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Clinical Investigation Title	Investigating hearing with Ponto 4, a bone anchored hearing solution
Investigation Code	BC110
Investigational Device (s)	Ponto 4 (Oticon Medical AB, Askim, Sweden) and fitting software Genie Medical BAHS (Oticon Medical AB, Askim, Sweden)
Methodology	Prospective, multi-center, single arm study
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Sponsor:	Oticon Medical AB Datavägen 37 B 436 32 Askim Sweden
Statement of compliance	This clinical investigation was performed in consistency with the current version of the Declaration of Helsinki, ISO 14155, the Medical Device Directive (MDD) 93/42/EEC, Regulation (EU) 2017/745 (MDR) and applicable regional or national regulatory requirements.
Date of report	30/6-2021
Author of report	Christina Wassard Maas, Clinical Trial Manager & Clinical Specialist, Oticon Medical, Kongebakken 9, 2765 Smørum, Denmark

REVISION HISTORY

Rev	Date	Description
1	30/6-2021	First version issued

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INTERNAL REFERENCES

Ref #	Document #	Document title
[1]	Doc-00071998	BC110 Clinical Investigation Plan
[2]	Doc-00072460	BC110 Non-substantial amendment to CIP
[3]	Doc-00072448	BC110 Data Management Plan
[4]	GOT server[1]	BC110_Database_LOCKED_20210423
[5]	Doc-00073450	BC110 Statistical Analysis Plan
[6]	Doc-00072545	BC110 Monitoring Plan
[7]	Doc-00073443	BC110 End-of-study Database Lock MOM
[8]	Doc-00115197	BC110: Clinical Data Report
[9]	Doc-00063691	C68 CIR
[10]	Doc-00065737	Clinical Data Report – percutaneous BAHS
[11]	Doc-00069593	CIR_C71
[12]	Doc-00067091	State of the Art - BAHS

[1] \\gotinfil01\Common\Clinical\Clinical study\Studies\BC110 Ponto 4\Trial Master File\17. Data Management\BC110 Database Lock_20210423

List of Abbreviations

AC	Air Conduction
BC	Bone Conduction
BAHS	Bone Anchored Hearing System
CHL	Conductive Hearing Loss
CI	Confidence Interval
eCRF's	Electronic Case Report Forms
FPFV	First Patient First Visit
GHSI	Glasgow Health Status Inventory questionnaire
ITT	Intention To Treat
LPLV	Last Patient Last Visit
MHL	Mixed Hearing Loss
PMCF	Post Market Clinical Follow-up
PPS	Per Protocol Set
PTA4	Pure Tone Average (consists of 500, 1000, 2000 and 4000Hz)
SAP	Statistical Analysis Plan
SD	Standard Deviation
SSD	Single Sided Deafness
SSQ	Speech Spatial and Qualities of Hearing Scale
SD	Standard Deviation
TMF	Trial Master File

1 SUMMARY

Title of the clinical Investigation: Investigating hearing with Ponto 4, a bone anchored hearing solution.

Short introduction: Oticon Medical first developed a percutaneous bone anchored hearing system (BAHS) in 2009. The latest generation BAHS manufactured by Oticon Medical AB, Askim, Sweden, the Ponto 4, was placed on the market in June 2019. This study was a post market clinical follow up (PMCF) study with the purpose of gathering knowledge on the use and performance of the Ponto 4 device and its' accessories on existing Ponto 4 users.

Subject population: In total, 20 subjects were included and completed the study. 15 subjects hearing losses were CHL/MHL and five had SSD; their average age was 56.1 years (min 18; max 81 years old). Thirteen subjects were tested at Aalborg University Hospital, and seven subjects were tested at Oticon Medical.

Objective: The purpose of this study was to investigate hearing with the Ponto 4 in already implanted BAHS users in terms of improvement of hearing (thresholds) and speech intelligibility. Additionally, the aim was to investigate the subjective experience of the Ponto 4(s) via patients reported outcomes (SSQ12 and GHSI questionnaires).

Study design: The study design was a prospective, multi-centre, single arm study consisting of one visit. At the study visit were sound field threshold, speech recognition, pure tone audiometry and patient related outcome measured. BC In-situ and audiometric data from the time of the fitting of Ponto 4 were collected retrospectively. The retrospectively collected was used for the calculation of effective gain, degradation of hearing loss and calculation of air to bone gap.

Results: The functional gain (PTA4) was 31.5 dB (SD 9.5) for all subjects, 29.6 dB (SD 9.6) for the CHL/MHL group and 36.3 dB (SD 7.9) for the SSD group, it was all significantly improvements. The effective gain also called the remaining air-to-bone gap for the CHL/MHL group was 7.05 dB (SD 6.10). Speech recognition in quiet was significant improved with 55.9 % (SD 31.7) comparing the aided to the unaided condition. Patient-related outcomes obtained via SSQ12 (total score 6.28 (SD 1.91) and GHSI (total score 65.4 (SD 11.7) showed a positive subjective experience of the Ponto 4(s) with mean scores slightly higher than reference data.

Conclusion: The study showed that the Ponto 4 subjects within intended use had improved hearing as measured with functional gain, speech recognition and subjective outcomes.

Date of initiation (FPFV): 2021-01-21

Date of completion (LPLV): 2021-02-24

2 INTRODUCTION

Bone conduction hearing systems use the body's natural ability to transfer sound through bone conduction (BC). The bone anchored hearing solution picks up sound and converts it into vibrations that are transferred via the skull bone to the inner ear (cochlea). Subjects with conductive or mixed hearing losses and subjects with lasting hearing loss following a middle ear disease or malformations, utilize that the vibrations are bypassing the conductive problem in the ear canal or middle ear, hence stimulating the cochlea directly. Subjects with single-sided deafness (SSD) utilize that the vibrations are transmitted to the cochlea on the contralateral side.

Oticon Medical first developed a bone anchored hearing system (BAHS) in 2009. The latest generation BAHS, the Ponto 4 (manufactured by Oticon Medical AB, Askim, Sweden), was placed on the market in June 2019. This study was a post market clinical follow up (PMCF) study with the purpose of gathering knowledge on the use and performance of the Ponto 4 device and its' accessories on existing Ponto 4 users.

3 INVESTIGATIONAL DEVICE AND METHODS

3.1 Investigational device description

The investigational device, the Ponto 4, used in the study is CE marked and FDA cleared since June 2019. The subject's own Ponto 4(s) were used in this study; hence no specific test device(s) were used. This was due to the nature of the study which intended to follow-up and investigate existing Ponto 4 user's outcomes for patients with conductive (CHL) or mixed hearing losses (MHL) or patients with single sided deafness (SSD). The Ponto 4 sound processors have prior to the study been fitted via Genie Medical 2019.1, and during the study visit the sound processors were also connected to Genie Medical BAHS 2019.1 (see specifications in Table 1).

The investigational device is intended to improve hearing for subjects with CHL/MHL by unilateral or bilateral fitting, as well as for subjects with SSD. The Ponto 4 is intended to be used either with the Ponto implant system or with specific compatible abutments and implants. The investigational device can also be used on a softband, headband or a testband (this study only collected data from the Ponto 4 used on compatible abutments and implants).

3.2 Devices and Accessories used in the investigation

The subject's own Ponto 4(s) were used in this study. The Ponto 4 and fitting software article numbers are listed in Table 1. The colors of the Ponto 4 devices used in the study were not recorded. All devices were fitted prior to any study related activities during a standard clinical fitting session at their regular audiologist.

Table 1 Overview of investigational devices and fitting software utilized in the study.

Name	Denomination	Article #	Initial CE	FDA clearance
Ponto 4	Chroma Beige (CBE) CO90	186777	2019	2019
	Terracotta (TC) CO94	186778	2019	2019
	Silver (SIL) CO44	186779	2019	2019
	Steel Grey (STG) CO92	186780	2019	2019
	Chestnut Brown (CNB) CO93	186781	2019	2019
	Diamond Black (DBL) CO63	186782	2019	2019
Fitting software	Genie Medical BAHS sales pack 2019.1	197603	2019	2019

The subjects' own accessories (connectivity device(s)) were included in this study for the exploratory objective where the subjects had to report usage and give satisfaction ratings for these – if they were using a connectivity device. Again, no specific connectivity device(s) can be listed, but an overview of the potential connectivity devices can be found in Table 2.

Table 2 Overview of potential connectivity devices.

LEGAL MANUFACTURER	DENOMINATION
SBO HEARING A/S	Oticon ON app 2.4.0
SBO HEARING A/S	Remote Control
SBO HEARING A/S	ConnectClip
SBO HEARING A/S	TV Adapter 3.0
OTICON A/S	EduMic

4 CLINICAL INVESTIGATION PLAN (CIP)

The revision history of the CIP is listed in

Table ***3***:

Table 3 Revision history of the CIP.

Revision #	Date	Document #	Amendment #	Description
1	02-12-2020	Doc-00071998 [*1*]	N/A	CIP first version (1.0)
1	25-01-2021	Doc-00072460 [*2*]	1.0	Non-substantial amendment due to withdrawal of participation from Site 1. A new site, Site 3, has been added.

4.1 Clinical Investigation Objectives

4.1.1 Primary objective

Primary objective	Corresponding endpoint/outcome variable(s)
A. To investigate the improvement in hearing with the Ponto 4(s) on the implanted ear for patients within the intended use.	1. Functional gain with Ponto 4, i.e. the difference between average unaided and aided sound field thresholds. The functional gain (PTA4) is calculated as the average of frequencies 500, 1000, 2000 and 4000 Hz.

4.1.2 Primary hypothesis

N/A

4.1.3 Secondary Objectives

Secondary objective(s)	Corresponding endpoint/outcome variable(s)
B. To assess the improvement of hearing with the Ponto 4 on the implanted ear(s).	1. Functional gain with Ponto 4, i.e. the difference between unaided and aided sound field thresholds, for frequencies 250, 500, 1000, 2000, 3000, 4000, 6000 and 8000 Hz.
C. To assess the improvement of speech recognition with Ponto 4 on the implanted ear(s).	1. Difference in speech recognition score in percent between unaided and aided, assessed in quiet.
D. To assess the subjective experience of the Ponto 4.	1. SSQ12 scores across all subjects.
E. To assess the quality of life of the Ponto 4.	1. GHSI scores across all subjects.
F. To assess the usage time with Ponto 4.	1. Self-reported usage hours per day during the month prior to the study visit across all subjects. 2. Self-reported usage hours per day analyzed separately for subjects with conductive/mixed hearing loss and single sided deafness (SSD).
G. To assess the degree to which the Ponto 4 compensates for the BC hearing loss in the implanted ear(s).	1. Effective gain defined as the difference in dB between aided sound field thresholds with Ponto 4, and BC In-situ thresholds on the aided ear(s) measured at the time of the fitting of Ponto 4(s). The effective gain is calculated for frequencies 250, 500, 1000, 2000, 3000, 4000, 6000 and 8000 Hz. 2. Effective gain with Ponto 4, see definition above, calculated in average for PTA4.
H. To evaluate the above objectives on individual levels.	1. Endpoints A1, B1, C1 analyzed as the proportion of subjects whose performance is better or equal in the unaided to aided comparisons, i.e. have a difference ≥0.
I. To assess the degree of inner ear hearing loss degradation on the implanted ear(s) (for SSD, the stimulated ear).	1. Hearing loss degradation is the difference in dB between masked (if not available unmasked) BC thresholds obtained at the study visit, and at the visit when Ponto 4(s) was fitted.
J. To assess if patients with CHL/MHL hearing loss has degraded to being outside fitting range on the implanted ear(s).	1. BC hearing loss (PTA4), measured at the study visit, being outside intended fitting range (PTA4>45 dB HL) compared to being inside fitting range (PTA≤45 dB HL) at the time of the fitting visit[2].
K. To assess if patients with CHL/MHL's air to bone gap (PTA4) has increased/decreased on the	1. The difference between masked (if not available unmasked) BC and AC thresholds, denoted 'air to bone gap', calculated for PTA4 from audiogram measured at

[2] In CIP [1] this has been formulated as study visit. The formulation has been corrected here.

implanted ear(s).	the study visit and the fitting visit.

4.1.4 Secondary Hypothesis

N/A

4.1.5 Tertiary Objectives

Tertiary objective(s)	**Corresponding endpoint/outcome variable(s)**
L. To assess the usage and performance of connectivity device(s)	1. Self-reported usage, usage hours and satisfaction ratings for connectivity device(s) previously given to the test subject.

4.2 Clinical Investigation Design

The study design was a prospective, multi-centre, single arm study consisting of one visit of approximately 3 hours (split into 2 visits if needed for subjects below 18 years old according to the investigators discretion).

At the study visit were the following measured: sound field threshold, speech recognition, pure tone audiometry and patient related outcome. BC In-situ and audiometric data for Ponto 4 were collected retrospectively from the fitting visit. The retrospectively collected was used for the calculation of effective gain, degradation of hearing loss and calculation of air to bone gap.

4.2.1 Method description

The purpose of this study was to investigate hearing with the Ponto 4 in already implanted BAHS users in terms of improvement of hearing (thresholds) and speech intelligibility. Additionally, the aim was to investigate the subjective experience of the Ponto 4(s) via two questionnaires (SSQ12 and GHSI).

The next paragraphs describe the methods for each test. Further details are given in the CIP [1].

4.2.1.1 Pure tone audiometry

Pure tone audiometry was measured according to standard clinical audiometry procedure at the study visit. This implied that masking should be applied if needed during AC and BC measurements. Unmasked AC and BC thresholds were always to be obtained for all frequencies. AC thresholds were obtained at 250 Hz, 500Hz, 1kHz, 2 kHz, 3kHz, 4kHz, 6kHz and 8kHz; BC thresholds were measured at 250 Hz, 500Hz, 1kHz, 2kHz, 3kHz and 4kHz.

4.2.1.2 Sound field audiometry

Detection of sound field thresholds presented in sound field from a loudspeaker placed at 1 meter's distance, 0 degrees azimuth from the subject. Warble tones at 250 Hz, 500Hz, 1kHz, 2kHz, 3kHz, 4kHz, 6kHz, 8kHz were presented according to clinical practice at the site. Thresholds were obtained both unaided and aided, and the test order was balanced between subjects. Bilaterally Ponto 4 fitted subjects were tested bilaterally. For subjects fitted unilaterally with Ponto 4, the contralateral ear was blocked with both an earplug and a headphone (but not masked).

During these measurements, the Ponto 4 was programmed in omni-directional mode, with noise reduction and feedback management system turned off.

4.2.1.3 Speech recognition in quiet

Speech recognition was measured in free field using the Matrix sentences test. The test has been validated for Danish (Wagener, Josvassen, and Ardenkjær 2003) and optimized to allow for comparability across languages (Kollmeier et al. 2015).
The Matrix test includes five-word sentences with a fixed syntactical structure and limited contextual cues. A formula selects a word from a category (name, verb, number, adjective and noun) and creates a five-word sentence. A word from each category is chosen at random to create the sentence. A list of 20 sentences is compiled from these words, ensuring that no sentence is repeated twice.

Speech was presented from a loudspeaker 1 meter in front of the subject (0 degree azimuth). The speech signal was fixed at 65 dB SPL (C-weighted). The subject had to repeat as many words as possible after each sentence. For the aided condition, Ponto 4 was tested in the subject's user settings. The test order of aided and unaided condition was balanced across subjects.

Prior to first condition, a training was conducted in the aided condition at a fixed speech level of 65 dB SPL (C-weighted). In total, four list were used, i.e. two list for training purposes and two test conditions.

Bilaterally Ponto 4 fitted subjects were tested bilaterally. For unilaterally Ponto 4 fitted subjects, the contralateral ear was blocked with both an earplug and a headphone (but not masked).

4.2.1.4 Patient reported outcome

Two subjective outcome questionnaires were used; the SSQ12 (Noble et al. 2013), which measures the real-world performance with Ponto 4, and the GHSI (Robinson, Gatehouse, and Browning 1996), which evaluates the quality of life. The subjects were to fill in the questionnaires at the clinic during the visit.

The validated questionnaire SSQ12 uses 12 questions to cover ratings of speech intelligibility, spatial aspects as well as quality of hearing. Subjects are to rate the different questions from 0 (not at all" to 10 (Perfectly).

The GHSI is validated and contains 18 health status questions that goes specifically to how the health problem, in this study the hearing loss, has affected subjects' quality of life at the time the GHSI was completed. Subjects were to respond to each question in a five-point scale ranging from high health status (a score of 5) through to low health status (a score of 1). The questionnaire is either to be filled in by the subject or to be completed through interview by the investigator. For this study, the latter method was chosen as is leads to more complete and comparable datasets (Hendry et al. 2016).

4.2.1.5 Self-reported usage hours with Ponto 4

Usage hours was assessed subjectively via the investigator asking the subject to assess what the average hours used per day has been during the last month.

4.2.1.6 Assessment of connectivity devices

Test subjects might have received connectivity devices when Ponto 4 was fitted, prior to the study. It has been be assessed whether and what device subjects are using as well as their benefit from these through a self-developed questionnaire (i.e. how satisfied are you with the connectivity device on 0-10 scale where 0 is very dissatisfied, 2.5 dissatisfied, 5 in between, 7.5 satisfied and 10 very satisfied).

4.3 Subject population

According to the CIP, it was planned to include 20 test subjects. The test subjects were enrolled from Aalborg Universitetshospital (Site 2) and from Oticon Medical via a data base with potential candidates interested in participating in clinical investigations (Site 3).

4.3.1 Inclusion Criteria

- Signed informed consent form
- 12 years and above
- Subjects with hearing loss fitted unilaterally or bilaterally with the Ponto 4(s) on abutment at least 1.5 months prior to being enrolled in the study
- Fluent in local language, as judged by the investigator

4.3.2 Exclusion criteria

- Participation in another clinical investigation which might cause interference with study participation.
- Subjects who do not have the ability or are un-willing to follow investigational procedures/requirements, e.g., to complete patient related outcome (PRO's) according to investigators discretion.

Only subjects that complied to all inclusion criteria and none of the exclusion criteria were found eligible for the study.

4.3.3 Early termination

- Inability to complete sound field audiometry.
- If the investigator assesses that the subject is not fit for participation in the study visit at any stage.

Subjects were free to discontinue participation at any time while the medical care of the subjects would not be affected.

4.3.4 Sample size

The sample size was based on achieving a 95% confidence interval of 11 dB for the functional gain. The sample size in the investigation was not hypothesis-driven, but rather based on 1) the typical size of studies on audiological outcomes within the bone-anchored hearing system field and 2) the precision of the primary endpoint. The precision can be expressed as the width of the two-sided 95% confidence interval (CI). Based on this, it was chosen to include a minimum of 20 subjects. See CIP [1] (section 11.2 and 11.2.1) for specifics on sample size calculation.

4.4 Visit schedule

The study consisted of one laboratory visit and for minors (teens between 12 and 18 years old) the single visit activities could be split into two according to investigators discretion.

Table 4 Overview of protocol activities performed at the study visit(s).

Protocol activity	Collected retrospectively from the fitting visit	Visit 1 (All adults ≥ 18 years)	Visit 2 (Optional for minors - <18 years)
Week	≥ 6 weeks	0	+ 2 weeks (+/- 1 week)
1. Informed consent procedure		x	
2. Inclusion/exclusion criteria		x	
3. Eligibility		x	
4. Subject characteristics		x	
5. BC In-situ thresholds	x		
6. Audiometry thresholds (AC and BC thresholds)[3]	x	x	
7. Speech recognition (Matrix Test) in quiet[4] [5]		x	(x)
8. Sound field audiometry [4] [5]		x	(x)
9. Completion of Patient Reported Outcomes (SSQ and GHSI) [6]		x	(x)
10. Self-reported usage hours with Ponto 4		x	(x)
11. Assessment of Connectivity devices [6]		x	(x)

4.5 Concomitant medications/treatments

Concomitant medications were not collected as not relevant for this study.

[3] Masked and unmasked
[4] Unaided and aided
[5] Can be performed at a Visit 2 for minors
[6] Can be completed at a Visit 2 or at home between Visit 1 and Visit 2 for minors

4.6 Duration of follow-up

N/A

4.7 Ethical considerations

Due to the nature of this study with the possibility of enrolling subjects between ages 12 and 18, it was decided to design the study with the option of splitting the study visit into two visits, if deemed necessary by the investigator.

This study included subjects who were already implanted and using a BAHS and therefore no interactions related to medical and audiological treatments were expected to occur.

4.8 Data quality assurance

Data management [3] and monitoring [6] was performed by Oticon Medical representatives as a part of data quality assurance.

4.9 Statistical Methods

Four populations were defined for the analysis of the study data:

1. The Per Protocol Set (PPS) included subjects included and measured in the study without any significant protocol deviations.
2. The Intention To Treat (ITT) included all data from consenting and included subjects in the study.
3. The main analysis and primary end-point analysis was performed on the Target population, i.e. the subset of the PPS population including subjects who were within the intended use for Ponto 4, thus excluding the following subject categories:
   - Subjects where the CHL/MHL hearing loss (PTA4) was outside the intended fitting range (PTA4 > 45 dB HL) at the study visit.
   - Subjects with SSD who were using a hearing solution (e.g. hearing aid) on the non-BAHS side.

   By defining the main analysis on the Target population, more precise data for patients who were fitted with Ponto 4 according to recommendations and who also were within intended fitting range (PTA4 ≤ 45 dB HL) was collected. The PPS, who was different from the Target population, described the performance of real-life use of the Ponto 4 sound processor.
4. Furthermore, for best performance the Ponto 4 was programmed to the recent hearing thresholds. As Ponto 4 was released in June 2019 there was a possibility that the hearing loss had degraded from the time when the patients were fitted until the study visit. Since this study design did not prescribe new device nor new fitting, this could influence the outcomes (a new fitting could give better performance with the same device). Therefore, a fourth analysis was performed for a subset of the Target population excluding subjects where the hearing loss (PTA4) had degraded by 10 dB or more between the BC thresholds measurement obtained at the time of the fitting of Ponto 4 compared to the BC thresholds measured at the study visit.

The primary objective of the study was to investigate the improvement in hearing with the Ponto 4 sound processor on the implanted ear(s) for patients within intended use (Target population). The following primary

endpoint was then defined:

- Functional gain with Ponto 4, i.e. the difference between average unaided and aided sound field thresholds. The functional gain (PTA4) is calculated as the average of frequencies 500, 1000, 2000 and 4000 Hz.

The primary endpoint has in Section 5 (Results) been described with Mean and 95% confidence interval (CI), as well as standard deviation (SD), Minimum, Maximum and Number of subjects. The main outcome is the mean and 95% CI.

Descriptive statistics were performed for all endpoints. The distribution of continuous variables has been given as Mean, standard deviation, Median, Minimum and Maximum whereas the distribution of categorical variables has been presented as number and percentage.

Statistical tests have been performed for endpoints A1, B1 and C1, for A1 and B1, the aided compared to unaided (functional gain), have been tested. In the case a normal distribution, a one-sample t-test will be used - if not, the Wilcoxon Signed-Rank test will be the choice. The tests have been performed at a significance level of 5% ($p<0.05$). Ordered categorical variables have been tested by the Sign test.

For an easy overview of significant p-values and their significance level, the following significance codes are used in the results:

Significance code	p-value
***	[0, 0.001]
**	(0.001, 0.01]
*	(0.01, 0.05]
	(0.05, 1] (not significant, no code)

4.9.1 Sample size calculation

The sample size in the investigation was not hypothesis-driven, but rather based on:

1. The typical size of studies on audiological outcomes within the bone-anchored hearing system field.
2. The precision of the primary endpoint. The precision can be expressed as the width of the two-sided 95% confidence interval (CI).

Studies from recent years were identified through literature search as part of the clinical evaluation, and in particular the state-of-the-art description for the Ponto system. Twenty-three studies were identified and included a median of 19 patients and an average of 21 patients.

The primary endpoint was presented by a point estimate combined with a two-sided 95% CI, to reflect the improvement of hearing on the implanted ear (for intended patients). Assuming 18 patients for evaluation (in the Target population), a 95% confidence interval of approximately 11 dB can be expected.

As described in the Statistical Analysis Plan [*5*], to achieve a sample size of 18 subjects for the primary objective where subjects who are outside intended use will be excluded from the main analysis population (Target population), the total sample size of the study was 20 patients.

5 RESULTS

The number of subjects within each of the four populations can be found below in Table 5.

Table 5 Overview of populations and number of included subjects.

Population	All subjects (n=20)
Per Protocol Set (PPS)	n=20
Intention To Treat (ITT)	n=20
Target population	n=19
Target population excluding subjects where the hearing loss (PTA4) has degraded by 10 dB	n=13

The two populations Per Protocol Set (PPS) and Intention To Treat (ITT) were identical and will in the following only be referred to as ITT.

5.1 Initiation and completion dates

Clinical investigation initiation date:	2021-01-21 (FPFV)
Clinical investigation completion date:	2021-02-24 (LPLV)

5.2 Patient demographics

In total, 20 subjects were included and completed the study. Thirteen subjects (subject IDs 001-013) were tested at Aalborg University Hospital, and seven subjects (subject IDs 301-307) were tested at Oticon Medical. All included subjects were adults above 18 years of age. Demographics for the total of included subjects (n=20) as well as for the MHL/CHL (n=15) and SSD (n=5) groups are shown in Table 6 with subject-specific characteristics in Table 7. Subjects were fitted with Ponto 4 between May 2019 and September 2020.

Table 6 Demographics and baseline characteristics by hearing loss for ITT (n=20).

Variable	Total (n=20)	MHL/CHL (n=15)	SSD (n=5)
Gender			
Male	11 (55.0%)	7 (46.7%)	4 (80.0%)
Female	9 (45.0%)	8 (53.3%)	1 (20.0%)
Age Mean (SD) Median (Min; Max) (95% CI for Mean) Number of subjects	 56.1 (17.6) 61.5 (18; 81) (47.8; 64.3) n=20	 55.3 (18.4) 62 (18; 74) (45.1; 65.4) n=15	 58.4 (16.6) 56 (43; 81) (37.8; 79.0) n=5
Type of hearing loss implanted ear			
MHL/CHL	15 (75.0%)	15 (100.0%)	0 (0.0%)
SSD	5 (25.0%)	0 (0.0%)	5 (100.0%)
Type of hearing loss non-implanted ear			
MHL/CHL	7 (35.0%)	7 (46.7%)	0 (0.0%)
SNHL	7 (35.0%)	4 (26.7%)	3 (60.0%)

Variable	Total (n=20)	MHL/CHL (n=15)	SSD (n=5)
Normal hearing	6 (30.0%)	4 (26.7%)	2 (40.0%)
BAHS Surgery			
Unilateral	18 (90.0%)	13 (86.7%)	5 (100.0%)
Bilateral	2 (10.0%)	2 (13.3%)	0 (0.0%)
Unilateral side			
Right	9 (50.0%)	8 (61.5%)	1 (20.0%)
Left	9 (50.0%)	5 (38.5%)	4 (80.0%)
Unilateral fitted subjects with a hearing loss on the non BAHS ear			
Hearing aid	3 (16.7%)	3 (23.1%)	0 (0.0%)
No hearing solution	15 (83.3%)	10 (76.9%)	5 (100.0%)

Table 7 Subject-specific demographics and baseline characteristics for ITT (n=20) from study visit.

Subject ID	Gender	Age	Type of hearing loss implanted ear	Type of hearing loss non implanted ear	BAHS side	Bilateral BAHS	Hearing aid on non BAHS ear	BC PTA4 Implanted ear [dB HL]	AC PTA4 Implanted ear [dB HL]	BC PTA4 Non implanted ear [dB HL]	AC PTA4 Non implanted ear [dB HL]
001	Female	69	MHL/CHL	SNHL	R			27.5	70	27.5*	31.25*
002	Male	69	SSD	SNHL	L			62.5	82.5	22.5*	27.5*
003	Female	62	MHL/CHL	SNHL	R			41.25	78.33**	26.25*	32.5*
004	Male	61	MHL/CHL	SNHL	R		x	45	78.75	33.75*	31.25*
005***	Male	74	MHL/CHL	SNHL	R			60.00**	**	25*	31.25*
006	Female	43	SSD	NH	L			18.75*	83.75*	16.25*	15*
007	Male	27	MHL/CHL	MHL/CHL	L			26.25	78.75	21.25*	33.75*
008	Male	24	MHL/CHL	MHL/CHL	L			1.25*	63.75*	1.25*	67.5*
009	Male	56	SSD	SNHL	R			12.5*	71.25*	10*	15*
010	Male	81	SSD	SNHL	L			35*	88.75*	30’	35*
011	Male	71	MHL/CHL	NH	L			25	83.75	13.75*	13.75*
012	Male	18	MHL/CHL	MHL/CHL	R		x	1.25*	65*	2.5*	38.75*
013	Female	57	MHL/CHL	MHL/CHL	L			25	42.5	11.25*	30*
301	Female	43	MHL/CHL	NH	L			1.25*	73.75*	5*	12.5*
302	Female	72	MHL/CHL	MHL/CHL	L+R	x		9.38*	58.13*	N/A	N/A
303	Male	59	MHL/CHL	NH	R			10*	73.33**	8.75*	15*
304	Male	43	SSD	NH	L			13.75*	85.00**	7.5*	12.5*
305	Female	62	MHL/CHL	MHL/CHL	L+R	x		18.13*	68.13*	N/A	N/A
306	Female	66	MHL/CHL	MHL/CHL	R		x	16.25*	66.25*	18.75*	33.75*
307	Female	64	MHL/CHL	NH	R			15*	85.00**	10*	11.25*
Average all subjects								**21.32***	**71.67**	**16.18***	**27.08***

* = Contains one or more unmasked frequencies.
** = Missing one or more frequencies to calculate PTA4.
*** = Subject 005 excluded in main analysis (Target Population) due to no measurable thresholds (BC and AC) on implanted ear.

5.3 CIP compliance

The study was conducted in compliance with the CIP and a total number of subjects that completed the study without major protocol deviations were 20 subjects (100%).

5.3.1 Protocol deviations

Major protocol deviations

There was no major protocol deviation deemed to affect the quality of the data of the primary and secondary endpoints.

Minor protocol deviations

Subject IDs 001-005: Only masked AC and BC thresholds were obtained for the implanted ear. Hence unmasked AC and BC thresholds were not collected as described in the CIP. More information can be found in BC110 End-of-study Database Lock MOM [7].

5.3.2 Analysis Populations

Data analysis was performed on three populations (PPS and ITT being the same).

As described in the CIP, the main analysis for this study will be shown and discussed below based on the Target Population (n=19). Consequently, the results from the remaining two populations (ITT and Target Population with degraded hearing loss ≥10 dB) will not be presented here. Full statistical analysis on all populations can be found in the statistical report [8].

For the Target Population, subject ID 005 was excluded from target population analysis due to not having the BC thresholds for all 4 frequencies to calculate PTA, hence including 19 subjects in the following analysis.

5.4 Primary objective results

The primary objective was to investigate the improvement of hearing with the Ponto 4(s) on the implanted ear(s) for patients within intended use via functional gain. The functional gain has been calculated as the difference between unaided and aided sound field thresholds for PTA4.

5.4.1 Functional gain for PTA4 (objective A1)

Table 8 shows the functional gain (PTA4) as well as the mean unaided and aided thresholds (PTA4). In the unaided condition, only 18 subjects had measurable thresholds for all 4 frequencies to be calculated for the PTA4 of functional gain.

The mean functional gain (unaided-aided) in this study was 31.5 dB (SD ± 9.5) with significantly better thresholds in the aided condition (26.0 dB HL, SD ± 6.4) compared to the unaided condition (57.1 dB HL, SD ± 12.5). The significance was found across for all subjects (p<.0001***) as well as on group level (MHL/CHL: p<.0001***, SSD: p=.0005***).

Table 8 Functional gain (PTA4) for all subjects and grouped by hearing loss.

	Sound field thresholds (PTA4) [dB HL]		**Functional gain [dB]**	**p-value**
	Unaided	**Aided**	**Unaided-Aided**	
Total	57.1 (12.5) 56.3 (33.8; 77.5) (50.9; 63.3) n=18	26.0 (6.4) 25 (17.5; 42.5) (22.9; 29.1) n=19	31.5 (9.5) 32.5 (15; 48.8) (26.8; 36.2) n=18	<.0001***
MHL/CHL	54.6 (11.5) 55 (33.8; 75) (47.7; 61.6) n=13	25.5 (6.3) 24.4 (17.5; 42.5) (21.9; 29.2) n=14	29.6 (9.6) 32.5 (15; 48.8) (23.8; 35.4) n=13	<.0001***
SSD	63.5 (14.1) 68.8 (42.5; 77.5) (46.0; 81.0) n=5	27.3 (7.2) 27.5 (17.5; 37.5) (18.3; 36.2) n=5	36.3 (7.9) 40 (25; 43.8) (26.5; 46.0) n=5	0.0005***

Mean (SD)
Median (min; max)
(CI for mean)
Number of subjects

For comparison over time, the t-test was used for continuous variables.

5.5 Secondary objective results

5.5.1 Functional gain for all frequencies (objective B1)

while

Table ***9*** gives an overview of the specific mean values, SD and corresponding p-values.

For the functional gain, a significant improvement of sound field thresholds was found between the unaided and aided condition across all frequencies (p<.0001***). See Figure 2 for unaided (subplot A) and aided (subplot B) thresholds.

Figure *1* shows the functional gain for all frequencies (250, 500, 1000, 2000, 3000, 4000, 6000 and 8000Hz) and the average of PTA4 while

Table ***9*** gives an overview of the specific mean values, SD and corresponding p-values.

For the functional gain, a significant improvement of sound field thresholds was found between the unaided and aided condition across all frequencies (p<.0001***). See Figure 2 for unaided (subplot A) and aided (subplot B) thresholds.

Figure 1 Functional gain for all frequencies and PTA4 across all subjects as well as grouped by hearing loss. Bolt indicates mean.

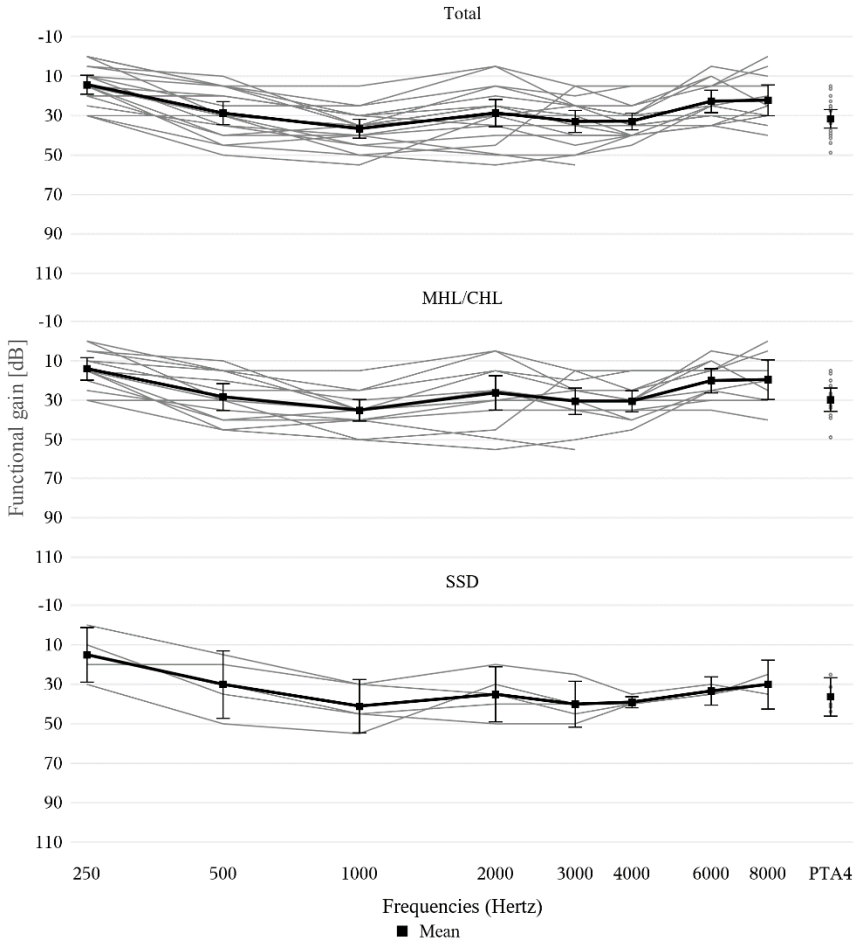
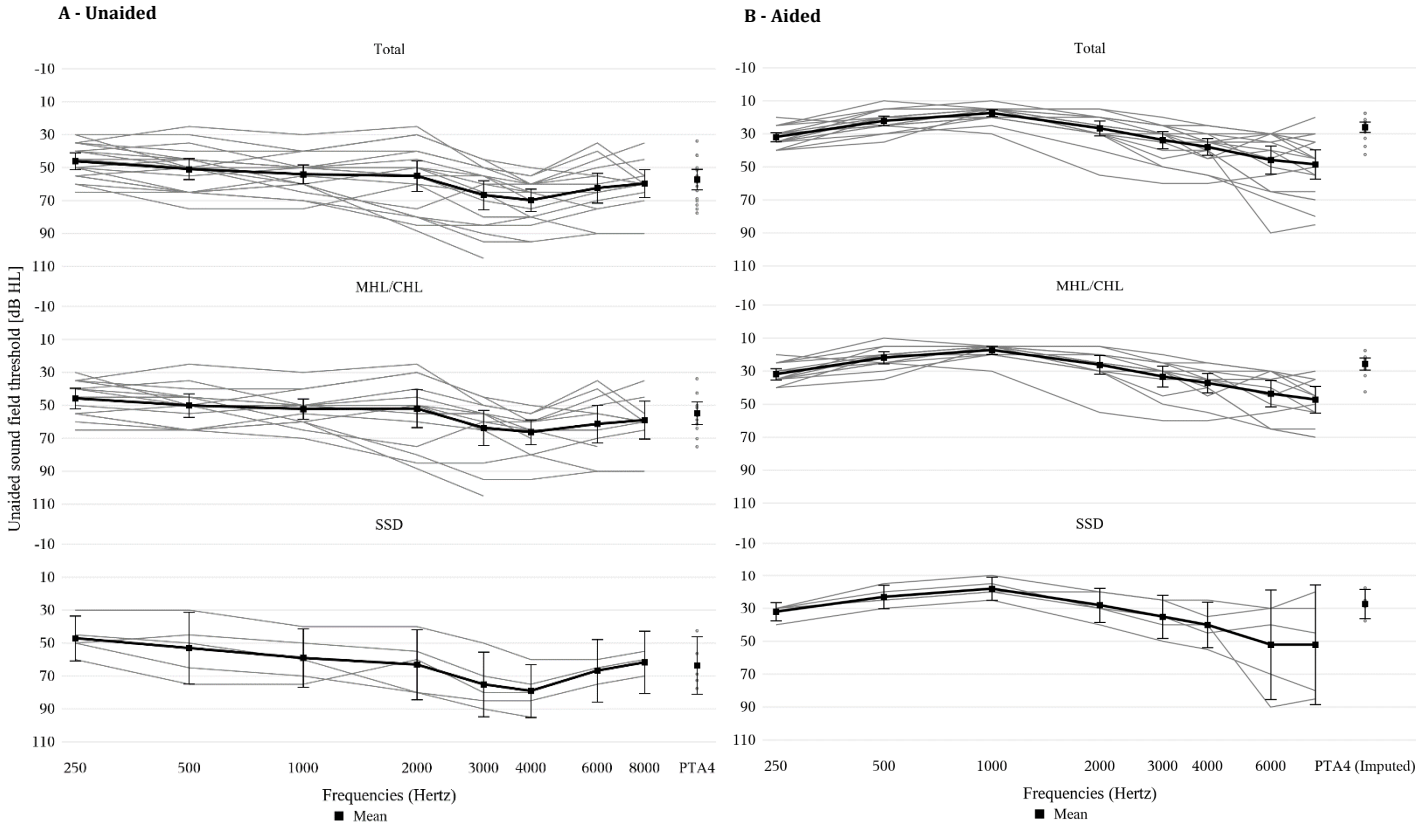


Table 9 Functional gain and the corresponding p-values for all frequencies.

	250Hz	**500Hz**	**1000Hz**	**2000Hz**	**3000Hz**	**4000Hz**	**6000Hz**	**8000Hz**
Total								
Functional gain	14.2 (9.9) 15 (0; 30) (9.4; 19.0) n=19	28.7 (12.0) 30 (10; 50) (22.9; 34.5) n=19	36.6 (9.9) 35 (15; 55) (31.8; 41.3) n=19	28.6 (13.8) 30 (5; 55) (21.7; 35.5) n=18	32.9 (11.6) 30 (15; 55) (27.3; 38.5) n=19	32.8 (8.6) 35 (15; 45) (28.5; 37.1) n=18	22.7 (10.2) 25 (5; 35) (17.0; 28.3) n=15	22.1 (12.3) 25 (0; 40) (14.2; 29.9) n=12
p-value	<.0001***	<.0001***	<.0001***	<.0001***	<.0001***	<.0001***	<.0001***	<.0001***
Mixed/Conductive								
Functional gain	13.9 (9.8) 15 (0; 30) (8.2; 19.6) n=14	28.2 (11.9) 30 (10; 45) (21.4; 35.1) n=14	35.0 (9.4) 35 (15; 50) (29.6; 40.4) n=14	26.2 (14.3) 25 (5; 55) (17.5; 34.8) n=13	30.4 (11.5) 30 (15; 55) (23.7; 37.0) n=14	30.4 (9.0) 30 (15; 45) (24.9; 35.8) n=13	20.0 (9.5) 20 (5; 35) (13.9; 26.1) n=12	19.4 (13.1) 20 (0; 40) (9.4; 29.5) n=9
p-value	0.0001***	<.0001***	<.0001***	<.0001***	<.0001***	<.0001***	<.0001***	0.0021**
SSD								
Functional gain	15.0 (11.2) 15 (0; 30) (1.1; 28.9) n=5	30.0 (13.7) 30 (15; 50) (13.0; 47.0) n=5	41.0 (10.8) 45 (30; 55) (27.5; 54.5) n=5	35.0 (11.2) 35 (20; 50) (21.1; 48.9) n=5	40.0 (9.4) 40 (25; 50) (28.4; 51.6) n=5	39.0 (2.2) 40 (35; 40) (36.2; 41.8) n=5	33.3 (2.9) 35 (30; 35) (26.2; 40.5) n=3	30.0 (5.0) 30 (25; 35) (17.6; 42.4) n=3
p-value	0.040*	0.0080**	0.0011**	0.0022**	0.0007***	<.0001***	0.0025**	0.0091**

	250Hz	500Hz	1000Hz	2000Hz	3000Hz	4000Hz	6000Hz	8000Hz
Mean (SD) Median (min;max) (CI for mean) Number of subjects For comparison over time, the t-test was used for continuous variables.								

Figure 2 Unaided (A) and Aided (B) sound field thresholds. Bolt indicates mean.



5.5.2 Speech recognition (objective C1)

Speech recognition was measured in quiet at a fixed input level (65 dB SPL (C)) using the Danish Matrix test, Dantale II. Aided and unaided conditions were measured, and the difference calculated.

On average, subjects scored 96.8% (SD ± 6.8) correct aided compared to 40.9% (SD ± 33.6) correct in the unaided condition (

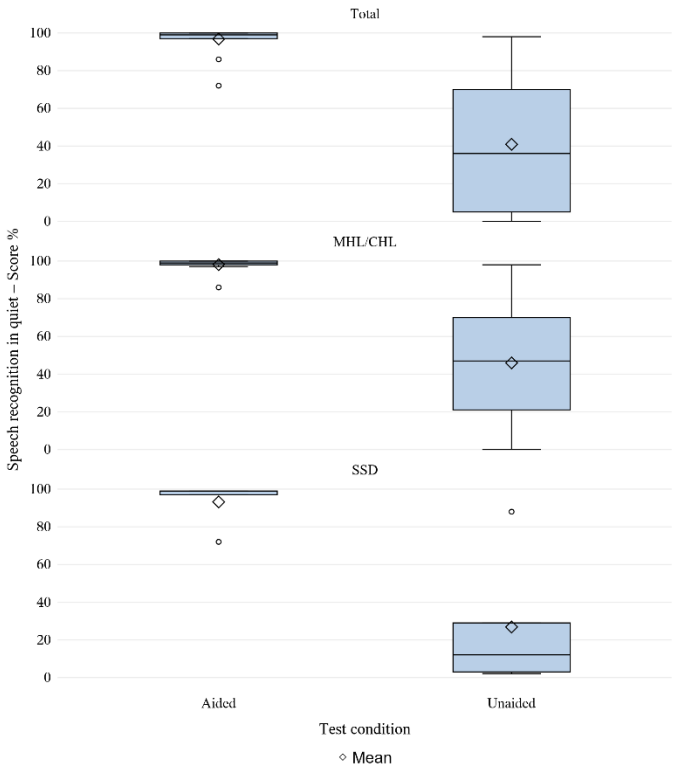
Table ***10***). The improvement of speech recognition from unaided to aided (55.9% point) was significant (p<.0001***). The spread of the scores across subjects were also smaller and closer to 100% in the aided condition compared to unaided, as can be seen in

Figure ***3***.

Table 10 Speech recognition score by unaided, aided and the difference between the two for total subjects and grouped by type of hearing loss.

	Speech recognition score in quiet [%]		**Difference [%]**	**p-value**
	Unaided	**Aided**	**Aided - Unaided**	
Total	40.9 (33.6) 36 (0; 98) (24.7; 57.1) n=19	96.8 (6.8) 99 (72; 100) (93.5; 100.1) n=19	55.9 (31.7) 64 (2; 99) (40.6; 71.2) n=19	<.0001***
MHL/CHL	45.9 (32.7) 47 (0; 98) (27.1; 64.8) n=14	98.1 (3.6) 99 (86; 100) (96.0; 100.2) n=14	52.1 (31.6) 51 (2; 99) (33.9; 70.4) n=14	<.0001***
SSD	26.8 (35.9) 12 (2.1; 88) (-17.7; 71.4) n=5	93.2 (11.9) 99 (72; 99) (78.4; 108.0) n=5	66.4 (32.9) 70 (11; 94.9) (25.5; 107.2) n=5	0.011*
Mean (SD) Median (min;max) (CI for mean) Number of subjects For comparison over time, the t-test was used for continuous variables.				

Figure 3 Boxplot and mean of speech recognition scores in percent for unaided and aided conditions in quiet.



5.5.3 SSQ (objective D1)

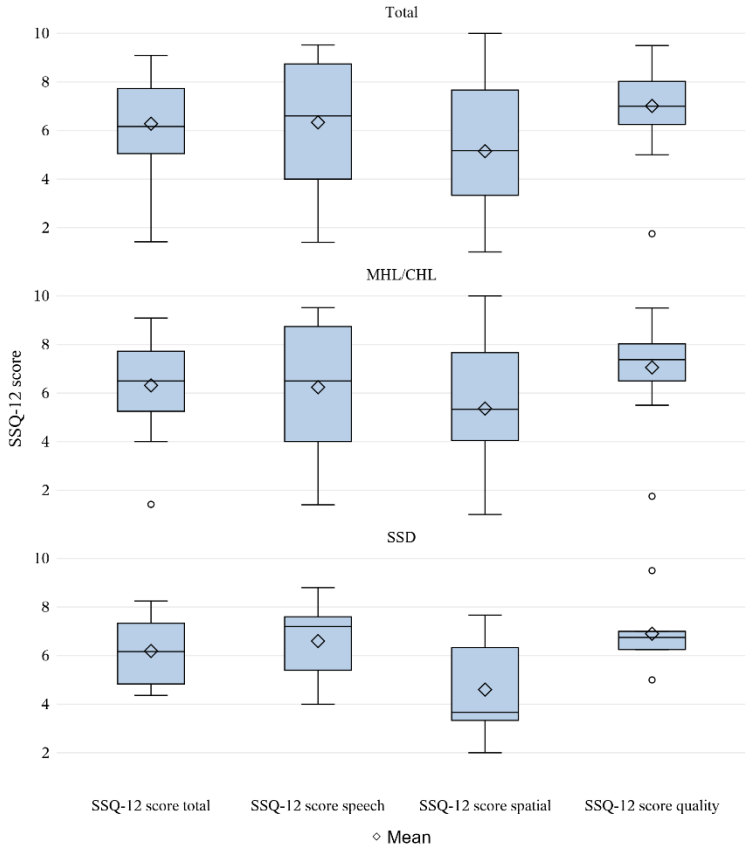
The mean SSQ12 scores are shown in Table 11 and visualized in

Figure ***4*** for each subscale (speech, spatial and qualities of hearing) for the total, and by type of hearing loss.

Table 11 SSQ12 questionnaire, subscales and total score, and by type of hearing loss.

	Total (n=19)	**MHL/CHL (n=14)**	**SSD (n=5)**
SSQ12 score total	6.28 (1.91) 6.17 (1.42; 9.09) (5.36; 7.20) n=19	6.31 (2.06) 6.5 (1.42; 9.09) (5.13; 7.50) n=14	6.19 (1.64) 6.17 (4.36; 8.25) (4.16; 8.22) n=5
SSQ12 score Speech	6.34 (2.30) 6.6 (1.4; 9.52) (5.23; 7.44) n=19	6.24 (2.49) 6.5 (1.4; 9.52) (4.81; 7.68) n=14	6.60 (1.90) 7.2 (4; 8.8) (4.24; 8.96) n=5
SSQ12 score Spatial	5.15 (2.51) 5.17 (1; 10) (3.90; 6.40) n=18	5.36 (2.64) 5.33 (1; 10) (3.77; 6.95) n=13	4.60 (2.33) 3.67 (2; 7.67) (1.71; 7.49) n=5
SSQ12 score Quality	7.01 (1.80) 7 (1.75; 9.5) (6.14; 7.88) n=19	7.05 (1.91) 7.38 (1.75; 9.5) (5.95; 8.16) n=14	6.90 (1.65) 6.75 (5; 9.5) (4.86; 8.94) n=5
Mean (SD) Median (min; max) (CI for mean) Number of subjects			

Figure 4 Boxplot and mean of SSQ12 scores in each subscale and total score, and by type of hearing loss.



5.5.4 GHSI (objective E1)

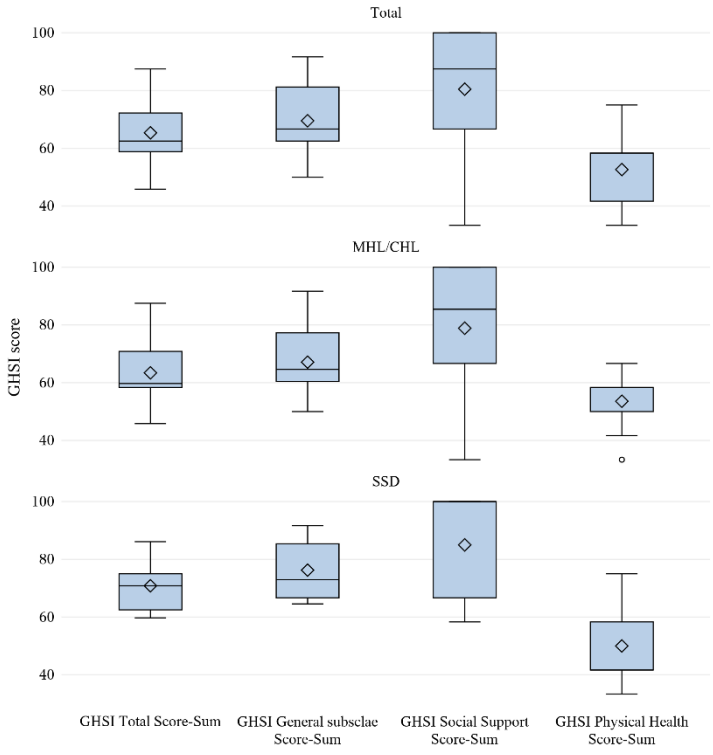
The mean Quality of life (GHSI) scores are shown in Table 12 and visualized in

Figure ***5*** for each subscale (General Subscale, Social Support and Physical Health) for the total, and by type of hearing loss.

Table 12 GHSI questionnaire, subscales and total score, and by type of hearing loss.

	Total (n=19)	**MHL/CHL (n=14)**	**SSD (n=5)**
GHSI Total Score-Sum	65.4 (11.7) 62.5 (45.8; 87.5) (59.7; 71.0) n=19	63.4 (11.8) 59.7 (45.8; 87.5) (56.6; 70.2) n=14	70.8 (10.5) 70.8 (59.7; 86.1) (57.8; 83.9) n=5
GHSI General Subscale Score-Sum	69.5 (12.5) 66.7 (50; 91.7) (63.5; 75.5) n=19	67.1 (12.2) 64.6 (50; 91.7) (60.1; 74.2) n=14	76.3 (11.8) 72.9 (64.6; 91.7) (61.5; 91.0) n=5
GHSI Social Support Score-Sum	80.5 (21.2) 87.5 (33.3; 100) (70.2; 90.7) n=19	78.9 (22.0) 85.4 (33.3; 100) (66.2; 91.5) n=14	85.0 (20.7) 100 (58.3; 100) (59.2; 110.8) n=5
GHSI Physical Health Score-Sum	52.6 (11.5) 58.3 (33.3; 75) (47.1; 58.2) n=19	53.6 (9.6) 58.3 (33.3; 66.7) (48.0; 59.1) n=14	50.0 (16.7) 41.7 (33.3; 75) (29.3; 70.7) n=5
Mean (SD) Median (min;max) (CI for mean) Number of subjects			

Figure 5 Boxplot and mean of GHSI scores in each subscale and total score, and by type of hearing loss.



5.5.4 Usage time across all subjects and grouped by hearing loss (objective F1 and F2)

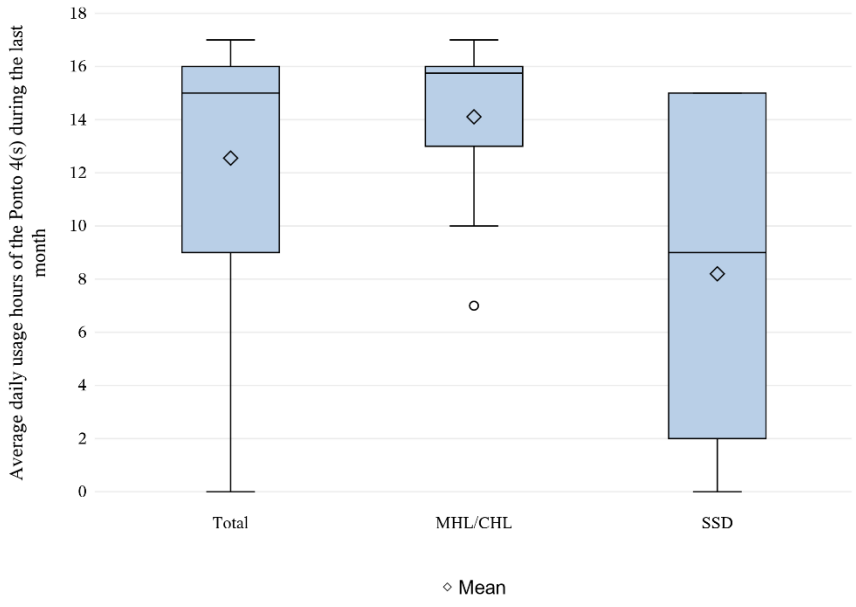
Average daily use of the Ponto 4(s) during the last month prior to the study visit for all subjects as well as grouped by hearing loss are shown in Table 13. The mean daily usage time of all subjects was 12.6 hours (SD ± 5.2). For the MHL/CHL group, the daily usage time was higher (14.1, SD ± 3.5) compared to the SSD group (8.20, SD ± 7.05).

Figure ***6*** clearly shows that the SSD group has a bigger spread in usage hours as compared to the MHL/CHL group.

Table 13 Average daily usage hours of the Ponto 4(s) during last month.

	Total (n=19)	**MHL/CHL (n=14)**	**SSD (n=5)**
Average daily usage hours of the Ponto 4(s) during the last month	12.6 (5.2) 15 (0; 17) (10.0; 15.1) n=19	14.1 (3.5) 15.8 (7; 17) (12.1; 16.1) n=14	8.20 (7.05) 9 (0; 15) (-0.55; 16.95) n=5
Mean (SD) Median (min;max) (CI for mean) Number of subjects			

Figure 6 Boxplot of usage time with Ponto 4(s).



5.5.5 Effective gain (objective G1 and G2)

The effective gain also called the remaining air-to-bone-gap is calculated as the difference between aided sound field thresholds obtained at the study visit and the BC in-situ thresholds from the time when the Ponto 4 was fitted. The effective gain has been calculated across all frequencies (250, 500, 1000, 2000, 3000, 4000,

6000 and 8000 Hz (Table 14) as well as for the PTA4 (Table 15) for the MHL/CHL group (SSD group has no air to bone gap, hence not included in these results). Effective gain is visualized in

Figure ***7***.

For MHL/CHL, mean aided sound field thresholds were measured to 25.5 dB HL (SD ± 6.3) while mean BC in-situ thresholds were 18.5 dB HL (SD ± 9.7). This results in a remaining air-to-bone gap as 6.74 dB.

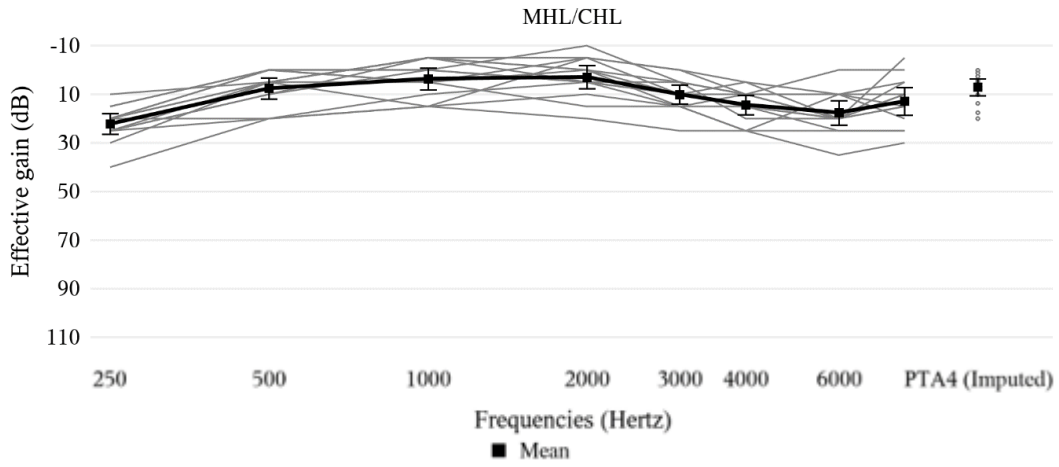
Table 14 Effective gain (difference between aided sound field and BC In-situ thresholds) for MHL/CHL.

	250Hz	**500Hz**	**1000Hz**	**2000Hz**	**3000Hz**	**4000Hz**	**6000Hz**	**8000Hz**
Mixed/Conductive								
Effective gain	22.0 (7.3) 20 (10; 40) (17.7; 26.2) n=14	7.14 (7.84) 5 (-2.5; 20) (2.62; 11.67) n=14	3.21 (7.69) 0 (-5; 15) (-1.22; 7.65) n=14	2.86 (8.25) 2.5 (-10; 20) (-1.91; 7.62) n=14	10.2 (7.0) 10 (0; 25) (6.2; 14.2) n=14	13.8 (7.1) 12.5 (5; 25) (9.6; 17.9) n=14	17.0 (9.4) 20 (0; 35) (11.5; 22.4) n=14	12.3 (9.7) 11.3 (-5; 30) (6.7; 17.9) n=14
Mean (SD) Median (min;max) (CI for mean) Number of subjects For comparison over time, the t-test was used for continuous variables.								

Table 15 Effective gain (PTA4) for MHL/CHL.

	PTA4 BC thresholds [dB HL]		**Effective gain [dB]**	**p-value**
	Aided sound field	**BC In-Situ**	**Aided - BC In-Situ**	
MHL/CHL	25.5 (6.3) 24.4 (17.5; 42.5) (21.9; 29.2) n=14	18.8 (9.6) 19.4 (2.5; 36.3) (13.2; 24.4) n=14	6.74 (6.33) 4.38 (0; 20) (3.09; 10.39) n=14	0.0008***
Mean (SD) Median (min; max) (CI for mean) Number of subjects For comparison over time, the t-test was used for continuous variables.				

Figure 7 Effective gain for all frequencies for MHL/CHL. Bolt lines indicate mean.



5.5.6 Evaluation on individual levels (objective H1)

For 100% of subjects in this functional gain analysis, an improvement ≥ 0 from unaided to aided condition was found for both PTA4 and for all individual frequencies (Table 9).

The same improvement (100%) from unaided to aided was also found for speech recognition (Table 10).

5.5.7 Hearing loss degradation (objective I1)

Hearing loss degradation for subjects with MHL/CHL is the difference in dB between masked (if not available, then unmasked) BC thresholds obtained at the study visit and at the visit when the Ponto 4(s) was fitted. For subjects with SSD, AC thresholds on the non-implanted ear were used for this calculation.

On group level (Table 16), no significant difference was found for PTA4 between thresholds measured at the fitting visit compared to those obtained at the study visit for neither the MHL/CHL (p=0.95) group nor the SSD group (p=0.25).

When looking into the subject-specific data (Table 17), only one subject (#13) had a hearing loss degradation larger than or equal to 10 dB (12.5 dB).

Table 16 Hearing loss degradation for all BC frequencies as well as for PTA4 with corresponding p-value.

	PTA4		**Difference in threshold Study visit – Fitting visit**	
	Threshold (fitting) (n=14)	**Threshold (study) (n=14)**		**p-value**
MHL/CHL	18.1 (11.1) 18.8 (0; 37.5) (10.6; 25.5) n=11	18.8 (13.9) 17.2 (1.3; 45) (10.7; 26.8) n=14	0.114 (5.761) 0 (-8.75; 12.5) (-3.757; 3.984) n=11	0.95
SSD	19.3 (7.1) 15 (13.8; 28.8) (10.4; 28.1) n=5	21.0 (9.8) 15 (12.5; 35) (8.9; 33.1) n=5	1.75 (2.88) 1.25 (-1.25; 6.25) (-1.82; 5.32) n=5	0.25
Mean (SD) Median (min;max) (CI for mean) Number of subjects				
For comparison over time, the t-test was used for continuous variables.				

Table 17 Subject-specific hearing loss degradation.

Subject ID	Type of hearing loss study side	AC PTA4 Degradation [dB]	BC PTA4 Degradation [dB]
001	MHL/CHL		-1.25
002	SSD	2.5	
003	MHL/CHL		3.75
004	MHL/CHL		*
006	SSD	1.25	
007	MHL/CHL		3.75
008	MHL/CHL		1.25
009	SSD	0.00	
010	SSD	6.25	
011	MHL/CHL		1.25
012	MHL/CHL		0.00
013	MHL/CHL		12.50
301	MHL/CHL		*
302	MHL/CHL		-3.13
303	MHL/CHL		-8.75
304	SSD	-1.25	
305	MHL/CHL		-0.63
306	MHL/CHL		*
307	MHL/CHL		-7.50
* = PTA4 cannot be calculated due to one or more missing frequencies			

5.5.8 Assessment of intended fitting range (objective J1)

BC hearing loss (PTA4) has been calculated for the study visit to see whether the subjects with MHL/CHL were within fitting range (within fitting range: PTA4 ≤45 dB HL).

Table 18 BC PTA4 of fitted ear from study visit for MHL/CHL and assessment of fitting range in dB HL.

Subject ID N=14	Side	250Hz (Imp. ear)	500Hz (Imp. ear)	1kHz (Imp. ear)	2kHz (Imp. ear)	3kHz (Imp. ear)	4kHz (Imp. ear)	250Hz Non BAHS	500Hz Non BAHS	1kHz Non BAHS	2kHz Non BAHS	3kHz Non BAHS	4kHz Non BAHS	BC PTA4 fitted ear	Within fitting range
MHL/CHL															
1	R	5	15	20	45	35	30	5*	15*	25*	40*	35*	30*	27.50	Yes
3	R	5	25	25	50	50	65	5*	25*	15*	30*	30*	35*	41.25	Yes
4	R	5	20	30	70		60	0*	15*	10*	65*	55*	45*	45.00	Yes
7	L	0, 0*	5, 5*	25, 25*	45, 40*	35, 30*	30, 15*	5*	5*	20*	40*	25*	20*	26.25	Yes
8	L	-10*	0*	0*	10*	5*	-5*	-10*	0*	0*	10*	5*	-5*	1.25	Yes
11	L	10, 5*	20, 15*	25, 10*	30, 20*	30, 25*	25, 25*	5*	10*	10*	15*	20*	20*	25.00	Yes
12	R	-5*	0*	5*	0, 0*	5, 5*	0, 0*	5*	0*	5*	5*	10*	0*	1.25	Yes
13	L	0, 0*	25, 0*	20, 0*	25, 20*	35, 30*	30, 20*	-5*	5*	0*	20*	35*	20*	25.00	Yes
301	L	10*	0*	5*	0*	15*	0*	0*	10*	5*	5*	0*	0*	1.25	Yes
302**	L	0*	5*	-5*	10*	25*	20*							7.50	Yes
	R	0*	15*	5*	10*	20*	15*							11.25	
303	R	0*	5*	5*	20*	25*	10*	0*	10*	5*	10*	15*	10*	10.00	Yes
305**	L	-5*	15*	15*	25*	10*	15*							17.50	Yes
	R	5*	15*	20*	20*	10*	20*							18.75	
306	R	15*	15*	15*	15*	20*	20*	10*	30*	15*	10*	15*	20*	16.25	Yes
307	R	0*	15*	10*	10*	20*	25*	0	5	10	5	10	20	15.00	Yes

Subject ID N=14	Side	250Hz (Imp. ear)	500Hz (Imp. ear)	1kHz (Imp. ear)	2kHz (Imp. ear)	3kHz (Imp. ear)	4kHz (Imp. ear)	250Hz Non BAHS	500Hz Non BAHS	1kHz Non BAHS	2kHz Non BAHS	3kHz Non BAHS	4kHz Non BAHS	BC PTA4 fitted ear	Within fitting range
* = Unmasked ** = Bilateral subjects.															

5.5.9 Assessment of air to bone gap (objective K1)

The difference between masked (if not available unmasked) BC and AC thresholds, denoted 'air to bone gap', has been calculated for PTA4 from audiogram measured at the study visit. Subjects with SSD are not included in this analysis.

Calculation of air to bone gap for PTA4 at study visit for subjects with MHL/CHL showed a mean value of 50.2 dB (Table 19). Individual PTA4 values and air to bone gap can be found in

Table ***20*** below.

Table 19 Air to bone gap (PTA4) at fitting and study visit across MHL/CHL subjects.

	Target population (n=14)	
	Fitting visit	**Study visit**
AC PTA4	66.3 (14.8) 71.3 (43.1; 87.5) (57.3; 75.2) n=13	68.1 (11.4) 68.1 (42.5; 83.8) (60.4; 75.7) n=11
BC PTA4	18.1 (11.1) 18.8 (0; 37.5) (10.6; 25.5) n=11	18.8 (13.9) 17.2 (1.3; 45) (10.7; 26.8) n=14
Air to bone gap for PTA4	45.8 (13.6) 42.5 (28.8; 63.8) (36.7; 54.9) n=11	50.2 (15.2) 50 (17.5; 72.5) (40.0; 60.4) n=11
Mean (SD) Median (min; max) (CI for mean) Number of subjects		

Table 20 Individual air to bone gap (PTA4, both AC, BC, fitting visit, and study visit) for all MHL/CHL subjects based on audiogram data.

	Implanted ear					
Subject	**PTA4AC fitting visit**	**PTA4BC fitting visit**	**PTA4AC study visit**	**PTA4BC study visit**	**Air to bone gap fitting visit**	**Air to bone gap study visit**
MHL/CHL						
001	71.25	28.75	70.00	27.50	42.50	42.50

	Implanted ear					
Subject	**PTA4AC fitting visit**	**PTA4BC fitting visit**	**PTA4AC study visit**	**PTA4BC study visit**	**Air to bone gap fitting visit**	**Air to bone gap study visit**
003	76.25	37.50	78.33*	41.25	38.75	37.08*
004	77.50	38.33*	78.75	45.00	39.17*	33.75
007	77.50	22.50	78.75	26.25	55.00	52.50
008	58.75	0.00	63.75	1.25	58.75	62.50
011	87.50	23.75	83.75	25.00	63.75	58.75
012	62.50	1.25	65.00	1.25	61.25	63.75
013	43.75	12.50	42.50	25.00	31.25	17.50
301	81.25	30.00*	73.75	1.25	51.25*	72.50
302	43.13	12.50	58.13	9.38	30.63	48.75
303	76.25	18.75	73.33*	10.00	57.50	63.33*
305	54.38	18.75	68.13	18.13	35.63	50.00
306	55.00*	30.00*	66.25	16.25	25.00*	50.00
307	51.25	22.50	85.00*	15.00	28.75	70.00*
Mean	**65.45**	**21.22**	**70.39**	**18.75**	**44.23**	**51.64**
* Has missing values in calculation of PTA4						

5.6 Tertiary objective results

5.6.1 Assessment of usage and performance of connectivity device(s) (objective L1)[7]

Subjects were asked to rate their connectivity device(s) (if they had any) from a scale of 0,0 (very dissatisfied) to 10,0 (very satisfied). Mean answers can be found in Table 21.

Table 21 Ratings of connectivity devices.

	Total (n=19)	**MHL/CHL (n=14)**	**SSD (n=5)**
On App	8.21 (2.10) 9 (4; 10) (6.87; 9.55) n=12	8.06 (2.38) 9 (4; 10) (6.23; 9.88) n=9	8.67 (1.15) 8 (8; 10) (5.80; 11.54) n=3
Connect Clip	6.90 (2.30) 6 (4; 9.5) (4.04; 9.76) n=5	7.13 (2.59) 7.5 (4; 9.5) (3.00; 11.25) n=4	6.00 n=1
Remote Control	8.00 (2.35) 9 (5; 10) (5.09; 10.91) n=5	7.50 (2.38) 7.5 (5; 10) (3.71; 11.29) n=4	10.00 n=1
Edu Mic	9.00 n=1	9.00 n=1	

[7] Usage hours were supposed to be obtained as well but unfortunately was not a part of (e)CRF.

	Total (n=19)	MHL/CHL (n=14)	SSD (n=5)
Mean (SD) Median (min;max) (CI for mean) Number of subjects			

5.7 Adverse events and Device Deficiencies

No adverse events nor device deficiencies were encountered during the study.

5.7.1 Serious Adverse Events

No serious adverse events were encountered during the study.

5.8 Missing data handling

Unmasked AC and BC thresholds for subjects 001-005 were not collected as according to the CIP. The missing data was deemed as a minor protocol deviation, hence did not influence the data quality. Missing variables IDs can be found in [7].

No subject was withdrawn or discontinued from the study and no subject was lost to follow-up.

6 DISCUSSION

This study design was a prospective, multi-centre, single arm study consisting of one visit of approximately 3 hours. The hearing with the Ponto 4 was investigated in adult BAHS users (no children were enrolled in this study) in terms of sound fields thresholds and speech recognition. Additionally, self-reported performance in everyday life as well as health and quality of life was evaluated via the SSQ12 (Noble et al. 2013) and GHSI (Hendry et al. 2016).

6.1 Functional gain

Concerning the primary endpoint, the results of functional gain showed a significant improvement of sound field thresholds in the aided condition compared to unaided - not only for the PTA4 (primary endpoint, A1), but for all measured frequencies (secondary endpoint, B1) for both the MHL/CHL group and the SSD group. The mean functional gain for PTA4 was calculated to 31.5 dB, meaning that subjects' mean sound field thresholds improved by 31.5 dB when wearing the Ponto 4 compared to not wearing a device regardless of having MHL/CHL or SSD. These results are in line with previous data on BAHS in general (Bosman et al. 2018; Rigato et al. 2016) with mean values of 40 dB and 32 dB, respectively and on Ponto 4 in particular [9] with mean value of 26.5 dB. In a literature review of functional gain (amongst other outcomes), a mean functional gain across 13 publications was 37.5 dB with a minimum and maximum of 20 dB and 48.3 dB, respectively [10.

6.2 Aided thresholds and effective gain

When looking into mean values of the aided thresholds obtained in this study (mean of 26 dB HL), these are also in line with results from the above-mentioned literature review where a mean aided threshold of 28.9 dB HL was found across 13 publications [10].

The effective gain (remaining air-to-bone gap) was found to be 6.74 (SD ± 6.33) for subjects with MHL/CHL. In a literature review of 8 studies [12], a mean effective gain of 5.1 with a SD of ± 8.7 was found which is in alignment with results from this current study.

6.3 Speech recognition

Concerning the secondary endpoint on speech recognition (endpoint C1), the overall score was significantly better aided (96.8%) compared to unaided (40.9%) ($p<.0001$). These results show that the subjects' speech recognition in quiet was close to 100% when wearing a Ponto 4 which is in line with previous studies performed with other Ponto's or bone-anchored devices in general (Bruschini et al. 2020; Della Volpe et al. 2020; Fan et al. 2019; Wang et al. 2018). This means that subjects who are wearing a BAHS device can recognize and repeat close to 100% of speech in quiet when presented at normal speech level.

6.4 Patient-related outcomes

For patient-related outcomes, the SSQ12 and GHSI questionnaires were used.

SSQ12

Self-reported performance obtained in the SSQ12 questionnaire had a mean value of 6.28 for the total score. This result is slightly higher (better) than a previous study utilizing the same shorter version of the SSQ

(SSQ12) where the mean value for the total score was 4.46 [11]. In order to evaluate in relation to reference data, one can look into results from the full SSQ (49 questions compared to 12) where the mean total score was 5.5 (Gatehouse and Noble 2004). The current results differ slightly from both which may be attributed to 1) the difference in length of SSQ and 2) the difference in device used and consequently also the signal processing utilized.

When looking further into the subscales from the SSQ12, the mean Spatial score was lower compared to the remaining subscales, as seen in the literature (Bosman et al. 2018; Bruschini et al. 2020). For SSD subjects, the Spatial score was even lower compared to the MHL/CHL group, as expected (Elkins et al. 2020). For spatial hearing, both cochlea's need to receive cues to localize sound. In asymmetrical and SSD cases, BAHS can/will possibly only stimulate one cochlea which is known to lead to poor sound localization due to limitations in restoring binaural cues (Elkins et al. 2020).

GHSI:

In the quality-of-life measure (GHSI), the subjects scored 65.4 on average (median 62.5) When looking into the reference data[8] for GHSI, the median (50th percentile) of 62.5 places the quality-of-life ratings between the 40th and 50th percentile for hearing aid provision. Not many studies utilize the GHSI questionnaire, but the mean values of 63.4 for MHL/CHL and 70.8 for SSD are slightly better compared to one other study where mean values of 60.9 and 63.8 was found for MHL/CHL and SSD, respectively (Koro and Werner 2019).

6.5 Other aspects

Average usage hours

The average usage hours for the last month prior to the study visit was 12.6. The average usage hours for the MHL/CHL group were higher (14.1 h) as compared to the SSD group (8.20 h); in the SSD group 1 subject did not use device at all during the last month because he/she only uses the device when working in the office (he/she has been working from home due to COVID-19). Usage hours are seldom reported, but it is known that SSD patients are not as dependent on their device as subjects with MHL/CHL, hence utilizing their device(s) less (Kompis, Wimmer, and Caversaccio 2017; Han et al. 2020)

Usage and satisfaction with connectivity devices

Twelve out of 18 subjects used the ON app, while respectively 5, 5 and 1 subjects were using the ConnectClip, Remote control and EduMic. Generally, the satisfaction was high with the connectivity devices one a scale from 0 (very dissatisfied) to 10 (very satisfied) with mean values of 8.21, 6.90, 8.00 and 9.00 with the ON app, ConnectClip, Remote control and EduMic, respectively. Ponto 4 is the first sound processor from Oticon Medical that uses these connectivity devices and there is yet no other studies that have recorded the usage of these connectivity devices.

7 OVERALL CONCLUSIONS

The study showed that the Ponto 4 subjects within intended use had improved hearing regarding functional gain, speech recognition and patient-related outcomes.

[8] https://studylib.net/doc/8450311/the-health-status-questionnaires-manual

8 ETHICS

An ethical approval was sought, but the local EC considered this study to be a project of quality assurance rather than a health research project, thus they provided a waiver for the study (Ethics Committee Journal nr: H-20050735).

9 INVESTIGATORS AND ADMINISTRATIVE STRUCTURE OF CLINICAL INVESTIGATION

Table 22 List of Investigators, sponsor representatives and external organizations as applicable.

Coordinating investigator –	Chris L. Jacobsen Audiologisk Afsnit Aalborg Universitetshospital Havrevangen 1, 6. sal 9000 Aalborg
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Sponsor:	Oticon Medical AB Datavägen 37 B 436 32 Askim Sweden
Monitor:	Jessica Ågren, Liselotte Borup
Data manager:	Valentina Zapata-Rodriguez
Statistician:	Mattias Molin, Statistika Konsultgruppen

10 SIGNATURES

Sponsor
On behalf of Oticon Medical AB, I approve the content of this report.

Date and signature:

Name and title

Coordinating Investigator
I approve the content of this report.

Date and signature:

Name and title

Principal Investigator
I approve the content of this report.

Date and signature:

Name and title

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