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The Standardized Treatment Procedure with the "F-UPS®" Mandibular Advancement Device (MAD) in the Treatment of Obstructive Sleep Apnea (OSA)

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SUMMARY

Background: In addition to the assisted ventilation method (PAP) for the therapy of OSA, the mandibular advancement device (MAD) has been available since 1984 by Meier-Ewert et al. as an alternative treatment method in the dental field. Since 01.01.2022, it can be prescribed at the expense of the statutory health insurance in Germany. It is not possible to ensure the quality and safety of the treatment procedures MAD (TPMAD) simply by following the medical device-independent recommendations and guidance and treatment guidelines. Due to different designs, a product-related assessment procedure with declaration of conformity (MDRC) is additionally required for the manufacturing and treatment process in accordance with MDR (EU Regulation 2017/745) on medical devices regarding quality (performance) and safety, as well as the maintenance of a quality management system oriented towards ISO 13485. To date, the literature lacks information on the methodology of TPMAD from the MDRC of a medical product (MP). The aim of this work is their first and exemplary description.

Method: The following methodology was chosen for the TPMAD in the MDRC of the MP F-UPS®:

- The Vector Diagram "Risk Profile" (RP) as a diagnostic tool for dental risk assessment.
- The 3D Bite Fork "JS-Gauge®" (Unique Device Identification, UDI 4260731570017T) (JG) as the bite fork for the registration of the start protrusion position (SPP).
- The MAD "F-UPS®" (UDI 426073157F-UPS3C) (F) for the therapy of OSA.
- The Vector Diagram "Performance Monitor" (PM) as an evaluation tool for assessing effectiveness

Results: This paper is the first to provide a contribution to the TPMAD methodology from the MDRC of an MP. The methodical individual steps with the RP, JG, F and PM map the complete TPMAD in a MDR compliant fashion. Through the standardization of the methodology, the assurance of quality and safety can be implemented effectively, efficiently and satisfactorily MDR compliant.

Keywords: Treatment Procedure; Medical Device Regulation; Obstructive Sleep Apnea; Dental Sleep Medicine; Risk Profile; Bite Gauges; JS-Gauge; Mandibular Advancement Device; F-UPS; Performance Monitor

Abbreviations: PAP: Positive Airway Pressure; MAD: Mandibular Advancement Device; TPMAD: Treatment Procedures MAD; MDRC: Product-Related Assessment Procedure with Declaration of Conformity; MDR: Medical Device Regulation, Regulation (EU) 2017/745; ISO: International Organization for Standardization; MP: Medical Product; RP: Vector Diagram „Risk Profil"; JG: 3D bite fork "JS-Gauge®" (SleepLikeMe-Medical, Germany); UDI: Unique Device Identification; F: Funktionally Adapted Mandibular Advancement Splint "F-UPS®" (SleepLikeMe-Medical, Germany); PM: Vector Diagram „Performance Monitor"; OSA: Obstructive Sleep Apnea; BL: Maximum Radiographic Bone Loss; BL/A: Age-Related Maximum Radiographic Bone Loss; BOP: Bleeding on Probing; CAL: Clinical Interdental Attachment Loss; PPD: Probing Pocket Depth; TM: Tooth Mobility; M: Missing Teeth; EK: Eichner Classification; OP: Occlusal Profile; P: Occlusal Paper; PR: Maximum Active Pain-Free Protrusion; MO: Maximum Active Pain-Free Interincisal Mandibular Opening; GCPS V2: Graded Chronic Pain Scale version 2.0; SPP: Starting protrusion position; FD: Futar® D fast (Kettenbach, Germany); P-SPP: Protrusion of the SPP; B-SPP: Bite Block of the SPP; CTD: Cusp Tip Distance of the Maxillary and Mandibular Tooth Row; R: Ruler with A Thickness of 0.5 mm (Aesculab® AA804R, Germany); T-SPP: Transversal Position of the SPP; GS: Guide Surfaces of the FF--UPS®UPS®; ES: Expansion Screws of the; F-UPS; FE: Fin Element of the F-UPS

Introduction

Obstructive sleep apnea (OSA) is the most common sleep-related breathing disorder and can lead to multiple, sometimes life-threatening health disorders [1-4]. Data on the prevalence of OSA in the literature vary from 4% to 90% for men and 2% to 78% for women, depending on the patient population and severity. The prevalence increases with increasing age, male gender, and higher body mass index (BMI) [5-7]. In this respect, the treatment of OSA also has a high socioeconomic significance. In addition to the gold standard of assisted ventilation (PAP) for the treatment of OSA, the mandibular advancement device (MAD) has continuously gained importance as an alternative treatment method in the dental field after its introduction in 1984 by Meier-Ewert et al. However, even though PAP has a higher effectiveness related to the reduction of the AHI, overall, due to the higher adherence of the MAD, the effectiveness for both treatment methods is equal in terms of daytime sleepiness, sleep quality, vigilance, and cognitive performance, quality of life, and depressive symptomatology, among others [8-11]. Most recently, this has led to the inclusion of the "mandibular advancement splint for obstructive sleep apnea" as a recognized treatment method in the treatment guideline of the German Joint Federal Committee on July 30, 2021 [12] and, according to the amendment agreements, has been available since January 1, 2022 at the expense of the German statutory health insurance.

Quality and Safety Assurance

While in the past there were no uniform, coherent recommendations on the TPMAD in the specialist scientific literature, there are now basic recommendations and standards recognized on a broad professional basis with the "S3 Guideline Non-restorative Sleep" [13,14], the "S1 Guideline the Mandibular Protrusion Splint (UPS)" [15] and the treatment guideline [12]. However, it is not possible to ensure quality and safety simply by observing these recommendations and standards. This is because the technical application of the TPMAD is largely based on the medical device MAD [16], which is available in a wide variety of designs for the practitioner. In this respect, in addition to the product-independent recommendations and standards on the method, a product-related assessment procedure with declaration of conformity (MDRC) is required for the manufacturing and treatment process in accordance with Medical Device Regulation, Regulation (EU) 2017/745 (MDR) [17] regarding the quality (performance) and safety of the respective medical product MAD. This procedure and this declaration cannot be prepared conclusively once for all MAD and all manufacturers (dental laboratories) in a generally valid manner. This must be done separately by each manufacturer and for each MAD type manufactured by him for the respective manufacturing and treatment process. In addition, this must be maintained within the framework of a quality management system which is oriented at least to International Organization for Standardization (ISO) 13485 [18]. A MDRC, as is generally known for custom-made dental products such as dental prostheses and as is issued by dental laboratories, is regularly not sufficient for the placing on the market of a MAD by the manufacturer. This is because, unlike dental prostheses, for which exemption conditions apply in accordance with the MDR, these do not apply to the MAD, which is one of the medical therapy devices. Accordingly, the contents of the accompanying documents must also fully comply with the requirements of the MDR.

Goal

So far, the literature lacks information on the methodology of TPMAD from the MDRC of the MP MAD. The aim of this work is its first and exemplary description.

Method

The following methodology was chosen for the TPMAD in the MDRC of the MP F-UPS®:

1. The Vector Diagram "Risk Profile " (RP) as a diagnostic tool for risk assessment.
2. The 3D Bite Fork "JS-Gauge®" (Unique Device Identification, UDI 4260731570017T) (JG) as the bite fork for the registration of the start protrusion position (SPP).
3. The MAD "F-UPS®" (UDI 426073157F-UPS3C) (F) for the therapy of OSA.
4. The Vektor Diagram "Performance Monitor" (PM) as an evaluation tool for assessing effectiveness.

Vector Diagramm, Risk Profile"

The dental findings for the initial and follow-up examinations were performed according to the RP [19] (Figure 1). The RP visualizes the patient-specific risk profile on the basis of disease characteristics that can provide information about the applicability of MAD therapy (predictors). With the RP, several predictors in a patient-specific constellation of findings can be easily recorded visually as a risk profile and compared with each other in their course during the follow-up. The risk assessment of the predictors is based on the three risk grades low (green), medium (yellow) and high (red) for the three areas periodontics, prosthodontics, and function [19- 23]. For the recording of two of the five periodontological predictors, the maximum radiographic bone loss (BL, in percent) and the age-related maximum radiographic bone loss (BL/A, BL in percent divided by age in years) are performed after evaluation of the Orthopantomogramm. The findings of the other periodontal predictors, bleeding on probing (BOP in percent), probing pocket depth (PPD, number of teeth in percent with PPD ≥4 mm) and maximum clinical attachment loss (CAL, in millimeters) are recorded clinically using the WHO probe. The prosthetic predictors capture the degree of tooth mobility (TM, number of teeth with TM ≥1), the number of missing teeth (M, number of missing teeth without considering wisdom teeth), and the Eichner classification (EK, without considering teeth with TM ≥1). The Eichner classification is performed separately for the implantological and dental prosthetic abutments (prosthetic classification) and for the occlusion,

including prosthetics if necessary (occlusal classification). The occlusal classification is indicated in the vector diagram with an asterisk (*). In addition, documentation of the occlusal profile (OP) may also be useful for forensic reasons. The OP is recorded for the six tooth regions molars, premolars, canines and anterior teeth in the maxilla to their antagonists in the mandible with 40 µm occlusal paper (P). If the P is torn, the occlusion is scored as negative, otherwise as positive. The functional predictors are recorded with the degree of protrusion (PR, maximum active pain-free protrusion without blockade in millimeters after three attempts from maximum retrusion into maximum protrusion with the aid of the bite fork, see below), the maximum jaw opening (MO, maximum active pain-free interincisial jaw opening without blockade in millimeters after three attempts) and the graded chronic pain scale version 2.0 (GCPS V.2).

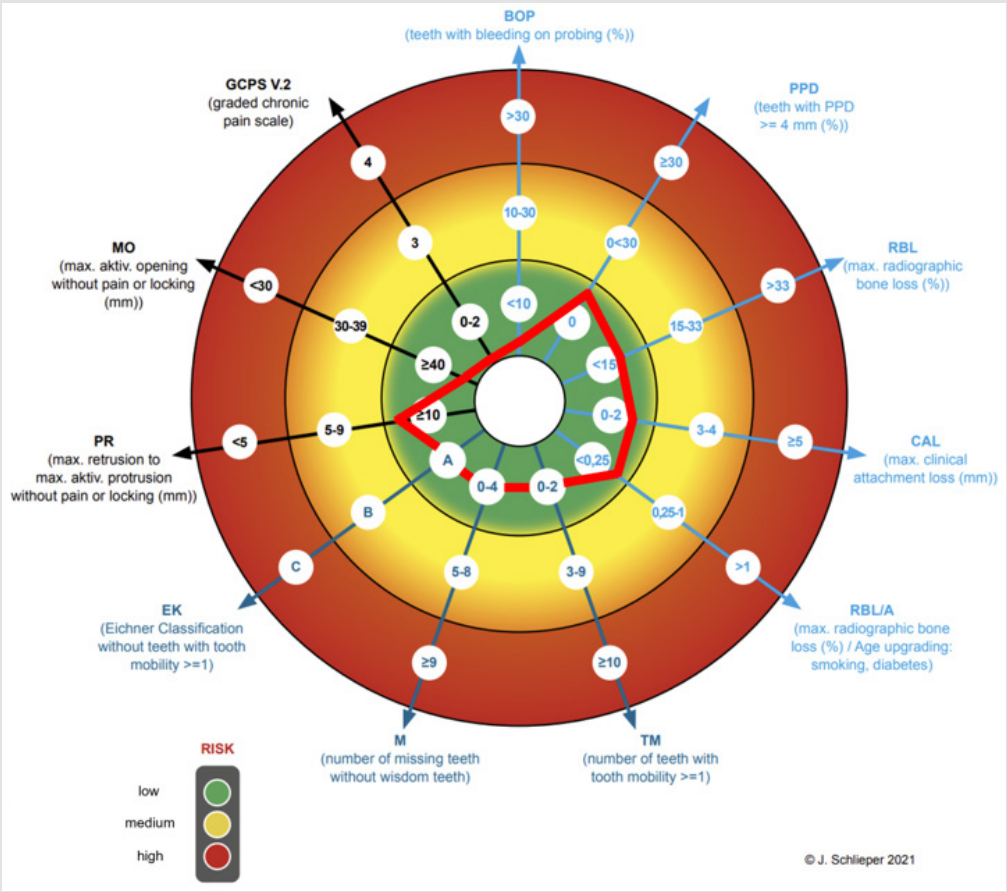


Figure 1: The Vector diagram "Risk Profile" (RP) with the average risk out of the MDRC of the MP F (red connecting lines).

The degree of PR was measured using the JG (SleepLikeMe-Medical, Germany) in the supine, relaxed treatment position, which is comparable to the supine sleeping position. Pathological functional findings in the head and neck region are noted in their localizations in right and left side view drawings. A low risk assessment can be assumed if all vectors are in the green range. In this case, the dental decision for MAD therapy is independent of a trade-off between risk and benefit. This dependence increases as the number of vectors with higher risk ratings increases and is greater the more areas of periodontics, prosthodontics, and function are affected. This risk/benefit assessment applies equally to the decision in favor of MAD therapy, if necessary, with preparatory measures, and to the decision to continue it, if necessary with accompanying measures. Because of the low prevalence for functional findings with increased risk, the necessity of functional diagnostic or functional therapeutic measures arises only in exceptional cases. In contrast, periodontal and prosthetic findings with increased risk are much more frequent, especially before the start of therapy. Figure 1 shows a performance monitor with an average expected result in the MDRC of the MP F (red connecting lines).

The 3D Bite Fork "JS-Gauge®"

Bite forks are used as a standard aid for determining the starting protrusion position (SPP) [24,25]. They offer the advantage over no aid and axiography that the three-dimensional adjustment of the SPP

can be performed and metrically recorded under evaluation of functional and neuromuscular findings. Interocclusal bite forks, which find their hold only by active biting of the patient between the dentition, are subject to positional instability during the adjustment and registration process, which can lead to a reduction in precision [26]. This working instability also prevents the adjustment of a casual, habitual transversal position by repeated opening and closing movements of the mandible out of or into the SPP. For these reasons, the adherent 3D bite fork JG fixed to the maxilla is used in this methodology (Figure 2). From the bite tray of the JG fixed to the maxilla with Futar® D fast (FD) (Kettenbach, Germany), a 3D-adjustable support goes to the mandibular incisor edges in the manner of a support pin registry. The JG allows neuromuscularly relaxed, interference-free adjustment and registration of the mandibular position relative to the maxilla in a lying, sleep-like treatment position. It is universally suitable for all jaw shapes and sizes and can be reprocessed and reused in accordance with MDR. The adjustment of the SPP takes place in five steps.

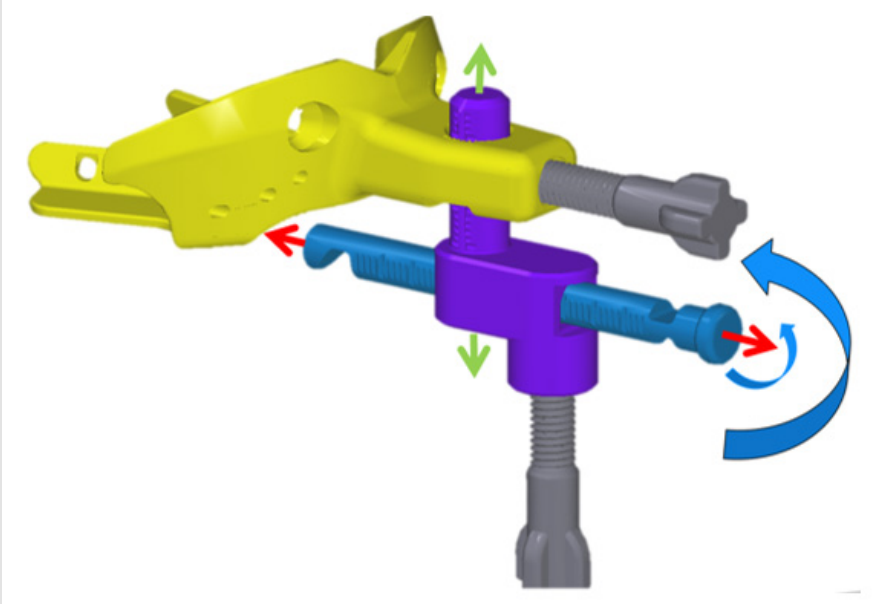


Figure 2: Adherent 3D bite fork JS-Gauge® with bite tray, marked yellow, a vertical pin, marked turquoise (movable in green arrow direction for vertical adjustment and rotatable in blue large arrow direction for habitual transversal adjustment) and a horizontal pin, marked blue (can be moved in the red arrow direction for sagittal adjustment and rotated in the blue small arrow direction for adjustment of positionally stable incisal support), and two locking screws, marked gray.

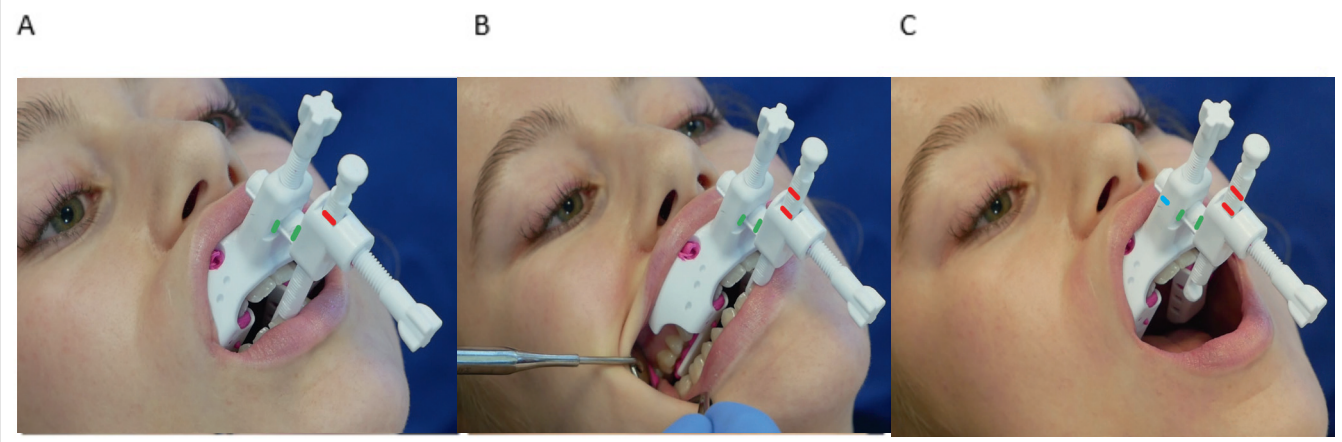
1. To measure the PR [25], the JG is used to make terminal movements into the max. retro- (Figures 3A, red line) and into the max. protrusion position until these can be reproduced at least three times on the horizontal pen with markings. The measurement is entered as MP in the JG. The protrusion of the SPP (P-SPP) is adjusted to a standard 5,0 mm (Figure 3B), unless a different adjustment is necessary until no pathological functional signs are found and the patient feels maximum comfort.

2. The bite block of the SPP (B-SPP) is adjusted with 2,0 mm as the smallest distance between the cusp tips of the maxillary and mandibular tooth row (cusp tip distance, CTD). To check this distance and a flat occlusal plane for the F to be fabricated (lower of the red marking in Figure 4), a ruler with a thickness of 0.5 mm (Aesculab® AA804R, Germany) (R) is swiveled between the mandibular tooth row and the bite block of the JG resting on the maxillary tooth row during adjustment with the JG. The distal cusps of the second molars and the third molars are not taken into account of CTD in order to keep the B-SPP as low as possible in the case of a pronounced Spee curve (compare Figure 4A with Figure 4B).

3. The adjustment of the transversal position of the SPP (T-SPP) is performed habitually by opening and closing movements out of and into the trough of the horizontal pin and is completed when it can also be reproduced three times (Figures 3B & 3C). The 3D adjustment is completed when the horizontal pin does not bend, no pathological functional findings occur in the adjusted SPP in the supine treatment position and the patient does not complain of discomfort within 5-10 minutes (Figure 3B).

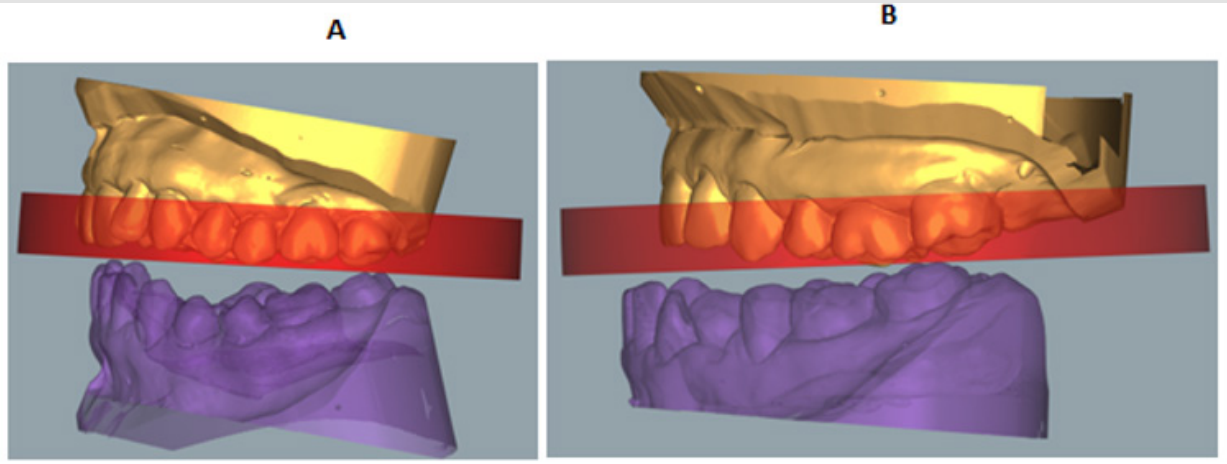
4. For the registration of the SPP, FD is first coded between 12-22-32-42 and the horizontal support pin frontally. Only after

curing is FD coded between the terminal two to three regions of the maxillary and mandibular tooth ranges in the analog procedure and these two lateral registrations are sent to the producing laboratory together with the frontal registration, which is removed from the JG. In the digital procedure, the intraoral scanner is used for registration instead of the lateral codes. The values of PR, P-SPP and MO are transmitted to the manufacturing laboratory.



Note: Opening (C) and closing (B) movements in the start protrusion position (SPP) to adjust the habitual transverse position (blue marking) in the MDR conformity assessment procedure. The 3D adjustment is performed in the supine treatment position and is completed if no pathological functional findings occur and the patient does not complain of dyscomfort within 5-10 minutes. Otherwise, deviate from this standard SPP accordingly.

Figure 3:
A. Mandible in P-SPP measured.
B. Mandible in P-SPP measured at 5,0 mm from maximum retrusion in the MDR conformity assessment procedure.



Note: - Sagittal: 5,0 mm protrusion (measured from maximum retrusion).
- Vertical: 2,0 mm interocclusal cusp tip distance (CTD) checked with a ruler with a thickness of 0.5mm (Aesculab® AA804R, Germany).
- Transversal: habitual transversal position.

Figure 4: Two exemplary computer-aided constructions of the occlusal plane of the maxillary and mandibular splint base of the F-UPS® with the SPP standardized in the MDR conformity assessment procedure for the F-UPS®:
A. Situation with pronounced Spee curve and retrogenia.
B. Situation with flat Spee curve and head bite.

The MAD "F-UPS®"

This method uses the patented F (Figures 5 & 6) which complies with the specifications of the Federal Joint Committee [12] according to a two-part MAD that is individually made to measure and protrusively adjustable in millimeter increments. By means of guide surfaces (GS) attached to both sides of the maxillary splint base and adjustable in their protrusion via expansion screws (ES), which correspond to the fin elements (FE) on the mandibular splint base, the protrusion can be controlled laterally separated and the mandibular opening functionally adapted. This control and functional adaptation via the GS and FE is such that the mandibular opening out of the SPP (Figure 6A) is only achieved with further protrusion of approx. 1-3 mm and is thus inhibited as long as the GS and FE remain in contact with each other (Figures 6A & 6B). Depending on the length of the FE, this contact is lost between approx. 15 mm to approx. 20 mm interincisal mandibular opening and fully releases the mandibular opening (Figure 6C). Frontal elastics can be dispensed with without exception because the protrusion movement when opening the jaw from the SPP inhibits the mandibular opening movement, the protrusion is not reduced up to a mandibular opening of 10 mm to 15 mm interincisal mandibular opening compared to the SPP and mandibular openings of more than 10 mm to 15 mm interincisal mandibular opening does not regularly occur during sleep [27]. Conversely, when the tip of the FE contacts the caudal portion of the GS, guidance of the mandible into the SPP begins.

Figure 5: The patented medical Product F-UPS®:
A. On the left, the upper part with the guide surfaces attached on both sides and adjustable in protrusion via expansion screws; on the right, the lower part with the fin elements attached on both sides.
B. Upper and lower jaw portion brought into protrusion-acting position with the tip of the fin elements in contact with the guide surfaces.

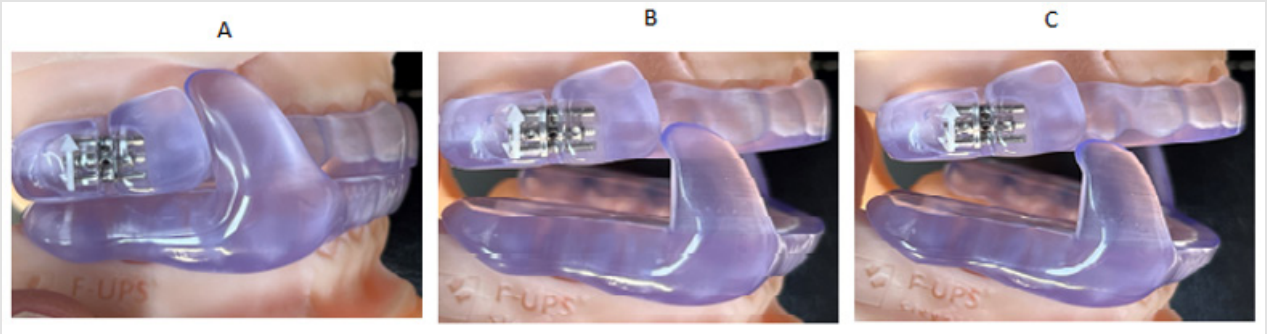


Figure 6: F-UPS® manufactured from thermoelastic resin using the CAD/CAM 3D printing process with patented fins attached in pairs to the sides of the mandibular base and the corresponding guide surfaces on the maxillary splint base, which are continuously adjustable via expansion screws [36].
A. Situation in the SPP.
B. Situation in 15 mm interincisal mandibular opening. After the protrusion increase from the SPP to 15-20 mm interincisal mandibular opening is overcome, which until then inhibits jaw opening during sleep, from then on the unconstrained release of jaw opening can take place under retrusion.
C. Situation in 23 mm interincisal mandibular opening with retrusion versus SPP.

To fascilitate the manufacturing, the F impressions of the maxilla and mandible were taken with alginate and the plaster models were fabricated with superhard plaster under the standardized conditions specified by the manufacturer. The use of intraoral scanners is possible as an alternative. The fabrication of the splint bases, including the GS and the corresponding FE, is carried out after accepting the SPP registered with the JG (Figure 3B), the transmitted values and the scanned plaster models or scan data using the 3D CAD/CAM program (Exocad, Germany). The 3D model is manufactured from thermoelastic resin in the printing process, and the ES is attached in a manual process. The latter can be dispensed with if the F are not manufactured with ES but with several interchangeable GS or maxillary splints with the desired ascending degrees of protrusion. The final design of the GS and the length adaptation of the FE is performed in the completely adjustable articulator according to the MO, the PR and the P-SPP. Lastly, the polishing is performed.

The Vektor Diagram "Performance Monitor" (PM)

After the integration of the F, a follow up with comparison to the initial findings is carried out after a familiarization phase of approx. 2-6 weeks on the basis of progress data. The aim here is to evaluate the effectiveness of the therapy with the individual risk/benefit analysis for the patient. This determines whether the indication for or against readjustment or even against continuation of the therapy must be made. This is done in an interdisciplinary exchange between sleep physician and dentist. Whether or to what extent the F is suitable for achieving the treatment goal, i.e. the effectiveness is sufficient, depends on the evaluation of two factors, 1. the extent of adherence [28] and 2. the extent of the effect. Relevant for the evaluation of adherence are the wearing duration and the subjective ratings of the patient according to the visual analog scale (VAS) regarding snoring (if present) and side effects [29], the benefit and especially regarding the wearing comfort of the F (Table 1). For the evaluation of the effect, the benefit perceived by the patient with regard to evaluation-relevant endpoints such as daytime sleepiness, sleep quality, and vigilance [30] basically applies. Measurement parameters from sleep medicine diagnostics by means of ambulatory pulse oximetry [31] arterial tonometry [32], polygraphy [33-35] and, in the absence of unambiguousness, polysomnography [14] also provide evidence for further objective evaluation.

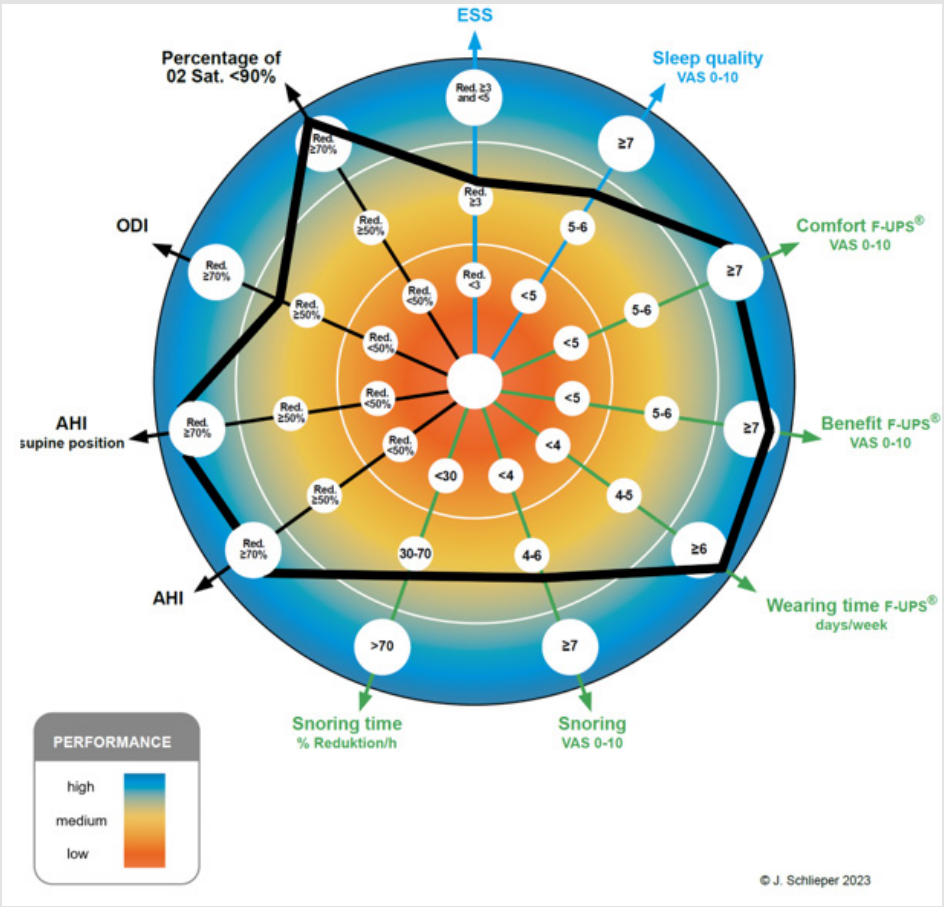


Figure 7: The Vector Diagram "Performance Monitor" (PM) with the average performance of the MP F out of the MDRC (black connecting lines).

Table 1: Assessment-relevant subjective and objective progression data (PM).

Assessment of adherence (subjective assessment by the patient)	• Wearing time of the F-UPS®: every night, 4 - 5 times per week, only on certain occasions.
	• Wearing comfort of the F-UPS® (VAS): uncomfortable 0 - 10 very comfortable.
	• Benefit of the F-UPS® (VAS): no benefit 0 - 10 very great benefit.
	• Effect of the F-UPS® against snoring (VAS): snoring unchanged strong 0 - 10 no snoring anymore.
Assessment of Effect (subjective assessment by the patient)	• Effect of F-UPS® on sleep (VAS): poor, still tired 0 - 10 very good, now rested.
	• Daytime sleepiness: Epworth Sleepiness Scale (ESS).
Further objective evaluation (objective measurements)	• Polysomnography / Polygraphy.

Performance monitoring in the form of a vector diagram can be helpful in evaluating the results from the patient's subjective assessments of the assessment-relevant endpoints and adherence as well as the results from objective measurements. The labels for the subjective assessments of the assessment-relevant endpoints are marked in blue with their vector arrows, the labels for the subjective assessment of adherence are marked in green with their vector arrows, and the labels for the objective measurements are marked in black with their vector arrows. Around the center, three color areas red, yellow and blue are grouped eccentrically for easier visualization of the result areas with low, red marked area, medium, yellow marked area, and high performance, blue marked area. Figure 7 shows the PM with the average performance of the MP F out of the MDRC (black connecting lines). Effectiveness is achieved when a high level of adherence and effect can be assumed and either there is no indication for readjustment according to the medical and dental risk-benefit analysis or, if readjustment were indicated, it would disproportionately jeopardize the level of adherence. A reassessment of the effectiveness of the therapy is performed at intervals that are adequate to the medical and dental RP. If the readjustment of the FA relates to the protrusion increase, this is initially performed at intervals of approx. 2 – 6 weeks in two partial steps of 1.75 mm each (10 x ¼ turn of the DS) and, if required in exceptional cases, thereafter in partial steps of 0.7 mm steps (4 x ¼ turn of the DS). The protrusion increase is performed independently of the severity of the OSA [32,36].

Conclusion

This paper is the first to provide a contribution to the TPMAD methodology from the MDRC of an MP. The methodical individual steps with the RP, JG, F and PM map the complete TPMAD in a MDR compliant fashion. Through the standardization of the methodology, the assurance of quality and safety can be implemented effectively, efficiently, and satisfactorily MDR compliant.

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