

Clinical Performance of Complete-Arch Implant-Supported Rehabilitations Using Monolithic Lithium Disilicate Restorations Bonded to CAD/CAM Titanium and Zirconia Frameworks up to 5 Years

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ABSTRACT

This clinical study evaluated the survival of monolithic lithium disilicate (ML) (IPS Emax, Ivoclar Vivadent) restorations bonded to complete-arch CAD/CAM made titanium or zirconia frameworks. Between August 2007 and December 2009, 15 patients (7 female, 8 male; mean age: 56.8 years old) received 30 implant-supported screw-retained rehabilitations with ML restorations cemented to CAD/CAM made titanium (T) (n=6) or zirconia (Z) frameworks (n=24) adhesively (Multilink Automix, RelyX Unicem) and followed up until December 2015. The evaluation protocol involved technical failures (chipping, debonding or fracture of crown/framework, screw loosening), Californian Dental Association (CDA) quality criteria (Romeo: Excellent; Sierra: Acceptable; Tango: Retrievable; Victor: Not acceptable) and biological failures (mucositis, peri-implantitis). Mean observation time was 60.3 months. No implants were lost, and all the prostheses were in situ. Four mechanical failures occurred in the form of minor chipping (n=3 in ML-Z, n=1 in ML-T) and major fracture in ML crown (n=1 in ML-Z). Romeo scores (N=370) decreased until final observation (N=347) and 23 Sierra scores were given to the restorations. Mucositis was observed in 3 patients and peri-implantitis in one patient. Complete-arch implant-borne FDPs made of monolithic lithium disilicate bonded to titanium or zirconia frameworks could be a promising alternative.

INTRODUCTION

In implant-borne fixed dental prosthesis (FDP) different options are today available as framework material for veneered restorations. Traditionally, metal framework substructures veneered with porcelain have been used for the rehabilitation of osteointegrated implants. Nevertheless, metal-ceramic restorations showed important rates of ceramic veneer chipping fractures^{1,2} that significantly increased in full arch implant supported rehabilitations.³

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One other alternative is using metallic frameworks veneered with resin-based materials in edentulous patients. However, the survival data present unfavourable results with 70% veneer fractures or 50% wear after 15 years of service.⁴ Zirconia has been introduced due to its high biocompatibility,⁵ low plaque surface adhesion,⁶ high mechanical and aesthetic properties.⁷⁻⁹ These properties have led to the introduction of zirconia-based restorations as alternatives to tooth supported traditional metal ceramic restorations and encouraged its application for implant-supported restorations as framework material.^{10,11} However, such reconstructions demonstrated even higher incidence of chipping fractures with 11.5 to 54% over 3 to 5 years of clinical service compared to their metal-ceramic counterparts showing 2.9 to 8.8% chipping fractures over the same period.¹² Typically, chipping of veneering ceramic on zirconia occurs more frequently than on metals as a consequence of mismatch in coefficient of thermal expansion (CTE) between zirconia and veneering material, developing thermal gradients during cooling processes, inadequate thickness for veneering material,^{13,14} and inappropriate frameworks without a proper anatomical design.¹³

In complete edentulous patients, impaired proprioception and rigidity of osseointegrated implants correlates with higher functional forces that might eventually further exacerbate fractures in the suprastructures in implant-borne FDPs.⁷ In order to overcome veneering material fractures, CAD/CAM made one-block monolithic zirconia ceramic was introduced. Primary drawback of this material is its possible decreased stability against low temperature degradation (LTD) particularly under mechanical stress in wet environment.¹⁵ Moreover, due to its high refractive index, zirconia does not present optimum optical properties.¹⁶ Increasing the final sintering temperature for the cost of decreased flexural strength could increase translucency of this material. The development of multilayered translucent zirconia ceramics could fulfill the optical expectations from zirconia but this material has not been investigated widely yet. Lithium disilicate glass-ceramic on the other hand, consists of approximately 70% lithium disilicate crystals ($\text{Li}_2\text{Si}_2\text{O}_5$) and minor quantities of lithium orthophosphate crystals (Li_3PO_4) displaying a refractive index similar to that of the dental tissues providing satisfactory aesthetics as well as considerably high flexural strength.¹⁷

Monolithic lithium disilicate FDPs can also be bonded on implant-borne titanium or zirconia frameworks.¹⁸ The presence and the length of distal cantilever part of the framework dictates the material selection, being titanium indicated for distal cantilever longer than one unit. This aspect is based on the CAD/CAM technology restrictions in that some of the systems do not allow fabrication of zirconia FDP frameworks frameworks with a distal cantilever longer than 1 unit (14 mm) (i.e. Procera CD/CM System).

This approach allows to increase the flexural strength of the superstructure material by bonding monolithic lithium disilicate crowns or FDPs on zirconia or titanium frameworks avoiding the use of veneering material consequentially decreasing

the risk of chipping fracture guaranteeing at the same time optimal aesthetics outcome. Furthermore, a key point, especially in such extended structures, is represented by the reparability of potential chipping fractures. In fact, the etchability of lithium disilicate and the different framework design allow to suitably manage minor as well more extensive fractures of the veneering material.

This clinical pilot study evaluated the performance of monolithic lithium disilicate restorations bonded to complete-arch CAD/CAM made titanium or zirconia frameworks on implant-borne FDPs and aimed to record failure types that may be of help for future randomized controlled clinical trials.

MATERIALS AND METHOD

Between August 2007 and December 2009, 15 patients (7 females, 8 males; mean age: 56.8 years old) received 30 implant-supported screw-retained FDPs and followed up until December 2015 (Table 1).

All patients were treated after signing in the appropriate informed consent. One clinician performed all prosthetic procedures and three dental laboratories manufactured the restorations. Four to eight implants were planned for the rehabilitation of each jaw.

A total of 168 (27 Nobel Speedy, 22 Branemark MKIV, 39 Branemark MKII, 49 Nobel Replace Select, 31 Nobel Active, Nobel Biocare AG, Zurich, Switzerland) implants with the same porous anodized surfaces (TiUnite, Nobel Biocare AG, Zurich Switzerland) were placed with either a flapless (n=45) or with flap approach (n=123). The implants were placed mainly axially (n=125) and in some cases tilted (n=43). The selection of axial or tilted implant placement was based on clinical and radiological evaluations in order to overcome the anatomic limitations of atrophic posterior jaws. The clinical protocol considered to create new complete dentures before the surgery. The dentures were fabricated in relation to a correct facial, aesthetic and functional analysis. These prostheses were used as try-ins and also used as reference for the 3D implant planning using the digital software. Tilted implants were used in all the clinical situations where residual bone volume did not allow for a conventional approach.

The rationale for the choice of Ti framework was dependent on the presence of distal cantilever more than 1 unit being approximately 14 mm length since in such cases zirconia was not indicated according to the manufacturer's instructions.

Nine patients were treated with immediate loading approach and 6 with delayed one. In all the patients treated with immediate loading, complete dentures were converted to fixed full-acrylic temporary FDPs and maintained in situ for 3 months in the mandible and 6 months in the maxilla. In case of delayed protocol, after the implant placement, complete dentures were replaced in the mouth after soft relining. All the patients were instructed to have soft diet for 2 months.

Table 1. Distribution and location of the monolithic fixed-dental-prostheses bonded on titanium and zirconia frameworks. *denotes presence of distal cantilever.

Gender	Age	Framework Material: Ti vs Zi	N of Dental Units	Follow-up (months)	Mechanical Complications	Biological Complications	Cantilevers	Number of Implants	Maxilla vs Mandible	Framework Material: Ti vs Zi	Adverse Events
F	45	Zi	10	36	-	-	*12 mm; 10 mm	4	Mandible	Zi	-
F	45	Zi	10	36	Minor Chipping (Mandibular Anterior)	-	-	6	Maxilla	Zi	-
F	59	Ti	12	40	-	Mucositis	*20 mm; 18 mm	4	Mandible	Ti	-
F	59	Zi	12	40	-	-	-	6	Maxilla	Zi	-
F	65	Zi	14	43	-	-	-	6	Mandible	Zi	Discoloration
F	65	Zi	14	43	-	-	-	8	Maxilla	Zi	Discoloration
M	67	Ti	12	46	-	-	*19 mm	4	Mandible	Ti	Discoloration
M	67	Ti	12	70	Minor Chipping (Maxillary Posterior)	-	*15 mm	6	Maxilla	Ti	Discoloration
F	60	Zi	12	48	-	-	*11 mm; 12 mm	4	Mandible	Zi	-
F	60	Ti	12	48	-	-	-	7	Maxilla	Ti	-
M	61	Zi	12	52	-	-	*10 mm; 13 mm	5	Mandible	Zi	Discoloration
M	61	Zi	12	52	-	-	*12 mm	6	Maxilla	Zi	Discoloration
F	64	Zi	12	54	-	-	*12 mm; 10 mm	4	Mandible	Zi	-
F	64	Zi	14	69	-	-	-	7	Maxilla	Zi	-
M	55	Zi	12	55	-	-	-	6	Mandible	Zi	-
M	55	Zi	14	55	Minor Chipping (Maxillary Posterior)	Mucositis	-	8	Maxilla	Zi	-
M	57	Zi	12	60	-	-	*12 mm; 11 mm	4	Mandible	Zi	Discoloration
M	57	Zi	12	60	-	-	-	6	Maxilla	Zi	Discoloration
M	52	Zi	12	66	-	-	-	6	Mandible	Zi	-
M	52	Zi	12	66	-	Peri-implantitis	-	6	Maxilla	Zi	-
F	47	Zi	12	67	-	-	*13 mm; 10 mm	6	Mandible	Zi	-
F	47	Zi	12	67	-	-	*9 mm	6	Maxilla	Zi	-
M	55	Ti	12	76	-	-	*15 mm; 19 mm	5	Mandible	Ti	-
M	55	Ti	12	76	-	-	-	6	Maxilla	Ti	-
M	50	Zi	14	78	-	-	*11 mm; 12 mm	5	Mandible	Zi	-
M	50	Zi	12	78	-	-	-	6	Maxilla	Zi	-
M	53	Zi	12	81	-	-	-	6	Mandible	Zi	-
M	53	Zi	12	81	-	-	-	6	Maxilla	Zi	-
F	62	Zi	14	83	Minor Chipping (Maxillary Posterior)	Mucositis	*13 mm; 12 mm	5	Mandible	Zi	Discoloration
F	62	Zi	14	84	Major fracture (Maxillary Anterior)	-	-	7	Maxilla	Zi	Discoloration

Following the healing period that ranged from 3 to 6 months depending on the surgical approach, definitive impressions were made at either the implant (97 fixtures) or abutment level (71 fixtures) (Multi-Unit Abutment, Nobel Biocare AG). Impressions were made using plaster (Snow White Plaster no. 2, Kerr, Romulus, Michigan, USA) utilizing an individual impression tray. An open-tray implant impression method was used for each patient and radiographs were referred to evaluate the ideal seating of each impression coping. In all the patients that were not treated with an immediate loading a new temporary restorations were created before to proceed with the final prosthesis. Temporary restorations were then evaluated from functional, aesthetic and oral hygiene maintenance point of view before finalizing the case. All definitive reconstructions were fabricated following the aesthetic and functional parameters of the provisional restorations.¹⁸ The final restoration were created always considering a cross-mounting technique was applied to mount the opposite arch cast in the articulator with the interim restorations screwed onto the master cast, using an interocclusal jig. A cross-mounting technique was applied to mount the opposite arch cast in the articulator with the interim restorations screwed onto the master cast, using an interocclusal jig. Temporary restorations were then evaluated from functional, aesthetic and oral hygiene maintenance point of view before finalizing the case. All definitive reconstructions were fabricated following the aesthetic and functional parameters of the provisional restorations.¹⁸ All frameworks were fabricated according to the instructions of the manufacturers with connector dimensions (12 mm²) and cantilever width and length. Both titanium and zirconia frameworks were obtained using a CAD/CAM technology (Procera Forte Scanner or Nobel Procera Scanner, Nobel Biocare AG).

The pink flange in the frameworks was fabricated using feldspathic porcelain (Zi-CT, Creation, Austria) in case of Zirconia framework and in composite in case of Titanium framework. The try in of the frameworks was executed with an acrylic reproduction of the wax-up placed above the frameworks in order to verify also the occlusion and the aesthetics.

The thickness of the lithium disilicate reconstructions ranged from to 1.5 to 4 mm at the occlusal aspect in relation to the vertical spaces available for the prostheses. The lithium disilicate full-contour monolithic single crowns were manufactured with lost-wax hot-pressing technology (IPS e.max Press, Ivoclar Vivadent). The shades were selected according to the expectations of the patients. High-translucency ingots (HT) were used in order to achieve natural appearance and restorations both in the anterior and posterior segments that were then stained (IPS Ivocolor Shade and Essence stains, Ivoclar Vivadent).

All lithium disilicate crowns were produced with a screw hole in order to proceed with extra-oral cementation of the crowns on the framework.¹⁸ Access screw holes were closed using teflon and then resin composite at the day of the final prosthesis delivery.

The intaglio surfaces of the restorations were etched with 5% hydrofluoric acid (IPS Empress gel, Ivoclar Vivadent) for 20 s, washed thoroughly with water and dried with oil free air. Then, silane (Monobond S, Ivoclar Vivadent; Ceramic Primer, 3M ESPE, Minn, USA) was applied a thin layer, waited for its reaction for 60 s and air-dried.

Titanium and zirconia framework surfaces were first air-borne particle abraded (CoJet-Sand, 30 µm silica-modified alumina (distance: 1 cm, pressure: 2 bar). The framework surfaces were air-blown, dried and silanized. In order to facilitate the correct positioning of the lithium disilicate restorations on the framework, specific abutment framework design (i.e. vertical and horizontal grooves) was employed and a silicone occlusal index or the articulator was used to check the right position. The crowns were adhesively luted (Multilink Automix, Ivoclar Vivadent; RelyX Unicem, 3M ESPE) based on the availability of the cement (*Figure 1a-e*).

Excess cement was then removed with a scaler after 5 s of photo-polymerization (Bluephase LED, Ivoclar Vivadent). Glycerin gel was applied on the margins and then restorations were photo-polymerized for 30 s from each direction. Each restoration was screwed in the mouth and access screw-holes were filled with polytetrafluoroethylene (Teflon) and resin composite. From the occlusion point of view, all cases were treated obtaining a posterior occlusal stability with anterior and canine guidance in order to avoid posterior contacts during dynamic movement of the mandible in function or parafunction. Also, a narrow occlusal table, with central fossa loading in intercuspal contact and low cusp inclination was established to minimize lateral loading in function and parafunction.¹⁹

A rigid acrylic night guard was provided for each patient to protect the reconstruction from occasional parafunctional habits, and the patients were informed about the importance of the daily wearing of this appliance. The patients were recalled every 4 months for hygiene maintenance and annually for potential occlusal adjustment. In addition to the recall intervals, the patients were asked to consult the clinic immediately when any complication was observed. The evaluation protocol was performed by one calibrated operator and involved the technical (chipping, debonding or fracture of crown/framework, screw loosening), Californian Dental Association (CDA) quality criteria regarding color match, ceramic surface, marginal discoloration and integrity (Romeo: Excellent; Sierra: Acceptable; Tango: Retrievable; Victor: Not acceptable), biological failures (mucositis, peri-implantitis) and patient satisfaction (Visual Analog Scale, VAS).²⁰ Patient satisfaction was assessed by posing 3 questions by an independent outcome assessor: 1) Are you satisfied with the function of your rehabilitation? 2) Are you satisfied with the aesthetic outcome of your rehabilitation? 3) Are you satisfied with your treatment overall? Patients marked their answers on a scale ranging from 0 (minimum agreement) to 10 (maximum agreement).

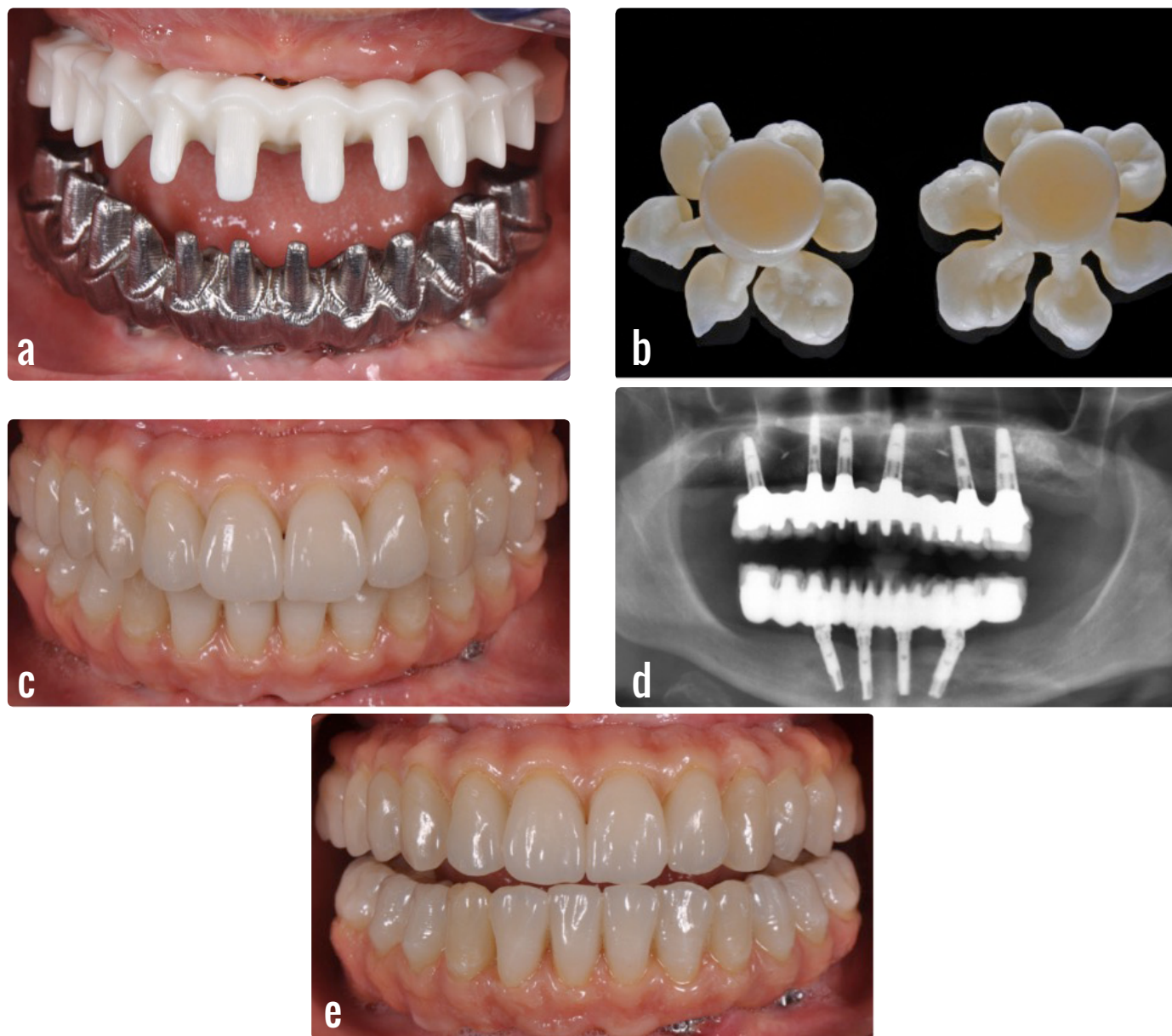


Figure 1a-e: Photos of a) frameworks in situ during try-in, b) full-contour lithium disilicate crowns obtained using press technology, c) final rehabilitation after the extra-oral cementation of the crowns on the abutments, d) X-ray evaluation after 5 years of function. Note that in the mandible, the presence of a 2-unit distal cantilever prevented the use of zirconia as a framework material, e) complete-arch rehabilitation after 5-years of function.

Radiographs were made at recalls but no standardized protocol was used to diagnose possible bone loss. During recall visits, the frameworks were not removed but mucositis and peri-implantitis diagnosis were made based on clinical examination of presence of inflammation, suppuration or bleeding. In such a clinical situation, x-rays were made to evaluate the implant-bone interface.

RESULTS

No drop-out was experienced up to final recall. Life table and distribution of the implant-borne FDPs is presented in Table 1. In total, 253 units were cemented with Multilink Automix and 117 with RelyX Unicem.

No implants were lost, and all the prostheses were in situ after a mean observation time of 60.3 months.

Four mechanical failures in the form of minor chipping (n=3 in ML-Z, after 16, 29 and 50 months and n=1 in ML-T after 70 months in function) and major fracture of the monolithic restoration (n=1 in ML-Z, 8 days in function) were observed. There was no correlation between the chipping and the crowns with the screw hole access.

Minor failures were repaired directly, the major fractured piece was re-cemented and all FDPs remained functional until the final follow up (Figure 2a-e). No other mechanical complications were observed such as screw loosening and/or zirconium dioxide framework fracture during the entire follow-up period.



Figure 2a-e: Photos of failures in the form of a) chipping on tooth no. 24 after 4 years of function, b) chipping repaired intraorally, c) major fracture on tooth no. 23, 8 days after delivery of the prosthesis, d) fractured segment of the lithium disilicate crown, e) recementation of the fragment on the abutment.

The peri-implant mucosa presented mucositis in 3 patients and peri-implantitis in one patient.

CDA criteria scores of Romeo (n=370) decreased over time until final follow up (n=347 Romeo; n=23 Sierra). The incidence of maximum agreement in VAS scores were 90% for question 1 on function and 100% for aesthetics (question 2) and 100% for overall satisfaction (question 3). In five patients (n=10 restorations), colour change was observed due to the loss of staining material at functional areas such as occlusal surfaces in the posterior segments and the palatal aspect of the maxillary canines and incisors.

Representative orthopantomographs are presented in Figures 3a-b demonstrating the impact of the treatment modality in edentulous patients.

DISCUSSION

The rationale for the treatment protocol employed in this study was to increase the clinical reliability of a prosthetic approach that combines zirconia or titanium framework with monolithic lithium disilicate restorations adhesively bonded on it, for full-arch implant-supported rehabilitations. The prosthetic

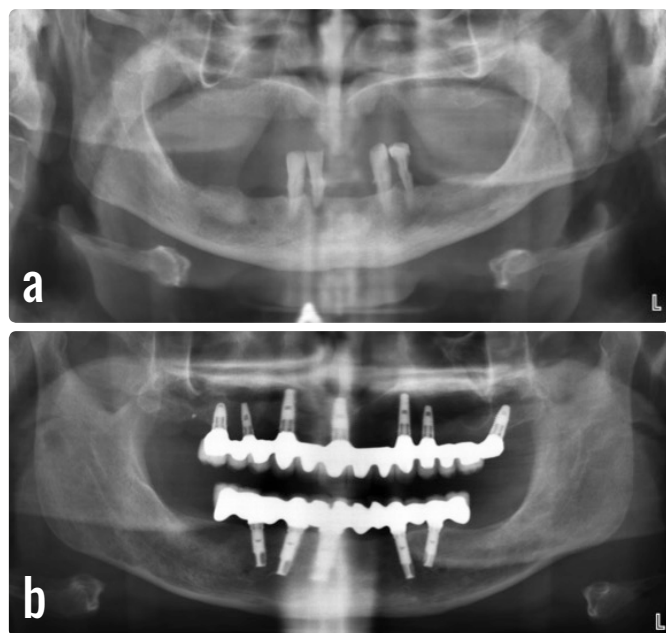


Figure 3a-b: Orthopantomographs of a representative case a) at baseline prior to extraction of existing teeth and b) cantilever FDP with titanium framework in the mandible and zirconia framework in the maxilla.

approach described in this study allows increasing the flexural strength of the superstructures (monolithic lithium disilicate 360-400 MPa) reducing the incidence of chipping fractures compared to the conventional layering technique approach.

In total, only 4 out of 360 units experienced mechanical complications in the form of monolithic lithium disilicate chipping fractures over a mean period of 60.3 months. The chipping cases were not on the crowns with the screw hole access. Therefore, it can be stated that the presence of the screw hole access do not affect the stability of such restorations. A previous retrospective study investigated a similar prosthetic approach where titanium and zirconia were used as framework material for implant supported full arches restorations.²¹ However veneering ceramic chipping fractures was observed in 41.6% of restorations. In fact the most common complication of layered porcelain restorations has been reported as the veneering material chip off fractures due to the low flexural strength of the feldspathic porcelain that ranges from 90 to 120 MPa, depending on the brand.^{22,23} This aspect becomes particularly important for edentulous patients where the occlusal forces are higher than dentate patients due to the complete absence of mechanoreceptors.¹⁹ In the absence of proprioception and pulp-dentin-enamel complex, individuals with implant-supported FDPs in both jaws, show an impaired regulation of the jaw muscle activity and reduced capacity to adapt chewing behaviour.²⁴ In the present study, only completely edentulous patients were included in order to evaluate the mechanical behaviour of the proposed prosthetic option in the most challenging occlusal scenario.

Recently, a retrospective clinical study evaluated monolithic lithium disilicate restorations bonded on zirconia and titanium frameworks showed high survival and success rates.²⁰ Nevertheless, only 2 of the 16 patients observed in the study were edentulous both in the maxilla and mandible. The lithium disilicate chipping fractures observed were all cohesive fractures. Three of them occurred in rehabilitations where zirconia was the framework material while one fracture was detected in presence of titanium framework. Nevertheless, these mechanical complications could be easily managed thanks to the easy retrieval of the suprastructures material.¹⁸ In fact, the etchability of the lithium disilicate allowed easy repair of all the fractures using composite material or adhesively reattaching the fractured fragment. Furthermore, the absence of undercuts in the framework design would allow managing potential more dramatic fractures of lithium disilicate restorations by replacing the entire crown or FDP.

The lack of veneering ceramic in the lithium disilicate monolithic restorations, that shows a refractive index similar to that of the dental tissues, did not affect the aesthetic outcomes.²⁵ Moreover, in the rehabilitation of edentulous patients where it was not necessary to emulate any existing natural dental structure high translucency monolithic lithium disilicate was able to guarantee pleasant aesthetics without any layering materials. The decrease in the incidence of optimum scores of Romeo according to CDA criteria indicated that such ceramics might also change colour over time. This could be attributed to the wear of superficial staining layer in functional areas. Interestingly, the patients did not notice the surface lustre loss in 5 cases.

In six full-arch rehabilitations, titanium was selected as framework material since zirconia is not indicated in presence of distal cantilever longer than one dental unit. Shortened dental arch concept could be considered as an alternative to distal cantilever FDPs in particular when the residual bone does not allow for the implant placement in the posterior areas.²⁶⁻²⁸ However, favourable data correlated to the clinical performance of distal cantilevers in case of screw-retained full-arch implant supported rehabilitation,²⁹ combined with high expectations of the patient regarding the aesthetic and functional parameters could encourage the clinicians to indicate distal cantilevers on implant-borne FDPs. In such cases where titanium was used as a framework material, monolithic lithium disilicate restorations were bonded onto titanium after the metal surface was masked with a layer of opaque in order to avoid the grey shine-through.²¹

Reconstructions in this study are being followed up for longer duration. It is important to acknowledge some limitation of this investigation, highlighting that this design cannot be used to demonstrate a direct superiority of this treatment protocol as compared to other prosthetic approaches. In addition, the sample size, being a pilot study, is relatively small to provide general guidelines. In the future, prospective controlled studies will be needed to verify the findings of this study and provide more robust data.

Today, as an alternative to bilayered ceramic FDPs, monolithic full-arch reconstructions also in full edentulous patients became available due to the simplified protocol requested and the reduced cost. Complete-arch dental implant-borne FDPs with monolithic zirconia are associated with high short-term success.³⁰ Despite the many advantages and short-term favorable reports, studies for longer duration are necessary to validate the broad application of this therapy. It has to be noted that in case of a failure, full arch monolithic zirconia FDPs could not be easily repaired with adhesive procedures, and they often require a buccal layering to compensate for the esthetic limitations of the zirconia.

CONCLUSIONS

From this study, the following could be concluded:

Complete-arch implant-borne FDPs made of monolithic lithium disilicate bonded to titanium or zirconia frameworks could be a promising alternative, providing that occasional minor or major fracture of the monolithic restorations, mucositis could also be expected in such reconstructions.

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DISCLOSURE

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