Preliminary Clinical Application of Complete Workflow of Digitally Designed and Manufactured Sports Mouthguards

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Purpose: To establish a complete digital workflow for the design and manufacture of sports mouthguards and to observe preliminary clinical effects. ***Materials and Methods:*** Eighteen healthy participants were included in this study. The self-controlled method was applied, and all participants were provided with two types of mouthguards. Digital mouthguards were designed and milled using CAD/CAM with polyetheretherketone, and conventional mouthguards were fabricated using the vacuum pressure–forming method with ethylene vinyl acetate. The order of wearing was determined using a random number table, and the washout period between was set as 1 month. Degrees of satisfaction in terms of retention, appearance, occlusal comfort, and labial comfort were evaluated. Distribution of occlusal force was tested using the T-scan analysis system. Participants were also asked to choose one mouthguard for future use. ***Results:*** The complete workflow of digitally designed and manufactured sports mouthguards was successfully established. No significant difference was noted in retention between the types of mouthguard. The appearance score ($P = .025$), occlusal comfort score ($P = .030$), and labial side comfort score ($P = .003$) of the digital mouthguard group were significantly higher compared to the conventional mouthguard group. T-scan analysis results showed that in centric occlusion, participants exhibited occlusal contact in the second molar alone while wearing conventional mouthguards, while the occlusal force was uniformly distributed with digital mouthguards. Sixteen participants selected the digital mouthguard for future use. ***Conclusion:*** Digital design and manufacture of sports mouthguards improved the occlusal design and greatly simplified and optimized the conventional fabrication process. *Int J Prosthodont 2020;33:99–104. doi: 10.11607/ijp.6348*

With increased popularity of participation in sports activities, the risk of sports-induced oral and dental injuries has also increased tremendously. Therefore, it is critical to establish feasible methods to prevent sports-related dental trauma. Mouthguards have been designed to protect teeth and surrounding structures and thus reduce the chances of orofacial trauma that could occur during sports or exercise.[1] Available evidence[2,3] suggests that mouthguards are effective in reducing the incidence of orofacial injuries. At present, mouthguard application is recommended in 29 sports, including water polo, karate, taekwondo, and handball.[4]

Considering the protective and effective results of wearing mouthguards, it is pivotal to investigate how to improve their design. At present, three types of mouthguards are available in the market: prefabricated stock mouthguards, mouth-formed mouthguards, and custom-made mouthguards that are individually fabricated by a dentist based on the patient's individual dentition model.[2,4] Conventional ethylene vinyl acetate (EVA) copolymers are most commonly used to fabricate mouthguards,

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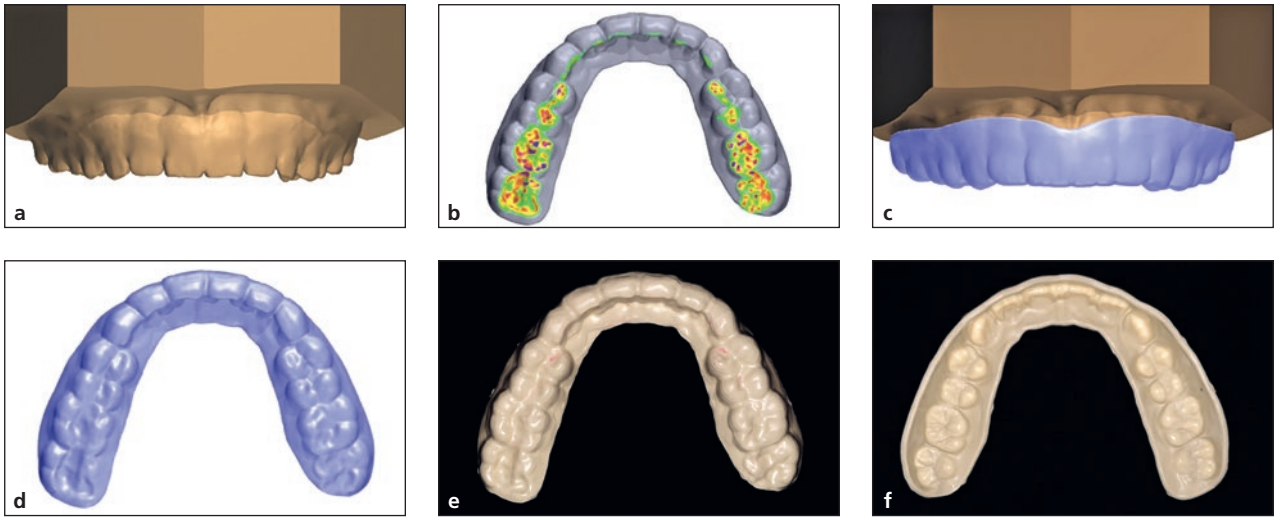

Fig 1 Digital design and fabrication of sports mouthguard. *(a)* Gingival and other adjacent undercuts on the labial aspect were filled. *(b)* Occlusal contact adjustment, *(c)* labial aspect, and *(d)* occlusal aspect of the digital design. *(e)* Occlusal aspect of the final sports mouthguard after milling. *(f)* Tissue face of the final sports mouthguard after milling.

partly because their physical and mechanical properties provide adequate shelf-life.[5] Moreover, the conventional EVA mouthguards can be effortlessly fabricated using the vacuum-pressure technique based on the user's dental cast.[6,7]

However, the whole process of producing conventional EVA mouthguards—involving impression-taking, preparation of a gypsum working model, and vacuum pressing—is complicated and cumbersome.[8] Recently, rapid development of computer-aided design/computer-assisted manufacturing (CAD/CAM) has provided new insights into the design and fabrication of mouthguards, although this field is still in its infancy. The aim of the present study was to first explore a feasible complete workflow of digital design and manufacture of sports mouthguards using the polymer polyetheretherketone (PEEK) and to observe the preliminary effects of their application.

MATERIALS AND METHODS

In total, 18 healthy volunteers (9 men and 9 women, aged 18 to 30 years) without severe malocclusion or temporomandibular joint disorders were included. The self-controlled experiment method was applied in this study. Digitally designed and manufactured mouthguards and conventional EVA mouthguards were prepared for all participants. Random numbers generated by the random number table were sealed in envelopes, and the envelopes were opened in the order of enrollment. The entire study duration was divided into three periods: *(1)* digital mouthguard–wearing phase; *(2)* conventional mouthguard–wearing phase; and *(3)* washout period. The order was 1(2)–3–2(1), decided by the random number in the envelope: An odd number meant wearing the digital mouthguard first for 1 month, and an even number meant wearing the conventional mouthguard first for 1 month. The washout period was set as 1 month. Subsequently, all participants were asked to finish a questionnaire. Before answering the questionnaire, each question was clearly explained to each participant. Questions pertained to degree of satisfaction in terms of retention, appearance, occlusal comfort, and labial comfort with both types of mouthguards, and each domain could be graded as good (A), acceptable (B), or poor (C). In addition, participants were asked to choose one mouthguard for daily use. The study was approved by the Biomedical Ethics Committee of the Stomatology Hospital, Peking University (ethical batch number: PKUSSIRB-201840161). All participants provided signed informed consent before entering the study.

Digital information, including oral soft and hard tissues of participants, was obtained using an intraoral scanner (TRIOS, 3Shape). The leaf gauge method was used to ensure a posterior teeth separation of approximately 2 mm. Intraoral silicone rubber impressions were recorded under this condition. Subsequently, the occlusal relationship was scanned, and occlusal registration was completed. Digital models were imported into 3Shape Dental System 2014; occlusal splint modules were used to design basic forms of the mouthguards according to the oral soft and hard tissue characteristics of each participant. Gingival and other adjacent undercuts were filled (Fig 1a). Virtual articulators were used to ensure uniform occlusal contact under centric occlusion. Moreover, protrusive and lateral occlusions of

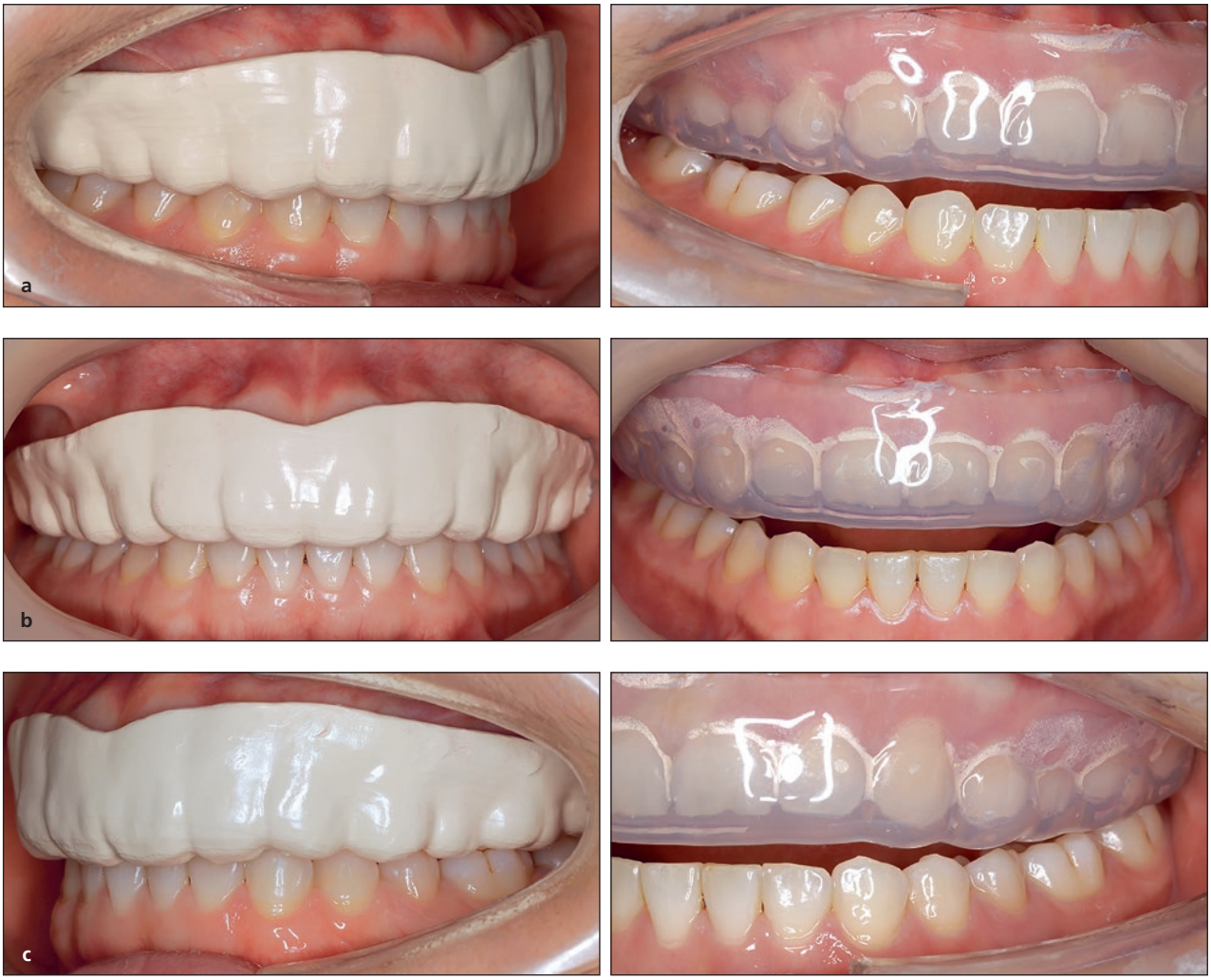

Fig 2 Digital (top) and conventional (bottom) mouthguards were tried-in under *(a)* right-side occlusion, *(b)* centric occlusion, and (c) left-side occlusion.

the mouthguards were adjusted to ensure there was no occlusal interference (Fig 1b). The STL file was sent to the dental laboratory and imported into the CAD/CAM system (Organical Multi S & Changer 20 and Organical Mill 2, Organical CAD/CAM). Based on the authors' previous research on characteristics of the material, PEEK trays were milled to obtain digital mouthguards.[9]

Conventional EVA mouthguards (Erkoflex, Glidewell Direct) (4-mm EVA) were fabricated using a traditional vacuum pressure–forming machine (erkoporm-3d+) by using work models of participants according to a previously published method.[10,11] For direct comparison of the occlusal conditions of the digital and conventional EVA mouthguards, the T-scan III occlusal analysis system was used to analyze static and dynamic occlusion, as well as to record distribution of occlusal forces in the dental arches.

Statistical analyses (McNemar-Bowker two-sided test) were performed using SPSS (IBM). The level of significance was set at $P \leq .05$. Statistics for satisfactory grades pertaining to retention, appearance, and occlusal comfort with use of the mouthguards were ordinal data of paired experimental designs.

RESULTS

A complete digital workflow for sports mouthguards was successfully established. With rounded edges, the labial flange extended to within 2 mm of the vestibular reflection (Fig 1c). The palatal flange extended to within 10 mm of palatal gingival margins and had tapered edges in order to reduce any feeling of discomfort (Fig 1d). Labial/palatal thickness was 2 mm. Occlusal thickness was initially set as 2 mm and was later adjusted in line

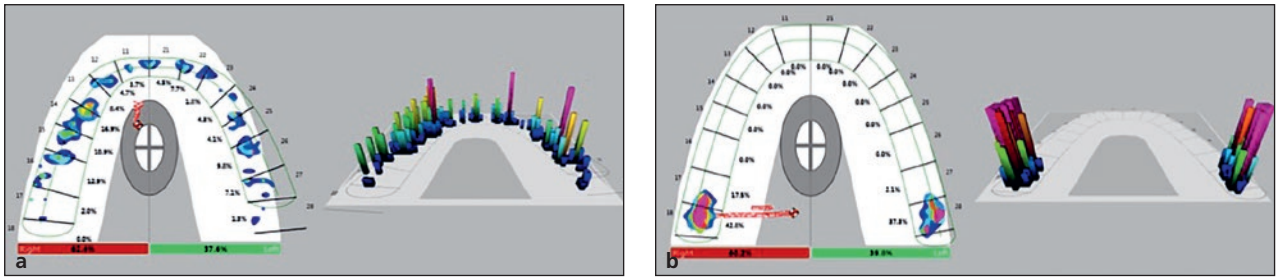

Fig 3 T-scan results in centric occlusion of a participant wearing the *(a)* digitally manufactured mouthguard and the *(b)* conventionally manufactured mouthguard.

Table 1 Evaluation of Retention of Digitally and Conventionally Manufactured Mouthguards

	Digital, n			
Conventional, n	A	B	C	Total, n
A	12	0	0	12
B	3	2	0	5
C	0	0	1	1
Total	15	2	1	18

A = good; B = acceptable; C = poor.

Table 2 Evaluation of Appearance of Digitally and Conventionally Manufactured Mouthguards

	Digital, n			
Conventional, n	A	B	C	Total, n
A	10	0	0	10
B	5	2	0	7
C	0	0	1	1
Total	15	2	1	18

A = good; B = acceptable; C = poor.

Table 3 Evaluation of Occlusal Comfort of Digitally and Conventionally Manufactured Mouthguards

	Digital, n			
Conventional, n	A	B	C	Total, n
A	7	0	0	7
B	6	3	0	9
C	0	1	1	2
Total	13	4	1	18

A = good; B = acceptable; C = poor.

Table 4 Evaluation of Labial-Side Comfort of Digitally and Conventionally Manufactured Mouthguards

	Digital, n			
Conventional, n	A	B	C	Total, n
A	2	0	0	2
B	10	1	0	11
C	2	2	1	5
Total	14	3	1	18

A = good; B = acceptable; C = poor.

with the actual occlusal space. Subsequently, the PEEK trays were milled to fabricate digital mouthguards (Figs 1e and 1f). Both digital and conventional mouthguards were tried-in in the participants' mouths (Fig 2).

Results of the questionnaire (Table 1) revealed no significant difference in retention evaluation between the two types of mouthguards ($P = .083$). Appearance scores ($P = .025$) (Table 2), occlusal comfort scores ($P = .030$) (Table 3), and labial-side comfort scores ($P = .003$) (Table 4) of the digitally manufactured mouthguard group were significantly higher than those of the conventionally manufactured mouthguard group. Sixteen participants (88.9%) chose digital mouthguards for future use. T-scan analysis results showed that in centric occlusion, only the second molar on both sides of conventional mouthguards had occlusal contact (Fig 3a), while digital mouthguards had stable and bilaterally balanced contact with mandibular teeth. Furthermore, occlusal forces were uniformly distributed in the digital mouthguard group (Fig 3b).

DISCUSSION

The protective effects of wearing mouthguards during sports and other physical activities have been affirmed in numerous studies.[12,13] At present, custom-made EVA mouthguards are usually prepared using vacuum pressure.[5] Due to the low elastic modulus of EVA (13 to 15 MPa), it is recommended for mouthguard fabrication (occlusal thickness 4 mm; labial thickness 3 mm; and palatal thickness 1 mm).[5] Unnecessary thickness would impair the comfort of wearing (particularly on the labial aspect) and the convenience of speaking.[14] Several studies have investigated issues with stretching of EVA during fabrication, which leads to decreased thickness of a mouthguard, particularly in the incisal region.[14,15] By observing occlusal spaces after elevation in an articulator, it can be seen that the space between the posterior teeth is smaller, whereas the space between the anterior teeth is larger. Of note, when wearing conventional EVA mouthguards, only a few occlusal points

exist in the posterior region. Long-term use of such mouthguards may lead to irreversible effects, resulting in changes in the occlusal relationship and even temporomandibular joint disorders.

At present, with rapid development of digital technology, the accuracy of design, manufacture, and milling have further improved.[16] However, to the present authors' knowledge, there is no report about the digital design and manufacture of sports mouthguards. Besides accurately controlling the ultimate thickness, these digital mouthguards were individually designed to guarantee uniform centric occlusal contact and no occlusal interference in protrusive and lateral occlusion. The T-scan analysis system was used to test the occlusal condition before and after wearing sports mouthguards. This system can effectively evaluate the distribution of occlusal force and track the central point of occlusal force,[17] which are objective advantages of digital designing. These data suggest that participants' subjective evaluations of occlusal comfort are consistent with T-scan analysis. The relatively higher score of occlusal comfort may be due to the more uniformly distributed occlusal forces in the digital mouthguard group, which was objectively reflected by the T-scan analysis.

The material PEEK used in the present study is an engineered plastic material with excellent mechanical properties, high temperature resistance, chemical corrosion resistance, and good wear resistance.[18] As its mechanical and physical properties are similar to those of cortical bone, enamel, and dentin, PEEK has a wide range of applications in dentistry, including for removable partial dentures, implant abutments, and crowns.[19,20] It is a tooth-colored material and has recently been used as a dental implant material in esthetic dentistry.[19] The thickness of the labial side of the digitally designed and manufactured sports mouthguards was decreased compared to the traditional mouthguards, exerting less impact on participants' lateral profile. This may be one of the reasons for the higher appearance evaluations of the experimental group. Moreover, because the digital data format is stereolithographic, mouthguards can be fabricated with the three-dimensional printing method by using PEEK or other appropriate materials.

Compared to conventional mouthguards, digitally designed and manufactured sports mouthguards significantly simplify the production process, save time and materials (such as impression and gypsum), and would also reduce errors in the transfer process of the impression and gypsum. Furthermore, each individual's digital design information could be stored in a database. Once an old mouthguard is damaged or needs replacement, doctors could retrieve the user's design information from the database at any time to create an identical mouthguard, which is both convenient and efficient. Furthermore, this would significantly decrease the adaptation time for users. If this new method is optimized and applied in clinical practice, it would offer a more feasible and easier way for fabrication of mouthguards. However, there are still certain issues that need further investigation. In a future study, the present authors will expand the sample size and explore more appropriate materials for fabrication of digital sports mouthguards.

CONCLUSIONS

To the present authors' knowledge, this is the first study to successfully establish a complete digital workflow for the design and manufacture of sports mouthguards, improving the occlusal design and material, greatly simplifying the manufacturing process, and saving medical resources. Further improvement of materials in future research will significantly optimize the application of this method in clinical dentistry.

ACKNOWLEDGMENTS

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Literature Abstracts

Evidence-Based Treatment Planning for the Restoration of Endodontically Treated Single Teeth: Importance of Coronal Seal, Post vs No Post, and Indirect vs Direct Restorations

Every orthograde endodontic procedure requires restoration of the coronal (access) cavity. The specific type of treatment used in individual cases greatly depends on the amount and configuration of the residual coronal tooth structure. In practice, there are Class I access cavities, as well as coronally severely damaged, even decapitated, teeth, and all conceivable manifestations in between. The latest attempts to review results from clinical trials to answer the question of whether post placement or crowning can be recommended for the restoration of endodontically treated teeth are inconclusive. For dental practitioners, this is not a satisfactory result. This appraisal evaluates the available evidence and trends for coronal restoration of single endodontically treated teeth with a focus on clinical investigations, when available. It provides specific recommendations for their coronal restoration to assist clinicians in their decision-making and treatment planning.

Atlas A, Grandini S, Martignoni M. *Quintessence Int* 2019;50:772–781. **References:** 53. **Reprints:** Alan Atlas, amatlas@upenn.edu —*Steven Sadowsky, USA*

Long-Term Survival and Peri-Implant Health of Titanium Implants with Zirconia Abutments: A Systematic Review and Meta-Analysis

The aim of this study was to evaluate the long-term implant survival rates of titanium implants with zirconia abutments and the effects on marginal bone loss (MBL) and pocket probing depth (PPD) compared to all-titanium implants. The electronic databases searched were the Cochrane Central Register of Controlled Trials, MEDLINE, EMBASE, and the Chinese Biomedical Literature Database. Two types of studies were included: clinical studies reporting the survival rate of titanium implants with zirconia abutments with a mean/median follow-up of at least 5 years, and clinical trials reporting the effects of implants with zirconia abutments on MBL and PPD compared to all-titanium implants. Two reviewers screened and selected the records, assessed the quality, and extracted the data of included studies independently. This review included 16 studies from 18 publications. None of the comparative studies was assessed as having a low risk of bias. The overall implant survival rate of implants with zirconia abutments was estimated to be 96% (95% CI 94% to 98%, I^2 = 0%). For the comparison between implants with zirconia abutments and all-titanium implants, the results significantly favored implants with zirconia abutments (for MBL, mean difference MD = –0.09, CI –0.17 to 0.00, P = .05, I^2 = 40%; for PPD, MD = –0.18, CI –0.32 to –0.05, P = .008, I^2 = 0%). Zirconia abutments were favored more when the prosthesis was an implant-supported overdenture rather than a single crown. Implants with zirconia abutments may have an acceptable performance on peri-implant health compared to all-titanium implants; however, the implant survival rate of implants with zirconia abutments was slightly lower than all-titanium implants in the long-term follow-up. Additional studies are needed to explain this dichotomy.

Cao Y, Yu C, Wu Y, Li L, Li C. *J Prosthodont* 2019;28:883–892. **References:** 38. **Reprints:** Chunjie Li, lichunjie77@qq.com —*Steven Sadowsky, USA*