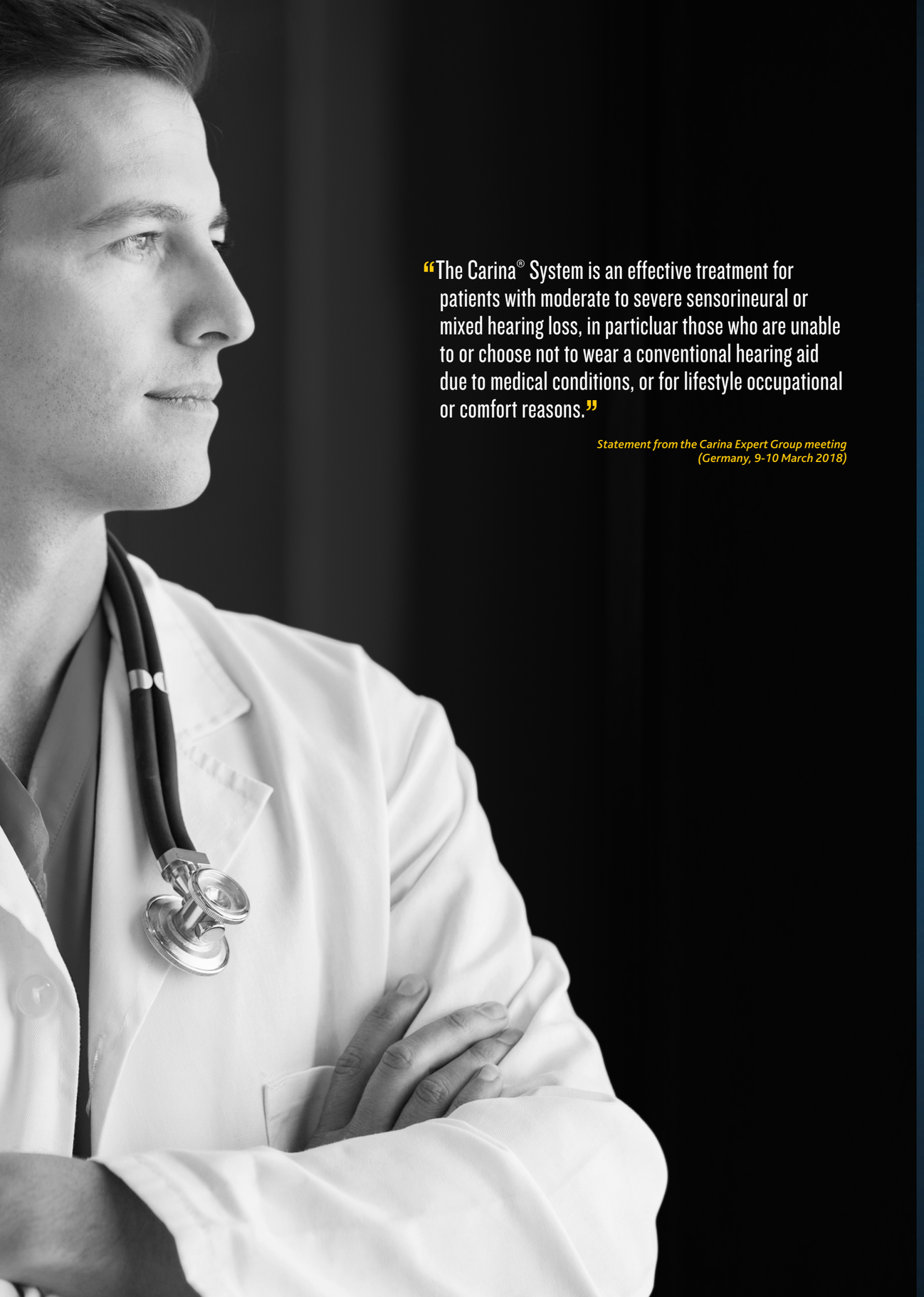
Cochlear™ Carina® Fully Implantable Middle Ear Implant System

A SUMMARY OF CLINICAL EVIDENCE

Hear now. And always

Cochlear®



"The Carina® System is an effective treatment for patients with moderate to severe sensorineural or mixed hearing loss, in particluar those who are unable to or choose not to wear a conventional hearing aid due to medical conditions, or for lifestyle occupational or comfort reasons."

Statement from the Carina Expert Group meeting (Germany, 9-10 March 2018)

Power to hear. Night and day.

Over the years, the Cochlear™ Carina® Active Middle Ear Implant System has been further developed and improved. The Carina System offers two ways to hear, namely with or without a Button® processor. It provides the power to compensate for severe hearing losses and offers a flexible hearing solution that can be adapted to the anatomy of the middle ear.

This review provides a summary of clinical evidence demonstrating that the Carina System is a safe and reliable fully implantable active middle ear implant that yields similar or better hearing performance compared to conventional hearing aids for adults with moderate to severe sensorineural or mixed hearing loss. It shows that Carina recipients are satisfied daily users and that the Carina System has significantly improved their quality of life.

This summary includes the latest outcomes of ongoing research[1] and the most recent peer-reviewed publications, involving 230 Carina recipients in total.

[1] Published in Journal of Hearing Science, 2018, vol. 8, pp. 55-386: Book of abstracts – 15th International Conference on Cochlear Implants and other Implantable Technology, Antwerp, 27-30 June 2018

Safety and Performance

Active middle ear device totally implanted – Carina® System: first results

PEIXOTO, C. M., MIRANDA, C., BENTO, M., OLIVEIRA, S., PRATAS, R., AND CORREIA DA SILVA, V.

Presented at the 15th International Conference on Cochlear Implants and other Implantable Auditory Technology in Antwerp (Belgium), 2018 and at the 122nd Annual Meeting of the American Academy of Otolaryngology-Head and Neck Surgery in Atlanta (US), 2018

Patients

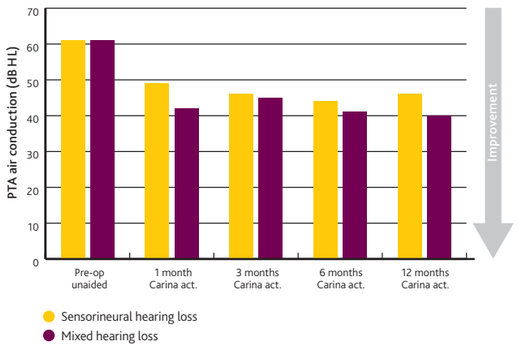
Fifteen adults between 20 and 71 years old were implanted with the Carina System. The actuator was coupled to the incus body in patients with sensorineural hearing loss (N = 9) and to the stapes head in patients with mixed hearing loss (N = 6).

Methods

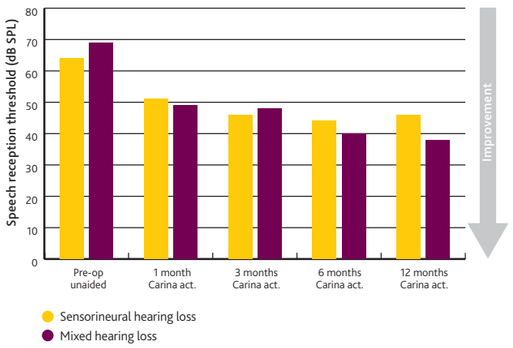
Pre-operatively, audiometric thresholds and word recognition in quiet were measured in the unaided condition. Speech recognition in noise was tested in the best-aided condition (conventional hearing aids). These tests were repeated with the Carina System 1, 3, 6 and 12 months after activation.

Results

There were no significant differences between the pre- and post-operative unaided air conduction, bone conduction, or speech reception thresholds. This shows that Carina implantation is a safe surgical procedure. Twelve months post-activation, air conduction thresholds improved by 15 dB and 21 dB for sensorineural and mixed hearing loss patients, respectively, with the Carina System compared to the unaided condition. Aided speech reception thresholds were 18 dB and 31 dB lower (improved) than the unaided thresholds for sensorineural and mixed hearing loss patients, respectively. Averaged across 16 speech-in-noise conditions[2], there was a clinically relevant improvement (14%) in speech perception with the Carina System compared to the best-aided condition (conventional hearing aids).



Pure-tone average (average of air conduction thresholds at 0.5-3 kHz) in the pre-operative unaided condition and in the Carina aided condition at 1, 3, 6, and 12 months post-activation for patients with sensorineural hearing loss (N = 9) and mixed hearing loss (N = 6).



Speech reception threshold (dB SPL, 50% word recognition) in the pre-operative unaided condition and in the Carina aided condition at 1, 3, 6, and 12 months post-activation for patients with sensorineural hearing loss (N = 9) and mixed hearing loss (N = 6).

[2] Six months after activation, recognition scores (% correct) were measured for words and sentences presented with competing speech or cafe noise (signal-to-noise ratio: 0 dB), for four speech-in-noise configurations (different directions of the speech and noise signals)

CONCLUSION

This study confirms that the Carina System is a safe and effective treatment for patients with sensorineural and mixed hearing loss.

The UK experience of the Cochlear™ Carina® fully implantable hearing device: bridging the gap in severe hearing loss

RAMSDEN, J., HUMPHRIES, J., KUMAR, S., SELVADURAI, D., DONNELLY, N., AND RAY, J.

Presented at the 15th International Conference on Cochlear Implants and other Implantable Auditory Technology in Antwerp (Belgium), 2018

Patients

Thirteen Carina recipients (median age: 56 years) were included in this study. They all had sensorineural hearing loss, and many had an additional conductive loss. The Carina System was implanted with the actuator coupled to the incus (except for 1 patient).

Methods

A sentence recognition test was used to evaluate speech recognition in quiet pre-operatively in the unaided condition and with a BAHA, and post-operatively with the Carina System in invisible mode and in power mode (with Button® processor).

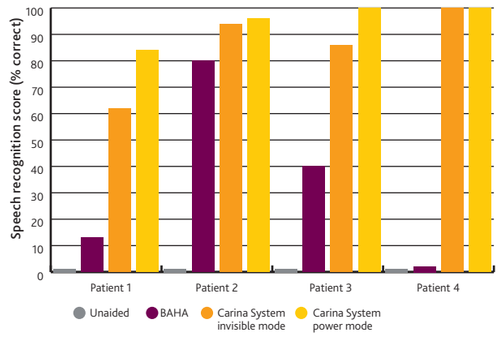
In addition, the pre- and post-operative hearing difficulty (disability) was rated by means of the Glasgow Hearing Aid Benefit Profile.

Results

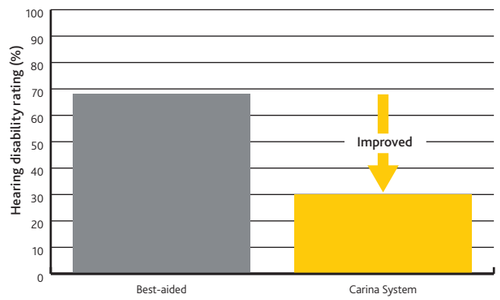
Speech recognition scores were 0%, 33%, 86%, and 95% on average, in the unaided condition, with a BAHA, with the Carina System in invisible mode, and with the Carina System in power mode, respectively.

Compared to the best-aided condition (hearing aid or BAHA), the rating of hearing disability dropped from ~70% to ~30% with the Carina System.

High satisfaction with the "natural" sound was reported.



Speech recognition scores (% correct) of 4 patients in unaided condition, with BAHA, with the Carina System in invisible mode, and with the Carina System in power mode.



Average hearing disability ratings from the Glasgow Hearing Aid Benefit Profile (N = 13).

CONCLUSION

Compared to the best-aided conditions, the Carina System yields improved speech recognition in quiet and significantly reduces hearing difficulty.

An adaptive feedback cancelling algorithm for the Cochlear™ Carina® hearing System: first clinical results

DEVÈZE, A., TRUY, E., BERGER, P., DUMOUCHEL, Y., AND TRINGALI, S.

Presented at the 15th International Conference on Cochlear Implants and other Implantable Auditory Technology in Antwerp (Belgium), 2018

Patients

Fourteen Carina recipients with mixed hearing loss (N = 7) or sensorineural hearing loss (N = 7) between 46 and 69 years of age, were enrolled in this clinical trial.

Methods

The participants were first fitted with the fixed feedback canceller (FFC) and then with the new, adaptive feedback canceller (AFC[3]) or vice versa (randomized).

After two months of experience with each of the feedback cancellers, patients' satisfaction was evaluated by 2 questions:

Q1: How would you rate your preference for the new feedback cancelling algorithm compared to your existing one?

Q2: How would you rate your preference for the new feedback cancelling algorithm compared to your existing one regarding sound quality?

In addition, word recognition in quiet was compared between the AFC and the FFC.

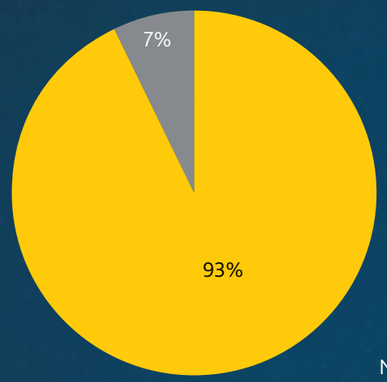
CONCLUSION

Compared to the FFC, the new AFC yields better sound quality resulting in higher patient satisfaction. Furthermore, the AFC improves word recognition at low input levels.

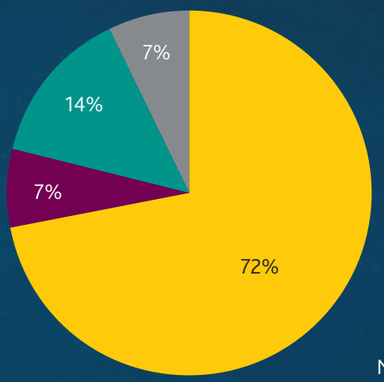
[3] Cochlear has developed a new feedback cancelling algorithm which automatically integrates the environmental and physical parameters to optimize sound quality. This new algorithm automatically adapts to new environments and simplifies the fitting (no need for positional noise measurements).

Results

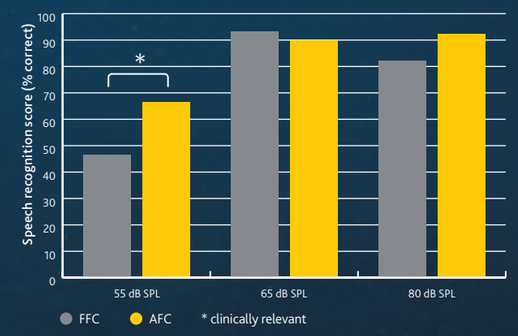
Q1: 93% of patients strongly preferred the new AFC over the FFC



Q2: 79% of patients preferred the sound quality with the new AFC over the FFC



With the new AFC, a clinically relevant improvement in word recognition was found (20%) when words were presented at 55 dB SPL. For higher presentation levels, speech perception was similar for the FFC and AFC.



Speech recognition scores (% correct) at presentation levels of 55, 65, and 80 dB SPL (N = 9).

Speech discrimination and aided threshold outcomes for Carina® patients, following re-programming with the new Carina fitting software 4.0

HUMPHRIES, J.

Presented at the 15th International Conference on Cochlear Implants and other Implantable Auditory Technology in Antwerp (Belgium), 2018

Patients

Four Carina recipients with mixed hearing loss implanted between 43 and 71 years of age, were upgraded with the new Carina fitting software featuring the adaptive feedback canceller (AFC), in contrast to the fixed feedback canceller (FFC) of the previous software. One patient was a bilateral Carina recipient.

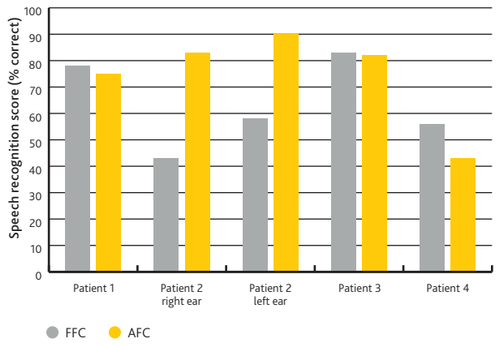
Methods

Word recognition scores in quiet were measured with both the FFC and the new AFC.

Results

Patients 1, 2, and 3 showed equivalent or better speech recognition with the AFC compared to the FFC. They all reported that sound quality was improved with the AFC. Patient 4 felt that the sound with the AFC was not as clear as with the FFC and was reprogrammed to the previous settings.

The audiologist noted faster initial fitting and re-programming with the new software.



Speech recognition scores (% correct, 60 dB SPL) of 4 patients with mixed hearing loss.

CONCLUSION

Compared to the FFC, the AFC yields improved sound quality and reduced fitting time.

Carina® System: the before and after of a fully implantable hearing device

JAIME, Y., GONZÁLEZ, N., AND ALMARIO, J.

Presented at the 15th International Conference on Cochlear Implants and other Implantable Auditory Technology in Antwerp (Belgium), 2018

Patients

This study included 13 Carina recipients who could not or did not want to use conventional hearing aids. They were 27 years of age on average at the time of the Carina implantation. Different coupling techniques were used, involving the incus, stapes, or round window.

Methods

All patients were tested pre-operatively in an unaided condition and 6 months after the Carina activation with the Carina device switched on and off.

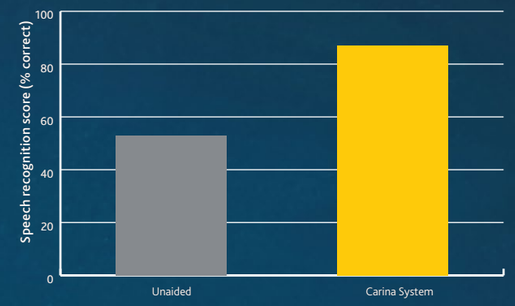
Audiometric thresholds, word recognition in quiet, and APHAB scores were evaluated.

Results

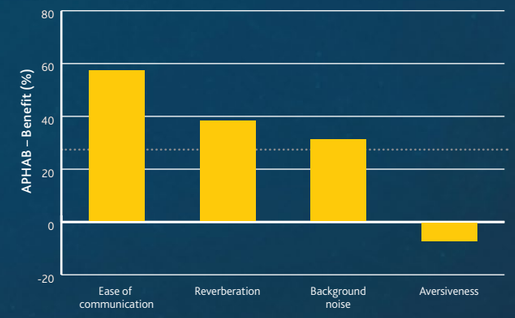
There were no significant differences between the pre- and post-operative unaided air or bone conduction thresholds, confirming the safety of the Carina implantation. For all audiometric frequencies (250 Hz-8 kHz), the aided thresholds with the Carina System were significantly lower (~20-25 dB HL better) than the unaided thresholds.

Word recognition scores significantly improved with the Carina System (87%) compared to the unaided condition (53%).

With the Carina System, a statistically significant benefit (≥ 27%) was found for ease of communication (EC, 57%), for communication in reverberant settings (RV, 38%), and for communication in noisy settings (BN, 31%). For aversiveness of sounds, a slight disadvantage was detected (AV, -7%), but this was not statistically significant (< 31%)[4].



Speech recognition scores (% correct, 65 dB SPL, N = 13).



Reported benefits with the Carina System compared to the unaided condition (N = 13). The dotted line indicates 27%, which is the significance cut-off for ease of communication (EC), reverberation (RV), and background noise (BN).

[4] The 90% significance cut-off is 27% for the subscales EC, RV, and BN, and 31% for the subscale AV (Cox and Alexander, 1995)

CONCLUSION

The Carina implant has a positive impact on the auditory performance and experience of patients who cannot or do not want to use conventional hearing aids.

Preliminary data on quality of life and daily hearing function for Carina® MEI recipients

PEIXOTO, C. M., CORREIA DA SILVA, V., GISBERT, J., ROVO, L., ARNDT, S., WEBER, B., HAGEN, R., AND BARAUNA, I.

Presented at the 15th International Conference on Cochlear Implants and other Implantable Auditory Technology in Antwerp (Belgium), 2018

Patients

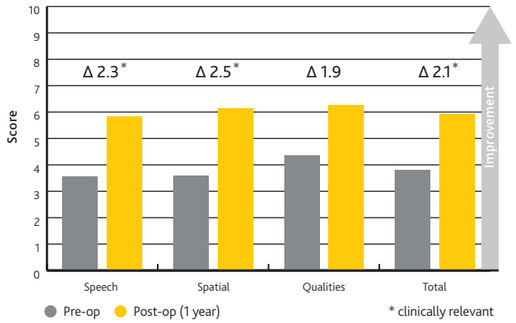
This multicenter observational study included 14 Carina recipients between 16 and 69 years of age from Brazil, Hungary, Germany, Portugal, and Spain. Ten of them (71%) had tried hearing aids before the Carina implantation.

Methods

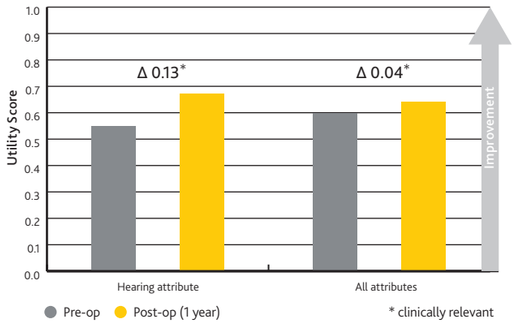
All patients completed two questionnaires: the Speech, Spatial and Qualities of Hearing Scale (SSQ) and the Health Utilities Index Mark 3 (HUI3). Both questionnaires were completed before and 1 year after Carina implantation to evaluate changes in self-assessed disability in daily hearing function (SSQ) and health-related functional abilities (HUI3). Increments (Δ) of > 2 points in the SSQ score and > 0.03 points in the HUI3 score constitute clinically relevant improvements.[4]

Results

One year after Carina implantation, clinically relevant improvements were observed for daily hearing function (SSQ) and health-related functional abilities (HUI3) compared to the pre-operative condition, which for most patients involved conventional hearing aids.



SSQ subscale scores and total score (N = 14).



Utility score for hearing and for all HUI3 attributes, i.e., vision, hearing, speech, ambulation, dexterity, emotion, cognition, and pain (N = 14).

CONCLUSION

Hearing-impaired persons implanted with the Carina System report clinically relevant improvements in daily hearing function and health-related functional abilities.

[4] For more information on clinically relevant differences regarding the SSQ and HUI3, see Noble et al. (2012) and Horsman et al. (2003).

Clinical results after implantation of a fully implantable hearing system in patients with chronic otitis media

LASURASHVILI, N., LAILACH, S., NEUDERT, M., BORNITZ, M., SEIDLER, H., AND ZAHNERT, T.

Presented at the 15th International Conference on Cochlear Implants and other Implantable Auditory Technology in Antwerp (Belgium), 2018

Patients

Ten Carina recipients between 52 and 81 years of age with mixed hearing loss, were included in the present study. All had undergone a second failed tympanoplasty and showed poor speech perception with conventional hearing aids.

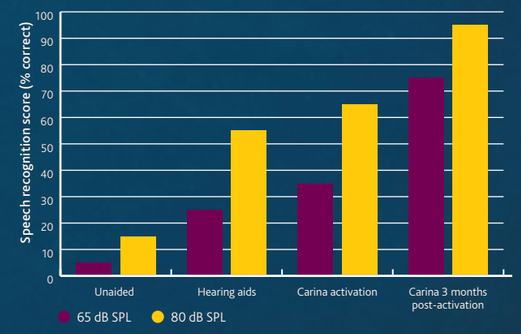
Methods

Bone conduction thresholds and word recognition in quiet were tested pre-operatively, at the time of the Carina activation, and 3 months after activation.

Results

There was no significant difference between the pre- and post-operative bone conduction thresholds, confirming that the Carina implantation is a safe surgical procedure.

Irrespective of presentation level – 65 or 80 dB SPL – a clinically relevant improvement in speech perception (> 10%) was shown with the Carina System compared to both the unaided and best-aided condition (conventional hearing aids). Speech perception improved already at first activation and continued to improve 3 months after activation.



Speech recognition scores (% correct) at presentation levels of 65 and 80 dB SPL (N = 10).

CONCLUSION

In cases of mixed hearing loss, the Carina System can effectively replace non-effective conventional hearing aids.

The Carina® middle ear implant: surgical and functional outcomes

BRUSCHINI, L., BERRETTINI, S., FORLI, F., MURRI, A., AND CUDA, D.

European Archives of Otorhinolaryngology, 2016, vol. 273, pp. 3631-3640

Patients

This retrospective multicenter study included 26 Carina recipients between 22 and 71 years of age. Twenty-one recipients had sensorineural hearing loss (81%) and 5 had mixed hearing loss (19%). The actuator was coupled to the incus (84%), round window (8%), or oval window (8%).

Methods

Audiometric thresholds were measured pre- and post-operatively. Word recognition in quiet (65 dB SPL) and the APHAB questionnaire were completed post-operatively with the Carina device switched on and off.

Results

Unaided air conduction thresholds were the same pre- and post-operatively, indicating that the Carina surgery is a safe procedure.

With the Carina System, audiometric thresholds improved significantly with a functional gain of 29 dB HL. Speech recognition scores increased from 24% in the unaided condition to 72% with the device switched on. The APHAB scores showed a significant benefit[5] for ease of communication (EC, 45%), communication in reverberant settings (RV, 59%), and communication in the presence of background noise (BN, 47%). No benefit was reported for aversiveness of sounds (AV, -12%).

[5] The 90% significance cut-off is 27% for the subscales EC, RV, and BN, and 31% for the subscale AV (Cox and Alexander, 1995)

CONCLUSION

The Carina System yields valid functional gain and significant improvement in speech perception in quiet. Most Carina recipients express a high degree of satisfaction, reporting improved hearing in different environmental conditions.

Long-term outcome data in patients following one year's use of a fully implantable active middle ear implant

UHLER, K., ANDERSON, M. C., AND JENKINS, H. A.

Audiology and Neurotology, 2016, vol. 21, pp. 105-112

Patients

This multicenter study included 50 Carina recipients (22 to 86 years old) with sensorineural hearing loss who had ≥ 3 months of experience with conventional hearing aids. In all patients, the actuator was coupled to the incus body.

Methods

Audiometric thresholds, word recognition in quiet, sentence recognition in noise, and APHAB scores were compared between an optimally fitted conventional hearing aid and the Carina System (3, 6, and 12 months after implantation).

Results

There were no significant differences in functional gain values for any patient between their personal hearing aid and the Carina System. Word scores decreased from baseline (with hearing aids) to the Carina aided condition 3, 6, and 12 months after implantation. However, this was not clinically relevant as the decrease was < 10%. Speech-in-noise performances did not differ significantly between baseline (with hearing aids) and the Carina aided condition 3, 6, or 12 months post-operatively. Twelve months post-operatively, patients rated communication in background noise better with the Carina implant than with their hearing aid (BN subscale APHAB).

CONCLUSION

There is no difference in performance between an appropriately fitted conventional hearing aid and the Carina implant. The Carina System can help individuals who choose not to use conventional hearing aids.

Comparison of Carina® active middle-ear implant with conventional hearing aids for mixed hearing loss

SAVAŞ, V. A., GÜNDÜZ, B., KARAMERT, R., CEVIZCI, R., DÜZLÜ, M., TUTAR, H, AND BAYAZIT, Y. A.

Journal of Laryngology and Otology, 2016, vol. 130, pp. 340-343

Patients

This study comprised 9 patients with mixed hearing loss who initially used conventional hearing aids and received a Carina implant between 33 and 57 years of age. The transducer was placed on the incus in 5 patients, on the oval window in 2 patients, and on the round window in 2 patients.

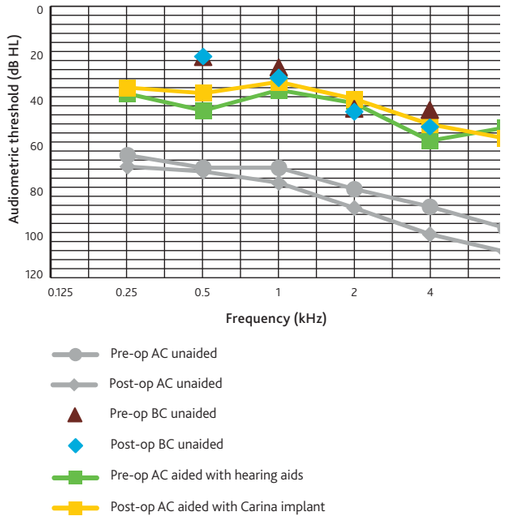
Methods

Pure-tone audiometry was performed pre- and post-operatively. A quality of life questionnaire – the Glasgow Benefit Inventory – was administered post-operatively.

Results

There were no significant differences between the pre- and post-operative unaided air or bone conduction thresholds, indicating that Carina implantation is a safe surgical procedure. There was no significant difference between the thresholds achieved with hearing aids and the Carina implant.

The Glasgow Benefit Inventory demonstrated benefits regarding general, social, and physical health with the Carina System compared to conventional hearing aids for all, except one patient. None of the recipients had complaints about sound quality, and they did not suffer any sensitivity to body noise.



Pre- and post-operative unaided air conduction (AC) and bone conduction (BC) thresholds, aided thresholds with conventional hearing aids, and aided thresholds with the Carina implant (N = 9).

CONCLUSION

Acceptance of Carina implants is better than with conventional hearing aids in patients with mixed hearing loss, although both yield similar hearing amplification.

Reliability

Evolution of the reliability of the fully implantable middle ear transducer over successive generations

DEBEAUPTE, M., DECULLIER, E., TRINGALI, S., DEVÈZE, A., MOM, T., DARROUZET, V., AND TRUY, E.

Otology and Neurotology, 2015, vol. 36, pp. 625-630

Methods

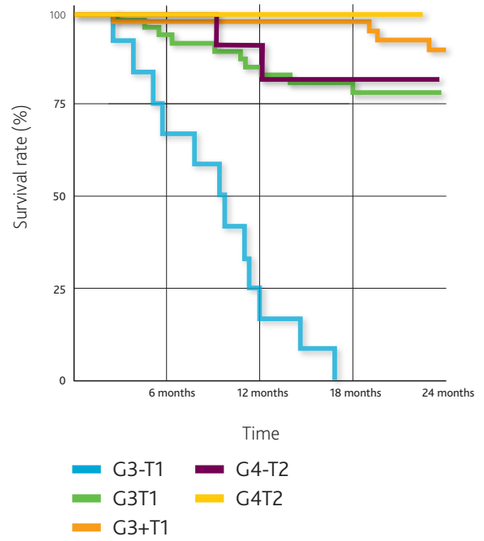
This multicenter study investigated the reliability of 157 Carina devices belonging to one of the five Carina versions. It concerned 123 adults implanted between September 2005 and July 2012. The reliability 2 years after implantation or at the maximal lifetime was reported by means of survival curves.

Results

Implant (G) and transducer (T) version	Modification(s) to previous version	Date of first implantation	Survival rate at 24 months
G3-T1	–	September 2005	0%
G3T1	Battery	October 2006	76.1%
GT3+T1	Coil	April 2008	84.2%
G4-T2	Transducer, connector	August 2010	81.8%
G4T2	Connector	December 2010	100%

Overview of the five Carina System versions

Thanks to successive technological modifications, the reliability of the Carina System has improved. The latest Carina version shows a 100% survival rate up to 22 months after implantation[6].



Survival rates (%) of the five Carina versions

[6] Since this publication, more long-term follow-up data have been collected. Preliminary analyses on this updated database demonstrate the same, maximum survival rates as reported by Debeaupte et al. (2015).

CONCLUSION

The latest Carina version is a reliable fully implantable middle ear implant system up to 22 months after implantation, showing a 0% failure rate.

A retrospective multicentre cohort review of patient characteristics and surgical aspects versus the long-term outcomes for recipients of a fully implantable active middle ear implant

LEFEBVRE, P. P., GISBERT, J., CUDA, D., TRINGALI, S., AND DEVÈZE, A.

Audiology and Neurotology, 2016, vol. 21, pp. 333-345

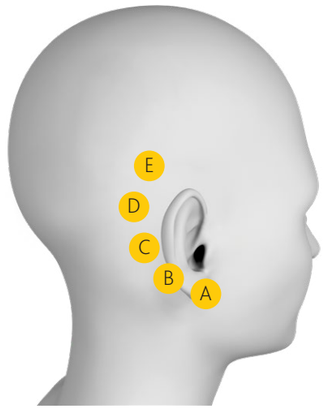
Patients

This multicenter retrospective survey involved 62 Carina recipients. Fifty-five recipients had sensorineural hearing loss (89%) and 7 recipients had mixed hearing loss (11%). The mean age at implantation was 39 years. At the time of data collection, the time elapsed since implantation was 3.5 years on average.

Methods

This study described the authors' preferred methods for microphone placement. During implantation of the microphone, surgeons have to consider patient-specific anatomy, the dimension of the microphone, the ability to secure the microphone and the avoidance of migration.

As for patient outcomes, satisfaction and feedback reports were assessed at the first fitting and ≥ 12 months post-operatively. Daily use was evaluated as well.



Different microphone location options. A: mastoid tip (15%), B: posterior inferior mastoid line (65%), C: posterior mastoid (11%), D: posterior (9%), E: posterior superior (0%).

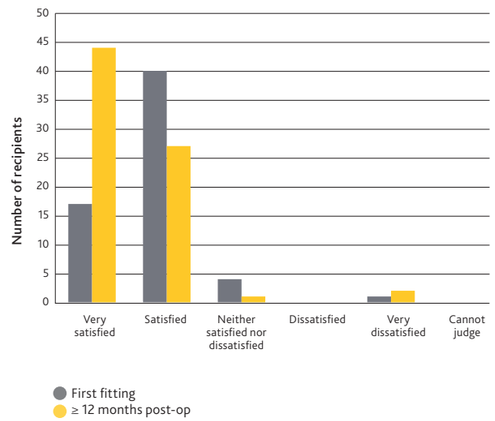
Results

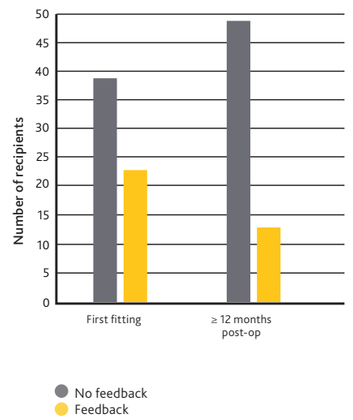
The microphone was most commonly placed on the posterior inferior mastoid line (65%, position B in the figure), consistent with the authors' surgical preference.

As for system feedback reports, these significantly decreased over time and showed a correlation with microphone location: the microphone on the posterior inferior mastoid line (the authors' surgical preference) correlated with less likelihood for feedback.

Most recipients were satisfied or very satisfied both at the first fitting and at the follow-up, and only very few were dissatisfied. Patient satisfaction was inversely correlated with reports of system feedback.

Consistent daily use was reported for 97% of the recipients who wore their system 10 hours a day. The primary motivations for the Carina implantation were work-related hearing needs for 52% and cosmetic reasons for 27% of the recipients. 19% were motivated by lifestyle issues and 2% by the inability to wear a conventional hearing aid in the implanted ear.





CONCLUSION

Carina recipients are satisfied daily users with very few reports of persistent feedback. The authors prefer a posterior inferior mastoid line position of the microphone whenever possible.

The fully implantable Carina System gives you the freedom to live your life the way you want to.

Output / Coupling

Optimum coupling of an active middle ear actuator: effect of loading forces on actuator output and conductive losses

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Methods

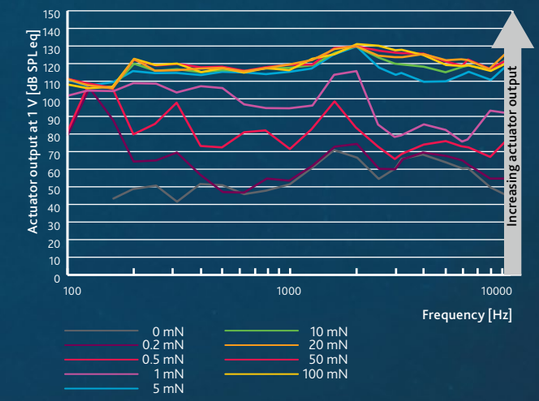
This temporal bone study was designed to verify whether the recommended 30 mN loading force[7] yields optimal coupling efficiency while bearing a low risk of introducing a conductive hearing loss.

Nine human cadaveric temporal bones were used to investigate the effect of different loading forces (0 – 100 mN) on the actuator coupling efficiency and on the sound transmission via the ossicular chain. Actuator coupling efficiency was quantified by measuring the actuator output through Laser Doppler Vibrometry of stapes motion. The occurrence of conductive losses was investigated by comparing acoustically stimulated stapes motion in an unloaded versus a loaded state.

Results

The highest coupling efficiency was achieved at forces above 10 mN with no further change at forces up to 100 mN.

At the recommended loading force (30 mN), conductive losses > 5 dB were observed in only one out of nine temporal bones, and only for frequencies above 6 kHz.



Median actuator output values for different loading forces

CONCLUSION

When used as recommended, the Carina surgical test system guides the surgeon to an optimal coupling efficiency with low risk of introducing a conductive hearing loss.

[7] The Carina surgical test system procedure recommends an extra ¼ turn after initial contact with the incus is established, resulting in a 30 mN loading force.

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