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Proposal of a Full Digital Workflow for a Bite Fork to Assess Mandibular Advancement during Drug-Induced Sleep Endoscopy (DISE) for Obstructive Sleep Apnea

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Citation: Grippaudo, C.; Rizzotto, G.; Lo Giudice, A.; Buccarella, C.; Negrini, S.; Anelli, F.; Corina, L.; Galli, J.; Fiorita, A. Proposal of a Full Digital Workflow for a Bite Fork to Assess Mandibular Advancement during Drug-Induced Sleep Endoscopy (DISE) for Obstructive Sleep Apnea. *Appl. Sci.* **2023**, *13*, 6647. https://doi.org/10.3390/app13116647

Academic Editor: Gianluca Gambarini

Received: 24 April 2023
Revised: 25 May 2023
Accepted: 29 May 2023
Published: 30 May 2023

Featured Application: This research proposes the use of a bite fork created with full digital workflow to evaluate the effect of mandibular advancement during sleep endoscopy.

Abstract: (1) Background. Drug-induced sleep endoscopy (DISE) is currently regarded as the gold standard diagnostic procedure to assess the site(s) of upper airway collapse in subjects affected by Obstructive Sleep Apnea Syndrome (OSAS). During DISE, a jaw thrust maneuver is performed to advance the mandible and to predict the effectiveness of outcomes of treatment with mandibular advancement devices (MADs). However, the maneuver is not predictable and could be influenced by specific patients' anatomical/functional conditions. The aim of this work is to propose a full-digital workflow for customizing an individual mandibular advancement fork, usable by otorhinolaryngologists during DISE. (2) Materials. Two patients with a diagnosis of mild-to-moderate OSAS (AHI $\geq$ 5 to $\leq$30/h of sleep) underwent orthodontic examination to verify the usability of the MAD. Intra-oral scans and registration were performed, including bite registration with 65% of mandibular advancement. The latter measurement was used as a reference to design a 3D-printed fork for DISE, as well as for the future MAD. Both patients underwent DISE in the operating room in the presence of an anesthesiologist, otolaryngologist, orthodontic specialist and neurophysiopathology technician. (3) Results. In the intraoperative polysomnography recording, during sleep, the presence of obstructive apnea was confirmed based on respiratory parameters (PNG1, PNG2, PNG3) with associated desaturation and increased muscle activities on PNG4 (mylohyoid muscle), EMG1 (right masseter muscle) and EMG2 (left masseter muscle). With the advancement fork in place, the immediate improvement effect on all respiratory parameters with normal saturation values and the complete suppression of masseter muscles were observed. Accordingly, both patients were considered potential good-responders to the MAD treatment. (4) Conclusions. The preliminary data shown are encouraging and would suggest that the fork represents a stable reference for the otorhinolaryngologist to evaluate the airway patency within the physiological range of movement. The efficiency of the work-flow from data registration to the DISE procedure and laboratory process

represent two significant advantages that justify the integration of a digital system in the management of patients affected by OSAS.

Keywords: drug-induced sleep endoscopy (DISE); mandibular advancement devices (MADs); jaw thrust maneuver; full digital workflow; PA12

1. Introduction

Obstructive Sleep Apnea Syndrome (OSAS) is the most common sleep breathing disorder and reaches a frequency of 3–18% in men and 1–17% in women [1,2].

OSAS is characterized by daytime sleepiness and/or impaired daytime performance and nocturnal snoring from a clinical point of view. During sleep, it is characterized by the appearance of repeated episodes of partial or complete obstruction of the upper airways associated with phasic falls in hemoglobin saturation from a pathophysiological point of view. The obstruction of the upper airways can be of various entities and multilevel and initiates various respiratory events. In the field of sleep disorders, we find many clinical pictures as insomnia, parasomnia, hypersomnia or excessive daytime sleepiness, restless legs syndrome, snoring, upper airway resistance syndrome (UARS), cot death syndrome, Pickwick syndrome and especially obstructive sleep apnea syndrome (OSAS), central, peripheral type and mixed [3].

Therefore, in addition to the nocturnal polygraphic examination, which remains the gold standard, it is necessary to identify reliable predictability screenings, such as composite questionnaires with anthropometric and clinical parameters, as well as biological markers, in order to then initiate sleep studies only for those most at risk [4].

Natural sleep endoscopy (NSE) is currently regarded as the gold standard of diagnostic tests to assess the site(s) of upper airway collapse. Borowiecki et al. described this procedure for diagnostic examination for the first time in 1978 [5].

During drug-induced sleep endoscopy it is possible to perform a mandibular advancement maneuver, called the jaw thrust maneuver. The purpose of the maneuver is to have indications on the possible outcomes of a symptomatic therapy of OSAS with oral devices for mandibular advancement (MAD) [6].

Mandibular advancement devices are custom-made appliances that can be used as a first-line treatment for mild-to-moderate OSAS patients [7].

To produce a mandibular advancement device, it is necessary to take a registration of the mandibular protrusion. To take the advancement record, the George Gauge™ (Great Lakes Dental Technologies, 200 Cooper Ave, Tonawanda, NY 14150, USA) is the most commonly used tool. The George Gauge™ allows for the millimeter measurement of the advancement and allows for the establishment of the height of the rise necessary for the thickness of the MAD, so that the patient can be in a comfortable position [8,9]. The advancement of the initiation of MAD therapy is usually between 65% and 70% of maximal protrusion, and the mandibular forward position may be increased during treatment in cases of titratable devices [10].

The mandibular advancement with the manual maneuver during DISE fails to give information on the exact position obtained or on the possible discomfort that the patient could have in maintaining it during sleep.

One way to get a more accurate assessment is to use a custom-made simulation bite. The simulation bite can be prepared by recording the exact advancement and thickness with the George Gauge™ or other systems that allow for an accurate measurement. In this way, both the mandibular advancement and the vertical mouth opening in the individualized therapeutic position can be recorded before the DISE. The mandibular advancement maneuver with the simulation bite provides more reliable predictions of the effectiveness of the MAD [11].

The advantage of using an individual simulation bite was demonstrated by Vroegop AV et al. [12]. The procedure described for making the bite requires the use of a registration paste, to be applied on a preformed rigid support, which has the shape of the dental arch. This support can be called a bite fork. First, the position of the upper arch on the fork is recorded, and subsequently, that of the lower arch in the advanced position. The fork described in the article thus has two layers of paste, which are cured after registration and reproduce the indentation of all teeth.

Our experience with DISE prompted us to look for an easier-to-use tool. It must in fact be considered that the sleeping patient does not open his mouth easily, and it is difficult to find the insertion of such a large fork with so many indentations. We focused on the search for new, more rigid materials, which would allow for the same evaluation effectiveness with an indentation limited to the incisor area only.

In the last decade, dentistry has adopted digital technologies in various diagnostic processes and for the production of devices. New technologies have led to the adoption, in many cases, of a completely digital workflow. The scanning of the dental arches and 3D printing are now daily processes, for which reliability and precision have been amply demonstrated. The advantage is speeding up the workflow and greater precision and individualization of the manufactured goods. This has led to the transformation of dental laboratories, which have integrated and largely replaced manual work with CAD-CAM (Computer-Aided Design/Computer-Aided Manufacturing) design [13,14].

Currently, the method of recording the advancement position with the George Gauge™ has been modified, with the use of intraoral scanners, which allow for the elimination of the use of silicon for the construction bite in most cases.

In our research, we have reproduced an individual fork, also in terms of width and thickness, with the CAD-CAM method. The indentation is limited to the upper and lower incisors only, and the material is stiff.

The purpose of this work was to test the handling and effectiveness of this individual mandibular advancement fork, built on an advance measurement of 65% of maximum advancement, using only a digital workflow.

2. Materials and Methods

In November 2022 two patients with breathing problems during sleep were seen at the institute of Otorhinolaryngology (Department of Head and Neck Surgery, "A. Gemelli Hospital", Catholic University School of Medicine and Surgery, Rome, Italy). All the usual diagnostic and interventional steps foreseen for this pathology were followed. The patients were a 57-year-old female, with BMI 24.61, and Epworth index 9, and a 57-year-old man, with BMI 24.34 and Epworth index 1.

From the otorhinolaryngoiatric examination, the female patient presented an oral cavity with a normal appearance, motility of the lingual and veil within the limits, Mallampati Friedmann type III. Furthermore, a modest deviation of the nasal septum to the left, hypertrophy of the inferior turbinates and free nasopharynx were observed, with a slightly hypertrophic base of the tongue, normal shaped epiglottis, glottic plane within the limits of morphology and motility, good respiratory space, free piriform sinuses and slight retrocricoid edema from laryngopharyngeal reflux. At the Muller maneuver, the oropharyngeal retropalatal space was reduced by 40%.

The Dynamic Polygraphy performed with the Nox T3 Polygraph (MedicAir Italia Srl., Via Monte Rosa 61, 20149 Milano, Italy) gave the following results: presence of some pathological respiratory events, obstructive apneas and hypoapneas, collected in clusters. The AHI was 6.5 events/hour (supine AHI = 11.1 events/h), associated with falls in hemoglobin saturation. The ODI was 6.5 events/h, almost constantly within the normal range (T90 = 0.2%), with a mean desaturation of 93.2% and mean saturation of 95.5%. There was associated snoring of a marked entity, which, coincident with the pathological respiratory events, was of the intermittent type, and considerable heart rate variability was recorded.

The second patient was a 57-year-old man with mild OSAS with a positional component. At the examination, the patient reported that he had been suffering from OSAS and snoring for years. Anterior rhinoscopy showed clear nasal passages, an irregular septum and bilateral inferior nasal turbinate hypertrophy. Mallampati was II–III, and the tongue, epiglottitis and mucous membranes were normal. The glottic plane was within the limits of morphology and motility, with good respiratory space and free piriform sinuses.

The Dynamic Polygraphy performed highlighted the presence of some pathological respiratory events, obstructive, central apneas and hypoapneas, collected in clusters and present above all in the supine position. The AHI was 12.9 events/h, but in the supine position, it was 24.7 events/h. It was associated with a fall in maximum oxyhemoglobin saturation of 89% and mean of 92.4%, with mean saturation of 94.9% and an ODI = 12.9 events/h. Snoring was marked and related to the supine position, and considerable heart rate variability was observed.

The results allowed for the classification of the patients as mild-to-moderate OSAS (AHI $\geq$ 5 to $\leq$30/h of sleep). From the results of the tests performed, the DISE and the visit with the orthodontic specialist were scheduled to assess whether there were conditions for the construction of a MAD.

Patients were informed of the purpose of the dental examination, which serves to establish the oral health status necessary for the application of the MAD. Furthermore, the need to take the bite registration in an advanced position was explained to the patients, which is necessary for the construction of the individual fork to be used during the DISE for the advancement maneuver. All patients were willing to participate and gave their consent.

The outcome of the orthodontic visit for the female patient highlights the presence of a Class 2 malocclusion with a deep bite. The state of health of the teeth and of the periodontium was good. The measurement of the mandibular advancement was recorded with the George Gauge™ according to the standard procedure [9], and the scans of the arches were performed with the Trios 3 intraoral scanner (3Shape, Niels Juels Gade 13, 1059 Copenhagen, Denmark) in the position of maximum intercuspidation and in advanced mandibular position of 65% of the maximum with the George Gauge™ inserted between the arches (Figure 1).

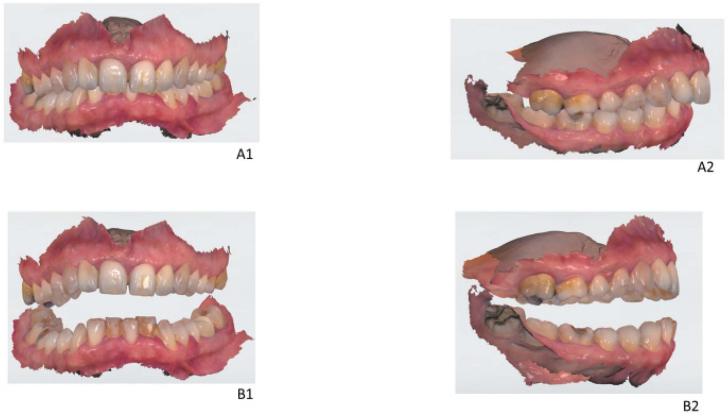

Figure 1. Images of dental scans of the female patient in habitual occlusion (**A1**,**A2**) and with the George Gauge™ (**B1**,**B2**). The image of the George Gauge™ is automatically removed by the artificial intelligence system of the program.

At the dental visit, the male patient's oral health status was judged as suitable for MAD therapy, and the arches were scanned and the mandibular advancement measurement was taken with the George Gauge in a similar way to the procedure described for the other patient. In both cases, the scans were sent to the laboratory, where a fork was designed for each of them, which adapted perfectly to the indentations of the upper and lower incisors in the recorded mandibular advancement position (Figure 2). The custom fork was then

printed in PA12, a biocompatible material, ready to be used during the DISE. The entire production process followed a digital workflow.

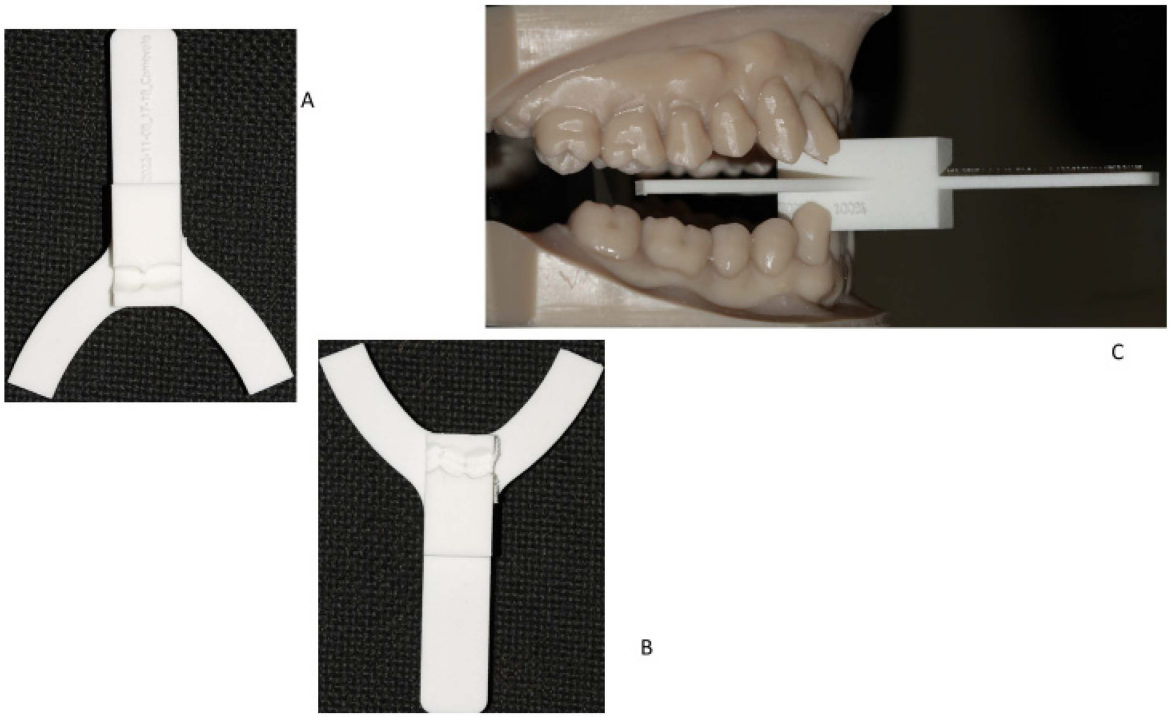

Figure 2. Images of the bite fork prepared for patient 2, with the indentations for upper (**A**) and lower (**B**) incisors, and positioned between the printed dental models (**C**).

The two patients successfully underwent DISE. The procedure was performed in the operating room under the presence of an anesthesiologist, otolaryngologist, orthodontic specialist and neurophysiopathology technician. The two patients received sedation with the administration of increasing doses of propofol (3 mg/kg/h). The mean duration of the procedure was 15+/−3 min. They already prepared for polysomnography intraoperative recording, and sedation was under continuous monitoring through bispectral index (BIS) monitoring (Apect Medical Systems, Newton, MA, USA) with mean values between 50 and 70. Then, a flexible nasopharyngoscope, into the nasal cavity of 3.4 mm in diameter, was introduced to visualize and record the pattern and degree of obstruction (nasopharynx, oropharynx, hypopharynx and larynx). During DISE, in the female patient, we observed a 100% concentric retropalatal obstruction site and 75% anteroposterior epiglottis prolapsed laryngeal obstruction site (Figure 3).

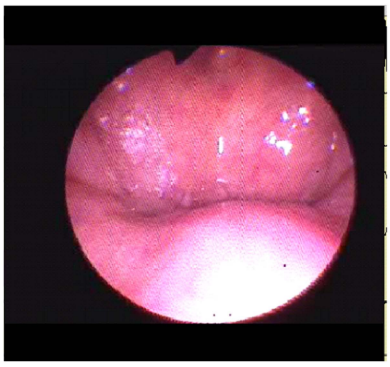

Figure 3. Image of patient 1 showing obstructive apnea.

An average BIS value of 45, a minimum of 25, an average SPO2 of 85 and a minimum of 76 are reported. In the male patient, we observed a retropalatal oropharyngeal obstruction site with 100% concentric prolapse and a retrolingual oropharyngeal obstruction site with 75% concentric prolapse. The average 65 and minimum 49 BIS values are reported, and the SPO2 values were 89% the average and 85% the minimum (Figure 4).

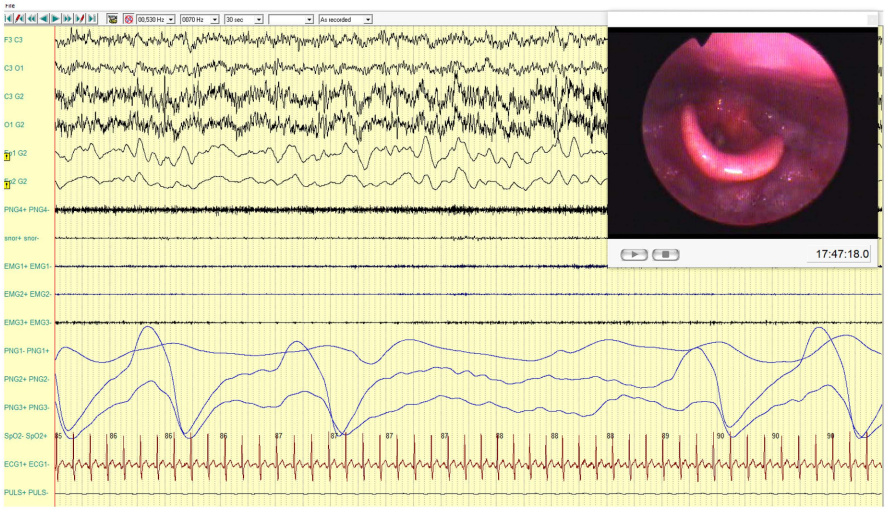

Figure 4. The figure shows the presence of obstructive apnea based on respiratory parameters (PNG1, PNG2, PNG3), with associated desaturation (87–89% range) and increased muscles activities on PNG4 (mylohyoid muscle), EMG1 (right masseter muscle) and EMG2 (left masseter muscle).

Finally, a bimanual mandibular advancement maneuver has been practiced for evaluating the degree of enlargement of the space in the sites of respiratory obstruction. With endoscopic evidence, we advanced the mandible from 4 to 5 mm by observing the positive effect on airway obstruction, snoring and oxygen saturation. The mandibular progress was then reproduced with the help of the fork: it was inserted into the mouth and the lower incisors were stuck in the groove of the lower part, which exactly reproduced their shape. Then, a front traction was performed on the fork handle, advancing the jaw until it was possible to insert the upper incisors in the groove present in the upper part, also faithfully identical to their morphology (Figure 5).

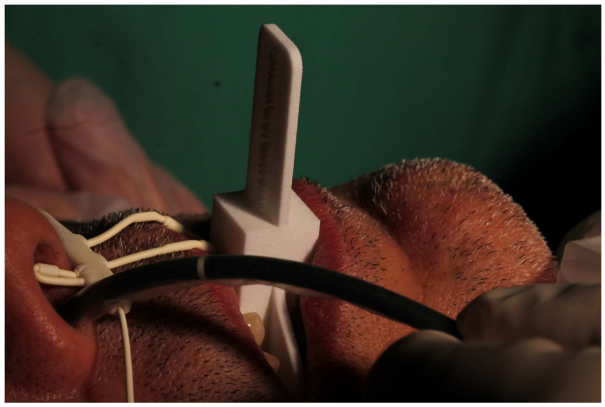

Figure 5. The bite fork positioned during DISE in patient 2.

After DISE, the female patient underwent functional septoplasty and decongestion of the inferior turbinates, and the male patient underwent only decongestion of the inferior turbinates, both of them with no complications in post-operative time.

3. Results

The validity of mandibular advancement in the therapeutical position determined based on the bite fork was confirmed, compared to the results of the bimanual advancement.

In the female patient, the values observed during the advancement with the fork (Figure 6) were more positive than those recorded by the anesthetist (Figure 7).

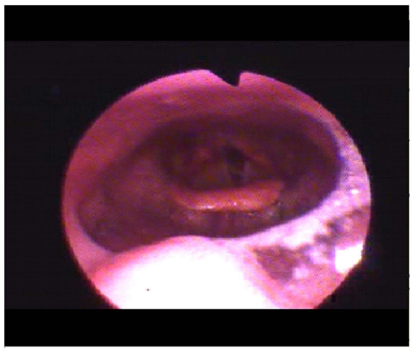

Figure 6. Result of the mandibular advancement with the fork.

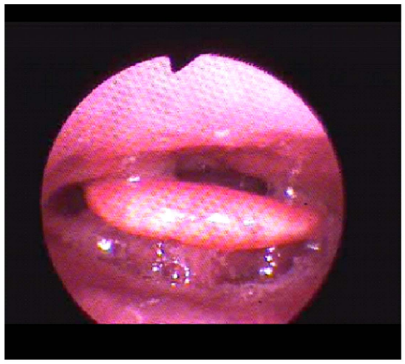

Figure 7. Result of the bimanual advancement of the mandible.

Similarly, for the male patient, results recorded were better with the fork advancement (Figures 8 and 9).

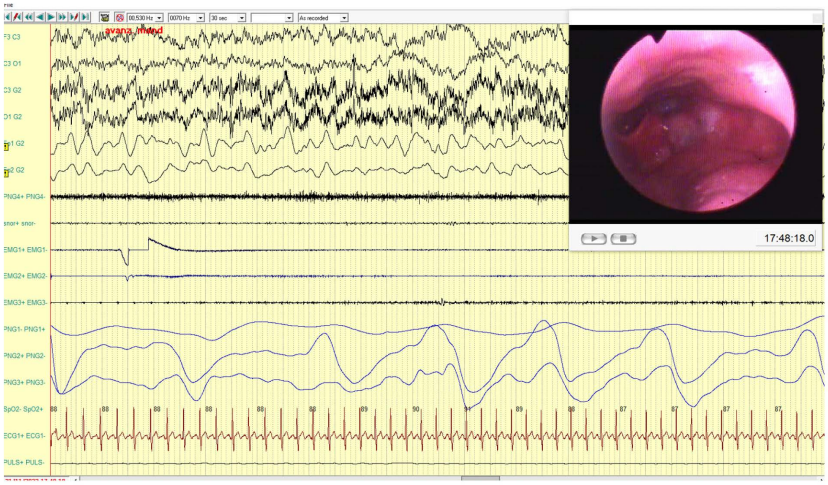

Figure 8. In this frame, it is possible to observe the persistence of obstructive apnea with desaturation (85–89% range) during the bimanual mandibular advancement maneuver. Furthermore, the persistence of muscle activities on intercostal muscle (EMG3) and on masseter muscles (EMG1, EMG2) is noticeable.

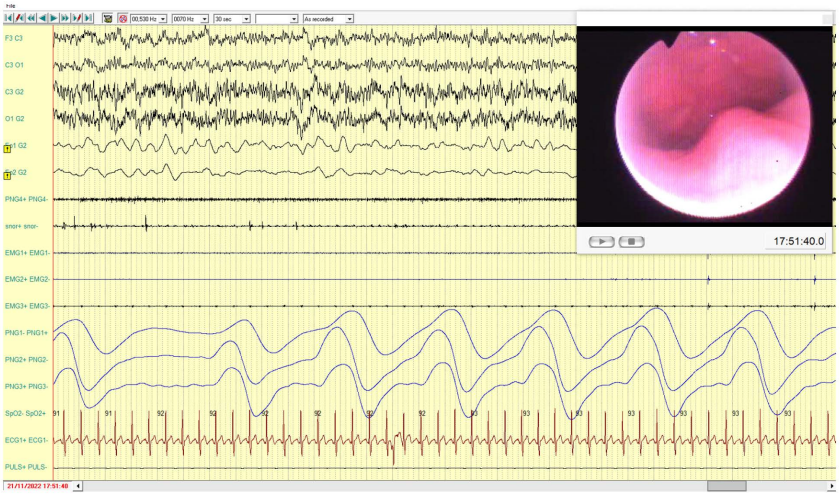

Figure 9. In this frame, the immediate improvement effect on all respiratory parameters with normal saturation values during the mandibular advancement with the fork in place is shown. In addition, masseter muscles are completely suppressed.

The better result shown by the fork advance, compared to the bimanual one, is probably due to the programmed height increase.

Thus, the patients were candidates to utilize an oral appliance. Since all the registrations of the position have already been taken, it is sufficient to communicate to the laboratory to produce the Oral Devices, without the need for a further dental visit.

4. Discussion

In the last decade, the usage of a custom-made simulation bite has been proposed to obtain reproducible and titratable mandibular protrusion during DISE, overcoming the limitations of a conventional chin-lift maneuver [15,16]. In this regard, it is critical to establish precisely the therapeutic mandibular advancement and the vertical dimension of the MAD, considering that the amount of mouth opening can reduce the protrusive capacity and increase the posterior position of the mandible [11].

Digital revolution has significantly influenced the clinical work-flow in dentistry and orthodontic fields, with CAD-CAM systems being the new leading process for appliance fabrication. In this regard, CAD-CAM systems provide easier data acquisition, data management and storage processes, better standardization of the procedures and communication tools [17]. In addition, the efficiency and the accuracy of the production of dental manufactures can be significantly improved using dedicated equipment [18,19].

In the present paper, we propose an easy and versatile full-digital process to generate a customized individual fork for mandibular advancement registration during DISE. Although custom-made simulation bite for DISE can be generated with an analogical procedure using conventional bite registration materials, there are specific advantages in using digital technology and CAD-CAM systems for the same purpose and those that the authors have experienced or assumed in the two clinical cases shown.

The first advantage is related to the effectiveness of registration detection. Using an intra-oral scanner and digital bite registrations with George Gauge™, it is possible to instantaneously visualize, on the screen, the relationship between the planned mandibular protrusion and the amount of increased vertical dimension (the future vertical dimension of the appliance). In doubtful cases, considering how critical the vertical dimension is for the effectiveness of the MAD, clinicians can request the production of two forks with different vertical dimensions that an otorhinolaryngologist specialist will test during DISE execution, even comparing the respiratory performance using different heights of the fork.

The second advantage is related to the quality of the patient's clinical examination. In this regard, it is appropriate to perform a preliminary and accurate evaluation of the TMJ's

function and relative range of movements prior to registering the mandibular protrusive positions for DISE. The gnathological examination should be made at the dental chair and must also include information about potential patients' pain and discomfort during prolonged advancement [20]. With the digital system, in cases of no severe limitations, it is possible to design a 3D-printed customized fork within the permitted range of movement for further evaluation with DISE. Lastly, digital systems streamline the diagnostic and clinical work-flow for the production of a customized mandibular advancement fork. Once the dental clinician takes digital registrations, all information is transferred to the lab technician for the production of a customized fork. The otolaryngology specialist receives the 3D-printed customized fork for DISE inspection without the need of preliminary registration. In addition, there is no need for a dental specialist in the operating room, since all functional parameters have been previously assessed at the dental chair. The production process will be even faster, when clinicians who are familiar with in-office 3D printing production can generate the customized appliance and send it to the specialist center or deliver it directly to the patient.

As for the handling of the fork, it only took a few seconds to find the indentation of the lower incisors. The rigidity of the material used made it possible to use the handle to pull the jaw forward without losing contact with the teeth inserted in the groove and also to easily engage the upper incisors.

5. Conclusions

The present paper presents a versatile digital work-flow to produce a customized fork for a mandibular guided advancement maneuver during DISE. The preliminary data shown are encouraging and would suggest that the fork represents a stable reference for the otorhinolaryngologist to evaluate the airway patency within the physiological range of movement. The effectiveness of functional/occlusal registration and the efficiency of the work-flow from data registration to the DISE procedure and laboratory process represent two significant advantages that justify the integration of a digital system in the management of patients affected by OSAS.

Author Contributions: Conceptualization, C.G. and A.L.G.; methodology, C.G., G.R. and A.F.; software, S.N. and F.A.; validation, C.B., L.C. and J.G.; formal analysis, A.F., G.R. and C.B.; investigation, C.G., G.R., A.F. and L.C.; resources, J.G.; data curation, G.R.; writing—original draft preparation, C.G., A.F. and A.L.G.; writing—review and editing, C.G.; visualization, A.F.; supervision, J.G. All authors have read and agreed to the published version of the manuscript.

Funding: This research received no external funding.

Institutional Review Board Statement: Ethical review and approval were waived for this study due to the following reason: the procedures followed are the standard ones for the treatment of OSAS patients who have to perform DISE. The novelty of the study consists of the use of the digital workflow for the construction of the fork for the advancement of the mandible. This does not constitute a risk or a modification of the therapeutic procedure.

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: The data presented in this study are available on request from the corresponding author. The data are not publicly available due to privacy.

Conflicts of Interest: The authors declare no conflict of interest.

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