Oral Appliances: New Field Study Examines their Medical Value and Quality-of-Life Impacts

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On March 1, 2016 a Field Study was initiated on patients of record at Chase Dental Sleep Care (CDSC), a dental sleep medicine practice dedicated to treating sleep breathing disorders located in the New York Metropolitan area. The Field Study involved the collection of patient data pre and post oral appliance insertion primarily focused on Quality of Life outcomes while forgoing the rigor of research and data analytics necessary for a white paper study intended for publication in a professional journal.

To help assess and quantify the effectiveness of oral appliances[1] in treating obstructive sleep apnea (OSA), our dental sleep practice conducted a two-part patient survey.

Exclusively for *Dental Sleep Practice* readers, we present our findings, which aim to help answer these two important questions about the device's effectiveness:

- What is the appliance's medical value (MV)?
- What is the appliance's impact upon patient quality of life (QOL)?

The results, within both dimensions, were generally quite positive. Taken together, the results strongly suggest that oral appliances represent an effective tool for OSA therapy.

About the surveys

A total of 249 patients had been delivered a mandibular advancement device and advised to come back for follow-up. Of that overall population, a subtotal of 115 patients came back, while 134 did not. Returnees thus represented less than half (46 percent) of the overall group.

Among returning patients, a total of 23 were included in the MV analysis as they underwent both pre and post oral appliance insertion sleep studies. Their medical progress was measured on the basis of before-and-after scores on the Apnea-Hypopnea Index (AHI) and/or the Respiratory Event Index (REI). For the purposes of this analysis, the two techniques are treated interchangeably.

For the QOL survey, a total of 111 patients were asked to complete a twelve-question survey.

When reviewing the survey results, it is important to keep three considerations in mind:

First, a particular patient's MV results may not align with that individual's QOL results. Patients showing medical improvement may report relatively less QOL improvement. The reverse may also be true.

Second, survey results may be affected by variations in the time periods over which assessments are made. For both MV and QOL results, some outcomes may take longer to manifest than others. If a follow-up test for MV test occurs too soon, or if QOL questions are asked too soon, results could potentially yield false negatives. More benefits may manifest over a longer period.

Third, more than half of the overall patient pool instructed to return for follow-up chose not to return. Yet all patients can generally be presumed to have a personal and medical interest in the appliance's success.

While we cannot know for certain, it seems a generally safe assumption that most non-returnees had been content with the appliance's effectiveness. Along these lines, returnees would presumably tend to be more likely to have product-related concerns. Satisfied patients would seem less likely to schedule follow-ups. It cannot be ruled out that there might be dissatisfied patients who simply abandoned therapy and chose not to return for follow-up.

So, if we assume that survey respondents would generally tend to be less-satisfied end-users, then the appliance may in fact be more effective than the results suggest. Precise results were not the intention of this field study, but there are helpful findings to assist the clinical team in talking with potential appliance users about the benefits of therapy.

Survey #1: Medical value of the oral appliance

For the MV component of the survey, 23 patients received before-and-after tests.

The MV sample included 13 men ranging in age from 26 to 71 years. The ten women ranged in age from 38 to 76 years. Males represented 56.5 percent of the overall sample.

There was considerable variation in time gaps between the two MV tests. Of the 23 participants, six were re-tested within six months, nine within seven months to one year, and four were re-tested within a period between one year and two years. Finally, six did not get re-tested until two years or more had elapsed.

Patients overall showed a high rate of improvement in their readings. Nineteen patients – amounting to 82.6 percent of everyone tested twice for medical value – came in with better scores.

The results presented in Table 1 suggest that the product may deliver somewhat better results for men than women, with improvement shown for 85 percent of men versus 80 percent of women.

MV survey results also revealed a general trend toward medical improvement with the passage of time (Table 2). What might account for this?

Table 1: Overall "Medical Value" – Survey Results by Gender

Patient Category	Patients Showing Improvement in Medical Value	Patients Showing Decline in Medical Value
Male patients (13)	11 (85% of men)	2 (15% of men)
Female patients (10)	8 (80% of women)	2 (20% of women)
Total sample (23 patients)	19 (83% of total)	4 (17% of total)

Sleep scientists understand that the body is adaptive. Inflammation tends to diminish over longer periods. Moreover, as a patient's breathing improves, we witness both neuro- and physiologic-dynamic improvements in the airway, along with other forms of amelioration.

Of 19 participants showing improvement, these three experienced the most substantial improvements:

- A 66-year-old woman's AHI results declined from 39.3 to 1.2 over a ten month span
- A 39-year-old man saw his AHI decrease from 41 to 5 over the course of 21 months
- A 56-year-old man's AHI score went from 50.9 to 19.7 over ten months

Of four patients exhibiting MV decline, a 65-year-old woman experienced the worst setback. Her AHI score increased from 6 to 11 over a nine-month period.

Extenuating factors could have contributed to downturns experienced by these four patients. Two had gained weight between tests, one had been consuming a larger amount of alcohol, and a fourth had adopted a new sleep position that could have helped lower her score.

Patients report consistent satisfaction with the appliance's effect on their quality of life.

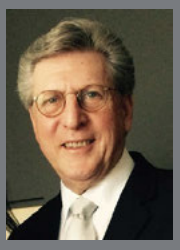

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Table 2: Medical Value – Patients by Gender and Age, Accompanied by Top-Line Results						
Males						
Age	Score 1	Date	Score 2	Date	Time Gap	Score Change
26	5.1 REI	9-2-16	1.5 REI	12-18-16	3 mo	-3.6
39	41 AHI	11-6-14	5 AHI	8-6-16	1 yr 9 mo	-36
40	26.9 AHI	7-31-16	21.9 AHI	5-14-17	9 mo	-5.0
49	12.9 AHI	8-19-13	1.4 AHI	3-17-17	3 yr 7 mo	-11.5
51	11.3 AHI	6-28-16	12.0 AHI	1-17-17	6 mo	+0,7
51	41 AHI	3-19-15	2.2 REI	2-9-17	2 yr 10 mo	-38.8
56	18.2 AHI	5-16-16	10.6 AHI	5-4-17	1 yr	-7.6
56	17.6 AHI	5-26-16	2.6 AHI	12-15-16	6 mo	-15.0
56	50.9 AHI	2-4-16	19.7 AHI	4-4-17	10 mo	-31.2
57	10.1 AHI	3-29-16	6.7 REI	5-13-16	1 mo	-3.4
57	19.7 AHI	5-21-12	1.5 AHI	7-26-12	2 mo	-18.2
67	55 AHI	2-21-14	74 AHI	9-22-16	2 yr 7 mo	+19
71	22.7 AHI	8-27-15	12.7 REI	5-15-17	2 yr 8 mo	-10
Females						
Age	Score 1	Date	Score 2	Date	Time Gap	Score Change
38	15.6 AHI	10-2-13	3.1 AHI	9-25-16	2 yr 11 mo	-12.5
43	10.0 AHI	7-1-16	6.0 AHI	1-28-17	7 mo	-4.0
44	8.4 AHI	1-23-13	3.0 AHI	2-6-14	1 yr	-5.4
51	7.0 REI	5-21-16	3.4 REI	12-15-16	7 mo	-3.6
57	23.3 AHI	8-29-11	31.9 AHI	7-22-16	4 yr 11 mo	+8.6
58	9.9 AHI	7-16-16	3.2 AHI	12-12-16	5 mo	-6.7
65	6 AHI	3-1-16	11 AHI	12-2-16	9 mo	+5
66	39.3 AHI	9-9-16	1.2 AHI	7-23-13	10 mo	-38.7
67	20.5 REI	5-24-16	8.8 REI	10-10-17	1 yr 4 mo	-11.7

Survey #2: The appliance's impact on the patient's quality of life over time – sleep related

This study's QOL component consisted of a twelve-question survey administered to 111 patients. Roughly 62 percent of the respondents were male.

Each patient was first asked the twelve questions two weeks after insertion of the appliance, and then again three months after insertion.

Five of the 12 QOL-related questions pertained to the patient's sleep-related experience. Seven questions addressed the product's daytime impacts.

Here are summaries of replies to the five sleep-related QOL topics:

Patients are getting more sleep

Two weeks after insertion, 54 percent of patients were getting greater than six hours of sleep per night. After three months, that percentage had risen to 66 percent.

Patients wake up at night less frequently

Two weeks after insertion, 59 percent of patients reported that the amount of times they had woken up at night had decreased. After three months, that percentage had risen to 69 percent.

Patients experience a more "deep/restful" sleep

After two weeks, 65 percent of patients reported a "more deep/restful sleep." After three months, that percentage had risen to 71 percent.

Patients dream more

Two weeks after insertion, 52 percent of patients said they had been dreaming. After three months, that percentage had risen to 57 percent.

Patients snore less

After two weeks, 32 percent of patients said they were not snoring on a daily basis. At the three-month mark, that percentage had risen to 48 percent.

Survey #2: The appliance's impact on the patient's quality of life over time – daytime variables

The survey also tracked seven daytime variables. Here is a reply summary:

Patients wake up feeling more refreshed

After two weeks, 58 percent of patients reported waking up more refreshed. After a three-month period, that percentage had risen to 71 percent.

Patients feel more daytime energy

Patients ranked their level of daytime energy on a 1-to-5 scale, from "poorest" to "best." Two weeks after insertion, 23 percent evaluated their daytime energy at the two highest-tier levels. When asked three months after insertion, that percentage had almost doubled to 45 percent.

Patients feel less daytime fatigue

After a two-week period, 55 percent of patients reported feeling less sleepy during the day. When asked three months after insertion, that percentage had risen to 69 percent.

Patients' memory improved

Twenty-one percent reported that their memory had improved two weeks after insertion. After three months, that percentage increased to 28 percent.

Facial muscles feel increasingly comfortable

After two weeks, patients were asked how their facial muscles felt along a five-point, "poorest" to "best" scale. Eighteen percent replied in two poorest levels. After three months, the percentage had declined to 10 percent. The percentage of "best" replies increased from 17 percent to 26 percent.

Clinicians should manage patients' expectations over how soon to expect results.

Patients feel less discomfort in jaw joints

Patients were asked how their jaw joint felt after appliance removal. Responses were listed on a five-point scale, from "poorest" to "best. Two weeks after insertion, 51 percent ranked themselves within the three poorest levels. This response rate declined to 38 percent after three months. The percentage of "best" replies increased from 18 percent to 28 percent.

Patients experienced less tooth discomfort

After two months, patients were asked -- on a five-point, "poorest" to "best" scale -- whether the appliance had had made their teeth "sore or sensitive." Those replying in the two "poorest" categories totaled 21 percent, a figure that declined to 13 percent after three months. The percentage of "best" replies increased from 13 percent to 21 percent.

Positive Results

The QOL survey results show that oral appliance therapy has the capacity to deliver some of the benefits quickly.

In the following questions, a majority of patients had experienced positive results within two weeks:

- Waking up at night less frequently (59 percent)
- Deeper and more restful sleep (65 percent)
- Waking up feeling more refreshed (58 percent)
- Feeling less sleepy during the day (55 percent)

Conclusions

Here are some top-line conclusions that can be drawn from this two-part survey:

Oral appliances appear to hold substantial medical value for patients in treating obstructive sleep apnea and its accompanying symptoms.

Patients report consistent satisfaction with the appliance's effect on their quality of life. Some improvements include:

- Reduced snoring
- Easier to sleep
- Waking up at night less frequently

Both medical value and quality of life results tend to improve with longer-term product usage.

Oral appliance therapy contributes to QOL improvement, the ultimate goal of therapy for most patients. Clinicians might not consider improved AHI score to be the sole factor determining therapy success.

Here are a few patient management suggestions arising from the survey results:

- Since the product's positive effects seem to improve over time, clinicians should manage patients' expectations over how soon to expect results
- The same suggestion as above could apply to the follow-up sleep study; one possible guideline would be a minimum of three months after the initial sleep study
- Encourage patients to schedule follow-up appointments to ensure proper monitoring, re-testing and product usage; and educate patients that the role of follow-up is to titrate their oral appliances for the better therapy results
- Educate the patients that AHI increase or no change doesn't mean the oral appliance therapy fails

The survey delivered encouraging results. We urge the dental sleep community to conduct additional research. This will boost our capacity to serve the health interests of our patients – and to minimize the harmful health impacts associated with obstructive sleep apnea. DSP

1. The appliances were a combination of Dorsal Fin and Herbst design, all manufactured by Whole You Respire Medical, Brooklyn, NY.