A Randomized Controlled Clinical Trial of Feldspathic Versus Glass-Infiltrated Alumina All-Ceramic Crowns: A 3-Year Follow-up

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Purpose: The aim of this randomized controlled clinical trial was to compare the outcome of feldspathic porcelain (group 1) and glass-infiltrated alumina all-ceramic (group 2) crowns. ***Materials and Methods:*** Patients were recruited based on inclusion/exclusion criteria, and 33 eligible subjects were assigned randomly to one of the two treatment groups. One hundred one crowns were placed predominantly in the anterior portion of the mouth and were cemented using resin cement. A baseline California Dental Association quality evaluation was completed, and Plaque and Gingival Index scores were recorded. Prosthetic and soft tissue scores were recorded for up to 3 years. ***Results:*** Five restorations experienced mechanical failure. Kaplan-Meier analysis showed that the 3-year survival probabilities for group 1 (0.94) and group 2 (0.95) restorations were comparable ($P = .484$). Plaque and Gingival Index scores for both groups were similar at the 3-year recall ($P > .999$). Marginal integrity, anatomical form, and color and surface scores were also similar for both groups ($P > .05$). ***Conclusion:*** Feldspathic and glass-infiltrated alumina all-ceramic crowns placed predominantly in the anterior portion have comparable biologic and prosthetic outcomes, as well as survival probabilities. *Int J Prosthodont 2011;24:77–84.*

Prosthetic materials used in the esthetic zone should allow clinicians to pursue durable, cost-effective, and simple interventions with predictable survival rates to meet the functional and reasonable demands of patients.[1] At present, there is an abundance of all-ceramic systems available for fabrication of single- and multiunit fixed prosthesis. An over 5-year assessment of all-ceramic crowns showed that Kaplan-Meier survival estimates were 69% for Cerestore (Kyocera) at 8 years, 86% for Dicor (Dentsply) at 7 years, 81% for HiCeram (Vita Zahnfabrik) at 6 years, and 92% for InCeram (Vita Zahnfabrik) at 5 years.[2] A systematic review also suggested that the 5-year survival rates of InCeram crowns and fixed partial dentures ranged from 91.7% to 100%, similar to the survival rates of conventional metal-ceramic crowns.[3] Likewise, another systematic review suggested that the 5-year survival of all-ceramic crowns placed in the anterior area is comparable to metal-ceramic crowns; 5-year survival rates of densely sintered alumina crowns (Procera, Nobel Biocare; 94.9%) and reinforced glass-ceramic crowns (Empress, Ivoclar Vivadent; 93.7%) were similar to those obtained for metal-ceramic crowns in the posterior zone. That review also suggested that lower survival rates of 90.4% and 84.4% could be expected for InCeram and glass-ceramic crowns, respectively, on premolar and molar teeth.[4] The most frequently cited reasons for failure of these restorations include chipping of the veneering porcelain, fracture of the restoration or tooth, faulty margins that cannot be repaired properly and lead to soft tissue breakdown or caries, and endodontic/periapical problems that necessitate replacement of the restoration or extraction of the tooth.

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In comparison with feldspathic porcelain, high-strength ceramics tend to be more opaque and pose a challenge when trying to match the natural tooth color in the esthetic zone.[5] Despite its lower mechanical strength, feldspathic porcelain, with or without intrinsic reinforcement, has been used for fabrication of complete crowns, laminates, and even single-unit partial crowns with predictable survival rates in the anterior region.[6–12] Nevertheless, clinical studies comparing the effectiveness of feldspathic all-ceramic crowns with other ceramic systems are scarce. The aim of this randomized controlled clinical trial was to compare the survival rates, soft tissue reactions, and prosthetic outcomes of feldspathic porcelain (Noritake, Noritake) and glass-infiltrated alumina (InCeram) all-ceramic crowns. It was hypothesized that the soft tissue outcomes of both ceramic systems would be comparable and that the incidence of mechanical failures of InCeram crowns would be lower than that for Noritake crowns because of the glass-infiltrated alumina reinforcement.[13]

Materials and Methods

A total of 33 consecutive patients were included in this study (7 men, mean age: 42 years; 26 women, mean age: 37 years). Patients were selected and recruited based on the following inclusion criteria: extensive loss of tooth structure indicating full veneer crowns or crowns needing replacement (ie, marginal discrepancy, secondary caries, fracture, esthetics), periodontal pocket depth < 3 mm, no history of previous periodontal flap surgery, good oral hygiene and low caries activity, no tooth mobility, and lack of excessive parafunctional activity leading to extensive loss of tooth structure, abfraction lesions, or cracks.

Patients who had history of drug abuse or life-threatening diseases (American Society of Anesthesiologists classification),[14] radiotherapy in the head and neck region, severe intermaxillary skeletal discrepancy, excessive parafunctional activity leading to wear of prosthetic teeth or fracture of dentures, and those who were heavy smokers were excluded from this study.

Study Design

This was a randomized, controlled, single-blind (prosthodontist) clinical trial on single-tooth feldspathic porcelain (group 1, Noritake) and glass-infiltrated alumina (group 2, InCeram) all-ceramic crowns. Patients were screened using the inclusion and exclusion criteria described previously, and eligible subjects were assigned to one of the two groups from January 2005 to March 2009. Allocation of patients was random, as described by Meijer et al,[15] and was terminated when 50 crowns were fabricated in each group. This resulted in 50 feldspathic porcelain crowns (12 patients) and 51 glass-infiltrated alumina crowns (21 patients). The number of smokers in groups 1 and 2 was 1 and 5, respectively.

Study Procedures

Each preexisting restoration was evaluated according to the California Dental Association (CDA) Quality Evaluation Index, if applicable[16] (Table 1), and Plaque[17] and Gingival[18] Index scores were also recorded (baseline measurements). The teeth were prepared to a 2-mm occlusal/incisal clearance and 1.5-mm rounded shoulder. The finish line was located approximately 0.5 mm subgingivally on the buccal aspect and at the gingival crest level for the other sides during tooth preparation in both groups. No bevel was incorporated into the finish line preparation. Both nonvital and vital prepared teeth had more than a 2 mm ferrule. Full-arch impressions were taken using a condensational polymerization silicone impression material (Speedex, Coltène), and irreversible hydrocolloid impressions (Blueprint cremix, Dentsply DeTrey) were taken of the opposing dentition.

InCeram crowns were fabricated according to the guidelines determined by the manufacturer (Fig 1). In brief, densely packed slurry (80 to 82 wt%) of pure aluminum oxide particles were fired at 1,120°C for 3 hours on a refractory die, followed by infiltration of lanthanum glass into the resulting porous coping during a second firing at 1,100°C for 4 hours.[19] The high-strength coping was then veneered with a feldspathic ceramic (Vitadur Alpha, Vita) to achieve the final esthetic restoration. For fabrication of the Noritake all-ceramic crowns, the refractory cast was obtained using a gypsum bonded investment material (Norivest, Noritake). After a bench setting time of 2 hours, the refractory cast was preheated at 1,080°C. The dies were prepared and immersed in water for 10 minutes. A 1.0- to 1.5-mm-thick initial dentin porcelain buildup (Super porcelain EX-3), followed by dentin and enamel porcelains and luster porcelain, was fired consecutively from 600°C to 930°C under vacuum pressure (heat rate: 45°C per minute). The crowns were glazed at 920°C without vacuum pressure. Then, the crowns were carefully divested to avoid breaking the ceramic, sandblasted with 50-μm aluminum oxide particles at 0.2 MPa, adjusted in their respective dies, and delivered to the patients (Fig 2). The crowns in both groups were cemented with dual-cured resin cement (Panavia F 2.0, Kuraray).

Table 1 Criteria for California Dental Association Rating14

Category	Score: Acceptable	Score: Unacceptable	Criteria
Marginal integrity	Excellent		No visible evidence of crevice along margin that explorer would penetrate; no evidence of ditching along margin
	SCR		Visible evidence of slight marginal discrepancy with no evidence of decay, repair possible but perhaps unnecessary; explorer gets stuck in one direction
		TFAM	Faulty margins cannot be properly repaired
		TPEN	Penetrating discoloration along margin of restoration in pulpal direction
		TCEM	Retained excess cement
		VMO	Mobile restoration
		VFR	Fractured restoration
		VCAR	Caries continuous with margin of restoration
		VTF	Fractured tooth structure
Anatomical form	Excellent		Restoration contour in functional harmony with adjacent teeth and soft tissues within good individual anatomical form
	SOCO		Restoration slightly overcontoured
	SUCO		Restoration slightly undercontoured
	SOH		Occlusion not completely functional
	SMR		Margin ridges slightly undercontoured
	SCO		Contact slightly open
	SFA		Facial flattening present
	SLG		Lingual flattening present
		TUCO	Restoration grossly undercontoured
		TOCO	Restoration grossly overcontoured
		TET	Occlusion affected
		TOC	Contact faulty
		TOV	Marginal overhang present
		VTO	Traumatic occlusion
		VUO	Gross underocclusion
		VPN	Restoration caused unremitting pain in tooth or adjacent tissue
		VDM	Damage to tooth, soft tissue, or supporting bone
Color and surface	Excellent		No mismatch in color shade or translucency between restoration(s) and adjacent teeth; restoration surface smooth; no irritation of adjacent tissue
	SMM		Slight mismatch between shade of restoration(s) and adjacent tooth or teeth
	SRO		Restoration surface slightly rough but can be polished
		TGI	Grossly irregular surface not related to anatomy and not subject to correction
		TMM	Mismatch between restoration(s) and adjacent tooth or teeth outside normal range of color, shade, or translucency
		VSF	Fractured surface
		VGP	Gross porosities in crown material
		VSD	Shade in gross disharmony with adjacent teeth

Each crown was assessed according to the CDA Quality Evaluation Index at delivery, 6 months, and annual checkups thereafter. Consequently, any change relative to the initial rating (delivery) was recorded at recalls, ie, a crown having a color and surface rating of SMM was rated excellent at the recall appointment only if a clinically discernable slight mismatch was still present. Plaque and Gingival Indices were also used to evaluate the restorations at 6 months and the annual checkups.

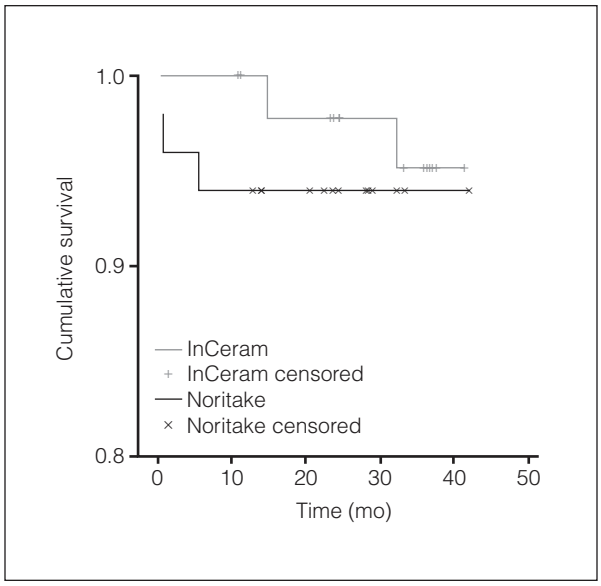
Fig 1a Pretreatment view of nonvital maxillary left central and lateral incisors restored previously with metal-ceramic crowns.

Fig 1b InCeram crowns were used to replace the existing metal-ceramic restorations.

Fig 1c In situ view of the definitive treatment.

Fig 2 **(a)** Pretreatment view of the maxillary incisors restored previously with all-ceramic crowns involving a ceramic core. **(b)** In situ view of Noritake crowns. Note the difference in translucency between **(c)** the preexisting crowns and **(d)** the definitive feldspathic crown.

Fig 3 Survival probabilities of the crowns in both groups (Kaplan-Meier analysis).



Statistical Analysis

For the comparison of prosthetic outcomes, the first incidence of any complication indicating replacement of a crown was taken into account, and the timing was referred to as the "failure period." A restoration was considered "failed" when any of the following was detected: porcelain chipping; catastrophic fracture of the crown, supporting tooth, or both; caries with or without periapical lesions; and excessive breakdown of the supporting tissues indicating extraction of the tooth. Excluding the indication for extraction, replacement of a crown was undertaken upon detection of any of these complications. A crown was considered as "survived" when these problems were not detected. During statistical assessment, the absence of a complication was referred to as "censored." Survival was evaluated by Kaplan-Meier analysis, and comparative evaluation between groups on survival probabilities (maximum time in function without experiencing any complications) was undertaken by the log-rank test at a 95% confidence level. CDA criteria were categorized into none (not applicable since there was no preexisting restoration on the tooth before treatment), excellent, acceptable, and unacceptable, with reference to Table 1. Likewise, Plaque and Gingival Index scores were grouped (ie, 0 and other [scores 1 and 2, respectively]). Between-group comparisons of CDA ratings and Plaque and Gingival Index scores were performed by the chi-square, Fisher exact, and McNemar binomial tests at a 95% confidence interval.

Results

Restorations and Survival Probabilities

Among the restorations, anterior replacements in groups 1 and 2 were 86% and 66%, respectively. A small percentage (5.88% and 3.92%, respectively) required post and core restorations. Chipping or wear was not observed in any of the restorations. Of the 101 crowns, 5 restorations failed. Three failures occurred in group 1 and 2 failures in group 2. In group 1, 2 failures were observed on nonvital maxillary right lateral incisors (without posts and cores) within the first month of function. Failure of these restorations was related to the fracture of the natural teeth above the cervical level, while no sign of chipping or fracture was detected in the crowns. The third failure was a fracture of the crown, which was replaced. In group 2, 1 crown (nonvital maxillary left second premolar) fractured and was replaced, whereas the other experienced fracture of both the crown and the tooth (nonvital mandibular left second premolar), indicating extraction.

Kaplan-Meier analysis showed that the mean survival time of the crowns in both groups was 40.3 ± 0.7 months, and 1- and 3-year survival probabilities were 0.97 and 0.94, respectively. The mean survival time in group 1 was 39.6 ± 1.3 months, and 1- and 3-year survival probability was 0.94; the mean survival time in group 2 was 40.5 ± 0.6 months, and 1- and 3-year survival probabilities were 1.00 and 0.95, respectively (Fig 3). The survival probabilities of both groups were comparable (P = .484, log-rank test).

Soft Tissue Outcome and CDA Ratings

Baseline Plaque Index scores for both groups were different ($P = .004$) due to an 81% incidence of score 2 in group 1. Likewise, baseline Gingival Index scores for both groups were different ($P = .024$) due to a 77.8% incidence of score 2 in group 1. There was an immediate enhancement in soft tissue response in both groups upon delivery ($P < .05$), which almost remained constant over time. The Plaque and Gingival Index scores of both groups was comparable at the 3-year recall ($P > .999$).

Baseline CDA scores of both groups were different (Table 2). At delivery, CDA ratings for marginal integrity and anatomical form were similar in both groups ($P = .20$ and $P = .48$, respectively), but color and surface scores were different ($P = .00$). The majority of group 1 restorations (70.8%) had an excellent rating, whereas 88.9% of group 2 restorations displayed slight color mismatch (SMM). Over the course of the study, marginal integrity scores of both groups were similar ($P > .05$). At the 3-year recall, anatomical form and color and surface ratings of both groups were similar ($P = .502$ and $P = .505$, respectively). Marginal integrity and color and surface ratings improved in group 1 ($P = .002$ and $P = .00$, respectively; McNemar binomial test) and group 2 ($P = .00$) in comparison to baseline records.

Discussion

In previous clinical studies,[20–22] the exclusivity in location, tooth preparation, and morphology among all-ceramic restorations placed in the same individual led to the use of the crowns as the unit of statistical analysis rather than patients; therefore, the same approach was followed during assessment of the crowns. Since conventional feldspathic porcelains have lower fracture strength and no reinforcement in comparison to slip-cast glass-infiltrated alumina,[23] the authors expected more chipping or fracture in group 1 at even early stages of function. Considering that two of the failures in group 1 were due to fracture of the tooth (reduced tooth mass as a consequence of a 1.5-mm shoulder), survival of the crowns seems comparable. Owing to the high-strength alumina core, fracture involving the core and the veneering porcelain was not expected for InCeram crowns in the present study. However, two posterior InCeram restorations on nonvital teeth experienced catastrophic fracture. In terms of mechanical failures, the very low incidence of fractures are in agreement with the reports of McLaren and White[24] and Segal,[25] who observed more mechanical failures in the posterior region and fractures due to excessive functional stress. They attributed the failures to external line angles of the tooth preparations, especially with copings of questionable thickness or rounded angles. Therefore, tooth preparation, as well as fabrication and adjustment of the coping, are critical steps in prosthetic treatment involving InCeram alumina crowns. In the present study, the teeth were prepared in a standard manner, and no sharp edges were present in the external preparation angles. Care was also taken during fabrication, adjustment, and cementation of the crowns.

Given the conditions of the present clinical study, a conventional survival analysis (Kaplan-Meier) was used to assess the survival probabilities of both types of restorations, and it seems that the survival of both types of restorations, placed predominantly in the anterior area, was similar. Considering the length of evaluation (mean: 39 to 40 months), however, this study should be considered preliminary. Since even conventional porcelain veneers are expected to last 10 to 15 years[26] and the incidence of mechanical failures was very low after the first month of placement in the present study, good prognosis may be expected for feldspathic all-ceramic crowns.

The biologic outcome of both types of restorations was comparable, and enhancement in soft tissue health was observed upon placement. Most of the crowns had Plaque and Gingival Index scores of 0, and the time-dependent change of the scores suggests that the Plaque and Gingival Index scores almost reached a steady state just after the first recall appointment. This finding could be attributed to the fact that faulty and unacceptable margins (TFAM: 27 restorations; Table 1) were replaced by acceptable margins with almost excellent ratings, and potential damage to the periodontium was prevented by limited penetration into the gingiva. In addition, porcelain has a well-known lower susceptibility to bacterial plaque in comparison to gold, resin, or even hard tooth structure.[27,28]

Several clinical studies on all-ceramic crowns have reported slight marginal discrepancies at a rate of less than 30%. Haselton and coworkers[29] detected marginal flaws at a rate of 16.5% in 80 InCeram alumina restorations in an observation period of 4 years. Likewise, Gemalmaz and Ergin[22] reported 19% SCR for IPS Empress crowns, and Naert et al[30] reported 18% SCR and 2 unacceptable margins for Procera all-ceramic crowns. In the present study, 100% of Noritake and 94.3% of InCeram crowns had excellent CDA ratings at the 3-year recall appointments; 5.7% of InCeram crowns had SCR, and none of the SCR sites experienced gingival recession, pocket formation, enduring pain, marginal leakage, or secondary

Table 2 Baseline and "Baseline Versus 3-Year Recall" CDA Ratings of Both Groups

				Baseline versus 3-year recall					
		Baseline measurements		Group 1	Group 2				
		Group 1	Group 2	Exc	Exc	SCR	VDM	SMM	VSF
Marginal integrity									
Exc	Count	6	0	4	—	—			
	% within MI	100.0	0.0	15.4	—	—			
None	Count	14	16	8	9	0			
	% within MI	46.7	53.3	30.8	27.3	0			
Acceptable	Count	8	12	4	7	0			
	% within MI	44.4	55.6	15.4	21.2	0			
Unacceptable	Count	21	23	10	15	2			
	% within MI	47.7	52.3	38.4	51.6	100			
Anatomical form									
Exc	Count	15	23	8	19		0		
	% within AF	39.5	60.5	30.8	54.3		0		
None	Count	14	16	8	9		1		
	% within AF	46.7	53.3	30.8	25.7		100		
Acceptable	Count	10	11	6	5		0		
	% within AF	47.7	52.3	23.1	14.3		0		
Unacceptable	Count	12	0	4	2		0		
	% within AF	100.0	0.0	15.4	5.7		0		
Color and surface									
Exc	Count	6	8	4	4			1	0
	% within CS	42.9	57.1	15.4	11.8			100	0
None	Count	14	16	8	9			0	1
	% within CS	46.7	53.3	30.8	26.5			0	100
Acceptable	Count	14	12	14	9			0	0
	% within CS	53.8	46.2	53.8	26.5			0	0
Unacceptable	Count	16	15	—	12			0	0
	% within CS	53.3	46.7	—	35.3			0	0

MI = CDA rating for marginal integrity: Marginal integrity ratings of both groups were different (P = .039) due to a high excellent rating in group 1; AF = CDA rating for anatomical form: Anatomical form ratings of both groups were similar (P = .119); CS = CDA rating for color and surface: Color and surface ratings of groups were different (P = .002) due to the VSD rating that appeared only in group 1, color and surface ratings of both groups were similar (P = .753) when ratings were grouped as none, excellent, and other (chi-square and Fisher exact tests); Exc = excellent.

caries during the follow-up period. No cement washout was detected and recementation was not required for any restoration. Color and surface scores were different between groups: 70.8% of group 1 restorations had an excellent rating and 88.9% of group 2 restorations displayed slight color mismatch (SMM). This finding could be attributed to opacity created by means of the alumina in InCeram and reduction in light transmission in the core ceramics (see Fig 2), which, in turn, alters the translucency, particularly in the cervical third region.

Conclusions

Within the limitations of this study, the following conclusions were drawn:

- Feldspathic and glass-infiltrated alumina all-ceramic crowns placed predominantly in the anterior area have comparable survival probabilities up to 3 years.
- Feldspathic and glass-infiltrated alumina all-ceramic crowns lead to similar biologic and prosthetic outcomes up to 3 years.

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