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ORIGINAL ARTICLE

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Evaluation of a super powerful bone-anchored hearing system and its users: A retrospective study

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Abstract

Introduction: Although the Baha 5SP has been commercially available for six years, very few studies have been performed on the device's efficacy. The current study aims to evaluate the characteristics and audiological results in patients with severe-to-profound mixed hearing loss fitted with this superpower sound processor.

Methods: This retrospective evaluation was conducted at a tertiary referral centre where a series of 82 adult patients with severe-to-profound mixed hearing loss were implanted with a percutaneous bone-anchored hearing system and fitted with a superpower sound processor between 2016 and 2019. Patients with incomplete or unreliable audiological data ($n = 24$) were excluded, resulting in 58 data sets for analysis. The main outcome measures were unaided and aided pure-tone thresholds and aided free-field speech perception in quiet.

Results: The median unaided air conduction (AC) threshold averaged across 0.5, 1 and 2 kHz ($PTA_{0.5-2kHz}$) of all patients was 75 dB hearing loss (HL); the median unaided AC averaged across 1, 2 and 4 kHz (PTA_{1-4kHz}) was 84 dB HL. For bone conduction and direct bone conduction, the median $PTA_{0.5-2kHz}$ was 52 and 47 dB HL, respectively. With the superpower device, the median free-field speech reception threshold was 54 dB sound pressure level (SPL), and the median speech perception score at 65 dB SPL was 80%.

Conclusions: At least 75% of the patients reached a maximum phoneme score of 70%. For patients with lower scores, the superpower device still provides a substantial hearing benefit. This makes the superpower device particularly suitable for patients with severe-to-profound mixed hearing loss with a contraindication for conventional hearing aids and/or cochlear implants.

KEYWORDS

Baha SuperPower, BCD, bone-anchored hearing system, direct bone conduction, effective gain, functional gain, severe-to-profound mixed hearing loss

1 | INTRODUCTION

Application of a bone conduction device (BCD) is a well-established method to overcome conductive or mixed hearing loss in patients who cannot use conventional hearing aids due to problems with occluding the ear canal (e.g., chronic/recurrent otitis) or anomalies of the outer and/or middle ear (e.g., malformation or absence of the ear canal and/or pinna).[1] A BCD consists of a sound processor (microphone and amplifier) and a (separate) transducer that converts sound into mechanical vibrations.

In the percutaneous application, vibrations generated by the BCD are directly transferred to the skull via a skin-penetrating abutment attached to a titanium implant. Compared to a non-surgical or passive transcutaneous system, a benefit of a percutaneous application is that vibrations are not dampened by soft tissue (e.g., skin and subcutaneous fat), leading to 10–15 dB more efficient transmission in the high frequencies.[2,3] However, even with a percutaneous BCD, much more power is required to achieve the same hearing levels as a conventional hearing aid.[4] Snik et al. estimated that the difference in efficiency between percutaneous BCDs and conventional hearing aids amounts to approximately 35 dB.[5] This difference is particularly relevant in patients with severe-to-profound mixed hearing loss fitted with a BCD, as additional gain is needed to compensate for the sensorineural component of the hearing loss.[6] In these cases, a BCD with a high maximum force output level (MFO) and a dynamic feedback suppression system to provide stable gain is highly desirable.

In 2016, Cochlear Bone-Anchored Solutions introduced the Baha® 5 SuperPower Sound Processor (further referred to as Baha 5SP). This device provides a higher MFO (82–96 dB hearing loss [HL])[7,8] and, according to the manufacturer, a larger fitting range (up to 65 dB bone conduction threshold)[9] than any other BCD currently available. Like its predecessor, the Baha® Cordelle II, the new superpower device consists of a transducer with a decoupled sound processor that can be worn at ear level ('head worn') or on the body (body-worn). Unlike the Baha Cordelle II, the superpower device provides advanced signal processing, including a dynamic feedback cancellation system.[8]

Although the Baha 5SP has been commercially available for 6 years, very few studies have been performed on the device's efficacy, probably because the device is not widely used. In 2018, Bosman et al. published data on the application of the Baha 5SP compared to the Baha 5P and the Baha Cordelle II in 10 patients.[7] This study concluded that 90% of their subjects preferred the Baha 5SP over the Baha Cordelle. Our tertiary referral centre, with a large group of Baha 5SP users, contains a wealth of information on the use of this device and its users. The current study aims to evaluate the characteristics and audiological results in patients with severe-to-profound mixed hearing loss fitted with the Cochlear Baha 5SP in our centre between 2016 and 2019.

Key points

- The Baha 5SP has the highest maximum force output level (82–96 dB hearing loss) of all bone conduction devices on the market.
- The Baha 5SP comprises a sound processor (microphone and amplifier) and a decoupled transducer.
- In patients with severe-to-profound hearing loss, we recommend wearing the processor on the chest: in this position, the device can provide the highest gain without too many feedback issues.
- Patients fitted with a Baha 5SP have relatively high speech scores despite their significant sensorineural hearing loss component.
- The Baha 5SP is particularly suitable for patients with severe-to-profound mixed hearing losses, with contraindications for a conventional hearing aid, and not (yet) eligible for a cochlear implant.

2 | PATIENTS AND METHODS

2.1 | Study design and participants

This retrospective evaluation was conducted at the Department of Otorhinolaryngology at Radboudumc, a tertiary referral centre. All patients fitted with a Baha 5SP as percutaneous BCD between 2016 and 2019 were identified. In all patients, device fitting was based on BC Direct, that is, direct bone conduction (dBC) thresholds followed by manual fine-tuning as preferred by the patient. The wearing option (ear level vs. body-worn) was based on the aided speech score at 65 dB sound pressure level (SPL), feedback issues, and user preferences.

Patients with incomplete data or less reliable audiological results due to, for example, cognitive or intellectual disability or suspected aggravation, were excluded from the audiological analysis. Patients were divided into two groups according to their wearing choice, that is, head-worn or body-worn. In addition, patients were classified based on additional hearing devices.

2.2 | Study parameters

Baseline characteristics, including age at fitting or audiological measurement, gender, cognitive or intellectual disability, hearing loss aetiology, implant side, BCD experience, previously used BCD, and device wearing choice, were obtained from the patients' medical charts. Also, information on additional hearing devices was collected. Medical charts were checked for patients with severe-to-profound mixed hearing loss to determine whether a cochlear implant (CI) was indicated.

Unaided air-conduction (AC) and bone-conduction (BC) pure-tone thresholds were measured using standard audiometric procedures and equipment (Interacoustics Equinox audiometer fitted with TDH-39P headphones and B-71 bone conductor), and pure-tone averages at 0.5, 1 and 2 kHz ($PTA_{0.5-2kHz}$) and at 1, 2 and 4 kHz (PTA_{1-4kHz}) were calculated.

In addition, dBC thresholds were measured.[2,10] As the name suggests, dBC bypasses soft-tissue attenuation, providing more accurate thresholds for a percutaneous BCD and, consequently, a more accurate fitting. The dBC thresholds were retrieved from the Baha® Fitting Software and averaged across 0.5, 1 and 2 kHz (dBC $PTA_{0.5-2kHz}$) and 1, 2 and 4 kHz (dBC PTA_{1-4kHz}).

Aided free-field speech perception in quiet was measured with standard Dutch consonant-vowel-consonant (CVC) monosyllables presented from a loudspeaker 1 m from the subject at 0° azimuth.[11] The performance-intensity function was measured with fixed 10-dB steps. The speech reception threshold (SRT), the level at which listeners attain a 50% correct phoneme score, was estimated from the performance-intensity function. Also, the percentage of correctly repeated phonemes at 65 dB SPL was measured.

The shift in SRT in patients with hearing loss relative to the SRT for normal hearing listeners corresponds well to the $PTA_{0.5-2kHz}$.[11] Aided $PTA_{0.5-2kHz}$ provides a good prediction of the aided SRT in quiet, within an error of ±7 dB.[11,12] For normal hearing listeners, the SRT lies at 25 dB SPL and a 100% phoneme score at 45 dB SPL. For example, an aided SRT at 55 dB SPL implies a shift in $PTA_{0.5-2kHz}$ of 30 dB. In an ideal fitting, all phonemes are intelligible at a conversational level, which means a phoneme score of 100% at 65 dB SPL, corresponding with a shift of the score of at most 20 dB and aided thresholds of 20 dB HL or better.

The efficacy of the fitting was estimated with two gain measures. The functional gain was calculated by comparing the aided $PTA_{0.5-2kHz}$ and aided SRT to the unaided situation. Functional gain closely relates to the patient's perceived benefit. This gain measure, the difference between aided and unaided speech intelligibility, was estimated by relating the shift in SRT to the unaided AC $PTA_{0.5-2kHz}$. However, functional gain poorly reflects BCD performance in patients with a substantial conductive component in hearing loss. Therefore, the *effective* gain, the difference between aided free field thresholds and BC thresholds, was also estimated by relating the shift in SRT to the unaided BC $PTA_{0.5-2kHz}$ and unaided dBC $PTA_{0.5-2kHz}$.[13]

2.3 | Statistical analysis

Data were analysed using the Statistical Package for Social Sciences (IBM SPSS for Windows, Armonk, NY: IBM Corp) version 25. Figures were created using GraphPad Prism (GraphPad Software, San Diego, CA) 5.03. For continuous variables, percentiles and ranges of the distribution are reported, and for dichotomous variables, frequencies are reported.

2.4 | Ethical considerations

This research did not fall under the purview of the WMO. Therefore, it did not require a positive opinion from a medical ethics review committee for implementation. The clinical investigation was performed in accordance with the current version of the Declaration of Helsinki (Fortaleza 2013) and Good Clinical Practice (International Conference of Harmonization Good Clinical Practice).

3 | RESULTS

3.1 | Patient characteristics

The study cohort comprised 82 adults (49% female) with severe-to-profound, primarily mixed, hearing loss. The median age at the 5 SP fitting was 74 years (mean 72, range 33–92 years). Most patients (72%) were fitted body-worn. Of all head-worn users (*n* = 21), 38% wore the device on the contralateral ear of the implant. Twenty-nine patients (35%) also used other hearing devices, for example, a conventional hearing aid (*n* = 13), a second percutaneous BCD (*n* = 12 with three bilateral Baha 5SP users), a cochlear implant (CI; *n* = 3) or a combination of devices (*n* = 1). Four patients (5%) were bilaterally implanted for a percutaneous BCD but did not use the other, non-superpower BCD. Six patients (7%) received an additional remote microphone ('minimic', Cochlear™ Wireless Mini Microphone 2+) at the moment of the fitting. In 14 cases (17%), the minimic was prescribed later.

For 20 patients (24%), the superpower device was their first BCD. In the group of experienced users, 38 patients (46%) were previously fitted with a Baha Cordelle, 9 patients (11%) were fitted with a Baha Intenso and 9 patients with a Ponto Plus Power. Other previously used devices included the Baha BP110, the Ponto Plus, the Ponto 3 SuperPower, and the Baha 5 Power (total *n* = 6). The median BCD experience of the entire patient group was 9 years (mean 9, range 0–27). With the 'new users' excluded, it was 11 years (mean 12, range 4–27).

Patient characteristics for the entire patient group and the 'complete audiological analysis' group are shown in Table 1.

3.2 | Bone conduction thresholds, speech perception and gain

Twenty-four patients (29%) were excluded due to incomplete data (*n* = 18) and/or criteria known to influence the reliability of audiological tests, for example, cognitive (*n* = 5) or intellectual disability (*n* = 6), or suspected aggravation (*n* = 1). For the remaining 58 patients, the median unaided AC $PTA_{0.5-2kHz}$ at the better ear was 75 dB HL (mean 73 dB HL, range 32–110 dB HL), and the unaided AC PTA_{1-4kHz} was 84 dB HL (mean 81 dB HL, range 37–117 dB HL). The median BC $PTA_{0.5-4kHz}$ was 54 dB HL (mean 53 dB HL, range 34–69 dB HL); for dBC, it was 51 dB HL (mean 50 dB HL, range 34–65 dB HL). The median BC $PTA_{0.5-2kHz}$ was 52 dB HL (mean 51 dB

TABLE 1 Characteristics of the entire patient group ($n = 82$) and the 'complete audiological analysis' group ($n = 58$).

	All patients		Complete audiology analysis	
	n	%	*n*	%
Total patients	82	100	58	100
Gender				
Female	40	49	23	40
Male	42	51	35	60
Age (years) at implantation	62.9 (15.5)		63.5 (15.2)	
Age (years) at 5SP fitting/tests	72.2 (12.8)		73.2 (12.1)	
Aetiology of hearing loss				
Chronic otitis media	58	71	39	67
(rev) tympanomastoid surgery	35	43	22	38
Sensorineural hearing loss	10	12	9	16
Otosclerosis	3	4	2	3
Other (e.g., combi/trauma/tumour)	10	12	8	14
Unknown	1	1	0	0
Previous device	62	76	43	74
Cordelle II	38	46	28	48
Intenso	9	11	5	9
BP110	1	1	1	2
Ponto Plus Power	9	11	6	10
Ponto Plus	2	2	2	3
Ponto 3SP	2	2	1	2
Baha 5P	1	1	0	0
New device	20	24	15	26
BCD experience incl new users (years)	9.2 (7.2)		9.7 (7.4)	
BCD experience excl new users (years)	12.1 (5.9)		12.9 (5.9)	
Wearing option				
Body-worn	59	72	41	71
Head-worn	21	26	16	28
Contralateral	8	10	5	9
Ipsilateral	13	16	11	19
Unknown	2	2	1	2
Additional devices	29	35	22	38
Conventional hearing aid	13	16	11	19
Bilateral BCD (non-users not incl)	12	15	8	14
Cochlear implant	3	4	2	3
Cochlear implant and BCD	1	1	1	2
Minimic	6	7	4	7

Abbreviation: BCD, bone conduction device.

HL, range 30–70 dB HL); for dBC, it was 47 dB HL (mean 46 dB HL, range 30–67 dB HL).

The distribution of the BC and dBC thresholds per frequency for all patients ($n = 82$) is presented in Figure 1A,B, respectively, expressed in 10%, 25%, 50% (median), 75% and 90% percentiles. Because the median BC values for the analysed group and excluded group were identical, the results of the analysed group were assumed to be representative of all 82 patients.

The median aided free-field SRT was 34 dB SPL (mean 33 dB SPL, range 20–48 dB SPL). The median aided speech perception score at 65 dB SPL was 80% (mean 79%, range 28%–100%). Figure 2A,B presents the correlation between the dBC $PTA_{0.5-2kHz}$ and the aided SRT and between the dBC $PTA_{0.5-2kHz}$ and aided speech perception score at 65 dB SPL, respectively.

The median functional gain was 42 dB (mean 39 dB, range −6 to 73 dB); for the effective gain and effective dBC-gain, it was 18 dB

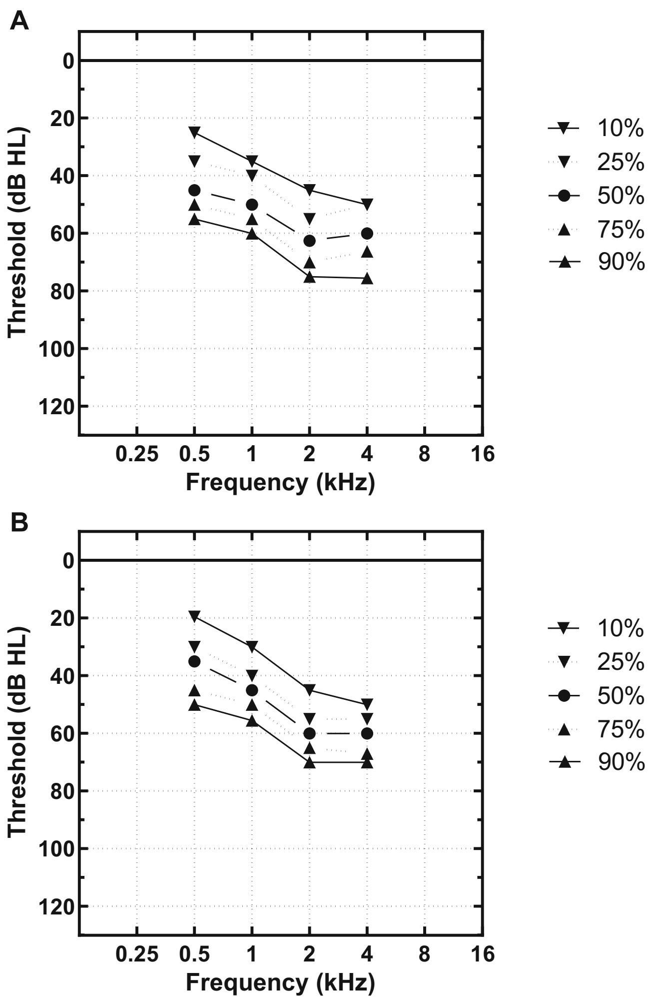

FIGURE 1 (A) Distribution of the pure-tone bone conduction (BC) thresholds per frequency expressed in 10%, 25%, 50%, 75% and 90% percentiles. (B) Distribution of the pure-tone direct bone conduction (dBC) thresholds per frequency expressed in 10%, 25%, 50%, 75% and 90% percentiles.

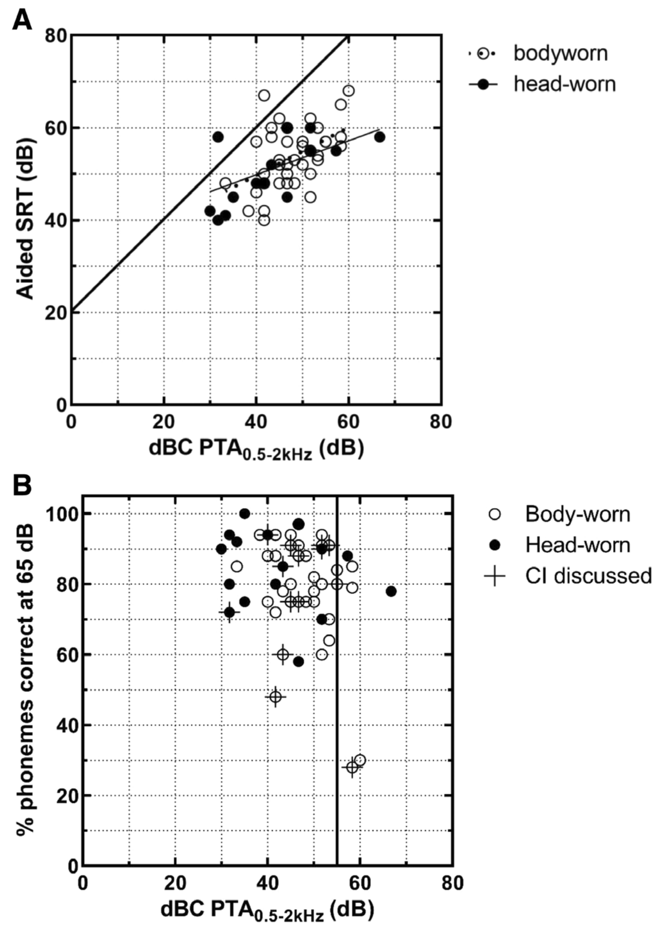

FIGURE 2 (A) Aided CVC phoneme SRT as a function of the dBC PTA$_{0.5-2kHz}$ ($n = 57$). The diagonal line represents the expected speech perception if air-bone gap is fully closed. (B) Aided CVC phoneme scores at 65 dB SPL as a function of the dBC PTA$_{0.5-2kHz}$ ($n = 57$). The plus sign marks that cochlear implantation has been discussed with the patient. The vertical line represents the maximum fitting range of 55 dB PTA$_{0.5-2kHz}$ HL according to Bosman et al.[7] BC, bone conduction; CVC, consonant-vowel-consonant; dBC, direct bone conduction; SRT, speech reception threshold.

(mean 17, range −8 to 42) and 14 dB (mean 13, range −6 to 29 dB), respectively.

4 | DISCUSSION

4.1 | Interpretation of the key findings

The current study evaluated the efficacy of the Baha 5SP. The Baha 5SP is the most powerful BCD sound processor with an MFO of 82–96 dB HL[7,8] when used on a percutaneous implant/abutment. According to the manufacturer, the device is suitable for patients with mixed hearing loss and a sensorineural component of the hearing loss up to 65 dB HL averaged across 0.5, 1, 2 and 3 kHz, but based on previous research at our centre, this average was found to be 55 dB HL.[7,14] Seventy-eight of 82 patients fell within this fitting range when measured with 'normal' BC, with a median PTA$_{0.5-2kHz}$ of 52 dB HL. The other four patients had a PTA$_{0.5-2kHz}$ between 67 and 70 dB HL. The same applied to 63 of the 64 patients measured through dBC, with a median PTA$_{0.5-2kHz}$ of 47 dB HL. For the analysed group ($n = 58$), the median unaided AC PTA$_{0.5-2kHz}$ was 75 dB HL. This last group's median estimated functional gain was 42 dB, as the median estimated effective gain was, based on dBC, 14 dB.

The patient who fell outside the fitting range of the manufacturer measured through dBC was a young man aged 35 with a medical history of ear-tumour surgery resulting in a mixed hearing loss with a dBC PTA$_{0.5-2kHz}$ of 67 dB and an unaided AC PTA$_{0.5-2kHz}$ of 79 dB. Despite the large sensorineural component of the hearing loss, speech perception was reasonably well, with an aided phoneme score of 78% at 65 dB SPL.

Twenty patients (24%) reached a phoneme score of at least 90%. The median score was 83%. This percentage is comparable to post-lingually deaf CI-using adults.[15] Only one superpower user reached the 100% phoneme score. Apart from cochlear dysfunction, the inability to reach a 100% score for the other patients may also be due to the limited dynamic range of a BCD in the high frequencies, which compromises especially consonant perception. Seven patients in the entire group (9%) and three in the analysed group of 58 patients (5%, Figure 2B) did not reach a 50% phoneme score at 65 dB SPL. At least 20 of all 82 patients (24%) and 7 patients of the analysed group (12%) could be considered candidates for cochlear implantation based on an aided phoneme score <70% at 65 dB SPL. For six of them, cochlear implantation had already been discussed. However, they refrained from the CI procedure for various reasons, for example, undesirable general anaesthesia due to poor health status, fear or unwillingness to undergo surgery, due to previous traumatic experiences, or an inability to engage in an intensive rehabilitation programme. For these patients, a superpower device is their last resort. Also, the superpower device allows for a more natural perception of music and environmental sounds.

At least 59 patients (72%) used the sound processor in the body-worn position, that is, on their chest. This position makes sense as patients with severe-to-profound mixed hearing loss need as much (stable) gain as possible. However, high gain settings quickly induce feedback issues when the sound processor comes too close to the transducer and/or skull. This clearly shows the dilemma of using this superpower device in the body-worn position: the demands of physics and aesthetics are at odds with each other.

4.2 | Strengths and limitations

With 82 subjects, the current study presents the most extensive data set on the Baha 5SP to date. However, it is essential to note that due to its retrospective nature, this study is limited by incomplete (audiological) data and missing specific non-standard measures or questionnaires (e.g., quality of life or device satisfaction). We attempted to obtain some insight into patient satisfaction through device usage. In 23 of the 58 analysed patients, we found that device usage consisted of all-day, everyday usage. This outcome does not necessarily guarantee satisfaction in all patients, but the high use level emphasises the patient's dependence on the device.

5 | CONCLUSION

The Cochlear Baha 5 SuperPower currently provides the highest gain and MFO of all BCDs on the market. These characteristics have greatly improved speech intelligibility in our patients with severe-to-profound mixed hearing loss.

In conclusion, this superpower device is particularly suitable for patients with severe-to-profound mixed hearing loss but with a contraindication for conventional hearing aids. If a cochlear implant is not an option, this device is a last resort. Suppose a cochlear implant is not an option. In that case, this device is a last resort—more awareness of the possibilities of a superpower BCD is needed when rehabilitating profound mixed hearing loss.

AUTHOR CONTRIBUTIONS

HK designed the work; ET, HK and AJ acquired and analysed data; ET, HK, AJ, MH and AB drafted, revised and approved the manuscript; ET, HK, AJ, MH and AB agreed to be accountable for all aspects of the work.

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CONFLICT OF INTEREST STATEMENT

The authors declare no other conflicts of interest.

PEER REVIEW

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DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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