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The first results of a totally implanted active middle ear device

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Abstract

Purpose The aim of this study was to assess the first outcomes of a fully implantable active middle ear device.

Methods Retrospective observational nonrandomized group study. Settings: Private hospital. Fifteen patients underwent device implantation between December 2014 and June 2017. The pre-operative and post-operative air conduction (AC) and bone conduction (BC) thresholds were evaluated. The functional gain, speech perception in silence and in noise, and localization abilities were also analyzed.

Results Sixteen active middle ear implantations were performed. Post-operatively, the mean pure tone thresholds were 50.5 dB (± 12.64) for BC and 64.9 dB (± 15.36) for AC. No differences were found between the post-operative and pre-operative audiometric thresholds before activating the system ($p > 0.05$). Post-operatively, the mean thresholds in the free field after the device was activated were 46.8 dB, 45.75 dB, 42.6 dB, and 43.38 dB at 1, 3, 6, and 12 months, respectively. The global results of speech understanding in silence were 50.7 dB, 47.18 dB, 42 dB, and 42 dB for 1, 3, 6, and 12 months, respectively. Patients with mixed hearing loss had better results than those with sensorineural hearing loss. Speech discrimination in noise and localization was improved.

Conclusions Despite the small number of patients, our results confirmed that this fully implantable active middle ear device is a viable treatment for patients with moderate-to-severe sensorineural hearing loss who cannot or do not want to use traditional hearing aids for clinical or cosmetic reasons.

Keywords Active middle ear prosthesis · Carina implant · Middle ear transducer

Introduction

For many years, the therapeutic approach for treating patients with conductive and/or mixed hearing loss (MHL) has consisted of middle ear surgery with the correction or replacement of the middle ear ossicles, and if necessary, the application of a hearing aid, as is usually performed for patients with sensorineural hearing loss (SNHL). However, several solutions have been progressively created recently [1].

Acoustic hearing aids amplify sounds and present it to the middle ear through the external auditory canal, whereas some active middle ear implants bypass the external auditory canal and directly vibrate the ossicular chain. These devices solve several problems that are present with acoustic hearing aids, such as feedback, signal distortion, insufficient high-frequency gain, especially in individuals with "ski-slope" hearing loss, and limitations of activities of daily living (e.g., the inability to participate in water activities, the need for constant maintenance, daily cleaning, battery replacement, and sound amplification during sleep for child care). It is also a good alternative in patients with persistent external otitis, external auditory canal occlusion, intolerance to hearing molds, and other associated issues [2, 3].

The rejection of acoustic hearing aids and the external components of implantable devices are often related to cosmetic issues and the stigma of inferiority or disability associated with them. These objections prompted investigations that have ultimately led to the development of fully implantable active hearing devices [2–4].

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Research on active middle ear implants started in 1935 when Wilska investigated the effect of iron particles placed on the tympanic membrane. In these experiments, a magnetic field created between the iron particles and an electromagnetic coil inside an earphone-induced vibration of the tympanic membrane. Middle ear implants, as we know them now, only arrived in the 70 s.

Depending on the location of the microphone and power source, active middle ear implants may be totally or partially implantable. Semi-implantable prostheses are composed essentially of an external processor which converts acoustic sound into an electrical signal, an implanted receiver coil, and a transducer applied to the ossicular chain which transforms the electric signal into vibrations. Totally implantable active devices are composed of single implants that incorporate the processor, microphone, battery, and actuator that is coupled to the middle ear [2, 4]. In the case of the implant used in this study, the sounds are captured by the microphone and transmitted to the sound processor, which analyses the sound information, amplifies it according to the programmed settings, and transforms it into electrical signals [2]. These signals are transmitted to the transducer and are converted into mechanical energy, which, depending on the different couplers used, causes the round window or a part of the ossicular chain to vibrate [3]. These implants can also be categorized, according to the type of transducer which they have, into piezoelectric, electromagnetic, or electromechanical implants [5–7].

Two different fully implantable devices are currently available: the Esteem®-Hearing Implant™, Envoy Medical Corporation, Saint Paul, MN, USA, and the Cochlear™ Carina® System, Cochlear Limited, Sidney, Australia. The latter implant is a recent version of the semi-implantable device, Otologics MET implant (Otologic, Boulder, CO, USA), which has an electromechanical transducer designed to address the amplification needs of adults with moderate-to-severe SNHL. It has various coupling accessories for different pathophysiological situations in the middle ear, and has obtained the CE mark approval for both sensorineural and conductive/MHL in 2006 [1, 2]. It comprises of four main components: the implant, implant programming device, remote control, and battery charger.

The aim of this study was to describe the audiological outcomes and complications of the fully implantable active middle ear device, Cochlear™ Carina® System, which is referred to hereafter as "totally implantable device" (TID).

Materials and methods

The CUF Porto ethics committee approved this retrospective observational nonrandomized group study and authorized the use of the clinical information of the patients. The procedures followed were in accordance with the tenets of the Helsinki Declaration.

The clinical information regarding the history of hearing loss, pre-operative and post-operative audiological evaluations, intra-operative findings, and intra-operative and post-operative complications of the patients were taken from the clinical database. Fifteen patients had undergone TID implantation at the Auditory Implant Unit, ENT Department of CUF Porto Hospital between December 2014 and June 2017. All the implants belonged to the last generation of the Cochlear™ Carina® System implants, which were developed by Cochlear® company.

Air conduction (AC) and bone conduction (BC) pure tone audiometry and speech audiometry were performed before and after the surgery with the device off and with it on. The free-field (FF) pure tone audiometry thresholds and FF speech audiometry thresholds were also documented. In the FF examinations, the patients were tested with the TID on, while the contralateral ear was masked by headphones. The pre-operative and post-operative AC and BC thresholds were reported as the pure tone averages at 0.5, 1, 2, and 3 kHz. Following the protocol for speech understanding in noise developed by the department, speech perception performed with phonetic balanced dissyllabic words (based on the Lafon word list) and speech recognition threshold (SRT) were reported in silence as well as in noise. An assessment of spatial sound location was also performed, from 0° to 180°, with a 30° angular difference [The detailed description of the protocol for speech discrimination in noise and sound localization may be reviewed at: Peixoto M. et al. (2018). Evaluation Protocol of Speech Discrimination in Noise with Auditory Implants. Gazeta Médica. 2018, 5(3); and Peixoto MC, et al. Evaluation protocol of sound localization. Otorrinolaringologia e Cirurgia Cérvico- Facial. Revista Portuguesa. 2018, 56 (2): 51–54].

A mastoid CT scan was performed on each patient to evaluate the anatomy of the ossicular chain and middle ear and the distance between the external auditory canal wall and the tegmen tympani to evaluate whether there was enough space for the placement of the actuator.

The implants were activated 6 weeks after surgery. The patients were monitored for device fitting and clinical evaluation at 1, 3, 6, and 12 months after activation.

Surgical technique: Retro-auricular access was gained with an "S" skin incision and a fibro-muscleo-aponeurotic flap. The temporoparietal bony bed was drilled for the placement of the processor of the device, which was fixed to the skull with the screws of the device. The microphone was inserted in a bony hole created in the mastoid tip and was fixed with screws. The thicknesses of the subcutaneous fibromuscular tissue and skin in the region where the microphone was to be placed were evaluated and reduced, if necessary, to allow better sound transmission. In patients with SNHL, a superior epitympanotomy was performed,

and the housing bracket was fixed to the mastoid cortex with three or four titanium screws. The transducer was coupled to the body of the incus. In patients with MHL, a mastoidectomy and a wide posterior tympanotomy were required to visualize and control the stapes and the position of the coupler through a combined transmastoid and transcanal approach. The transducer was coupled to the head of the stapes with a specific coupler ("clip piston-like"). The function of the facial nerve was monitored when a posterior tympanotomy was performed. In each patient, the right coupling load of the transducer was evaluated using the telemetric system of the device: the Transducer Loading Assistant (TLA).

Statistical analysis

The data are presented as mean and standard deviation (SD). Statistical analyses were performed using International Business Machines-Statistical Package for the Social Sciences (IBM SPSS), 24th version. Statistical significance was defined as a two-sided p value of < 0.05. The Wilcoxon signed-rank test was used to compare the total scores before and after implantation. Friedman's test was used to compare the effects of the implants on global hearing during the first year of implant use. Analysis of the collected data was performed by an external consultant statistician.

Results

Sixteen TIDs were surgically implanted between December 2014 and June 2017. Table 1 summarizes the demographic variables of the patients included for analyses. The percentage of female patients was 53%. The mean (SD) patient age was 56.5 (± 13.36) years at the time of the intervention, and the mean duration of hearing loss was 15.6 (± 13.69) years. In this study, 80% of the subjects were implanted in the right ear, and 60% had SNHL type of hearing loss.

Pre-operatively, the mean pure tone audiometric thresholds in the ear proposed for surgery were 49 (± 12.2) dB for BC and 60.7 (± 8.6) dB for AC. Figure 1 summarizes the pre-operative audiometric characteristics of the patients.

Post-operatively, the overall mean pure tone audiometric thresholds in the operated ear when the device switched off were 50.5 (± 12.6) dB for BC and 64.9 (± 15.4) dB for AC. Table 2 summarizes the results of the Wilcoxon rank test pairwise comparison before and after implantation in patients with MHL and those with SNHL. No statistically significant differences were found between the pre-operative and post-operative BC and AC thresholds with the device switched off.

The overall mean post-operative thresholds in FF with the device switched on were 46.8 (± 9.9) dB, 45.75 (± 9.9) dB, 43.6 (± 11.7) dB, and 45.38 (± 11.53) dB, at 1, 3, 6, and 12 months, respectively. Table 3 shows the results in patients with MHL and SNHL. No external microphone (BAP) was used in any testing. With this device, an extra power mode can be introduced if necessary.

Table 1 Demographic and clinical characteristics from the patients

Patients (no)	Gender	Age at intervention	Middle time of hearing loss	Pre-operative hearing aids	Type of hearing loss
1	M	51	46	No	Mixed
2	M	66	18	No	SNHL
3	F	51	29	Yes	SNHL
4	M	71	3	Yes	SNHL
5	M	45	4	No	SNHL
6	M	62	30	No	Mixed
7	M	63	2	No	Mixed
8	F	64	1	Test	SNHL
9	F	40	35	Yes	SNHL
10	F	69	10	Yes	SNHL
11	F	65	9	No	SNHL
12	F	60	20	No	SNHL
13	M	20	6	No	Mixed
14	F	62	11	No	Mixed
15	F	58	10	Yes	Mixed

Speech understanding in silence was analyzed using SRT analysis in FF with the device switched on and with contralateral masking. The pre-operative overall SRT in the implanted ear was 66.0 dB (± 32.6 SD). After implantation, the SRT was 61.7 dB (± 19,9 SD). At 1, 3, 6, and 12 months after implant activation, the SRT were 51.7 dB (± 9.57 SD), 48.18 dB (± 8.15 SD), 45.0 dB (± 13.36 SD), and 45.0 dB (± 11.83 SD), respectively. Table 3 presents these results in patients with MHL and SNHL. Statistically significant differences were found between the pre-operative evaluation and the assessment with the implant.

Speech understanding in noise was also analyzed using 16 conditions that combined speech (words and sentences) and noise (speech noise and "cafe noise") in four possible conjugations related to the position of the implant. The results showed improvements in all the 16 conditions analyzed. The overall results are presented in Table 4. When we analyzed the results in patients with SNHL and MHL, the results were superposed.

With regard to sound localization, three conditions were analyzed: 1, pre-operative assessment without the implant; 2, assessment with the implant connected and masking on the contralateral ear; 3, assessment with the implant connected and without masking on the contralateral ear. Conditions 2 and 3 were evaluated at 3, 6, and 12 months of follow-up. The results presented correspond to 12 months

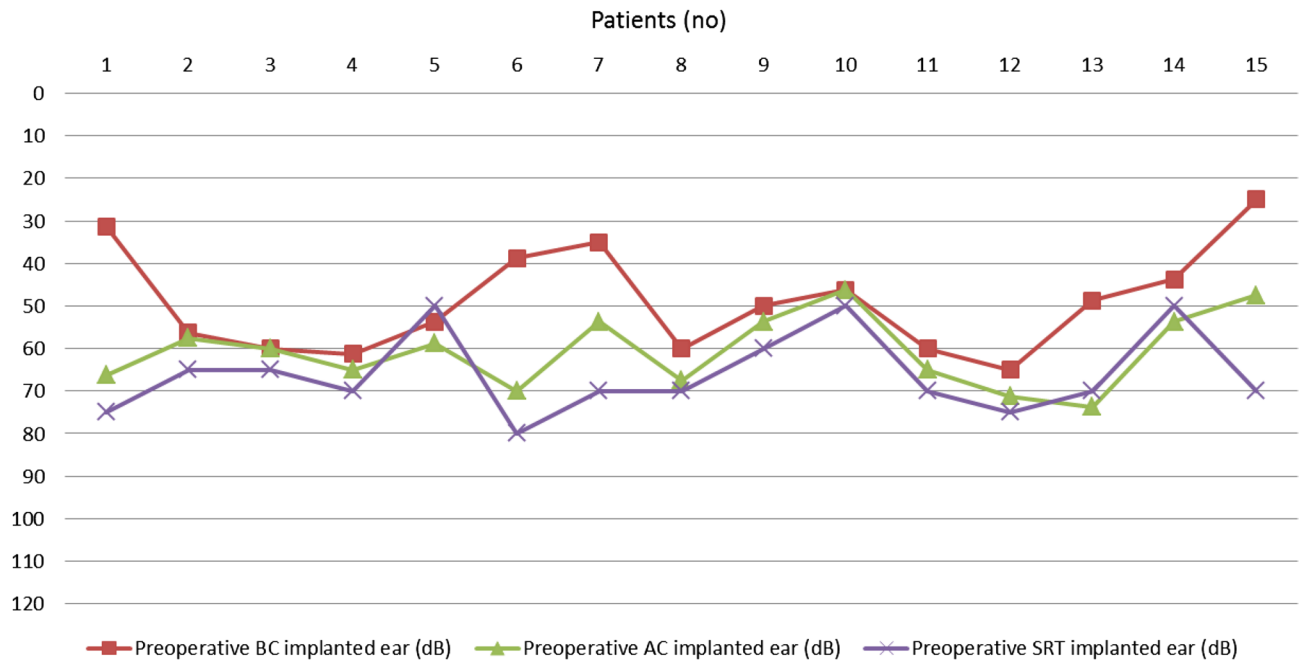

Fig. 1 Preoperative audiometric characteristics (mean values)

Table 2 Comparison of BC, AC, and SRT pre-and post-operatively in MHL and SNHL patients

		MHL			SNHL		
		Mean	(SD)	*p* value*	Mean	(SD)	*p* value*
BC implanted ear (dB)	Pre	37.08	(8.576)	0.416	56.94	(5.966)	0.623
	Post	41.25	(13.670)		57.34	(6.030)	
AC implanted ear (dB)	Pre	60.83	(10.567)	0.686	60.56	(7.632)	0.214
	Post	57.71	(17.183)		69.72	(12.775)	
SRT implanted ear (dB)	Pre	69.17	(10.206)	0.461	63.89	(8.937)	0.119
	Post	59.17	(21.075)		76.11	(18.671)	

*p value of < 0.05

Table 3 Free-field implant results and speech discrimination in silence at 1, 3, 6, and 12 months; comparison with pre-operative evaluation

	MHL			SNHL		
	Mean	(SD)	*p* value	Mean	(SD)	*p* value
Pre-operative AC implanted ear (dB)	61	(11)	**0.028**	61	(8)	0.092
Implant 1 month	42	(6)		49	(11)	
Implant 3 months	45	(18)		46	(7)	
Implant 6 months	41	(18)		44	(11)	
Implant 1 year	40	(18)		46	(7)	
Pre-operative SRT implanted ear (dB)	69	(10)	**0.027**	64	(9)	0.068
Implant 1 month SRT (dB)	49	(12)		51	(7)	
Implant 3 month SRT (dB)	48	(15)		46	(7)	
Implant 6 month SRT (dB)	40	(9)		44	(11)	
Implant 1 year SRT (dB)	38	(10)		46	(7)	

Significant *p* values are highlighted in bold

of follow-up. The results are reported as mean error and global error. The mean error/global error were 59° (±15.3 SD)/370° (±118.1 SD), 76° (±18.0 SD)/476° (±144.7 SD), and 50° (±20.8 SD)/317° (±144.7 SD) in conditions 1, 2, and 3 respectively. Table 5 summarizes the results of the localization abilities in the three conditions in patients

Table 4 Speech discrimination in noise: pre- and post-operative comparison—overall results

		C1		C2		C3		C4	
		Mean	Test stat	Mean	Test stat	Mean	Test stat	Mean	Test stat
Words/speech noise	Pre	47.8	0.088	78.9	0.672	71.1	0.777	64.4	0.833
	Pos	66.7		83.3		73.3		70.6	
Words/cafe noise	Pre	48.3	**0.024**	86.7	0.493	60.0	0.203	53.3	**0.028**
	Pos	80.6		86.9		73.3		78.9	
Sentences/speech noise	Pre	40.8	0.093	85.6	0.893	59.2	**0.049**	61.7	0.171
	Pos	66.1		85.7		77.8		73.3	
Sentences/café noise	Pre	49.2	0.237	74.7	0.150	64.2	0.075	57.5	**0.028**
	Pos	70.0		86.0		80.8		75.0	

Significant *p* values are highlighted in bold

Table 5 Sound localization abilities comparison between pre- and post-operative evaluation in MHL and SNHL

	MHL		SNHL	
	Mean(0°)	(SD)	Mean(0°)	(SD)
C1 Mean error	66	(16.3)	57	(15.7)
C2 Mean error	69	(12.1)	79	(19.9)
C3 Mean error	56	(11.5)	48	(23.3)

with MHL and SNHL. We found statistically significant differences ($p = 0.046$) between conditions 1 and 2. No differences were found between conditions 2 and 3 ($p = 0.08$) or between conditions 1 and 3 ($p = 0.22$).

No intra-operative complications or skin complications were detected. During the follow-up periods, problems with feedback of variable degrees were present in all the patients. These problems were severe in one patient (patient 1) and a revision surgery with replacement of the device was performed.

Changes in implant functioning with altitude were detected in one patient (patient 3) and were resolved with fitting adjustments.

One patient (patient 6) complained of a lack of gain and stopped using the implant, because he had a significant improvement in the AC threshold after the middle ear surgery.

Discussion

This TID has been designed for patients with moderate-to-severe SNHL, a pure tone average in the range of 40 to 80 dB HL, and a speech recognition index for monosyllabic words of 40% or greater. The audiological data from this study confirm the criteria described above. It is contraindicated in patients with vestibular changes, degenerative bone disorders, active middle ear disease, retro-cochlear or central nervous system disorders, prelingual hearing loss, and progressive or fluctuating hearing loss [2, 3, 8]. This TID is not currently MRI compatible.

In our data, no statistical differences were found between the AC and BC thresholds pre-operative and those post-operatively with device off, implying that the surgery itself and the contact between the electromechanical transducer and the ossicular chain did not significantly change the middle ear function or cochlear status. These results were similar to those found by Jenkins et al. and Fredrickson et al. [9, 10].

No major surgical complications, such as local infection or partial device extrusion, were found in our results. In literature, most of the articles published refer to the old generations of TID (known as FIMOS prosthesis). The complications and results of these TIDS of the previous generation are quite different from what we reported in this study in which we implanted only the last generation of active middle ear implants. Jenkins et al. in 2008 referred to a significant number of explanted implants [9]. Rameh et al. have reported their results on MET, Carina, and Vibrant Soundbridge implantations, and have pointed out that the revision surgery index due to implant dysfunction is 16% in MET implants [11]. Debeaupte et al. describe their experience with the successive generations of FIMOS devices. They report that all the first-generation devices in their series had been explanted, whereas the most recent devices had survival rates of 100% [11–14].

With regards to the function of the device, no loss of external communication or malfunction was seen. The most common difficulty seen during the follow-up period

was related to sound feedback that was present in variable degrees in all the patients in this study. This complaint required several appointments for fitting adjustments and a revision surgery in one patient.

Lefebvre et al. showed that the satisfaction of the patient was inversely correlated with the reports of system feedback [12]. In this context, different authors presented their concerns with the different positions of the microphone, which was claimed to be responsible for these problems with feedback [2]. The microphone is very sensitive to changes in the thickness of the tissue. Jenkins et al. defined three possible locations to place the microphone: the temporalis region [anterior and superior to the external auditory canal (EAC)], the retro-auricular region (posterior to the EAC), and the mastoid tip. Bruschini et al. presented that the best point to place the microphone is the region with the minimum tissue thickening changes during movements of the head and neck and suggested that the location posterior to the EAC in a muscle pocket should be preferred [2, 9, 12, 13]. The microphone was positioned in the tip of the mastoid in all the cases in our study, and adjustments to the thickness of the skin and soft tissues were made.

Changes in the implant functioning with altitude were detected in one patient and were resolved with fitting adjustments. This could have been due to the changes in the impedance.

With regards to the auditory outcomes, we noticed a gain of 15–20 dB 1 year after the surgery and a superior functional gain in patients with MHL when compared with patients with SNHL. The same relation was seen by Klein et al. who showed a functional mean gain of 21.3 dB (range, 9.3–39.0 dB). Their review shows an average improvement in the functional gain (10.4 dB) [15].

An improvement in speech discrimination is one of the most important outcomes in these patients. In this context, speech discrimination in silence using SRT and speech discrimination in more challenging situations with environment noise were evaluated, trying to reproduce the difficulties the patient faces in daily life. Speech discrimination in silence improved significantly in patients with MHL with a gain of 29 dB in SRT 1 year after surgery. A progressive improvement was seen in the first 6 months, with more stable results afterwards. Thus, 6 months seemed to be the critical period for the stabilization of results. Bittencourt et al. shows that this period is necessary for the skin and soft tissues to adapt to the microphone once it is attached to the skull [3]. This was the case in our surgical technique, as well. A longer period might be necessary if a soft-tissue pocket is used [3]. The improvement of speech discrimination in patients with SNHL was around 18–20 dB which was lower than that in patients with MHL. We did not find any specific reason for the difference in the results between patients with mixed hearing loss and those with SNHL. We presume that it could be related to the better post-operative AC and BC thresholds of patients with MHL. Another reason for this difference could be related to coupling. Although we used the TLA in all patients with SNHL, for its corrected attachment to the body of the incus, a coupler with the clip piston attached to the head of the stapes might have been more stable.

Jenkins et al. reported that the coupling efficiency of the implant to the middle ear ossicles is crucial for the performance of the patient with an implantable hearing device. Insufficient pressure limits the energy transfer and too much pressure produces conductive loss. Furthermore, an increased coupling efficiency allows more amplification and less battery consumption [13].

Speech discrimination in noisy environments improved in all the categories tested, although only some of these were found to be statistically significant. The small size of the sample did not allow us to make general conclusions. However, it is possible to see that the TID, and the possible restoration of binaural hearing, can improve speech understanding in noisy environments. The analysis was made using the best auditory condition, which means that the contralateral ear was not masked and, in some cases, was fitted with a hearing aid. Thus, the results were the comparison between the best hearing conditions pre-operatively and post-operatively. The protocol developed in the department does not include the evaluation of the implant alone (with contralateral masking), because we think that this situation does not recreate the natural and social conditions of the patient or evaluate the bilateral/binaural condition. The mean gain in all categories, referred to as the difference in the percentage of words and sentences understood by the patients pre-operatively and post-operatively, was 14.3%.

The localization abilities also improved after the implantation of the TID, and was noted by the reduction in the global and mean error from condition 1 with better ear alone to condition 3 which corresponded to binaural condition. In patients with MHL, the mean error in condition 1 was 66° and that in condition 3 was 56°. In patients with SNHL, the mean error in condition 1 was 57° and that in condition 3 was 48°. Thus, the restitution of hearing in the implanted ear seems to contribute to the binaural rehabilitation.

In conclusion, our results agreed with other results described in literature and confirmed that the TID offers a viable treatment for patients with moderate-to-severe mixed hearing loss and SNHL who cannot or do not want to use the traditional hearing aids for clinical or cosmetic reasons. This kind of auditory implant can offer freedom and comfort in environments, such as showering, swimming, and sporting activities, that are not suitable for other implants. The audiometric results demonstrated that the device can be implanted without affecting the residual cochlear hearing levels and without major complications.

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Compliance with ethical standards

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

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