Statistical Analysis Plan

FINAL

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Ponto 3 SuperPower

Oticon Medical AB

Investigating hearing with Ponto 3 SuperPower, a bone anchored hearing aid - Investigating hearing with Ponto 3 SuperPower, a bone anchored hearing solution.

BC107

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LIST OF ABBREVIATIONS

Abbreviation	Definition
AC	Air conduction
ANOVA	Analysis of variance
BAHS	Bone-anchored hearing system
BC	Bone conduction
CHL	Conductive hearing loss
CI	Cochlear implant
CIP	Clinical Investigational Plan
DB	Database
dB	Decibel
DD	Device deficiency
GBI	Glasgow Benefit Inventory
HA	Contralateral hearing aid
ITT	Intent-to-Treat
Max	Maximum
MHL	Mixed hearing loss
Min	Minimum
MOM	Minutes Of Meeting
NR	Noise reduction
P3SP	Ponto 3 SuperPower
PP	Per-Protocol
PTA3	Pure tone average, calculated on average for frequencies 500, 1000 and 2000 Hz
PTA4	Pure tone average, calculated on average for frequencies 500, 1000, 2000 and 4000 Hz
SD	Standard deviation
SSD	Single sided deafness

1 STUDY DETAILS

1.1 Study Objectives

1.1.1 Primary objective

- To investigate the improvement in hearing with the Ponto 3 SuperPower for patients with CHL/MHL.

1.1.2 Secondary objectives

- To investigate the improvement in hearing with the Ponto 3 SuperPower for patients with CHL/MHL per frequency.
- To assess speech recognition in quiet and in noise with Ponto 3 SuperPower on the implanted ear(s) for patients with CHL/MHL.
- To assess the speech recognition in noise with Ponto 3 SuperPower for patients with SSD.
- To assess the degree to which the Ponto 3 SuperPower compensates for the BC hearing loss on the implanted ear(s) for patients with CHL/MHL.
- To assess the quality of life of the Ponto 3 SuperPower.
- To evaluate the above objectives on individual levels.
- To assess the air to bone gap (PTA4) on the implanted ear(s) for patients with CHL/MHL.
- To assess the skin condition around the abutment.

1.2 Study Design

The study is a retrospective study. Subject inclusion for this clinical investigation (see inclusion and exclusion criteria below) will be performed among subjects who has been fitted with the Ponto 3 SuperPower after it was CE market and available on the market since December 2016.

The endpoints in the study will investigate the improvement of hearing with the Ponto 3 SuperPower.

An overview of the data collections performed in the study can be found in the table below.

All study data collected will be recorded in electronic Case Report Forms (eCRF) via an electronic Data Capture System (described in more details in chapter 12).

Data collection Schedule	Retrospectively collected from clinical routine visits:	
	Ponto 3 SuperPower fitting	Follow-up visit(s)
1: Inclusion/exclusion criteria	X	
2: Eligibility	X	
3: Subject characteristics	X	
4: BC In-situ thresholds	X	
5: Audiometry thresholds (AC and BC thresholds)	X	
6: Speech recognition test (AB Isophonemic Monosyllabic Word test -short, and/or BKB sentence test) 1. Speech recognition in noise 2. Speech recognition in quiet		X
7: Aided sound field audiometry		X
8: Patient Reported Outcomes (GBI)		X
9: Skin reaction (Holger score)	X	X

1.3 Treatment Groups

All subjects have been fitted with the Ponto 3 SuperPower. Each subject will be its own control.

1.4 Sample Size

The sample size in the investigation is based on the typical size of retrospective studies on sound processor outcomes within the bone-anchored hearing system field.

For the primary endpoint there is no hypothesis to test, but a sample size at least as large as similar studies within state-of-the-art is considered appropriate. A total of 3 retrospective studies on sound processors from recent years that included functional gain as outcome, were identified [E]. The number of included subjects with functional gain reported on in the identified studies ranged from 6 to 53. The study with 6 subjects actually included 46 in total whereof 40 were fitted on softband. One study included 20 subjects for which functional gain were reported whereas the total number of subjects in the study was 49 (29 subjects only had surgical outcomes

reported). The third study included 53 subjects, all of which had functional gain reported.

Year	Title	Author	Number of subjects	Number of subjects in groups
2018	Hearing improvement with softband and implanted bone-anchored devices and modified implantation surgery in patients with bilateral microtia-atresia.	Wang et al.	46	6 (percutaneus) 40 (softband)
2016	Bone anchored hearing implants without skin thinning: the Gruppo Otologico surgical and audiological experience	Caruso et al.	49	20 (audiological outcome) 29 (surgical outcome)
2016	Bone Anchored Hearin Aid (BAHA) in children: Experience of tertiary referral centre in Portugal	Rosa et al.	53	

Due to the retrospective design, no drop-outs are considered. Based on the typical sample size in similar studies within state-of-the-art and achieving a sufficient number of patient represented in the hearing loss categories for CHL/MHL population, 55 subjects was concluded as an appropriate number to include in the study.

2 STUDY POPULATIONS

2.1 Definition of Study Populations

Due to the retrospective design, no safety population will be defined for the study. The intention-to-treat (ITT) population will include all subjects included in the study. No per-protocol (PP) population will be defined as this study collects data retrospectively and thus the expectation is that not all data for the described procedures will be available for all patients. Instead, the ITT population will be divided into two separate target groups depending on the type of hearing loss in the subjects.

The decision of the populations will be made prior to DB lock and information regarding each patient's population belonging will be found in the DB lock MOM.

The Target populations (TPs) are defined as:

- TP1: Subjects with conductive or mixed hearing losses (within intended use for Ponto 3 SuperPower): pure tone average (PTA3) bone conduction (BC) threshold on the BAHS(s) ear(s) better than or equal to 65 dB HL, based on BC threshold when Ponto 3 SuperPower were fitted.

- TP2: Subjects with single sided deafness (SSD) (within intended use for Ponto 3 SuperPower): pure tone average air conduction (AC) threshold of the hearing ear being better than or equal to 20 dB HL AC (measured at 0.5, 1, 2 and 3 kHz). In case AC is larger than 20 dB HL then the patients must not use a hearing aid on the other side.

Additional analyses will be performed on one subset of the TP1:

- Bilaterally fitted Ponto 3 SuperPower users with CHL/MHL. This is to avoid any contribution from the non-Ponto 3 SuperPower fitted ear in unilaterally fitted users or bimodally users (BAHS on one ear, hearing aid on the other), since all measurements have been performed without masking or blocking of the contralateral ear.

3 STUDY VARIABLES

3.1 Baseline Variables

3.1.1 Demographics and Baseline Characteristics

Subject level variables

- Gender (Male/Female)
- Age at fitting visit (years)
- Side (Right/Left/Bilateral)
- Type of hearing loss/hearing (MHL/CHL / SSD / SNHL / Normal hearing). The variables V1_Demo_HLright and V1_Demo_HLleft will be used to classify each subject into either MHL/CHL or SSD.
    - In case of Unilateral subject the hearing loss at that implanted side decides the subject's type of hearing loss.
    - In case of Bilateral subject, the type of hearing loss of the best ear decides the subject's type of hearing loss.
- Sequential or non-sequential implantation (Sequential/Non-sequential). Bilateral subjects only.
- Hearing solution on the non-BAHS ear (Unilateral subjects only).

Ear level variables

- Year of BAHS surgery
- Type of hearing/hearing loss on right and left ear (MHL/CHL / SSD / SNHL / Normal hearing)

3.1.2 AC and BC audiograms

AC and BC thresholds are measured unmasked and masked for at least one of the ears (commonly the implanted ear). The selection of the AC and BC thresholds depends on the type of hearing loss, as follows:

1. AC thresholds

For CHL/MHL and SSD subjects, AC thresholds are reported using AC unmasked thresholds if the AC masked threshold is not available. No imputations will be using to calculate the average AC thresholds across patients per frequency and the calculation of PTA4 per patient. AC thresholds should be reported for:

- CHL/MHL, unilateral, implanted ear
- CHL/MHL, unilateral, non-BAHS side (if available)
- CHL/MHL, bilateral, both implanted ears (if available)
- SSD, non-implanted ear
- SSD, BAHS side (if available)
- CHL/MHL+SSD (combined group, including SNHL if any), 1) CHL/MHL, unilateral/bilateral, implanted ear; 2) SSD, non-implanted ear; 3) SNHL, unilateral/bilateral, implanted ear

2. BC thresholds

For CHL/MHL and SSD subjects, BC thresholds are reported using BC unmasked thresholds if the BC masked threshold is not available. No imputations will be using to calculate the average BC thresholds across patients per frequency and the calculation of PTA4 per patient. BC thresholds should be reported for:

- CHL/MHL, unilateral, implanted ear
- CHL/MHL, unilateral, non-BAHS side (if available)
- CHL/MHL, bilateral, both implanted ears (if available)
- SSD, non-implanted ear
- CHL/MHL+SSD (combined group, including SNHL if any), 1) CHL/MHL, unilateral/bilateral, masked for implanted ear; 2) SSD, unmasked for non-implanted ear; 3) SNHL, unilateral/bilateral, implanted ear

3.2 Efficacy Variables

3.2.1 Primary Efficacy Variable

Functional gain with Ponto 3 SuperPower, i.e. the difference between unaided AC thresholds and aided sound field thresholds as the (PTA4) of frequencies 500, 1000, 2000 and 4000 Hz for patients with CHL/MHL ($ITT_{CHL/MHL}$ / TP1 / Bilaterally patients) (Objective A).

Unaided AC thresholds is defined as the masked, if not available unmasked, AC thresholds obtained with headphone TDH39. Unaided AC for the implanted ear will be used for the calculation of functional gain. In case of a bilateral Ponto fitting it is the best ear, calculating PTA4 for both ears and then choose the best one, AC that will be used.

Aided sound field thresholds are defined as sound field audiogram obtained as follow-up after Ponto 3 SuperPower fitting. The aided sound field has only been conducted on patients with CHL/MHL.

PTA4 will be calculated as the mean value of all non-missing values. A sensitivity (variable) analysis will be made for patients where all four including frequencies are non-missing.

Also analyse as the proportion of subjects whose performance is better or equal in the unaided to aided comparisons, i.e. have a difference >0, =0 and <0 (Objective H).

3.2.2 Secondary Efficacy Variables

- Functional gain with Ponto 3 SuperPower, i.e. the difference between average unaided AC thresholds and aided sound field thresholds for frequencies 500, 1000, 2000, 3000 and 4000 Hz for patients with CHL/MHL ($ITT_{CHL/MHL}$ / TP1 / Bilaterally patients) (Objective B). See definitions and analysis populations above. Also analyse as the proportion of subjects whose performance is better or equal in the unaided to aided comparisons, i.e. have a difference >0, =0 and <0 (Objective H).
- Aided speech recognition (%) in quiet measured with the BKB sentence test for patients with CHL/MHL ($ITT_{CHL/MHL}$ / TP1 / Bilaterally patients) (Objective C).
- Aided speech recognition (%) in noise measured with the BKB sentence test for patients with CHL/MHL ($ITT_{CHL/MHL}$ / TP1 / Bilaterally patients) (Objective C).
- Aided (and unaided if present, including change) speech recognition (%) in quiet measured with the AB[s] short list test for patients with CHL/MHL ($ITT_{CHL/MHL}$ / TP1 / Bilaterally patients) (Objective C).
- Aided (and unaided if present, including change) speech recognition (%) in noise measured with the AB[s] short list test for patients with CHL/MHL ($ITT_{CHL/MHL}$ / TP1 / Bilaterally patients) (Objective C).
- Difference in speech recognition score (%) for speech recognition in noise measured with the AB[s] short list test between unaided and aided when speech is directed to the aided ear, and noise is directed to the non-implanted ear for patients with SSD (ITT_{SSD} / TP2) (Objective D). Also analyse as the proportion of subjects whose performance is better or equal in the unaided to aided comparisons, i.e. have a difference >0, =0 and <0 (Objective H).
- Difference in speech recognition score (%) for speech recognition in noise measured with the AB[s] short list test between unaided and aided when speech is directed to the non-implanted ear, and noise is directed to the aided ear for patients with SSD (ITT_{SSD} / TP2) (Objective D). Also analyse as the proportion of subjects whose performance is better or equal in the unaided to aided comparisons, i.e. have a difference >0, =0 and <0 (Objective H).
- Effective gain with Ponto 3 SuperPower, i.e. the difference between aided sound field thresholds and the BC In-situ thresholds on the aided ear(s) measured when the Ponto 3 SuperPower(s) was fitted. The effective gain is calculated as the average (PTA4) of frequencies 500, 1000, 2000 and 4000 Hz for patients with CHL/MHL ($ITT_{CHL/MHL}$ / TP1 / Bilaterally patients) (Objective E). In case of a bilateral Ponto fitting it is BC In-situ thresholds for the best ear, calculating PTA4 for both ears and then choose the best one, that will be used. Average PTA4 across patients should be reported and computed for all the patients, and for only individuals where all four frequencies (500, 1000, 2000 and 4000 Hz) are non-missing. The latter PTA4 should be used for the figures. Used in sensitivity analyses.
- Effective gain is defined as the difference between aided sound field thresholds measurement with Ponto 3 SuperPower(s) and BC In-situ thresholds at the time when the Ponto 3 SuperPower was fitted. The effective gain is calculated for each frequency: 500, 1000, 2000 and 4000 Hz for patients with CHL/MHL ($ITT_{CHL/MHL}$ / TP1 / Bilaterally patients) (Objective F). In case of a bilateral Ponto fitting it is BC In-situ thresholds for the best ear, calculating PTA4 for both ears and then choose the best one, that will be used.
- Glasgow Benefit Inventory (GBI) scores (ITT / TP1 / TP2) (Objective G). Presented per before and after fitting of Ponto 3 SuperPower for:

- Total score
- General subscale
- Social support subscale
- Physical health

- The difference between masked (if not available unmasked) BC and AC thresholds, denoted 'air to bone gap', calculated as the average (PTA3) of frequencies 500, 1000 and 2000 Hz and for each frequency, from audiogram measured in connection with the fitting of Ponto 3 SuperPower for patients with CHL/MHL ($ITT_{CHL/MHL}$ / TP1) (Objective I). In case of a bilateral Ponto fitting it is the best ear, calculating PTA3 for both ears and then choose the best one, that will be used. PTA3 will be calculated as the mean value of all non-missing values. A sensitivity (variable) analysis will be made for patients where all four including frequencies are non-missing.
- Holgers score (scale 0-4) assigned by investigator at fitting and post-fitting follow up (ITT / TP1 / TP2) (Objective J).

3.2.3 Additional Efficacy Variables

- Self-reported usage of connectivity device(s) previously given to the test subject (ITT).

3.3 Safety Variables

3.3.1 Serious Adverse Events

Serious Adverse Events (SAE) will not be summarized in tabulations, but all SAEs will be presented in subject listings with the following information:

Variable	**Coding**
SAE Criteria	0=Death, 1=Life-threatening illness or injury, 2=Permanent impairment/ Chronic disease, 3=Hospitalization, 4=Medical or surgical intervention, 5=Foetal distress, foetal death or congenital physical or mental or birth defect, 6=Not applicable
Action taken	0=Interrupted use of the Medical Device, 1=Permanent discontinue of Medical Device, 2=Treated with medication, 3=None, 4=Unknown
Outcome	0=Resolved, 1=Resolved with sequalae, 2=Ongoing, 3=Death
Intensity	0=Mild, 1=Moderate, 2=Severe
Relationship to procedure	0=Not related, 1=Possible, 2=Probable, 3=Causal
Relationship to device	0=Not related, 1=Possible, 2=Probable, 3=Causal
Anticipated?	0=No, 1=Yes

Event Categorisation	0=AE (Adverse Event), 1=SAE (Serious Adverse Event), 2=ADE (Adverse Device Event), 3=ASADE (Anticipated Serious Adverse Device Event), 4=USADE (Unexpected Serious Adverse Device Event)
What is the current location of the device	0=Investigational/study site, 1=Sponsor, 2=Subject, 3=Manufacturer, 4=Remains implanted, 5=Discarded, 6=Unknown, 7=Other

4 STATISTICAL METHODOLOGY

4.1 General Methodology

The descriptive statistics of continuous variables will be given as Mean, standard deviation (SD), Median, Q1, Q3, Minimum, Maximum and 95% CIs. The distribution of categorical and dichotomous variables will be given as number and percentage.

Statistical tests will be performed for Functional gain (PTA-4 and frequencies), difference in speech recognition score between unaided and aided (AB[s] short list test for SSD patients), effective gain (PTA-4 and frequencies), and GBI scores (from before and after fitting). Continuous data will be tested for normality using the Shapiro-Wilk test. Paired t-test will be performed if the data is normally distributed. Wilcoxon signed-rank test will be performed if the data is not normally distributed. For categorical change variables i.e. change <0, 0 and >0 sign test will be used to test whether the change is significant or not. Pearson's correlations (or Spearman's if the data is not normally distributed) will be used to test correlations.

All tests will be two-tailed and conducted at 0.05 significance level. All analyses will be performed by using SAS® v9.4 (Cary, NC).

All analyses will be performed on the ITT population and the Target populations (TP1 and TP2) where applicable. Subgroup analyses (combined group (CHL/MHL+SSD and SNHL if any) and the subgroups CHL/MHL & SSD) will be conducted for the ITT population. Additional analyses will be performed on one subset of the TP1:

- Bilaterally fitted Ponto 3 SuperPower users with CHL/MHL. This is to avoid any contribution from the non-Ponto 3 SuperPower fitted ear in unilaterally fitted users or bimodally users (BAHS on one ear, hearing aid on the other), since all measurements have been performed without masking or blocking of the contralateral ear.

An overview of the analysis per objective is presented in the table below.

Objectives	ITT	Target	Effect of Ponto 3 SuperPower (bilaterally fitted CHL/MHL subjects)
A	X	X (TP1)	X
B	X	X (TP1)	X
C	X	X (TP1)	X
D	X	X (TP2)	
E	X	X (TP1)	X
F	X	X (TP1)	X
G	X	X (TP1 + TP2)	
H	X	X (TP1 + TP2)	X

I	X	X (TP1)	
J	X	X (TP1 + TP2)	

The additional analysis on the connectivity devices will be conducted on the ITT population.

Generally, PTA4 (for functional gain, effective gain, air-to-bone gap, aided sound field audiometry, AC- and BC audiometry and BC in-situ measurements) will be calculated as the mean value of all non-missing values. Sensitivity analyses will be made for patients where all four including frequencies are non-missing.

4.2 Missing Data

Missing data (i.e., single questions, single thresholds) will not be imputed and will be disregarded from the analysis.

4.2.1 Database codings

1. SMART TRIAL codes

   The SMART TRIAL codes will be treated as Not A Number (NANs) and will be disregarded from the analysis. Applicable for the BC107 study are:

   - .b: Not answered.
   - .c: Not answered due to cancel.
   - .d: Not answered due to discontinuation in study.
   - .e: Not answered due to exclusion.
   - .h: Not answered, hidden by show rule(s).
   - .n: Marked as ‘Answer not available’.
   - .ns: Possibility not selected.

2. 999: Data not measurable

The code is used for sound field audiometry, AC- and BC thresholds (i.e., if a threshold is not measurable the code ‘999’ must be entered manually by the investigator). The code will be treated as Not A Number (NANs) and will be disregarded from the analysis.

4.3 Patient Disposition and Data Sets Analyzed

The number of subjects included in each of the ITT, TP1 and TP2 populations will be summarized totally and by type of hearing loss.

4.4 Protocol Violations/Deviations

Not applicable since this is a retrospective study.

4.5 Demographics and Baseline Characteristics

Demographics and baseline characteristics will be analyzed according to the methods described in section “General Methodology” above, and summarized for the following populations:

- ITT totally and by CHL/MHL and SSD.
- TP2.

- TP1.
- Subset from TP1: Bilaterally fitted CHL/MHL subjects.

4.6 Efficacy Analyses

4.6.1 Primary Efficacy Analysis

The primary analysis on functional gain (PTA4) will be made according to the methods described in general methods above. Paired t-test will be the primary test since the functional gain if the case of normally distributed data and Wilcoxon signed-rank test will be performed If non-normality is shown by Shapiro-Wilk test.

The primary endpoint will be reported as defined in general methodology. The main outcome is the mean and 95% CI.

Figures will be made using the sensitivity analyses (only subjects with all four frequencies present).

Primary endpoint will be analysed for the following populations:

- $ITT_{CHL/MHL}$ (main primary analysis).
- TP1.
- Subset from TP1: Bilaterally fitted CHL/MHL subjects.

4.6.2 Secondary Efficacy Analyses

All secondary efficacy analyses will be described descriptively according to general methods above. Functional gain frequencies, difference in speech recognition score between unaided and aided (AB[s] short list test for SSD patients), effective gain (PTA-4 and frequencies), and GBI scores (from before and after fitting) will be tested statically, see general methods.

4.6.3 Additional Efficacy Analyses

The additional analysis on the connectivity devices will be described descriptively according to general methods above.

4.7 Safety Analyses

4.7.1 Adverse Events

Adverse events will be presented with number of events and number and percentage of subjects having events.

5 INTERIM ANALYSES

No interim analysis will be performed.

6 CHANGES OF ANALYSIS FROM PROTOCOL

No changes of analysis from the protocol were made.

7 LISTING OF TABLE, FIGURES AND LISTINGS

Details of the tables, figures and listings can be found in the Appendix BC107 TFL guidelines (filename: BC107_SAP_Tables_Figures_Listing_Guidelines_version 1.0_2021_11_25).

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14.1.1.2	Bar chart of the proportion with a difference >0, =0 and <0 of functional gain for frequencies 500, 1000, 2000, 3000 and 4000, and PTA4, for the combined group and the CHL/MHL group (ITT Population)
14.1.1.3	*SUBPLOT A*: Mean unaided AC threshold and 95% CIs for frequencies 500, 1000, 2000 and Hz, and PTA4 *SUBPLOT B*: Mean aided sound field threshold and 95% CIs for frequencies 500, 1000, 2000 and 4000, and PTA4 for the combined group and the CHL/MHL group (ITT Population)
14.1.2.1	Bar chart of the mean aided speech recognition (% correct words) and 95% CIs measured in quiet and in noise with the BKB sentence test for the combined group and the CHL/MHL group (ITT Population)
14.1.2.2	Boxplot and mean of the aided speech recognition (% correct words) and 95% CIs measured in quiet and in noise with the BKB sentence test for the combined group and the CHL/MHL group (ITT Population)
14.1.2.3	Bar chart of the mean aided speech recognition (% correct words) and 95% CIs measured in quiet and in noise with the AB[s] short list test for the combined group and the CHL/MHL group (ITT Population)
14.1.2.4	Boxplot and mean of the aided speech recognition (% correct words) measured in quiet and in noise with the AB[s] short list test for the combined group and the CHL/MHL group (ITT Population)
14.1.2.5	Bar chart of the mean speech recognition (% correct words) and 95% CIs by aided, unaided and their difference, measured in quiet and in noise with the AB[s] short list test for the combined group and the CHL/MHL group (only for patients with both measurements) (ITT Population)
14.1.2.6	Boxplot and mean of the aided speech recognition (% correct words) by aided, unaided and their difference, measured in quiet and in noise with the AB[s] short list test for the combined group and the CHL/MHL group (only for patients with both measurements) (ITT Population)
14.1.3.1	Bar chart showing mean unaided and aided speech recognition score (% correct words) and 95% CIs measured in noise with the AB[s] short list test when speech is directed to the aided ear, and noise is directed to the non-implanted ear for the combined group and the SSD group (ITT Population)
14.1.3.2	Boxplot and mean of the unaided and aided speech recognition score (% correct words) measured in noise with the AB[s] short list test when speech is directed to the aided ear, and noise is directed to the non-implanted ear for the combined group and the SSD group (ITT Population)
14.1.3.3	Bar chart of the proportion with a difference >0, =0, <0 of unaided vs aided speech recognition score (% correct words) measured in noise with the AB[s] short list test when speech is directed to the aided ear, and noise is directed to

	the non-implanted ear for the combined group and the SSD group (ITT Population)
14.1.3.4	Bar chart showing mean unaided and aided speech recognition score (% correct words) and 95% CIs measured in noise with the AB[s] short list test when speech is directed to the non-implanted ear, and noise is directed to the aided ear for the combined group and the SSD group (ITT Population)
14.1.3.5	Boxplot and mean of the unaided and aided speech recognition score (% correct words) measured in noise with the AB[s] short list test when speech is directed to the non-implanted ear, and noise is directed to the aided ear for the combined group and the SSD group (ITT Population)
14.1.3.6	Bar chart of the proportion with a difference >0, =0, <0 of unaided vs aided speech recognition score (% correct words) measured in noise with the AB[s] short list test when speech is directed to the non-implanted ear, and noise is directed to the aided ear for the combined group and the SSD group (ITT Population)
14.1.4.1	Mean effective gain and 95% CIs for frequencies 500, 1000, 2000, 3000 and 4000 Hz, and PTA4 (ITT population)
14.1.4.2	*SUBPLOT A*: Mean aided sound field threshold and 95% CIs for frequencies 500, 1000, 2000, 3000 and 4000 Hz, and PTA4 *SUBPLOT B*: Mean BC in-situ threshold with Device A and 95% CIs for frequencies 250, 500, 1000, 2000, 3000, 4000, 6000 and 8000 Hz, and PTA4 (ITT population)
14.1.5	Boxplot and mean of the Glasgow Benefit Inventory (GBI) scores in each subscale (General, Social, Physical) and total score collected before and after fitting of the P3SP, for the combined group and by type of hearing loss (ITT population)
14.1.6.1	Mean and 95% CIs difference between AC and BC thresholds, denoted 'air to bone gap' (dB), calculated for frequencies 500, 1000 and 2000 Hz, and PTA3, for the combined group and the CHL/MHL group (ITT population)
14.1.6.2	*SUBPLOT A*: Mean AC threshold (dB HL) and 95% CIs for frequencies 250, 500, 1000, 2000, 3000, 4000, 6000 and 8000 Hz, and PTA3 *SUBPLOT B*: Mean BC threshold (dB HL) and 95% CIs for frequencies 500, 1000 and 2000 Hz, and PTA3, for the combined group by type of hearing loss (ITT population)
14.1.7	Bar chart showing the mean and 95% CIs Holger scores collected pro and post fitting of P3SP, for the combined group and by type of hearing loss (ITT population)
14.1.8	Bar chart showing the self-reported usage of connectivity device(s) for the combined group and by type of hearing loss (ITT population)
14.2.1.1	Mean functional gain and 95% CIs for frequencies 500, 1000, 2000 and 4000 Hz, and PTA4, for the CHL/MHL group (TP1)
14.2.1.2	Bar chart of the proportion with a difference >0, =0 and <0 of functional gain for frequencies 500, 1000, 2000, 3000 and 4000, and PTA4, for the CHL/MHL group (TP1)
14.2.1.3	*SUBPLOT A*: Mean unaided AC threshold and 95% CIs for frequencies 500, 1000, 2000 and Hz, and PTA4

	SUBPLOT B: Mean aided sound field threshold and 95% CIs for frequencies 500, 1000, 2000 and 4000, and PTA4 for the CHL/MHL group (TP1)
14.2.2.1	Bar chart of the mean aided speech recognition (% correct words) and 95% CIs measured in quiet and in noise with the BKB sentence test for the CHL/MHL group (TP1)
14.2.2.2	Boxplot and mean of the aided speech recognition (% correct words) measured in quiet and in noise with the BKB sentence test for the CHL/MHL group (TP1)
14.2.2.3	Bar chart of the mean aided speech recognition (% correct words) and 95% CIs measured in quiet and in noise with the AB[s] short list test for the CHL/MHL group (TP1)
14.2.2.4	Boxplot and mean of the aided speech recognition (% correct words) measured in quiet and in noise with the AB[s] short list test for the CHL/MHL group (TP1)
14.2.3.1	Mean effective gain and 95% CIs for frequencies 500, 1000, 2000, 3000 and 4000 Hz, and PTA4 (TP1)
14.2.3.2	*SUBPLOT A*: Mean aided sound field threshold and 95% CIs for frequencies 500, 1000, 2000, 3000 and 4000 Hz, and PTA4 *SUBPLOT B*: Mean BC in-situ threshold with Device A and 95% CIs for frequencies 250, 500, 1000, 2000, 3000, 4000, 6000 and 8000 Hz, and PTA4 (TP1)
14.2.4	Boxplot and mean of the Glasgow Benefit Inventory (GBI) scores in each subscale (General, Social, Physical) and total score collected before and after fitting of the P3SP for the CHL/MHL group (TP1)
14.2.5.1	Mean and 95% CIs difference between AC and BC thresholds, denoted 'air to bone gap' (dB), calculated for frequencies 500, 1000 and 2000 Hz, and PTA3, for the CHL/MHL group (TP1)
14.2.5.2	*SUBPLOT A*: Mean AC threshold (dB HL) and 95% CIs for frequencies 250, 500, 1000, 2000, 3000, 4000, 6000 and 8000 Hz, and PTA3 *SUBPLOT B*: Mean BC threshold (dB HL) and 95% CIs for frequencies 500, 1000 and 2000 Hz, and PTA3, for the CHL/MHL group (TP1)
14.3.1.1	Bar chart showing mean unaided and aided speech recognition score (% correct words) and 95% CIs measured in noise with the AB[s] short list test when speech is directed to the aided ear, and noise is directed to the non-implanted ear for the SSD group (TP2)
14.3.1.2	Boxplot and mean of the unaided and aided speech recognition score (% correct words) measured in noise with the AB[s] short list test when speech is directed to the aided ear, and noise is directed to the non-implanted ear for the SSD group (TP2)
14.3.1.3	Bar chart of the proportion with a difference >0, =0, <0 of unaided vs aided speech recognition score (% correct words) measured in noise with the AB[s] short list test when speech is directed to the aided ear, and noise is directed to the non-implanted ear for the SSD group (TP2)
14.3.1.4	Bar chart showing mean unaided and aided speech recognition score (% correct words) and 95% CIs measured in noise with the AB[s] short list test when speech is directed to the non-implanted ear, and noise is directed to the aided ear for the SSD group (TP2)

14.3.1.5	Boxplot and mean of the unaided and aided speech recognition score (% correct words) measured in noise with the AB[s] short list test when speech is directed to the non-implanted ear, and noise is directed to the aided ear for the SSD group (TP2)
14.3.1.6	Bar chart of the proportion with a difference >0, =0, <0 of unaided vs aided speech recognition score (% correct words) measured in noise with the AB[s] short list test when speech is directed to the non-implanted ear, and noise is directed to the aided ear for the SSD group (TP2)
14.3.2	*SUBPLOT A*: Mean AC threshold (dB HL) and 95% CIs for frequencies 250, 500, 1000, 2000, 3000, 4000, 6000 and 8000 Hz, and PTA3 *SUBPLOT B*: Mean BC threshold (dB HL) and 95% CIs for frequencies 500, 1000 and 2000 Hz, and PTA3, for the SSD group (TP2)
14.3.3	Boxplot and mean of the Glasgow Benefit Inventory (GBI) scores in each subscale (General, Social, Physical) and total score collected before and after fitting of the P3SP for the SSD group (TP2)
14.4.1.1	Mean functional gain and 95% CIs for frequencies 500, 1000, 2000 and 4000 Hz, and PTA4, for the CHL/MHL group (TP1-Bilateral)
14.4.1.2	Bar chart of the proportion with a difference >0, =0 and <0 of functional gain for frequencies 500, 1000, 2000, 3000 and 4000, and PTA4, for the CHL/MHL group (TP1-Bilateral)
14.4.1.3	*SUBPLOT A*: Mean unaided AC threshold and 95% CIs for frequencies 500, 1000, 2000 and Hz, and PTA4 *SUBPLOT B*: Mean aided sound field threshold and 95% CIs for frequencies 500, 1000, 2000 and 4000, and PTA4 for the CHL/MHL group (TP1-Bilateral)
14.4.2.1	Bar chart of the mean aided speech recognition (% correct words) and 95% CIs measured in quiet and in noise with the BKB sentence test for the CHL/MHL group (TP1-Bilateral)
14.4.2.2	Boxplot and mean of the aided speech recognition (% correct words) measured in quiet and in noise with the BKB sentence test for the CHL/MHL group (TP1-Bilateral)
14.4.2.3	Bar chart of the mean aided speech recognition (% correct words) and 95% CIs measured in quiet and in noise with the AB[s] short list test for the CHL/MHL group (TP1-Bilateral)
14.4.2.4	Boxplot and mean of the aided speech recognition (% correct words) measured in quiet and in noise with the AB[s] short list test for the CHL/MHL group (TP1-Bilateral)
14.4.3.1	Mean effective gain and 95% CIs for frequencies 500, 1000, 2000, 3000 and 4000 Hz, and PTA4 (TP1-Bilateral)
14.4.3.2	*SUBPLOT A*: Mean aided sound field threshold and 95% CIs for frequencies 500, 1000, 2000, 3000 and 4000 Hz, and PTA4 *SUBPLOT B*: Mean BC in-situ threshold with Device A and 95% CIs for frequencies 250, 500, 1000, 2000, 3000, 4000, 6000 and 8000 Hz, and PTA4 (TP1-Bilateral)

14.4.4.1	Mean and 95% CIs difference between AC and BC thresholds, denoted 'air to bone gap' (dB), calculated for frequencies 500, 1000 and 2000 Hz, and PTA3, for the CHL/MHL group (TP1-Bilateral)
14.4.4.2	*SUBPLOT A*: Mean AC threshold (dB HL) and 95% CIs for frequencies 250, 500, 1000, 2000, 3000, 4000, 6000 and 8000 Hz, and PTA3 *SUBPLOT B*: Mean BC threshold (dB HL) and 95% CIs for frequencies 500, 1000 and 2000 Hz, and PTA3, for the CHL/MHL group (TP1-Bilateral)

7.3 Listing of Listings

Listing Number	Listing Title
16.2.1	Populations
16.2.2	Demographics and Baseline Characteristics
16.2.3	Audiograms and air to bone gap
16.2.4	Functional gain, aided sound field threshold and unaided AC threshold
16.2.5	Difference in speech recognition score (% correct words) measured in noise with the AB[s] short list test when noise is directed to the non-implanted and aided ear for the SSD group
16.2.6	Difference between aided and unaided speech recognition score (% correct words) measured in quiet and in noise with the AB[s] short list test for the CHL/MHL group
16.2.7	Effective gain, aided and BC in-situ thresholds
16.2.8	Device Deficiencies
16.2.9	Adverse Events