

## CLINICAL RESEARCH

# Patient satisfaction with laser-sintered removable partial dentures: A crossover pilot clinical trial

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## ABSTRACT

**Statement of problem.** Clinical data regarding newly introduced laser-sintered removable partial dentures (RPDs) are needed before this technique can be recommended. Currently, only a few clinical reports have been published, with no clinical studies.

**Purpose.** This clinical trial compared short-term satisfaction in patients wearing RPDs fabricated with conventional or computer-aided design and computer-aided manufacturing (CAD-CAM) laser-sintering technology.

**Material and methods.** Twelve participants with partial edentulism were enrolled in this pilot crossover double-blinded clinical trial. Participants were randomly assigned to wear cast or CAD-CAM laser-sintered RPDs for alternate periods of 30 days. The outcome of interest was patient satisfaction as measured using the McGill Denture Satisfaction Instrument. Assessments were conducted at 1, 2, and 4 weeks. The participant's preference in regard to the type of prosthesis was assessed at the final evaluation. The linear mixed effects regression models for repeated measures were used to analyze the data, using the intention-to-treat principle. To assess the robustness of potential, incomplete adherence, sensitivity analyses were conducted.

**Results.** Statistically significant differences were found in patients' satisfaction between the 2 methods of RPD fabrication. Participants were significantly more satisfied with laser-sintered prostheses than cast prostheses in regard to general satisfaction, ability to speak, ability to clean, comfort, ability to masticate, masticatory efficiency, and oral condition ( $P < .05$ ). At the end of the study, 5 participants preferred the laser-sintered, 1 preferred the cast RPD, and 3 had no preference.

**Conclusions.** The use of CAD-CAM laser-sintering technology in the fabrication of removable partial dentures may lead to better outcomes in terms of patient satisfaction in the short term. The conclusion from this pilot study requires confirmation by a larger randomized controlled trial.

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## Clinical Implications

Laser-sintered removable partial dentures could be considered a promising alternative to the fabrication of conventional cast prostheses.

Removable partial dentures (RPDs) are a conservative and low-cost option that restores missing teeth in patients with partial edentulism, improving their quality of life.<sup>1-7</sup> These prostheses have an important impact on millions of patients worldwide and important commercial implications.<sup>8-11</sup> More than 13% of adults in North America and Europe wear RPDs.<sup>10,12</sup>

RPD frameworks are conventionally made of cast alloys, using the lost-wax technique, a laborious manual process that is prone to human error.<sup>13</sup> In order to overcome the limitations of the lost wax technique, the fabrication of RPD frameworks using digital rapid prototyping techniques has recently been introduced.<sup>14</sup> Rapid prototyping is the collective term for different processing technologies that fabricate accurate 3-dimensional (3D) objects directly from computer-aided design (CAD) in a short time.<sup>15</sup> This manufacturing technique allows the production of complex 3D shapes such as RPD frameworks.<sup>16</sup>

Rapid prototyping additive manufacturing technologies include stereolithography, selective laser melting, selective laser sintering, selective deposition modeling, 3D printing, and direct inkjet printing.<sup>16</sup> Stereolithography was the first prototyping technique introduced commercially and the first one used to fabricate RPD frameworks in the early 2000s.<sup>17</sup> Stereolithography was used to fabricate resin sacrificial patterns for RPD frameworks that were then conventionally cast to create the definitive RPD metal framework.<sup>17,18</sup> The resulting framework showed acceptable fit<sup>19</sup>; however, this technique can still introduce errors into the casting process itself.

In 2006, the selective laser melting technique was introduced to allow direct manufacturing of the computer-designed metal framework, which eliminated the casting steps.<sup>20</sup> This was done by using a physical sculptor to virtually build the framework.<sup>20,21</sup> The methodology was expensive and time consuming, and to overcome these limitations, software was developed to virtually design RPDs without the need for a sculptor.<sup>22</sup> However, as these programs were not specifically designed for RPDs, the time needed to determine the path of insertion, eliminate undesirable undercuts, and draw the framework components was extensive. The first software (Tang Long CAD), developed specifically for designing RPD frameworks for rapid prototyping, was released in 2010.<sup>23</sup>

Selective laser sintering technologies allow fabrication of 3D metal objects in successive cross-sections.<sup>15</sup> The superior precision of laser-sintering technologies can reduce the errors of manual processing, thereby increasing the quality of the prostheses while reducing manufacturing costs and rendering the treatment accessible to a larger section of the population.<sup>14</sup> Selective laser sintering has been used to fabricate inlays, crowns, implants, and surgical guides.<sup>24-28</sup> Currently, several laboratories worldwide fabricate RPDs digitally. Clinical trials are needed to evaluate this new technology in RPD fabrication before its use can be recommended. However, the clinical performance of RPDs produced digitally from CAD and computer-aided manufacturing (CAM) and rapid prototyping technologies has been reported in only a few clinical reports.<sup>14,19,20,29,30</sup> The authors are unaware of published clinical studies comparing conventional RPDs with those produced by CAD-CAM processes. Therefore, the purpose of this pilot crossover randomized clinical trial was to compare CAD-CAM RPDs with conventional RPDs in terms of patient satisfaction after 1 month of prosthesis use.

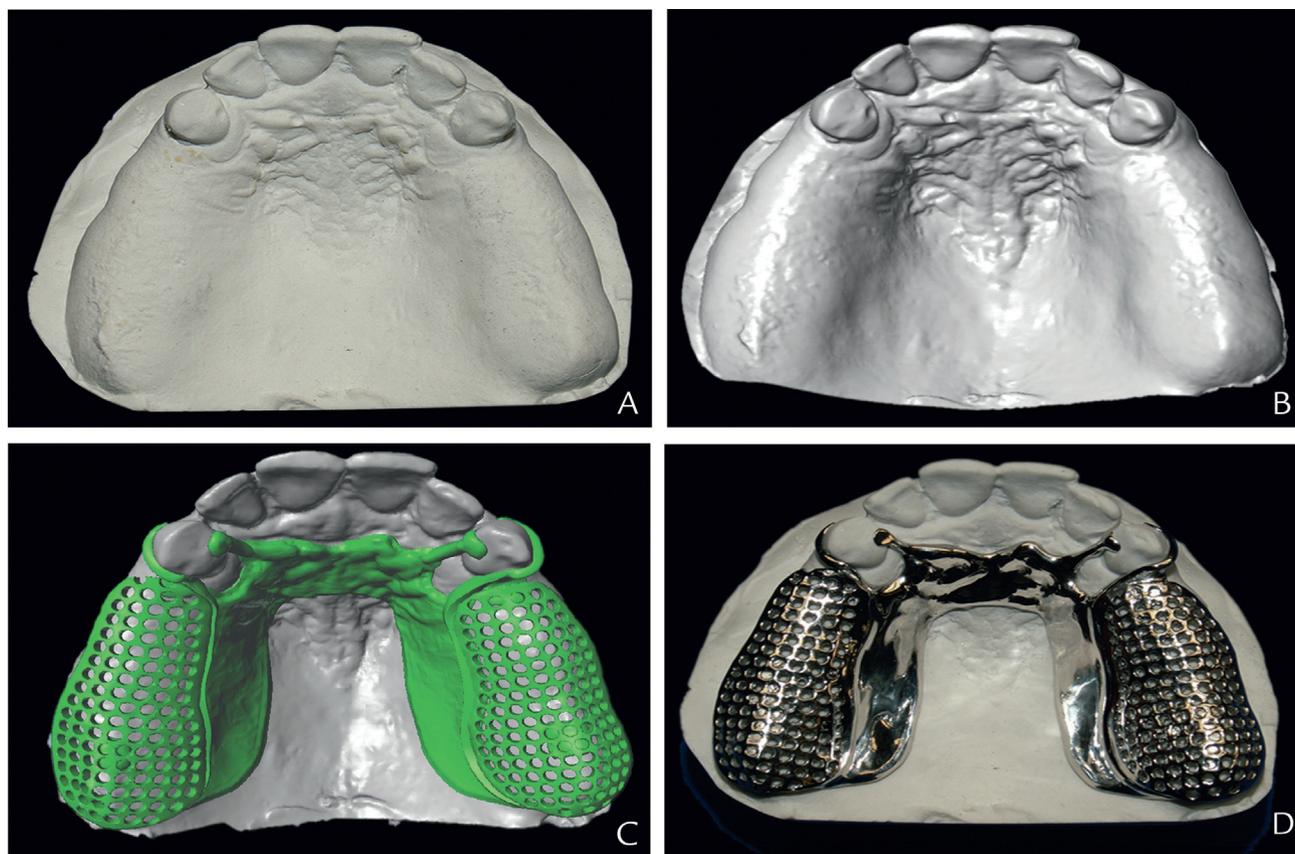
## MATERIAL AND METHODS

Ethical approval for the study protocol was obtained from McGill University Institutional Review Board (12-452 BMD), and the trial protocol was registered in the US Clinical Trials Registry NCT02769715. The Consolidated Standards Of Reporting Trials (CONSORT) statement was followed in reporting the study results.<sup>31</sup>

Patients who visited the predoctoral clinic at McGill University (Montreal, Quebec, Canada) for the restoration of missing teeth with RPDs in the academic years 2013 to 2015 were invited to participate in the study. Study participants received a written, detailed description of the study and signed a consent form.

For inclusion in the study, participants had to have partial edentulism; have adequate buccolingual and occlusal space for prosthetic teeth and metal framework; be able to maintain adequate oral hygiene and clean their prostheses; not have major systemic health problems that could interfere with general oral health (American Society of Anesthesiology 1 or 2); and be capable of giving written, informed consent and fill out questionnaires in English or French.

The study design consisted of a double-blind pilot crossover trial. Participants were randomized to wear their RPDs in 1 of 2 sequences by tossing a coin: cast then laser-sintered RPDs (Cast-Laser) or laser-sintered then cast RPDs (Laser-Cast). The length of each sequence was 1 month without any washout period. Treatment was administered by a predoctoral student supervised by a prosthodontist. The student, supervisor, and participant were all blinded to the type of RPD. The



**Figure 1.** Steps for fabricating laser-sintered RPD. A, Definitive cast of participant with partial edentulism. B, STL image of definitive cast scanned with 3D scanner. C, Virtual build-up of RPD framework. D, Laser-sintered RPD framework. RPD, removable partial denture. STL, standard tessellation language.

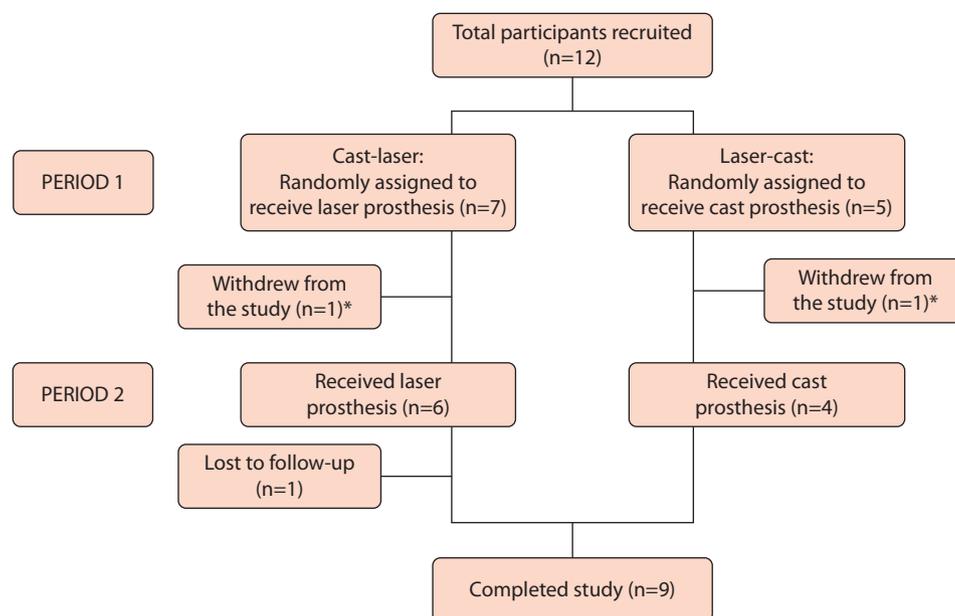
principal investigator (F.T.) was responsible for preparing the laboratory work authorizations and sending the definitive impressions to the dental laboratory to ensure the masking process.

The participants were treated according to standardized clinical procedures. Both types of prostheses were fabricated simultaneously from the same definitive cast. The cast was scanned first with a 3D scanner (3Series; Dental Wings) to fabricate the laser-sintered RPDs (Fig. 1A, B). The definitive cast was then reused to fabricate the conventional RPDs following standard procedures. To fabricate the framework for laser-sintered RPDs, the path of insertion was determined on the digital file, and the survey line was drawn. Then, the entire framework design was built virtually in 3D format using software (3Shape CAD Points; 3Shape) (Fig. 1C). The standard tessellation language (STL) file was then transferred to the rapid prototyping machine (PM100 Dental & PM100T Dental; Phenix Systems), and the definitive framework was produced using cobalt-chromium alloy powder (Sintech Metal) and the selective laser sintering technique (Fig. 1D). Similar acrylic resin teeth (Ivostar & Posteriors; Ivoclar Vivadent AG) were used for both types of RPD. The tooth

arrangement and prosthesis base waxing were replicated using a plaster index. All laboratory procedures were performed by 1 technician at the same dental laboratory.

Prosthesis adjustment was performed at the delivery visit for both prostheses, which were identified by numbers. Then, 1 prosthesis was chosen randomly based on a coin toss and given to the participants. Participants were scheduled for 1-, 2-, and 4-week follow-up visits, and any necessary adjustments were conducted at these visits. At the 4-week follow-up, the participants were given the second prosthesis and scheduled for the same follow-up plan. Participant preferences in regard to type of prosthesis was assessed at the final follow-up visit.

During the follow-up visits, participants were asked to fill in the McGill Denture Satisfaction questionnaire. This 9-item questionnaire has been validated and used in various clinical trials to measure patient satisfaction in regard to ease of cleaning, ability to speak, comfort, esthetics, stability, ability to masticate several types of food, masticatory efficiency, oral condition, and general satisfaction.<sup>32-35</sup> Participants were asked to rate each item from 0 to 100 on a Visual Analog Scale (VAS), where zero meant totally unsatisfied. Participants' complaints and compliments were also recorded.



**Figure 2.** Participant recruitment. \*Participant completed period 1 but did not receive second denture it did not fit and was discarded.

To calculate sample size, a minimum clinically significant difference in general satisfaction with a RPD was assumed as 10 mm with a standard deviation of 8, based on the results of a previous crossover trial.<sup>36</sup> Accordingly, at  $\alpha=.05$ , a minimum of 8 participants were required to achieve a power of 80%. Accordingly, 12 participants were recruited to account for potential dropouts. To detect the treatment effect, linear mixed models were built for 4-week data. In the initial model, intervention (prosthesis type), period, sequence and period by treatment interaction were considered as fixed factors and participant as a random factor. Period-by-treatment interaction was used to test for the carryover effect; as this interaction was not statistically significant ( $P=.391$ ), the final model was fitted without it. Between-subject variations during the adaptation period were presented using line graphs. The intention to treat principle was respected and  $\alpha=.05$  was used for all tests. Sensitivity analysis for complete treatment only ( $n=9$ ) was conducted to assess the robustness of the findings to potential incomplete adherence. Statistical software (Stata 14; StataCorp) was used for analysis.

## RESULTS

Twelve participants (8 men and 4 women) were recruited. Seven participants received cast RPDs first, whereas the other 5 participants received laser-sintered RPDs first. One participant was lost to follow-up after receiving the second prosthesis, and 2 participants withdrew from the study because 1 of the 2 prostheses did not fit: a laser-sintered RPD in 1 participant and a cast RPD in the other participant (Fig. 2). The mean

**Table 1.** Baseline demographic and prosthesis-related data for participants categorized by treatment sequence

Variable	Cast-Laser Group (n=7), n (%) <sup>a</sup>	Laser-Cast Group (n=5), n (%) <sup>b</sup>
Age (y), mean $\pm$ SD	63 $\pm$ 8	69.4 $\pm$ 14.9
Sex		
Male	4 (57)	4 (80)
Female	3 (43)	1 (20)
Arch		
Upper	2 (28.5)	1 (20)
Lower	1 (14.3)	3 (60)
Both	4 (57)	1 (20)
Cases with missing anterior teeth	3 (42.8)	1 (20)
Kennedy class		
I	4 (36.4)	4 (16.6)
II	4 (36.4)	1 (66.6)
III	2 (18.2)	0
IV	1 (9)	1 (16.6)
Previous RPD		
Yes	5 (71.4)	4 (80)
No	2 (28.6)	1 (20)
Opposing arch		
RPD	4 (57)	2 (40)
NT	3 (42.8)	1 (20)
CD	0	2 (40)
Dropouts	2 (28.5)	1 (20)

CD, complete prosthesis; NT, natural teeth; RPD, removable partial dentures. <sup>a</sup>Cast-Laser patients received cast prosthesis first. <sup>b</sup>Laser-cast patients received laser-sintered prosthesis first.

participant age was 65.6  $\pm$ 11.3 years. More than half of the RPDs (76%) were Kennedy class I or II. Participants' demographic data and oral conditions are shown in Table 1. Individual demographic data are presented in Supplemental Table 1.

**Table 2.** Treatment effect from mixed model analysis for all satisfaction items

Satisfaction Item	Treatment Coefficient (mm) <sup>a</sup>	±SE (mm)	Z	P	95% CI	
					Lower Bound	Upper Bound
General satisfaction	12.5	4.7	2.66	.008	3.3	21.8
Ease of cleaning	7.3	2.8	2.58	.010	1.8	12.9
Ability to speak	12.1	5.1	2.52	.012	2.9	22.9
Comfort	7.3	3.0	2.42	.016	1.4	13.3
Esthetics	4.6	5.1	0.89	.372	-5.5	14.6
Stability	15.6	7.7	2.02	.044	0.4	30.7
Ability to masticate	15.4	6.3	2.42	.015	2.9	27.8
Masticatory efficiency	6.8	3.0	2.29	.022	1.0	12.7
Oral condition	6.2	3.0	2.09	.036	0.4	12.0

SE, standard error. <sup>a</sup>Treatment coefficient of the visual analog scale of McGill Denture Satisfaction instrument. A positive value (>0) indicates "in favor" of the laser-sintered RPDs, as the laser-sintered prosthesis was used as the reference for the dummy variable of treatment; therefore, a positive regression coefficient indicates higher satisfaction for the laser-sintered than the cast prosthesis.

For general satisfaction, the linear mixed model showed a statistically significant treatment effect ( $P=.008$ ) but no significant period ( $P=.131$ ) or sequence effect ( $P=.686$ ) (Table 2, Supplemental Table 2). Participants rated laser-sintered RPDs higher than cast RPDs for general satisfaction, with a mean difference of 12.5 mm ( $P=.008$ ; 95% confidence interval [CI], 3.3-21.8).

Participants reported significantly higher satisfaction with the laser-sintered prosthesis than with the cast prosthesis in terms of the ability to clean them, speech, comfort, stability, masticatory ability, masticatory efficiency, and perception of the oral condition ( $P<.05$ ), as shown in Table 2 and in Supplemental Table 2. Period and sequence effects were not statistically significant ( $P>.05$ ) for any of the satisfaction items except for the ability to masticate, which showed a significant period effect ( $P=.017$ ) (Supplemental Table 2). Sensitivity analysis results for complete treatment only ( $n=9$ ) was similar to the results of the intention to treat analysis (Supplemental Table 3). Participants were significantly more satisfied with the laser-sintered than the cast RPDs in regard to all satisfaction items ( $P<.05$ ) except esthetics ( $P=.148$ ) (Supplemental Table 3).

The line graph analysis (Fig. 3) showed that, for most of the questionnaire items, the mean satisfaction scores of the laser-sintered RPDs increased from the first week to the fourth week, except for the oral condition. This item showed a stable score throughout the follow-up period (Fig. 3). However, the mean satisfaction scores for the cast RPDs showed a gradual decrease in general satisfaction, ease of cleaning, and stability and a gradual increase in comfort scores during the follow-up periods. The scores for masticatory efficiency and ability, speech, and oral condition were stable throughout the follow-up period.

The means of within-subject satisfaction score differences between laser-sintered and cast RPDs are

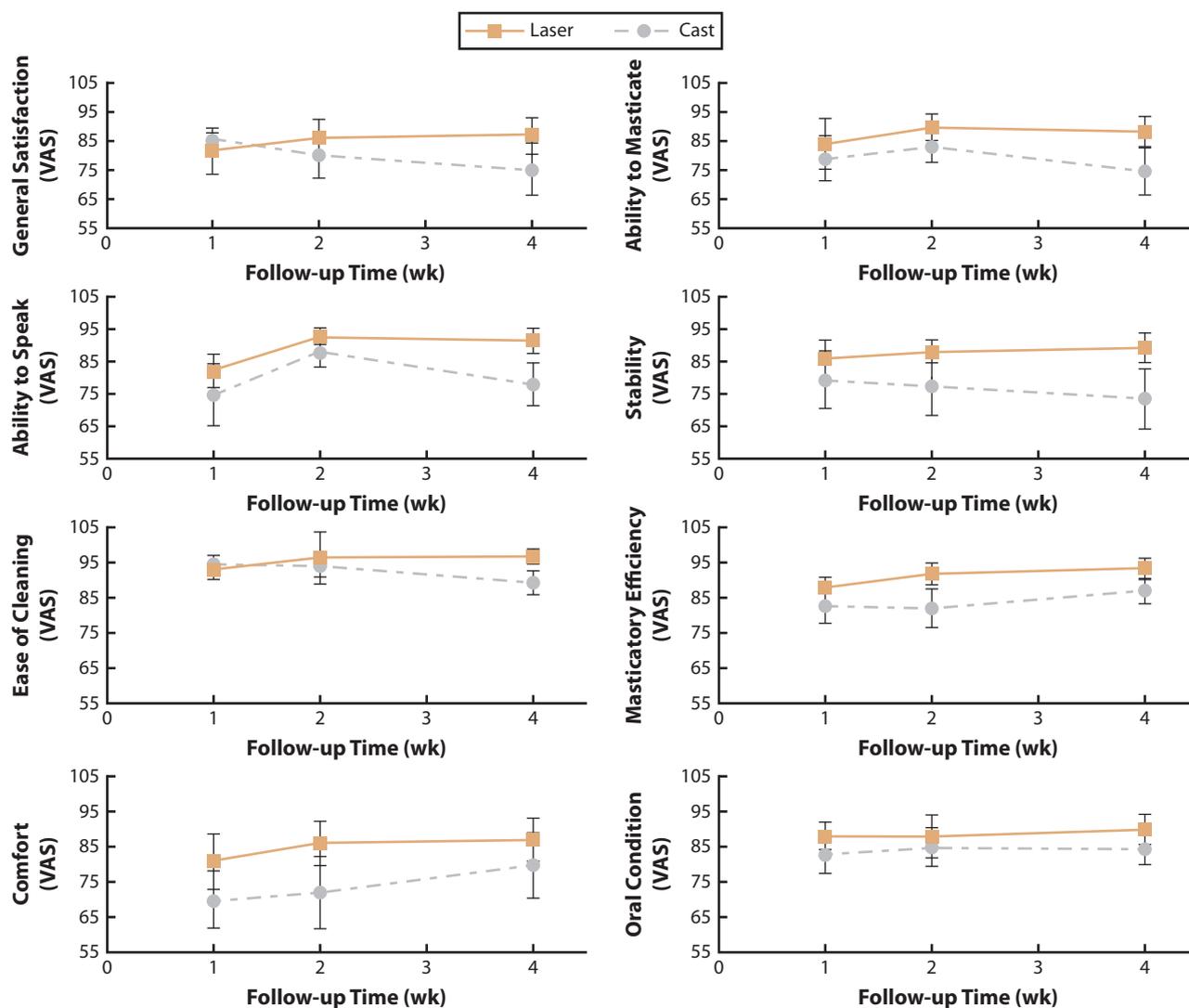
presented in Supplemental Figure 1. Supplemental Table 4 represents the mean and standard deviation (SD) for all variables at all follow-up times.

This study showed that the most common complaints by participants regarding their RPDs were related to fit and retention, followed by soft tissue ulceration and mastication problems. Participants reported fewer complaints and more compliments when they were using the laser-sintered RPDs than when using the cast RPDs (Table 3). Every participant who started with a laser-sintered RPD ( $n=4$ ) preferred it at the end of the study. Among the participants who received the cast RPD first, 1 preferred the cast RPD, 3 found no difference between the 2 prostheses, and 1 preferred the laser-sintered RPD.

## DISCUSSION

Laser sintering is a relatively new technology in dentistry and has only been assessed through observational studies in fixed and implant dentistry.<sup>26-28</sup> To the best of the authors' knowledge, this study is the first randomized controlled clinical trial that evaluated patient satisfaction of laser-sintered RPDs. In the current study, participants were significantly more satisfied with the laser-sintered prostheses than the cast prostheses in terms of general satisfaction, ability to clean and speak, comfort, masticatory ability, masticatory efficiency, and oral condition. The greatest effect size was recorded for stability, followed by ability to masticate, general satisfaction, and ability to speak. The other satisfaction items had a smaller effect size with minimal clinical value.<sup>34</sup>

In this study, patient satisfaction with cast prostheses falls within the range of that of previous studies. Mean satisfaction scores for laser-sintered prostheses were among the highest reported for RPDs, regardless of the study design or measurement tools (Supplemental Table 5),<sup>1-6,8,11</sup> despite the fact that most of the RPDs in this study were Kennedy class I or II, which has been shown to affect satisfaction negatively compared with Kennedy class III or IV.<sup>37</sup> This significant difference in participants' general satisfaction between cast and laser-sintered prostheses could be related to the enhanced mechanical properties of laser-sintered alloys.<sup>26</sup> Laser-sintered cobalt-chromium alloy is harder and denser and has better microstructural organization and higher yield strength and ultimate tensile strength than cast alloys.<sup>26</sup> These superior mechanical properties along with better precision may improve clasp retention and stability, which is known to greatly increase patient overall satisfaction and comfort.<sup>7</sup> Indeed, the participants in this study were more satisfied with the stability and subsequently masticatory capabilities of the laser-sintered prostheses than with the cast prostheses.



**Figure 3.** Trend over time of both laser-sintered and cast prostheses for satisfaction items that were significantly different among the treatments (general satisfaction, ease of cleaning, ability to speak, comfort, stability, masticatory ability, masticatory efficiency, and oral condition). VAS, visual analog scale measurement in survey, 0 to 100 mm.

The participants were more satisfied with the ability to speak when using the laser-sintered RPD than the cast RPD. This is probably due to the better stability and retention reported for laser-sintered RPDs. Indeed, the ability to speak correlates positively with the stability and retention of the prosthesis.<sup>34,38</sup>

In this study, participants were significantly more satisfied with the masticatory ability and efficiency of laser-sintered prostheses than with cast prostheses with identical tooth arrangements and acrylic resin bases. This can be explained by the stability of the prostheses, which also scored significantly higher for laser-sintered compared with that of cast RPDs. Participants' assessment of masticatory ability is usually consistent with their assessment of stability, comfort, and general satisfaction, which, in this study, were higher for laser-sintered RPDs than for cast RPDs.<sup>35</sup>

Regarding esthetics, no significant differences in participants' satisfaction were found between the prostheses. This was expected, as the esthetics of RPDs is more related to tooth arrangement, size, shade, and denture bases than to the metal framework. Participants were significantly more satisfied with laser-sintered RPDs in terms of ability to clean when compared with cast prostheses. A possible explanation is that laser-sintering technology produces more precise fits that may reduce food accumulation beneath the prostheses.<sup>26</sup>

The satisfaction rating for laser-sintered RPDs increased gradually over time, whereas it was inconsistent with cast RPDs. This may indicate that participants had an easier adaptation period using laser-sintered rather than cast RPDs. The gradual decrease in satisfaction with cast RPDs can be related to the fatigue of cast clasps over time, which affects prosthesis retention,

**Table 3.** Complaints and compliments reported by participants during the follow-up period

Participants' Subjective Comments	Laser-Cast Group (n=10)	Cast-Laser Group (n=11)
<b>Complaints</b>		
Soft tissue ulceration/pain and soreness		
Prosthesis or clasp hurting the tongue or gum	2	3
Loss of retention		
Prosthesis does not fit properly and needs to be adjusted	0	1
Prosthesis is loose	1	3
Denture is unstable	0	1
Denture feels too tight	0	1
Mastication problems		
Difficult or painful to chew	1	1
Cheek biting	0	1
Esthetic problems		
Unesthetic front tooth	1	1
Hygiene problems		
Food trapped under prosthesis	0	1
Miscellaneous		
Metal taste in mouth	1	0
Denture is irritating and causes nausea	0	1
Denture is thick	0	1
<b>Total complaints</b>	<b>6*</b>	<b>15*</b>
<b>Compliments</b>		
Denture is easy to remove	0	1
Denture is very light	2	0
Denture is tight	1	0
Denture fits very well	2	0
<b>Total compliments</b>	<b>5*</b>	<b>1*</b>

\*Sum of all complaints or compliments.

thereby affecting general satisfaction.<sup>39</sup> The fatigue behavior of laser-sintered clasps has not yet been studied, but based on the reported improved mechanical properties, it is expected to be an improvement over casting.<sup>26</sup>

At the end of the study, 5 participants preferred the laser-sintered prosthesis over the cast prosthesis while blinded, and the reasons given by the participants (explained in Results) confirm the results of this study and support the hypothesis regarding the accurate fit and enhanced retention of laser-sintered prostheses.

The most frequent complaint about the prostheses was related to fit and retention, followed by ulceration of the tongue or gingiva and masticatory problems, all of which are common findings in RPDs studies.<sup>40</sup> Participants reported fewer complaints, especially related to prosthesis looseness, when they used the laser-sintered prostheses, which supports the other results in this study.

This new technology in fabrication has some limitations. The high initial cost of the laser sintering machine and the necessary software in addition to the time and expertise needed to learn this technology are some of the limitations.<sup>14-23</sup> Another limitation is that currently this

technique cannot be used for all patients, since some special designs cannot be produced easily because of the limitations of the available software and the manufacturing process.<sup>14-23</sup> Future work should be directed towards the improvement of the software to expand the application of this technology.

The strengths of this study include the use of patient-centered outcome; the randomized crossover design; the double-blinding; and inclusion of participants' complaints, compliments, and their preferred choice of treatment. Moreover, evaluating participant satisfaction at 3 time points provided an insight into following the prosthesis performance over time.

There are some limitations to this study. First, the small sample size and short follow-up limit the generalizability to long-term clinical performance. Although, the crossover design used in this study was justified for decreasing interparticipant variation and providing power with a small sample size, it has some disadvantages, including the potential for a carryover effect.<sup>35</sup> A washout period is usually recommended to erase the physical and psychological carryover effects but is not always possible. As in this study, it would not be ethical to leave the participants without a prosthesis.<sup>35</sup> Therefore, a larger clinical trial with a longer follow-up is recommended.

## CONCLUSIONS

Within the limitations of this pilot crossover double-blinded clinical trial, the following conclusion was drawn.

1. The use of laser sintering technology for the fabrication of RPDs may lead to higher short-term satisfaction for patients with partial edentulism than conventional methods.

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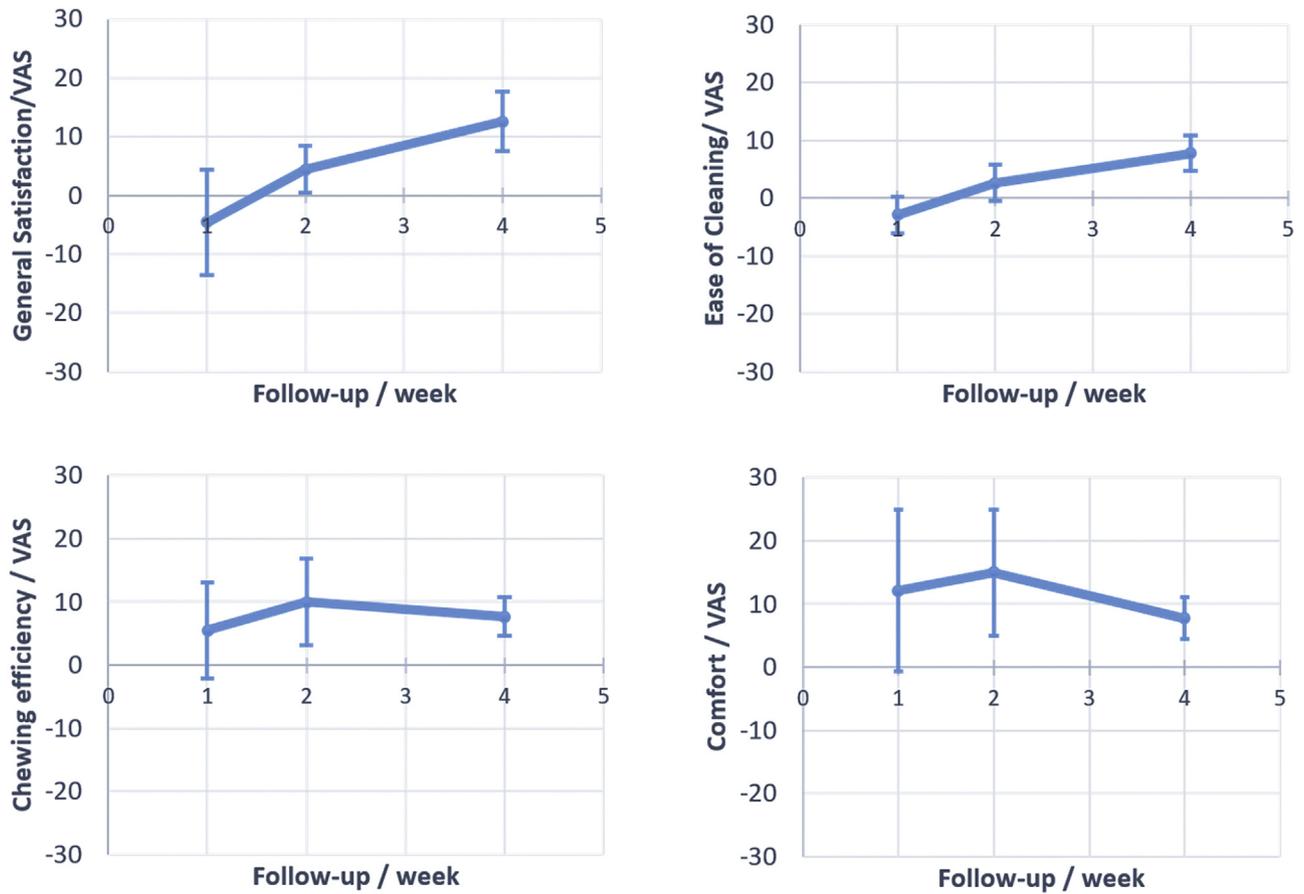
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**Supplemental Figure 1.** The trend over the follow-up periods within subject mean difference of satisfaction scores (laser-sintered—cast) for general satisfaction, ease of cleaning, comfort, and masticatory efficiency. Mean difference and standard errors are show.