

1 **Access to aidable residual hearing in adult candidates for cochlear implantation in the**
2 **UK**

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Abstract

Guidance from the National Institute for Health and Care Excellence (NICE) permits candidates to receive a cochlear implant provided they only hear sounds louder than 90 dB HL at 2 and 4 kHz. In some patients, their level of residual hearing may be sufficient to warrant the use of a hearing aid in their non-implanted ear. A survey of unilaterally-implanted adults indicated that those implanted since the publication of NICE guidance were almost seven times more likely to use a hearing aid than those implanted prior to this. If contralateral hearing aid use provides additional benefits over implant use alone, it may be appropriate to consider the capacity to use residual hearing following implantation when determining candidacy.

Keywords: cochlear implants, bimodal aiding, cochlear implant candidacy, bimodal candidate, contralateral hearing aid, residual hearing.

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53 **Introduction**

54 Traditionally, cochlear implants (CIs) for adults in the UK were typically restricted to those
55 with profound deafness, or little or no access to useful residual hearing (UKCISG 2004).
56 They were therefore unlikely to benefit from the use of an acoustic hearing aid (HA) in their
57 non-implanted ear following implantation. By the early 2000s, studies were emerging that
58 demonstrated the capacity of cochlear implantation to provide benefit in patients with greater
59 levels of residual hearing (Cullen et al., 2004; Dowell et al., 2004). Hearing preservation
60 techniques were also being proposed to maximise the retention of residual hearing in the
61 implanted ear (Lenarz et al., 2009). The publication of guidance from the National Institute
62 for Health and Care Excellence (NICE 2009) formally expanded candidacy criteria in the UK
63 to include adults with severe-to-profound hearing loss with some measurable residual hearing
64 (up to 90 dB HL at 2 & 4 kHz) and open-set speech discrimination (less than 50% key words
65 correct when presented in quiet).

66

67 Notably, NICE guidance places no restriction on low frequency hearing other than its
68 capacity to support speech perception. Therefore, CI recipients in the UK may still have
69 access to potentially useful and aidable low frequency hearing despite the restriction that
70 NICE guidance places on their pre-operative speech perception abilities. Zhang *et al* (2010)
71 demonstrated that low frequency information can still contribute to speech understanding
72 when combined with a CI even if it is not sufficient to support open-set speech perception by
73 itself. However, it is likely that obtaining benefit from the level of residual acoustic hearing
74 available to UK candidates would require the use of a HA. It is possible, therefore, that NICE

75 guidance may have increased the proportion of implant recipients who use a contralateral
76 acoustic HA with their CI; i.e. who listen ‘bimodally’.

77

78 The most recent large outcomes study in the UK was conducted before the publication of
79 NICE guidance (UKCISG 2004). It is therefore unclear whether the combined effects of the
80 guidance, the emerging evidence of the benefits of residual hearing, and the development of
81 hearing preservation techniques in the late 2000s led to an increase in access to residual
82 hearing among candidates and consequently to an increase in the use of contralateral acoustic
83 HAs in the UK. A survey of adult unilateral CI users was conducted to establish whether
84 those implanted since the publication of NICE guidance are more likely to use a HA in their
85 non-implanted ear compared to those implanted in or prior to 2009.

86

87 **Methods**

88 A total of 623 surveys were sent to unilateral CI recipients at the Nottingham Adult Implant
89 Programme and to 404 recipients at the Midlands Hearing Implant Programme. The inclusion
90 criteria were: (1) 18 years or older; (2) unilateral CI recipient; (3) implanted in the UK.
91 Eligible participants were given the option to return a paper survey or complete it online
92 using Survey Monkey. The study was given a favourable opinion by the Health & Social
93 Care Research Ethics Committee B (REC reference 15/NI/0054).

94

95 Respondents were asked to indicate their age, which ear was implanted, the year of implant
96 surgery (or the first surgery if they had been subsequently re-implanted), whether they were
97 implanted in the UK, which was their better-hearing ear before surgery, and whether they
98 currently use a HA in their non-implanted ear. Responses about which ear was implanted and
99 which was perceived to be the better-hearing ear prior to implantation were used to classify

100 patients into one of three sub-groups: (1) implanted in their worse ear; (2) implanted in their
101 better ear; and (3) ear status prior to implantation similar or unknown. The proportion of HA
102 users was established in each sub-group and 95% confidence intervals were calculated using
103 Wilson's procedure (Newcombe, 1998).

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105 Respondents were divided into two categories: those who were implanted prior to the
106 publication of NICE guidance, and those who were implanted since. Binary logistic
107 regression established whether patients implanted since were more likely to use a HA than
108 those implanted before NICE. The regression model controlled for the age at time of survey
109 completion as HA usage would be expected to decline with age as any residual hearing
110 deteriorates and those implanted before NICE were likely to have been older than those
111 implanted since. The model also controlled for whether patients were implanted in what they
112 considered to be their better or worse ear as those implanted in their better ear may have been
113 less likely to wear a HA contralaterally. Missing data was found to constitute less than 5% of
114 the data across all variables (year of implantation, HA usage, age, better ear prior to
115 implantation) and was treated as missing at random. Rather than excluding those cases,
116 missing data from a patient on any one variable was accounted for by estimating (imputing)
117 the value that would have been most likely given their values on the other variables; i.e.
118 multivariate imputation. Fifty imputations by chained equations were conducted using the
119 'mice' package in the R statistical programming environment (van Buuren and Groothuis-
120 Oudshoorn, 2011). The overall regression model comparing HA usage rates before and after
121 NICE was run both with and without imputation to confirm that the pattern of effects was not
122 driven by the use of this procedure.

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125 **Results**

126 In total, 314 paper responses and 44 online responses were received representing a response
127 rate of 35%. One respondent was excluded on the basis of age (under 18 years) and four on
128 the basis of their country of implantation (outside the UK). Table 1 contains a summary of
129 the remaining 353 responses. Forty-three percent of respondents received their implant in the
130 six years since NICE guidance, 23% in the preceding six years between 2004 and 2009, with
131 the remainder having been implanted in the 19 years between 1985 and 2003. Almost one
132 third of all respondents reported using a contralateral HA and nearly 60% recalled having a
133 better-hearing ear prior to implantation.

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136 Table 1 here

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139 Figure 1 shows the proportion of reported contralateral HA users separately for those
140 implanted before and after the publication of NICE guidance. Across the whole sample, HA
141 use was found to increase by 34.3% from a pre-NICE score of 13.3% to a post-NICE score of
142 47.6% ($\chi^2(1)=45.1$, $p<.001$). A significant increase in HA use was apparent in all three sub-
143 groups with the largest increase observed among those who reported being implanted in their
144 worse ear (40.3% increase to 56.7% from 16.4%, $\chi^2(1)=38.4$, $p<.001$).

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147 Figure 1 here

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150 To assess whether HA use increased gradually over time or abruptly following the
151 publication of NICE guidance, the proportion of reported contralateral HA users was
152 calculated for all those who were implanted within consecutive 3-year periods between 2004
153 and 2015 (Figure 2). A similar proportion of contralateral HA users was observed amongst
154 those implanted in 2004-6 (22.2%) and 2007-9 (18.5%; $\chi^2(1)=0.01$, $p=.54$). The proportion of
155 HA users then increased significantly amongst those implanted in 2010-12 (37.7%;
156 $\chi^2(1)=4.3$, $p<.05$), and increased further in the most recent period from 2013-15 (54.5%;
157 $\chi^2(1)=3.4$, $p<.05$).

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160 Figure 2 here

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163 The logistic regression model indicated that reported HA use was almost three times more
164 likely among those who indicated that they were implanted in their worse ear compared to
165 those implanted in their better ear (OR=2.9, 95% confidence interval 1.5 to 5.6). No
166 significant influence of age was observed ($\chi^2(4)=4.8$, $p=.31$). After controlling for these
167 factors, the regression model indicated that patients implanted in the six years since the
168 publication of NICE guidance were almost seven times more likely to use a HA than those
169 implanted anytime between 1985 and 2009 (OR=6.7, 95% confidence interval 3.6 to 12.3)
170 and almost four times more likely than those implanted in the six years immediately
171 preceding the publication of the guidance (2004 to 2009, OR=3.69, 95% confidence interval
172 1.82 to 7.47).

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176 **Discussion**

177 It is possible that the reported HA use rates of around 30% across all respondents and 48%
178 across those implanted since NICE may be over-estimates. Some HA non-users may have
179 decided that the survey was not applicable to them even though the survey was sent to CI
180 recipients regardless of whether they used a HA or not and the supporting information clearly
181 stated that we also wished to hear from those who do not use a HA. Additionally, the number
182 of respondents implanted since NICE guidance was almost as numerous as those implanted
183 before (43% and 51% respectively with 6% missing data) despite only six years having
184 elapsed since its publication. Therefore, the survey respondents may have been self-selecting
185 on the basis of HA use. Nevertheless, the results would seem to suggest that HA use has
186 increased substantially since NICE guidance and confirm that there may be at least 100
187 'bimodally-aided' listeners across just two UK implant programmes.

188

189 Although the proportion of implant recipients who reported using a contralateral HA
190 increased significantly around the time that NICE guidance was published (Figure 2), it is
191 unclear whether this increase can be solely attributed to the guidance alone. Research
192 outlining the potential benefits of implanting candidates with greater levels of residual
193 hearing (Dowell et al., 2004) and advances in hearing preservation techniques to minimise
194 the risk of irreversible damage from implantation (Lenarz et al., 2009) were being published
195 around the same time. However, it seems plausible that the observed effect on HA use among
196 UK implant recipients can be attributed, at least in part, to the publication of the NICE
197 guidance that likely led to changes in referral patterns and consequently greater levels of
198 residual hearing in contemporary candidates for implantation.

199

200 Recent evidence suggests that some UK patients can derive benefits from the combined use
201 of a CI and a HA (Visram et al, 2012; Green et al, 2014). However, the reasons why such a
202 relatively large proportion of recent CI recipients continue to use a contralateral HA despite
203 their limited access to residual hearing remain largely unclear. Only if characterised through
204 further research would it then be possible to examine how those specific benefits could be
205 optimised when fitting one or both devices. Should further evidence emerge that this
206 ‘bimodal’ listening configuration provides additional benefits over implant use alone, it may
207 be appropriate to consider the potential for a patient to continue to use their residual hearing
208 following implantation when determining candidacy.

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210 Despite the apparent increase in the number of bimodally-aided patients suggested by the
211 current results, clinical practice does not appear to have adapted its focus away from
212 maximising benefit from use of the CI alone. A recent survey of UK audiologists working
213 across adult implant programmes suggested that both devices are still typically maintained by
214 two separate service providers (Fielden and Kitterick, 2015). Thus, further research is still
215 required to explore how the provision of services could be adapted to support and manage the
216 effective use of both devices.

217

218 **Conclusion**

219 Since the publication of the NICE guidance in 2009, there has been a significant increase in
220 reported contralateral HA use among adult unilateral CI users. As a result, there may now be
221 many more CI users who benefit from simultaneous access to electric and acoustic
222 information. It may therefore be appropriate to consider a patient’s capacity to exploit their
223 residual hearing following implantation when assessing candidacy for implantation.

224

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230 identifying participants.

231 The authors declare no conflicts of interest.

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261 stimulation is added to electric stimulation. *Ear and Hearing*, 31, 63-69.

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264 **Legends**

265 **Figure 1.** Proportion of reported contralateral hearing aid users across the whole sample ('All
266 patients') and within sub-groups identified by whether they were implanted in their worse
267 ear, their better ear, or did not report having a better ear prior to implantation
268 ('Same/Unknown'). Error bars plot the 95% confidence intervals for the proportions.
269 Asterisks indicate the result of comparing the proportions using Wilson's test, *** $p < .001$, **
270 $p < .01$.

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272 **Figure 2.** Proportion of reported contralateral hearing aid users in the 6 years immediately
273 pre- and post- NICE guidance, divided into 3-year time bins. Error bars plot the 95%
274 confidence intervals for the proportions. Asterisks indicate the result of comparing the
275 proportions using Wilson's test, *** $p < .001$, * $p < .05$.

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277 **Table 1.** Summary statistics of the 353 respondents whose data were included in the analysis.
278 In cases where an ear had been re-implanted, the year of the first implantation was taken as
279 the year of surgery.

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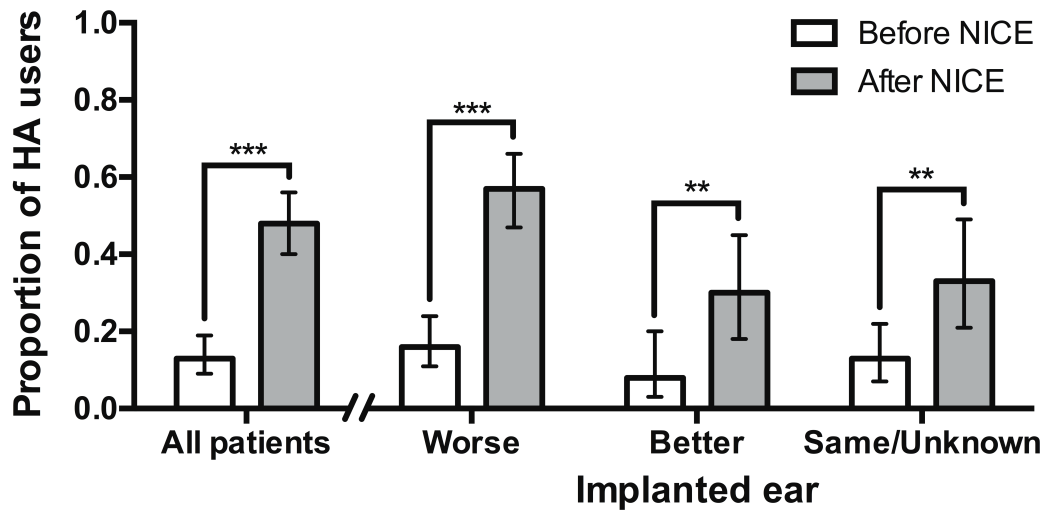
Characteristics	Category	N	%
Age at time of survey	18–32 years	62	17.56
	33–47 years	55	15.58
	48–62 years	68	19.26
	63–77 years	114	32.29
	Over 78 years	48	13.60
	Missing data	6	1.70
Implanted ear	Left	152	43.06
	Right	191	54.11
	Missing data	10	2.83
Year of surgery	1985-2003 (pre-NICE)	99	28.05
	2004-2009 (pre-NICE)	82	23.23
	2010-2015 (post-NICE)	151	42.78
	Missing data	21	5.95
Contralateral HA user	Yes	103	29.18
	No	247	69.97
	Missing data	3	0.85
Better ear prior to implantation	Implanted ear	111	31.44
	Non-implanted ear	94	26.63
	Same	98	27.76
	Unknown	36	10.20
	Missing data	14	3.97

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Table 1

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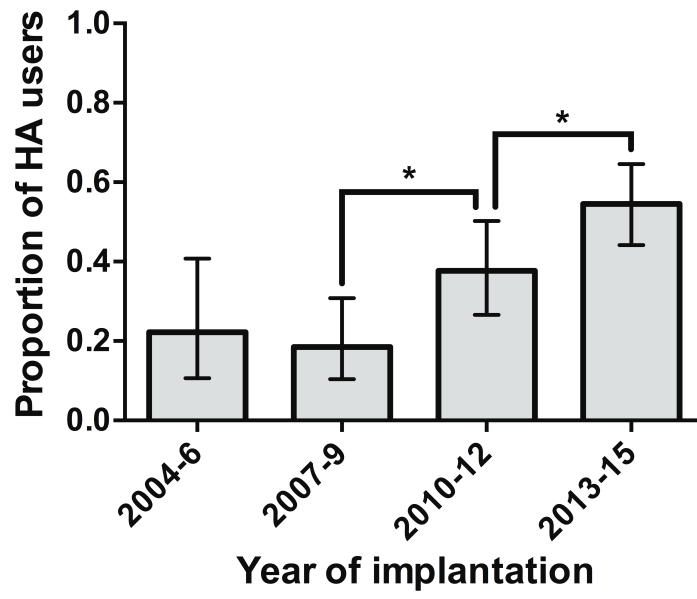


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Figure 1

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Figure 2