Received: 1 March 2023 | Revised: 4 April 2023 | Accepted: 21 April 2023

DOI: 10.1111/jerd.13062

CLINICAL ARTICLE

WILEY

Plaque accumulation on the fitting surface of full-arch implant-supported fixed prostheses with contact or noncontact pontics: A split mouth randomized controlled trial

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Funding information
Capital Health Research and Development of Special Fund, Grant/Award Number: 2018-2-4102; National Program for Multidisciplinary Cooperative Treatment on Major Diseases, Grant/Award Number: PKUSSNMP-201908

Abstract

Objective: To explore the differences in plaque accumulation on the fitting surface of full-arch implant-supported fixed prostheses with contact or noncontact pontics.

Materials and Methods: Nineteen patients (20 prostheses, 7 in the maxilla, and 13 in the mandible) intending to undergo full-arch implant-supported immediate function prostheses were recruited. During immediate restoration and using the midline as the boundary, one side was restored as a pontic and mucosa noncontact type (the test group), and the opposite side was restored as a pontic and mucosa contact type (the control group). In a follow-up 6 months after the surgery, the cleanliness of the fitting surface of the immediate prosthesis was evaluated by plaque staining and debris index determination. Patient satisfaction was investigated by questionnaire.

Results: Twenty prostheses from 19 patients included in the randomized controlled trial were followed up. Among the 20 prostheses, the percentage of area covered with plaque was significantly lower in the test group compared with that in the control group (31.5 ± 15.8% vs. 43.7 ± 15.3%; $p < 0.001$). The debris index in the test group was lower than that in the control group, although the difference was not statistically significant (2.77 ± 0.73 vs. 3.15 ± 0.90; $p > 0.05$). In the patient satisfaction survey, most of the patients were satisfied with most aspects of the prostheses, however, nearly half of the patients were not satisfied with the cleaning.

Conclusions: The pontic and mucosa noncontact prosthetic design reduces plaque accumulation on the fitting surface, which is beneficial for maintaining oral cleanliness. However, the majority of study samples were mandible and conclusions may not be fully applicable to maxilla. Trial registration: www.chictr.org.cn (ChiCTR1900028576).

Clinical Significance: The noncontact design in full-arch implant-supported fixed prostheses may be an effective measure of improving oral hygiene promotion. There is need for more research that can further improve oral hygiene of patients with full-arch implant-supported prostheses.

KEYWORDS
complete, denture, immediate, oral hygiene, prostheses and implants

1 | INTRODUCTION

Studies have shown that poor oral hygiene and plaque accumulation are major risk indicators for peri-implant disease, including peri-implant mucositis, which is characterized by the presence of peri-implant signs of inflammation, and peri-implantitis, the clinical manifestations of which also include peri-implant bone loss.[1–16] Meanwhile, it has been reported that patients who have been totally edentulous or with a terminal dentition for a long time are often unable to cooperate with oral hygiene maintenance at home.[17–21] Therefore , improving the oral cleanliness and reducing plaque accumulation are feasible measures to prevent biological complications for patients with full-arch implant-supported fixed prostheses. However, patients with full-arch implant-supported fixed prostheses have reported difficulties in cleaning the prostheses and maintaining oral hygiene. In addition, there are scarce definite reports on professional and home-care hygiene maintenance methods in the literature.[19,22–25] Currently, the fitting surface of the full-arch implant-supported fixed prostheses (mainly the pontic) is designed to contact the mucosa, while the noncontact design is rarely reported. Previous studies showed that fitting surface of the prostheses in close contact with the mucosa avoids problems with speech, aesthetics, and food-trapping, but impedes effective cleaning.[26,27]

This split-mouth randomized controlled trial was designed to explore the differences in plaque accumulation on the fitting surface of the full-arch implant-supported fixed prostheses with different pontic designs, and provide a basis for the clinical design of easy-to-clean full-arch implant-supported fixed prostheses. The null hypothesis tested was that there would be no differences in the cleanliness of the fitting surface of the immediate prostheses with the two different pontic designs.

2 | MATERIALS AND METHODS

2.1 | Participants

This study performed at the Department of Oral Implantology, Peking University School and Hospital of Stomatology (China) and was conducted according to the principles of the Declaration of Helsinki relating to biomedical research involving human subjects. The study protocol was approved by the local ethics committee (Institutional Review Board of Peking University School and Hospital of Stomatology, Approval Number: PKUSSIRB-201949118) and was registered in the Chinese Clinical Trial Registry (Registration Number: ChiCTR1900028576; Registration Date: December 17, 2019). The study was sponsored by grants from the Capital Health Research and Development Special Project (2018-2-4102) and the National Program for Multidisciplinary Cooperative Treatment on Major Diseases (grant number PKUSSNMP-201908). Nineteen edentulous patients scheduled for full-arch implant-supported fixed prostheses were consecutively enrolled in the study between December 2019 and January 2021. A total of 20 dental arches were enrolled in the study, comprising a single prosthesis in 18 patients (6 in the maxilla and 12 in the mandible) and both maxillary and mandibular prostheses in one patient. After being informed of the purpose of the study and details of the procedures, each participant provided written informed consent. This study was conducted as per the CONSORT clinical trial guidelines and the study flowchart is shown in Figure 1.

Patients included in the study met all of the following inclusion criteria: (1) Patients with edentulous jaw or potential edentulous jaw, requiring full-arch implant-supported fixed prosthesis. (2) Aged over 18 years. (3) In good medical health; nonsmoker and without detrimental lifestyle habits such as excessive alcohol consumption. (4) Enough bone in the maxilla and/or mandible. (5) Sufficient primary stability can be achieved to support immediate prostheses.

Patients were excluded if they fulfilled any of the following exclusion criteria: (1) Severe parafunctional habits (e.g., bruxism or clenching). (3) A psychological or mental illness that affects the patient's daily oral hygiene maintenance. (4) Pregnancy or lactation. (5) Lack of compliance.

A literature review provided insufficient data to compare with the current study. Therefore, the sample size was calculated by the results of the author's previous research results, the percentage plaque area coverage of which were (58.7 ± 20.4)% and (43.0 ± 13.1)%, and the required sample size of each group was 19 cases through the calculation of PASS11 software ($\alpha = 0.05$, power = 0.80). Finally, this study adopted 20 cases (20 half prostheses) in each group.

2.2 | Treatment process

The operation was performed under local anesthesia using aseptic techniques. During the operation, a full-thickness flap was raised at the ridge crest and the sharp alveolar crests were removed to flatten the alveolar ridge and obtain a favorable vertical distance. For each edentulous jaw, four to six implants (Nobel Active, Nobel Biocare, Gothenburg, Sweden; Camlog, Basel, Switzerland) were inserted according to the preoperative plan and the manufacturer's standard guidelines. The two posterior implants were tilted distally approximately 45° relative to the occlusal plane to avoid the maxillary sinus and inferior alveolar nerve. All implants were placed under a final insertion torque >35 N·cm to ensure sufficient primary stability for immediate function. After implant insertion, straight or angulated abutments were applied to the upright or tilted implants to achieve a passive fit for the prosthesis.[28,29]

After the surgery, the immediate prostheses should be implanted by the same prosthodontist within 6 h. Open-tray multiunit impression transfer copings (Nobel Biocare, Gothenburg, Sweden; Camlog, Basel, Switzerland) were fastened to the abutments with screws and connected with self-curing composite resin materials (DMG, Hamburg, Germany). The pick-up technique was used to take impressions with silicone elastomeric material. Vertical dimensions were recorded and bite registrations were taken after removing the impression transfer copings. Implant-supported immediate prostheses (10–12 teeth) constructed from acrylic resin (Cold-Curing Acrylics, Vertex-Dental,

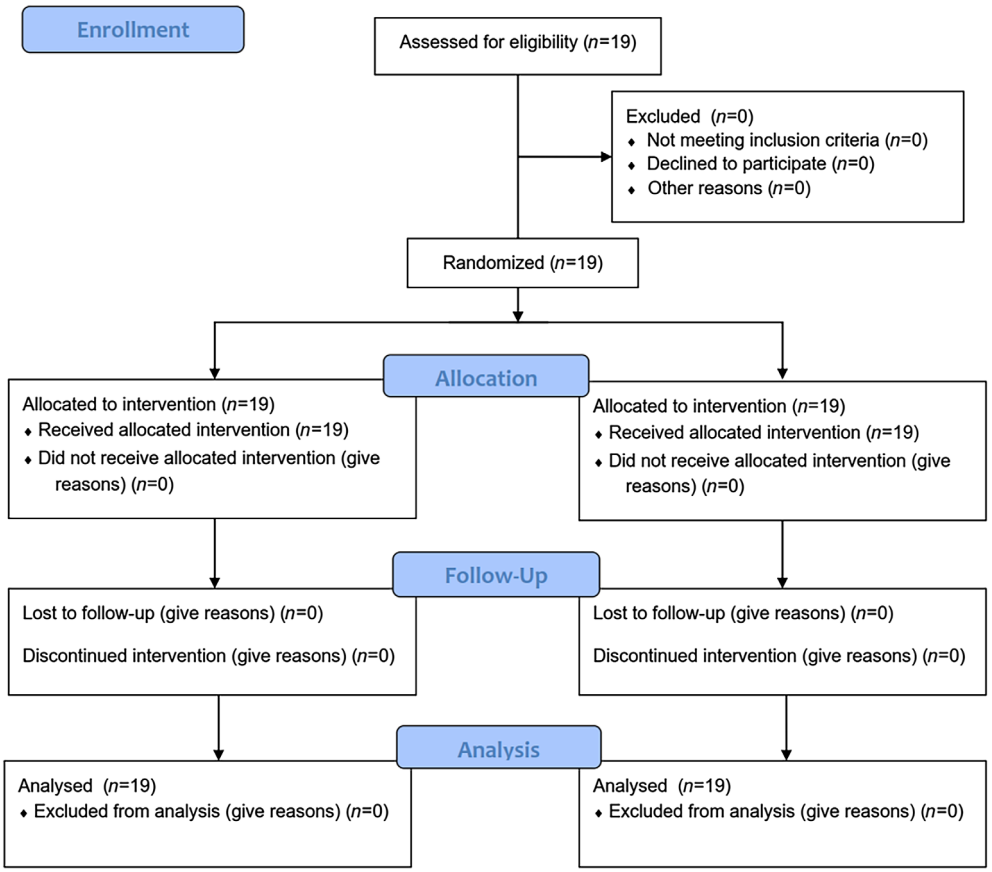

FIGURE 1 CONSORT 2010 flow diagram.

Soesterberg, Netherlands) with titanium cylinders were manufactured at the dental laboratory. The fitting surface of the pontic was slightly convex shape towards the alveolar ridge, with cleaning gaps reserved on both sides of the abutment to facilitate cleaning. Using the midline as the boundary, the left and the right sides of the prosthesis were randomly assigned to the test and control groups by coin toss, respectively. If the coin faced up, the left side of the prosthesis was constructed using a pontic and mucosa contact type design (the control group), and the right side of the prosthesis was constructed using a pontic and mucosa noncontact type design (the test group), with a 2 mm gap between the fitting surface of the bridge and the alveolar mucosa (Figure 2). And vice versa.

After immediate restoration, patients were instructed in aspects of oral hygiene instructions. The patients were instructed to maintain a soft food diet for the first 3 months postrestoration. All patients were scheduled for follow-up examinations at 2 weeks, 3 months, and 6 months after immediate restoration. The final prosthesis was typically fabricated at 6 months postsurgery and immediate restoration.[30,31]

2.3 | Follow-up and measures

For participants with full-arch implant-supported fixed prostheses, the immediate prostheses were removed during the follow-up at 6 months post-surgery when impressions were obtained for the

FIGURE 2 Design of the immediate prostheses.

construction of the definitive prostheses. After confirming that the prosthetic and abutment screws were not loose, the oral mucosa and abutments, as well as the debris and calculus on the fitting surface of the prostheses were photographed using a digital camera (Canon DS126321, Canon Incorporated, Tokyo, Japan; Figure 3).

With the midline as the boundary, the debris and calculus on the fitting surface of the prosthesis and oral mucosa were evaluated using the clinical photos. An evaluation indicator, the debris index, was used to quantitatively describe the amount of debris in the edentulous alveolar mucosa and the fitting surface of the prostheses. It was

modified from the simplified debris index (DI-S) proposed by Greene and Vermillion.[32] The debris index was classified as follows: 0 = no debris or coloring; 1 = scattered plaques on the fitting surface of the prostheses or alveolar mucosa (around the abutment); 2 = thin (≤1 mm) continuous bands of plaque on the fitting surface of the prostheses or alveolar mucosa (around the abutment); 3 = debris coverage ≤1/3 of the total area; 4 = debris coverage 1/3–2/3 of the total area; and 5 = debris coverage >2/3 of the total area.

After removing the prostheses, the fitting surface were rinsed with tap water for 60 s before being stained with a plaque-disclosing agent (methylene blue). The prostheses were then rinsed again with running water for 60 s and fixed in the same container using ultralight clay. The prostheses were then photographed at a fixed distance under conditions that were identical to those used to obtain the previous set of images.[3,26,33]

Image processing software (PowerPoint 2019, Microsoft, Redmond, WA, USA) was used to delete the background of the photo after plaque staining, and only the fitting surface of the prosthesis was retained (Figure 4A,B). Using the midline as the boundary, the fitting surface was divided into left and right sides before the photo was converted to a monochromatic binary image through Image J 1.52 V software (National Institutes of Health, Bethesda, MD, USA; Figure 4C). By adjusting the threshold value, the stained and unstained parts of the plaque appeared black and white, respectively (Figure 4D). The plaque coverage as percentage of the total area of the fitting surface of the prostheses was calculated using these images.

Patient satisfaction with the implant and its function were surveyed by using a questionnaire (seven questions) covering the subjective opinion and overall satisfaction of edentulous patients regarding chewing, comfort, aesthetics, convenience, cleanliness, speech. For each question, patient satisfaction was classified as follows: none, slight, medium, high, and very high.

FIGURE 3 Debris on the fitting surface of the prosthesis.

2.4 | Statistical analysis

Statistical analysis was carried out via software SPSS 25.0 for Windows (IBM Corporation, Chicago, IL, USA). Descriptive statistics were calculated by determining mean values ± standard deviation (SD). Clinical data were analyzed by paired-samples *t*-test, and $p < 0.05$ was set as the threshold for statistical significance.

3 | RESULTS

All 19 patients (20 immediate prostheses, 40 half prostheses) who received full-arch implant-supported fixed prostheses in this study completed the follow-up. Among them, 11 were males and 8 were females, with an average age of 63.4 ± 11.3 years (range 43–

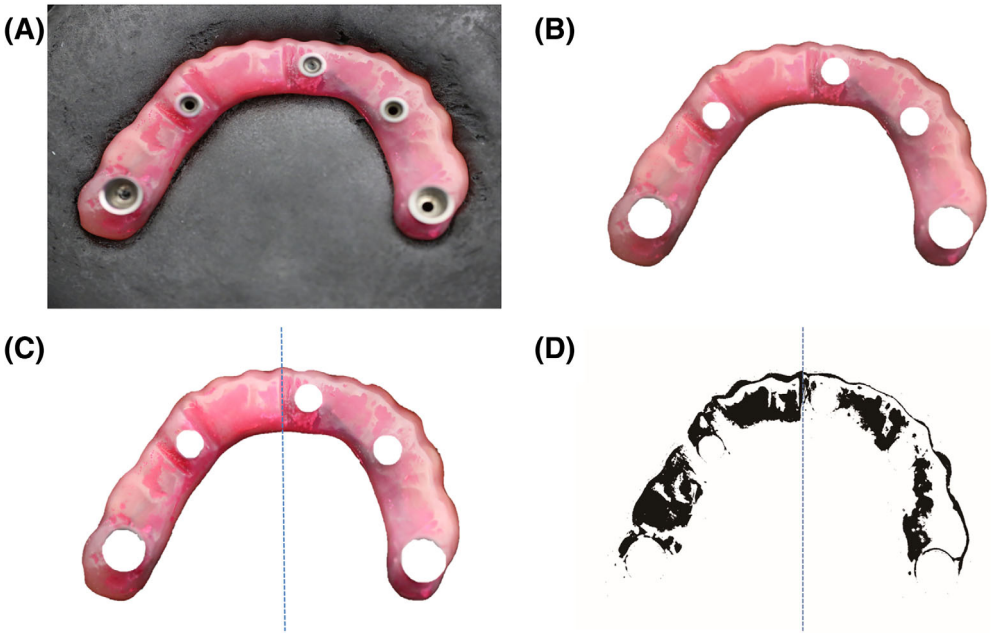

FIGURE 4 Evaluation process of plaque accumulation on the fitting surface of the prostheses. (A) The original photograph; (B) The image after deleting the background; (C) Dividing the image into left and right parts; (D) Converting the image to a monochromatic binary image, and calculating the percentage of plaque area.

79 years). A total of 20 prostheses (7 maxillary and 13 mandibular) were included in the study.

The 6-month survival rate of all implants was 100%. All 20 immediate prostheses were in good condition and functioned normally, with no loosening or mechanical complications during the follow-up period. For the 20 prostheses, the debris indexes of the fitting surface and the alveolar mucosa were 2.96 ± 0.82 and 1.38 ± 0.64, respectively. And the mean plaque coverage as a percentage of the total fitting surface were (38.1 ± 17.2)%.

The debris index of the fitting surface of the control group (3.15 ± 0.90) was higher than that of the test group (2.77 ± 0.73), although the difference did not reach the level of statistical significance ($p > 0.05$; Table 1). The percentage plaque area coverage of the fitting surface in the control group was significantly higher than that in the test group ([43.7 ± 15.3]% vs. [31.5 ± 15.8]%; $p < 0.001$; Table 2). There was no significant difference in the debris index of the alveolar mucosa between the test and the control groups ($p > 0.05$; Table 3).

Comparisons of the maxillary and mandibular prostheses showed that the percentage plaque coverage was significantly lower in the test group than that in the control group ($p < 0.05$; Table 4). However, there was no significant difference in debris index (both on the fitting surface and alveolar mucosa) between the two groups.

All patients completed the 7-item questionnaire on patient satisfaction and hygiene maintenance of their prostheses. The results of the questionnaire are shown in Table 5. All of the patients reported high or very high satisfaction with the prostheses in chewing, comfort, convenience and the overall aspects. However, more than half of the patients (57.9%) did not report high or very high satisfaction with cleanliness. Meanwhile, three patients (15.8%) thought that the satisfaction with speech was not high after wearing the prostheses.

4 | DISCUSSION

The present study compared the cleanliness of the fitting surface of the immediate prostheses with the two different pontic designs. The null hypothesis could be rejected only for the percentage plaque area coverage of the fitting surface.

In this study, the author used the method of plaque staining described in previous studies to calculate the percentage of plaque coverage on the fitting surface.[3,26,33] However, the author further

TABLE 1 The debris index on the fitting surface of prostheses.

Group	Number of cases	Debris index (mean ± SD)	*t*	*p*
Test	20	2.68 ± 0.70	−2.371	0.07
Control	20	3.06 ± 0.85		

Abbreviation: SD, standard deviation.

TABLE 2 The percentage plaque area covering the fitting surface of the prostheses.

Group	Number of cases	Plaque area covering the fitting surface of the prostheses (%; mean ± SD)	*t*	*p*
Test	20	31.5 ± 15.8	−8.199	<0.001
Control	20	43.7 ± 15.3		

Abbreviation: SD, standard deviation.

TABLE 3 The debris index on the alveolar mucosa.

Group	Number of cases	Debris index (mean ± SD)	*t*	*p*
Test	20	1.19 ± 0.40	−2.087	0.054
Control	20	1.56 ± 0.73		

Abbreviation: SD, standard deviation.

TABLE 4 The percentage plaque area covering the fitting surface of the prostheses.

	Group	Number of cases	Plaque area covering the fitting surface of the prostheses (%; mean ± SD)	*t*	*p*
Maxillary	Test	7	34.5 ± 18.4	−3.836	0.012
	Control	7	48.0 ± 18.5		
Mandible	Test	13	29.8 ± 14.9	−8.058	<0.001
	Control	13	41.4 ± 13.7		

Abbreviation: SD, standard deviation.

TABLE 5 The results of the patient satisfaction.

Questions	None	Slight	Medium	High	Very high
Q1 (chewing)	0/19	0/19	0/19	2/19 (10.5%)	17/19 (89.5%)
Q2 (comfort)	0/19	0/19	0/19	5/19 (26.3%)	14/19 (73.7%)
Q3 (aesthetics)	0/19	0/19	1/19 (5.3%)	2/19 (10.5%)	16/19 (84.2%)
Q4 (convenience)	0/19	0/19	0/19	4/19 (21.1%)	15/19 (78.9%)
Q5 (cleanliness)	0/19	0/19	11/19 (57.9%)	5/19 (26.3%)	3/19 (15.8%)
Q6 (speech)	0/19	1/19 (5.3%)	2/19 (10.5%)	10 /19 (52.6%)	6/19 (31.6%)
Q7 (overall)	0/19	0/19	0/19	7/19 (36.8%)	12/19 (63.2%)

standardized this approach by using ultra-light clay to hold the restoration in the same container and taking all the photographs with the same camera and parameters, thus reducing system error and providing more accurate and reliable results. Although there are many 3D evaluation methods, the application of 3D method to plaque coverage assessment has not been reported.

Peri-implant accessibility (ease of cleaning) has been reported to be associated with peri-implantitis.[14] It has also been reported that placing small notches on specific sites in a full-arch implant-supported fixed prosthesis so that patients can see the sites requiring cleaning contributes to plaque control and long-term peri-implant health.[19] However, the author's previous study showed more plaque accumulation at these specific sites than other parts of the fitting surface, which was contrary to the original intention of the notching sites.[34] Such plaque accumulation may be related to the gap height between the fitting surface and the mucosa, with a narrow gap limiting access for oral hygiene. In this prospective study, the author conducted a split-mouth randomized controlled trial of plaque accumulation on the fitting surface of full-arch implant-supported fixed prostheses with contact or noncontact pontics incorporating a 2-mm gap between the fitting surface and the mucosa. It has been found that the percentage plaque coverage on the fitting surface of the test group (pontic and mucosa noncontact type) was lower than that of the control group (pontic and mucosa contact type), and the same was true for the maxillary and mandible prostheses. These findings provide evidence that the noncontact type design is conducive to self-cleaning, and reducing plaque accumulation on the fitting surface. This effect is similar to that achieved with the "sanitary bridge" design in traditional fixed bridge, and indicate that the noncontact design could improve the cleanliness of the prosthesis. However, the effectiveness of this design when applied to the definitive prostheses and its long-term effects remain to be clarified.

The pontic and mucosa noncontact design of full-arch implant-supported fixed prostheses has been reported to cause speech and aesthetic problems.[26] However, other studies have shown that patients using this type of prostheses can learn to reduce air leakage by increasing lip pressure to mitigate speech problems. [27,35] And yet, the issue of patient satisfaction has not yet been systematically investigated. In this prospective study, the survey of patient satisfaction revealed that three patients (all maxilla) had problems with speech, mainly manifested as air leakage. In combination with clinical visual observation, the survey also showed that the noncontact full-arch implant-supported fixed prostheses had little effect on aesthetics, which may be due to the fact that these patients usually require osteotomy during the operation, resulting in a bone height that is lower than the smile line. Thus, this study indicates that the pontic and mucosa noncontact type of full-arch implant-supported fixed prostheses is conducive to maintain oral hygiene without significant increase in the risk of speech and aesthetic problems. However, for patients with edentulous maxilla, careful consideration should be given to using this design in case of speech problems. In addition, more than half of the patients (57.9%) thought that they could not achieve satisfactory results in terms of cleaning, which is also the main problem that this study aims to solve.

This study conducted a split-mouth pilot study on the design of immediate prostheses, using a noncontact pontic design to explore whether it can reduce plaque accumulation and improve cleanliness. However, the following limitations of this study should be noted. This study investigated only temporary prostheses and did not include definitive prostheses, resulting in a limited observation time. The majority of study samples were mandible and conclusions may not be fully applicable to maxilla. Different denture materials may also have an effect on plaque accumulation.[36] In this study, only acrylic resin was used, and other materials, such as titanium and zirconia, were not compared. Pronunciation tests were not conducted in this study, which may lead to inaccurate evaluation of patients' speech function. Other factors such as the degree of polishing may also have an impact on oral hygiene. Further studies with a larger sample size, longer observation time, and more comprehensive evaluation of factors related to the use of full-arch implant-supported fixed prostheses are required to improve outcomes and provide detailed evidence on this topic. The influence of different denture materials also needs to be considered in the future. Pronunciation also needs to be evaluated in more accurate methods, such as involving a speech therapist, rather than just through questionnaires.

5 | CONCLUSIONS

Within the limitations of this clinical study, it may be concluded that the pontic and mucosa noncontact design reduces the accumulation of plaque on the prosthesis fitting surface, which might improve the oral hygiene of patients. However, the majority of study samples

were mandible and conclusions may not be fully applicable to maxilla. The effect of this design on pronunciation also needs further study.

AUTHOR CONTRIBUTIONS

Zhenjiang Gong: Investigation, statistics, data collection, data analysis, data interpretation, drafting article. **Ye Lin:** Concept, critical revision of article, approval of article. **Ping Di:** Concept, design, resources, critical revision of article, approval of article.

ACKNOWLEDGEMENTS AND DISCLOSURE

The authors thank Capital Health Research and Development Special Project (grant number 2018-2-4102) and the National Program for Multidisciplinary Cooperative Treatment on Major Diseases (grant number PKUSSNMP-201908) for their support. The authors thank Mr. Qiang Hao, the dental technician from the Department of Oral Implantology at Peking University School and Hospital of Stomatology in Beijing for his lab work. The authors thank Mrs. Di Xu and Yachun He from the Department of Oral Implantology at Peking University School and Hospital of Stomatology in Beijing for coordination and assistance during the study. The authors do not have any financial interest in the companies whose materials are included in this article.

FUNDING INFORMATION

This study was supported by the Capital Health Research and Development Special Project (grant number 2018-2-4102) and the National Program for Multidisciplinary Cooperative Treatment on Major Diseases (grant number PKUSSNMP-201908).

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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How to cite this article: Gong Z, Lin Y, Di P. Plaque accumulation on the fitting surface of full-arch implant-supported fixed prostheses with contact or noncontact pontics: A split mouth randomized controlled trial. *J Esthet Restor Dent*. 2023;35(7):1077-1084. doi:10.1111/jerd.13062