Benefits of a contralateral routing of signal device for unilateral Naída CI cochlear implant recipients

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1. Abstract

Purpose: Many bilaterally deaf adults are only able to receive one cochlear implant (CI), resulting in suboptimal listening performance, especially in challenging listening environments. Adding a contralateral routing of signal (CROS) device to a unilateral CI is one possibility to alleviate these challenges. This study examined the benefit of such a CROS device.

Methods: Thirteen adult subjects with at least 6 months of CI use, and no or limited benefit of a hearing instrument in the contralateral ear were included in the study. The perceived benefit of a CROS device in everyday listening environments was evaluated up to one year after initial fitting using several questionnaires. Speech intelligibility performance was determined using the French matrix sentence test in quiet and in two speech-in-noise setups and was followed for three months after CROS fitting.

Results: Subjects indicated high satisfaction with the practical usability of the CROS device and long-term device retention was high. Perceived benefits in everyday listening environments were reported. Formal speech intelligibility tests revealed statistically significant median improvements of 6.93 dB SPL (Wilcoxon $Z = 2.380$, $p = 0.017$) in quiet and up to 8.00 dB SNR (Wilcoxon $Z = 2.366$, $p = 0.018$) in noise. These benefits were accessible immediately without a need for prolonged acclimatization.

Conclusions: Subjective satisfaction and device retention as well as speech intelligibility benefits in quiet and in noise prove the CROS device to be a

valuable addition to a unilateral CI in cases of bilateral deafness where bilateral implantation is not an option.

2. Introduction

Cochlear implantation has become the standard auditory rehabilitation for adults and children with bilateral severe to profound hearing loss. Although several studies show the benefits of bilateral cochlear implantation with respect to sound localisation and listening in noise [1–5], individual results vary and the few available cost-utility analysis in adult recipients reports provide insufficient evidence to draw definite conclusions [6, 7]. Consequentially, bilateral implantation, especially in adults, is currently not funded in many healthcare systems. Therefore, many bilaterally deaf adults receive only one cochlear implant (CI). Even if bilateral implantation is reimbursed in adults, medical reasons might prevent implantation of the second side. Additionally, patients may choose not to undergo a second CI surgery, for example because they are concerned about surgery risks or because they wish to preserve that ear for future treatment options.

Irrespective of the reason preventing the second implantation, these bilaterally deaf unilaterally implanted subjects will continue to experience limitations due to the head shadow effect. Audibility of sound sources located away from the implanted ear is reduced resulting for example in impaired speech intelligibility in noise and reduced awareness of the surrounding sounds.

To alleviate these difficulties, one treatment option is a contralateral routing of signal (CROS) device, consisting of a microphone placed on the non-hearing/ implanted ear. Signals from that side are picked up and transmitted to the hearing/implanted side.

While long established in the hearing aid community [8], CROS devices in combination with unilateral CIs have only recently been investigated [9–18]. These studies consistently demonstrated a speech intelligibility benefit provided by the CROS device when the target speech source is located on the side of the non-implanted ear. When noise is located on the side of the non-implanted ear, a decrease in speech intelligibility was observed, the degree of which varies depending on the exact test setup.

In addition to acute speech intelligibility testing, chronic data have been collected, with a maximum take home of two weeks. While Weder [14] did not show a significant perceived improvement after chronic trials, a subjective benefit was observed in other studies on the Abbreviated Profile of Hearing Aid Benefit (APHAB, [19]) [10,11], in the Speech subscale of the abbreviated Speech Spatial and Qualities of Hearing Scale (SSQ12, [20]) [16] and in the Spatial subscale of the Speech Spatial and Qualities of Hearing Scale (SSQ, [21]) [10]. However in the Guevara study which evaluated a CROS device with a wire connection [11], only two of the eight subjects were still using their CROS device after six months, citing difficulties in noisy environments and trouble with the connecting wire.

The Phonak Naída Link CROS device investigated in the current study provides a wireless solution, designed to improve wearing comfort. Additionally, the device carries a mute button to silence input from the CROS side in noisy listening environments. Both features have previously been reported as useful

enhancements to the tested prototype devices [11, 13, 14]. The device can be used with the Advanced Bionics Naída CI Q70 and Q90 sound processors.

Our study focusses on the long-term evaluation of perceived everyday benefits of using the CROS device. Subjects were followed closely for 3 months after fitting of the CROS device using measures of real life benefit and subjective satisfaction as well as repeated speech intelligibility testing. A one-year follow-up questionnaire evaluated the long-term retention rate and satisfaction with the CROS device.

3. Materials and Methods

A prospective, single centre, within-subjects repeated-measures design was chosen for this study. ') v

3.1. Study Population

Thirteen adult subjects were identified from the clinic's database. All subjects were implanted with an Advanced Bionics CII or HiRes90k cochlear implant for at least six months and had used the Naída CI Q70 sound processor for at least three months prior to testing. Three subjects clinically used a hearing aid in the contralateral ear, with limited benefit (defined as < 20% monosyllabic words in quiet). Two subjects were implanted in the contralateral ear but did not use the second CI due perceived to lack of benefit. Detailed subject information is provided in table 1.

3.2. Device Fitting

The most recent Advanced Bionics sound processors, the Naída CI Q70 and Q90, have the ability to communicate wirelessly with another Naída CI processor, or with some Phonak hearing instrument models, including a CROS device. The Naída Link CROS device consists of a microphone, radio transmitter and battery worn on the unilateral CI recipient's non-implanted ear. The microphone signal from the CROS device is transmitted wirelessly to the Naída CI sound processor and mixed with the microphone signal from the implanted side with a mixing ratio of 50:50 before being coded by the sound processor.

In addition to the CROS device, a loaner Naída CI processor was used for the duration of the study. The loaner sound processor was fitted with each subject's clinical program, according to the clinic's standard fitting routine and no changes were made to the fitting parameters. The Advanced Bionics SoundWave 3.1 fitting software was used, which allows the activation of a HiBAN (Hearing Instrument Body Area Network) link between the CI processor and the Naída CROS device. The CROS device is an out-of-the-box solution and works automatically with the Naída CI processor without the need for any additional fitting. Subjects were counselled on use of the mute button which allows them to easily disable input from the CROS device in situations where it would enhance unwanted noise rather than speech.

3.3. Subjective evaluation

Three questionnaires were used to record each subject's self-assessment of their hearing abilities as well as their satisfaction with the CROS device:

1) The Abbreviated Profile of Hearing Aid Benefit (APHAB; [19]), a 24-item self-assessment inventory, requires subjects to report the amount of trouble they experience with communication in various everyday situations. The APHAB includes four subscales: Ease of communication (EC), Reverberation (RV), Background noise (BN), and Aversiveness (AV). Scores are given on a scale from A (I always experience this) to G (I never experience this). A percentage score from 1% to 99% is assigned to each category to yield a mean percentage for each subsection.

2) The abbreviated Speech Spatial Qualities Questionnaire (SSQ12, [20]) requires subjects to rate their listening abilities on a Likert scale from 1 (not at all) to 10 (perfectly). The SSQ12 includes three sub scales relating to aspects of speech, spatial and other qualities of hearing.

3) An adapted version of the Auditory Performance and Satisfaction Scale for Single-Sided Deafness (APS-SSD, [18, 22]) focuses on specific situations encountered in real life where a CROS device may be beneficial, grouped into three categories: hearing at home, hearing at work or school, and hearing in social situations. Each situation is rated on a scale from 0 (Can function fine) to 6 (Cannot function at all). It additionally contains a category on the satisfaction with and usability of the CROS device (see Electronic Supplementary Material).

3.4. Speech perception tests

Speech intelligibility was measured in quiet and noise in a sound treated room using the French Matrix test (Framatrix, Auritec, Hamburg, Germany, [23]). Subjects were asked to repeat semantically unpredictable sentences with a fixed structure: name, verb, number, common name, color. Prior to testing, at least one practice list of 20 sentences for testing in quiet, and two practice lists for testing in noise were presented to the subject to avoid training effects. For testing in quiet, the speech recognition threshold (i.e. speech level required for 50% word intelligibility) was measured in dB SPL by adaptively adjusting the signal level. Speech was presented from - 90° azimuth, on the CROS side. For testing in noise, the speech reception threshold (SRT; i.e. signal-to-noise-ratio (SNR) required for 50% word intelligibility) was measured in dB SNR by adaptively adjusting the signal level while stationary speech-shaped noise was fixed at 65 dB. Noise was presented from + 90° azimuth on the CI side, while speech was presented either from – 90° azimuth (CROS side) or from 0° azimuth (front). The two conditions were tested in random order. All loudspeakers were positioned at 1m distance from the subject's head. In all test conditions, subjects were tested with and without the CROS device in random order. Lower speech recognition thresholds as well as lower SRTs indicate better performance.

3.5. Measurement schedule

Subjects were invited to the clinic for four appointments. An overview of the study schedule is provided in table 2. At baseline, all subjects received a loaner Naída CI processor, fitted with their clinical everyday program(s), and the CROS device. Subjects were tested in quiet and noise with the Naída CI processor with and without the CROS device at the baseline, 1 month and 3 months appointments. The CROS device was removed at the 3 months appointment and subjects used the Naída CI processor only for a further two weeks. Subjects were asked to complete questionnaires at each visit regarding their recent listening configuration (Naída CI processor alone or with the CROS device). At the last visit, the loaner Naída CI processor and the CROS device were returned and subjects were given the option to receive the CROS device free of charge once the appropriate market certification was obtained. All subjects were provided with a CROS device after completing the study. After approximately 1 year, these subjects were provided with a follow-up questionnaire evaluating device retention as well as long-term satisfaction with the CROS.

3.6. Statistical analysis

Statistical analyses were performed using Statistica 12 software (TIBCO Software Inc., Palo Alto, USA) with a level of significance set at 0.05. Due to the low N, non-parametric analyses were chosen.

3.6.1. Speech perception tests

Significance of the CROS benefit (i.e. difference in performance between CI only and CI + CROS condition) was tested using the Wilcoxon signed rank statistic. Differences in performance over time as well as differences in CROS benefit over time were analysed using Friedman ANOVA followed by post-hoc Wilcoxon signed rank tests. Bonferroni corrections were applied where necessary.

3.6.2. Subjective evaluation

Analysis of the subjective feedback collected via questionnaires focused on the respective subscales. The two CI only timepoints (baseline and 3.5 months) and the two CI + CROS timepoints (1 month and 3 months) were combined and contrasted using Wilcoxon signed rank tests.

4. Results

Three of the 13 originally recruited subjects chose to withdraw from the study after the baseline or 1 month visit. Subject 11 withdrew from the study for personal reasons. Subjects 4 and 9 clinically used a HA in the contralateral ear and discontinued use of the CROS device in favour of their clinical HA.

Of remaining ten subjects, eight performed speech tests in quiet. The remaining two subjects were unable to perform the French matrix test. In

noise, one further subject was unable to complete the matrix test at the baseline appointment resulting in seven complete datasets.

At baseline, 1, 3 and 3.5 months, questionnaires were completed by all ten subjects. At 1-year follow-up, questionnaires were returned by eight subjects.

4.1. Subjective evaluation

To analyze the subjective feedback, responses from the baseline and 3.5 months appointments and responses from the 1 month and 3 months appointments were combined to form two categories: CI only and CI + CROS. The two categories were then compared regarding each questionnaire's respective subscales as well as one overall score for each questionnaire. These results are displayed in figure 1.

For the APHAB and SSQ12 questionnaires, no significant differences between the CI only and CI + CROS categories were found for any of the respective subscales or the overall scores. For the experience portion of the adapted APS-SSD questionnaire, significant differences were found for the 'Social' and 'General' subscales but not for the remaining two subscales or the overall score. Results of the Wilcoxon signed rank statistic for all questionnaires is summarized in table 3.

The satisfaction portion of the adapted APS-SSD questionnaire revealed high satisfaction with several aspects of the CROS device itself indicated by median ratings lower than 3 (figure 2a). Responses from eight subjects who provided

answers at the 1 month, 3 months and 1 year appointments were combined for each item.

In addition, the average score across all items of the APS-SSD satisfaction portion was analyzed regarding changes across time (see figure 2b). No statistically significant difference in average satisfaction score was found between the different timepoints (1 month, 3 months and 1 year).

The questionnaire further revealed that the CROS device was used most of the time with median usage times of 11.5h (1 month), 11h (3 months) and 10.25h (1 year). When asked for the preferred device configuration by the end of the study, nine out of the ten subjects who completed the study clearly preferred the CROS device while the remaining subject stated no preference. One year after the end of the study, only one out of eight responses reported a preference for the CI alone.

4.2. Speech intelligibility

Median speech perception scores in quiet (Fig. 3) as well as the two noise scenarios $S_{CROS}N_{CI}$ (Fig. 4a) and S_0N_{CI} (Fig.4b) are presented in figures 3 and 4 for the baseline, 1 month and 3 months appointments.

In quiet, the median differences in performance between the CI only and CI + CROS conditions were 6.93 dB SPL, 4.15 dB SPL and 3.38 dB SPL at the baseline, 1 month and 3 months appointments.

In $S_{CROS}N_{CI}$, the median differences in performance between the CI only and CI + CROS conditions were 6.15 dB SNR, 7.75 dB SNR and 8.00 dB SNR at the baseline, 1 month and 3 months appointments. In $S_{CROS}N_{CI}$, the median differences in performance between the CI only and CI + CROS conditions were 2.10 dB SNR, 2.00 dB SNR and 2.65 dB SNR at the baseline, 1 month and 3 months appointments. All differences were found to be statistically significant (Wilcoxon signed rank test, statistics reported in table 4).

Furthermore, Friedman analysis revealed that overall performance improved across the appointments for CI only in quiet ($x^2(2) = 10.75$, $p = .005$), for CI + CROS in quiet ($x^2(2) = 7.75$, $p = .021$), for CI only in $S_{CROS}N_{CI}$ ($x^2(2) = 8.00$, $p = .018$), for CI + CROS in $S_{CROS}N_{CI}$ ($x^2(2) = 7.14$, $p = .028$) and for CI only in S_0N_{CI} ($x^2(2) = 7.14$, $p = .028$). Performance for CI + CROS in S_0N_{CI} ($x^2(2) = 3.71$, $p = .156$) as well as the CROS benefit in quiet ($x^2(2) = 1.35$, $p = .508$), in $S_{CROS}N_{CI}$ ($x^2(2) = .28$, $p = .867$) and in S_0N_{CI} ($x^2(2) = 4.96$, $p = .084$) remained stable across the appointments.

5. Discussion

Three subjects withdrew throughout the course of the study. Subject 11 withdrew for personal reasons and reported satisfaction with the CROS device. Subjects 4 and 9 stated higher satisfaction with their clinical HA as reason for

their discontinuation. While both patients only achieve limited speech intelligibility with their HA alone (6% and 18% monosyllabic words in quiet), both patients receive a sizeable bimodal benefit of 23% and 30% respectively, suggesting that bimodal benefit rather than contralateral speech scores may be a more suitable criterion for CROS candidacy. Conversely, subject 3 who also received 30% bimodal benefit with the clinical HA reported high satisfaction with the CROS device compared to the clinical HA.

This indicates that CROS candidacy and the acceptance of CROS in bimodal CI users depend to a large extend on personal factors and cannot be predicted by speech intelligibility with the HA or bimodal benefit alone. Since the Naída Link CROS device does not require personalized fitting and the Naída CI processor is easily activated for use with the CROS device, a trial phase with the CROS device could be realized within the clinical routine to determine the best rehabilitation option (CROS or HA) in bimodal CI users with limited bimodal benefit or limited contralateral speech intelligibility.

The subjective evaluation revealed few significant changes. Especially the validated, general questionnaires APHAB and SSQ12 proved not sensitive enough to capture CROS benefits by showing no significant changes in any of the subscales or the overall score. Considering that these questionnaires were designed for HA users and are not geared towards listening environments or situations where a CROS benefit can be expected, the lack of significance is not surprising, even though Grewal et al [10] and Guevara et al [11] were able to demonstrate a significant CROS benefit in the APHAB questionnaire and Grewal

et al. [10] and Dwyer et al. [16] in the SSQ and SSQ12 respectively. The dedicated adapted APS-SSD questionnaire did show significant improvements in the 'Social' and 'General' subscale. The remaining subscales 'Home' and 'Work/School' as well as the overall score did not reveal significant changes, indicating that even dedicated questionnaires might not be sensitive enough to capture CROS benefits. Subjects were asked to fill in the questionnaires at each appointment independently without access to their previous ratings. Providing subjects access to their previous responses, therefore enabling a comparative rating, may have improved the questionnaires sensitivity to subtle changes. The high preference for the CI + CROS configuration, immediately after the study as well as after one year, indicates the usefulness of and perceived benefit provided by the CROS device nonetheless.

The usefulness and perceived benefit despite the lack of significant improvements in the questionnaires is further supported by the free feedback provided by subjects. Several subjects indicated feeling more balanced with the CROS device, being more aware of surrounding sounds and missing the CROS immediately if the batteries run out. Notably, several subjects also indicated improved localisation abilities with the CROS device. While localisation performance with the CROS device was not investigated in this study, by design the device does not provide binaural auditory input and can therefore not be expected to enable or improve localisation abilities as confirmed by previous studies [14, 15]. We therefore suggest that subjects

indicating improved localisation abilities rather refer to improved awareness of surrounding sounds, especially sounds originating towards the unimplanted ear.

Speech intelligibility tests in quiet and in noise expectedly yielded good results in favourable conditions: median improvements of up to 6.9 dB and 8.0 dB with the CROS device when speech is presented from the CROS side in quiet an in noise respectively and up to 2.7 dB in noise when speech is presented from the front.

In many cases, direct comparison of these outcomes to previously published studies is precluded by the use of different speech materials as well as different test setups in the respective studies. While Wimmer et al. [15] used comparable speech material (German matrix sentence test [24]), the CROS device tested consisted of a directional microphone rather than the omnidirectional microphone tested here, complicating direct comparisons. Ernst et al. [17] however used comparable speech material and included the $S_{CROS}N_{CI}$ condition reported here allowing a direct comparison: their reported CROS benefit (median difference) of 7.23 dB s compares quite well to the 8.0 dB found here.

Unfavourable conditions where speech is presented from the CI side and noise from the CROS side or diffusely were not included in this evaluation. In these conditions, the CROS device adds additional noise and performance is expected to decrease as has previously been shown [9, 12, 13, 16]. To avoid this performance decrease in unfavourable listening conditions, the CROS device

tested here features a mute button which can be used to silence undesired input from the CROS side.

The overall performance increased significantly over time in almost all listening conditions. This could either indicate subjects' general speech intelligibility improving over time or the subjects becoming more familiar with the used speech test material. The subjects included in this study have used their CI for at least 10 months with an average CI use of 5 years and 3 months, leading us to exclude a general learning effect as the cause of the improved performance over time. The French matrix sentence test used in this study is not routinely used in the clinic, therefore most subjects were not familiar with this closed set speech material. Although the most pronounced improvement is seen during the first two test lists and therefore two practice lists are generally considered sufficient to avoid training effects, long-term training effects using closed-set speech material have been shown for the German matrix sentence test [25]. We therefore suggest a training/learning effect to have caused the overall performance improvement over time.

In contrast to the overall performance, CROS benefits remained stable over time in all listening conditions. No acclimatisation or learning was required, subjects benefitted from the CROS device immediately after fitting.

6. Conclusion

The Naída Link CROS device was designed as an addition to a unilateral CI in cases of bilateral deafness when bilateral implantation is not an option. It was shown to increase speech intelligibility for speech sources located toward the unimplanted side. Subjects reported satisfaction with the CROS device itself and perceived benefits in their everyday listening environments such as increased sound awareness. The high long-term retention rate further confirms the CROS device to be a valuable addition to a unilateral CI.

Compliance with ethical standards

Conflict of interest: The authors declare that they have no conflict of interest.

Ethical approval: All study procedures were approved by the ethical committee, 'Comité de Protection des Personnes Sud-Est V' and the French competent authority, ANSM (Agence Nationale de Sécurité du Médicament et des produits de santé) and were conducted in accordance with the ethical standards defined by the Declaration of Helsinki. The study was registered as N° NCT03078920 at www.clinicaltrials.gov.

Informed consent: Informed consent was obtained from all individual participants included in the study.

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8. Tables

Table 1 Detailed subject demographics

Subject	Age	Gender	Etiology	Implant Side	Duration of CI experience (yrs/mos)	Contralateral HL (avg. PTA @ 0.5, 1, 2, 4kHz)	Regular HI use contralateral	Note
1	76	m	meningitis, otosclerosis	l	1/2	130	no	
2	65	f	meningitis	r	7/3	130	no	
3	62	m	Menière's disease	l	0/10	85	yes	HA, 0% WiQ
4	69	m	congenital syphilis	l	0/10	92.5	yes	HA, 6% WiQ
5	67	f	otosclerosis	r	6/4	123.75	no	
6	59	m	chronic otitis media	r	7/6	130	no	
7	55	f	familial	l	1/6	113.75	no	
8	56	f	hydrocephalus	r	1/1	130	yes	CI, non-user
9	51	f	unknown	r	7/0	106.25	yes	HA, 18% WiQ
10	22	f	unknown	l	6/8	130	no	
11	57	f	familial, otosclerosis	l	8/10	92.5	yes	CI, non-user
12	50	f	auto-immune disease	l	11/1	96.25	no	
13	63	m	trauma, TB fracture	r	8/6	103.75	no	

HL = hearing loss, HI = hearing instrument, HA = hearing aid, TB = temporal bone, WiQ = contralateral monosyllabic word score in quiet (Lafon lists)
Shaded rows indicate subjects who withdrew from the study

Table 2 Study visits and procedures in chronological order

Visit	**Speech Test**	**Questionnaire**
baseline	Lafon quiet (screening) • CI only Matrix quiet • CI only • CI + CROS Matrix noise • CI only • CI + CROS	SSQ12 • CI only APHAB • CI only
chronic experience CI + CROS		
1 month	Matrix quiet • CI only • CI + CROS Matrix noise • CI only • CI + CROS	SSQ12 • CI + CROS APHAB • CI + CROS APS-SSD • CI + CROS
chronic experience CI + CROS		
3 months	Matrix quiet • CI only • CI + CROS Matrix noise • CI only • CI + CROS	SSQ12 • CI + CROS APHAB • CI + CROS APS-SSD CI + CROS
chronic experience CI only		
3.5 months		SSQ12 • CI only APHAB • CI only APS-SSD (subset) • CI only
chronic experience CI + CROS/CI only (depending on subject's choice)		
1 year		APS-SSD (subset) • CI + CROS

Table 3 Results of Wilcoxon signed rank statistic for APHAB, SSQ12 and APS-SSD questionnaires. Grey shading indicates statistical significance.

		Z	p
APHAB	Ease of Communication	0.296	0.767
	Background Noise	0.764	0.445
	Reverberation	0.140	0.889
	Aversiveness	0.153	0.878
	Global	0.357	0.721
SSQ12	Speech	0.357	0.721
	Spatial	1.070	0.285
	Quality	0.357	0.721
	Overall	1.125	0.260
APS-SSD	Home	1.529	0.126
	Work/School	0.770	0.441
	Social	2.090	0.037
	General	2.666	0.008
	Overall	1.886	0.059

Table 4 Results of Wilcoxon signed rank statistic for speech intelligibility measurements in quiet and in noise. Grey shading indicates statistical significance.

	quiet (N = 8)		S_{CROS} N_{CI} (N = 7)		S_0 N_{CI} (N = 7)	
	Z	p	Z	p	Z	p
baseline	2.380	0.017	2.366	0.018	2.197	0.028
1 month	2.380	0.017	2.366	0.018	2.028	0.043
3 months	2.521	0.011	2.366	0.018	2.366	0.018

9. Figure Captions

Fig. 1 Subject responses to the APHAB (a) and SSQ12 (b) questionnaires and the experience portion of the APS-SSD (c) questionnaire. For APHAB and APS-SSD, lower scores indicate better performance while for the SSQ12, higher scores indicate better performance. Statistically significant differences are indicated by asterisks

Fig. 2 Subject responses to the satisfaction portion of the adapted APS-SSD questionnaire. Responses averaged across timepoints for each item (a) and responses averaged across items for each timepoint (b). Lower numbers indicate higher performance with a rating of 3 corresponding to 'neither satisfied not dissatisfied'

Fig. 3 Speech intelligibility performance in quiet in terms of speech recognition threshold measured in dB SPL at baseline, 1 month and 3 months. Lower numbers indicate better performance. Statistically significant differences are indicated by asterisks

Fig. 4 Speech intelligibility performance in noise in terms of speech reception threshold measured in dB SNR in $S_{CROS}N_{CI}$ (a) and S_0N_{CI} (b) at baseline, 1 month and 3 months. Lower numbers indicate better performance. Statistically significant differences are indicated by asterisks