Short-term clinical performance of zirconia single crowns with different framework designs: 3-year clinical trial

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ABSTRACT: Purpose: The present prospective clinical study evaluated the influence of coping design on the fracture resistance of CAD/CAM zirconia single crowns layered with dedicated ceramics. **Methods:** 56 subjects were provided with 90 zirconia single crowns in posterior regions. Tooth preparations were standardized and the abutment teeth were randomly distributed into three groups, according to three different coping designs (flat design, FD; porcelain-fused-to-metal-like crowns, PFM; anatomically-guided, AG). The zirconia cores were produced using a CAD/CAM software and then were hand-layered with dedicated ceramics. All crowns were cemented with a self-adhesive resin luting agent and the patients were recalled for follow-up visits after 1 month, 6 months, 1, 2 and 3 years of clinical service. The function, esthetics and marginal adaptation of the restorations were evaluated. Statistical analyses were performed to evaluate survival and success of the restorations. **Results:** Success rates of 100% were reported in Group 2 and Group 3 while the percentage was 80% in Group 1. Three chippings were noticed in Group 1 (FD) and two crowns needed to be replaced after 3 years, resulting in a survival rate of 93.3%. Group 2 and Group 3 had significantly higher 3-year success rates than Group 1 ($P < 0.05$). Based on the present clinical results, the following conclusions were drawn: the porcelain-fused-to-metal-like and the anatomically-guided frameworks for zirconia single crowns performed better clinically than the flat designed cores in posterior regions after 3 years; standardized tooth preparations achieved even thicknesses of the bilayered restorations; the proper support given to the veneering ceramic by the correct design of the zirconia framework could significantly reduce the risk of chipping during function (*Am J Dent* 2015;28:235-240).

CLINICAL SIGNIFICANCE: The results of the present clinical study showed porcelain-fused-to-metal-like and the anatomically-guided frameworks for zirconia single crowns performed better clinically than the flat designed cores in posterior regions after 3 years, which may allow clinicians to decide what kind of coping design should be chosen when using zirconia single crowns. Moreover, the interpretation and discussion of the clinical and statistical meaning of "survival" and "success" are reported, in order to fill the gap between laboratory and clinical studies.

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Introduction

Zirconia has interesting characteristics to be used in dentistry such as optimal mechanical properties, natural-tooth appearance, insolubility in a water environment, low corrosion potential, no cytotoxicity, reduction of bacterial adhesion, and radiopacity.[1,2] Recently, the use of zirconia as 'white metal' for prosthetic copings, frameworks, and implant abutments has been reported.[3,4]

In vitro studies[5-10] evaluated zirconia mechanical properties and some other variables with a possible influence on its behavior during clinical service.

Zirconia has also been widely tested in in vivo studies[11-17] for single copings, frameworks of fixed dental prostheses (FDPs), and implant abutments.

Chipping of porcelain layered zirconia prostheses is a major drawback of zirconia and has been controversial.[11,14,17] Chipping and delamination of the veneering ceramic has been described as a frequently occurring problem, ranging between 0% and 15.2% in recent studies and increasing up to 54% on implant-supported prostheses.[2,18-22] Porcelain chipping on zirconia is mainly due to material-related causes but other variables may be also dependent on the prosthetic design, just like core-ceramic thickness ratio and framework architecture.[1,2] An inadequate shaping of the framework would not provide proper, uniform support to the layering ceramic and this could play a paramount role in the occurrence of chipping.[2]

Recently, three different designs of zirconia copings for single-unit porcelain fused to zirconia crowns were proposed to standardize the in vitro tests, in order to better analyze the variables influencing chipping.[23] Particularly, the following shapes were tested: reproduction of the abutment contour (flat design, FD), wax-up as for porcelain-fused-to-metal crowns (PFM) and anatomically guided (AG), designed to keep the thickness of the overlying porcelain veneering constant. The latter proved to be clearly more resistant under loading than the other two types of copings.

The present randomized prospective clinical study evaluated the influence of coping design on the fracture resistance of CAD/CAM zirconia single crowns layered with dedicated ceramics under clinical conditions. The null hypothesis was that there were no differences between the three types of coping design under clinical service.

Materials and Methods

Subjects were selected for the study on the basis of the following inclusion criteria:[11]

- Age above 18 years with at least one tooth in need of crowning;
- Good general health (ASA I or ASA II);
- Good oral hygiene;
- Vital or endodontically treated teeth;
- Periodontally healthy;

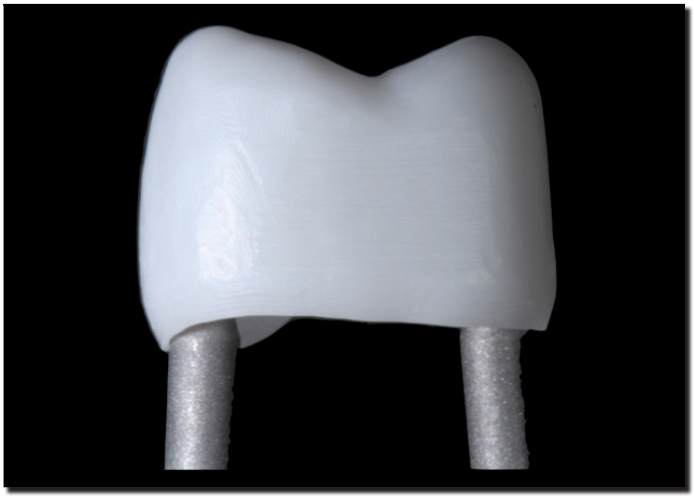

Fig. 1. Sample of Group 1: flat design (FD).

- Minimum of 20 teeth;
- No evident signs of occlusal parafunctions and/or temporo-mandibular disorders.

Conversely, the following exclusion criteria were adopted:

- Subjects preferring implant-supported restorations;
- High caries activity;
- Occluso-gingival height of abutment teeth < 4 mm;
- Reduced interocclusal distance or supraerupted opposing teeth;
- Unfavorable crown-to-root ratio.

Fifty-six consecutive subjects (32 females and 24 males) with a mean age of 43.6 years (SD= 13.5), in need of at least one posterior layered zirconia single crown each in premolar and/or molar regions were considered for the study. They were recruited in the Department of Medical Biotechnologies, Fixed Prosthodontics and Dental Materials of the University of Siena, Italy, from September 2011 to January 2012. A total of 90 posterior teeth were selected: 34 molars (18 maxilla and 16 mandible) and 56 premolars (36 maxilla and 20 mandible). All the treated posterior teeth had natural dentition in the opposite arch. Informed written consent was obtained from each participant. The study protocol was approved by the Institutional Ethics Committee of the University of Siena, (approval number: ABTM001) (clinicaltrials.gov #NCT020906567). The present study was performed in accordance with the CONSORT guidelines.[24]

An experienced dental hygienist prepared the subjects from a periodontal point of view and a first impression was taken with an irreversible hydrocolloid (GC Aroma Fine Plus[a]) in order to pour the study casts and fabricate the resin composite temporary crowns. The casts of both dental arches were mounted into an articulator.

A standardized tooth preparation was performed with occlusal and axial reduction of 1.5 mm and a chamfer finish line that was placed 0.5 mm supragingivally. All internal line angles were rounded and the shoulders were smoothed by means of hand chisels. All the preparations were made by the same experienced prosthodontist. The interim restorations were relined intraorally on the prepared teeth; then smoothed with soft rubber and polishing cups to obtain an optimal marginal adaptation between the crowns and the soft tissues. Finally, the interim restorations were cemented in the same session with a eugenol-free temporary cement (Freegenol[a]). The interim restorations were worn by the subjects for 3 weeks, so as to allow the soft tissues to recover from any possible preparation trauma and recover to complete health status.

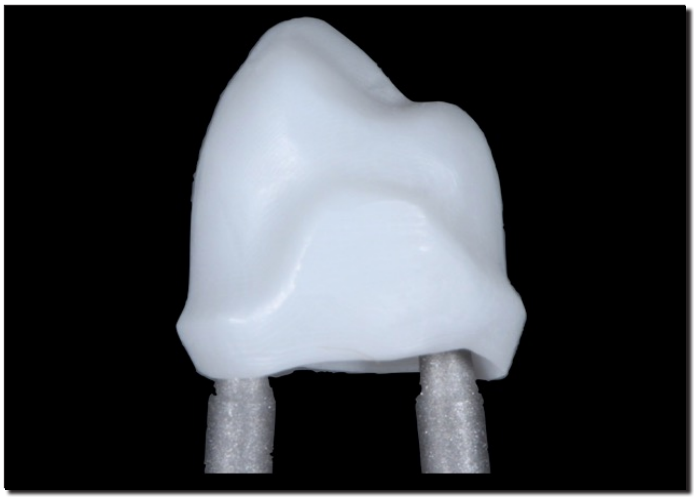

Fig. 2. Sample of Group 2: wax-up as for porcelain-fused-to-metal crowns (PFM).

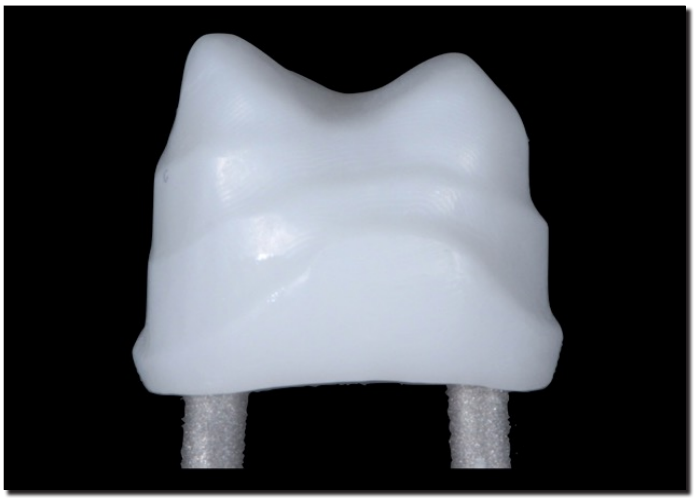

Fig. 3. Sample of Group 3: anatomically-guided, designed to keep constant the thickness of the overlying porcelain veneering (AG).

After the healing period, the temporary crowns were removed and the tooth preparations refined using a stereo-microscope at ×10 magnification (Zeiss OpMi1[b]). One-step precision impressions were taken using vinyl polyether silicone impression materials (EXA'lence[a]) with custom autopoly-merizing acrylic resin trays (SR-Ivolen[c]) made by the same dental technician at least 24 hours before the impression. The impressions were poured using an extra-stone plaster type IV (Fuji Rock[a]) after 5 hours in order to allow the elastic return of the impression material. The resin composite temporary crowns were relined intraorally, polished and cemented as previously described.

The abutment teeth were randomly distributed into three groups of 30 samples each according to three different coping designs, using a computer-assisted randomization and a dedicated software, as follows:

Group 1: Reproduction of the abutment contour (flat design, FD; Fig. 1);

Group 2: Wax-up as for porcelain-fused-to-metal crowns (PFM; Fig. 2);

Group 3: Anatomically-guided, designed to keep constant the thickness of the overlying porcelain veneering (AG; Fig. 3).

Table 1. 3-year recall data: chipping frequency.

	Group 1 FD	Group 2 PFM	Group 3 AG
No chipping frequency (No chipping relative frequency %)	24 (80%)	30 (100%)	30 (100%)
Chipping frequency (Chipping relative frequency %)	6 (20%)	0 (0%)	0 (0%)

Table 2. 3-year success and survival rates of the experimental groups. Different letters label stastically significant differences in the 3-year success rate according to the Fisher's exact test.

Group	Outcome			Total	Significance (P< 0.05)
	Success	Survival	Failure		
Group 1 (FD)	24	4	2	30	A
Group 2 (PFM)	30	0	0	30	B
Group 3 (AG)	30	0	0	30	B
Total	84	4	2	90	

In order to standardize as much as possible the shape of the experimental copings, each framework was waxed-up by the same experienced dental technician with a minimum thickness of 0.5 mm; then the copings were scanned by a computer aided design-computer aided manufacturing (CAD-CAM) software (Aadva[a]) and the zirconia cores were fabricated. The porcelain veneering was performed using a ceramic material dedicated to zirconia (Initial Zr-FS[a]), characterized by a special adaptation to the coefficient of thermal expansion (CTE) of the zirconia frameworks ($9.4 \times 10^{-6}K^{-1}$). Slow cooling was done in order to dissipate the residual stresses within the bilayered restorations. The pressure layering technique was adopted following the manufacturer's instructions.

At the intraoral try-in, slight occlusal adjustments were made with a diamond bur when needed, carefully checking the occlusal contacts. The final restorations were glazed and cemented using a self-adhesive resin cement (G-CEM[a]) following the manufacturer's instructions. The luting agent was inserted into the crowns and the patients were requested to hold them under occlusal compression until the cement set; then, the excess cement was carefully removed.

The cementation time was considered the baseline to record data. The subjects were recalled for follow-up visits after 1 month, 6 months, 1, 2 and 3 years of clinical service. The function, esthetics and marginal adaptation of the restorations were evaluated according to the United States Public Health Service (USPHS) criteria[13] at the baseline and at the follow-up appointments by two independent examiners blinded to the group assignment and calibrated. In order to collect and classify the clinical outcomes, 'success' was defined by the percentage of restorations that remained in situ without any modification, 'survival' by the percentage of restorations that remained in situ with modifications but still under clinical acceptability, and 'failure' by the percentage of restorations that needed to be replaced.[25]

The subjective satisfaction was evaluated using Visual Analog Scales (VAS), allowing the subjects to rate the overall function and esthetics of the restorations (0 = worst, 10 = best).

Table 3. Kaplan-Meier event frequency and relative frequency per year.

	Chipping frequency (Chipping relative frequency %)		
	Group 1 - FD	Group 2 - PFM	Group 3 - AG
1-year recall	3/30 (10%)	0/30 (0%)	0/30 (0%)
2-year recall	1/27 (3.3%)	0/30 (0%)	0/30 (0%)
3-year recall	2/26 (6.7%)	0/30 (0%)	0/30 (0%)
Overall	6/30 (20%)	0/30 (0%)	0/30 (0%)

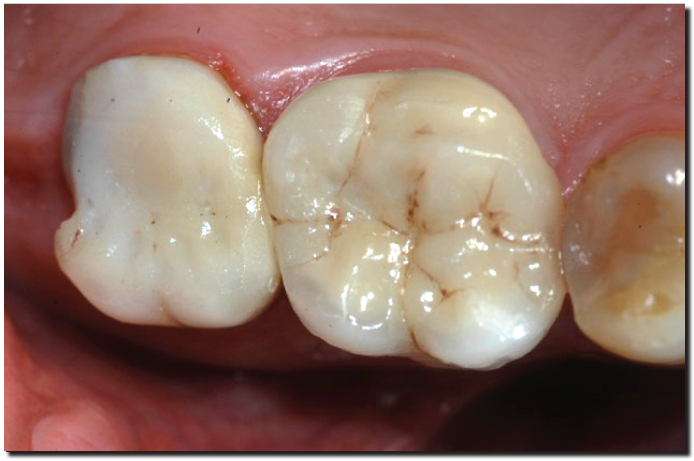

Fig. 4. Zirconia core failure evidenced on a maxillary molar after 3 years of clinical function.

Statistical analysis - The subjects' characteristics and clinical variables were balanced between the groups. The Fisher's exact test was applied to assess the statistical significance of between-group differences in the 3-year success rate. The level of statistical significance was set at P< 0.05.

Furthermore, the Kaplan-Meier curves were obtained for descriptive purposes and statistically compared with the Mantel-Cox Log-Rank test in order to verify whether the coping design significantly influenced the time to the chipping event. The level of statistical significance was set at P< 0.05.

The statistical analyses were performed using a statistical package software (IBM SPSS Statistics for Windows,[d] Version 21.0).

Results

Three-year success rates of 100% were reported in Groups 2 and 3, while the percentage was 80% in Group 1 (Table 1). Two crowns needed to be replaced in Group 1, resulting in the survival rate of 93.3% in Group 1 and of 100% in Groups 2 and 3 (Table 2).

After 3 years of clinical service, Group 1 (FD) showed four chippings and two core fractures, while Groups 2 and 3 showed no complications. Particularly, in zirconia copings with flat design (FD) three showed chipping after 1 year, 1 more after 2 years and two framework failures were noted after 3 years of clinical service (Table 3). All the cohesively fractured porcelain surfaces did not impair function; consequently, they were classified as 'survival' and were gently finished and polished with proper fine and extra-fine diamond burs, rubber points and polishing wheels. The zirconia core failures were all on maxillary second molars (Fig. 4).

The USPHS criteria evaluation and the relative 3-year results are reported in Tables 4 and 5 respectively. The results

Table 4. USPHS criteria evaluation.

	Alfa (A)	Bravo (B)	Charlie (C)	Delta (D)
Core fracture	No core fracture	-	-	Core fracture
Veneering fracture	No fracture	Chipping but polishing possible	Chipping down to the framework	New restoration is needed
Occlusal wear	No occlusal wear on restoration or on opposite teeth	Occlusal wear on restoration or on opposite teeth < 2 mm	Occlusal wear on restoration or on opposite teeth > 2 mm	New restoration is needed
Marginal adaptation	No probe catch	Slight probe catch but no gap	Gap with some dentin or cement exposure	New restoration is needed
Anatomic form	Ideal anatomic shape, good proximal contacts	Slightly over- or under-contoured, weak proximal contacts	Highly over- or under-contoured, open proximal contacts	New restoration is needed

Table 5. Results of the USPHS criteria evaluation.

		Alfa (A)	Bravo (B)	Charlie (C)	Delta (D)
Core fracture	Group 1 (FD)	28 (93.3%)	0	0	2 (6.7%)
	Group 2 (PFM)	30 (100%)	0	0	0
	Group 3 (AG)	30 (100%)	0	0	0
Veneering fracture	Group 1 (FD)	25 (83.3%)	3 (10%)	0	2 (6.7%)
	Group 2 (PFM)	30 (100%)	0	0	0
	Group 3 (AG)	30 (100%)	0	0	0
Occlusal wear	Group 1 (FD)	26 (86.7%)	2 (6.7%)	0	2 (6.7%)
	Group 2 (PFM)	28 (93.3%)	2 (6.7%)	0	0
	Group 3 (AG)	29 (96.7%)	1 (3.3%)	0	0
Marginal adaptation	Group 1 (FD)	27 (90%)	1 (3.3%)	0	2 (6.7%)
	Group 2 (PFM)	29 (96.7%)	1 (3.3%)	0	0
	Group 3 (AG)	30 (100%)	0	0	0
Anatomic form	Group 1 (FD)	28 (93.3%)	0	0	2 (6.7%)
	Group 2 (PFM)	29 (96.7%)	1 (3.3%)	0	0
	Group 3 (AG)	30 (100%)	0	0	0

Table 6. Results of the VAS evaluations.

	0	1	2	3	4	5	6	7	8	9	10
Group 1	2	-	-	-	-	-	1	2	-	3	22
Group 2	-	-	-	-	-	-	-	-	-	1	29
Group 3	-	-	-	-	-	-	-	-	1	-	29

of the VAS evaluation are shown in Table 6.

According to the clinical outcomes and to the occurrence of chipping, PFM-like frame design (Group 2) and anatomically-guided zirconia cores (Group 3) resisted significantly better to occlusal loading and clinical function than flat design frameworks (Group 1). Statistically significant differences were found among Group 1 (FD) and the other experimental groups (PFM and AG); conversely, no statistically significant differences were found between Group 2 (PFM) and Group 3 (AG) (Table 2).

The Fisher's exact test showed that chipping was significantly more frequent in the FD groups than in the PFM and AG groups (P= 0.003, Table 2).

The Kaplan-Meier curves are shown in Fig. 5; the Mantel-Cox Log-Rank test indicated that the FD coping design had a significantly shorter chip-free time than the other coping designs (P= 0.001).

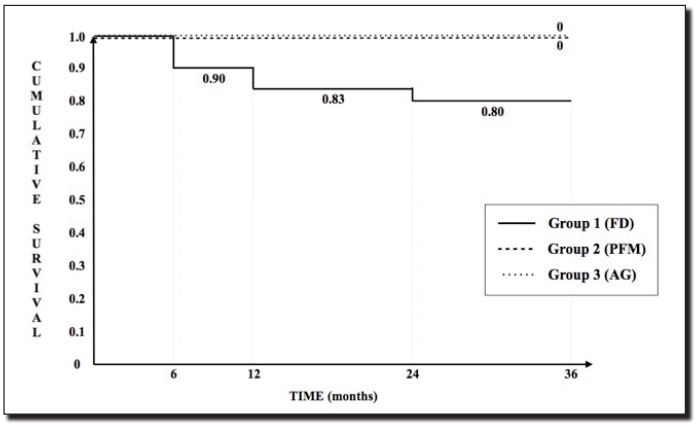

Fig. 5. Kaplan-Meier plots for the experimental coping designs.

Discussion

The prediction of clinical behavior of zirconia prostheses based on in vitro results has been often difficult, and almost impossible to correlate success and failures reported in clinical trials with in vitro data.[26] In the present study, an in vivo protocol was performed after designing the single crowns as previously tested in a recent in vitro study[23] to evaluate three different framework designs for single crowns. In these studies, the manufacturing of the three groups of zirconia-ceramic crowns was the same for coping design and ceramic layering and firing; the same materials were used, the thicknesses of

zirconia and porcelain were carefully checked with the same standards during the laboratory steps, as well as the design of the copings, the layering technique and the temperature of firing and cooling. The results of the fracture resistance tests achieved under in vitro conditions were partially in agreement with the 3-year clinical results reported in the present investigation. Particularly, the results of this randomized, prospective clinical study showed that it is possible to mainly correlate, under certain limitations, in vitro and in vivo studies. Surprisingly, Group 2 (PFM) showed better results under clinical conditions (i.e. 100% success after 3 years of clinical service) than under laboratory conditions, showing that clinical behavior can be different than in vitro outcomes. The positive clinical result of PFM crowns can be due to the high loading resistance of zirconia-ceramic crowns under clinical conditions, much higher than normal occlusal loading.[11,13,14,17,27,28] Occlusal loading in in vitro conditions is different than that under clinical conditions; also, during laboratory investigations the samples are stressed until the fracture/failure overloads the crowns. However, the PFM design used in this study was already proposed many years ago for porcelain-fused-to-metal crowns, when zirconia was not available, and has shown very positive clinical results in the last 30 years.[11,27,28]

Chipping of porcelain was reported in other clinical studies[29-31] and the survival rates ranged between 78% and 100% after 5 years of clinical service. In these studies, natural teeth were usually used as abutments and only one study reported results on zirconia restorations luted to titanium abutments.[17] Chipping fractures of the veneering ceramic can occur with or without exposing the underlying zirconia framework. A higher frequency of chipping was noted in posterior than in anterior teeth.[17]

Several methods have been proposed to clinically classify such a drawback. Heintze & Rousson[28] pointed out in a systematic review that survival of zirconia can be classified in three grades: grade 1 = polishing, grade 2 = repair, and grade 3 = replacement. Moreover, Pjetursson et al[27] defined "survival" by the percentage of restorations remaining in situ with modifications but still under clinical acceptability. Anusavice[26] proposed a method for reporting chipping and bulk fractures and defined the "success" as the achievement of treatment planning goals and expectations, while "failure" as the inability of a restoration to perform as expected under typical clinical and patient conditions. The latest definition seems to be very reasonable particularly because it does reflect the expectations of patients for well-performing restorations. In order to avoid misunderstanding between the definitions of success and survival, in the authors' opinion "success" should be defined by the percentage of restorations that remained in situ without any modification, "survival" should be defined by the percentage of restorations that remained in situ with modifications but still under clinical acceptability, while "failure" should be defined by the percentage of restorations that needed to be replaced.

In the present clinical study, two conventionally-defined "failures" were reported in Group 1 after 3 years; moreover four cohesive fractures of the veneering ceramic not impairing function also occurred. However, chipping events can disappoint the patient as well as the practitioner and achieving "survival" of the restorations cannot be the goal at the baseline. Consequently, it is worth noticing how the statistical meanings of "survival" and "success" are different from these clinical outcomes and clear definitions of such parameters would be paramount to better interpret and compare the numerical results of clinical trials.[25,26,32,33]

The results of the present clinical investigation are in agreement with those of other studies[22,34-40] reporting that an anatomically designed framework could be recommended to minimize the chance of chipping, since it offers correct support to the overlying ceramic.

Zirconia copings are usually made by CAD-CAM systems and any of them has its own software. Unfortunately, to date most of the software available cannot produce by default different coping designs, thus time-consuming procedures are usually needed to obtain such anatomical core design. In order to make the most appropriate anatomical framework design, wax-up made by the dental technician and its scanning are still needed. Consequently, the software is a factor that can influence greatly the clinical success of zirconia restorations and needs to be improved in quality, reliability and efficacy.[25]

Recently, Gherlone et al[41] reported the results of a retrospective clinical study on the survival of zirconia-based single crowns fabricated from intraoral digital impressions. Although the survival rate was 100% after 3 years of clinical service, the chipping rate increased from 9.3% after 12 months to 14% after 24 months and 30.2% after 36 months, resulting in a success rate of 69.8%. These results may be due to the type of finish line adopted in the study (i.e. knife-edge)[34] or to the use of intraoral digital impression instead of the use of a laboratory scanner;[42] furthermore, such evidence shows the need for improvement of these innovative devices and impression techniques.

The coping designs of Groups 2 (PFM) and 3 (AG) left the zirconia cores exposed to the oral environment, in order to give proper support to the veneering porcelain; such a choice could influence the material characteristics over time because of hydrothermal stress. Several authors[1,2] pointed out that the low temperature degradation (LTD) or "aging" of zirconia is a process strictly related to the phase transformation toughening of the material that decreases its physical properties and leads to a possible accelerated degradation. Although, LTD is considered a risk factor for mechanical prosthetic failures, to date no direct relationship has been demonstrated by scientific evidence in the clinical service.[1,2] Further studies on longer clinical trials are needed to clarify this issue.

Finally, it is worth noticing how the use of the same materials, fabrication procedures and clinical techniques can be helpful in comparing the results of in vitro and in vivo investigations, so as to improve and standardize evaluation criteria over time.

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