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Effect of Using Karadent Framework on the Supporting Structures in Distally Extended Partial Denture Cases: A Clinical and Radiographic Study

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ABSTRACT

Background: Prosthetic rehabilitation of class I partial edentulous mandible is one of the problems in removable prostheses. The purpose of this study was to evaluate clinically and radiographically the changes in the supporting structures in distally extended partial denture cases either constructed from vitallium or karadent. **Patients and methods**: Twelve mandibular bilateral partially edentulous male patients (Class I Kennedy classification), with age ranging between 35-60 years were selected for this study from those attended to the prosthodontic department, Faculty of Dentistry, Suez Canal University. The patients were given a detailed explanation concerning the present state, alternative treatment plans and the proposed procedures.Clinical and radiographic evaluations were carried out for every patient at insertion 6, and 12 months. **Results:** Bony changes of the supporting structures was greater in Karadent than in Vitallium in both sides of the ridge. Pocket depth scores were greater in Vitallium than in Karadent in distal abutments of both sides. Gingival index scores were greater in Vitallium than in Karadent in distal abutments of both sides. **Conclusion:** The use of karadent with its superior properties, is better accepted by the patients, regarding esthetics, retention and efficiency.

Keywords: Removable Partial Denture; Karadent Framework; Partial Denture Cases

INTRODUCTION

Partial edentulism is a growing issue resulting in multiple problems that adversely affects mastication, speech, facial appearance and tempero-mandibular disorders, all results in difficulty to achieve an adequate restoration in a partially edentulous patients **(1)**.

Replacement of missing teeth is a common patient need, so appropriately designed removable partial dentures (RPD) should restore the functions of speech, mastication and deglutition, enhance appearance, preserve the remaining teeth and supporting tissues of the patient and generally contribute to the normal function of the

stomatognathic system **(2)**. Free end RPDs are of the most critical situations in achieving long term success especially in the mandible as it has decreased amount of bony ridge **(3)**.

Polymethyl methacrylate (PMMA) has been the most popular material used for denture fabrication since its introduction, but it has some problems that lead to denture failure. The traditional use of the metal clasp materials as cobalt chromium (Co-Cr), gold, stainless steel and titanium hampers esthetics and leads to allergic reactions **(4)**.

Thermoplastic resin materials such as nylon, acetal resins and karadent was a trial to improve esthetics and solve the problem of allergy. A non-metal, esthetic clasp denture produces a metal-free smile to the patient, comfortable to wear without causing any metal allergy and therefore it is superior to conventional clasp dentures **(5)**. The thermoplastic monomer free semi-rigid microcrystalline polymer (karadent) is introduced to the market in 2016. Karadent became a good alternative framework material for removable denture construction **(6)**.

Evaluation of the changes in the supporting structures of distal extension removable partial dentures radiographically is done by using the cone-beam computed tomography (CBCT) as it seems to be one of the most advanced and promising resources in this field **(7)**.

Therefore the present study aiming for clinical evaluation by measuring the gingival index and pocket depth. Also, radiographical evaluation by measuring bone height and width using CBCT radiograph.

PATIENTS AND METHODS

Twelve mandibular bilateral partially edentulous male patients (Class I Kennedy classification), with age ranging between 35-60 years were selected for this study from those attended to the prosthodontic department, Faculty of Dentistry, Suez Canal University. Clinical and radiographic evaluations were carried out for every patient at insertion 6, and 12 months. Approval of the Research Ethical Committee of the Faculty of Dentistry, Suez Canal University (IRB#100/82) was obtained before starting the study.

Inclusion criteria:

Patients with mandibular Kennedy class I arches, with remaining lower right and left 2nd premolars, opposing maxillary full set of dentition. They have good oral hygiene. The remaining teeth are free of periodontal diseases having adequate bony support with no mobility. Edentulous residual ridges have normal morphology with minimal undercuts and without sharp edges, tori or tumors, covered with healthy firm mucosa, free of any signs of inflammation or flabby tissues. Patients with an angle class I maxillo-mandibular relationship with adequate interarch space. Last tooth extraction performed at least six months before commencing the treatment.

Exclusion criteria:

Patients with para-functional habits (Bruxism and clenching). Patients with any septic foci or impacted teeth as verified by panoramic radiograph. Patients with tilted or rotated abutments, and soft tissue undercuts involved in the design were excluded.

Patients grouping and Preparation:

Patients were randomly and equally divided into two groups according to the type of RPD: Group I received a mandibular RPD constructed of Cobalt Chromium. Group II received a RPD constructed of the thermoplastic karadent material.

Abutment teeth were prepared for both groups as follows: proximal guiding planes of 1.5 mm occluso-gingival height on mandibular second premolars. Mesial saucer shaped occlusal rests were prepared in mandibular second premolars. Lingual rest seat were prepared on each canine as indirect retainers.

Prosthetic procedures:

For each group, a removable partial denture frameworks were constructed; in the first group it was fabricated in vitallium (group 1) and the other framework was fabricated in karadent (group 2).

I. Fabrication of cobalt chromium removable partial framework:

Maxillary and mandibular preliminary impressions were made with irreversible hydrocolloid (Alginate impression material Cavex CA 37, Cavex, Netherlands. Holland) in a modified stock tray. The impressions were poured in dental stone (Super-cal IV, COE laboratories Inc., USA) study casts were obtained. Intraoral Mouth preparation was done. On the primary cast, mandibular custom acrylic resin tray (Self cured acrylic resin, Acrostone, Dental Factory, Egypt) was made. The custom tray was border molded using green stick compound (Green stick compound, Kerr, Kerr U.K. limited, Netherlands) and secondary impression was made using medium body elastomeric impression material (Orsnwash L zetal plus impression material, zermack SpA, Italy) and poured to obtain mandibular master cast. Duplicating the modified master cast was done. Refractory casts were obtained made with phosphate bonded investment material. Wax patterns were fabricated using preformed casting wax sheets on the refractory casts then were sprued then investing is done.The mould was then placed in burn out furnace. Casting procedures carried out with chrome cobalt alloy in an Induction casting machine. Sprues were cut-off and the investment material still adhering to the casting was removed by sandblasting. Finishing and polishing was then carried out using diamond burs and stones and rubber polishing points, discs and wheels.The occlusion rims were fabricated on the frameworks which were fitted on the cast.

II. Fabrication of karadent removable partial framework:

Including the same steps as group 1, maxillary and mandibular preliminary impressions and intraoral mouth preparation were done. Occlusion blocks were fabricated on the master cast. Jaw relation was registered, mounted on semi-

adjustable articulator (Hanau Modular Articulator System; Waterpik Technologies, Inc.), and semi-anatomical teeth was done according to lingualized non-balanced occlusion followed by the try in step to verify all the framework components and determine any needed corrections that would be done. The wax patterns were fabricated using preformed wax sheets on the casts then the wax patterns were sprued When the wax was boiled and washed out and the mold was created, injection of Karadent (Karadent by TCS Dental Inc. US) was carried out with the apparatus called Thermopress 400 injecting unit (BREDENT Themopress 400. bredent.co.uk), set display at 310-320°C for 14-16 min 150-165 PSI (melting time and temperature depends on furnace type and calibration). The cartridge of injecting material was introduced into one of the two heating cylinders after a Vaseline base lubricant has been applied at its closed end. The cartridge membrane is pointed to the flask chamber. After processing finishing and polishing was performed utilizing soft brushes and flourishing paste to obtain karadent framework. The finished RPDs were inserted in the patient mouth. Patients were instructed about the placement and removal of the partial denture.

Clinical evaluation

The Gingival Index and pocket depth Scores were recorded for each case at the intervals (0, 6, 12) at mesiobuccal, midbuccal, distobuccal, mesio-lingual, midlingual and distolingual of each abutment tooth. The average of these records was calculated and then the patient recalled for reassessment of oral hygiene and gingival health.

Modified gingival index

The gingival tissues around the abutment were isolated and gently dried by a piece of gauze, and then each surface was individually scored according to the Gingival Index Scores (Loe and Silness) **(8)**.

All the readings obtained from the clinical evaluation (probing depth and modified gingival index) in each interval (0, 6, 12), were taken for the right and left sides individually then the average of the clinical changes as all were calculated for each interval in both groups and tabulated for statistical analysis.

Probing depth

The distance between the gingival margin and the base of the clinical pocket was measured using Williams graduated periodontal probe *. The probe was inserted in line with long axis of the tooth until meeting resistance when contacting the bottom of the pocket. The measurement were made at mesiobuccal, midbuccal, distobuccal, mesio-lingual, midlingual and distolingual of each abutment tooth .The average of these records was calculated and recorded, the mean was calculated and then the patient recalled for reassessment of oral hygiene and gingival health.

Radiographic evaluation

Patients were frequently recalled for inspection and post insertion adjustments. Follow up visits were scheduled zero, six, and twelve months after denture insertion

for making radiographic records using CBCT radiographic machine (Williams Probe, Hu-Friedy, Chicago, IL, USA) to evaluate changes in height and width of the residual ridge and changes of distal crestal bone height of the abutment teeth.

Patients were instructed to remove their dentures before imaging. The temple supports of the machine were adjusted towards the patients so that they were positioned on both sides of their heads and closed to grip them. Patients were nstructed not to move during the exposure time (20 seconds). After exposure, the 3D image appeared on the computer screen display, the head support was opened and the patients were dismissed.

After exposure, the 3D image appeared on the computer screen display. The bone height and width of the residual ridge distal to the terminal abutment in both sides of the mandible were evaluated, using the linear measurement system of the software (Ondemand 3D) ** supplied by the cone beam CT.

RESULTS

The mean (±SD) pocket depth change in the distal abutment in Vitallium and Karadent was 2.31±0.73 and 1.94±0.70; respectively. The differences between Vitallium and Karadent in pocket depth change in the distal abutment was non-significant as revealed by independent samples t-test (p>0.05 ns). The mean pocket depth change in the distal abutment showed a highly significant difference among sections (0, 6, and 12mm) in Vitallium, however, it was non-significant in Karadent as revealed by ANOVA **(Table 1).**

The differences between Vitallium and Karadent in Gingival index change in the distal abutment was significant as revealed by independent samples t-test (p>0.05 ns). The mean gingival index change in the distal abutment showed a significant difference among sections (0, 6, and 12mm) in Vitallium, however, it was non-significant in Karadent as revealed by ANOVA **(Figure 1)**.

Table (1): The pocket depth change in the distal abutment in both Vitallium and Karadent groups, at different section level (0, 6, 12).

Time	Pocket depth Changes in the distal abutment		independent samples t-test
	Group I	Group II	*p*-value
0	1.67 ± 0.26 bc	1.50 ± 0.32 c	>0.05 ns
6	2.33 ± 0.52 ab	2.00 ± 0.84 bc	>0.05 ns
12	2.92 ± 0.74 a	2.33 ± 0.68 ab	>0.05 ns
Total	2.31 ± 0.73	1.94 ± 0.70	>0.05 ns
ANOVA	0.004**	>0.05 ns	
Two-way ANOVA			
Source of variation	F-ratio	*p*-value	
Corrected model	4.47	0.004**	
Section	9.16	0.001***	
Group	3.288	0.080 ns	

Section x Group	**0.37**	**>0.05 ns**	

NS; non-significant at *p*-value>0.05, * Significant at p<0.05; ** highly significant at p<0.01; *** very high significant at p<0.001. Means with different letters in columns are significantly different according to Duncan's multiple Range Tests (DMRTs) at 0.05 level. *(DMRTs) at 0.05 level.*

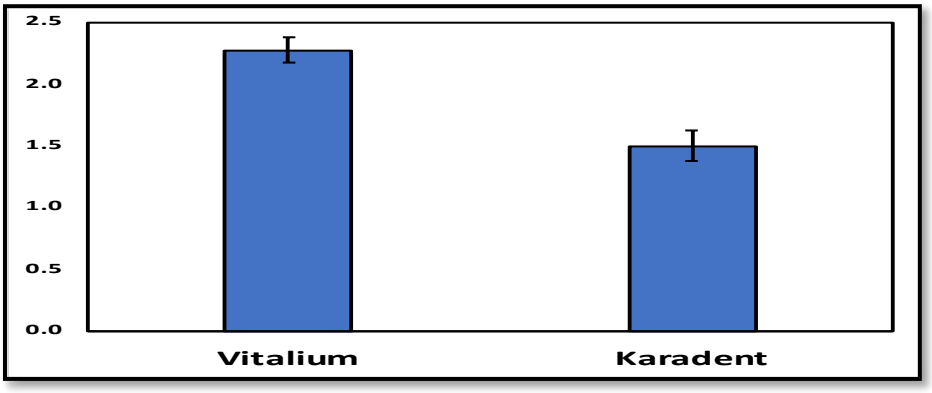

Figure (1): Bar chart presenting the Gingival index change in the distal abutment in Vitallium and Karadent groups.

DISCUSSION:

Polymethyl methacrylate (PMMA) has been the most popular material used for denture fabrication, it has several advantages. The traditional use of the metal clasp materials as cobalt chromium Co-Cr hampers esthetics, increases the weight of the prosthesis and leads to allergic reactions. All these problems have led to the introduction of thermoplastic resin materials **(9)**.

More recently, the thermoplastic monomer free semi-rigid microcrystalline polymer (karadent by TCS, INC, USA) is introduced to the market and became a good alternative framework material for removable denture construction **(10)**.

This study aims to examine and evaluate the effect of karadent framework on the supporting structures in distally extended partial denture cases, clinically and radiographically.

As for the flexibility of the denture, it is intended to reduce trauma associated with wearing a partial denture by preventing stress from being transferred to the adjacent teeth and tissues **(11)**.

In this study RPD was selected as the treatment choice as it is one of the most commonly used prostheses to restore it, and is used extensively in several indications including Kennedy Class I, it's also an applicable treatment solution for partially edentulous patients in general due to economical and senility reasons, Preserving good oral hygiene.

The selected patients were males only to exclude the possibility of osteoporotic changes in the menopausal women. The metabolic hormonal factors influence the osteoblastic and osteoclastic activity. Therefore, contribute strongly to bone resorption **(12)**.

Patients with a previous experience with RPD were excluded to exclude the patient related issues with old uncomfortable denture so allowing him to be more cooperative, so eliminating the patient related factors which contributes in denture failure **(13)**.

The design of the finished partial denture was the same for all patients for more reliable results. The design was formulated according to the common principles and concepts followed in distal extension cases **(14)**.

In this study the RPI clasp retainer was used. Which is of stress breaking effect to achieve abutment preservation and highly recommended to retain free end saddle RPDs. It has been thought to be more retentive than occlusally approach clasps as it possess an inherit tripping action, The I bar also moves mesiogingivally away from the tooth under masticatory load. It is with average thickness of 1.5 mm, as it considered appropriate clasp thickness to get better retention according to previous studies who reported that appropriate retentive force will need to be attained by increasing the thickness and width of the clasp arms in thermoplastics relative to those of conventional metal clasp **(15)**.

The occluso-gingival height of the guiding plane on the distal abutment tooth is around 1.5 mm to provide parallel path of insertion and permit the partial denture to rotate slightly around the mesial occlusal rest as downward force occur on the artificial teeth. This slight movement allows the release of the denture from the guiding planes thereby avoiding the creating of torqueing or twisting forces on the abutment **(15,16)**.

The commonly used major connectors for the mandibular arch are lingual bar and lingual plate. The major connector design used in this study was a lingual plate instead of the conventional lingual bar to better withstand the torsional forces from the distal extension RDP. Moreover, to be used as indirect retainers **(17)**.

Saucer shape mesial occlusal rests were prepared on abutment teeth to provide vertical support for the partial denture and transmit vertical forces with the long axes of the teeth and avoid the friction effect of box shape rests. Mesial occlusal rests are done as it considered vital for class I cases because the fulcrum line runs from the distal abutment of one side to the distal abutment on the other side, so when tissueward forces are applied on the denture base mesial rests prevents torqueing the distal abutments as it exerts a mesial force on it rather than a distal displacing force. Also, retainer designs with a distal rest tend to move the clinical crown distally and the root mesially at the apex, resulting in horizontal forces in the bone **(18)**.

In this study the intervals were decided to be 0, 6, 12 months as a sufficient period to allow collecting reliable data regarding gingival and bony changes, as done in other similar studies evaluated the effect of prosthetic appliances on supporting bone and clinical changes **(19-21).**

In this study, the total bony changes of the supporting structures was measured by the CBCT software. CBCT digital imaging was used in this study as it provides accurate 3D image, with minimal dose of radiation compared to conventional CT system, the researchers found that it provides different sections in various planes,

therefore it can accurately be used to determine the width and height of the region bone **(22).**

For the bone height changes, its measured from the panoramic view starting from a point about 10 mm distal to the mental foramen to the crest, while the width of the mandible was measured from the cross sectional view between the buccal and lingual aspects of the mandible at a point located 7 mm above the superior border of the mental foramen simulating measurement procedures in a previous studies **(23).**

In this study the gingival and pocket depth of the abutments were recorded and monitored as the successful rehabilitation with removable partial dentures requires the presence of healthy periodontal tissues. Clinical probing was done with Williams graduated periodontal probe and selected because it gives direct results without need for special equipment. It is regarded as an important and reliable diagnostic parameter in the continuous monitoring of the cases. The severity of periodontal diseases was precisely assessed through measuring periodontal pocket depth **(24).**

Modified Gingival index was measured for the main abutments according to Loe and Silness. It was created for precise assessment of the gingival condition and records qualitative changes in the gingiva **(25).**

The crestal bone loss was measured in the panoramic view from the superior border of the mental foramen then a vertical line is drawn tangential o the distal surface of the root of the distal abutment and extended to touch the distal crestal bone of the abutment simulating measurement procedures in a previous studies. Crestal bone height was measured from the distal aspect as in distal extension removable partial denture the excessive torqueing forces act on the abutments distally towards the edentulous area by time lead to distal wall resorption and tooth movement, as More than 90 % of the osteoclasts were observed in the areas with strain intensity higher as stated in a previous study **(26).**

Patients were instructed for strict proper oral hygiene before dentures construction and after delivery, as this reduce the possibility for microbial invasion and exclude the effect of improper oral hygiene on the health of periodontal tissues, it also facilitate correlation of the changes occurring in the supporting structures to the variation in the design material **(27).**

The present study revealed superior results regarding the amount of bone loss with vitallium and superior results regarding gingival and periodontal conditions around the terminal abutment with the use of the thermoplastic semi-rigid microcrystalline polymer (karadent). In this study, both RPDs showed a tendency for bone resorption, as assessed by the measurement of distal residual ridge height and width and crestal bone height around the distal abutment throughout the study period, these findings is consistent with those of previous studies, as they found that reduction in bone volume was closely related to edentulism and the use of denture despite its material of construction. So, Bone loss could thus refers to chronic progressive process that may be increased by functional forces encouraged by the RPD and exceeding the physiologic limit of tissue tolerance, regardless of all the effort made to control base movement and following biomechanical designing and construction of removable denture **(25).**

These results was in accord with other studies stated that the metallic RPD appears to make less adverse effect on the residual ridge in Kennedy Class I partially edentulous patients than thermoplastic ones. Also that non-metal clasp dentures with clasps are made of the same material of the prosthetic base can cause greater damage to supportive tissues including abnormal resorption of the alveolar bone, the absence of a metallic support and large displacement caused by flexible bases on the supporting tissues can lead to acceleration of alveolar ridge resorption **(28).**

Other studies supporting the results of this study stated that a properly designed major connector should be rigid to distribute the forces throughout the arch and reducing load concentration while controlling movement of the prosthesis, as the flexible major connector causes injury to the residual ridges and impingement of underlying tissues, resulting in greater bone loss. When the stress transmitted to the abutment teeth and the residual ridge was analyzed for distal extension RPDs of different materials; conventional metallic Co-Cr RPDs, and thermoplastic RPD, It concluded that Co-Cr RPDs group showed the least stresses transmitted to the supporting tissues compared to the thermoplastic group that showed the highest mean values of microstrain induced to the abutment teeth and the residual ridge **(29).**

When the bite force was evaluated in metallic and thermoplastic resin denture bases in bilateral free end saddle cases at three and six months after denture insertion, the result revealed that the biting force significantly increased in metallic dentures more than thermoplastic resin one in all follow-up periods. So, it can be supposed that the use of materials with lower modulus of elasticity result in greater mobility of the denture as the chewing strokes are increased and it worsens stabilization leading to stimulation of bone resorption than with the use of metallic one, and this findings are also supporting the results of this study **(30).**

Other studies showed different results that are against the findings of this study, as it was concluded that using partial denture with gingival approach clasps made from thermoplastic resin showed better effect on marginal bone loss as compared by using partial dentures with metal retainers. The resiliency of the major connector of the flexible RPD is acting as a stress breaker to distribute the stress between the abutments and edentulous ridge without harmful effect on the abutment teeth especially in cases of the tissue supported saddles. By clinical and radiographical evaluation of the effect of flexible acrylic clasp and framework versus metal on abutment teeth in implant modified distal extension cases, crestal bone changes were statistically significant in metallic RPD group **(31).**

Another study stated that the flexible bases tend to absorb the occlusal load and minimize the harmful effect on both abutment and residual ridge due to flexible and resilience nature of the material, so the thermoplastic mandibular distal extension removable partial denture material was superior to vitallium material regarding preservation of abutment alveolar bone **(32).**

The fatigue resistance (amount of clasp deformation) of thermoplastic clasps and Cobalt-Chrome (Co-Cr) clasps after attachment/detachment cycles on abutment teeth revealed that Co-Cr clasps had significant clasp deformation more than

thermoplastic clasps leads to transfer of vertical forces through the jaw bone which might influence the intensity of strain and resorption rate **(33).**

Studies regarding the modulus of elasticity of denture base materials reported that bone height changes with the thermoplastic framework was less than the metal framework, this may be due to the flexibility and a lower modulus of elasticity of the thermoplastic base than PMMA that transmit less load onto the abutment and the mucosa under the partial denture. So, concluded that the use of partial denture made of material with a lower modulus of elasticity was associated with less bone height changes. This factor is directly affecting the amount of pressure transmitted by the material and the extent of the area to which it is transmitted. It was also stated that materials with a low modulus of elasticity may flex and absorb impact energy from impact force, acting as a shock absorbent and resulting in decreased stress transmission to the underlying tissues, translated as a relative decrease in the amount of bone loss surrounding the abutment **(34,35).**

In this study, the mean of clinical pocket depth in Vitallium and Karadent was greater in vitallium compared to karadent RPD, the mean pocket depth showed a non-significant difference among groups of both Vitallium and Karadent as revealed by ANOVA. Also the mean of clinical gingival index was greater in Vitallium compared to Karadent RPD, the mean gingival index showed a highly significant difference among groups of both Vitallium and Karadent as revealed by ANOVA.

This is in accord with studies evaluated different removable denture materials in Kennedy class I partially edentulous situation revealed statistically significant results in favor of polyamide RPDs in the parameters of gingival index, plaque index and pocket depth **(36)**. In another study the gingival tissues of the anterior teeth with esthetic clasps did not show evidence of inflammation. Polyamide clasps appeared to be functional regarding retention and there was no evidence of excessive mobility of the abutments **(37).**

A study comparing a cast RPD and another flexible polyamide one , it is found that the flexible RPDs is a viable alternative to cast RPDs in Kennedy class II partially edentulous situation in the short term **(38).**

Others mentioned that flexibility of the thermoplastics reduced the load on the abutments, also the flexible RPDs having a stress breaking action on the abutment teeth. Hence, it could be hypothesized that thermoplastic frameworks would be an applicable alternate for diminished periodontal support abutments when managing Kennedy class I **(39).**

CONCLUSION:

RPD effect on the supporting structures of Kennedy class I cases is an ongoing process, controllable rather than stoppable by addition of distal implants and alteration of materials of RPD components.

Within the limitations of this study, it was concluded that the use of karadent with its superior properties, is better accepted by the patients, regarding esthetics, retention and efficiency. The metallic partial denture appears to make less adverse

effect on the supporting bone in Kennedy Class I partially edentulous patients than semi rigid thermoplastic ones (karadent). The abutment teeth reacted more favorably and offers superior results regarding gingival condition around the terminal abutment with the use of the thermoplastic semi-rigid microcrystalline polymer (karadent).

Recommendation

The thermoplastic PRD lacks an important factor of the traditional PRD, in particular, a rigid framework. Therefore, the recommendation of this study is to reinforce it with metal (hybrid design) to provide the PRD with sufficient rigidity with a metallic major connector and sufficient support with metallic rests and to compare its effect on supporting structure of distally extended cases with cobalt chromium RPDs.

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Author contribution: Authors contributed equally in the study.

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