

Multicentre evaluation of the Naída CI Q70 sound processor: feedback from cochlear implant users and professionals

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Abstract

The aim of this survey was to gather data from both implant recipients and professionals on the ease of use of the Naída CI Q70 (Naída CI) sound processor from Advanced Bionics and on the usefulness of the new functions and features available. A secondary objective was to investigate fitting practices with the new processor.

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See online Appendix for CI User survey.

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©Copyright J. Martin et al., 2016 Licensee PAGEPress, Italy Audiology Research 2016;6:160 doi:10.4081/audiores.2016.160 A comprehensive user satisfaction survey was conducted in a total of 186 subjects from 24 centres. In parallel, 23 professional questionnaires were collected from 11 centres.

Overall, there was high satisfaction with the Naída CI processor from adults, children, experienced and new CI users as well as from professionals. The Naída CI processor was shown as being easy to use by all ages of recipients and by professionals. The majority of experienced CI users rated the Naída CI processor as being similar or better than their previous processor in all areas surveyed. The Naída CI was recommended by the professionals for fitting in all populations. Features like UltraZoom, ZoomControl and DuoPhone would not be fitted to very young children in contrast to adults.

Positive ratings were obtained for ease of use, comfort and usefulness of the new functions and features of the Naída CI sound processor. Seventy-seven percent of the experienced CI users rated the new processor as being better than their previous sound processor from a general point of view. The survey also showed that fitting practices were influenced by the age of the user.

Introduction

Cochlear implantation has become a standard procedure for the treatment of severe to profound deafness. Since the early days of single channel implantation in the 1960s and 1970s, the technology has evolved to become more sophisticated. New cochlear implant (CI) sound processors deliver enhanced signal processing and incorporate improved microphone technology from the hearing aid field. These new features have improved the speech perception performance of implant recipients but have also presented them with hearing devices that are more complicated to manage.

Users' views are becoming a key part of healthcare provision and if collected in a systematic way, can make an important contribution to future service and product development.³ One way of achieving this aim is by using questionnaires to collate user satisfaction data to support the introduction of new devices for a specified user group. Much of the published data in this area focuses on patient satisfaction with the hearing performance of the device in question and not the ease of use, even though control and ease of use of the CI system is an important factor in choice of implant brand.⁴ Some studies have used the Satisfaction with Amplification in Daily Life (SADL) questionnaire to evaluate patient satisfaction in a standardised way; however ease of handling is not specifically reported and forms a very small part of this questionnaire.⁵⁻⁷ In the studies where ease of use data has been reported, the questionnaires used have been custom designed. For example, Anderson *et al.* (2003) looked at the ease of use of the Tempo+ cochlear implant sound processor in children, Ho *et al.* (2003) looked at the satisfaction of adult users with a new body worn bone





anchored hearing aid, Lorens et~al.~(2012) compared a newer and older version of the same electro-acoustic sound processor product and Briaire et~al.~(2016), reported comfort and ease of use data for the NeptuneTM waterproof sound processor. $^{8\cdot11}$

In 2013, Advanced Bionics (AB) launched the Naída CI 070 (Naída CI) sound processor which is compatible with the HiRes 90KTM, CII and AdvantageTM cochlear implants. It is significantly smaller in volume than the previous behind-the-ear processor, HarmonyTM and offers three sizes of rechargeable batteries and one disposable Zinc-Air battery option. The Naída CI also incorporates new sound processing features based on existing technology used in Phonak (Staefa, Switzerland) hearing aids. These algorithms were further developed and adapted to CI technology. They include an adaptive beamformer option called UltraZoom, which improves hearing performance in noisy conditions, specifically when speech is coming from the front and Binaural VoiceStream TechnologyTM. ^{12,13} Many implant candidates now receive bilateral implants and Binaural VoiceStream Technology on the Naída CI provides wireless transmission of data between devices, allowing bilateral cochlear implant users to synchronize hearing across the two ears. ¹⁴ DuoPhone and ZoomControl deliver the signal picked up on one side of the head, to the contralateral ear and OuickSync allows for easy, instant and simultaneous adjustments of volume and program settings on both Naída CI sound processors by adjusting the settings on only one sound processor.

The aim of this project was to gather data from both implant recipients and professionals on the ease of use of the Naída CI sound processor as well as on usefulness of the new functions and features. Professionals are often a group from whom feedback is not reported. A secondary objective was to investigate fitting practices for the new processor. Of particular interest was if a difference existed between the fitting and use of the different features across older and younger recipients. The common perception is that the more complex sound processor features are not fitted to the very old or the very young, but little evidence exists to support or refute this view. A comprehensive survey of service provision in the United States looked at comparative programming and rehabilitation practices across younger/middle age adults (<65 years) and older adults (≥65 years). The survey showed that despite acknowledging the issues relating to providing an implant service to older candidates, patterns of clinical practice were generally not modified on the basis of age.

Materials and Methods

When the Naída CI was introduced, a comprehensive user satisfaction survey was conducted which included questions on the ease of use and comfort of the new processor as well as on the use of some of the new functions and features. Recipients, who had used a previous generation Advanced Bionics sound processor, compared the Naída CI to their previous device. As well as user data, a survey of professional satisfaction with the ease of use and fitting of the different features was also included.

Outcome measures

CI users

Subjective feedback was collected through a paper version questionnaire, which was provided to both adults and children to evaluate the practicality, comfort, ease of use and sound quality of the Naída CI sound processor. It could be completed either by the CI recipient or by the parent or legal guardian of the recipient. Subjects were required to be either existing users of another Advanced Bionics processor who were converted to the Naída CI, or new users of a CI using the Naída CI from first activation. All the CI recipients were asked to complete the questionnaire after at least one month's use of the new sound processor. There were no exclusion criteria.

The questionnaire contained 25 questions. It was divided into four sections: the first section was related to general information; the second section contained questions about the use of the Naída CI processor; the third section compared the previously used sound processor to the Naída CI processor (for upgraded users only); and the fourth section enabled the subject to write any comments about his/her experience with the Naída CI processor (Appendix).

Subjects rated the ease of use and usefulness of several aspects of the new sound processor on a ten point Likert scale where 1 meant Very difficult/Not useful/Not satisfied and 10 meant Very easy/Very useful/Highly satisfied.

The project was conducted in multiple centres following the local ethical requirements. Before taking part in the survey, all participants signed a data release form handed out by their clinician.

Professionals

Professionals were asked to complete a questionnaire (either online or a paper version) after experience with the new processor and accessories. The questionnaire contained a total of 30 questions about the use and fitting of the Naída CI processor and a comparison to previous AB sound processors.

Statistics

Responses from the Likert scale were assumed to be linear. The numerical values were summarized by medians and the distributions of observations were displayed using bar charts. Statistics suitable for analysis of ordinal data were used. Non-parametric statistical analyses were used to compare two (CI users vs. professionals groups or new CI users vs. upgraded users groups) or more independent groups (age groups), with either a Mann-Whitney U test or a Kruskal Wallis test. All tests were two sided and considered statistically significant when the corresponding p-value was less than 0.05. When overall significance was reached for the Kruskal Wallis test, post-hoc corrections were applied with a corrected alpha divided by the number of pairwise comparisons that were made. In our case, this led us to run Mann-Whitney U tests with an alpha value of 0.005 (controlling for ten pairwise comparisons).

The CI users' population was divided into 5 age groups in order to evaluate if age had an impact on any of the outcomes. The following age groups were chosen: [0-10]; [11-18]; [19-40]; [41-60]; >60. These represent the main categories of the population such as children, teenagers, adults or older adults and include a reasonable amount of subjects in each group.

Results

Participants

In total, 186 subjects' questionnaires were collected from 24 centres in The Netherlands, Belgium, Germany, Italy, United-Kingdom, South Africa, Lebanon, India, Spain and France. Fifty-eight were from children (below 18 years old) with a mean age of 10.2 years old (SD=4.7) and 117 were from adults with a mean age of 52.2 years old (SD=16.7) (in eleven cases, the age information was missing). There were 69 new users who had at least one month's experience with the processor and 117 were existing users with between approximately six months and 13 years of implant use. Upgraded recipients used either the Harmony, Auria or CII behind-the-ear processors or the Neptune or PSP body worn sound processors before the Naída CI. Table 1 shows the description of the population.

In parallel, 23 professional questionnaires were collected from 11 centres, with most of the professionals programming a population from very young children to elderly adults. Participating centres were experienced centres implanting cochlear implants for at least 5 years.

Results have been divided into the questions relating to general ease of use, use of the new functions and features, professional fitting practices and comparisons to previous generations of Advanced Bionics processors.

Ease of use

Results are presented here for the ease of use questions, for the new processor for both CI users and professionals. Seventy-four percent of the profession-

Table 1. Description of the CI user population.

	Amount of subjects (SD) [N]	Mean age in years
All Children Adults Unknown	186 58 117 11	38.3 (24.3) [N=175] 10.2 (4.7) [N=58] 52.2 (16.7) [N=117]
New CI users Upgraded CI users Previous processors	69 117 89 Harmony 16 Auria 3 PSP 3 Neptune 2 CII BTE 2 Auria and Harmony 2 Unknown	46.6 (22.7) [N=67] 33.2 (23.9) [N=108]



als and 84% of the CI users rated general ease of use of the Naída CI processor as 7 out of 10 or greater. More than 70% of respondents in the CI user group rated all the tasks as being easy to perform (a rating equal to, or above, 7 out of 10) with the exception of connecting and removing the ear hook/T-Mic $^{\rm IM}$ 2 from the processor, where 59% gave the same ratings. The T-Mic 2 is an alternative microphone option, which places the microphone near the outer ear. A cover protects this microphone and needs to be regularly changed. Attaching/removing the T-Mic 2 cover appeared to be the hardest task for the professionals, with a median score of 5 out of 10 (N=19).

When comparing the median ratings between the two groups, there were only significant differences for attaching/removing the T-Mic 2 cover (Mann–Whitney U = 291.5, N "CI users" = 66 – median=7, N "Prof"= 19 – median=5, P<0.001) and exchanging the disposable battery (Mann–Whitney U = 414, N "CI users" = 69 – median=9, N "Prof"= 18 – median=7, P<0.05). For both tasks, recipients found it significantly easier to do than professionals (Figure 1).

Naída CI users can use either disposable batteries or rechargeable batteries.

Not all subjects had the opportunity to try both options. However, they both appeared to be very easy to use with median ratings of 9 (N=69) and 10 (N=184) out of 10, respectively. Subjects were very satisfied with the PowerCel charger with median 9 out of 10 (N=171) (Table 2).

Professionals now have access to a new tool for checking the microphone's functionality: the listening check. This was rated as being very easy to use with a median score of 9 out of 10 (N=14). Fitting the microphone options was a task rated as easy with a median score of 7.5 out of 10 (N=20). A remote control, AB myPilot, is now available with the Naída CI, which offers status information and the options to change programs, volume and sensitivity settings. In addition, the ComPilot provides a wireless connectivity to accessories as well as remote control functions to adjust the processor for increased listening comfort. Use of the ComPilot requires the processor to be programmed with the ComPilot enabled and use of the AB myPilot requires the processor to be paired with the AB myPilot. Professionals rated the programming or pairing of these accessories as being easy with a median score of 8 out of 10 (N=15) (Table 2).

Table 2. Ease of use ratings on the Naída CI processor and accessories from CI users and professionals (amount of responses, median, minimum and maximum scores).

			Median		Minimum		Maximum	
	CI users	Professionals						
General ease of use	177	23	9	8	2	4	10	10
Attach/remove T-Mic 2 cover	66	19	7	5	1	1	10	8
Connect/Remove earhook/T-Mic 2-processor	88	23	7	6	1	1	10	10
Connect/Remove headpiece cable-processor	155	23	9	9	2	4	10	10
Connect/remove headpiece-cable	151	23	9	9	1	4	10	10
Connect/Remove battery-processor	184	23	10	9	1	5	10	10
Exchange disposable battery	69	18	9	7	3	2	10	10
PowerCel charger satisfaction	171	/	9	/	1	/	10	/
Volume control	122	23	9	9	1	4	10	10
Program button	159	23	9	8	1	4	10	10
Change mic cover	68	19	8	7	1	2	10	10
Listening check use	/	14	/	9	/	7	/	10
Microphone options fitting	/	20	/	7.5	/	2	/	10
AB myPilot or ComPilot pairing	/	15	/	8	/	4	/	10

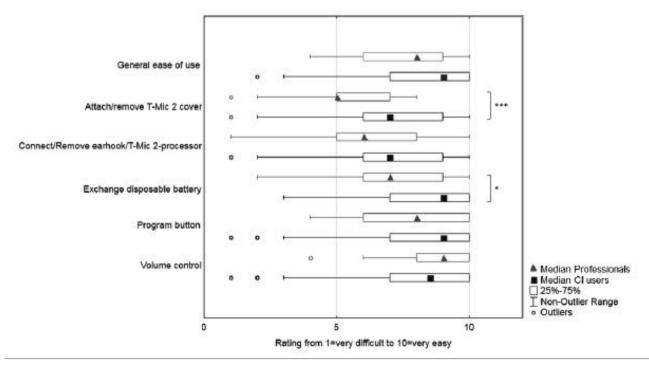


Figure 1. Distribution of ease of use ratings for tasks listed on the y-axis for CI users (in dark grey - square) and professionals (in light grey - triangle).



In order to analyze the ease of use questions by age, subjects were divided into 5 groups: [0-10]; [11-18]; [19-40]; [41-60]; >60 (NB: in the 0-10 group the majority ratings were from parents). There was no difference in the ratings across age groups, except for "connect/remove headpiece cable from the processor" (Kruskal Wallis H (4, n=146) = 11.1, P=0.03). Teenagers [11-18] rated this task statistically less easy than the [41-60] age group (Mann-Whitney U=27, N[11-18]=27 & median=8, N[41-60]=37 & median=10, P=0.003).

When comparing ratings between new CI users and existing CI users, there was no difference between median ratings (Mann Whitney U Test).

Usefulness of new functions and features

CI users reported on the usefulness of new functions and features of the Naída CI.

Seventy percent of subjects who rated the UltraZoom feature, rated it as being useful with ratings of 7 out of 10 or greater (N=90). Eighty-two of these respondents had also provided age information, allowing analysis of the data by age group. Only 4 subjects provided ratings in the [0-10] age group, so this group was excluded from the analysis. There was no difference in median values across the different groups (Kruskal-Wallis test).

Detailed analysis of the usefulness of QuickSync, DuoPhone and ZoomControl was not possible because only 13 (for QuickSync) and eight (for DuoPhone and ZoomControl) users answered questions about these features. Those subjects who did respond reported them as being very useful with median ratings of 9 out of 10 for QuickSync and 8 out of 10 for both DuoPhone and ZoomControl.

Both the internal alarms (N= 138, median=9/10, 86% rated 7/10 or over) and tri-coloured LED (N= 149, median=9/10, 74% rated 7/10 or over) were also found to be useful.

In addition, 80% of subjects rated the disposable battery option as being very useful (N=76, median=9/10).

Professional fitting practices

Professionals were asked to report on their current fitting practices. Twenty-three professional questionnaires were returned. Professionals were asked which processor type they would recommend for which patient groups and multiple responses could be given (Figure 2). The Naída CI was recommended for fitting in all populations. The number of recommendations of the Naída CI

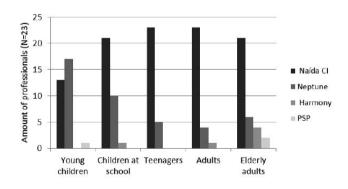


Figure 2. Recommendations of type(s) of processors per category of population.

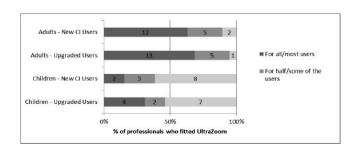


Figure 3. Percentage of professionals who fitted UltraZoom depending on the population.

processor was significantly higher compared to the other processor types in all groups ($\mathrm{Chi^2}$ P<0.05) except for young children, where there was a similar frequency of recommendations to the Neptune processor.

Professionals were asked about their past experience of fitting UltraZoom on the Naída CI processor. Among professionals who fitted adults, more than half of them fitted UltraZoom to all or most of this population. In contrast, in professionals fitting children, more than half of them never fitted UltraZoom in children (Figure 3). There was no difference in fitting practice between new and upgraded users.

Feedback on the bilateral features was limited. The bilateral functions were rated as easy to fit with median scores above 8 out of 10 (QuickSync: medi-

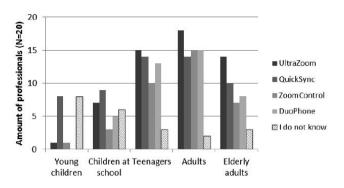


Figure 4. Recommendations on features fitting per category of population.

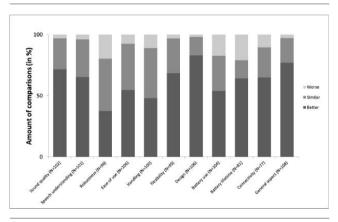


Figure 5. Comparison of the Naída CI processor to previous Advanced Bionics sound processors by CI users: percentage of worse, similar or better ratings per area.

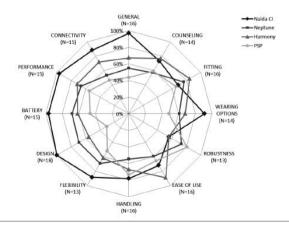


Figure 6. Ranking of Advanced Bionics sound processors in various areas by professionals, converted into a percentage (a score of 100% meaning that the processor has been rated first rank by all the respondents for this specific item).



an=8.5/10, N=10; ZoomControl: median=8/10, N=11; DuoPhone: median=8/10, N=10). However, they were rated as "Neutral" when asked how easy it was to counsel recipients on their use (median=6/10; N=11).

Professionals were then asked 'Which feature(s) would you advise for specific user categories?'. More than one answer could be given and an "I do not know" option was included. The results are shown in Figure 4. Among professionals who knew which features to fit, there was a statistically significant difference in fitting advice between the various categories of population (Chi²(4)=36.39, P<0.001) for all the features except QuickSync, which was recommended for all ages. As the age categories of the population increased, more professionals agreed on recommending UltraZoom, ZoomControl and DuoPhone. There was a tendency for the number of recommendations for these features to decrease in the elderly adult category, which was significant compared to the adult group for DuoPhone and ZoomControl (Chi²P<0.05). There was a large significant difference when comparing the young children group to the adult group for fitting UltraZoom, ZoomControl and DuoPhone: all, or almost all, of the professionals questioned would recommend these features to adults, whereas they would not to young children (Chi² P<0.001). In addition, when looking at these two populations, there was a statistically significant higher rating of "I do not know" for the young children compared to the adults $(Chi^2(1)=4.8, P=0.03).$

Comparison of the Naída CI processor to previous AB sound processor

Both the CI users and professionals were asked to compare the previous processor types to the new Naída CI. CI users were only required to make comparisons to their previous processor, but professionals were asked to compare as many of the processor types as they could.

CI users

Upgraded users were also asked to compare the Naída CI processor to their previous processor. Figure 5 shows the percentage of subjects who rated each aspect as being better (dark grey), similar (medium grey) or worse (light grey) with the Naída CI processor compared to their previous processor. Among the 110 respondents, 108 previously wore a Harmony and/or Auria BTE processor and 2 previously wore a CII BTE. The Naída CI was rated as similar or better by more than 79% of the subjects, for all areas. The areas of least satisfaction were for battery use and lifetime and robustness, with around 20% of subjects rating these as being worse with the Naída CI processor. The new design of the Naída CI processor was rated as being better by 83% of the subjects (the highest percentage among all the surveyed areas). For 92% of subjects, the new processor is at least as easy to use as their previous processor. When asked about their general view of the processor, 97% of the users rated the Naída CI to be the same or better than their existing processor, with 77% rating it as better.

Professionals

Some professionals had experience with all four processors and were thus able to rank the processors against each other for each of the aspects listed. Ratings were given with 1 = best processor / 2 = second best processor / 3 =third best processor / 4 = fourth best processor or "no answer", when there was no experience with that device. If several processors were similar in a specific area, they were ranked the same. A value was calculated for each processor and each aspect taking into account the ratings and the number of respondents. Figure 6 shows these values converted to a percentage for each aspect and each processor - a score of 100% meaning that the processor had been rated first rank by all the respondents for this specific item. The Naída CI was compared favourably with the other processors and was particularly preferred by professionals for its design, battery type options, performance, connectivity options, wearing options and from a general point of view. Indeed, all the respondents rated the Naída CI processor as first rank for its design, and all except two respondents ranked it first for its performance, battery type options and from a general point of view. Areas ranked with lower satisfaction among the professionals were fitting, robustness and ease of use. For fitting, the Naída CI was ranked behind the Harmony and Neptune processors and ranked similarly to the PSP. Robustness was ranked similarly to the Harmony and below both the bodyworn PSP and Neptune processors. The Naída CI was considered to be easier to use than the Neptune and PSP but less easy than the Harmony.

Discussion

The Naída CI was rated by the majority of users as being easy to use by both new CI users and those upgraded from an older device. The Naída CI sound processor was rated similarly by both CI users and professionals in all areas except for attaching/removing the T-Mic 2 cover and exchanging the disposable batteries. Indeed, CI users rated these tasks as easier to do than the professionals, likely because CI users have performed them many more times than the professionals, illustrating that familiarity is an important factor.

When comparing the ease of use results across age groups, there was no difference between the groups for most of the tasks. Even users who were older than 60 did not have an issue with manipulation of a small behind the ear device. Surprisingly, the only significant ease of use difference between groups was for the older group [41-60], who found connecting and removing the headpiece cable from the processor significantly easier than the teenagers [11-18]. However, for both groups this task was rated as being very easy to do with median ratings of 8 out of 10 for the teenagers [11-18] and 10 out of 10 for the [41-60] group.

The UltraZoom adaptive beamformer technology was rated as being useful by all age groups. However, only 90 users out of 186 rated this feature and only 4 ratings were obtained in the [0-10] years old category. This may be because not all users were fitted with UltraZoom at the initial fitting or they had not had the opportunity to try it before completing the questionnaire or would have benefitted from more counselling about the use of this feature. In addition, professionals reported that they would not fit features like UltraZoom, DuoPhone or ZoomControl in young children. All these features require the recipient to manually change the program on the processor depending on the situation and young children may not be able to make the change by themselves or be able to recognise the situation(s) in which they should use this feature. This requirement is particularly true for UltraZoom, which provides a benefit in specific situations where the speaker is in front of the CI user. The future development of automatic scene analysis functions might alleviate this problem as the settings will be changed automatically, depending on the incoming signal. A significantly higher amount of professionals did not know which features to fit for young children compared to adults. This confusion might be linked to a lack of consensus about the use of noise reduction programs/features for this population. There was also a tendency towards a reduction in the number of professionals recommending fitting of these features in the elderly adult category, which was statistically significant when compared to the younger adult group for DuoPhone and ZoomControl. Concerns about fitting these features may be similar to those concerns for the younger children age group, in that manual adjustment of the program in the correct situation is required. However, there is no evidence in this survey that would support this conclusion. These results show that in contrast to the survey by Rossi-Katz and Arehart, 2011,15 fitting practice was affected by age, both young and old. It also highlights the importance of professionals' training on these new and advanced features as well as the importance of counselling the cochlear implant user correctly. In order to support professionals, some European guidelines were developed by AB in consultation with the International Audiology Advisory Board. 16 In addition, the content of this article is a useful reference for both professionals who are, or will be fitting the Naída CI processor and its preliminary content was also presented to international conferences and communicated to professionals.

The Naída CI was recommended by professionals for fitting in all populations and there was no preference for fitting in one particular age group. However, for young children there was no significant difference between the recommendation of the Neptune or the Naída CI. The Neptune offers good robustness, nothing on the ear and waterproofness, which might be the reasons why it was also recommended for this age group.

Existing CI users compared the Naída CI processor to their previous processor very positively on most of the aspects surveyed. However, these results are affected by subject response bias towards the new product, but nonetheless the processor was compared less favourably to the older processors for the battery use, battery lifetime and robustness. The issues with battery life are likely to be improved through the selection of a higher capacity battery or the use of a new speech processing strategy called HiResTM Optima (also available with the Neptune and Harmony processors) which is designed to optimize battery life, while delivering the same performance as that of HiRes Fidelity 120.¹⁷ Not all users had been converted to this strategy at the time of the questionnaire. The comments on robustness have prompted modifications to the Naída CI design which have been made since the survey was conducted. The Naída CI benefited from reinforced headpiece cables, optimized battery connectors, and a further refined T-Mic 2 and earhook solution to provide a very robust and reliable system. With such design modifications and longer experience with the equipment, the robustness aspect might be rated differently if the survey was administered again.

When the professionals were asked to compare the Naída CI to other processors, the Naída CI was scored first for eight out of twelve of the features surveyed. The body worn Neptune and PSP processors were ranked better than the Naída CI and Harmony behind the ear processors for robustness, reflecting the more robust design features of a body worn device. Lack of familiarity with the new processor probably contributed to the lower rankings compared to the





Harmony for fitting and ease of use since the Naída CI processor offers more flexibility and more connectivity options than the Harmony. On the other hand, the Naída CI processor was highly preferred in general, for its design and also for its performance, which is enhanced by the new front-end features available. 12,13 With the large number of features and options available on the Naída CI, it could have been expected to contribute to increased difficulty in counselling recipients. However, counselling was found to be equivalent to the Harmony.

The results of the study must be considered in the context of its limitations. A non-standardized questionnaire was used, designed by Advanced Bionics and the ratings recorded were subject to a degree of response bias because a new product was being tested. This was a particular problem for the subjects who were upgraded to the newer technology, where a natural bias towards the new can be expected. Unfortunately, it was impossible to blind recipients to the type of processor they were using. A sample bias might also have been present as all the professionals and subjects had already chosen to use Advanced Bionics products and were thus happy with their usability. However, studies of this nature are important to highlight any issues or difficulties with a new product and to enable comparisons to be made across different groups.

Conclusions

This large multicentre evaluation showed high satisfaction with the new Naída CI Q70 processor from adults, children, experienced and new CI users, and professionals. Positive ratings were obtained for ease of use, comfort and usefulness of new functions and features. The majority of experienced CI users rated the Naída CI processor as being similar to or better than their previous processor in all the areas surveyed. The Naída CI was recommended by the professionals for fitting in all populations and there was no preference for fitting in one particular age group. However, fitting practices were influenced by age of the user. In particular, features like UltraZoom, ZoomControl and DuoPhone would not be fitted to very young children in contrast to adults. There was clearly uncertainty in how to approach fitting advanced features to some age groups from some of the professionals surveyed, emphasizing the need for further clinical research, experience and training in these areas.

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