

# Prospective clinical comparative evaluation of implant-supported zirconia-lithium disilicate bilayered ceramic and metal-ceramic posterior prostheses: a 3-year follow-up

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**PURPOSE.** The aim of this study was to evaluate the clinical performance and survival rate of implant-supported zirconia-lithium disilicate (Zr-LiSi) bilayered ceramic prostheses over 3 years. **MATERIALS AND METHODS.** This study included 71 patients, including 34 with implant-supported metal-ceramic prostheses (control group) and 37 with implant-supported Zr-LiSi bilayered ceramic prostheses (test group). The implant survival rate and incidence of prosthetic and biological complications (veneer fractures, dislodgement of screw-access hole filling material, screw loosening, peri-implant mucositis and peri-implantitis, and marginal bone loss) were investigated. The survival rate was analyzed using Kaplan-Meier survival curves, and the identity between two groups was confirmed by the log-rank test. **RESULTS.** Both groups showed a 100% survival rate, whereas the prosthetic survival rates were 77% and 73% for the metal-ceramic and Zr-LiSi groups, respectively. Biological complications did not appear in the metal-ceramic group, and 16.2% of peri-implant mucositis occurred in the Zr-LiSi group, which was significant ( $P < .05$ ). Prosthetic complications occurred in 5.8% of the metal-ceramic group with veneer fractures and did not occur in the Zr-LiSi bilayered ceramic group. **CONCLUSION.** This study revealed that posterior Zr-LiSi bilayered ceramic implant prostheses showed high survival rates and similar survival rates to metal-ceramic implant prostheses; however, additional consideration should be given to avoid overcontouring. Zr-LiSi bilayered ceramic implant prostheses may be an option for posterior implant-supported prosthetic treatment. [J Adv Prosthodont 2025;17:59-69]

## KEYWORDS

Metal-ceramic; Peri-implant mucositis; Prospective clinical study; Survival rate; Zirconia-lithium disilicate

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## INTRODUCTION

The implant-supported metal-ceramic prostheses were reported to have a good long-term survival rate.<sup>1</sup> However, porcelain veneer fracture is a major clinical complication, which was observed in 13 – 34% of prostheses for > 5 years.<sup>2</sup> Implant-supported bilayered ceramic prostheses are esthetically better than metal-ceramic prostheses. The zirconia monolithic prostheses have excellent fracture resistance in the case of 3Y-TZP but are opaque. 5Y-PSZ, a translucent zirconia, is more esthetic than 3Y-TZP. On the contrary, esthetics may be affected by titanium abutments. As another alternative, improving esthetics by veneering various materials on 3Y-TZP, which has excellent masking effects, has been attempted. For example, if lithium disilicate (LiSi)-reinforced glass ceramic is heat-pressed on the zirconia substructure, high mechanical properties and esthetic results can be expected.<sup>3</sup>

Several *in vitro* studies have reported the bond strength of zirconia and LiSi.<sup>4,5</sup> LiSi heat-pressed on the zirconia method is accompanied by airborne-particle abrasion, and liner treatment can be expected to achieve effective and appropriate interfacial bonding between these two ceramics; however, clinical research is insufficient.<sup>6</sup>

Compared with cement-retained types, screw-retained implant prostheses can simultaneously satisfy passive fit and retrievability. However, the screw-retained implant prostheses are more vulnerable to fracture because of the screw holes present on the occlusal surface.<sup>7</sup> The screw and cement retained (SCR) implant prosthesis used in this study utilized both the advantages of the screw-retained prostheses and the convenience of the cement-retained prostheses. However, the presence of a screw-access hole impairs the prosthesis integrity, increasing the possibility of fractures.<sup>8</sup> Moreover, clinical research on how hole formation affects fractures in this SCR type implant-supported Zr-LiSi bilayered ceramic prostheses is insufficient.

This prospective study was conducted to determine the clinical outcomes, such as implant survival rate and prosthetic and biological complications, when metal-ceramic implant and Zr-LiSi bilayered ceramic

implant prostheses were manufactured as SCR types. Specifically, this study aimed to investigate the clinical results of implant prostheses made with Zr-LiSi bilayered ceramic prostheses by comparing them with conventional metal-ceramic prostheses. The null hypothesis is that there is no difference in clinical results between the implant-supported metal-ceramic and Zr-LiSi bilayered ceramic prostheses.

## MATERIALS AND METHODS

The study protocol was approved by the Institutional Review Board Anonymized of Dental Hospital (IRB No. Anonymized-IRB2017-A001). The inclusion criteria were as follows: patients who had partially edentulous areas in the maxillary and mandibular posterior teeth restored with implants and patients with good overall health and no problems with implant restoration. The exclusion conditions were as follows: patients with anterior implants and parafunctional habits such as bruxism and clenching and prosthetics in which the veneer in the marginal area was not supported by the substructure to standardize the design.

All participants provided written informed consent before entering the study. In total, 82 patients aged 28 – 75 years were screened. Among patients with missing posterior teeth, those receiving restoration using one or two implants splinted were eligible. The required number of events and the power for the log-rank test were calculated according to Schoenfeld's formula (Sample Size Calculator, Version 1.063, Vienna, Austria) [Computer software], retrieved from <https://homepage.univie.ac.at/robin.ristl/samplesize.php?test=logrank>. Thus, a total of 71 patients were included, whereas 11 were excluded and dropped out because they did not meet the required recall check period of at least 16 months, which was the test condition.

Restorations were randomly assigned to either metal-ceramic prostheses or Zr-LiSi bilayered ceramic prostheses using Microsoft Excel 2016 (Microsoft Corp., Redmond, WA, USA) random function. According to the ITI Consensus implant placement protocol, implant placement was performed in edentulous areas with a type 3 early implant placement or type 4 late implant placement protocol after a healing peri-

od of at least 1 month after extraction. After implant placement, impressions were taken for the definitive prosthesis, which was inserted 6 months later for the maxilla and 3 months later for the mandible. The load was set to delay loading according to the loading protocol of ITI Consensus.

Because the shape of the abutment may vary depending on the prosthesis type, a customized abutment was first manufactured. The margin of the customized abutment was fabricated to match the height of the gingival margin. After creating a customized abutment, metal-ceramic prostheses or Zr-LiSi bilayered ceramic prostheses were assigned to the patients using the random function of Microsoft Excel. The abutment and two types of implant prostheses were all fabricated by a single skilled technician to reduce the variation in manufacturing.

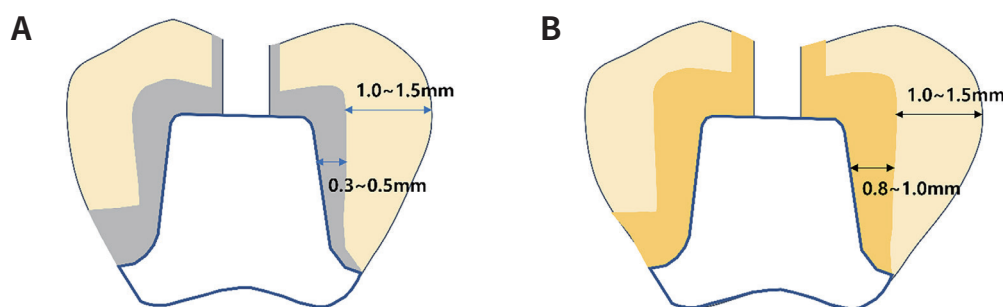
In the prosthesis design, the veneer material could be uniformly present at a thickness of 0.5 – 1.0 mm over the substructure for both metal-ceramic prostheses and Zr-LiSi bilayered ceramic prostheses. The substructure was designed to support the screw-access hole. On the buccal side, the substructure and veneer were manufactured to meet at a right angle (butt joint). On the lingual side, the substructure was designed to support approximately half the prosthesis height (Fig. 1). In prostheses containing > 2 implants, they were manufactured by splinting (connecting).

Clinical examination, photography, and radiography were performed on the day of prosthesis placement. After the delivery of the prostheses, patients

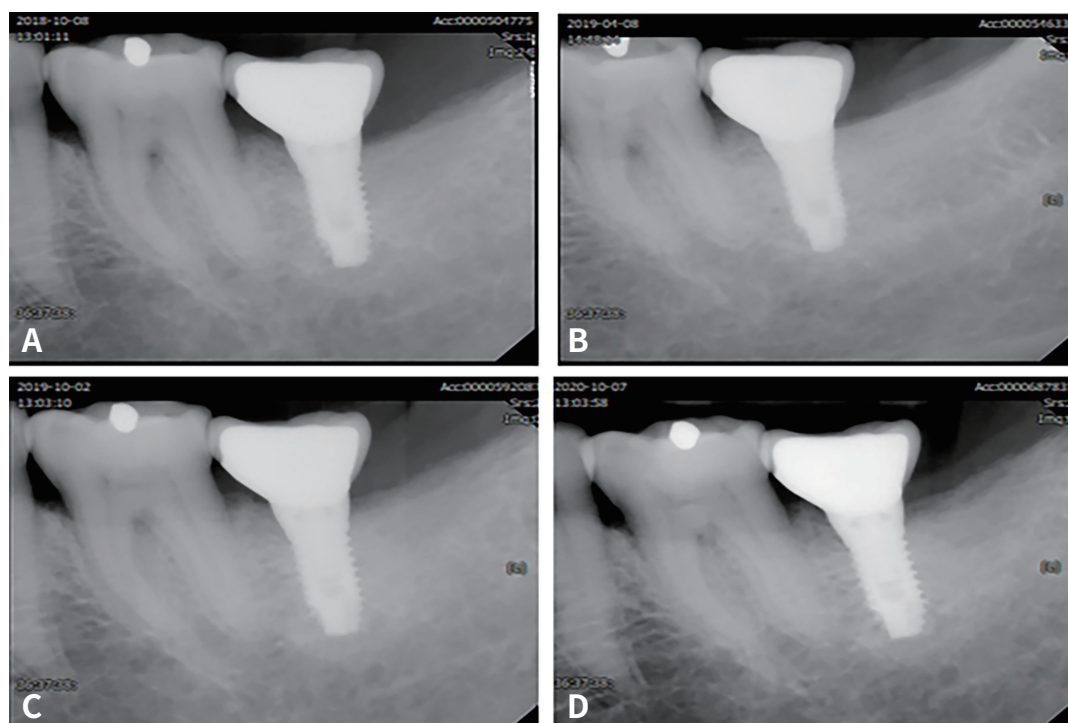
visited the hospital for checkups at 1, 3, 6, and 12 months and at 1-year intervals thereafter. Clinical photographs and radiographs were taken at each examination (Fig. 2). On the day of prosthesis placement, additional photos of the occlusal contact point were taken to confirm the effect of occlusion. In addition, when retightening the screw during examination, even a slight feeling of rotation was recorded as a screw loosening and re-tightened with 30 Ncm.

On the day of examination, prosthetic and biological complications were investigated. Incidents such as veneer fractures, partial fracture of the veneer material (chipping), dislodgement of the screw insert filling material, screw loosening, tissue inflammation around the implant, and marginal bone loss were recorded in the chart. When complications occurred, appropriate adjustments and treatment were carried out accordingly. Prosthetic survival is defined as the condition in which a prosthetic component remains functional without technical complications or discomfort for the patient.<sup>9</sup>

Statistical analysis was performed using IBM SPSS version 25.0 (IBM Corp., Armonk, NY, USA). Implant failure, fracture of implant veneer, screw loosening, dislodgement of screw insertion filling material, and peri-implant mucositis were confirmed through Kaplan–Meier survival curves to determine the survival rate by observation period. Complications that occurred between the two groups of metal-ceramics and Zr-LiSi were recorded. The data identity was confirmed using the log-rank test. Statistical significance was analyzed at the 95% confidence interval level.



**Fig. 1.** Design of abutment and implant prostheses. (A) Metal-ceramic, (B) Zirconia-lithium disilicate.



**Fig. 2.** Intraoral radiographs. (A) 1 month, (B) 3 months, (C) 6 months, (D) 12 months.

## RESULTS

The mean functional duration of the 71 patients was 29 (range, 18 – 40) months. Finally, 34 metal-ceramic implant and 37 Zr-LiSi bilayered ceramic implant prostheses were included.

Of the 103 implants included in the study, 92 were externally connected implants, and 11 were internally connected implants. Moreover, 69 externally connected implants were USII (Osstem Corp., Seoul, Korea), 23 were Sola (Shinhung Corp., Seoul, Korea), and 11 internally connected implants were Luna (Shinhung Corp., Seoul, Korea). In addition, 17 implants were accompanied by bone grafting at the time of implant placement, and 86 did not have bone grafting.

Tables 1 and 2 summarize the characteristics of the implants according to the prosthesis type. No implant failure occurred in the metal-ceramic and Zr-LiSi bilayered ceramic prostheses, resulting in a 100% implant survival rate. According to the definition of survival rate, 77% and 73% of the prostheses did not require any additional treatment and were without any complications in the metal-ceramic and Zr-LiSi

bilayered ceramic groups, respectively.

No biological complications occurred in metal-ceramic prostheses, whereas peri-implant mucositis occurred in 16.2% ( $n = 6$ ) of Zr-LiSi bilayered ceramic prostheses, and the degree of swelling needed to be adjusted because of the patient's discomfort (Fig. 3). When comparing the incidence of peri-implant mucositis using the log-rank test, a significant difference was found between the metal-ceramic and Zr-LiSi bilayered ceramic groups ( $P = .04$ ). Peri-implant mucositis involves soft tissue inflammation without bone loss. Peri-implant mucositis was assessed through clinical parameters such as bleeding on probing and observations of tissue color and consistency.

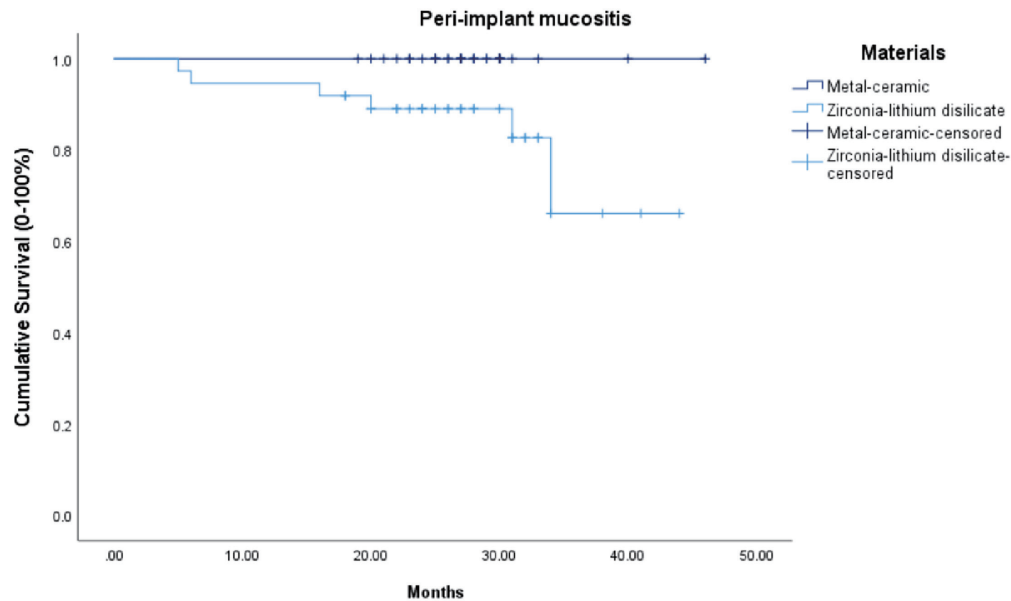
The mean marginal bone loss was 0.09 mm in the metal-ceramic and 0.01 mm in the Zr-LiSi bilayered ceramic groups. Bone loss of 0.5 – 1.0 mm occurred in five metal-ceramic and in one Zr-LiSi bilayered ceramic prostheses, with a bone loss amount of 0.5 mm. Bone loss of up to 1 mm occurred in the metal-ceramic prostheses; however, this value was within the normal range and was less than the success criterion of 1.5 mm by Albrektsson *et al.* (Table 3).<sup>10</sup>

**Table 1.** Implant prostheses included in study

	Sex		Implant		Intra-arch location		Inter-arch location	
	Male	Female	Single	Multiple	Premolar	Molar	Maxilla	Mandible
Metal-ceramic	17	17	17	17	17	17	15	19
Zirconia-lithium disilicate	19	18	24	13	11	26	10	27

**Table 2.** Implant included in study

Connection type		Implant system			Guided bone regeneration (GBR)		Surgery	
External	Internal	USII	Sola	Luna	With GBR	Without GBR	1 stage	2 stage
92	11	69	23	11	17	86	63	40



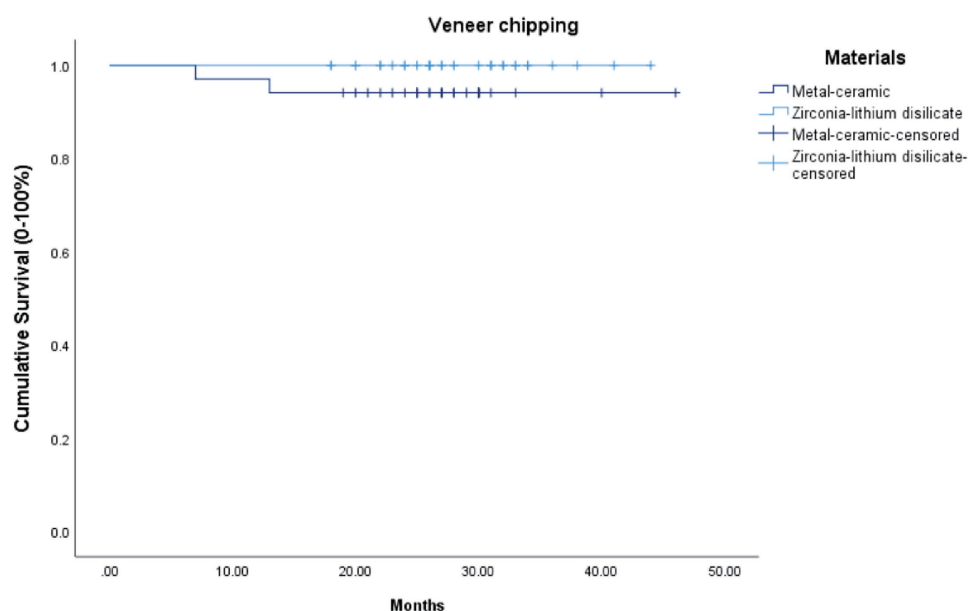
**Fig. 3.** Kaplan-Meier survival function of peri-implant mucositis.

**Table 3.** Biological complications

	Metal-ceramic		Zirconia-lithium disilicate	
	0		6 (16.2%)	
Peri-implant mucositis			Male	Female
			1	5
			Maxilla	Mandible
			1	5
			Single	Splint
			5	1
	5 (14.7%)		1 (2%)	
Marginal bone loss	Mean	0.09 mm	Mean	0.01 mm
	Maximum	1 mm	Maximum	0.5 mm

For prosthetic complications, fracture of the veneer material occurred in 5.8% ( $n = 2$ ) of metal-ceramic prostheses but not in Zr-LiSi bilayered ceramic prostheses (Fig. 4). Two fractures occurred in male and female participants, respectively, and both were located in the mandibular molars. Screw loosening

occurred in 8.8% ( $n = 3$ ) of metal-ceramic prostheses and 5.4% ( $n = 2$ ) of Zr-LiSi bilayered ceramic prostheses. The rates of screw-access hole filling material loss were 8.8% (3 items) in metal-ceramic prostheses and 13.5% (5 items) in the Zr-LiSi bilayered ceramic prostheses (Table 4).



**Fig. 4.** Kaplan-Meier survival function of veneer chipping.

**Table 4.** Prosthetic complications

	Metal-ceramic		Zirconia-lithium disilicate	
	2 (5.8%)		0 (0%)	
Veneer fracture	Male	Female		
	1	1		
	Maxilla	Mandible		
	0	2		
	3 (8.8%)		2 (5.4%)	
Screw loosening	Maxilla	Mandible	Maxilla	Mandible
	3	0	0	2
	Single	Splint	Single	Splint
	2	1	1	1
	3 (8.8%)		5 (13.5%)	
Loss of screw hole restoration	Maxilla	Mandible	Maxilla	Mandible
	1	2	1	4
	Single	Splint	Single	Splint
	1	2	5	0



## DISCUSSION

The null hypothesis that there would be no difference in the clinical outcomes between implant-supported metal-ceramic and Zr-LiSi bilayered ceramic prostheses was rejected. In this 3-year clinical study, no implant failure occurred in both metal-ceramic and Zr-LiSi bilayered ceramic groups. In other words, the implant survival rate was 100%. This survival rate is higher than that reported in previous studies<sup>2,9,11-13</sup> because the implant placement process followed the traditional placement and loading periods. Some bone loss occurred in some of the metal-ceramic and Zr-LiSi bilayered ceramic prostheses; however, no significant difference was found. All peri-implant bone losses occurred within 1 year of function and were within 1.0 mm. According to the implant success criteria by Albrektsson *et al.*,<sup>10</sup> this normal bone resorption can occur during the normal bone remodeling process; thus, it can be said to meet the success criteria in terms of bone loss.

In the Zr-LiSi bilayered ceramic group, no fracture occurred during the 3-year follow-up (0%). However, in the metal-ceramic group, two fractures (5.8%) occurred (Fig. 4). This incidence rate of fracture in the metal-ceramic group was lower than that reported by Pjetursson *et al.* (7.8 – 13.2%)<sup>11,14</sup> and similar to that reported by Jung *et al.* (3.5 – 4.5%).<sup>12,15</sup> The overall fracture incidence rate for the two groups combined was 2.8%, which was lower than those in previous reports.

In the analysis of two clinical trials, fractures occurred in both mandibular molars. More fractures occurred in the posterior teeth than in the anterior teeth.<sup>16,17</sup> The results of these clinical trials were comparable, with fractures occurring in the mandibular molars. Regarding sex, one case of fracture occurred in a prosthesis in each of the male and female groups. The average maximum occlusal force of Asians is 480.8 N for men and 412.3 N for women.<sup>18</sup> Although the maximum occlusal force differs by sex, no difference in the fracture incidence rate was reported according to sex.<sup>13</sup> This study evaluated SCR type implant-supported prostheses with screw-access hole. According to Wittneben *et al.*,<sup>8</sup> more fractures occurred in screw-retained implants than in cement-re-

tained implants. The screw-access hole disrupts the continuity of the substructure and veneer, affecting mechanical strength and increasing fracture risk. However, the overall fracture incidence rate was 2.8% in cement- and screw-retained implants in this study, which was lower than that in previous studies. This is thought to be due to appropriate prosthesis design and careful occlusal adjustment.

No peri-implant mucositis occurred in the metal-ceramic group; however, it occurred in 6 cases (16.2%) in the Zr-LiSi bilayered ceramic group. Patients who had peri-implant mucositis complained of food getting stuck around the implant and bleeding when brushing their teeth. In addition, a patient directly expressed that the prosthesis was too bulky. During intraoral examination, food and plaque were deposited under the prosthesis, and bleeding on probing was noted.

Of the six Zr-LiSi bilayered ceramic prostheses in which peri-implant mucositis occurred, five were mandibular prostheses and one was a maxillary prosthesis. According to Serino and Ström,<sup>19</sup> peri-implant mucositis is highly likely to occur if oral hygiene management is impaired because of prosthesis overcontouring. Among the implant prostheses, five occurred in the female group and one in the male group.<sup>20</sup> This result is contrary to that reported by Ferreira *et al.*,<sup>21</sup> who found that peri-implant mucositis occurred more often in men. However, contradictory results were obtained because of the small number of prostheses in which peri-implant mucositis occurred.

When the prosthesis that developed peri-implant mucositis caused by excessive swelling was removed and redelivered by adjusting the overcontoured area, the severity of mucositis decreased. Tapia *et al.*<sup>22</sup> reported the same result, i.e., peri-implant mucositis was improved after adjusting the overly fused prosthesis. According to Schwarz *et al.*,<sup>23</sup> the risk of peri-implant mucositis did not differ by prosthesis and abutment material. Therefore, peri-implant mucositis occurred because oral hygiene was impaired by the overcontoured profile of Zr-LiSi bilayered ceramic implant prostheses rather than by material differences.

In this study, the incidence rate of peri-implant mucositis in Zr-LiSi bilayered ceramic implant prostheses

was 16.2%, which is higher than the biological complication rate (7.1 – 9.7%) in previous studies.<sup>2,9,11-13</sup> Sailer *et al.*<sup>24</sup> described a higher rate of biological complications in screw-retained implant prostheses than in cement-retained implant prostheses. This might be related to the healing of inflammation after screw loosening and retightening.<sup>25</sup>

In this study, all prostheses were SCR types, which can reduce the risk of biological complications caused by residual cement, which is a disadvantage of the cement-retained type. Therefore, a more important cause was the overcontoured shape of the implant prostheses, which is a common phenomenon in CAD-CAM prostheses. When manufacturing implant prostheses, the veneer material must have uniform thickness. The minimum thickness of the metal substructure that can be manufactured is 0.3 mm; however, the thickness of the zirconia substructure was 0.8 mm. This can be seen in the thickness difference between the metal and zirconia substructure around the screw-access hole observed from the occlusal plane. Even if the veneer thicknesses of metal-ceramic and Zr-LiSi bilayered ceramic prostheses were the same, the thickness of the zirconia substructure at the time of design was thicker than the metal substructure. Despite slight dimensional discrepancies in the definitive prosthesis, the CAD-designed substructure was crafted to closely adhere to the specified dimensions. However, the veneering ceramic was tailored to accommodate the patient's specific situation, resulting in some variations. The dimensional differences primarily stemmed from the substructure. Generally, Zr-LiSi ceramic prostheses exhibited an overcontour pattern approximately 0.5 mm larger than that of metal-ceramic prostheses. Therefore, the Zr-LiSi group can be manufactured overcontoured. To reduce the incidence of peri-implant mucositis, the Zr-LiSi bilayered ceramic implant prosthesis design should consider the emergence profile and gingival type.

According to Pjetursson *et al.*,<sup>26</sup> when comparing metal-ceramic and zirconia monolithic structure implant prostheses, no significant difference was found in the incidence of soft tissue complications. In contrast, in the present study, significantly higher soft tissue complications occurred in the Zr-LiSi bilay-

ered ceramic prostheses than in metal-ceramic ones because Pjetursson *et al.* used a zirconia monolithic structure. Thus, the possibility of prosthesis overcontouring was lower than that of the Zr-LiSi bilayered ceramic structure in the present study.<sup>1</sup>

Another possible cause is the difference in plaque accumulation. In an *in vivo* experiment of plaque accumulation on dental ceramic materials, zirconia showed a low plaque accumulation rate (19.0%); however, LiSi showed a relatively high plaque accumulation rate (46.8%).<sup>27</sup> Therefore, Zr-LiSi bilayered ceramic prostheses, where the area in contact with the mucosa is lithium, demonstrated a relatively high plaque accumulation rate (46.8%). Because the bilayered design has a higher risk of plaque accumulation than the monolithic zirconia structure, greater caution is required in reducing the thickness of the zirconia or in the design of the titanium implant abutment.

In this study, complete screw loosening with mobility and screw loosening were recorded, even with a slight feeling of rotation during retightening during regular checkups. In this study, screw loosening occurred in 8.8% of the metal-ceramic prostheses, 5.4% of the Zr-LiSi prostheses, and 7% of the overall prostheses. The rates were similar to 5.3 – 12.7% in previous studies.<sup>2,11-13</sup> In the previous study, passive diagnosis detected the occurrence during a patient's visit; however, in this study, an active diagnosis detected the occurrence through active retightening. Thus, a much stricter standard was applied than the actual occurrence frequency in other studies. In the study by Nissan *et al.*,<sup>28</sup> screw-retained implants showed a higher screw loosening rate than cement-retained implants. All implant prostheses in the present study are cement- and screw-retained implants and have the advantages of both screw-retained and cement-retained implants; thus, screw loosening would be less than that of existing screw-retained implants. However, compared with previous studies, the screw loosening incidence rate was comparable. According to Binon,<sup>29</sup> more screw loosening events occurred in external connection-type implants than in internal connection-type implants. Although 89% of the implants included in this study were externally connected, with screw loosening occurring in 8.8% of the metal-ceramic and 5.4% of the Zr-LiSi prostheses.



Previous studies of screw loosening by an implant connection type have reported that internal connections are more resistant to screw loosening than external connections.<sup>30,31</sup> However, Vigolo *et al.*<sup>32</sup> and Chae *et al.*<sup>33</sup> reported the lack of significant difference in the incidence of screw loosening between the two connections. In the present study, we attempted to investigate the effect of the connection type on the incidence of screw loosening; however, the internal connection type was used in only 11 of the 103 implants, which limited the statistical analysis.

The connection type or submerging implant installation may influence the results. However, according to previous studies, they do not significantly affect the clinical outcomes. Camps-Font *et al.*<sup>34</sup> reported that the implant abutment connection design does not influence implant survival and biologic complication rates. Nemli *et al.* showed that non-submerged implants exhibited a slightly higher initial success rate and less bone loss over 24 months than submerged implants. However, no significant differences in marginal bone loss were found between the two groups.<sup>35</sup>

Owing to the limitations of dental clinical trials, a complete double-blinded randomized controlled trial is impossible. Moreover, the number of prostheses included in each group was 34 and 37, which was insufficient for comparison of complication rates of each group. However, the sample size for each group was small to enable determining the risk of complications for each variable such as maxilla and mandible, single type, splinted type, internally connected type, and externally connected type. Small sample sizes and single-center designs may limit the study's statistical power and generalizability, leading to potential type II errors and biased outcomes. These limitations hinder the representation of a wider population and may introduce investigator bias due to similar methodologies. To enhance reliability and applicability to diverse contexts, multicenter studies with larger samples are recommended.

Despite these limitations, the results were meaningful in that implant-supported Zr-LiSi bilayered ceramic prostheses were evaluated and compared with the most commonly used metal-ceramic prostheses, which has been difficult to directly compare clinically.

## CONCLUSION

In this study, Zr-LiSi bilayered ceramic implant prostheses were compared through clinical evaluations with conventional metal-ceramic implant prostheses in terms of biological and prosthetic complications, and the following conclusions were obtained: First, the Zr-LiSi bilayered ceramic implant prostheses did not fracture during the 3-year observation period; however, two fractures (5.8%) occurred in metal-ceramic implant prostheses. Second, Zr-LiSi bilayered ceramic implant prostheses had a higher incidence of peri-implant mucositis than metal-ceramic implant prostheses ( $P < .05$ ). This is due to the overcontouring of the Zr-Li-Si prosthesis, and the symptoms of peri-implant mucositis were improved by modifying the emergence profile. Finally, no difference was found between implant-supported metal-ceramic and Zr-LiSi bilayered ceramic prostheses in the incidence of screw loosening and dislodgement of screw-access hole filling material.

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