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Preliminary clinical evaluation of traditional and a new digital PEEK occlusal splints for the management of sleep bruxism

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Summary

Objective: To compare the manual time and preliminary clinical effects between the digital manufactured occlusal splints for sleep bruxism patients with those of traditional hard splints.

Methods: Sixteen individuals (18 to 44 y/o) with clinically diagnosed sleep bruxism were selected based on the inclusion criteria. All patients were divided into two groups, and a random control method was applied. Digital splints (test group) were designed and milled using CAD/CAM. Hard splints (control group) were made of transparent acrylic resin in laboratory office. The manual time spent including impression obtaining, splint production and clinical occlusal adjustment was recorded. A visual analog scale was used to report the subjective evaluations. The maximum depth loss and volumetric loss of the occlusal surface of splints in posterior tooth were measured. SPSS software was used for statistical analysis ($P = .05$).

Results: Comparing with control group, the manual time spent in test group was significantly less in all of three procedures ($P < .001$). The VAS scores for retention were not significantly different ($P = .086$), but the wearing comfort scores of test group were significantly higher ($P < .001$). Both maximum depth loss ($P = .007$) and volumetric loss in test group were significantly less than control group ($P = .005$).

Conclusion: In the current study, the digitally manufactured splints exhibit significantly improved comfort and time efficiency than traditional hard splints. Moreover, the new milling material (PEEK) has better wear resistance than acrylic resins.

KEYWORDS
CAD, CAM, manual time, occlusal splint, subjective evaluation, wear measurement

1 | INTRODUCTION

Sleep bruxism (SB) is defined previously as a kind of repetitive jaw-muscle activity mainly manifested by grinding, clenching, and/or bracing or thrusting of the mandible during sleep.[1] Although the aetiology of bruxism is not exactly clear, many studies regarded it as multiple causes including morphological, psychosocial, genetic and other possible factors.[2-5] Long-term SB can lead to tooth wear, jaw-muscle pain and occlusal trauma, and in some severe forms can cause difficulty with speech or swallowing.[6] With the deepening of research in recent years, some studies have constantly discussed and updated the definition of SB.[7-9] Therefore, it tends to be regarded as a risk factor rather than a kind of disease. In 2018, Lobbezoo et al stated in a new study that SB should be regarded as a 'behaviour' among

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people without other diseases. It can be a risk, or it may play a protective role.[9] The use of occlusal splints is one of the most common management strategies for SB owing to its proven ability to improve the symmetry of masseter and temporalis activities, relieve force on the TMJ and other structures of the masticatory system, and to disperse occlusal force so that teeth wear can be reduced.[10-12] Most existing occlusal splints are fabricated in two methods including hard acrylic with wax-up and soft vacuum formed. So far, it is generally believed that the effect of hard splints is equivalent or superior to soft ones.[13,14] However, this traditional method requires a number of steps both in clinic and dental laboratory.[2,3,10,15]

With the rapid development of digital technology, computer-aided design (CAD) and computer-aided manufacturing (CAM) have become increasingly widely used in dentistry. Accordingly, CAD/CAM was applied to fabricate occlusal splints for patients in some previous studies. Edelhoff et al fabricated tooth-coloured occlusal splints made of polycarbonate, which had better quality and material properties than those of traditionally manufactured splints.[16] Ye et al created splints of different dental model offsets using digital design and light processing (DLP) and confirmed their precision.[17] The evidence suggests that those splints were similar to traditional ones in comforts and retention. Moreover, they performed better in time efficiency and material quality.[18,19]

Thus, this study aimed to compare the manual time and preliminary clinical effects between a new proposed digital fabricated PEEK occlusal splint and traditional hard splints. The null hypotheses for this study stated that there would be no differences between them.

2 | MATERIALS AND METHODS

2.1 | Subjects

The study was carried out in the Department of Prosthodontics, Peking University Hospital of Stomatology. Ethical approval was obtained by the biomedical ethics committee of Stomatology Hospital, Peking University (Ethical batch number: PKUSSIRB-201840161). It can be clinically diagnosed probable SB according to the grading system proposed by Lobbezoo et al[9] if (a) positive self-report: the patient reports or is told to grind or clench his teeth during the night and (b) positive clinical inspection: the patient has facet of teeth wear, sound of bruxism or discomfort of masticatory muscle in clinic examination. Individuals who had previously received any orthodontic or prosthodontic treatment, patients with sleep-related conditions (such as obstructive sleep apnoea syndrome), subjects with any cognitive incapacity or medical disorders and individuals with severe malocclusion or other malformations that may affect occlusion were excluded. Sixteen individuals ranging in age from 18 to 44 years with clinically diagnosed SB were selected based on the inclusion criteria and divided into two groups (n = 8) according to the random number in envelopes. The test group used digital manufactured splints, and the control group used hard splints. A random control methodology was applied and consent forms were signed before the study.

2.2 | Digital fabrication protocol

The oral information of the patients was obtained by an intra-oral scanner (3Shape Trios, 3Shape A/S). To provide sufficient occlusal space, the leaf gauge method was used so that the vertical distance between the posterior teeth was approximately 1.0 mm. The occlusal relationship under these conditions was recorded with silicone rubber, and it then scanned and registered with maxillary and mandible dentitions.

The scanning data were imported into CAD software (3Shape Dental System 2018, 3Shape A/S), and the Splint module was used to design the basic form of the occlusal splint. Since the undercut might hinder the seating of splint, the undercut near the neck of the posterior buccal side was filled in the direction of the path of insertion. On the other side, the retention of the digital fabricated splint is depended on undercut, so about 0.2 mm of undercut was retained without affecting the insertion of the splint. The labial shell of the anterior tooth area (3-3) was removed to enhance the aesthetic effect, and the buccal and palatal flange was extended to the gingival margins to ensure retention of the splints. The shell thickness was 1.0 mm, and the internal compensation was set as 0.1 mm. The thickness of the occlusal surface was then adjusted in tune with the actual occlusal space. Distance map was used for reference to ensure uniform occlusal contact under the central occlusion. A virtual articulator was used to simulate protrusive and lateral occlusion in order that the occlusal surface could be adjusted to make sure no occlusal interference existed.

The final splint models were saved in stereolithography (STL) file format and then imported into the milling software in the dental laboratory. Based on our previous research into material properties, polyether ether ketone (PEEK) was considered satisfactory for milling occlusal splints with the CAM machine (Organical Multi S & Changer 20, Organical CAD/CAM GmbH) (Figures 1 and 2).

2.3 | Traditional fabrication process

For the traditional procedure, an impression of the maxillary teeth was obtained and gypsum models were prepared. To manufacture hard splints, the models were mounted on the articulator according to the same occlusal relationship from leaf gauge. Moreover, the vertical occlusal distance was increased properly to ensure the strength of splints. The wax-up was made using the distance on the upper model and then packing with transparent acrylic resin.[2,11]

2.4 | Experimental procedure

2.4.1 | Manual time comparison

The manual time consisted the time spent by the technician and clinician, and it was timed with a stopwatch and recorded in minutes for both methods. In this study, the patient's clinical procedures were carried out by a prosthetic clinician with a deputy senior title, and

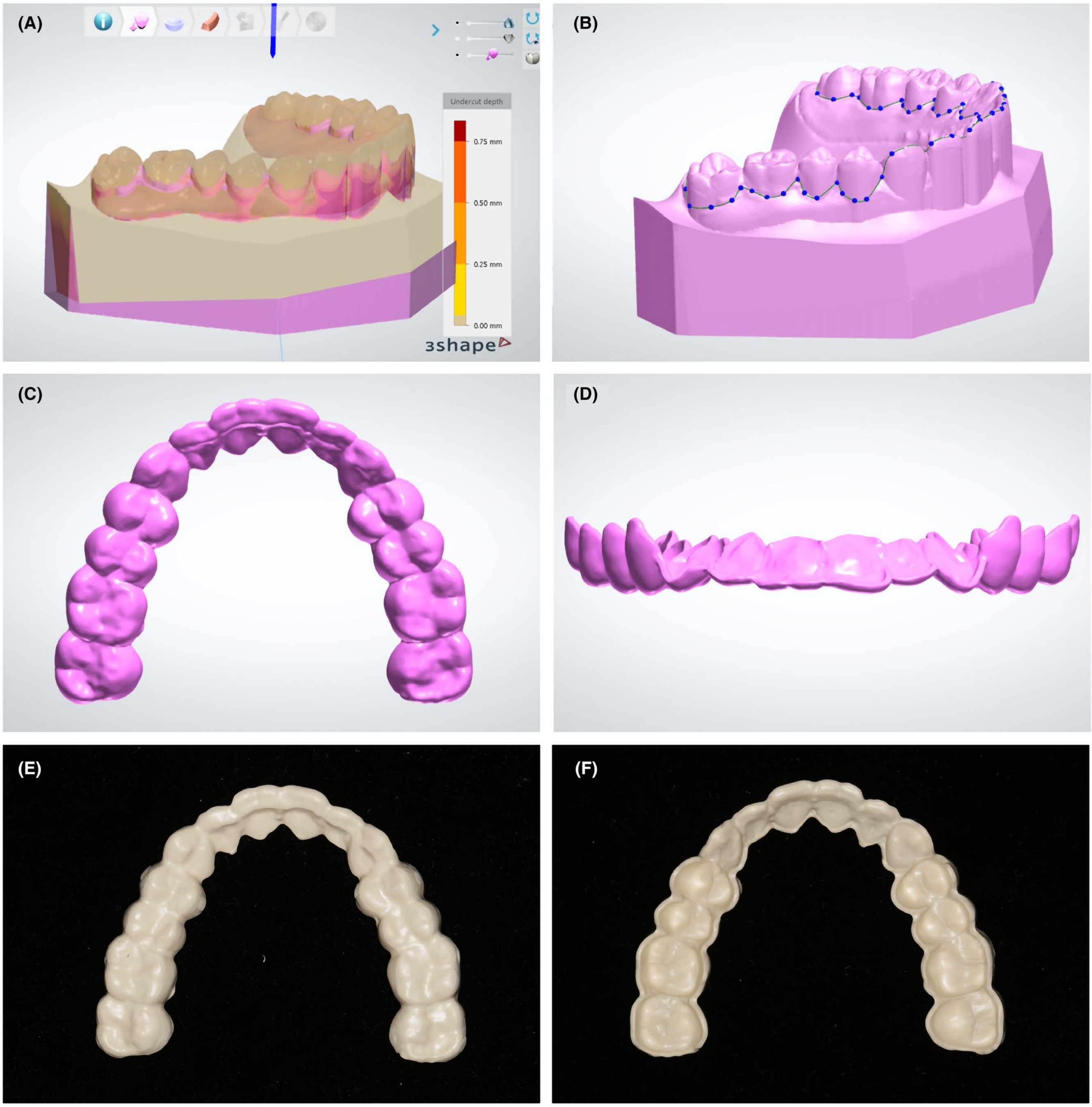

FIGURE 1 Digital design and fabrication of splints. A, Set the path of insertion. B, Draw the shell range of the splint. C, An individually designed occlusal surface according to a patient's individual occlusion. D, The labial shell of the anterior teeth area is removed, and the buccal and palatal flange is extended to the gingival margin. E, Occlusal side of a final splint after PEEK milling. The lingual shape of the splint was tailored designed to get uniform contact with mandible teeth. F, Tissue side of a final splint after PEEK milling

the splint fabrication was finished by two skilled technicians separately. For both groups, the manual time was composed of impression obtaining, splint production and clinical try-in. To be specific, it referred to intra-oral scanning, digital design, polishing and occlusal adjustment in group A and impression making, model pouring, articulator mounting, wax-up making, flasking, polishing and occlusal adjustment in group B. In addition, the time for milling with CAM machine was not included since it did not require manual participation. A single investigator clocked the technicians and clinician, and none of them were aware of the time being noted or for what purpose.

2.4.2 | Patients' subjective evaluation

A visual analog scale (VAS) was used to report the subjective evaluations of patients at the first follow-up visit. Patients were asked

FIGURE 2 A digitally designed splint being tried in the mouth of a patient. A, At rest. B, Under centric occlusion. C, Under right-side occlusion. D, Under left-side occlusion

to report their feelings about retention and wearing comfort of the traditional splints and the new proposed digital PEEK occlusal splints. Then, they would quantify their feelings according to the VAS. The retention was assessed in terms of wearing, large opening movement, lateral movement and speaking. Similarly, the wearing comfort was assessed in terms of both labial and occlusal comfort. It was guaranteed that these patients totally comprehended these corresponding factors. The VAS scores ranged from 0 to 100, with the leftmost point indicating 'very poor' and the rightmost 'very good'. The distance between the mark point scored by patients and the origin point was measured by the same operator, and the data were converted into an evaluation score based on the established standard of VAS.

2.4.3 | Wear loss measurement

In order to measure the clinical wear loss of both splints, it is necessary to obtain the occlusal surface shape of the splints before and after worn. The baseline scan was carried out after occlusal adjustment at the first follow-up visit. The splint was placed on the maxillary model and scanned. The exported files were labelled 't/c-b*n*' where 't/c' refers to 'test group' or 'control group', 'b' indicates 'baseline', and *n* is the patient number. For instance, the file name of hard splint for the second patient was 'c-b2'. The scans were stored as STL files to allow further analysis and comparison later. Since the traditional splints were transparent, a layer of powder was sprayed evenly on the splints before scanning. The patients were told to wear the occlusal splint every night during sleep. The follow-up scan was performed 12 weeks after baseline scan by the same operator with the same scan protocol (hard splints with powder coating). The scanned model files were saved in STL file format as 't/c-fn'', where 'f' indicates 'follow-up'.

Both baseline and follow-up data were imported into Geomagic Control X. The baseline data were set as the reference model, and the follow-up data were set as the test model. Initial alignment was conducted first, and then, the buccal area was selected to perform best fit alignment. The best fit alignment process was carried out with a 100% sampling rate and 500 iterations. It was repeated several times until the root mean square (RMS) value reached a satisfactory level. 3D deviation analysis was carried out between test and reference models, and the range results were displayed in a colour map with the upper and lower limits set as 1.0 mm. To quantify wear loss differences, the entire occlusal surface of the posterior teeth was selected so that the depth loss and volumetric loss could be measured. The maximum deviation between test model and reference model indicated the maximum depth wear loss of the splint. The maximum depth loss was measured in μm.

To measure the volumetric loss, the registered splint models were then imported into Geomagic Studio 2014. The worn area of one-side posterior teeth was selected on both splint models according to the deviation colour map. The remaining unworn area was deleted. The normal of the follow-up splint model was flipped, and then, the two models were combined. With the function of 'filling holes' in the software, a bridge was built between the two surfaces of the selected area. After several bridges were established, the internal holes were filled to complete the 3D construction of the worn area (Figure S1). The volumetric loss was modelled on the other side in the same way. The volume of the reconstructive models was calculated by the built-in function of the software. The volumetric wear loss was recorded in mm^3.

2.5 | Statistical analysis

Descriptive statistics are presented as means and standard deviations. Group t test was performed to analyse manual time, VAS scores and wear loss value. The level of significance was set at $P = .05$. SPSS software (IBM, SPSS, Statistics 20) was used for statistical analysis.

3 | RESULTS

The results of manual time of two groups are shown in Table 1 and Table S1. To make the time comparison more specific, the workflow of each group was divided into three procedures: impression obtaining, splint production and clinical try-in. For all of three procedures, the manual time spent in test group was significantly less than control group ($P < .001$). In the comparison of total manual time, test group spent significantly less than control group ($P < .001$).

Mean values of the VAS scores were evaluated for significant differences in Table 2. There was no significant difference in retention evaluation scores between the two kinds of splints ($P = .086$), but the wearing comfort scores for the digitally manufactured splints were significantly higher than those for the traditional splints ($P < .001$).

The colour map (Figure 3) shows the deviation results before and after wearing of the two splint types, which means the worn area of the splint. The green area means a deviation less than 0.05 mm, while the blue means a negative deviation of more than 0.05 mm. The darker the blue, the greater the wear loss. For both types, wear loss mainly appears in the posterior teeth area.

Table 3 shows the maximum depth loss and volumetric loss in posterior area for two kinds of splints. The maximum depth loss in the test group was significantly less than control group ($P = .007$). Besides, the volumetric loss also shows significant differences between two groups. The volumetric loss in test group was less than control group ($P = .005$).

4 | DISCUSSION

The null hypotheses in this study were partly rejected. In the study, the digital method in test group shows better time efficiency, and the digital fabricated PEEK splint shows better wearing comfort and less clinical wear than control group. However, both types of splints have acceptable retention that can meet the clinical requirement.

While most previous studies have defined bruxism as a kind of 'disorder', Lobbezoo et al, in a review of 2018, proposed that bruxism should be considered a kind of 'behaviour' in otherwise healthy individuals. Although the exact pathogenesis of SB is still unclear, several studies have shown that it is the result of multiple factors including anatomical structure and psychological status.[3,20] Researchers have different views on sleep bruxism, but wearing occlusal splint has been supported and confirmed as a common management by most of the literature and it is recommended to wear at night.[21] Though soft splints were also used as a kind of management of bruxism,[15] more studies suggest better effect with hard ones. Cruz-Reyes et al assessed the electrical activity of the temporal and masseter muscles in patients with bruxism using soft splints or occlusal stabilisation splints, finding a statistically significant difference between two groups. They regarded hard stabilisation splints as a better choice.[13] Narita et al investigated the effects of soft and hard occlusal splints on fatigue, occlusal force and EMG activity. They stated that the usage of a soft occlusal splint caused an awareness of tiredness while the hard splint as well as natural dentition did not.[14] Thus, the hard occlusal splint was used as control group in the present study.

In this study, the test group spent significantly less time in manual process and performed better comfort in patients' evaluation. With the development of digital technology, the accuracy of design and manufacturing has been dramatically improved. The present results are in line with a study of Dedem et al; they investigated that some of the main advantages of digital manufacturing of Michigan splints

TABLE 1 Mean values and standard deviations (SD) of manual time (impression obtaining, splint production and clinical try-in) in test and control groups and the differences between values according to the Student t test ($P < .05$*)

	Test	Control	*t* value	*P* value
Impression obtaining (min)	6.9 ± 0.9	9.7 ± 1.1	−5.585	<.001*
Splint production (min)	28.1 ± 3.6	106.6 ± 7.1	−27.888	<.001*
Clinical try-in (min)	11.8 ± 4.1	43.1 ± 5.9	−12.311	<.001*
Total (min)	46.8 ± 6.4	159.4 ± 8.1	−30.917	<.001*

TABLE 2 Mean values and standard deviations (SD) of VAS scores in test and control groups and the differences between values according to the Student t test ($P < .05^*$)

	Test	Control	*t* value	*P* value
Retention	86.7 ± 5.0	82.2 ± 4.7	1.850	.086
Wearing comfort	84.7 ± 3.4	74.6 ± 4.0	5.421	<.001*

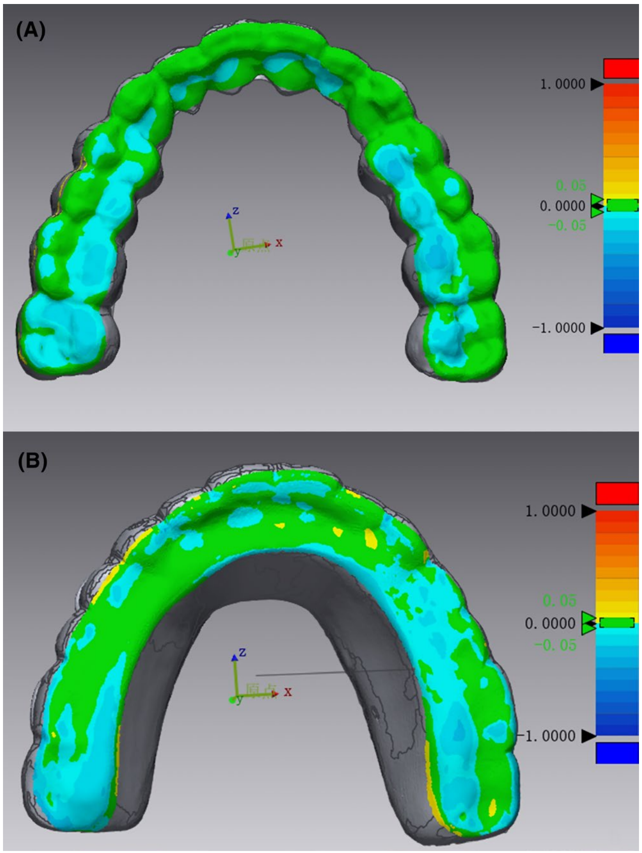

FIGURE 3 Colour maps of deviation between before and after wearing the splints, the green area means a deviation less than 0.05 mm, while the blue means a negative deviation of more than 0.05 mm. The darker the blue, the greater the wear loss. A, Deviation of test group. B, Deviation of control group

over impression-based manufacturing were the time-efficient process, the high material quality and the possibility of manufacturing duplicate splints.[19] Furthermore, Waldecker et al fabricated an occlusal device with a fully digital process using an intra-oral scanner (CEREC Omnicam with Sirona Connect v4.4; Dentsply Sirona) and 3D-printed resin.[22] They tested fit, occlusion and patient-friendly handling and stated that although only minor occlusal corrections were required, it was suitable for the fabrication of occlusal devices in a digital procedure.

Existing materials such as EVA, polyvinyl chloride and acrylic resin exhibit good impact resistances, but it is not easy to control their shape in the heat moulding process. However, PEEK is a kind of special engineering plastic with excellent properties, such as heat

TABLE 3 Mean values and standard deviations (SD) of maximum depth loss and volumetric loss in test and control groups and the differences between values according to the Student t test ($P < .05^*$)

	Test	Control	*t* value	*P* value
Maximum loss (μm)	147.0 ± 31.3	202.8 ± 38.6	−3.179	.007*
Volumetric loss (mm^3)	9.9 ± 1.2	12.4 ± 1.8	−3.304	.005*

resistance, outstanding self-lubrication, chemical-corrosion resistance and excellent wear ability. Because of its excellent biocompatibility, PEEK is often used as a bone-implant material in implant restoration.[23] Furthermore, PEEK has also been employed in the digital manufacture of removable partial dentures.[24,25] Several previous studies have investigated the two-body wear rate and three-body abrasion of PEEK,[26,27] and they concluded that PEEK performed better resistance. However, clinical research on the wear resistance of PEEK materials has not yet been reported. In the present study, splints made of PEEK showed less wear loss after wearing 12 weeks, which indicates that PEEK can meet clinical requirements in splint manufacture. The main component of the acrylic resin used to make hard splint was polymethyl methacrylate (PMMA), and the molecular weight of PEEK is about three times that of PMMA. In a study of clinical wear of similar dental materials, some scholars have proposed that the larger the molecular weight, the better toughness and wear resistance.[28] In this study, due to the superior physical properties, the thickness of PEEK splint was thinner. The thinnest part can even reach 0.5 mm, which reduces the peculiar sense and improves wearing comfort of patients.

When performing subjective evaluation of occlusal splints, patients were asked to rate their satisfaction using questionnaires used in previous studies.[29] In this study, VAS was used to make the evaluation results more precise. In the current study, 3D data for the upper and lower dentition and occlusal relationship after elevation was obtained using an intra-oral scanner. The centric relation was obtained by leaf gauge method and recorded with silicone rubber, which was transferred between the upper and lower models. Leaf gauge was originally proposed by Long et al in 1973 to record centric relation and achieve the adjustment of occlusal relationship.[30] According to Long et al, the centric relation referred to the condyles in their most retruded and superior position in the glenoid fossae. Moreover, Fleigel et al pointed out in a study that the usage of leaf gauge method in splint fabrication could make patients feel more comfortable.[31] Such studies have stated that the centric relation position could be successfully obtained via proper methods. In our study, the gauge was put between the anterior teeth, and the number of leaves was adjusted to make patients feel the first contact between posterior teeth. The silicone rubber was used to record the occlusal relationship so that the aimed position could be obtained. Then, the occlusal relationship could be recorded through scanning of this silicone rubber. According to the patients' occlusal distribution after elevation, customised design of occlusal splints was carried out using CAD software. Uniform contact between the upper and lower dentition was ensured so that patients' occlusion was not changed. In addition, aesthetic and comfort factors were considered in the design process. The wrapping range of the anterior teeth was cut down to the incisor edge in order to reduce oral-foreign-body sensation and increase labial comfort. Besides, the coverage of the buccal side can also be appropriately removed to reduce the patient's foreign body sensation. Moreover, in the present study, three patients in control group reported soreness, and two reported mouth dryness in the morning. However, there was no similar report in test group. A probable explanation may be the different thickness of two types of occlusal splints. The thickness of traditional splints was about 2 mm, while the PEEK splints in test group were much thinner.

Currently, 3D reverse engineering software is widely used to analyse deviations between digital models. Pagano et al stated that such commercial programs are a reliable way to evaluate the precision of digital scanning.[32] The reference and test models are aligned using an iterative closest point (ICP) algorithm, a methodology that is widely used to orient several 3D objects by pairing their corresponding data. For instance, Latham et al evaluated the effects of digital scanning with different scan patterns, comparing the reference standard scans with experimental scans using Geomagic Control X.[33] Furthermore, DeLong et al investigated several methods to measure wear, concluding that it is best to use 3D scanning to compare sequential images of a surface.[34] Moreover, Martina et al measured the wear loss for dentures using surface analysis software (Match 3D, Version 1.6, Willytec/SD Mechantronic).[35,36] For occlusal splints, Kentaro proposed an evaluation system which can analyse the location and direction of wear facets and surface loss. This system could observe not only the surface loss but also the warp deformation of the splint by scanning the splint made of a specific elastic material on the cast.[37] In the current study, Geomagic Control X and Geomagic Studio was used to calculate the depth and volume losses for both kinds of splints. This method was first described by Mehl et al[38] and has been proven to be an appropriate way of assessing clinical wear.[39-41] Thus, compared with traditional measurement techniques, the application of reverse engineering software in the current study allowed more intuitive and accurate assessment of the results.

Unlike the traditional process, the complete digital workflow for fabricating occlusal splints for SB patients features improved design of the occlusal surface, a simplified working procedure, and greatly medical resource-economic. Furthermore, it enables doctors to store the dental data of patients. In addition, because the STL file format is very common, the occlusal splints can also be fabricated with additive manufacturing methods (eg 3D print method) using PEEK or other appropriate materials. Moreover, the PEEK occlusal splints have better wear resistance with a longer service life. In the current study, the digital fabrication process and the advanced material can provide a new option for SB management. Since the emerging development of digital technology in recent years, the CAD/CAM-fabricated occlusal splints will be more convenient and efficient for doctors, technicians and patients. Of course, the cost of digital dentistry should also be taken into account. Due to the high cost of software copyright, high-tech machine and personnel training, the price is not very friendly to the patients at this stage. But it will no longer be an issue with the continuous popularisation of digital application in the dental field.

However, like most pilot studies related to occlusal splints, further observations of the effects of long-term wearing on SB are still required and the sample size needs to be expanded. Furthermore, the clinical efficacy of the novel splint is also required with some instrumental assistance.

5 | CONCLUSION

Compared with traditional occlusal splints, the digitally manufactured splints exhibit significantly improved wearing comfort and time efficiency. Moreover, the use of a new milling material (PEEK) has better wear resistance than traditional acrylic resins.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

AUTHOR CONTRIBUTIONS

Y.L and Y.Z contributed to conception and design, financial support, data analysis, manuscript editing and final approval of manuscript, revised the manuscript for intellectual content and agreed to be accountable for all aspects of the work. S.W contributed to literature search, data collection and analysis, manuscript draft and final approval, revised the manuscript for intellectual content and agreed to be accountable for all aspects of the work. Z.L, H.Y and W.Z contributed to case collection and data analysis, final approval of manuscript, revised the manuscript for intellectual content and agreed to be accountable for all aspects of the work.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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