

# A randomized trial of the effectiveness of an ultrasonic denture hygiene intervention program among community-dwelling elders\*

## Purpose

This study aimed to assess the effectiveness of ultrasonic denture hygiene interventions in improving denture cleanliness among elderly individuals.

## Materials and Methods

Sixty-six participants who had received upper metal framework removable partial dentures within the past 5 years were randomly allocated into three denture hygiene intervention groups: group 1 (mechanical cleaning with a toothbrush and ultrasonic cleaning with cetylpyridinium chloride), group 2 (mechanical cleaning with a toothbrush and ultrasonic cleaning with distilled water), and control (mechanical cleaning with a toothbrush only). Denture cleanliness was assessed at baseline and 1-month using: i) Denture Cleanliness Index (DCI) scores; ii) plaque coverage percentage; and (iii) microbiological samples for bacterial and yeast detection. Differences between groups were assessed with one-way analysis of variance and Chi-squared tests.

## Results

Mean DCI scores and mean percentages of plaque coverage area were significantly reduced in group 1 and group 2, compared to the control group for both cobalt chromium (CoCr) and acrylic fitting surfaces ( $p < 0.001$ ). No significant differences were found between groups 1 and 2 with regard to the prevalence and viable counts of yeasts or total microbial viable counts. No significant differences in the investigated clinical and microbiological parameters were observed between CoCr and acrylic surfaces following the intervention period.

## Conclusion

The ultrasonic cleaner was significantly more effective than mechanical cleaning in the reduction of biofilm coverage on metal framework removable partial dentures over a 1-month intervention period. Nevertheless, the adjunctive use of cetylpyridinium chloride with ultrasonic cleaning did not yield additional benefits.

**Keywords:** Cetylpyridinium, Denture cleansers, Plaque, Randomized controlled trial, Ultrasonic

## Introduction

Tooth loss is very common amongst elders in Hong Kong. Approximately 60% of non-institutionalized elderly (65 to 74 years old) have dental prostheses and over a third wear removable partial dentures (RPDs) (1). Denture hygiene has been increasingly recognized as a public health concern, especially with elders who, for diverse reasons, have difficulties in maintaining denture hygiene. The loss of manual dexterity, long-term diseases such as dementia, and lack of knowledge or guidance on proper cleaning methods are commonly cited factors (2, 3). The lack of regular oral hygiene practices not only leads to a build-up of dental plaque and

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periodontal disease, but also to the establishment of an oral reservoir of respiratory pathogens (4).

As such, the large majority of studies on oral health interventions have been targeted at improving oral care and the cleaning of the existing dentition with a wide range of mechanical oral hygiene aids such as electric toothbrushes, as well as chemotherapeutic agents delivered in the form of mouthrinses, sprays, and gels (5-8). A systematic review reported a lack of evidence, particularly in terms of randomized controlled trials, regarding the comparative effectiveness of mechanical or chemical methods to clean dentures (9). Additionally, all retrieved studies pertained to acrylic complete dentures worn by edentulous patients, and no study investigated cleaning methods for RPDs with metallic components. The latter is not suitable for cleansing with microwave irradiation or soaking in bleach, which have been suggested for the complete sterilization of complete acrylic dentures (10). Cruz *et al.* (11) published a clinical trial on ultrasonic denture cleaning and found a significant reduction in the percentage of biofilm coverage area compared to the control group; however, this study only assessed acrylic complete dentures. Currently, there is a lack of clinical studies assessing denture cleaning methods for partial dentures, especially those with a metallic framework.

The aim of this study was to investigate the effectiveness of a denture hygiene program using a combination of ultrasonic mechanical cleaning and an antiseptic agent (cetylpyridinium chloride [CPC]). Ultrasonic cleaning provides a mechanical cavitation effect which loosens and removes adherent microbial biofilms (10). CPC is a quaternary ammonium compound with established antimicrobial properties and has a long track record of *in vivo* use as a mouthrinse (12). While previous *in vitro* studies have demonstrated its compatibility with RPDs incorporating metal components such as frameworks and clasps, the utility of CPC as a denture cleanser in combination with ultrasonic cleaning has not yet been investigated (13).

The objective of this study was to compare the effectiveness of three denture hygiene interventions: (1) ultrasonic cleaning with 0.07% CPC, (2) ultrasonic cleaning with distilled water, and (3) mechanical cleaning with a soft toothbrush and liquid detergent [Control group] in improving denture cleanliness among community-dwelling elders over a 1-month period. The secondary objectives were to evaluate changes in microbial levels and to compare the effects of the interventions on acrylic and metallic denture fitting surfaces. The null hypotheses were that there would be no differences in denture cleanliness or microbial levels between the three intervention groups, as well as no differences in outcomes between acrylic and metallic denture surfaces.

## Material and Methods

### Ethical statement

The protocol for this randomized controlled single-blind trial was approved by the Institutional Review Board of the University of Hong Kong (approval number UW 16-266).

### Sample size estimation

Denture plaque was the primary outcome variable in this study. Based on 80% power, a statistical significance level set at 0.05, and a previously documented mean plaque coverage score of 28.11 (standard deviation=19.64), we determined that 20 patients were required in each group to detect a 20% difference in denture plaque coverage scores among groups (14). Taking into account an anticipated 10% dropout rate, the proposed sample size was 66 participants (22 per group) (14).

### Study population

The study population comprised elders aged 65 years old or above who were previously provided with cobalt chromium (CoCr) RPDs within the past 5 years at a dental hospital. A full list of patients meeting these inclusion criteria was generated from the computerized patient database. A total of 66 patients were selected by random sampling; these patients were contacted by letter and telephone and invited to undergo a clinical examination. Written informed consent was obtained, and ethics approval was granted by the appropriate institutional review board.

### Study protocol

The baseline and 1-month review examinations included assessments of oral health and denture cleanliness. Denture cleanliness was assessed clinically and microbiologically by a single assessor, who was blinded to treatment allocation and not involved in the provision of denture hygiene instructions (conducted by a research assistant). Intra-examiner reproducibility was determined in a randomly selected subset (10%) of participants. A basic intra-oral examination was conducted and recorded with dental charts. Dental plaque levels and gingival status were assessed with the Silness and Løe Plaque Index (PI) and the Gingival Bleeding Index (GBI), respectively (15, 16). Dental caries (DMFT index) and periodontal status (Community Periodontal Index [CPI]) were assessed in accordance with World Health Organization guidelines (17). Sociodemographic characteristics and baseline PI, GBI, DMFT, and CPI scores were compared among groups to confirm the absence of bias in the randomization process.

Denture cleanliness was assessed both qualitatively and quantitatively. Qualitative assessment comprised disclosing denture plaque on the fitting surface with a plaque disclosing agent (GUM® Red-Cote® Liquid; Sunstar Americas, Inc., Chicago, IL, USA) and rating the denture according to Denture Cleanliness Index (DCI) criteria (18). The DCI score was graded by visual assessment of the stained area of the denture fitting surface. CoCr frameworks and acrylic saddles were graded separately. Quantitative analysis of denture cleanliness was determined by obtaining photographic images for planimetric assessment (4). Images of the dentures were captured by a digital camera (Nikon D80 AF-S Nikkor 60mmf/2.8G ED, Nikon Inc., Tokyo, Japan) with a fixed manual setting (aperture F29; exposure time 1/100 ISO 125). The film-object distance was standardized by a camera stand. Plaque coverage of the fitting surfaces was quantitatively determined with Adobe Photoshop® (CC2014: Adobe Sys-

tems Inc., San Jose, CA). In brief, the JPG file of each denture image was opened, and a "magnetic lasso" tool used to outline the margin of the CoCr framework, which was cut and pasted to a new file. The "magic wand" tool was used to select the plaque-stained area (threshold 30), and this was copied and pasted to a new file. The percentage of plaque coverage area was determined by total plaque pixels/total denture surface pixels. The same procedures (steps 1–4) were repeated for the acrylic saddles.

The imprint technique was used to obtain microbiological samples from denture fitting surfaces (19, 20). In brief, (2.0 x 2.0 cm) and (0.5 x 0.5 cm) sterile foam pads were pressed to the denture fitting surface of the CoCr major connector and acrylic resin saddle for 60 seconds. Imprint samples were then transferred to tubes containing 10 mL saline, vortexed, and spiral plated on Sabouraud agar (yeast) and blood agar (total microbial count). Colony-forming units (CFU) were enumerated for all samples, and pure cultures were obtained for storage (-70°C) and subsequent identification. Pure cultures were identified by colony morphology, Gram stain, and commercial identification kits (ID32C [bioMerieux Vitek; Hazelwood, MO, USA]).

#### *Cleaning protocols*

Following baseline assessments, participants were randomly allocated to one of three groups: Group 1 (Mechanical cleaning of the RPD with a soft toothbrush and liquid detergent, plus ultrasonic cleaning [42 kHz] for 7 min and 30 s with 0.07% CPC mouthrinse [Oral-B® Pro-Health™; Boston, MA, USA], once daily); Group 2 (Mechanical cleaning with a soft toothbrush and liquid detergent and ultrasonic cleaning [42 kHz] for 7 min and 30 s with distilled water, once daily); and Group 3 (Control group, mechanical cleaning with a soft toothbrush and liquid detergent, once daily).

Randomization (block randomization; random number table; sequentially numbered, sealed, opaque envelopes) was performed by a research assistant who was not involved in the clinical assessment of outcome measures. Participants were provided with verbal and written denture hygiene instructions. Customized oral hygiene instructions for participants' remaining natural dentition were provided on a one-to-one basis. The principal investigator conducting the clinical assessments was blinded to treatment group allocation. A manual toothbrush and standard sodium fluoride toothpaste were provided to participants in all groups.

#### *Statistical analysis*

Changes in continuous variables within groups from baseline to 1 month were analyzed by two-way analysis of variance (ANOVA) and paired t-tests (or nonparametric equivalent); a complete case analysis was performed. One-way ANOVA and two-sample t-tests (or nonparametric equivalent) were used to investigate differences between the three intervention groups. Comparisons of categorical variables between the three intervention groups were performed with Chi-squared tests, while changes within groups from baseline to 1 month were identified with the Cochran Q test. Multiple linear regression analyses were used to evaluate potential independent factors associated with continuous

variables and categorical variables at baseline and 1 month. All analyses were conducted with the Statistical Package for Social Sciences (SPSS) for Windows software, version 16.0 (SPSS Inc., Chicago, IL, USA).

## **Results**

During the recruitment period, a total of 84 patients were contacted by phone; 19 patients declined to participate in the study, citing reasons such as time conflicts due to employment, disabilities affecting mobility, and lack of interest. Three patients did not meet inclusion criteria. A total of 66 patients (48 female; 18 male) were recruited at baseline examination and randomly allocated into one of three groups. Two patients dropped out prior to the 1-month review. One patient reported that she could not operate the ultrasonic cleaner. Another subject did not return for review due to time conflicts. The mean age of the patients was  $66.97 \pm 6.91$  years, and the average denture service life was  $19.05 \pm 5.63$  months. There was a significantly higher percentage of females (90.9%) than males in Group 3. There were no significant differences in age, mean denture service life, Kennedy classification type, PI scores, DMFT, CPI, or loss of attachment (LOA) between groups at baseline.

#### *DCI assessment*

The mean DCI scores on CoCr major connectors were not significantly different between groups at baseline (Table 1). Within-group comparisons found significantly lower mean DCI scores at review compared to baseline, for both groups 1 and 2 ( $p < 0.001$ ). A significantly higher mean DCI score at review was found in group 3 ( $2.09 \pm 0.75$ ) compared to group 2 ( $1.15 \pm 0.37$ ) and group 1 ( $1.14 \pm 0.56$ ) ( $p < 0.001$ ), while no significant differences were noted between groups 1 and 2. Group 1 ( $1.45 \pm 0.86$ ) and group 2 ( $1.00 \pm 0.86$ ) had significantly larger mean DCI change scores than group 3 ( $0.23 \pm 0.68$ ;  $p < 0.001$ ) (Table 1).

The mean DCI scores on acrylic saddles did not show significant differences at baseline between groups ( $p = 0.189$ ). Significantly lower mean DCI scores were observed on review compared to baseline in both groups 1 ( $p < 0.001$ ) and 2 ( $p < 0.001$ ). At review, group 3 ( $1.95 \pm 0.72$ ) demonstrated significantly higher mean scores than group 1 ( $1.09 \pm 0.53$ ) and group 2 ( $1.15 \pm 0.59$ ) ( $p < 0.001$ ). Mean DCI change scores in group 1 ( $1.68 \pm 0.95$ ) and group 2 ( $1.20 \pm 1.01$ ) were significantly higher than that in group 3 ( $0.36 \pm 0.79$ ;  $p < 0.001$ ). There were no significant differences in mean DCI scores between CoCr major connectors and acrylic saddles within groups at either baseline or review. Mean change scores were not significantly different between CoCr and acrylic surfaces in any of the three groups.

Factors assessed for association with DCI scores of CoCr major connectors included age, sex, denture wearing time, PI and BI at baseline, DMFT, CPI, LOA, patient compliance, Kennedy classification of dentures, yeasts, DCI scores and plaque coverage percentage. Multiple linear regression analyses identified that denture wearing time ( $p = 0.014$ ) and CPI scores ( $p = 0.025$ ) were significantly associated with DCI scores at baseline. After the clinical trial, however, only interventions 1 and 2 ( $p < 0.001$ ), DCI scores at baseline

( $p < 0.001$ ), and the presence of yeast on CoCr ( $p = 0.024$ ) were significantly associated with 1-month DCI scores (adjusted  $R^2 = 0.53$ ). DCI scores (on acrylic) were not significantly associated with any of the investigated factors at baseline; interventions 1 and 2 ( $p < 0.001$ ) were significantly associated with 1-month DCI scores (adjusted  $R^2 = 0.38$ ).

#### Plaque coverage scores

At baseline, the mean percentage of plaque coverage on CoCr major connectors was not significantly different among the three groups ( $p = 0.596$ ) (Table 2). All three groups demonstrated a significant reduction in mean plaque coverage scores at review compared to baseline ( $p < 0.05$ ). A significantly lower mean plaque coverage score was found in group 1 ( $17.89 \pm 12.9$ ) and 2 ( $16.22 \pm 9.22$ ) compared to group 3 on review ( $39.60 \pm 20.68$ ;  $p < 0.001$ ). Mean changes in plaque coverage scores in group 1 ( $28.70 \pm 16.59$ ) and group 2 ( $22.79 \pm 17.88$ ) were significantly greater than in group 3 ( $8.3 \pm 11.39$ ;  $p < 0.001$ ). No significant differences were observed between groups 1 and 2.

There were no significant differences in mean plaque coverage scores among acrylic saddles, between groups at baseline (Table 2). Within-group comparisons found significantly lower mean plaque coverage scores at review compared to baseline, for all three groups ( $p < 0.05$ ). At review, the mean percentages in group 1 ( $19.33 \pm 12.34$ ) and group 2 ( $17.82 \pm 10.09$ ) were significantly lower than group 3 ( $38.83 \pm 17.96$ ;  $p < 0.001$ ). Mean plaque coverage change scores were significantly higher in group 1 ( $34.98 \pm 24.11$ ) and 2 ( $28.40 \pm 22.58$ ), compared to group 3 ( $5.21 \pm 11.23$ ;  $p < 0.001$ ). Comparisons of mean plaque coverage scores between CoCr and acrylic surfaces did not yield significant differences within groups at baseline and review, or in the change scores between groups. BI ( $p = 0.039$ ) and DMFT ( $p = 0.049$ ) were significantly associated with plaque coverage percentage on CoCr major connectors at baseline; only interventions 1 and 2 ( $p < 0.001$ ) and plaque coverage percentage (baseline) remained significant in the final model at review (adjusted  $R^2 = 0.64$ ). None of the investigated factors were significantly associated with plaque coverage percentage on acrylic at baseline; plaque coverage percentage at 1

month was associated with interventions 1 and 2 ( $p < 0.001$ ), as well as plaque percentage coverage at baseline ( $p = 0.006$ ; adjusted  $R^2 = 0.38$ ).

#### Microbiological assessments

Median microbial viable counts (CFU/mL) on CoCr surfaces were significantly lower at review compared to baseline in group 1 ( $p = 0.009$ ) and group 2 ( $p < 0.001$ ); no significant differences were observed in group 3 ( $p = 0.097$ ). No significant differences were found between groups with respect to changes in microbial viable counts from baseline to 1 month ( $p = 0.259$ ). No significant differences were observed when comparing median microbial viable counts (CFU/mL) on CoCr surfaces between groups at baseline ( $p = 0.940$ ) or review ( $p = 0.842$ ). Group 1 demonstrated significantly lower mean yeast viable counts (CFU/mL) at 1-month review compared to baseline ( $p = 0.004$ ). There were no significant differences in mean yeast viable count change scores between groups. Acrylic saddles in group 1 ( $p = 0.019$ ) and group 2 ( $p < 0.001$ ) exhibited a significant reduction in microbial viable counts (CFU/mL) at 1 month compared to baseline. No significant difference was found in group 3 ( $p = 0.153$ ). There were no significant differences between groups in median CFU/mL at baseline ( $p = 0.539$ ) and after 1 month ( $p = 0.665$ ). Reductions in microbial viable counts were significantly greater in group 2 compared to group 3 ( $p = 0.047$ ). There were no significant differences in microbial viable counts on CoCr compared to acrylic surfaces, with the exception of a higher median CFU/mL on acrylic surfaces in Group 2 at baseline ( $p = 0.035$ ). No significant differences were observed at review.

#### Patient compliance

Just over half ( $n = 38$ ) of the subjects remembered to submit their log diary, in which they had documented their denture cleaning schedule, at the review appointment. All submitted log diaries reflected a strict compliance to daily denture cleaning, according to the proposed protocol. Of those participants who forgot to return their diary, nearly 80% ( $n = 51$ ) reported that they had cleaned their dentures

**Table 1.** Comparison of DCI scores between CoCr and acrylic surfaces among and within groups [mean (SD)].

	N=64	Group 1 N=22	Group 2 N=20	Group 3 N=22	p-value <sup>†</sup>	Multiple comparisons
	Mean (SD)					
CoCr surfaces	DCI (baseline)	2.59 (0.91)	2.27 (0.94)	2.32 (0.89)	0.462	
	DCI (review)	1.14 (0.56)	1.15 (0.37)	2.09 (0.75)	$P < 0.001$	(1)=(2)<(3)
	p-value <sup>†</sup>	$P < 0.001$	$P < 0.001$	0.135		
	DCI change score	1.45 (0.86)	1.00 (0.86)	0.23 (0.68)	$P < 0.001$	(1)=(2)>(3)
Acrylic surfaces	DCI (baseline)	2.77 (0.75)	2.45 (0.80)	2.32 (0.95)	0.189	
	DCI (review)	1.09 (0.53)	1.15 (0.59)	1.95 (0.72)	$P < 0.001$	(1)=(2)<(3)
	p-value <sup>†</sup>	$P < 0.001$	$P < 0.001$	0.062		
	DCI change score	1.68 (0.95)	1.20 (1.01)	0.36 (0.79)	$P < 0.001$	(1)=(2)>(3)

One-way analysis of variance<sup>‡</sup>; Paired-Samples T test<sup>†</sup>; SD, standard deviation; CoCr, cobalt chromium; DCI, Denture Cleanliness Index; N, number of patients; Group 1, mechanical cleaning with a toothbrush and ultrasonic cleaning with cetylpyridinium chloride; Group 2, mechanical cleaning with a toothbrush and ultrasonic cleaning with distilled water; Group 3, mechanical cleaning with a toothbrush only.

every day. The common reasons for poor compliance for the rest of the subjects included travelling away from home during the intervention period, or being too busy or indifferent to do so. The majority of participants (95.24%) who received ultrasonic cleaners reported that they were satisfied with them. They felt that the cleaners were quiet and effective, and some participants commented that they “felt good” when they saw debris dislodged from the dentures during the cleaning process. Negative comments were mainly related to the time-consuming operating procedure of the ultrasonic units, while a few (n=3) participants in group 1 who used the ultrasonic cleaner together with the mouthrinse (0.07% CPC) reported the noticeable accumulation of dark stains on the dentures.

### Discussion

This study addressed the lack of evidence regarding the effectiveness of denture cleaning methods on partial dentures, especially those with a metallic framework. The results suggested that ultrasonic cleaning was significantly more effective than the control (cleaning with a soft toothbrush and liquid detergent) in the reduction of biofilm coverage on metal framework RPDs over a 1-month intervention period. The adjunctive use of CPC with ultrasonic cleaning, however, did not yield improved outcomes compared to water. Therefore, the null hypothesis of no differences in denture cleanliness among the three intervention groups was partially rejected.

Denture hygiene was assessed with respect to three aspects: DCI scores, plaque coverage percentage, and microbiological tests. Group 1 and group 2 showed significantly more reduction in mean DCI and plaque coverage scores than group 3, while no significant differences could be shown between groups 1 and 2. This applied to both CoCr and acrylic surfaces. These findings concur with those previously published by Cruz *et al.* (11), who reported that ultrasonic vibration could improve denture hygiene in terms of decreasing the biofilm coverage area in acrylic complete

dentures. The adjunctive use of CPC (group 1) in our study, however, suggests the lack of any additive effect over water (group 2). Patient age was not a significant factor associated with denture hygiene. Denture service life, however, was significantly associated with DCI scores of CoCr surfaces, and plaque coverage scores of both CoCr and acrylic. This may be explained by a longer history of denture use and a potentially higher frequency of cumulative defects on the denture surface, which may have provided more favorable habitats for biofilm formation.

Microbiological tests indicated that group 1 had significant reductions in microbial viable counts (CoCr and acrylic) and yeasts; group 2 exhibited similar results. Significantly greater reductions in microbial viable counts were observed for acrylic saddles in group 2 compared to the control, while trends towards greater reductions were consistently observed in groups 1 and 2 compared to the control. Thus, the null hypothesis of no differences in microbial counts among the three intervention groups was partially rejected. These results could imply that the use of ultrasonic cleaners may have additional beneficial effects against microbial levels compared to manual brushing only. The lack of statistical significance might be due to the limited sample size, which was powered to detect differences in denture plaque. Previous studies conducted among patients with complete acrylic dentures have reported significantly greater reductions in total bacterial and mutans streptococci counts with combined effervescent tablet and ultrasonic cleaning, relative to ultrasonic cleaning alone, while effects on yeast counts have been inconsistent (21-24).

Previous studies have suggested a relationship between bacterial colonization and surface roughness: the rougher the surface, the more retentive and less susceptible to mechanical removal the biofilm attachment is (25). A well-polished metal surface is thought to be more resistant to biofilm attachment than acrylic. When a denture has been in prolonged use, the acrylic surface exhibits various kinds of defects such as cracks, porosities, and fractures (26). Improper denture cleaning methods, for example using abrasive dentifrice to

**Table 2.** Comparison of plaque coverage scores between CoCr and acrylic surfaces among and within groups [mean (SD)].

	N=64	Group 1 N=22	Group 2 N=20	Group 3 N=22	p-value <sup>‡</sup>	Multiple comparison
	Mean (SD)					
<b>CoCr surfaces</b>	Plaque coverage score (baseline)	46.59 (20.41)	41.72 (19.29)	47.96 (23.88)	0.596	
	(review)	17.89 (12.96)	16.22 (9.22)	39.60 (20.68)	P<0.001	
	p-value <sup>†</sup>	P<0.001	P<0.001	0.002		
	Plaque coverage change score	28.70 (16.59)	22.79 (17.88)	8.35 (11.39)	P<0.001	(1)=(2)>3
<b>Acrylic surfaces</b>	Plaque coverage score (baseline)	54.32 (20.44)	49.06 (20.71)	43.54 (20.83)	0.232	
	(review)	19.33 (12.34)	17.82 (10.09)	38.83 (17.96)	P<0.001	
	p-value <sup>†</sup>	P<0.001	P<0.001	0.041		
	Plaque coverage change score	34.98 (24.11)	28.40 (22.58)	5.21 (11.23)	P<0.001	(1)=(2)>3

SD, standard deviation; CoCr, cobalt chromium; N, number of patients; Group 1, mechanical cleaning with a toothbrush and ultrasonic cleaning with cetylpyridinium chloride; Group 2, mechanical cleaning with a toothbrush and ultrasonic cleaning with distilled water; Group 3, mechanical cleaning with a toothbrush only Paired-Samples T test<sup>†</sup>; One-way ANOVA<sup>‡</sup>

brush the fitting surface, increases the roughness of the acrylic surface. Such factors contribute to and facilitate microbial colonization and biofilm formation. In this study, however, no significant differences were shown between the CoCr and acrylic surfaces in terms of bacterial or yeast viable counts, DCI scores, or plaque coverage scores at both baseline and review; an exception was the viable bacterial count on blood agar. Thus, the null hypothesis of no differences in outcomes between CoCr and acrylic surfaces was partially rejected. This may be explained by the effectiveness of the post-operative instructions given to all patients, which included appropriate ways of handling and cleaning dentures by soft bristle toothbrushes without toothpaste. In addition, the mean denture service life was relatively short ( $19.05 \pm 5.63$  months), and the fitting surfaces were observed to be in good condition; thus, this may have accounted for the lack of significant differences compared to the CoCr surfaces.

Some limitations in the present study are acknowledged. The first is the low rate of documented patient compliance; slightly more than half of the patients (59%) returned completed log diaries to document their level of adherence to the proposed daily denture hygiene regimen. Nevertheless, all submitted log diaries reflected strict compliance; furthermore, of those participants who forgot to return their log diary at the review assessment, the vast majority (nearly 80%) reported that they had cleaned their dentures every day using the prescribed regimen. Nevertheless, documented compliance was not found to be a significant factor associated with denture cleanliness in the regression analyses. Thus, the results suggest that the use of ultrasonic cleaning was still significantly more effective than conventional cleaning, even with the lack of strict adherence to daily use. Another limitation was that the sample size was not large enough to detect significant differences among specific pathogens. In addition, some participants ( $n=16$ ) were still under professional dental care in the teaching clinics. Treatments such as scaling or OHI were prescribed during the research period, which may have provided extra positive outcomes in terms of oral hygiene condition.

Further investigation of adjunctive agents that can be used with ultrasonic cleaning, and which are also compatible with metal framework RPDs, are needed. Future studies with larger sample sizes and longer follow-up times will be required in order to determine the effectiveness of ultrasonic denture cleaning in reducing the prevalence and viable counts of oral opportunistic pathogens. This is especially pertinent in medically compromised and institutionalized elderly, who have been shown to have poorer oral health and denture hygiene. As such, the expansion of this denture hygiene intervention to other vulnerable groups is of paramount importance, and warrants further study.

## Conclusion

Within the limitations of this randomized clinical trial, ultrasonic cleaning was shown to be equally effective in the reduction of biofilm coverage on both CoCr and acrylic denture surfaces during a 1-month intervention period. The adjunctive use of CPC did not provide additional benefits over distilled water, with regards to the improvement of denture hygiene.

**Türkçe özet:** Toplulukta yaşayan yaşlılar arasında bir ultrasonik takma diş hijyeni müdahale programının etkinliğinin rastgellenmiş incelemesi. Amaç: Bu çalışma, yaşlı bireylerde protez temizliğini iyileştirmede ultrasonik protez hijyeni müdahalelerinin etkinliğini değerlendirmeyi amaçladı. Gereç ve Yöntem: Son 5 yıl içinde üst metal hareketli bölümlü protezleri olan 66 katılımcı rastgele üç protez hijyeni müdahale grubuna ayrıldı: grup 1 (diş fırçası ile mekanik temizlik ve setilpiridinyum klorür ile ultrasonik temizlik), grup 2 (diş fırçasıyla mekanik temizleme ve damıtılmış suyla ultrasonik temizleme) ve kontrol (yalnızca diş fırçasıyla mekanik temizleme). Protez temizliği başlangıçta ve 1. ayda aşağıdakiler kullanılarak değerlendirildi: i) Protez Temizlik İndeksi (DCI) puanları; ii) plak kaplama yüzdesi; ve (iii) bakteri ve maya tespiti için mikrobiyolojik numuneler. Gruplar arasındaki farklılıklar sırasıyla tek yönlü varyans analizi ve Ki-kare testleri ile değerlendirildi. Bulgular: Ortalama DCI skorları ve ortalama plak kaplama alanı yüzdeleri, hem kobalt krom (CoCr) hem de akrilik bağlantı yüzeyleri için grup 1 ve grup 2'de kontrol grubuna göre anlamlı derecede azaldı ( $p < 0,001$ ). Grup 1 ve 2 arasında mayaların prevalansı ve canlı sayıları veya toplam mikrobiyal canlı sayıları açısından önemli bir fark bulunmadı. Müdahale süresinden sonra CoCr ve akrilik yüzeyler arasında incelenen klinik ve mikrobiyolojik parametrelerde anlamlı bir fark gözlenmedi. Sonuç: Ultrasonik temizleyici, 1 aylık bir müdahale süresi boyunca metal hareketli bölümlü protezlerde biyofilm kaplamasının azaltılmasında mekanik temizlemeden önemli ölçüde daha etkiliydi. Bununla birlikte, setilpiridinyum klorürün ultrasonik temizleme ile birleşik kullanımı ek faydalar sağlamadı. Anahtar kelimeler: Setilpiridinyum, Protez temizleyiciler, Plak, Randomize kontrollü çalışma, Ultrasonik

**Ethics Committee Approval:** The protocol for this randomized controlled single-blind trial was approved by the Institutional Review Board of the University of Hong Kong (approval number UW 16-266).

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