Received: 3 March 2020 | Revised: 29 October 2020 | Accepted: 8 November 2020

DOI: 10.1111/coa.13672

ORIGINAL ARTICLE

WILEY

Treatment choice in single-sided deafness and asymmetric hearing loss. A prospective, multicentre cohort study on 155 patients

Mathieu Marx[1,2] | Isabelle Mosnier[3] | Christophe Vincent[4] | Nicolas-Xavier Bonne[5] | David Bakhos[6] | Emmanuel Lescanne[6] | Jonathan Flament[3,7] | Daniele Bernardeschi[3] | Olivier Sterkers[3] | Bernard Fraysse[1] | Benoit Lepage[8] | Benoit Godey[9] | Sébastien Schmerber[10] | Alain Uziel[11] | Michel Mondain[11] | Frédéric Venail[11] | Olivier Deguine[1,2]

[1]Service d'Otologie, Otoneurologie et ORL Pédiatrique, Hôpital Pierre-Paul Riquet, CHU Toulouse Purpan, France

[2]Brain & Cognition Research Centre, UMR 5549, Université Toulouse III, France

[3]AP-HP, GHU Pitié-Salpêtrière, Service ORL, Otologie, Implants Auditifs et Chirurgie de la Base du Crâne, Paris, France

[4]Service d'ORL, Hôpital Salengro, CHU Lille, France

[5]Inserm, CHU Lille, Service d'ORL, U1192 - PRISM, Univ. Lille, Lille, France

[6]Service d'ORL, Hôpital Bretonneau, CHU Tours, Tours, France

[7]Laboratoire Audika, Paris, France

[8]Unité de Soutien Méthodologique à la Recherche, Faculté de Médecine, Université de Toulouse, Toulouse, France

[9]Service d'ORL, Hôpital Pontchaillou, CHU Rennes, Rennes, France

[10]Service d'ORL, CHU Grenoble, La Tronche, France

[11]Service d'ORL, Hôpital Gui de Chauliac, CHU Montpellier, Montpellier, France

Correspondence
Mathieu Marx, Service d'Otologie, Otoneurologie et ORL pédiatrique, Hôpital Pierre-Paul Riquet, Place du Dr Baylac, 31059 Toulouse cedex, France
Email: marx.m@chu-toulouse.fr

Funding information
Ministère de la Santé, Grant/Award Number: 13 7053 10

Abstract

Objectives: To describe the treatment choice in a cohort of subjects with single-sided deafness (SSD) and asymmetric hearing loss (AHL). To assess the reliability of the treatment trials.

Design: In this national, multicentre, prospective study, the choice of subjects was made after two consecutive trials of Contralateral Routing Of the Signal (CROS) hearing aids and a Bone Conduction Device (BCD) on a headband. Subjects could proceed with one of these two options, opt for cochlear implantation or decline all treatments.

Setting: Seven tertiary university hospitals.

Participants: One hundred fifty-five subjects with SSD or AHL fulfilling the candidacy criteria for cochlear implantation, with or without associated tinnitus.

Main outcome measures: After the two trials, the number of subjects choosing each option was described. Repeated assessments of both generic and auditory-specific quality of life were conducted, as well as hearing assessments (speech recognition in noise and horizontal localization).

Results: CROS was chosen by 75 subjects, followed by cochlear implantation (n = 51), BCD (n = 18) and abstention (n = 11). Patients who opted for cochlear implantation had a poorer quality of life ($P = .03$). The improvement of quality of life indices after each trial was significantly associated with the final treatment choice ($P = .008$ for generic indices, $P = .002$ for auditory-specific indices). The follow-up showed that this improvement had been overestimated in the CROS group, with a long-term retention rate of 52.5%.

Conclusions: More than one third of SSD/AHL subjects are unsatisfied after CROS and BCD trials. Repeated quality of life assessments help counselling the patient for his/her treatment choice.

Key points

- In this large cohort of SSD/AHL subjects, 50% chose to be treated by CROS hearing aids and one third by cochlear implantation.
- The treatment choice was mainly driven by subjective factors, measurable by repeated quality of life evaluations.
- The quality of life improvement reported after the CROS trial was overestimated when considering the same measurements at 6 months after the trial.
- In contrast, the improvement reported after the BAHA trial seemed more reliable.
- Long-term retention and usage rates are the key indices to assess treatment effectiveness in SSD/AHL, higher after CI (>80%) than with bone conduction (64%) or CROS hearing aids (52.5%).

1 | INTRODUCTION

Single-sided deafness (SSD) is a condition affecting approximately 1% of the adult population.[1] Its prevalence includes subjects with congenital and acquired SSD, due to a variety of aetiologies including congenital Cytomegalovirus infection or idiopathic sudden sensorineural hearing loss in adults. Strictly defined , SSD refers to a unilateral profound deafness with a pure-tone average (PTA) in the better ear ≤ 30 dB HL, while asymmetric hearing loss (AHL) is those subjects with a PTA in the better ear of between 70 and 30 dB HL.[2,3] The disability common to these hearing deficits is the disruption of binaural hearing, leading to difficulties in localising sound sources and understanding speech in noisy environments. Some patients may also suffer severe tinnitus, which was for instance the main symptom targeted in the first report on cochlear implantation in a series of SSD subjects.[4] Since then, several valuable studies have proposed SSD and AHL as extended indications for cochlear implants (CI), underlining the fact that it was the only treatment likely to restore binaural hearing.[5-7] However, SSD and AHL are heterogeneous conditions meaning several options should be considered other than CI. Contralateral Routing Of Signals (CROS) is a different approach and consists of transferring the sound coming in to the poor ear to the better ear, using either CROS hearing aids with Bluetooth or bone conducting devices such as the Bone-Anchored Hearing Aid (Cochlear Ltd, Sydney) or Ponto (Oticon medical, Askim).

Another characteristic of CROS hearing aids and bone conducting devices is that patients can try them to evaluate their effect, and recent consensus papers thus recommended the trial of both devices before considering cochlear implantation. But the definition of a trial failure remains unclear, simply relying on the rejection of the device after a period of testing for which the duration varies. Several studies attempted to identify the candidacy criteria for rehabilitation by bone conducting devices in SSD subjects, taking into account the outcomes of a preliminary trial. Among them, Pennings et al[8] stated that only 50% of SSD subjects interested in bone conduction device (BCD) treatment after a first short trial within the clinic eventually proceeded to surgery. This rate approximated 30% according to Saroul et al[9] and mostly involved SSD subjects where hearing benefits can be demonstrated during spatialised assessments of speech recognition in noise. The high rate of device rejection implies that a significant proportion of SSD subjects remain untreated and that abstention is de facto an option in the follow-up of these patients.

The first part of this national, prospective, multicentre study aimed to describe the treatment choice between CROS hearing aids, BCD, cochlear implantation and abstention in a large population of SSD/AHL adult subjects. Our second objective was to explore the putative audiological measures which might contribute to this choice. Finally we evaluated long-term usage of the CROS and BCD for those who chose these options.

2 | METHODS

2.1 | Design & participants

This was a national multicentre prospective study (see Figure 1 and [10] for the study protocol). Adult participants (age > 18) were recruited in 7 tertiary referral centres in France. We included participants with unilateral, severe-to-profound hearing loss, measured using pure-tone audiometry (PTA) and confirmed by the absence of auditory brainstem responses. We excluded patients with SSD/AHL due to a vestibular schwannoma or disrupted cochlear anatomy, because such participants were not potential candidates for a CI. To capture the heterogeneity of this population, we did not exclude patients on the basis of duration of deafness, or associated tinnitus, and accepted hearing thresholds in the better ear of between 0 to 60 dB HL.

2.2 | Initial trials

All participants underwent an initial trial of the Phonak Target™ 3.0 CROS systems (Sonova Holding AG, Stäfa) fitted by an experienced audiologist, using software provided by the company. In cases of AHL hearing loss in the better ear was corrected. This trial lasted for 3 weeks.

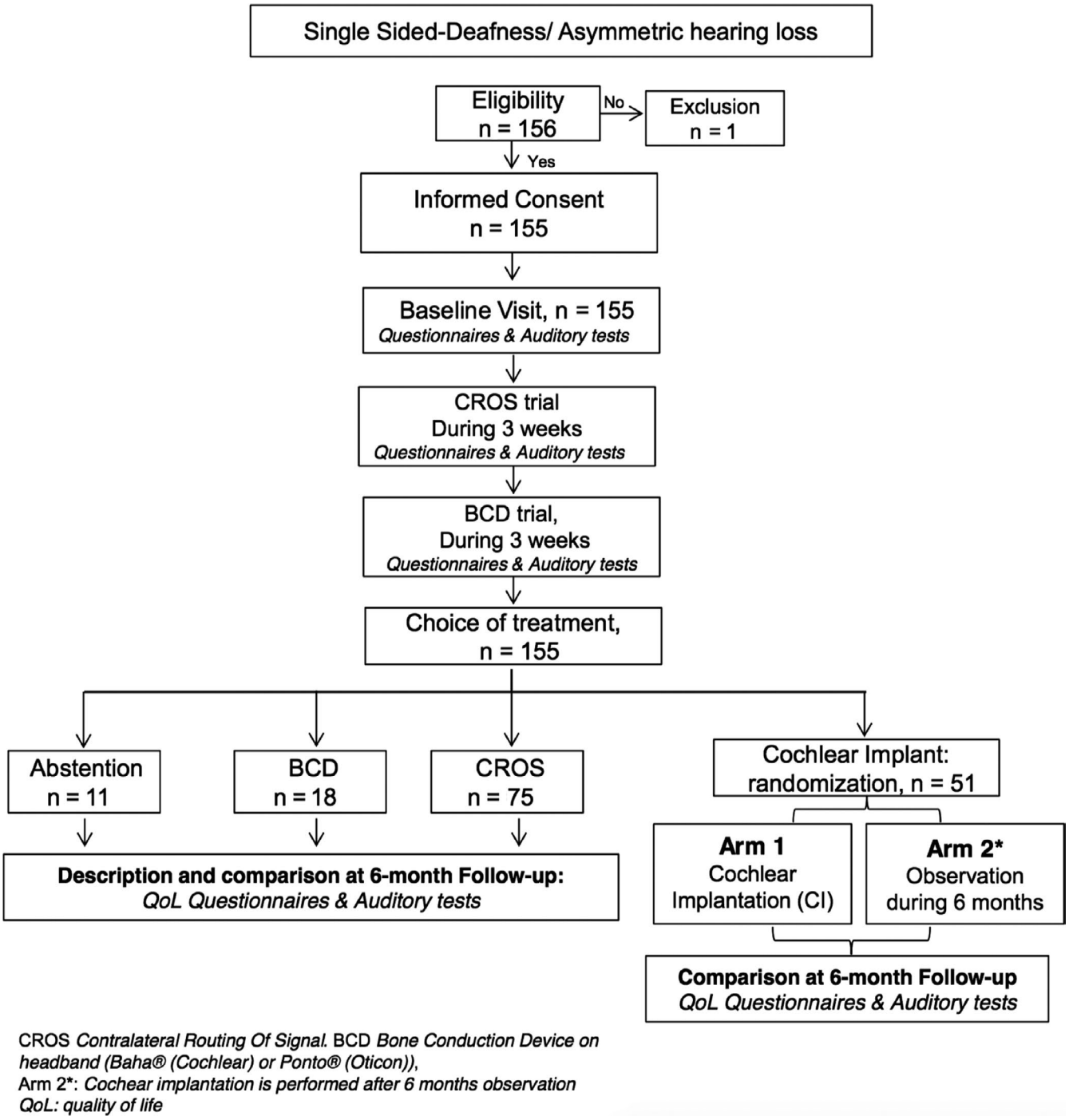

FIGURE 1 Flow chart of the study with number of subjects included, allocated to intervention and included in the statistical analysis

Subsequently, all participants underwent a trial with either a Baha BP 110® (Cochlear Ltd) or Ponto® (Oticon medical) BCD fitted on a headband. The processor was fitted by an experienced audiologist following the company's guidelines. This trial also lasted for 3 weeks.

We measured audiological performance using each device as the Root Mean Square (RMS) for localisation error, and speech recognition in noise using the FrMatrix test. The FrMatrix test[11] is a standardised and adaptive test which measures the signal-to-noise ratio allowing 50% of correct recognition (SNR50). It was performed in three different spatial conditions: signal to the poor ear, noise to the better ear (SpeNbe), signal and noise mixed in front of the subject (S0N0), signal to the better ear and noise to the poor ear (SbeNpe).

2.3 | Final choice of treatment

After the trials, participants were given the option to:

1. Abstain from any further treatment

2. Return to using a CROS hearing aid
3. Return to using a bone conducting device, which was then surgically implanted
4. Cochlear implantation

For participants selecting cochlear implantation, we performed an open-label randomised controlled clinical trial of two parallel arms: Observation for 6 months followed by CI, versus immediate CI.

2.4 | Outcome variables

We recorded how many participants chose each final treatment among the different options. We compared each group to variables that could influence this choice, including:

- audiological factors: deafness side, PTA in the better ear, severity of tinnitus using a Visual Analogue Scale (VAS), measures of localisation and speech in noise performance during the initial trials
- quality of life (QoL) assessed using a generic questionnaire (EuroQol-5D, EQ-5D) and an auditory-specific questionnaire (Nijmegen Cochlear Implant Questionnaire, NCIQ).

All subjects were also interviewed between 45 and 67 months after final choice treatment to assess use and long-term retention of the treatment chosen. They indicated if the device chosen was used daily, occasionally or not at all.

2.5 | Analyses

Quantitative variables were described as mean ± standard deviation. Comparisons between groups for audiological factors and QoL assessments were performed using the Kruskal-Wallis test for continuous variables, and the Chi-square or Fisher's exact test for categorical variables. Outcomes obtained after each trial (CROS then BCD) were described and compared to their baseline values using paired t tests. To estimate and compare the evolution of the outcomes at each trial (CROS then BCD), longitudinal linear mixed models were applied, adjusted for baseline values and "final choice group"×"trial time" interactions in the different groups. Finally, the outcomes of the CROS and BCD trials was assessed using Bland & Altman's method which determined limits of agreement between outcomes obtained just after the trial and final outcomes 6 months after the corresponding treatment.

TABLE 1 Demographic characteristics per group

	Abstention n = 11	CROS n = 75	BCD n = 18	RCI n = 51
Sex	8M/3F	35M/40F	7M/11F	21M/30F
Mean age (SD)	53.1 (20.2)	51.9 (13.8)	49.7 (14.5)	55.1 (11.4)
Deafness side	4R/7L	39R/36L	9R/9L	30R/21L
Aetiology				
Idiopathic sudden snhl	1	24	7	23
Meniere's disease	1	8		2
Labyrinthine trauma		9	1	3
Labyrinthitis		4	4	3
Unknown	9	30	6	20
Deafness duration				
<3 y	2	33	9	25
Between 3 and 5 y	1	6	2	2
Between 5 and 10 y	1	8	1	6
Between 10 and 30 y	6	15	2	13
>30 y	1	12	4	5
Missing data		1		
PTA better ear dB HL (SD)	27.5 (22.2)	26.8 (20.2)	21.8 (16.7)	29.2 (17.5)
PTA poor ear dB HL (SD)	106.8 (19)	106.9 (26.1)	110.9 (17.2)	101.3 (20.6)

Abbreviations: dB HL, decibel hearing level; F, female; L, left; M, male; PTA, pure-tone average; R, right; SD, standard deviation; SSNHL, sudden sensorineural hearing loss.

3 | RESULTS

3.1 | General description

One hundred fifty-five subjects were included in this study (71 males, 84 females). PTA was 105.4 dB HL (±22.9) in the poor ear and 27.1 dB HL (±19) in the better ear. 67.1% (104/155) of subjects were considered as SSD subjects (PTA ≤ 30 dB HL) and 32.9% (51/155) of subjects as AHL subjects (PTA between 30 and 60 dB HL). The aetiology was unknown in more than 40% of cases, and idiopathic sudden sensorineural hearing loss in 34% of subjects (see Table 1 for others). 45% of subjects had a deafness duration < 3 years while 38% had deafness for more than 10 years.

At the end of the two trials (see Figure 1), 75 subjects opted for CROS hearing aids (CROS group), 18 for BCD (BCD group), and 51 were randomised to the cochlear implant (RCI group). 11 subjects declined all options (abstention group). There was no significant difference between groups in terms of aetiology ($P = .16$), deafness duration ($P = .49$), deafness side ($P = .58$), hearing thresholds in the better ear ($P = .32$), or tinnitus severity (measured on VAS severity, $P = .77$).

Localisation accuracy was not different between groups (mean RMS error ranging from 62.1° (±20.4) in the abstention group to 76.8° (±24.1) in the BCD group , $P = .11$). Only one baseline difference was shown for speech recognition in noise scores, with significantly poorer mean SNR50 obtained in the randomised group (0.3 dB ± 10.9) compared to BCD (−5.5 dB ± 11.1) and abstention (−5.2 dB ± 6.5) groups ($P = .04$) under SbeNpe conditions. Likewise, the mean NCIQ score was significantly poorer in the group RCI (51.8 pts ± 15.5) compared to the abstention group (68.5 pts ± 14.2; $P = .03$) with intermediate values in CROS (57 points (pts) ±16.9) and BCD (58.5 pts ± 14.8) groups. The analysis of the global QoL, assessed using a VAS in the EQ-5D questionnaire, showed poorer values in the RCI group (67.5 ± 21.6) compared to groups CROS (75.8 ± 18.5) and BCD (84.2 ± 10.3) ($P = .005$). The results for the binaural hearing tests, QoL measurements and their evolution are respectively summarised for the four different treatment groups in Tables 2 and 3.

3.2 | Reliability of BCD and CROS trials

The evolution of the different criteria after the CROS trial and BCD trial was compared according to the treatment group, using longitudinal mixed models to investigate further the importance of these two trials in the decision to opt for a treatment. No significant difference was found for SNR50 or localisation accuracy modifications, whatever the measurement. For instance, the evolution of SNR50 in SpeNbe after CROS trial was not better in group CROS (−6.1 dB ± 13.3) than in other treatment groups (−3 ± 3.2 in the abstention group; −9.7 ± 31.1 in the BCD group; −5 ± 5.5 in the RCI group). In contrast, the scores for generic (EQ-5D) and auditory (NCIQ) QoL were more improved in the CROS group after the CROS trial (respectively + 7.89, 95% confidence interval 95%CI [4.09; 11.69] and +12.1, 95%CI [9.47; 14.72] and in the BCD group after the BCD trial (respectively +9.86, 95%CI [4.44; 15.28] and +10.79,

TABLE 2 Evolution of hearing outcomes for speech recognition in noise and localisation, that is mean scores (standard deviation), at baseline, after CROS and after BCD trials, according to the treatment group

			Final treatment choice			
			Abstention	**CROS**	**BCD**	**RCI**
Outcomes baseline and after trials	Baseline SNR50 (dB)	SpeNbe	4.9 (11.9)	5.3 (15.3)	7.2 (34.2)	4.5 (9.1)
		S0N0	5.6 (24.7)	0.6 (8.4)	3.7 (26.6)	1.3 (6)
		SbeNpe	**−5.2 (6.5)**	−2 (10.5)	**−5.5 (11.1)**	**0.3 (10.4)**
	Baseline Localisation accuracy	Error rate (%)	64.3 (27)	63.3 (21.2)	61.1 (19.7)	70.2 (16.6)
		RMS error (°)	62.1 (20.4)	65.8 (24.5)	76.8 (24.1)	74.7 (20.7)
	SNR50 after CROS trial (dB)	SpeNbe	−1.5 (3.3)	−0.3 (6.9)	−2.5 (4.7)	0 (6.4)
		S0N0	−0.9 (4.4)	−0.6 (5.8)	−2.1 (3.8)	−0.2 (3.6)
		SbeNpe	−2.8 (4.4)	−2 (6.8)	**−5.6** (4.2)	**−1.1** (5.5)
	Localisation accuracy after CROS trial	Error rate (%)	68.4 (26.4)	69.3 (20.6)	61.9 (26.1)	71 (15.2)
		RMS error (°)	69.3 (29.8)	74 (23.2)	78.4 (31.5)	79.4 (19.2)
	SNR50 after BCD trial (dB)	SpeNbe	1.9 (6)	2 (8.3)	−2.5 (5.9)	1.3 (7.1)
		S0N0	−1.3 (5.6)	−0.6 (5.7)	**−3.4 (3.1)**	**−0.4 (3.9)**
		SbeNpe	−3.6 (7.6)	−2.3 (9.8)	−7 (5.3)	−2.6 (6.8)
	Localisation accuracy after BCD trial	Error rate (%)	64.6 (27.1)	63 (21.6)	52.8 (28.2)	69.2 (16)
		RMS error (°)	66 (34.9)	64 (27)	63.4 (31.3)	76.9 (21.1)

Note: Significant differences between groups are indicated in bold.

TABLE 3 Evolution of quality of life measurements, that is mean scores (standard deviation), at baseline, after CROS and after BCD trials, according to the treatment group

			FINAL TREATMENT CHOICE			
			Abstention	CROS	BCD	RCI
Outcomes baseline and after trials	Baseline QoL measurements	EQ-5D score	84.4 (21.7)	76.7 (26.4)	83.8 (18.1)	73.6 (24.5)
		EQ-5D VAS	67.2 (16.2)	75.8 (18.5)	84.2 (10.3)	67.5 (21.6)
		NCIQ	68.5 (14.2)	57 (16.9)	58.5 (14.8)	**51.8 (15.5)**
		VAS tinnitus severity	37.1 (27.3)	47.9 (34)	43.4 (40.2)	47.8 (36.2)
	QoL measurements after CROS trial	EQ-5D score	90.9 (14.2)	85.2 (21.5)	84.6 (17.7)	75.8 (27.8)
		EQ-5D VAS	**70.5** (13.5)	80.4 (15)	**85** (13.3)	72.5 (19.4)
		NCIQ	**70** (15.4)	68.8 (13.1)	68.5 (13.5)	**56.1** (18.7)
		VAS tinnitus severity	36.7 (26)	37.2 (34.5)	34.1 (39.3)	46.4 (36.7)
	QoL measurements after BCD trial	EQ-5D score	86.7 (16.6)	78.3 (25.5)	**90.9 (17.4)**	**76.6 (24.9)**
		EQ-5D VAS	**65.9 (24.6)**	75 (20.9)	**87.9 (10.7)**	69.8 (19.6)
		NCIQ	**73.6 (11.9)**	60.9 (15.2)	68.7 (13.7)	**55.1 (17.9)**
		VAS tinnitus severity	45 (27.6)	46 (33.4)	34.1 (37)	44.6 (37.2)

Note: Significant differences between groups are indicated in bold.

95%CI [5.71; 15.87] (P = .008 for EQ-5D and 0.002 for NCIQ, see Figure 2). In the RCI group, there was no significant evolution of QoL after CROS or BCD trial neither for EQ-5D (respectively +2.31, 95%CI [−3.31; 7.92] and +4.36, 95% CI [−1.39; 10.1]) nor for NCIQ (respectively +3.82, 95% CI [−0.66; 6.98] and +2.91, 95% CI [−0.28; 6.11]). Likewise, tinnitus severity did not improve across trials in the RCI group (−1.22, 95% CI [−7.09; 4.65] after CROS trial and −2.92, 95% CI [−8.83; 2.99] after BCD trial).

Bland & Altman's method was then applied to NCIQ measurements to assess the agreement between the outcomes obtained just after CROS and BCD trials, and those obtained 6 months after the treatment had been chosen. Among subjects who chose CROS, the final NCIQ improvement at 6 months post-treatment was significantly lower than that observed just after the CROS trial with a mean difference of −4.5 pts (95%CI [−7.8; −1.3]). Conversely, the NCIQ improvement measured 6 months after treatment by a BCD was comparable to the improvement measured just after the BCD trial with a mean difference of 1.4 pts (95% confidence interval [−5.2; 8]).

3.3 | Long-term retention and usage

All subjects were contacted between 45 and 67 months after the treatment choice (mean: 58 months ± 4.4) to assess the use of the corresponding device. One hundred and twenty one subjects were interviewed (11 in the abstention group, 59 in the CROS group, 14 in the BCD group and 37 in the RCI group). In the CROS group, 19 (32.2%) and 12 subjects (20.3%) respectively reported daily or occasional usage of the device, while 28 participants (47.5%) abandoned the treatment. For BCD, 6 subjects (42.9%) reported a daily use of the device, 3 subjects an occasional use and 5 (35.7%) discontinued the treatment. In the RCI group, 28 subjects (75.7%) used their CI on a daily basis, 2 subjects reported occasional usage and the device was not used by 7 subjects (18.9%).

4 | DISCUSSION

Our study provides a prospective overview of hearing performance, QoL and treatment choices in a large cohort of SSD/AHL subjects. In their recent cross-sectional study on more than 160 000 subjects with moderate-or-worse unilateral hearing loss, Golub et al[1] reported that only 4.2% of them used any type of hearing aid. Interestingly, more than two thirds of these subjects considered their global hearing as excellent or only slightly impaired. However, subgroups of this heterogeneous population report more frequent and severe handicap and patients with associated incapacitating tinnitus probably experience the most severe consequence of SSD or AHL.[4,12] Likewise, up to 86% of subjects report hearing handicap following idiopathic sensorineural hearing loss.[13] In our study, patients who chose cochlear implantation probably experienced more severe handicap than patients who opted for another treatment. Although there was no significant baseline difference between groups in terms of tinnitus severity, aetiology or

binaural performance, this was demonstrated by the poorer scores for QoL, using both generic (EQ-5D) and auditory-specific (NCIQ) indices. NCIQ captures a global hearing disability, which made our participants choose CI when it was too important.

4.1 | Importance of CROS and BCD trials

Such trials are recommended in the assessment of SSD/AHL patients[2,3] and our results are in agreement with previous literature on their relevance. Kompis et al[14] and Desmet et al[15] assessed retrospectively different factors which might contribute to the decision to opt for or decline a BCD in SSD. In a similar way to our study, there was no association with the duration and aetiology of the deafness, nor was any audiological measurement, and importance of subjective benefit was emphasised. Indeed, we demonstrated that the choice to opt for a BCD or CROS was associated with greater improvements in QoL after the corresponding trial. A recent prospective study showed that SSD patients who finally proceeded to cochlear implantation showed little binaural benefit from CROS and BCD trials.[16]

Successive trials of CROS and BCD on a headband and repeated QoL assessments would therefore help in counselling the patient on his/her decision. However, our 6-month and long-term results demonstrate that by contrast to the BCD trial, the benefit experienced after the CROS trial was significantly overestimated. This should also be taken into account when counselling patients.

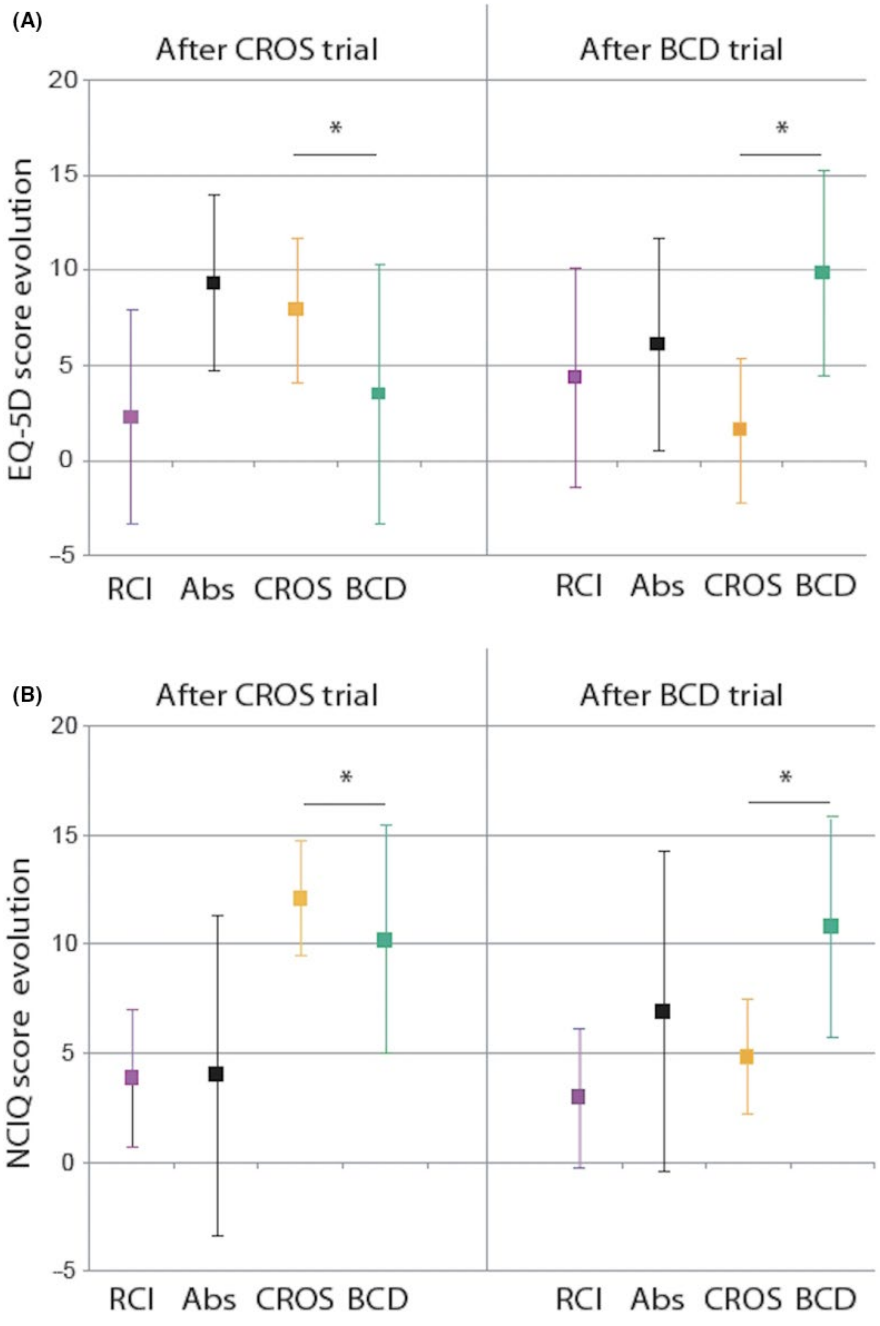

FIGURE 2 Comparisons of EQ-5D scores evolution (A) and NCIQ scores evolution (B) after CROS trial and after BCD trial according to the treatment group. *Indicates significant differences between groups CROS and BCD

4.2 | Biases and limitations

Heterogeneity is an intrinsic characteristic of SSD/AHL population and was important in our subjects, in terms of duration of hearing loss, hearing status of the better or severity of tinnitus. The fact that all the costs were covered by the programme reduces the bias due to the lack of reimbursement, which has been identified as a factor limiting the choice of a BCD in SSD.[15]

5 | CONCLUSION

In this large population of patients with SSD or AHL, almost 50% of subjects opted for treatment by CROS hearing aids while cochlear implantation was chosen in approximately one third of cases, with respective long-term retention rates of 52.5% and 81%. The choice of treatment was mainly driven by subjective factors which should be taken into account during the assessment period of these patients using repeated quality of life evaluations.

ACKNOWLEDGEMENTS

This study was financed by the French Ministry of Health (tender for research focusing on medical costs PRME2013 number 13 7053 10). We thank Ms Soumia Taoui for her precious help in coordinating all the centres and the numerous institutions involved. We are grateful to all the participants who took part in this study and wish to extend our sincere thanks to the collaborating clinical teams, research associates and audioprosthesists at the University Hospitals of Toulouse, Paris, Lille, Montpellier, Tours, Rennes and Grenoble.

AUTHORS CONTRIBUTION

MM, BL, OD and BF designed the study. MM lead author responsible for manuscript draft. BL author responsible for statistical analyses. All other authors included participants to the study and all authors provided significant inputs to the first versions of the manuscript. All read and approved the final manuscript.

ETHICAL APPROVAL

This study was approved by the "South West and Overseas" Ethics committee and by the National Agency for of Drug Safety in May 2014 (n°2014-A00533-44).

DATA AVAILABILITY STATEMENT

The datasets generated and/or analysed during the current study are available from the corresponding author on reasonable request.

ORCID

Mathieu Marx https://orcid.org/0000-0001-8295-8885
Isabelle Mosnier https://orcid.org/0000-0003-0458-4827
David Bakhos https://orcid.org/0000-0003-1417-5082

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How to cite this article: Marx M, Mosnier I, Vincent C, et al. Treatment choice in single-sided deafness and asymmetric hearing loss. A prospective, multicentre cohort study on 155 patients. *Clin Otolaryngol*. 2021;46:736–743. https://doi.org/10.1111/coa.13672