Opening up the world of sound with hearing implants

Jes Olsen President, Oticon Medical

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President, Oticon Medical

Curriculum

- Born in 1960
- B.Sc. in electronic engineering and electroacoustics
- Employed with Group since 1986
- General Manager, Oticon AB, Stockholm 1993-1996
- Various senior management roles in Oticon, including Vice President of R&D 1997-2008
- President, Oticon Medical since 2008



Agenda

Hearing implants market
Oticon Medical
The Neuro System: Scientific-based outcomes
Prof. Prof. h.c. Dr. med. Thomas Lenarz, Hannover Medical School
The Neuro system: Status
The Ponto system: Innovation fuelling better outcomes
Q&A



The market for hearing implants



Primary technologies within hearing implants

Cochlear implants (CI)



Bone anchored hearing systems (BAHS)



A cochlear implant makes sense of sound for people with severe to profound sensorineural hearing loss A bone-conducting hearing system is suited for people with conductive hearing loss, unilateral hearing loss or single-sided deafness

Cochlear implant (CI) market



Where does CI market growth come from?



Bone anchored hearing systems (BAHS) market



Where does BAHS market growth come from?





Oticon Medical



History of Oticon Medical

Bone anchored hearing systems (BAHS)

O 2007 Oticon Medical established in Gothenburg, Sweden	2009 Launch of t Ponto Systa – bringing o sound qual BAHS	the Ponto P em – the fir digital anchore ity to power p	ro Power W st bone – ed digital bo processor cc	D12 /ide Ponto implant the industry's largest one-to-implant ontact	2013 Ponto Plus and Ponto Plus Power – the first and most powerful family of processors with	2015 Minimally Invasive Ponto Surgery (MIPS) – a truly new perspective on tissue preservation	2016 Ponto 3 family – the world's most powerful family of abutment-level sound processors
	-			2013 Oticon Medical William Deman acquires Neurel	wireless connectivity / t ec		
Cochlear im 1976 First multi- channel cochlear implantation in France by Prof. Chouard	1977 Development and production of cochlear implants established in Nice, France	1992 Digisonic DX10 – the first digital multi-channel cochlear implant	2001 Digisonic BTE – our first BTE sound processor	2012 Digisonic® SP EVO – the atraumatic electrode array to preserve residual hearing	2013 Saphyr Neo collection – better speech understanding in noise with Voice Track & Crystalis XDP	2015 Launch of the Neuro system Neuro Zti implant and Neuro One sound processor	Today Neuro 2 – where sound meets design

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William Demant/ Oticon Medical's position in hearing implants 0-0 Size and cosmetics Audiology **Product** innovation **Fitting software** Reliability Access to key markets **Brand recognition** Market access **End-user lead generation Global infrastructure** Leading in BAHS **Advancements**

Synergies with the William Demant Group



BrainHearing™

⁶⁶ The ears hear things...

...the brain makes sense of them ⁶⁶



From BrainHearing[™] in hearing aids ...



OpenSound Navigator

Keeping speech clear and other sounds available, but not disturbing

Enjoy **30%** better speech understanding Reduce your listening effort by **20%** Remember 20% more of your conversations

... to BrainHearing[™] in hearing implants

BAHS

SWIR: Direct Sound Transmission vs. Skin drive



under ecological test conditions. Ear & Haring, vol 37, supplement 1, 145S-154S

CI: Combined SWIR and pupilometry



Speech audiometry scores with Speech Omni Compared to Opti Omni in 6 Neuro Cl users

Committed to BrainHearing™

- Our portfolio of studies is large and growing
 - **EEG** measures ٠
 - Behavioural tests, e.g. SWIR Recall ٠
 - Pupilometry solutions (several set-ups, SMI, Tobii, Pupil labs etc.)
 - Functional near-infrared spectrometry ٠
 - Heart rate changes ٠
 - Infield research platform (self-assessment app, ٠ sound, HR data)
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Partner in several EU H2020 projects on cognitive hearing



befahren, Tort

Patient journey – focus on people

- With hearing implants, you are on a life-long journey with the end-user
- Continuous innovation and long-term commitment are crucial factors for success
- Winning the customers takes time and it should
- You should be easy to do business with and ensure easy access to information
- Recurring business and obligations when winning the customers' loyalty





Patient journey – funnel



ENT Newborn hearing screening Hospital Retail Communities On-line activities



Availability Functionality Product sourcing Partnerships Research



Fine-tuning Innovation (upgrades) Accessibility Compatibility

Awareness Counselling After care

Patient journey – synergies with rest of Group



Customer network Group retail Diagnostic division Power house of hearing On-line communities



Global presence Strong infrastructure Audiological expertise Professional relations Strong brand



Support centres Global presence On-line activities In it to win it

Awareness

Counselling

After care



Oticon Medical: Our world





The Neuro system: Scientific-based outcomes



Neuro Zti cochlear implant

New standard in MRI compatibility

No risk of magnet extrusion at 1.5T– rigid body No pain due to receiver movement – fixation system Removal made easy and safe for compatibility at 3T





Fig. 1. AP skull film demonstrating 90 degree rotation of the internal magnet. There is associated protrusion of the scalp tissues (arrowheads).

First independent study published Todt et al., JOHNS 2018

Comparing two technical solutions for MRI compatibility: Neuro Zti and Competitor A



Neuro Zti is comparable to the best competitor product in the domain and outperforms products from two other manufacturers.

BrainHearing[™] and the Neuro 2 sound processor

Speech Omni setting in FreeFocus directional system



Providing measurable benefits ...



Speech audiometry scores with Speech Omni compared to Optimised Omni in six Neuro CI users ... that patients want to use



Subjective preference in different listening situations for Speech Omni vs. Optimised Omni in 35 Neuro CI users 2

UNIQUE

Neuro 2 sound processor

New standard in terms of battery life and design

Industry-unique aesthetic characteristics in combination with superior performance and increased outcomes

Objective measure: Speech audiometry scores





Opening Up the World of Sound With Hearing Implants

Thomas Lenarz, MD PhD

Department of Otolaryngology Hannover Medical School, Germany

WDH Capital Market's Day, London June 12, 2018



Hearing Disorders



Medizinische Hochschule

Hannover

Hearing Loss: A GROWING GLOBAL EPIDEMIC





Hearing Loss in Germany



Hearing Loss: Auditory Devices





Cochlear Implant





The "success story" of Neuroprotheses > 500.000 Recipients Worldwide Candidates in Germany: 1 Million Implanted in Germany: 50.000								
Contact with the world of sound	Speech discrimination in a majority	Speech discrimination in all	Speech in noise & music perception in all					
First	Then	Now	Future					

Fig. 49. Photograph of the portable prototype speech processor developed by the University of Melbourne.



States -

History and Future of Active Implants

"...implants that rely for functioning on a source of electrical energy or any source of power other than that directly generated by the human body ..."(90/385/EEC MEDDEV)



Cmhh

Medizinische Hochschule

DH7

Conservative Market - Expectations

Devices Implanted per Year



Conservative means early Saturation!

Innovative Breakthrough like PM are always possible, but:

Medical Devices have long Delays due to Testing & Approval!







Objective: Develop auditory precision medicine









Precision Medicine

Every patient with hearing
Precision Treatment for HearingLoss

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Hearing 4all

Clinical translation challenges

Artificial synapse

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- Analogue-digital conversion
- Complete restoration of physiological hearing

Cochlear Implant Program in Hannover

Steps toward excellence:

1984	1st CI
1992	Children's implant Center
2003	German Hearing Center
2003	Collaborative Research Grant Medical implants
2013	Center of Excellence Hearing4All
2016	VIANNA in NIFE
2016	Fraunhofer Center of Biomedical Excellence

 Clinic – with 25,000 outpatients and 6,000 inpatients each year 600 Cochlear Implantations per year – 10.000 in total
 German Hearing Center – patients go with hearing loss
 NIFE– laboratories of experimental otology basic research
 VIANNA – transfer basic science into new products Companies
 Fraunhofer ITEM – production, testing and certification

Centre of BioMedical Excellence

Translational Medical Engineering

Hannover

Auditory and Neuroimplant Research Cluster

Hannover Medical Park

German Hearing Center (DHZ)

- Integrated care for hearing impaired people
- One-stop shop
- Complete spectrum of diagnostic procedures
- Candidate selection
- Postoperative care and rehabilitation
- Conservative treatment of hearing loss
- Service centers of manufacturers for direct support of patients
- Remote care center hub and spoke
- Clinical research in fields of speech coding, electrodes, and acoustic implants

Head of clinical service: Prof. Dr. Anke Lesinski-Schiedat

Head of technical service and research: Prof. Dr. Andreas Büchner

Remote Care : Patient monitoring and Service

Hub and Spoke: 25 partners across Germany

Full service with spare parts, implant check and upgrade

Can be connected to the CI center any time

Future self fitting and automated patient monitoring through data transfer

Remote Care with 2 way audio-visual connect

CI Center

Satellite

Hannover Medical School Experience with Oticon Neuro Implant

Because sound matters

The Neuro Cochlea-Implant system

Neuro One

- Oticon Technology Inside (Inium)
- Coordinated Adaptive Processing

Neuro Zti

- Compact design
- Future-proof technology
- Conventional and atraumatic electrode arrays

The Neuro Cochlea-Implant system

Neuro 2

- Oticon Technology Inside (Inium)
- Coordinated Adaptive Processing
- Smallest BTE processor in the market

Neuro Zti

Compact design Future-proof technology Conventionel and atraumatic electrode arrays

Neuro Zti: feature summary

- Antenna protection inside the case
- 2nd generation fixation system
- Removable magnet
- MRI safe up to 3T with magnet removed
 - 1,5T with magnet in place

Electrode options

Insertion Length: 26 mm

- 24 independent high-precision current sources
- Configurable ASIC with substantial reserves for future development in the area of signal processing
- 28 hermetic sealed feed through
- Build-in DSP for signal processing
 - ECAP
 - future: E-BERA or other AEPs

- Oticon BrainHearing™ Technology
- Up to now, 67 Oticon Neuro ZTI systems implanted at MHH
 - Average age: 62,3 yr.; avg. hearing impairment: 26,7 yr.; avg. deafness: 13,5 yr.

- All patients fulfill our expectations related to achieved listening performance with CI
- Automatic features of the Inium Sense chipset (AGC-free signal processing, beam former, noise reduction, etc.) are easy to program und perfectly accepted by the patients
- ECAP measurement system provides curves with good signal-to-noise ratio. We are collecting data for further analysis of reliability.

Oticon Neuro Implantation at Hannover Medical School

Because sound matters

First data on Neuro 2

- Since February 2018, the Neuro 2 sound processor is available
- Up-to-now, 55 upgrades have been conducted
- Patients report significant improvements in sound quality and clarity
- Therefore, we are conducting comparing measurements at each upgrade visit with both, Neuro One and Neuro 2 sound processors in the sound field.

Preliminary performance data

Preliminary performance data

Summary

- In total, 67 Oticon Neuro Systems have been implanted at MHH
 - All surgeries have been conducted without complication
 - Pleased with level of OM inter-operative support provided
- All Neuro Zti patients at MHH are within expected listening performance, Neuro 2 obtains significantly better speech understanding results compared to Neuro One
- The signal processing chain in Neuro 2 is controlled by the Inium Sense Chip. Der Inium Sense Chip is widely
 used in Oticon's high-end hearing aids and allows for latest signal processing advances to be utilised in
 cochlear implant systems.
- As for all CI systems, technical support by the producer is essential. We are very satisfied with the support
 provided by Oticon Medical.

Thank you

The Neuro system: Status

The Neuro system

Neuro 2 launch status

William Demant/

- 500+ patients fitted with Neuro 2 in key markets
 - First users fitted at the end of February
- Focus on upgrading Neuro One exchange program users
 - Excellent feedback from users on: Sound quality, usability, battery life, rechargeable batteries and the comfortable physical fit of BTE on their ear
- Professionals are very excited about the easy fitting process and the general quality of the new Genie Medical CI
- Significant interest in the system; comprehensive training programmes are ongoing at key CI centres
- The vast majority of exchanges have been completed in the addressable markets
- Focus on roll-out to remaining markets

Genie Medical CI – designed for audiologists

Logarithmic frequency axis

Live bilateral loudness adjustments

Multiple design awards for Neuro 2

reddot award 2018 winner

Red Dot Award 2018 Winner for Product Design (Healthcare)

winner

(Bionics)

reddot award 2018

Red Dot Award 2017

Winner for Design Concept

iF Design Award 2018 Winner for Product Design (Medical Device)

Danish Design Award Finalist 2018 (Daily Life)

2018 WINNER
EUROPEAN
PRODUCT
DESIGN
AWARD

European Product Design Award 2018 Gold prize winner (Life ScienceDesign/Aids/ Prosthetics)

German Design Award Winner 2018 for Excellent Product Design (Medical, Rehabilitation and Health Care) Good Design 2017 Winner (Personal)

GOOD

DESIGN

A'Design Award Winner 2018 Gold (Scientific Instruments, Medical Devices and Research Equipment Design)

IDA Design Awards Gold Winner 2017 (IndustrialAnd Life Science Design-Aids/Prosthetics)

The Ponto system: Innovation fuelling better outcomes

Ponto 3 SuperPower: The strongest abutmentlevel sound processor

Significantly better speech understanding in complex situations

Including effect of FreeFocus feature

Significantly better patient ratings

Including effect of higher maximum output

Bosman AJ, et al. (2018). On the evaluation of a superpower sound processor for bone-anchored hearing. Clinical Otolaryngology.

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Ponto on softband: A proven solution for children

Data from bilateral microtia-atresia infants

- (i) Children's auditory development reported for 40 infants
 - Ponto sound processor on a softband improves auditory development
- (ii) Treatment gives significant improvement over time
 - On average, close to normal scores being achieved after 24 months' use of the sound processor

Wang, Y., e tal (2018). Hearing improvement with softband and implanted boneanchored hearing devices and modified implantation surgery in patients with bilateral microtia-atresia. International journal of pediatric otorhinolaryngology.

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Ponto: Long-term randomised controlled study of 60 implants

Excellent stability and survival over three years

• High implant stability and survival rates

Mean implant stability, ISQ Low

Very few skin complications with Ponto implants

 Only 2% of visits reported skin complication in need of treatment (Holgers ≥2)

Kruyt, I. J., et al. (2018). Three-year Outcomes of a Randomized Controlled Trial Comparing a 4.5-mm-Wide to a 3.75-mm-Wide Titanium Implant for Bone Conduction Hearing. Otology & Neurotology.

First clinical data on the Ponto BHX implant support earlier pre-clinical data

Clinical data from world-leading centres

• High implant stability and survival rates

Supporting unique osseointegration properties

• Stronger than bone

1 | INTRODUCTION

Successful bone-anchored hearing implantation requires good osseointegration of the titanium implant in the temporal bone and humples soluted ensuring the The later during a funder discussed. Queen Elizabeth University Hospital (Birmingham, England) and James Cook University Hospital (Middlesbrough, England). In these centres, patients eligible for bone-anchored hearing implantation test all available hearing restoration options in daily life situations to

Oticon Medical – well positioned for growth

- Strong product portfolio in BAHS and CI with great outcomes
- Scientific approach to support customer choice
- Well integrated with Group R&D and Operations

Positioned to exceed long-term market growth

- Global infrastructure and a strong local support organisation
- Substantial synergies for market access

Long-term commitment and support from owner



Q&A