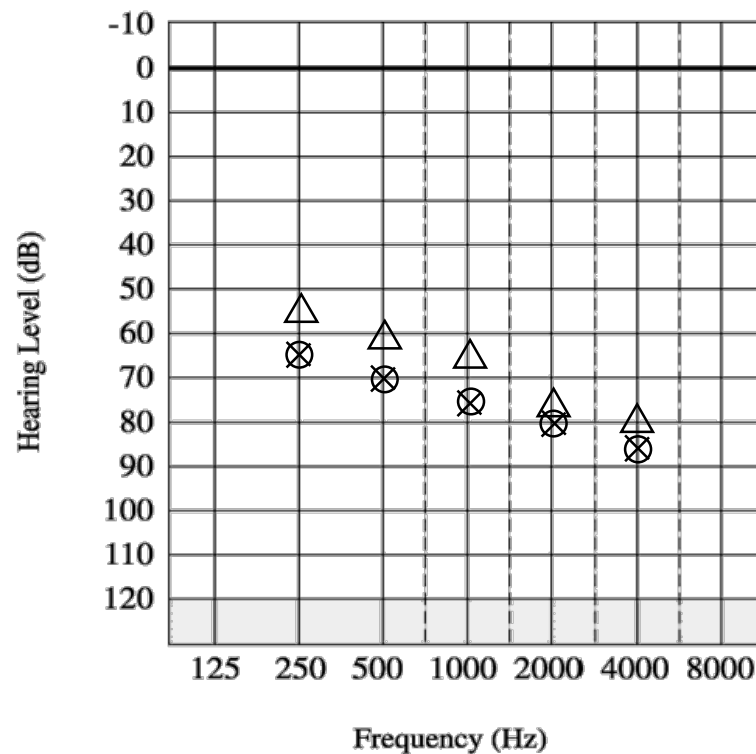
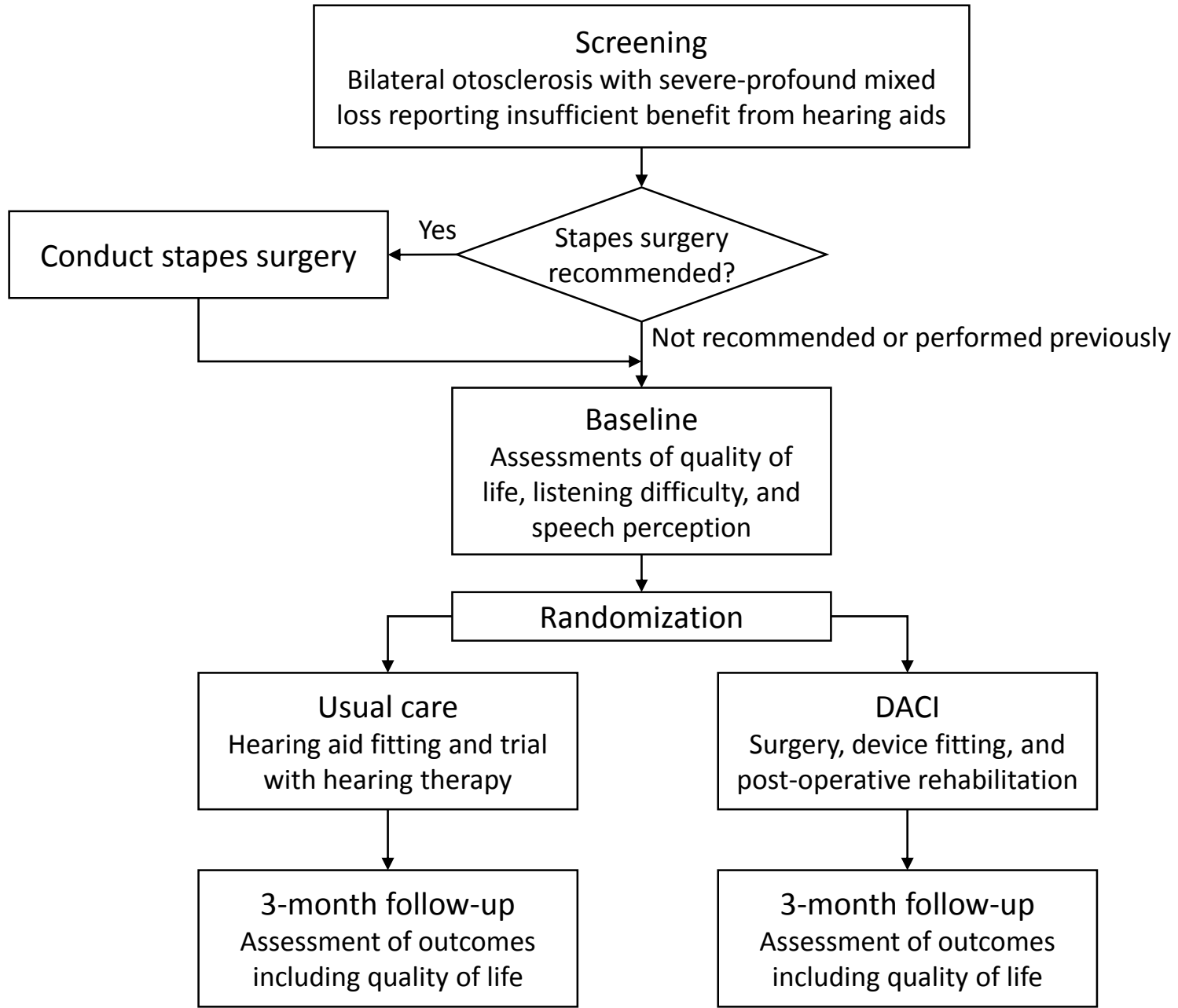


Figure 3



**Table 1: Respondents choices for the most important outcome to assess when measuring treatment benefit in adults with advanced otosclerosis. The outcome domains have been sorted based on the proportion of respondents who identified them as the ‘most important’ outcome to measure to assess treatment effect. The values in parentheses represent the number of respondents.**

<i>Outcome domain</i>	<i>Most important</i>	<i>2nd most important</i>	<i>Total</i>
Quality of life reported by the patient	38% (11)	17% (5)	55% (16)
Ability to understand speech in quiet listening conditions	17% (5)	21% (6)	38% (11)
Ability to understand speech in noisy listening conditions	17% (5)	14% (4)	31% (9)
Level of listening difficulty reported by the patient	14% (4)	17% (5)	31% (9)
I don't know	7% (2)	0% (0)	7% (2)
Ability to localise sounds (tell where they are coming from)	3% (1)	0% (0)	3% (1)
Level of effort required to listen reported by the patient	3% (1)	10% (3)	14% (4)
Sensitivity to sound (e.g. pure-tone/soundfield audiometry)	0% (0)	7% (2)	7% (2)
Other	0% (0)	0% (0)	0% (0)

**Table 2: Level of agreement across 19 participants in the consensus process with 16 statements generated from the initial open round.**

<i>Statement</i>	<i>Round 1</i>	<i>Round 2</i>
I would always recommend a hearing aid trial to patients with advanced otosclerosis before stapes surgery, as long as the patient is willing.	<b>93%</b>	<b>95%</b>
For otosclerosis patients with BC thresholds worse than 55 dB but who are also outside of CI criteria, either a hearing aid alone or in combination with stapes surgery is the best treatment that is currently available.	<b>93%</b>	<b>95%</b>
I would not recommend stapes surgery for cases of advanced otosclerosis with sloping high-frequency loss because the risks would outweigh the potential benefits to speech perception.	36%	16%
I would not recommend stapes surgery to patients with advanced otosclerosis if their speech discrimination is worse than 30% correct.	57%	37%
There is currently a lack of treatment options for otosclerosis patients with BC thresholds worse than 55 dB, who are outside of CI criteria, and who still struggle with HAs after receiving stapes surgery or if surgery is not recommended.	79%	<b>89%</b>
For patients whose BC thresholds are worse than 55 dB and who are not close to CI criteria, I would not recommend stapes surgery if their air-bone gap is less than 20 dB.	64%	63%
I would consider a bone-anchored hearing device for a patient with otosclerosis if their BC thresholds are better than 55 dB.	71%	74%
Patients with otosclerosis whose BC thresholds are 50 dB are approaching the limits of what a bone-anchored hearing device can aid.	<b>86%</b>	<b>89%</b>
I would always recommend a headband trial before surgery to provide a bone-anchored hearing device.	<b>93%</b>	<b>89%</b>
The acoustic gain of a bone-anchored hearing device is insufficient for otosclerosis patients with BC thresholds worse than 55 dB.	<b>86%</b>	<b>89%</b>
I would always recommend stapes surgery to patients with advanced otosclerosis before referring them for a new implantable intervention.	64%	68%
I would not refer otosclerosis patients whose needs are currently unmet by currently-available treatments for a new implantable intervention if their speech discrimination is better than 50% correct.	57%	26%
I would refer otosclerosis patients whose needs are currently unmet by currently-available treatments for a new implantable intervention, as long as there is at least an 80% chance of the patient receiving additional benefit.	71%	<b>89%</b>
I would refer otosclerosis patients whose needs are currently unmet by currently-available treatments for a new implantable intervention even if a conductive component remained, as long as I am sure that their previous stapes surgery was done competently.	64%	68%
Clinical trials are needed to evaluate new treatments for otosclerosis patients whose needs are currently unmet by currently-available treatments.	<b>100%</b>	<b>100%</b>
I would support clinical trials to evaluate treatments for otosclerosis patients whose needs are currently unmet by currently-available treatments.	<b>100%</b>	<b>100%</b>

**Table 3: Suggested inclusion and exclusion criteria for a trial of DACI in the United Kingdom.**

<b><i>Inclusion criteria</i></b>
Bilateral severe-to-profound hearing loss defined as average AC thresholds > 70 dB HL <sup>1</sup>
Bilateral otosclerosis
BC thresholds worse than 55 dB HL
Where recommended, has undergone stapes surgery that closed the air-bone gap to within 10 dB <sup>2</sup>
Completed a hearing aid trial
<b><i>Exclusion criteria</i></b>
Reports receiving sufficient benefit from acoustic hearing aids
Simultaneously satisfies both of the following criteria: <sup>3</sup> <ol style="list-style-type: none"> <li>1. A score of less than 50% on Bamford–Kowal–Bench (BKB) sentence testing at a sound intensity of 70 dB SPL</li> <li>2. AC thresholds &gt;90 dB HL at 2 and 4 kHz</li> </ol>

<sup>1</sup> Following definition of categories of hearing loss from British Society of Audiology (2011)

<sup>2</sup> Following definition of a resolved conductive component from Kisilevsky et al (2010)

<sup>3</sup> Following guidance on the candidacy criteria for cochlear implantation from NICE (2009)