

# Bed Partners' Perspectives and Sleep Quality After Hypoglossal Nerve Stimulation Therapy for Obstructive Sleep Apnea

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**Introduction:** Hypoglossal nerve stimulation (HGNS) is a treatment option for patients with moderate-to-severe obstructive sleep apnea (OSA) and intolerance or non-acceptance of positive airway pressure (PAP) therapy. Improvements in respiratory outcomes, sleepiness and quality of life have been demonstrated in treated patients. We aimed at evaluating the bed partner's perspective on HGNS therapy.

**Methods:** In a cross-sectional exploratory prospective study (Clinical Trial Registration: DRKS00030554), 33 consecutive bed partners of patients treated with a unilateral, respiratory-coupled HGNS device in a tertiary medical center completed a 23-item custom-made questionnaire with questions that addressed the bed partner's perceptions and their satisfaction with HGNS therapy.

**Results:** Bed partners reported that the patients were more comfortable with HGNS therapy (97.0%) compared to PAP therapy, their own sleep quality was better (90.9%) and their sexual partnership was equivalent in 69.0% and better in 27.3%. Their partners' snoring was reported as reduced in 87.9%. This trend was especially reported by bed partners of therapy responders. Bed partners did not need to motivate the patients to use HGNS therapy (81.8%), were satisfied with their partners' HGNS therapy (78.9%) and would recommend HGNS therapy to others (81.8%). Response to HGNS treatment or sex did not influence the reported outcomes.

**Conclusion:** Bed partners of HGNS-implanted OSA patients perceive the HGNS therapy mostly positive and are very often satisfied with this therapy. Nonetheless, single aspects of HGNS therapy for OSA may be experienced differently by the patients' bed partners.

**Keywords:** bed partner, sleep apnea, hypoglossal nerve, neurostimulation, questionnaire

## Introduction

Respiratory-coupled stimulation of the hypoglossal nerve (hypoglossal nerve stimulation, HGNS) has emerged as a reliable therapeutic option for patients with moderate-to-severe obstructive sleep apnea (OSA) who cannot tolerate first-line therapy with positive airway pressure (PAP). This approach involves the implantation of a neurostimulation device, designed to deliver controlled, respiration-synchronized electrical impulses to the hypoglossal nerve during sleep. In this way, the OSA-associated collapse of the airways is prevented by activation of the protrusor tongue muscles with resulting improvement of the apnea/hypopnea index, nocturnal oxygenation and daytime sleepiness.<sup>1</sup>

Inadequately treated OSA leads to a poorer quality of life compared to the general population.<sup>2</sup> Accordingly, the quality of life of OSA patients improves after initiation of HGNS treatment.<sup>1</sup> Also, the quality of life of bed partners, as measured by the 36-item Short Form Health Survey (SF-36) and the SAQLI, has been shown to benefit under treatment of OSA patients with PAP therapy.<sup>3</sup> The effects of PAP therapy on bed partners were also investigated within a large European cohort of OSA patients.<sup>4</sup> The 5-year follow-up results of patients treated with HGNS have shown a significant improvement in the Epworth Sleepiness Scale (ESS) and the Functional Outcomes of Sleep Questionnaire (FOSQ).<sup>5</sup> These measures also demonstrated an improved quality of life following HGNS therapy. Despite these very favorable results, less is known about how HGNS therapy is perceived as a novel OSA therapy alternative by the bed partners of HGNS-treated patients.

While PAP therapy has the advantage that it develops almost full therapeutic effect from the first night of treatment, HGNS therapy often requires several weeks or months of adaptation and neurostimulation parameter titration before the optimal therapeutic stimulation level is reached. This may be challenging for both patients and bed partners, especially if the initial HGNS stimulation settings of the HGNS therapy do not lead to a quick therapeutic success and need be readjusted. HGNS patients are no longer equipped with a positive airway pressure machine, connecting tube and mask, which must be worn throughout the night, but use a form of OSA therapy that is invisible to the bed partner: in addition to the equipment required for PAP therapy, HGNS only needs to be activated before going to bed. In contrast to PAP therapy, HGNS therapy is silent, does not require any plug-in power source during the night, does not restrict movement and has almost no impact on patients' appearance. In addition, no cleaning is required, there are no hygiene issues (as is the case with PAP equipment) and the therapy-related hardware is easy to transport when traveling.

As most adults share the bed with a bed partner,<sup>6</sup> sleep plays a crucial role in social experiences. For example, couple sleep can have a positive influence on the other partner's health and well-being.<sup>7</sup> Bed partners' satisfaction and sleep quality may not only affect the immediate ambient sleep environment but also impacts the patient's adherence to therapy and ultimately treatment success.

Therefore, the aim of this study was to investigate how bed partners of HGNS-treated patients perceive and ultimately rate HGNS therapy. In addition, the study aimed to investigate if bed partners are satisfied with HGNS therapy or would recommend it to others. It was hypothesized that HGNS therapy has a positive effect on bed partners of implanted patients. A custom-made questionnaire was developed to answer these research questions.

## Methods

### Study Design

In our sleep medicine center, HGNS implantation is performed in the clinical routine as an alternative therapy for OSA patients with PAP intolerance. For this study, to mitigate selection bias, we considered consecutive bed partners of all patients who were implanted with a unilateral, respiratory coupled HGNS device from Inspire Medical Systems, Inc. (Maple Grove, MN, USA) between June 2022 and March 2024. All patients met the following indication criteria for HGNS implantation:

- A definitive diagnosis of OSA and the exclusion of other sleep-related breathing disorders, intolerance or non-acceptance to PAP therapy,
- an apnea-hypopnea index (AHI) between 15 and 65 respiratory events (ie, apneas and hypopneas) per hour of sleep with less than 25% central apneas as recorded on diagnostic polysomnography (PSG) throughout the night,
- a body mass index (BMI) of less than 35 kg/m<sup>2</sup>,
- the absence of complete concentric collapse at the velar level during drug-induced sleep endoscopy (DISE), and
- the absence of chronic neurodegenerative or severe psychiatric disease.

The implanted HGNS device was activated according to clinical standard operating procedures four weeks after its implantation. There was no PSG-based nocturnal titration, but the stimulation parameters were set and adjusted during the day based on PSG results and patients' comfort. All patients routinely undergo follow-up PSG at our sleep medicine center, usually ten to twelve weeks after HGNS activation. In the time between activation and follow-up PSG, patients are contacted and supported by phone. In case of any complications or any events related to handling of the HGNS therapy, patients were referred and consulted in our outpatient department.

When HGNS patients presented for follow-up PSG, they were informed about the questionnaire and asked to forward it to their bed partners to complete. A prepaid return envelope has been provided for return shipment. All bed partners were informed about the content of the study in a personal interview. Participation in the study was voluntary and was neither part of the HGNS patient selection nor the indication process. All included bed partners agreed to participate in written form. Only bed partners who reported that they were in a committed partnership with HGNS patients were considered for inclusion in the study. The disclosure of separated sleep did not automatically lead to exclusion from the study. One criterion for inclusion in the study was that the bed partners slept in the same room as HGNS patients for at least 75% of the nights, which was reported by all included bed partners at the time of recruitment to the study. However,

after evaluation of the questionnaires,  $n = 2$  bed partners stated that this criterion was not met. Due to the potentially far-reaching effects of HGNS therapy on life beyond sleep quality (eg sex life, perception of the relationship, overall satisfaction with the therapy, etc), these patients were included in the study analysis. The absence of a written consent and being under the age of 18 led to exclusion from the study. In addition, the statement of shared sleep less than 75% of nights during recruitment for the study led to exclusion.

## Questionnaire for Bed Partners

To assess the perception and satisfaction of bed partners of patients with HGNS, we developed a novel customized questionnaire (“UM questionnaire on the quality of life of bed partners of patients treated by hypoglossal nerve stimulation”- *LEBEGLONE*). The questionnaire contained questions about demographics of the bed partner and the HGNS patient as well as questions about the partnership between those. These were followed by an evaluation of the HGNS therapy from the bed partner’s perspective and specifically by questions on satisfaction with the therapy. The answers were either predefined and had to be ticked or a free-text field had to be filled in (shown below as “free-text answer”).

This survey using the questionnaire is a pilot study designed to record the satisfaction of bed partners of HGNS patients. Although the questionnaire used has not been yet validated, our aim was to capture the feedback from patients and bed partners after HGNS therapy in a clinically meaningful, structured and standardized way. For this purpose, a survey of three sleep medicine experts was initiated within our sleep medicine center to determine which questions the experts consider relevant based on their clinical expertise and experience. To increase participant compliance, Likert scales were predominantly used with the option of selecting a predetermined response. As with any other form of sleep-related therapy, the bed partner is a decisive factor for therapy tolerance and compliance. When developing the questions, important factors that can influence sleep and the comfort of the bed partner were taken into account. In addition, a validated questionnaire, which records the contentment of bed partners of PAP patients,<sup>4</sup> was taken into account to enable a comparison in the future.

The original questionnaire was written and provided in German language. The translation into English was performed with assistance from DeepL (Cologne, Germany). The translation was done for publication purposes only. All surveyed patients and their bed partners had native German language skills and answered the questionnaire in German language. The questionnaire has not yet been subjected to a validated translation. The questionnaire for bed partners contained the following 23 questions (“Q1-23”) with corresponding answer options (“A”):

- Q1: Age of bed partner?  
A1: *Free text answer* years.
- Q2: Sex of bed partner?  
A2: Male, female.
- Q3: Age of partner with HGNS therapy?  
A3: *Free-text answer* years.
- Q4: Sex of partner with HGNS therapy?  
A4: Male, female.
- Q5: Duration of partnership?  
A5: *Free-text answer* years.
- Q6: Do you and your partner sleep in the same room?  
A6: Yes, sometimes, no.
- Q7: How long has your partner been using the HGNS therapy?  
A7: *Free-text answer* years and months.

- Q8: How many nights per week does your partner use the HGNS therapy on average?  
A8: *Free-text answer* nights.
- Q9: Did your partner use mask therapy (PAP) before the HGNS therapy?  
A9: Yes, no, do not know.
- Q10: If yes: How long has your partner used the mask therapy?  
A10: *Free-text answer* years and months.
- Q11: If yes: How would you rate the comfort of the HGNS therapy compared to the mask therapy?  
A11: See answer selection 1 below.
- Q12: Do you sleep better since your partner has been using the HGNS therapy?  
A12: See answer selection 1 below.
- Q13: Does your partner snore less/less often since using the HGNS therapy?  
A13: See answer selection 2 below.
- Q14: Has your sex life improved since your partner has been using HGNS therapy?  
A14: See answer selection 1 below.
- Q15: Are you glad that you and your partner opted for HGNS therapy?  
A15: Yes, no, do not know.
- Q16: Do you motivate your partner to switch on the HGNS therapy before going to sleep?  
A16: Yes, no, do not know, not necessary.
- Q17: Does it bother you if your partner uses the HGNS therapy?  
A17: Yes, no, do not know.
- Q18: Has your relationship improved since your partner has been using the HGNS therapy?  
A18: Yes, no, do not know.
- Q19: Did you imagine the handling of the HGNS therapy as it is in reality?  
A19: Yes, no, do not know, other-namely *free-text answer*.
- Q20: Can you imagine your partner using the HGNS therapy permanently?  
A20: Yes, no, do not know.
- Q21: Would you recommend HGNS therapy to others?  
A21: Yes, no, do not know.
- Q22: How satisfied are you overall with the HGNS therapy for your partner?  
A22: See answer selection 3 below.
- Q23: How would you rate your partner's satisfaction with the HGNS therapy?  
A23: See answer selection 3 below.

Answer selection 1: Much better (1), significantly better (2), slightly better (3), equivalent (4), worse (5).

Answer selection 2: Very much less (1), significantly less (2), slightly less (3), equivalent (4), stronger (5).

Answer selection 3: Very satisfied (1), satisfied (2), neither (3), dissatisfied (4), very dissatisfied (5).

Subsequently, the bed partners were asked to select only one predefined answer or to fill in the free-text field. However, one bed partner chose two predefined answers ("significantly better (2)" and "equivalent" (4)) for Q12. In this solitary case,

the average (“slightly better (3)”) was calculated and used for analysis. If bed partners wrote their own answer that was not intended as a choice alongside a predetermined answer, their answers were not scored. The bed partners were not asked about their own medical history, especially not about the presence of sleep-related breathing disorders.

## Statistics

GraphPad Prism version 5.01 (Boston, MA, USA) was used for statistical analysis and graphical illustration. Categorical variables were described as number and percentage (%). Continuous variables were described as mean and standard deviation (SD) after evaluating the normality of distribution. To evaluate the Likert scales, the chi-square test was used to find out whether the observed quantity of responses deviated statistically significant from the assumption of an equal distribution of responses. If a question was not answered, the corresponding bed partner was excluded from the evaluation (eg,  $n = 1$  bed partner did not answer Q15, then the statistical evaluation of Q15 was carried out with  $n = 32$  instead of  $n = 33$  bed partners). For the comparison of responders and non-responders, the Likert Scales were dichotomized and compared by chi-square test. Odds ratios and 95% confidence intervals were calculated whenever statistically possible. Response to HGNS treatment was defined according to the Sher criteria, namely a. a reduction of more than 50% to the AHI numerical value compared to the baseline pre-treatment value and at the same time b. an AHI  $<20$  events/hour after treatment. Additional separate analyses have been done to test whether sex of the bed partners or OSA patients’ response to HGNS treatment influenced the bed partners’ reported outcomes. A  $p$ -value  $<0.05$  was denoted statistically significant. Because of the exploratory nature of the study, no multiplicity adjustments were done. With the number of responses given, only high odds ratios of 13.5 can be provided with 80% power and a response rate of 50% in the non-responders by using a two-sided chi-square test and a significance level of  $\alpha=5\%$ .

## Ethical Considerations

Participation in the study was voluntary. All study participants gave written consent after they had been previously thoroughly informed about the aim and the procedures of this study. All the principles of the Helsinki Declaration for studies in humans were respected and fulfilled. The Ethics committee of the Rhineland-Palatinate Chamber of Physicians approved the protocol (approval no. 2022-16702).

## Study Registration

Before beginning with participants’ recruitment, this study has been registered in the respective Clinical Trial Registry (no. DRKS00030554).

## Results

### Demographic Characteristics of the Study Population

A total of  $N = 40$  patients who had undergone HGNS treatment have been contacted. The average AHI value of all patients was  $39.88 (\pm SD = 21.22)$  events per hour of sleep, and the average BMI was  $29.39 (\pm SD = 2.87)$  kg/m<sup>2</sup>.

We received a total of  $n = 33$  completed questionnaires from bed partners, which were included in the following analysis. Answers to Q1-6 were analyzed in the following: The bed partners were  $56.6 \pm 11.8$  years old (see Q1), 9 were male (27.3%) and 24 were female (72.7%) (see Q2). Corresponding, partners using the HGNS therapy were  $57.2 \pm 10.3$  years old (see Q3), 9 were female (27.3%) and 24 were male (72.7%) (see Q4). The partnerships were of a duration of  $23.0 \pm 14.1$  years (see Q5) and  $n = 25$  of the couples always slept in the same room (75.8%). Only sometimes  $n = 6$  couples slept in the same room (18.2%), while  $n = 2$  couples never slept in the same room (6.0%) (see Q6).

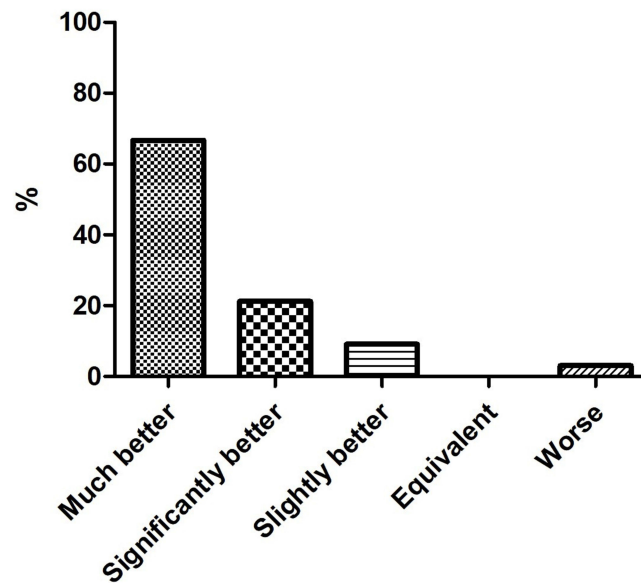
### Evaluation of Hypoglossal Nerve Stimulation Therapy Utilization and Previous Therapy with Positive Airway Pressure

After evaluating the study population, we analyzed the quantity of used HGNS and previous PAP therapy. For this section, answers to Q7-10 were investigated: The partners have been using the HGNS therapy for  $12.9 \pm 7.8$  months (see Q7). The range of HGNS use was at least 2 months to a maximum of 29 months. HGNS therapy was used 7 nights per

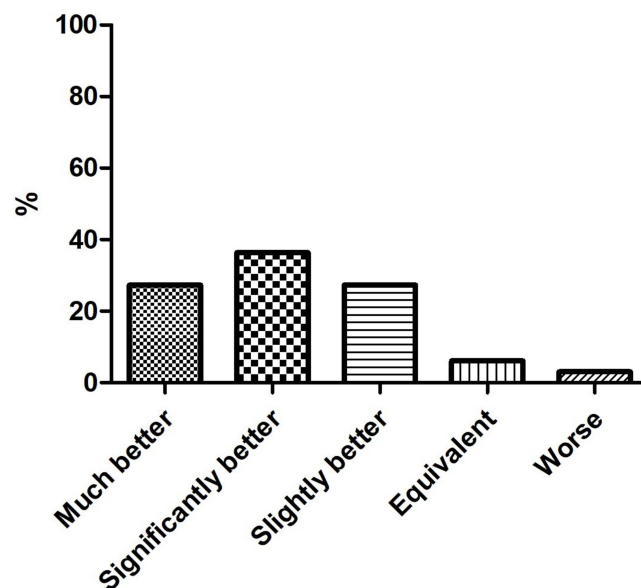
week in  $n = 30$  cases (90.9%) and 6 nights per week in  $n = 3$  cases (9.1%) (see Q8). PAP therapy had been used by  $n = 29$  patients (87.9%) for  $6.1 \pm 4.2$  years prior to HGNS therapy (see Q9-10).

## Evaluation of Comfort and Personal Effects After Starting Hypoglossal Nerve Stimulation Therapy

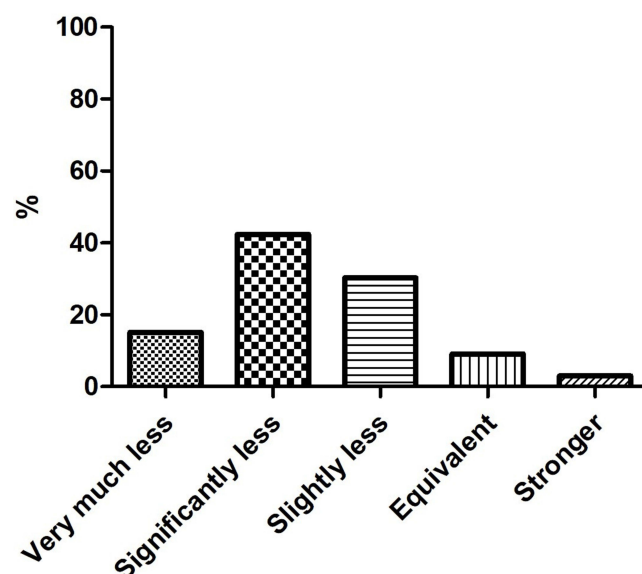
Subsequently, answers to Q11-14 were analyzed: Bed partners most frequently found the patients' comfort with the HGNS therapy to be *much better* (66.7% of all answers,  $p < 0.0001$ ) compared to the PAP therapy (see Q11 and Figure 1). In addition, bed partners most frequently reported sleeping *significantly better* (36.4% of all answers,  $p = 0.0075$ ) since their partner started using HGNS therapy (see Q12 and Figure 2). Bed partners felt that their partners snored *significantly less* (42.4% of all answers,  $p = 0.0023$ ) since the HGNS therapy was used (see Q13 and Figure 3). Sex life has been described as *equivalent* (69.0% of all



**Figure 1** Graphical illustration of Q11 ("How would you rate the comfort of the HGNS therapy compared to the mask therapy?").



**Figure 2** Graphical illustration of Q12 ("Do you sleep better since your partner has been using the HGNS therapy?").

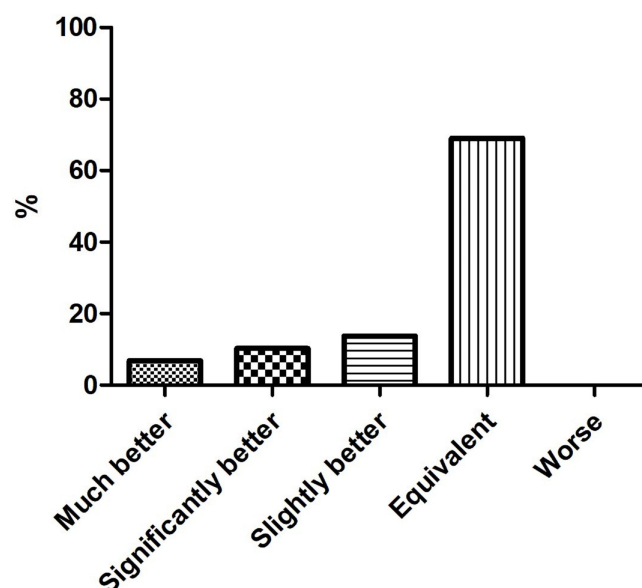


**Figure 3** Graphical illustration of Q13 ("Does your partner snore less/less often since using the HGNS therapy?").

answers,  $p < 0.0001$ ) or better (in 31%) since the start of therapy (see Q14 and Figure 4). In general, most bed partners reported to be glad that they and their partner opted for HGNS therapy (87.9% yes, 3.0% no, 9.1% do not know,  $p < 0.0001$ ) (see Q15). Finally, bed partners most frequently described that their relationship improved since their partner used the HGNS therapy (40.0% yes, 33.3% no, 26.7% do not know,  $p = 0.6703$ ) (see Q18). An overview of the exact distribution of responses to Q11-14 can be found in Table 1.

### Perception of Handling the Hypoglossal Nerve Stimulation Therapy

For this section, Q16-17 and Q19 were reviewed: Bed partners reported most frequently that they do not need to motivate their partner to switch on the HGNS therapy (18.2% yes, 9.1% no, 0% do not know, 72.7% not necessary,  $p < 0.0001$ ) (see Q16 and Figure 5). In addition, the bed partners in their vast majority did not feel disturbed by their partners using



**Figure 4** Graphical illustration of Q14 ("Has your sex life improved since your partner has been using HGNS therapy?").



**Table 1** UM Questionnaire on the Quality of Life of Bed Partners of Patients Treated by Hypoglossal Nerve Stimulation (LEBEGNONE) with Responses of the Bed Partners (A1-23) to the Questions of the Questionnaire (Q1-23). For a Better Understanding, the Table Is Subdivided Into 23 sections, Corresponding to Each Question/Response of the Questionnaire

Q1	Age of bed partner?					
A1	56.6 ± 11.8 years					
Q2	Sex of bed partner?					
A2	Male			Female		
n (%)	9 (27.3)			24 (72.7%)		
Q3	Age of partner (patient) with HGNS therapy?					
A3	57.2 ± 10.3 years					
Q4	Sex of partner with HGNS therapy?					
A4	Male			Female		
n (%)	24 (72.7%)			9 (27.3)		
Q5	Duration of partnership?					
A5	23.0 ± 14.1 years					
Q6	Do you and your partner sleep in the same room?					
A6	Yes		Sometimes		Never	
n (%)	25 (75.8)		6 (18.2)		2 (6.1)	
Q7	How long has your partner been using the HGNS therapy?					
A7	12.9 ± 7.8 months (range = 2–29 months)					
Q8	How many nights per week does your partner use the HGNS therapy on average?					
A8	7 nights/week in 30 cases (90.9%), 6 nights/week in 3 cases (9.1%)					
Q9	Did your partner use mask therapy (PAP) before the HGNS therapy?					
A9	Yes		No		Do not know	
n (%)	33 (100)		0 (0)		0 (0)	
Q10	If yes: How long has your partner used the mask therapy?					
A10	6.1 ± 4.2 years					
Q11	If yes: How would you rate the comfort of the HGNS therapy compared to the mask therapy?					
A11	Much better	Significantly better	Slightly better	Equivalent	Worse	p-value
n (%)	22 (66.7)	7 (21.2)	3 (9.1)	0 (0)	1 (3.0)	< 0.0001
Q12	Do you sleep better since your partner has been using the HGNS therapy?					
A12	Much better	Significantly better	Slightly better	Equivalent	Worse	p-value
n (%)	9 (27.3)	12 (36.4)	9 (27.3)	2 (6.1)	1 (3.0)	0.0075
Q13	Does your partner snore less/less often since using the HGNS therapy?					
A13	Very much less	Significantly less	Slightly less	Equivalent	Stronger	p-value
n (%)	5 (15.1)	14 (42.4)	10 (30.3)	3 (9.1)	1 (3.0)	0.0023

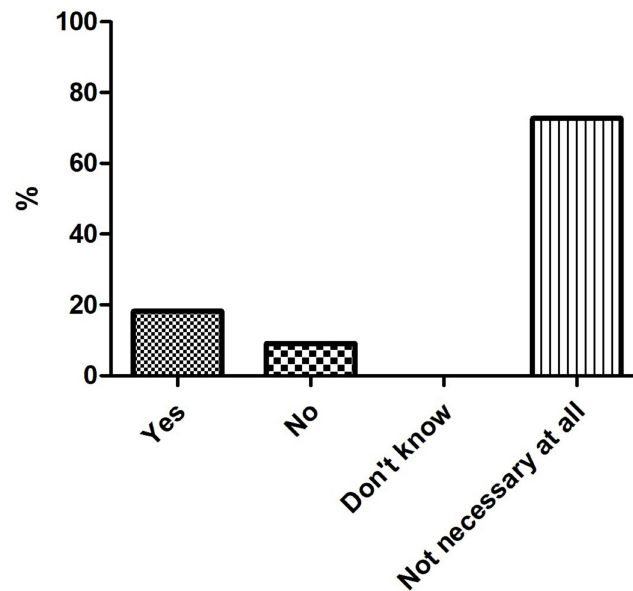
(Continued)



**Table 1** (Continued).

Q14	Has your sex life improved since your partner has been using HGNS therapy?					
A14	Much better	Significantly better	Slightly better	Equivalent	Worse	p-value
n (%)	2 (6.9)	3 (10.3)	4 (13.8)	20 (69.0)	0 (0)	< 0.0001
Q15	Are you glad that you and your partner opted for HGNS therapy?					
A15	Yes	No	Do not know	p-value		
n (%)	29 (87.9)	1 (3.0)	3 (9.1)	< 0.0001		
Q16	Do you motivate your partner to switch on the HGNS therapy before going to sleep?					
A16	Yes	No	Do not know	Not necessary at all	p-value	
n (%)	6 (18.2)	3 (9.1)	0 (0)	24 (72.7)	< 0.0001	
Q17	Does it bother you if your partner uses the HGNS therapy?					
A17	Yes	No	Do not know	p-value		
n (%)	1 (3.0)	31 (93.9)	1 (3.0)	< 0.0001		
Q18	Has your relationship improved since your partner has been using the HGNS therapy?					
A18	Yes	No	Do not know	p-value		
n (%)	13 (39.4)	11 (33.3)	9 (26.7)	0.6703		
Q19	Did you imagine the handling of the HGNS therapy as it is in reality?					
A19	Yes	No	Do not know	Other (free text)	p-value	
n (%)	19 (59.4)	1 (3.0)	7 (21.2)	6 (18.8)	< 0.0001	
Q20	Can you imagine your partner using the HGNS therapy permanently?					
A20	Yes	No	Do not know	p-value		
n (%)	32 (97.0)	1 (3.0)	0 (0)	0.6703		
Q21	Would you recommend HGNS therapy to others?					
A21	Yes	No	Do not know	p-value		
n (%)	27 (81.8)	1 (3.0)	5 (15.2)	<0.0001		
Q22	How satisfied are you overall with the HGNS therapy for your partner?					
A22	Very satisfied	Satisfied	Neither	Dissatisfied	Very dissatisfied	p-value
n (%)	15 (45.5)	11 (33.3)	4 (12.1)	3 (9.1)	0 (0)	< 0.0001
Q23	How would you rate your partner's satisfaction with the HGNS therapy?					
A23	Very satisfied	Satisfied	Neither	Dissatisfied	Very dissatisfied	p-value
n (%)	13 (39.4)	17 (51.5)	1 (3.0)	2 (6.1)	0 (0)	< 0.0001

HGNS therapy (3% yes, 94% no, 3% do not know,  $p < 0.0001$ ) (see Q17). In general, most bed partners imagined the handling of HGNS therapy as it is (59.4% yes, 3% no, 21.2% do not know, 18.8% other,  $p < 0.0001$ ; one bed partner wrote “less stimulation on the tongue and faster familiarization”, one bed partner wrote “even better”, one bed partner wrote “no snoring, better mood, fitter”, one bed partner wrote “I thought that my partner would also be able to sleep better/sleep through the night”, and one bed partner wrote “more effective”) (see Q19, Table 1).



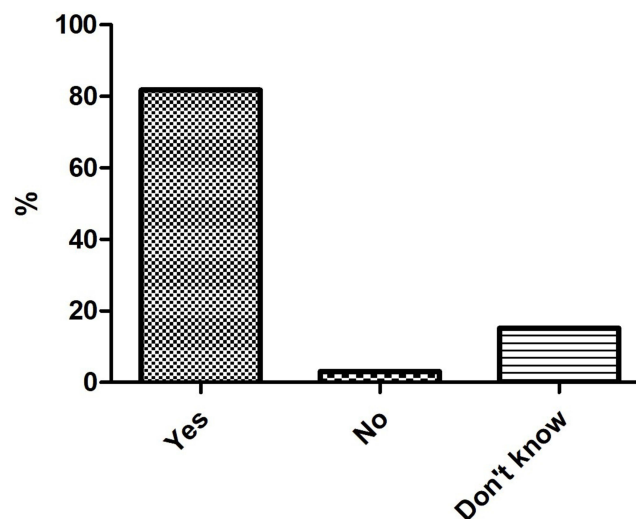
**Figure 5** Graphical illustration of Q16 ("Do you motivate your partner to switch on the HGNS therapy before going to sleep?").

## Future Perspectives Regarding HGNS

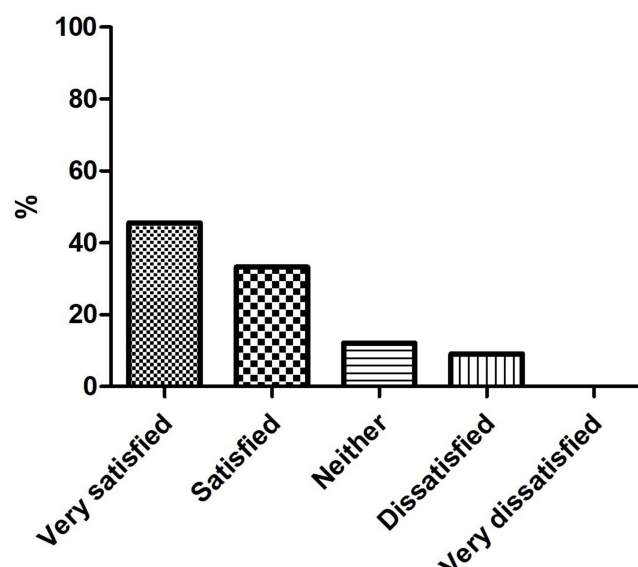
Q20-21 were analyzed to investigate expectations of the bed partners regarding future use of HGNS by the patients and whether they would recommend this therapy to others:  $n = 32$  partners (97%) said they could imagine their partner using HGNS therapy permanently (3% no, 0% do not know,  $p < 0.0001$ ) (see Q20). Matching this,  $n = 27$  partners (81.8%) would recommend HGNS therapy to others (3.0% no, 15.2% do not know,  $p < 0.0001$ ) (see Q21, [Figure 6](#) and [Table 1](#)).

## Personal and Partner-Related Satisfaction

Finally, Q22-23 were investigated: Bed partners most frequently reported to be *very satisfied* (45.5% of all answers,  $p = 0.0001$ ) with HGNS therapy (see Q22 and [Figure 7](#)). Accordingly, bed partners rated their partner's satisfaction with the HGNS therapy most frequently as *satisfied* (51.5% of all answers,  $p < 0.0001$ ) (see Q23). An overview of the exact distribution of responses can be found in [Table 1](#).



**Figure 6** Graphical illustration of Q21 ("Would you recommend HGNS therapy to others?").



**Figure 7** Graphical illustration of Q22 ("How satisfied are you overall with the HGNS therapy for your partner?").

## Analysis of the Findings Based on Response to Treatment According to Sher Criteria

HGNS-responders and non-responders have been evaluated according to Sher criteria (50% reduction in AHI, AHI < 20 events/h).<sup>1</sup> If the Sher criteria are applied in our study cohort, then  $n = 11$  (33.3%) were bed partners of responders and  $n = 22$  (66.7%) were bed partners of non-responders. No statistically significant difference was found between any of the responses of bed partners of responders compared to those of non-responders (see [Supplement Table 1](#)).

## Evaluation of the Findings by Sex of the Bed Partners

Nine (27.3%) bed partners of patients were male and  $n = 24$  (72.7%) were female. The sole significant difference when comparing the responses of male to female bed partners was found for Q9 ("Did you partner use PAP before HGNS?") in which female bed partners gave significantly more positive answers than male bed partners did. All other questions of the questionnaire showed no significant differences when comparing the responses of bed partners according to sex (see [Supplement Table 2](#)).

## Discussion

Detailed studies addressing the impact of the HGNS therapy on the OSA patients' bed partners have been lacking. The present study therefore aimed to investigate how bed partners of implanted patients rate the HGNS therapy in terms of different aspects of everyday life as well as their partnership and if those ultimately would recommend it to others.

We provide evidence that bed partners rate comfort of HGNS use by patients much better than PAP, sleep better after HGNS treatment of their partners, are glad for their partners' decision to have HGNS, they do not need to motivate their partners to use HGNS, are not bothered by device use, can imagine their partners using HGNS permanently in the future and would recommend this therapy to others. Of note, Sher criteria-based response of patients to HGNS treatment did not cause any significant difference in bed partners' reports. This fact should be considered in future studies. In addition, it turned out that reported satisfaction and experience were not dependent on the sex of the bed partner. These results are novel and, in addition to objective metrics of clinical sleep medicine practice (such as AHI), represent a potentially significant addition to HGNS patient education and counseling and overall therapy evaluation.

As sleep is often a shared experience in adults, it is likely that sleep disorders such as OSA have a profound impact on sleep and daytime functioning of bed partners. Therefore, an increasing body of literature suggests that OSA is a shared problem and that adequate treatment is beneficial for the overall health of bed partners.<sup>8</sup> Untreated OSA, for example, negatively affects the partners' quality of life, as the SF-36 score has proven to be significantly worse among partners of

OSA patients compared to the general population.<sup>9</sup> Conversely, partners of patients with moderate-to-severe OSA reported improvements in sleep quality, daytime alertness, mood, quality of life, and partnership after initiation of PAP therapy.<sup>10</sup> Accordingly, one main result of the present study demonstrates a reported improvement in sex life in 31% of bed partners. Therefore, HGNS therapy for OSA may positively influence quality of life for both patient and bed partner. This aspect should be further evaluated in the future and be specifically considered in HGNS patient/bed partner education and counseling and the personalized treatment decision process.

A recently published study investigating the effects of PAP therapy on bed/relationship partners of PAP patients in ten European countries reports that the partners largely perceive PAP therapy as an enrichment for their relationship. However, a longer duration of therapy again had a negative effect on the statements made about PAP therapy, particularly regarding intimacy.<sup>4</sup> Other studies on this subject investigated the impact of partners on patients' PAP therapy: Their key findings indicated that involving (bed) partners increase PAP adherence as well as acceptance and thus improve the overall quality of life of patients and their (bed) partners,<sup>11,12</sup> especially when couple-based treatment is favored.<sup>13</sup> Whether this effect can also be demonstrated for HGNS therapy would be an interesting starting point for further research.

Additionally, partners of patients with OSA treated with oral appliances reported improvement in sleep quality and increased bed sharing, but no change in marital satisfaction.<sup>14</sup> However, no change in daytime sleepiness was detected in partners of patients with simple snoring or OSA that were treated with radiofrequency tissue ablation treatment (RFTA).<sup>15</sup> In the same study, significant reductions in anxiety and depression symptoms were found among partners of patients with OSA treated with RFTA. In addition, a large body of literature shows that partners have a direct influence on the health decisions of OSA patients: Positive partner involvement, such as encouragement or a collaborative approach, can lead to greater patient engagement, while negative partner involvement, such as criticism or nagging, can have the opposite effect.<sup>8</sup> Sleep plays a central role in relationships. Sleep can have both positive and negative influences, and appropriate, satisfactory treatment of sleep disorders such as OSA is beneficial for bed partners.

Such an improvement in the bed partners' attitudes, experiences and satisfaction may be due to the concomitant improvement in the sleep pattern of the HGNS-treated patients, especially the improvement in their insomnia-related sleep features.<sup>16</sup> This positive effect of HGNS treatment on insomnia appears to be significantly greater compared to PAP-therapy.<sup>17</sup> If HGNS-treated patients remain longer asleep overnight and show less sleep disruption due to improvements in their comorbid insomnia, then it is reasonable to expect that their bed partners would also experience less sleep disruption.

The presented study has strengths and limitations that need to be addressed. The main strength of this study is that it focuses on a previously unconsidered area of the evaluation of HGNS in clinical practice. The study has the advantage that all considered patients were implanted in one single sleep medicine center and thus confounders, eg, due to diverse procedures in multiple centers, changing surgeons, different implant types, etc., could be minimized. Selection bias was mitigated by including bed partners of consecutive OSA patients treated with OSA; also, it should be noted that much more OSA patients were non-responders than responders according to the Sher criteria.

However, this study has some limitations: First, the number of bed partners included in this study is relatively small, which may limit the statistical power of the concluded results. Second, given that the analysis was based on a predefined questionnaire, there was little scope for individual answers. The questionnaire depicts selected parts of the perception of HGNS therapy and may not consider aspects that might be of greater importance for individual bed partners. Third, the evaluation of this study only considers personal perception and reports and does not correlate with treatment success after the patients received HGNS implantation, eg, based on the degree of reduction of the AHI or oxygen desaturation index (ODI), nor the improvement of oxygen saturation or the reduction of the percentage of oxygen desaturation lower than 90% (t90). This aspect (the correlation of bed partners' reported outcomes with more objective clinical metrics) would be an interesting starting point for further research. Given that the results and their interpretation are based on self-reported data, recall bias must be considered, which may have had a false positive/negative impact on the observed results.

However, the reported trends regarding HGNS therapy perception are significant, especially given the methods used to mitigate selection bias. Nevertheless, these trends should be re-evaluated for various different demographic groups of patients.

Future studies need to focus on the above limitations and investigate them in larger study populations to strengthen the reported results. It should also be noted that we asked about satisfaction with HGNS therapy after a relatively short treatment period, namely after  $12.9 \pm 7.8$  months. In the future, it will be interesting to investigate whether satisfaction is influenced by the duration of therapy. Therefore, longitudinal studies should be conducted that follow bed partners of HGNS patients over a longer period of time. In addition, future studies should also include concomitant standardized quality of life questionnaires, such as the SF-36 or other to allow potential comparisons. These measures could be used to directly compare the effects of HGNS therapy on bed partners with those of PAP therapy and other OSA treatments.

## Conclusion

In this study, the bed partners' perspective on HGNS treatment for patients suffering from moderate-to-severe OSA not tolerating PAP-treatment can be summarized as mostly positive with a definitive trend supporting bed partners' satisfaction with this therapy. Nonetheless, inter-individual bed partners' perceptions may vary.

## Abbreviations

AHI, Apnea/Hypopnea Index; ESS, Epworth Sleepiness Scale; FOSQ, Functional Outcomes of Sleep Questionnaire; HGNS, Hypoglossal Nerve Stimulation; ODI, Oxygen Desaturation Index; OSA, Obstructive Sleep Apnea; PAP, Positive Airway Pressure; PSG, Polysomnography; SF 36, Short Form 36.

## Data Sharing Statement

The raw data associated with this manuscript may be available in anonymized form from the corresponding author according to local data protection policies upon reasonable request.

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## Author Contributions

**Contributor Roles:** Conceptualization: HG, KL. Data curation: CS, KL, HG. Formal analysis: CS, KL, CR, CM, HG. Investigation: CS, KL, HG. Methodology: HG, KL, CR. Project administration: KL, CM. Software: CR, CS. Supervision: HG, CM. Validation: CS, KL, CR, CM, HG. Visualization: CS. Writing – original draft: CS, KL. Writing – review & editing: CR, CM, HG. Authors' key: Christopher Seifen (CS), Katharina Ludwig (KL), Christian Ruckes (CR), Christoph Matthias (CM), Haralampos Gouveris (HG). All authors agreed on the journal to which the article will be submitted, reviewed and agreed on all versions of the article before submission, during revision, the final version accepted for publication, and any significant changes introduced at the proofing stage, agreed to take responsibility and be accountable for the contents of the article.

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